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Cover caption: Nasima Akter of United Nations Children’s Fund uses a mid-upper arm circumference tape to check a child in Bangladesh for malnutrition © 2018 Maggie Moore, United States Agency for International Development
EDITORIALS

A Call to Action: Reinvigorating Interest and Investments in Health Infrastructure

Infrastructure investments can contribute substantially to alleviating burdens of morbidity and mortality while also providing a positive return on investment in the long term.

Lindsay M. Mallick, Joshua Amo-Adjei
https://doi.org/10.9745/GHSP-D-21-00674

COMMENTARIES

Motivation and Performance of Community Health Workers: Nothing New Under the Sun, and Yet... 

We know that both financial and nonfinancial incentives matter if we want community health workers (CHWs) who are motivated and performing. What are the practical implications for CHWs themselves and for effective management of viable CHW programs?

Eric Sarriot, Tom Davis, Melanie Morrow, Telesphore Kabore, Henry Perry
https://doi.org/10.9745/GHSP-D-21-00627


The World Health Organization COVID-19 Partners Platform represents the first step toward a new model of health crisis information sharing across stakeholders and could evolve into an engagement mechanism of choice for future cross-border public health emergencies.

Angela K. Shen, M. Anne Yu, Ann Lindstrand, Sanjiv M. Baxi, Océane Jousset, Katherine O’Brien, Lucy Boulanger
https://doi.org/10.9745/GHSP-D-21-00460

VIEWPOINTS

Equitable Open Access Publishing: Changing the Financial Power Dynamics in Academia

The growth in open access publishing in academia benefits readership but disproportionately hinders unfunded or lesser-funded researchers. Few journals create comprehensive means to bridge these inequities, calling for a shift in academic publishing practices.

Dominique Vervoort, Xiya Ma, Hloni Bookholane
https://doi.org/10.9745/GHSP-D-21-00145
Household Survey Measurement of Newborn Postnatal Care: Coverage, Quality Gaps, and Internal Inconsistencies in Responses

Reliable measurement of postnatal content of care is currently lacking despite the critical importance of care in this vulnerable period. We found that there is a large quality-coverage gap with missed opportunities for quality care as well as internal inconsistencies in responses to newborn questions.

Kimberly Peven, Louise Tina Day, Debra Bick, Edward Purrssell, Cath Taylor, Joseph Akuze, Lindsay Mallick
https://doi.org/10.9745/GHSP-D-21-00209

Projecting the Impact of Nutrition Policy to Improve Child Stunting: A Case Study in Guatemala Using the Lives Saved Tool

We projected the impact of a Scaling Up Nutrition intervention policy, the Great Crusade, and found that increasing intervention coverage is unlikely to improve child stunting outcomes in Guatemala to meet Sustainable Development Goals by 2030.

Scott Tschida, Ana Cordon, Gabriela Asturias, Mónica Mazariegos, Maria F. Kroeker-Lobos, Bianca Jackson, Peter Rohllof, David Flood
https://doi.org/10.9745/GHSP-D-20-00585

Beyond Institutionalization: Planning for Sustained Investments in Training, Supervision, and Support of Community Health Worker Programs in Bangladesh

Institutionalizing community health workers (CHWs) is insufficient for improving program quality. Governments must plan for sustained investments for salaries and benefits, as well as systems enabling adaptive management of the CHW cadres. Greater coordination is needed at the global level to pool and align donor investments to support the ecosystem underlying CHW programs.

Shongkour Roy, Shivani Pandya, Md. Irfan Hossain, Timothy Abuya, Charlotte E. Warren, Paloma Mitra, Ubaidur Rob, Sharif Hassain, Smisha Agarwal
https://doi.org/10.9745/GHSP-D-21-00156

Impact of Solar Light and Electricity on the Quality and Timeliness of Maternity Care: A Stepped-Wedge Cluster-Randomized Trial in Uganda

Lack of access to reliable energy is a major neglected health system challenge to maternal and child health. We found that installing a solar energy system intervention in rural Ugandan maternity facilities led to modest increases in the quality of maternity care and reductions in delays in care.

Slawa Rokicki, Brian Mwesigwa, Peter Waiswa, Jessica Cohen
https://doi.org/10.9745/GHSP-D-21-00205
Health Sector Resource Mapping in Malawi: Sharing the Collection and Use of Budget Data for Evidence-Based Decision Making

By tracking budgets for health through its annual resource mapping exercise, the Government of Malawi generated evidence for planning and budgeting, quantifying resource needs, mobilizing funds to fill financial gaps, and coordinating investments across stakeholders with different priorities toward common goals. The exercise was adapted to conduct COVID-19 resource mapping to inform planning and coordination of the national pandemic response.

Ian Yoon, Pakwanja Twea, Stephanie Heung, Sakshi Mohan, Nikhil Mandalia, Saadiya Razzaq, Leslie Berman, Eoghan Brady, Andrews Gunda, Gerald Manthalu

https://doi.org/10.9745/GHSP-D-21-00232

Evaluation of 2 Intervention Models to Integrate Family Planning Into Worker Health and Livelihood Programs in Egypt: A Difference-in-Differences Analysis

Integrating family planning and reproductive health messages into worker health programs and livelihood programs may offer a unique approach for raising young people’s awareness of family planning and reproductive health.

Nahla Abdel Tawab, Elizabeth Tobey, Maryam Essam, Sara Chace Dwyer, Aparna Jain

https://doi.org/10.9745/GHSP-D-21-00124

Participation in a Community-Based Women’s Health Education Program and At-Risk Child Development in Rural Kenya: Developmental Screening Questionnaire Results Analysis

A community-based intervention focused on women’s health education may help protect against early childhood developmental delays in resource-limited settings.

Megan S. McHenry, Lauren Y. Maldonado, Ziyi Yang, Gertrude Anusu, Evelyn Kaluhi, Astrid Christoffersen-Deb, Julia J. Songok, Laura J. Ruhl

https://doi.org/10.9745/GHSP-D-20-00349

Uptake of Encapsulated Ferrous Fumarate Double Fortified Salt in the Public Distribution System in India: A Value Chain Analysis

Initiating and sustaining large-scale encapsulated ferrous fumarate double fortified salt interventions in the public distribution system in India poses several challenges that can be minimized by strengthening double fortified salt value chains.

Meena Haribhau Jadhav, Marthi Gurunath Venkatesh Mannar

https://doi.org/10.9745/GHSP-D-20-00448
Using a Pharmacy-Based Surveillance System to Improve Standards for TB Care in Kerala, India

A pharmacy-based surveillance system in Kerala, India, has helped to improve TB patient notifications from the private sector, build better public-private partnerships, and improve the quality of TB diagnosis. Pharmacy-based surveillance has the potential to strengthen TB surveillance and facilitate standards of TB care.

Rakesh PS, Shibu Balakrishnan, Rakesh Ramachandran, Smitha Nandhan, Nidhish Issac Samuel, Pramodkumar PP, Suja Aloysius

https://doi.org/10.9745/GHSP-D-21-00346

Enhancing Performance and Sustainability of Community Health Worker Programs in Uganda: Lessons and Experiences From Stakeholders

We conducted a 1-day workshop—a unique opportunity to engage stakeholders at all levels of community health worker (CHW) program involvement—to discuss learned experiences and strategies to enhance and sustain the CHW program in Uganda.

David Musoke, Edwinah Atusingwize, Rawlance Ndejjo, Charles Ssemugabo, Penelope Siebert, Linda Gibson

https://doi.org/10.9745/GHSP-D-21-00260

Can We Use Routine Data for Strategic Decision Making? A Time Trend Comparison Between Survey and Routine Data in Mali

Routine data, which is available more regularly than the "gold standard" survey data, can be used to inform programmatic decisions in Mali at the national level. However, caution must be used if using data at a subnational level.

Talata Sawadogo-Lewis, Youssouf Keita, Emily Wilson, Souleymane Sawadogo, Ibrahim Téréra, Hamadoun Sangho, Melinda Munos

https://doi.org/10.9745/GHSP-D-21-00281

Accuracy of Using Mid-Upper Arm Circumference to Detect Wasting Among Children Aged 6–59 Months in Nepal

When comparing the sensitivity and specificity of mid-upper arm circumference (MUAC) versus weight-for-height z-scores (WHZ) to identify wasting in children aged 6–59 months in Nepal, our findings suggest that only using MUAC compared to WHZ to screen may exclude a large number of children who could be at risk of severe or moderate acute malnutrition.

Krishna Prasad Lamsal, Kedar Raj Parajuli, Bhim Kumari Pun, Ramesh Prasad Adhikari, Manoj Bashyal, Baburaja Dangol, Kenda Cunningham

https://doi.org/10.9745/GHSP-D-20-00450
Effects of Pharmacist Intervention on Community Control of Hypertension: A Randomized Controlled Trial in Zunyi, China

There has been growing interest in the role of pharmacists in managing chronic conditions. We tested the effects of a pharmacist intervention on community control of hypertension. Findings showed significant short-term improvement in patient knowledge, medication adherence, and lowered blood pressure.

Ying Li, Guoqin Liu, Chaojie Liu, Xianhong Wang, Yalin Chu, Xiaoqing Li, Wenhao Yang, Yewei Shen, Fang Wu, Wenzhi Zhang

https://doi.org/10.9745/GHSP-D-20-00505

The Development and Inclusion of Questions on Surgery in the 2018 Zambia Demographic and Health Survey

Data from household surveys serve as the backbone to sustainable development planning. For the first time, questions on surgery have been included in a nationwide Demographic and Health Survey, showing that it is feasible to integrate these questions into a large-scale survey.

Sabrina Juran, Sanna Moren, Vatshalan Santhirapala, Lina Roa, Emmanuel Makasa, Justine Davies, Jose Miguel Guzman, Lars Hagander, Hampus Holmer, Mark G. Shrime, Thomas G. Weiser, John G. Meara, Stefanie J. Klug, David Ljungman

https://doi.org/10.9745/GHSP-D-20-00619

From Insecurity to Health Service Delivery: Pathways and System Response Strategies in the Eastern Democratic Republic of the Congo

We identify the mediating factors through which insecurity affects both health service quality and delivery and investigate the strategies adopted to sustain service provision in the provinces of North and South Kivu, Democratic Republic of the Congo.

Chiara Altare, Vito Castelgrande, Maphie Tosha, Espos Bwenge Malembaka, Paul Spiegel

https://doi.org/10.9745/GHSP-D-21-00107

Nutrition Capacity Building to Meet National Priorities: Lessons Learned in Developing and Implementing Malawi’s First Dietetics Program

We describe the lessons learned in building nutrition capacity through the development and implementation of the first dietetics training program in Malawi.

Sanele Nkomani, Lynne M. Ausman, Elizabeth Marino-Costello, Bernadette Chimera, Alexander Kalimbira, Agnes Mwawgwa, Molly Uebele-Harrigan, John Phuka, Shibani Ghosh

https://doi.org/10.9745/GHSP-D-20-00687
PROGRAM CASE STUDIES

Results-Based Financing for Health: A Case Study of Knowledge and Perceptions Among Stakeholders in a Donor-Funded Program in Zambia

The lack of a fully developed results-based financing model before implementation of a program in the health sector begins can lead to difficulty in communicating about the program to different actors involved and delay components of implementation.

Rachel Bergman, Birger C. Forsberg, Jesper Sundewall
https://doi.org/10.9745/GHSP-D-20-00463

REVIEWS

Leveraging the Client-Provider Interaction to Address Contraceptive Discontinuation: A Scoping Review of the Evidence That Links Them

After examining existing evidence on contraceptive counseling and its impact on discontinuation, this scoping review identifies principles and priorities for better rights-based counseling, yet also illuminates the need for more evidence to understand relationships between counseling and discontinuation.

Kendal Danna, Alexandra Angel, Jamee Kuznicki, Laetitia Lemoine, Klaire Lerma, Amanda Kalamar
https://doi.org/10.9745/GHSP-D-21-00235

Lessons Learned During the COVID-19 Pandemic to Strengthen TB Infection Control: A Rapid Review

In light of competing health priorities of COVID-19 and TB, we propose recommendations to strengthen health system preparedness for optimal TB control across low- and middle-income countries during and after the COVID-19 pandemic.

Helena J. Chapman, Bienvenido A. Veras-Estévez
https://doi.org/10.9745/GHSP-D-21-00368

FIELD ACTION REPORTS

How Home Delivery of Antiretroviral Drugs Ensured Uninterrupted HIV Treatment During COVID-19: Experiences From Indonesia, Laos, Nepal, and Nigeria

During the COVID-19 pandemic, home delivery of antiretrovirals for HIV treatment proved to be a feasible approach for ensuring treatment continuation amid facility closures and travel restrictions. Antiretroviral home delivery is a model warranting further consideration as an additional option for decentralized drug delivery for HIV treatment.

Theresa Hoke, Moses Bateganya, Otoyo Toyo, Caroline Francis, Bhagawan Shrestha, Phayvieng Philakone, Satish Raj Pandey, Navindra Persaud, Michael M. Cassell, Rose Wilcher, Holly Mahler
https://doi.org/10.9745/GHSP-D-21-00168
Development of an Innovative Digital Data Collection System for Routine Mental Health Care Delivery in Rural Haiti

Mental health information systems in low-resource settings are scarce worldwide. Data collection was accurate, yet sustainable staffing was a challenge when using task-shared clinical providers for data collection in health centers in rural Haiti. Integrating mental health data collection within existing data collection systems would help close this key gap.


https://doi.org/10.9745/GHSP-D-20-00486

SHORT REPORTS

Health System Redesign to Shift to Hospital Delivery for Maternal and Newborn Survival: Feasibility Assessment in Kakamega County, Kenya

Service delivery redesign is needed to accelerate progress toward improved health outcomes. Kakamega County, Kenya, demonstrates that there is a strong base of health system assets that would serve as a starting point to successfully implement maternal and newborn health service delivery redesign.

Kojo Nimako, Anna Gage, Caroline Benski, Sanam Roder-DeWan, Khatra Ali, Charles Kandie, Aisha Mohamed, Hellen Odeny, Micky Oloo, John Tolo Boston Otieno, Maximilla Wanzala, Rachel Okumu, Margaret E. Kruk

https://doi.org/10.9745/GHSP-D-20-00684

TECHNICAL NOTES

Mid-Upper Arm Circumference Tapes and Measurement Discrepancies: Time to Standardize Product Specifications and Reporting

Mid-upper arm circumference (MUAC) is a widely used anthropometric measure to identify children with acute malnutrition. The use of different tapes of varied materials and thicknesses to measure MUAC has led to discrepancies. This indicates the need for global standardization of MUAC tape design.

Ritu Rana, Hatty Barthorp, Marie McGrath, Marko Kerac, Mark Myatt

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A Call to Action: Reinvigorating Interest and Investments in Health Infrastructure

Lindsay M. Mallick, a,b,c Joshua Amo-Adjé d

See related article by Rokicki et al.

Person-centered care and measurement of the client experience has captured the spotlight in the field of quality of care,1 especially amidst growing awareness of pervasive mistreatment and disrespectful care.2,3 Despite the importance of this topic, a focus on strengthening infrastructure cannot fall by the wayside. In this issue of GHSP, Rokicki et al. draw our attention to structural aspects of delivery care and demonstrate their importance in health care delivery.4

In essence, infrastructure is essential for high-quality care, yet improvements in health infrastructure in low- and middle-income countries (LMICs) have not progressed on pace with the increasing demand for health services, especially in sub-Saharan Africa.5 A renewed focus on infrastructure to both improve health and protect and retain the health care workforce—a focus that works in tandem with efforts to promote person-centered care, is environmentally friendly, and aims to equip facilities to handle infectious disease outbreaks—is direly needed. Here, we make the plea to reinvigorate interest and investments in health infrastructure.

QUALITY CANNOT OCCUR IN THE ABSENCE OF ADEQUATE INFRASTRUCTURE

In the past several decades, we have seen a dramatic increase in the use of health care facilities, especially for childbirth in LMICs, but the investments in improving access and use of services have not yielded expected decreases in maternal and newborn deaths.5,7 As Rokicki et al. mention,4 lack of high-quality care for many common, treatable conditions currently contributes to more excess deaths than lack of use of health care facilities,8 thus warranting further examination of health systems and quality of care.

Quality of care is a multidimensional construct that encompasses a spectrum of inputs and processes integral for achieving optimal health and satisfaction with care. Infrastructure—namely, electricity, water, equipment, and physical resources—along with medicines and human resources, is the most basic, foundational requirement of quality of care. These elements, which together constitute readiness for care,9 are “nonnegotiables” for providing health services; protecting clients and providers; and avoiding preventable infections, illness, and death.10 The Figure depicts a hierarchical structure in which we envision the cross-section of various quality of care frameworks,11–14 wherein infrastructure is at the base of the pyramid of quality health care upon which other aspects of quality and optimal health outcomes rest.

While infrastructure is critical for high-quality care, it is not a measure of services provided,14 and inadequate service provision can occur even amidst sufficient infrastructure and resources.15 Yet, the inverse does not hold, and this cannot be overemphasized. Care cannot be safe without clean water and access to sanitation, it cannot be effective without light and necessary equipment, equitable when rural facilities are most poorly prepared, timely without nearby lifesaving surgical theaters or transportation to access them, and patient-centered without attentive and skilled providers.

INFRASTRUCTURE IS A REQUIREMENT FOR ADEQUATE PERSON-CENTERED CARE

Infrastructure that allows for adherence to medical standards is a requirement for person-centered care. Person-centered care entails establishing (adult) clients as partners in their care, and through that, trust in the health care system. But without reliable energy, adequate water, and sanitation, and other vital components of health system infrastructure, clients’ health and trust are in jeopardy. When these aspects of care are unavailable, it poses a risk to health, further undermines trust, deters future care seeking, and worsens health outcomes.10

HUMAN RESOURCE PROTECTION AND RETENTION THROUGH INFRASTRUCTURE INVESTMENT

Even more important when considering the deleterious impact of the coronavirus disease (COVID-19) pandemic

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on human resources, adequate infrastructure protects health care workers and is associated with provider satisfaction, recruitment, and retention of the workforce.16–18 Water, sanitation, ventilation, and sharps (e.g., needles) control are necessary for infection prevention and control. Health care workers stationed at facilities without sufficient infrastructure are risking their own health to care for communities and provide suboptimal care for their patients. The lack of infrastructure, most pronounced in rural communities, is a reason often cited for poor retention of health care workers,16–18 especially when their services can be provided more lucratively in environments safer for both clients and staff. Thus, where human resources are sparse, basic infrastructure must be prioritized to acquire, protect, and retain staff.

**ADEQUATE ENERGY, WATER, HYGIENE, AND SANITATION WILL SAVE LIVES**

With high-quality care and appropriate labor and delivery management, which is contingent on having adequate health infrastructure, an estimated 1.3 million fetal, neonatal, and maternal lives can be saved by 2030 in the 75 countries where nearly all respective deaths occur.19 Rokicki et al.8 demonstrated that solar electric installation was associated with certain improvements in quality of care, specifically related to infection control, postpartum hemorrhage prevention, and newborn care, which are keystones for mortality prevention.

Electricity, either renewable or grid-powered, is also vital for lighting, medical equipment, refrigeration for preserving medicines and vaccines, ventilation, heating for sterilization, air, or water, and communication systems for record keeping, reporting, and referral processes,20,21 yet more than half of health facilities among 78 African, Asian, and Oceanic LMICs lack access to reliable electricity.22 When electricity is available, it is often unreliable, as found in 60% of the facilities in the 78 countries studied. Outages can also be chronic and enduring; for example, Ghana experienced a multiyear power crisis between 2012 and 2016, where electricity was unstable throughout the entire country. These frequent and prolonged power outages were detrimental for the health care system; one study found that the risk of mortality in facilities in Ghana increased by 43% when power was out for more than 2 hours.23

There are risks and consequences of seeking care in facilities without adequate water, sanitation, and hygiene (WASH) structures, yet the statistics for the availability of WASH are grimmer than those statistics for electricity. In those same 78 LMICs, only two-thirds of health facilities had improved toilets, 3 of 5 had soap, and half had piped water; worse, only 2% had all 4: toilets, soap, water, and waste management.22 The World Health Organization (WHO)/United Nations Children’s
Fund (UNICEF) Joint Monitoring Programme for WASH estimates that this translates to 900 million people accessing health care facilities without water and 1.5 billion without sanitation services. Among hospital or facility-acquired infections during birth are largely preventable through tetr

Although hospital or facility-acquired infections during birth are largely preventable through tetanus vaccination and clean birth practices (e.g., handwashing and sanitary umbilical cord care), infection acquired during this time is a leading cause of death for mothers and babies. There is also an increased risk of developing antimicrobial resistance when clients are exposed to human waste (which carries antimicrobial-resistant pathogens) in health care facilities that lack improved toilets or have poor sanitation systems.

## INFRASTRUCTURE NEEDS DURING COVID-19

The COVID-19 pandemic has revealed additional health care system gaps that are essential for managing infectious respiratory diseases such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Recently, the Demographic and Health Surveys Program highlighted limited readiness to manage infectious diseases according to Service Provision Assessment surveys conducted in health facilities across 3 regions of the Global South. Between 1 to 6 in 10 facilities have communication equipment (a landline, facility-owned, or supported private cellular phone or a short-wave radio) necessary to refer patients to higher-level facilities for intensive or specialist care and coordinating supportive therapy with oxygen. Although a lack of data is a barrier to assessing oxygen needs more broadly, only 16% or less of facilities in 7 countries with recent Service Provision Assessment surveys reported availability of oxygen. However, efforts to scale up oxygen are underway, and the WHO COVID-19 Essential Supplies Forecasting Tool (https://apps.who.int/iris/rest/bitstreams/1342089/retrieve) can help to estimate needs for oxygen and other equipment, supplies, and drugs for care and treatment of COVID-19. In addition, recommendations for managing patient oxygen needs in resource-constrained settings are compiled and summarized by Serpa Neto et al.

For reducing transmission in health care facilities, adequate air filtration and ventilation are paramount alongside management of patient flow and personal protective equipment for health care workers. The increased use of intensive care units in the face of COVID-19 further stresses the need for health infrastructure. In intensive care units especially, adequate heating, ventilation, and air conditioning systems are central to maintaining positive pressure or negative pressure rooms to reduce the spread of airborne pathogens. High-efficiency particulate air filtration or negative pressure zones can reduce the risk of spread of infections in intensive care units, operating rooms, or other areas where procedures generate aerosolized particles. In resource-constrained settings, these systems are limited in their ability; however, health care administrators can also use several strategies to limit spread including using personal protective equipment, triaging patients to evaluate urgency, postponing nonemergent procedures, and improving COVID-19, and isolating COVID-19 positive or suspected cases. These recommendations and others are detailed in the WHO’s Maintaining Essential Health Services: Operational Guidance for the COVID-19 Context.

As shown by Our World in Data (https://ourworldindata.org/covid-vaccinations), as of December 2021, only 6% of the population in low-income countries had been vaccinated, compared with 74% in high-income countries. The disparate rollout of vaccines against SARS-CoV-2 relates both to vaccine equity—the sharing of vaccines and technology—as well as infrastructure-related challenges in the vaccine cold chain, wherein vaccines must be maintained below or near-freezing temperatures (with temperature variation across different vaccines) from manufacturer to distribution sites. This is particularly problematic in areas that are rural, lack road infrastructure, are susceptible to transportation barriers during wet seasons, or have facilities that lack electricity for storage. In 2016, Gavi, the Vaccine Alliance (the organization largely responsible for COVID-19 vaccine rollout in LMICs through COVAX), established the Cold Chain Equipment Optimization Platform, which can be used to plan investments to ensure maintenance of cold chains and, ultimately, improve coverage. A scale-up of these cold chain management and other vaccine efforts are essential to reduce the burden of COVID; without these, COVID-19 will likely remain endemic, with a persisting cycle of mutations of new variants.

## CLIMATE-FRIENDLY AND CLIMATE-RESISTANT ENERGY, WATER, AND SANITATION SOLUTIONS

It is most responsible to plan for improvements in infrastructure by considering their environmental impacts. Further, the reality of climate change is such that new installations must be robust...
to endure extreme and worsening weather conditions. While these installations may require substantial initial investments, they have the benefit of lowering long-term operation costs, reducing health care costs, and yielding an overall cost savings.\textsuperscript{10,38,39}

How countries should invest in energy should be determined based on available resources and careful examination of the feasibility and cost-effectiveness of renewable energy versus conventional, grid-powered energy. Renewable or hybrid renewable systems that draw from multiple sources of renewable energy, including wind and solar energy, can deliver sustainable, reliable, environmentally friendly methods of powering basic equipment at health care facilities and have been proposed to meet demands in both urban and rural areas.\textsuperscript{21,40} The Hybrid Optimization Model for Electric Renewables software (owned by UL), for example, can assist with planning such investments through techno-economic simulations that take into account geographic-specific information.\textsuperscript{21,40}

To improve WASH in health care facilities, the WHO outlines 8 practical steps, including conducting assessments, establishing goals and standards, investing in infrastructure, monitoring WASH systems, training health care workers, engaging communities, and conducting further research.\textsuperscript{41} Recently, UNICEF has supported using wind and solar-powered water pumping systems, that while requiring substantial up-front costs, are environmentally friendly, climate-resistant, and have long-term cost payoffs.\textsuperscript{39} UNICEF details programmatic approaches for improving access to water, including collaboration with climate-sector actors and consideration of local needs and resources.\textsuperscript{38}

Among other climate-friendly suggestions for waste management, the WHO recommends consideration of steam-based methods over incineration for de-contamination of infectious waste to prevent any further environmental harm.\textsuperscript{10} Moat and Lavis provide an additional resource for developing evidence-informed policies that can be broadly applied to consider other aspects of infrastructure development.\textsuperscript{42}

\section{INFRASSTRUCTURE INVESTMENT FOR THE GREATEST GAINS}

To be sure, investments in infrastructure for health can be costly and seem untenable in resource-constrained settings. These investments compete with other equally important areas. Nonetheless, infrastructure investments can contribute substantially to alleviating burdens of morbidity and mortality while also providing a positive return on investment in the long term.\textsuperscript{10}

In summary, advocacy for better infrastructure must continue until facilities are equipped to handle the health issues they face. Although providing poor quality of care pervades even the most well-equipped service environments, high-quality care is only possible in settings where key infrastructure requirements are met. Any new infrastructure investments should consider environmentally friendly options durable to the extreme weather conditions resulting from climate change, while also bolstering readiness requirements for current and future infectious disease outbreaks. Future human resources, client care-seeking behaviors, and optimal health outcomes depend on these investments.

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\section{REFERENCES}


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Motivation and Performance of Community Health Workers: Nothing New Under the Sun, and Yet. . .

Eric Sarriot,a Tom Davis,b Melanie Morrow,c Telesphore Kabore,d Henry Perrya

Key Messages

- We consider the types of incentives that motivate community health workers’ (CHWs) performance and the implications at 2 levels of systems analysis—first, for CHWs themselves and then for appropriate management of an invaluable human resource by CHW programs.

- The World Health Organization recommendations on commensurability of CHW compensation with the job demands—and corresponding professionalization—represent the culmination of decades of work, advances, forgetfulness, rediscovery, collective wisdom, and available evidence.

- Tapping into communities’ own organizing potential through volunteerism is, however, a force in both high-income and low- and middle-income countries.

We offer predictions for the future direction of CHW programs:

- National CHW programs—whether implemented by states or non-state partners—will be a growing opportunity to viably strengthen national health systems.

- Partnerships between state and non-state actors will be key to sustain effective CHW programs in national PHC strategies at scale.

- The social-versus-institutional anchoring of CHW programs will be an enduring challenge for their performance and sustainability. Dual models (paid CHWs and volunteers), if ethically managed, will be a promising approach for efficiency and scale.

See related article by Roy et al.

INTRODUCTION

GHSP has shared with some regularity research and practice papers on the recruitment, training, compensation, roles, support, potential, and performance of community health workers (CHWs). We are not alone in wanting CHW cadres to be taken seriously and engaged effectively. The (redundantly named) “community health community” took very favorably the recommendations of the World Health Organization (WHO) on CHW programs,1,2 which was the culmination of decades of work, advances, forgetfulness, rediscovery, and new lessons. The WHO recommendations provided an authoritative treatment of our collective wisdom and available evidence.3 In this issue of GHSP, Roy et al. bring us to Bangladesh—a country with notable governmental and nongovernmental efforts to structure CHW programs for effective primary health care (PHC)—to consider what factors drive the motivation, and consequently the performance, of CHWs.4 Roy et al. apply a robust qualitative methodology, provide insightful analyses, and offer a rich discussion about implications for program management. One of the findings is that4:

CHWs shared a range of nonmonetary and monetary factors that have affected their motivation, performance, and job satisfaction.

A cursory reader well-versed in CHW programs (for example, the 20-year-old seminal publication of Bhattacharyya et al. on CHW incentives and disincentives5) might be forgiven for pondering, “We already know that both financial and nonfinancial incentives matter if we want motivated and performing CHWs. What is new in this?” The question is timely as a new Health Research Policy and Systems6 supplement issue (including a summation of lessons on incentives and remuneration of CHWs) now updates the work of Bhattacharyya et al.,5 the CHW Reference Guide,8 and more recently, the 29 country case studies by Perry on national CHW programs.9 Indeed, some findings recur across contextual studies and accrue a recognizable body of evidence, even if they do not have the sharp edges of controlled experiments.

As we are in the age of “systems thinking” in global health, we consider 2 systems of a different order: the...
biological-psychosocial system of CHW workers as individuals and the social-institutional system in which CHW programs are anchored.

**PEOPLE ARE SYSTEMS TOO**

We can examine some of the ways to break down the incentives and disincentives to CHW motivation, starting with the central question (for programmers) of financial compensation and the thorny corollary issue of volunteerism.

Without going out on a limb, we observe that throughout history, regardless of the field of practice, financial compensation has been a consistent incentive for giving one’s time and energy to a project or corporate entity. Why would individuals providing health promotion or health care at the community level be any different? We have now entered the age where this principle is recognized by both advocates and technical authorities, although practice struggles to follow the principle.9,10 Given the scale of CHW programs required to achieve their potential, appropriate compensation has a nonnegligible cost, even if the investment is cost-effective.9,11 Does this mean, however, that volunteerism should be retired completely once governments and programs have budgeted for enough CHW staff costs? Probably not.

Volunteerism exists in community work, in organizing global health conferences, as a learning opportunity for young (and not-so-young) professionals through internships, for the arts, and for 1,001 community life activities, fairs, political and faith-based activities, not to mention writing commentaries. It is called “volunteerism” precisely because it is an exception to the established principle that “workers are worthy of their hire.” While abuses of the past are rightly recognized, volunteerism has its own benefits to volunteers. People who volunteer report better health and greater happiness than people who do not, a relationship that is not driven by socioeconomic differences between volunteers and nonvolunteers.12 Volunteerism has health benefits including reduced hypertension and increased psychological well-being.13

Additionally, if we consider the role of social support and social capital in community health,14 the potential of broad community engagement processes, the very scale of PHC efforts trying to reach “the last child” and neglected communities, and the strength of people coming together, it would be foolish, counterproductive, and even patronizing to toss aside volunteerism as a resource. In the end, what global health “influencers” should stand up against is the abuse of volunteers when long hours (e.g., more than 4 hours per week) are required of people with limited agency and who are faced with a precarious livelihood. In the aforementioned supplement, Colvin et al.7 remind us of the WHO recommendation on compensation, namely of commensurability with the job demands and of explicit formulation through written agreements. While the CHW-community health volunteer (CHV) “dual model” requires clearly differentiating the management of a professionalized workforce (paid CHWs) from the engagement of volunteers—and there are fears that dual models might still be exploitative16—it seems to be a promising approach for efficiency and scale.9,15 Volunteerism is a force in societies, and we have examples of health sector interventions that have learned to tap into communities’ own organizing potential.15,17-21

Beyond payments, there are multiple ways to support workers’ intrinsic motivation and performance. It is reassuring and perhaps humbling that what we are learning about motivation of CHWs aligns with prior lessons from the management and psychosocial sciences. Examples can be useful. The seminal work of Richard Ryan and Edward Deci on self-determination theory posits that individuals have 3 basic psychological needs: autonomy (or self-determination), relatedness (or belongingness), and competence.22,23 Accordingly, the satisfaction of these needs leads to intrinsic motivation. In another model, Josh Epstein’s Agent_Zero agent-based model,24 an individual’s (or “agent’s”) “disposition to act” is based on 3 immediate drivers: cognitive or volitional, emotional, and social (a form of “peer contagion”). The similarities with the drivers of motivation for other behaviors—such as vaccine uptake—are notable.25,26 In previous unpublished work, Save the Children used this model to review 95 publications from the literature on CHWs and human resources for health, business and management, and psychology. This review identified a nonexhaustive list of more than 120 factors of motivation (sometimes external, sometimes internal, sometimes overlapping), which are associated with Epstein’s 3 drivers of

“If we consider the role of social support and social capital in community health, the very scale of PHC efforts trying to reach “the last child,” and the power of people coming together, it would be counterproductive to toss aside volunteerism as a resource.”

“Motivation” can be a confusing word in development as it refers to both an internal disposition and to means for promoting the individual disposition, which effectually leads to performance if contextual conditions allow it. In this article and to keep it simple, we will use “motivation” to mean the internal propensity of an agent to take action, the “disposition to act” (in the Epstein model).
Motivation and Performance of Community Health Workers

Cognitive factors include the type of professional goals, difficulty of tasks, sense of efficacy and skills, professional opportunities, rewards and compensation, workload, etc. Emotional factors include recognition and support from members of the community, feeling valued, respected, and supported by health system supervisors, pride, and sense of purpose. These positive emotional factors have negative corollaries when absent, such as anxiety and feeling overwhelmed or isolated. A large behavior change program in Mozambique found that the respect gained from other people in Care Group Volunteers’ social network—and seeing the results of the project—were key motivators for volunteers (in addition to cognitive factors, such as skills development). All surveyed volunteers reported that they were more respected by other women in their community because of their participation as a volunteer. They reported being more respected by community leaders (64%), their husbands (61%), their parents (48%), and health facility staff (25%). Global lessons confirm the findings of this study.

The different processes, which can influence cognitive and emotional drivers are known, and their effects on one or the other are sometimes difficult to tease out. Quality supportive supervision, for example, can boost both cognitive factors (skills and competencies) and emotional ones (feeling valued and supported). Other processes that affect motivation include training, equipping, providing compensation, a title, a career path, but also symbolic and practical things such as providing a uniform, a backpack, or a public recognition ceremony.

Coworkers can contribute to both drivers, but Epstein’s model acknowledges a direct influence of peers’ motivation on an agent’s own motivation. This “peer contagion” is a phenomenon known to both team managers and social network researchers. Peer contagion happens when social contacts with other CHWs reinforce positive or negative overall motivation. This can be through geographic proximity, formal group meetings, informal peer support, competition, learning and sharing experiences, and increasingly through digital communication. In simple English, the feelings, motivation, and energy of those close to or like us influence our feelings, motivation, and energy in the workplace, both positively and negatively, and this is also true for CHWs. Effective program management must be cognizant of these factors and influence positively the cognitive and emotional motivation of CHWs, as well as their group dynamics. The link between motivation and performance is however dependent on context and systems’ conditions, which enable or disable performance. The proverbial “no commodities, no program” may be an illustration of how heavily these constraints can undermine the best programmatic efforts and intrinsic motivation.

The recent work by Colvin et al. reviews a considerable body of work on the topic but focuses on the incentives provided to CHWs, which are organized under 4 categories: financial, nonfinancial, health system, and community level. This leads us to rapidly consider the systems giving life to CHW programs, before indulging in the risky business of predictions.

## CHW Programs, from Projects to Systems

The first question for us, donors, national leaders, program practitioners, and researchers, is why we would think that the motivation of CHWs should be any different from that of other mortals in their respective workplaces? The PHC case for the value of CHWs for delivery of positive health outcomes—as part of comprehensive and coherent strategies—has been made and made repeatedly over half a century. CHW programs can work and deliver, this we know. What we—starting with national, state, and nonstate leaders—need to get better at is to shift from epidemiological and disease control mindsets (“what works?”) to organizational and management paradigms (“how can it work better?”) and properly address all incumbent duties of leadership, organization, and management of programs. This demands that we properly understand the systems in which these programs need to be anchored and that we manage accordingly. At a macro/policy level, this fits into a more comprehensive view of health systems, hopefully now broader than the useful but dated “building blocks,” notably because we need to work with community-level systems and their levers. Country and program leaders need to operate from a community-inclusive system for health perspective. At the micro, subnational, and implementation level, the CHW logic model (Figure) presents a compelling description of the dual anchoring of CHW programs in both institutional (a still traditional “building blocks” view of health systems) and social (communities) realities and offers a useful systems map.
reflected in other narratives and tools. The sum of these elements represents a health system as initially intended, differences in models reflecting differences in the central analytical perspective, not in the overall reality.

While aware of the variously attributed statement, “predictions are difficult, especially about the future,” we would like to conclude with 4 overarching predictions about where these management and systems considerations may take us in the future.

1. National CHW Programs—Whether Implemented by the State or Nonstate Partners—Will Be a Growing Opportunity to Viably Strengthen National Health Systems

At times, there is an unspoken sense that when health norms and outcomes improve or when GDP per capita gets higher, we will somehow end up with our health needs taken care of by hospitals, clinics, health facilities, and doctors, and finally be free of CHW programs, which we stigmatize as a lower-income country, non-governmental organization (NGO)-driven “thing.” This is perhaps more of a blind spot than as an explicit statement by thought leaders in our field (see for example a recent call to rethink health systems, which entirely skips the necessary investments for community health). But CHW programs are not an artifact of external development assistance; they are a central and adaptable part of effective and viable systems for health, regardless of the income status of a country. High-income countries may have been able to project a mistaken facility-centric vision of health but only for a time. Throughout HICs, we see breaches in the connection of health systems to communities possibly due to this blind spot, for example, through vaccine hesitancy and refusal and the huge burden that unhealthy lifestyles have on health status in HICs. In LMICs, there was a major learning moment at the
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Dual models of paid CHWs and volunteers will need to be effectively and ethically managed, with proper differentiation of their status, roles, and motivations.

time of Ebola, and we have now a reckoning about the necessity of community health and CHWs in this time of novel coronavirus disease (COVID-19). 36,37 Interestingly, this moment is shared by LMICs and HICs. The literature on CHWs in HICs is slowly growing from addressing COVID-19, access to health care, and noncommunicable diseases, among others.38–46 Of course, epidemiological, economical, and demographic conditions will ultimately drive CHW programs in different directions, for example, toward noncommunicable diseases or toward universal health coverage-related access and social issues.

The need for health-focused CHWs in LMICs is with us to stay, even for some curative services, but time will tell whether we will see an evolution toward the social side of the health and social services spectrum over time.48 Roles cannot be expected to be static in an ever-changing environment, but what should be expected from good governance and management is clarity of roles, focus on achievable (“do-able”) missions, fitness to the needs and structures of primary health care, compensation, and proactive and diligent management.

2. Partnership for Effective PHC and CHW Programs Will Be a Keyword of Our Future Success

While the governance of CHW programs needs to fit under 1 national health strategy, this strategy will be able to choose from a plurality of possible state or nonstate partners as program managers. We now have plenty of evidence for both nationally run CHW programs45 and for programs run by NGOs and even private hospitals seeking to expand their PHC activities. The stigmatizing of “parallel” NGO programs, if perhaps occasionally deserved, is probably also a reflection of governance gaps. It seems to disappear when governments are deliberate in advancing community health and in creating constructive partnerships for public goods with civil society.8 NGOs have often provided a learning platform and testing ground for innovations,2 and they are a somewhat irreplaceable force for mobilization and organization as soon as new threats emerge, from HIV to Ebola to COVID-19. In Maryland, United States, the Baltimore Health Corps was born under the impetus from faith-based organizations, social justice groups, Johns Hopkins University, and the city government. Partnership will endure as a keyword for future PHC programs and will be key to the performance and adaptability of CHW programs.

Dual models of paid CHWs and volunteers will need to be effectively and ethically managed, with proper differentiation of their status, roles, and motivations. It may be unrealistic to expect governmental structures to manage with the required agility the mobilization of volunteers, which, by definition, will come and go. Partnership of the health sector with local government and with civil society organizations has already shown strong potential and will continue to be needed. We need to move beyond all-or-nothing debates, whether debates on paid CHWs and volunteer programs or on the complementary role of the state and civil society, especially since both have legitimacy and need of one another. The health of the public depends on both. Ultimately, nations—inclusive of citizens, civil society, private entities, and the state—need to choose the governance and PHC architecture that suits them to face evolving challenges and to fine-tune arrangements in an ongoing manner. Local adaptive management, negotiation, and learning within pluralistic health systems need to take over global (well-meaning) one-size-fits-all mandates.

3. The Social-Versus-Institutional Anchoring of CHW Programs Will Be an Enduring Challenge for Their Performance and Sustainability

We will continue to evolve our programs and will need to differentiate between CHWs and CHVs. This will require adaptive contextual processes. CHWs were born out of a need to anchor health promotion within communities. Selection of CHWs by their communities to ensure both their integration in the social landscape and community ownership has been an essential feature of CHW programs. This remains the case, but the dual anchoring of CHWs is progressively going to shift from communities first to the “health system” as CHWs are expected to provide more and more professional work and hours with hopefully more and more appropriate compensation. This professionalization comes with a shift in accountability (from communities to health structures), the appeal of career paths, and the geographic mobility this

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8See example in Switzerland with the Agents de Santé (https://agentsante.ch/), in Baltimore, Maryland with the Baltimore Health Corps (https://www.baltimorecorps.org/baltimore-health-corps).

2A full review of this issue goes beyond the scope of this article, but Bangladesh, Ethiopia, Ghana, Nepal, and Rwanda came to mind.
affords. There is also the temptation from managers in frontline facilities to pull CHWs away from community work to help with the limited staffing of their facilities. This pull may be attractive to some CHWs themselves, who may find time in facilities to be perhaps easier, certainly providing more shade in hot climates, and more social opportunities than long treks and walks to reach the last mile. Finally—as some of our co-authors have already observed—professional CHWs are becoming more educated, and this will out-select some community resource persons who would have become CHWs under a previous model. All in all, it does not require a behavioral economist to acknowledge that programs with professionalized CHWs will have the unavoidable tendency of moving CHWs from a social (community) to an institutional (facility) anchoring. Again, dual models with both volunteers (CHVs) and professional CHWs may be a possible solution. This complexity will need careful management.

At this point, the line between the paid CHWs and CHVs often remains blurred. After all, the WHO recommendations are only 4 years old, and it takes time to evolve out of old program habits. Furthermore, policy decisions can have significant budgetary implications, and large program shifts are subject to “path dependency” : once a direction has been taken, it may be challenging to reverse. Governments are consequently cautious about budgets, and budgets are dependent on habits, which are difficult to change. Many countries are still dealing with different types of CHWs, providing a range of different services, under a range of varied compensation and financial incentive schemes, delivered by different managing institutions. Contextual scenario mapping, planning, problem solving, optimization through operations research, ongoing learning, and adaptive management will be key in guiding these programs toward coherence, performance, and sustainability.

4. Effective National Programs Will Be Led by Managers Who Expend Energy to Uncover and Optimize the Drivers of Motivation of Their CHWs at the Intersection of Their Institutional and Social Anchoring

Returning to the motivation of CHWs, we can now recognize that motivation can only be built on top of policy, program design, social anchoring, and institutional management platforms. While service organizations operating at scale can make short-term gains by pressuring their human resources, the long-term health of organizations (not to mention ethics) rests on a competent and motivated workforce. Health systems, or rather community-inclusive systems for health, are no different.

The job of CHW program managers—along with country policy makers, civil society actors, and researchers—will be to identify (and adjust at appropriate times) what combination of factors under their influence can advance the internal cognitive, emotional, and peer-influence factors of CHW motivation. This demands proactive steps in management. Our research models must consequently evolve to address more specific questions. CHW program managers will have to combine lessons from psychosocial research with management science, operations research, and qualitative studies to improve the effectiveness of their programs step by step, through a motivated workforce.

Interestingly, Roy et al. show us what it takes to turn a “paper workforce” into motivated human capital, starting with timely and quality research. Colvin et al. usefully seek to translate 4 types of CHW incentives from their review (see above) into a dozen or so policy and management “prompts,” which will deserve consideration context-by-context.

Our research and evaluation need to evolve from one-off testing of project interventions (a new external incentive, a new process creating a new cadre for a new task) to the consideration of the effective implementation of programs through the dynamic challenges of time. This requires a view of programs as ongoing systems, which need to ethically support the intrinsic motivation of CHWs—cognitive, emotional, and social.

Finally, context not only matters, but it centrally matters. The world is increasingly urbanized, and the health benefits of urbanization are unequally distributed, with peri-urban, informal settlements, and megacities’ poverty bringing a new scale of challenges. CHWs have operated in both rural and urban contexts, but in LMICs, rural has dominated. More research and learning will be needed in urban contexts.

CONCLUSION

Global patterns and lessons about CHW programs will continue to emerge, but it is local, national, and contextual applied research to hear the voices of CHWs and inform proactive management that will move us forward. National leaders must step forward, in LMICs and HICs, to internalize and
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COMMENTARY


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Key Messages

- The World Health Organization COVID-19 Partners Platform was conceived and implemented to support key operational engagement across health services and preparedness activities at the country, regional, and global levels.
- Use of the Platform is broadly applicable during public health emergencies but has proven as a critical asset to coordinate and accelerate deployment of vaccines for COVID-19 vaccination programs.
- The Platform is a dynamic environment created to accommodate the evolving needs of any pandemic response.

INTRODUCTION

On January 30, 2020, the Director-General of the World Health Organization (WHO) declared the coronavirus disease (COVID-19) outbreak a public health emergency of international concern under the 2005 International Health Regulations. This triggered a cascade of events that led to the introduction of the COVID-19 Strategic Preparedness and Response Plans (SPRP) that emphasized the importance of responding to the crisis as “One UN.”

While country readiness and response plans are key to tackling international public health emergencies, planning and coordinating across WHO member organizations have been challenging, and particularly so during an evolving global pandemic. To make the SPRP operational, WHO Health Emergencies Programme created the COVID-19 Partners Platform (referred to as the Platform; https://covid19partnersplatform.who.int/), conceived and implemented alongside other key operational support platforms and partnerships across health services and preparedness sectors (Table) to provide overall coordination and operational support to countries. This multidisciplinary effort aimed to guide the efforts of national and international partners, including donors, to support governments urgently to prepare, detect, and respond to epidemics and inform national planning while putting countries in the driver’s seat.

COVID-19 is a uniquely pressing emergency that can benefit from the real-time coordination of planning and tracking of activities that offers the following capabilities.

1. Consolidation of technical guidance and self-assessments enabling countries, territories, and areas to develop and refine their readiness and response plans in one place, avoiding siloes, difficult-to-access hard-copy storage, and email burden.
2. A secure web-based platform easily accessible even in low-bandwidth regions, with robust registered-user management processes under WHO standards for data privacy and protection.
3. Functionalities for all stakeholders across the public health landscape to share information and make decisions, including WHO Member States, United Nations agencies, implementation partners, suppliers, and donors.
4. Sustainability, as the Platform was conceived to be reproducible and scaled to prepare and respond to concurrent and future health emergencies.

The Platform facilitates country planning aligned with global strategies, which has proved to be an important function for countries. The Platform enables the exchange of information, documentation of readiness in
The Platform enables the exchange of information, documentation of readiness in subcountry level areas, and serves as a mechanism by which a broad set of donors can provide funding at a desired level of specificity as benchmarked by country needs.

### THE PLATFORM

The Platform operates under 3 principles: transparency, collaboration, and efficiency. Transparency, in that all information is meant to be visible across users, meaning that the Platform aims to be “a common source of truth” for public health operational information on country readiness for and response to COVID-19. As a tool, it provides transparency for country resource needs and donor support through contributions. This transparency then facilitates collaboration among the donor community, technical community, and country by enabling direct connection among donors and recipients that then translates into internationally recommended actions supporting COVID-19 national response plans. By facilitating near real-time visibility on plans, needs, and resources, across national, regional, and global levels (Figure 1), the Platform supports the efficiency of operations and anchors the country at the center, enabling the “right people with the right information at the right time” to make decisions leading to timely and appropriate actions.

In parallel, early on in the pandemic response, the Platform facilitated requests for critical supplies by serving as a “doorway” to the WHO Supply Portal, an open marketplace based on standard packages of supplies (e.g., personal protective equipment kits and laboratory kits) that could be scaled up for the population at risk. The Platform provided a means by which countries could share not only their readiness and response plans but also their resource needs. This transparency on country resource needs provided visibility that could inform donors supporting global efforts. Up-to-date mapping of donor resources further allowed donors to focus on resource gaps in countries as they were identified.

The initial scope of the Platform was 8 key pillars targeted in the SPRP for country readiness in February 2020. These pillars encompassed well-established areas of public health readiness and response: (1) country-level coordination, planning, and monitoring; (2) risk communication and community engagement; (3) surveillance, rapid-response teams, and case investigation; (4) points of entry; (5) national laboratories; (6) infection prevention and control; (7) case management; and (8) operations support and logistics. As the pandemic escalated from April 2020 onward, a ninth...
pillar related to the continuation of essential health services was established as a paramount priority to address the increasing demand for care caused by COVID-19 while also maintaining essential health services (e.g., antenatal care).3–6 In February 2021, a critical tenth pillar, COVID-19 vaccine deployment, was added as a central strategy in the response effort.4–6 Underpinning these strategic pillars is also the recognition that "research and innovation," as a de facto eleventh pillar, is a fundamental dimension of the response woven into the formal 10 pillars.4 Figure 2 illustrates these strategic pillars with interventions (vertical bars) and capacities (horizontal bars) that are facilitated by multidisciplinary national and subnational structures.5

The Platform is a web-based tool accessible by more than 4,000 active users representing 1,000 unique organizations spanning over 200 countries, territories, and areas. The platform is not a public application, but rather a tool reserved for public health responders. Of these countries, approximately two-thirds have shared their plans on the Platform, and 90 have shared their collective resource needs, which total more than US $9.3 billion across the first 9 pillars of health readiness and response. With this information, the Platform has become an information hub for global COVID-19 readiness and resource distribution where countries can interact transparently with global donors. This has resulted in more than US $9.1 billion in resources tracked to countries through the Platform from 77 donors.4 Without the Platform, such funding would normally be tracked through individual countries without a global matching of resources and needs and no systemwide visibility, thereby further contributing to what makes this platform a unique response tool.

What drives the distinct nature of the Platform is that countries are at the center, surrounded by key stakeholders including donors and implementing partners, enabling engagement with governments in a secure digital space through a clearinghouse of information central to decisions about response activities and funding to support response activities. All of this can then be tracked over time. Although a framework for evaluation and usability is currently under development, the application and use of the Platform in real-world settings is well illustrated in the current activity supporting COVID-19 vaccine deployment, through Pillars 10 and Pillar 11, the latest additions to the Platform.

**PILLAR 10: COVID-19 VACCINE DEPLOYMENT**

As of June 17, 2021, Pillar 10 of the Platform was accessible by 1,184 users across 124 countries, territories, and areas. Of the total users of Pillar 10, approximately 59% are country administrators and 23% are implementing partners and donors. As the pandemic continues and the roll-out of COVID-19 vaccines extends inevitably into...
2022 and 2023, it is expected that more users will come onto the Platform as interest heightens in supporting countries to meet global vaccination goals. The functions of the platform have served countries and the overall response effort by: (1) providing an overview of country needs based on their COVID-19 national deployment and vaccination plans (NDVPs), including resource needs; (2) serving as a mechanism to receive, review (when needed), and house strategic documents, as well as receive funding requests for operational support; and (3) mapping donor resource contributions to countries.

1. Provide an Overview of Country Needs Based on Their COVID-19 NDVP

While the race to develop vaccines has resulted in several safe and effective vaccines broadly available for use through emergency regulatory mechanisms, the last mile is to deploy these vaccines at a scale and pace that have never been attempted.\(^7\)\(^-\)\(^8\) This vaccination effort, the largest in history, will require intense coordination and collaboration globally, regionally, and at country levels. Toward this end, countries must also be prepared for vaccine deployment in unique ways as global supply constraints dictate a phased rollout across priority populations of adults.\(^9\)\(^-\)\(^10\)

Over time, with the rapid and accelerated development and production of COVID-19 vaccines, the Platform has taken on a coordinating role as part of COVAX, the worldwide initiative aimed at equitable access to the vaccines. COVAX is directed by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations, and WHO, with the United Nations Children’s Fund (UNICEF) as a key delivery partner and the Pan American Health Organization as the procurement agent in the Americas. To support country delivery and readiness, the Platform provides country-specific information (e.g., total population, coverage, adsorption rate, and supply data) that is critical for country planning and management of doses and vaccination campaigns. These data support the fundamental principles of the Platform: to enable transparency, visibility, and action for countries, donors, and stakeholders alike.

Through the leadership of WHO, UNICEF, and partners, 89 of 92 advance market commitment (AMC) countries, areas, and territories developed NDVPs, which serve as playbooks for organizing vaccination activities to strengthen immunization, health services, and health systems so that they can successfully introduce COVID-19 vaccination.\(^11\) Additional self-financing countries have also prepared NDVPs. The Platform became the single place for countries to upload an NDVP as a requirement to qualify for allocations of COVID-19 vaccines through COVAX. The Platform supported the rapid submission and review of 89 AMC and 19 non-AMC country plans. Review and approval of country readiness plans along with appropriate regulatory authorization are among the requisites for allocation and final release of vaccine doses from the COVAX facility to countries. Plans were uploaded onto the Platform within 3 days of the launch of the functionality, and initial rapid reviews of the NDVPs through regional review
committees were completed within a week. The
Platform allowed the experts of the regional review
committees to review and assess the NDVPs—
either directly online or offline—against predeter-
mined criteria. This then allowed for analysis of
areas of vulnerability in NDVPs, providing a global
and regional snapshot of country readiness that
could highlight areas of need for technical assis-
tance and further support. A heat map of these
assessments, stratified by WHO region (Figure 3),
illustrates the ability to do this type of analysis.

While regional review committees were set up
to execute this review function in initial NDVP
submissions, additional revisions to the NDVP
have not been reviewed, though the Platform can
easily accommodate this function. Further, the
Platform has the capacity and capability to receive
as many updated plans as countries wish to submit,
particularly as the evolving needs of the pandemic
dictate updates and revisions. Revisions may
include changes to national targets and milestones
and expansion of target groups including hard-to-
reach, underserved, refugees, and migrants; lessons
learned from initial roll-out including coordination
management of multiple products; human resource
surge requirements; and expansion and adaptations
to cold chain and logistics or any other dimension of
plans a country may wish to revise.10

Notably, 81 NDVPs were also reviewed by
WHO humanitarian experts supporting fragile,
vulnerable, and conflict countries to determine if
there was adequate inclusion of vulnerable popu-
lations (e.g., refugees, asylum seekers, and those
dedicated to relieving their suffering). Because of
the ability to access country plans and provide
technical support to countries for this area of plan-
nung, revisions to country plans were made imme-
diately. Weeks later, Gavi approved 5% of COVAX
AMC funding for doses to be deployed through
COVAX via a “humanitarian buffer.” This mecha-
nism seeks to address vulnerable populations that
might not be included in other allocation and access
mechanisms (e.g., in instances of state failure and
conflict and areas controlled by non-state armed
groups and thus inaccessible to governments).

Country NDVPs also serve as guide rails for the
costing of activities needed to resource programs
adequately to vaccinate their populations success-
fully. Then, donors can understand the costs for
each activity and how to deploy new and strength-
ened existing systems around these costing com-
ponents. Countries can then assess and align
within available domestic resources around their
plan without crowding out other existing services
all the meanwhile minimizing duplication. The
use of bottom-up costing tools that fit around vari-
ous modalities (e.g., fixed facility and campaigns),
as well as population priority groups, is key to en-
suring campaigns are not underresourced.

To fully understand the resource needs for
implementing a country’s NDVP, countries costed
their activities. Countries are encouraged to use
the WHO COVID-19 vaccine introduction-and-
deployment costing tool (CVIC tool 2.2, (https://
www.who.int/publications/i/item/10665337553)
and upload their needs onto the Platform.12

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**FIGURE 3.** Heat Maps of National Deployment and Vaccination Plan Assessments With Blinded Samples of
10 Countries From 2 World Health Organization Regions

Different regions highlight different areas of need
(including to different depths) with respect
to their country planning. This ability
to distinguish with
country level
granularity can inform
a more targeted
approach to
supporting country
planning efforts.
Countries could also choose to provide outputs manually through drop-down menus across 9 common costing categories using whatever method or tools they wished. The process of developing consensus around these 9 common costing categories galvanized partners and donors to agree on a unified and standardized way for the Platform to display countries’ needs and donor contributions. No successful campaign can occur without a vaccine, but a vaccination program is much wider than the product alone. Notwithstanding the tremendous global effort to ensure equitable distribution of vaccines, the highest risk to the program is not having enough resources to implement the vaccination program successfully.

2. Serve as a Mechanism for Receiving, Reviewing, and Storing Strategic Documents and Receiving Funding Applications
The first function provides a country view and context of needs and resources important to country planners and funders who wish to support countries. The Platform has been successfully used as a way for countries to apply for Gavi and UNICEF COVID-19 delivery support for the deployment of vaccines. The data that are captured as part of the application form asks countries to explain their needs, relative to their NDVPs. It also includes the total costed needs for their COVID-19 vaccination program as well as domestic and external sources of revenue. In doing so, there is a quantified residual gap of financing that is displayed of needs yet to be met. This residual gap is shown on a dashboard by the Platform, stratified by costing categories and by domestic government and donor contributions (Figure 4) to visualize the management of funding support and further amplify the principle of transparency. Figure 4 demonstrates how the Platform has evolved to meet the needs of donor partners and countries alike, beyond getting a plan in place.

3. Map Donor Contributions
The impact of COVID-19 on vulnerable countries has been devastating, threatening gains in economic growth and development while at the same time exacerbating existing inequities, particularly in the world’s poorest economies. Donors across the immunization and development community have committed to addressing the goals of equitable access to vaccines through both broad-scale vaccination programs and resilient recovery (e.g., reducing extreme poverty).13–16 The ability for donors to have visibility across other donor contributions provides a means to address gaps in need across the immunization program. The Platform provides this visibility across 9 major common domains of need for immunization programs: (1) technical assistance for planning, coordination, and delivery; (2) vaccine doses and related devices and supplies; (3) human resources including training; (4) vaccination delivery; (5) supply chain and cold chain; (6) data management, monitoring and evaluation, and oversight; (7) vaccine safety surveillance and injection safety; (8) demand generation and communication; and (9) additional interventions such as maintaining essential health services.13 All donors (e.g., development banks and philanthropic foundations), regardless of the type of support (e.g., bilateral or multilateral), and all users of the Platform can see these mapped donor contributions.

As the global donor community ramps up support for COVID-19 vaccine deployment in countries,11 it is critical to see the granular distinctions of which needs are resourced. Otherwise, it will become difficult to ensure the total needs of countries are met. For example, some donors may wish to finance the purchase of COVID-19 vaccines, which represent the largest proportion of costs that need to be financed, in addition to supporting widespread testing, improved treatment, and strong health systems critical to saving lives and supporting global economic recovery. Meanwhile, other donors may wish to support technical assistance or delivery and operational costs. The donor resource mapping on the Platform already provides significant insight into this global view.

LESSONS LEARNED
The Platform represents a real improvement from previous platforms and tools, but it is only the first step. Care will need to be taken to learn lessons from its implementation and to make refinements appropriately. Some critical lessons are already apparent, particularly that the Platform can rapidly respond to the needs of users through the dynamic response (i.e., serve as a platform to apply for funding support). In terms of further refinement of the platform, the value of diverse perspectives is clear: including a full spectrum of stakeholder input to support the broad needs of diverse groups coming together around a single challenge. Human-centered design thinking, although not new, has proven its particular importance during an emergency—designers make all the difference in the experience. The design and launch of the Platform are only the beginning:
user adoption requires time (and patience), training, communication, and support (e.g., aid to translate recommendations to country context, 1-on-1 tailored sessions, and translations). There will always be a continuing need to adjust to the pandemic in real-time to make sure that the platform stays relevant and continue to be used widely. High adoption rates are critical for the Platform to deliver on its full potential. In addition, continued attention needs to be given to the safety and governance of the platform.

In terms of preparation for the next pandemic, there is a clear need to maintain a communication and engagement platform in readiness. Data and metrics that allow countries to assess their readiness to face pandemics must be regularly generated, collected, and analyzed, even during “peacetime.” The Platform is a good candidate for this role if it continues to evolve as required by public health emergency response.

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Equitable Open Access Publishing: Changing the Financial Power Dynamics in Academia

Dominique Vervoort,a Xiya Ma,b Hloni Bookholane

Key Messages

- Open access publishing is steadily growing but associated with high article processing charges that exacerbate disparities between funded and unfunded researchers.
- Early-career and underrepresented researchers often are not eligible for waivers or discounts, thus resulting in either publishing barriers or financial hardship.
- Journals should adopt equitable solutions that enable every author to pursue open access publishing regardless of one’s funding status or affiliation.
- Publishing companies should rethink open access publishing models to reduce the financial barriers for readers and authors alike.

Open access (OA) publishing is increasing, allowing articles to be read by anyone, anywhere. The publishing costs for these articles (article processing charges, APCs) are typically paid by the authors or their respective funders. In global health, authors pay an average of US$2,732 per OA publication. Articles that are freely accessible are more read, shared, and cited, ultimately benefitting scientific discourse and integration in public health, medicine, and other sciences. In response to the growing interest in OA publishing, journals are increasingly adopting OA models: some adopt hybrid models that allow authors to choose whether or not to publish OA, some adopt full OA, and some simply create an entirely new sister journal as an OA alternative to their own. However, few create means to support authors who are not funded by research grants, their institutions, or institutional agreements. Those that do should be commended for taking this step, especially given how rare such genuinely equitable OA models are.

To date, a majority of journals remain hybrid, allowing both subscription-based publishing (i.e., not OA, no APCs to publish) and an OA option (i.e., freely accessible for readers, but APCs to publish). For example, in the fields of cardiology and cardiac surgery, 60.9% of journals are hybrid. Although this may appear a sensible approach, hybrid journals rarely provide waivers or considerable discounts to authors who cannot afford such APCs, which typically range from a few thousand US dollars to a staggering US$11,000. In addition, hybrid journals have median APCs of up to 50% higher compared to fully OA journals, as observed in cardiovascular journals (median US$3,250 (interquartile range, IQR: US$3,000–US$3,500) for hybrid journals vs. a median US$2,100 (IQR: US$1,404–US$2,538) for fully OA journals). Some hybrid journals consider requests for waivers on a case-by-case basis; this is commonly decided based on the first or corresponding author’s country affiliation. Authors from low- or middle-income countries (LMICs) and/or with affiliations in LMICs deservedly tend to be favored, although they are not always successful in obtaining a waiver or discount. However, few hybrid journals consider requests from authors who are not from LMICs but who may not be able to afford APCs (e.g., graduate students, researchers without grant or institutional funding, underrepresented.

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minorities), referring them to the option to publish under the subscription model for free. At large, only 37.4% of hybrid cardiovascular journals provided any form of waiver or discount. Along the same lines, fully OA journals do not provide a subscription-only alternative, completely sidelining those unable to afford APCs and unable to obtain a waiver.

While the intention of increasing access to quality research from LMICs is laudable, few journals process waivers automatically, commonly requiring researchers to submit extensive applications and not always be provided with a full waiver. Moreover, many journals also exclude authors from upper-middle-income countries, such as Brazil and South Africa, from the waiver or discount option and require them to fully cover the APCs. This occurs despite substantial financial barriers that researchers from upper-middle-income countries experience because of great variation in the ability to obtain institutional funding or pay out-of-pocket. These reasons may partly explain why researchers from LMICs are more likely to cite journals with lower APCs, whereas researchers from high-income countries (HICs) are more likely to cite journals with higher APCs. One explanation of this phenomenon would be that LMIC researchers access and publish their work in OA journals that are financially more attainable to them, whereas this barrier is rarely an issue for HIC researchers. This results in silos that decrease LMIC research visibility to a wider audience. Approximately 94% of APCs are paid to journals owned by the 10 largest publishers from HICs, a model that sustains an oligopoly that prevents publishers from feeling the need to reduce APCs, even if making a profit. The current system further does not consider inequity within HICs that leads to the authors’ inability to afford APCs for such fully OA journals. This limits the dissemination of information, which can lead to significant consequences for policy makers who are best placed to address systemic issues driving public health disparities.

While there will always be costs to publish quality research due to journals’ fixed and variable expenses, journals have salaried editorial staff, who manage journals’ administrative processes, proofread submissions, check for plagiarism, and send submissions for peer review. After an article is accepted, publishing companies or outsourced companies ensure formatting and typesetting for publication. Further, journals have costs to host and manage their online content, website, marketing, promotion, advertising, indexing, rights, and more. Lastly, the website, submission system, and files require a secure server to host a journal. These costs can be considerable, as they depend on contextual factors (e.g., salaries tied to standard of living, outsourcing tied to company size, reputation, and services, and hardware or software tied to suppliers and markets).

However, APCs by some journals may be higher than the costs to publish. Editorial boards and peer reviewers are typically not paid and contribute their voluntary time to much of the publishing process. Further, journals were traditionally printed; today, journals have online formats with many journals moving away from print versions due to the costs and ecological impact. OA articles are exclusively digital, avoiding printing costs. Lastly, most journals are either partially subsidized (e.g., by societies or institutions) or have sponsored partnerships that cover a considerable portion of journals’ fixed costs. Some indexed journals have shown that APCs need not be high: compared to thousands of dollars in most journals, APCs are US$1,749 for PLoS One, US$399 for PeerJ, and free for Cureus. Although journals and publishers rarely report or even know the true costs per article, they have been reported as low as US$290–US$300 per article with some publishers, questioning the added value of high APCs.

The COVID-19 pandemic could be an opportunity to rethink the business models of scientific publication and empower different stakeholders to sustain this practice. The coronavirus disease (COVID-19) pandemic has greatly illustrated the power of OA and open science, as publishers and journals decided to make COVID-19-related research freely accessible to all. This crisis could be an opportunity to rethink the business models of scientific publication and empower different stakeholders to sustain this practice beyond the pandemic. For instance, inspiration could be drawn from local journals in Latin America that have long embodied such OA practices as a result of their “widespread ethos of free-to-publish and free-to-read research,” by which they often even forgo APCs altogether. Public health, by its very nature, should pursue exactly that: evidence-based information available to all, not just for those able to afford journal access or fortunate enough to have the right academic affiliation. As an example, primary care professionals, community health workers, and nongovernmental organizations are at the front lines of global and public health but are rarely able to freely access scientific literature; ironically, as they often contribute significantly to performing the research that is done. What ethical argument prevents them from accessing materials published by the billion-dollar industry that is academic publishing, whose profit margins are as high as 20%–30%?)
Recent trends and transformative agreements in the publishing landscape do provide hope for more equitable publishing practices in the near future. First, European institutions, along with major funders such as the Wellcome Trust and Bill & Melinda Gates Foundation, have signed on to the adoption of “Plan S,” which requires articles supported by public grants to be published in OA as of 2021. Although this greatly benefits European researchers, it may place increasing barriers for those from other institutions unless similar models are adopted elsewhere. Nevertheless, many concerns, including those of few journals following Plan S recommendations, are slowly being addressed as journals increasingly sign on and flexibility of journal choices is expanded in response to the academic community’s requests. Second, Research4Life is an initiative in collaboration with the World Health Organization, other United Nations agencies, Cornell University, Yale University, the International Association of Scientific, Technical, and Medical Publishers, and nearly 200 publishers. Through the Hinari Access to Research for Health Programme, Research4Life provides free or low-cost access to health-related academic literature for researchers and institutions in LMICs. However, given the current limited scope of the Hinari program, increased international support from all parties is required. Lastly, read-and-publish agreements, such as those supported by the European Public Health Association, have been adopted in various countries. This requires countries or consortia to pay publishers a lump sum to access articles, which is used for publishing costs, thereby creating a theoretical cost-neutral model that ensures OA for readers and authors from these countries or institutions.

Implementation of novel and more equitable OA models and practices will be critical. Barriers to publishing are widespread for researchers worldwide as research grants are minimal and highly concentrated in select countries and institutions and obtaining them has only become more challenging during the COVID-19 pandemic. Moreover, the inaccessibility of both OA and subscription journals is giving rise to more predatory journals, which promise quick and OA publication of articles with minimal to no review against a fee that is substantially lower than average APCs. This option is becoming increasingly attractive to vulnerable authors worldwide and has only been amplified by the publish-or-perish culture in academia, the notable barriers to scientific publication, and the COVID-19 pandemic.

Although these predatory journals are OA, they pose a threat to the access of evidence-based information as they typically publish misinformation, do not send articles for peer review, and keep research published in these journals hidden from the scientific community because they are generally not indexed in established databases, all of which may negatively affect authors’ reputations. Thus, reducing the barriers to scientific publishing, especially regarding the high APCs that impede unfunded researchers from pursuing fully OA journals and often even hybrid journals, is an important step toward equity in today’s academic environment.

Various opportunities arise. Journals and publishers should become more transparent about their use of funds to justify high APCs, especially when non-APC revenue is clearly generated (e.g., advertisements). Further, journals not associated with large publishers can offset fixed costs by collaborating with institutions, agencies, or societies to share servers and receive subsidies. Similarly, strategic partnerships with sponsors can generate revenue for fixed costs. Lastly, journals and publishers ought to consider tiered fee discounts and waivers—where possible, automated—to allow lesser-funded or unfunded researchers to pursue OA. Given the profit margins observed among large publishers, these waivers and discounts can be offset accordingly and be considered an investment in the future of academic publishing and accelerate medicine and public health.

Journals adopting OA models are to be commended but should be encouraged to increase opportunities to reduce publication fees and support unfunded or lesser-funded authors. Open access publishing is not only the future; it is the key to regaining public trust in science, retaining early-career academics, strengthening public and health policy, addressing public health disparities, and leveling the playing field for all researchers alike.

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Household Survey Measurement of Newborn Postnatal Care: Coverage, Quality Gaps, and Internal Inconsistencies in Responses

Kimberly Peven, Louise Tina Day, Debra Bick, Edward Purssell, Cath Taylor, Joseph Akuze, Lindsay Mallick

Key Findings

- Reports of receipt of a newborn postnatal care check do not necessarily reflect adequate provision of interventions resulting in large gaps between reported contact coverage and recommended content of newborn postnatal care (26%–89%) in 15 low- and middle-income countries.
- We found internal inconsistencies in survey responses regarding receipt of newborn postnatal care (“no” to whether anyone checked on the newborn’s health, but “yes” to questions on specific newborn interventions), which were as high as 16% in Malawi.

Key Implications

- Co-coverage measures may provide a useful summary of contact and content, reflecting coverage and an aspect of quality for tracking and monitoring progress towards global goals.
- Researchers can use this individual-level measure for equity analyses and to easily carry out multicountry studies or time-trend studies.
- Gaps in the provision of newborn care interventions indicate missed opportunities for delivering high-quality postnatal care. Facility managers and policy makers should identify bottlenecks or gaps in service provision that can be addressed to improve the quality of care.

ABSTRACT

Background: Reliable measurement of newborn postnatal care is essential to understand gaps in coverage and quality and thereby improve outcomes. This study examined gaps in coverage and measurement of newborn postnatal care in the first 2 days of life.

Methods: We analyzed Demographic and Health Survey data from 15 countries for 71,366 births to measure the gap between postnatal contact coverage and content coverage within 2 days of birth. Coverage was a contact with the health system in the first 2 days (postnatal check or newborn care intervention), and quality was defined as reported receipt of 5 health worker-provided interventions. We examined internal consistency between interrelated questions regarding examination of the umbilical cord.

Results: Reported coverage of postnatal check ranged from 13% in Ethiopia to 78% in Senegal. Report of specific newborn care interventions varied widely by intervention within and between countries. Quality-coverage gaps were high, ranging from 26% in Malawi to 89% in Burundi. We found some internally inconsistent reporting of newborn care. The percentage of women who reported that a health care provider checked their newborn’s umbilical cord but responded “no” to the postnatal check question was as high as 16% in Malawi.

Conclusion: Reliable measurement of coverage and content of early postnatal newborn care is essential to track progress in improving quality of care. Postnatal contact coverage is challenging to measure because it may be difficult for women to distinguish postnatal care from intrapartum care and it is a less recognizable concept than antenatal care. Co-coverage measures may provide a useful summary of contact and content, reflecting both coverage and an aspect of quality.

INTRODUCTION

Progress in reducing neonatal mortality has been slower than progress in reducing older child mortality despite the availability of evidence-based interventions that could reduce deaths. Most newborn deaths occur in the first 2 days of life, so universal coverage of high-quality postnatal care is critical. After a facility birth, current recommendations are for healthy mother/newborn dyads to be cared for in facilities for the first 24 hours. After homebirth, the first postnatal contact is recommended to occur as soon as possible within 24 hours of birth. Recommended interventions include physical assessment, counseling of the family on danger
Newborn health coverage data are increasingly available owing to increased focus on newborns in global accountability frameworks, yet gaps in newborn quality of care data persist.

The analysis focused on the postnatal check and 5 health care provider-initiated specific newborn care interventions included in the standard DHS questionnaire.

signs in the newborn, support for breastfeeding, cord care, delayed bathing, appropriate clothing, encouragement of communication and play with the newborn, and promotion of infant vaccination.5

Reliable measurement of postnatal content of care is currently lacking despite the critical importance of care in this vulnerable period. Currently, the global tracking indicator for newborn postnatal care focuses on postnatal contact (e.g., postnatal check)6,7 without tracking whether those checks included recommended interventions.6 However, there is increasing interest in tracking content and quality of care over care contacts.9

Newborn health coverage data are increasingly available as the focus on newborns in global accountability frameworks has increased,10 yet gaps in newborn quality of care data persist. To better understand the quality-coverage gap, recent efforts to develop and investigate measures of effective coverage are underway. However, calculation of this measure often depends on the availability of both population-based survey data linked to health facility data or other quality of care data.11-13 As health facility surveys with publicly available data are not widely collected, proxies from survey data are often used. Measurement of quality of care in population-based surveys has typically used proxies of contact coverage, timeliness, and skill level of the health care provider.14 However, it is well established that reported contact with the health system is not indicative of receipt of adequate quality of care. In antenatal care measurement, the gap between contact with the health system and delivery of a comprehensive set of recommended interventions for antenatal care has been described by Hodgins and D’Agostino15 as the “quality-coverage gap.” This gap has also been shown for maternal and newborn postnatal care where across 17 countries, 65% of women/newborns had a skilled attendant at birth but only 3% received a total of 7 specific postnatal care interventions and practices.16 Additional questions on provider-initiated interventions for newborns added to the Demographic and Health Survey Program (DHS) core questionnaire in 2015 provide an opportunity to further evaluate the quality-coverage gap for newborns.17

National and international tracking relies on contact coverage indicators to guide policy, assess success, and inform service redesign, despite little assessment of the reliability of standard measures.18 Qualitative research exploring women’s understanding of survey questions about receipt of a postnatal check for their newborn found that many did not understand what was meant by a postnatal “health check.”19 Postnatal check is commonly used as a proxy for receipt of newborn care at the population level. Given these recently added questions asked about postnatal care interventions, we can examine a proxy for the quality-coverage gap using a household survey-based measure of co-coverage (an index summing the total number of interventions received by a newborn out of a specified set of interventions) for postnatal care and examine internal consistency in responses to newborn-related questions.

In this article, we examine the concordance between the global postnatal care indicator—reported receipt of a newborn postnatal check (A)—and reported receipt of specific newborn care interventions (B) using nationally representative DHS surveys in sub-Saharan Africa and South Asia (Box). Specific aims included:

1. Describe survey-reported coverage of newborn postnatal check (A) and specific newborn care interventions and gaps in quality (B)
2. Describe internal consistency in survey-reported postnatal checks (A) and specific newborn care interventions (B)

**METHODS**

We included data from recent DHS surveys (2015–2018) in low- and lower middle-income countries in sub-Saharan Africa and South Asia. Countries were included if the questionnaire wording for postnatal checks and newborn care interventions matched the DHS7 core questionnaire wording shown in Table 1. The countries, years of the survey, number of women interviewed, and number of births in the 2 years before the survey, are shown in Table 2. DHS surveys are nationally representative, cross-sectional surveys using a standard core questionnaire that is comparable across countries and over time. Surveys are conducted with women of reproductive age (15–49 years) and collect important health and demographic information, including women’s detailed birth histories. The DHS Program introduced a general newborn postnatal check question to their standard questionnaire in the fifth phase of the project (2003–2008).21,22 In the seventh phase of the project, 5 further questions were added about specific health care provider-initiated interventions for newborns in the first 2 days of life.17

We focused our analysis on the postnatal check (A) and 5 health care provider-initiated specific newborn care interventions included in the standard DHS questionnaire (B), namely, the following: B1, umbilical cord check; B2, temperature
BOX. Definitions of Terms

Newborn postnatal check (contact coverage): Coverage of a newborn postnatal health check in the first 2 days of life (“yes” response to the survey question defined in Table 1 row A).

Specific newborn care intervention coverage (content coverage): Coverage of specific newborn care interventions in the first 2 days of life (“yes” response to survey questions in Table 1 rows B1–B5: B1, umbilical cord check; B2, temperature measurement; B3, counseling on danger signs in the newborn; B4, breastfeeding counseling; and B5, observation of breastfeeding).

Co-coverage: An index of the number of specific newborn care interventions received (sum of “yes” responses to survey questions in Table 1 rows B1–B5: B1, umbilical cord check; B2, temperature measurement; B3, counseling on danger signs in the newborn; B4, breastfeeding counseling; and B5, observation of breastfeeding).

Any contact with a health care provider: Coverage of either a newborn postnatal check (A) AND/OR any of the specific newborn care interventions (B1–B5) in the first 2 days of life.

Quality-coverage gaps:

1. Intervention-specific quality-coverage gap: The difference between any contact with a health care provider and coverage of a specific newborn care intervention (100 minus the percentage with intervention coverage, among those with any contact with a health care provider).

2. Full content quality-coverage gap: Any contact with a health care provider but not complete content coverage of all specific newborn care interventions.

Internal inconsistency: Newborns with a reported umbilical cords check (B1) and no reported postnatal check (A) (Table 3).

### TABLE 1. Postnatal Care Intervention Survey Questions, Postnatal Care Interventions, and Question Wording From the DHS-7 Core Questionnaire

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Question</th>
</tr>
</thead>
</table>
| A Postnatal check | For facility births, women are asked about a newborn postnatal check while they were still in the facility. Later, they are asked separately about a newborn postnatal check after they left the facility. A postnatal check is counted if they report a check in the facility or after.  
  438. Now I would like to talk to you about checks on (NAME)’s health after delivery—for example, someone examining (NAME), checking the cord, or seeing if (NAME) is OK. Did anyone check on (NAME)’s health while you were still in the facility?  
  445. I would like to talk to you about checks on (NAME)’s health after you left (FACILITY IN 430). Did any health care provider or a traditional birth attendant check on (NAME)’s health in the two months after you left (FACILITY IN 430)? |
| B1 Umbilical cord check | 457 a) During the first two days after (NAME)’s birth, did any health care provider do the following: Examine the cord?  
  457 b) During the first two days after (NAME)’s birth, did any health care provider do the following: Measure (NAME)’s temperature? |
| B2 Temperature measurement | 457 c) During the first two days after (NAME)’s birth, did any health care provider do the following: Counsel you on danger signs for newborns?  
  457 d) During the first two days after (NAME)’s birth, did any health care provider do the following: Counsel you on breastfeeding? |
| B3 Danger sign counseling | 457 e) During the first two days after (NAME)’s birth, did any health care provider do the following: Observe (NAME) breastfeeding? |

Abbreviation: DHS, Demographic and Health Survey.
measurement; B3, counseling on danger signs in
the newborn; B4, breastfeeding counseling; and
B5, observation of breastfeeding. Table 1 shows
the question wording from the DHS7 core ques-
tionnaire. We did not include newborn care
outcomes that were woman/family led (e.g.,
breastfeeding, prelacteal feeds).

To be consistent with global indicators for post-
natal care, we limited the analysis to the most recent
births within 2 years before the survey. We included
any postnatal check (pre- or post-discharge) in the
first 2 days (Table 1). We excluded newborns who
died in the first 2 days of life or who were born in
the 2 days before the survey. The sample sizes for
each country are shown in Table 2.

All analyses were completed separately by
country, adjusting for the complex sampling de-
sign, which ensures that each sample is nationally
representative, and using the weights provided in
the child datasets to account for sampling proba-
bility and nonresponse for each survey. We con-
ducted all the statistical analyses using R,
adjusting for the complex sampling design by us-
using the survey package.

AIM 1: DESCRIBE COVERAGE OF
NEWBORN POSTNATAL CARE AND
NEWBORN CARE INTERVENTIONS
AND GAPS IN QUALITY

Contact and Content Coverage
First, we present simple coverage of newborn post-
natal checks (A) and each of 5 specific newborn
care interventions among all newborns (B1 to B5)
in the sample defined above for descriptive compari-
sion of differences in coverage. Second, we con-
structed a co-coverage index of specific newborn
care interventions (B) by adding the total number of
interventions received among 5 possible provider-
initiated interventions, a method similar to Victora
et al. and Carvajal-Aguirre et al.

Quality-Coverage Gaps
To understand gaps in quality coverage, we ana-
lyzed newborns for whom any contact with a
health care provider was reported but who did
not receive all expected interventions (B1 through
B5). We defined the denominator, coverage of any

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**TABLE 2. Included Countries, Survey Year, and Sample From Demographic and Health Surveys on Postnatal Checks and Newborn Care Interventions**

<table>
<thead>
<tr>
<th>Country</th>
<th>Survey Year</th>
<th>Number of Women Intervieweda,b</th>
<th>Number of Last (Most Recent) Births in the 2 Years Before the Surveya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>2017–2018</td>
<td>15,928</td>
<td>5,390</td>
</tr>
<tr>
<td>Burundi</td>
<td>2016–2017</td>
<td>17,269</td>
<td>5,358</td>
</tr>
<tr>
<td>Cameroon</td>
<td>2018</td>
<td>13,527</td>
<td>3,843</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>2016</td>
<td>15,683</td>
<td>4,221</td>
</tr>
<tr>
<td>Guinea</td>
<td>2018</td>
<td>10,874</td>
<td>2,948</td>
</tr>
<tr>
<td>Malawi</td>
<td>2015–2016</td>
<td>24,562</td>
<td>6,567</td>
</tr>
<tr>
<td>Mali</td>
<td>2018</td>
<td>10,519</td>
<td>4,075</td>
</tr>
<tr>
<td>Nepal</td>
<td>2016</td>
<td>12,862</td>
<td>1,958</td>
</tr>
<tr>
<td>Nigeria</td>
<td>2018</td>
<td>41,821</td>
<td>12,616</td>
</tr>
<tr>
<td>Pakistan</td>
<td>2017–2018</td>
<td>12,264</td>
<td>3,855</td>
</tr>
<tr>
<td>Senegal</td>
<td>2017</td>
<td>16,787</td>
<td>4,401</td>
</tr>
<tr>
<td>Tanzania</td>
<td>2015–2016</td>
<td>13,266</td>
<td>4,091</td>
</tr>
<tr>
<td>Uganda</td>
<td>2016</td>
<td>18,506</td>
<td>5,781</td>
</tr>
<tr>
<td>Zambia</td>
<td>2018</td>
<td>13,683</td>
<td>3,845</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>2015</td>
<td>9,955</td>
<td>2,417</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>247,506</td>
<td>71,366</td>
</tr>
</tbody>
</table>

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a Weighted.
b From ICF International.

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postnatal contact, as whether a woman responded that her baby received a postnatal check (A) or reported at least 1 specific newborn care intervention (B1, B2, B3, B4, or B5). We defined this broadly to reduce the potential that a case was excluded from the denominator due to misinterpretation of the question about a postnatal check by the respondent. We examined quality-coverage gaps using different numerators. First, we describe the proportion of newborns reported as receiving each specific newborn care intervention (B1 through B5) among those with any postnatal contact (A or one of B1 through B5). The quality-coverage gap for each intervention is the difference between any postnatal contact coverage and intervention-specific coverage (100 minus the percentage with intervention coverage). Second, we calculated co-coverage of the 5 specific newborn care interventions (B) among newborns with any postnatal contact (A or one of B1 through B5).

**AIM 2: DESCRIBE INTERNAL CONSISTENCY IN REPORTING POSTNATAL CHECKS AND SPECIFIC NEWBORN CARE INTERVENTIONS**

**Internal Consistency in Reporting Contact and Content of Newborn Care**

We constructed a variable for internal inconsistency based on the responses to 2 questions—report of a postnatal check (A) and report of the newborn’s cord being checked (B1). The postnatal check survey question uses an example of checking the newborn’s cord when explaining what a postnatal check is; therefore, a newborn who has had the umbilical cord checked should also be considered to have had a postnatal check. Thus, we calculated the proportion of newborns who had a reported postnatal check (A) among those newborns who were reported as having their umbilical cords checked (B1). This is shown as a proportion of all newborns in the sample with all possible combinations of postnatal check and umbilical check results as shown in Table 3.

**Concordance Between Interventions**

To determine if any interventions are well represented by measurement of the postnatal check, and better understand the concordance between newborn care interventions and reported postnatal checks, we calculated agreement of responses between pairs of interventions or intervention and postnatal check. This was done by summing the total number of newborns who received both interventions and the number who received neither intervention, divided by the total number of newborns.

**Ethics**

The ICF International Institutional Review Board (IRB) conducted an ethical review of all survey tools and protocols, and an IRB in the host country approved each country survey. Interviewers obtained informed consent and ensured voluntary participation before each interview.

Ethical approval to conduct these analyses was granted by King’s College London College Research Ethics Committee (LRS-17/18-5570). The project was registered with the King’s College London Data Protection Registration (DPRF-17/18-8170), in compliance with European data regulations. We accessed these datasets through a written agreement with the DHS Program.

**RESULTS**

Background characteristics of the sample are shown in Supplement Table 1. The proportion residing in an urban area ranged from 9.0% in Burundi to 53.8% in Nepal. Having any education ranged from 26.0% in Guinea to 98.7% in Zimbabwe. Facility birth ranged from 36.0% in Ethiopia to 93.1% in Malawi.

**Coverage of Newborn Care and Quality-Coverage Gaps**

Report of a postnatal check within 2 days of birth ranged from 12.9% (95% confidence interval [CI]=11.1,14.9) of newborns in Ethiopia to 78.0% (95% CI=75.7,80.3) in Senegal (Figure 1). Report

**TABLE 3. Two-Way Table Showing Plausible and Internally Inconsistent Survey Response Possibilities for Postnatal Check and Umbilical Cord Check**

<table>
<thead>
<tr>
<th>Umbilical Cord Check</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postnatal check</td>
<td>Yes</td>
<td>Plausible (coverage)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Internal inconsistency</td>
</tr>
</tbody>
</table>
of specific newborn care interventions varied widely by intervention within countries as well as between countries. For example, in Senegal, while 29.4% of women reported a health care worker observed them breastfeeding, 70.3% reported a health care worker checked the newborn’s umbilical cord. Coverage of all specific newborn care interventions was low in Ethiopia and Nigeria, where each of the interventions was reported for less than one-third of newborns. Zimbabwe and Malawi achieved higher coverage of all postnatal interventions of interest with at least 6 of 10 newborns reported as receiving each intervention (Figure 1); however, a co-coverage index score (total number of interventions received) of all 5 interventions was still under 50% (Table 4, Figure 2), even in these 2 countries with the highest coverage (range 0–5 in all countries).

Coverage gaps for any contact with a health worker in the first 2 days of life ranged from 10.0% in Malawi to 61.2% in Ethiopia (Figure 2). Despite a small coverage gap in Senegal (13.3%), coverage of all 5 interventions was low, at 23.2% (Table 4). The quality-coverage gap was lowest in Nigeria (31.2%), although coverage of any contact with a health care provider was low (44.1%) as was coverage of all 5 interventions (12.9%). The combined coverage and quality-coverage gaps (percentage of newborns without all 5 interventions) ranged from 50.2% in Zimbabwe to 97.8% in Burundi.

Among newborns with any postnatal contact (a postnatal check or any specific newborn care intervention), coverage of specific newborn care interventions was not universal (Figure 3). Quality-coverage gaps were highest in Burundi, where individual intervention coverage was not higher than 12%, leaving a quality-coverage gap of >88%. Quality-coverage gaps were lowest (<29%) in Zimbabwe, where individual intervention coverage was >71%. Mean co-coverage ranged from 0.5 interventions in Burundi to 4.0 in Zimbabwe (among newborns with any postnatal contact, Figure 4).

**Internally Inconsistent Responses in Reporting Newborn Postnatal Care**

Although the postnatal check survey question includes the example of checking the cord, among
those with reported umbilical cord checks, postnatal checks were not universally reported. Internally inconsistent responses (“yes” to a check on the umbilical cord but “no” to a postnatal check) were as high as 15.9% in Malawi (Figure 5). This internal inconsistency was lowest in Burundi (<1%), where coverage of umbilical cord checks was very low (6.5%).

**Agreement Between Postnatal Check and Newborn Care Interventions**

Agreement between the postnatal check and specific newborn care interventions was low with some variation by intervention and country, ranging from 47% to 89% (Figure 6). Agreement between pairs of newborn care interventions ranged from 57% to 97%. Agreement was high between intervention pairs in Ethiopia and Nigeria (>90%), where coverage of care was consistently low across interventions and survey responses for most interventions was “no.” Agreement was lowest in Pakistan and Senegal, where coverage of some interventions was more than double coverage of other interventions. The intervention of being counseled on breastfeeding had the highest agreement with other newborn care interventions.

**DISCUSSION**

These findings highlight a quality-coverage gap for newborn care and discordance between survey indicators for newborn postnatal checks and receipt of specific newborn care interventions. While reported postnatal check was representative of coverage of newborn care interventions in some countries (Guinea, Nepal, Zimbabwe), a postnatal check over- or underestimated coverage of newborn care interventions in other countries (Angola, Burundi, Mali, Nigeria, Senegal).

**Challenges in Assessing Newborn Postnatal Care Coverage**

Contact coverage for maternal and newborn care declines at each stage along the continuum of care from pregnancy (antenatal care) to birth (skilled attendance) and is lowest for postnatal care. Where contact coverage occurs, quality-coverage gaps have been noted across this continuum. Even among women receiving their first antenatal care check in the first trimester and with

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**TABLE 4. Co-coverage of Provider-Initiated Newborn Care Interventions in 15 Low- and Middle-Income Countries**

<table>
<thead>
<tr>
<th>Country</th>
<th>Co-coverage (Number of Interventions), %</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benin</td>
<td>39.2 6.7 10.5 8.1 9.3 26.3 2.2 (2.10)</td>
<td></td>
</tr>
<tr>
<td>Burundi</td>
<td>89.3 3.8 2 1.4 1.2 2.2 0.3 (0.96)</td>
<td></td>
</tr>
<tr>
<td>Cameroon</td>
<td>37.9 5.8 8.4 9.5 10.2 28.3 2.3 (2.12)</td>
<td></td>
</tr>
<tr>
<td>Ethiopia</td>
<td>63.6 10.8 10.5 6.1 4.3 4.7 0.9 (1.46)</td>
<td></td>
</tr>
<tr>
<td>Guinea</td>
<td>50.6 5.2 5.5 6.2 8.8 23.7 1.9 (2.15)</td>
<td></td>
</tr>
<tr>
<td>Malawi</td>
<td>12.5 5 8.6 12.3 17.6 43.9 3.5 (1.76)</td>
<td></td>
</tr>
<tr>
<td>Mali</td>
<td>53 9.6 7.9 6.1 7.1 16.3 1.5 (1.95)</td>
<td></td>
</tr>
<tr>
<td>Nepal</td>
<td>40.1 5.1 8.2 8.5 11.9 26.2 2.3 (2.12)</td>
<td></td>
</tr>
<tr>
<td>Nigeria</td>
<td>72.6 3.8 4 3.1 3.6 12.9 1 (1.81)</td>
<td></td>
</tr>
<tr>
<td>Pakistan</td>
<td>29.9 13.4 15.4 13.8 14 13.6 2.1 (1.80)</td>
<td></td>
</tr>
<tr>
<td>Senegal</td>
<td>27.1 4 16.8 14.4 14.5 23.2 2.5 (1.91)</td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td>50.3 9.9 9.1 8.6 9.2 12.8 1.5 (1.88)</td>
<td></td>
</tr>
<tr>
<td>Uganda</td>
<td>49.6 8.6 8.2 7.7 7.7 18.2 1.7 (2.00)</td>
<td></td>
</tr>
<tr>
<td>Zambia</td>
<td>32.6 3.5 5.2 5.6 8.9 44.2 2.9 (2.23)</td>
<td></td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>14.7 2.9 5.7 9.6 17.3 49.8 3.6 (1.81)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: SD, standard deviation.
at least 4 checks during pregnancy, the full suite of recommended interventions is not always reported. \cite{15,28} As in our study, a quality-coverage gap for provider-initiated newborn care interventions was found in Nigeria, Ethiopia, and India, where no woman or newborn had received the full recommended content during a postnatal check. \cite{27} Evidence of a quality-coverage gap is further supported by observational evidence. \cite{29-32} However, it is possible a woman reported a postnatal check, remembering a visit at a facility or at home, but could not report specific interventions due to recall or never being informed about the interventions delivered.

Qualitative research in Ghana found that for facility births, newborn checks take place out of the mother’s sight, and women were rarely informed about the types of checks being done. \cite{33} Unclear or poorly defined terms in health surveys can have large or systematic effects on results. \cite{34} Qualitative research with women regarding their understanding of a “health checkup” has shown that women needed some guidance to understand what it meant to check their baby’s health. \cite{19} Although labor, birth, and antenatal care are well-known and branded concepts, postnatal care does not appear to be understood in the same way. \cite{33} As such, direct questions about postnatal checks are likely to underestimate coverage. On the other hand, research has shown that women overreport newborn interventions received. \cite{35} In some settings, the newborn may be kept away from the mother, who is thought to be too tired following birth to participate in newborn care, and care is provided by traditional birth attendants, health workers, or female relatives. \cite{36,37} World Health Organization standards for quality of maternal and newborn care in health facilities include the recommendation that women and families receive clear and accurate communication about the care newborns receive. \cite{38} Such improvements to experience of care around the time of birth may improve accuracy of survey-reported newborn care.

Measurement of postnatal care is complicated. A single provider may be caring for 2 people (the
woman and the baby), and checks may occur at multiple time points and in different places (labor ward, postnatal ward, home, outpatient). As Moran et al.14 highlighted, beyond a lack of consensus on when the postnatal period begins, operationalizing a cutoff for postnatal care measurement in household survey questions would remain a challenge. When postnatal checks reported in the first hour are considered as solely intrapartum care, postnatal care coverage levels drop considerably.39 Additionally, qualitative interviews with women in Tanzania have shown that women did not differentiate between postnatal care and the Expanded Programme on Immunisation (covering vaccination up to or beyond 1 year of age).40 To improve the validity of the postnatal check question, as referred to earlier, an example of a postnatal intervention (checking of the umbilical cord) was added to the DHS questionnaire following recommendations from qualitative research on women’s understanding of the postnatal check question.19,21,41 Although the report of a postnatal check was higher for newborns who had a reported umbilical cord check compared with those who did not have a cord check, we still found inconsistency between reported postnatal checks and reported umbilical cord checks. A woman who reports that her newborn received an umbilical cord check could also be expected to report a postnatal check, as an umbilical cord check was used as an example of a postnatal check. Yet this study shows that this was not always the case. Further research is needed to explore the reason behind this discrepancy, including comprehension of the question or confusion regarding the timeline. The latest version of the DHS questionnaire has updated the wording for the postnatal check survey question, “Now I would like to talk to you about checks on (NAME’S) health—for example, someone examining the cord, or talking to you about how to care for (NAME).”42 DHS translates questionnaires into primary languages for each country using back-translation and...
pretests them to ensure they are understandable to women. Questionnaires are not officially translated further into less widely spoken languages or languages without a written script. Instead, interviewers are instructed to modify the wording of questions to fit local dialects and culture without changing the meaning of the question; however, some aspects of the postnatal care questions may be lost in translation. In Malawi, where internally inconsistent reporting of newborn care was highest, most interviews were conducted in Chichewa using a Chichewa questionnaire, and <1% of interviews included in the analysis were conducted in a language different from the questionnaire itself. Conversely, in Guinea, the questionnaires were all in French, while the interviews were conducted largely in Soussou, Peul, and Malinke among others.

**Challenges in Assessing Quality of Newborn Postnatal Care**

As evidenced by this study, a “health check” is not necessarily reflective of the level of specific newborn care interventions received in a given country due to substantial quality-coverage gaps in many countries and wide differences in coverage of various newborn care interventions. While coverage of newborn care interventions was higher among newborns receiving a postnatal check, examining only this as an indicator ignores the substantial number of newborns who received provider-initiated newborn care interventions but whose mothers did not report a postnatal check. Some women may believe postnatal checks are only required for sick newborns. Research has shown women know checks had occurred because they were asked a question (e.g., on breastfeeding) or when equipment (e.g., thermometer) was used.

Previously, the Every Newborn Action Plan Measurement Improvement Roadmap proposed using early breastfeeding as a tracer indicator for essential newborn care; however, research has shown that this indicator did not correlate highly with other elements of essential newborn care besides skin-to-skin contact in 1 study. While this study focused on postnatal care and only included provider-initiated interventions, agreement...
between postnatal check and other interventions was low for most interventions in most countries. This result may be due to inconsistent survey responses (not reporting a postnatal check but reporting specific newborn care interventions) or a result of poor quality of care and the quality-coverage gap (a check occurred but complete care was not provided). We found counseling on breastfeeding had slightly higher agreement with a postnatal check than other newborn care interventions although other research has shown counseling interventions to have lower validity in surveys than those reflecting physical examination. Additionally, counseling interventions during antenatal, family planning, and sick child care are commonly overreported. As such, measuring survey reports of observation of breastfeeding may be more important than counseling on breastfeeding.

While tracking content coverage and quality could be done with specific individual tracer indicators (measuring 1 intervention to estimate the coverage of multiple interventions or quality coverage), this article, in addition to Sitrin et al., shows that this is not likely to be useful given such low agreement. Quality newborn care could instead be estimated with effective coverage measures. Effective coverage, which draws from quality metrics, is defined as the proportion of a population in need of a service that receives services from a facility equipped to provide care (input-adjusted effective coverage) or receives services in line with quality standards (quality-adjusted), or when health outcomes are gained (outcome-adjusted). For postnatal care, due to difficulties in attributing neonatal mortality to specific services, Marsh et al. recommended measuring quality-adjusted effective coverage—which encompasses timely and appropriate response and respectful care and treatment. While effective coverage is an important and valuable concept, it can be challenging to measure because it usually involves combining data from different sources, possibly measured at different times, and facility data related to postnatal care are limited in some settings or may not be commonly publicly available. Further, while input-, quality-, or outcome-adjusted measures of effective coverage are useful for national monitoring, they are not typically measured at the individual level. Conversely, co-coverage is measured at the individual level, only requires data from a single source, and may be more accessible to data users.
than effective coverage measures, which can involve linking multiple datasets as described above. Co-coverage can more specifically show the proportion of the population receiving most or all of the recommended postnatal care interventions, providing a more granular understanding of gaps in care provision to better inform service development needs. Furthermore, co-coverage can be useful for equity analyses to identify high-risk groups lagging behind and may be particularly advantageous when used to replace multiple coverage estimates in multicountry or time trend analyses. However, country-specific questionnaire adaptations or differences may inhibit cross-country comparison. It is worth noting that this measure of co-coverage can only be used to summarize interventions for healthy or full-term newborns, which may preclude special interventions for small and sick newborns.

**Strengths and Limitations**

This study is one of the first to look beyond the quality-coverage gap and examine internal consistency between newborn care interventions and postnatal checks. It adds to our understanding of postnatal care measurement and the reliability of the questions that provide essential global monitoring information for health service improvement.

Although this study included data from 15 nationally representative surveys covering a range of geographic regions and care coverage levels, limitations should be noted. These analyses were based entirely on self-report from women about the care their newborns received after birth. Validation studies for some of these indicators have been conducted previously, producing inconsistent findings. For example, in Kenya and Swaziland, interventions such as counseling on breastfeeding and counseling on danger signs in the newborn met criteria for individual-level accuracy and low population-level bias, whereas other interventions such as examining the baby did not meet these criteria. A recent large validation study on survey measurement of maternal and newborn indicators did not validate the interventions in this analysis but did show limited potential for content of care indicators in surveys.
discussed in this article may relate to women’s under-
standing of the survey questions or the care their newborns received, inconsistencies may also be related to inter-interviewer differences. Future research may use DHS fieldworker questionnaires to examine data consistency in relation to worker characteristics. Additionally, recent changes in the postnatal check question wording may improve question understanding in future surveys; however, it may limit comparability of questions for trend analysis.42

Furthermore, when women reported receiving a postnatal check for their newborn but not any of the newborn care interventions in this study, their report may be accurate if they received interventions beyond the 5 we considered. To limit the effect of this bias, where possible we limited the analysis on internal consistency to the specific situation cases in which women reported their newborns as receiving a cord check but reported no newborn postnatal check, as checking the cord is an example in the newborn postnatal check question.

CONCLUSION
Prompt, safe, and high-quality postnatal care is vital for improving newborn survival. Reliable and standardized measurement of content of care is essential to drive improvements in coverage and quality. In low- and middle-income country surveys, we found coverage of newborn care varied widely by intervention, making a single question about receipt of a health check or a tracer indicator a poor proxy for coverage of comprehensive newborn care. To improve global measurement and tracking of postnatal care, collecting information on content of care is critical. While facility data and effective coverage measures may identify bottlenecks in service provision that can be used to improve quality of care, co-coverage measures are useful for program managers to understand content coverage and show what proportion of the population is receiving all or most important interventions for newborn postnatal care. Use of co-coverage measures will allow for additional analysis of survey data, particularly of equity in coverage and care to identify high-risk groups lagging behind. Additionally, as each year more births occur in health facilities, investment in and use of routine data systems can complement surveys to track content of newborn care.

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Author contributions: KP conceived the study, which KP, LM, and EP designed. KP analyzed the data with support from LM, LTD, and EP. All authors interpreted the results. KP wrote the first draft of the manuscript, LM, LTD, DB, EP, CT, and JA critically revised the manuscript. All authors contributed to and approved the final manuscript.

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REFERENCES


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Projecting the Impact of Nutrition Policy to Improve Child Stunting: A Case Study in Guatemala Using the Lives Saved Tool

Scott Tschida, a Ana Cordon, a Gabriela Asturias, b Mónica Mazariegos, c María F. Kroker-Lobos, c Bianca Jackson, d Peter Rohloff, a,e David Flood, a,f

Key Finding
- Scaling-up coverage of evidence-based nutrition interventions recommended by the international community would only lead to a small improvement in child stunting in Guatemala and are unlikely to meet the ambitious national goals set for 2024 or the 2030 SDGs.
- Our results support an increased focus on strategies that address the social determinants that contribute to stunting rather than a narrow focus on nutrition-specific interventions.

Key Implications
- Large improvements in child stunting in some high-burden countries like Guatemala are unlikely to be achieved solely based on increases in nutrition intervention coverage.
- Multisectoral nutritional and social policies are needed to address the structural drivers of stunting.

ABSTRACT

Background: Child stunting is a critical global health issue. Guatemala has one of the world’s highest levels of stunting despite the sustained commitment to international nutrition policy best practices endorsed by the Scaling Up Nutrition (SUN) movement. Our objective was to use Guatemala as a case study to project the impact of a recently published national nutrition policy, the Great Crusade, that is consistent with SUN principles.

Methods: We used the Lives Saved Tool (LiST) to project the impact of scaling-up of nutrition interventions proposed in the Great Crusade and recommended by SUN. Our outcomes were changes in stunting prevalence, number of stunting cases averted, and number of cases averted by intervention in children under 5 years of age from 2020 to 2030. We considered 4 scenarios: (1) intervention coverage continues based on historical trends, (2) coverage targets in the Great Crusade are achieved, (3) coverage targets in the Great Crusade are achieved with reduced fertility risk, and (4) coverage reaches an aspirational level.

Results: All scenarios led to modest reductions in stunting prevalence. In 2024, stunting prevalence was estimated to change by −0.1% (95% confidence interval [CI]= 0.0%, −0.2%) if historical trends continue, −1.1% (95% CI= −0.8%, −1.5%) in the Great Crusade scenario, and −2.2% (95% CI= −1.6%, −3.0%) in the aspirational scenario. In 2030, we projected a stunting prevalence of −0.4% (95% CI= −0.2%, −0.8%) and −3.7% (95% CI= −2.8%, −5.1%) in the historical trends and aspirational scenario, respectively. Complementary feeding, sanitation, and breastfeeding were the highest-impact interventions across models.

Conclusions: Targeted reductions in child stunting prevalence in Guatemala are unlikely to be achieved solely based on increases in intervention coverage. Our results show the limitations of current paradigms recommended by the international nutrition community. Policies and strategies are needed to address the broader structural drivers of stunting.

BACKGROUND

More than 149 million children under 5 years of age worldwide have inadequate linear growth, which is also referred to as child stunting. Stunting is a crucial global child health issue given its negative impacts on health and well-being throughout the lifespan. In

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In February 2020, the new Guatemalan government led by President Alejandro Giammattei released the most recent national nutrition policy, the Gran Cruzada Nacional por la Nutrición (“Great National Crusade for Nutrition,” henceforth “Great Crusade”). Like previous national nutrition policies that were influenced by the SUN framework, the Great Crusade focuses on evidence-based interventions delivered during the 1,000-day window. Interventions in the Great Crusade include both nutrition-specific and nutrition-sensitive interventions. Nutrition-specific interventions address the immediate determinants of stunting through micronutrient supplementation, breastfeeding promotion, complementary feeding, and other strategies. Nutrition-sensitive interventions address the structural underpinnings of chronic malnutrition by targeting poverty, education, women’s empowerment, environmental protection, social safety nets, and other targets. One of the Great Crusade’s principal goals is to reduce the prevalence of child stunting by 7% by 2024.

However, it is uncertain if the Great Crusade can reach this ambitious goal. Previous national policies have not met stunting prevalence targets. Nutrition-specific interventions form the backbone of the Great Crusade’s recommendations, but these interventions tend to have small effect sizes on stunting in clinical trials. Nutrition-sensitive interventions put forth by the Great Crusade, while promising, have limited evidence of benefit on child growth. Finally, implementation of nutrition interventions in Guatemala historically has been inconsistent, which may limit the impact of national policies.

The objective of our study was to project the impact of the 2020 Guatemalan national nutrition policy, the Great Crusade. We used a popular maternal and child health modeling program, the Lives Saved Tool (LiST), to carry out our projections. Realistic projections can show the potential impact and uncertainties of nutrition policy in Guatemala and assist in the policy’s implementation. Finally, as a case study in the real-time application of a policy modeling tool, this study may assist policymakers in other low- and middle-income countries who wish to project the impact and uncertainty of maternal and child health policies in their own countries.

**METHODS**

This modeling study used observational data and LiST to project the policy impact of the Great Crusade. LiST is a publicly available maternal and...
child health modeling tool within the Spectrum software package version 5.761 (Avenir Health). Previous publications have detailed LiST’s methodology. List is a linear and deterministic model that uses publicly available data to project maternal and child outcomes including stunting. Although not a probabilistic model, LiST contains an uncertainty analysis. LiST can assess uncertainty by randomly sampling distributions around the model’s inputs. We used LiST’s uncertainty analysis tool by running 250 iterations with plausibility bounds set to 95%. Our projections are included in a Supplement. LiST was developed in 2003 and is maintained by the Johns Hopkins Bloomberg School of Public Health with funding from the Bill and Melinda Gates Foundation. Since its development, LiST has been used in more than 110 peer-reviewed research publications. Many LiST publications have been seminal contributions in the field of global maternal and child health such as Disease Control Priorities 3rd Edition and the 2008 and the 2013 Lancet Maternal and Child Undernutrition Series papers.

Data Sources
Data inputs necessary to project stunting in LiST cover 4 broad categories: (1) demographics, (2) baseline child and maternal health characteristics, (3) intervention coverage levels, and (4) intervention effectiveness.

National-level default input data for most countries including Guatemala are available for download through Spectrum. The default data sources include demographic surveys, academic research, and estimates produced by international bodies such as the World Health Organization (WHO), United Nations Children’s Fund (UNICEF), United Nations Population Fund (UNFPA), World Bank, and United Nations. Default data are updated either annually or as often as national surveys are released.

We carefully reviewed each default input for Guatemala, and, using our knowledge of local data sources, updated inputs with more recent or appropriate values. With one exception, data on intervention effectiveness were not changed from the default values estimated from systematic reviews, meta-analyses, Delphi methods, and randomized control trials. In May 2020, after consulting with a member of the LiST team at the Johns Hopkins Bloomberg School of Public Health, we were informed of new intervention effectiveness estimates for water, sanitation, and hygiene (WASH) interventions. We then manually updated these estimates in the model. A complete list of data sources and input parameters used in this study can be found in the Supplement.

Outcomes
We defined policy impact through our primary outcomes of changes in stunting prevalence, number of stunting cases averted, and number of stunting cases averted by intervention. Stunting is defined in LiST as children with a height-for-age that is 2 standard deviations or more below the median of the WHO Child Growth Standards.

Intervention Variables
We first reviewed the interventions that impact child stunting in LiST and cross-referenced them with the interventions recommended in the Great Crusade. Of the 15 stunting-related interventions included in LiST, 14 were proposed in the Great Crusade. We subsequently excluded 2 interventions described in the Great Crusade that are not epidemiologically significant in Guatemala and 2 additional interventions for which data were not available. Our final model included 10 interventions (Table and Supplement). Of note, the Great Crusade includes interventions, such as education and conditional-cash transfer programs, that are not included in LiST because there is no high-level evidence that they are effective.

Scenarios
We modeled 4 scenarios of intervention coverage change from 2020 to 2030. We chose this period because it encompasses both the Great Crusade’s targets in 2024 as well as the SDG targets in 2030. Each scenario started with the same inputs for the baseline year of 2020 and continued over time based upon the below assumptions. Baseline, 2024, and 2030 coverage levels can be found in the Supplement.

Scenario 1: Historical Trends
Our baseline scenario estimated future coverage levels based on past historical trends. As described below and similar to prior LiST analyses, we estimated future trends in intervention coverage based on regression models of historical survey data. The key assumption of this scenario is that past intervention coverage trends predict future coverage.

Scenario 2: Great Crusade
Intervention coverage levels were set to the goals detailed in the Great Crusade. From 2024 to 2030, coverage levels remained static.
**Scenario 3: Great Crusade With Decreased Fertility Risk**

Intervention coverage levels were set to the goals detailed in the Great Crusade. Fertility risk was lowered by eliminating pregnancies before 18 years of age and birth intervals of less than 24 months by 2030. This scenario assumed a hypothetical implementation of policies and interventions to eliminate teen pregnancy and short interpregnancy intervals. These measures have been associated with improved child stunting in international and national surveys but were not otherwise included as an intervention in the models.37,38

**Scenario 4: Aspirational Coverage**

Intervention coverage levels were set to reach 90% by 2024. From 2024 to 2030, coverage levels remained static.

**Analyses**

**Data Preparation**

Given that the majority of survey data available in Guatemala were at least 3 years old, we updated model input parameters for the baseline year of 2020. We estimated baseline levels by fitting a logistic regression curve fixed to pass through the last available data point of population-averaged survey data. Shifting the trendline in this manner has been done in a prior LiST study and reflects our greater confidence in more recent survey estimates in Guatemala.36 Stata version 16.1 was used in these analyses.

Consistent with previous LiST studies, increases in intervention coverage over time were assumed to increase linearly from the base year.39,40 In instances in which coverage inputs exceeded 90%, we fixed values at 90% for the remaining years to reflect a reasonable upper bound for coverage. We did not fix the upper bound of WASH interventions, as we believe that these interventions will follow a meaningful trend of improvement beyond this level.

Consistent with previous LiST studies, increases in intervention coverage over time were assumed to increase linearly from the base year.39,40 In instances where coverage inputs exceeded 90%, we fixed values at 90% for the remaining years to reflect a reasonable upper bound for coverage. We did not fix the upper bound of WASH interventions, as we

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**TABLE. Stunting-Related Interventions Included in the Models**

<table>
<thead>
<tr>
<th>Interventions in the Lives Saved Tool That Affect Stunting</th>
<th>Interventions Covered in the Great Crusade</th>
<th>Interventions Included in the Models</th>
<th>Reason Not Included in Models</th>
<th>Baseline (2020) Coverages, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium supplementation in pregnant women</td>
<td>X</td>
<td></td>
<td>Data not available</td>
<td></td>
</tr>
<tr>
<td>Multiple micronutrient supplementation in pregnancy</td>
<td>X</td>
<td>X</td>
<td></td>
<td>82.3</td>
</tr>
<tr>
<td>Breastfeeding (early initiation)</td>
<td>X</td>
<td>X</td>
<td></td>
<td>66.2</td>
</tr>
<tr>
<td>Complementary feeding education</td>
<td>X</td>
<td>X</td>
<td></td>
<td>62.6</td>
</tr>
<tr>
<td>Complementary feeding education and supplementary feeding</td>
<td>X</td>
<td>X</td>
<td></td>
<td>62.6</td>
</tr>
<tr>
<td>Vitamin A supplementation</td>
<td>X</td>
<td>X</td>
<td></td>
<td>26.0</td>
</tr>
<tr>
<td>Zinc supplementation</td>
<td>X</td>
<td>X</td>
<td></td>
<td>86.1</td>
</tr>
<tr>
<td>Basic sanitation</td>
<td>X</td>
<td>X</td>
<td></td>
<td>65.4</td>
</tr>
<tr>
<td>Point-of-use water filter or piped in water</td>
<td>X</td>
<td>X</td>
<td></td>
<td>89.2</td>
</tr>
<tr>
<td>Handwashing with soap</td>
<td>X</td>
<td>X</td>
<td></td>
<td>76.9</td>
</tr>
<tr>
<td>Rotavirus (2 doses)</td>
<td>X</td>
<td>X</td>
<td></td>
<td>88.4</td>
</tr>
<tr>
<td>Kangaroo mother care</td>
<td>X</td>
<td></td>
<td>Data not available</td>
<td></td>
</tr>
<tr>
<td>Balanced energy supplementation</td>
<td>X</td>
<td></td>
<td>Not described in the Great Crusade</td>
<td></td>
</tr>
<tr>
<td>Insecticide-treated nets and indoor residual spraying for malaria control</td>
<td>X</td>
<td></td>
<td>Not epidemiologically significant</td>
<td></td>
</tr>
<tr>
<td>Intermittent preventive treatment of malaria in pregnancy</td>
<td>X</td>
<td></td>
<td>Not epidemiologically significant</td>
<td></td>
</tr>
</tbody>
</table>
believe that these interventions will follow a meaningful trend of improvement beyond this level.

**Ethics and Preregistration**
This study uses de-identified data and did not require approval by the Institutional Review Board of the University of Michigan (UM00177760). We preregistered our analysis at the Open Science Foundation on April 13, 2020.41

## RESULTS

### Changes in Stunting Prevalence
The projected impact of scaling up intervention coverage for each scenario is depicted in Figure 1. The shaded area represents 95% confidence intervals (CIs), which for the Great Crusade (fertility) model are omitted to simplify the figure given overlapping uncertainty bands.

#### 2020–2024 Outcomes
If intervention coverage levels increase at historical levels stunting prevalence is projected to change in 2024 by $-0.1\%$ (95% CI=$0.0\%$,$-0.2\%$). The projected change in stunting prevalence in the Great Crusade model by 2024 is a $-1.1\%$ (95% CI=$-0.8\%$,$-1.5\%$) change. The projected change in stunting prevalence in the Great Crusade with reduced fertility risk model is nearly identical at $-1.1\%$ (95% CI=$-0.8\%$,$-1.6\%$). Our aspirational model projects a $-2.2\%$ (95% CI=$-1.6\%$,$-3.0\%$) change in stunting prevalence by 2024.

#### 2020–2030 Outcomes
In the Great Crusade model that assumes coverage goals are attained in 2024 and then maintained from 2024 to 2030, the model projected a change in the prevalence of stunting of $-1.8\%$ (95% CI=$-1.4\%$,$-2.6\%$). The historical trends and aspirational scenarios projected a change in stunting from 2020 to 2030 of $-0.4\%$ (95% CI=$-0.2\%$,$-0.8\%$) and $-3.7\%$ (95% CI=$-2.8\%$,$-5.1\%$), respectively.

### Stunting Cases Averted in 2024 and 2030
Figure 2 shows the estimated number of stunted cases that would be averted by scenario per year. The shaded area represents 95% CIs, which for the Great Crusade (fertility) model are omitted to simplify the figure given overlapping uncertainty bands.

**Stunting Cases Averted in 2024 and 2030**

<table>
<thead>
<tr>
<th>Scenario</th>
<th>2020–2024 Averted</th>
<th>2020–2030 Averted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Historical Trends</td>
<td>1.1% (95% CI=0.8%, 1.4%)</td>
<td>2.6% (95% CI=2.0%, 3.3%)</td>
</tr>
<tr>
<td>Aspirational Model</td>
<td>1.6% (95% CI=1.2%, 2.2%)</td>
<td>3.2% (95% CI=2.7%, 3.7%)</td>
</tr>
</tbody>
</table>

This study used LiST to project the impact of the 2020 Guatemalan national nutrition policy, the Great Crusade. We found that increases in intervention coverage proposed in the Great Crusade are unlikely to improve child stunting outcomes to a sufficient degree to meet 2024 national targets or 2030 SDG targets. We also described the uncertainty of our projections and the relative impact of different interventions. Our study has implications for
the optimization of nutrition in Guatemala and other low- and middle-income countries.

Our modeling study of nutrition policy in Guatemala reveals limitations in the SUN framework that focuses on scaling up evidence-based nutrition interventions. Despite strong political commitment to the SUN movement since 2010, Guatemala has not met historical stunting targets and, as our study...
FIGURE 3. Contribution of Interventions on Cumulative Stunting Cases Averted by Scenario (A) 2020–2024 (B) 2020–2030

Only interventions that contribute at least 1.0% of the total are included in colored subsegments.
shows, may have difficulty meeting future goals. In the 2013 *Lancet* series on Maternal and Child Health, it was estimated that increasing the coverage of 10 evidence-based interventions to 90% in 34 high-burden countries would result in a 20% relative reduction in stunting prevalence.\textsuperscript{23} Our models suggest that increasing intervention coverage to 90% in Guatemala would result in a 4.7% relative reduction in stunting in 2024 and 8.0% relative reduction in 2030. The modest impact of nutrition coverage expansion in Guatemala compared with other countries may be explained by the relatively high baseline intervention coverage in Guatemala. Taken together, our findings imply that there may be substantial heterogeneity in impact between countries that implement evidence-based nutrition stunting interventions endorsed within the SUN framework. In other country case studies, contextual differences and variations in investments both within and outside the health sector have been proposed as explanatory factors for improvements in stunting.\textsuperscript{22}

Our findings also reveal the limitations of currently available evidence to prevent stunting. Except for WASH, all the stunting interventions incorporated in LiST and included in our models are nutrition-specific interventions. These interventions are supported by high-level evidence, but their effect sizes are generally modest. As an example, complementary food supplementation in food-insecure populations causes a 0.10 (95% CI=0.03, 0.17) improvement in length-for-age Z-scores.\textsuperscript{43} Nutrition-sensitive interventions focusing on the broader context of nutrition including poverty, agriculture, social safety nets, education, and other areas have been proposed as a potential way to generate more sizeable reductions in stunting.\textsuperscript{44,45} In Peru, for example, large improvements in child stunting observed from 2000 to 2013 were likely attributable to economic growth, increased societal participation, poverty-reduction strategies, and increased health spending.\textsuperscript{46,47} Furthermore, a retrospective review of 5 exemplar countries that made significant improvements in stunting found that nutrition-sensitive strategies accounted for 50% of the total stunting reduction.\textsuperscript{42} Despite compelling ecological evidence, nutrition-sensitive interventions have not consistently shown improvements in linear growth in randomized controlled trials. Future research is urgently needed in this area.\textsuperscript{21}

Our study supports the emerging criticism of SUN’s emphasis on technical solutions to address stunting. An independent review of the SUN
Our models. In LiST, complementary feeding is defined as the percentage of mothers who received counseling on complementary feeding practices and continuing breastfeeding after 6 months. Complementary feeding has a particularly large impact in the aspirational models, and we estimate that increasing complementary feeding intervention coverage to 90% by 2024 would avert 243,000 total stunting cases from 2020 to 2030. After complementary feeding, the intervention contributing the greatest impact on stunting reduction between the Great Crusade and aspirational models was breastfeeding promotion. Interventions such as complementary feeding and breastfeeding promotion are “double-duty actions” that also can confer beneficial impacts on obesity and other diet-related noncommunicable diseases. Notably, some interventions such as multiple micronutrient supplementation in pregnancy, rotavirus vaccine, and vitamin A supplementation had minimal impact on stunting due to high levels of coverage at baseline, small effect sizes, or limited need. Previous research has suggested an association between family planning and child stunting, but our models found that decreasing fertility risks had a very small impact on stunting. Our results suggest that efforts to reduce stunting should focus resources on scaling up coverage of specific interventions (complementary feeding, basic sanitation, and breastfeeding) over others (multiple micronutrient supplementation in pregnancy, rotavirus vaccine, and vitamin A supplementation) during the Great Crusade’s implementation phase.

Our study makes a useful methodological contribution to the broader literature that uses LiST and other modeling tools to project maternal and child health outcomes. To our knowledge, this is the first study that uses LiST to project the impact of a national health policy as the policy is launched. The strengths of this study include our choice of a well-established modeling tool (LiST) and our detailed assessments of uncertainty. Policy analyses often report exact predictions without assessments of uncertainty, a practice criticized in the literature as “incredible certitude.” We agree that uncertainty should be transparently and appropriately communicated in policy analyses including maternal and child health models such as LiST. We depict the uncertainty of our models in Figures 2 and 3 where greater changes in intervention coverage and time were accompanied by larger uncertainty. We also updated default inputs with new and nonpublic data sources. Finally, we addressed the gap between the last Demographic

**Efforts to reduce stunting should focus resources on scaling up coverage of specific interventions over others during the Great Crusade’s implementation phase.**

movement has acknowledged that (1) there is limited evidence that SUN has improved nutrition outcomes of member countries, (2) some countries including Guatemala that closely adhere to SUN have not observed meaningful improvements in stunting, and (3) SUN’s standardized approach does not sufficiently account for local country factors. Other critics have argued that SUN emphasizes short-term technical solutions with limited consideration of the structural causes of stunting. In this view, even SUN’s nutrition-sensitive interventions primarily serve to benefit commercial food systems that disrupt indigenous food cultures, decrease confidence in local foods, and reduce biodiversity. In Guatemala and elsewhere, critics of SUN have pointed out conflicts of interest, human-rights concerns among adolescent mothers, and detachment from communities affected by malnutrition. Although our study does not address these broader critiques, our results buttress criticisms against SUN’s emphasis on narrow technical interventions and call for increased focus on strategies that address the social determinants that give rise to stunting. With respect to our study’s implications in Guatemala, a principal target of the Great Crusade is a 7% reduction in stunting prevalence from 2020 to 2024. Our study suggests that this target is very ambitious and unlikely to be achieved solely based on scaling-up interventions recommended by SUN and outlined in the Great Crusade. According to our projections, even aspirational levels of coverage would only reduce stunting prevalence by −2.2% (95% CI=−1.6%−3.0%) in 2024, −0.6% per year. Previous reviews of countries that made significant strides in improving stunting have shown that per year reductions in stunting greater than 1% are possible. The previous Guatemalan national nutrition policies from 2012 to 2016 and from 2016 to 2020 were also unable to reach targets of a 10% absolute reduction in stunting. Importantly, while the Great Crusade confers only a small absolute reduction in stunting prevalence in our models, we also project that the policy would avert over 42,000 total stunting cases from 2020 to 2024 and 217,000 total cases from 2020 to 2030. This absolute number of cases averted may be viewed as substantial by policy makers and nutrition stakeholders in a country with a total population of 16.9 million people.

We found dramatic differences in impact among interventions recommended by SUN and included in the Great Crusade. Complementary feeding and basic sanitation contribute to more than half of the stunting cases averted in most of the literature as “incredible certitude.” We agree that uncertainty should be transparently and appropriately communicated in policy analyses including maternal and child health models such as LiST. We depict the uncertainty of our models in Figures 2 and 3 where greater changes in intervention coverage and time were accompanied by larger uncertainty. We also updated default inputs with new and nonpublic data sources. Finally, we addressed the gap between the last Demographic

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Projecting Stunting in Guatemala Using the Lives Saved Tool www.ghspjournal.org
and Health Survey in Guatemala (2014–2015) and the first year of our projection (2020) by estimating baseline 2020 inputs using a methodology from the literature.

**Limitations**

Our study has several limitations. First, our study assesses only a single country, Guatemala. We justify our focus on Guatemala given the country’s unique position of extraordinary stunting prevalence and sustained commitment to SUN. Furthermore, country case studies have a rich tradition in informing global policy within the maternal and child health field. Second, LiST was designed to estimate the impact of evidence-based interventions with known effect sizes. We are unable to estimate the impact of nutrition-sensitive interventions in the Great Crusade that have uncertain effect sizes such as education and conditional-cash transfer programs. We also are unable to model complex secular trends in stunting prevalence in Guatemala that are likely to be occurring as the country is becoming wealthier and more educated. Third, our study focuses on linear growth—represented by stunting—as a central metric of early child health. However, there has been increasing criticism of the causal assumptions between linear growth in children and long-term developmental outcomes. Pioneering studies in Jamaica and meta-analyses show that early childhood education and stimulation interventions can improve child development without improving growth. In Guatemala, community-based interventions targeting the determinants of child development (and not solely growth) are important but are not considered in our study.

A final limitation involves the uncertainty of nutrition policy in Guatemala during the COVID-19 pandemic. The Great Crusade was published in February 2020 before the first documented case of COVID-19 in Guatemala. Undoubtedly, COVID-19 will have direct and indirect effects on nutrition in Guatemala. Reports of increased food insecurity and acute malnutrition have emerged, while funds destined for nutrition programs are being rerouted to fight COVID-19. We chose not to consider COVID-19 in our analysis for 3 reasons: (1) our primary goal was to assess the Great Crusade as a policy document, (2) the lack of currently available COVID-19 data in Guatemala make any long-term projections impractical, and (3) modeling health system shocks in LST requires different modeling techniques and assumptions.

**CONCLUSION**

This modeling study using LiST found that that the most recent Guatemalan national nutrition policy, the Great Crusade, will have difficulty achieving 2024 national targets or 2030 SDG targets solely based on increases in intervention coverage. Our results show the limitations of technical solutions to nutrition put forth by the international nutrition community. Despite more than a decade of political commitment on the issue of nutrition, Guatemala may continue to have exceptionally high prevalence of stunting over the coming decade. We recommend the prioritization of interventions that are projected to confer the largest impact such as complementary feeding, breastfeeding, and basic sanitation. Policies and strategies are needed to address the broader social structures that predispose children to stunting.

**Author contributions:** ST and DF designed the study and executed the analysis. AC, GA, MM, MFK, BJ, and PR all made contributions to the study design, data collection, and data analysis. All authors contributed to the production of the manuscript.

**Competing interests:** None declared.

**REFERENCES**


En Español

Proyección del Impacto de La Política Nutricional para Mejorar el Retraso del Crecimiento en Niños: Un Estudio de Caso en Guatemala Usando la Herramienta Lives Saved Tool
Hallazgos Clave

- La ampliación de la cobertura de las intervenciones nutricionales basadas en evidencia, recomendadas por la comunidad internacional, sola-mente contribuirán a una pequeña mejora en el retraso del crecimiento de los niños en Guatemala, y es muy poco probable que se cumpla la ambiciosa meta nacional fijada para el 2024 o con los ODS para el 2030.
- Nuestros resultados apoyan un enfoque para aumentar las estrategias que abordan los determinantes sociales del retraso del crecimiento en lugar de un enfoque estrecho enfocado en intervenciones específicas de nutrición.

Implicaciones Clave

- Es poco probable que se logren grandes mejoras en el retraso del crecimiento de los niños en algunos países con alta prevalencia como Guatemala, solamente con ampliar la cobertura de las intervenciones específicas de nutrición.
- Se necesitan políticas nutricionales y sociales multisectoriales para abordar los determinantes estructurales del retraso del crecimiento.

RESUMEN

Contexto: El retraso del crecimiento en niños es un asunto crítico de salud a nivel mundial. Guatemala tiene una de las prevalencias más altas de retraso del crecimiento en niños en el mundo, a pesar de su compromiso sostenido con las intervenciones nutricionales respaldadas por el Movimiento para el Fomento a la Nutrición (SUN por sus siglas en inglés). Nuestro objetivo fue utilizar a Guatemala como un estudio de caso y proyectar el impacto de la política nacional de nutrición recientemente publicada, la Gran Cruzada por la Nutrición, que es consistente con los principios de SUN.

Métodos: Usamos la herramienta Lives Saved Tool (LiST) para proyectar el impacto de ampliar la cobertura de las intervenciones nutricionales propuestas en la Gran Cruzada por la Naurición y recomendadas por SUN. Nuestros resultados fueron cambios en la prevalencia de retraso del crecimiento, el número de casos evitados de retraso del crecimiento, y el número de casos evitados de retraso del crecimiento por cada intervención en niños menores de 5 años de edad del 2020 al 2030. Consideramos cuatro escenarios: (1) cobertura de las intervenciones basada en las tendencias históricas, (2) metas de cobertura de la Gran Cruzada por la Nutrición alcanzadas, (3) metas de cobertura de la Gran Cruzada por la Nutrición alcanzadas al disminuir la tasa de fertilidad y (4) cobertura ampliada a un nivel aspiracional.

Resultados: Todos los escenarios resultaron en reducciones modestas de la prevalencia de retraso del crecimiento. En 2024, estimamos que la prevalencia de retraso del crecimiento cambiaría en –0.1% (intervalo de confianza 95% [IC]= 0.0%, –0.2%) si las tendencias históricas continúan, –1.1% (IC 95%=–0.8%–1.5%) en el escenario de la Gran Cruzada por la Nutrición, y –2.2% (IC 95%= –1.6%–3.0%) en el escenario aspiracional. En 2030, proyectamos una prevalencia de retraso del crecimiento de –0.4% (95% CI= –0.2%–0.8%) y –3.7% (95% CI= –2.8%–5.1%) en el escenario de tendencias históricas y en el escenario aspiracional, respectivamente. La alimentación complementaria, saneamiento y la lactancia materna fueron las intervenciones de mayor impacto en todos los modelos.

Conclusiones: Es poco probable que la reducción en la prevalencia de retraso del crecimiento propuesto en Guatemala sea lograda solamente con el aumento de la cobertura de las intervenciones. Nuestros resultados muestran las limitaciones de los paradigmas actuales recomendados por la comunidad internacional de nutrición. Se necesitan políticas y estrategias que aborden los determinantes estructurales del retraso del crecimiento.

Peer Reviewed

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Beyond Institutionalization: Planning for Sustained Investments in Training, Supervision, and Support of Community Health Worker Programs in Bangladesh

Shongkour Roy, Shivani Pandya, Md. Irfan Hossain, Timothy Abuya, Charlotte E. Warren, Paloma Mitra, Ubaidur Rob, Sharif Hossain, Smisha Agarwal

Key Findings

- The community health worker (CHW) program in Bangladesh faces many systemic challenges related to inadequate technical recognition, training opportunities, identification as government employees, access to transportation, provision of working tools, and the workplace environment.
- The study highlighted tensions between family welfare assistants and health assistants owing to differences in their compensation structures despite comparable responsibilities—a situation that has resulted in demoralization of the cadres.
- Despite being institutionalized, the challenges faced by the CHW cadres in Bangladesh are very similar to CHW programs in other countries, highlighting the need to move beyond institutionalization to sustained investments in a supportive ecosystem for CHW programs.

Key Implications

- Changes to technical ranks and wages for the health care sector need to take a sector-wide lens so that wages for all health care workers can be systematically calibrated.
- Efforts to institutionalize CHWs should be accompanied by plans for sustained investments in and support for training, adequate compensation, supervision, access to working tools, and recognition of CHWs.

ABSTRACT

Introduction: Bangladesh has a long history of mature and institutionalized community health worker (CHW) programs in primary health care. However, there is a lot of variability in the performance of the CHW programs in Bangladesh, as well as challenges associated with retention of CHWs. This study describes the challenges for CHWs, which in turn affect their motivation and performance.

Methods: This study was conducted from December 2019 to January 2020 in 4 districts in Bangladesh: Cox’s Bazar, Khulna, Rajshahi, and Sylhet. Twenty focus group discussions were conducted with 121 participants, including family welfare assistants (FWA), health assistants (HA), and their direct supervisors. Thirty in-depth interviews were conducted with upazila and district-level stakeholders. Data were analyzed using a thematic approach with a particular focus on CHW motivation, job satisfaction, and incentive preferences for improving morale and performance.

Results: Several nonmonetary and monetary factors affect CHWs’ motivation, performance, and job satisfaction. Recognition by the community, availability of promotions and technical recognition, increased training opportunities, reduced workloads, identification as government employees, access to transportation, provision of working tools, and improvements in the workplace environment were identified as important nonmonetary incentives. CHWs also discussed the importance of sufficient salaries and allowances.

Discussion: Several factors impede the effectiveness of the CHW programs in Bangladesh. Changes to technical ranks and wages for the health care sector need to take a sector-wide lens to enable systematic calibration of wages for all health care workers. This study highlights that institutionalization of CHWs without adequate and sustained support for continued training, compensation, supervision, access to working tools, and recognition is insufficient to drive change. Identifying pragmatic strategies that can be supported through existing government budgets to address these factors is vital to sustaining the community health workforce in Bangladesh.

INTRODUCTION

Bangladesh has made great strides toward improving population health outcomes and meeting the Sustainable Development Goals, as evidenced by improvements in life expectancy at birth and under-5 mortality. Bangladesh is credited with creating one
Sustained Investments in Community Health Worker Programs in Bangladesh

Understanding the incentives and support received and valued by CHWs can help structure programs to improve overall CHW motivation, satisfaction, and performance.

areas to cover, which has increased CHWs’ overall dissatisfaction with their roles and responsibilities. Furthermore, “trends of feminization,” referring to when female CHWs leave their positions due to marriage or career changes, particularly affect CHWs within the family planning department (i.e., FWAs), given that it is an all-female cadre. These issues adversely affect not only CHWs but also the communities they serve and support; therefore, it is important to identify appropriate strategies to address these challenges to strengthen Bangladesh’s community health program.

The WHO Guideline on Health Policy and System Support to Optimize Community Health Worker Programs identified that both nonmonetary and monetary incentives are important in supporting and motivating CHWs and can reduce CHW attrition. In their analysis of how incentives affect motivation for both salaried and volunteer CHWs across 6 countries (including Bangladesh), Ormel et al. provided further support for the value of both nonmonetary and monetary incentives, indicating that solely providing financial incentives is likely to be insufficient in maintaining motivation. Studies among nongovernmental organization CHWs in Bangladesh similarly identified the importance of providing monetary incentives, as well as social prestige, recognition, and community acceptance, among others, in improving CHW retention. A systematic review of 14 studies of interventions for CHW performance improvement found moderate-quality evidence toward the impact these interventions had on community health outcomes, noting improvements in specific behavioral outcomes, use of services, and quality of care provided. These findings emphasize the importance of providing both nonmonetary and monetary incentives as strategies toward improving CHW programs, which includes boosting CHW motivation, satisfaction, and performance.

In alignment with recommendations of prior research, Bangladesh’s recent National Strategy for Community Health Workers report outlined the provision of monetary and nonmonetary incentives to better recognize and support CHWs. This represents a significant and crucial first step toward better working conditions for CHWs and aligns with the recent Astana Declaration, which underscored the importance of CHWs in advancing universal health coverage. Given the immense value of CHWs and the role they play in promoting and improving health outcomes in Bangladesh, it is necessary to identify ways to better motivate them and improve their working conditions through the provision of realistic and desirable incentives at the...
policy level. This work is especially critical now as the national government is currently in the process of deploying new CHW cadres and restructuring incentives for the existing cadres. This study provides a stronger understanding of the current CHW context in Bangladesh and their preferences for incentives, as well as the disincentives that increase dissatisfaction with their role.

**METHODS**

**Ethical Approval**
The research protocol was approved by the Population Council’s Institutional Review Board (PC IRB 872) and the Bangladesh Medical Research Council Institutional Review Board (BMRC/NREC/2016-2019/114).

**Study Setting and Population**
This study was conducted in 4 districts of Bangladesh: Cox’s Bazar, Khulna, Rajshahi, and Sylhet. These study sites were selected to represent perspectives from different regions of Bangladesh (Figure 1). Cox’s Bazar was selected as a study district given the high percentage of CHWs supporting the Rohingya refugee population in the district; over 720,000 Rohingya refugees migrated to Bangladesh in August 2017, which created the fastest-growing refugee crisis globally. Over 1,000,000 displaced Rohingya refugees now reside in camps located within 2 upazilas (administrative subunits) within the district: Ukhiya and Teknaf.

Participants were grouped into 3 categories: CHWs, CHW supervisors, and upazila and district-level stakeholders. CHWs included HAs and FWAs. CHCPs were not included in the study due to their role in primarily supporting the CCs; this study focused on CHWs working within the community and making home visits. CHW supervisors included assistant health inspectors (AHIs), health inspectors (HIs), and family planning inspectors (FPIs). AHIs and HIs operate as the direct supervisors for HAs under DGHS; AHIs are union level and HIs are upazila/district level. FPIs are the direct supervisors for FWAs under DGFP and serve at the union level. Upazila- and district-level stakeholders included civil surgeons, deputy directors of family planning, upazila health and family planning officers, and medical officers in maternal and child health, among others. Figures 2 and 3 provide an overview of Bangladesh’s community health system structure.

In Bangladesh, CHWs and their supervisors are government employees, who receive government salaries and allowances. Currently, their salary pay scale is dictated by their grade position. Before July 2015, HAs and FWAs had a similar pay scale and both were in the third-class position. In July 2015, the Bangladesh government, through the eighth national pay scale, changed the class positions and grades for government employees; FWAs became 17th grade and HAs 16th grade. FWAs were effectively demoted, as their grade was one below HAs, which resulted in a change and decrease with the pay scale.

**Study Design and Data Collection**
Focus group discussions (FGDs) were conducted with CHWs and CHW supervisors and in-depth
FIGURE 1. Map of Study Area of Community Health Worker Challenges Affecting Motivation Conducted in 4 Districts in Bangladesh: Cox’s Bazar, Khulna, Rajshahi, and Sylhet

LEGEND
- Included Bangladesh Districts

FIGURE 2. Bangladesh’s Community Health System Structure
interviews (IDIs) were conducted among upazila- and district-level stakeholders between December 2019 and January 2020. Twenty FGDs were conducted among 121 participants, which included HAs, FWAs, and their direct supervisors (HI, AHI, FPI), and 30 IDIs were conducted with upazila- and district-level stakeholders (i.e., civil surgeon, deputy directors of family planning, upazila health and family planning officers, upazila family planning officer); there were a total of 151 participants overall (the Table shows participant breakdown by district). Semistructured FGD and IDI guides were created to help guide the discussions. Questions focused on the types of incentives and disincentives that supported CHW motivation, satisfaction, and retention; the relationship between CHWs and health care facilities; the relationship between CHWs and the community; and government financial capacity and goodwill toward CHW programs.

The study team worked with DGHS and DGFP, under the Ministry of Health and Family Welfare, to initially orient them on the study protocol and to gain approval and access to health care facility staff. Participants were purposively selected. All participants provided informed consent before their participation. FGDs and IDIs were facilitated by trained postgraduate facilitators. FGDs had 2 facilitators, with one moderating the discussion and the second taking notes. The duration of the FGDs and IDIs ranged from 1 to 2 hours. The FGDs and IDIs were held in Bangla, audio-recorded, and subsequently transcribed and translated into English for analysis.

Data from the FGD and IDI transcripts were coded and analyzed using QSR International’s NVivo 12 software. A thematic content analysis technique was applied, which comprised a mix of inductive and deductive coding. The coding framework was adapted from one initially developed for one of the 4 countries included in the larger study; through an iterative process, a team of 3 researchers read through the transcripts and identified emerging themes to include in the coding framework. To ensure inter-rater reliability, the researchers familiarized themselves with the data and the coding framework by coding 2 transcripts independently and discussing each together to come to a consensus on coding strategies. A constant comparison approach was applied to systematically compare and analyze the coded data to provide a comprehensive picture of incentives and to summarize the similarities and differences in the perception and experiences of incentives between different stakeholders and study sites.

RESULTS

The discussions with the CHWs, CHW supervisors, and upazila/district-level stakeholders provided critical insights into factors that influence and inhibit CHW motivation, job satisfaction, and performance.
Nonmonetary Factors
Recognition by the Community, Health Care Facilities, and the Government
Recognition of CHWs’ responsibilities can help further motivate their job satisfaction and performance. CHWs reported generally positive relationships with and recognition by the community, with CHWs sometimes being referred to as doctors:

They call us as doctors. If they have any problems, they come to us. —CHW Supervisor FGD

CHWs’ relationship with health care facilities was more strained, due to tensions between CHW cadres—specifically between FWAs and HAs/CHCPs. As aforementioned, FWAs are under DGFP, and HAs/CHCPs are under DGHS. Discussions suggested poor collaboration and lack of mutual support between FWAs and HAs/CHCPs that ultimately served to undermine FWAs ability to work effectively:

There are CHCPs and HAs who work in community clinic. When FWAs are trying to collaborate with them, sometimes they are not getting proper recognition. It is a big issue to work [with] each other. —Upazilla/District-Level Supervisor IDI

Furthermore, CHWs noted that tangible forms of recognition need to be provided to them from the policy level, namely through promotions and technical recognition. Technical recognition refers to being provided technical training (e.g., to become a community skilled birth attendant), which can, in turn, improve their salary scale and credibility. Currently, regarding promotion, there is no scope for FWAs and limited scope for HAs, which has adversely affected their motivation.

Yes, promotion. I joined in 1990. Thirty years have passed. This work feels boring now. I feel that if there was promotion for us, we would be happy with our work. I have worked all my life being in the same rank. Nowhere in Bangladesh you can see this situation, only in the family planning department. —FWA/CHW FGD

One employee passes 30–35 years working for the same post. Very few get the promotion based on the seniority level. […] They join the department as health assistant, also retire from the department as the health assistant. They do not get the opportunity to become AHI or HI. How cruel is this! —CHW Supervisor FGD

Identification
CHWs noted that methods of identification can help support their ownership of their work, as well as recognition by the community and health care facilities. CHWs discussed identification cards, branded uniforms (e.g., t-shirts, aprons), and branded working tools (e.g., umbrellas, carrier bags). CHWs shared that the lack of adequate identification resulted in difficulties in executing their responsibilities. Wearing something that identified them as a CHW would indicate their function in the communities and better allow them to perform their jobs more effectively.

In Sadar, the FWAs don’t have a uniform. It’s like their identity. It represents them as FWA. Whenever they roam without their uniform, people get scared of them. It’s a city, it’s full of danger. People of Sadar often assume that they are frauds and do not want to believe them. The FWAs have to assure them saying that they are FWAs, they are from the government. How can they do their job without a basic apron? —CHW Supervisor FGD

Means of Transportation
CHWs often travel by foot in communities or must wait for transportation, which can increase the
amount of time it takes to get around and complete their work. CHWs discussed the need to have bicycles or scooters/motorcycles, as it would help them be more mobile and increase their access to and time in communities, especially in remote, hard-to-reach areas. Additionally, it would help ease the weight they have to carry, given that CHWs carry their supplies with them.

One has said there should be one HA for 6,000 population, but I am working with [around] 13,000 people. So, to work in eight subblocks, to visit the ward, visit the house, one motorcycle can be provided either by government or donor. If it is provided, the service will be faster, sounder, and more successfully done by us. —HA/CHW FGD

Having transportation also would enable CHWs to better mobilize the community and increase awareness about important health topics.

I have a motorcycle of my own. [...] I used a loudspeaker to spread the news of EPI (Expanded Program on Immunization). I drove my motorcycle through the area where EPI will take place and the recorded details about the session was being played through the loudspeaker. The recording was in local language and I played the record, drove the bike. After this, there was no such place where the news had not been reached. It was a great advantage. There are some places where rickshaw couldn’t go but motorcycle can. The motorcycle is really important here. So I have a request that please deliver this message that motorcycle is really important for HA. I think 100% coverage is achievable if they are provided with a bike. —HA/CHW FGD

Provision of Tools and Medical Supplies

CHWs discussed the need for tools and resources that would enable them to work more efficiently, including medicines, logistical support, job aids, and smartphones/tablets. Both CHW cadres want to be able to distribute medicines as they felt that it would not only be an essential and needed service for the community, but it would also strengthen the relationship between CHWs and the community. FWAs currently are not able to distribute medicines outside of family planning methods and vaccines.

For FWA, it would also be helpful to carry a motorcycle. If they have a motorcycle, they would be able to move more quickly to perform their duties. —CHW FGD

One has said there should be one HA for 6,000 population, but I am working with [around] 13,000 people. So, to work in eight subblocks, to visit the ward, visit the house, one motorcycle can be provided either by government or donor. If it is provided, the service will be faster, sounder, and more successfully done by us. —HA/CHW FGD

Given the increasing workloads and the supplies they must carry during their household visits, CHWs discussed that it would be beneficial to digitize aspects of their work. CHWs felt that having a smartphone or a tablet would enable them to work more effectively:

Our notebooks are getting larger. Our notebooks are at least 3 kg in weight, and it is increasing in size after adding those 19 columns regularly. So, if the extent of our work is increasing so much, why are we not given tablets? —CHW Supervisor FGD

Training

Both CHW cadres are meant to receive 1 month of “basic” training for their job; however, CHWs reported often not receiving it:

I’ve joined in 2016 but haven’t got my basic training yet. Even people who have joined back in 2008 didn’t get their basic training yet. —CHW Supervisor FGD

In addition to this, CHWs want to have refresher trainings and new trainings to reinforce and expand upon their knowledge and skills. CHWs reported that trainings on counseling methods, taking blood pressure, different types of medication, vaccinations, and so forth occur infrequently, providing them with little opportunity to update their knowledge. CHWs also desired to receive technical training, which would increase their technical recognition and could improve their salary grades; for example, FWAs wanted technical trainings to become certified community skilled birth attendants. Additionally, CHWs discussed the importance of being trained on how to use digital devices.

We vaccinate a child from very beginning of life. So, if anything happens to him, the liability is ours. If something happens to any child, whole area would be upside down. We have the liability of child death. In this case, we don’t receive much training. Even CHCPs receive 6 months training. But we haven’t received any basic training. There are 30 types of medicines here [family welfare centers]. We don’t even have any training about them. We are going on with our own experience. No basic training has been done about this. If we receive training, our skill would be more developed. —HA/CHW FGD

The problem is, whenever we talk about technical issues, higher officer or line doctor suppress us saying, “What do you want? You didn’t join with the educational qualification of a technical [employee].” [...] So, we want that when we get appointed, we will be given a one-year technical training for the rank. —HA/CHW FGD
CHWs feel that their workload has become quite burdensome, which has significantly affected their motivation and morale. CHWs feel that their workload has become quite burdensome, which has significantly affected their motivation and morale. Given the lack of an adequate CHW to population ratio, the existing CHWs are often overstretched and are responsible for supporting more people than originally intended, which has adversely affected CHWs and raised concerns about their ability to work effectively.

Every ward has 10,000 people. [...] For having trouble with manpower, we serve about 20,000 people per unit. Who used to serve three wards in a Union Parishad, now that person has to work for six wards, where it is supposed to be two people per ward. In [Location], we had three person working for health service, but about 50% of manpower is gone [retired] by now. Last appointment was in April 2010. Some people retired or got promoted in the meantime. But no appointment was conducted for these vacant posts. —HA/CHW FGD

How am I going to serve them [the community] or counsel them properly? How am I going to reach every mother in my area? I have to reach to them. I have to hurry. Sometimes they request us to stay a bit more but I can’t. We are getting hurried from the health complex, we are getting hurried from community clinics, and family planning is not an easy job to do. We are being over-pressured. —FWA/CHW FGD

Workload

Workplace Environment

Although CHWs primarily work in the community and CCs, there may not always be dedicated space available for them to work. CHWs feel that this needs to be addressed in some capacity because the lack of a dedicated workplace environment adversely affects their performance, as well as their relationships with the community and health care facilities. CHWs desired improvements in 2 types of workplace environments: EPI centers and CCs. For EPI centers, CHWs discussed challenges faced within the community of hosting sessions in people’s homes, noting that it places a further burden on community members, which also affects CHWs’ ability to provide services if the community member is not willing to share their home. Some CHWs noted that it might be worth paying community members to use their home or renting facilities elsewhere within the community:

If we could rent their room and do our EPI sessions there, it would be a lot easier. Government doesn’t have to make a new facility for us as well. We could keep all our logistics there and prepare ourselves better.

Thus, we can develop our relationship between each other. —CHW Supervisor FGD

At the CCs, CHWs often find there is no space for them to work despite having to provide services from CCs 3 days a week. FWAs noted this problem happened to their cadre frequently. Given that FWAs are expected to be at CCs 3 days out of the week, the lack of a dedicated space for them has become demotivating and insulting. It also further exacerbates tensions between the CHW cadres.

Now let me talk about the community clinic. It has three rooms: one for CHCP, one for HA, and [the] last one is a balcony. When a FWA brings a mother for check-up in the community clinic, they do not find a private place for the mother. They told us to use the balcony. How can we use a balcony to check-up [on] the pregnant mother? She deserves some privacy. The HAs use the room for EPI and let the FWAs use the balcony for satellite. There should be a separate room for the FWAs. Our health department has two children, one is his own, the other is his stepson. Family planning sector is [his] step-son. —CHW Supervisor FGD

Monetary Factors

Salary

As government employees, CHWs receive a monthly salary; however, the amount provided is often not enough. CHWs are discontent with their salary levels. For FWAs, the change in class positions resulted in a decrease of their salary grade. This caused significant upset among FWAs, especially as HAs maintained their higher-grade position.

In agriculture department, field workers get second class [13th grade] salary. But we get fourth class [17th grade] salary. Salary discrimination should be eradicated. [...] In our union, we have four FWAs though we need nine of them. If one person carry this much pressure, how can success come? FWAs also work in the technical side as they push injection. If their salary could be equal as technical side, it would help to get better outcome from [their] field work. —CHW Supervisor FGD

For HAs, their salary level remains stagnant despite promotions to higher ranks (e.g., AHI/HI):

The salary discrimination needs to be taken care of. If an HA gets the same basic of 20,180 Taka, as an AHI or HI gets the [same], then why would he address HI as sir? —CHW Supervisor FGD

Both of these issues are considerably demotivating and demoralizing for CHWs:
Tourism allowance was specifically seen in discussions in Cox’s Bazar; CHWs cited the high cost of living due to Cox’s Bazar also being a tourist destination.

**DISCUSSION**

Our study identifies several challenges that are unique to and have direct implications for the health care sector in Bangladesh. First, tension between HAs and FWAs, owing to the differences in their government technical grade and salary scales despite comparable responsibilities, undermines the motivation of the CHWs. In practice, minimal differences exist in the responsibilities and the workload of FWAs and HAs, yet HAs are placed at a higher technical rank and salary bracket. Changes to technical ranks and wages for the health care sector need to take a sector-wide lens so that wages for all health care workers can be systematically calibrated.

Second, the study highlights the importance of the workplace environment in fostering motivation and the ability to execute responsibilities effectively. The scope of activities undertaken by CHW cadres have evolved over the last decade, without the necessary attention to how they will be executed. FWAs are required to spend a few days a week at the CCs, however, they lack dedicated physical spaces where they can conduct clinical assessments, many of which require privacy. HAs often conduct their EPI sessions in community members’ homes and face challenges when those homes are not available to them. CHWs noted that this has often caused strain within the community-CHW relationship. As such, it may be important to consider possible alternatives such as renting a community member’s home or another existing community-owned location. Discrepancies regarding dedicated workspace also highlighted tensions between cadres, as some FWAs reported the lack of a dedicated workspace and disregard for their cadre in the CCs due to the differences in government rank and salary scales.

Third, CHWs continue to be seen as a quick-fix solution to emergent health challenges, including chronic disease, a refugee health crisis, and a global pandemic. CHWs who serve the community in Cox’s Bazar highlighted the unique challenges and risks they face in serving the large Rohingya refugee settlement. This is also being highlighted globally in the context of COVID-19 as CHWs are serving to identify positive cases and conduct contact tracing. As revisions to CHW and health care worker compensation structures are considered,
provisions need to be in place to account for adequate training and risk allowance. This is of particular importance for CHW cadres because they are typically deployed to respond to emergent situations without adequate investment in preparing or supporting them. Any changes to CHWs’ scope of work need to take into account the burden of work they are required to undertake versus the time allocated for them to do it.21 As community change agents, it is expected that CHWs will be required to respond to the needs and priorities of the community; however, the ever-expanding tasks need to be routinely assessed against what is feasible.

The study also identifies other programmatic challenges faced by the CHW cadres in Bangladesh—adequate recognition, means of identification and transportation, access to working tools, and training opportunities—that have already been extensively documented in the literature related to CHW programs globally.7,22–25 Bangladesh is unique in having multiple cadres of CHWs that are scaled nationally and institutionalized within the Ministry of Health with a formal technical rank, salary, and pension. Global advocacy efforts to institutionalize CHWs are often focused on the need for formal recognition as government employees, as well as salaries and other benefits accrued because of government employment.8,26–29 However, in the case of Bangladesh, we see that the mature institutionalized CHW cadres face many of the same challenges faced by fledgling cadres in other countries. These systemic challenges have downstream effects on how effective the CHW programs are, as well as on the health of the community.

We argue that institutionalizing CHWs, while valuable, is insufficient for improving the quality of such programs without adequate and sustained investments in the necessary ecosystem that supports such programs. As identified in the CHW logic model, mobilizing inputs at the policy, funding, and organizational level toward a stronger health system is indispensable for high-performing CHW programs.30 Fundamentally, to be effective, CHWs need adequate training, opportunities to receive in-service training to maintain and upgrade their knowledge, consistent access to necessary logistics and supplies that will facilitate their job, supervision, appropriate means of transportation, and a compensation structure that is balanced with their workload. Often, donor investments for CHW programs support training only in a priority health area such as family planning or HIV, without any consideration of or investments in the supporting ecosystem that is critical to the effectiveness of these programs. Our study highlights that even in the case of mature, institutionalized CHW cadres, there are no shortcuts to achieving community-level impact. Governments must continue to plan for sustained investments not only in the direct salaries and benefits of the health care workers but also in ensuring that systems are in place for adaptive management of the CHW cadres based on changing community needs, assessing performance, and aligning support with the expected output. Greater coordination is needed at a global level to pool and align donor investments to facilitate appropriate support for the ecosystem that facilitates the success of CHW programs.

The study identifies several factors that impede the effectiveness of the CHW programs in Bangladesh. The results of our study are consistent with findings from the literature showing the importance of considering both nonmonetary and monetary incentives to support CHWs.8,26,28,29,31–35 The study provides perspectives from CHWs from 4 geographically distinct districts in Bangladesh, including a district with a predominantly refugee population, furthering understanding of factors that ultimately affect CHW job satisfaction and community value for their work. Despite being scaled and institutionalized cadres, the challenges identified are like those in countries with fledgling CHW programs. This study highlights that institutionalization of CHWs without adequate and sustained support for continued training, compensation, supervision, access to working tools, and recognition is insufficient to drive change. Identifying pragmatic strategies that can be supported through existing government budgets to address these factors is vital to sustaining the community health workforce in Bangladesh.

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Impact of Solar Light and Electricity on the Quality and Timeliness of Maternity Care: A Stepped-Wedge Cluster-Randomized Trial in Uganda

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Key Findings

- Universal access to modern energy and safe childbirth are global health priorities that are inextricably linked, yet little research has rigorously examined the adoption and effectiveness of solar energy systems in resource-constrained settings.
- In sub-Saharan Africa, health facilities lack access to reliable light and electricity. We evaluated the implementation and effectiveness of the We Care Solar Suitcase, a complete solar electric system that provides medical lighting and electrical power for charging small medical devices and mobile phones, on the quality of maternal and infant care.
- The intervention was adopted well by health providers, increased facility brightness, and led to modest increases in the quality of maternal care based on clinical observations of deliveries.
- Reliable light is an important driver of timely and adequate health care and may improve providers’ ability and timeliness in performing actions needed to reduce the risk of postpartum hemorrhage.

Key Implications

Ministries of health, development partners, and other health care reform stakeholders should:

- Invest in modern and renewable energy systems for health care facilities.
- Ensure access to reliable energy is included in larger efforts to improve quality of care via systemic changes to health systems.

ABSTRACT

Background: We evaluated the impact of solar light installation in Ugandan maternity facilities on implementation processes, reliability of light, and quality of intrapartum care.

Methods: We conducted a stepped-wedge cluster-randomized trial of the We Care Solar Suitcase, a complete solar electric system providing lighting and power for charging phones and small medical devices, in 30 rural Ugandan maternity facilities with unreliable lighting. Facilities were randomly assigned to receive the intervention in the first or second sequence in a 1:1 ratio. We collected data from June 2018 to April 2019. The intervention was installed in September 2018 (first sequence) and in December 2018 (second sequence). The primary effectiveness outcomes were a 20-item and a 36-item index of quality of intrapartum care, a 6-item index of delays in care provision, and the percentage of deliveries with bright light, satisfactory light, and adequate light.

Results: We observed 1,118 births across 30 facilities. The intervention was successfully installed in 100% of facilities. After installation, the intervention was used in 83% of nighttime deliveries. Before the intervention, providers on average performed 42% of essential care actions and accumulated 76 minutes of delays during nighttime deliveries. After installation, quality increased by 4 percentage points (95% confidence interval [CI]=1.8) and delays in care decreased by 10 minutes (95% CI=−16, −3), with the largest impacts on infection control, prevention of postpartum hemorrhage, and newborn care practices. One year after the end of the trial, 90% of facilities had LED lights in operation and 60% of facilities had all components in operation.

Conclusions: Reliable light is an important driver of timely and adequate health care. Policy makers should invest in renewable energy systems for health facilities; however, even when reliable lighting is present, quality of care may remain low without a broader approach to quality improvements.

BACKGROUND

Reducing maternal and neonatal mortality are global public health priorities, yet progress on these goals remains intractably slow. The burden of maternal mortality in low-income countries is staggering—if countries could meet the Sustainable Development Goal of 70 maternal deaths per 100,000 live births by 2030, the lives of an estimated 1.6 million mothers would be saved.1 With
dramatic increases in facility-based deliveries over the past 30 years, the major barrier to meeting this target now lies not in increasing access to health facilities, but in improving the quality of care delivered in these facilities. A recent analysis found that over half of maternal and neonatal deaths in low-income countries result from poor-quality care rather than from nonutilization of care. High-quality care requires the provision of effective, timely, and safe health services, delivered by a well-trained and motivated workforce, in a facility equipped with essential infrastructure and supplies, functioning health information systems, and good leadership and governance.

One of the major neglected health system challenges to maternal and child health is the lack of access to reliable energy. Reliable light and electricity are critical for nearly all aspects of safe childbirth, including equipment sterilization, infection control, powering essential medical devices, and nighttime examinations and procedures. Lack of reliable light may hinder providers’ ability to manage complications and cause them to delay necessary care actions, putting both mother and infant at risk. Frequent blackouts may also create stressful working conditions for health care workers, generate patient mistrust, and promote inequities in care. Yet a study across 78 low- and middle-income countries (LMICs) found that 59% of health facilities lack access to reliable electricity. In sub-Saharan Africa, one-quarter of health facilities have no connection to the electrical grid; among connected facilities, frequent and prolonged interruptions to power are common. This crisis has been compounded by the health and economic consequences of the coronavirus disease (COVID-19) pandemic, a time when proper infection control in health facilities is imperative to mitigate the spread of the virus.

The significance of access to affordable, reliable, and modern energy in strengthening health systems has been recognized by the United Nations’ Sustainable Energy for All (SEforAll) and United States Agency for International Development (USAID) Powering Health Care initiatives. While improved sources of reliable lighting are needed in many health systems in LMICs, there are significant barriers to expanding grid power to unconnected health facilities, including the high cost per mile to extend and maintain a grid to remote areas and the strain such extensions would place on already weak and unreliable infrastructure. Moreover, recent experimental evidence on the demand for rural residential grid connections has found low willingness to pay for electrification among residents; however, aligning programs for new grid connections with opportunities for productive use (e.g., developing small businesses) may facilitate a higher willingness to pay.

Renewable energy sources such as solar power may provide a clean, efficient, and cost-effective opportunity to increasing access to reliable light and electricity for health facilities in resource-constrained settings. However, there are several challenges to the implementation of solar energy systems in rural health facilities. Health care workers may be reluctant to adopt new technology if they do not see an immediate benefit, or they may use it inconsistently or incorrectly. This outcome is a common finding in the implementation of mobile health and electronic health registration systems in LMICs. Poorly designed technology can quickly fall into disrepair, while inadequate maintenance, such as lack of replacement of batteries, can result in disuse. Finally, there is difficulty in sustainability and scale-up. Evidence is needed on whether adopting and integrating solar energy into rural health facilities (1) is feasible, (2) improves reliability and brightness of light, and (3) affects quality of care. Most prior quantitative studies examining the relationship between reliable light and health care quality are observational and are subject to unobserved confounding related to patient, provider, and facility factors. As far as we are aware, the only randomized trials evaluating the impact of providing electricity or light on health outcomes in LMICs have included electricity upgrades as part of a broader package of infrastructure, training, supervision, and mentoring, complicating any inference about the specific role that electrification and bright light play in quality of care and patient outcomes. Further, detailed data on light and quality of care—for example, through actual observations of light and health care worker actions—are rarely available.

We conducted a stepped-wedge cluster-randomized controlled trial in Uganda to evaluate the impact of implementing the We Care Solar Suitcase, a complete solar electric system that provides medical lighting and electrical power for charging small medical and communication devices. We first examine the implementation of the intervention in health facilities. We then assess the extent to which using the Solar Suitcase improves light brightness using light sensors and direct observations of light sources.
METHODS

Study Setting
The study took place in maternity facilities in Uganda. From 2011–2016, the maternal mortality ratio for Uganda was 336 deaths per 100,000 live births, while the perinatal mortality rate was 38 deaths per 1,000 pregnancies.23,24 In 2016, 73% of deliveries in Uganda occurred in a health facility.23

Uganda’s health sector hierarchy includes national and regional hospitals, followed by a district health system composed of health centers of levels II through IV. These health centers generally staff low- and mid-level providers who provide care for uncomplicated deliveries.

Study Design
The study design was a stepped-wedge cluster-randomized controlled trial as a staggered rollout of the intervention was necessary owing to limited resources. Facilities were randomized into 1 of 2 sequences, with the first sequence receiving the intervention between the first and second periods of data collection, and the second sequence receiving the intervention between the second and third periods of data collection (Supplement Figure 1). Details of the study methods have been published in the study protocol.25

Participants
Clusters were primary health facilities in the Central, Eastern, and Western regions of Uganda. We conducted a census of all primary health facilities offering delivery services in these regions. We then excluded facilities that did not meet the inclusion criteria. Details of inclusion and exclusion criteria are specified in Supplement Table 1. In brief, criteria for facilities were (1) level II, III, or IV; (2) open 24 hours a day; (3) the presence of unreliable overhead light; (4) no automatic referral of women elsewhere during blackouts; and (5) willingness of the medical officer in-charge to participate. All health care workers that worked in the maternity ward at these facilities were eligible for interview and observation. Pregnant women aged 16 and older who were admitted to the facilities for labor and delivery and provided written informed consent were eligible to participate.

Randomization
Randomization of facilities was conducted using Stata’s randomize command, with stratification by geographic cluster and a measure of baseline light availability. The randomization that achieved the best balance based on baseline quality of care and facility volume was chosen (Supplement Table 2 has details on stratification and balancing variables). The allocation sequence was generated by the study investigators. Due to the nature of the intervention, neither participants nor researchers were blinded to allocation.

Ethical Approval
The study was approved by Institutional Review Boards at the Harvard T. H. Chan School of Public
Impact of Solar Light on Quality of Care in Uganda

Quality of Care Surveys. Using this observation tool adapted from the Maternal Observations of Deliveries using an extensive clinical detail, enumerators indicated whether items that are essential for high-quality care were provided during labor, delivery, and the early postpartum period. Enumerators observed and recorded the care delivered by providers during labor and delivery over 4 stages: arrival and first examination, first stage of labor, second and third stages of labor, and the first hour postpartum. For each item in the observation tool, enumerators recorded whether the item was completed by a health care worker and, if it was completed, recorded a timestamp as to when the item was completed. In addition, enumerators indicated the sources and brightness of light at each of the 4 stages of the observation. The brightness was recorded as “very bright,” “somewhat bright,” “dim,” and “pitch black.” Definitions for the level of brightness for these categories are provided in Supplement Table 3; enumerators were trained to interpret these categories uniformly according to these definitions. Finally, after an observation was complete, enumerators reviewed the patient’s chart to retrieve information on patient age, parity, and gestational age.

To reduce disruption and influence, enumerators were trained to avoid interaction with providers and patients. Enumerators were provided with digital watches for recording timestamps. To maximize interrater reliability, enumerators were extensively trained on the definition of each item in the observation checklist under the leadership of the study obstetrician. Details on enumerator protocol and interrater reliability are provided in Supplement Table 2.

Data collection was conducted on paper questionnaires, then inputted electronically using double data entry. A Stata user-written code file was used to identify discrepancies between entries, which were resolved by the project manager by referring to the original paper questionnaire and/or by contacting the enumerator. Data management procedures were in place to ensure data quality, including daily checks by the project manager on incoming data to identify data outliers, logical inconsistencies, and missing data.

At the end of each data collection period, enumerators conducted provider interviews to record information on provider demographics, work experience, training, and attitudes. Enumerators also conducted facility assessments with the medical officer in charge to record information on facility staff, monthly patient volume, and electricity interruptions.

Finally, light sensors were installed (HOBO 4-Channel Analog data logger) in the delivery rooms...
of each facility that recorded the light (measured in lux) at each minute for the duration of the study.

Data collection tools were piloted at 5 facilities before study rollout to ensure usability, clarity, and inter-enumerator reliability. Light sensors were also piloted to ensure correct implementation procedures and data usability. Data from these pilot facilities were not included in the final sample.

**Implementation Outcomes**

We applied the RE-AIM framework to guide evaluation of implementation outcomes. We assessed the reach of the intervention by examining the percentage of eligible facilities that participated in the study, as well as the representativeness of study facilities and women delivering in facilities by comparing facility and participant descriptive characteristics with national-level estimates. We examined the implementation of the intervention by determining the percentage of facilities with successful installations and the percentage of health care workers successfully trained. We examined adoption via enumerator-reported main source of light used during the delivery observation before and after implementation of the Solar Suitcase. Sources of light included the Solar Suitcase, electrical grid, other overhead solar light, generator, kerosene lamp, flashlight, and daylight. We also examined whether health care workers self-reported that they felt comfortable using the components of the Solar Suitcase (binary measure) and how often they reported using the various components (lights, headlamp, and fetal Doppler) on a 5-point Likert scale. We examined maintenance by the percentage of facilities with Solar Suitcase components still in operation at 3 post-trial follow-up visits, ranging from 5 months to 1 year after the completion of the trial.

**Effectiveness Outcomes**

The primary effectiveness outcomes pre-registered on ClinicalTrials.gov include measures of light, quality of care, and health care worker satisfaction. This article reports on the light and quality of care outcomes. Health care worker outcomes will be reported in a separate paper.

We examined changes in reliability and brightness of light in several ways. We constructed a binary variable for “bright light,” which was equal to 1 if the room was “very bright” or “somewhat bright” throughout the entire labor and delivery observation and 0 if the room was “pitch black” or “dim” at any point during observation. The rationale for this breakpoint was that providers were

not able to adequately provide care in conditions that were dim or pitch black, according to the definitions for these categories. We also constructed a binary variable for a “satisfactory light source,” which was equal to 1 if, throughout the entire observation, one of the following overhead sources was used: Solar Suitcase, electrical grid, other overhead solar light, generator, or daylight. This variable was equal to 0 if any of the following light sources were used during the observation: kerosene lamp, candle, flashlight, solar lamp, or no light at all. The satisfactory sources of light were defined as overhead lights that light the entire room, as opposed to ground-level lights that must be moved to see different areas of the room and only light a small area. The rationale was that moving and holding a light source is dangerous as it occupies and contaminates a health care worker’s hands; moreover, unsatisfactory sources such as kerosene lamps and candles are fire hazards and contribute to indoor air pollution. We also combined the source and brightness of the light into a variable indicating “adequate light,” which was defined as a binary variable equal to 1 if the light was from a satisfactory source and was “bright” (“very bright” or “somewhat bright”) for the duration of observation.

Finally, light sensors were used to measure the number of minutes of light and the level of brightness during the day and night (details on light measures are provided in Supplement Table 3).

Quality of care was measured via enumerator observation by extracting 2 indices of quality and 1 index of delays in care from the extended MCHIP observation tool. First, we used a 20-item quality of care index developed for and validated in low- and middle-income settings. The index is composed of 20 indicators representing essential components of the process quality of intrapartum and immediate postpartum care in facility deliveries, between the initial patient assessment and first hour postpartum (Supplement Table 4 has individual items). Second, we extended this index to include an additional 16 items to create a 36-item index, with additional items adapted from the MCHIP tool. The longer index captures additional items that may be particularly affected by the Solar Suitcase, such as checking the fetal heart rate and disposal of waste. Both indices were constructed as the percentage of total items performed per delivery observation and thus range from 0% to 100%. We also calculated section indices across areas of (1) history taking/communication, (2) patient assessment, (3) infection control, (4) prevention of postpartum hemorrhage, and (5) newborn care.
Lastly, we constructed a “delays in care” index, capturing items that occur throughout the delivery process, including time between facility arrival and first contact with health care worker, time between facility arrival and first vaginal examination, time between delivery and provision of uterotonic, time between delivery and assessment of perineal and vaginal lacerations, time between delivery and drying baby with towel, and time between delivery and initiation of breastfeeding. Measurements and definitions of outcomes are provided in more detail in Supplement Table 3.

Statistical Analysis
Results from baseline (period 1) were used to provide initial estimates on power and sample size. Sample size calculations were conducted using the stepped-wedge function in Stata v15. We estimated the detectable effect sizes assuming 22 births per facility (average cluster size) for 2 steps, 13 clusters randomized at each step, 80% power, and $\alpha=0.05$. We assumed, conservatively, that 61% of deliveries before the intervention would be conducted without adequate light, with an intracluster correlation (ICC) of 0.20. Our minimum detectable effect size for adequate light was 13 percentage points. For quality, we assumed an average pre-intervention score of 44%, with an ICC of 0.4. Our minimum detectable effect size based on these conservative estimates was 11 percentage points. In practice, our observed cluster size was 38 births per facility, which led to a larger detectable effect size than estimated in power calculations.

We first conducted an analysis of the causal effect of the intervention on outcomes using linear regression models with facility fixed effects. The parameter of interest was the coefficient on an indicator for whether the observation occurred in a facility that had been randomized to receive the Solar Suitcase installed at the time of observation or not. To account for the varying amount of time spent observing at each facility (due to differences in patient volume and availability of light), models were also adjusted for the duration of time spent in facilities (measured by the number of enumerator shifts worked at each facility in each period). Standard errors were clustered at the facility level.

We analyzed all observations as well as the subset of observations in which at least some part of the observation occurred during the nighttime hours of 6:00 pm to 7:00 am. Our rationale was that, while clinical care provided during nighttime hours would likely be the most directly affected by the adequacy of light, facility lighting may be dim and could benefit from brighter light even in daytime hours.

In our analysis, we first present the sources of light used to conduct deliveries during nighttime hours (6:00 pm to 7:00 am) before and after the intervention, presenting the light source at the time the newborn was delivered. We next present the impact of the intervention visually, plotting linear predicted values over period and sequence from the regression models described above. Finally, we present regression results.

Sensitivity Analysis
We conducted several sensitivity analyses, including alternate specifications, adjustment of standard errors using the wild cluster bootstrap method, imputation of missing data, assessment of enumerator bias or Hawthorne effects, assessment of whether there was selection of providers or patients into better lit facilities after implementation, and the inclusion of observations that resulted in a multiple birth, stillbirth, or infant death (Supplement Table 5 includes methodological details of sensitivity analyses).

Patient and Public Involvement
This research was done with guidance from of the Uganda Ministry of Health, Directorate of Clinical Services, which provided authorization to conduct the research in particular districts, as well as input into health facility selection. At a district level, input on facility selection and support for the study were provided by district health officers. Results will be disseminated to the Ministry of Health.

RESULTS
Reach
All facilities that met the inclusion criteria agreed to participate in the study and all health care workers within these facilities eligible for participation also agreed to participate (Figure 1). Facilities included in the study were similar to primary-level facilities in Uganda. In the most recent nationally representative survey of health facilities in Uganda (2013), 84% of primary facilities offer 24-hour facility-based delivery services and 51% have unreliable electricity.

Between June 2018 and April 2019, 1,183 patients arrived at study facilities to deliver. Of these, 59 were excluded at arrival, with the most common reason being that the patient arrived in the active stage of labor so that written consent was not
possible to obtain before delivery. Additionally, we excluded 8 observations that were twin deliveries, 2 that resulted in a newborn death, and 5 that resulted in a stillbirth. The final sample size was 1,118 birth observations.

Table 1 shows pre-intervention characteristics of facilities, providers, and patients, as well as tests for balance in these characteristics across the facilities randomized to receive the intervention first (sequence 1) and the facilities randomized to receive the intervention second (sequence 2). No systematic evidence of imbalance was apparent, with the $P$-value for the $F$-test on joint equality equal to 0.24. The mean number of staff present was 7 in our sample, compared with 8 in the national survey sample of primary-level facilities.33 On staff, we observed more midwives/nurses (70%) than clinical officers (15%) and nursing assistants (15%), compared with 44% midwives/nurses, 13% clinical officers, and 44% nursing
assistants in the national survey. Facilities in the sample also experienced higher patient volume (34 average deliveries per month) compared with the national sample (14 average deliveries per month). Women delivering were an average of 24.5 years old, with a parity of 2.3, and an average gestational period of 38.1 weeks. In comparison, a national sample of pregnant women in Uganda had an average age of 25.8, with a parity of 1.2.23

### TABLE 1. Baseline Characteristics of Maternity Health Care Facilities in Uganda (N=30) a Included in the Study of the Solar Suitcase Intervention on the Quality of Intrapartum Care

<table>
<thead>
<tr>
<th></th>
<th>Overall N=30</th>
<th>Sequence 1 n=15</th>
<th>Sequence 2 n=15</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of observations per facility, mean (SD)</td>
<td>38 (16)</td>
<td>36 (19)</td>
<td>39 (14)</td>
</tr>
<tr>
<td>No. of days spent observing, mean (SD)</td>
<td>30 (12)</td>
<td>30 (12)</td>
<td>30 (12)</td>
</tr>
<tr>
<td>No. of MCH staff employed, mean (SD)</td>
<td>7 (4)</td>
<td>6 (3)</td>
<td>8 (5)</td>
</tr>
<tr>
<td>Monthly patient volume, mean (SD)</td>
<td>34 (17)</td>
<td>30 (18)</td>
<td>37 (16)</td>
</tr>
<tr>
<td>Primary source of electricity, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None/lanterns</td>
<td>12 (40)</td>
<td>6 (40)</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Grid</td>
<td>11 (37)</td>
<td>5 (33)</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Solar</td>
<td>7 (23)</td>
<td>4 (27)</td>
<td>3 (20)</td>
</tr>
<tr>
<td>Facility government owned, n (%)</td>
<td>28 (93)</td>
<td>13 (87)</td>
<td>15 (100)</td>
</tr>
<tr>
<td>Facility level, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health center II</td>
<td>5 (17)</td>
<td>3 (20)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Health center III</td>
<td>22 (73)</td>
<td>11 (73)</td>
<td>11 (73)</td>
</tr>
<tr>
<td>Health center IV</td>
<td>3 (10)</td>
<td>1 (7)</td>
<td>2 (13)</td>
</tr>
<tr>
<td>Provider age, mean (SD)</td>
<td>34 (5)</td>
<td>33 (5)</td>
<td>35 (6)</td>
</tr>
<tr>
<td>Provider years of experience, mean (SD)</td>
<td>8 (6)</td>
<td>7 (5)</td>
<td>9 (7)</td>
</tr>
<tr>
<td>Proportion of providers with secondary education, mean (SD)</td>
<td>0.02 (0.07)</td>
<td>0.04 (0.10)</td>
<td>0.00 (0.00)</td>
</tr>
<tr>
<td>Proportion of providers with certificate, mean (SD)</td>
<td>0.60 (0.32)</td>
<td>0.62 (0.35)</td>
<td>0.58 (0.31)</td>
</tr>
<tr>
<td>Proportion of providers with diploma, mean (SD)</td>
<td>0.38 (0.32)</td>
<td>0.34 (0.34)</td>
<td>0.42 (0.31)</td>
</tr>
<tr>
<td>Proportion of providers in officer position, mean (SD)</td>
<td>0.15 (0.22)</td>
<td>0.15 (0.22)</td>
<td>0.16 (0.22)</td>
</tr>
<tr>
<td>Proportion of providers in midwife/nurse position, mean (SD)</td>
<td>0.70 (0.26)</td>
<td>0.61 (0.28)</td>
<td>0.79 (0.23)</td>
</tr>
<tr>
<td>Proportion of providers in nursing assistant position, mean (SD)</td>
<td>0.15 (0.22)</td>
<td>0.24 (0.26)</td>
<td>0.06 (0.12)</td>
</tr>
<tr>
<td>Quality score, mean (SD)</td>
<td>44.2 (8.4)</td>
<td>43.5 (7.9)</td>
<td>45.0 (9.0)</td>
</tr>
<tr>
<td>Delay index score (minutes), mean (SD)</td>
<td>73.5 (16.9)</td>
<td>76.4 (19.4)</td>
<td>70.7 (14.1)</td>
</tr>
<tr>
<td>Proportion of adequate light throughout observation, mean (SD)</td>
<td>0.44 (0.21)</td>
<td>0.47 (0.22)</td>
<td>0.41 (0.20)</td>
</tr>
<tr>
<td>Mother’s age (years), mean (SD)</td>
<td>24.5 (2.5)</td>
<td>25.0 (2.8)</td>
<td>24.1 (2.1)</td>
</tr>
<tr>
<td>Mother’s parity, mean (SD)</td>
<td>2.3 (0.6)</td>
<td>2.3 (0.5)</td>
<td>2.3 (0.7)</td>
</tr>
<tr>
<td>Gestational age (weeks), mean (SD)</td>
<td>38.1 (0.9)</td>
<td>38.0 (0.9)</td>
<td>38.1 (0.9)</td>
</tr>
<tr>
<td>Overall F-test</td>
<td>0.24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: MCH, maternal and child health; SD, standard deviation.

*The overall F-test is a joint test of orthogonality of all variables. Quality score is the percentage of items performed of the 20-item index. Delay index score is the sum of 6 items in the delays index (Supplement Table 3).*
Implementation and Adoption
Over the course of the trial, the Solar Suitcase intervention was successfully installed in 100% of facilities, with 76% of health care workers trained on its use by the contractor and another 13% trained by another health care worker in the facility. Figure 2 shows adoption of the Solar Suitcase into the health facilities by examining sources of light used to conduct deliveries during nighttime hours (6:00 pm to 7:00 am) before and after the intervention, as measured by direct observation. Across all deliveries that occurred during nighttime hours (n=571), there were 690 light sources used; 20% of deliveries used more than 1 light source. Before the intervention, 44% of these light sources used were either a kerosene lamp or flashlight, compared with 0% of light sources used after the intervention was deployed. After it was deployed, the Solar Suitcase was used in 83% of all nighttime deliveries and made up 65% of all light sources used.

Health care workers’ self-reported use of the Solar Suitcase was consistent with the results from direct observation shown in Figure 2. Ninety percent of health care workers agreed that they felt comfortable using the Solar Suitcase and 88% of health care workers used the Solar Suitcase LED lights for most or every nighttime delivery, although less than 10% of health care workers used the Solar Suitcase lights during the day. Use of the headlamp and fetal Doppler components were less consistent: 56% of health care workers never or rarely used the headlamp, while 29% never or rarely used the fetal Doppler (Supplement Table 6).

Effectiveness
Figure 3 presents the graphic representation of the impact of the intervention on measures of adequate light and quality of care. The figure demonstrates that sequence balance was achieved in period 1 for both adequate light and quality outcomes. While the proportion of all deliveries with adequate light was the same across sequences in period 1 at 56%, this proportion increased to 100% in period 2 for facilities in sequence 1, while it remained stagnant for facilities in sequence 2. In period 3, both sequences indicated 100% of deliveries were conducted with adequate light. The results on quality have a similar trapezoidal shape in the figure, providing strong evidence that the changes in outcomes can be attributed to the intervention.

We formalize this descriptive analysis with the results of the regression models (Table 2). Before the intervention, 56.1% of all observed deliveries (42.4% of deliveries with some nighttime hours) were conducted with bright light and 66.3% of all deliveries (55.7% of deliveries with some nighttime hours) were conducted with a satisfactory light source (Table 2). Similarly, 54.4% of deliveries were conducted with adequate light (41.0% of deliveries with some nighttime hours). The intervention had a
large and significant impact on all light measures, increasing the proportion of all deliveries conducted with bright light by 43.7 percentage points (95% CI=35.9, 51.5), the proportion with a satisfactory light source by 33.3 percentage points (95% CI=27.2, 39.4), and the proportion with adequate light by 45 percentage points (95% CI=37.2, 52.8). Estimates were larger for the subset of deliveries with some nighttime hours. These results indicate that after the intervention, 100% of all deliveries and nighttime deliveries were conducted with a bright, satisfactory light source and adequate light. The calculated ICCs were generally lower than assumed.

Results of the analysis of sensor data were consistent with enumerator-reported outcomes on light (Table 3). The intervention significantly increased the number of daily minutes of light by 141 minutes (95% CI=7.6, 274.3), from 856 minutes to 997 minutes. While the level of brightness was not significantly affected by the intervention during the daytime hours, the level increased by 10.1 percentage points (0.71, 19.6) during nighttime hours, from 14.5 to 24.7.

Regarding results on quality of care, among all observed deliveries, the average pre-intervention quality score was 42.6% for the 20-item index and 53.9% for the 36-item index (Table 2). Deployment of the intervention increased the 20-item quality index by 3.1 percentage points (95% CI=0.04, 6.2) to 45.7%, and the 36-item index by 4.2 percentage points (95% CI=1.47, 6.98) to 58.1%. Results for the subset of observations with some nighttime hours were slightly larger (4.1 and 4.7 percentage points for the 20-item and 36-item indices, respectively). Among all observations, delays in care were reduced by 11.24 minutes (95% CI=−16.47, −6.01), from an average of 74.3 minutes before the intervention to 63.1 minutes after the intervention. Similar results on delays in care were found for the subset of observations with some nighttime hours (−9.67 minutes [95% CI=−16.06, −3.29]).

Estimates of the impact of the intervention on

FIGURE 3. Impact of Solar Suitcase Intervention on Adequacy of Light and the 20-Item Quality of Care Index, for all Observed Deliveries (n=1,118) and for Observed Deliveries With Some Nighttime Hours (n=743) in Maternal Health Care Facilities in Uganda

After the intervention, 100% of all deliveries and nighttime deliveries were conducted with a bright, satisfactory light source and adequate light. "Adequate light" indicates that all observed parts of observation were perceived to be under a bright light and from a satisfactory light source. Quality score is the percentage of items performed of the 20-item Tripathi index. Supplement Table 3 has detailed definitions of variables. Results from predicted margins of linear regression with facility fixed effects. Nighttime hours refers to between 6:00 pm and 7:00 am.
TABLE 2. Linear Estimates of the Impact of the Solar Suitcase Intervention on Light and Quality of Intrapartum Care* in Maternal Health Care Facilities in Uganda

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N</th>
<th>ICC</th>
<th>Average before intervention, %</th>
<th>Average after intervention, %</th>
<th>Difference, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All observed deliveries</td>
<td>1,118</td>
<td>0.07</td>
<td>56.1</td>
<td>100</td>
<td>43.7 (35.9, 51.5)</td>
</tr>
<tr>
<td>I. Light brightness and source</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deliveries with bright light</td>
<td>1,118</td>
<td>0.07</td>
<td>56.1</td>
<td>100</td>
<td>43.7 (35.9, 51.5)</td>
</tr>
<tr>
<td>Deliveries with satisfactory light source</td>
<td>1,118</td>
<td>0.07</td>
<td>66.3</td>
<td>100</td>
<td>33.3 (27.2, 39.4)</td>
</tr>
<tr>
<td>Deliveries with adequate light</td>
<td>1,118</td>
<td>0.07</td>
<td>54.4</td>
<td>99.4</td>
<td>45 (37.2, 52.8)</td>
</tr>
<tr>
<td>II. Quality of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-item quality index</td>
<td>1,118</td>
<td>0.21</td>
<td>42.6</td>
<td>45.7</td>
<td>3.1 (−0.04, 6.24)</td>
</tr>
<tr>
<td>36-item quality index</td>
<td>1,118</td>
<td>0.21</td>
<td>53.9</td>
<td>58.1</td>
<td>4.2 (1.47, 6.98)</td>
</tr>
<tr>
<td>6-item delays index, min</td>
<td>805</td>
<td>0.12</td>
<td>74.3</td>
<td>63.1</td>
<td>−11.24 (−16.47, −6.01)</td>
</tr>
<tr>
<td>Observed deliveries with some nighttime hours</td>
<td>743</td>
<td>0.14</td>
<td>42.4</td>
<td>100</td>
<td>57.5 (46.0, 69.1)</td>
</tr>
<tr>
<td>I. Light brightness and source</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deliveries with bright light</td>
<td>743</td>
<td>0.17</td>
<td>55.7</td>
<td>100</td>
<td>44.7 (35.4, 53.9)</td>
</tr>
<tr>
<td>Deliveries with adequate light</td>
<td>743</td>
<td>0.14</td>
<td>41.0</td>
<td>100</td>
<td>59 (47.6, 70.4)</td>
</tr>
<tr>
<td>II. Quality of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-item quality index</td>
<td>743</td>
<td>0.22</td>
<td>42.3</td>
<td>46.5</td>
<td>4.1 (0.57, 7.68)</td>
</tr>
<tr>
<td>36-item quality index</td>
<td>743</td>
<td>0.22</td>
<td>53.9</td>
<td>58.5</td>
<td>4.7 (1.58, 7.78)</td>
</tr>
<tr>
<td>6-item delays index, minutes</td>
<td>575</td>
<td>0.13</td>
<td>76.0</td>
<td>66.3</td>
<td>−9.67 (−16.06, −3.29)</td>
</tr>
</tbody>
</table>

Abbreviations: 95% CI, 95% confidence interval; ICC, intracluster correlation.

* Results show point estimates and 95% confidence intervals. Standard errors are clustered at the facility level. The constant refers to the mean outcome in the preperiod. Nighttime hours refer to hours between 6:00 pm to 7:00 pm. Bright light indicates enumerator reported “perfectly bright” or “bright” (as opposed to “dim” or “dark”) across all 4 sections of the observation. Satisfactory light source indicates that the light source during all 4 sections was either daylight, the grid, solar, or a generator. Adequate light indicates that all 4 sections of the observations used a satisfactory light source and were reported to be bright. Quality of care indices are defined in Supplement Table 3. Delays index is missing for observations in which any one of the 6 delays items is missing.

The largest impacts of the intervention were found in infection control, prevention of postpartum hemorrhage, and newborn care.
**Maintenance**

We examined the percentage of facilities with Solar Suitcase components in operation across 3 posttrial follow-up visits, up to 1 year after the completion of the trial. At 1 year after the end of the trial, 93% of facilities had the Solar Suitcase LED lights still in use (i.e., functioning and available). The percentage of facilities with the following components still in use 1 year after follow-up were fetal Doppler (90% of facilities), headlamps (83%), and USB ports (83%) (Supplement Table 14). The main challenges reported for why components were not in use were that they were malfunctioning, stolen, or missing and that newly arrived health care workers were not trained to use them. Additionally, 27% of facilities reported that LED lights from the Solar Suitcase, while functioning, did not last through the night or became dim.

**DISCUSSION**

The results of this stepped-wedge cluster-randomized trial show that a solar energy system intervention in rural Ugandan maternity facilities was well adopted, increased brightness and adequacy of lighting for maternal and infant care, and led to increases in the quality of care received by women and newborns. While over 40% of deliveries were conducted by flashlight or kerosene lamp at baseline, receipt of the solar light intervention increased the proportion of deliveries conducted with adequate light to 100%. Deployment of the intervention also increased quality of care, particularly in the areas of infection control, prevention of postpartum hemorrhage, and newborn care, while decreasing delays in the provision of care.

Reports from health care workers confirmed the widespread use of the Solar Suitcase LED lights and USB ports. However, fewer used the associated devices: 56% of health care workers reported not making use of the headlamps and 30% reported not using the fetal Doppler. In interviews, a common explanation given from health care workers for the inconsistent use of the Doppler was insufficient gel to use with the device as well as technical difficulties in using it. These results are consistent with World Health Organization research finding that many complex medical devices in low-resource settings do not function as intended.34 Regarding maintenance measures, 93% of facilities reported using the LED lights 1 year after the end of the trial period. However, some challenges to maintained use were identified, with 27% of facilities reporting that the solar lights did not last through the night or became dim. In the long term, conducting an energy audit with facilities would produce valuable information on a facility’s energy usage to tailor the Solar Suitcase or design and install other renewable solutions that meet facility needs.35

The introduction of reliable light decreased delays in performance of essential care actions. Delays in care, often referred to as the “third delay” in the 3-delays model of access to delivery care, can result in undiagnosed and untreated complications that increase the risk of maternal mortality and morbidity.36 This study found that adequate light can significantly reduce the time that passes between a patient’s arrival at a facility and their first interaction with a health care provider, which is critical for women with high-risk pregnancies.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Average Before Intervention</th>
<th>Average After Intervention</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes of light per 24 hours</td>
<td>856</td>
<td>997</td>
<td>141.0 (7.6, 274.3)</td>
</tr>
<tr>
<td>Level of brightness during daytime (7:00 am to 6:00 pm)</td>
<td>47.9</td>
<td>54.2</td>
<td>6.3 (−2.2, 14.8)</td>
</tr>
<tr>
<td>Level of brightness during nighttime (6:00 pm to 7:00 am)</td>
<td>14.5</td>
<td>24.7</td>
<td>10.1 (0.71, 19.6)</td>
</tr>
</tbody>
</table>

Abbreviation: 95% CI, 95% confidence interval.

*a Results show point estimates and 95% confidence intervals. Standard errors are clustered at the facility level. Regression controls for month of year and facility fixed effects. One facility (in Sequence 2) had a broken sensor and was not included. The number of minutes of light per day is calculated as the number of minutes over a threshold of 20% of the maximum seen in that facility. Results robust to using any threshold between 1% and 35% (results not shown). Level of brightness is on a 0–100 scale, as the percentage of the maximum light the sensor in each facility could read.

**TABLE 3. Linear Estimates of the Impact of the Solar Suitcase Intervention in Maternal Health Care Facilities in Uganda on Objective Measures of Light Using Sensor Data**

*We found that adequate light can significantly reduce the time that passes between a patient’s arrival at a facility and their first interaction with a health care provider, which is critical for women with high-risk pregnancies.*
Consistent with previous literature on maternal care quality in sub-Saharan Africa, the observed quality of maternity care in this sample of primary care Ugandan facilities was insufficient, with a large number of essential processes of care not provided. Before the intervention was deployed, providers were performing only 42% of the essential care items for safe deliveries.
The introduction of adequate light increased this to 46%, including items of known clinical significance such as assessing the completeness of the placenta and checking for lacerations, a 9.5% increase. The improvement in quality observed in this study is similar to that of other quality improvement interventions in LMICs. An overview of systematic reviews found that the use of reminders to prompt providers to perform actions produced a median relative effect of 14%, while multifaceted interventions produced modest to moderate improvements in professional practice of between 5% and 20%.40

Overall, the results provide support for the importance of providing all Ugandan maternity facilities with reliable, bright light, but they also indicate that even when facilities have high-quality light, conditions may still be insufficient to ensure safe childbirth. These results underscore recommendations from global health quality improvement committees that efforts to improve quality must include transformative, systemic changes across all levels of the health system.41,42

While the magnitude of the effect sizes on quality is modest, the intervention may have greater impacts in countries where access to reliable light is lower. Moreover, several potential benefits to improved lighting are not captured in this evaluation. For example, women may be more likely to decide to deliver in a well-lit facility and may also be less likely to be referred to higher-level facilities due to electricity interruptions, which can be dangerous when such facilities are distant and transportation is unreliable. There may also be impacts on health care worker morale and retention, which we will examine in future publications. Overall, given limited resources in LMICs, cost-effectiveness analyses could help clarify priorities for health sector investment in health system strengthening across domains of energy access, medical equipment and supplies, health financing, service delivery, and human resources.43

This study has several strengths. We used direct clinical observations of care, which is the gold standard in assessing quality of care. We also used both observations of sources and brightness of light and light sensors to validate our results. Results from the light sensors found that the intervention increased the number of daily minutes of light and the brightness of the room during nighttime hours, corroborating the enumerator-reported results of brightness. Our study design, a stepped-wedge cluster-randomized controlled trial, allowed for observation before and after deployment of the intervention in all facilities and minimized risk of confounders.

Limitations
This study also has several limitations. First, while direct observation of care is the gold standard in assessing quality, it also has limitations including the possibility that providers change their behavior as a result of being watched (the Hawthorne effect). The possibility also exists that enumerators do not always score the care they observe accurately. In our sensitivity analyses, we did not find strong evidence for either of these effects on the results. Second, the lack of blinding is a limitation. Enumerators may have scored quality of care better when a facility received a Solar Suitcase because they anticipated a positive effect of the intervention. However, the quality metric we used is validated as a reliable, objective measure. Moreover, enumerators were not deployed to the same facilities in all 3 periods. Another possibility is that enumerators record higher or lower scores when there is better light because they can see more clearly. However, the direction of this effect is ambiguous, and we found no evidence of this in our qualitative debriefings with enumerators. Finally, our analysis focused on uncomplicated vaginal deliveries and was not designed or powered for analysis of quality of care during complications. Thus, these results do not speak to any potential impact of better lighting on the management of maternal or newborn complications.

CONCLUSIONS
Universal access to modern energy sources and safe childbirth are both key sustainable development goals.44 Moreover, identifying effective approaches to improving the quality of health care in LMICs is an urgent public health goal.45 We find that reliable light is an important driver of timely and adequate health care and may improve providers’ ability and timeliness in performing actions needed to reduce the risk of postpartum hemorrhage. Investment in modern and renewable energy systems for health care facilities is a critical priority; our results support recommendations by international organizations such as SEforAll, USAID, and the World Bank to develop guidance on energy access and clinical equipment needs of community-level primary health facilities and to facilitate large-scale facility electrification efforts.42,46,47 However, quality of care may remain low even in the presence of reliable light without a broader, systemic approach to high-quality health systems strengthening.
Acknowledgments: We are grateful to the study participants and our Uganda Ministry of Health partners who devoted their time to this study. From We Care Solar, we thank Brent Moellenberg for advice on installation of and measurement from light sensors and power monitors, Feza Greene for help assessing facility eligibility and obtaining study approvals, and Laura Stachel and Christina Briegleb for extremely valuable input on the study. From Innovations for Poverty Action, we thank Juliana Kayaga for superb guidance on the clinical observations, Juliet Ajiilong for excellent field management, Ivan Sengenda for invaluable support in data collection, Ashiraf Mawanda for implementation of the pilot for this project, Laura Schmucker for excellent project management, Damien Kirchhoffer and Jesse Pinchoff for early input into the study design, and Ginger Galub for interim project management. We also gratefully acknowledge our anonymous reviewers. Their helpful comments strengthened this article.

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Author contributions: SR, BM, PW, and JC designed the study. SR, BM, and JC developed the protocol and managed implementation and data collection. SR and JC conducted data analysis and wrote the manuscript. SR, BM, PW, and JC provided substantial comments to the writing of the manuscript. All authors read and approved the final manuscript.

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REFERENCES


Peer Reviewed

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Health Sector Resource Mapping in Malawi: Sharing the Collection and Use of Budget Data for Evidence-Based Decision Making

Ian Yoon,a Pakwanja Tweep, Stephanie Heung,a Sakshi Mohan,b Nikhil Mandalia,b Saadiya Razzaqa,a Leslie Berman,a Eoghan Brady,c Andrews Gunda,a Gerald Manthalub

Key Findings

- Resource mapping, an exercise conducted by the Government of Malawi, has tracked budgets for health since 2011 using a census-survey data collection approach.
- We describe 4 ways that data have been used to improve efficient allocation of resources and mobilize new funding for government priorities. This includes national- and district-level planning and budgeting, prioritizing and coordinating existing funds by estimating resource availability, mobilizing new resources by conducting financial gap analyses against costed national strategic plans, and generating evidence to support the national response to the coronavirus disease 2019 (COVID-19) pandemic.
- Institutionalization of the resource mapping process and tools has been supported by iterative design improvements that mitigate implementation challenges and ensure that collected data are relevant to the needs of policy makers. In turn, this drives demand for resource mapping data from health sector stakeholders.

Key Implications

- Policy makers should ensure that health resource-tracking exercises are fit for their purpose and designed around the end user.
- A flexible approach to resource tracking is advantageous if resource allocation decisions are to be responsive to health emergencies such as the COVID-19 pandemic.

ABSTRACT

Background: In 2011, the Ministry of Health in Malawi developed and institutionalized a resource-tracking process, known as resource mapping (RM), to collect information on planned funding flows across the health sector to support resource allocation and mobilization decisions. We analyze the RM process and tools and describe key uses of the data for health financing decision making to achieve universal health coverage (UHC).

Methods: We applied a case study approach, written as a collaboration between policy makers who have led the RM process in Malawi and the implementation team who have developed tools, collected data, and reported results over the period. It draws on our experiences in conducting RM in Malawi to document the RM process and data, key uses of data, implementation challenges, and lessons learned. We conducted a gray literature review to understand rounds of RM in which we did not participate. Finally, we conducted a search of published literature to situate our work in the international health resource-tracking literature.

Results: The RM exercise in Malawi is iteratively designed around the needs of the end users and policy priorities of the government, which in turn drives institutionalization of the exercise. We describe 4 ways in which RM data has been used, including national and district planning and budgeting; prioritization and coordination of existing funds by estimating resource availability; mobilization of new resources by conducting financial gap analyses against costed national strategic plans; and generation of evidence to support the national response to the coronavirus disease 2019 pandemic.

Discussion: To achieve UHC goals in Malawi, RM has equipped the government and development partners with critical data used for resource mobilization and coordination decisions. Lessons learned from RM in Malawi may be applicable to other countries starting or refining their own health resource-tracking exercise.

INTRODUCTION

The Government of Malawi (GOM) strives to "provide adequate health care, commensurate with the health needs of Malawian society and international standards of health care." As articulated in the National Health Policy 2017–2030 and the Health Sector Strategic...
The resource mapping exercise seeks to improve the availability of health financing data for decision making by consolidating budget information from all health sector funders and implementers into one database.
they tended to focus on single programs or disease areas (20) or expenditure estimates through national health accounts (135). Our search revealed a paucity of published research specific to resource tracking for health in Malawi and the region. We found only 1 such published study analyzing health expenditures and 1 Government of Malawi unpublished internal data document. Neither referenced the MOH-led RM exercise, which was ongoing at the time of these studies’ publication.

RESOURCES MAPPING: PROCESS AND DATA
From 2011 to the time of writing, 6 rounds of RM have been conducted in Malawi with the seventh round in progress to answer the following key questions:

- What is the total committed funding for health, and how does it vary over time?
- Who is planning to fund and implement health programs?
- How is the funding distributed across disease areas, interventions, geographical areas, and cost inputs?
- How is funding aligned to government priorities per its national strategic plans?

The data are collected through a customized classification system that captures the necessary parameters (Table 4) for each financial commitment and is embedded in a data collection template (Supplement). Table 2 illustrates the scope and comprehensiveness of RM. MOH has tracked approximately US$15 billion of financial resources for health from 2011 to 2020, with an average of 177 submitting organizations per year (unpublished internal data, Government of Malawi). These organizations include government ministries, departments, and agencies; bilateral/multilateral partners; and nongovernmental organizations. Private funding, such as out-of-pocket payments and voluntary health insurance, is not tracked through RM.

As shown in Figure 1, the RM process is divided into 3 stages: (1) planning and updating of data collection tools; (2) data collection, cleaning, and consolidation; and (3) data analysis, results dissemination for use in planning, and solicitation of feedback. Importantly, the RM process is cyclical, with learnings from previous rounds feeding into the planning and implementation of future exercises. The RM exercise is iteratively designed so that it remains relevant to policy decisions and straightforward to conduct.

USES OF RESOURCE MAPPING DATA IN DECISION MAKING
The iteratively designed process and data collection tool has enabled the generation of RM data that can inform a range of health financing decisions. We classify the use cases of RM data into 4 categories: (1) planning and budgeting, (2) improving allocative efficiency through coordination of existing funding, (3) securing increased funding for quantified resource gaps, and (4) responding to the coronavirus disease (COVID-19) pandemic.

Planning and Budgeting
RM data are used by MOH during its annual budgeting process at both the national and district level. At the national level, RM data are imported into the annual MOH budgeting tool and provide MOH departments with visibility into existing development partner funding during the development of annual government workplans and budgets.

RM data are also used for district planning, budgeting, and partner coordination by GOM district health offices (DHOs). Integration of RM data into the district planning process supports DHOs in identifying earmarked commitments for their district. However, as data collection is conducted at the national level, district-level figures may not reflect actual budgets in the district. Therefore, as part of the government’s routine planning and budgeting cycle, DHOs validate national RM estimates with a district-level census of commitments from development partners to fully understand the financial envelope for health in their specific district. By collecting more granular, accurate
funding information, DHOs can enhance coordination and alignment between district governments and their partners (unpublished internal data, Government of Malawi).

**Improving Efficiency Through Coordination of Existing Funding**

National strategic plans (NSPs) are instrumental in defining and coordinating a cohesive approach for governments and partners. With an estimated 115 funding sources and 227 implementing partners in the country, these plans are critical for minimizing both duplication and transaction costs and improving efficiency.\(^{10,15}\) RM data have spurred prioritization of NSP activities by illustrating the funding constraints for diseases, interventions, and health systems areas. For example, the HIV/AIDS NSP 2015–2020 estimated HIV resource availability using RM data to inform a participatory prioritization process. The initial cost of the HIV NSP 2015–2020 was US$1.7 billion, which was greater than the US$1.6 billion available. The resource need was driven by HIV testing costs with ambitious treatment targets requiring larger testing volumes. An aggregation of testing budgets using RM data showed insufficient funding compared with the testing cost estimated in the plan, suggesting that the proposed testing strategy was financially unrealistic. Using this information, the National AIDS Commission engaged civil society organizations,

<table>
<thead>
<tr>
<th>TABLE 2. Summary of Data Collected During 6 Rounds of the Ministry of Health Resource Mapping Exercises in Malawi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitting organizations</td>
</tr>
<tr>
<td>Financing sources</td>
</tr>
<tr>
<td>Implementing agents</td>
</tr>
<tr>
<td>Type of financial data collected</td>
</tr>
</tbody>
</table>

**FIGURE 1. Example Resource Mapping Process Schematic**

Abbreviations: MDAs, ministries, departments, and agencies; NGOs, nongovernmental organizations.
MOH, and development partners to optimize HIV testing strategies under different resource availability scenarios. As a result, these stakeholders agreed to a coordinated and targeted testing strategy with estimated savings of US$42 million over 5 years. Analyses were also conducted by activity type to demonstrate potential duplication in activities such as trainings. This evidence supported stakeholders in redirecting overlapping funding toward other underfunded, priority interventions. Thus, the HIV NSP 2015–2020 costs were brought in line with available funding, while also maintaining the plan’s service delivery targets.16

**Secured Funding for Quantified Resource Gaps**

Gap analyses for programs and activities using RM data and NSP costs can support the development of investment cases for resource mobilization. For instance, by conducting HIV and tuberculosis gap analyses with RM data, MOH has mobilized resources and informed programming of approximately US$1.3 billion through 3 successful grant applications to the Global Fund since 2012.17–19 The flexibility of the RM classification system and tool was critical because both MOH strategic priorities and the Global Fund requirements changed between 2012 and 2019. For example, in preparation for the 2015–2017 application, the RM classification system was modified so that funding for activities in the dataset could be disaggregated by beneficiary groups and programmatic interventions in accordance with Global Fund specifications. This mapping produced detailed estimates of resource availability against forecasted financial need, supporting MOH in articulating its investment case within the framework of the Global Fund funding mechanism.

**COVID-19 Resource Mapping**


To support resource mobilization, limit duplication, and monitor movement of financial commitments away from other essential health services, MOH initiated a rapid COVID-19 Resource Mapping exercise (COVID RM). This exercise built upon the pre-existing institutional capacity developed through the 6 rounds of the annual sector-wide RM. The government’s familiarity with the existing RM process as well as the flexibility of the RM tool and classification system expedited modification of the RM exercise for COVID-19 resource tracking. With COVID RM, MOH tracks commitments against the objectives and activities of the National COVID-19 Plan. The tool was rolled out for data collection by partners who were accustomed to the sector-wide RM exercise and needed minimal assistance in submitting their COVID-19 budgets. As a result, data collection has been accelerated, enabling frequent updating of commitments and ensuring that data remain relevant and accurate.

COVID RM data can be used to inform resource allocation decisions at both the national and district level. For example, as Figure 2 shows, US$32.1 million is available for Objective 7: Supplies and Equipment. This amount is below the resource requirements outlined in the National COVID-19 Plan and suggests a funding gap of approximately US$11.7 million, thus justifying additional investment.

COVID RM data can also be disaggregated to the district level. This information has been shared with the DHOs to support subnational COVID-19 planning, resource allocation, and partner coordination. Partner commitments for COVID-19 are incorporated into the DHOs’ annual district health plans. This process ensures that activity funding is transparent to all stakeholders and supports effective coordination of the COVID-19 response subnationally (unpublished internal data, Government of Malawi).

**DISCUSSION**

**Challenges and Lessons Learned**

Because the exercise is iteratively designed, each successive round of RM can incorporate lessons learned from the previous round as well as respond to emerging issues. To illustrate the advantages of iterative design, we note 4 lessons from 6 rounds of RM and the adjustments made to respond to the issues involved. These lessons learned may be informative for other countries interested in developing or strengthening their own resource-tracking exercises.

1. Flexibility of the RM classification system must be leveraged so that the dataset can be rapidly adapted to answer MOH’s priority policy questions. For instance, the COVID-19 pandemic presented a significant challenge as
an entirely new set of programmatic classifications was required to estimate resource availability for novel interventions included in the national COVID-19 response. The remainder of the RM classification system remained intact, and thus only targeted updates to the data collection tool were needed (unpublished internal data, Government of Malawi). This approach was also supported by clear documentation of the classification adjustment process, including standard operating procedures and guidelines, that facilitated rapid adjustments to the RM tool. Flexible tool design and proactive identification of data end-users can enable resource-tracking exercises globally to better support evidence-driven resource allocation and coordination toward changing government priorities.

2. Through iterative learning, opportunities have been identified to expedite the RM process and ensure that data are available in a timely manner to inform GOM and partner decision making. Since a primary use of the data is to inform MOH planning and budgeting for the next financial year, completion of RM is time dependent. One challenge to timely completion of the exercise is the capacity of submitting organizations to complete the data entry tool. In the first round of RM, MOH headquarters and national-level partners participated in data entry trainings, which reduced the time and the number of follow-ups needed to complete the submission, as well as increased submission quality relative to DHOs and district-based implementing partners who did not receive these trainings. In subsequent rounds, these trainings were expanded to include DHOs as well as district-based implementing partners (unpublished internal data, Government of Malawi). Another improvement on the follow-up process was the prioritization of the largest financing organizations. RM shows that the 10 largest health funders provide approximately 90% of financial commitments to the health sector (unpublished internal data, Government of Malawi). Therefore, while all submitting organizations receive follow-up where needed, the RM team prioritizes close consultations and follow-ups with the 10 largest funders to ensure that the submissions from these organizations are of high quality. Focused prioritization can support resource-tracking teams globally in expediting completion of the exercise and navigating the trade-off between data quality versus timeliness.
3. Incorporating feedback mechanisms into the data collection tool to guide users through data entry can increase data quality. A challenge to data quality is that the diverse financial reporting systems of both GOM and development partners may not clearly map to the RM classification system, leading to erroneous data entry. To reduce these errors, automated data quality and completion checks were included in the tool to support organizations in reporting information as aligned to RM classifications. In addition, a dashboard providing a summary of total resources reported by the submitting organization was added so organizations could validate their budgets and address potential issues in advance of submission to MOH (unpublished internal data, Government of Malawi). Automated checks may assist resource-tracking exercises that have challenges with template completeness and data quality.

4. Impact of staff turnover can be reduced through development of standard operating procedures and checklists that codify data collection, cleaning, and analysis. Over 6 rounds of RM, average government turnover in the RM team between rounds was 70%. Such turnover slows the exercise and can reduce data quality as each new team must learn key steps in the RM process, and experiences and insights gained by previous team members may be lost. To improve exercise continuity despite turnover, an RM “toolkit” with these standard operating procedures and checklists was compiled to document learnings and support the induction of new team members (Table 3) (unpublished internal data, Government of Malawi). Clear and specific documentation can also support learning across resource-tracking exercises both within and across country contexts.

### Future Directions for Resource Mapping

With 6 rounds completed, RM provides critical data used for resource mobilization and coordination and has been institutionalized within the annual MOH planning and budgeting processes. Figure 3 shows considerable, although nonlinear, progress has been made in shifting human resource contributions for RM away from CHAI and toward MOH. While MOH has always led the process, their human resource contribution initially focused on exercise planning, identifying use cases for the data, and disseminating results. Over time, MOH has increasingly invested human resources into other components of the exercise, including collecting and analyzing data, as well as mobilizing and managing funding for the exercise. External support now targets technical issues such as major tool modifications, classification system revisions, and ad hoc data analytics.

Moving forward, the use of RM could be further enhanced in several ways. First, MOH can continue to encourage other health resource-tracking exercises to leverage the comprehensiveness of RM data and limit parallel or duplicative resource-tracking processes. For example, MOH recently harmonized WHO’s national health accounts (NHA) with RM to produce estimates of budgets (RM) and expenditures (NHA) for health through a single data collection process. This process lowers the human resource burden for both submitting organizations and the MOH team and ensures that the same dataset is used consistently across the health sector.

Second, RM data could be analyzed to answer new questions of policy importance. For example, resource availability estimates from RM might be compared with Essential Health Package costs at the district level to assess if financial commitments are adequately supporting the provision of the benefits package and progression toward UHC. Additionally, district data could be used to assess

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### TABLE 3. Documents Compiled in Malawi Resource Mapping Toolkit to Support Institutionalization and Sustainability

<table>
<thead>
<tr>
<th>Data Collection Planning</th>
<th>Database Consolidation and Cleaning</th>
<th>Analysis and Report Writing</th>
<th>Other Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roadmap template</td>
<td>Database consolidation tool</td>
<td>RM report template</td>
<td>RM - NHA parameter mapping</td>
</tr>
<tr>
<td>Organization contact information database</td>
<td>Database consolidation SOP</td>
<td>RM analysis templates</td>
<td></td>
</tr>
<tr>
<td>Submission tracker</td>
<td>Database standardization SOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submission management protocol</td>
<td>Removal of double-counting SOP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data entry training materials</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: NHA, national health account; SOP, standard operating procedures.
the funding landscape at the subnational level since health budgets and the number of development partners vary across districts. Such analysis could inform targeted aid coordination interventions accounting for the severity and type of financial fragmentation in each district. However, since nationally collected data can often misrepresent district-level commitments, improving subnational aid coordination will inevitably require further budget transparency between DHOs, implementing partners, and funders.

Third, the RM team can continue to strengthen cross-country learning on RM best practices, as the RM processes and tools are often applicable between countries. For example, the harmonization of RM and NHA in Malawi drew from lessons learned from the Zimbabwe experience, specifically leveraging the crosswalk process between the RM and System of Health Accounts classification systems in Zimbabwe. The lessons learned from Malawi have also proved cross-applicable to others. For example, the Government of Ethiopia refined its own resource-tracking exercise building on the Malawian experience. However, cross-country learning is not confined to the technical details. Countries can also assess the relevance of RM data use in Malawi to both inform development or refinement of their own RM exercise and identify opportunities for data use.

Limitations of Resource Mapping

The trade-off between data quality and data granularity remains a challenge for RM. For example, RM data capture the programmatic area (e.g., HIV/AIDS) as well as interventions within each area (e.g., HIV testing) and subinterventions (e.g., HIV self-testing). The sixth round of the exercise included 10 classifications for program areas, 54 classifications for programmatic interventions, and 73 classifications for programmatic subinterventions. This detailed system provides the granularity needed by different end users and has informed program-specific resource-tracking exercises. However, the classification system simultaneously reduces data quality as organizations face challenges in disaggregating their budgets by the RM categories. To mitigate this problem, the classification systems of the first 5 rounds of RM included a “cross-cutting” category that was meant to encompass “funding for health systems or general administrative costs as well as ... programs that fund multiple disease areas but could not be ... disaggregated.” However, the result was that 41% of total resources were reported as “cross-cutting” in the initial 5 rounds, suggesting inappropriate tagging of programs as “cross-cutting” and underreporting of programmatic financing. In the sixth round of the exercise, this category was converted to “health system strengthening,” prompting organizations to use the category for systems-strengthening activities only and fully disaggregate their programmatic financing elsewhere in the tool.

Expanding the uptake of RM requires more detailed data to inform specific policy decisions,
<table>
<thead>
<tr>
<th>Type</th>
<th>Data Element</th>
<th>Definition of Data Element</th>
<th>Illustrative Example</th>
<th>Corresponding NHA Dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Financiers and Implementers</td>
<td>Submitting organization</td>
<td>Organization that submitted budgeting information</td>
<td>Action Aid</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Financing source</td>
<td>The organization or entity financing the activity</td>
<td>Global Fund</td>
<td>Health providers, health care financing schemes, revenues of health care financing schemes</td>
</tr>
<tr>
<td></td>
<td>Primary implementing agent</td>
<td>Primary organization or entity that is carrying out implementation</td>
<td>Action Aid</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Subimplementing agent</td>
<td>Additional organization or entity carrying out the activity as a subgrantee of the primary implementing agent, if applicable</td>
<td>Southern African AIDS Trust</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Programs, Projects, Activities</td>
<td>Project name</td>
<td>Specific project that is supported by the activity</td>
<td>TB/HIV epidemic control</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Activity</td>
<td>Free-form text to describe the specific activity within the intervention</td>
<td>Comprehensive programs for people in prisons</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Programmatic function</td>
<td>Programmatic area, function, or disease supported by the activity</td>
<td>HIV including viral hepatitis and other sexually transmitted infections</td>
<td>Health care function, disease classification</td>
</tr>
<tr>
<td></td>
<td>Programmatic intervention level 1</td>
<td>General intervention supported by the activity, dependent on the programmatic function</td>
<td>Prevention</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Programmatic intervention level 2</td>
<td>Detailed intervention supported by the activity, dependent on the programmatic intervention level 1</td>
<td>Behavior change communication for HIV</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Essential Health Package intervention</td>
<td>Alignment to Malawi’s Essential Health Package interventions</td>
<td>Community health promotion and engagement</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Target population</td>
<td>Subpopulation targeted for HIV, TB, and malaria interventions only</td>
<td>People in prisons and other closed settings</td>
<td>Beneficiary characteristics</td>
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<tr>
<td>3. HSSP II Alignment</td>
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<td>Classification of activities according to the relevant HSSP II objectives</td>
<td>Human resources for health</td>
<td>Factors of provision</td>
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<tr>
<td></td>
<td>HSSP II sub-area</td>
<td>Classification of activities according to the relevant HSSP II sub-areas, dependent on the selection for HSSP II objective</td>
<td>Health worker training, in-service</td>
<td>N/A</td>
</tr>
<tr>
<td>4. Geography</td>
<td>District</td>
<td>Percentage of funding earmarked for specific district(s); if central level, can be specified as 100% central level</td>
<td>50% Mwanza, 50% Thyolo</td>
<td>N/A</td>
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<tr>
<td>5. In-Service Training Details</td>
<td>Type of training</td>
<td>Modality of the training, (e.g., on the job, offsite, or virtually/online)</td>
<td>Offsite</td>
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<td></td>
<td>Health worker cadre</td>
<td>The health worker cadre that the training focused on (e.g., pharmacy, nursing, laboratory, etc.)</td>
<td>Nursing</td>
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<td>Health worker cadre</td>
<td>The specific health worker cadre targeted by the training, dependent on the selection for health worker cadre</td>
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<td></td>
<td>Number of health workers targeted</td>
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<td>Activity frequency</td>
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<td>Monthly implementation plan</td>
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but data quality and timeliness may be compromised when the data solicited are too granular and do not map well to the existing financial systems of partner organizations. The RM exercise must therefore balance the trade-off between the granular data needed to inform the policy priorities of the end users versus the development of a streamlined, user-friendly tool that facilitates completion of the RM process in a timely manner.

Finally, RM is a method of tracking financial commitments from many disparate resource pools and implemented by many agents. However, a commitment to UHC may require greater efficiency in resource use through increased financial pooling of health services, as well as increased domestic resource mobilization. Ultimately, a government-funded, pooled system would not require RM as it is currently implemented. However, RM continues to fill an important information gap in the interim.

## CONCLUSION

To achieve ambitious UHC goals in Malawi, it is imperative that additional funding is mobilized for health and the limited funding available is efficiently allocated toward GOM’s priorities. To this end, RM data have equipped GOM and development partners with critical information regarding available funding in the health sector. RM data enabled the quantification of resource needs, informed resource mobilization efforts to fill funding gaps, and supported coordination of disparate investments across stakeholders with different priorities and planning processes toward common goals. Moreover, the exercise’s flexibility and the longstanding familiarity of government and partners with RM has facilitated rapid adaptation of the exercise to track resources for the COVID-19 response. Finally, an institutionalized RM will continue to be iteratively designed to ensure it remains relevant to the government’s evolving policy priorities.

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### Author contributions:

All authors contributed to the design of the work. Ian Yoon wrote the report with input and critical feedback from all authors. Stephanie Heung, Saadiya Razzaq, Leslie Berman, and Eoghan Brady provided supervision of the work.

### Competing interests:

None declared.

### REFERENCES


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Evaluation of 2 Intervention Models to Integrate Family Planning Into Worker Health and Livelihood Programs in Egypt: A Difference-in-Differences Analysis

Nahla Abdel Tawab, a Elizabeth Tobey, b Maryam Essam, a Sara Chace Dwyer, b Aparna Jain b

Key Findings

- Integrating family planning and reproductive health (FP/RH) messages into a livelihood training program for job seekers in urban Souhag, Egypt, was an effective way to improve knowledge and attitudes around FP/RH among young men and women.
- Integrating FP/RH into a worker health program for garment factory workers in Port Said, Egypt, was less effective at changing knowledge and attitudes among young male and female workers.
- In both governorates, no change in modern contraceptive use among married respondents was observed as a result of the intervention models.

Key Implications

- Integrating FP/RH into worker health and livelihood programs may offer promising approaches for reaching young people in Egypt with FP/RH messages, but programmers and researchers need to consider context, reach, and sustainability when designing interventions and evaluations.

ABSTRACT

Recent increases in fertility rates in Egypt and an increase in desired fertility among unmarried young people highlight the need for renewed attention to awareness of and demand for family planning (FP) among young people. Between 2017 and 2018, the United States Agency for International Development-funded Evidence Project tested 2 intervention models to increase awareness of and demand for FP and reproductive health (RH) services among people aged 18–35 years in Souhag and Port Said governorates, Egypt. In Souhag, FP/RH information was integrated into a 5-day livelihood training program for job seekers. In Port Said, garment factory workers received FP/RH information through trained peer educators, social and behavior change materials, and social media. Workshop participants and factory workers interested in FP services were referred to private project-trained physicians and pharmacists. We present the results of an evaluation of the impact of each intervention on young people’s reported exposure to FP messages and their FP knowledge, attitudes, and behaviors. Phone interviews were conducted with participants in intervention and comparison groups before and after the intervention. In Souhag, 1,519 intervention group participants (778 at baseline; 741 at endline) and 1,082 comparison group participants (699 at baseline; 383 at endline) completed the phone interview. In Port Said, 1,958 participants from intervention factories (1,145 at baseline; 741 at endline) and 1,082 comparison factories (621 at baseline; 426 at endline) completed the phone interview. A difference-in-differences analysis compared intervention and comparison groups between baseline and endline. Results showed significant differences in knowledge and attitudes over time between the intervention and comparison groups in Souhag but less so in Port Said. FP use did not change among project participants in either governorate. We discuss lessons learned from integrating FP into worker health and livelihood training programs and methodological considerations for evaluating such interventions.

INTRODUCTION

Egypt, a lower middle-income country, is currently facing an increase in fertility trends after several years of steady decline. Egypt’s fertility rate increased from an average of 3.0 births per woman in 2008 to 3.5 births per woman in 2014, while use of any family planning (FP) method among married women of reproductive age (15–49 years) declined from 60.3% in 2008 to
58.5% in 2014. The increase in fertility was coupled with an increase in the desired number of children among never-married young people aged 15–29 years, from 2.6 children in 2009 to 2.9 children in 2014.

Since the mid-1960s, Egypt has had a successful FP program due in part to strong government commitment and many years of donor support. However, several political, economic, and programmatic changes have weakened the FP program over the past decade, and as a result, 53% of married women aged 15–49 years reported no exposure to FP messages in the media in 2014, compared with 33% of married women in 2008. Similarly, the quality of FP counseling declined as the proportion of FP users aged 15–49 years who received information about side effects for their selected method dropped from 56% in 2008 to 48% in 2014. Since 2014, there has been renewed interest in FP and strong support of the national FP program from Egyptian political leadership and various government bodies.

In 2017, 60% of Egypt’s population was younger than 30 years and 24% was between age 18 and 29 years. This age group formed nearly 40% of Egypt’s labor force. Reaching young men and women with correct and accurate FP information is paramount, given that they will determine the trajectory of future fertility rates in Egypt. However, Egypt’s FP program has traditionally focused on married women who already have children because it is assumed that young married couples would want to have children immediately after marriage. The lack of accurate FP and reproductive health (RH) information given to young men and women makes them vulnerable to misinformation and the risk of unintended pregnancy. Many young men and women without children have misconceptions and concerns about FP side effects, particularly regarding future fertility. Moreover, sustainability of the national FP program remains a challenge, as 53% of FP users in Egypt rely on the public sector for FP service delivery. Thus, international donors have been recently supporting interventions to encourage young women (and men) to use private sector services and hence relieve some of the burden on government facilities.

**Integrating FP/RH Into Worker Health and Livelihood Programs**

In recent years, international companies have been collaborating with governments and non-governmental organizations (NGOs) to implement programs to improve the health and well-being of garment factory workers. These programs have typically focused on occupational health and safety, but more recently, international companies have been collaborating with governments and NGOs to implement worker health programs that focus on other health topics unrelated to their occupation. Although few worker health programs have been evaluated and documented, results to date are promising. In South Africa, for example, garment workers who participated in a 6-week wellness program that included weekly aerobic exercise classes showed significant improvements in perceived quality of life and, for some, exercise-related behaviors. Gap’s PACE program, which was implemented in more than 60 factories in Bangladesh, Cambodia, China, India, and Vietnam, involved a 9-module course that covered a range of topics from communication skills and decision making to general health and reproductive health. By the end of the course, improvements in women’s reports of self-esteem, self-efficacy, belief in their ability to produce quality work, and their perception that their actions positively influence their workplace were observed.

Fewer programs have focused on improving factory workers’ access to RH information and services. An evaluation of the Partnering to Save Lives project in Cambodia, for instance, found significant improvements on 7 of 14 key RH knowledge, attitude, and behavior indicators. The evaluation also found that while more women of reproductive age were using a modern contraceptive method at endline compared with baseline, women’s RH knowledge was mixed. Chat!, the project’s behavior change communication package that included interactive trainings, video dramas, guided discussions, and male engagement sessions was found to be positively associated with women’s empowerment to discuss and use contraceptives as well as increased knowledge and use of contraception. Another program in Cambodia, the WorkerHealth intervention, combined service delivery and advocacy to improve FP/RH outcomes of female factory workers and showed a high uptake of FP/RH services.

Less evidence exists on programs that aim to integrate FP/RH information and services into livelihood programs. A literature review focused on the integration of FP with microfinance and livelihood programs found some evidence suggesting integrated economic and FP programs increased knowledge and use of FP, but scant information on best practices for designing integrated FP and livelihood programs. An assessment of linked RH
and livelihood programs for youth found minimal effectiveness for FP/RH outcomes and that programs often faced many challenges in providing both health and livelihood services. Between 2017 and 2018, the Population Council/Evidence Project tested 2 models to increase awareness of and demand for private FP services among young people in Souhag and Port Said governorates, Egypt. This article presents the results of an evaluation that was conducted with intervention and comparison groups, before and after the intervention. Using a difference-in-differences (DiD) analysis, the evaluation examined the effect of each intervention on young people’s exposure to FP messages and their FP knowledge, attitudes, and behaviors. The article also discusses lessons learned from the implementation and research as well as methodological considerations for measuring the impact of such interventions.

### PROGRAM DESCRIPTION

#### Souhag Project Setting

Souhag is a predominantly rural governorate located in the southern part of the country and has a population of nearly 4.9 million people. It is one of the poorest governorates in Egypt and has one of the highest unemployment rates in the country (14.4%). Contraceptive use is low, as 29% of married women aged 15–49 years used a modern method in 2014, while unmet need for FP is high, at 25.9%.

#### Souhag Intervention Overview

The intervention focused on urban male and female (married or unmarried) job seekers aged 18–35 years who had completed at least primary education, residing in 6 Souhag districts. Even though some of those job seekers may not have been married or had children, we believed it was important to raise their FP awareness at this stage before they decide to have children.

An announcement for a 5-day integrated FP/RH and livelihood training workshop (2.5 days for FP/RH and 2.5 days for livelihood skills) was shared with young people by the Women’s Association for Health Improvement staff, and beneficiaries’ networks. Interested young people completed an application, and those who met the age, education, and district criteria were notified of the workshop start date, which was approximately a month later.

Participants received a 5-day training in integrated FP/RH and livelihood. This training included basic FP/RH information as well as skills to assist young people in finding employment (e.g., writing a CV, presenting for a job interview). Training was offered by trained peer educators, young men and women with good communication and leadership skills. PEs offered 2 sessions simultaneously—1 for young men and 1 for young women. Each session included 25–30 participants. Social and behavior change materials (including posters, booklets, and fliers) and information on the Ma3looma social media Facebook page, which offers information and provides answers to questions about FP, were shared with participants. A total of 2,664 participants (884 young men and 1,780 young women) participated in the integrated FP/RH livelihood workshop. During the workshops, participants were given a list of names and contact information of private-sector physicians and pharmacists who had been trained by the project in FP service provision. Participants were told that they could seek additional information and services from those providers.

A total of 70 private physicians and 168 pharmacists were trained in Souhag between November 2017 and March 2018. Training of physicians was for 5 days and covered FP counseling, intrauterine device (IUD) insertion, and infection control procedures. The physicians belonged to for-profit and not-for-profit (i.e., NGO) sectors. Pharmacists participated in a 1-day training on basic information about FP methods (oral pills, IUDs, injectables, and condoms) and communication skills. Regular monitoring visits to the above providers measured the quality of service provision, number of referrals, and utilization of FP services.

#### Port Said Project Setting

Port Said is a coastal governorate that lies in the northeast of Egypt and has a population of nearly 750,000 people. In 2014, 57% of married women aged 15–49 years in Port Said used a modern FP method. The governorate has a Free Investment Zone that includes multiple factories that produce merchandise exempt from taxes and for export. This zone includes 27 factories with nearly 38,000 employees, 60% of whom are female. Of those employed in the factories, 65% are between the ages of 18 and 35. One intervention factory has 11 subfactories that employ nearly 13,000 individuals. The remaining factories employ an average of 1,000 individuals. More than half of the factory workers employed in Port Said’s Free Investment Zone reside in neighboring governorates, where FP/RH information and services are less accessible than in Port Said.
Five intervention and 2 comparison factories were selected for participation in this project. The main selection criteria were that the factory had a minimum of 1,000 workers and at least half of its labor force was female. Eight of the factories in the Free Investment Zone met the above criteria. Factories that were ready to start immediately were assigned to the intervention group while 2 of the other 3 were assigned to the comparison group. Owners of the third factory were initially reluctant to participate in the project and hence that factory was not included in the study. Eventually, that factory, along with the other 2 comparison factories, received the intervention at a later stage (not included in this study).

**Intervention Overview**

The intervention, implemented in partnership with Port Fouad Childhood and Motherhood Association, was aimed at male and female workers aged 18–35 years in 5 garment factories in the Free Investment Zone of Port Said. Factory managers requested that we also raise awareness of nutrition, physical exercise, and cancer and named the project “Youth Health Project.” In collaboration with the factory management team and factory coordinators, we selected 10 to 30 male and female employees from each factory to serve as PEs and provide health messages, including FP/RH messages, to factory workers. A total of 186 PEs (107 male and 79 female) received 2.5 days of training in FP/RH and other health information, communication, and advocacy skills, and use of social media. Each trained PE was assigned an average of 40–50 factory workers with whom to share 12 FP/RH messages through face-to-face communication over 12 months. PEs shared FP/RH information with their fellow workers during lunch and tea breaks and/or bus rides and distributed social and behavior change communication materials containing FP/RH information. In larger factories, each PE was assigned to deliver messages to up to 100 workers. For sustainability purposes and to avoid work disruption, we chose to have PEs deliver messages to their coworkers on an ad hoc one-on-one basis, as opposed to a lecture format. PEs also introduced their fellow workers to Ma3looma social media Facebook page. PEs reached approximately 21,400 factory workers over a period of 1 year through face-to-face messages, social and behavior change communication materials, and Ma3looma social media Facebook page.

One nurse in each factory was trained in FP counseling. PEs referred factory workers to the trained infirmary nurse for additional FP/RH information and counseling. Factory workers who expressed interest to the nurse in receiving an FP method were referred to designated private-sector physicians and pharmacists who had also been trained by the project. We trained a total of 39 physicians and 183 pharmacists in Port Said between November 2017 and March 2018. The above physicians belonged to for-profit and not-for-profit (i.e., NGO) sectors. Regular monitoring visits to those private sector providers assessed the quality of service offered, number of referrals, and utilization of FP services. Factory nurses were also asked to keep a record of the number of workers they referred to private providers each month. Several private doctors offered a discounted rate to project participants to try to attract them to their facilities.

### METHODS

#### Study Design

A quasi-experimental evaluation assessed the effect of the 2 intervention models on FP knowledge, attitudes, and behaviors (Supplement). In each governorate, phone interviews were conducted with participants in the intervention and comparison groups before and after the intervention.

#### Souhag Study Samples

In Souhag, the intervention group included young people who attended the 5-day integrated livelihood and FP/RH training. The Women’s Association for Health Improvement obtained participants’ phone numbers during workshop registration, which occurred 30–40 days before the workshop began, and asked participants if they would be willing to share their phone numbers with the research team. A total of 2,521 young men and women who registered for the training agreed to have their numbers shared with the research team. Data collectors were given a list of phone numbers of the above participants and were asked to interview 1,600 of them (800 before the workshop took place [i.e., baseline], and 800 at 3–6 months later [i.e., endline]). This target sample size was powered to assess a 5% increase in the current use of modern FP methods. A total of 1,519 phone interviews were conducted with intervention group participants (778 at baseline and 741 at endline).

The comparison group consisted of young men and women of the same age who did not
participate in the intervention. These respondents were identified by random digit dialling in urban Souhag. Data collectors asked the person who answered the phone about their age and educational attainment. Those who were 18–35 and who had at least completed primary schooling were invited to participate in the study. A total of 1,082 interviews were conducted with comparison group participants (699 at baseline and 383 at endline). It is possible that the endline sample in both intervention and comparison groups may have included participants who participated in both the baseline and endline interviews for their respective treatment groups. However, those cases are unlikely to be very many and hence the data are treated as cross-sectional.

Port Said Study Samples
In Port Said, the intervention group consisted of factory workers employed in the factories where the Youth Health Project was conducted. Before implementation of the intervention, PEs obtained verbal consent from factory workers for their telephone numbers to be shared with the research team. Facility managers then provided the research team with a database of all factory workers’ phone numbers. A total of 2,946 phone numbers were shared with the research team at baseline. A total of 1,958 interviews were conducted with workers from the 5 intervention factories (1,145 at baseline and 813 at endline). This sample size was powered to assess a 5% increase in the current use of modern FP methods over the course of the intervention.

The comparison group consisted of factory workers employed in 2 factories in the Investment Zone where the intervention was not conducted. Like the intervention group, managers from those comparison factories provided the research team a database of employees’ phone numbers. As the number of phone numbers provided from comparison factories was fairly small, data collectors tried all numbers that were given to them. Data collectors asked the person who answered the phone about their age and the factory where they worked. Those who were 18–35 and who were literate were invited to participate in the study. A total of 1,047 interviews were conducted with factory workers from the 2 comparison factories (621 at baseline and 426 at endline). As with the Souhag sample, we did not expect respondents in the intervention and comparison groups who participated in the baseline to have participated in their respective group’s endline and vice versa, and hence the data are treated cross-sectionally.

A risk of contamination bias existed in Port Said because workers may be peers with people working at different factories and often move between factories themselves. However, it should be mentioned that locations where the intervention occurred, including bus rides and lunch breaks, were specific to workers in a given factory. Thus, workers in a comparison factory could not have received the intervention directly at the facility but could have neighbors or friends in the intervention factories who shared the messages.

Data
Baseline interviews were conducted in Souhag from October 2017 to March 2018 and endline interviews occurred between March 2018 and September 2018. In Port Said, baseline interviews were conducted between September 2017 and September 2018 and endline interviews occurred between August 2018 and March 2019. Endline data for both the intervention and comparison group were collected in Souhag 3–6 months after each cohort completed their 5-day training course and hence endline data collection took 6 months, as the courses were held sequentially. In Port Said, endline data collection for both the intervention and comparison factories took place while the intervention was being implemented with factory workers in other factories, which occurred at staggered timelines across factories. It is noteworthy that because the intervention was meant to be sustainable and conversations between PEs and factory workers took place on an as-needed basis, there was no cut-off point for the intervention. Thus, some workers may have received their FP/RH messages one month before the endline, others may have received them 2 months earlier depending on their needs. Baseline data collection lasted 12 months and endline data collection lasted 6 months.

The same questionnaires were used in Souhag and Port Said at baseline and endline. A variety of information was gathered including respondent characteristics, use of social media, knowledge and attitudes of FP and fertility, willingness to use FP methods, and exposure to various aspects of the intervention. Experiences using FP methods were only asked of married respondents. All interviews were conducted in Arabic.

Ethics
Ethical approval was obtained from the Population Council Institutional Review Board, and government
approval was obtained to conduct the overall project. Informed consent was obtained from all respondents before each interview.

**Challenges in Data Collection**
The factory worker telephone databases provided by factory managers in Port Said sometimes contained nonworking phone numbers because factory workers change their SIM cards frequently. Wrong numbers accounted for 35% of all dialed numbers in Port Said, while in Souhag they accounted for 22% of all dialed numbers. This may have led to selection bias if workers whose phone numbers were missing differed systematically in some way from those who were interviewed.

Because the survey used phone interviews (as opposed to face-to-face), the questionnaires were kept very narrow in focus. As a consequence, not all variables that may be related to the outcome variables were included in the questionnaires, which may have led to specification bias.

**Measures**
The outcome variables assessed in this analysis were exposure to FP messages and FP knowledge, attitudes, and behaviors. Those outcome variables were determined based on the content of messages that were shared with workshop participants (in Souhag) or given to PEs to share with their coworkers (in Port Said). The knowledge and attitude indicators were chosen to assess the effect of the intervention in combating myths and misconceptions about FP methods, which are common among young people in Egypt, and the behavioral outcome was selected to assess whether the interventions affected contraceptive use. There were 2 exposure indicators: (1) hearing, reading, or seeing anything about FP in the preceding 6 months, and (2) ever hearing about the Ma3looma website.

**Knowledge Outcomes**
Three knowledge indicators were assessed including (1) having ever heard of an FP method; (2) knowing 3 or more modern FP methods; and (3) knowing which FP method prevents the transmission of sexually transmitted infections (STIs). Knowledge of 3 or more modern FP methods was captured by asking respondents: “Can you name FP methods that you know?” Respondents spontaneously named FP methods and were probed with “What else?” to elicit additional responses. Those who could name at least 3 methods—including pills, IUD, injectable, implant, vaginal methods (diaphragm, foam, or jelly), male condom, female condom, female sterilization, male sterilization, or emergency contraception—were categorized as knowing at least 3 modern methods. Knowledge of which FP methods prevent transmission of STIs was determined if respondents spontaneously named condoms as the method that protects against both pregnancy and STIs.

**Attitudinal Outcomes**
In terms of attitudinal questions, respondents were asked whether they agreed with the following statement: “FP methods can affect female future fertility and it may reflect negatively on future pregnancies.” Responses were captured on a Likert scale ranging from strongly agree, agree, neutral, disagree, strongly disagree, or don’t know. Responses were combined into a new dichotomized variable of disagree or strongly disagree categorized as disagree versus all other responses. In the second attitudinal indicator, respondents who were not married and married respondents who reported that they or their spouses were not using an FP method at the time of the interview were asked whether they would be willing to use an FP method in the future. Those who responded “yes” were coded as willing to use an FP method in the future, while those who responded “no” or “don’t know” were coded as not willing.

**Behavioral Outcome**
The behavioral indicator was whether currently married respondents (or their spouse) were using any FP method at the time of the interview.

Other variables used to adjust the analysis included respondents’ background characteristics, namely age, residence, sex, education, employment status, marital status, and number of living children.

**Analysis**
For each governorate, descriptive statistics were calculated for the intervention and comparison groups at baseline. Chi-squared tests were used to assess differences in characteristics at baseline between the comparison group and the intervention group. To assess the effect of the intervention on knowledge, attitudes, and behavior in each governorate, a DiD analysis was conducted. The DiD analysis used for this study can be represented by the following equation:
The DiD estimate \( \delta_{DD} \) measures the change in outcomes that can be attributed to the intervention, and \( \bar{Y} \) represents the proportion of each sample with the desired outcome for a given variable.

By subtracting the change over time in the outcome variable for the comparison group from the change over time in the intervention group, the DiD accounts for any change that might have occurred in the population naturally and thus cannot be attributed to the intervention. The DiD requires an assumption that this trend would be similar in the intervention and comparison groups. Unadjusted and adjusted DiD estimates were calculated to account for differences in respondent characteristics between groups.

**RESULTS**

Table 1 presents the background characteristics of respondents in the intervention and comparison groups in Souhag and Port Said at baseline. In Souhag, respondent background characteristics were significantly different between the comparison and intervention groups for age, sex, education completed, employment status, marital status, and number of children at baseline. In Port Said, similar significant differences were observed for age, education completed, marital status, number of children, and having ever heard of an FP method between the comparison and intervention groups.

Table 2 presents DiD estimates for all outcome indicators in Souhag, including adjusted estimates to account for differences between groups. Results of the DiD analysis show significant differences in changes over time between the intervention and comparison groups on 7 of the 8 indicators, with the intervention group showing improvements across all 7 indicators. For example, the DiD estimate for having heard, read, or seen anything about FP in the 6 months preceding the survey was 41 percentage points and 28 percentage points for having heard of the Ma3looma website. In terms of knowledge indicators, the DiD estimates were 13 percentage points for having ever heard of an FP method, 22 percentage points for knowing 3 or more modern FP methods, and 36 percentage points for knowing that condoms are the FP method that also prevents against STIs. For attitudinal indicators, the DiD was 19 percentage points for disagreeing with “FP methods can affect female fertility and it may reflect negatively on future pregnancies.” The DiD for being willing to use FP in the future showed that among those not currently using an FP method, there was a slight, but significant increase for the intervention group compared with the comparison over time, at 7 percentage points. However, regarding whether the intervention affected behavior, no significant difference was found in the proportion of married respondents (or their spouses) who were currently using FP over time compared with change observed in contraceptive use among respondents in comparison factories.

**Port Said**

Table 3 presents DiD estimations in Port Said for all outcome indicators. Few significant differences were found in intervention exposure, knowledge, attitudes, and behavior outcomes for changes observed over time in the intervention group compared with those in the comparison group. The DiD estimate for the proportion of respondents who disagreed with the statement “FP methods can affect female fertility and it may reflect negatively on future pregnancies” was significant at 8.3 percentage points. Although the proportion of the intervention group disagreeing with the statement only increased by 2.7 percentage points, the proportion of the comparison group disagreeing dropped by 5.6 percentage points, leading to a significant DiD estimate of 8.3 percentage points. Similar to Souhag, there was no significant difference in the behavioral outcome of current use of FP among married respondents, with a DiD estimate of −1.7 percentage points.

**DISCUSSION**

The purpose of this study was to assess the effect of 2 intervention models on changes in FP knowledge, attitudes, and behaviors among young job seekers in urban Souhag and young factory workers in Port Said, Egypt. Results from the DiD analysis suggest that the intervention in Souhag was effective in improving FP/RH indicators related to exposure, knowledge, and attitudes. However, in Port Said, there was only 1 significant DiD estimate for the statement “FP methods can affect female fertility and it may reflect negatively on future pregnancies.” The findings from this implementation research also present valuable lessons for future FP/RH worker health and livelihood training interventions and evaluations.
TABLE 1. Background Characteristics of Respondents in a Study to Assess the Effect of 2 Intervention Models on Family Planning Knowledge, Attitudes, and Behaviors in Souhag and Port Said, Egypt

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<td>37.3</td>
<td>30.1</td>
<td>22.2</td>
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<td>62.5</td>
<td>83.2</td>
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<td>16.8</td>
<td>15.5</td>
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<tr>
<td>Sex a</td>
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<tr>
<td>Male</td>
<td>35.6</td>
<td>47.4</td>
<td>77.4</td>
<td>78.7</td>
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<tr>
<td>Female</td>
<td>64.4</td>
<td>52.6</td>
<td>22.6</td>
<td>21.3</td>
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<tr>
<td>Education completed a,b</td>
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<td>0.1</td>
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<td>Primary/preparatory</td>
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<td>68.9</td>
<td>67.3</td>
</tr>
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<td>University/higher</td>
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<td>40.5</td>
<td>16.2</td>
<td>23.2</td>
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<td>Employment status a</td>
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<td>Currently employed</td>
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<td>43.8</td>
<td>100</td>
<td>100</td>
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<tr>
<td>Unemployed and searching</td>
<td>36.8</td>
<td>24.5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Out of labor force</td>
<td>32.5</td>
<td>31.8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Marital status a,b</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>55.5</td>
<td>34.9</td>
<td>40.5</td>
<td>48.0</td>
</tr>
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<td>Engaged/marriage contract</td>
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<td>6.9</td>
<td>14.4</td>
<td>17.4</td>
</tr>
<tr>
<td>Married</td>
<td>33.9</td>
<td>56.4</td>
<td>42.8</td>
<td>32.1</td>
</tr>
<tr>
<td>Widowed/divorced/ separated</td>
<td>2.3</td>
<td>1.9</td>
<td>2.3</td>
<td>2.6</td>
</tr>
<tr>
<td>Number of living children a,b</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>71.3</td>
<td>50.6</td>
<td>63.4</td>
<td>73.8</td>
</tr>
<tr>
<td>1</td>
<td>10.2</td>
<td>11.0</td>
<td>15.6</td>
<td>13.9</td>
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<td>2</td>
<td>8.9</td>
<td>17.0</td>
<td>15.9</td>
<td>9.0</td>
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<td>3 or more</td>
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<td>21.3</td>
<td>5.1</td>
<td>3.4</td>
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<tr>
<td>Ever heard of a family planning method b</td>
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<tr>
<td>Yes</td>
<td>83.3</td>
<td>83.1</td>
<td>76.5</td>
<td>68.3</td>
</tr>
<tr>
<td>No/don’t know</td>
<td>16.7</td>
<td>16.9</td>
<td>23.5</td>
<td>31.7</td>
</tr>
</tbody>
</table>

a Statistically significant for Souhag at P<.01.
b Statistically significant for Port Said at P<.01.
### TABLE 2. DiD Estimates of Young People’s Exposure to FP and Their FP Knowledge, Attitudes, and Behaviors in Souhag, Egypt

<table>
<thead>
<tr>
<th>Group</th>
<th>Percentagea</th>
<th>DiD Results</th>
<th></th>
<th>Adjusted Percentage Point Estimate</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Endline</td>
<td>Percentage Point Estimate</td>
<td>Adjusted Percentage Point Estimateb</td>
<td></td>
</tr>
<tr>
<td><strong>Exposure outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heard, read, or seen anything about FP in the last 6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>28.1</td>
<td>74.1</td>
<td>41.3c</td>
<td>40.2c</td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>18.9</td>
<td>23.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has heard of Ma3looma website</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Intervention</td>
<td>17.6</td>
<td>49.4</td>
<td>28.0c</td>
<td>27.7c</td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>8.7</td>
<td>12.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Knowledge outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever heard of an FP method</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Intervention</td>
<td>83.3</td>
<td>96.1</td>
<td>12.6c</td>
<td>11.5c</td>
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</tr>
<tr>
<td>Comparison</td>
<td>83.1</td>
<td>83.3</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Knows 3 modern FP methods</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Intervention</td>
<td>56.0</td>
<td>83.0</td>
<td>22.0c</td>
<td>19.6c</td>
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</tr>
<tr>
<td>Comparison</td>
<td>49.6</td>
<td>54.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knows FP method that prevents sexually transmitted infections</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>18.0</td>
<td>56.8</td>
<td>36.4c</td>
<td>35.0c</td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>13.0</td>
<td>15.4</td>
<td></td>
<td></td>
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<tr>
<td><strong>Attitudinal outcomes</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Disagrees with “FP methods can affect female fertility and it may reflect negatively on future pregnancies”</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>52.6</td>
<td>73.5</td>
<td>18.6c</td>
<td>17.8c</td>
<td></td>
</tr>
<tr>
<td>Comparison</td>
<td>46.2</td>
<td>48.6</td>
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<tr>
<td>Willing to use FP in the future (among individuals not currently using an FP method)d</td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Intervention</td>
<td>88.8</td>
<td>94.5</td>
<td>6.5e</td>
<td>6.0e</td>
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<tr>
<td>Comparison</td>
<td>85.9</td>
<td>85.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Behavioral outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Among married individuals who are not currently pregnant/whose wives are not currently pregnant</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently using FPf</td>
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<td></td>
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<tr>
<td>Intervention</td>
<td>62.6</td>
<td>62.9</td>
<td>0.1</td>
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<tr>
<td>Comparison</td>
<td>62.4</td>
<td>62.5</td>
<td></td>
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</tbody>
</table>

Abbreviations: DiD, Difference-in-Differences; FP, family planning.

* Sample sizes at baseline were n=778 for the intervention group and n=699 for the comparison group. Sample sizes at endline were n=741 for the intervention group and n=383 for the comparison group.

* Adjusted for age, residence, gender, education, employment, marital status, and number of children.

* \( P \leq .01 \).

* Sample sizes at baseline were n=644 for the intervention group and n=490 for the comparison group. Sample sizes at endline were n=587 for the intervention group and n=263 for the comparison group.

* \( P \leq .05 \).

* Sample sizes at baseline were n=214 for the intervention group and n=335 for the comparison group. Sample sizes at endline were n=245 for the intervention group and n=192 for the comparison group.
### TABLE 3. DiD Estimates of Factory Workers’ Exposure to FP and Their FP Knowledge, Attitudes, and Behaviors in Port Said, Egypt

<table>
<thead>
<tr>
<th>Group</th>
<th>Percentagea</th>
<th>DiD Results</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Endline</td>
<td>Percentage Point Estimate</td>
<td>Adjusted Percentage Point Estimateb</td>
</tr>
<tr>
<td><strong>Exposure outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heard, read, or seen anything about FP in the last 6 months</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Intervention</td>
<td>16.2</td>
<td>17.2</td>
<td>−4.9</td>
<td>−4.7</td>
</tr>
<tr>
<td>Comparison</td>
<td>16.9</td>
<td>22.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Has heard of Ma3looma website</td>
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<td>Intervention</td>
<td>6.1</td>
<td>10.2</td>
<td>−3.8</td>
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<tr>
<td>Comparison</td>
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<td></td>
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<tr>
<td><strong>Knowledge outcomes</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever heard of an FP method</td>
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<tr>
<td>Intervention</td>
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<td>−7.8c</td>
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<td>Comparison</td>
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<td>−0.3</td>
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<td>Comparison</td>
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<td>31.2</td>
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</tr>
<tr>
<td>Knows FP method that prevents sexually transmitted infections</td>
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<td>−0.1</td>
<td>−0.9</td>
</tr>
<tr>
<td>Intervention</td>
<td>12.9</td>
<td>15.1</td>
<td></td>
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<tr>
<td>Comparison</td>
<td>14.3</td>
<td>16.7</td>
<td></td>
<td></td>
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<tr>
<td><strong>Attitudinal outcomes</strong></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Disagrees with: “FP methods can affect female fertility and may reflect negatively on future pregnancies”</td>
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<td></td>
<td>8.3c</td>
<td>9.2c</td>
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<tr>
<td>Intervention</td>
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<tr>
<td>Comparison</td>
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<td>Willing to use FP in the future (among individuals not currently using an FP method)d</td>
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<td>2.1</td>
<td>2.0</td>
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<tr>
<td>Intervention</td>
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<td>71.6</td>
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<tr>
<td>Comparison</td>
<td>74.3</td>
<td>77.0</td>
<td></td>
<td></td>
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<tr>
<td>Behavioral outcomes (among married individuals who are not currently pregnant/whose wives are not currently pregnant)</td>
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<tr>
<td>Currently using FPc</td>
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<td>−1.7</td>
<td>−0.9</td>
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<tr>
<td>Intervention</td>
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<td>69.9</td>
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<tr>
<td>Comparison</td>
<td>59.5</td>
<td>68.6</td>
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<td></td>
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</table>

**Abbreviations:** DiD, Difference-in-Differences; FP, family planning.

* Sample sizes at baseline were n=1,145 for the intervention group and n=621 for the comparison group. Sample sizes at endline were n=813 for the intervention group and n=426 for the comparison group.

* Adjusted for age, residence, gender, education, employment, marital status, and number of children.

* *P ≤ 0.05.

* Sample sizes at baseline were n=896 for the intervention group and n=521 for the comparison group. Sample sizes at endline were n=564 for the intervention group and n=343 for the comparison group.

* Sample sizes at baseline were n=398 for the intervention group and n=168 for the comparison group. Sample sizes at endline were n=356 for the intervention group and n=121 for the comparison group.
Results suggest that the integrated livelihood and FP intervention was effective in increasing knowledge and positive attitudes toward FP among young people in urban Souhag.

Implementation Successes and Challenges

While the evidence base on programs that aim to integrate FP/RH information and services into livelihood programs is small, results from our DiD analysis suggest that the integrated livelihood and FP intervention was effective in increasing knowledge and positive attitudes toward FP among young people in urban Souhag. The results from this analysis are similar to those from a literature review on the integration of FP into microfinance and livelihood programs that found some evidence suggesting increased knowledge and use of FP after these programs.13

Part of the success in Souhag may be due to the highly structured nature of the intervention. For example, PEs and workshop participants met on predetermined dates, messages were delivered according to a largely fixed schedule, and all participants completed the 5 days of training and received the same FP messages during the 5-day workshop (2.5 days for livelihood skills and 2.5 days for FP/RH information). However, similar to challenges faced in the implementation of the workplace health program HERproject in Bangladesh, high turnover of PEs can be a challenge.16 The Souhag livelihood training program faced similar challenges, with PEs opting for more stable, full-time jobs rather than the part-time, temporary PE positions. Of 60 PEs who had been trained by the project in Souhag, 18 left the project by the end of the first year. The results, coupled with the implementation learnings, suggest that highly structured programs may be more effective in improving RH/FP knowledge and attitudes, but additional research is needed to identify best practices for retaining PEs or targeting permanent employees as PEs.

Previous evaluations of worker health programs that offered health education to factory workers through PEs have been shown to raise awareness of general and reproductive health, use of clinic services, and workers’ hygiene and other health behaviors improved.15–17 Our DiD analysis, however, found that the worker health intervention implemented in Port Said was not effective in changing factory workers’ knowledge, attitudes, or behaviors. Several programmatic issues during the implementation of the intervention in Port Said may have minimized the worker health program’s effect. The intervention was implemented with PEs who worked in various capacities in the factories, and this may have reduced the time available to convey FP/RH messages to their coworkers. The time available for PEs to communicate messages was limited to tea and lunch breaks or bus rides. As a result, very few PEs were able to speak to the target number of colleagues to reach in a given month. In larger factories, the PE to worker ratio was 1:100, which made it even more difficult for PEs to reach their target workers each month. Not surprisingly, due to these challenges and because the intervention/comparison surveys were conducted at the facility rather than the individual level, the proportion of factory workers in intervention factories who reported exposure to FP/RH messages at endline was quite small, at 17%. Moreover, messages were communicated by PEs on an ad hoc basis, depending on the needs and interests of individual workers. Thus, not all workers received the same messages in a given month.

The above challenges in integrating FP/RH messages into workers’ health programs are not uncommon. In Bangladesh, the PEs in the HERhealth project disseminated messages during work breaks similar to Port Said and turnover of PE was also an implementation challenge.16 However, a similar DiD analysis found the HERHealth project had a positive effect on female workers’ health knowledge and behaviors. We hypothesize that differences in how the 2 projects were implemented may help explain why the intervention was not effective in Port Said. First, the ratio of PE to female factory workers under the HERHealth project was between 1:21 and 1:26, whereas the ratio was up to 1:100 in Port Said. Second, the HERHealth PE training in Bangladesh was covered over 10 weeks, versus 5 days plus monthly sessions thereafter in Port Said. Additional research is needed to understand the essential program components that will lead to better results for workplace programming.

The DiD analysis did not reveal changes in FP behaviors at either intervention site, possibly due to cost. The project referred participants to private sector providers, some of whom may have had relatively high fees that project participants may not have been able to afford. In Port Said, more than half of the workers came from neighboring governorates and were reluctant to miss work hours to visit the private providers trained by the project and who were located within the Port Said governorate. The model in Port Said also involved a 2-step referral process (from PEs to factory nurses for counseling and from factory nurses to private sector providers for a method), which may have created barriers to workers’ access to FP services. In response to the above challenges, the project eventually facilitated setting up a Women’s Health clinic to provide FP/RH services to more than 20,000 female workers in the Investment
Zone. An evaluation from workplace programming found that substantial changes in menstrual hygiene management were observed because the intervention also worked with factory clinics to expand access to sanitary menstrual hygiene products in addition to disseminating menstrual hygiene health messages via PE. Thus, the addition of the Women’s Health clinic in Port Said’s Investment Zone may complement the education in a similar way and increase use of FP/RH services. Implementation research on the acceptability and effectiveness of this intervention will be necessary for expanding the evidence base for including service provision in worker health education for FP/RH.

In both governorates, more than half of married participants in this study had no children. These married participants with no children were far less likely to be using FP (3%) than their counterparts with children (76%, data not shown), which may be due in part to traditional values that favor having at least 1 child before using contraception. This may explain why significant increases in FP use were not seen, despite increases in the proportion of respondents who would be willing to use FP in the future in Souhag.

Research Limitations

Souhag

In Souhag, although phone numbers were obtained directly from workshop participants during registration, participants often shared their phones with other family members so when the research team called, the participant may not have been in possession of the phone. The male/female distribution of survey participants differed only slightly from the makeup of the workshop participants (70% female to 30% male for the survey versus 60% female and 40% male for the workshop). In Souhag, the sampling strategy may have led to some biases in the study findings. Participants at baseline and endline were sampled cross-sectionally, so the same respondents were not necessarily interviewed at baseline and endline. However, some may have been interviewed at both time points, although this proportion could not be determined. Regardless, DiD estimations are calculated the same way for both panel and cross-sectional data, and quasi-experimental design using comparison and intervention groups interviewed before and after the intervention mitigates the selection bias associated with the sampling. Although the intervention participants were not selected randomly, efforts were made to ensure that the intervention and comparison groups were similar in terms of age, educational attainment, and geographic residence. However, there were significant differences between the comparison and intervention groups. For example, the comparison group was older than the intervention group, which might have been more susceptible to learning new information, attitudes, and behaviors. To mitigate the effects of any confounding variables and reduce any bias that may have been introduced due to the groups being significantly different, the DiD analyses were adjusted for respondent characteristics.

Port Said

In Port Said, the project experienced difficulty in determining intervention cutoff points and reaching survey respondents. As the content of messages that were communicated to factory workers varied depending on the needs of each worker, there was no clear cutoff point for the intervention. As mentioned earlier, the duration between receiving FP/RH messages and the endline interview varied for different workers depending on their needs, as the interventions and surveys were conducted on a factory rather than an individual level. In addition, worker movement across garment factories is common as workers move from one factory to the other to respond to purchase orders. Some workers may have moved from intervention to comparison factories and vice versa. In addition, workers from both intervention and comparison factories may live in similar neighborhoods and take similar buses to and from work, so diffusion of the intervention to the comparison group may have occurred. These 2 factors may have contributed to the lack of significant results between the intervention and comparison groups. Similarly, worker movement within the same factory occurs across factory halls/departments, some of which did not have a trained PE, which may have contributed to the lack of significant findings. Also, it should be noted that phone numbers of factory workers that were shared with the research team belonged to factory workers in the entire factory and not necessarily those workers who were reached by the PEs. It is also important to note that the endline sample in Port Said included an overrepresentation of workers from larger factories, which had a low PE to worker ratio. Finally, female factory workers were less likely to answer phone calls from the project’s research staff, which skewed the distribution of male to female respondents. The typical sex distribution of factory workers in Port Said is 40% males and 60% females, while
the distribution of respondents in this study was 78% males and 22% females.

The above challenges in conducting the research in Port Said, along with the sampling strategy, may have led to some biases in the study findings. Similar to Souhag, participants were sampled cross-sectionally before and after the intervention, so the same respondents were unlikely to be interviewed at both baseline and endline, although some may have been. Additionally, although the intervention occurred at the facility level and not the individual level, efforts were made to ensure that the factories chosen for the intervention and comparison groups were similar. The comparison and intervention groups were similar in terms of age as well. Finally, although the 2 groups were significantly different on some respondent characteristics, which may have introduced bias into the results, we adjusted the DID analyses for individual-level characteristics to mitigate the effects of any confounding variables on the results.

CONCLUSION

Worker health and livelihood training programs may offer a unique venue for conveying FP/RH messages to young people if the context is taken into consideration. For example, in factory settings, the number of PEs in a given factory should be proportionate to the number of workers in that factory. PEs need to be selected from workers who have more control over their time or whose work involves some mobility (e.g., line supervisors or human resources officers). In addition, future programs could consider innovative ways for PEs to stand out and be more visible and identifiable by their coworkers (e.g., by having PEs wear special buttons), especially in larger factories where the PE to worker ratio may be low, which could improve information exchange. PEs could also complement face-to-face communication with social and behavior change materials and social media platforms like Facebook and WhatsApp. However, close attention would be needed in identifying ways to protect workers’ privacy and confidentiality if sensitive information is exchanged over social media platforms. Finally, raising FP/RH awareness of factory workers cannot be left to PEs alone. The factory nurse could play a more proactive role in conducting FP/RH education seminars and integrating FP/RH messages to factory workers who are seeking other services such as first aid. The role of nurses could be expanded to include overseeing health education activities provided by PEs, training PEs, and providing one-on-one FP/RH counseling to factory workers. Factory management also needs to take ownership of worker health programs and establish structures and systems within the factory to sustain the program.

Likewise, livelihood programs could offer an opportunity for raising young people’s awareness about FP/RH if the 2 components are integrated efficiently. The impact of one-off integrated trainings on reproductive behaviors could be enhanced by linking participants to designated FP services that are accessible to workshop participants. However, sustainability of those integrated livelihood programs (i.e., getting governments or employers to support the costs of the FP/RH component) remains a challenge. Policy makers, donors, program managers, and business owners need to recognize that linking FP/RH with livelihood programs benefits both sectors.

More research is needed to demonstrate the economic benefits of integrating FP/RH into livelihood and worker health programs. Additional research on the effect of respondents’ relationships, communication about FP/RH topics with partners, and gender attitudes and norms would provide a more robust examination of any changes in behavior and attitudes over time. Also, more implementation research is needed to identify key components of successful integrated FP/RH and livelihood/worker health programs, such as length of PE training and ideal ratios of PEs to workers, and to evaluate the long-term impact of those programs on workers’ well-being, productivity, and retention as well as the return on investment of such programs. Additionally, research designs to evaluate the impact of worker health programs should take into consideration the mobile nature of work in factory settings, the casual nature of discussions between PEs and workers, and the frequent changing of SIM cards by factory workers. Mechanisms for tracking workers’ mobility within and across factories and obtaining updated lists of workers’ phone numbers should be developed in future research studies. Lastly, additional research is needed on the acceptability and effectiveness of adding a Women’s Health clinic to the Investment Zone of Port Said, in terms of the use of FP/RH services among workers.

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Author contributions: Nahla Abdel Tawab, principal investigator, took a lead role in conceptualizing the study and overseeing the implementation of all project activities. She took a lead role in writing the discussion section. Elizabeth Tobey took the lead in writing the methodology section and conducting DD analysis and provided technical support to the project. Maryam Essam took the lead in writing a description of the intervention and took part in writing the introduction as well as implementation of the intervention. Sara Chace Dwyer conducted a desk review of global literature on worker health and integrated FF and livelihood programs and took part in writing the introduction and discussion sections. Aparna Jain provided technical assistance to the project, participated in the conceptualization of the article, and took the lead in reviewing and editing it.

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REFERENCES


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Participation in a Community-Based Women’s Health Education Program and At-Risk Child Development in Rural Kenya: Developmental Screening Questionnaire Results Analysis

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Key Findings
- Infants in Chamas had a lower likelihood of at-risk development compared to those in the control group. Older infant age at time of screening and having natural or uncovered walls was also associated with lower odds of at-risk development.
- Our findings offer evidence to support that by addressing health literacy, providing community in a supportive environment, and offering a means to combat social determinants of child developmental delays, the Chamas for Change intervention may help protect children from developmental delays in this resource-limited setting in Kenya.

Key Implications
- When looking to revise current strategies to help protect children from developmental delay in this setting, policy makers should consider interventions that leverage existing resources to ensure their sustainability.

ABSTRACT

Background: Over 43% of children living in low- and middle-income countries are at risk for developmental delays; however, access to protective interventions in these settings is limited. We evaluated the effect of maternal participation in Chamas for Change (Chamas)—a community-based women’s health education program during pregnancy and postpartum—and risk of developmental delay among their children in rural Kenya.

Methods: We analyzed developmental screening questionnaire (DSQ) data from a cluster randomized controlled trial in Trans Nzoia County, Kenya (ClinicalTrials.gov, NCT03187873). Intervention clusters (Chamas) participated in community health volunteer-led, group-based health lessons twice a month during pregnancy and postpartum; controls had monthly home visits (standard of care). We screened all children born during the trial who were alive at 1-year follow-up. We labeled children with any positive item on the DSQ as “at-risk development.” We analyzed data using descriptive statistics and multilevel regression models (α=.05); analyses were intention-to-treat using individual-level data.

Results: Between November 2017 and March 2018, we enrolled 1,920 pregnant women to participate in the parent trial. At 1-year follow-up, we screened 1,273 (689 intervention, 584 control) children born during the trial with the DSQ. Intervention mothers had lower education levels and higher poverty likelihood scores than controls (P<.001 and P=.007, respectively). The overall rate of at-risk development was 3.5%. Children in Chamas clusters demonstrated significantly lower rates of at-risk development than controls (2.5% vs. 4.8%, P=.025). Adjusted analyses revealed lower odds for at-risk development in the intervention arm (OR=0.50; 95% confidence interval=0.27, 0.94).

Conclusions: Maternal participation in a community-based women’s health education program was associated with lower rates of at-risk development compared to the standard of care. Overall, rates of at-risk development were lower than expected for this population, warranting further investigation. Chamas may help protect children from developmental delay in rural Kenya and other resource-limited settings.

INTRODUCTION

Early childhood development (ECD) lays the foundation upon which every individual’s cognitive, social,
and emotional abilities are built. As such, investing in ECD not only benefits individuals but also boosts shared prosperity and helps eliminate extreme poverty.1,2 However, recent data suggest that more than 43% of children under age 5 years living in low- and middle-income countries (LMICs) are at risk for developmental delays.1 Among children at risk, more than 60% reside in sub-Saharan Africa.3 This inequity perpetuates intergenerational cycles of poverty, particularly in rural communities where children are often denied equal access to resources and opportunities that nurture ECD.

The World Health Organization (WHO) estimates that 45% of children under age 5 years in Kenya are at risk for developmental delays (56% rural, 25% urban), translating to an estimated 138% loss in annual adult wages.5 Multifaceted challenges have limited the success of recent efforts (e.g., government policies, school-based programming) to bolster ECD. These challenges include inadequate financial investment in early education, poor access to health services that protect against known risk factors (e.g., malnutrition, recurrent and/or chronic infections), and limited awareness of the deleterious role of chronic stress (e.g., harsh punishment) on development.6 Moreover, few policies focused on ECD target the first 1,000 days of life—a critical period during which the brain undergoes rapid change and establishes a framework for lifelong learning.7 Inadequate antenatal care,8–10 malnutrition,1 and maternal depression,11 during this period can also have long-standing negative consequences.1,7,12 Effective interventions that protect against developmental delays within rural, resource-limited settings are urgently needed to address these disparities.

In 2012, the Academic Model Providing Access to Healthcare partnership and Republic of Kenya Ministry of Health established the Chamas for Change (Chamas) program to help improve maternal, newborn, and child health (MNCH) in rural western Kenya.13,14 Chamas is a longitudinal program that supports women during pregnancy and for the first 1,000 days of the infants’ lives with community-driven, group-based health education. Importantly, this intervention integrates known strategies to improve outcomes for women and infants, including ECD, while leveraging existing resources in rural Kenyan communities. A pilot study evaluating the first year of this program demonstrated significant associations between participation and the likelihood of practicing positive MNCH behaviors, including attending adequate antenatal care and exclusively breastfeeding.13,14

To test our hypothesis that maternal participation in Chamas improved MNCH outcomes, including ECD, we conducted a cluster-randomized controlled trial in Trans Nzoia County, Kenya. In this article, we report results from developmental screening questionnaires (DSQ) completed on children born during the trial at 1-year follow-up.

**METHODS**

**Study Design and Setting**

We analyzed DSQ data from a 2-arm cluster randomized controlled trial in 74 communities across 4 subcounties (Cherangany, Saboti, Kwanza, and Kiminini) in Trans Nzoia County, Kenya. We chose a cluster-randomized design to minimize contamination due to intervention exposure between neighboring villages. We defined clusters as community health units—geographically defined health service delivery areas for populations of 5,000 people overseen by community health volunteers (CHVs).16 We randomized community health units 1:1 (non-stratified, non-matched) using a simple random allocation sequence to participate in Chamas (intervention) or receive recommended monthly home visits from CHVs (standard of care) for 1 year. Data collectors, analysts, and investigators were masked to cluster allocation throughout the study; however, trial arms were identifiable to participants and CHVs by design.

We selected Trans Nzoia due to its geographic and socioeconomic diversity, as well as the presence of longstanding collaborations between the Government of Kenya, Ministry of Health, and Academic Model Providing Access to Healthcare. Trans Nzoia has nearly 1 million residents who largely subside on agricultural businesses and raising livestock. Moreover, health indicators for mothers and infants are consistently poorer than national estimates, reflecting a need for increased attention to MNCH policy and programming.17

**Procedures**

Pregnant women presenting to the local health facility for their first antenatal care visit by 32 weeks’ gestation were eligible to participate in the parent trial. Participants were allocated to each arm by their randomized community of residence. At approximately 1-year follow-up (i.e., 12 months of Chamas participation, initiating prenatally), we screened all children born during the trial with the DSQ, with no additional exclusion criteria. Data collectors traveled to participant homes to collect in-person data using electronic tablet-based, structured questionnaires. We synced data at the end of each collection day to a central, academic database.
encrypted server. Research assistants made 3 attempts to contact participants over a 2-week period before declaring them lost to follow-up.

Intervention details are described in our protocol (ClinicalTrials.gov NCT03187873) and previous publications. A detailed summary of the intervention is noted within Supplement 1. Briefly, Chamas clusters convened twice per month for 12 months for group-based health lessons led by CHVs. Each group typically included 15–20 women, their infants, 2 CHV facilitators, and 2 postmenopausal mentor mothers. Health lessons during the first year of the program promoted positive MNCH behaviors during pregnancy (e.g., attending adequate antenatal care) and infancy (e.g., exclusively breastfeeding and immunizing infants). Women were also introduced to topics contributing to risk factors and social determinants associated with developmental delays such as infant growth monitoring and nutrition, disease prevention, childhood harsh punishment, and parental stress. These and other developmentally focused lessons are largely addressed during the second and third years of the curriculum. After each lesson, women were also invited to participate in an optional microfinance program called Group Integrated Savings for Health and Empowerment (GISHE). Participation in GISHE was completely optional so as not to deter women without financial means to contribute to group savings from joining Chamas. Women who chose to participate were encouraged to use savings and loans generated by GISHE to enroll in health insurance, pay for school fees and educational materials, and/or start small businesses.

Control clusters had monthly CHV home visits during the antenatal and postpartum period as recommended by the current standard of care. During monthly visits, CHVs aimed to collect basic health information, recognize antenatal and early postpartum danger signs, aid in infant growth monitoring, and refer individuals requiring services to health facilities. Further, CHVs were expected to encourage women to adopt the same positive health behaviors emphasized in Chamas, namely: attending antenatal care, delivering in health facilities, exclusively breastfeeding, adopting modern methods of contraception, fully immunizing infants, and ensuring adequate infant nutrition.

Our primary outcome of interest was the rate of “at-risk development” across study arms. We defined “at-risk development” as any child who screened positive in 1 or more functional domains on the DSQ. We selected the DSQ as it has been validated for use among children less than aged 2 years in an LMIC. Of note, this tool is a screening questionnaire and not a diagnostic neurodevelopmental assessment. This validated questionnaire asks parents to report responses to 8 dichotomous “yes/no” questions in each of the following functional domains, which are specific to age (in months): gross motor, fine motor, vision, hearing, cognition, socialization, behavior, and speech. A list of the DSQ testing items can be viewed within Supplement 2. We considered any “yes” response a positive screen. Data collectors used age-appropriate DSQs for each infant by imposing an electronic checkpoint in RedCap (coded by birthdate). Lastly, if participants carried a multiple gestation pregnancy, we conducted independent questionnaires for each child.

To assess modifying effects of covariates, we collected baseline sociodemographic and reproductive health data for all participants. We used the validated Kenya 2015 Poverty Probability Index (PPI) tool to calculate individual poverty likelihood scores using the National Poverty Line Look-Up Table. This tool comprises 10 questions that assess sociodemographic factors such as county of residence, household education level, housing materials, and recent household purchases. Answers are coded using a numeric scoring system and summarized in a composite PPI score, which can be converted to a percentage value for poverty probability. We additionally collected end-line data on participant attitudes toward harsh punishment, infant birth weight, and age of first mixed-feeding as these variables have demonstrated significant associations with developmental delay outcomes in previous studies. We used a single item from the validated ISPCAN child abuse screening tool, parent version, to assess harsh punishment. Responses were collected using a 5-point Likert scale, ranging from “strongly disagree” to “strongly agree.”

**Statistical Analysis**

The sample size calculation was based on the study’s primary outcome, which was facility-based births. This calculation used methods described by Rutterford et al. for a proposed mixed-effects regression analysis using derived baseline estimates. We assumed a mean cluster size of 20 individuals, with 77 clusters (equally allocated between arms) and intracluster correlation

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**Study Outcomes**

Our primary outcome of interest was the rate of “at-risk development” across study arms. We
coefficient of 0.44 (based on pilot data\textsuperscript{14}), and 20% attrition. With these assumptions, a total of 1,280 individuals would be needed to detect a 4.7% difference on the risk difference scale with 80% power at a (2-tailed) significance level of .05. A total of 1,273 (66.3%) of participants completed the study at 12-month follow-up with DSQ data: we included 689 individuals from 37 clusters in the intervention (69.2%) and 584 individuals from 37 clusters in the control (63.2%) arms for analysis.

We assessed individual-level outcomes on all participants with complete DSQ data at 12-months follow-up. We used an intention-to-treat approach by evaluating all intervention participants, regardless of Chamas attendance. We summarized participant characteristics in a tabular form. We calculated frequencies and percentages for categorical variables, as well as means and standard deviations for continuous variables. We compared proportions using chi-squared tests and means using independent t-tests.

We compared proportions of at-risk development among children within each study arm using chi-square tests. We used simple descriptive statistics to determine DSQ testing items and domains for which children most commonly screened positive. We reviewed available sociodemographic as well as endline variables and identified potential confounders using clinical judgment and evidence from the literature. We performed a univariate analysis with each identified variable and included those demonstrating statistical significance ($P<.05$) or clinical meaning in our adjusted multivariate logistic regression model. We reported overall tests for each variable as well as estimated odds ratios with their 95\% confidence intervals (CI). For households with twin children, we included DSQ data from the twin screened first in our regression model to limit bias introduced from duplicating covariate data from the same household and mother.

We decided a priori to restrict analyses solely to participants with both complete DSQ data and complete PPI data. We disaggregated items within the PPI to appropriately adjust for specific confounding variables known to impact child development (e.g., primary caregiver education level, head of household education level, housing materials).\textsuperscript{32,33} We conducted all statistical analyses in SAS 9.4 (SAS Institute, Cary, NC) statistical software and with $\alpha$ set to .05.

Ethical Considerations
We prospectively registered the parent trial with ClinicalTrials.gov (NCT03187873). Our study received ethics approval from the Institutional Research Ethics Committee at Moi Teaching and Referral Hospital and Moi University (IREC/2018/269) and the Office of Research Administration at Indiana University (1905296355). We obtained written informed consent from participants before data collection.

Role of the Funding Source
The funders had no role in the research design, collection, analysis, or interpretation of data, writing this report, or the decision to submit this manuscript for publication. The corresponding author had full access to all data in the study as well as final responsibility for the decision to submit this manuscript for publication.

Results
Between November 27, 2017, and March 8, 2018, we enrolled 1,920 pregnant women from 74 communities to participate in the parent trial. At 1-year follow-up, we screened 1,273 (689 intervention, 584 control) of their children with the DSQ (Figure). Among those without DSQ data, 36 children in the intervention arm and 42 children in the control arm died before follow-up. Lastly, all 12 twin pairs in our study cohort had concurrent DSQ screening results between the twins.

Table 1 summarizes sociodemographic data for our study population (N=1,273). Among included households, the mean child age was 10.9 months (standard deviation [SD]: 2.3) and maternal age was 26.8 years (SD: 6.4). The majority of mothers were married (83.8\%, $n=1,067$) and unemployed (63.0\%, $n=802$). Overall, arms were fairly balanced; however, controls had more household members educated beyond primary school (41.1\% vs. 37.6\%; $P<.001$) and a lower poverty likelihood (29.0\% vs. 32.0\%; $P=.007$) compared to intervention participants. Participants lost to follow-up were similar in number across study groups and attrition was not significantly associated with sociodemographic characteristics.

The overall rate of at-risk development among our study cohort was 3.5\% ($n=45$). When divided into study groups, we observed a significantly lower rate of at-risk development in the intervention arm (2.5\% vs. 4.8\%, $P=.025$). We noted variable rates of at-risk development across child age (in months) at the time of screening (Table 2). The only significantly different rate between study arms, however, occurred at 8 months of age (10\% (4/40) control vs. 0\% (0/46) intervention, we observed a significantly lower rate of at-risk development in the intervention arm (2.5\%) compared to the control arm (4.8\%).
The highest proportion of positively screened items pertained to the speech (33.7%, 30/89); gross motor (18.0%, 16/89); and cognition (11.2%, 10/89) domains. All remaining domains—fine motor, vision, hearing, socialization, and behavior—individually comprised no more than 4.5%–10.1% of remaining positive screening items.

We recorded outcomes on maternal attitudes toward harsh punishment, age of first mixed-
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (N=1,273) N (%)</th>
<th>Intervention (n=689) n (%)</th>
<th>Control (n=584) n (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child’s age, months, mean (SD)</td>
<td>10.9 (2.3)</td>
<td>11.2 (2.4)</td>
<td>10.5 (2.2)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mother’s age, years, mean (SD)</td>
<td>26.8 (6.4)</td>
<td>27.0 (6.6)</td>
<td>26.7 (6.1)</td>
<td>.341</td>
</tr>
<tr>
<td>Categorized mother’s age, years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18</td>
<td>48 (3.8)</td>
<td>32 (4.8)</td>
<td>16 (2.8)</td>
<td></td>
</tr>
<tr>
<td>18–24</td>
<td>462 (36.8)</td>
<td>240 (35.8)</td>
<td>222 (38.1)</td>
<td></td>
</tr>
<tr>
<td>25–32</td>
<td>487 (38.8)</td>
<td>259 (38.6)</td>
<td>228 (39.2)</td>
<td></td>
</tr>
<tr>
<td>&gt;32</td>
<td>256 (20.4)</td>
<td>140 (20.9)</td>
<td>116 (19.9)</td>
<td>.266</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>20</td>
<td>18</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single/divorced/separation/widowed</td>
<td>206 (16.2)</td>
<td>117 (17.0)</td>
<td>89 (15.2)</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>1067 (83.8)</td>
<td>572 (83.0)</td>
<td>495 (84.8)</td>
<td>.401</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>802 (63.0)</td>
<td>437 (63.4)</td>
<td>365 (62.5)</td>
<td></td>
</tr>
<tr>
<td>Temporary work</td>
<td>74 (5.8)</td>
<td>41 (6.0)</td>
<td>33 (5.7)</td>
<td></td>
</tr>
<tr>
<td>Self-employed/permanently employed</td>
<td>397 (31.2)</td>
<td>211 (30.6)</td>
<td>186 (31.9)</td>
<td>.885</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Highest educational level of household head*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-primary/none/other</td>
<td>181 (14.3)</td>
<td>87 (12.7)</td>
<td>94 (16.1)</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>592 (46.6)</td>
<td>342 (49.9)</td>
<td>250 (42.8)</td>
<td></td>
</tr>
<tr>
<td>Secondary/post-primary/vocational</td>
<td>391 (30.8)</td>
<td>218 (31.9)</td>
<td>173 (29.6)</td>
<td></td>
</tr>
<tr>
<td>College or higher</td>
<td>106 (8.4)</td>
<td>39 (5.7)</td>
<td>67 (11.5)</td>
<td></td>
</tr>
<tr>
<td>Missing data (n)</td>
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<td>3</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Highest educational level of any member*</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.001</td>
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<tr>
<td>Pre-primary/none/other</td>
<td>103 (8.2)</td>
<td>44 (6.5)</td>
<td>59 (10.1)</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>485 (38.5)</td>
<td>268 (39.6)</td>
<td>217 (37.2)</td>
<td></td>
</tr>
<tr>
<td>Secondary/post-primary/vocational</td>
<td>468 (37.1)</td>
<td>272 (40.2)</td>
<td>196 (33.6)</td>
<td></td>
</tr>
<tr>
<td>College or higher</td>
<td>205 (16.3)</td>
<td>93 (13.7)</td>
<td>112 (19.2)</td>
<td>.002</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>12</td>
<td>12</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Household food access (during last 7 days)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bread</td>
<td>834 (65.8)</td>
<td>439 (64.3)</td>
<td>395 (67.6)</td>
<td>.209</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>6</td>
<td>6</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Meat/fish</td>
<td>924 (72.8)</td>
<td>488 (71.2)</td>
<td>436 (74.7)</td>
<td>.173</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Bananas</td>
<td>782 (62.0)</td>
<td>405 (59.6)</td>
<td>377 (64.8)</td>
<td>.057</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>11</td>
<td>9</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Household items*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Towels</td>
<td>761 (59.9)</td>
<td>398 (58.0)</td>
<td>363 (62.2)</td>
<td>.134</td>
</tr>
<tr>
<td>Missing data (n)</td>
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<td>3</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*Continued*
<table>
<thead>
<tr>
<th>TABLE 1. Continued</th>
<th>Total (N=1,273) N (%)</th>
<th>Intervention (n=689) n (%)</th>
<th>Control (n=584) n (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermos flask</td>
<td>899 (71.1)</td>
<td>492 (72.1)</td>
<td>407 (69.8)</td>
<td>.362</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>8</td>
<td>7</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Housing: wall material&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Natural walls</td>
<td>994 (78.2)</td>
<td>561 (81.7)</td>
<td>433 (74.1)</td>
<td></td>
</tr>
<tr>
<td>Finished walls</td>
<td>262 (20.6)</td>
<td>124 (18.1)</td>
<td>138 (23.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Uncovered wall</td>
<td>15 (1.2)</td>
<td>2 (0.3)</td>
<td>13 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Housing: floor material&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Natural floor</td>
<td>933 (73.6)</td>
<td>523 (76.4)</td>
<td>4110 (70.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>335 (26.4)</td>
<td>162 (23.7)</td>
<td>173 (29.7)</td>
<td>.015</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>% poverty likelihood&lt;sup&gt;b&lt;/sup&gt; (at national poverty line&lt;sup&gt;a&lt;/sup&gt;, mean (SD)</td>
<td>0.3 (0.2)</td>
<td>0.32 (0.20)</td>
<td>0.29 (0.21)</td>
<td>.007</td>
</tr>
<tr>
<td>Missing data (n)</td>
<td>134</td>
<td>94</td>
<td>49</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: SD, standard deviation.
<sup>a</sup>Indicates variables included within the poverty probability index.
<sup>b</sup>The % poverty likelihood was derived based on the participants who had non-missing values on variables with <sup>a</sup> in the table. We excluded 6 intervention and 6 control second-born twins among live dyads assessed.

**TABLE 2.** Rates of Child At-Risk Development, by Age and Study Group, in a Cluster-Randomized Study on the Effect of Maternal Participation in a Women’s Health Education Intervention on Early Childhood Development, Tranz Nzoia County, Kenya

<table>
<thead>
<tr>
<th>Child Age (Months) (N=1,273)</th>
<th>Intervention</th>
<th>Control</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (N=5)</td>
<td>0/2</td>
<td>2/3</td>
<td>.400</td>
</tr>
<tr>
<td>2 (N=5)</td>
<td>0/2</td>
<td>0/3</td>
<td></td>
</tr>
<tr>
<td>3 (N=8)</td>
<td>0/5</td>
<td>1/3</td>
<td>.375</td>
</tr>
<tr>
<td>4 (N=6)</td>
<td>1/3</td>
<td>1/3</td>
<td>1.000</td>
</tr>
<tr>
<td>5 (N=9)</td>
<td>0/6</td>
<td>0/3</td>
<td></td>
</tr>
<tr>
<td>6 (N=6)</td>
<td>2/2 (100.0%)</td>
<td>3/4</td>
<td>1.000</td>
</tr>
<tr>
<td>7 (N=55)</td>
<td>2/29 (6.9%)</td>
<td>3/26 (11.5%)</td>
<td>.659</td>
</tr>
<tr>
<td>8 (N=86)</td>
<td>0/46</td>
<td>4/40 (10.0%)</td>
<td>.043</td>
</tr>
<tr>
<td>9 (N=132)</td>
<td>2/59 (3.4%)</td>
<td>4/73 (5.5%)</td>
<td>.691</td>
</tr>
<tr>
<td>10 (N=169)</td>
<td>0/78</td>
<td>4/91 (4.4%)</td>
<td>.125</td>
</tr>
<tr>
<td>11 (N=243)</td>
<td>1/114 (0.9%)</td>
<td>1/129 (0.8%)</td>
<td>1.000</td>
</tr>
<tr>
<td>12 (N=236)</td>
<td>3/114 (2.6%)</td>
<td>3/122 (2.5%)</td>
<td>1.000</td>
</tr>
<tr>
<td>13 (N=169)</td>
<td>2/120 (1.7%)</td>
<td>2/49 (4.1%)</td>
<td>.580</td>
</tr>
<tr>
<td>14 (N=102)</td>
<td>1/73 (1.4%)</td>
<td>0/29 (0)</td>
<td>1.000</td>
</tr>
<tr>
<td>15 (N=42)</td>
<td>3/36 (8.3%)</td>
<td>0/6</td>
<td>1.000</td>
</tr>
<tr>
<td>TOTAL</td>
<td>17/689 (2.5%)</td>
<td>28/584 (4.8%)</td>
<td>.025</td>
</tr>
</tbody>
</table>
feeding, and infant birthweight to adjust for their modifying effects on at-risk development. Mothers in the intervention arm more commonly agreed or strongly agreed with the use of physical punishment to discipline their children (80.6% vs. 71.1%; \(P < .001\)). Mean infant birthweight differed slightly between study arms, however, both were clinically normal (3.5 kg control vs. 3.4 kg intervention, \(P = .036\)). Lastly, mothers in the intervention arm more commonly delayed mixed feedings after 3 months of age compared to controls (80.1% vs. 75.4%; \(n=1260; P = .049\)).

Multivariate logistic regression models demonstrated randomized study group (\(P = .03\)), housing wall material (\(P = .018\)), and child’s age (in months) at screening (\(P < .001\)) were significantly associated with likelihood of at-risk development (Table 3). Specifically, infants in Chamas had lower odds of at-risk development compared to controls (\(OR=0.50; 95\% CI=0.27, 0.94\)) (Table 4). Participants with natural or uncovered walls demonstrated lower odds of at-risk development than those with finished walls (\(OR=0.27; 95\% CI=0.09, 0.80\)). Older infant age (in months) at the time of screening was also associated with a protective effect (\(OR=0.82; 95\% CI=0.73, 0.92\)).

### DISCUSSION

In 2015, the inclusion of ECD in the United Nation’s Sustainable Development Goals (SDGs) was a landmark in the history of global policy surrounding this issue. Protecting, supporting, and promoting ECD is essential to accomplishing the first SDG, “to ensure that all human beings can fulfill their potential in dignity and equality.” Despite invigorated efforts and national commitments to support ECD, however, programs globally remain challenged by multi-factorial obstacles including inadequate and uncertain funding, inefficient resource allocation, and persistent health disparities. Moreover, recent investments in sub-Saharan Africa have largely focused on bolstering early education for children aged 4–5 years; while important, these strategies miss a critical window to intervene during the first 1,000 days of life. In this context, we rigorously evaluated the effect of a community-based women’s health education program on at-risk development among children in rural Kenya. Our intention-to-treat analysis using a large sample from a geographically diverse catchment demonstrated a significant protective association between Chamas participation and at-risk development. Specifically, infants in Chamas demonstrated half the odds of at-risk development compared to those whose mothers received Ministry of Health recommended home visits.

The Chamas model embraces a multipronged approach to enhancing MNCH outcomes, including ECD. By providing women with opportunities to gain health literacy in a peer supportive environment, Chamas empowers women with both knowledge and community to improve outcomes for themselves and their infants during a critical developmental period. Further, among a subset of women...

<table>
<thead>
<tr>
<th>Factor</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study randomization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.50&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.27, 0.94&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Control (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Categorized mother’s age (in years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18</td>
<td>0.91</td>
<td>0.14, 5.84</td>
</tr>
<tr>
<td>18–24</td>
<td>1.42</td>
<td>0.57, 3.53</td>
</tr>
<tr>
<td>25–32</td>
<td>1.47</td>
<td>0.60, 3.62</td>
</tr>
<tr>
<td>&gt;32 (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single/divorced/separated/widowed</td>
<td>0.86</td>
<td>0.36, 2.05</td>
</tr>
<tr>
<td>Married (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>2.16</td>
<td>0.93, 5.00</td>
</tr>
<tr>
<td>Temporary work</td>
<td>3.30</td>
<td>0.97, 11.26</td>
</tr>
<tr>
<td>Self-employed/permanently employed (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Highest educational level of household head</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-primary/none</td>
<td>1.55</td>
<td>0.39, 6.11</td>
</tr>
<tr>
<td>Primary</td>
<td>1.60</td>
<td>0.47, 5.46</td>
</tr>
<tr>
<td>Secondary</td>
<td>0.65</td>
<td>0.18, 2.41</td>
</tr>
<tr>
<td>College or higher (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Housing- wall material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Natural/uncovered walls</td>
<td>0.27&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.09, 0.80&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Finished walls (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Housing- floor material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Natural floor</td>
<td>3.02</td>
<td>0.97, 9.26</td>
</tr>
<tr>
<td>Other (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Age of mixed feeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3 months</td>
<td>0.63</td>
<td>0.33, 1.20</td>
</tr>
<tr>
<td>≤ 3 months (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Attitudes towards harsh punishment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strongly agree/ agree</td>
<td>5.71</td>
<td>0.40, 81.53</td>
</tr>
<tr>
<td>Disagree/strongly disagree</td>
<td>5.42</td>
<td>0.36, 82.04</td>
</tr>
<tr>
<td>Neither agree or disagree (reference)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Child’s birth weight (in kilograms)</td>
<td>0.64</td>
<td>0.40, 1.02</td>
</tr>
<tr>
<td>Child’s age in months (in months)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.82&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.73, 0.92&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup>Excluded 168 subjects due to missing values for primary outcome or covariate data, with 1,105 children remaining for analysis.

<sup>b</sup>Statistically significant with α set at .05.

<sup>c</sup>At the time of developmental screening questionnaire evaluation.
of women that also engaged in microfinance activities through GISHE, this approach may have also helped mitigate important social determinants of health (e.g., inadequate funds to pay for health services). Though the latter is not a focus of this report (and will be explored in future publications), we speculate all 3 components of the model significantly contribute to its success. Our findings offer evidence to support that by addressing health, providing community, and offering a means to combat social determinants, this intervention may help protect children from developmental delays in this resource-limited setting.

It is important to note that at the point of DSQ testing, Chamas participants received limited education related to child development-focused topics, and instead, prioritized topics related to basic infant care, including proper nutrition, breastfeeding, watching for worrisome signs in the first 2 weeks of life, and the importance of setting routines, with 1 session on infant development. Interpreted in context, these findings underscore that when other factors known to impact child development are addressed, such as antenatal care attendance, facility-based delivery, exclusive breastfeeding, and adequate nutrition, rates of developmental delay may simultaneously decrease.\(^1\)\(^2\)\(^4\)\(^8\) This hypothesis is supported by literature from other LMICs that highlight a synergistic relationship between reinforcing positive MNCH behaviors and mitigating developmental delay risk.\(^2\)\(^8\)\(^9\) However, recent studies measured the effectiveness of 1 or 2 focused interventions on improving ECD outcomes and most have had mixed results. A recent trial that evaluated a water, sanitation, and hygiene intervention combined with nutritional counseling and supplementation in Zimbabwe demonstrated differential ECD improvement based on HIV status, with HIV-exposed children experiencing greater benefit than those uninfected.\(^3\)\(^0\)\(^1\) A home-based program in Pakistan that combined nutritional services and responsive caregiving training also demonstrated improvement in ECD outcomes.\(^4\)\(^2\)\(^4\)\(^3\) Very little data exist, however, on programs utilizing multiple concurrent strategies like in Chamas. As such, our findings build upon a growing body of evidence that supports MNCH strategies for mitigating developmental delay risk while also underscoring the importance of addressing its social determinants.

The rate of at-risk development was lower among infants in our cohort compared to population-based modeling estimates. Less than 4% of infants in our cohort demonstrated at-risk development, which is significantly lower than an estimated 45% in Kenya and 43% across LMICs.\(^3\)\(^5\) Of note, the national and international estimates of at-risk development are modeled using population data for extreme poverty and stunting as proxies for at-risk development, rather than individual-level evaluations, which generally yield greater precision. Even with more informed modeling, using data from health surveys, cohort studies, and hospital databases, the estimates of identified developmental disability in young Kenyan children is 10%,\(^3\)\(^4\) which is still higher than this trial’s estimate. Due to the varying definitions of at-risk development or developmental disability and the data used for modeling, it is difficult to compare those values with individual-level screening with the DSQ. When our findings are compared to other studies using the DSQ, rates of at-risk development within this study are comparable, albeit, still slightly lower than expected. These studies determined rates of at-risk development of 4.8%–7.3% in children under age 2 years using the DSQ.\(^4\)\(^5\)\(^6\) Within the DSQ validation trial in Bangladesh, 17% of children tested were identified as at-risk for developmental delays.\(^2\)\(^6\) Because the DSQ was administered among a myriad of other questions, the risk for response bias and interpretability of questions across different cultural contexts may complicate these results. Additional investigations, such as formative work and cognitive interviews to ensure face validity of questions, testing alongside clinical examinations, or more detailed developmental assessments, are needed to evaluate the DSQ’s adequacy in identifying infants with at-risk development in this setting.

Our study found that the majority of mothers in both the intervention and control groups agreed with using physical punishment to discipline their children, although this was more common among those in the intervention group. Corporal punishment as a discipline method is associated with worse child behavioral and developmental outcomes; however, most evidence is focused on outcomes of children older than those within our cohort (i.e., aged older than 5 years).\(^4\)\(^7\)–\(^4\)\(^9\) Positive parenting training is integrated within the Chamas curriculum after 2 years of program enrollment, thus study participants had minimal exposure at the time of assessment. Mothers would have relied on their prior knowledge and experiences to guide their views on physical punishment, which is very common in Kenya,\(^5\) and the higher rates of physical punishment use among the intervention group was likely incidental. The long-term impact of childhood physical punishment and parental exposure to positive parenting on ECD
should be explored within this cohort in future studies.

Aligned with current evidence, this study found that delayed introduction of mixed feeding was protective against at-risk development. Exclusive breastfeeding in the first 3–6 months of life has been associated with improved cognitive outcomes early in life; however, that benefit may not be maintained as children become school-aged. While the mechanism for this effect is unclear and likely multifactorial, delayed mixed feeding improves nutritional status. Malnutrition is a critical risk factor for worsened developmental outcomes. Although our analyses were limited by the absence of objective nutritional markers, we predict this adjustment would have minimally impacted our primary outcome. Children within the control group had a lower probability of poverty and, by proxy, would have been more likely to access nutritious foods. Future studies involving this cohort will work toward obtaining anthropometric measurements on study participants.

Moreover, our findings demonstrated that as the age of the child increased, the rates of at-risk development decreased. One potential explanation for this finding is related to the left-shifted or skewed distribution of age within this study cohort toward the upper end of the age range, allowing for a more reliable interpretation of the data through the model at older ages. Another potential explanation for this age-related difference is the enhanced reliability of testing in older children. The American Academy of Pediatrics recommends beginning developmental screening at 9 months, as many skills emerge by and differentiate at this age, resulting in a more reliable evaluation of developmental status. While less reliable, screening for at-risk development within younger aged children can be helpful to allow for those identified as having delays to be referred to appropriate therapies during the first 1,000 days of life, when they are most likely to gain the most benefit from the services. Longitudinal assessment of this cohort should be explored to understand the stability of developmental status over time.

An unexpected finding of our analysis was the decreased odds of at-risk development associated with uncovered or natural walls compared to finished walls. Finished walls are typically correlated with higher socioeconomic status, which has demonstrated association with improved developmental outcomes. There is evidence to suggest the quality of a child’s home environment, such as the housing quality, residential mobility, and availability of learning materials, may impact ECD. However, few studies have looked at specific housing materials, and none have specified an association between wall material and ECD. Attempting to quantify poverty status in LMICs poses significant challenges and limitations. However, tools that incorporate multiple variables to differentiate individuals on economic statuses, such as the PPI, can be helpful. While it is unclear at this time why a finding associated with higher socioeconomic status is linked with increased odds of at-risk development, we hypothesize that more complex mediators may come into play when a family has finished walls. For example, families with finished walls within their home may have 2 income-earning parents, requiring childcare for the infants. In settings like Kenya, there are limited options for high-quality, stimulating childcare, a variable for which no data were collected for this study. Another potential mediating factor may be potential exposure to lead paint, which is still used in parts of Kenya and is known to be associated with worse developmental outcomes. However, these ideas are speculative in nature and should be further explored. More delineated knowledge about household factors and their implications on child development is needed.

Our study also has notable strengths. First, by using a cluster-randomized design, we strengthen the reliability as well as contextual relevance of our results for future implementation in a community-based setting. Second, we successfully recruited and collected data on a large cohort of participants across 4 diverse sub-counties in Trans Nzoia, strengthening the generalizability of our findings. Third, by conducting an intention-to-treat analysis, our findings suggest any degree of exposure to the Chamas intervention may yield protective benefits against developmental delay. This analysis approach helps simulate a real-world context where perfect program attendance is unexpected. Fourth, this cohort was sufficiently large to generate significant results in our outcome of interest. These results help strengthen our understanding of developmental delay and potentially associated risk factors in a resource-limited setting. Lastly, we used a validated questionnaire to assess ECD, which also expands upon limited data to support the utility of this screening tool in other LMICs.

Limitations
Our study has several limitations. We experienced moderate loss to follow-up rates, highlighting
Women living within rural areas of Kenya tend to be more difficult to trace for follow-up due to limited details regarding the location of their residence (i.e., no street addresses) and lack of cell phone access or cellular network coverage. Individuals who are self-employed as casual laborers must frequently move for employment opportunities. We believe these are the major reasons for lost-to-follow-up within our cohort, but more formal analysis may be required. Another limitation to this study is that the DSQ requires mothers to subjectively affirm responses to a set of observed behaviors, which risks introduction of both response and recall biases. Screening mechanisms that triangulate data from both subjectively recorded data and observed behaviors would improve the reliability of these outcomes; however, it is worth noting that these evaluations are often cost-prohibitive, particularly in resource-limited settings. Lastly, some variables that may influence child development, such as anthropometrics and nutritional status, were not included within our follow-up evaluations due to limited trial resources. We hope future studies of this intervention will include these data to limited our analyses.

**POLICY IMPLICATIONS AND CONCLUSIONS**

A significant advantage of the Chamas model is that it leverages existing resources (e.g., CHVs) and emphasizes collaborative investment from key stakeholders to ensure the program iteratively responds to the community’s needs. While other group-based caregiver interventions have demonstrated positive results for ECD, many of these strategies introduce resource-related challenges that may compromise long-term quality and sustainability in these settings.\(^1\)\(^,\)\(^2\) A cost-effectiveness analysis of the Chamas model was performed and found to be US$46 per beneficiary, with both mother and infants included as beneficiaries, and would decrease to US$33 per beneficiary if continued within the same region over time (full analysis detailed in Supplement 3). Further, this analysis of DSQ data from a cluster randomized controlled trial demonstrated Chamas’ potential to improve ECD outcomes. Our findings suggest this community-based intervention focused on health education for pregnant and postpartum women may support ECD as compared to the standard of care. As such, policy makers should consider the Chamas model when looking to revise current strategies to help protect children from developmental delay in this setting.

In summary, maternal participation in a community-based women’s health education program was associated with lower rates of at-risk development among their children compared to the standard of care. Overall, rates of at-risk development were lower than expected for this population, warranting further investigation. Chamas may help protect children from developmental delay in rural Kenya and other resource-limited settings. Future studies are needed to clarify this association and to improve our model so that we may continue to support women and children across Kenya and in other resource-limited settings.

**ACKNOWLEDGMENTS:** We thank our study participants, community health volunteers, research assistants, and staff without whom this work would not be possible. We additionally thank the sub-county and county Ministry of Health representatives in Trans Nzoia County, Kenya, for their support and collaboration. The Chamas for Change parent trial was made possible through the generous support of the Saving Lives at Birth partners: the United States Agency for International Development (USAID), the Norwegian Agency for Development Cooperation (Norad), the Bill & Melinda Gates Foundation, Grand Challenges Canada, the U.K. Department for International Development (DFID), and the Korea International Cooperation Agency (KOICA). It was prepared by the Chamas for Change team and does not necessarily reflect the views of the Saving Lives at Birth partners or the institutions with which the authors are affiliated.

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**Author contributions:** LJR, ACD, JJS conceptualized and sought funding for this study. LYM developed the protocols and data collection instruments, with oversight from LJR. MSM helped select an appropriate screening tool to conduct developmental assessments for the parent trial, with feedback provided by LYM and LJR. GA and EK oversaw data collection activities and data management processes. All authors contributed to developing our statistical analysis plan. MSM and LYM completed the first draft of this manuscript. ZY completed all statistical analyses with significant input from MSM and LYM. All authors contributed substantially to revising this article critically for important intellectual content. All authors contributed to the final manuscript and approved submission for publication.

**Data sharing:** The deidentified data set and a data dictionary will be made available with publication of the trial after obtaining relevant Institutional Research Ethics Committee approval of a proposal and signed data access agreement. Inquiries can be made to co-author, Dr. Lauren Y. Maldonado (lymaldonado@mgh.harvard.edu).

**Competing interests:** None declared.

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Uptake of Encapsulated Ferrous Fumarate Double Fortified Salt in the Public Distribution System in India: A Value Chain Analysis

Meena Haribhau Jadhav,a Marthi Gurunath Venkatesh Mannarb

Key Findings

- Double fortified salt (DFS) interventions using encapsulated ferrous fumarate premix passed rigorous efficacy evaluations but faced challenges in showing impact at scale. Several technological, market-related, and policy barriers contributed to the reduced coverage and impact of the public-sector-led DFS interventions in India.

- Value chain analysis can be a useful method to identify and address demand and supply-side barriers to scaling up DFS in settings where the scale-up criteria are met.

Key Implications

- Initiating and sustaining large-scale encapsulated ferrous fumarate DFS interventions in the public distribution system in India involve several challenges that can be minimized through strengthening DFS value chains. Critical interventions for addressing barriers in India's DFS value chain include—building an enabling institutional environment, demand creation through consumer awareness, strengthening institutional markets through public financing, managing cost and risks through public-private partnerships, and assuring quality during commercial scale-up.

- Considering the high price of DFS when introduced through private markets and the preference of a significant population to low-cost salt options, routing DFS through the public distribution system targeting low-income populations (that enables cost reduction through bulk purchase and subsidizes the product's retail price) is essential.

ABSTRACT

Food fortification is a powerful strategy to reach large populations with multiple micronutrients added to a single food vehicle. The impact depends on the sustained provision and utilization of adequately fortified food by a large population (mainly in low-income and food-insecure settings). We apply a value chain (VC) analysis framework to diagnose and address the barriers to the uptake of encapsulated ferrous fumarate double fortified salt (DFS) distributed through public-sector-led DFS interventions in India.

We adapt the VC requirements framework proposed by Henson and Humphrey to identify and categorize barriers along the DFS VC as technological, market-related, and policy-related. We conducted a desk review of published and unpublished literature on DFS and information available in the public domain, semi-structured interviews with VC stakeholders from the private sector, program data from implementing organizations, and participation in multistakeholder consultations on DFS.

Major supply-side barriers were under-developed private markets, inconsistent demand from public markets, unpredictable returns-on-investments, and inadequate business incentives to invest in DFS. The product's weak consumer orientation, uncreated consumer demand, low awareness of fortified foods, inadequate nutrition signaling were significant demand-side barriers. Technological barriers related to the requirement of high-grade salt for DFS production and residual organoleptic property of mild discoloration of food. Policy barriers related to inadequate and irregular financing for distributing subsidized DFS through the public distribution system; insufficient policy support for risk-sharing and managing costs associated with fortification; and a weak institutional environment for sustaining DFS interventions.

Building an enabling institutional environment, demand creation through consumer awareness, strengthening institutional markets through public financing, managing cost and risks through public-private partnerships, and assuring quality during commercial scale-up are critical interventions necessary to ensure impact at scale.

INTRODUCTION

This article focuses on the University of Toronto double fortified salt (DFS) formulation (iodized salt fortified with iron) that uses the microencapsulated ferrous fumarate DFS (EFF-DFS) technology. While evidence on the effectiveness of DFS to reduce anemia in large-scale applications is still evolving, the efficacy of DFS has been proved.1-3 After a successful launch of DFS...
interventions in several states, the uptake of DFS in India has been slower than expected and has met several challenges. The purpose of this study is to diagnose and address the barriers that restrict the uptake of DFS through the public distribution systems in India. The intention is not to advocate for DFS but review its application through public distribution systems in India and propose solutions that can strengthen existing DFS value chains.

Micronutrient deficiencies affect nearly one-third of the global population and transcend generations, severely limiting individual potential and national development. Iron deficiency is one of the major problems of public health concern worldwide, with adverse consequences related to maternal and child health, cognitive development in children, and work productivity in adults. At least 25% and 37% of the anemia burden in preschool children and women of reproductive age, respectively, is associated with iron deficiency and is mainly a result of dietary deficiency.

Pharmaceutical supplementation programs have shown limited impact as they are often resource-intensive and face challenges related to product availability, the functioning of supply chains, cultural acceptability, coverage, compliance, and sustainability. Food-based approaches promoting foods naturally rich in micronutrients or enriched through fortification are viable, cost-effective, and sustainable solutions to micronutrient malnutrition, especially in developing countries.

Food fortification, in particular, can reach large populations with multiple micronutrients added to a single food vehicle that is consumed widely and consistently. The World Health Organization included the reduction of anemia prevalence in women of reproductive age group by 50%, as one of the global targets for improving maternal, infant, and young child nutrition, to be achieved by 2025. Providing iron through large-scale fortification—along with addressing other determinants of micronutrient malnutrition (such as sanitation and health care)—is an essential intervention to achieve this global nutrition target. Sustained provision and utilization of adequately fortified food, reaching a wider population (especially those affected by micronutrient deficient diets), is critical to improving micronutrient intakes through food fortification. Salt is a universally available and affordable commodity, consumed daily in almost uniform quantities in all parts of the world. It is centrally processed and packaged, and hence an ideal food vehicle for fortification. The Universal Salt Iodization program, with mandatory salt iodization now covering 129 countries, have established the potential of salt as a global carrier of micronutrients on a continuous and sustained basis—a unique advantage over most other food vehicles.

Building on these efforts, attempts to include iron and other micronutrients along with iodine to salt are being tested and scaled up in India. Along with DFS, variations of multiple fortified salts have been developed at the University of Toronto research laboratory as a potentially viable strategy to alleviate other nutritional deficiencies such as folic acid, vitamin B-12, and zinc (Levente Diosady, University of Toronto, personal communication, June 2020). This study reviews the application of DFS to inform the design and implementation of fortified salt formulations in the Indian context. We apply a value chain (VC) framework to diagnose and address the supply- and demand-side barriers along the DFS value chain (DFS-VC) that restricted the uptake of DFS in the Indian context, specifically focusing on the public-sector-led interventions. A VC is defined as the full range of activities required to bring a service from conception, through different phases of production, delivery to final consumers, and final disposal after use.

Food VC approaches have been mainly used to improve the livelihoods of food processors, streamline the supply chain, and maximize profits, and in rural development to enhance commercial relations for economic benefits. Value chain analysis (VCA) has been used to investigate food production, nutrition, and food safety in the dairy VC in Tanzania, reduce micronutrient deficiencies while creating livelihood opportunities for VC actors through the introduction of fortified rice in Myanmar, assess the potential of the private sector manufacturers of fortified foods to reach poor households, and evaluate the status of flour fortification in Kenya on the adoption of mandatory fortification practices by millers. Thus, in the nutritional context, VCA is used as a diagnostic tool for food-based VCs to identify barriers (and potential solutions) to improved availability, accessibility, affordability, and acceptability of micronutrient-dense foods. VC-based solutions include a broad range of interventions such as information and education, research and technology, chain reorganization, and financial incentives to develop new policies and standards—used singly or in a combination.
METHODS

Methods and Analytical Framework for the DFS-VCA

Applying the VCA method \(^{19}\) (Box) calls for different approaches depending on the VCA context and objectives. The narrow perspective of VCA is limited to the activities of a single firm and its position in relation to its suppliers and buyers. In its broad perspective, VCA looks at the complex range of activities of VC actors, moving from the production of raw materials along the linkages with other enterprises engaged in processing, trading, retailing, etc., to its final link with the consumers. \(^{20}\) Both the narrow and broader approach can sometimes transcend geographical boundaries (global VCs) depending on the location of value-chain stakeholders, especially retailers and buyers. We use the broad approach of VCA throughout this article.

Through this exploratory study, we identify barriers (and potential solutions) to the uptake of DFS in the Indian context. We adopt a qualitative approach using the VCA as a tool for data collection and as a framework for analysis. Through VCA mapping, we begin by outlining the DFS-VC, its core functional components and processes, key stakeholders (actors), and their roles. Next, applying the “requirements of the VC for nutrition interventions” framework, \(^{21}\) we identify barriers to the DFS-VC functioning and development in India. Finally, we review the literature that addresses barriers and solutions to strengthen the VCs in the nutritional context and inform the development and strengthening of the DFS-VC in India.

Data sources include a desk review of policy documents and information available in the public domain on DFS; consumer data from sensory trials; program data from a DFS field intervention in Uttar Pradesh, India; and field implementation experiences of organizations implementing DFS interventions. All sales data and price data used in this report are from manufacturers’ records, as shared by their representatives. The first author interviewed 1 premix producer and 3 DFS producers to collect primary data on DFS production and sales. Two more salt producers were interviewed briefly, but we could not get in-depth data from these sites. Limiting the field visits to large-scale manufacturers supplying DFS to ongoing public sector interventions, we visited the DFS production plants located in the major salt-producing states of Gujarat, Rajasthan, Tamil Nadu, and the premix production plant in Rajasthan. The information collected through these semi-structured interviews was further enriched and validated by documenting stakeholder perceptions in 3 national-level DFS consultations attended by the first author. The consultations involved representatives from the salt industry, organizations implementing DFS interventions, and government representatives. Data were analyzed qualitatively using thematic analysis based on the themes of the VC requirements framework. \(^{21}\) The Supplement Table presents the data collection and analysis framework.

VCA methodology has been applied for assessing nutrition VCs using different frameworks. \(^{21–24}\) Barriers in VCs of other commodities relate to consumer taste preferences and perceptions of nutritional value, regulatory failures, and institutional constraints, \(^{25}\) inadequate VC coordination, and weak producer organization, \(^{26}\) low and uncreated demand, barriers to the managing of costs, risks,

**BOX.** Value Chain Analysis Framework

1. Systematically map the core processes involved in taking a raw material through various stages of production, storage, and distribution, to the final consumption of the end products.
2. Map actors along the VC (e.g., producers, distributors, retailers, and consumers) and assessing their relationships in terms of the flow of products and information, profits and cost structures, destination, and volumes of domestic and foreign sales.
3. Identify the distribution of benefits along the VC by analyzing the margins and profits.
4. Assess the VC governance:
   - Internal: relationships and coordination mechanisms between VC stakeholders such as setting criteria for other actors like quality standards, delivery times, and volumes
   - External: institutional arrangements, legislation, and regulations
5. Examine the potential for upgrading at all stages along the VC through constraints and opportunities analysis.

Abbreviation: VC, value chain.
and uncertainty for businesses, poorly developed markets and resulting low availability, and requirement of long-term funding for public distribution.27 Thus, VC barriers span the full spectrum of the demand-supply continuum and require a comprehensive framework for evaluation. To identify the barriers to the development and functioning of the DFS-VCA in India, we adopt a comprehensive framework including both demand- and supply-side requirements for well-functioning VCs.21 The absence of these requirements can be viewed as a barrier to the efficient functioning of the VC. The critical requirements are extracted from sources (Table 1).21,28

To make our assessment more action-oriented, we further elaborate the framework to categorize the barriers as related to technology, market, and policy.

**FINDINGS**

**Mapping the Core Components, Processes, and Stakeholders of the DFS-VC**

The core components of the DFS-VC are schematically mapped in Figure 1 and further elaborated here.

**Raw Materials Used in EFF-DFS Production (Iodized Salt and DFS Premix)**

India ranks third in salt production behind the United States and China, producing approximately 28 million of the 280 million tons of annual global salt production. Of the 28 million tons produced annually in India, human consumption accounts for 6 million tons, mostly as iodized salt. Three states: Gujarat, Rajasthan, and Tamil Nadu, produce respectively 70%, 18%, and 11% of the iodized salt produced in the country. The private sector contributes to more than 95% of salt production. The Bureau of Indian Standards sets production standards for iodized salt and DFS. The specifications for EFF-DFS production require a higher salt purity (when compared to iodized salt) of ≥98% sodium chloride, lower moisture (<1.5%), and magnesium contents (<0.1%).29

DFS is prepared by adding the EFF-DFS premix to refined iodized salt. The premix consists of a ferrous fumarate iron core that is color-coated using food-grade titanium dioxide and encapsulated using hydroxypropyl methylcellulose and hydrogenated soy oil to form an encapsulated ferrous fumarate premix. Ferrous fumarate is the common form of iron used in multi-vitamin-mineral tablets. It is a recommended formulation for salt fortification based on organoleptic and bioavailability considerations. However, it is dark brownish and needs to be color masked before encapsulation and blending with salt for addition to foods. Titanium dioxide is an [U.S. Food and Drug Administration] -approved food-grade whitener, which is used in EFF-premix production to mask the dark brownish color of ferrous fumarate and make a white premix particle for blending into salt — Levente Diosady, University of Toronto, Personal communication, June 2020

This premix is added to iodized salt at a 1:160–200 ratio to produce DFS with iron content at the specified level (850–1100 ppm).30,31

**DFS Premix and DFS Production**

Three DFS premix production plants in India—located in 3 states: Rajasthan, Gujarat, and Maharashtra—use the EFF technology. These plants supply premix on-demand to the DFS manufacturing plants that are currently operational in the country. The capital cost of building a premix production plant with a capacity of 1500 tons/year is estimated to be approximately INR 70 million (approximately US$1 million). To date, India has a DFS premix production capacity of approximately 6,000 metric tons/year (adequate to produce approximately 1 million metric tons of DFS). However, only 10%–20% of this capacity is currently used due to low market demand for DFS. There are nearly 19 salt producers in India who hold a license from the Food Safety and Standards Authority of India (FSSAI); however, only 6–7 are currently operational. Figure 2 maps the number and the geographical locations of the DFS and premix producers in the country. DFS manufacturers must purchase the premix and blend it with refined iodized salt in their salt plants to produce DFS. To blend the premix with iodized salt, DFS producers require additional equipment costing approximately INR 10 million (approximately US$0.14 million). Salt fortification in India has 2 unique advantages: an established domestic salt production and distribution capacity and the concentration of more than 60% of the edible salt market across a small number of private producers (4 to 5), potentially facilitating a public-private partnership. Four years since the inclusion of DFS interventions among public health approaches to address iron deficiency anemia, the DFS market in India is still in its infancy. DFS reached approximately 4% of the country’s population mainly contributed by the public-sector distribution across 6 states in 2018. Based on geographic coverage of the DFS interventions, the implementing states accounted for varying
levels of population coverage ranging from (1% to 23%) (author’s calculations) (Table 2).

**The Current Market and Distribution Channels of DFS**

DFS distribution in India is predominantly routed through VCs of 3 major public food distribution programs with a minuscule contribution through private sector markets. Consequently, the beneficiaries of the public food distribution programs are the major consumers of DFS. The 3 major public food distribution channels operational across India are the public distribution system (PDS), the mid-day meal scheme for school children, and the Supplementary Nutrition Program for preschool-age children under the Integrated Child Development Services Scheme. The PDS (implemented through the Ministry of Consumer Affairs, Department of Food & Civil Supplies) is the key arm of India’s food security system to provide essential foods to low-income populations at subsidized prices. There are more than 500,000 PDS outlets across India (also called fair price shops), serving more than 800 million beneficiaries (75% of the

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**TABLE 1. Demand- and Supply-Side Requirements for a Well-Functioning Value Chain for Double Fortified Salt**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition awareness</td>
<td>Consumers will value nutrient-dense foods only if they are aware of the benefits of improved nutrition</td>
</tr>
<tr>
<td>Signaling</td>
<td>Consumers should have the knowledge and skills to identify nutrient-dense foods from those that are not</td>
</tr>
<tr>
<td>Availability</td>
<td>Nutrient-dense foods should be available in locations that are accessible and socially acceptable to the consumers</td>
</tr>
<tr>
<td>Affordability</td>
<td>Consumers should be able and willing to pay for the added cost of fortification</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Nutrient-dense foods should be acceptable to consumers based on physical appearance, organoleptic properties, consumption patterns, and preparation practices</td>
</tr>
<tr>
<td>Capturing value</td>
<td>Actors along the VC should be able to capture a sufficient share of the value they create through their contributions to the production processes of nutrient-dense food</td>
</tr>
<tr>
<td>Sufficient incentives along the VC</td>
<td>The value captured along the VC should be equitably distributed to actors in the form of incentives</td>
</tr>
<tr>
<td>Value coordination and governance</td>
<td>The VC stakeholders are individual entities that are interdependent and therefore require efficient coordination in sharing of information, alignment of business strategies, and implementation of joint promotional activities</td>
</tr>
<tr>
<td>Managing costs, risks, and uncertainty</td>
<td>The added costs and risks for adding additional nutrients to foods requires public policies that promote and sustain partnerships between the private business and the public sector</td>
</tr>
<tr>
<td>Appropriate institutional environment</td>
<td>Adequate institutional mechanisms are required, such as legal frameworks that shape markets, food standards and regulations, and policies for managing costs and risks</td>
</tr>
</tbody>
</table>

Abbreviation: VC, value chain.

**FIGURE 1. Simplified Representation of the Double Fortified Salt Value Chain in India**

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To date, at least 20 states procure free-flow refined iodized salt for distribution through the fair price shops. In 2016, DFS was introduced through the PDS, starting with Jharkhand and Uttar Pradesh, followed by a few other states: Andhra Pradesh, Telangana, Karnataka, and Rajasthan. Iodized salt and DFS distribution through the PDS are state-initiated interventions and not centrally funded. They vary in coverage (statewide vs. few districts, processes (prices/subsidies and quantities distributed), and sustainability (duration of government commitment to supply subsidized DFS/replace existing subsidized iodized salt).

In 2017, the Ministry of Women and Child Development, which oversees the Integrated Child Development Scheme, and the Ministry of Education, which oversees the mid-day meal scheme (the central government’s 2 food distribution programs that serve hot cooked meals to preschool and school-age children) issued directives requiring the use of DFS in those schemes. Following the directive, the supply of DFS through these channels was expected to increase significantly. In public institutions such as panchayats, Integrated Child Development Scheme block offices float local DFS procurement tenders for distribution of DFS to their beneficiaries. Medium-sized retailers bid for these tenders purchase DFS from manufacturers (often rebranding the DFS with their names) and supply the Integrated Child Development Scheme and mid-day meal programs. Notwithstanding the strong political commitment and the promotion of DFS by the Government of India, the process of scaling up DFS in the public sector at the state level has been slower than expected.

FIGURE 2. Map of Double Fortified Salt and Premix Producers in India
DFS flows through established commercial distribution channels for iodized salt in the open market and passes through 4–5 middle-level wholesalers and retailers before it reaches retail stores for sale. Although there are currently at least 10 different brands of DFS launched in the private sector, these brands have near negligible sales and have not penetrated the commercial market. High production cost, low demand for DFS, and organoleptic changes in stored salt and cooked food have been identified as the main reasons. Nonetheless, India is the single largest producer and consumer of DFS globally, mainly due to the inclusion of DFS in the government’s food security programs. The DFS-VC in India is a unique model of private production and public distribution. A total of approximately 180,000 metric tons of DFS was produced by private sector salt manufacturers and supplied to public distribution programs in 2018 (Table 2).

The DFS-VC in India is a unique model of private production and public distribution. The DFS-VC in India is a unique model of private production and public distribution. A total of approximately 180,000 metric tons of DFS was produced by private sector salt manufacturers and supplied to public distribution programs in 2018 (Table 2).

### The Consumer VC of DFS

Institutional markets currently drive the demand for DFS in India. The beneficiaries of the PDS and ICDS are the primary consumers of DFS in the country (estimated DFS coverage under these schemes in 2018 at 50 million of the approximately 750 million active beneficiaries in India). They constitute a large population, mostly low-income, primarily concentrated in the rural areas, with often low awareness on nutrition and even lower on fortification, and a preference for low-cost products for daily household needs. These populations rely more heavily on purchasing essential foods at subsidized prices through the PDS. However, these populations also have cultural habits related to salt usage, such as a preference for the crystal salt and family traditions of buying specific salt brands. They also have expectations of the taste and appearance of cooked food that DFS formulations have to meet (research experiences of the author).

### VC Governance and Policy Environment

VC governance can be categorized at 2 levels: (1) Internal, coordination of the VC stakeholders directly involved in the production and supply of the fortified commodity; (2) External, legislative, and governmental policies that govern the functioning of the VC. The internal governance mechanism of the DFS-VC in India is currently fragmented and unorganized. At the external level, the FSSAI under the Ministry of Health is the central regulating and monitoring agency for food products, including DFS. It has set standards...
for nutrient levels and permitted stabilizers/coating agents in DFS; standards of DFS quality, packing, and labeling of DFS packets; and standards for quality assurance at DFS factory premises. FSSAI also houses the Food Fortification Resource Centre, which acts as a program management unit for the FSSAI to inform, promote, manage, and coordinate activities related to fortified food products. Table 3 lists the key stakeholders involved in the DFS-VC and their functions that contribute to the VC.

### TABLE 3. Stakeholders of the DFS VC in India and Their Roles

<table>
<thead>
<tr>
<th>Component of DFS VC</th>
<th>Organizational Set-up/Stakeholders</th>
<th>Process/Function</th>
<th>End Product/Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production of raw material</td>
<td>Manufacturers of pharmaceutical/food grade ferrous fumarate</td>
<td>Production of pharma grade iron from crude iron</td>
<td>Ferrous fumarate powder (used in iron pharmaceutical preparations and DFS premix)</td>
</tr>
<tr>
<td>DFS premix production</td>
<td>Manufacturers of: Durum semolina wheat flour, Titanium dioxide (food grade), HPMC, HSO</td>
<td>Production and supply of raw materials required for binding and encapsulating the ferrous fumarate iron core: Durum Semolina – for binding of ferrous fumarate powder, Titanium Dioxide – used as a whitening agent, HSO and HPMC – used for encapsulation</td>
<td>Other raw materials (food grade/pharma grade) (used in the food processing/pharma industry and DFS premix production)</td>
</tr>
<tr>
<td>DFS premix production</td>
<td>DFS premix manufacturers</td>
<td>Ferrous fumarate powder binding to produce DFS premix core through a process of binding and extrusion. These particles are then coated with a whitening agent (Titanium dioxide) and encapsulated using soy stearin and HPMC coating</td>
<td>DFS premix</td>
</tr>
<tr>
<td>DFS production</td>
<td>Salt manufacturers</td>
<td>DFS premix is procured by salt manufacturers and blended with iodized salt to produce DFS</td>
<td>DFS</td>
</tr>
<tr>
<td>Storage distribution and marketing</td>
<td>Raw salt producers</td>
<td>Small scale raw salt producers mine salt from sea or lake brine and sell raw salt to refineries for further processing</td>
<td>Raw salt for processing to refineries/salt manufacturers</td>
</tr>
<tr>
<td>Consumption of DFS (Consumer value chain)</td>
<td>Beneficiaries of public food distribution programs</td>
<td>Consumption of food cooked with DFS or receiving subsidized DFS for use at homes</td>
<td>Regular use of DFS</td>
</tr>
<tr>
<td>Value chain governance</td>
<td>Consumers in the private sector</td>
<td>Purchase of table salt from markets and choice of salt</td>
<td></td>
</tr>
<tr>
<td>Value chain governance</td>
<td>Salt producer and trader associations</td>
<td>Salt producer and trader associations: Coordination between salt producers and traders</td>
<td>Developing and sustaining the DFS market</td>
</tr>
<tr>
<td>Value chain governance</td>
<td>Food Safety and Standards Authority of India</td>
<td>Setting of fortification standards</td>
<td>Promotion of fortified products through capacity building and training of manufacturers and promotional campaigns among consumers</td>
</tr>
<tr>
<td>Value chain governance</td>
<td>Confederation of Indian Industry</td>
<td>Developing a market for DFS and other commercial coordination</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DFS, double fortified salt; HPMC, hydroxypropyl methylcellulose; HSO, hydrogenated soy oil; VC, value chain.
Barriers Along the DFS-VC

Technology-Related Barriers
The technology-related barriers mainly affect 3 aspects of the VC requirements: availability, affordability, and acceptability. Fortification has added costs, which the consumers often bear unless the costs are subsidized through public interventions. The premix cost is a significant addition to the price of fortified foods (estimated at 80%–90% of the incremental cost). Consumers must either be willing to pay for this incremental cost (with the precondition that they are aware of the increased nutrient content) or be provided with subsidized DFS through public funding. Another limitation of technology that affects affordability and availability is that high-quality salt is required for DFS production. Approximately 60% of salt in the Indian market falls in the high-grade category. Refining some salts to suit the technological and regulatory requirements of DFS is cost-intensive. State governments who invite proposals to supply DFS set up a competitive process based on the lowest-bidder contracting system, lowering the price to a bare minimum with minimal profit margins for the producers. This results in salt manufacturers compromising the quality of salt and premix used for DFS supplied to public programs.

Food fortification works best when it is a covert intervention and indistinguishable from the regular food items in its sensory properties. Technological limitations of the premix encapsulation and the compromised quality of encapsulation during commercial scale-up affect the product acceptability. Under well-controlled manufacturing conditions, it is possible to produce a high-quality premix that would produce DFS with minimal organoleptic changes when blended with a high-quality refined salt. However, when the quality of the premix or the raw salt is compromised (such as weak encapsulation of premix or substandard raw salt), the premix particles are more visible, and the discoloration of food (an inherent property of iron) is more intense.

Private and Public-Sector Market-Related Barriers
Market-related barriers are identified as the main constraints to the VC development of DFS. The barriers resulting in a weak DFS market affect almost all aspects of the VC requirements such as nutrition awareness; nutrition signaling; availability; affordability; acceptability; sufficient incentives along the VC; VC coordination and governance; managing costs, risks, and uncertainty; and sufficient investments for the VC stakeholders; VC coordination and governance; and managing costs, risk, and uncertainty (on the supply side). There is currently an uncreated demand for DFS, especially as a nutritional product. Low awareness regarding fortification is the primary reason for this uncreated demand. Mechanisms for nutritional signaling in the case of DFS are inadequate and have not reached most consumers, especially from the low-income groups. Institutional demand for DFS from public sector markets has been unpredictable and inconsistent. Bundling DFS with ration kits in the PDS did not necessarily ensure utilization at the consumer level (as consumers preferred to use their regular salt to which they were habituated). At the same time, behavior change interventions by governments were minimal. Additionally, the low market value of DFS and unpredictable returns make DFS a high-risk investment for salt and premix manufacturers. Fortification also involves an increase in the cost of production, primarily contributed by the premix. In the absence of subsidizing mechanisms, these costs are transferred to the consumers. Salt is a low-priced and inelastic commodity offering little scope for value capture by VC actors. An average family of 5 members spends less than INR 180 (US$2.40) annually on salt. Increased purchase and consumption of DFS is possible only if it replaces the iodized salt that consumers currently buy. Price-conscious consumers opt for a lower-value product of the same brand. In the absence of information on fortification and the low value given to salt as a nutritional product, lower-income households prefer to buy the low-priced options of iodized salt (several such brands are available with a sizeable rural market). The slow-moving DFS-VC due to uncreated demand for fortified foods is the main reason the VC stakeholders cannot capture sufficient value for the services they provide. Additionally, the DFS-VC is still undeveloped and fragmented, and the VC stakeholders are not organized. Also, policy support for risk-sharing between public and private sectors has been inadequate.

Policy Barriers
Policy barriers for DFS uptake relate to nutrition awareness, nutrition signaling; availability; affordability; acceptability; sufficient incentives along the VC; VC coordination and governance; managing costs, risks, and uncertainty; and appropriate institutional environment. Nutritional awareness and empowering consumers with signaling mechanisms are primarily public-sector functions. Such mechanisms, though existent, have been inadequate. The private sector rarely
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The current DFS-VC in India can be characterized as “low demand and inconsistent supply.”\textsuperscript{22} VC researchers have suggested the following interventions for VCs with these shortcomings: capacity building for primary production, producer organization, social marketing to stimulate demand, subsidies for consumption, and incentives for risk taking by producers and retailers.\textsuperscript{22} However, the following challenges are anticipated while pushing an innovative product such as DFS in VCs, especially through public-sector channels.

- Demand assessment is challenging for innovative products. Inflexible and inefficient supply chains could lead to shortages affecting the availability or overstocking of the product in the field affecting quality and consumer acceptability given the relatively short shelf life of DFS.
- A mass media campaign is necessary for overcoming the technological limitations of DFS, such as visible premix particles and color change of cooked food; however, behavior change takes time.
- Considering the slow uptake of DFS, governments would tend to replace the product with alternatives (where available) or divert the limited funding to other interventions.
- Consumer forums and citizen groups may perceive the pushed product as an infringement on their rights.
- Producers may find DFS a risky investment, given the uncertainty around DFS uptake and scale.

While these are valid concerns, DFS is still in the testing phase, and conclusive decisions would need program maturity. Focusing on strengthening the DFS-VC and closely monitoring and demonstrating the impacts on the nutrition status of populations would still make it a worthwhile intervention.

Successful DFS interventions would need a public health movement with cross-sectoral partnerships involving governments, producers, donors, researchers, and people representatives to build an environment where the innovation would survive and thrive. We propose the following interventions for strengthening the DFS-VC in India, in order of priority: building an enabling institutional environment, demand creation through consumer awareness, managing costs and risks through public-private partnerships, strengthening institutional markets through public financing, and assuring quality during commercial scale-up.

**Building an Enabling Institutional Environment**

Researchers adopting a VC approach have observed that political commitment is essential for the sustainability of food fortification interventions that are often business-driven but led by governments or donors.\textsuperscript{36} DFS programming and
implementation in India is characterized by fragmented efforts by a couple of organizations with limited coordination at the national level. Advocacy efforts by these organizations have led to its inclusion in policy documents but without committed budgets. Initiating and sustaining DFS interventions are left to the Food and Civil Supplies department of state governments, who consider anemia reduction a health department mandate. Therefore, the leadership of the nutrition and health-related departments and national organizations at the central level backed by funding for the states is needed. However, with limited evidence on effectiveness, DFS remains an unproven product and has yet to attract the attention of public health advocates outside the fortification sector. The successful implementation of 2 well-established salt-related public health programs in India—universal salt iodization and salt reduction—promises a unique model for joint efforts and increased impact.

**Demand Creation Through Consumer Awareness**

Consumer demand is the key driving factor around which the other elements, such as production capacity, distribution and supply chains, and marketing, get organized. In comparison to iodine, promotional activities around DFS have been minimal and nongovernmental organizations advocating for DFS are few. Mass media have been successfully used in India in other public health programs such as family planning, HIV prevention, and the salt iodization program. Such mass-media communication in the case of DFS is challenging due to the current perception of DFS as still an experimental product (mainly due to issues of acceptability resulting from a slight color change of food cooked with DFS, and the risk of being mistakenly perceived as promoting higher quantities of salt in the diet). Joint messaging in partnerships with salt reduction programs and the communication messages around anemia reduction in complementary interventions would help bolster the program.

**Strengthening Institutional Markets Through Public Financing**

High investments required for quality DFS manufacturing increase the market price of DFS by 30%–50% higher than iodized salt. In private markets, the additional costs are passed on to the customers limiting DFS to be viewed as a premium product targeted at high-income consumers. In the public sector, this cost difference is much lower due to bulk purchasing (15%–30%). Given this evidence and the preference of a significant proportion of consumers to low-cost salt options, the public sector channeling DFS at a subsidized rate to low-income populations is essential. The market for DFS in India is currently driven and sustained by the public sector channels such as the PDS. In the absence of awareness of fortified products, and consequently, low demand for DFS, promoting and ideally having mandatory inclusion of DFS in public food distribution programs (especially the PDS with expansive coverage of nearly 70% of the country’s population), along with adequate investments in behavior change interventions, is the quickest way to deliver the DFS to large low-income populations. Considering the low consumer demand, we suggest a quasi-mandatory approach, where DFS is mandatorily part of the government-subsidized food basket kit and available at all outlets. However, its purchase at the consumer level should be voluntary. Thus, ensuring the availability of DFS at purchase points near consumer homes and curbing any profit-driven promotion of DFS through the government channels. Demand-based inclusion of DFS in the PDS would create a more long-standing and assured market for DFS, leverage the currently underutilized capacity of DFS production plants, and create incentives for the private sector to further invest in expanding the DFS production.

Considering the public health importance of DFS and its potential to benefit large populations in a cost-effective manner, governments may also provide financial incentives to DFS producers until the programs achieve maturity. These incentives may include central government funding for subsidizing DFS, exemption or reduction of taxes on premix, and concessions in transportation taxes. When supplied and subsidized by the PDS, the incremental costs of DFS can be absorbed by government budgets to reach low-income and price-conscious consumers with DFS priced lower than the cost of iodized salt in the open market. Low-income populations are vital demography to which micronutrient interventions are directed. Routing subsidized DFS through the PDS targets the most vulnerable and affected populations at scale with more significant impact, simultaneously creating an assured public sector market that acts as a risk-sharing mechanism between businesses and the governments. While the financial burden of subsidies on government budgets is assumed to be significant, depending on their fiscal space, state governments have the choice to
provide 1 or more items, such as edible oil, sugar, kerosene (cooking fuel), and iodized salt, at subsidized rates.

Managing Cost and Risks Through Public-Private Partnerships
Investing in VCs of nutrient-dense foods serving low-income populations can involve significant risk and uncertainty for businesses. However, it could also offer an avenue to expand the market share of businesses that have already saturated the high-end markets. Public-private partnerships are an effective strategy for orienting food and nutrition VCs to the nutrition requirements of the low-income populations and those most affected by nutritional deficiencies. These partnerships can enable investments in new product development of fortified foods, expand the distribution network for existing fortified foods in rural areas, and influence consumer preferences to strengthen consumer demand for micronutrient-rich processed/packaged foods. In the case of DFS, the private sector has been limited to DFS production and supply to the state governments with DFS interventions, limiting their status to that of a contracted vendor. The salt industry has not been a partner to the public health movement around DFS, despite India having a corporate social responsibility mandate for large private organizations. However, it is encouraging to note that at least 6–7 salt producers have included DFS as a trial product and have actively bid for government procurement tenders. With an enabling institutional environment, private producers could invest in new business opportunities through DFS. The public-sector channels distributing DFS may benefit from the private-sector strengths in product research and branding, advertising and marketing, and efficiency in supply chains. Simultaneously, the public sector could offer incentives to cover the financial risks to producers investing in a low-demand product, as elaborated in the section related to institutional strengthening through public financing.

Assuring Quality During Commercial Scale-Up
There is a risk of quality being compromised during the commercial scale-up of an innovative product. The government plays a crucial role in providing guidelines and enforcing quality through rigorous checks and monitoring along the VC. Presently, the government has limited resources for establishing a robust monitoring mechanism. Donor commitments in this area through funding support and technical expertise to strengthen government capacity in this function are suggested.

This article is the first-ever review of DFS from a VC perspective and identifies bottlenecks to DFS uptake and opportunities for improvement along the VC. It also helps understand the trade-offs involved in scaling DFS as a public health strategy to address iron deficiency anemia. Additionally, it identifies solutions to be implemented through a VC framework, as often low-stream coverage problems need fixing further up the VC. The article contributes to the VC literature as an example of a practical application of the broad VCA approach to an important public health intervention to address a widely prevalent nutritional deficiency. Our article highlights the critical role of policy for the survival of an innovative health product in a low-demand market. It brings out the challenges of implementing a public health program that heavily relies on the private salt industry but is driven by government health mandates.

Finally, our findings are specific to the Indian context. The situation of India is unique due to the presence of a country-wide public sector delivery platform that enables cost-effective channeling of privately produced DFS to low-income consumers at accessible delivery points and a subsidized rate. Other countries may need different models to achieve the same level of efficiency and cost-effectiveness. They may need different subsidization mechanisms at the level of producers or consumers. Nonetheless, considering the scale of its programs, India would serve as a significant learning lab for effectiveness studies for DFS interventions once these programs attain maturity.

Limitations
With the introduction of DFS in public health programs to address anemia as recently as 2016, the VC of DFS in India is still in the developmental stages. Performing a VC analysis at this early stage was challenging due to fewer stakeholders representing the salt industry and being actively engaged in DFS production, resulting in a small sample size for data collection. Therefore, a qualitative approach was adopted using mixed methods, relying heavily on secondary data (or physical records) and unconventional data collection methods such as consultation workshops. Reliance on secondary data may have affected data quality. Also, most of the insights for the DFS-VC come from the public sector markets (government-driven DFS interventions), missing out on the private domain due to the negligible or
near-absent presence of DFS in the open market. The private sector perspectives outlined in the article relate to a few large-scale manufacturers supplying DFS to public sector programs. Their opinions are likely biased in favor of DFS linked to commercial considerations. However, given the fact that all the 3 DFS producers mentioned DFS as a failed product in the private sector (due to costs and color change of cooked food) rules out any biased responses from these manufacturers. Also, we missed out on the perspectives of other private salt manufacturers who attempted to launch DFS in the private sector but failed and others who never adopted DFS. Their insights are likely to inform action further to reposition the intervention more sustainably.

### CONCLUSION AND POLICY IMPLICATIONS

In conclusion, we identify market-related barriers as the main challenge for DFS uptake in India. The uncreated demand for fortified products (including fortified salt) and the resulting low market are crucial challenges. However, creating a need for a public health good where none exists is primarily considered a role of the public sector. Therefore, building an enabling institutional environment through public policies that promote the DFS market and regulate quality during commercial scale-up are crucial policy actions for sustainable DFS interventions. Government ownership and support for the production and promotion of DFS are essential for expanding and sustaining demand for the product. Long-term funding commitments by the government for distributing subsidized DFS could be the trigger to accelerate scale-up in the public sector (encouraging DFS producers to promote the product in the private sector simultaneously). However, once the programs achieve maturity, investments in DFS should be periodically reviewed to examine evidence on nutrition outcomes and cost-effectiveness. Strengthening DFS value chains is critical to realize the potential of DFS to have a large-scale impact in reducing iron-deficiency anemia in India.

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Using a Pharmacy-Based Surveillance System to Improve Standards for TB Care in Kerala, India

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Key Findings

- Efforts to strengthen implementation of Schedule H1 regulation involved increasing advocacy efforts with the state government and local stakeholders, improving communication with stakeholders, educating chemists on data collection, and improving the quality of documentation of prescriptions.
- State program managers of the National TB Elimination Program used the information from Schedule H1 registers to identify missing TB cases and improve TB notification, identify providers who prescribe private anti-TB drugs and sensitize them to the Standards of TB Care in India, and sensitize providers on prescribing practices for TB.

Key Implications

- Program managers may use pharmacy-based surveillance data judiciously to identify the missing TB cases, engage health care providers in prescribing practices, and improve the quality of TB diagnosis and care.
- Policy makers may realize the potential of pharmacy-based surveillance to improve TB patient notification, build public-private partnerships, and enhance standards for TB care.

ABSTRACT

Introduction: Eleven anti-TB drugs were included in the Government of India’s Schedule H1 drug regulations in 2014. The National Strategic Plan for TB Elimination in India 2017–2025 recognized the opportunity to strengthen the TB surveillance system and improve the quality of TB care by implementing the Schedule H1 regulation. However, there were no documented systematic large-scale efforts to use Schedule H1 regulation to support TB surveillance or improve the quality of care. We aimed to document the process of implementation of the Schedule H1 regulation to enhance the quality of TB care and strengthen the TB surveillance system in Kerala, India.

Methods: We conducted 33 in-depth interviews of the drugs control department enforcement officers, chemist shop owners, private-sector doctors, leaders of professional medical associations, and program managers and key staff of the TB Elimination Program in Kerala. Major themes identified were the process of implementation of Schedule H1 and how the National TB Elimination Program used the information. Findings from the qualitative interviews were corroborated with the quantitative information from the annual program performance reports and anti-TB drug sales data.

Results: The TB Elimination Program of Kerala used the information from the Schedule H1 drug register to identify the missing TB cases and strengthen TB notification, identify providers for engagement and extend support to them for ensuring standards of TB care, and provide feedback to providers regarding prescription practices. Stakeholders felt that implementation of Schedule H1 surveillance has helped to improve TB patient notifications from the private sector, build better public-private partnerships, and improve the quality of TB diagnosis and treatment in Kerala.

Conclusion: Pharmacy-based drug sales data collected either through regulatory or non-regulatory methods have immense potential to support TB elimination programs.

BACKGROUND

Compared to the public sector, the private health sector dominates TB care in India. A 2019 report revealed that approximately 540,000 TB cases were missing from the surveillance system across India; a major portion of missing cases were thought to be due to the gap in the notification of TB from the private sector. This raised many concerns about the quality of care that TB patients consulting the private sector in India receive. To improve TB care and services in the private...
sector, the Government of India established several policies including the Standards for TB Care in India, mandatory TB notification, and Schedule H1 drug regulation.5–7

To monitor the indiscriminate use of certain antibiotics and prevent the emerging threat of resistance to antimicrobial agents, in 2014, the Government of India established Schedule H1 notification, which was an amendment to the Drugs and Cosmetics Rules of 1945—the legislation that regulates the import, production, sale, prescription, and use of medicines.6 Schedule H1 notification controls over-the-counter sales of certain drugs, such as third and fourth generation antibiotics and psychotropic drugs, and includes 11 anti-TB drugs. The law mandates that Schedule H1 drugs can be sold by pharmacists, known as chemists in India, only on production of a valid prescription by a registered modern medicine practitioner, who has a valid qualification granted by an approved authority in the modern scientific system of medicine (excluding the homeopathic system of medicine). The chemist also needs to maintain a separate Schedule H1 register that includes the patient’s identity, prescribing doctor’s contact information, drug name and dispensed quantity, and date. The chemist must retain the register for at least 3 years. Each state’s drugs control department is responsible for enforcing the policy.6

The implementation of Schedule H1 regulation has varied across the states.8 In most parts of the country, utilization of Schedule H1 notification was restricted to the dissemination of information. The National Strategic Plan (NSP) for TB Elimination in India 2017–2025 recognized the opportunity to strengthen the TB surveillance system by effectively implementing the Schedule H1 notification. NSP also aims at quality improvement through monitoring the quality of prescriptions. However, there were no documented systematic large-scale efforts to use Schedule H1 policy to support TB surveillance or improving the quality of care.9

Kerala, a state in southern India, has a population of 34.5 million. The Government of Kerala is committed to end TB and achieve Sustainable Development Goals.10 In 2019, Kerala had notified 68 incident TB cases per 100,000 people compared to the national notification of 159 incident TB cases per 100,000 people.2 In 2016, there was a felt need among the state program managers of the National TB Elimination Program (NTEP) to improve the TB surveillance in Kerala. The state program advocated with the state government to implement Schedule H1 notification more rigorously. Since 2016, the Government of Kerala has reinforced Schedule H1 implementation for anti-TB drugs as a joint venture by the drugs control department and state TB Elimination program, with monitoring from the top administrative level. In this article, we aim to document the process of implementation of the Schedule H1 surveillance to enhance the quality of TB care and strengthen the TB surveillance system in Kerala, India.

■ METHODS

We conducted 33 in-depth interviews (IDI) of people who were closely associated with the implementation of Schedule H1 including drugs control department enforcement officers (7), chemist shop owners (5), chemist’s association leaders (3), NTEP district-level program managers (3), NTEP subdistrict level staff (7), private sector doctors (5), and professional medical association leaders (3). Demographic characteristics of the participants are provided in the Table. Persons to be interviewed were nominated by higher officials of the drugs control department, chemist’s association leaders, leaders of professional medical associations, and the state program manager of the NTEP. Conscious efforts were taken to ensure geographical representativeness to include participants from various districts and rural and urban areas. We contacted participants by telephone, communicated the purpose of the interviews, and explained the prerequisites for the interview (stable internet connection, peaceful atmosphere, and [preferably] with video turned on). IDIs were conducted until saturation was reached and no new themes arose among each category.

We developed an interview guide with questions to capture the evolution, process, and current status of implementation of Schedule H1 related to anti-TB drugs and the ways the NTEP used the information from the Schedule H1 register. Effective probing questions to explore specific areas of interest and additional questions to find out more about relevant issues were customized for each participant. It was piloted with 3 people: a chemist, an NTEP district-level staff person, and a private doctor. Data from pilot interviews were not used for analysis.

All interviews were conducted in the local language, Malayalam, and all except 1 interview were conducted online with the video turned on. Time was fixed based on the convenience of the participant. Other than the participant and interviewer, another researcher was present during
The interview. All IDIs were conducted by A1 (male, public health expert) who was well experienced in conducting qualitative studies and was fluent in Malayalam. The presence of a female rapporteur was ensured while interviewing women. The interviewer ensured that the themes were fully discussed and that all participants were given a chance to express all their views. All interviews were conducted from January–February 2021.

The aims of the study and implications for participation were explained to all participants at the beginning of the interview. Informed consent and permission for video recording were obtained from the participants before the interviews. Confidentiality was ensured, and participants were given a chance to opt out freely at that stage without giving any reason. All but 1 private-sector doctor contacted participated. Two participants called and discussed additional points after formal interviews. Each interview lasted for approximately 40 minutes (range 23 minutes–65 minutes).

IDIs were later transcribed verbatim and translated into English. One researcher recorded the proceedings, identifying key themes and monitoring verbal and nonverbal interactions by watching the video recordings. The transcripts were then manually coded by 2 researchers and emerging themes and subthemes were identified. Sections with similar coding were grouped according to the predetermined themes. Repeated themes were marked as important in red. All the flagged statements were put together and synthesized. The team read the transcripts and notes and reached a consensus. Any disagreements were discussed regularly within the team to reach a consensus regarding theme coding. Important responses were quoted, which evoked spontaneous discussion, around which a lot of time was spent and had some emotional cues attached.

Annual NTEP program performance reports were checked to obtain quantitative information related to notification from the private sector and quality of care indicators. Quantitative information from the report published by the NTEP at Kerala related to anti-TB drug sales were also captured. Information obtained through qualitative interviews was corroborated with the quantitative information available.

Ethics approval was obtained from the Independent Ethics Committee of Centre for Public Health Protection (IEC-CPHP-2019-10/12), Kerala, India.

RESULTS

We have compiled the findings of the IDIs into 2 categories: implementation of Schedule H1 and ways the NTEP used the Schedule H1 information.
Implementation Process of Schedule H1 Surveillance

1. NTEP Advocacy With State Government

To strengthen TB surveillance and to ensure that public health authorities are notified about all patients, NTEP TB program managers convinced the state administrators to effectively implement Schedule H1 notification related to anti-TB drugs with monitoring mechanisms from the highest administrative level. State government orders were issued for joint visits to chemist shops by NTEP key staff and drugs control department enforcement officers in November 2016, making both the departments accountable. The purpose of their visit was to educate the chemist shops regarding the Schedule H1 register and facilitate mandatory TB notification with their support. Quarterly reviews were conducted by the state health authority with the drugs control department and NTEP state program manager.

2. Information, Education, and Communication of Chemists

NTEP and the drug control department jointly convened bi-annual meetings at the district level of chemist’s associations, chemist’s shop owners, and private chemists to highlight the importance of maintaining the Schedule H1 register for anti-TB drugs and conducted annual sensitization sessions for chemist shop owners and chemists. Posters regarding the need to maintain the information of patients were prepared and publicly displayed in all chemist’s shops. WhatsApp groups were formed regionally by the district-level staff of NTEP including mapped chemists, drug enforcement officials, and chemist association leaders specifically for better communication related to the implementation of Schedule H1 and addressing queries of chemists related to NTEP services.

3. Rapport and Exchange of Information

The enforcement officers regularly collected the list of chemist’s shops that stocked/sold anti-TB drugs from the distributors, mapped the shops, and kept the list updated. They shared the information with NTEP district program managers. Of the approximately 15,000 private chemist outlets in Kerala, only 650 stocked or sold anti-TB drugs according to the latest list. NTEP staff at the subdistrict level were asked to visit these chemist shops monthly and maintain a good rapport with them. Maintaining good rapport between NTEP staff and the chemists made the process of information exchange easier. Contact information was exchanged mutually. The chemist shops provided digital and print copies of the monthly consolidated Schedule H1 reports to NTEP staff.

4. Review of Schedule H1 Surveillance Activities

During monthly meetings at the district level, NTEP reviewed the staff efforts to collect Schedule H1 information. Each staff explained the process indicators, such as the number of chemist shops stocking anti-TB drugs, number of shops visited that month, details of cases not found in NIKSHAY (the case-based online management information system of NTEP) but found in the Schedule H1 register, and follow-up actions required. Drugs control department enforcement officers were also invited by the NTEP district program managers while reviewing Schedule H1 surveillance activities at the monthly review meetings. Visiting chemist shops was also part of periodic internal evaluations of NTEP conducted from the state level.

NTEP district program manager used to check our tour diary and see how many chemist shops we have visited. We need to present the information that we obtained from Schedule H1 and its status in every monthly NTEP review meeting.—NTEP district-level staff

Posters regarding the need to maintain the information of patients were prepared and publicly displayed in all chemist’s shops.

5. Advocacy Campaigns

Every year, 1-week long state-wide campaigns have been conducted to reinforce the importance of maintaining Schedule H1 registers. A dedicated team comprising 62 drugs control department enforcement officers, 127 NTEP key staff, and 42 chemist’s association representatives visited the mapped chemist’s shops to reeducate them on the importance of maintaining the Schedule H1 register, verify the status of maintenance of Schedule H1 register, ensure that details of all anti-TB drug sales were conveyed to the local program managers of NTEP, provide onsite feedback and support to them in case of any gaps identified. The team also displayed public education materials related to Schedule H1 at chemist’s shops.

6. Quality Improvements in Documentation

Because of limited staff and high customer turnover, it was difficult to document all patient information at the chemist shops. Chemist’s association leaders opined that more than 90% of chemist shops were using computer-generated bills. Most of the chemist shops used the billing software developed by 7 private companies. They also reported that based on the felt need by chemists, the billing
software of approximately 70% of chemist shops had been modified by the software developers to select Schedule H1, if applicable, against each sale. Provisions for autogenerated Schedule H1 reports were made in the billing software itself, a solution introduced by the billing software developers.

Some chemists described unclear prescriptions by doctors as a challenge for completing the information in the Schedule H1 register. Chemists reported that the doctor’s name was missing in approximately 10%–20% of prescriptions.

Prescriptions will not clearly mention the names of doctors. They will only have designations especially those coming from medical colleges. Patient will also find it difficult to track the doctor if we send him/her back. We don’t want patient to suffer. So, we issue the drugs leaving that [name of doctor] column blank. —Chemist’s association leader

NTEP program managers discussed the issue of unclear prescriptions with hospitals and professional medical associations, which then facilitated communication to all their members to write clear prescriptions with the doctor’s name.

Frequent meetings with the chemists and the chemist’s association by district authorities helped in devising local solutions and resulted in improving the quality of the documentation.

7. Enforcements

Most of the efforts were focused on education, communication, and quality improvements. Drug enforcement officials warned many chemists of imposing penalties in case of noncompliance; however, no one imposed any penalties in this regard to date.

Ways NTEP Used the Information From Schedule H1

Initially, in 2016, NTEP at Kerala tried to enter the information received from the Schedule H1 register directly to NIKSHAY. However, staff identified 3 challenges to this process of feeding the information directly to NIKSHAY.

1. Chemists found it difficult to collect patients’ contact information accurately. NTEP program managers at the district level reported that approximately 20%–25% of the patients identified through the Schedule H1 register could not be contacted because of incomplete/incorrect contact information.

When we call patient, they become really upset. They may not have TB. They might have been prescribed this for something else. It has led even to open complaints against us by the patient. —NTEP district-level staff

2. NTEP program managers at the district level also reported that approximately 5%–10% of patients who were prescribed anti-TB drugs did not have TB. They were prescribed the drugs for other conditions, such as staphylococcus bone infections, urinary tract infections, or as chemoprophylaxis against non-tuberculous conditions.

3. Patients purchased medicines from different chemist shops and different districts during anti-TB treatment, making it difficult to
eliminate duplication of information. Out of enthusiasm, I notified all the cases that I obtained through Schedule H1 from chemist shop in 2016. Then only I understood that some of them were not really having TB, some of them were already notified in the neighboring districts, many of them could not be contacted due to incomplete information. That year the entire districts treatment success rate went down. —District TB program manager

After these initial experiences, the practice of notifying TB directly from the Schedule H1 register was stopped. Based on the initial experiences, from 2018 onward, the state program managers of NTEP evolved their own Schedule H1 surveillance system. NTEP at Kerala used the information from Schedule H1 for 3 purposes (Figure).

1. Identify the Missing TB Cases and Strengthen TB Notification

To identify missing cases, NTEP staff verified NIKSHAY data against the consolidated Schedule H1 register and wrote a NIKSHAY identification number next to each name in the register. They contacted the health providers of cases that did not have an identification number to get the additional information and offered support to the providers to complete the notification.

In 2018, 18 TB cases that we identified from Schedule H1 were not in NIKSHAY. It was 3 doctors who treated those 18 cases. We met those doctors, sensitized them about mandatory TB notification, and offered them support for notification. Last year, we got only 2 cases from Schedule H1 surveillance that were not in NIKSHAY. —District TB program manager

Based on Schedule H1 data, I used to write friendly letters to doctors who did not notify TB offering them support for notifications. Now they inform all TB cases the moment they diagnose. —District TB program manager

Private sector notifications improved, almost doubled over last 2 years, directly from private doctors and hospitals in my district after we implemented Schedule H1. Doctors and hospitals now knew that we have a mechanism to identify if they have not notified. They now understood that we are serious about it. —District TB program manager

2. Identify Private-Sector Providers for Engagement and Extending Support for Ensuring Standards of TB Care in India (STCI)

NTEP identified the providers who prescribed private anti-TB drugs and then sensitized/trained them in STCI. NTEP offered the providers free drugs including TB preventive therapy for eligible contacts, free diagnostics, support for contact investigations, and linkages to social welfare schemes to help providers ensure STCI to their patients.

Schedule H1 surveillance has definitely helped us in engaging private sector. We could identify all providers who deals with TB and directly talk to them. 90% of those doctors are now prescribing NTEP drugs. —District TB program manager

From Schedule H1 surveillance we identified that a good number of prescriptions are being sent to private chemist shops from government medical colleges especially from surgical and super specialty departments. That was mainly because of their ignorance about the NTEP. Through medical college core committee, we organized formal letters and sensitization sessions targeting them. The prescriptions from government medical colleges have come down now. —District TB program manager

Most of the doctors were more willing to offer NTEP drugs now to the patients. Only in some circumstances like patients who want to travel abroad or patients who insists on private drugs are being prescribed private anti-TB drugs. Implementation of Schedule H1 has played a major role in this attitude change. —Private sector doctor

Sale of anti-TB drugs dropped like anything over last 3 years. Very few doctors are now prescribing private anti-TB drugs. Very few chemists are stocking and selling it. —Drug control department enforcement officer

3. Provide Feedback to Doctors Regarding Prescription Practices

District TB program managers provided feedback to doctors about prescribing practices directly or indirectly through professional medical associations.

We have projected a few prescriptions after removing all identities during doctor’s meeting. —Professional association leader

We have observed a sudden cluster of cases in an area through Schedule H1 register. When we investigated all those were prescribed anti-TB drugs by a single pediatrician who recently settled in our area. We met him, sensitized about diagnostic algorithm, made him attended a training on pediatric TB. We made arrangements for free GeneXpert test for his patients. Now he uses anti-TB drugs judiciously. —District TB program manager
Quality of TB Diagnosis and Treatment Improved as a Byproduct

NTEP program managers, professional association leaders, and private-sector doctors agreed that there was a decrease in the use of empirical anti-TB drugs by clinicians for patients who did not have a definitive diagnosis and there was an increased effort for obtaining a definitive diagnosis of TB before initiation of anti-TB drugs. Private-sector doctors mentioned a “self-standardization” in the practice of diagnosing and treating TB and an effort to follow standards of TB care.

I feel the major drop in sales was due to decline in the practice of doctors prescribing empirical [anti-TB drug]. Now they think twice before prescribing an empirical [anti-TB drug]. —Private-sector doctor

We have noticed an improvement in quality of TB prescriptions. Quinolones were being prescribed with many of the TB prescriptions previously. Now we could not find many. —Chemist

Other Insights During the Implementation of Schedule H1 Surveillance

Apart from the above-mentioned uses, the NTEP program received other insights regarding the use of anti-TB drugs, including the use of anti-TB drugs to treat TB in elephants. This led to further investigations into the magnitude of zoonotic TB.

I have noticed unusually high proportion of anti-TB drug sales from a chemist shop which is not matching with records. On further investigation, I found that the drugs were being used for treatment of TB among elephants. That was a new insight. —Drug control department enforcement officer

No differences were noticed among the experiences of providers from urban or rural districts.

Quantitative Data From the Program Reports

The state drugs control department regularly collects the details of the sale of rifampicin-containing products from all drug companies selling anti-TB drugs in the state. State program managers of NTEP have analyzed the drug sales data and reported that anti-TB drugs sales in Kerala have decreased by 70% in 2019 compared to 2015.12 Official TB surveillance data of the state showed an annual decline of 22% in last 3 years, closing the gap in the surveillance system.13

DISCUSSION

The article describes the process of implementing the Schedule H1 system to enhance the quality of TB care and strengthen the TB surveillance system in Kerala, India. The information obtained from the qualitative interviews corroborated with the official data in terms of increase in notification from the private sector, decline in private anti-TB drug sales, and increased efforts for obtaining a microbiological confirmation for TB in the private sector. For the process of subnational certification for TB elimination by the Government of India, an independent verification agency surveyed 83,000 individuals who were selected using a multistage random sampling in Kerala in February 2021 to identify missing TB cases in the community.14 The survey revealed that there were no missing TB cases in the community. Schedule H1 surveillance may not be the only reason for this finding, but the surveillance has helped the state to identify TB cases missing from the surveillance system and close the gaps. It also helped the NTEP to identify the correct providers for engaging. Although it is a regulatory tool, Schedule H1 was used to build partnerships between NTEP and the private health care providers.

A study done in another state in southern India showed that pharmacy-based surveillance has identified approximately one-fourth of the total TB patients notified.15 There are many efforts from other Indian states of Chhattisgarh and Punjab to use Schedule H1 to support TB surveillance. Schedule H1 may provide a good opportunity to support TB surveillance if effectively executed and information of prescription details is used.

The national strategy for TB elimination in India has envisioned prescription audits based on Schedule H1 information for quality improvement.16 Experiences from a private tertiary care center in Kerala showed that establishing a peer audit system resulted in decreasing the number of inappropriate prescriptions from 38% (2017–2018) to 18% (2018–2019).16 Prior implementation of a lung health project in a primary health care setting in Kerala also demonstrated that the presence of standards, good quality trainings, and monitoring of prescriptions have trimmed the
antibiotic use by 50% among patients with chronic respiratory diseases over a year.17 These experiences show that incorporating the prescription audit for improving the quality of TB diagnosis and treatment is meaningful. Kerala plans to establish a systematic peer audit system with the help of a coalition of professional medical associations to further improve the quality of TB diagnosis and treatment.

Although the Government of India established the Schedule H1 act in 2014, the Government of Kerala only started enforcing it systematically for anti-TB drugs after advocacy by the NTEP. Enforcement for other drugs in Schedule H1 is still suboptimal in the state. In Kerala, most of the chemist shops selling anti-TB drugs was also limited in Kerala due to a lower disease burden and good public-private partnerships, so coordination and managing information was easy. In high-burden settings, an information system, such as a uniform electronic tool to capture the information that interacts with the NTEP database, could be considered. In such scenarios, capacity needs to be built among program managers to establish systems for decentralized compilation and use of information locally for appropriate actions. It should be noted that surveillance of prescriptions and Schedule H1 register and backtracking based, if not done in a mutually agreeable and professional manner, may threaten or erode the trust of the private sector “fraternity.”

Experiences from the current study may be helpful for settings working to strengthen their TB surveillance system to reach Sustainable Development Goals/End TB targets and United Nations high-level meeting targets or trying to engage private sectors/triying to improve standards of TB care. Pharmacy-based drug sales data collected either through regulatory or non-regulatory methods have immense potential to support TB elimination programs.

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Author contributions: RPS and SB conceived the study. All authors discussed and approved the protocol. RPS conducted all interviews. RR and SN coordinated and transcribed the interviews. RPS, SB, NIS, PPP, and SA analyzed the data. RPS drafted the manuscript. All authors modified and approved the manuscript.

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REFERENCES


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Enhancing Performance and Sustainability of Community Health Worker Programs in Uganda: Lessons and Experiences From Stakeholders

David Musoke,a Edwinah Atusingwize,a Rawlance Ndejjo,a Charles Ssemugabo,a Penelope Siebert,b Linda Gibsob

Key Findings

- Capacity building and use of technology, supervision, and motivation, as well as stakeholder engagement and collaboration, are key to the success of community health worker (CHW) programs.
- Strengthening recruitment, training, and retention strategies; improving motivation; streamlining coordination mechanisms; and developing and strengthening community health policies are needed to enhance the performance of CHWs.

Key Implications

- Policy makers including the Ministry of Health and implementing partners need to consider CHW needs, existing structures, and policies for enhanced performance of CHWs.
- The workshop methodology can be used in health systems research to inform policy, practice, and programming particularly in low- and middle-income countries, such as Uganda.

ABSTRACT

Background: Community health worker (CHW) programs in Uganda have contributed to improved health outcomes in recent years. However, opportunities for engaging the various stakeholders supporting CHW programs have been limited. This article presents workshop findings where several stakeholders shared their lessons and experiences that can enhance performance and sustainability of CHW programs in Uganda.

Methods: We collected qualitative data from stakeholders from government, private, and community organizations, as well as CHWs, involved in CHW programs in Uganda during a 1-day workshop. The workshop involved plenary presentations and group discussions on critical aspects of CHW programs. All proceedings from the workshop were audio-recorded, transcribed, and analyzed by thematic content analysis.

Results: Four major themes emerged from the workshop: lessons learned in implementing CHW programs, challenges affecting CHW programs, performance of CHWs, and ensuring sustainability of CHW programs. Key lessons learned related to 3 main subthemes: capacity building and use of technology, supervision and motivation, and stakeholder engagement and collaboration. Challenges affecting CHW programs identified included poor coordination, fragmented data collection systems, high program expectations, inadequate support mechanisms, and high dropout rates. Mechanisms for improving the performance of CHWs emphasized the need to: strengthen recruitment, training, and retention strategies; improve motivation; streamline coordination mechanisms; and develop and strengthen community health policies. The sustainability of CHW programs requires institutionalization; sustainable funding; economic empowerment of CHWs; local ownership; and a strengthened research agenda.

Conclusion: To improve the performance and sustainability of CHW programs, stakeholders such as policy makers and implementing partners need to consider CHW needs, existing structures and policies, as well as local support.

BACKGROUND

Over the past 2 decades, the national community health worker (CHW) program in Uganda, known locally as village health team members, has been successful especially in the areas of integrated community case management (iCCM) of childhood illnesses, maternal and child health, and HIV/AIDS. Despite these successes, there have been many missed opportunities.
for realizing the full potential of CHW programs in Uganda, including lack of consistency in the selection process of CHWs, which creates distrust within communities. Other health system challenges that affect CHW programs in Uganda include inadequate refresher training, high workload, lack of supervisory support and feedback mechanisms, insufficient remuneration, distrust of CHWs among health care providers, and stock-outs of medicines and supplies. In addition, funding of the national CHW program has been insufficient, with much of the responsibility left to implementing partners, particularly nongovernmental organizations (NGOs), working across the country. Given these substantial drawbacks, there is a need to strengthen performance and ensure sustainability of CHW programs in Uganda to achieve universal health coverage.

Several strategies for improving the performance of CHW programs exist globally. An integrated approach where community members work with health care providers and other stakeholders from the public and private sectors in designing programs has been shown to promote joint ownership and improve CHW performance. Through this approach, stakeholders provide collaborative supervision and constructive feedback, a balanced package of incentives, and practical monitoring using community and health system data. In fact, the integrated community and health system approach has been reported to reduce workload and increase CHW credibility. However, fragmentation exists among the national CHW program in Uganda which is partly responsible for the challenges currently being faced. In addition, remuneration of CHWs using a mixture of financial and nonfinancial incentives has been shown to enhance CHW performance and sustainability of CHW programs compared to performance-based financing mechanisms. Whereas performance-based financing has not been embraced in Uganda, CHWs in the country are volunteers, hence they do not receive any regular remuneration for their services. However, they may occasionally receive some financial and nonfinancial support (such as t-shirts) from partners working with them. Other effective approaches that have been reported to strengthen CHW programs include frequent supervision and continuous training, which remain inadequate in Uganda.

In Uganda, several stakeholders, including the Ministry of Health (MOH), NGOs, and universities, are involved in and support CHW programs. These stakeholders engage CHWs through recruitment, training, supervision, data collection, motivation, as well as implementation of health programs such as treatment of childhood illnesses, sexual and reproductive health, and control of communicable diseases. However, opportunities for learning across the various stakeholders supporting CHW programs have been minimal, limiting the sharing of lessons and experiences. As such, it is important to engage various stakeholders involved in CHW programming to harmonize approaches that can enhance performance and sustainability. Findings from such engagements can be used by the MOH and implementing partners in Uganda as well as other low- and middle-income countries (LMICs) as they design interventions to improve CHW programs. Although vast evidence exists on CHWs in Uganda, there is minimal literature on stakeholder experiences in supporting their programs. In addition, the use of workshops to engage participants regarding CHW programs in Uganda (and elsewhere) has hardly been explored. Therefore, we conducted a workshop to explore stakeholders’ experiences of implementing and supporting CHWs programs in Uganda to learn of ways in which performance and sustainability of CHWs programs could be enhanced.

**BOX.** Community Health Worker Program in Uganda

In a bid to advance the Alma Ata declaration goal of Health for All, now popularly referred to as universal health coverage, the Ugandan health system underwent several reforms. Among these reforms was the introduction of the community health workers (CHWs) program, locally known as village health teams members. The criteria the program uses to select community members to be CHWs includes aged 18 years or older, able to read and write in their local language, and has a high level of integrity. After their initiation training, CHWs engage with communities to identify local health problems and needs, mobilize them for health interventions, and refer and link them to health providers including follow-up. CHWs also collect and maintain records, conduct home visits, treat children aged under 5 years, and provide basic health education. CHWs are the first contact of the community with the health system and are particularly beneficial in rural areas across Uganda that have limited access to health care. They primarily report to health facilities in their areas that are mandated to provide them with supervisory support.
METHODS

Study Setting and Participants

In 2018, we conducted a 1-day workshop in Kampala, Uganda, as part of a project aimed at strengthening the CHW program in Wakiso district, Uganda. The project was implemented under the partnership between Nottingham Trent University (NTU), United Kingdom, and Makerere University School of Public Health (MakSPH), Uganda. This workshop was planned independently of other project activities. The workshop was attended by 51 participants who were chosen from government agencies, institutions, and organizations based on their involvement in supporting CHW programs in Uganda, including implementers/NGO staff, researchers/academics involved in CHW programs, students, policy makers from national and subnational levels (Table 1), as well as CHWs from Wakiso district.

Data Collection

The workshop comprised 3 sessions: (1) presentation of key lessons learned about CHW programs from 4 selected implementing partners, (2) facilitated group discussions on critical aspects of CHW programs; and (3) plenary, where all groups provided feedback from their respective discussion. Each group had an average of 15 people and included policy makers, local government officials, implementers/NGOs, academia, and the community. Details on the specifics of the workshop session are included in the Supplement.

Before the group discussions, the researchers introduced the themes to the workshop participants:

1. Experiences of working with communities for health improvement including what has worked, challenges faced, and how they have been addressed.

2. Enhancing support to CHWs to improve their performance in health service delivery considering their recruitment, training, retention, supervision, motivation, reporting, transportation, equipment and supplies, and use of technology.

3. Increasing sustainability of CHW programs in Uganda considering funding, enabling environment, local government engagement and support, collaboration, monitoring and evaluation, research, innovations, and learning fora.

The researchers distributed themselves among the 3 groups and participated minimally in the discussions to allow other participants to share their experiences. In addition, the researchers did not act as moderators or notetakers for the groups. The researchers clearly described the workshop’s purpose, emphasizing that the activity was solely for research, which provided an environment that ensured all participants (especially those from the community) felt comfortable and facilitated sharing of experiences and opinions openly. In addition, researchers stressed that contribution from all participants was important to get the perspectives of the various stakeholders who attended. During the discussions, the group moderators ensured that all members had an opportunity to make contributions, which enabled various participants’ perspectives, including those from the community, to be heard. Indeed, the moderators did not allow any group members to dominate the discussions at the expense of others. The moderators intermittently requested contributions from certain members whose views were particularly needed or those who had made minimal input to the discussion. Therefore, the discussions had significant contributions from various group participants including CHWs.

<table>
<thead>
<tr>
<th>Category</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementers / NGO staff</td>
<td>19 (37.3)</td>
</tr>
<tr>
<td>Researchers / academia</td>
<td>16 (31.4)</td>
</tr>
<tr>
<td>Students</td>
<td>7 (13.7)</td>
</tr>
<tr>
<td>Policy makers</td>
<td>6 (11.8)</td>
</tr>
<tr>
<td>CHWs</td>
<td>3 (5.9)</td>
</tr>
</tbody>
</table>

Abbreviations: CHWs, community health workers; NGO, non-governmental organization.

*The participants were from Makerere University School of Public Health, Nottingham Trent University, MOH, World Vision, Wakiso District Local Government, Amref Health Africa, Save the Children, Living Goods, Nkumba University, Kabale University, Mbarara University of Science and Technology, FHI 360, Management Sciences for Health, United States Agency for International Development Regional Health Integration to Enhance Services in East Central Uganda Activity, Wise Choices for Life, BRAC, Clinton Health Access Initiative, Africa Community Centre for Social Sustainability, Action for Community Development, Wellshare International, Kampala Capital City Authority, and Mildmay.*
Data Analysis
The presentations, facilitated group discussions, and other deliberations at the workshop were audio-recorded and transcribed verbatim in English. The notetakers were involved in providing feedback from the groups during the plenary session. The transcripts from the workshop were proofread by 2 experienced researchers in qualitative research and later imported into Atlas.ti 8.0 for data analysis. Initially, coding was done by the 2 researchers who independently read the transcripts several times and developed codes. The 2 researchers discussed the codes and arising issues and agreed on a coding framework. Thematic content analysis following the semantic approach was used, and the emerging codes documented. Afterward, all codes were synthesized into emerging subthemes, and subthemes into themes, which are presented in the results supported by quotations.

Ethical Considerations
This study was approved by Makerere University School of Public Health Higher Degrees, Research and Ethics Committee as part of the project aimed at strengthening the CHW program in Wakiso district. The study was also approved and registered by the Uganda National Council for Science and Technology. Workshop participants were informed and approved of the use of findings for various dissemination including reports, publications, and conference presentations. All data collected from the workshop were handled confidentially, and participants were kept anonymous.

RESULTS
Workshop presentations and group discussions highlighted various critical issues in the design, implementation, and evaluation of CHW programs in Uganda. From the analysis of the workshop proceedings, 4 major themes emerged: lessons learned in implementing CHW programs, challenges affecting CHW programs, enhancing performance of CHWs, and ensuring sustainability of CHW programs.

Lessons Learned in Implementing CHW Programs
Key lessons learned related to 3 main subthemes: capacity building and use of technology, supervision and motivation, and stakeholder engagement and collaboration.

Capacity Building and Use of Technology
Stakeholders stressed that capacity building involving regular training and onsite mentorship of CHWs (within communities) is necessary to support their work. They noted that onsite mentorship encouraged the participation of CHWs who did not attend trainings held away from their villages due to transportation challenges. It also emerged that capacity building using technology (e.g., mobile devices) enabled CHWs to perform their roles better and offered benefits, including improved data quality (collection and reporting), helped learn new skills, and motivated and empowered CHWs. With technology and its benefits, stakeholders noted that community health work will continuously advance and can be enhanced if incorporated in the design of CHW programs. However, stakeholders were concerned about the cost implication as well as limited or no mobile phone network coverage in some rural communities, which challenged technology-based interventions and systems.

...There are many other opportunities which technologies can offer. It comes with a little bit of cost but is worth it. The challenge with technology is some of the rural communities have poor network access which is a huge problem. You have to look for a point where there is a signal before you can do anything with your phone. That is hard in many villages and limits [CHWs’] interest in use of technology. —Member from an NGO, Group 3

Supervision and Motivation
Stakeholders noted that in addition to deployment and training, effective supervision of CHWs remains key. For example, they noted that supervision by CHW parish coordinators was fundamental in linking CHWs to health facilities and enabling delivery of drugs and other supplies. In addition, they reported that regular feedback and collection of reports from CHWs was a key motivation for their performance. They also noted that to motivate CHWs to perform and show appreciation, CHWs were usually given nonfinancial incentives (e.g., certificates and branded t-shirts), which CHWs appreciated. In addition, the availability of adequate equipment and supplies as key inputs for CHWs to be able to continuously respond to community needs and motivation to perform better was strongly emphasized. Stakeholders strongly agreed that while the national CHW program in Uganda was voluntary, financial benefits are also important for
enhanced performance to motivate and show appreciation for their services.

We [CHWs] feel good standing there wearing a t-shirt, having a bag, an umbrella and gum boots. We appreciate the incentives we sometimes receive . . . that form of motivation emphasizes to us that we are still relevant and recognized . . . but also financial incentives to cover some expenses would enable us work better. —CHW, Group 2

**Stakeholder Engagement and Collaboration**

Workshop participants stressed that continuous stakeholder engagement through regular meetings with all partners at central and local levels including CHWs was fundamental. In addition, stakeholders noted that involving communities in all CHW program processes (design, implementation, and evaluation) ensures community ownership. It was also emphasized that influential community persons such as local, religious, and traditional leaders are important in successful community entry and promoting health interventions in communities. Stakeholders also agreed that strategies that foster collaboration between implementing partners and the government both support and strengthen CHW programs. It was also stressed that public-private partnerships allow effective program alignment and integration with national health priorities, which is important for desirable service delivery. For instance, stakeholders highlighted that financial resources from districts and health facilities together with funding from development partners have substantial promise for program sustainability if collaboratively well planned for and used.

**Challenges Affecting CHW Programs**

CHW programs face several challenges including poor coordination, fragmented data collection systems, high program expectations, inadequate support mechanisms, and high dropout rates.

**Poor Coordination**

Stakeholders emphasized that proper coordination of CHW programs provides great opportunities for planning and interactions that enable partners to share experiences. However, stakeholders reported poor coordination among implementing partners and the government, evidenced through inadequate communication, inconsistent and insufficient facilitation mechanisms, non-streamlined workloads for CHWs, and implementation of parallel CHW programs. Besides having a few meetings with some partners, stakeholders felt that the MOH had not provided an adequate supportive environment for effective communication with all stakeholders, sometimes leading to contradictory information during implementation that affected progress and relevance of some programs. They reported that the lack of standard facilitation mechanisms for CHWs was common, with some development partners providing higher facilitation compared to government programs. Stakeholders said that this lack of uniformity in facilitating CHWs attracted most of them to prefer supporting nongovernmental than government programs. However, unfair operations among some development partners were noted. For example, CHWs reported that some partners provided insufficient transport refunds without considering the long distances CHWs traveled from hard-to-reach communities.

They can invite you [CHW] for a meeting and give you UGX 2,000 [approximately 0.50 US$] a day as transport refund yet we [CHWs] come from far places where one may be actually using UGX 10,000 [approximately 3 US$] for transport which makes that refund very unfair. —CHW, Group 1

**Fragmented Data Collection Systems**

There were concerns about the poor data quality, which was related to nonstreamlined reporting mechanisms among implementing partners including the government. Various partners used different reporting tools and indicators specific to their needs and funding requirements. Consequently, CHWs got burdened with many different reporting materials and processes, which reduced their efficiency and quality of reports. One NGO member described such challenges:

Implementing partners . . . have their own reporting tools and indicators . . . yet other indicators that should be entered in the MOH reporting tool are left out. Therefore, that kind of parallel reporting is a problem. —Member from an NGO, Group 3

**High Program Expectations**

Stakeholders felt that local leaders and communities had high expectations of CHW programs and various partners lacked honesty and transparency, which, in turn, raised expectations by communities and CHWs that many programs could not meet. For instance, beyond a program’s objectives, some implementing partners’ programs were perceived as a solution for all prevailing health
challenges in the communities. Similarly, some communities had high expectations of CHWs, who they then perceived as being nonresponsive and underperformers regarding their responsibilities.

CHWs are mandated to only treat children under the age of 5 years, but you can go to a family and they have a sick person beyond that age. For that reason, CHWs find it very difficult to treat such a person. Then community members say that these CHWs are not doing their job because of not treating such a patient. —Health care provider, Group 3

**Inadequate Support Mechanisms**

Another challenge that CHWs faced was related to unsupportive systems as the overall support for CHWs from communities and the wider health system was reportedly limited. Support from key stakeholders, which is important for CHWs’ performance, was inadequate and characterized by unequal treatment from some implementing partners, inappropriate reception at health facilities, and negative community attitudes. CHWs that were not involved in iCCM were less engaged in activities of most partners, which demotivated them as they felt less valuable and unrecognized in their communities. Many CHWs felt that the MOH and some health care providers did not value their role and contribution to health service delivery including when they attended health facilities. Similarly, the lack of proper community orientation about CHW roles was related to negative attitudes toward them.

CHWs are trying to do a lot but it’s not well recognized in our country. There is a challenge of CHW recognition and at times they find themselves not attended to when they go to the health facility because for example the nurse on duty claims, “I don’t know you.” There is that attitude of giving them less attention, yet this is one of the things which would really motivate them to work hard. Another challenge is that there is unequal treatment where you will find CHWs fragmented and treated according to which partner is working with them.

—Member from an NGO, Group 2

**High Dropout Rates**

High dropout rates, particularly among young and male CHWs, was another challenge. Discussions revealed that many male and young CHWs dropped out to look for paying jobs soon after they had been recruited and trained. Some CHWs were reported to have too high expectations of the work despite it being a voluntary service.

Stakeholders were concerned that these high dropout rates created gaps in the general delivery of community health services and that replacement of CHWs was costly to the program in terms of time and financial resources. Specifically, they noted that all new CHWs would need to undergo an initiation training, which was reportedly costly and therefore was not conducted as often as necessary.

We had initially thought we would have younger CHWs. But when they come, you invest so much in training them and 3 months down the road they say, “I am going to look for a job.” Then you need to recruit other people and have to retrain again. So regarding youth participation in CHW programs, we have failed.

—District health team member, Group 1

**Enhancing Performance of CHWs**

Discussions on ways to improve CHW performance emphasized strengthening recruitment, training, and retention strategies; improving motivation; streamlining coordination mechanisms; and developing and strengthening community health policies.

**Strengthen Recruitment, Training, and Retention Strategies**

To enhance CHW performance and retention, stakeholders recommended streamlining the recruitment criteria, which ensures active involvement of communities and proper communication of CHW roles to all stakeholders. Stakeholders said that CHW recruitment criteria should be improved and operationalized to avoid ambiguity. Standardizing capacity building by using uniform training materials and appropriate technology was also recommended to help CHW performance and retention.

Stakeholders stressed that the need to ensure more males and young people are involved in CHW programs. They noted that male CHWs were able to support community mobilization and contribute significantly to the health of men, while young people would be well-positioned to get involved in youth-friendly services including engaging their peers. Therefore, they recommended considering relevant and responsive strategies for innovative recruitment of CHWs catered to increasing gender and age diversity.

Most CHWs are women, as well as being 40 years and above therefore there is need for more diversity. We have struggled to have more young people engaged
Stakeholders noted that the availability of incentives (financial and nonfinancial), enhanced transportation, manageable workload, and adequate support and engagement were important elements for CHW motivation. They also noted the importance of providing nonfinancial incentives to CHWs through recognition at important community events and showing CHWs appreciation with certificates after training sessions. In addition, stakeholders had strong opinions that providing regular financial incentives for CHWs would be essential in improving their performance. Stakeholders recommended providing CHW coordinators with motorcycles to enhance transportation, which would improve supervision including timely delivery of supplies and collection of reports. Similarly, ensuring adequate numbers and distribution of CHWs in all villages would reduce their workload as well as distances traveled to communities. Additionally, the provision of meals and reimbursement of transport costs whenever CHWs were invited for trainings and other activities was seen as crucial to avoid the financial difficulty that they often find themselves in.

When a CHW is moving from one village to another, they are taking off time to serve. Many times, they have to use their own resources if they need a meal during their work. So, what we should advocate for is that CHWs should be financially facilitated while doing community health work. Therefore, whatever cost they incur while doing their work should be reimbursed. We need to strike that balance regarding how much voluntary work they can do without much support. —Member from an NGO, Group 3

Discussions also revealed that guaranteeing adequate support for and involvement of CHWs to improve program inclusiveness by implementing partners is vital for their motivation. Many stakeholders said that any unfair engagement regarding incentives or training activities can potentially demotivate CHWs. For example, they recommended that all CHWs (regardless of involvement in iCCM) should be equally involved and supported to play their role in improving community health.

Streamline Coordination Mechanisms

Proper planning, transparency, and accountability. Proper coordination of all stakeholders at national and district levels was recommended to ensure appropriate planning, transparency, and accountability of CHW programs. Regular meetings of all implementing partners were believed to be an opportunity to present and share progress that would avoid miscommunication, varying compensation policies, unnecessary expectations among stakeholders, and duplication of efforts. At the community level, stakeholders noted that strong coordination also ensures effective mobilization of CHWs and communities including political leaders.

There is need to streamline district coordination and planning and hold quarterly meetings to review what has been done which will ensure transparency of all partners. —Member from an NGO, Group 2

Support supervision of CHWs. Stakeholders noted that strengthened supervision by the MOH and districts by providing appropriate leadership, including overseeing all activities conducted by implementing partners, would enable CHWs to improve their performance. Stakeholders also agreed that efforts such as consistent follow-up of activities and regular refresher trainings to ensure adherence to standardized protocols can reinforce overall supervision and should be prioritized.

Many stakeholders strongly articulated a need to prioritize harmonizing data collection and management by standardizing tools and digitalizing reporting systems to ensure real-time data collection and reporting. Stakeholders agreed that uniform reporting tools were an opportunity for improving data quality, reducing CHW workload, and supporting systematic program monitoring by districts and the MOH. The significance of aligning various technologies such as mobile digital applications, used by different partners to avoid discrepancies and delays in reporting, was also emphasized as being key for greater impact of CHWs on the wider health system.

There is fragmentation... partners use different technologies and applications... I think more integration of technologies is required, particularly by the MOH. Maybe the ministry can recommend a standard technology and application so that monitoring of CHW work by all implementing partners is easier and consistent. —Member from an NGO, Group 3
Recognizing that CHWs cannot do much when they are not fully supported by the national health system, stakeholders called for active and fruitful engagement of policy makers in CHW programs.

**Develop and Strengthen Community Health Policies**
Recognizing that CHWs cannot do much when they are not fully supported by the national health system, stakeholders called for active and fruitful engagement of policy makers in CHW programs. Stakeholders highlighted the need for developing new policies or strengthening existing ones to streamline broader concerns of training, supervision, and motivation of CHWs. The issue of inadequate equipment and supplies was emphasized, and stakeholders called for policies aimed at ensuring consistent availability of supplies such as drugs necessary to improve CHW performance. In addition, stakeholders called for better implementation of such policies as opposed to developing good ones that remain nonoperational.

**Ensuring Sustainability of CHW Programs**
Deliberations from the workshop regarding the sustainability of CHW programs at national, district, and community levels stressed the need for institutionalization of CHW programs, sustainable funding, economic empowerment of CHWs, local ownership of CHW programs, and strengthened CHW research agendas.

**Institutionalization of CHW Programs**
Institutionalization of CHW programs was important for strengthened partnership and collaboration among all stakeholders that should be focused on effective supervision, performance monitoring, and good management (including transparency and accountability). Stressing the importance of clear government leadership for all CHW programs (even if they use different implementation models), stakeholders emphasized that different partners should work within government structures for enhanced sustainability.

Besides improved national coordination, it was noted that institutionalization is significant for continuous steering of program implementation, prioritization, and funding for key interventions, as well as creation of a strong foundation for sustainability. The need for a national CHW forum was suggested to allow for the regular engagement of stakeholders (including community members and CHWs) to share experiences, challenges, and progress of various interventions. This forum would also be used to discuss strategies to continuously advance the role of CHW programs in addressing the current and future communicable and noncommunicable disease burden and other health concerns in the country.

**Sustainable Funding**
The importance of ensuring sustainable funding for CHW programs by the MOH and implementing partners was a key area of debate during the workshop. Most stakeholders emphasized that by increasing budget allocations at national and district levels for CHW programs, the government can strengthen its ownership and commitment and accure significant community health benefits.

*Government providing more resources for the CHW program is something that we should advocate for because CHWs greatly support community health, know the communities very well, understand the people, and can better identify many community problems because they live within these communities.* —Member from an NGO, Group 1

Pooled funding by implementing partners, which was believed to be more sustainable than disaggregated support, was strongly recommended. The stakeholders agreed that it was important for resources to be pooled together that can then be appropriately managed to equitably support CHW programs. It was also noted that collaborative resource mobilization benefits communities and CHWs, builds sustainable programs, and increases capacity to advocate for further support including partnerships.

**Economic Empowerment of CHWs**
Stakeholders suggested 2 major mechanisms that can help CHWs feel more empowered and could be used to develop a strategy to sustain their involvement given the lack of remuneration they suffer: (1) establish CHW-focused savings and credit cooperative organizations to enhance their access to financial credit for income-generating activities; and (2) train CHWs in entrepreneurship to develop hands-on skills (e.g., tailoring and improved farming practices) to enhance their productivity to sustainably meet economic demands.

CHWs too need money to meet their personal and household needs. And if they have easy access to savings and credit groups, they are members and would easily get affordable loans, could help their development hence supporting them to do community work. Of course, teaching them other income-generating activities, for example, farming would also be beneficial for sustaining themselves financially.

—Community member/leader, Group 3

**Local Ownership of CHW Programs**
Program ownership by communities, CHWs, and district health teams is considered central for
sustainability. The stakeholders discussed the following 2 major mechanisms for ensuring that communities owned and sustained CHW programs.

**Transparent implementation and community sensitization.** Stakeholders agreed that transparent and accountable implementation during all processes, including CHW recruitment and deployment, was key in building community trust. Building strong ownership of programs and undertaking community sensitization (including among local leaders) on the role of the CHW and the public’s expectations would help to create more positive attitudes and recognition of their work. Stakeholders also agreed that the local government and health care providers should identify and use opportunities during community gatherings to sensitize people about CHW programs. Other strategies that have the potential to increase awareness and ownership of CHW programs included a public-private partnership with relevant agencies, such as communication companies that could support community sensitization.

**Increased CHW involvement and streamlined program benefits.** Discussions highlighted the need for increased CHW involvement in their programs from design to evaluation. Such involvement would warrant CHWs’ sustained commitment by reconciling their expectations, demands, roles, and work mechanisms with all implementing partners. To ensure that CHWs can remain relevant, are retained, and sustained in the long term, stakeholders stressed the need for streamlined benefits such as a career path including alignment with government-wide initiatives. For instance, stakeholders recommended a priority consideration for upgrading qualifying CHWs into new programs such as the proposed national community health extension workers (CHEWs) program to motivate them and highlight their potential career growth.

Can we have CHWs move from just being volunteers . . . I have not seen it but I would love to see some of them growing in their career, skills and becoming maybe something higher than when they joined the program? That is career growth, something that would be of interest and benefit them as well. —Member from an NGO, Group 3

The introduction of a community health insurance scheme was also discussed as part of streamlining wider CHW program benefits. CHWs themselves have health needs that they must meet, and stakeholders were concerned about the potential challenges in maintaining their own health while voluntarily promoting the health of others in communities. Developing community health insurance initiatives to reduce health-related economic consequences among communities, with additional benefits for CHWs as a form of motivation, was noted to be essential for program sustainability. Stakeholders strongly felt that community health insurance, with benefits for CHWs such as cost-subsidized services, would empower and motivate them to work with less worry about their own health demands and related expenses.

**Strengthened CHW Research Agenda**

The stakeholders called for strengthening research focusing on CHWs to contribute to evidence-based strategies for sustained community health programs. They stressed that CHW programs should be driven by data in all aspects of design, implementation, and evaluation—which should all incorporate research. However, stakeholders noted that many questions remain unanswered, including the amount of financial resources required to effectively implement CHW programs in Uganda which could be answered through research. Workshop proceedings also revealed a requirement for holistic support for research institutions to ensure that there is the required expertise, funding, and favorable environments, as well as infrastructure to conduct responsive studies for CHW programs in the country.

If you were to ask what budget is needed to implement a CHW program in one subcounty, no one would probably attempt that question . . . so, I think you have brought in the element of research and the need to give out an investment case [for CHW programming], and this is where universities need to help with research, because we NGOs, that is something important for us, to know the cost of engaging CHWs. —Member from an NGO, Group 1

All emerging workshop themes and sub-themes are summarized in Table 2.

**DISCUSSION**

This study explored stakeholders’ lessons and experiences in implementing and supporting CHW programs in Uganda. Whereas concerns of training, supervision, and motivation have long been known to affect CHWs, our findings emphasize the importance of technology as well as stakeholders closely working together in improving CHW programming. CHWs in Uganda are lay community members whose capacity
ought to be built to fully understand their roles and responsibilities and provide them with the information and skills they require. The capacity-building avenues include initiation and refresher training and supportive supervision whose relevance has previously been emphasized.7,11,17,20,21 Previous studies have also underscored the importance of supportive supervision for CHWs by health care providers, including accompaniment and shadowing, which gives them important feedback and confidence to perform their roles, improves their acceptability, and builds community trust.22–24 Although not fully explored in Uganda, capacity building of CHWs using technology has been recognized for facilitating other tasks, such as data collection and reporting, and improving outcomes, such as CHW motivation and empowerment. A systematic review that evaluated program outcomes when using mobile tools noted that mobile technologies support CHWs to receive alerts and reminders, facilitate health education sessions, and conduct person-to-person communication. 25 This review noted that mobile tools helped CHWs to improve the quality of care provided, the efficiency of services, and the capacity for program monitoring, thus presenting a key opportunity for CHW programs. Therefore, it is prudent for MOH and other stakeholders in Uganda supporting CHWs to fully embrace technology as a tool that can improve CHW performance and outcomes.

The role of motivation from both financial and nonfinancial incentives in CHW programs cannot be overemphasized. Previous studies conducted in Uganda suggest that CHWs valued nonfinancial incentives more than financial ones.26,27 However, financial incentives continue to be emphasized by CHWs and other stakeholders such as implementing partners supporting CHWs programs.20,21,24 The World Health Organization, through their guidelines on health policy and system support for optimizing CHW programs, recommends that practicing CHWs should be recognized as part of the workforce and provided with a financial package in line with assigned duties, training, roles, and working hours.28

Our study also highlighted the relevance of CHW stakeholder engagement and collaboration at different levels, including with the community. Involvement of all actors leverages available resources, influences the acceptability of programs, and enhances community buy-in and ownership.9,24,29 Stakeholder involvement also streamlines planning and effective service delivery9,24,29 in line with national policies and should be strengthened and incorporated within community health programming. Opportunities for stakeholders interacting often as well as jointly participating in planning, implementation, and evaluation of CHW programs would have benefits in improving community health.

Our study noted several challenges that affect CHW programs in Uganda including poor coordination, fragmented data collection systems, high program expectations, inadequate support mechanisms, and high dropout rates. Similarly, a 2014 Uganda survey highlighted differences in implementation of the strategy and found several gaps in supervision, motivation, and coordination of programs.30 Many of these challenges have also been reported by previous studies conducted in the country.11,21,31,32

From our study, the need for younger CHWs and males to support the CHW program was highlighted as previously observed.33,34 Even

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**TABLE 2. Key Themes and Subthemes From a 1-Day Workshop on the Uganda CHW Program**

<table>
<thead>
<tr>
<th>Lessons Learned in Implementing CHW Programs</th>
<th>Challenges Affecting CHW Programs</th>
<th>Strategies to Improve CHW Performance</th>
<th>Ensuring Sustainability of CHW Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity building and use of technology</td>
<td>Poor coordination</td>
<td>Strengthen recruitment, training, and retention strategies of CHWs</td>
<td>Institutionalization of CHW programs</td>
</tr>
<tr>
<td>Supervision and motivation</td>
<td>Fragmented data systems</td>
<td>Improve motivation of CHWs</td>
<td>Sustainable funding</td>
</tr>
<tr>
<td>Stakeholder engagement and collaboration</td>
<td>High program expectations</td>
<td>Streamline coordination mechanisms</td>
<td>Economic empowerment of CHWs</td>
</tr>
<tr>
<td></td>
<td>Inadequate support mechanisms</td>
<td>Develop and strengthen community health policies</td>
<td>Local ownership of CHW programs</td>
</tr>
<tr>
<td></td>
<td>High dropout rates</td>
<td></td>
<td>Strengthened CHW research agenda</td>
</tr>
</tbody>
</table>

Abbreviation: CHW, community health worker.
When identified and trained, attrition among these groups is usually high, which can be attributed to the unattractive CHW voluntary role, as males are the main income earners and young people usually search for better opportunities.\textsuperscript{35,36} However, the World Health Organization CHW guidelines reported no specific evidence of the relevance of age and gender as selection criteria for CHWs and recommended that recruitment and selection procedures should prioritize other criteria such as relevant life experience, acceptability, caring attitude, commitment, and other individual attributes.\textsuperscript{28} Nevertheless, the guidelines recommend maximizing women’s participation and promoting their empowerment as well as considering the sociocultural context of operation.\textsuperscript{28} Our earlier study established that although there were more female CHWs, male CHWs could perform some roles while supporting their communities.\textsuperscript{33} These roles include quick response to emergencies, community mobilization for public health interventions, and activities involving manual labor such as protecting water sources. The challenges affecting CHW programs related to gender and age ought to be readily addressed to improve the diversity and effectiveness of Uganda’s CHW programs. Certainly, having a good mix of age and gender for CHWs is likely to improve service delivery in communities.

To enhance the performance of CHW programs, stakeholders suggested the need for strengthened recruitment, training and retention strategies, improved motivation avenues, streamlining of coordination mechanisms, and development and strengthening of community health policies. These recommendations are in line with those provided by previous studies in Uganda.\textsuperscript{11,17,21,22,32} In addition, the Uganda MOH-commissioned review of the CHW strategy recommended the need to strengthen the program with clear recruitment, funding, coordination, motivation, and supervision mechanisms.\textsuperscript{30} Thereafter, the MOH suggested plans to introduce CHEWs as a paid cadre of CHWs and prescribed their functionality mechanisms. The CHEWs would be based at the parish level and support the work of the existing CHWs (VHTs) including supervision, data collection and reporting, and diagnosis and management of simple illnesses.\textsuperscript{37} However, it has been argued that the CHEWs approach may not be adequately funded, will face practical and logistical implementation challenges, and could create tension with the current CHWs and community.\textsuperscript{38} Therefore, there is a need to rethink an effective and contextual community health strategy for Uganda to deal with the current challenges and guide the institutionalization of the program to enable CHWs to achieve their full potential and spur public health benefits.

Beyond performance, stakeholders highlighted measures to enhance the sustainability of CHW programs. These measures included fully institutionalizing CHW programs, which should involve engaging with and empowering communities, implementing national programs at scale, ensuring sufficient and sustainable financing for community health systems, and integrating community data into the health information system.\textsuperscript{39} In addition, effective program design and management, its fit with specific communities served, and integration within the broader political, economic, and health system environment are key factors for scaling up and sustaining CHW programs in LMICs.\textsuperscript{40} Institutionalization should improve national coordination of CHW programs led and directed by the government, create mechanisms for sustainable funding of programs, and ensure their local ownership as suggested by our study rather than dependency on external donor-led programs. Since the CHW program in Uganda currently depends on voluntary labor, alternative income-generation streams should be established to support CHWs to meet their financial needs. In reality, CHW livelihoods are similar to that of the communities they serve, and they too are vulnerable to shocks such as food insecurity aligned with poor coping mechanisms.\textsuperscript{31} Thus, measures such as the establishment of savings and credit cooperative organizations and equipping CHWs with entrepreneurship skills as suggested in our study are important to empower them to improve their livelihoods. To further improve the sustainability of CHW programs, the research agenda on CHWs as established in our study needs to be strengthened. Research needs to be incorporated into all aspects of CHW programming to provide opportunities for learning and system improvements. Research on CHW programming could also provide preliminary evidence before implementing large-scale programs and incorporating continuous process improvements. The role of the MOH, implementing partners, and academic institutions remain paramount in building capacity, finding sustainable funding streams, and creating a favorable environment to advance the CHW research agenda in Uganda.

**Strengths**

A key contribution of this article to the literature is the use of workshop methodology in health
systems research. Although workshops are not a traditional method for engaging participants and collecting data, their use has increased in recent years. As our study demonstrated, some of the benefits of using workshops include bringing together a diverse range of individuals to generate data for research, obtaining a wealth of data on a topic of interest in a short period, and learning from others’ experiences during the process, which is not possible using other data collection methods. Given that the stakeholders who participated in the workshop were working in various parts of Uganda, the results from the study provide a general representation across the country. However, key concerns regarding the use of workshops include power dynamics and positional.

Unlike focus group discussions that may have participants of the same social class or cadre, a workshop may have a diverse range of individuals involved. As an example, our workshop included policy makers, implementers including health care providers, researchers, and CHWs. For this reason, power dynamics need to be considered during the workshop planning as it could dictate the extent of participant engagement. Indeed, certain participants (such as community members) may not openly express their views in the presence of high-ranking officials some of whom may be their supervisors or superiors. We addressed this concern by emphasizing that the workshop was solely for research purposes and encouraged participants to feel free to share their views and experiences. In addition, we advised the group moderators to ensure all participants contributed to the discussions hence avoiding domination by a few individuals. Regarding positionality, the role that the researchers play in the workshop process can influence the outcome of the activity including the level of participant involvement. In our study, we ensured the researchers did not moderate any of the group discussions and their contribution was minimal to minimize the researchers’ influence on the workshop proceedings. However, other researchers have shared their personal stories as part of workshops to situate themselves in a more equal position with participants. Nevertheless, such a level of engagement of researchers in discussions may best suit a workshop that has 1 cadre of participants. With these benefits and concerns in mind, the workshop methodology can be explored by other health systems researchers as a means of engagement and discussion with various individuals collectively on a subject of interest.

Limitations
Although we made the workshop as inclusive as possible, stakeholders from some organizations did not attend. Future related studies may explore using a framework that combines performance and sustainability as a basis to inform the analysis and subsequent discussion.

CONCLUSION
To improve the performance and sustainability of CHWs programs, stakeholders such as policy makers including MOH officials, district health authorities, and implementing partners, need to consider CHW needs, existing structures, and policies, as well as local ownership and support. The workshop methodology can be used in the future in health systems research to inform policy, practice, and programming, particularly in LMICs.

Acknowledgments: Our appreciation goes to all the workshop participants.

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Author contributions: DM and LG were the project leads for Uganda and the UK, respectively, as well as involved in conceptualizing the study, implementation, and writing the manuscript. EA, RN, CS, and PS were involved in implementing the study including data analysis and interpretation as well as manuscript writing. All authors read and approved the final manuscript.

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Can We Use Routine Data for Strategic Decision Making? A Time Trend Comparison Between Survey and Routine Data in Mali

Talata Sawadogo-Lewis, Youssouf Keita, Emily Wilson, Souleymane Sawadogo, Ibrahim Téréra, Hamadoun Sangho, Melinda Munos

Key Findings

- The direction and magnitude of the time trends of contraceptive prevalence rate, institutional delivery, and 3 doses of the diphtheria, pertussis, and tetanus (DPT3) vaccine from 2001 to 2012 were similar at the national level between data sources.
- At the regional level, routine data tended to overestimate DPT3 coverage, and underestimate institutional delivery and contraceptive prevalence relative to survey data.
- Routine data are appropriate for use for program planning. However, it does not seem to be appropriate for use for impact evaluations, particularly at the regional level.

Key Implications

- Program planners and evaluators can continue to use routine data to detect overall trends but until the quality of routine data is improved, they should refrain from using it for impact evaluations.

ABSTRACT

Background: Countries with scarce resources need timely and high-quality data on coverage of health interventions to make strategic decisions about where to allocate investments in health. Household survey data are generally regarded as “gold standard,” high-quality data. This study assessed the comparability of intervention coverage time trends from routine and survey data at national and subnational levels in Mali.

Methods: We compared 3 coverage indicators: contraceptive prevalence rate, institutional delivery, and 3 doses of diphtheria, pertussis, and tetanus (DPT3) vaccine, using 3 Mali Demographic and Health Surveys (DHS 2001, 2006, and 2012–2013) and routine health system data covering 2001–2012. For routine data, we used local health information system (HIS) annual reports and an HIS database. To compare time trends between the data sources, we calculated the percentage point change and 95% confidence interval from 2001–2006 and 2006–2012. We then computed the absolute and relative differences between the 2 data sources for each indicator over time at national and regional levels and assessed their level of significance.

Results: The direction and magnitude of the time trends of contraceptive prevalence rate, institutional delivery, and DPT3 vaccine from 2001 to 2012 were similar at the national level between data sources. At the regional level, there were significant differences in the magnitude and direction of time trends for institutional delivery and the DPT3 vaccine; contraceptive prevalence trends were more consistent. Routine data tended to overestimate DPT3 coverage, and underestimate institutional delivery and contraceptive prevalence relative to survey data.

Conclusion: Routine data in Mali—particularly at the national level—appear to be appropriate for use to inform program planning and prioritization, but routine time trends should be interpreted with caution at the subnational level. For program evaluations, routine data may not be appropriate to draw accurate inferences about program impact.

BACKGROUND

All countries, especially those with scarce resources, need to make strategic decisions about where to allocate investments in health. Timely, high-quality, population-based data on coverage of key health
interventions are necessary to evaluate project or program impact and thus guide future efforts. Household survey data—including from U.S. Agency for International Development-funded Demographic and Health Surveys or United Nations Children’s Fund-funded Multiple Indicator Cluster Surveys—are generally considered to use “gold standard” methods and, therefore, to produce high-quality population-based data. These data are publicly available and free to access. However, because the surveys are expensive to conduct, they are conducted relatively infrequently. Country decision makers must make frequent programmatic decisions and adjustments, and survey data, typically available every 3 to 5 years, cannot be used for this purpose. In addition, while survey data are typically available at the subnational level (e.g., regional level), they are usually not available for smaller geographic areas such as districts.

To overcome these limitations, country-level planners often turn to routine data sources to fill these data gaps. Routine data collected by the health system are typically available on a monthly or quarterly basis. If properly collected and managed, they allow stakeholders to observe changes in coverage from year to year that can be important for time-sensitive decision making. At the district health facility level, they serve as an appropriate source for operational decision making. Because they are collected and managed by national staff from the health system, their collection is more sustainable. Finally, routine data are relatively inexpensive to collect.

Health information systems (HIS), which rely on routine data, can have significant limitations. Although many countries publish annual reports based on HIS data, it can be difficult to access the data underlying the reports. Some indicators of interest are not collected or are not aggregated in the HIS; when indicators are available, the data are sometimes of poor quality. In many countries, the HIS is limited to data from public health facilities; data from private facilities are not included. For intervention coverage measures, the denominators—the estimates of the population in need—are often based on census projections. The accuracy of these projections can be affected by factors like the time since the last census and internal population movements.

Despite these well-documented limitations, routine data are often the de facto data source used for programmatic planning in low- and middle-income countries, particularly where no recent household survey exists. Within the context of the Global Affairs Canada-funded National Evaluation Platform—dedicated to improving evidence-based decision making—a team of Malian researchers found that at least 5 major maternal, newborn, and child health and nutrition (MNCHN) programs rely on HIS data as their source of coverage indicator data in Mali. A 2013 evaluation of Mali’s HIS concluded that it had poor data quality in general, due in large part to poor data archiving and uneven record keeping. Regional HIS data were also found to be of generally higher quality than district-level data.

Reducing maternal, newborn, and under-5 mortality is a priority for the Government of Mali, and data are needed to inform this work. Mali’s decennial plan for health and social development (Plan Décentrel de Développement Sanitaire et Social 2014–2023) recognizes the need to increase routine data quality, timeliness, and use for decision making at all levels.

Given that routine data are widely used for planning and evaluation and to fill the gaps in between household surveys in Mali, it is of interest to decision makers to understand the comparability of these data. While some differences in the levels of coverage indicators between the 2 data sources are expected (because routine data are limited to the public health sector and because of some differences in indicator definitions), it would be useful to know whether the HIS captures the same time trends as population-based surveys. To answer this question, we compared time trends in routine and household survey data from 2001 to 2012 in Mali for 3 indicators to inform the use of routine data by decision makers in Mali.

METHODS

This analysis focused on 3 indicators: modern and traditional contraceptive prevalence rate (CPR), 3 doses of diphtheria, pertussis, and tetanus vaccine (DPT3), and institutional delivery. We focused on these because they were the most complete indicators across regions and years in the HIS and represented a range of services across the continuum of care.

Data Sources and Quality Assessment

We used DHS data collected in 2001, 2006, and 2012–2013 in Mali. Data were collected in all regions and the district of Bamako in 2001 and 2006. In 2012, the regions of Tombouctou, Gao, and Kidal, and 3 districts in the Mopti region (Douentza, Ténenkou, and Youwarou) were excluded due to security concerns.
For routine data, coverage estimates were obtained from HIS-validated annual reports. Numerators and denominators were double extracted in a standardized format for each indicator, year, region, and at the national level from 2001 to 2012. For each indicator, the numerator as reported in the HIS (e.g., number of institutional deliveries) was independently extracted from the electronic database by 2 different individuals and then compared. Cases of discordance were discussed and verified by returning to the HIS database (Développement Sanitaire du Mali) until consensus was reached among the data extractors. Access to data was facilitated by the fact that the authors carrying out this work were part of Mali’s National Evaluation Platform, as Keita et al describe. This group of researchers includes members at the Cellule de Planification et de la Statistique, where HIS data are stored.

Table 1 compares HIS and DHS definitions of the 3 indicators, and Table 2 shows changes in indicator definitions in the routine HIS data over time.

Data Analysis
We calculated cluster-stratified survey-weighted coverage estimates and standard errors using DHS data for each indicator and survey at national and regional levels. To calculate estimates for routine data, we divided the numerator as reported in the HIS by the estimated population denominator (using population projections from the 2009 national census) at national and regional levels. We also calculated the standard errors for the survey and routine coverage estimates.

Because we had 3 survey estimates available, we defined 2 time intervals for comparison: 2001–2006 and 2006–2012. We visualized survey and routine coverage estimates with their 95% confidence intervals and compared the direction of the time trends in each interval.

To assess whether time trends from routine and survey data differed significantly from 2001 to 2006 or from 2006 to 2012, we standardized the difference of differences by subtracting the difference between 2001 and 2006 for survey data from the difference between 2001 and 2006 for routine data and dividing this quantity by the square root of the sum of survey and routine variance. Assuming a Gaussian distribution with mean 0, and standard deviation 1, we calculated the probability of a difference as or more extreme than the one we observed between survey and routine data. We reported P values for each comparison, aware that there is a 5% chance that a random observation from a Gaussian distribution will have a significant p-value, based on chance alone. We did not adjust P values for multiple comparisons.

Analyses were conducted using R version 3.5.1. All analysis files are publicly available: https://doi.org/10.5281/zenodo.5649508.

RESULTS

Data Availability
We were able to obtain coverage estimates from the routine reports and databases for the national level and all regions for the 3 indicators we examined from 2001 to 2012.

| TABLE 1. Indicators Definition According to Routine and Survey Data, Mali 2012 |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Indicators                      | HIS (Routine)   | DHS             |                  |                  |
|                                 | Numerator       | Denominator     | Numerator       | Denominator     |
| Contraceptive prevalence        | Total number of women consulting family planning services in health facilities | Total number of women aged 15–49 years | Number of women aged 15–49 years at risk of getting pregnant that are using a method of contraception | Total number of women aged 15–49 years at risk of getting pregnant |
| Institutional delivery          | Total number of births in community health facility and district hospital (public only) | Total number of births expected during the year | Number of children surveyed born in a health institution (private or public) | Total number of births |
| DPT3 vaccine                    | Number of children aged 0–11 months who received DPT3 | Total number of children 0–11 months | Number of children aged 12–23 months who have received DPT3 | Total number of children aged 12–23 months |

Abbreviations: DHS, Demographic and Health Survey; DPT3, 3 doses of the diphtheria, pertussis, and tetanus vaccine; HIS, health information system.
National-Level Time Trends

Figures 1, 2, and 3 show time trends in CPR, DPT3, and institutional delivery, respectively, at national and regional levels using routine and survey data. Figure 4 shows the percentage point change for survey versus routine data. Based on survey data, time trends for CPR were essentially flat from 2001 to 2012, DPT3 increased sharply from 2001 to 2006 and declined slightly from 2006 to 2012, and institutional delivery increased slowly from 2001 to 2012. At the national level, the direction of the time trends was consistent between routine and survey data for all indicators and time periods. Notably, both routine and survey data identified a slightly negative trend in DPT3 coverage from 2006 to 2012. However, the magnitude of the time trends was significantly different between routine and survey data for institutional delivery, and, for 1 time period, for DPT3 (Tables 3 and 4). In addition, there were large differences between the point estimates from routine and survey data; routine data underestimated coverage of CPR and institutional delivery and overestimated DPT3 coverage relative to survey data.

Regional-Level Time Trends

Time trends for all 3 indicators varied widely between regions, particularly for DPT3 and institutional delivery using routine data, and there was far less consistency between survey and routine time trends, relative to national estimates (Figures 1, 2, and 3). All regions had at least 1 statistically significant difference between routine and survey time trends except Tombouctou from 2001 to 2006 and Koulikoro from 2006 to 2012 (Tables 5 and 6).

CPR time trends at the regional level were not significantly different between routine and survey data; the only exceptions were Gao (2001–2006), and Ségou (2006–2012) (Tables 5 and 6). In addition, the direction of the CPR trends was consistent between routine and survey data except for Kidal and Tombouctou (2001–2006), although in both cases the difference between the routine and survey estimates was very small.

DPT3 trends were significantly different for 4 of 9 regions from 2001 to 2006 and 5 of 6 regions from 2006 to 2012 (Tables 5 and 6). In addition, the direction of the DPT3 time trend was different between routine and survey data for all 6 regions from 2006 to 2012. Similarly, institutional delivery time trends were significantly different between routine and survey data for 6 of 9 regions from 2001 to 2006 and 3 of 6 regions from 2006 to 12. The direction of time trends for institutional delivery was mostly consistent between routine and survey data, with 1 exception in 2001–2006 and 2 exceptions in 2006–2012.

Discussion

We aimed to compare routine and survey data trends over approximately 10 years at national and regional levels in Mali. We found that time trends for CPR, DPT3, and institutional delivery indicators in Mali were broadly similar between routine and survey data at the national level but were much more inconsistent at the regional level. This comparison is relevant to country and global stakeholders for several reasons. First, although household surveys are the preferred source for population-based measures of coverage, they are only available intermittently—every 3–5 years or even more infrequently—and therefore are of limited utility to support regular decision making. Second, routine data are available at low levels of disaggregation and would be a more granular alternative to survey data. Third, in Mali, researchers and planners already rely heavily on routine data. Given that the HIS is managed by Ministry of Health staff and that sense
FIGURE 1. Contraceptive Prevalence Rate Time Trends by Survey and Routine Data, at National and Regional Levels From 2001 to 2012, Mali

FIGURE 2. Diphtheria, Pertussis, and Tetanus Vaccine Coverage Time Trends at National and Regional Levels According to Routine and Survey Data From 2001 to 2012, Mali

Abbreviation: DPT, diphtheria, pertussis, tetanus.
of country ownership over these data is high, routine data are more sustainable than externally coordinated and funded household surveys. However, it is important to understand to what extent these data may capture population changes in intervention coverage.

Previous studies have reported poor quality of routine data, but there have been limited assessments of external validity. Other analyses have found differences between routine and survey data with respect to point estimates, and some have found few identifiable patterns. We note that there were differences in indicator definition between survey and routine data (Table 5). This is frequently the case with survey and routine data because the data sources capture different kinds of data and may in part explain the differences we observed. However, routine data are often used to proxy survey data, so comparing the 2 data sources remains relevant. We focused primarily on the comparability of time trends rather than specific indicator levels, as both the direction and magnitude of time trends are often used by stakeholders to make decisions about which interventions or geographic areas to prioritize.

We found that national-level time trends were more comparable than regional-level trends, which may be due to the denominators used for the routine coverage estimates. Denominators for coverage indicators in routine data are typically based on projections from the most recent census. Internal migration—which would affect regional and district denominators but not national denominators—is often not captured in census projections. Depending on how recent these data are, the accuracy of the denominator may be affected. The most recent census available in Mali at the time of the analysis was held in 2009. An alternate approach for groups looking to replicate this analysis could be to use DHS-derived denominators for this analysis which would capture the distribution of women of reproductive age, births, and children by region.

The comparability of survey and routine data was generally better for CPR than for DPT3 and institutional delivery. This may be related to the fact that CPR changed very little from 2001 to 2012. In addition, the denominator for CPR, all women aged 15 to 49, is broader than the denominator for the other 2 indicators (pregnant women, and children aged 12–23 months) and may be less subject to error in census projections.

We found that at the national level, routine data overestimated vaccine coverage but under-

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**FIGURE 3.** Institutional Delivery Rate Time Trends at National and Regional Levels According to Routine and Survey Data From 2001 to 2012, Mali

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estimated CPR and institutional delivery. Women (and men) may access contraceptives outside of health facilities (e.g., private pharmacies), which may account for the underestimation of CPR. Similarly, women may give birth at private clinics, and these births are generally not captured in the routine HIS. Vaccination is generally delivered through the public health system, and overestimation of vaccination coverage in routine data is well-documented.\textsuperscript{20,22}

\textbf{TABLE 3.} National Level Time Trend Change in Proportion Indicator Coverage According to DHS and Routine Data, 2001–2006, Mali

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<tbody>
<tr>
<td>CPR</td>
<td>0.0017</td>
<td>0.0043</td>
<td>0.0045</td>
<td>0.0002</td>
<td>0.0028</td>
<td>−0.6505</td>
<td>.52</td>
</tr>
<tr>
<td>DPT3</td>
<td>0.2867</td>
<td>0.0183</td>
<td>0.3089</td>
<td>0.0018</td>
<td>0.0222</td>
<td>−1.2073</td>
<td>.23</td>
</tr>
<tr>
<td>ID</td>
<td>0.0848</td>
<td>0.0097</td>
<td>0.1384</td>
<td>0.0013</td>
<td>0.0536</td>
<td>−5.4768</td>
<td>0\textsuperscript{a}</td>
</tr>
</tbody>
</table>

Abbreviations: CPR, contraceptive prevalence rate; DHS, Demographic and Health Survey; DPT3, 3 doses of diphtheria, pertussis, and tetanus vaccine; ID, institutional delivery; SE, standard error.

\textsuperscript{a}Statistically significant.
Data extraction and cleaning for this analysis was a time- and labor-intensive process that required meticulous processing. Changes in district boundaries and indicator definition further complicated the process. Doing this rigorous, detail-oriented endeavor regularly is not realistically feasible. However, we note that at the time of analysis, Mali did not have the District Health Information System, version 2 (https://www.dhis2.org/) (DHIS2) in place.23 It is likely that the time and effort burden required for this process would have been considerably lighter if such a platform had already been established.19 With additional investments in building both more robust reporting systems18,20,22,24 and strong data use capacity including regular data quality assessments,8,25,26 routine data quality is likely to improve and this level of 1-time, in-depth data cleaning may not be necessary.

With the introduction of DHIS2 in Mali, more standardized indicator definitions will be used. The capacity of this platform to produce data visualizations at more granular levels (i.e., health facility or district level) and to increase detection of data quality issues at that level can lead to improved quality of aggregated data at the regional or national level. Building an information culture whereby managers are incentivized to use the data collected to make concrete changes in their health facility or district is a way to ensure that HIS data quality continues to improve.27 In a case study from Ethiopia, integrated supportive supervision—where managers aim to work with staff to review data and find solutions rather than adopting a punitive approach—has led to more accurate data being recorded and to data being used for decision making.28 While our findings currently do not support using routine data for impact evaluations, initiatives such as these could eventually result in data of sufficient quality to be appropriate for this purpose.

**Limitations**

Because DHSs were conducted only every 5–6 years, we were not able to look at more granular time trends. Additionally, the 2012 DHS excluded 3 regions and several districts due to the security situation in these areas at the time of data collection. Because of this, we were unable to assess if our findings held true from 2006 to 2012 in excluded regions.

Furthermore, since household survey data are generally assumed to be of higher quality than routine data, we assumed that the DHS data represented “truth.” We recognize, however, that household survey data has its own set of data quality issues29,30 and some household survey estimates may have substantial nonsampling error. In addition, regional estimates in the Mali DHS had wide confidence bounds due to relatively small sample sizes that may have limited our ability to detect significant differences between survey and routine data at the regional level.

We focused only on the external consistency of routine data and did not look at other data quality metrics, namely completeness, timeliness, internal consistency, and representativeness. Assessing these metrics may have led to a more complete picture of where data quality gaps exist and how they could be addressed. Taken together, these limitations may limit the validity of our findings if, for example, the DHS results did indeed have significant data quality issues or if other dimensions of data quality not explored in this article were of low quality.

### TABLE 4. National Level Time Trend Change in Proportion Indicator Coverage According to DHS and Routine Data, 2006–2012, Mali

<table>
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<tr>
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<th>Routine Data</th>
<th>Difference Between Survey and Routine</th>
<th>Z Score</th>
<th>P Value</th>
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Abbreviations: CPR, contraceptive prevalence rate; DHS, Demographic and Health Survey; DPT3, 3 doses of diphtheria, pertussis, and tetanus vaccine; ID, institutional delivery; SE, standard error.

aStatistically significant.
CONCLUSION

Given the frequent use of routine data in maternal, newborn, and child health programs in Mali, we aimed to assess the difference between indicator time trends from routine and household survey data to guide decision makers in Mali.

Improving the data quality and accessibility of routine data is a high priority in many LMICs, and as part of this effort, it is important to assess the quality and usability of routine data in their current state. Trends in routine data appeared comparable to trends in household survey data at

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Abbreviations: CPR, contraceptive prevalence rate; DHS, Demographic and Health Survey; DPT3, 3 doses of diphtheria, pertussis, and tetanus vaccine; ID, institutional delivery; SE, standard error.

*Statistically significant.
the national level and therefore may be appropriate for use at that level, but time trends in routine data should be interpreted with caution at the subnational level.

Given these findings, routine coverage data in Mali may not be suitable for impact evaluations, as evaluators need precise, accurate estimates of change to understand the extent to which a program is working. However, these data might be useful for planning and prioritization, if stakeholders keep in mind the potential error associated with subnational estimates. Given the potential for routine data to be a sustainable and timely source of appropriately disaggregated data, the push for improving the quality of routine data through exercises such as these should continue to be prioritized.

Acknowledgments: We would like to acknowledge members of the National Evaluation Platform’s Mali Technical Task Team for their support in this work. We also thank Jonathan Alcazar for his support in formatting this manuscript.

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Author contributions: MKM, YK, SS, IT, and EW designed the analysis plan. EW, IT, SS conducted the analysis. TSL, MKM, YK, HS, and EW wrote the first draft and edited additional versions. All authors approved the final manuscript.

Competing interests: None declared.

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Abbreviations: CPR, contraceptive prevalence rate; DHS, Demographic and Health Survey; DPT3, 3 doses of diphtheria, pertussis, and tetanus vaccine; ID, institutional delivery; SE, standard error.

*Statistically significant.
En Français

Peut-on utiliser les données de routine pour la prise de décision stratégique? Une comparaison des tendances temporelles entre les données d’enquête et de routine au Mali

Contexte: Les pays aux ressources limitées ont besoin de données actualisées et de haute qualité sur la couverture des interventions de santé pour prendre des décisions stratégiques sur l’affectation des investissements dans la santé. Les données d’enquêtes auprès des ménages sont généralement considérées comme des données de références, de haute qualité. Cependant, les enquêtes sont coûteuses et menées infiniment, alors que les décisions et les ajustements en matière de programmes et d’investissement doivent être prises beaucoup plus fréquemment. Cette étude a évalué la comparabilité des tendances temporelles de la couverture des interventions à partir des données de routine et d’enquête aux niveaux national et infra-national au Mali.


Résultats: Nous avons constaté que la direction et l’ampleur des tendances temporelles du taux de prévalence contraceptive, de l’accouchement médicalisé et du vaccin DTC3 de 2001 à 2012 étaient similaires au niveau national entre les sources de données. Cependant, au niveau régional, il y avait des différences significatives dans l’ampleur et la direction des tendances temporelles pour l’accouchement en établissement et le vaccin DTC3, tandis que les tendances de la prévalence contraceptive étaient plus cohérentes. Les données de routine avaient tendance à surestimer la couverture du DTC3 et à sous-estimer l’accouchement médicalisé et la prévalence contraceptive par rapport aux données d’enquête.

Conclusion: Les données de routine au Mali – en particulier au niveau national – semblent appropriées pour être utilisées pour guider la planification et la hiérarchisation des programmes, mais les tendances temporelles de routine doivent être interprétées avec prudence au niveau sous-national. Cependant, pour les évaluations de programme, les données de routine peuvent ne pas être appropriées pour tirer des conclusions précises sur l’impact du programme.
Accuracy of Using Mid-Upper Arm Circumference to Detect Wasting Among Children Aged 6–59 Months in Nepal

Krishna Prasad Lamsal, a Kedar Raj Parajuli, b Bhim Kumari Pun, c Ramesh Prasad Adhikari, c Manoj Bashyal, d Baburaja Dangol, e Kenda Cunningham f

Key Finding
- Mid-upper arm circumference (MUAC) had a lower sensitivity compared to weight-for-height z-score (WHZ), indicating it can detect only a small proportion of the total number of children aged 6–59 months who are wasted.

Key Implication
- Using sensitivity and specificity criteria, the poor performance of MUAC compared to WHZ to identify cases of severe and moderate wasting in infants and children aged 6–59 months suggests a need to further refine admission criteria, including the choice of indicators and cutoffs.

ABSTRACT

Background: In countries with a high prevalence of undernutrition, timely, accurate screening at the community level is essential to identify children with wasting. The World Health Organization recommends using either weight-for-height z-scores (WHZ) and mid-upper arm circumference (MUAC) or both measures and signs of edema to be used to identify children with severe acute malnutrition for treatment. We compared WHZ and MUAC cutoffs to identify wasting among children aged 6–59 months in Nepal, using WHZ as the reference standard.

Methods: We used cross-sectional anthropometric data for 3,169 children aged 6–59 months from a 2017 cross-sectional dataset, representative of 42 of Nepal’s 77 districts. We used descriptive statistics, receiver operating characteristic (ROC) curves, and kappa statistics to compare the use of MUAC and WHZ to identify wasting. The Youden index was calculated to determine the optimum MUAC cutoffs.

Results: The prevalence of wasting was 3.1% and 10.5% using MUAC and WHZ, respectively. We found 13.6% sensitivity for severe acute malnutrition (SAM) (MUAC < 115 mm) and 21.0% sensitivity for moderate acute malnutrition (MAM) (MUAC ≥ 115 to < 125 mm), with specificity of 99.7% and 91.2%, respectively. The sensitivity of MUAC for children aged 6–23 months was higher than for children aged 24–59 months. The total area of the ROC curve was 0.53 for the MUAC cutoff for SAM and 0.56 for MAM. The optimum MUAC cutoffs for SAM and MAM were 125 mm and 132 mm, respectively.

Conclusions: Although MUAC can be used as a rapid screening tool to detect wasting in children aged 6–59 months, using the recommended MUAC cutoffs captures only a small proportion of the total number of wasted children. The poor sensitivity and specificity of MUAC compared to WHZ suggests a need to refine admission and discharge criteria for acute malnutrition management programs to ensure that wasting among infants and children in Nepal is consistently and accurately diagnosed and treated.

INTRODUCTION

Undernutrition has devastating individual and public health consequences: it weakens individuals’ immune systems, worsens illnesses for individuals, and is linked to poor economic growth and poverty. Furthermore, undernourished children who survive have diminished learning capacity and lower productivity in adulthood. Acute malnutrition, especially severe acute malnutrition (SAM), is an unstable condition resulting from a relatively short duration of nutritional

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deficit that is often complicated by concurrent infective illness. A severely wasted child has a more than 11-fold increased risk of death compared to a non-wasted child.2–4

In countries with a high prevalence of undernutrition, timely, accurate screening at the community level is essential to identify children with acute malnutrition. More than 500,000 deaths annually could be prevented globally by timely and proper treatment of acute malnutrition.5 Children aged 6–59 months who have a mid-upper arm circumference (MUAC) <115 mm, a weight-for-height z-score (WHZ) <−3 standard deviation (SD) (based on the World Health Organization [WHO] Child Growth Standards), and/or nutritional edema are considered to have SAM. Likewise, children aged 6–59 months having WHZ <−2 to ≥−3 SD and/or MUAC ≥115 mm to <125 mm are classified as having moderate acute malnutrition (MAM).4 MUAC is a widely used tool, especially in resource-limited countries to identify wasting and is closely associated with mortality risk. WHO recommends using either or both WHZ or MUAC and the presence of nutritional edema to assess the prevalence of acute malnutrition and for admission and graduation criteria for treatment programs.

The prevalence of child undernutrition in Nepal is among the highest in the world. Among children aged under 5 years, 10% are wasted (low weight-for-height) including 2% severely wasted; this alarmingly high level has persisted for at least 2 decades.6,7 To reduce the prevalence of wasting, the Government of Nepal, in collaboration with donors and nongovernmental partners, has been implementing community and health facility-based programs. Since 2009, when the community-based management of acute malnutrition (CMAM) program was piloted, more than 40,000 female community health volunteers have used only MUAC to find wasted children in their communities. In contrast, health facility workers in Nepal use both WHZ and MUAC as well as nutritional edema as criteria to admit children to outpatient therapeutic centers, stabilization centers, and nutrition rehabilitation homes. However, only MUAC is used as the measure for discharge in SAM management programs and as the admission and discharge measure for MAM management programs.7,8

Researchers have raised concern about the effectiveness of using MUAC as a wasting screening tool because of its low sensitivity compared to WHZ.9–11 As per Fernandez et al.11 using MUAC <115 mm identified only 10 of 165 children with WHZ <−3. Thus, using MUAC <115 mm during community-level screening would leave more than 90% of children with a WHZ <−3 without therapeutic treatment. In other words, only using MUAC to screen for malnutrition globally would result in 14.4 of the 16 million children in 2016 with SAM (defined as WHZ <−3) not identified or treated. Therefore, understanding how MUAC performs, versus WHZ, in the detection of wasting in different populations is important. Prior studies on this have been mostly hospital-based rather than community-based and most were conducted in Africa. To date, no studies have been conducted in Nepal and very few studies done in South Asia to assess the accuracy of MUAC versus WHZ for detection of wasting. Several studies have also raised questions on the appropriateness of using the same cutoff for all children aged 6–59 months, given some findings of age and gender variation.12–15 Because WHZ and MUAC are the major anthropometric tools used to identify wasting in children, comparing the accuracy of both tools to identify wasting provides a better sense of the accuracy of measurements. Few studies have been done to compare the diagnostic accuracy of MUAC by assuming WHZ as a gold standard.10,12,15 Using WHZ as the reference standard, we aimed to identify the magnitude of discrepancies in the identification of wasted children in Nepal by MUAC versus WHZ, whether these discrepancies vary by child age or gender, and ideal MUAC cutoffs for more thorough detection of children with SAM and MAM.

**METHODS**

This study uses a cross-sectional dataset collected by a local survey firm in July–September 2017 across 16 of Nepal’s 77 districts, including a total sample of 3,169 children aged 6–59 months. Structured questionnaires were used to interview the young child’s mother and a household head (with preference given to a male decision maker, when available) to obtain socioeconomic and demographic information, as well as to measure knowledge and practices related to nutrition, reproductive health and family planning, agriculture and food security, empowerment, and exposure to health and nutrition-related interventions.

Anthropometry, including length/height, weight, and MUAC of each child, was measured by a team of 20 trained and standardized data collectors. The length of children aged 6–23 months and height of children aged 24–59 months were measured using the vertical stadiometer, following WHO guidelines.16 Weight was measured with an electronic digital
weighing scale (Seca scale) and read to the nearest 0.1 kg with minimum light clothing. Calibration of the Seca scales was done before weighing each child. For MUAC measurement, we used nonstretchable and flexible MUAC tapes procured from United Nations Children’s Fund. The measurement was taken at the midpoint of the acromion of the scapula and the olecranon of the ulna of a child. The height/length and MUAC of each child were measured twice and the measurements averaged to get the final raw length/height, weight, and MUAC measurements.

These anthropometric data were then transformed into WHZ z-scores. The prevalence of wasting was calculated by using both WHZ and MUAC. To classify children as SAM and MAM using WHZ, we used cutoffs of < -3 SD WHZ and ≥ -3 to < -2 SD WHZ, respectively. To classify children as SAM and MAM using MUAC, we used cutoffs of < 115 mm and ≥115 mm to < 125 mm, respectively. We assumed WHZ as the reference measure and tested the sensitivity of MUAC cutoffs versus WHZ. The sensitivity and false-positive rates (1-specificity) of MUAC were determined using WHO classification for SAM and MAM. To assess the performance of MUAC cutoffs compared to the standard recommended by WHO to define SAM and MAM, receiver operating characteristic (ROC) curves were constructed and categorized as: 50%–60% very poor, 61%–70% poor, 71%–80% fair, 81%–90% good, and 91%–100% with excellent sensitivity. The ROC curve is the plot of sensitivity versus false-positive rate of MUAC cutoffs. The area under the curve (AUC) is the area between the curve and the segment (0,0) and (1,1), which corresponds to a random classifier. A larger AUC indicates a more accurate diagnosis of acute malnutrition, defined by WHZ cutoffs. Kappa statistic was used to analyze inter-rater agreement between MUAC and WHZ by assuming: < 0% as none, 0%–20% as poor, 21%–40% as slight, 41%–60% as fair, 61%–80% as good, 81%–92% as very good, and 93% or more as excellent agreement. To identify the MUAC cutoff with the highest sensitivity and specificity, the Youden index, which is the difference between the true-positive rate (sensitivity) and the false-positive rate, was calculated.

All analyses were done using STATA (Version 15).

**Ethical Approval**

We obtained ethical clearance from the Ministry of Health and Population, Nepal Health Research Council, Kathmandu, Nepal (NHRC #1620/2017). All respondents gave written informed consent before the interview and collection of anthropometric data. No treatment or incentive was given to the study participants.

**RESULTS**

Selected background characteristics of the surveyed households and children aged 6–59 months are presented in Table 1. Children were on average aged 28 months; slightly less than half (43.7%) were aged 6–23 months, and the rest (56.2%) were aged 24–59 months. More than half (55.8%) of the children were male, and more than half (56.5%) resided in the hilly region of the country, versus the lowland plains and mountains of Nepal. Almost half (49.6%) of the surveyed children were from a socially excluded ethnic group. Among the children, 28.0% were stunted (low height-for-age). The overall prevalence of wasting based on WHZ was 10.5%, comprised of 2.1% SAM and 8.5% MAM, whereas only 0.4% SAM and 2.7% MAM were found based on MUAC.

We found 13.6% sensitivity for SAM (MUAC < 115 mm) and 21.0% sensitivity for MAM (MUAC ≥ 115 mm to < 125 mm) with specificity of 99.7% and 91.2%, respectively. The total area under the ROC curve was 0.53 for the MUAC cutoff for SAM (< 115 mm). The kappa value for the SAM cutoff was 9.0%. The total area under ROC curve was 0.56 for the MAM cutoff ≥ 115 mm to < 125 mm. The kappa value for the MAM cutoff was 17.0%.

Comparison of ROC and kappa by child gender and age are shown in Table 2. The total AUC of the SAM cutoff for male and female children were 0.51 and 0.56, respectively. The kappa value for the SAM cutoff among boys was 4.0% and 16.0% for girls. The total AUC of the MAM cutoff for boys and girls was 0.52 and 0.62 with kappa values 11.0% and 24.0%, respectively.

Among the children aged 6–23 months, 11.5% were identified as wasted including 8.9% with MAM and 2.6% with SAM using WHZ, but only 5.0% SAM and 0.7% MAM were identified as wasted using MUAC. Among children aged 24–59 months 9.8% were identified as wasted using WHZ including 8.2% with MAM and 1.6% with SAM, whereas using MUAC, only 0.7% and 0.2% of these children were diagnosed with MAM and SAM, respectively. The total AUC of the SAM cutoff was 0.61 and 0.51 for children aged 6–23 months and 24–59 months, respectively. The kappa value of the SAM cutoff for children aged 6–23 months was 12.0% and 6.0% for children aged 24–59 months. Likewise, the total AUC of the MAM cutoff for children aged 6–23 months and 24–59 months were
The kappa value of the MAM cutoff for children aged 6–23 months was 25.1% and 7.0% for children aged 24–59 months. Table 3 shows the sensitivity, specificity, and Youden index at various MUAC cutoff values for diagnosing SAM. The optimum cutoff of MUAC for SAM was found to be 125 mm with a maximum Youden index of 49.9%. Similarly, the best cutoff point of MUAC for optimum diagnosis of MAM was found to be 132 mm with a Youden index of 30.5% (Table 4).

### DISCUSSION

This study compares the sensitivity and specificity of MUAC versus WHZ to identify wasting in children aged 6–59 months in Nepal, to contribute to local and global debates on how to ensure the timely and accurate diagnosis of wasting, a prerequisite to identifying and treating millions of children globally suffering from undernutrition. This is the first-ever study comparing the performance of MUAC and WHZ in Nepal to identify wasted children and among the few studies globally to use population-based, rather than hospital/treatment center-based, data to explore variations in the MUAC and WHZ indicators. This study looks at discrepancies in classification overall and then separately by child age and child gender. The percentage of wasting, as measured by WHZ, was found to be almost the same as the national prevalence found in the recent demographic and nutritional surveys. The prevalence was found to be almost the same as the national prevalence found in the recent demographic and nutritional surveys.
health survey done in 2016 (10.5% vs. 9.8%). Among these wasted children, we found that 2.1% were SAM and 8.5% were MAM, but when using MUAC we only found 0.4% SAM and 2.7% MAM. When comparing the 2 methods for identification, and using WHZ as the reference standard, the total AUC of MUAC for both SAM and MAM, showed that in 53% and 56%, respectively. These are close to an AUC of 0.5, which is the same as complete randomness, and suggests that the current MUAC cutoffs are poor tools for detecting wasting.

With WHZ as the reference standard, we found MUAC only had 13.6% sensitivity for SAM (MUAC < 115 mm) and 21% sensitivity for MAM (MUAC ≥115 mm to <125 mm), with a specificity of 99.7% and 91.2%, respectively. This is consistent with various studies that have reported a very wide range of sensitivity of MUAC, ranging from 17.5% to 43.5% and consistently higher specificity. A study by Grellety et al. in a therapeutic feeding center that included 2,205 South Sudanese children concluded that MUAC <115 mm would have failed to identify 33.0% of the children with SAM, while 98.0% were identified by WHZ < −3 SD alone and 100% by MUAC <130 mm. A systematic review and meta-analysis by Grellety and Golden concluded that the use of MUAC alone to identify SAM children, versus using both WHZ and MUAC, would exclude many children from treatment and thus, result in an additional 300,000 SAM related deaths annually. In Asia, the evidence around these challenges with using MUAC to identify and treat malnourished children is building. Fiorentino et al. also found in Cambodia that the sensitivity of MUAC ranged from 6.5% to 32.9% in children with acute malnutrition and from 0.0% to 18.2% in children with severe acute malnutrition. According to Talapalliwar and Garg the sensitivity and specificity of MUAC <115 mm was 13.6% and 99.3%, respectively and the current cutoff can only capture a small proportion of all children with SAM, in the context of tribal populations in India. Our findings also show that many Nepalese children could be excluded by using only MUAC to identify wasting.

Similarly, since MUAC >115 mm is being used in Nepal as a single criterion to discharge children with SAM from outpatient therapeutic centers, proper nutritional rehabilitation will be missed, and thousands of Nepalese children will be discharged as cured who could still be suffering from undernutrition or at increased risk of relapse. Finally, many studies to date focus on SAM, but MAM management programs, especially blanket and targeted supplementary feeding programs in Nepal, use MUAC only. These findings show that a large number of children with MAM are being missed and not provided with nutrition rehabilitation, counseling, and support because MUAC was the only anthropometric measurement used. Existing literature suggests that MUAC-only based programs tend to identify significantly more girls and younger children than those identified by

| TABLE 2. Area Under ROC Curve and Kappa Value to Compare MUAC and WHZ Cutoffs for Children Aged 6–59 Months, Nepal |
| --- | --- | --- | --- |
| | SAM (<115 mm) | MAM (≥115 mm to <125 mm) |
| | Area Under ROC | Kappa, % | Area Under ROC | Kappa, % |
| Overall | 0.53 | 9 | 0.56 | 17 |
| Sex | | | | |
| Male | 0.51 | 4 | 0.52 | 11 |
| Female | 0.56 | 16 | 0.62 | 24 |
| Child age, months | | | | |
| 6–23 | 0.61 | 12 | 0.61 | 25 |
| 24–59 | 0.51 | 6 | 0.53 | 7 |
| Stunting | | | | |
| Stunted | 0.51 | 10 | 0.56 | 16 |
| Not stunted | 0.54 | 10 | 0.56 | 16 |

Abbreviations: MAM, moderate acute malnutrition; MUAC, mid-upper arm circumference; ROC, receiver operating characteristic curve; SAM, severe acute malnutrition; WHZ, weight-for-height/length z-score.

These findings show that a large number of children with MAM are being missed and not provided with nutrition rehabilitation, counseling, and support because MUAC was the only anthropometric measurement used.
In this study, the total AUC for male children was slightly lower than for female children (0.51 vs. 0.56), with kappa 4.0% and 16.0%, respectively, which indicates that MUAC captured faintly more wasted female children than male children. The ROC and kappa results in this study also suggest that MUAC may be a more useful approach for the diagnosis of both SAM and MAM in children aged less than 2 years than for older children. Prior studies also provide similar evidence of age variation in the ability of MUAC to detect both SAM and MAM.23,25–27 The age dependency may be due to variation of muscle mass with increasing age of children.

### TABLE 3. Sensitivity, Specificity, and Youden Index at Various Cutoffs of MUAC for SAM in Children Aged 6–59 Months, Nepal

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<thead>
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<th>MUAC, mm</th>
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Abbreviations: MUAC, mid-upper arm circumference; SAM, severe acute malnutrition.
In line with previous studies, the results of our Youden index analyses, which identify an ideal performance point by calculating the optimum level of sensitivity and specificity, suggest that current MUAC cutoffs must be increased to capture more cases of wasting. The optimum MUAC cutoff point to identify children with SAM was found to be 125 mm. Likewise, the best cutoff for MUAC to optimally identify children with MAM was found to be 132 mm. Talapalliwar and Garg also found the optimal cutoff of MUAC to be 125 mm for proper detection of SAM and 136 mm for diagnosing MAM. Laillou et al. suggested that a MUAC cutoff of 133 mm would allow the inclusion of more than 65% of children with a WHZ $<-3$ to be considered wasted. Similarly, a recent study by Tessema et al. in Ethiopia concluded that implementation of a MUAC-only screening program, using a cutoff of $<115$ mm for the identification of SAM, is unethical as it may lead to many children remaining undiagnosed and untreated. They suggested a MUAC cutoff $<133$ mm for optimum identification of children with SAM. Furthermore, consistent with our findings, Fiorentino et al. concluded that MUAC cutoffs by age group and

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Abbreviations: MAM, moderate acute malnutrition; MUAC, mid-upper arm circumference.
gender should be revised for community-level screening and treatment of wasting.

**Limitations**

A limitation of this study is that we could not analyze relationships between the screening tools and mortality, screening tools and response to treatment such as weight gain, or time for nutrition rehabilitation/graduation from treatment. We have used a cross-sectional dataset, which could not capture information on response to treatment or recovery/survival. Furthermore, screening and exclusion of children with edema were not done in these analyses, which could offer yet another interesting perspective on the prevalence of acute malnutrition. We used WHZ as a reference standard, but WHZ itself is not without its challenges for diagnosis and treatment of wasting, including the need for all health workers to be trained and standardized to ensure accuracy of measurement and for anthropometric equipment to be maintained in good condition.

**CONCLUSION**

This study confirms that MUAC, using WHZ as the reference standard, can detect wasting but in only a small fraction of all wasted children, leaving the majority of wasting in Nepal undetected and untreated. The poor performance in terms of sensitivity and specificity confirms the need to either increase the MUAC cutoff values or adopt both MUAC and WHZ at every health facility and in acute malnutrition management programs for early, rapid, and accurate diagnosis and treatment of wasting in Nepal. Therefore, WHZ should also be used as the admission and discharge criteria, rather than MUAC alone, as a standalone anthropometric criterion at therapeutic centers. Additionally, the Government of Nepal and development partners will need to continue to work with communities to ensure that more children are brought to the health facilities where these criteria would be used. Furthermore, while evidence-based updating is done to policies and programs for the treatment of undernutrition, governments and development partners should continue to invest in prevention efforts. Multisectoral policies and programs focused on the prevention of all forms of child malnutrition should continue so that the prevalence of wasting does not remain above 10% for another 20 years. The findings of this study can help the Government of Nepal and development partners to update screening and management approaches for acute malnutrition to enable timely and proper nutrition rehabilitation of children aged under 5 years.

**Acknowledgments:** The authors also acknowledge Dr. Bernadette Cichon at No Wasted Lives/Action Against Hunger, for her feedback on an early draft of the manuscript.

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** Disclaimer:** The contents of this publication are the sole responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government.

**Author contributions:** KPL and KJC jointly conceptualized the study. KPL and RA did the data analysis. KPL wrote the first draft of the manuscript. KRP reviewed the manuscript as a focal person of the Government of Nepal. BD, BP, and MB reviewed the anthropometric data. KJC did the final review of the manuscript. All authors participated in the interpretation of the data and critical revisions of the manuscript. All authors read and approved the final manuscript.

**Competing interests:** None declared.

**REFERENCES**


Effects of Pharmacist Intervention on Community Control of Hypertension: A Randomized Controlled Trial in Zunyi, China

Ying Li,a,b Guoqin Liu,a Chaojie Liu,c Xianhong Wang,a Yalin Chu,a Xiaqin Li,a Wenhao Yang,a Yewei Shen,a Fang Wu,a Wenzhi Zhangd

Key Finding

- The results from this randomized controlled trial of a pharmacist intervention, which included patient education and medication, are encouraging, showing significant short-term (at 3–6 months) improvement in blood pressure control, patient knowledge on hypertension, and medication adherence.

Key Implications

- Community pharmacists can contribute to better management of chronic conditions, such as hypertension, as part of an interdisciplinary team in an integrated care network to improve the continuity and coordination of patient care.
- The findings shed some new insight into the unique role that pharmacists can play by working in partnership with the health care providers, patients, and other community health workers.

ABSTRACT

Objective: We aimed to test the effects of pharmacist intervention on the community control of hypertension through a comparative randomized controlled trial.

Methods: We recruited adult hypertensive patients with comorbidity or confusion with medication (n=636) from 2 community health centers in Zunyi, China. They were randomly and equally divided into 2 groups. Both groups received the usual care and participated in the community systematic management program of hypertension. Participants in the intervention group were given interventions from pharmacists, including a monthly review of medications, patient education, and medication adjustment advice to medical doctors over 6 months. Participants’ blood pressure was assessed at baseline, 3 months, and 6 months. Participants’ knowledge and medication adherence were measured using a questionnaire before and after the trial.

Results: Compared to the control group (n=298), a significantly higher percentage of participants in the intervention group (n=290) had their blood pressure under control 3 months (46.9% vs. 38.3%, P=.034) and 6 months (60.7% vs. 40.9%, P<.001) after the interventions. Difference-in-differences analyses showed that the pharmacist intervention resulted in an increase in knowledge scores by 12.55 points (P<.001), a decrease in systolic blood pressure by 6.65 mmHg (P=.001), and a decrease in diastolic blood pressure by 7.26 mmHg (P=.001) compared to the controls after adjustment for variations in potential confounding factors. The odds of participants passing the hypertension knowledge tests in the intervention group was 4.45 times those in the control group (P<.001). Similarly, it was found that the intervention group had higher odds of not needing any medication adjustments (adjusted odds ratio [AOR]=2.75, P<.001) and having their blood pressure under control (AOR=2.18, P=.002) compared to the control group.

Conclusion: It is evident that pharmacist intervention has significant short-term effects on improving the knowledge and medication adherence of hypertensive patients, as well as timely medication adjustments from medical doctors, resulting in lowered blood pressure and an increased control rate. Further studies should explore the long-term sustainability of the effects of community pharmacist intervention.

INTRODUCTION

Hypertension is the most common chronic disease and a primary risk factor for cardiovascular and cerebrovascular diseases. Although effective treatment regimens exist for hypertension that can significantly
reduce mortality and prevent the development of complications.\(^1\) the control of blood pressure has remained a great challenge. The World Health Organization (WHO) estimated that 1.13 billion people in the world have hypertension.\(^2\) But more than four-fifths have failed to bring their blood pressure under control, resulting in 10 million deaths every year.\(^3\) Hypertension also brings substantial financial burdens to the world, which affect low- and middle-income countries (LMICs) disproportionately. About two-thirds of hypertensive patients in the world live in China.\(^2\) A study found that hypertension treatments account for 6.61% of the total health expenditure in China.\(^4\)

There are many underlying reasons for the poor control of blood pressure, of which poor knowledge of patients and nonadherence to prescribed therapy are deemed critical contributing factors.\(^5\)–\(^7\) It is widely believed that optimizing drug treatment is the key to achieving the successful control of blood pressure.\(^5\)–\(^9\) A systematic review and meta-analysis showed that 83.7% of cases of uncontrolled hypertension are a result of nonadherence to drug therapy.\(^7\) But unfortunately, there is no simple solution. Many efforts have been made to address this issue, ranging from patient education and guidelines on professional practice to technological innovations.\(^10\) Empirical evidence has highlighted the importance of cross-disciplinary collaboration and partnerships between health care providers and patients.\(^11\)

In recent years, interest has grown in enhancing pharmacist services in primary care for improved management of hypertension. Pharmacist services have shifted focus from ensuring drug supply to providing patient-centered care. Studies conducted in high-income countries, such as the United States and Canada, have demonstrated that pharmacist interventions on hypertension can help achieve remarkable results,\(^12\)–\(^14\) including improved adherence to drug therapy, lowered blood pressure, better health outcomes, and savings in relation to medical expenditure.\(^15\)–\(^20\) Consequently, the Canadian\(^8\)\(^,\)\(^21\) government has issued guidelines and standards for community pharmacist care for hypertensive patients. As a highly skilled profession, community pharmacists have performed well in monitoring chronic conditions, educating patients, and providing medication consultations to medical doctors and patients.\(^11\)\(^,\)\(^15\)\(^,\)\(^22\)

However, there is a dearth of evidence on the effectiveness of community pharmacist interventions on hypertension in LMICs. In a systematic review on the impact of interventions by community pharmacists on the control of hypertension, Cheema et al.\(^23\) identified only 5 of 16 randomized controlled trials conducted in LMICs. There is a consensus that community-oriented primary care is the most appropriate setting for managing hypertension, which requires continuous and coordinated care.\(^24\) In high-income countries, pharmacists are usually more easily accessible in the community than medical doctors, giving community pharmacists an advantage in managing hypertension. But this is not necessarily the case in LMICs where a shortage of properly trained pharmacists is common.\(^25\)

This study fills the gap in the literature by testing the impact of pharmacist interventions on hypertension in primary care facilities in China. Since 2009, the Chinese government has increased its investment in primary care dramatically. A total of 9,352 (in 2018) community health centers were developed over a short period, covering the entire population.\(^26\) In line with the international evidence, community health care services have been shown to serve as a major force in managing chronic conditions. However, workforce development in community health care services has been focused on general practice and community nursing. Little attention, if any, has been paid to the development of community pharmacists although all community health care services dispense medications. The outcome of the primary care reform in China has attracted serious debate.\(^27\) It appears that the management programs for chronic diseases have been far from successful. In 2018, only 30% of hypertensive patients received antihypertension treatments,\(^28\) well below the level (40%–80%) of high-income countries such as Canada, Australia, the United Kingdom, the United States, and Germany.\(^29\) The community management of chronic diseases is delivered in China free of charge by a general practice team as part of the essential public health service package.\(^30\)\(^,\)\(^31\) High workloads of the general practice team and a lack of attention to medication adherence have often been blamed for the unsatisfactory outcome.\(^4\)\(^,\)\(^32\)\(^,\)\(^33\) Indeed, community health care services have been struggling to attract medical doctors. In China, about 1.53 million medical doctors (2.5 per 1,000 population) work in primary care, accounting for 39% of the medical workforce.\(^34\) Adding to the complexity is the low qualifications of primary care medical workers (31% do not have a medical degree),\(^35\) the high prevalence of irrational prescriptions,\(^28\) and the self-medication of consumers.\(^36\) As a result, there have been increasing calls recently from
both researchers and policy makers to explore the role of community pharmacists.

## MATERIALS AND METHODS

### Study Setting

A comparative randomized controlled trial was conducted in 2 urban community health centers in the Zunyi municipality of Guizhou province in China. The trial was registered with the Chinese Clinical Trials Registry (registration number: ChiCTR1900028368).

Zunyi has a population of more than 6 million. In 2018, it had an average gross domestic product (GDP) of US$5,656 per capita,\(^3\) about half of the national average in mainland China.\(^4\) According to the World Bank, Zunyi is ranked at the lower end of middle-income economies.\(^5\)

Community health services were developed in China as a hub for the delivery of primary health care services, covering essential medical services, disease prevention and control, care for vulnerable populations, rehabilitation, family planning, health education, and health promotion. Each community health center was designated to cover a residential community ranging in number from 20,000 to 60,000 people. Zunyi has 19 urban community health centers.\(^6\) In 2018, a total of 822,600 patients sought medical attention from these health centers.

Two medium-sized urban community health centers were selected from the Huichuan district, the economic, political, and cultural center of Zunyi. Huichuan was ranked 48 among the 219 economic and technological development zones in China.\(^7\) A total of 6,500 hypertensive patients registered with the 2 centers over the past 9 years.

### Study Participants

Eligible participants of this study were those aged 18 years or older who had a confirmed diagnosis of hypertension. They had enrolled in the community systematic management program for hypertension and received relevant services. The participants also had to meet at least 1 of the following criteria: (1) taking antihypertensive medications; (2) having coexisting chronic conditions such as diabetes; (3) reporting confusion with their own medication regimen; or (4) missing medicines frequently. Pregnant and lactating women and patients with recorded cognitive impairments were excluded from this study.

Eligible patients who sought medical attention for hypertension from the 2 community health centers from January to April 2018 were invited by their doctors to participate in this study. In total, 746 were invited and 110 rejected. This resulted in a sample size of 636 participants, who were randomly allocated into the control and intervention groups equally. Eventually, 28 participants dropped out of the intervention group, compared with 20 in the control group (Figure 1).

The final sample size (n=588) included for data analysis was large enough to enable the detection of a 20% difference in the percentage of participants with blood pressure under control between the 2 groups. A national survey showed that about 38% of hypertensive patients had their blood pressure well controlled,\(^8\) but the government aimed for a 60% goal.\(^9\) A sample of 160 participants in each group would be required to detect the significance of such an achievement at \(\alpha=0.05\) and \(\beta=0.80\) according to the formula below:

\[
N = \frac{Z^2aP(1-P) + Z^2b \phi C^2(1-P_c) + P_c(1-P_c)}{(P_c - P_e)^2}
\]

Where \(Z_a\) for \(\alpha\) level is the corresponding standard normal, \(Z_b\) for \(\beta\) level is the corresponding standard normal, \(N\) is the required sample size for each group, and \(P_e\) and \(P_c\) represent the percentage of participants with their blood pressure under control in the control and the intervention groups, respectively; \(P_e = (P_c + P_e)/2\).

The sample size was also large enough to enable detection of a very small effect size (0.1) for the continuous indicators (knowledge and medication adherence scores) while \(\alpha\) being set at 0.05 and statistical power \((1-\beta)\) being set at 0.8.\(^10\)

### Randomization

The random allocation of study participants was conducted by the researchers who were not involved in the implementation of the trial. The eligible patients were sorted in order according to the age of participants with their blood pressure under control in the control and the intervention groups, respectively; \(P_e = (P_c + P_e)/2\).

First, a starting point was randomly identified in the table. Then a backward or forward direction was randomly determined to retrieve 636 random numbers from the identified starting point of the table. Finally, the random numbers were mapped with the participants in sequence, which were then reordered from small to large. The first 318 patients

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**Figure 1:** Flow chart of the study participants.
with smaller numbers were assigned to the control group, while the rest were assigned to the intervention group.

**Trial Protocol**

The trial started in June 2018 and lasted for 6 months.

All the participants received the usual care and continued their community systematic management program delivered by a team comprising general practitioners, nurses, and public health workers. The systematic management program for hypertension was part of the National Essential Public Health Package being offered to all eligible community residents for free. Once every 3 months, follow-up with hypertensive patients was conducted at outpatient appointments, telephone interviews, and home visits by monitoring patients’ blood pressure and heart rate; changes in symptoms, comorbidities, and critical complications; risk factors (such as body mass index, smoking, drinking, salt intake, and physical exercise); and medication compliance. The patients identified with poorly controlled conditions were supposed to be given further medical advice or referred to a specialist clinic if needed and followed up again 2 weeks later. The routine follow-up arrangement was complemented with an annual physical examination, including blood tests and electrocardiograms. In addition to the community systematic management program, patients also had the freedom to bypass community health services to seek medical attention from hospitals covered by social health insurance programs. By 2011, almost all Chinese citizens had been covered by social health insurance policies, albeit with varied benefit entitlements.

This trial tested the effectiveness of additional interventions involving pharmacists on the control of blood pressure. Five registered pharmacists were recruited from local tertiary hospitals (in China, very few, if any, properly trained registered pharmacists work in community health services). All of them had a master’s degree and had engaged in clinical practice for more than 8 years. They showed a strong willingness to participate in the trial and maintained high levels of commitment throughout the trial. The pharmacists conducted a medication review for each patient in the intervention group based on the data collected through the baseline survey. A medication adjustment plan, if needed, was then developed considering the safety, effectiveness, and adherence barriers. The medication adjustment plan was further reviewed and fine-tuned monthly by the pharmacists based on a chart report. The monthly medication chart was developed by the assistants (medical students) of the pharmacists through outpatient appointments, home visits, or telephone interviews, during which they recorded patient uptake and adherence to the prescriptions.
A correct answer was given a score of 1, otherwise 0. Four of the items contained more than 1 correct answer. This resulted in a summed score ranging from 0 to 32. The summed score was transformed into a percentage score, with a higher score indicating higher knowledge and >60% being considered “pass.” Consultations were sought from 10 experts specialized in medicine, pharmacy, and public health on the content validity of the scale. The scale had a Cronbach’s $\alpha$ of 0.919, indicating excellent internal consistency.

3. Medication adherence: Medication adherence refers to the degree to which a patient implements the medication treatment regimen. It was assessed using a validated 8 item scale developed by Morisky (MMAS-8).47 Respondents were asked to answer “yes” (1) or “no” (0) to the first 7 items. The last item was rated on a 5-point Likert scale ranging from 0 to 1. The scores were then summed, with a higher score indicating higher adherence. A score lower than 6 was deemed low adherence, while a score of 8 was considered high adherence. The MMAS-8 had a Cronbach’s $\alpha$ of 0.786 in this study, indicating good internal consistency. In addition, the percentage of participants taking antihypertensive medications regularly and the percentage of participants with a treatment regimen with no need for adjustment were also calculated.

Data Collection
The blood pressure of the participants was recorded before the trial (baseline, June 2018) and 3 and 6 months after commencement of the trial. Data about hypertension knowledge and medication adherence were collected twice through a questionnaire survey: once at the baseline and again at the end of the trial, which also included information about the sociodemographic characteristics (age, gender, and education), risk factors (smoking, drinking, exercise, and salt intake), duration of diagnosed hypertension, and coexisting chronic conditions of the respondents.

Participating pharmacists’ assistants conducted household visits, measured blood pressure, and administered the questionnaire through face-to-face interviews. All the assistants were postgraduate or undergraduate medical students and were trained and assessed against the 2017 National Guidelines for Prevention and Control of Hypertension in Primary Care before interacting with patients. A quality control officer examined logical errors embedded in the returned questionnaires.
Data Analysis
This was a comparative trial. Although it was not possible to conduct a blinded trial, data were not analyzed until the trial ended. Data were input into Epidata 3.1 and analyzed using Stata version 15.0. A P value of less than .05 was considered statistically significant.

The number and percentage of participants with different sociodemographic characteristics were described. Differences in the outcome indicators between the intervention and control groups were compared using independent sample t-tests for the continuous measurements or Chi-square tests for the categorical measurements. Paired t-tests or Chi-square tests were performed to examine changes in the outcome indicators over time. Difference-in-differences (DID) analyses were performed to provide additional evidence on the effects of pharmacist intervention based on a linear regression model (for continuous measurements) or logistic regression model (for categorical measurements), adjusting for potential variations in confounding factors including age, gender, education, lifestyle (smoking, drinking, salt intake, and physical exercises), duration of hypertension, and coexisting chronic conditions:

\[
y_{it} = \beta_0 + \beta_1 \cdot \text{group}_{it} + \beta_2 \cdot \text{time}_{it} + \beta_3 \cdot \text{group}_{it} \cdot \text{time}_{it} + \varphi X_{it} + \varepsilon_{it}
\]

Where \( y \) is the outcome indicator (dependent variable), \( i \) represents each individual, \( t \) is different times; \( i \) is a dummy variable with 0 indicating pre-trial and 1 indicating post-trial; group indicates the group allocation of participants (0=control, 1=intervention); \( X \) represents all the control variables; \( \varepsilon \) is a random error. The interaction effect between group and time (group multiplied by time) detects the effect of the intervention. An enter approach was adopted.

Ethics Approval
The study protocol was approved by the Ethics Committee of Zunyi Medical University. The trial was registered with the Chinese Clinical Trials Registry (registration number: ChiCTR1900028368).

Before the trial and data collection, the study nature, objectives, and details were explained to the potential participants. Written informed consent was obtained from those who were willing to participate in the study. The participants were informed about their right to withdraw from the study, which would not result in any negative consequences on their services and treatment. They were assured of confidentiality.

RESULTS

Participant Baseline Characteristics
A total of 588 patients completed this study: 290 in the intervention group and 298 in the control group. The study participants had an average age of 65.98 years (standard deviation [SD]=9.48). More than half (57.32%) were female. The majority (52.72%) had only completed primary school education. About 18.71% were smoking, 26.02% were drinking, and 17.86% had high salt intake (>5 g a day) at the time of the baseline survey. Approximately 86.73% reported regular daily exercise of moderate intensity, such as walking, housework, sports, and recreational activities (according to the WHO, these activities consume about 3–6 metabolic equivalent oxygen). About one-fifth (19.39%) of the participants reported coexisting chronic conditions. More than 30% of the participants had been living with hypertension for 10 or more years. But less than 10% had their blood pressure under control.

Blood Pressure
Control of blood pressure improved over time in both groups (P<.005). However, a significantly higher percentage of participants in the intervention group had their blood pressure under control (<140/90 mmHg or <150/90 mmHg for those aged over 65 years with no complications) at the end of the trial compared with the control group (60.7% vs. 40.9%, P<.001), despite a lack of difference in the baseline (Table 2).

The effects of the intervention became significant 3 months after the trial (46.9% vs. 38.3%, P=.034) and continued until the end of the trial (Figure 2).

Although there were no significant differences at baseline in systolic blood pressure (SBP) (P=.147) and diastolic blood pressure (DBP) (P=.713) readings between the intervention and control groups, significant differences appeared in...
<table>
<thead>
<tr>
<th>Table 1. Baseline Characteristics of Study Participants in a Randomized Controlled Trial on Effect of Pharmacist Interventions on Management of Hypertension, China</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td><strong>Age, years</strong></td>
</tr>
<tr>
<td>&lt;65</td>
</tr>
<tr>
<td>65–79</td>
</tr>
<tr>
<td>≥80</td>
</tr>
<tr>
<td><strong>Education</strong></td>
</tr>
<tr>
<td>Primary school</td>
</tr>
<tr>
<td>Middle school</td>
</tr>
<tr>
<td>High school</td>
</tr>
<tr>
<td>University</td>
</tr>
<tr>
<td><strong>Smoking</strong></td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td><strong>Drinking</strong></td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td><strong>Regular daily exercise</strong></td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td><strong>Salt intake</strong></td>
</tr>
<tr>
<td>Light</td>
</tr>
<tr>
<td>Medium</td>
</tr>
<tr>
<td>Heavy</td>
</tr>
<tr>
<td><strong>Years of living with hypertension</strong></td>
</tr>
<tr>
<td>&lt;10</td>
</tr>
<tr>
<td>11–20</td>
</tr>
<tr>
<td>&gt;20</td>
</tr>
<tr>
<td>Not sure</td>
</tr>
<tr>
<td><strong>Other chronic conditions</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td><strong>Blood pressure (mmHg)a</strong></td>
</tr>
<tr>
<td>&lt;120/80</td>
</tr>
<tr>
<td>120–139/80–89</td>
</tr>
<tr>
<td>140–159/90–99</td>
</tr>
<tr>
<td><strong>Continued</strong></td>
</tr>
</tbody>
</table>
both SBP ($P<.001$) and DBP ($P<.001$) 3 months after the trial. The gaps between the 2 groups remained at the end of the trial ($P<.001$) (Table 3). The intervention group ended up with significantly lower SBP and DBP readings than the control group. Both groups experienced a drop in SBP over time, but to a greater extent in the intervention group. The DBP reading declined in the intervention group, compared with a slight rise in the control group.

### Hypertension Knowledge

Hypertension knowledge scores increased over time in both groups ($P<.001$). However, significantly higher knowledge scores were found in the intervention group at the end of the trial compared with the control group (77.46±19.33 vs. 61.00±26.98, $P<.001$), despite a lack of difference in the baseline. At the baseline, about 37% of participants in the intervention group and 32% in the control group passed (scored over 60) the knowledge tests.

#### TABLE 1. Continued

<table>
<thead>
<tr>
<th>Time</th>
<th>Intervention (n=290) No. (%)</th>
<th>Control (n=298) No. (%)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>95 (32.8%)</td>
<td>92 (30.9%)</td>
<td>.62</td>
</tr>
<tr>
<td>Third month</td>
<td>136 (46.9%)</td>
<td>114 (38.3%)</td>
<td>.03</td>
</tr>
<tr>
<td>Sixth month</td>
<td>176 (60.7%)</td>
<td>122 (40.9%)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

### FIGURE 2. Changes in Systolic and Diastolic Blood Pressure Readings (mmHg) Among Participants in a Randomized Controlled Trial on Effect of Pharmacist Interventions on Management of Hypertension, China

- **SBP**: Blood pressure was presented as SBP/DBP and the higher grade prevails.
tests \((P=.2)\). This increased to 84\% and 51\% in the intervention group and the control group, respectively, at the end of the trial \((P<.001)\) (Table 4).

**Medication Adherence**

Significant differences in patient adherence to medications were found at the baseline between the intervention and control groups. Participants in the intervention group were more likely to take medications regularly \((P<.001)\), adhere to prescriptions \((P<.001)\), and have no need to adjust their treatment regimen \((P=.02)\). Such differences remained at the conclusion of the trial \((P<.001)\) although participants in both groups experienced significant improvement \((P<.05)\) (Table 5).

**Results of DID Analyses**

The DID analyses confirmed that the intervention improved control of blood pressure significantly in terms of the 3 outcome indicators after adjustments for potential variations in confounding factors (Table 6). The intervention resulted in an increase in knowledge scores by 12.55 points \((P<.001)\), a decrease in SBP readings by 6.65 mmHg \((P=.001)\), and a decrease in DBP readings by 7.26 mmHg \((P<.001)\) in comparison with the controls. The odds of participants passing hypertension knowledge tests in the intervention group was 4.45 times those in the control group \((P<.001)\). Similarly, it was found that the intervention group had higher odds of not needing any adjustments of the treatment regimen \((AOR=2.75, P<.001)\) and having their blood pressure under control \((AOR=2.18, P=.002)\) compared with the control group.

**DISCUSSION**

This study shows that community pharmacist interventions improve knowledge and medication

<table>
<thead>
<tr>
<th>TABLE 3. Blood Pressure Readings of Study Participants in a Randomized Controlled Trial on Effect of Pharmacist Interventions on Management of Hypertension, China</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention, mean±SD</strong></td>
</tr>
<tr>
<td><strong>Systolic blood pressure</strong></td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Third month</td>
</tr>
<tr>
<td>Sixth month</td>
</tr>
<tr>
<td><strong>Diastolic blood pressure</strong></td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Third month</td>
</tr>
<tr>
<td>Sixth month</td>
</tr>
<tr>
<td><strong>P value</strong></td>
</tr>
</tbody>
</table>

Abbreviation: SD, standard deviation.

<table>
<thead>
<tr>
<th>TABLE 4. Hypertension Knowledge of Study Participants in a Randomized Controlled Trial on Effect of Pharmacist Interventions on Management of Hypertension, China</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge Score, mean±SD</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Sixth month</td>
</tr>
<tr>
<td><strong>P Value</strong></td>
</tr>
</tbody>
</table>

Abbreviation: SD, standard deviation.
adherence of hypertensive patients in the short term, which may have the potential to serve as an effective strategy for achieving the target control rate set by the Chinese government. Six months after the trial, 60.7% of the participants who received pharmacist interventions had their blood pressure under control, already exceeding the governmental target. In contrast, only 40.9% of the participants in the control group had their blood pressure under control, 19 percentage points below the governmental target. The marginal contribution of pharmacist interventions is high according to the DID analyses—more than doubling the odds of having blood pressure under control. This result is consistent with the findings of previous studies, although most were conducted in high-income countries.50–53 It shed some light on the hope in LMICs that hypertension can be controlled through community pharmacist intervention programs. Santschi and Colosimo54 concluded in a meta-analysis that better control of blood pressure can be achieved if pharmacists

<table>
<thead>
<tr>
<th>Antihypertensive Treatment</th>
<th>Intervention, No. (%)</th>
<th>Control, No. (%)</th>
<th>P Value for Group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration of medicines</td>
<td>Regularly</td>
<td>234 (80.7%)</td>
<td>277 (95.5%)</td>
</tr>
<tr>
<td></td>
<td>Intermittently</td>
<td>43 (14.8%)</td>
<td>13 (4.5%)</td>
</tr>
<tr>
<td></td>
<td>Ignored</td>
<td>13 (4.5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Medication adherence score</td>
<td>Low (&lt;6)</td>
<td>63 (21.7%)</td>
<td>13 (4.5%)</td>
</tr>
<tr>
<td></td>
<td>Medium (6-7)</td>
<td>80 (27.6%)</td>
<td>14 (4.8%)</td>
</tr>
<tr>
<td></td>
<td>High (=8)</td>
<td>147 (50.7%)</td>
<td>263 (90.7%)</td>
</tr>
<tr>
<td>Need for adjustment on treatment regimen</td>
<td>No</td>
<td>93 (32.1%)</td>
<td>184 (63.4%)</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>197 (67.9%)</td>
<td>106 (36.6%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome Indicator</th>
<th>Effect of Pharmacist Intervention</th>
<th>Linear Regression Model for Continuous Measurement</th>
<th>Logistic Regression Model for Categorical Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unadjusted ( \beta ) Coefficient</td>
<td>Adjusted ( \beta ) Coefficient^a</td>
<td>Unadjusted Odds Ratio</td>
</tr>
<tr>
<td></td>
<td>Estimate (95% CI)</td>
<td>P Value</td>
<td>Estimate (95% CI)</td>
</tr>
<tr>
<td>Hypertension knowledge score</td>
<td>12.74 (12.56, 12.91)</td>
<td>&lt;.001</td>
<td>12.55 (12.38, 12.71)</td>
</tr>
<tr>
<td>Systolic blood pressure reading</td>
<td>-6.52 (-6.63, -6.41)</td>
<td>.001</td>
<td>-6.65 (-10.39, -2.91)</td>
</tr>
<tr>
<td>Diastolic blood pressure reading</td>
<td>-7.15 (-7.23, -7.08)</td>
<td>&lt;.001</td>
<td>-7.26 (-9.27, -4.80)</td>
</tr>
<tr>
<td>% of patients with ( \geq 60% ) hypertension knowledge score</td>
<td>4.13 (2.47, 6.94)</td>
<td>&lt;.001</td>
<td>4.45 (2.60, 7.59)</td>
</tr>
<tr>
<td>% of patients with no need for adjustment on treatment regimen</td>
<td>2.57 (1.56, 4.24)</td>
<td>&lt;.001</td>
<td>2.75 (1.64, 4.60)</td>
</tr>
<tr>
<td>% of patients with blood pressure under control</td>
<td>2.04 (0.35, 0.57)</td>
<td>.003</td>
<td>2.18 (1.33, 3.58)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.
^aAdjustment for variations in gender, age, education, salt intake, smoking, drinking, physical exercise, duration of hypertension, and other chronic conditions.

TABLE 5. Antihypertensive Drug Treatment of Study Participants in a Randomized Controlled Trial on Effect of Pharmacist Interventions on Management of Hypertension, China

TABLE 6. Difference-in-Differences Analyses on the Effects of Pharmacist Interventions on Study Participants’ Blood Pressure
Six months after the trial, 60.7% of the participants who received pharmacist interventions had their blood pressure under control, already exceeding the government target.

Pharmacists can assist medical doctors to assess and adjust medication regimens for hypertension. take a leading role in community interventions and engage in teamwork monthly. The intervention protocol tested in this trial aligns well with their proposal. However, our study did not test the long-term effect of the intervention, which warrants further studies.

The study provides new insight into the potential role of pharmacists in the community control of hypertension in the Chinese health system context. It proved that pharmacist services in primary care can bring additional benefits, boosting the achievements of the existing medical doctor-led management program for hypertension. Two major mechanisms are likely to have enabled such an outcome.

First, pharmacists, as a profession that specializes in medications, are well positioned to educate patients on the appropriate use of medicines, which can be done through public education and individualized consultation services. This study adopted both approaches and showed that the knowledge score of the participants who received pharmacist interventions increased by 30 points, compared to less than 20 of those in the control group. This resulted in over 80% of participants passing the knowledge tests in the intervention group, more than thirty percentage points higher than that in the control group. There is evidence that the knowledge improvement had translated into better medication adherence as indicated by the higher increase in the percentage of participants in the intervention group taking regular medications and obtaining high medication adherence scores. International evidence shows that knowledge is indeed critical in helping hypertensive patients to better understand their conditions and adopt appropriate actions to control blood pressure. According to Amer and Nazir, pharmacists can help hypertensive patients reduce their concerns over the long-term use of medications, one of the major reasons for the intermittent use and ignorance of medications. It is worth noting that there was still space for further improvement of knowledge in the study participants when the trial concluded. Future studies should explore the knowledge attitudes belief behavior chain reactions of hypertensive patients.

Second, pharmacists can assist medical doctors to assess and adjust medication regimens for hypertension. This study revealed that the need for the adjustment of drug therapy was very high before the commencement of the trial: 67.9% for the intervention group and 76.5% for the control group. This is not surprising given the low qualification profile of general practitioners in China. There is strong evidence suggesting that the timely adjustment of drug therapy is critical for the control of blood pressure. This study showed that the need for medication adjustments in the participants in the intervention group dropped from 67.9% to 30.5%, compared with a slight decline in the control group from 76.5% to 69.5%. The pharmacist interventions contributed to a more than doubling of the odds of not needing any medication adjustments in comparison with the control group. Unlike Hirsch’s trial, this study did not allow pharmacists to initiate, adjust, or discontinue antihypertensive drug therapy independently. All changes had to be made on the advice of the general practitioners. In China, pharmacists have no prescription rights. They play an auxiliary role with a focus on dispensing prescribed medicines, which is not unique to China. Despite their restricted role, pharmacist interventions in this study achieved a similar effect size on the control of blood pressure compared to that in Hirsch’s trial. Although we did not explore the underlying mechanism of the effect, it is clear that pharmacists could contribute to better management of hypertension. The possible reasons must be discussed in the context of the Chinese health system. There have been serious concerns in China that medical doctors are often overloaded and have failed to dedicate sufficient time to communicate with patients, let alone to engage patients. Clinical pharmacists played a bridging role in this trial. They not only communicated with and educated the patients but also liaised with medical doctors for better management of patients’ blood pressure.

It is important to note that as in many other LMICs, pharmacists in China are in short supply. Their functions are complementary to those of medical doctors, nurses, and public health workers. This study is by no means suggesting that pharmacists should bridge the shortfall of general practitioners in China. Pharmacist interventions have to be considered as an integral part of interdisciplinary team efforts for the community control of hypertension. In some countries, community pharmacists have been designated specific roles in managing chronic diseases. But China has yet to do so. By the end of October 2019, there were a total of 509,374 registered pharmacists in China, which is the equivalent of 3.7 pharmacists per 10,000 population. This level is very low compared to other countries. According to
the World Federation of Pharmacists, 6.2 pharmacists per 10,000 population are recommended, although developed countries such as Australia and Canada have far more (10–20) pharmacists per 10,000 population. The gap in the supply of pharmacists is even greater than that of medical doctors.

A systems approach is needed to maximize the role and functions of pharmacists, in particular, to manage chronic diseases. The distribution of registered pharmacists in China is currently heavily concentrated in large metropolitan areas and large institutions. Very few, if any, pharmacists work in community health services. Although hospital pharmacists have started to increase their involvement in ward rounds and medication consultations, their main role is still dispensing prescribed medicines. In 2017, medication therapy management was written into the revised service specification for registered pharmacists for the first time in China. This signals a shift toward “patient-centered” pharmacist services. After many years, the Chinese government has started to call for an accelerated transformation of pharmaceutical care. This provides an opportunity to explore how pharmacist services can be incorporated into the most recent development of the integrated care network, in which large hospitals are encouraged to establish partnerships with primary care institutions to improve the continuity and coordination of patient care.

The pharmacist education system in China needs to be reformed. University degree programs should place greater emphasis on patient-centered services to better prepare students for the expanded role of registered pharmacists. Meanwhile, large numbers of pharmacy workers (or pharmacist assistants as labeled in this study) need vocational and continuing education to fulfill a function beyond dispensing/sales of medicines. Community health services can also offer placement opportunities for medical and pharmacy students in senior years or at postgraduate levels to enhance their competency in managing chronic diseases through drug therapy. Serious challenges lie ahead. These changes not only require strong funding and policy support but also require recognition of the new identity of the pharmacist profession.

To the best of our knowledge, this is the first randomized controlled trial in China testing the effects of community pharmacist interventions on the control of hypertension. We followed a strict protocol for this randomized control trial. The study participants were randomly selected and highly diversified, which indicates a potential for the results to be generalized to other groups of patients with hypertension. However, the pharmacists who conducted the interventions were highly selective. They were well respected due to their high degree qualification and work status (tertiary hospital). This would limit the potential of the results to be generalized. China has a serious shortage of clinical pharmacist workforce. It will be challenging to add further workloads on the already overloaded pharmacists.

Limitations
This study has several limitations. First, the trial ended after 6 months due to resource restrictions. It did not test the long-term effect of the interventions. Second, this study did not perform detailed costing analyses on the interventions, but we recorded an average of 14 minutes of contact time per month from the pharmacists and their assistants for each participant in the intervention group. Third, the trial could not adopt double blindness in the design. Improvement in the control group was observed in this study, albeit at a smaller scale. We could not exclude the potential flowover effect when a medical doctor serves both patients in the intervention and control groups. This may lead to an underestimation of the effect size of the interventions. Fourth, a baseline difference in medication adherence appeared between the intervention and the control groups although the 2 groups of participants were randomly allocated. This was an unexpected result possibly due to the high diversity of patients with hypertension and the limited sample size. A stratified randomization strategy may generate a more balanced sample.

CONCLUSION
The value of pharmacists may have been underappreciated. This study shows that pharmacists can make a significant contribution to improving community management of hypertension through educating patients and providing medication consultations with medical doctors, although the
long-term effect remains unclear. This study demonstrated that community pharmacist interventions have significant short-term effects on improving the knowledge and medication adherence of hypertensive patients, as well as timely adjustments of drug therapy regimens from medical doctors, resulting in lowered blood pressure and increased control rate. However, more and better-educated pharmacists would be needed before such an initiative can be introduced. Equally important is the improvement of the entire care process centered around the need of patients. This often requires adjustments of roles and functions of various health professionals. There is a need to increase the public and policy makers’ awareness about the important role of community pharmacists in managing chronic conditions. Further studies should assess the long-term effect and cost-effectiveness of such services.

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REFERENCES


The Development and Inclusion of Questions on Surgery in the 2018 Zambia Demographic and Health Survey

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Key Findings

- Based on this pilot survey, which responded to the call to collect, aggregate, and analyze global anesthesia and surgery data, we conclude that it is feasible to integrate surgical questions into a large-scale sample survey to provide insight into surgical needs at a national level.
- Approximately 5% of women and 2% of men had undergone an operation in Zambia in the past 5 years. Among women, cesarean delivery was the most common surgery, while circumcision was the most common procedure among men.
- The diagnosed unmet need for surgical care in Zambia is estimated to be 65%.

Key Implications

- For health system strengthening, baseline data and monitoring of progress are necessary. Improved data capabilities allow for mapping out and understanding systems.
- Data collection mechanisms pertinent to surgical care need to become part of routine data collection processes.
- There is a need to build on existing data collection mechanisms to avoid adding unnecessary burden, information overload, and data collection fatigue.
- The replicable design of the Demographic and Health Survey allows for the systematic collection of comparable surgical data in other settings. Similar questions could be included in other surveys as well.
- There is a need to establish data pathways to ensure clear responsibilities among national and international institutions and integrate surgical metrics into existing mechanisms for sustainable data collection.

ABSTRACT

Background: While primary data on the unmet need for surgery in low- and middle-income countries is lacking, household surveys could provide an entry point to collect such data. We describe the first development and inclusion of questions on surgery in a nationally representative Demographic and Health Survey (DHS) in Zambia.

Method: Questions regarding surgical conditions were developed through an iterative consultative process and integrated into the rollout of the DHS survey in Zambia in 2018 and administered to a nationwide sample survey of eligible women aged 15–49 years and men aged 15–59 years.

Results: In total, 7 questions covering 4 themes of service delivery, diagnosed burden of surgical disease, access to care, and quality of care were added. The questions were administered across 12,831 households (13,683 women aged 15–49 years and 12,132 men aged 15–59 years). Results showed that approximately 5% of women and 2% of men had undergone an operation in the past 5 years. Among women, cesarean delivery was the most common surgery; circumcision was the most common procedure among men. In the past 5 years, an estimated 0.61% of the population had been told by a health care worker that they might need surgery, and of this group, 35% had undergone the relevant procedure.

Conclusion: For the first time, questions on surgery have been included in a nationwide DHS. We have shown that it is feasible to integrate these questions into a large-scale survey to provide insight into surgical needs at a national level. Based on the DHS design and implementation mechanisms, a country interested in including a set of questions like the one included in Zambia, could replicate this data collection in other settings, which provides an opportunity for systematic collection of comparable surgical data, a vital role in surgical health care system strengthening.

INTRODUCTION

Globally, it is estimated that 5 billion people do not have access to essential surgical, obstetric, and anesthesia care. Scaling up access to surgery, obstetrics, and anesthesia health care services is key to accelerating progress toward the SDGs. The 2015 World Health Assembly Resolution 68.15 and Decision A70.22 recognize the role of surgical and anesthesia health care for universal health coverage (UHC) and the importance of surgery and anesthesia as crosscutting treatment
modalities in resilient health systems. Furthermore, the World Health Organization (WHO) along with the 3rd edition of the Disease Control Priorities recommend basic surgical health care to the essential packages of interventions delivered at first-level hospitals in low- and middle-income countries (LMICs)\(^6\). Yet, many LMICs continue to have a large unmet need for surgical health care\(^7\)–\(^12\) while most public health data collection tools remain blind to the problem.

To achieve ambitious goals and strengthen health systems to ensure no one is left behind, data are needed to track progress. The Lancet Commission on Global Surgery developed 6 indicators for data collection and developed methods to create standardized and comparable datasets across countries over time. These indicators assess the preparedness, delivery, and impact of surgical health care\(^1\). Some of these indicators have been recognized as World Bank Development Indicators\(^13\), and all 6 are included in the WHO list of 100 core health indicators\(^14\). However, the availability of data regarding surgical, anesthesia, and obstetric care remains low\(^15\). To become part of routine data collection processes, it is necessary to establish nationally driven sustainable data collection mechanisms pertinent to surgical care. Meanwhile, in light of demands being placed on national statistical systems to report numerous development indicators, there is a need to build on existing data collection mechanisms to avoid adding unnecessary burden, information overload, and data collection fatigue. This would include other household surveys, such as Multiple Indicator Cluster Surveys, and facility-based tools (e.g., District Health Information System, Service Provision Assessment questionnaire, and the Service Availability and Readiness Assessment).

Household surveys are considered the most reliable data source on individual knowledge, attitude, and practice, as well as critical determinants of health status and health usage\(^16\). Household surveys can fill crucial gaps, assessing the need for surgical care and providing data on the main barriers to meet such needs as limited evidence exists on the barriers to access surgical and anesthesia care\(^17,18\).

The Republic of Zambia has taken a leadership role in promoting surgical and anesthesia health care as an essential component of UHC. The Zambian Ministry of Health (MOH) prioritized the development and costing of a National Surgical Plan (2017–2021) launched at the World Health Assembly in 2016 and fully integrated into the Zambian National Health Strategic Plan 2017–2021\(^19,20\).

The 2018 Zambia Demographic and Health Survey (ZDHS)\(^21\) was implemented by the Zambia Statistics Agency (ZamStats) in collaboration with the MOH. It was financed by the United States Agency for International Development (USAID), the Department for International Development of the United Kingdom, and the Global Fund. Due to Zambia’s commitment to advance surgical health care, this survey offered an opportunity to explore the addition of questions addressing surgical needs. Under the leadership of the Zambian MOH, it was decided to develop a short set of questions that could be added to this survey and would show the feasibility of using household surveys to collect data on access to surgical care. Whereas the National Surgical Plan was based on modeled and pre-existing data, implementation of surgical questions in ZDHS provides for systematic, continuous, and reproducible data collection, yielding more reliable, nationally representative, and comparable results. The ZDHS, although collecting fewer data points, is nationally representative. Local leadership is a prerequisite for ownership, in-depth engagement of local stakeholders around surgical systems strengthening, and national health policy planning\(^22,23\).

We aimed to describe the design of a set of surgical questions for DHS and their integration into the 2018 ZDHS. We also present preliminary results from these questions, with the intent to

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provide insight into the utility of ZDHS to collect data on the perceived need for, and access to, surgical care in Zambia.

**METHODS**

USAID has been implementing the DHS Program for more than 30 years, collecting and disseminating data on population and health through more than 400 surveys in over 90 countries since 1984. DHS data are gathered through nationally representative, repeated household surveys, using standardized questionnaires and enables comparison between and across countries. Questionnaires consist of a core module and a series of elective modules that countries select from. There are 5 standard model questionnaires; man’s, woman’s, household, fieldworker, and biomarker questionnaire, where elective modules can be added, such as the survey on maternal mortality.

**Surgery Question Design**

Based on matching of variables and classification systems of existing data collection mechanisms, the authors identified data sources for surgical statistics, including facility-based data as well as population-based approaches. As a population-based approach, household surveys were considered advantageous as they can reach those who otherwise would not have access to or have not tried to reach surgical care.

Questions on access to surgical, anesthesia, and obstetric care were designed for addition to the female and male DHS questionnaires planned for roll out in Zambia. Questions were designed through an iterative consultation process during 2017 and 2018, involving an expert panel from the surgical research community with a research focus on global surgical data. The 13 group members (SJ, SM, VS, LR, JD, MS, TW, LH, HI, EM, JGM, JMG, DL) from Africa, Europe, North America, and South America brought together expertise from the fields of medicine, epidemiology, statistics, and demography. The expert group proposed a longer list of questions, while statisticians from the ZamStats provided guidance on the selection of the final set of questions to prioritize the inclusion of locally relevant surgical health care metrics and avoid information overload and data collection fatigue. Adhering to the DHS questionnaire format, the questions were fine-tuned for clarity, comprehensibility, and utility.

The consultation process reached consensus on 5 topics representing 4 central themes:

1. Surgical volume (service delivery)
2. Types of surgery (service delivery)
3. Diagnosed need for surgical health care (diagnosed burden of surgical disease)
4. Barriers to accessing surgical health care (access to care)
5. Maternal mortality (quality of care)

These topics were used as a basis to construct a set of nonambiguous questions with good face validity.

**Surgical Volume (Service Delivery)**

The Lancet Commission on Global Surgery estimates an operative volume of 5,000 surgical cases per 100,000 population as a minimum threshold target. The first question aimed at generating an estimate of surgical volume and an output measure of service delivery by asking: “Have you ever undergone a surgical operation in the past 5 years?”

The overall definition of surgical procedure applied in this work follows that of the Lancet Commission of Global Surgery, which is a procedure performed in an operating room under any kind of anesthesia. The timeframe of 5 years was deemed an ideal between achieving adequate power without risking substantial recall bias.

**Types of Surgery (Service Delivery)**

To establish the met need of surgery by broad categories of procedures, the next question asked respondents that had undergone surgery in the past 5 years, “What type of operation(s) were they?” Response options were provided from a spectrum of common surgical procedures, and several responses could be recorded for each subject (Table 1).

The interviewer manual provided explanations for interviewers to use if further clarification regarding procedures were necessary. These procedures were selected because they were considered as common, conceptually accessible for laypeople, and rely on the availability of a wide array of surgical services, providing additional insight about the surgical capacity in the country. Stratification by procedure was adopted as it was considered valuable in providing possible insight for projecting infrastructure and workforce development needs. The inclusion of cesarean delivery, laparotomy, and open fracture management are recognized as “Bellwether procedures,” therefore
may reflect broader surgical system capacity regionally. During data collection, when looking at the open responses in the option “Other (specify),” ZamStat added and coded the following response variations not considered in the questionnaires:

- Mastectomy (women’s questionnaire only)
- Fistula repair (women’s questionnaire only)
- Ectopic pregnancy (women’s questionnaire only)
- Hysterectomy (women’s questionnaire only)

### TABLE 1. Surgery-Related Questions Added to the 2018 Zambia Demographic and Health Survey

<table>
<thead>
<tr>
<th>Women’s and Men’s Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you ever undergone a surgical operation in the past 5 years?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>What type of operation(s) were they? (Name all that apply)</td>
</tr>
<tr>
<td>Hernia operation</td>
</tr>
<tr>
<td>Cesarean delivery (women’s questionnaire only)</td>
</tr>
<tr>
<td>Hydrocele operation (men’s questionnaire only)</td>
</tr>
<tr>
<td>Laparotomy (cutting open the abdomen)</td>
</tr>
<tr>
<td>Lump removal</td>
</tr>
<tr>
<td>Abscess drainage</td>
</tr>
<tr>
<td>Wound closure</td>
</tr>
<tr>
<td>Open fracture</td>
</tr>
<tr>
<td>Other (specify)</td>
</tr>
<tr>
<td>In the last 5 years has a doctor or another healthcare worker told you that you might need (another) operation?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Were you able to access it?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Why did you not access it? (Record all mentioned)</td>
</tr>
<tr>
<td>I could not reach the doctor</td>
</tr>
<tr>
<td>I could not afford the operation</td>
</tr>
<tr>
<td>I could not afford to get to the hospital</td>
</tr>
<tr>
<td>I could not afford the time off work</td>
</tr>
<tr>
<td>It was too far to get to the hospital</td>
</tr>
<tr>
<td>I did not trust the operation would make me better</td>
</tr>
<tr>
<td>Fear of care</td>
</tr>
<tr>
<td>Out of shame</td>
</tr>
<tr>
<td>My spouse/family would not let me go</td>
</tr>
<tr>
<td>Other (specify)</td>
</tr>
<tr>
<td>Maternal Mortality Module</td>
</tr>
<tr>
<td>Did (name) receive a cesarean delivery?</td>
</tr>
<tr>
<td>Did (name) die in the hospital?</td>
</tr>
</tbody>
</table>
• Female tubal ligation (women’s questionnaire only)
• Circumcision (men’s questionnaire only)
• Appendicitis
• Minor operation
• Eye surgery

Diagnosed Need for Surgical Health Care (Diagnosed Burden of Surgical Disease)
The third question is assessing the perceived total demand for surgical health care by asking respondents, “In the last 5 years has a doctor or another health care worker told you that you might need (an/another) operation?” We deemed this question to be a pragmatic proxy for actual need for surgery, validated by a health care worker, that owned some validity rather than simply asking if subjects themselves believed they needed surgery.

Barriers to Accessing Surgical Health Care (Access to Care)
Unmet need for diagnosed surgical care is defined as the number of individuals who in the last 5 years had been recommended by a doctor or another health care worker that they needed surgery and could or did not access it. Multiple response options to the question, “Why did you not undergo it [the surgery]?” were built upon social, cultural, structural, and financial dimensions as well as the patient’s beliefs, views, and expectations. Structural barriers refer to the location of health care facilities and the availability of these facilities to the population, while financial dimensions refer to medical and non-medical costs such as transport and time off work. Here, ZamStat added the response alternative that the surgery was not needed anymore.

Maternal Mortality (Quality of Care)
Although quality of care is multifaceted and complex to measure, perioperative mortality is considered a baseline indicator of surgical care quality. Due to the need for case mix and risk factor adjustment for interpretation of this indicator a specific intervention ideally should be chosen. The volume and homogeneity of the cesarean delivery make this an appropriate choice. Also, mortality after cesarean delivery has been recognized in both systematic reviews and prospective observational data to discriminate strongly on health system quality, with estimates that maternal mortality after cesarean deliveries are 50–100 times higher in LMICs than in high-income countries.

Information on maternal death after cesarean delivery health care may be limited due to the overall low number of cases of maternal death in sampled households, owing to the rarity of maternal deaths. However, the expert panel felt this was an essential quality metric that should be explored in this pilot survey to measure and improve 1 component of the quality of obstetric health care. Quality of maternal health care is an essential health measure, and this may provide critical data for quality improvement.

In the maternal mortality section of the ZDHS survey, respondents were asked about the survival of their siblings. Two questions for all women, relevant for surgical analysis, were included. In the case of sisters having died during childbirth or within 2 months after the end of a pregnancy or childbirth, respondents were asked “Did (name) receive a cesarean delivery?” A second question about that same woman, and/or those women that were pregnant when they died (all maternal deaths), was asked “Did (name) die in the hospital?”

Data Collection
In parallel to the consultative process of question design, stakeholders within and associated with the Zambia MOH argued for the adoption of the questions regarding surgical care in the 2018 ZDHS. In 2018, questions to collect data on access to timely essential surgery and surgical volume were added to the woman’s and man’s health questionnaire and the adult and maternal mortality module of the ZDHS. While the woman’s questionnaire was used to collect information from women aged 15–49 years; the man’s questionnaire was used to collect information from men aged 15–59 years. All permanent residents of a selected household or visitors who stayed in the households the night before the survey were eligible to be interviewed. Data were collected by the implementing organization (ZamStats) and were gathered for the individual interviewed, apart from questions on maternal mortality, which were aimed at sisters of women who had passed during pregnancy, childbirth, or within 42 days of delivery or end of a pregnancy.

After the questionnaires were finalized in English, they were translated into 7 major languages: Bemba, Kaonde, Lozi, Lunda, Luvale, Nyanja, and Tonga. Data collection took place...
from July 18, 2018, to January 24, 2019, as part of a standard DHS. The sampling frame used for the 2018 ZDHS was the 2010 Population and Housing Census of the Republic of Zambia conducted in 2010 by ZamStats. Twenty-two teams of 7 enumerators set out to gather information from sampled 13,595 households across the Zambian territory.

Data Analysis
SPSS was used to extract data from 2 datasets containing data from the men’s questionnaire and the women’s questionnaire, also holding data on adult and maternal mortality, called “men’s recode” and “individual recode,” respectively. This has been presented using descriptive frequency analysis with calculations of percentages of the survey population. Results for surgical volume were already disaggregated by sex, age, and place of residence in the ZDHS main report and are presented as such in this text. No missing values were found for the data relevant for surgical care.

RESULTS
The group reached consensus on adding 5 questions to the women’s and men’s questionnaire and 2 questions to the maternal health questionnaire (Table 1).

Of the 13,595 households sampled, 12,943 were occupied and 12,831 interviewed, yielding a response rate of 99.1%.21 Of these, 4,714 households with urban and 8,117 households with rural residence were interviewed. Please see ZDHS 2018 publication21 for full sampling methodology.

Surgical Volume (Service Delivery)
In the sampled population of 25,830 individuals, 13,683 were women aged 15–49 years and 12,132 were men aged 15–59 years. We found that 631 (4.6%, 95% confidence interval [CI]= 3.0%, 6.2%) women and 230 (1.9%, 95% CI=0.1%, 3.7%) men had undergone at least 1 operation in the last 5 years yielding a total of 861 surgical procedures. Subjects were able to report on having undergone several procedures.

Type of Surgery (Service Delivery)
The most common surgical procedure overall was cesarean delivery (n=470). Figure 1 presents the other types of surgery with their respective frequencies.

Diagnosed Need For Surgical Health Care (Diagnosed Burden of Surgical Disease)
Among all respondents, 157 persons reported that, in the past 5 years, they had been told by a doctor or other health care worker that they might need surgery. Combining these with the 861 individuals that underwent surgery, this suggests a total diagnosed need for surgery of 3.97% (n=1026, 95% CI=2.78%, 5.16%) in the sampled population over the past 5 years.

Barriers to Accessing Surgical Health Care (Access to Care)
Of the 157 persons who reported having been told they needed surgery, 55 persons reported they had undergone the relevant operation. Based on the previous definition and the numbers ZDHS yields, an estimate of the diagnosed unmet need for surgical care in Zambia is at 65%, where 102 of 157 people did not undergo the surgery which they were recommended. The reasons for not accessing care are listed in Table 2.

Maternal Mortality (Quality of Care)
In the maternal mortality section of the ZDHS survey, respondents were asked about the survival of their siblings. The results for the respondents’ sisters are listed in Table 3.

The maternal mortality ratio was calculated for the ZDHS in their publication for the 7-year period before the 2018 ZDHS, as an estimate of 252 deaths per 100,000 live births (CI 158, 357).

DISCUSSION
The surgical questions were piloted in Zambia with an extremely high response rate of 99.1% displaying limited utilization of surgical services for women (4.6%) and men (1.9%) in the last 5 years. Cesarean delivery constituted nearly 4 of 5 surgical procedures in women.

Of the 157 people who reported having been told they needed surgery, 55 patients had undergone surgery, indicating a met need among diagnosed patients of 35%. The actual need is expected to be largely underestimated due to several barriers to seeking and receiving surgical care. Recognizing the challenge of capturing the true population-based need for surgery, the data coming from this question provide an insight into the need for surgery that was diagnosed by a provider. We recognize that it will underestimate the overall burden of surgical disease, as it excludes all of those who have never been diagnosed. It could be
possible to include more subjects by asking about perceived surgical need, but the most relevant information would be achieved by diagnosing and reporting every need.

Although 861 people reported having undergone surgery, 157 people reported having been told that they needed an/another operation, and the gap between these 2 still needs to be investigated. The questions regarding surgical volume and diagnosed need for surgical health care as well as barriers to accessing surgical health care were considered to represent different aspects of receiving surgery. Therefore, their results were not combined when calculating diagnosed unmet need.

Fear and mistrust were the most cited reasons for not seeking surgical care despite health provider recommendations. This may indicate that the perceived quality of surgical care is variable in this group of surveyed patients, impacting health care utilization. Qualitative community-based studies may further elucidate patient perceptions of surgical system performance. To monitor unmet need for surgery as a component of universal health coverage, it is essential to account for people who need but do not access surgery and to ascertain the barriers.

Sample household surveys appear to be the most appropriate source for this. With improved definitions, collection, and aggregation, surgical indicators can play a great role in informing evidence-based health policy to improve access to safe, affordable, and timely surgical, obstetric, and anesthesia health care. Previous data collection on surgical health care has often been 1-time initiatives driven by academic institutions, predominantly

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**FIGURE.** Type of Surgery\(^a\) Performed in the Last 5 Years Among Women (n=630) and Men (n=230), 2018 Zambia Demographic and Health Survey

\(^a\)Cesarean delivery (3.4% of women) has been omitted, as the frequency was much higher than the second most common procedure.
from high-income countries and estimates available on the need for surgical health care in LMICs are frequently modeled based on small sample studies. Existing data are very heterogeneous, making comparison difficult across countries and time. Further, aggregated data often hide subnational disparities, hence disaggregated data are needed to investigate the true unmet need of surgical health care and the inequalities in access to health care at the global, national, and subnational levels.

This pilot of integrated questions on surgical health care suggests that the question design proved successful overall. Low surgical volume due to poor access to surgical care may require a longer recall period to obtain sufficient power. Thus, 5 years was considered a golden mean between the 2 trade-offs.

Cesarean delivery was the most common surgical procedure and represented 4 of 5 surgeries for women. This is consistent with literature where cesarean delivery makes up a large proportion of the surgical volume in countries with very low health expenditure per capita, whereas this has been shown to be a much smaller percentage of 2.7% in high-expenditure countries. Maternal mortality is a rare event on a population level. The 2 questions related to maternal death after cesarean delivery in ZDHS yield case numbers too low for further analysis. This suggests that, for better resolution, quality of care, in contrast to access to care, primarily ought to be investigated in the population with met need, (i.e., through facility assessments and targeted patient-related outcome measures). One limitation with the structure of interviewing women regarding deaths of sisters is that multiple siblings may have reported on the death of 1. However, this also applies to survivors and is an inherent part of the DHS structure.

The gap in surgical data is concerning, particularly in the poorest countries of the world. The paucity of surgical data globally and the challenges

### TABLE 2. Reasons Why 2018 Zambia Demographic and Health Survey Respondents Reported Not Accessing Surgical Health Care in Zambia

<table>
<thead>
<tr>
<th>Reason</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
<th>Population, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not trust the operation would make me better</td>
<td>7</td>
<td>8</td>
<td>15</td>
<td>0.06</td>
</tr>
<tr>
<td>Fear of care</td>
<td>6</td>
<td>8</td>
<td>14</td>
<td>0.05</td>
</tr>
<tr>
<td>Could not reach the doctor</td>
<td>7</td>
<td>7</td>
<td>14</td>
<td>0.05</td>
</tr>
<tr>
<td>It was not needed anymore</td>
<td>1</td>
<td>13</td>
<td>14</td>
<td>0.05</td>
</tr>
<tr>
<td>Could not afford the operation</td>
<td>4</td>
<td>7</td>
<td>11</td>
<td>0.04</td>
</tr>
<tr>
<td>Spouse/family would not let me go</td>
<td>5</td>
<td>5</td>
<td>10</td>
<td>0.04</td>
</tr>
<tr>
<td>Could not afford to get to the hospital</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>0.02</td>
</tr>
<tr>
<td>Was too far to get to the hospital</td>
<td>3</td>
<td>1</td>
<td>4</td>
<td>0.02</td>
</tr>
<tr>
<td>Could not afford time off work</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>0.01</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>0.05</td>
</tr>
<tr>
<td>Sum</td>
<td>41</td>
<td>61</td>
<td>102</td>
<td>0.40</td>
</tr>
</tbody>
</table>

### TABLE 3. 2018 Zambia Demographic and Health Survey Respondents’ Answers on Maternal Mortality

<table>
<thead>
<tr>
<th>Total Number of Female Siblings of Respondents</th>
<th>36,114</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total deaths among female siblings</td>
<td>3,986 (11% of female siblings, 95% CI=10%, 12%)</td>
</tr>
<tr>
<td>Total maternal deaths</td>
<td>221 (5.5% of deaths among female siblings, 95% CI=2.5%, 8.6%)</td>
</tr>
<tr>
<td>Total cesarean deliveries among maternal deaths</td>
<td>81 (37% of maternal deaths, 95% CI=26%, 47%)</td>
</tr>
<tr>
<td>Total maternal deaths in hospital</td>
<td>48 (22% of maternal deaths, 95% CI=10%, 34%)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.
with systematic and reliable data collection have hindered surgical system strengthening. Incor-
porating surgical questions into DHS facilitates sys-
tematic collection of population-based data that is sustainable, replicable, and comparable. The quality of the data is assured by following up with a set of quality control tables that allows DHS for online and real-time verification of data that is being collected. However, as the information on surgery was collected for the first time in a DHS, there is no reference for comparison.

Future Directions
Going forward, validation of survey responses with clinical examination and other forms of diagnostic evaluation, such as radiographic testing, in a defined population would be valuable. A potential development would be to integrate sample surveys data with population census data to allow the generation of small area estimates for more granular data.

Future DHS can rely on the lessons learned and data collected in Zambia for quality assessments. Based on the inclusion process of questions in the ZDHS and a successful argument for inclusion of these questions in wave 8 of the DHS, the DHS Program has designed a new module with these questions integrated.

In addition to DHS, questions on surgical health care could be included in other household surveys such as Multiple Indicator Cluster Surveys. Similarly, facility-based surveys such as the Service Provision Assessment questionnaire and the Service Availability and Readiness Assessment could benefit from the inclusion of questions pertinent to surgery to capture domains of health care not currently captured by facility assessments.

Limitations
As individuals may have undergone multiple procedures within the 5 years, a limitation may be the challenges to recall that information for several years back. A further limitation is that data from the survey are likely to underestimate unmet need for surgical health care. The 3-delay model on barriers faced by mothers in accessing maternal health care is readily applicable to surgical health care. The first delay, “delay in seeking health care,” is considered a significant barrier, where a combination of health literacy and access to community health care are key factors. Furthermore, assumptions are made that the health care professionals who screen patients are able and willing to recognize and communicate the need for surgical health care. We recognize that the respondents’ responses relied on self-assessments of the patient population, without professional validation of physical conditions, which has been the approach of other similar studies. 

CONCLUSIONS
Questions on surgical health care were successfully developed and implemented in ZDHS. The aims to generate evidence on the perceived prevalence of surgical conditions, a characterization of the diagnosed need for treatment as well as the identification of inequalities and barriers to access were achieved.

The Zambian experience serves as guidance for other countries on how to introduce new questions into existing DHS modules and as an example for other countries to replicate Zambia’s efforts to integrate surgical data collection into existing household surveys. The collected data can provide important information on the needs of the population and the surgical system and may be of great use for policy makers and other stakeholders.

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Author contributions: SJ, JGM, and JMG conceived the original idea and were in charge of overall direction and planning. Input was provided by JD, LH, HH, MS, and TGW. EM led implementation at the national level and follow-up. SJ and DL supervised the project. JM and SK supervised the project. Local knowledge of the design was by EM. SJ, SM, and DL analyzed the data with support from VS and LR. SJ, SM, VS, LR, and DL wrote the manuscript with support from EM, JD, LH, HH, MS, and TGW.

Competing interests: None declared.

REFERENCES


Peer Reviewed

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From Insecurity to Health Service Delivery: Pathways and System Response Strategies in the Eastern Democratic Republic of the Congo

Chiara Altare, Vito Castelgrande, Maphie Tsho, Espoir Bwenge Malembaka, Paul Spiegel

Key Findings

- Insecurity affects health service delivery and quality in eastern Democratic Republic of the Congo through 3 main pathways: violence, mobility restrictions, and resources availability.
- Of several mediating factors that play a role in service delivery and quality, the 2 most important are health care workforce availability and drug/equipment accessibility.
- Health care providers are implementing a variety of strategies to address such barriers, showing some capacity to adapt, adjust, and transform due to insecurity. Most of the response strategies reflect the absorptive capacity and address the lack of human resources. Adaptive solutions tried to address the lack of access, and transformative interventions address the challenges posed by insecurity.

Key Implications

- Understanding the mechanisms through which insecurity affects health service provision and quality is central to designing appropriate response strategies.
- The effectiveness and cost-effectiveness of response strategies to chronic insecurity should be assessed to provide guidance to increasingly fragile health systems.

INTRODUCTION

The provinces of North and South Kivu in eastern Democratic Republic of the Congo (DRC) have experienced insecurity since the early 1990s. Despite a peace agreement in 2002 and elections in 2006, unrest...
continued with more than 140 armed groups in the region fighting for the control of natural resources and land in 2018.1 Communities are highly affected, with almost a quarter of the population classified as in need of humanitarian assistance in 2017 and 2018 (in North Kivu, 2.2 million people and 1.6 million, respectively; in South Kivu, 1.4 and 1.7 million people, respectively).2,3 Hundreds of thousands of people are displaced; in 2017, there were an estimated 1.2 million and 650,000 internally displaced people in North and South Kivu, respectively.4

The health situation in North and South Kivu remains dire. Mortality has decreased from the levels characterizing the Congo wars in the 1990s, but both maternal and child mortality remain high (473/100,000 live births in 20175 and 85/1,000 live births in 2019,6 respectively). The country is extremely vulnerable to infectious diseases, with multiple concomitant outbreaks occurring in 2020 (Ebola virus disease, measles, cholera, plague, monkeypox, coronavirus disease [COVID-19], and vaccine-derived poliovirus)7 as well as a high malaria prevalence. Infectious diseases (such as malaria and TB) remain the main causes of death among both children and adults, exacerbated by a high prevalence of child undernutrition (49.6% and 48% of the children aged under 5 years are stunted in North and South Kivu, respectively).8

Health services for women and children are provided by a variety of public, private, national, and international actors attempting to meet population needs.9 Coverage of health services varies importantly by service (particularly between basic vs. emergency services)10 and between urban and rural areas leading to a varying degree of unmet health needs. Over the years and without any solution to the conflict in sight, health actors working in North and South Kivu have been obliged to learn how to adapt their interventions to the context to maintain an acceptable level of preventive schedulable service coverage.10 This seems to be more challenging for emergency services, for which there is limited access by the Kivu population.

The capacity of a health system to respond adaptively to external shocks that challenge its functioning is a key attribute of a resilient health system and is a common feature across varying definitions of resilience.11–14 A resilient health system aims to minimize service disruptions despite shocks such as conflict, natural disasters, or outbreaks, making it a prerequisite for achieving and sustaining universal health care.15 In a context like eastern DRC where the health system faces both acute and chronic challenges, the concept of everyday resilience as an emergent feature of complex adaptive systems16 can help frame the adaptive and transformative approaches adopted by the system in response to a changing environment.

As resilience is a dynamic and context-specific process, documenting experiences from different settings contributes to global learning and sharing of experience. In this article, we reflect on the resilience of the health system in North and South Kivu in response to chronic levels of insecurity. We identify the mediating factors through which insecurity affects both service quality and delivery and investigate the strategies that health care providers from local government, United Nations (UN) agencies, and international nongovernmental organizations (NGOs) adopt to sustain service provision. Building upon Blanchet’s resilience framework12 and looking at the North and South Kivu health system as a complex adaptive system,16 we aim to enhance understanding of health system resilience strategies to inform health care providers at national and international levels designing response plans in similar conflict-affected settings.

**METHODS**

**Study Design**

This analysis is embedded within a broader research project conducted by the BRANCH (Bridging Research and Action in Conflict settings for the Health of women and children) consortium in 10 conflict-affected countries to investigate factors that shape decision making and maternal and child health service delivery.17 In DRC, we conducted a mixed-methods case study, using both secondary quantitative and primary qualitative data. More details are provided in the article presenting the results of the case study.18 In this sub-study, we use qualitative data to identify operational challenges and investigate strategies to maintain service delivery and quality. While service delivery is also influenced by decision making and policy making, we limited the scope of this article to operational aspects to allow for more detailed discussion.

**Study Setting**

The case study was conducted in the North and South Kivu provinces in DRC in 2018. North Kivu has experienced higher intensity violence.
than South Kivu, both in terms of casualties and events. Few fatalities have occurred in South Kivu since 2012, despite numerous violent events throughout the years. Violence against civilians (33.2%) and battles with no change of territory (31.2%) were the most frequent forms of violent episodes in both provinces.\(^{18}\)

Two health zones in each province were selected due to their history of conflict and insecurity (in terms of active armed clashes, population displacement, and accessibility) during the previous 5 years. The decision was taken in consultation between the research team and representatives of the provincial health offices. In North Kivu, the health zones of Mweso and Ruanguba were visited; in South Kivu, those of Minova and Walungu. Mweso experienced extensive violence, population displacement, and attacks on health facilities; Ruanguba was the center of the March 23 Movement (M23) offensive in 2012–2013; Minova and Walungu have experienced extensive conflict over land issues and customary power.\(^{19}\)

### Data

Qualitative data were collected through individual or group interviews with representatives of private and public health care providers currently working in North and/or South Kivu. These included staff of the Ministry of Health, UN agencies, NGOs, faith-based organizations as well as health care workers (chief midwives, chief nurses, and community health workers). We visited 1 hospital, 1 health center, and 1 health post in each health zone to ensure health facilities of different sizes, services, and resources were included in the study. Two referral hospitals (1 per province) were visited as well.

We conducted 51 in-depth interviews (IDI) and 4 focus group discussions (FGDs), with a total of 84 respondents (Table 1). Participation was voluntary. Oral informed consent was obtained from all participants, who needed to be aged 18 years or older and working in the position for more than 30 days.

We developed and piloted an interview guide for each respondent group to reflect their role and the mandate of their organizations. Questions aimed to inquire about availability and quality of provided maternal and child health services; factors affecting decision making and program implementation (including human resources, funding, information management, infrastructure, and coordination); challenges and opportunities; adaptations to programs to respond to population displacement and insecurity; and level and type of insecurity in the communities. All interview guides were developed in French; the interview guides for FGDs and facility health care workers were translated into Swahili by the research team members (native speakers). Translation into Swahili was tested during the pilot of the guides and fine-tuned until an agreed-upon formulation was found. A 4-day training of the interviewers was conducted in Bukavu to familiarize them with the project objectives and the data collection tools. The case study coordinator (CA) led the training together with the field research coordinator (MT). Interview guides were piloted in a health facility in Bukavu, which was not included in

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**TABLE 1.** Participants in In-Depth Interviews and Focus Group Discussions in Analysis of Insecurity and Health Service Provision and Quality in North and South Kivu Provinces, Democratic Republic of the Congo

<table>
<thead>
<tr>
<th>In-Depth Interview Participants by Affiliation</th>
<th>North Kivu</th>
<th>South Kivu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministry of Health (DPS/MCZ)</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Nongovernmental organization</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>United Nations agency</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Health care providers</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Focus Group Discussion Participants</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Community health workers</td>
<td>17</td>
</tr>
<tr>
<td>(40% Male; 60% Female)</td>
<td>20</td>
</tr>
<tr>
<td>(75% Male; 25% Female)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: DPS, Division Provinciale de Santé (Provincial Health Division); MCZ, Médecin Chef de Zone (Chief Medical Officer of the health zone).
the sample. Data collection took place between August and September 2018.

Data Management and Analysis
Interviews took place in French or Swahili according to the preference of the respondent. Recordings were transcribed in French. Data management and coding were done in NVivo. The codebook included both predefined codes addressing issues the study aimed to explore and additional ones that arose from the interviews. Two team members coded the transcripts after having tested and compared coding approaches to ensure harmonization. Thematic analysis methods were used, whereby data were compiled, disassembled, and then reassembled. Framework analysis was used to explore data. A matrix output (with cases as row and codes as column) was developed to systematically summarize data and facilitate constant comparison within and across cases and topics.

Ethics Approval and Consent to Participate
The Johns Hopkins Bloomberg School of Public Health determined that this study was not human subjects research and therefore did not require institutional review board oversight (IRB 8652). In DRC, the study protocol was reviewed and approved by the Université Catholique de Bukavu’s Institution Review Board (UCB/CIES/NC/02/2018). Oral consent was obtained from all study participants before initiating data collection.

FINDINGS
Three main drivers affecting health service delivery and quality were identified from the interviews (Figure): violence, reduced mobility, and resource availability.

Driver 1: Overall Insecurity and Attacks on Health Care Workers and Facilities
The first way through which insecurity affects service delivery is through direct or feared violence. This has multiple mediators.

Availability of the Health Care Workforce
The occurrence of attacks on health facilities or health care workers often forces health staff to leave the affected area. Partners may be forced to withdraw their presence from the affected area and interrupt activities until security is reestablished. The same is true when the health care...
workers live with the constant fear that they or their health facilities could be attacked.

Insecurity affects the availability and quality of services; with insecurity qualified health staff flee, we can no longer supply or provide quality care. —NGO worker

**Increased Stress**

When health care workers decide to stay and work in the insecure area, they report that they often work under stressful conditions comprising fear, restlessness, and instability. These weigh heavily on the psychological health of the staff who reported struggling to concentrate and focus:

> We are not psychologically stable when we are scared; and if we are scared, this can disrupt the care. —Hospital health care provider

This can increase the risk of committing mistakes or having other lapses in judgment.

> I do not know if there is anybody who has heard a firearm shot and who is in good health, I do not know if such a person exists. If there is insecurity, you will understand, this affects our mentality, it affects our behavior; when the behavior is concerned, are we going to provide quality care? The answer is no. —Health facility health care provider

When you know that there is no peace, you can be struck any time, you cannot care for someone, and even if you treat someone, it hits you somewhere... and it limits our actions, our normal reaction to save... you work and you say, “Oh my God, they are going to find me here...” you are somehow traumatized. —Health facility health care provider

**Availability of Drugs and Equipment**

Participants reported that attacks on health facilities had both direct and indirect consequences. An immediate consequence of the destruction and plundering of health facilities is the reduced availability of functioning equipment and medications.

> ... A health center has recently been burgled in [health zone xx]... all material has been plundered; with the plundering of all medicaments if a severe case arrives, there will be no medicament available to treat them, and they can die. This is an effect of insecurity I think. —FGD participant

In situations of chronic crises like the one in eastern DRC, respondents also reported a sort of “investment reticence,” as the willingness to invest in equipment or supply decreases as the next plundering is around the corner.

> Better not to bring [inputs] as the beneficiaries will not benefit from it;... [the armed groups] will steal and sell it, and when the donor will see the inputs on the market, it will be the partner who will be incriminated. —NGO worker

It is not easy to go and look for medicines and (at the same time), we are worried about how to keep the drugs. We cannot buy in great quantity, because you are scared that you will buy for [the armed groups]. I buy in small amounts like a woman going to the market. If I buy in great quantity, they might come and loot. —Health facility health care provider

**Driver 2: Reduced Mobility and Access of Health Care Workers and Patients**

The second challenge identified by the respondents relates to mobility and access constraints that insecurity causes. This works through various pathways.

**Availability of Health Care Workforce**

Health care workers are hindered in reaching the health facilities due to ongoing insecurity either near the facility or along their access route to the facility.

> If the security is threatened, we do not work during the night, we stay at home, and if someone calls you that there is a patient who is turning worse at the hospital, you have to understand that nobody will be available to treat her/him, nobody will put himself in the insecurity to treat a patient. —Health facility health care provider

If the facility is staffed by visiting clinicians, they may need to abbreviate their service provision hours to travel home before darkness:

> I remember a health facility where they were obliged to close the structure at 3 pm and come back the following day at 8 am, as spending the night there... it meant taking a lot of risks... —Ministry of Health/Division Provincial de Santé

...like that Friday, when there were some gunshots in my health area, we started working at noon... —Health facility health care provider

The same case can be made if there is any form of curfew imposed, either by the government or by the agency providing logistical support.
**Delays in Reaching Care**

Respondents noted that in insecure settings, reaching health care providers can become challenging. Ambulances often struggle to reach patients, and when they do, the route to the health facility may be obstructed. Delays in reaching care also speak to individuals’ mobility being limited, either because of the fear of violence or because of limited availability of financial means to pass checkpoints or access ambulance services.

...Pregnant women delivered under difficult conditions as they didn’t have access to the health facilities anymore, thus they preferred deliver at home instead of running the risk of the journey to the health facility.

—NGO worker

The population takes on a self-management policy with regard to health matters. —Health facility health care provider

In these scenarios, they tend to resort to home-based solutions such as home deliveries, self-medication, or traditional treatment.

You will see now, people are resorting to what? You will see people will turn to traditional medicine, they will take herbs, they will take them with the consequence of anemia, and community deaths. ... —Health facility health care provider

They will risk the journey to health facilities only in the case of complications or once symptoms of an illness or injury have become too great to bear:

This does affect us because we have many severe cases, given the security situation, clients arrive late, sometimes they do not arrive at all... this affects us... —NGO worker

**Increased Cost of Transportation**

When the standard means of accessing health care facilities for both patients and providers are cut off, the use of alternative but higher cost options may be necessary. It was reported that in certain cases, it has been necessary to circumnavigate the insecure areas and travel through Uganda to reach northern parts of North Kivu from Goma. Other times, clinicians needed to access facilities via chartered air services such as helicopters or humanitarian flight services; similarly, patients that require critical care needed to be evacuated by air; and medications, equipment, and materials also needed to be transported in the same way.

As these methods of transit come at increased costs and require specialized capacity, respondents reported that the number of possible transports is limited, meaning a reduced amount of materials and number of people that can be transported.

A box of nutrition products which will probably cover [the treatment] of 1 child weighs 15 kg. When you have to pay US$3–4 per kg you see how difficult it is to implement such activity. —UN agency staff

**Reduced Training and Supervision**

Respondents noted that health staff in conflict-affected areas also may lose access to ongoing training efforts and effective supervision. They highlight the fact that during periods of insecurity, visits from supervisors or training personnel tend to be considered as less essential for the ongoing operations of that health facility. These visits may be interrupted, postponed to more stable times, or conducted remotely. Without being able to directly observe conditions and practice as the health facilities, quality can be compromised:

It is true, we go there where there is instability, but when there is really insecurity, all what I just told you about our system of regular quarterly visits for the monitoring and monthly for the supervisions, to visit health facilities to ensure service quality, ... now, if this is an area where the NGOs [ ] can get nowhere, we won’t be able to enter the health facility, we cannot really say that we will assure the quality of the provided service.

—NGO worker

**Availability of Drugs and Equipment**

In addition to mobility challenges for patients, clinicians, trainers, and supervisors, respondents also noted that access constraints limit their capacity to send necessary supplies and materials in conflict-affected areas. Delays in the delivery lead to increased risk of stock-out of drugs, vaccines, and other medical materials, compromising the capacity to provide treatment and care.

Yes, this affects the availability of medicines. This means that during insecurity the district office or whoever provides us with medicines cannot pass, how can they reach our position? Thus, there will be stock-outs in the health zone which can easily affect the health center. —Health facility health care provider

**Delays in Implementation of Activities**

Respondents noted that medical activities may be put on hold during periods of insecurity. Such is
the case when mobile clinics are deployed or specialist services are available only at certain scheduled intervals. These activities are often postponed until sufficient levels of security can be assured again, though there is often no set date for the resumption of these services. This has consequences on the overall implementation of work, as well as on the achievement of funding objectives and milestones.

We need to reassure ourselves of the security conditions, we cannot expose our staff to the risk of death because they want to help. In short, the workplan will not be observed. —NGO worker

We have problems with our activity planning. For example, I can plan my visit [to the health facility] taken the inconvenient security context into account. This will delay [everything]. . . this has the consequence to extend the implementation of activities and even unjustly will influence the results. —NGO worker

Driver 3: Resource Availability

The third way in which insecurity affects health service delivery is by the often sudden reduction in patient volume at the health facility level. In a country implementing user fees, such reductions in patients mean that the facility has less revenue available to ensure its normal level of operation:

Patients are our first chief. With the little amounts they give us, this helps us buying medicaments, paying staff, and having the facility working. —Health facility health care provider

Unfortunately, the government’s support is close to zero; for this reason, the majority of the staff wishes the number of visits will increase, which is not really the objective of public health (smile). —Health facility health care provider

The same is true when patients presenting to the health facility are more destitute because of the ongoing conflict and thus have a decreased ability to pay. The facility receives less revenue, but in this case, it also has patients that need care, leading to increasing debts unless specific mechanisms exist that cover costs of vulnerable people (usually provided by external technical and financial partners [TFP]).

More specifically, respondents noted 2 mediators through which reduced patient volume affects service provision and quality.

Availability and Motivation of Health Care Workforce

Health facilities use the fees paid by patients to cover the premium for health care workers, which complements the meager salary paid by the government. As these complementary premiums are often what makes staff activity sustainable, payment shortfalls can impact the motivation of the staff to report and provide clinical care, affecting overall availability and quality of care. Retention of health care workers becomes difficult as staff need to look for alternative income sources and tend to look for positions with stable payment (usually those supported by TFP).

First of all, the system is poorly funded, which causes that if we look at what service providers earn, this does not suffice to cover their survival needs. There, you will find some service providers who are demotivated, and this generates instability of resources. Looking for better (opportunities) elsewhere, health [care] workers run away and desert as well. This means that you can invest in a health provider with training, capacity building, but after a while they will leave and go somewhere else. —FGD participant

We can well recruit a skilled health [care] worker, but if we cannot take care of them, at a certain point as we just said that this staff is demotivated, this staff will simply run away. You have to recruit appropriately and ensure an acceptable minimum to stabilize the staff. —Ministry of Health/Division Provincial de Santé official

Therefore, reduced resources have an immediate impact on service availability and quality but also a broader reduced return of investment of capacity-building activities as turnover risks are high.

Availability of Drugs and Equipment

A related consequence of reduced facility revenue is an increased risk of drug stock-outs. Health facilities that are not supported by a TFP use part of the user fees for purchasing their medical supplies and medicines. Reduced revenue leads to less availability both in terms of quantity and variety.

When utilization decreases, the health facility does not yield, and when it does no longer yield anything, it is difficult to purchase medicines, it is difficult to pay staff, thus the facility has problems in its overall functioning. —Health facility health care provider

Reduced human resources have an immediate impact on service availability and quality but also a broader reduced return of investment of capacity-building activities as turnover risks are high.

Strategies to Address the Identified Challenges

Organizations providing services described a variety of strategies they used to overcome the
identified challenges. Solutions can be regrouped by addressing 3 areas: lack of human resources, lack of access, and insecurity.

**Addressing Lack of Human Resources**
Respondents reported 4 strategies to compensate for reduced health care workforce.

1. **Task shift from higher to lower level or from foreign to national staff.** Respondents reported how community health workers are put in charge of needs assessments and management of additional diseases when external teams from the health zone office or the TFP cannot access a given area. Another example of task shifting is substituting a foreign staff person with national staff, who are considered to have easier access in insecure areas.

2. **Implement a “self-supervision” model.** Registered nurses in charge of a health facility are trained to temporarily take over a supervision role usually attributed to the health zone technical team. We trained the chief nurses from each health center on supervision; each one is considered as an internal supervisor and if the Health Zone Central Office team doesn’t arrive, the chief nurse acts officially as internal supervisor. Secondly, we trained the supervisors from the central offices of the health zone, so when the team from [NGO] is prevented from being there, the supervisors from the health zone do the supervision. Therefore, we have strengthened the system in such a way that if we cannot be there or are prevented from being there, we know they can still do something to ensure quality services. —NGO worker

3. **Rapidly train agents, or nurses, who have been trained only for a specific task but are then given additional tasks but without having received complete training.**

4. **Train a pool of staff (instead of only 1 person) to anticipate the high turnover.**

**Addressing Lack of Access**
Respondents described 4 strategies used to compensate for the reduced mobility and access.

1. **Implement a contingency plan that limits field presence and movements and therefore the exposure of humanitarian staff to insecurity.** This was mainly reported by NGOs, rather than government health care workers.

2. **Use mobile clinics to bring a set of health services to communities when individuals have difficulties in reaching the health center.**

3. **Establish maternity waiting homes (known as "Binyolas") to allow close-term pregnant women to stay within the health facility while awaiting the onset of labor.** Given the current pattern of armed conflict in the Kivu mostly characterized by one-off attacks or clashes between armed groups rather than prolonged military sieges, during phases/days of relative peace between armed clashes, a woman may decide to go to the nearest health facility with a maternity waiting area until the onset of labor.

4. **Distribute preventive drugs both at the facility level and patient level.** In certain cases (and specifically for chronic diseases), some organizations give out “security drugs,” (i.e., supply of medications for a longer period so that patients can go to the health facility less frequently).

For example, in our TB or HIV program, we give out “security medicines” it is usually necessary for a patient to come every month to get drugs, but we give 3 months because of insecurity. This is specific when it is needed to flee, and you do not have the possibility to go back for medicines. —NGO worker

**Addressing Insecurity**
Besides operational challenges, organizations also implement activities to address overall security and acceptance at 2 levels. At the community level, organizations aim to strengthen acceptance and facilitate the implementation of activities through dialogues and engagement with different population groups. This entails working with community members to establish an appropriate way to gather, share, and use information about community needs and organization’s activities and find an acceptable way to implement programs. Humanitarian organizations have also developed codes of conduct, agreements, and operational standards to ensure they are accountable to the population they serve.

For security, yes, the overall strategy that we use is to promote acceptance which is our trademark in our communities, and we ensure […] that our programs are [of] high quality; that the promises we make to our beneficiary population are kept; we provide information first to the population and to the partners; for each commitment, we sign a protocol and we make every effort to respect this protocol; […] we have codes of conduct for the
staff, for our partners ensuring that we don’t do anything foolish in the community, codes of conduct linked to sexual life, to protection, against exploitation and sexual abuse, code of conduct against fraud, fraud sensitivity, and all that, because there are stories like that which once started create problems down the road. —NGO worker

The second strategy is advocating and increasing awareness at national and international levels by tracking attacks on health care and advocating for safe humanitarian space. A specific human resource is usually appointed as security focal point or security advisor who monitors the situation, approves movements, and advises on risk-management strategies.

**DISCUSSION**

Three main pathways linking insecurity and health service delivery and quality in eastern DRC emerged from the study participants’ recounts: via violence, mobility restrictions, and resources availability. The effect of these drivers is mediated by several system-level or individual-level factors (Table 2). Two of these factors (health care workforce availability and drug/equipment accessibility) were reported in each of the pathways, highlighting both their centrality and their vulnerability for health service delivery and quality. Human resource availability was affected differently by each driver: in terms of willingness to be stationed in a certain area (violence), in terms of capacity to access the health facility (mobility), and in terms of sustainability and motivation of performing the duties (resources). Similarly, the presence of drugs/equipment in a health facility could vary in case of looting or damages (violence), delays in delivery (access), or delays in procurement due to lack of funding (resources). While these mediators are not surprising and in line with other conflict-affected settings, their identification can inform response strategies.

Outlining drivers and pathways is conceptually useful as it allows us to untangle the more complex dynamics that shape reality and provides insight into the mechanisms behind outcomes. However, a linear interpretation of such processes is too simplistic as it does not recognize that processes are shaped by the interaction of many system components, which (both the interaction itself and the components) vary according to the context, the severity of the challenges, the actors involved, competing priorities, and other external factors. Looking at the health system as a complex adaptive system allows us to acknowledge the pathways and related solutions while embracing uncertainty, the uniqueness of the context, and emergent characteristics. Adaptation, learning, and flexibility to emerging issues are even more relevant in humanitarian crises which are precarious by nature.

Resilience has been recognized as an emergent property of complex adaptive systems, arising from the combination of absorptive, adaptive, and transformative strategies. The majority of the solutions reported by respondents attempt to address the lack of human resources. Applying Blanchet’s approach, these can mainly be classified as absorptive strategies aimed at maintaining service delivery using the same level of resources and capacity. Task shifting, the expansion of job descriptions, and the increased reliance on community health workers has been used in several

<table>
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<tr>
<th>Level</th>
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<td>Health system</td>
<td>Health care workforce availability</td>
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<td></td>
<td>Drugs and equipment availability</td>
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<td>Delays in reaching care</td>
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<td>Delays in implementing activities</td>
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<td>Individual</td>
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<td>Reduced motivation</td>
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- Outlining drivers and pathways is conceptually useful as it allows us to untangle the more complex dynamics that shape reality and provides insight on the mechanisms behind outcomes.
Conflict-affected settings including Syria, Somalia, Uganda, and Sierra Leone with positive results. However, permanent insecurity often makes accountability, quality assurance, and health system regulation difficult, challenging the capacity to ensure that such adaptations do not turn into lucrative opportunities or lead to lower standards of service provision. Anecdotal examples include registered nurses running health facilities while appointed medical doctors provide more lucrative surgical activities or run parallel private facilities in safer areas or nurses conducting surgeries and cesarean deliveries (despite not being trained for this) as they are the only health professional available in a given area. While this article focuses on insecurity, the lack of financial and human resources and related strategies to overcome it also characterizes broader fragile settings, where the government role may be limited affecting recruitment, retention, and distribution of health care workers.

While adaptive capacity was shown in only 1 human-resource-related solution, it characterizes all attempts to address lack of access. In fact, the activation of a contingency plan, the use of mobile clinics, maternity waiting homes, and the introduction of “security drugs” show the capacity of health care providers to adjust to the new situation and provide alternative ways to maintain service delivery. Mobile clinics are extensively used in humanitarian settings to increase equity in access despite their comparatively high cost, complexity, and inefficiency. Yet, they remain at times the only feasible way to reach communities. Runaway bags ensure treatment continuity by reducing the risk of interruption due to abrupt service disruption. They can therefore represent a temporary solution in times of insecurity and are best suited for chronic conditions such as HIV or TB. Community health workers are playing an increasing role in ensuring continuity of health service provision as well as monitoring and evaluation of health programs (through community-based data collection systems for instance), particularly in areas affected by conflict.

Lastly, the interventions aimed at addressing insecurity can be classified as transformative, as they introduce approaches that would not be necessary without insecurity or are designed to address a specific consequence of insecurity. While community engagement is (or should be) standard practice in the design and implementation of any program to ensure relevance, acceptability, sustainability, and overall success, community dialogues in insecure settings become mechanisms to ensure safety and security of humanitarian workers and communities and require specific negotiation skills that consider conflict, history, and power dynamics. Similarly, the need to establish a mechanism to track attacks on health care illustrates the capacity to integrate a new function in the system (i.e., advocacy for the end of such attacks and of the perpetrators’ impunity).

While lack of resources has been reported as one of the main challenges for health facilities, this tends to apply to health facilities that rely solely on governmental funding. Conflict-affected health zones have received greater amounts of funding and external support in the form of humanitarian aid compared to the least insecure zones. This led to a 2-tiered system where health facilities supported by TFP have the capacity to provide more and better services, while health facilities relying on out-of-pocket expenses are faced with volatile resources and therefore struggle to ensure the continuity of services.

Insecurity was reported to affects service provision and quality by impacting both the system as a whole and the health care workers as individuals. Stress, fear, and reduced motivation can compromise health service quality even when equipment and medicines are available. Yet, no intervention aimed at providing psychological support to health care workers was mentioned by the respondents. Individual strategies seemed rather to rely on personal religious values or sense of duty and attachment to the community (results not shown). Studies on how health care workers experienced and responded to conflict showed that a resilient health care workforce can contribute to the overall resilience of the system. However, they also highlighted the possible dissonance between individual and system level-coping strategies (such as dual practice or taking on other jobs outside the health system to complement salary).

Limitations
This study has several limitations. First, our study reported on challenges in health service delivery as perceived and experienced by service providers only. Although we interviewed actors that have different roles along the “service delivery chain” (i.e., national authorities, donors, and implementers, including both national and international project staff and health care workers) to triangulate findings and obtain a comprehensive understanding of the situation, because we did not include beneficiaries among the respondents, the communities’
perspectives on quality of services and actual access could not be presented. Unfortunately, this was beyond the scope of the BRANCH project and the research team could not influence this decision. Our analysis thus provides a partial view of the challenges to increasing health service coverage and quality. Second, the discussed solutions only reflect the experience of the interviewed organizations and are not based on a quantitative assessment of the relative effectiveness or cost-effectiveness of each solution. As evaluating the effectiveness of such efforts was beyond the scope of this study and of the BRANCH overarching project, further research is needed to assess the absolute and relative performance of the proposed solutions. Finally, 1 of the originally targeted health zones in North Kivu (Beni) was not accessible at the time of qualitative data collection due to the Ebola epidemic. Therefore, another health zone was selected among the most affected by violent events.

**CONCLUSION**

We used interviews from health care providers to analyze how insecurity affects the delivery and the quality of maternal and child health services. The 3 main drivers are violence, mobility restrictions, and financial resources availability, but numerous mediators have been identified. Understanding the mechanisms behind outcomes allows the design of appropriate response strategies. Yet, no process is linear, rather it is influenced by the uniqueness of the context as well as the uncertainty characterizing humanitarian settings. Health actors in eastern DRC have shown some capacity to adapt, adjust, and transform due to insecurity. However, further research is needed to measure the effectiveness of such strategies to provide guidance for increasingly vulnerable health systems.

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**Competing interests:** None declared.

**REFERENCES**


En Français

De l’insécurité à la préstation de services de santé: voies et stratégies de réponse du système dans l’est de la République démocratique du Congo

Résumé


Trois principaux facteurs reliant l’insécurité à la qualité et la prestation des services de santé ont émergé: via la violence, les restrictions de mobilité et la disponibilité des ressources. L’effet de ces moteurs est médial par plusieurs facteurs au niveau du système ou au niveau individuel. Deux facteurs ont été signalés dans chaque voie: la disponibilité du personnel de santé et l’accessibilité aux médicaments et à l’équipement. Les ressources humaines ont été affectées différemment par chaque conducteur: en termes de volonté d’être stationné dans une certaine zone (violence), de capacité d’adaptation (mobilité), de structure de santé (mobilité), et de durabilité et de motivation des tâches (ressources). De même, la présence de médicaments/équipements variait en cas de pillage ou de dégâts (violence), de retard de livraison (mobilité), ou de retard d’approvisionnement (ressources). Bien que les médiateurs ne soient pas surprenants, leur identification permet de concevoir des stratégies de réponse appropriées. La majorité des solutions signalées tentent de remédier au manque de ressources humaines et reflètent la capacité d’absorption. La capacité d’adaptation caractérise les tentatives pour remédier au manque d’accès (plan d’urgence, cliniques mobiles, maisons d’attente de maternité, médicaments de sécurité). Enfin, les interventions

Principales conclusions

- L’insécurité affecte la prestation et la qualité des services de santé dans l’est de la RDC à travers 3 voies principales: la violence, les restrictions de mobilité et la disponibilité des ressources.
- Plusieurs facteurs médiateurs jouent un rôle: les 2 plus importants sont la disponibilité du personnel de santé et l’accessibilité aux médicaments/equipements.
- Les prestataires de soins de santé mettent en œuvre diverses stratégies pour surmonter ces obstacles, montrant une certaine capacité à s’adapter, à s’ajuster et à se transformer en raison de l’insécurité. La majorité des stratégies d’intervention reflètent la capacité d’absorption et traitent le manque de ressources humaines; des solutions adaptatives ont tenté de remédier au manque d’accès et des stratégies de transformation aux défis posés par l’insécurité.

Implications clés

- Comprendre les mécanismes par lesquels l’insécurité affecte la prestation et la qualité des services de santé est essentiel pour concevoir des stratégies de réponse appropriées.
- L’efficacité et la rentabilité des stratégies de réponse à l’insécurité chronique doivent être évaluées pour fournir des orientations aux systèmes de santé de plus en plus fragiles.

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Nutrition Capacity Building to Meet National Priorities: Lessons Learned in Developing and Implementing Malawi’s First Dietetics Program

Sanele Nkomani, Lynne M. Ausman, Elizabeth Marino-Costello, Bernadette Chimera, Alexander Kalimbira, Agnes Mwangwela, Molly Uebele-Harrigan, John Phuka, Shibani Ghosh

Key Messages

- We developed the first-ever clinical dietetics program in Malawi to equip students with knowledge, attitudes, and skills in nutrition support, health promotion, and disease prevention at the community and health facility levels.
- We addressed challenges in curriculum implementation, lack of supervision, and lack of capacity-building resources by using unique approaches and building partnerships with existing programs and professionals.
- Building a dietitian workforce to serve the needs of the population requires a commitment to funding the program, building research capacity, and developing regulatory and practice guidelines.

ABSTRACT

The current nutrition situation in Malawi, characterized by high rates of malnutrition in communities and hospitals and a rapidly increasing burden of overweight/obesity and diet-related noncommunicable diseases, highlights the urgent need for registered dietitians, who have a proven track record in the prevention and management of all forms of malnutrition and improving patient outcomes. However, dietetics practice has been described as underdeveloped and fragmented in many parts of Africa, exacerbated by a severe and chronic shortage of dietetics professionals and a lack of nutrition and dietetic education programs in most African countries.

We share early lessons learned in the development and implementation of the first dietetics program in Malawi. Within 6 years, the program produced 10 graduate dietitians who have filled the first clinical dietitian posts in Malawian public hospitals. This early success can be attributed to the model used to develop and implement the program, which included early stakeholder engagement to define the priority skills and competencies of a Malawian dietitian, the use of internationally recognized training standards, and the development of strategic institutional partnerships that brought together complementary skills and expertise. Furthermore, using existing resources and recruiting students with a nutrition and health background accelerated implementation. The current dietetics curriculum responds to the national nutrition and health policy direction and strategic objectives. Early and sustained government engagement was crucial in creating demand and securing career prospects for graduates. Although still in its infancy, dietitians in Malawi are poised to contribute significantly to alleviating the country’s complex nutrition challenges.

INTRODUCTION

Registered dietitians are recognized globally as being essential to delivering preventative and curative health services and integral members of multidisciplinary health care teams.1–2 A dietitian’s skills and competencies rest on their ability to interpret and effectively communicate complex theoretical nutrition knowledge to health care providers, policy makers, communities, and individuals, to promote and maintain health across the lifespan and in different disease states.3 Dietetic interventions have shown to be highly efficacious in
improving health outcomes and reducing costs for numerous conditions at all levels of health care.3–6

Despite a globally observed exponential growth in the dietetics profession, the dietitian’s role remains underdeveloped and fragmented across Africa. More than 60% of African countries do not have academic programs for training dietitians and the “registered dietitian” title is not protected by law in many African countries.1,7 Most African countries, including Malawi, lack dietetics professional associations, have no formal registration requirements for dietitians and dietetics programs, nor any codes of ethics or a well-articulated scope of practice.1,2,7 All these factors are important for building the integrity of the profession.

Moreover, most nutrition professionals in Africa receive education and skills largely focused on public health and community nutrition. This nutritionist cadre is critical and has been at the forefront of combating undernutrition, which persists as a major contributor to morbidity and mortality in sub-Saharan Africa. However, management of malnutrition in clinical settings, whose etiologies and treatment are often specific to underlying disease processes, which is just as critical and requires strong integration of medicine and nutrition, is largely underdeveloped. Dietitians specialize in the integration of medical nutrition therapy in individualized patient management plans, while also being adept in working in community-based/public health interventions. Considering the need for developing the dietetics profession, we share the experience and lessons learned in developing and implementing the first dietetics training program in Malawi.

**HEALTH AND NUTRITION SITUATION IN MALAWI**

Malawi is a low-income country with a population of approximately 17 million people, 82% of whom are rural and have a national life expectancy of 61 years.8,9 Malawi’s health infrastructure faces chronic and severe shortages of health care professionals, basic equipment, and medications, rendering it inadequate for the needs of the population.10 Clinical nutrition services are limited, as shown by low rates of screening, diagnosis, and prescription of nutrition therapy interventions in hospitals, particularly for nonpediatric populations. Up to 40% of clinicians use intravenous dextrose as the sole nutrition supplement as opposed to nutritionally complete enteral or parenteral formulations for critically ill patients.11 These patients present with severe and complex metabolic derangements that require aggressive and often specialized nutrition support.6,11

In a small study of 25 patients, the average rate of malnutrition in hospitalized surgical patients in Malawi was 80%, which is double the world average.12,13

Concurrently, Malawi’s burden of undernutrition in communities remains high, with 37% of children aged under 5 years stunted and 12% underweight.14 Noteworthy is that Malawi has made significant progress in reducing the rates of stunting by more than 10 percentage points in the last 10 years.14 Micronutrient malnutrition is also a major public health concern, with 28% of preschool children and 15% of women having iron deficiency and 60% of women, men, and children having zinc deficiency.15 While infectious diseases such as HIV/AIDS, malaria, and diarrheal diseases are the leading causes of morbidity and mortality in Malawi,16 the picture is changing with an increase in diet-related noncommunicable diseases (NCDs), such as cardiovascular diseases, certain cancers, and diabetes mellitus.

Driven by unhealthy diets/lifestyles and overweight/obesity, NCDs are now the leading cause of death globally and show no signs of abating, especially in low and middle-income countries.17 In Malawi, 28% of adult women are overweight or obese, and the rate nearly doubles (44%) in urban areas compared to the national average.8,18 The prevalence of hypertension is estimated at 33% of the adult population, 8.7% have abnormal lipid profiles, and diabetes affects about 6% of the population.8,18

Having access to adequate food for the promotion of good health and self-sufficiency is a human right and a central feature of key national documents, including the “National Multi-Sector Nutrition Policy 2018–2022” and its accompanying “National Multisector Nutrition Strategic Plan.”19 Of the 8 strategic goals outlined in both national documents, dietetic interventions respond directly to 4: prevention of undernutrition, treatment and control of acute malnutrition, prevention and management of overweight and nutrition-related NCDs, and enhancement of nutrition education.

We outline the process to determine the need for the program along with discrete steps in the development and implementation of the program. We also identify lessons learned and future directions for the continued growth of dietetics training and the profession in Malawi.

**ASSESSING THE NEED FOR DIETITIANS IN MALAWI**

We conducted several scoping exercises aimed at understanding the context in Malawi and identifying
resources available for running a quality dietetics training program. We identified institutional strengths to implement quality training and key stakeholders that included government officials, whose support was essential to implement the program and promote dietetics practice (Figure 1).

In 2012, we undertook a needs assessment that highlighted the lack of dietitians in Malawi and determined gaps in the health care team that needed to be filled.21 We surveyed university leadership and faculty, Ministry of Health staff and leadership, United Nations agencies, and other nongovernmental organizations. Survey respondents stated that the lack of clinical nutrition experts left major gaps in diet therapy, nutrition education, and technical guidance in nutrition programs in Malawi. Respondents all strongly agreed upon the critical need to address the lack of knowledge and skills in nutrition management of diet-related NCDs and critically ill, hospitalized patients, resulting in the development of a program with a clinically focused curriculum that emphasized hospital-based nutrition support interventions and diet-related NCD prevention and management. The program focused on a cadre with research, professionalism, and leadership competencies to generate evidence and drive the development of clinical

**CURRICULUM DEVELOPMENT**

We reviewed the existing Bachelor of Science degree in nutrition and food science at Lilongwe University of Agriculture and Natural Resources (LUANAR) to determine areas where course content merged with the minimum requirements for dietetics and gaps that needed to be filled by the dietetics curriculum. The areas of convergence became the prerequisite requirements for entry into dietetics training (Figure 2). In some instances, new competency-based course content was developed, and in others, existing postgraduate courses were adapted to meet dietetic competencies. Resources for the new course content were modeled from existing well-established standards from the United States of America, South Africa, Kenya, and the International Confederation of Dietitians (ICD) that prescribe minimum course content, length, scope, and competency standards.21 Course content was further tailored to respond directly to the needs of Malawi, articulated at the national policy level and through the needs assessment.22,23

**FIGURE 1. Steps in Developing Malawi’s First Dietetics Training Program**

- Identify appropriate in country site/host for dietetics program
- Identify local and/or international partnerships to support development and implementation
- Leverage existing resources for developing and implementing a quality program
- Develop standard curriculum
- Accreditation of curriculum buy local regulating bodies
- Identify and fill resource gaps
- Leverage the strength of existing course content and develop new courses specific to dietetics
- Standards of training and human resources (curriculum development, teaching and clinical supervision, and course content)
- Adequate funding streams, political will, and government support for program and compliance to international dietetics and local academic training standards
THE FIRST MALAWIAN DIETETICS PROGRAM

The first Malawian clinical dietetics program was created in collaboration with LUANAR, the Feed the Future Innovation Lab for Nutrition based at Tufts University, and the Kamuzu University of Health Sciences (KUHeS) in Blantyre, Malawi (formerly known as the University of Malawi, College of Medicine). The Malawi Mission of the United States Agency for International Development (USAID Malawi) provided funding for the program.

The program equips students with knowledge, attitudes, and skills in nutrition support, health promotion, and disease prevention at the community and health facility levels. During the first 12 months of didactic instruction, students take courses in biomedical sciences, medical nutrition therapy, human behavioral sciences, and research methods (Figure 2). In the subsequent 8 months, students fulfill practical internship requirements in clinical nutrition, community nutrition, and food service management. After completing the 20-month program, graduates receive a postgraduate diploma in clinical dietetics and are encouraged to advance to a recently introduced master’s degree, which together take at least 32 months to complete. The criteria for program admission include a bachelor’s degree in nutrition or related biomedical science and a minimum grade point average in prerequisite courses (Figure 2). These criteria and requirements are in line with international training standards for dietitians, with the intent of increasing the rigor of training. All students must pass a final qualifying exam to be eligible for registration to practice.

PROGRAM IMPLEMENTATION

Both the diploma and master’s programs were approved by the LUANAR senate (as the host institution of the program), the Malawi Medical Council, and the National Council for Higher Education. In April 2016, the first cohort of 6 students was admitted; a second cohort of 10 students was admitted in 2018. At the time of writing this article, 10 students have completed all requirements for registration as dietitians. Of the 16 students in the first and second cohorts, 6 either failed to meet pass requirements or dropped out of the program before completion.

Curriculum implementation relied heavily on leveraging the strengths of a strategic partnership between LUANAR, KUHeS, and Tufts University.

FIGURE 2. Structure of Postgraduate Diploma in Clinical Dietetics in Malawi
As an agricultural university with a vibrant and nationally recognized department of human nutrition, LUANAR’s expertise and postgraduate courses in food science, public health nutrition, and nutrition epidemiology were adapted to meet dietetics core competencies. Tufts University and KUHeS provided teaching support in core dietetics courses, medical nutrition therapy, nutrition counseling and behavior change, and nutritional biochemistry. Tufts provided technical leadership and ensured the benchmarking of the program to quality standards. KUHeS was also central in providing the platform and supervision for clinical practice.

Considering the lack of dietetics expertise and supervision capacity in Malawi, we identified 2 positions, supervising dietitian and clinical coordinator, that were critical for the daily management of the program, teaching, and supervision. A content expert in clinical dietetics, the supervising dietitian had an advanced degree in dietetics and extensive clinical experience. The clinical coordinator, a Malawian trained medical doctor, brought medical expertise coupled with knowledge and experience on Malawian health care delivery.

An evaluation of dietetics practical training needs against the available resources revealed the lack of adequate critical care nutrition resources (enteral and parenteral nutrition support). In light of this need, the University of Cape Town (UCT) hosted Malawian students for a 6-week exchange program in critical care and surgical nutrition support. The exchange program was critical in building capacity and fulfilling competencies in critical care nutrition support and surgery for the Malawian students, who would have otherwise not been exposed to these resources.

Approaches to providing adequate supervision focused on self-directed methods of learning, which included problem-based learning, peer supervision, and role emerging placements. Because of the lack of dietitians to shadow in Malawian hospitals, role emerging placements were particularly useful, and have gained global traction in allied health care professional training as a viable solution for balancing competing demands of providing quality practical training with limitations in supervisor coverage.24,25 In the latter rotations of the program, students were paired and placed in situations where they were the only dietitians providing services and often reporting back to a non-dietitian on-site supervisors (e.g., doctors, nurses, and nutritionists), with the supervising dietitian providing oversight and support. This approach proved useful in establishing input for dietetic services and met a recognized need for dietetic services.

### STAKEHOLDER ENGAGEMENT AND ADVOCACY

While developing the program with various stakeholders, we encountered some barriers that included inadequate knowledge of dietitians’ roles, lack of recognition, and low acceptance of the dietitian’s role in health care. We actively worked on promoting the new dietetics cadre at the government policy level and to fellow clinicians in hospitals through frequent stakeholder engagements that took many forms.

These stakeholder engagements included aligning the program’s aims and objectives to the strategic nutrition and health objectives of the Malawian government through multiple consultations with the government at key points, starting with scoping visits, the needs assessment, and regular program updates to senior Ministry of Health officials. During this process, we identified a need to create demand for dietitians as part of the health care teams. We worked closely with the Department of Clinical Services to establish the first clinical dietetics posts in civil service.

To immerse key government decision makers in clinical dietitians’ roles, we invited senior government officials, comprising directors of clinical services, nutrition, and human resources, to visit both a Malawian hospital and UCT teaching hospitals, where students completed their critical care and surgery rotations. This “show, tell, and involve” strategy was instrumental in fast tracking a roadmap for recruiting and integrating dietitians into Malawian clinical services. Although the full integration of dietitians is a long-term goal, the government has shown strong commitment by creating posts and hiring the first graduate registered dietitians. The visits also helped orient the stakeholders on resources needed for optimal practice. We supported the government with mapping the resources needed for optimal practice including procurement needs for specialized enteral and parenteral nutrition support and the development of national hospital food service guidelines. For the first time, these guidelines quantify and standardize the nutritional content of meals served to patients and have therapeutic adaptations for common conditions, such as diabetes and chronic kidney failure, in hospitalized patients.

To further address the barrier of inadequate knowledge of dietitians’ roles in clinical care, we facilitated clinical nutrition training for doctors...
and nurses at 2 major referral hospitals in Malawi. Thirty-five critical care nurses and doctors attended a hands-on short course in enteral and parenteral nutrition support administration. This was a precursor to the introduction of ready-to-hang, pump-assisted enteral nutrition administration at 2 of the largest critical care units in Malawi.

LESSONS LEARNED
The need for dietetic professionals to join health care teams to combat both forms of malnutrition and tackle the rising prevalence of NCDs in developing countries is urgent. Since 60% of African countries were in a similar situation as Malawi before the introduction of the dietetics program, we believe that several lessons can be drawn from the experience in Malawi that may apply to other countries.

Engage Stakeholders Early and Often
First, engaging with stakeholders from the beginning at both the policy and implementation level garnered government support and drove demand for dietitians in government health services. Sustained engagement efforts with key government stakeholders including sharing regular updates/progress reports, sensitizing them to dietitian roles, and involving senior government management in training students and career development, was crucial in creating a program that developed competencies and skills that responded directly to the country’s needs. This response, in turn, was a key factor in gaining high-level government support.

Develop Career Opportunities
The creation of the first-ever posts for dietitians and subsequent deployment of both cohorts of graduates within months of their graduation was a major achievement considering that more than 50% of existing health care professional posts in Malawi are vacant. All 10 of the graduates are employed by the government and now cover all 4 tertiary hospitals in the country. We believe that securing employment prospects and career paths for dietitians early in the training program has been and will continue to be a crucial enticing factor for recruiting students, evidenced by the 3-fold increase in the number of applications from the first to the second cohort.

Build Professional Networks and Partnerships
At the implementation level, we found that continuous benchmarking of courses, rotation sites, and competencies was critical in identifying gaps in dietetics training and developing quick remedies for such gaps. For example, the UCT exchange program was a stop-gap remedy that improved the quality of critical care nutrition support training to a level that was not possible in Malawi given the available resources levels there.

Since there were few dietitians in Malawi, the quality of training and exposure relied heavily on leveraging the strengths of partnerships and multiple stakeholder engagement. The medical school partnership was crucial to implementing clinical rotations and gaining quick acceptance and recognition of dietitians in the hospital. The UCT exchange program exposure was also very valuable for Malawian students and preceptors. Students gained confidence in resources for nutrition support that were not available in Malawi and were exposed to an established clinical nutrition service operation, which can be modeled in Malawi. Malawian preceptors also learned about supervision and assessment of students in practical rotations, leading to improved quality in training.

This also highlights the importance of building strong networks with regional dietetics experts who assisted with strengthening our program by vetting examinations and performing a curriculum review. The continued fostering of relationships with regional experts has also opened doors for institutional collaborations in capacity building and research. Two program graduates have completed master’s degrees in nutrition with the North-West University, South Africa, for example. In addition, networking with local Malawian dietitians also contributed vastly to improved preceptor support. The preceptors were role models to students and brought extensive practical experience in the Malawian context. Another successful strategy for dietetics clinical practice was a series of dietetics-orientated capacity-building workshops and seminars for other health care professionals. These efforts raised the awareness of the role of the dietitian and advanced multidisciplinary collaboration.

Build Knowledge Capacity for Dietetics Among Nutritionists
This program was built on maximizing existing capacity for nutrition training by reviewing, adapting, and adapting existing nutrition coursework and matching with dietetics competencies, then filling the gaps with new course content. The recruitment of qualified nutritionists and people with biomedical backgrounds meant that a
significant portion of dietetics coursework needs and competencies had already been fulfilled in the student’s undergraduate degrees. This led to a shorter program and fast-tracked graduate output. However, through early and continuous evaluation of student performance, we observed many students, particularly those with a nutrition background, struggled to transition from their undergraduate biomedical science knowledge base to the expectations of the dietetics program. This may explain the 37.5% average failure rate observed in both cohorts. Hence, we designed an 8-week “bridging course” to mitigate this gap in nutritional biochemistry, nutrition in the lifecycle, and medical terminology. We hoped that this would lead to a smoother transition between the student’s prior knowledge and the rigor of the dietetics program. This may be applicable in other countries, especially in Africa where there are more nutritionist training programs than dietetics.

**Create Alternative Models for Supervision Support**

There remained an acute shortage of supervision capacity for students during clinical placements/rotations, a high supervisor-to-student ratio, and no established role for dietitians in clinical placements. We had anticipated this problem given the limitations in dietetics practice in Malawi. Nonetheless, this shortage posed a serious threat to quality training that will likely continue until a critical mass of dietetics educators/instructors exists. We used a role emerging placements model, which works ideally in places where there are no structures and roles for dietitians, and were highly successful in empowering students, building confidence in communication, promoting clinical reasoning, and improving their sense of their own role in multidisciplinary teams. Under supervision, students were encouraged to directly interact with the medical teams on patient management by contributing to medical rounds and documenting directly in clinical notes after approval by supervisors.

**CONCLUSION**

A strong case has been made for registered dietitians as an essential piece in solving the nutrition challenges in Malawi. We describe how capacity for the dietetics professional practice has been built thus far. We believe that our case study can be extended to other developing countries that are undergoing similar epidemiological transitions with similar resource constraints impeding the quality of health care professional training.

A major priority for the program going forward is to increase graduate output and build a critical mass of dietitians to sustain the practice. To that end, LUANAR has secured an additional 5-year USAID grant to provide scholarship support for about 25 more students and sustain the program for an additional 5 years. Through this grant, LUANAR will prioritize training dietitian educators through mentorship with regional and international experts. There is a need to secure more sustainable sources of funding from the government and diversify sources of funding by securing research grants and competitive tuition rates.

Efforts to build the national research agenda are underway with 90% of the graduates of the program now pursuing Masters in Dietetics degrees and undertaking groundbreaking research on nutrition outcomes in clinical care. The new grant is also set to bolster the research capacity through training more master’s students and funding research. Evidence will ultimately inform practice, improve the quality of care, and justify the role of dietitians in Malawi.

Important steps in promoting professional dietetics practice made thus far have included advocacy, forming a dietetic association, drafting regulatory guidelines that define the scope of dietetics practice and have credentialing requirements for both individuals and training institutions, and engaging national regulators for enacting the guidelines and drafting practice guidelines. These are all structural priorities that protect the registered dietitian title and the public from imposters. Future priorities should focus on strengthening regulation of practice and the association as key bodies promoting practice.

The development and implementation of the first academic program for dietitians marks the genesis of the profession in Malawi. However, sustained investment in the expansion and improvement of practice conditions is needed for dietitians to realize their full potential.

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program implementing partners. MUH: editing. SG: contribution to the conception, design.

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Results-Based Financing for Health: A Case Study of Knowledge and Perceptions Among Stakeholders in a Donor-Funded Program in Zambia

Rachel Bergman,a Birger C. Forsberg,b Jesper Sundewallc

Key Messages
- The intended incentive structure of results-based financing (RBF) makes it particularly important that program implementers communicate to beneficiaries of a program before implementation begins about the nature of the program and that RBF will be used.
- Improved decision making and communication about the requirements and expectations of an RBF program can enhance stakeholders’ knowledge and perceptions of the program, and ultimately make implementation easier.

Key Findings
- The lack of a fully developed RBF model meant the program was more difficult to communicate to the different actors involved.
- The lack of knowledge of the RBF program and the existence of incentives raises doubts about whether the program incentivized actors for the intended targets.

Key Implications
- Program managers should recruit stakeholders from all governments and organizations involved in program financing and implementation to participate in the design of RBF schemes so that they can effectively communicate the structure and indicators to different levels of their respective organizations.
- Program implementers using RBF should have a flexible plan in place for the RBF model before implementation begins, even if the plan might change.

ABSTRACT
In 2015, the Zambian government and the Swedish International Development Cooperation Agency (Sida) signed an agreement in which Sida committed to funding a program for Reproductive, Maternal, Newborn, Child, Adolescent Health and Nutrition (RMNCAH). The program includes a results-based financing (RBF) model that aims to reward Zambian districts for improved district-wide results on relevant indicators with additional funding. We aimed to describe stakeholders’ knowledge of the RBF model and perceptions of the incentive structure during the first 18 months of the program’s implementation. This study illuminates the possible pitfalls of implementing an RBF scheme without giving attention to all necessary steps of the process. A qualitative case study was used and included a review of documents, in-depth interviews, and observations. From February–April 2017, we conducted 37 in-depth interviews, representing the views of 12 development partner agencies, government departments, and health facility staff throughout Zambia. We used a qualitative framework analysis. Findings show that the Zambian government and Sida had different perceptions on what levels of the health system RBF will incentivize and that most districts and hospital administrators interviewed were unaware of the indicators that the RBF was part of the RMNCAH program at all. The lack of knowledge about the RBF scheme among respondents suggests the possibility that the model did not ultimately have the necessary preconditions to create an effective incentive structure. These results demonstrate the need for improved communication between stakeholders and the importance of sufficiently planning an RBF model before implementation.

INTRODUCTION
Results-based financing (RBF) is an umbrella term used to describe any program in which a funder—often a national government or agency, or a foreign development partner—transfers money, material goods, or other incentives to a recipient agent conditional on the recipient achieving predefined output or outcome targets.1-3 An incentive is anything that motivates or encourages the agent to achieve the desired results that are agreed upon with the funder.4,5 Although not distinct from RBF, results-based aid refers to cases in which a bi- or multilateral development partner funds a national government of a partner country and the national government bears the responsibility of delivering results.2,6 Development partners typically see results-
based mechanisms as methods to make aid more effective. This position is in line with the 2005 Paris Declaration on Aid Effectiveness, in which participating countries agreed that programs can be managed using a result-based mechanism to improve aid effectiveness.\textsuperscript{2,7}

Oxman and Fretheim provided an overview of systematic reviews analyzing RBF schemes in lower- and middle-income countries (LMICs). They outlined 7 characteristics that can differ between RBF\textsuperscript{2} programs, including the indicators chosen to measure results, the method by which results are measured, the type and magnitude of incentives used, and the level of a government or sector incentivized.\textsuperscript{1} However, their overview, as well as other systematic reviews, shows that there is insufficient evidence to support the concept that RBF leads to better performance, whether it is used to incentivize individuals or entire levels of a sector.\textsuperscript{2,8} Many studies of RBF programs lack adequate controls that would allow impact to be assessed.\textsuperscript{6} Even when studies have used a randomized control trial design to control for founders, they have been inconclusive on the impact of RBF.\textsuperscript{6,9} In fact, evidence from a variety of settings points to the various risks and perverse effects RBF can have.\textsuperscript{9}

Still, past RBF schemes have suggested RBF can strengthen health systems and demonstrated key concepts that can help implementers optimize the characteristics of an RBF program for impact.\textsuperscript{10,11} All stakeholders—both the funders and the recipients—should be involved in the design of the program, and the scheme should be communicated to those who will benefit so that they know the intended results.\textsuperscript{1,6} Oxman and Fretheim noted specifically that financial rewards and other incentives did not have an impact in countries when intended recipients lacked awareness of the potential rewards.\textsuperscript{1} The choice of indicators used in a program, and choosing ones that the national government knows about and uses, is also critical for the effectiveness of an RBF program.\textsuperscript{6,12}

Although some studies have attempted to analyze the results and impact of RBF, fewer have looked at the challenges involved in actually planning an RBF scheme (i.e., creating and setting one up) especially at the system level rather than individual level.\textsuperscript{2,6,13} We aim to fill that gap by providing an understanding of the possible consequences that can arise when the implementation of a program has started but a full plan for implementation of its RBF scheme is not yet developed. In the case of the Reproductive, Maternal, Newborn, Child, Adolescent Health and Nutrition (RMNCAH) program, this resulted in implementers being unable to communicate about the existence of an RBF program and its components, including indicators for which results are measured and the amount of funding recipients can incur for improved results. We examine an RBF scheme designed for the health sector in Zambia, particularly one at this stage of implementation, to use as a case study for assessing the impact of stakeholders’ knowledge and perceptions of an RBF model on the model’s implementation. The study is illustrative in that it gives an example of how an RBF project is implemented and how it contributes to improved knowledge on how RBF is understood in practice. Additionally, we describe opportunities for improving decision making and in communicating requirements and expectations for an RBF program.

\section{SIDA’S SUPPORT FOR THE RMNCAH PROGRAM}

Although the World Bank reclassified Zambia from a low-income country to a lower-middle-income country in 2011, foreign aid continues to be an important part of the Zambian health sector financing as it has for several decades.\textsuperscript{14,15} The public health sector is structured into national, provincial, district, and community levels.\textsuperscript{16} At the national level, the Ministry of Health (MOH) organizes the overall health sector, and provincial health offices (PHOs) and district health offices (DHOs) provide coordination at the provincial and district levels, respectively. Health service delivery facilities fall into categories at each of these levels: tertiary hospitals at the national level, level 2 general hospitals at the provincial level, level 1 hospitals at the district level, and health posts and health centers at the community level.\textsuperscript{16,17} Primary health care includes all health services at the district and community levels, which both fall under the supervision of and receive funding from DHOs.\textsuperscript{16}

From 2012 to 2014, the World Bank supported a pilot RBF program in Zambian districts that used monetary incentives to motivate individual health

\textsuperscript{*RBF schemes can take various forms depending on many characteristics, including who is funded and targeted by the incentives. For instance, in the health sector, a development partner can fund a recipient government or target individual health care providers. A discussion of the full range of varying RBF characteristics is outside of the scope of this article.} See Oxman and Fretheim for more information.
care providers to improve and increase the provision of maternal and child health services. An impact evaluation of the program suggests that districts that received enhanced financing without RBF showed comparable improvement in health care indicators compared to districts that received RBF. Based on some of the design features of the World Bank’s RBF program, in 2015, the Swedish International Development Cooperation Agency (Sida) and the Government of the Republic of Zambia signed an agreement for government-to-government financial support that would last 5 years, from 2016 to 2020, and include fixed and RBF components to improve 5 indicators related to RMNCAH. Sweden’s Appraisal of Intervention, titled “Health support for women, children and youth in Zambia,” provides insight into the country’s objectives and intentions regarding this agreement. The €42.8 million grant included both fixed and variable tranches (VTs), and funds from both would be directed to DHOs for the 22 districts in the southern and eastern provinces of Zambia. Funds could be used at the discretion of districts to support their RMNCAH work, including hiring new staff but excluding bonuses to individual staff members. Despite these decisions about how funds would be disbursed, program documents did not provide any explanation about the theory of change or the incentive structure for disbursements.

The fixed component involved each participating district receiving a portion of a fixed tranche of funds each year (70% of the entire grant) based on the allocation formula the government already uses to disburse money to districts. The Sida funds represented a significant increase in resources at the district level. For many districts, the Sida funds accounted for 20%–30% more on top of their usual government allocations for district-level health care operations, and some districts received an even larger share. Based on performance according to an RBF model, 30% of the grant money (€12.8 million) was released as a VT. While half of the VT was based on 5 indicators (Table 1) chosen to measure RMNCAH performance (second VT), half was based on a “budget execution indicator” that measured the government’s execution of its national health budget by the Ministry of Finance (first VT). The 5 RMNCAH indicators used for the second VT were chosen through discussion between Sida and the Government of the Republic of Zambia, and no process was determined for how they would be changed, if necessary, and how the changes would be communicated to relevant actors. The intention was for there to be 5 annual VTs throughout the project life cycle, with the first disbursement made at the end of 2016. At the time research was conducted in April 2017, a payment had not yet been made, and Sida and the MOH had not finalized the formula that Sida would use to calculate how much of the VT it would release nor how much the MOH would allocate to each district based on their individual performance on the 5 key RMNCAH indicators (Figure).

### TABLE 1. Indicators Chosen to Measure RMNCAH Program Performance in Zambia

<table>
<thead>
<tr>
<th>Original Indicators, 2015</th>
<th>Current Indicators (Changed in June 2016)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women receiving antenatal care by skilled personnel at least 4 times during pregnancy</td>
<td>Women receiving antenatal care by skilled personnel at least 4 times during pregnancy</td>
</tr>
<tr>
<td>Births attended by skilled health personnel</td>
<td>Births attended by skilled health personnel</td>
</tr>
<tr>
<td>Newborns receiving postnatal care visits within 2 days of birth</td>
<td>Newborns receiving postnatal care visits within 6 days of birth</td>
</tr>
<tr>
<td>Children under 2 receiving the full immunization package</td>
<td>Children under 12 months receiving the full immunization package</td>
</tr>
<tr>
<td>Children aged 0–59 months with signs of pneumonia who received antibiotics</td>
<td>Number of women accepting family planning for the first time</td>
</tr>
</tbody>
</table>

Abbreviation: RMNCAH, Reproductive, Maternal, Newborn, Child, Adolescent Health, and Nutrition Program.

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1In Zambia, Sida is represented by the Embassy of Sweden. Although the Embassy is responsible for the appraisal and follow-up of any financial contributions, Sida provides the funding and is the name most often used by stakeholders of an agreement to identify the Swedish government as a financial development partner. Thus, we use Sida to refer to Sweden’s role as a development partner in Zambia.

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Based on performance according to an RBF model, 30% of the grant money is released as a variable tranche.
**METHODS**

**Study Design**

We used a case study approach, which “allows investigators to focus on a “case” and retain a holistic and real-world perspective” and study a phenomenon under the assumption that it is not completely distinct from its context. We explored stakeholders’ perceptions of implementing the support from Sida for a program for RMNCAH within the broader context of RBF and development assistance for health. The illustrative case study design also allows for a flexible design and holistic understanding using different data sources. From February to April 2017, we collected data, including reviewing policy documents and other forms of secondary data, conducting in-depth interviews, and collecting observational data.

The main researcher was based in Lusaka, Zambia. That provided access to policy documents, representative stakeholders from the Ministry of Health (MOH), and cooperating partners (CPs)—international agencies and civil society groups.
that partner with the Zambian government—for conducting interviews and relevant policy meetings regarding the RMNCAH program and health sector overall. Data were also collected from government offices and health facilities in the Southern province and the Eastern province of Zambia.

We defined incentive as something that creates motivation in an individual or among a collective entity to achieve a certain result, which can be specific RBF funding provided to districts through the RMNCAH program or the knowledge that results will be monitored for improvements. We defined program knowledge as including an individual’s ability to convey the objective and indicators of the RMNCAH program, as well as his or her understanding that the RMNCAH program included an RBF component.

**Policy Document Review**
The study was grounded in an in-depth review of Sida’s agreement with the Government of the Republic of Zambia and the Appraisal of Intervention on the RMNCAH program, which provides insight into Sweden’s objectives and intentions regarding the agreement. Other policy documents that were reviewed include the MOH’s Joint Annual Review Reports from 2008–2012, work plans and budgets for the Eastern and Southern provincial health offices (PHOs), work plans and budgets for selected districts, and the 2016 Zambia Household Health Expenditure and Utilization Survey.

**In-Depth Interviews and Sampling**
In-depth, semistructured interviews were used to obtain information and perceptions on the RMNCAH program implementation from key stakeholders at organizations and agencies identified during a preliminary review of relevant policy documents and literature. We developed an interview guide for each level based on a literature review of the Zambian health sector and information from policy documents. It was piloted and further developed after initial evaluation. Questions were designed to be open-ended to avoid leading the respondents’ answers and addressed perceptions of the initial implementation of the RMNCAH program and the understanding of and attitudes regarding the RBF component of the program. New themes that emerged during the interviews, which may not have been foreseen in the initial planning and preparation of the interview guide, were pursued if deemed relevant.

We used purposive sampling to select respondents for interviews based on their ability to provide “intimate knowledge” of RMNCAH, all or parts of the RMNCAH program, or RBF. In total, we conducted 38 interviews with 37 different respondents from 6 categories: (1) MOH officials (at the central, provincial, and district levels); (2) bilateral development partners (Sida, U.S. Agency for International Development [USAID], and the European Commission); (3) multilateral development partners (the World Bank); (4) nongovernmental organization representatives (Clinton Health Access Initiative [CHAI]); (5) hospital and facility administrators; and (6) health workers. Each category was represented by at least 3 respondents to ensure multiple perspectives from each.

**Attendance at Policy Meetings and Meetings on RBF**
The researcher conducted nonparticipatory observations of 3 policy meetings in Lusaka, Chipata, and Eastern Province, as well as 3 RBF program meetings between Sida, MOH officials, and other key stakeholders. Observations were used to understand the process by which the RBF design was created and the perspectives and perceptions that stakeholders involved had about the process and design. These meetings also provided the researchers with a context for the Zambian health sector and the stakeholders involved and insight into how data is collected and analyzed at the district level. Furthermore, this allowed the researchers to identify key informants, such as district health directors and Sida-contracted employees at PHOs as sources for data.

**Data Collection and Analysis**
Participants provided verbal consent to the interviewer. The head of the Bilateral Development Cooperation at the Embassy of Sweden, at the time research was conducted, provided written consent for his quotes to be published under his title. A letter from the Permanent Secretary of the MOH endorsing the study was presented to an MOH staff member at the provincial levels. Interviews lasted 1–1.5 hours, and most were conducted within the respondents’ place of work. We recorded 23 of the 38 interviews. During all interviews, the researcher took detailed notes, and transcriptions were made after recorded interviews.

Anonymity was ensured to those participants that requested it. The researcher has enhanced anonymity by referring broadly to respondents as “MOH official,” “CP,” “facility administrator,” or
“health worker” when appropriate. Program officers for the RMNCAH program, who did not request anonymity, were specifically identified when necessary. When relevant, the level of the health sector at which an MOH official works is specified by referring to them as “MOH Central official,” “PHO official,” or “DHO official.”

A key feature of a qualitative case study is that analysis is conducted throughout the process of data collection. During interviews and policy meetings, and upon reviewing transcripts or notes, the researcher processed and sifted through data, maintaining a flexible approach that allowed for new ideas and themes to guide further investigation. Information gathered from these various sources was used to verify collected data. A framework analysis, as described by Ritchie and Spencer, was employed to facilitate a dynamic yet systematic analysis of the interview and observational data, and to ensure that the analysis was grounded in the original accounts of participants and observations made throughout the study.

As an additional analytic technique used throughout the study, predictions made before the start of the research were compared to the emerging data through pattern matching. Using these techniques, the researchers characterized stakeholders’ perceptions regarding which levels of the health system should be incentivized and receive funding, as well as their knowledge of the RBF model and the indicators used to measure performance.

## RESULTS

Results indicate that during the first 18 months of implementation, many respondents responsible for carrying out the RMNCAH program lacked any knowledge that it included an RBF component for disbursing a portion of the grant and had different perceptions on the degree to which DHOs and facilities would be incentivized by the program’s VT funding. Many also did not know which specific RMNCAH indicators had been chosen to measure performance. Respondents also revealed misunderstandings regarding the budget execution indicator. At the time of data collection, Sida had not yet dispersed any of the VTs.

**Lack of Knowledge That Program Will Use RBF**

Most respondents agreed that funding from the RBF component is meant to target the service delivery points of RMNCAH and that the main purpose is to encourage the districts and facilities to work to improve indicator performance. However, there was less agreement regarding whether individual health workers might feel any extra incentive or motivation from funding received through the RBF component. The Appraisal of Intervention policy document broadly suggests that the RBF is not intended to incentivize individual health workers or facilities. Respondents who believed health workers were aware of the RBF, such as a hospital administrator interviewed, suggested that health workers would feel motivated to contribute and help the facility gain extra resources.

In contrast and in line with the development partner’s intention, a DHO official stated:

> Individual health workers wouldn’t be motivated unless [the RBF] is well explained.

Table 2 shows the stakeholders that knew the program’s RBF component at the time of data collection. Fewer than half of the respondents confirmed they knew that RBF would be used in the RMNCAH program. All MOH Central and PHO officials claimed to know about the use of RBF, but while all MOH Central officials could explain details of the model, not all PHO officials, including RMNCAH program staff, could do the same. The CP who admitted not knowing about the RBF model did not have a role in planning the program.

An MOH central official and 2 PHO officials asserted that the DHOs knew about the program’s RBF and the intended monetary incentives directed toward them at the time research was conducted. An RMNCAH program coordinator within the MOH financed by Sida attended the RBF planning sessions with CHAI and Sida. The coordinator collaborated on the design and was responsible for communicating about the program and RBF scheme to the PHOs and DHOs through 1-on-1 meetings and policy meetings. One of 10 respondents interviewed at DHOs could provide any information that confirmed that they knew it would be used. The 3 respondents that admitted that they did not know that the program would use RBF were all district health directors (i.e., the top officials responsible for health at the district level).

Additionally, several MOH officials expressed the perception that while the DHOs would feel motivated by receiving extra funds, the VT based on RMNCAH performance wouldn’t serve as an “incentive” for them even though it could expand funding:

> The DHO doesn’t have much incentive because we won’t share it among ourselves…it’s just extra resources to run programs. —MOH official
“Facility staff” refers to hospital administrators and health workers at both hospitals and clinics. Two MOH officials and a hospital administrator stated that facilities and health workers were aware of the RBF, yet of 6 administrators and practitioners interviewed, the only respondent at a facility that knew about the RBF was the hospital administrator.

**Lack of Knowledge Regarding Indicators for the Second VT**

The development partner’s vision for the principles that should guide the RBF component of its support to Zambia for the RMNCAH program are outlined in the Appraisal of Intervention:

> When linking finance to performance it is very important that the indicators are relevant and measurable and that the measurements can be done in an objective and indisputable way.

This policy document also states that the 5 RMNCAH indicators chosen to measure performance for the second VT were chosen from 29 coverage indicators “that can monitor real-time change” in data and are all regularly recorded in the national health management information system (HMIS). However, respondent interviews revealed that 3 of the 5 RMNCAH indicators initially chosen are not tracked in the government’s HMIS, a system for collecting data from various levels of the health sector.

According to an MOH central official, the indicators were changed to indicators that are included in regular data collection in facilities in June 2016, halfway through the first performance year, when the MOH wanted to start reporting indicator performance. At that point, facilities and districts should have started measuring the indicators for the first 2 quarters of the year.

Most respondents directly involved with the RMNCAH program or Zambian health system—Sida and USAID staff, MOH officials, and health care workers or administrators—were asked if they could list the performance indicators used (Table 3). Fewer than half of respondents could name the indicators, and 2 named the initially chosen indicators that have since been changed (“cite the old ones”). All CPs, 3 of 5 MOH Central officials, and half of the PHO officials interviewed could name the specific indicators. At DHOs, where indicator performance is evaluated, only 1 of 10 respondents could name the correct indicators, which was fewer than any other stakeholder type. Two of the 5 respondents at the facilities named the correct indicators.

One PHO official who could name the performance indicators ultimately used in 2016 and knew that 3 had been changed expressed uncertainty about which indicators would be used for 2017 stated:

> I hope that there’s been revision of these indicators. They’ve been replaced for the annual report in 2016, but I don’t know if they’ll stay [for the rest of the program].

The head of the Bilateral Development Cooperation at the Embassy of Sweden expressed the perspective that it was not a problem that most respondents involved in the program at the district and facility levels did not know the 5 key indicators used for reporting in 2016:

<table>
<thead>
<tr>
<th>Stakeholder Type</th>
<th>Yes</th>
<th>No</th>
<th>Yes/No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>MOH central official</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>PHO official</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>DHO official</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Facility staff</td>
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<td>8</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>12</td>
<td>9</td>
<td>37</td>
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</tbody>
</table>

**Abbreviations:** CP, cooperating partner; DHO, district health office; MOH, Ministry of Health; PHO, provincial health office; RMNCAH, Reproductive, Maternal, Newborn, Child, Adolescent Health, and Nutrition.

*a* Indicates respondents who had heard of the RMNCAH program’s RBF scheme or suggested their familiarity with it but could not or did not provide any detailed information that demonstrated that they had heard of the scheme before the researcher mentioned it.
[People] should [know]. But on the other hand, the incentive shouldn’t be to achieve the indicators. The incentive should be to achieve certain results. I’m not saying it’s not necessary [for people to know] – I’m sure there could have been advantages with that. But it’s potentially also problematic – the reason we have many indicators is also that you don’t change your work in order to achieve 1 indicator.

Lack of Plans for VT Disbursement

Before starting the program, CPs and MOH Central officials had not established a method for calculating how much of the VT each district would receive. At the time research was conducted, over a year into the program, meetings were held to determine the formula that would be used to calculate disbursement.

Representatives from Sida, MOH Central, and CHAI took part in initial meetings about the disbursement formula, and USAID representatives joined for future meetings. Discussions revolved around how the program would measure improvement on the chosen indicators and the proportion of the VT a district would receive based on different levels of performance. A representative from CHAI presented different models for disbursement, suggesting that district performance could be compared based on raw changes in measurements of indicators or changes in measurements proportional to population.

During interviews separate from these meetings, Sida staff reasoned that it was an advantage not to have this aspect of the RBF model set before the start of the program because it allowed for those involved with the design to factor in lessons learned from the first year of the program’s implementation.

In answering a question about why the RMNCAH program was started even though the MOH had not implemented certain technical requirements that Sida had requested in the terms of the program, the head of the Bilateral Development Cooperation at the Embassy of Sweden shed light on why the RBF was launched without a complete design:

We wanted the program to start, but we had also waited for years. And every year we wait, we either have to do nothing, which has consequences, or other things that we didn’t necessarily fancy, like working through NGOs or other contractors outside the government... so of course we wanted to have everything in perfect order before we started. On the other hand, that’s not going to happen, so we had to start something.

DISCUSSION

This study reviewed the establishment of a program in the health sector in which RBF played a significant role 18 months after it started. We contacted a broad set of stakeholders to assess if there was a difference in knowledge between people working in high and low levels of the health sector and whether the knowledge cooperating partners had corresponded to actors within the high or low levels of the sector. We found that actors from top to bottom of the health system did not have the same perceptions or level of knowledge regarding the program’s RBF scheme. Beyond gaps in knowledge, stakeholders also had perceptions

<table>
<thead>
<tr>
<th>Stakeholder Type</th>
<th>Yes&lt;sup&gt;b&lt;/sup&gt;</th>
<th>No&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Cite June 2016 Indicators</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP</td>
<td>4</td>
<td>0</td>
<td>0</td>
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<td>MOH central official</td>
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<td>2</td>
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<td>PHO official</td>
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<td>DHO official</td>
<td>1</td>
<td>7</td>
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<td>10</td>
</tr>
<tr>
<td>Facility staff</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>5</td>
</tr>
</tbody>
</table>

Abbreviations: CP, cooperating partner; DHO, district health office; MOH, Ministry of Health; PHO, provincial health office; RBF, results-based financing; RMNCAH, Reproductive, Maternal, Newborn, Child, Adolescent Health and Nutrition.

<sup>a</sup>Some individuals included in the summarized responses looked up the indicators on their computers. However, all of them did not respond with the correct indicators, and thus this should not affect analysis.

<sup>b</sup>Individuals who responded with at least 4 of 5 of the new key indicators are included in the “yes” column.

<sup>c</sup>Some individuals included in the “no” column named the indicators in the Program Document for the goal to “reduce maternal, newborn and child mortality and malnutrition” but did not name the specific indicators used to measure results for RBF.
When individuals on the ground lack knowledge about RBF, those most influenced by the policy cannot offer feedback and help improve it.

About the RBF component that did not align with each other nor with the intended purpose of using the RBF tool as outlined in project documents. Here, we discuss the underlying reasons for these gaps in knowledge and differing perceptions, the possible impacts they have on the successful implementation of RBF in a health system, and potential ways to improve knowledge and alignment in perceptions in the future.

Although data on the 5 selected indicators were collected in the first year of the program, details about the RBF model had not been communicated throughout the health system. Fewer than half of the 37 respondents expressed a complete lack of knowledge regarding the use of RBF, and almost all the respondents at the district level did not know RBF will be used or could not provide any details or information about how the model will work.

The purpose of the RBF model, as described in both documents and discussions with CPs and MOH officials, is to incentivize better performance and service delivery, although stakeholders had differing perceptions on whether money should go to the DHOs or the facilities. By definition, an incentive provides individuals or groups with motivation for a certain course of action or behavior. Thus, for an RBF model to create an effective incentive structure, a minimum precondition is that those targeted by the model know that the model and the incentive exist. The RMNCAH RBF model was intended to target individuals at the district and facility levels, yet interviews with them suggest knowledge of the model was very limited. In fact, this level of the system had the lowest fraction of individuals that were aware of the scheme. This raises questions about how effectively they are incentivized by RBF.

Importantly, the RBF model is also meant to incentivize the health workers and health facility staff. Lack of communication may be the reason stakeholders had different perceptions on who should be incentivized, which in turn can have implications on the program outcomes. If individuals at these levels had known about RBF from the start of the grant period, they may have felt motivated to ensure that their performance was measured based on accurate data from regularly reported indicators and may have realized the issue earlier during the implementation process.

Beyond stakeholders’ doubts that the incentives are effective, Paul et al. noted that performance-based financing programs can weaken health systems in cases when recipients do not have a clear understanding of how and why they get RBF bonuses. Subnational health officials and health workers play key roles in implementing any program on the ground and can counter challenges that arise throughout implementation when the design and goals are communicated to them.

When individuals on the ground lack knowledge about RBF, those most influenced by the policy cannot offer feedback and help improve it. For instance, CPs and MOH central officials did not notice for several months that the RMNCAH performance indicators they chose are not all included in the HMIS. This implied that the indicators selected were not sufficiently adapted to the Zambian context. A factor in this may have been that the CPs had special requests that the MOH felt obliged to comply with even if it meant putting new requirements on the established system. Health workers and staff at facilities and DHOs are very familiar with the indicators tracked in HMIS as it is part of their job to collect and input data into the system.

The low numbers of individuals at the district and facility levels who could name the performance indicators and that the initial indicators were not all tracked in HMIS also demonstrate that the indicators have not been internalized in the health system. Literature suggests that a national government should be fully aware of the indicators used and feel a sense of power over them to optimize the impact of RBF. Yet, according to the United Nations Development Program, studies often indicate that the biggest challenge to performance management is choosing indicators that will satisfy the objectives of all stakeholders at various levels within a given public sector. Thus, regardless of whether or not individuals in the DHOs and facilities generally know if an RBF scheme will be used, the lack of awareness regarding the indicators the model uses could affect the eventual impact of the scheme.

The head of Bilateral Development Cooperation at the Swedish Embassy in Lusaka indicated the perception that although people should know what indicators are used, they do not need this knowledge for the RBF to work. Sida wants the health sector to achieve improvements in RMNCAH overall rather than just on specific indicators. The perception of the head of the Bilateral Development Cooperation reflects a worry that RBF recipients will neglect unrewarded activities that are not measured and distort other health outcomes. This type of “perverse incentive”—an incentive that can unintentionally lead to undesired results that undermine the aims of a
program—has been noted in past RBF studies. In an analysis of an RBF scheme implemented by the Gavi, the Vaccine Alliance, Heaton and Keith suggested as a solution to this perverse incentive that programs use performance indicators based on components of health systems strengthening instead of specific health indicators. Still, while the possibility of distortion is a concern, the use of indicators to measure results is an inherent characteristic of an RBF scheme, and thus respondents’ lack of knowledge about them implies a lack of communication within the health system.

Sida staff reasoned that the lack of a finalized RBF formula that would be used to calculate dispersals of the VT was advantageous. This standpoint is supported by frameworks that promote concepts of iterative learning to design development programs. In their problem-driven iterative adaptation approach to development interventions, Andrews et al. (2012) proposed that a key element of system reform is active learning through experimentation of design and implementation. In low-resource settings like Zambia, implementing interventions should allow for the context to shape the design on a continuous basis and incorporate lessons learned from what works and what does not work on the ground. When the approach has been put into practice, the use of iterative learning has allowed national governments to work through challenges that arise in projects driven by development partners.

Still, to use a process of iterative learning, a program must be planned at least to the extent that it can be implemented and experimented in actual practice. The RMNCAH program started with an incomplete RBF design. Sida and the MOH waited for feedback about the chosen indicators and information from the lower levels of the health system that might help them develop the RBF component’s design, but the lower levels of the system lacked knowledge about the program that would allow them to provide feedback because they were waiting for instructions about the RBF component and what the program actually included. Both waited for communication and additional knowledge about the program from each other, which meant that initial implementation and experimentation never occurred and information could not be gathered about the functionality of RBF in the Zambian context. Communicating about an initial plan, even if it will be revised, necessitates creating a process of information dissemination that can help gather feedback about the initial design from participants and can help clarify channels of communication for disseminating any changes to the plan or additional information in the future.

Previous literature on strategic planning and RBF schemes asserts that planning, in general, is necessary for assessing results and impact and monitoring any progress that occurs. Thus, a continued lack of planning may affect the efficient exchange of knowledge and comprehensive assessment of the program’s results moving forward.

Limitations

While this study achieved its aims, it did suffer from certain limitations. Due to a limit of time and resources, the researcher could not interview more individuals in remote districts, which could have provided a broader range of perceptions regarding RBF and the intended incentive structure, as well as a larger pool of respondents to better understand communication between various levels of the health system. The researcher could not contact some of the stakeholders in the RMNCAH agreement and implementation that stakeholders mentioned in interviews. It was also difficult to return to respondents for a second interview, so some information gathered in the process of data collection could not be triangulated by all types of stakeholders. The limit of times and resources also meant that the research was designed to only focus on the initial phase of implementation and did not follow the RMNCAH program through its completion. Ideally, further studies would be conducted to look at implementation after a longer period has passed since the program’s initiation. Additionally, during fieldwork in Southern province, the researcher was largely subject to supervision from the PHO. A driver was provided for transportation and PHO staff introduced the researcher to relevant staff at the DHOs and facilities. The researcher accepted this supervision as a way of adhering to MOH protocol and for convenience in accessing respondents. These introductions, however, may have altered the respondents’ perceptions of the researcher and limited the scope of possible informants sought by the researcher.

CONCLUSION

This study illuminates important considerations for planning and implementing an RBF scheme throughout an entire sector. Stakeholders interviewed displayed limited knowledge about the RBF model, the results that would be rewarded, and how the rewards would be calculated.
Although an RBF scheme might benefit from being iterated throughout the implementation period, it is recommended that a flexible plan is in place for a program during the initial phase of implementation so that all actors have at least basic knowledge and understanding from the onset on its intended results and incentive structure. We recommend that all relevant stakeholders from each government or organization participate in the design of the RBF scheme so that they can effectively communicate the structure and indicators to the different levels of their respective organizations. While these recommendations apply to RBF schemes, preparation and a shared understanding of programmatic details among stakeholders is important for any reforms to the health sector.

A follow-up to this study could examine if the challenges experienced during implementation impacted performance and the ability of Zambian districts to make improvements on the chosen RMNCAH indicators. More broadly, research could examine the minimum knowledge RBF recipients need about an RBF model implemented in LMICs to create an effective incentive structure and determine the preconditions for a viable scheme.

Acknowledgments: Special thanks to the Ministry of Health within the Government Republic of Zambia, particularly those who participated in interviews and facilitated our research. Thanks also to Helle Malsted Ahnass and the Master’s Program in Global Health at Karolinska Institutet for their advising and support in arranging this study.

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Author contributions: RB designed the project, collected data, and wrote and prepared the manuscript. BCF advised and edited. JS designed the project, led on advising, and edited.

Competing interests: At the time this study was conducted, Dr. Sundewall was employed by the Swedish International Development Cooperation Agency and based in Lusaka, Zambia.

REFERENCES


LEVERAGING THE CLIENT-PROVIDER INTERACTION TO ADDRESS CONTRACEPTIVE DISCONTINUATION: A SCOPING REVIEW OF THE EVIDENCE THAT LINKS THEM

Kendal Danna, a Alexandra Angel, a Jamee Kuznicki, a Laetitia Lemoine, a Klaira Lerma, b, c Amanda Kalamara a

Key Findings

- Reasons for discontinuation, while complex, include contraceptive counseling as an element that could be optimized to better support clients to choose methods that will enable voluntary continuation.
- Information exchange during counseling—in particular how providers do or do not prepare clients for side effects—is associated with contraceptive discontinuation.
- There is a need for evidence-based understanding of associations between common counseling approaches/tools and discontinuation. This lack of evidence incurs risk of using techniques that do not effectively lead to client satisfaction.

Key Implications

- Policy makers should lead a call for better understanding of associations between existing and new counseling approaches and their impact on health outcomes, especially contraceptive discontinuation while in need.
- Program managers should consider using more evidence-based counseling approaches as part of a strategy for decreasing method-related discontinuation of contraception. Where evidence does not support the impact of existing approaches on health outcomes, improved tools and strategies should be developed and evaluated before use.
- Implementers should include indicators of interpersonal relations and information exchange as key measures of person-centered contraceptive counseling.

ABSTRACT

Despite considerable investment and effort, unmet need for contraception remains an obstacle to improved family planning outcomes. One influencing factor is the frequency of contraceptive discontinuation among users who desire to prevent pregnancy, often due to method-related concerns and side effects. Contraceptive users have the right to be supported during counseling to voluntarily choose methods that align with their individual needs and preferences. Contraceptive counseling, as a key component of quality of care, is particularly important for providers to reduce unmet need among their clients. This scoping review examined the state of the evidence on contraceptive counseling and its impact on discontinuation. The review first examines the association between quality of care and contraceptive discontinuation, then looks to what the current body of evidence suggests are women’s contraceptive counseling priorities, and lastly, explores whether specific counseling tools and approaches have been evaluated with discontinuation as an outcome. The results identified general principles and priorities for good counseling including person-centeredness, client-tailored information exchange, clear and concise information on side effects and bleeding changes, reducing providers’ implicit and explicit biases, and trust and respect between the client and provider. The review of the literature also found that evidence to support the use of specific counseling tools and approaches to reduce contraceptive discontinuation is insufficient; research should be designed to determine which specific elements of the client-provider interaction can be improved to significantly impact contraceptive discontinuation. This evidence could inform how the global community of practice might improve and leverage specific counseling approaches and tools to address the most common predictors of discontinuation.

INTRODUCTION

International family planning stakeholders have been working to address unmet need for decades, but the problem remains a widespread, complex challenge. Addressing contraceptive discontinuation, a compounding factor, could reduce unintended pregnancies that result from unmet need.

Discontinuation is not inherently problematic; contraceptive users should have the ability and agency to discontinue use at any time and for any reason. However, an estimated 1 in 5 mistimed pregnancies and 1 in 6 unplanned pregnancies follow discontinuation for...
reasons other than the desire to become pregnant. This phenomenon of contraceptive discontinuation while women are in need poses a challenge and signals a deeper issue. Although family planning has long been a recognized right, if users are discontinuing a method while still in need, it may indicate that the right is not being assured by the family planning community of practice. Although some of these users will later decide to reintitate use, others may never take up another method of contraception despite their desire to prevent pregnancy.

An analysis of Demographic and Health Survey (DHS) data from 34 countries found that 38% of married women with unmet need were previously using a method of contraception. It has also been estimated that rates of unintended pregnancy would be 44%–81% lower if contraceptive failure or discontinuation while in need had not occurred. Discontinuation is especially common among young people who are known to discontinue methods at statistically higher rates than other users. Adolescents and unmarried women may face unique barriers and biases that can stand in the way of continued contraceptive use.

Person-centered, quality care is an essential component of the effective provision of health care services and systems; the United Nations Committee on Economic, Social, and Cultural Rights recognizes the right of access to available, accessible, and quality health care. This right to quality in care is accounted for in Bruce’s and Jain’s framework for family planning quality of care, a widely recognized framework in the family planning community. This framework outlines privacy, respect, confidentiality, and information exchange as integral components of a person’s right to high quality when seeking care, particularly when interacting with a provider. Contraceptive counseling is a foundational moment in the client-provider interaction. During counseling, the 2 specific quality of care areas—as Bruce and Jain outlined—of interpersonal relations and information exchange are most evident. If a client clearly understands their options and has a better experience with their provider, it is suggested that they will feel better supported to choose a method that will enable a positive user experience and leave them more likely to desire continuing method use. Uncovering the links between improvements in quality of care in counseling and method discontinuation would allow the community of practice to better supply clients with counseling that addresses their needs, leaves them satisfied, and ensures their right to quality care.

Evidence exploring predictors of discontinuation strongly suggests users’ complex perspectives on, and experiences with, side effects is a factor that has the highest association with contraceptive discontinuation while in need. The World Health Organization (WHO) analyzed 60 DHS surveys from 25 countries and found that method-related concerns were the most common reason for discontinuation across all methods. Other analyses have found that the experience of side effects, as well as fears and misconceptions about the health consequences of irregular bleeding, play a leading role in contraceptive discontinuation and that adolescents have higher rates of discontinuation than older women. Addressing this common predictor of discontinuation during counseling could be pivotal to reducing unmet need and improving clients’ satisfaction and user experience.

To better understand the current state of the evidence on the connections between counseling and the outcome of discontinuation, we undertook a scoping review of the literature available. This review sought to highlight what the evidence has documented on the relationship between client and provider information exchange and contraceptive discontinuation while in need. The primary aims were to summarize the global literature on contraceptive counseling approaches and to assess individual techniques and tools for counseling to identify elements of the client-provider interaction that may decrease rates of discontinuation while in need. A secondary aim was to assess the literature on contraceptive counseling approaches specific to the adolescent population, as they face greater barriers.

### METHODS

#### Search Strategy

The scoping review focused on literature related to contraceptive counseling interventions and strategies and their outcome measurements to understand the link between counseling and outcomes such as contraceptive discontinuation. We searched 3 electronic databases, PubMed, EMBASE, and PsycINFO, using a broad approach with the following search terms: “contraception,” “contraceptive method(s),” “family planning,” and “contraceptive behavior;” “birth control”; together with “communication,” “education,” “conversation,” “consultation,” “counseling.”

We then repeated the above search strategy with the following additional terms: “intervention,”
“strategy,” “outcome assessment,” “patient satisfaction,” “quality of care,” “quality of health care,” “decision making,” and “health behavior” to yield further literature.

To assess counseling priorities for youth, we used the above strategy and added the following terms: “youth(s),” “adolescent(s),” “teen(s),” “teenager(s),” and “young adult.” The concept of young adult (i.e., 24 years or younger) is relatively new, and many databases do not have this term until 2010 or after. As such, we conducted manual screening for this population.

Additionally, we identified unpublished papers in a gray literature search with Google Scholar and Google using manual search methods, using the above terms until only duplicate sources were identified, and no new sources were found.

**Inclusion Criteria**

We only included publications in English. No literature was excluded based on country of origin. We included publications from January 1, 1990, to November 30, 2018. All study types and designs including qualitative, quantitative, and mixed methods, were considered; this includes systematic reviews, meta-analyses, commentaries, and technical reports.

**Study Selection**

All resulting article titles and abstracts were screened by KL for inclusion. Peer-reviewed and gray literature were included if the publication described an intervention with a named outcome variable defining success or effectiveness of a contraceptive counseling-related intervention. Gray literature was limited to theses and technical reports. The reference list of identified publications was searched for additional sources. Commentaries were included if found to be substantive of the objectives of the review.

A cursory scan of the updated literature as of September 28, 2020, and snowball referencing was conducted by KD and yielded 9 additional articles for inclusion.

In total, the search resulted in 2,156 articles, of which 54 were ultimately included in the scoping review (Figure and Table). The most common reasons for initial exclusion included article type, including systematic reviews, letters to the editor, clinical commentaries, and perspectives publications. Seventy-four full-text articles were then assessed, and articles with no named outcome variable or intervention, irrelevant specialized focus (e.g., HIV patients accessing mobile health clinics), and commentaries were excluded.

The 54 full-text articles were read and relevant data were extracted to describe: (1) the contraceptive counseling described in the article; (2) a description of any evaluation of the contraceptive counseling that occurred; and (3) the outcome measures (the Supplement includes additional details on articles).

**RESULTS**

This scoping review first explores the evidence that broadly links the client-provider interaction during counseling with contraceptive discontinuation. Next, to better understand the intricacies of this relationship, we explore what clients and providers identify as their counseling priorities and preferences, with a specific focus on counseling around side effects. Lastly, we look at which individual approaches to counseling have been evaluated and the evidence of any impact that these interventions have on reducing, or not, contraceptive discontinuation.

For this review, authors consider contraceptive discontinuation while in need to describe users who voluntarily stop using their chosen method of contraception while they still desire to prevent pregnancy. As the methodologies and design of the research studies presented here may vary, the definitions of discontinuation used in these studies may also vary. The definitions used in each study can be found within the source documents, there may be some variation in whether authors consider discontinuation to encompass method switching. We have not attempted to describe these variations, nor did we exclude any research based on how discontinuation was defined.

**Quality Care, Client-Provider Interaction, and Discontinuation**

**Quality of Care and Contraceptive Discontinuation: Observational Evidence**

While the umbrella term of quality of care is wide, common themes do emerge when reviewing researchers’ explorations of the linkages between overall quality of care and discontinuation.

Blanc et al. assessed how discontinuation varies with the quality of the service delivery environment across 15 countries and whether discontinuation could be used as an indicator for the quality of services (measured by the Family Planning Program Effort score measuring the quality of services); the assessment relied on DHS analysis. They found that between 7%–27% of discontinuation for
reasons other than a desire to become pregnant could be attributed to poor service delivery. Blanc et al. concluded that more research was urgently needed to understand the relationship between the counseling component of service delivery and discontinuation rates. This finding influenced subsequent family planning delivery interventions and motivated more emphasis on measuring and improving quality of care to prevent discontinuation among clients. Blanc et al. also conclude that the reduction of method failure and discontinuation rates can make a substantial contribution toward reducing unintended pregnancy. Several studies have explored which elements of the client-provider interaction may be related to method discontinuation. Chakraborty et. al highlight the important impact of information exchange on method discontinuation. Using data from a prospective cohort study in Pakistan and Uganda, the authors found that clients who had scored their counseling session higher on the Method Information Index—a measure of information exchange that looks at whether clients are informed about method options, potential side effects, and what to do if they experience side effects—were less likely to have discontinued their chosen method at 12 months.

In 2016, Dehlendorf et al. conducted a large prospective cohort study in the United States that sought to determine if the quality of interpersonal care during contraceptive counseling was associated with contraceptive use over time. They found a positive effect on continuation at 3- and 6-months: patients who reported better interpersonal communication were more likely to continue using their chosen contraceptive method and to be using a highly or moderately effective method at 6 months. The most important factor noted by clients was “provider invests in beginning” and “eliciting the client’s perspective,” which included greeting the client warmly, eliciting the client’s concerns and preferences, using open-ended questions, making small talk, and showing interest in the impact of contraceptive use on the client’s life.

Abdel-Tawab and RamaRao assessed the association between client-provider interaction and contraceptive discontinuation through a scan of peer-reviewed publications and project reports. They found observational evidence of a strong positive association between the client-provider interaction and contraceptive continuation. Several observational studies have further detailed “good care” during the client-provider interaction—measured by provider responsiveness to client questions, appreciation of the need for privacy, provider trustworthiness and empathy, information provided, adequate time for...
**TABLE.** Details of Articles Included in Scoping Review of Client-Provider Interaction During Counseling and Contraceptive Discontinuation

<table>
<thead>
<tr>
<th>Authors and Date</th>
<th>Key Finding Related to Contraceptive Discontinuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Madden et al., 2013</td>
<td>U.S. study examined discontinuation seen in clients in the contraceptive CHOICE project; however, counseling was not a variable in the analysis. The authors did not set out to examine the effects of their contraceptive counseling approach and therefore did not look at its effects on discontinuation.</td>
</tr>
<tr>
<td>Liu et al., 2013</td>
<td>Higher quality of counseling, particularly measures of information provision, method choice, and interpersonal relations was associated with higher rates of continuation among DMPA-SC adopters in Nigeria.</td>
</tr>
<tr>
<td>Blanc et al., 2002</td>
<td>Analysis of DHS data from 15 countries showed a large proportion of discontinuation while in need caused by poor quality of the service environment, this discontinuation has a substantial effect on fertility outcomes. Mixed evidence on the use of discontinuation as an outcome indicator for the quality of care. More evidence is needed to understand the relationship between counseling and discontinuation.</td>
</tr>
<tr>
<td>Koenig et al., 1997</td>
<td>High quality of care was associated with a 72% higher likelihood of contraceptive discontinuation at up to 30 months in Bangladesh.</td>
</tr>
<tr>
<td>Sanogo et al., 2003</td>
<td>Quality of care in Senegal at the time of family planning adoption was a significant determinant of whether a client would be using contraception over 1.5 years later.</td>
</tr>
<tr>
<td>Kim et al., 1998</td>
<td>Analysis of counseling sessions in Kenya showed that contraceptive decision making and informed choice could be improved if providers took a more active role in counseling and related information provided to a client’s circumstances and needs.</td>
</tr>
<tr>
<td>Fruhauf et al., 2018</td>
<td>From Burkina Faso, Ethiopia, Kenya, and Uganda, there was mixed evidence on the impact of quality (measured using a newly developed composite index) on contraceptive use. Discontinuation over time was not measured.</td>
</tr>
<tr>
<td>Chakraborty et al., 2019</td>
<td>Higher scores on the 3-question Method Information Index—measuring client-reported receipt of contraceptive information—were associated with continued use of family planning over 12 months among clients in Pakistan and Uganda.</td>
</tr>
<tr>
<td>Dehlerdorf et al., 2016</td>
<td>U.S. study on quality of interpersonal care, particularly establishing rapport and eliciting the patient perspective measured using the Interpersonal Quality of Family Planning, influenced contraceptive use and continuation.</td>
</tr>
<tr>
<td>Dehlerdorf et al., 2018</td>
<td>U.S. study on Interpersonal Quality of Family Planning showed positive associations with satisfaction with counseling and with the chosen method.</td>
</tr>
<tr>
<td>Abdel-Tawab and Rama Rao, 2010</td>
<td>Inconsistent results showed observational evidence of a strong association between the client-provider interaction and continuation. However, evidence of interventions to improve counseling and impact continuation was not as strong.</td>
</tr>
<tr>
<td>Ramarao et al., 2003</td>
<td>Quality of care at the time of service delivery was positively associated with continuation at follow-up in the Philippines.</td>
</tr>
<tr>
<td>Abdel-Tawab and Roter, 2002</td>
<td>Analysis of counseling sessions in Egypt showed that client-centered counseling sessions, as opposed to provider-centered, were 3 times more likely to result in client satisfaction and method continuation at 7 months.</td>
</tr>
<tr>
<td>Jain et al., 2019</td>
<td>Quality of care among contraceptive adapters in India was predictive of method continuation in that clients who were provided counseling that scored higher on a 10-item index of quality that included information exchange and interpersonal relations were 3 times more likely to continue using their chosen method after 3 months.</td>
</tr>
<tr>
<td>Cotton et al., 1992</td>
<td>Women in Niger and the Gambia who reported they were not adequately counseled on side effects were more likely to discontinue their chosen method.</td>
</tr>
<tr>
<td>Nawar et al., 2004</td>
<td>After intervention to improve counseling in Egypt, including supportive supervision for providers, improving the facility’s physical environment, and provider training, no effect was observed on discontinuation even though the client-provider interaction improved.</td>
</tr>
<tr>
<td>Leon et al., 2004</td>
<td>After an intervention to improve counseling in Peru, including provider training in the use of the Balanced Counseling Strategy, uptake among the intervention group improved but there was no observed effect on discontinuation.</td>
</tr>
<tr>
<td>Jain et al., 2012</td>
<td>Following an intervention to improve quality of care at the time of counseling in the Philippines, when the control and intervention groups were pooled, quality of care was found to be associated with discontinuation, but this effect was not seen when comparing between the control and intervention groups.</td>
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<td>Modesto et al., 2014</td>
<td>Findings showed no significant differences between the intensive and routine counseling (on side effects) groups in Brazil on the discontinuation rates due to unpredictable menstrual bleeding of the 3 contraceptives. The authors concluded that routine counseling may be sufficient for many women to help reduce premature discontinuation rates and improve continuation rates and user satisfaction among new users of long-acting reversible contraceptive methods.</td>
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<tr>
<td>Lunde et al., 2017</td>
<td>Findings in the United States highlighted a need for better, anticipatory advising at the time of counseling that better prepared clients for side effects they may experience.</td>
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<td>Villavicencio and Allen, 2016</td>
<td>Reviews the importance of supporting clients in the United States to understand and manage contraceptive-induced bleeding changes and highlighted the evidence supporting better anticipatory counseling as a strategy to improve rates of continuation.</td>
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<tr>
<th>Authors and Date</th>
<th>Key Finding Related to Contraceptive Discontinuation</th>
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<tr>
<td>Goldhammer et al., 2018</td>
<td>Women in Australia reported a desire for consistent and accurate contraceptive information and less bias from providers, regardless of age. Discontinuation was not evaluated.</td>
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<td>Littlejohn and Kimpor, 2017</td>
<td>Findings explored the different ways that providers in the United States discussed side effects during contraceptive counseling and highlighted the importance of counseling clients on the medical uncertainty of contraceptive side effect experience.</td>
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<td>Canto de Cetino et al., 2001</td>
<td>Women in Mexico in the intervention group were provided with detailed pretreatment and ongoing counseling on common side effects of injectables and encouraged to return for follow-up visits, which was shown to lead to a higher likelihood of continuation.</td>
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<td>Lei et al., 1996</td>
<td>Women in China in the intervention group were provided with intensive structured pretreatment and ongoing counseling on common side effects of injectables and encouraged to return for follow-up visits, which was shown to lead to a higher likelihood of continuation.</td>
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<td>Grimes and Schulz, 2011</td>
<td>Authors asserted that counseling on side effects was not optimistic may create a nocebo effect, whereby clients were more likely to report side effects.</td>
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<td>Holt et al., 2018</td>
<td>Women in Mexico reported a desire for privacy, confidentiality, informed choice, and respectful treatment. They also wanted clear, complete, and correct information during counseling. The authors also highlighted variations in counseling preferences among groups of different ages and educational statuses. Discontinuation was not evaluated.</td>
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<td>Teshome et al., 2017</td>
<td>In Ethiopia, among those counseled on family planning (n=139), women were significantly more likely to be satisfied with the family planning service they received if their provider discussed their partner’s attitudes about family planning, and their own concerns about family planning. Discontinuation was not evaluated.</td>
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<tr>
<td>Donnelly et al., 2014</td>
<td>Findings demonstrated the different counseling priorities between clients and providers in the United States, in particular the elements of counseling that clients rank as most important—“how does the method work to prevent pregnancy,” and “is it safe”—vs. the providers’ priorities of “how is it used” and “how often does a patient need to remember to use it.” No evaluation of discontinuation.</td>
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<tr>
<td>De la Vara-Salazar et al., 2018</td>
<td>Analysis of provider surveys in Mexico demonstrated variations in the quality of counseling between urban and rural providers, with rural providers providing better counseling overall. Cultural barriers to quality counseling are also discussed.</td>
</tr>
<tr>
<td>Brittain et al., 2018</td>
<td>Findings demonstrated that young people’s preferences during counseling and highlights elements of counseling that are barriers to quality care. Young people value confidentiality, supportive client-provider interactions, specialized provider training, and the removal of logistical barriers to family planning.</td>
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<tr>
<td>Gomez and Wapman, 2017</td>
<td>Findings explored young U.S. Latinx and Black women’s perceptions of their counseling experience and highlight the implicit pressure they receive and bias they perceive from their providers. Clients reported feeling pressured to choose a particular method, or family planning in general, and rapidly discontinuing these methods following these poor counseling experiences.</td>
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<tr>
<td>Johnson et al., 2010</td>
<td>Testing of the WHO decision-making tool in 3 countries showed that provider training in this tool resulted in better quality counseling overall, particularly regarding increased client participation, more tailored counseling, and better information exchange. Discontinuation was not evaluated.</td>
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<tr>
<td>Kim et al., 2005</td>
<td>Provider training in Mexico on the WHO decision-making tool resulted in better quality counseling overall, particularly about information exchange, more tailored counseling, and client involvement in decision making. Discontinuation was not evaluated in this study.</td>
</tr>
<tr>
<td>Chinn Quee et al., 2007</td>
<td>While clients in Nicaragua who were counseled by providers in the intervention group, those trained in the use of the WHO decision-making tool, reported an improved counseling experience, there was no significant difference between contraceptive use or discontinuation when compared to the control group.</td>
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<td>Kim et al., 2003</td>
<td>Clients in Indonesia who were part of the intervention were coached on how to ask questions, express concerns, and seek clarifications. Participants in this group participated more fully in counseling sessions, asked more questions, and articulated concerns. There was a marginally significant effect on discontinuation, with participants in this group being less likely to discontinue use of their method after 8 months.</td>
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<tr>
<td>Whittaker et al., 2015</td>
<td>Study findings from the United States validated that the motivational interviewing technique could be effective with postabortion clients seeking family planning care.</td>
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<tr>
<td>Whittaker et al., 2016</td>
<td>Twice as many clients in the United States in the intervention group initiated a family planning method following motivation interviewing-based counseling. This group was more likely to still be using their method when followed up at 3 months.</td>
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<tr>
<td>Dehlendorf et al., 2019</td>
<td>After interaction with the My Birth Control app, clients in the United States in the intervention group rated their counseling session higher on measures of quality, but no effect was seen on contraceptive discontinuation.</td>
</tr>
<tr>
<td>Brandi and Fuentes, 2020</td>
<td>The authors argued that the use of tiered effectiveness as a primary aspect of counseling has the potential to undermine patient autonomy and choice.</td>
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consultation, and choice of methods provided—and found that it positively impacts contraceptive continuation. In their analysis of provider communication styles during counseling sessions, Abdel-Tawab and Roter showed that users who had been engaged in a consultation with a provider that measured well on a “client-centeredness index” with traits such as solidarity with the client, information giving, and facilitation—using language that encourages the client to express her ideas—were 3 times more likely to be continuing users at 3 months. Clients in this study were less likely to continue using their method if their provider used directive or negative language—such as statements of disagreement or “expressions of tension” such as “don’t you believe me, I told you the IUD would be good for you.” In the most recent review discussed here, Jain et al. confirmed the predictive association between quality of care and method continuation. These authors evaluated the validity of a 10-item index measuring the quality of care and found that when clients were given information on the effective use of their selected method (including about side effects and how to use the method) and information on continuity of care (including information about the timing of their next visit and the possibility of switching to another method if their selected method was not suitable) they were 3 times more likely to continue use after 3 months.

Liu et al. researched sociodemographic predictors of continued subcutaneous depot medroxyprogesterone acetate (DMPA-SC; brand name Sayana Press) injectable use after 3-months of initiation in Nigeria’s private sector. As a part of the study, authors also sought to document counseling quality and side effect experiences as factors influencing discontinuation. Overall, Liu et al.
found that higher quality of counseling, which was evaluated using measures of information provision, interpersonal relations, and method choice, was associated with higher rates of continuation. The authors suggested that even small differences in the quality of care provided at the time of method uptake can influence continuation. In the study, 70% of women reported that their provider asked or informed them of potential side effects; however, respondents rated the quality of this information exchange lower compared to other measures of quality. Other observational results echo these findings.

While these observational studies demonstrate a clear association between the client-provider interaction and continuation, Abdel-Tawab and RamaRao also concluded that interventions to improve these interactions have not demonstrated a measured improvement in contraceptive discontinuation.

**Quality of Care and Contraceptive Discontinuation: Interventions**

Studies in Egypt and Peru, conducted by the Population Council, assessed the impact of different program interventions aiming to improve client-provider interactions on contraceptive counseling and subsequent method use. In Egypt, the intervention involved facilitative supervision for providers, improving the clinic's physical environment, and provider training focused on information provision and communication with clients about follow-up. Observed client-provider interaction improved, but there was no effect on discontinuation of the method, method change, or attainment of reproductive intentions, as measured at 6- and 13-months post-intervention. In Peru, the intervention included provider training in counseling and the use of job aids, specifically, the Balanced Counseling Strategy. At the 1-year evaluation, the intervention resulted in more clients using contraception compared to the control group of clients who were not trained on discontinuation, but no observed effect on discontinuation. Other specific counseling interventions are described in more detail later in this article.

In 2012, Jain et al. published their report on a large longitudinal intervention study in the public sector of the Philippines evaluating the impact of provider training and implementation of a facilitative supervision program on the quality of care in family planning clinics where service providers were trained in effective information exchange. They found the intervention improved the provider’s knowledge of the contraceptive technologies and quality of care reported by clients. The rate of unintended pregnancy decreased with improved quality of care within the intervention group—trending toward a statistically significant difference compared to the control group. When observed together, the likelihood of discontinuation did indeed decrease as the quality of care at the time of counseling improved; however, a comparison of the control and experimental groups did not show a significant effect of this provider-level training intervention on contraceptive use outcomes, including the likelihood of continuation, unintended pregnancy, or unwanted birth.

Looking specifically at interventions focused on counseling on side effects, the findings are similarly mixed. For example, contrary to what the observational evidence would suggest, Modesto et al., in their randomized clinical trial, did not find any significant differences between the discontinuation rates of clients counseled intensively on side effects and bleeding disturbances when compared to a control group.

Though there are promising interventions that improve the quality of care overall, these findings suggest that researchers have not, within this body of evidence, determined which elements of care create a client-provider experience that significantly impacts contraceptive discontinuation.

**The Importance of Counseling Around Side Effects**

Side effects and the fear of side effects influence the client’s decision to use and continue family planning methods, so it is important to consider how providers use the counseling session to prepare clients for what they may experience. We looked directly at the evidence landscape around how counseling practices can more effectively address side effects.

Each client’s risk of experiencing side effects from their method of choice is unknown, especially the most cited reason for discontinuation, unscheduled bleeding. Yet, multiple studies emphasize that clients desire counseling on side effects that is tailored to their needs.

Littlejohn and Kimport sought to examine how providers communicated this uncertainty to clients during contraceptive counseling through an observational study in the United States. Authors analyzed the audio transcripts of counseling sessions using qualitative methods. They found that providers presented the positive side effects (e.g., lighter periods).
as side effects that are to be expected but presented the negative side effects (e.g., painful periods) as only possible. Serious side effects were not discussed in half the sessions. Authors posit that clients may discontinue a method if she finds that what she was counseled to expect does not match her experience.

Further supporting this link between counseling on side effects and discontinuation, Canto de Cetina and Lei et al. found that women who received detailed pretreatment counseling and ongoing counseling on the common side effects of injectables—including the possibility of menstrual changes—and were encouraged to follow up with the provider, were more likely to continue using injectables than the control group.

Though the evidence is strong that effective counseling on side effects is beneficial to the client, there are varying opinions on precisely how to best address side effects during counseling. Grimes and Schulz comment that by raising the potential for side effects (specific to oral contraceptives) with clients during a counseling session, providers could be inadvertently drawing their client’s attention to the occurrence of these side effects, when otherwise the same client might not have noted the side effect or been aggravated by it. They encourage “optimistic counseling” that tells clients they will feel well. Since providers are aware that side effects are the most common reason for discontinuation of oral contraception, Grimes and Schulz argue that the power of suggestion might influence how they present information. While there is no rigorous evidence to support this hypothesis, it does suggest complex dynamics during the counseling experience that could impact discontinuation.

Overall, clients signal strongly that they desire thorough counseling on side effects, and there is some evidence to suggest that they will be less likely to continue using their chosen method of contraception if they are not properly counseled and prepared for possible side effects.

**Counseling Priorities and Preferences**

Several studies have considered what clients themselves desire from their counseling sessions with a provider. These elements of the counseling experience are important to understanding how the experience could be improved to address contraceptive discontinuation.

Holt et al. conducted a qualitative study with focus groups of women in Mexico to assess contraceptive counseling preferences. Women reported a desire for privacy, confidentiality, informed choice, and respectful treatment—key components of quality of care. Women desired clear, complete, and correct information and personalized counseling based on their needs, preferences, and prior method history, as opposed to counseling based on method effectiveness. Older, less educated women wanted the provider to give their own opinion about what method would be best for them, whereas younger women in the study, who typically had a higher education, desired more complete information about their options so that they could make an autonomous decision.

Teshome et al. found in their descriptive cross-sectional study of 400 women attending prenatal clinics in Ethiopia that women were more likely to be highly satisfied with the counseling experience when asked about their partner’s attitudes about contraception and their own concerns or worries about using family planning methods.

Donnelly et al. used cross-sectional surveys to rank clients’ and providers’ priorities when receiving or sharing contraception information during counseling sessions. Women in this U.S.-based study rated, “How does the method work to prevent pregnancy?” as the most important consideration, with, “Is it safe?” as a close second. Providers rated, “How often does a patient need to remember to use it?” and “How is it used?” equally as the most important consideration. The greatest discrepancy between clients and providers in importance ratings was for religious acceptability, concealability, and method documentation for health insurance paper-work or medical notes, all of which were more important to providers. This study demonstrates how clients and providers may prioritize different information during contraceptive counseling and suggests that this may result in differing perceptions of the quality and effectiveness of the information exchange.

De la Vara-Salazar et al. found that cultural and societal factors also play an important role in the counseling experience. They conducted a country-wide cross-sectional study in Mexico to assess geographic and institutional factors associated with contraceptive counseling and to identify cultural barriers that providers perceive as limitations for their clients. The authors found that rural providers had better odds of offering adequate counseling, as determined by adherence to national standards and provider surveys. They speculated that this could be an effect of the close ties between providers and populations in rural areas of Mexico—leading to improved interpersonal communication during counseling. Additionally, authors documented that providers who perceived that their clients’ religion would prevent
them from asking about family planning services were less likely to provide satisfactory contraceptive counseling, revealing the importance of removing provider preconceptions from the counseling experience.

**Counseling Priorities for Youth**

While the literature on elements of counseling that are significant for youth is limited, the evidence available is important as contraceptive discontinuation among this age group is prevalent and contraceptive counseling during youth might be one of the first autonomous interactions clients have with health care providers. Brittain et al. conducted a systematic review of 37 articles and found that young people value confidentiality, supportive client-provider interactions, specialized provider training, and the removal of logistical barriers to family planning. Participants also cited refusal to provide certain methods, assuming the client needs contraception, rushed interactions, insufficient information about methods, and general demeanor that discourages the disclosure of sexual experiences as barriers to effective counseling.

Gomez and Wapman conducted a qualitative study of contraceptive decision making among young Latinx and Black women aged 18–24 years in the United States. The authors found that the pressure these young women of color felt from their providers during contraceptive care, such as providers emphasizing some methods over others, tone of voice or affect, and minimization of or failure to adequately describe side effects, resulted in women adopting methods they quickly discontinued and impacted their intentions or ability to access contraceptive care in the future. Similar findings in Australia from Goldhammer et al. documented that young women aged 18–23 years wanted to be offered a full range of methods, regardless of their age (while also noting that they sensed provider bias due to their age). Women also reported they wanted very detailed counseling on potential side effects. Findings are echoed in a study by Lunde et al., where young women reported they wanted more concrete examples of possible side effects and personal narratives of side effects experienced by other young women. Young women wanted individual predictions of side effects—not non-concrete, general warnings.

Further emphasizing the nuance and complexities of the counseling experience, users stated that although they were told about the possibility of side effects, they felt unprepared and did not expect the side effects they experienced. The authors identified the need for better, anticipatory advising at the time of counseling, including telling clients what to do if they experience side effects that the client finds unfavorable.

Together, this evidence highlights that clients of all ages desire a relationship with their provider that exhibits respect and trust; they want correct and relevant information, especially about side effects; and they hope for a person-centered interaction that affords them the dignity of making an informed choice about their contraceptive use, free from provider bias.

**Evidence for the Use of Specific Counseling Approaches to Impact Discontinuation**

In summarizing the principles of good counseling, we wanted to better understand if and how existing counseling tools, techniques, and frameworks have integrated these priorities. We looked at whether current approaches to counseling had been evaluated for impact on family planning outcomes, including discontinuation.

While association between the overall client-provider interaction and discontinuation has been assessed, there has been less rigor in studying how using specific counseling approaches affects discontinuation. This review examined several distinct counseling practices and tools, of which just 5 have been directly evaluated for their impact on discontinuation: the WHO decision-making tool, Balanced Counseling Strategy, Smart Patient Coaching, Motivational Interviewing, and My Birth Control. The methodological design of the studies measuring the impact of these counseling approaches was varied.

The WHO Decision-Making Tool for Family Planning Clients and Providers, a job aid that uses a model of shared decision making between the provider and client, has been evaluated the most frequently, though outcomes of the evaluations are not consistent. The approach is a client-centered strategy that allows for technical expertise to be provided and for clients to express their needs, preferences, and concerns. This tool is a double-sided flipchart: 1 side is addressed to the client while a corresponding page is meant for the provider. Johnson et al. found that the tool improved provider’s counseling performance (i.e., increased client engagement and more tailored counseling) and client communication (clients engaged in more decision making), but they did not measure contraceptive discontinuation. Other publications have evaluated this tool and found...
that it improved measures of information exchange both as a job aid to providers and as a decision aid to clients. However, Chin-Quee et al. was the only study to evaluate its impact on discontinuation and found that while using the tool demonstrated an improved counseling experience for the client, there was no demonstrable effect on discontinuation.

The Balanced Counseling Strategy, a tool that aims to provide more tailored information to clients during counseling with the use of job aids, was evaluated by Leon et al. The study found that use of the tool did result in more clients using contraception. However, in this evaluation, there was no observed effect on discontinuation. Interestingly, while the Balanced Counseling Strategy is a commonly used counseling tool, the scoping review found no other evidence assessing its links with contraceptive discontinuation.

Smart Patient Coaching, an approach whereby an educator in the waiting room provides coaching to clients on how to ask questions, express concern, and seek clarifications from providers, was evaluated in Indonesia. Client’s coached with this approach are reminded that “the provider wants to hear from them” and their subsequent interactions with providers were evaluated based on measures of how actively clients engaged in their counseling sessions. Smart Patient Coaching resulted in more shared decision making during counseling, with clients asking more direct and assertive questions after coaching. This had a small positive effect on contraceptive discontinuation at the 8-month follow-up (3.9% in the intervention group vs. 7.8% in the control group).

Motivational interviewing is a patient-centered counseling style that seeks to create a collaborative relationship between the interviewer (provider) and client. It uses open-ended questioning, reflective listening, empathic statements, and exploration of ambivalence to obtain a client’s intrinsic motivation for behavior change. Motivational interviewing trains providers to support clients to build confidence and self-efficacy. This approach was evaluated by Whitaker et al., who found that twice as many women (aged 15–29 years) in the motivational interviewing-based counseling intervention initiated and continued to use long-acting reversible contraceptives when followed up after 3 months compared to women who were not provided with those techniques.

Most recently, My Birth Control—a tablet-based tool designed to help users select a contraceptive method that aligns with their values and preferences—was evaluated through a cluster-randomized design of family planning clients. The client is meant to interact with My Birth Control before visiting a provider, and clients in the control and intervention groups were followed up at 4 and 7 months. Clients in the intervention group rated their counseling higher on measures of quality, including informed decision and greater knowledge, but no significant effect was seen on contraceptive discontinuation at 7 months.

The WHO has also developed the tiered effectiveness tool, a visual job aid that places contraceptive methods on a spectrum of how effective they are at preventing pregnancy with typical use. This tool is recommended by several professional organizations in the United States. Some in the family planning community, such as Stanback et al., have advocated that informed choice can only be achieved if the client has information—especially about effectiveness—on all available methods. Others, however, have argued that this approach may undermine patient autonomy and choice. While this tool is commonly used during counseling and is often integrated into structured counseling approaches, no studies were found evaluating this tool for impact on discontinuation or other outcomes. There remains debate in the family planning community of practice over whether the effectiveness of a method should be the most prominent aspect of contraceptive counseling.

The scoping review identified other approaches, tools, and frameworks, such as The Birth Control Navigator (United States), Contraceptive Counseling and Care (Mexico), the Quality in Contraceptive Counseling Framework, Contraceptive Counseling Best Practices to Ensure Quality Communication and Enable Effective Contraceptive Use, GATHER (United States), reproductive life planning, and the NORMAL tool for counseling on contraceptive induced bleeding changes, but studies assessing use or the effectiveness of these different counseling approaches are limited, and none of them look at method discontinuation.

Finally, in an effort to pinpoint what attributes make for a good contraceptive counseling tool, Wyatt et al. assessed the qualities of the job aids themselves through a systematic review. Authors identify the necessity for decision aids to be evidence-based, evaluated, and created in collaboration with intended users to guarantee relevant attributes are included. But they admit this can be challenging, as counseling priorities differ among groups of clients and over one’s lifespan. The authors did not discuss discontinuation.
While many approaches to counseling are commonly used, the evidence around their effectiveness is weak. When tools are evaluated, there is not enough evidence to validate their effectiveness when using contraceptive discontinuation as a primary indicator of effective and high-quality counseling.

**DISCUSSION AND IMPLICATIONS**

For myriad reasons, users discontinue using contraception while they still desire to prevent pregnancy. The most prevalent reason seen here is method-related side effects and bleeding disturbances that are either intolerable for the user or lead to fears of infertility, pregnancy, or health issues. The practical implications of discontinuation can be severe: the client may face health risks—which may include unplanned pregnancy and unsafe abortion—if her need for contraception is not met. Since reasons for discontinuation while in need are complex, efforts to address it must consider all aspects of quality of care. This review finds that contraceptive counseling is an element of rights-based care that could be optimized to better support clients to choose methods that will enable a positive user experience; however, more research is needed to understand how the constellation of counseling strategies, techniques, and specific tools could be varied to reduce discontinuation while in need as an outcome.

Numerous observational studies reveal that the exchange of information between the client and the provider during counseling is associated with contraceptive discontinuation. In particular, the way that providers prepare clients for the side effects they might expect from their contraceptive options is of utmost importance. Clients should be invited to fully engage during their counseling session. They should be encouraged to participate in a dialogue to exchange information, ask questions themselves, seek clarifications, and share their concerns. In turn, providers should ensure that the information they offer about method options is relevant to the client’s unique needs, providing them with the information they need to make an informed and voluntary choice about their preferred method.

In addition to the exchange of information, the relationship dynamics between the client and the provider have also been shown to have a measurable impact on the likelihood of method discontinuation. Ensuring that the client feels respected by the provider is an absolute priority. Trust and solidarity are key components of quality interpersonal relations. Clients are sensitive to explicit or implicit provider bias, and when perceived, this negatively impacts the client’s counseling experience. Provider bias and preconceptions—around age, parity, religion, appropriate method choice, etc.—can lead to perceived pressure to choose a method that may not be right for the client, resulting in dissatisfaction with and discontinuation of her method. To avoid this, the provider should be trained in evidence-based approaches to recognize their own biases, elicit the client’s perspective, listen actively, and be responsive to the client’s needs. Indeed, provider bias may be a factor that is producing the mixed evidence around the impact of contraceptive counseling approaches to affect discontinuation. Without first addressing provider attitudes and perceptions, it is much more difficult to truly improve the quality of counseling all women receive.

When considering the subset of the literature reviewed that explores specific tools and practical approaches used during counseling, there is limited evidence to understand how these job aids and techniques impact contraceptive outcomes, such as discontinuation while in need. As counseling approaches evolve, it is important that they be optimized by integrating the elements of existing models that have, in this review, shown promise toward impacting discontinuation (e.g., techniques to improve the participation of the client in shared decision making, techniques and aids to support providers in counseling around side effects, and training for providers to ensure respectful, person-centered care, etc.). A summary of the principles of high-quality counseling that have been identified in this review can be seen in the Box. The community of practice should prioritize a better understanding of the association between these priorities and contraceptive discontinuation. If an evidenced-based understanding of this remains limited, family planning programs risk using tools and techniques that do not effectively lead to client satisfaction and voluntary continued use of their contraceptive method.

A scan of the literature presented here highlights regional variations in the breadth of evidence available. Many of the studies reviewed were implemented in mid- to high-income regions, like the United States and Europe. Indeed, when looking at the subset of literature exploring practical approaches to counseling, this review has not uncovered any research on the
**BOX. Summary of Quality Counseling Principles**

- Counseling should be responsive to clients’ individual priorities, questions, and concerns.
- Counseling should support shared decision making between the client and the provider, where the client’s wishes come first. Clients should have the ability to choose which contraceptive method they want and should receive what they choose regardless of age, marital status, religion, or provider bias, etc.
- Counseling should ensure clients have confidence in the privacy and confidentiality of their sessions.
- Providers should display trustworthiness, empathy, and solidarity with the client, friendliness, and warmth. Encourage open-ended questions, dialogue, and listening.
- Counseling should encourage discussion around the client’s reproductive health goals and their experiences and preferences for contraception. Discuss how individual methods can help them achieve those goals.
- Counseling should provide information that is accurate and relevant to the client, narrowing down the client’s options based on their stated needs and preferences.
- Counseling should address and prepare clients for potential side effects of their method options and provide concrete examples of how these might affect their health and lifestyle.
- Counseling should support shared decision making between the client and the provider, where the client’s wishes come first. Clients should understand the impact they might have on family planning outcomes, particularly discontinuation while in need.
- Counseling should prepare clients for follow-up, including the understanding of warning signs that require attention by a health care provider. Make a plan for follow-up appointments if necessary.

Although many common counseling approaches are currently used across contexts and programmatic interventions, there is limited evidence that existing tools and trainings improve the clinician-provider interaction and/or result in better health outcomes. When tools are evaluated, evidence is lacking to support that they are effective when thinking about discontinuation as an outcome.

It is also critical to remember that quality of care does not end at the moment a client has left a health facility with a method. Indeed, quality throughout the continuum of the care experience could be improved to address discontinuation. Effective counseling approaches that are grounded in the principles of person-centered quality of care should be rigorously studied within various contexts for their measured impact on health outcomes, especially contraceptive discontinuation while in need. These approaches and tools should then be prioritized for widespread dissemination and use.

**CONCLUSION**

Evidence suggests that there are links between the counseling clients receive from health care providers and their subsequent experience and behavior with their contraceptive method. However, the evidence on specific counseling interventions and approaches and their impact on contraceptive discontinuation is mixed and evidence gaps remain. Improving the quality of care through better interpersonal relations and improved information exchange during counseling is important. While discontinuation is not the only primary outcome of relevance, the impact of discontinuation on the incidence of unintended pregnancies is substantial.

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### Author contributions
All authors, except for KL, helped to conceive of the initial research idea. KD is the lead author of the manuscript and has been involved in the review process since inception, she was also...
REFERENCES


Lessons Learned During the COVID-19 Pandemic to Strengthen TB Infection Control: A Rapid Review

Helena J. Chapman,a Bienvenido A. Veras-Estévezb

Key Findings

Current challenges in TB control efforts, such as an unprepared public health system leadership and infrastructure and an overwhelmed health care workforce, will require novel approaches, practices, and renewed political commitment to maintain sustainable TB programs.

We described proposed recommendations that may strengthen health system preparedness for optimal TB control across low- and middle-income countries:

- Ensuring leadership and governance for sustainable national health care budgets
- Building networks of community stakeholders
- Supporting high-quality health care workforce training and safe workplace environments
- Using digital health interventions for TB care

Key Implications

- National health systems should develop national policies that promote integral, patient-centered TB care, facilitate the implementation of ethical community interventions, support operational research, and allow the integration of appropriate eHealth applications.
- Program managers who understand challenges in TB prevention and control with coexisting health priorities can serve as instrumental leaders and patient advocates to deliver high-quality and sustainable TB care that leads to achieving targets of the End TB Strategy.

ABSTRACT

Introduction: Over the past 5 years, substantial global investment has resulted in reduced TB incidence rates by 9% and mortality rates by 14%. However, the coronavirus disease (COVID-19) pandemic has hindered access and availability of TB services to maintain robust TB control. The objective of this rapid review was to describe the challenges to be addressed and recommendations to strengthen health system preparedness for optimal TB control across low- and middle-income countries during and after the COVID-19 pandemic.

Methods: Five databases were used to systematically search for relevant articles published in 2020. The 5-step framework proposed by Arskey and O’Malley and adapted by Levac et al. guided the review process. Thematic analysis with grounded theory principles was used to summarize themes from selected articles and integrate analyses with barriers reported from authors’ previous TB research.

Results: Of the 218 peer-reviewed articles, 20 articles met the inclusion criteria. Four emerging themes described challenges: (1) unprepared health system leadership and infrastructure, (2) coexisting health priorities, (3) insufficient health care workforce support for continued training and appropriate workplace environments, and (4) weak connections to primary health centers hindering community engagement. Four recommendations were highlighted: (1) ensuring leadership and governance for sustainable national health budgets, (2) building networks of community stakeholders, (3) supporting health care workforce training and safe workplace environments, and (4) using digital health interventions for TB care.

Conclusions: National health systems must promote patient-centered TB care, implement ethical community interventions, support operational research, and integrate appropriate eHealth applications. TB program managers and primary care practitioners can serve as instrumental leaders and patient advocates to deliver high-quality and sustainable TB care that leads to achieving the targets of the End TB Strategy.

INTRODUCTION

Of respiratory infections, TB is the leading cause of global morbidity and mortality, causing 10 million new TB cases and 1.4 million TB deaths in 2019.1 TB is spread through aerosol droplets, including those smaller than 5 microns, infected with M. tuberculosis from an infected individual to a susceptible individual. One-third of the global population, which is estimated to have an asymptomatic M. tuberculosis infection, has a 5%-10% risk of developing TB disease during their...
lifespan.2 With substantial global investment and political commitment over the past 5 years, TB incidence and mortality rates have continued to decrease by 9% and 14%, respectively.1 To minimize disease transmission, strict adherence to evidence-based infection control and prevention measures are recommended in clinical and community settings.3

The End TB Strategy has set ambitious milestones for 2025 and targets to end TB by 2035.4 Three pillars place precedence on expanding patient-centered TB prevention and control efforts, forming policies and multisector collaborations across communities and public and private sectors, and ensuring continued attention on scientific research innovations for TB care.5 However, these robust efforts have been redirected to support the coronavirus disease (COVID-19) response measures. Economic and human resources for health have been diverted to emergency care and contact tracing of COVID-19 patients, and laboratories have been repurposed for COVID-19 diagnostic testing.6 As a result, health care services for infectious diseases and comorbidities of significant burden—like TB, HIV/AIDS, and malaria—diminished,7 and citizens were fearful to seek TB diagnostic and treatment services.6 During the Ebola virus disease outbreak in West Africa in 2014–2015, similar observations were reported, such as reductions in TB, HIV, and malaria case notifications and treatment, reductions in health care utilization including vaccination coverage, and the breakdown of community cohesion due to fear, apprehension, and socioeconomic impacts.7–9

Health systems should recognize the syndemic effects of TB and COVID-19 and analyze 3 factors for best clinical and community management practices of competing health priorities. First, the social determinants of health draw attention to the impact of social environments (e.g., education and income), physical environments (e.g., residence and transportation), and access and quality of health care services, including access to broadband internet.10,11 Second, the One Health concept promotes the development of multidisciplinary collaborations to advance clinical and research applications focusing on the human-animal-environment nexus.12,13 Third, the “knowledge-action” gap can result from limitations in the access of up-to-date scientific knowledge (e.g., health care professions curricula and continuing education), health system infrastructure (e.g., financial resources and surveillance programs), and social environments (e.g., access to health care services and influence of news sources).14,15 Hence, the primary health care workforce can contribute to public debates and community campaigns, develop patient education materials on pressing health issues,9,16 and lead efforts to implement evidence-based findings that can optimize clinical, educational, and research practices related to TB care.

To date, numerous countries have reported reduced TB case notifications during the COVID-19 pandemic, reflecting the importance of “The Clock is Ticking” theme for World TB Day 2021.17,18 Over the next 5 years, modeling estimates depict that countries with high TB burden will report up to 20% increased TB mortality or 1.4 million TB deaths,17,19 which will negatively impact the End TB Strategy timeline.20 In this article, we summarize encountered challenges to be addressed and proposed recommendations from the literature that can strengthen TB prevention and control efforts during and after the COVID-19 pandemic. Moving forward, national health systems can integrate these recommendations into future practices and policies that strengthen health care service delivery, health care professions education, and research capacity related to TB care.

## METHODS

A rapid review was conducted to review the current literature, identify gaps, and synthesize findings,21,22 related to challenges and recommendations for TB prevention and control in low- and middle-income countries. We used the 5-step framework proposed by Levac et al.,23 which was adapted from Arksey and O’Malley,24 in our search strategy: (1) identify the research question; (2) identify relevant studies; (3) select studies, (4) chart the data; and (5) collate, summarize, and report the results.23,24 The research questions were: (1) What are the existing challenges in TB prevention and control efforts during the COVID-19 pandemic? and (2) What are the proposed recommendations that can strengthen TB prevention and control efforts during and after the COVID-19 pandemic? This search was simultaneously integrated with findings reported from a previous qualitative study that examined challenges in TB prevention and control in a middle-income country, the Dominican Republic.25–27

### Search Strategy and Selection Criteria

On January 10, 2021, 2 authors (HJC, BAV) searched 5 databases (PubMed, Scopus, Web of Science, EBSCO Academic Search Premier, SciELO Citation Index). They used the terms “COVID-19,”
“coronavirus,” “health systems,” and “tuberculosis,” to include original articles, reviews, commentaries, and letters, published between January 1, 2020, and December 31, 2020. After removing duplicate articles, authors independently reviewed each abstract and included articles that described the impacts of TB control efforts during the COVID-19 pandemic and proposed recommendations to strengthen health system efforts for TB control. If any disagreement occurred, authors discussed the abstract until consensus was finalized. Articles written in languages other than English were not excluded.

Articles were excluded if they did not include content related to TB and COVID-19, if clinical aspects of TB and COVID-19 management were described or if the focus deviated from the impact of COVID-19 on TB prevention and control efforts of the health system. Authors incorporated relevant citations from selected articles in the analysis. The article screening and selection process is shown in Figure 1.

**Data Extraction and Analysis**

After full-text review, authors used the matrix method, with paper trail, documents, review matrix, and synthesis folders, to extract data from each article. Data included the country or continent focus, study objective, and main summary points related to challenges to overcome and recommendations for TB prevention and control.

After compiling this information, authors used a qualitative thematic analysis applying grounded theory principles to identify themes or patterns from selected articles and explore the connections between existing challenges and proposed recommendations to improve TB prevention and control. The 6-step approach of Braun and Clarke guided the analysis, where authors expanded upon the final themes identified from previous TB research to examine health care workers’ perceived barriers to adherence to TB prevention measures in the Dominican Republic. Authors independently reviewed the initial codes.
and extracted information to support and expand their meaning. They jointly reviewed and agreed on all final codes, compiled them into relevant themes, and developed a conceptual model.

**RESULTS**

The search yielded 218 articles, and after 58 duplicate articles were removed, 160 titles and abstracts were reviewed by both authors. Of the 160 articles, 19 articles met the inclusion criteria, and 1 additional article was added from the manual reference search of these articles. Of the 20 included articles, articles described the TB burden in Africa (n=8), Asia (n=2), and the world (n=10). Article types included 4 letters, 9 perspectives, 5 reviews, and 2 original research articles. Emerging themes from selected articles were identified as existing challenges to be addressed and proposed recommendations to strengthen TB prevention and control efforts (Figure 2).

The characteristics of each article, including proposed recommendations to strengthen TB control efforts during and after the COVID-19 pandemic, are shown (Table 1 and Supplement).

**Existing Challenges in TB Prevention and Control**

Four emerging themes on existing challenges in TB prevention and control efforts are displayed (Table 2).

1. An unprepared public health system leadership and infrastructure was described by limited short-term plans, inadequate funding for high-burden diseases, and limited foresight to identify key factors that hinder TB control efforts.
2. Coexisting health priorities were exacerbated with disruptions in routine TB care, limited understanding of how natural emergencies impact established health programs, and lack of oversight on the importance of TB programs.
3. Insufficient health care workforce support for continued training and appropriate workplace environments was impacted by the demanding schedules of health care workers and the need for reassigned roles to meet national requests.
4. Weak connections to primary health centers resulted in interrupted community-based programs that hindered patient-provider interactions on routine health care services and negatively impacted early diagnostics and adherence to management.

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**FIGURE 2.** Conceptual Figure That Incorporates Recommendations to Mitigate Existing Challenges and Improve TB Control

- Robust leadership and governance for sustainable national health budgets
- Unprepared health system leadership and infrastructure
- Coexisting health priorities
- Insufficient support for health workforce
- Support for health workforce training and safe workplace environments
- Weak connections to primary health centers
- Using digital health interventions for TB care

Coexisting health priorities were exacerbated with disruptions in routine TB care, limited understanding of how natural emergencies impact established health programs, and lack of oversight on the importance of TB programs.
TABLE 1. Selected Articles for the Rapid Review of Literature on Recommendations for TB Prevention and Control During the COVID-19 Pandemic in Low- and Middle-Income Countries

<table>
<thead>
<tr>
<th>Authors</th>
<th>Country or Continent</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Togun et al.6</td>
<td>UK, Africa</td>
<td>Noting differences between low- and high-income countries in TB priorities (active vs. latent TB), provision of health care services, and mechanisms for social protection, the global response should be comprehensive and long-term, increasing investments in research, innovative digital technology, and public health.</td>
</tr>
<tr>
<td>Hogan et al.19</td>
<td>Global</td>
<td>The most significant impact to increased mortality was the interruption to antiretroviral therapy for HIV, reductions in timely diagnosis and treatment of new cases for TB, and the interruption of planned net campaigns for malaria.</td>
</tr>
<tr>
<td>Visca et al.20</td>
<td>Global</td>
<td>With expected increases in TB incidence and mortality, ensuring high levels of adherence to TB treatment through digital innovation can minimize the burden on patients and the health care workforce.</td>
</tr>
<tr>
<td>Adamu et al.31</td>
<td>Africa</td>
<td>COVID-19 response strategies should shift from isolated programs to integrated health system interventions that are connected with existing programs in public and private sectors.</td>
</tr>
<tr>
<td>Alene et al.32</td>
<td>Global</td>
<td>Health systems should aim to maintain routine TB services during the COVID-19 pandemic and hence mitigate the impact of COVID-19 on TB prevention and control programs.</td>
</tr>
<tr>
<td>Amimo et al.33</td>
<td>Africa</td>
<td>Appropriate economic and epidemiological considerations are required to minimize hardships faced by vulnerable populations to access essential health care services for COVID-19 and other epidemic diseases.</td>
</tr>
<tr>
<td>Bhargava and Shewade34</td>
<td>India</td>
<td>Federal support is required to improve economic and nutrition livelihood through cash transfers, public distribution system of food, and high-quality community TB surveillance and clinical management.</td>
</tr>
<tr>
<td>Bulled and Singer35</td>
<td>South Africa</td>
<td>International cooperation and country-specific efforts that reflect local resources and needs are required to overcome significant public health risks by the COVID-19 pandemic.</td>
</tr>
<tr>
<td>Dara et al.36</td>
<td>Global</td>
<td>Complementary COVID-19 and TB responses, including capacity building, active surveillance and monitoring systems, and sustainable economic investment, have the potential to curb disease transmission. People-centered care models, digital technologies, and community-based services can be adapted for the COVID-19 and TB epidemics.</td>
</tr>
<tr>
<td>Homolka et al.37</td>
<td>Global</td>
<td>TB diagnostic and research infrastructures can be leveraged for SARS-CoV-2 testing and sequencing to examine virus evolution and diversity. High-quality management principles for TB/SARS-CoV-2 diagnostic testing must be followed to ensure validity, reduce biosafety hazards, and support TB diagnostic services.</td>
</tr>
<tr>
<td>Jain et al.38</td>
<td>India</td>
<td>Restructuring services—such as multimonth dispensing, video-supported therapy, and community-based services—can strengthen TB programs.</td>
</tr>
<tr>
<td>Loveday et al.39</td>
<td>South Africa</td>
<td>Integrating COVID-19 systems to support TB prevention and control can include developing a platform for public engagement on disease monitoring, strengthening contact tracing with GIS mapping, offering mobile- or video-supported counseling and clinical management, improving health information and surveillance systems, and increasing federal investment.</td>
</tr>
<tr>
<td>McQuaid et al.40</td>
<td>Global</td>
<td>To ensure continued access to person-centered TB care, sustainable funding, innovative digital technology, and robust community-based surveillance activities can be expanded to reduce the TB and COVID-19 burden.</td>
</tr>
<tr>
<td>Mohammed et al.41</td>
<td>Ethiopia</td>
<td>Continued investment in TB care and research activities is key to minimizing disruptions to health and research services.</td>
</tr>
<tr>
<td>Mukwenha et al.42</td>
<td>Zimbabwe</td>
<td>Through collaborations with local and international partners, Zimbabwe leaders can strengthen HIV/TB services by ensuring stockpile availability of diagnostic testing, disseminating accurate health information to TB patients, and adopting real-time surveillance systems.</td>
</tr>
<tr>
<td>Papadimos et al.43</td>
<td>Global</td>
<td>Deploying point-of-care diagnostics and focusing on telemedicine platforms (albeit challenges like suboptimal internet connectivity or insufficient encryption) have the potential to enhance screening efforts and prevent excess TB mortality.</td>
</tr>
</tbody>
</table>

Continued
Proposed Recommendations to Strengthen TB Prevention and Control Efforts
Emerging themes on proposed recommendations to strengthen TB prevention and control efforts are listed (Table 3).

Ensuring Leadership and Governance for Sustainable National Health Budgets
With the risk of national emergency scenarios—whether natural disasters, infectious disease outbreaks, or conflict—nations should implement policies and strategies and allocate funding that strengthens prevention and mitigation efforts for infectious and chronic diseases. 48,52,53 Political commitment is essential to support core health care services that sustain high-quality point-of-care diagnostics and treatment plans for TB patients as well as balancing these needs with the coexisting pandemic.19,37,41–43 These actions can focus on long-term and comprehensive care for TB and coexisting priorities like COVID-19.6,32,36,45 Following the World Health Organization’s call that all nations should conduct and utilize research capacity, researchers can investigate key scientific questions raised during coinciding pandemics.37,41,46 For example, operational research should be conducted to examine the influence of social determinants of health on TB and COVID-19, vaccine effectiveness and community acceptability, and adherence to recommended pharmaceutical regimens.39,40,45,50 These research findings can inform national health priorities, which can provide a framework for the appropriate allocation of economic resources. Supported by appropriate legislature, authorities can recommend actions for the health sector to best distribute resources for current health priorities and unanticipated emergency scenarios.50

Building Networks of Stakeholders to Sustain Community Resources
Forming a network of stakeholders—or community groups comprised of individuals who represent different disciplines but share common goals31—can help identify community needs and health system vulnerabilities related to TB prevention and control. As community stakeholders share approaches and lessons learned, a multisectoral response that aims to reduce TB burden can drive community engagement with families6,31,43,49 and support health care workers in facilitating educational activities as a platform to increase TB awareness and reduce stigma.41,45 By working with community stakeholders, health leaders can identify high-risk communities of poor health status, including inadequate nutrition, overcrowded living conditions, and unemployment, and advocate for creative solutions to improve public welfare programs.34,35,38 These programs can drive national action to offer social protection for TB patients, such as cash transfers or food parcels, and essential psychosocial support.45 Coupled with these health promotion activities, community-based research can highlight the use of key epidemiology tools and trends to better understand the transmission of emerging diseases like COVID-19 and emphasize the existing syndemic.
### TABLE 2. Four Emerging Themes on Existing Challenges in TB Prevention and Control Efforts

<table>
<thead>
<tr>
<th>Theme Description</th>
<th>Quote</th>
<th>Stakeholder Perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unprepared health system leadership and infrastructure</td>
<td>National leadership with a limited short-term plan: … in times of outbreaks, most leaders tend towards control as a style of action together with the temporality of change perceived as short-lived shocks31</td>
<td>Political leadership</td>
</tr>
<tr>
<td></td>
<td>Limited sustainable funding for high burden diseases: The other challenge being faced is limited funds for HIV and TB programmes due to poor funding by government42</td>
<td>Political leadership, research funding agencies, philanthropic trusts and foundations</td>
</tr>
<tr>
<td></td>
<td>… the current pandemic has put significant competitive pressure on research and development in other infectious disease areas43</td>
<td></td>
</tr>
<tr>
<td>Foresight to identify factors that hinder TB control efforts:</td>
<td>Taken together, the social, economic and biomedical consequences of the COVID-19 pandemic are likely to combine to create a perfect storm with respect to [TB]45</td>
<td>Political leadership, public health leadership, health and social science researchers</td>
</tr>
<tr>
<td>Coexisting health priorities</td>
<td>Impact of disruptions on routine TB care: With the disruptions and reorganization of services in response to the pandemic, delays in TB diagnosis and treatment initiation may result in increased transmission and new cases39</td>
<td>Public health leadership, health care workers</td>
</tr>
<tr>
<td></td>
<td>Lack of understanding of impact of national emergencies on other established health programs: Given the severity of projections, hospitals across the globe are creating additional critical care surge capacity and limiting patient routine access to care for other diseases like [TB]41</td>
<td>Public health leadership, health care workers</td>
</tr>
<tr>
<td></td>
<td>Limited oversight of the importance of TB programs: … health service and political leadership, the media and the public focusing on pandemic management and response with limited oversight and accountability of TB programmes46</td>
<td>Public health leadership, health care workers, media sources</td>
</tr>
<tr>
<td>Insufficient health care workforce support for training and appropriate workplace environments</td>
<td>Demanding schedule of the health care workforce: Health workers have been reassigned to meet the COVID-19 testing demand, leading to very few people conducting HIV and TB testing. Medical staff anxiety and burnout is also playing a role in testing, as staff are overwhelmed with COVID-19 testing42</td>
<td>Public health leadership, health care workers</td>
</tr>
<tr>
<td></td>
<td>Health care workforce reassigned to national needs: In many countries, pulmonologists, and infectious disease and public health experts (those also involved in [TB] prevention and care) together with ICU specialists are or have been re-deployed to the frontline to fight COVID-1920</td>
<td>Public health leadership, health care workers</td>
</tr>
<tr>
<td></td>
<td>Lack of sustainable investment in the health care workforce for clinical and research training: Investing in people and in research training ahead of public health emergencies generates downstream dividends by strengthening health system resilience for tackling pandemics46</td>
<td>Public health leadership, health care workers, academic institutions</td>
</tr>
<tr>
<td>Weak connections to primary health centers hindering community engagement</td>
<td>Interruptions of community-based programs hinder patient-provider interactions related to routine health care services: Although the actual effects on disease programmes remain unclear, some community-based programmes are already being scaled back and experience in high-income settings has shown a substantial reduction in engagement with regular medical care during recent periods of high health system demand19</td>
<td>Public health leadership, health care workers, community leadership, patients</td>
</tr>
<tr>
<td></td>
<td>Community-based programs link citizens to early TB diagnostics and adherence to management: Many low-income and middle-income countries have high burdens of these three diseases, and millions of people depend on large-scale programmes to control and treat them. … Interruptions to control programmes could result in major setbacks, compounding the direct impact of COVID-1919</td>
<td>Public health leadership, health care workers, community leadership, patients</td>
</tr>
</tbody>
</table>

### TABLE 3. Four Emerging Themes on Recommendations to Strengthen TB Prevention and Control Efforts

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Quote</th>
<th>Stakeholder Perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ensuring leadership and governance for sustainable national health budgets</strong></td>
<td>Investing in research: Research, guidance and funding are urgently required to identify, prioritise and deliver those interventions that could best alleviate the impact of COVID-19-related disruptions. Building upstream operational research capacity has generated downstream dividends in strengthening health system resilience for tackling pandemics.</td>
<td>Political leadership, public health leadership, research funding agencies, philanthropic trusts and foundations</td>
</tr>
<tr>
<td><strong>Prioritizing community TB care:</strong></td>
<td>Decentralise TB treatment to community health workers and increase access to TB treatment for home-based TB care. Support private hospitals, and academic or research centres, to provide TB testing and treatment.</td>
<td>Political leadership, public health leadership, community leadership</td>
</tr>
<tr>
<td><strong>Renewing political will to support existing and emerging health priorities:</strong></td>
<td>...strong political will and support for research communities are essential, especially in low- and middle-income settings, to advocate for and allocate resources needed to investigate these coinciding pandemics.</td>
<td>Political leadership, public health leadership, research funding agencies, philanthropic trusts and foundations</td>
</tr>
<tr>
<td><strong>Supporting social protection of all citizens:</strong></td>
<td>Provision should also be made for TB-specific social protection, which could take the form of cash transfers or food parcels for TB-affected households. This (restoring routine TB services) has to be followed by a combination of measures: access to food through universal PDS, direct cash transfers and making gainful employment available.</td>
<td>Political leadership, public health leadership, community leadership</td>
</tr>
<tr>
<td><strong>Promoting national leadership:</strong></td>
<td>...it is critically important that political leaders possess appropriate cognitive abilities, procedural hard stops, and advisory capacity to put into place effective solutions.</td>
<td>Political leadership</td>
</tr>
<tr>
<td><strong>Building networks of community stakeholders</strong></td>
<td>Promoting shared learning among community stakeholders: A positive aspect to these two pandemics colliding is that people—communities, public health professionals and policy makers—can learn from each other.</td>
<td>Public health leadership, health care workers, community leadership, policy makers</td>
</tr>
<tr>
<td><strong>Forming multi-sectoral community partnerships:</strong></td>
<td>Non-governmental organisations may partner with governments and national TB programmes to mitigate the effects of the COVID-19 pandemic on the provision of biomedical care for TB-affected households. This might include sharing diagnostic and laboratory capacity and strengthening caregiver and community health worker roles to support care delivery.</td>
<td>Public health leadership, health care workers, community leadership, non-governmental organizations</td>
</tr>
<tr>
<td><strong>Establishing key connections with researchers:</strong></td>
<td>However, as is the case for the capacity of TB diagnostic services, careful planning and close collaboration between the TB, HIV, and COVID-19 research communities will be crucial not to overburden these infrastructures, especially in resource-poor settings.</td>
<td>Community leadership, academic institutions</td>
</tr>
<tr>
<td><strong>Integrating efforts to build trust and reduce stigma in health system efforts:</strong></td>
<td>...it is therefore important to establish reliable health services and strategies that prioritise care for both TB and COVID-19 patients. This approach will assist in building trust in the health system and allow people to take meaningful measures to keep themselves and their families safe.</td>
<td>Public health leadership, community leadership, patients</td>
</tr>
<tr>
<td><strong>Supporting high-quality health care workforce training and safe workplace environments</strong></td>
<td>Reinforcing clinical training through short courses: Provide short-term training for students and health professionals and recruit additional staff to work on TB programs.</td>
<td>Public health leadership, health care workers, academic institutions</td>
</tr>
<tr>
<td><strong>Building research capacity:</strong></td>
<td>SORT IT teaches multiple and practical skills for activities such as generating and utilizing data, conducting operational research and using evidence to influence policy and/or practice. Moreover, with a renewed global focus on active case-finding in TB programs, resources dedicated for COVID-19 community-based research, such as household contact tracing or seroprevalence surveys, could easily be linked to programs to test for TB as well, providing a gateway for training, capacity building, and future TB research.</td>
<td>Public health leadership, health care workers</td>
</tr>
</tbody>
</table>

Continued
syndemic and closely linked influencing factors like poverty. This insight can be applied to current and future plans of TB programs, especially for the diagnosis and management of active and reactivation TB cases. Health authorities can also streamline public health efforts in COVID-19 and TB control by minimizing duplicated or non-essential approaches and guiding simultaneous surveillance services for rapid response. By identifying potential funding partners in the public and private sectors, additional financial resources and equipment can be distributed to health facilities.

Community fora can offer public platforms to share and discuss evidence-based findings that can promote a call to action for policy changes.

Supporting High-Quality Health care Workforce Training and Safe Workplace Environments

A competent health care workforce must be prepared with appropriate knowledge and skills to simultaneously manage endemic and emerging health threats. Health care workers should receive adequate training, appropriate incentives to provide care, and mental health and psychosocial support. Continuing education programs can offer up-to-date information about clinical guidelines, best practices, public health principles, and timely health topics. This information can offer insight on the influence of social determinants on TB and COVID-19 patients, especially the impact of comorbidities (e.g., diabetes mellitus), environmental contamination (e.g., air pollution), and economic hardships (e.g., poverty and overcrowded living conditions), and strategies to reduce stigma and discrimination. Community fora can offer public platforms to share and discuss evidence-based findings that can promote a call to action for policy changes. These key contributions to health systems...
will support the delivery of holistic, patient-centered care services for TB patients.

Health care workers should receive additional skills-based training in field epidemiology with case studies for outbreak investigations and operational research for TB prevention and control. This training can offer skills in identifying priority health issues, literature reviews, connecting with community stakeholders, data collection and analysis, and scientific writing.39,41,49

However, with increasing clinical and community health responsibilities—including allocation of staff and resources to new disease priorities—it is important to monitor and evaluate health care workers for mental health stressors and mitigate risk of burnout.39,41

### Using Digital Health Interventions for TB Care

Existing electronic health technologies (eHealth), defined as platforms that use information and communication technologies,52 have the potential to change the paradigm in TB management. These digital innovations can offer remote support through video-supported therapy and electronic medication monitors for health care workers to guide TB patients through their clinical management, identify and monitor co-morbidities, and encourage treatment adherence.33,36,38,39 Mobile health solutions (mHealth) facilitate the delivery of short message service (SMS) and WhatsApp messages as well as geographic information systems (GIS) mapping for direct contact and delivery of test results and health information.39,47 especially reaching at-risk communities.33 With increased public interest observed during the COVID-19 pandemic, these digital approaches can enhance public engagement on infectious disease monitoring and offer informative fact sheets on multiple infectious diseases.39,44 These telemedicine applications, albeit with clear benefits for provider-patient engagement, raise potential questions for health care delivery. Some remaining issues include the ability to ensure patient safety, warrant data privacy and storage, conduct appropriate virtual physical exams, follow limited established protocols, evaluate cost-effectiveness, and assess adherence to improve overall equity and efficiency.31,43,44 Although comprehensive in-person evaluations cannot be eliminated from acute and chronic patient care,42 an integrated approach of in-person consultations and complementary telemedicine applications can pave the future for TB prevention and control efforts.

### DISCUSSION

This is the first known rapid review to examine the existing challenges to be addressed and proposed recommendations to strengthen TB efforts in low- and middle-income countries during and after the COVID-19 pandemic. The End TB Strategy targets were approached in 2020, but not met, with established targets of 20% decrease in incidence rates (reported 9% decrease) and 35% decrease in mortality rates (reported 14% decrease), with continued challenges in the Americas and African regions.1,53,54 Increased attention to TB efforts will be fundamental in the upcoming years to combat the decreased TB notification rates reported during the COVID-19 pandemic; support national policies that prioritize integral, patient-centered TB care; and expand current initiatives to end TB transmission.53

Since emerging One Health threats continue to affect the global society, health leaders must be innovative in their contributions to clinical and community settings. Global health systems must be vigilant and prepared to adapt current evidence-based practices to meet societal needs of the next decade.55 In this review, selected studies identified challenges in TB control efforts—such as overwhelmed health systems and insufficient support for the health care workforce—that will require novel solutions to improve access and availability of diagnostic and treatment services for TB patients. The use of ground-breaking approaches, data, and practices that can help identify specific challenges, such as country-specific social, economic, and cultural contexts that influence health-seeking behaviors and treatment adherence,35 should be considered in maintaining sustainable TB programs.

A robust national health system with skilled leadership, trained health care workforce, health system and research investment, and direct connections with community stakeholders has the potential to achieve the national and international objectives of the Sustainable Development Goals (SDG 3.3) and the End TB Strategy. Political commitment will enhance national preparedness and guarantee an immediate public health response, noting stressors (e.g., dual health priorities) to a well-functioning health system.56 Continued investment in operational TB research is essential to identify knowledge gaps, develop sophisticated scientific inquiries, establish methodological and analytical approaches, and implement findings in public health practice.54,57,58

Strengthening links with primary care centers and relevant community stakeholders will elucidate...
local needs and resources as well as knowledge gaps related to TB care. National programs that advocate for public welfare and social protection for TB patients, including cash transfers, food parcels, housing resources, and psychosocial support, can minimize existing inequities in TB care, alleviate additional psychological stress, and offer indispensable support to TB patients and their families.\textsuperscript{45,59} Partnerships that expand public sector engagement with the private sector (public-private mix) for TB care are essential to meet the targets of the End TB Strategy, including ensuring prompt TB diagnosis and treatment, reducing hardships associated with catastrophic health care costs, and ultimately curbing TB transmission.\textsuperscript{51,62} National health statistics from active surveillance programs provide data on population health risks to authorities for health decision-making activities. Through qualitative research designs, health researchers can capture barriers related to TB treatment adherence, primary care providers’ perspectives on TB control, and social determinants of health.\textsuperscript{27,62,63} Further exploration of the role and acceptance of digital innovations to TB care can be examined among the health care workforce and community members.\textsuperscript{64}

Supporting a highly trained health care workforce and safe workplace environments is the responsibility of national health systems, especially with the renewed emphasis on the public-private mix for TB care and prevention. Comprehensive training with required annual continuing education hours for the health care workforce across the public and private sector will reinforce robust technical capacity, offer uniformity across institutions, and expand reach to resource-limited areas.\textsuperscript{65} Appropriate incentives for health care workers, such as financial bonuses, professional recognition, and supervisory positions, have the potential to motivate self-confidence and morale in professional competencies as well as enhance work satisfaction and productivity.\textsuperscript{66} Without this support, the brain drain phenomenon can lead to significant health care workforce shortages as workers migrate to other countries that offer improved working conditions, higher salaries or incentives, personal security, and professional recognition.\textsuperscript{67} Supervisors can also provide mentorship and objective feedback, encouraging health care workers to reach specific milestones in their performance plan.\textsuperscript{68}

Digital health interventions can transform TB care by disseminating essential health information, supporting treatment adherence, and encouraging health-seeking behaviors among TB patients. With increased interest and versatility among health professional students, social media platforms have been successfully used to expand health communication efforts during the Ebola virus disease outbreak in West Africa\textsuperscript{69} and guide One Health community field campaigns.\textsuperscript{70} It has the potential to combat the “infodemic”—defined as the rapid spread of false information—of TB and other stigma-associated diseases like COVID-19\textsuperscript{71} as well as streamline operational networks in the public-private mix approach.\textsuperscript{62} Furthermore, telemedicine applications have strengthened provider-patient engagement and TB diagnostic and treatment adherence through text messaging\textsuperscript{72} and computer-aided technology.\textsuperscript{73} Patient safety issues, however, should be evaluated, especially ensuring data security and storage, confirming internet connectivity and related infrastructure, and training health workers in remote technologies.\textsuperscript{43,73} Although the use of broadband internet can substantially enhance the innovative delivery of TB health care services and educational programs, national health systems should identify existing disparities in internet access that can further exacerbate the “digital divide” as a social determinant of health.\textsuperscript{11,74}

### Limitations

This study has a few limitations. First, although the authors participated in the data analysis and selected the final themes, they recognize that data may be interpreted in alternative ways.\textsuperscript{75} Second, the study utilized 5 databases for peer-reviewed articles but may have overlooked other relevant papers in the gray literature or other scientific databases. Finally, this study did not evaluate the quality of described challenges and recommendations of selected articles, although this task is not obligatory for rapid reviews.\textsuperscript{24} However, authors did critically analyze the study findings from original research articles and reviews with more substantial detail, than the letters and perspective articles.

### CONCLUSION

This rapid review summarizes areas for improvement in health system preparedness for optimal TB control across low- and middle-income countries. These findings can aid in the development of national policies to promote integral, patient-centered TB care, facilitate the implementation of ethical community interventions, support operational research, and allow the integration of appropriate eHealth applications. By better understanding challenges in TB prevention and control with coexisting health priorities,
TB program managers and primary care practitioners can serve as instrumental leaders and patient advocates to deliver high-quality and sustainable TB care that leads to achieving targets of the End TB Strategy.

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How Home Delivery of Antiretroviral Drugs Ensured Uninterrupted HIV Treatment During COVID-19: Experiences From Indonesia, Laos, Nepal, and Nigeria

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Key Messages

- Across diverse contexts, home delivery of antiretroviral (ARV) medications was a feasible and acceptable approach for ensuring access to HIV treatment when COVID-19-related lockdowns and travel restrictions imposed barriers to treatment.
- The ARV home delivery models were rapidly designed and successfully implemented to meet emergency needs brought on by the pandemic. Home delivery of ARVs requires further attention before it can be implemented at greater scale in response to the current pandemic and when health services face future shocks.

Key Implications

- Governments and their partners are urged to seek financing mechanisms and reinforcement to commodity management systems needed to sustain this mode of decentralized service delivery.
- National HIV program leaders are encouraged to advocate for official, permanent policy changes supportive of home delivery of ARVs. Health policy makers should consider the relevance of home delivery to all chronic health needs requiring long-term delivery of medication to clients.

ABSTRACT

Introduction: Faced with the coronavirus disease (COVID-19) pandemic, governments worldwide instituted lockdowns to curtail virus spread. Health facility closures and travel restrictions disrupted access to antiretroviral (ARV) therapy for people living with HIV. This report describes how HIV programs in Indonesia, Laos, Nepal, and Nigeria supported treatment continuation by introducing home delivery of ARVs.

Methods: Staff supporting the programs provided accounts of when and how decisions were taken to support ARV home delivery. They captured programmatic information about home delivery implementation using an intervention documentation tool. The 4 country experiences revealed lessons learned about factors favoring successful expansion of ARV home delivery.

Results: Three of the countries relied on existing networks of community health workers for ARV delivery; the fourth country, Indonesia, relied on a private sector courier service. Across the 4 countries, between 19% and 51% of eligible clients were served by home delivery. The experiences showed that ARV home delivery is feasible and acceptable to health service providers, clients, and other stakeholders. Essential to success was rapid mobilization of stakeholders who led the design of the home delivery mechanisms and provided leadership support of the service innovations. Timely service adaptation was made possible by pre-existing differentiated models of care supportive of community-based ARV provision by outreach workers. Home delivery models prioritized protection of client confidentiality and prevention measures for COVID-19. Sustainability of the innovation depends on reinforcement of the commodity management infrastructure and investment in financing mechanisms.

Conclusion: Home delivery of ARVs is a feasible client-centered approach to be included among the options for decentralized drug distribution. It serves as a measure for expanding access to care both when access to health services is disrupted and under routine circumstances.

INTRODUCTION

Governments worldwide rapidly instituted social distancing policies and lockdowns in 2020 to decrease the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease (COVID-19).1,2 The restrictions disrupted routine health services, including initiation and continuation of...
Home Delivery of Antiretrovirals During COVID-19: 4 Countries’ Experiences

antiretroviral therapy (ART) for people living with HIV (PLHIV). In some low- and middle-income countries (LMICs), health care workers have been redeployed to support the COVID-19 response, causing human resource shortages in routine services. Travel restrictions, clinic closures, and fears about the risk of infection at health facilities have discouraged health facility visits. The current COVID-19 pandemic and the possibility of future global health security threats restricting access to health facilities make it imperative to find alternative ways of delivering services to PLHIV in the interest of avoiding increased morbidity and mortality associated with treatment interruptions. The solutions are relevant not only to the continuity of HIV services but also to delivery of care for other health conditions requiring extended care, including TB, diabetes, and cardiovascular disease.

Research evidence and programmatic experiences in LMICs demonstrate the potential of differentiated service delivery (DSD) models for sustaining PLHIV on treatment. Endorsed by the World Health Organization in 2016, DSD describes client-centered service delivery approaches that adapt the timing, mode, and place of HIV services to the needs and preferences of a specific client population. DSD models include community-based provision of antiretroviral drugs (ARVs) to PLHIV established on ART through varied mechanisms, including client-led community adherence groups, provider-led adherence clubs, and community drug distribution points. Clients typically receive medication supplies lasting between 3 and 6 months through an approach known as multimonth dispensing (MMD). They are required to return to the health facility periodically for a clinical consultation (typically every 12 months) and viral load sample collection. The COVID-19 pandemic has evoked calls for countries to accelerate the formulation of policies and implementation strategies supportive of both DSD and MMD that reduce the frequency of contact between health care workers and PLHIV, thereby reducing both bidirectional risks of SARS-CoV-2 transmission and burden on the health care system. Some approaches leverage the private sector through decentralized drug distribution through private pharmacies or automated dispensing.

Research has shown the feasibility and effectiveness of a community-based strategy: ARV delivery within or close to clients’ homes. Studies in Uganda, Kenya, and Tanzania have documented positive results associated with home delivery, indicated by improved adherence, treatment continuity, clinical outcomes, client satisfaction, and cost savings to the health system and clients. Despite the success of interventions tested on a small scale, they have not been incorporated widely into routine practice. National policies in many LMICs do not explicitly encourage ARV home delivery, and governments and their implementing partners have not invested in service delivery mechanisms to operationalize the practice. Drug supply shortages interrupt HIV programs’ delivery of multimonth drug supplies; yet for operational costs to be affordable, deliveries should be limited to no more than 2–3 times per year. Other factors deterring expansion of home delivery of ARVs include intensive health system resource requirements needed for a high-functioning community health worker (CHW) program and persistent doubts about CHWs’ ability to effectively deliver treatment for chronic conditions such as HIV/AIDS. Additionally, HIV programs are challenged with maintaining client confidentiality to minimize the risk of stigma and discrimination experienced by PLHIV when home deliveries are made.

The COVID-19 pandemic has compelled HIV programs to overcome those and other barriers and to accelerate policy and programmatic change supporting ARV home delivery, not only during restrictions but as a client-centered model for populations inadequately served by other models. We present experiences from 4 LMIC settings where governments rapidly adjusted policies and service delivery mechanisms to provide ARVs to PLHIV in or near their homes. These 4 programs were selected based on the authors having direct access to programs where home delivery was rapidly introduced to adapt to COVID-19. The scenarios offer insights from experiences in geographically, culturally, and programmatically diverse settings. Program descriptions are followed by a discussion of lessons learned by technical advisors about the factors supporting and inhibiting ARV home delivery as a solution for sustaining clients on HIV treatment when access to facility-based services is compromised.

PROGRAM EXPERIENCES

With support from U.S. Agency for International Development (USAID) and the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), FHI 360, an international nongovernmental organization supporting HIV programs in approximately 40 countries, provides technical assistance and implementation support to the featured HIV service delivery programs in Indonesia, Laos, Nepal, and Nigeria. To prepare this multicountry account, FHI 360 program staff serving as technical advisors
retrospectively compiled programmatic information about HIV services and home delivery using an intervention documentation tool (Supplement). Staff provided background information on COVID-19-related lockdowns including when they were enforced and their influence on health service delivery and care-seeking practices. They also documented when and how policy change came about to support ARV home delivery.

Jakarta, Indonesia: Home Delivery Using Courier Services

The USAID- and PEPFAR-funded Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES) project offers technical support to HIV programming in Jakarta province to ensure that key and priority populations living with HIV initiate and sustain treatment. In March 2020, the Jakarta Government responded

Discreet packaging of antiretroviral drugs in Jakarta, Indonesia. © 2020 Ade Sonyville and Arifin Fitrianto/LINKAGES/FHI 360 Indonesia

| TABLE. Summary of Antiretroviral Drug Home Delivery Interventions in 4 Countries |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
|                                  | Nigeria         | Indonesia       | Nepal           | Laos            |
| Client groupsa                  | General population/rural population | Key populations, their partners and children, and other priority populations | Female sex workers, MSM, transgender people, and migrants and their spouses | MSM/transgender people and their partners who are living with HIV |
| No. of facilities participating in home delivery | 21 | 109 | 19 | 3 |
| Recommended frequency of clinical consultation for established ART clients | Every 6 months | Every 6 months | Every 6 months | Every 6 months |
| Recommended frequency of viral load testing for established ART clients | Every 6 months | Every 12 months | Every 12 months | Every 6 months (for first year) and every 12 months for year 2 onward |
| Modification for viral load testing during the COVID-19 pandemic | Sample collection in the community | Transport of samples to private laboratories | Sample collection in the community | No change: facility-based collection required |
| Clients who received home delivery, n (% of eligible for home delivery) | 4,138 (51) | 4,948 (19) | 2,836 (21) | 126 (26) |

Abbreviations: ART, antiretroviral therapy; MSM, men who have sex with men.

a Terms reflect client groups’ preferred descriptions.
to the COVID-19 pandemic by introducing large-scale social restrictions (known as “PSBB”) that limited domestic and international travel, imposed work-from-home policies on nonessential businesses, closed schools, constrained religious and cultural activities, and banned large social assembly. Public transportation was severely limited, and health facility staff were required to work alternating shifts, reducing facilities’ ability to deliver care. The March 2020 provincial government circular specifically restricted face-to-face HIV community-based services, as mandated by the provincial government. By contrast, private sector services—particularly those that deliver essential goods—were exempted from large-scale social restrictions. Those transport companies put in place measures to protect their delivery staff, including PPE, sanitization protocols, and frequent rapid testing.

Recognizing this opportunity for private sector engagement, LINKAGES rapidly convened provincial health officials, clinical and community providers, and PLHIV representatives in virtual meetings to consider ARV home delivery. The Jakarta Provincial Health Office was initially reluctant to implement home delivery of ARVs due to concerns about maintaining confidentiality and financing the intervention. Decision makers were convinced after LINKAGES pledged to support technical, programmatic, and financial aspects of rollout and to work closely with provincial and district-level officials on monitoring this intervention. Once the Provincial Health Office introduced home-based ARV delivery into emergency regulations in March 2020, LINKAGES technical advisors joined provincial officials in establishing systems for ordering and transporting ARVs through Jak-Anter, a home-based ARV delivery system that uses ride-based apps and transport courier service such as Tiki, JNE, Grab, or Gojek. Facilities first pay the transportation fees and then are reimbursed by USAID/LINKAGES every week based on the number of clients served, as documented by clients with a phone message, photo, or WhatsApp message. Delivery firms use rigorous COVID-19 screening and safety protocols and provide PPE to protect drivers and clients, and they have committed resources for giving a one-time payout to any driver-partner who undergoes the government-mandated quarantine or tests positive for COVID-19.

Providers were initially reluctant to utilize Jak-Anter due to concerns about the timeliness of fee reimbursement and the added work of preparing, packaging, and arranging transport of medicine. Some PLHIV clients expressed worries about confidentiality and privacy, believing fellow community members could identify individuals with HIV infection through home-based drug delivery visits. Adoption increased over time, with the rise attributed to team-based provider incentives for patient retention, as well as improved service branding and promotion that emphasized protection of privacy. From March to December 2020, 4,948 unique PLHIV—or 19% of 26,203 PLHIV across 109 facilities—received home-based ARV delivery services through the LINKAGES’ Jak-Anter system. Although retention specifically among Jak-Anter clients has not been analyzed, retention was more than 95% throughout 2020 among all ART clients in PEPFAR-supported sites in Jakarta. The Provincial Health Office incorporated home delivery into official policy and is working with LINKAGES technical advisors to scale the practice further through the Jak-Anter home-based ARV delivery system. The intervention is currently donor supported, with USAID/LINKAGES reimbursing health facility administrative costs and delivery costs. ARVs are the sole drug offered by the public sector health services through a home delivery system in Indonesia, with the Jakarta Provincial Health Office now exploring expansion of home-based delivery services for other medical treatment priorities.

Laos: Home Delivery by Community-Based Supporters

In Laos, LINKAGES supports HIV services in 3 central hospitals in the capital city, Vientiane. People...
with positive tests were offered treatment through a variety of DSD models. Confronted with the COVID-19 pandemic, the Government of Laos enforced a full country lockdown from March 29 to April 19, 2020. Health facility access was permitted for emergencies only. PLHIV due for their ARVs could access health facilities through pre-appointment arrangement and only in the morning. Clients were required to carry a potentially stigmatizing letter from the hospital or their appointment card to show to the police while on the road; they also had to show this documentation to the guard before entering health facilities.

Recognizing how these restrictions reduced access to health services and threatened privacy, LINKAGES initiated home delivery of ARVs by collaborating closely with the Laos National Program for HIV, other implementing partners (IPs), UN agencies, and the Global Fund. Similar to the experience in Nepal, planning efforts involved rapid virtual engagement of governmental program officials, clinical and community providers, and PLHIV beneficiaries. Once the Ministry of Health authorized ART home delivery on an emergency basis in May 2020, ART sites established systems for drug ordering and transport. Health care providers offered outreach workers, known as community-based supporters (CBSs), on-the-job training to conduct the home-based delivery intervention; instruction covered confidentiality, consent, counseling, and safe delivery of ARVs, including COVID-19 prevention measures. ART sites issued CBSs a letter authorizing essential travel to present to police at checkpoints. After consulting records to identify stable ART clients who are eligible for MMD, the health care provider contacts the PLHIV using established communication lines via phone or social media to inform the client about the home delivery option, assess interest, and ask permission for the CBS to initiate the process. The CBS then contacts the client to offer home delivery or to agree on another place in the community to meet. For PLHIV who dec-line home delivery, the CBS assists with pre-appointment arrangement for a visit to health facilities. Initially, home delivery packages had drugs lasting 3–4 months for stable PLHIV; this increased to 4–5 months by the end of June 2020. In conducting home/community delivery of ARVs, CBSs are expected to follow the same protocol for privacy and confidentiality that is used for home visits to PLHIV for the provision of adherence and retention support. Regarding protections from COVID-19, the outreach workers travel to communities on their motorbikes, and they are provided face masks and hand sanitizer.

Between May and September 2020, a total of 126 PLHIV had received home delivery, accounting for 26% of 480 individuals who were due for refill. Those who declined this service were more apt to be living with friends or parents or on a military base; others declined because they had established a close rapport with the facility-based health care providers and wanted to maintain that contact. Although home delivery is just one factor influencing HIV program outcomes, viral load suppression remained above 95% throughout 2020 in the PEPFAR-supported sites. With the ease in restrictions in Laos, home delivery of ARVs continues to be an attractive option for some clients who live far from the hospital or who struggle financially to travel to the hospital. The intervention depends on donor support, with transportation and lunch allowances for CBSs paid by either LINKAGES or the Global Fund ($5 to $8.50 per client served).

**Nepal: Home Delivery by CHWs**

In Nepal, LINKAGES collaborates with the national government, 21 IPs, and national networks of key populations and PLHIV to deliver HIV services in 19 of the country’s 77 districts. The COVID-19 nationwide lockdown raised an urgent need for service delivery adaptations to support clients in continuing ART. All LINKAGES-supported Nepal city clinics were closed during the lockdown period (March–July 2020); local orders dictated that clinics remain closed, and movement continued to be restricted in districts with more than 200 active COVID-19 cases. As of November 2020, only 3 of 19 LINKAGES-supported clinics were open, and ART sites that were open operated with limited opening hours and capacity.

Nepal’s 2020 National HIV Testing and Treatment Guidelines support community-based ART and ARV dispensing sites as a DSD model, without a specific policy supporting home-based ARV delivery. To adapt to COVID-19-related restrictions, LINKAGES rapidly engaged stakeholders to plan and initiate home delivery. Collaborators included representatives of the National Center for AIDS and STD Control (NCASC), IP organizations, clinic- and community-based ART service providers, and PLHIV networks. CBSs and peer navigators affiliated with IPs, are the frontline implementers of the home delivery intervention in 19 project districts. LINKAGES Nepal IPs collaborate with 29 ART sites in preparing lists of PLHIV who are due for a refill. IP staff...
members contact clients to inform them that their treatment is available at the ART site or community-level facility. PLHIV have the option of picking up ARVs from designated ART sites or city clinics or they can opt to have the outreach worker deliver ARVs to their home or to a chosen location in the community. To date, there has been no official change in national policy authorizing ARV home delivery, although it has become an acceptable component of existing community-based services. Between March 1 and September 30, 2020, LINKAGES-supported partners in Nepal provided ARV drugs to 2,836 PLHIV in or near their homes, accounting for 21% of all eligible PLHIV within the supported sites. One factor limiting use of home delivery was that PEPFAR services were transitioning to the use of tenofovir, lamivudine, and dolutegravir, a treatment requiring patients to visit health facilities. Although no data are available showing how home delivery affected retention, Nepal’s overall 12-month retention in 2020 was 96.7%.

Akwa Ibom State, Nigeria: Home Delivery by CHWs

About 6 months before COVID-19 was first detected in Nigeria, home delivery of ARVs was first introduced in a large primary health facility in Akwa Ibom state—where the USAID-funded Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) project supports the government in providing HIV treatment services in 102 health facilities. Noting in March 2019 that only 73% of those who had started ART 12 months prior were still receiving care, program staff considered DSD approaches to make treatment more patient centered and accessible. Community ART refill groups were not regarded as a good option because of stigma and the wide geographic dispersion of clients’ households in Mbo, a local government area (LGA) where the facility is located. Supported by Nigeria’s National Policy on Task Shifting and Task Sharing for Essential Health Care Services, health center staff together with SIDHAS technical advisors decided to initiate home delivery of ARVs.
in August 2019. The service was offered to clients established on ART, defined as those on ART for at least 3 months, who had no opportunistic infections and were free of adverse drug reactions.

Home delivery of ARVs took on greater importance when the COVID-19 lockdown was enforced in Akwa Ibom state in mid-March 2020. At the height of restrictions (April–May 2020), vehicular movement was prohibited, although health care workers were permitted to travel with an Essential Duty Pass. Limited supplies of face masks and their prohibitive cost when they were available further deterred clients from accessing health facilities. Some clients in the 21 LGAs served by SIDHAS refrained from going to health facilities due to the fear of contracting the virus: 9,303 of 65,288 clients (14%) missed HIV clinic appointments in the 2 months preceding the lockdown, a time when media reported COVID-19 infections in Nigeria. Home delivery was extended from 21 to 80 health facilities to ensure uninterrupted refills. This extension required engaging with the clients, state and LGA officials, health facility staff, and civil service organizations such as the Network of People Living With HIV/AIDS in Nigeria (NEPWHAN); training health care providers and outreach workers on the new model; and activating toll-free numbers to provide ongoing support to the clients.

In this model, health facilities use client data to generate weekly lists of clients eligible for home refills; clients are clustered by location, and case managers are assigned to provide the service. Community health extension workers, case managers, and patent medicine vendors have been trained by pharmacists to collect prepacked ART from respective facilities and to deliver it to clients at home or an alternative pick-up location proposed by the client, such as churches, schools, shopping malls, or market stalls. Program staff travel by boat, canoe, motorcycle, tricycle (“keke”), and on foot to reach the households. The program provides outreach workers with personal protective equipment (PPE) (face masks and sanitizers) and screens them for COVID-19 symptoms. When health facilities contact clients by phone to schedule a home visit, they assess knowledge about COVID-19 and presence of COVID-19 symptoms; clients with symptoms are referred to the state COVID-19 response team for testing. SIDHAS helps to cover CHWs’ transportation costs using funds designated for tracking clients through home visits.

Between May and November 2020, 4,138 of the 8,136 (51%) clients on ART in Mbo LGA were receiving prepacked ARVs by home delivery, with overall client retention at 99%. Reflecting on their experiences with patients who chose not to use home delivery, program implementers posited that this could be due to concerns about confidentiality, privacy, and stigma or to a preference for other DSD options that are
convenient for them, such as fast track clinics or refill clubs.

LESSONS LEARNED ON ACCELERATING INTRODUCTION AND EXPANSION OF HOME DELIVERY OF ARVS

The 4 country programs spanning diverse LMIC contexts demonstrate the feasibility of home delivery as a routine DSD approach for HIV treatment in LMICs. The following are key lessons learned from those experiences from the perspective of technical advisors who supported the programs.

Rapidly Engage Stakeholders

Rapid stakeholder engagement to design and endorse service innovations was instrumental to the success of these 4 HIV programs in adapting successfully to the COVID-19 pandemic. With the World Health Organization’s March 2020 pandemic declaration and the national and local restrictions that quickly followed, HIV program partners recognized the urgency of service delivery adjustments to ensure continuity of care for ART clients. Each of the programs engaged virtually with stakeholders, including governmental health program officials, clinical and community providers, and PLHIV beneficiaries. Policy adjustments required intensive, sustained dialogue advocating for the safeguarding benefits of home delivery for both PLHIV beneficiaries and providers. Review of client data reflecting missed appointments and travel distances helped to make the case that home delivery would greatly support clients and improve retention in HIV care.

Involving PLHIV and their advocates in intervention design and launch of service delivery innovations was an essential form of stakeholder engagement. Their input allowed interventions to be tailored to beneficiaries’ varied needs and preferences. In Laos, for example, program implementers were advised home delivery would be more effective if it is conducted by PLHIV support groups, community organizations, or the staff of services like the Youth Clinic. Similarly, in Nepal, the intervention involved mobilizing and building the capacity of PLHIV CBSS and peer navigators to conduct home delivery, capitalizing on their thorough knowledge of the community.

Institutionalization of home delivery as a standard of care requires supportive policies. None of the 4 countries have policies explicitly supporting ART home delivery. Jakarta is in the process of putting home-based care into policy at local levels, and the circular letter instituted in March 2020 provided the impetus for broader policy discussions. Facing the COVID-19 emergency, government officials recognized that programs needed stop-gap solutions and reacted quickly by approving home delivery on an emergency basis. For the service innovation to be implemented permanently, decision makers will need to reconvene to effect official policy change. Decision making should be guided by examining initial home delivery experiences and considering practical plans for implementing home delivery at scale. Engaging in advocacy for client-centered approaches, HIV programs could be aided by joining forces with representatives of other health programs that could more effectively serve clients requiring long-term drug therapy through home delivery of treatment. Extending home delivery to include the provision of medications for other chronic conditions would benefit clients while also potentially increasing efficiency for the health system.

Invest in DSD Models

Differentiated models of care allow ART programs to adapt to contextual shocks and to avoid service disruptions. Governments and their IPs were able to adapt to the COVID-19 emergency through ARV home delivery due to pre-existing policies and practices supporting DSD. MMD, the practice of providing virologically suppressed clients with ARV refills every 3 or 6 months, contributed to the feasibility of ARV home delivery; visiting clients more frequently would have been more expensive and logistically difficult. Although support for MMD has grown markedly in PEPFAR-supported countries in recent years, the supply chain infrastructure requires reinforcement to make this the universal service delivery norm. A growing base of successful experience with community-based provision of ARVs by outreach workers without clinical credentials laid the foundation for rapid approval of home delivery in the face of the COVID-19 crisis. Continued investment in DSD models is warranted to alleviate the burden on already overstrained health facilities and to prepare for future shocks threatening service continuity. Additional evidence is needed to refine the models, test alternatives, and assess their cost-effectiveness. Attention should also be focused on the professionalization of the nonclinically credentialed outreach workers responsible for community-based ARV delivery, to the extent that it is a factor impeding formal policies supporting their role. Notably, peer educators, peer
navigators, and other community-based cadres are increasingly recognized as an essential part of a country’s health workforce. In 3 of the 4 case examples provided in this article, home delivery of ART was provided by community-based health workers. National policymakers should acknowledge the essential leadership role that communities play in the delivery of health services through increased domestic financing of community-led services, including home delivery of ART.

Protect Outreach Workers and Clients
Protections for outreach workers and clients are essential features of home delivery approaches. Foremost, measures were introduced to minimize the risk of SARS-CoV-2 transmission between individuals delivering ART (outreach workers/rideshare employees) and clients. Programs developed detailed protocols to screen CHWs for COVID-19 symptoms, to refer suspected cases to the public health system for testing, to quarantine individuals who were potentially infected, and to link people with positive test results to care. HIV programs also developed and disseminated materials with educational messages on preventive measures such as physical distancing and hand washing. Finally, workers responsible for home delivery received PPE such as face masks, gloves, and hand sanitizer.

Another fundamental protective measure was the emphasis on ensuring client confidentiality. Across countries, a factor presumed to inhibit acceptance of home delivery among some clients was fear of inadvertent disclosure of HIV status that could place the client at risk of stigma or violence. Programs introduced measures for privately contacting the clients to obtain consent and to assess and minimize the risk of violence or other harm that may be associated with home delivery of ART. These built on pre-existing processes for obtaining consent for home visits for adherence support sought from all clients as they initiate ART. Programs packed medicines discreetly so the contents could not be identified. For clients with remaining concerns about undesired disclosure of their HIV status to co-residents, programs pivoted to offer delivery alternatives. For example, outreach workers arranged to meet PLHIV clients somewhere outside their homes, such as at the bus station, the village entrance, or the park.

Ensure Intervention Sustainability
For home delivery to continue beyond emergency situations, like the current COVID-19 pandemic, mechanisms are needed to ensure intervention sustainability. A reliable ARV supply chain is essential to supporting the sustainability of home delivery. At the initial peak of the COVID-19 pandemic, disruptions in international air shipments and national transport threatened the supply chain. When programs were initially challenged in implementing MMD due to strained drug supplies, home delivery allowed frequent dispensing while reducing client and provider COVID-19 exposure risk that would occur in busy health facilities. For home delivery to be efficient, however, programs must have ARV supplies sufficient to allow MMD. High-level stakeholder engagement in some of the countries resulted in some improvements in commodity management but concerns about potential ARV shortages persist. For home delivery to be offered permanently at a broader scale, forecasting must be more streamlined based on client projections and accurate consumption data.

The sustainability of home delivery also depends on HIV programs devising new health financing measures to support the intervention. Home delivery was necessary for many clients to prevent treatment interruptions at the peak of COVID-19. The model will still be needed as countries experience additional waves of the pandemic. Ongoing funding will be required to support home delivery for specific client groups, and costs associated with home delivery need to be systematically assessed to inform sustainability discussions.

The 4 country scenarios were possible through the infusion of supplementary resources offered by donor-funded projects already supporting HIV services. Even with external support, resources are insufficient to extend home delivery in time and space. In Nigeria, for example, serving the increasing numbers of patients opting for home-based refills has become too costly for its HIV program to sustain. Increased support for DSD models that include community participation and task-sharing will build the infrastructure necessary to sustain home delivery. Just as community-led services have been critical to an effective HIV response in LMIC, these services have proven to be essential to HIV programs’ resilience during the COVID-19 pandemic. Increased investment in community-led services will help build the infrastructure necessary to sustain home delivery. Programs can justify investment in all the supports required for home delivery by producing programmatic data and completing cost-effectiveness modeling showing that it is a valuable addition to

For home delivery to be offered on a permanent basis at a broader scale, forecasting must be more streamlined based on client projections and accurate consumption data.
the ARV refill options, contributing to increased retention of clients in care, a persistent challenge to national HIV programs.37–39

Limitations
The featured home delivery interventions were introduced independently and at different times in each country in response to the pandemic. Under these emergency circumstances, a valid comparator was not put in place, thereby limiting conclusions that can be drawn about the public health impact of the intervention. Similarly, mechanisms were not introduced to track individual clinical outcomes or to capture the resources required to prepare and implement the home delivery interventions, thereby precluding cost-effectiveness analyses. The case studies were primarily based on program implementers’ accounts and did not include primary data collection with providers or clients; the accounts may therefore be favorably biased. Finally, the featured programs were well financed due to donor support. The Akwa Ibom program was part of a focused PEPFAR initiative known as a surge, resulting in high numbers of clients initiating ART. The documented experiences are likely not transferable to programs with dire resource constraints.

CONCLUSION
The home delivery model is a client-centered, community ART management program that improves the quality of life for PLHIV by providing a convenient means of uninterrupted access to ART. Experiences in the 4 countries suggest that inclusive engagement of all stakeholders, swift adoption of supportive policies, and service delivery models that are responsive to client preferences help to create feasible, acceptable home delivery interventions. Community-based and key-population-led service providers were poised to advance the differentiated service delivery approaches that COVID-19 necessitated, including home delivery of ART. Continuing to invest in communities and give them the legal and political legitimacy to operate in a way that reflects how important they are to health system functioning could help bolster health systems’ flexibility and resilience in the face of future pandemics. Providing home delivery of ARV medications is a promising option to ensure safe and sustained access to lifesaving HIV treatment among PLHIV in places where COVID-19-related lockdowns, quarantines, and physical distancing restrictions may impose substantial barriers to treatment retention. The documented programs show that home delivery could complement other out-of-facility models that could be rapidly activated to ensure treatment continuity in the face of future pandemics or localized disasters. Implementation experiences illustrate how programs can reduce access gaps by responding to client needs and preferences and adapting to external circumstances.

Rigorous evaluation is still needed to examine how home delivery complements and compares to other DSD models in terms of its impact on treatment continuity and clinical outcomes like viral suppression. Such research should explore the circumstances under which home delivery fills needs not met by other DSD models, an issue that could be informed through primary data collection with clients, providers, services managers, and community stakeholders. Also needed is a systematic assessment of the financial, human, logistical, and material resources required to sustain home delivery in different contexts. Such evidence could be used to guide thoughtful design and implementation of well-conceived responses to future pandemics and other shocks limiting access to health services. In the context of the current COVID-19 crisis, we propose that governments and donors support rapid scale-up of the home delivery DSD model to ensure that PLHIV can be retained on lifesaving treatment during these extraordinary times. For maximum resilience when confronted with other threats to HIV service continuity, HIV programs are encouraged to explore options for sustaining home delivery of ARVs as well as other services such as HIV testing services, pre-exposure prophylaxis, and family planning.

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Development of an Innovative Digital Data Collection System for Routine Mental Health Care Delivery in Rural Haiti


Key Findings

- Balancing time for clinical duties with time for data collection was a key challenge when using task-shared health care workers to collect data.
- Feedback of data to users, ongoing supervision, and opportunities for rewards for high-performers may help increase provider buy-in for new data collection systems.
- Retaining paper forms alongside digital data collection systems or the inclusion of decision support tools directly within digital data collection systems may be needed to fully support health care worker learning in a task-shared mental health system.

Key Implications

- Program managers should carefully consider sustainable staffing from the beginning when designing digital data collection projects.
- Program managers should consider how digital data collection systems can incorporate decision support tools to sustainably support ongoing learning of task-shared providers.
- Policy makers should integrate mental health data collection within other data systems to leverage infrastructure and resources for mental health.

ABSTRACT

Introduction: Effective digital health management information systems (HMIS) support health data validity, which enables health care teams to make programmatic decisions and country-level decision making in support of international development targets. In 2015, mental health was included within the Sustainable Development Goals, yet there are few applications of HMIS of any type in the practice of mental health care in resource-limited settings. Zanmi Lasante (ZL), one of the largest providers of mental health care in Haiti, developed a digital data collection system for mental health across 11 public rural health facilities.

Program Intervention: We describe the development, implementation, and evaluation of the digital system for mental health data collection at ZL. To evaluate system reliability, we assessed the number of missing monthly reports. To evaluate data validity, we calculated concordance between the digital system and paper charts at 2 facilities. To evaluate the system’s ability to inform decision making, we specified and then calculated 4 priority indicators.

Results: The digital system was missing 5 of 143 monthly reports across all facilities and had 74.3% (55/74) and 98% (49/50) concordance with paper charts. It was possible to calculate all 4 indicators, which led to programmatic changes in 2 cases. In response to implementation challenges, it was necessary to use strategies to increase provider buy-in and ultimately to introduce dedicated data clerks to keep pace with data collection and protect time for clinical work.

Lessons Learned: While demonstrating the potential of collecting mental health data digitally in a low-resource rural setting, we found that it was necessary to consider the ongoing roles of paper records alongside digital data collection. We also identified the challenge of balancing clinical and data collection responsibilities among a limited staff. Ongoing work is needed to develop truly sustainable and scalable models for mental health data collection in resource-limited settings.

INTRODUCTION

In large and complex health care settings, electronic health management information systems (HMIS) play a crucial role in ensuring that high-quality and valid data are routinely collected. The ability to make decisions informed by data is essential for providers to be able to provide high-quality longitudinal care and for...
countries to be able to track services, measure the quality of care delivered, and work toward international development targets, such as the Sustainable Development Goals (SDGs). For the first time in 2015, the SDGs included mental health, bolstering the emerging movement to expand access to quality mental health care globally. However, in resource-limited settings, there are few examples of the application of electronic HMIS in mental health care delivery, making evaluation and tracking of services challenging. In Haiti, as in many other low- and middle-income countries (LMICs), there is no national HMIS for mental health.

There is a need for the development, implementation, and evaluation of digital data collection systems for mental health, particularly those that can be deployed in resource-limited settings. Nongovernmental organizations (NGOs) involved in developing and delivering mental health services in low-resource contexts where mental health data collection is limited or nonexistent can contribute by helping develop and test mental health electronic data collection systems within their programs. This article describes a digital data collection system for mental health data developed, implemented, and evaluated in rural Haiti. We identify key lessons learned about digital mental health data collection in low-resource settings.

### PROJECT CONTEXT

Zanmi Lasante (ZL) is a partner organization of the health systems strengthening nonprofit organization Partners In Health (PIH). ZL has provided health care in rural Haiti for more than 30 years and serves a primary catchment area of more than 1.3 million people across 11 rural public health facilities in the Central Plateau and Lower Artibonite departments through a public-private partnership with the Haiti Ministry of Health. After the 2010 earthquake, ZL developed and implemented a mental health system using the “5 x 5” framework, which defines 5 minimum skills packages needed to provide basic mental health care and 5 implementation rules to support the implementation of task-shared mental health care in a low-resource health system. The ZL mental health care system is described in detail elsewhere. In brief, the system of mental health care provided at ZL uses a task-sharing model, in which nonspecialists, including bachelor’s level psychologists, who may have had limited clinical practice when hired at ZL, and community health workers, deliver components of care. Persons who screen positive for a possible mental health diagnosis in either the community or at a facility are referred for a full mental health evaluation at a facility. After the mental health evaluation, referrals are made for psychotherapy, psychoeducation, medication management, or other follow-up provided by a collaborating team of providers and as determined by the appropriate ZL care pathway (Figure 1).

When introducing mental health services at ZL and in response to limited internet infrastructure in rural Haiti, a paper-based data collection system was developed to aggregate mental health service volume at ZL health facilities each month. At each facility, the psychologist would manually count the total number of mental health patient visits that occurred that month. Practically, there were several implementation challenges with this system, including significant labor required to manually count patient visits each month, which led to long delays in submitting data. Variability in how counts were completed across facilities and having only aggregate data available—meaning it was not possible to count or monitor individual patients—reduced the validity and usability of data. It was also not possible to include the community-level activities of community health workers using this manual approach. This context and the lack of electronic HMIS for mental health in low-resource settings globally informed the programmatic decision in late 2015 to develop and implement a digital data collection system for mental health data at ZL facilities. The goal was to develop a system that could longitudinally and confidentially collect patient data to enable data-driven programmatic decision making for mental health services and would be effective in rural Haiti. The project was intended to document only facility-level activities, with the goal that community-level community health worker data would be added later.

### PROGRAM INTERVENTION

To design the digital data collection system, the project team, comprised of ZL staff and PIH staff, conducted a series of in-depth individual interviews over about 1 month with the following stakeholders: ZL leadership; the ZL information technology team; ZL monitoring and evaluation team; members of the ZL and PIH mental health teams; health facility medical directors and providers; and the PIH medical informatics team. In addition to aiming to increase the buy-in of each of these
stakeholders, these meetings collected input on the appropriate and feasible platform, content, technical specifications, and staffing for the data collection system.

**Design**

Based on input from the individual meetings, the Open Medical Record System (OpenMRS), an open-source medical record system, was chosen for system development. Though this was the first known use of OpenMRS for mental health data, it was recommended because it was already in use elsewhere within the ZL system, allowed different permissions for different users, and is widely used in LMICs for electronic data collection.19-21 Informed by indicators used more broadly at ZL, along with best practices for mental health data collection in LMICs, 87 administrative (e.g., type of provider present at the visit), clinical (e.g., diagnoses), and service provision (e.g., interventions provided) indicators were identified that would need to be derived from the data collection system (Figure 2).22 A data collection form was developed to be able to collect the data elements needed to calculate these indicators. Draft data collection forms were initially developed in Microsoft Word, which allowed an iterative process of refining wording, order, and content by the PIH and ZL mental health teams. Based on best practices in HMI and feedback from the PIH medical informatics team, structured data entry was used wherever possible to record the data elements, in the form of dropdowns or autocomplete fields to ensure ease of use for users and reduce skipped fields.21,23

Since the system was intended to facilitate programmatic and clinical decision making, key design inputs were made from providers and clinical supervisors. Initially, the intention was to include only high-level diagnoses (e.g., depression, anxiety, or psychotic disorders) to ease diagnosis among task-shared providers who had less experience with diagnosis. However, psychologists requested that a much wider and more dimensional range of diagnoses be included within the platform (e.g., mild, moderate, or severe depression) so that they could continue to learn about the full range and severity of mental health diagnoses over time and become more specific in their clinical documentation. Clinical supervisors also supported this design decision as it would help

**FIGURE 1.** Zanmi Lasante Depression Care Pathway Used at Health Facilities in Rural Haiti

Abbreviations: CHW, community health worker; IPT, interpersonal psychotherapy; SW, social worker; ZLDSI, Zanmi Lasante Depression Symptom Inventory.

*Administer the Zanmi Lasante Depression Symptom Inventory every 2 weeks.

Illustration prepared by Partners in Health.
ensure patient safety if supervisors could more easily track severity. Another key design input from clinical supervisors was the inclusion of space for free-text clinical notes alongside structured data entry. Free-text notes were not intended to be used to assess data quality or calculate indicators. However, within mental health care, free-text clinical notes are an important part of clinical documentation alongside quantitative measures and inform both safe longitudinal care of patients and clinical supervision of trainees.24

Based on ZL leadership, monitoring and evaluation, and mental health team feedback, it was determined that psychologists were the most appropriate cadre of staff for mental health data collection because they spent the most time working with mental health patients and learning about mental health conditions and had managed the prior paper-based mental health data visit counts. Additionally, they often took on the unofficial role of patient navigator for mental health patients at ZL health facilities and were, therefore, well placed to enter data on patient interactions with nurses and physicians that related to mental health. Clinical supervisors of psychologists suggested that data for each day’s patients be entered at the end of each day to protect time for psychologists to have patient sessions earlier in the day.

Stakeholders also underscored the importance of the system being able to run with little to no internet access, as 10 of 11 health facilities did not have internet at the time of system development. At the only site that had internet, the mental health data collection system was integrated with other data systems, but at others, mental health data was siloed. The system was developed to run without internet on a series of password-protected Lenovo laptops distributed to each facility and stored in locked offices. A user ID and password were also necessary each time a person accessed the data collection system, which further ensured data privacy. Alphanumeric identifiers unique to each patient were generated by the laptops so that all data exports were anonymized and data exports did not undermine patient privacy. Minimizing the loss of collected data in a rural environment with limited infrastructure and tech support was also critical. Data backups were automated to run any time a laptop was connected to wireless internet. Data exports were coordinated to run and be submitted to the project team during monthly meetings held at a central facility, which also had internet. System performance and the need for any maintenance were monitored daily by psychologists at each site, who would alert the project team to any issues and receive tailored...
support, as well as monthly by project staff at the centralized meetings. It was determined that clinic-based paper forms would be retained at least during the initial rollout of the project to be able to conduct an initial quality evaluation of the digital system.

Implementation
After completing the design stage, pilot testing of the data collection system on a test server before deployment led to further refinement and the development of training materials and standard operating procedures for data collection (Supplement). The system was piloted for several weeks in April 2016 at 2 of 11 health facilities, leading to further minor revisions and refinement of training materials. Subsequently, a full-day training on entering data, with supervised practice, was provided to psychologists representing all ZL facilities, and the platform was rolled out to all 11 health facilities between May and July 2016. Any data not collected from January 2016 to the date of rollout at that facility was retroactively entered with the support of the ZL monitoring and evaluation team.

Evaluation
Several strategies were used to evaluate the project 6 months after its complete rollout across the ZL system. In recognition of the fact that patients might have attended mental health services at 2 nearby sites concurrently, overlap in individuals between site caseloads was examined. To assess the reliability of data collection both overall compared to the prior paper-based system, the percentage of monthly reports successfully submitted via the digital data collection system was calculated and compared to the percentage of monthly reports submitted via the prior paper-based system.

To assess data validity, the team assessed concordance between the Zanmi Lasante Depression Symptom Inventory (ZLDSI), a measure of depression developed and validated in Haitian Creole, as documented in the digital system and original paper charts. The digital system was defined as concordant with the paper system if the value recorded in the digital system exactly matched the value in the paper original. The ZLDSI was selected as the measure of concordance because it was the clinical tool used most widely at mental health patient encounters. Concordance was assessed at 2 sites identified by clinical supervisors as being representative of the mental health patient cohort at ZL, with 1 site representing smaller facilities and 1 site representing larger facilities. All data on patients with depression digitally recorded at the 2 representative facilities between January 1, 2016, and January 31, 2017, were extracted. Of a possible 456 patients, 40 patients were randomly selected at 1 site, and 25 of a possible 255 were randomly selected from the second site. For each patient, the first and most recent visits for depression at which a ZLDSI score was recorded were selected. Two project coordinators searched for corresponding paper ZLDSI forms in facility archives, recorded whether there was a match with the digital system, and made de-identified copies of paper originals. A third project team member verified concordance with the de-identified copies.

To evaluate the system’s ability to calculate usable indicators, 4 priority indicators were selected, 1 indicator representing a key component of care for all new patients and 1 indicator each to represent depression, epilepsy, and psychotic disorder, the key areas of mental health care provided at ZL. The 4 indicators were: ZLDSI score at first encounters for all new patients; ZLDSI score at every visit for patients with depression; documentation of number of seizures over the past 30 days at every encounter for patients with epilepsy; and a recorded score on the Abnormal Involuntary Movement Scale (AIMS) at every encounter for all patients being prescribed an antipsychotic medication. As described above, the ZLDSI is a locally developed depression screening tool and is meant to be used at first visits with all new patients and all visits for patients with depression. Seizure frequency is widely recognized as a key outcome measure in treating epilepsy, which is commonly included in mental health care in LMICs. The AIMS is a 12-item scale administered and scored by clinicians to detect the occurrence of dyskinesias in patients receiving neuroleptic medications. Percentages were calculated for recorded ZLDSI screens of the total number of first visits, recorded ZLDSI screens of the total number of depression visits, recorded seizure frequency of the total number of epilepsy visits, and recorded AIMS results of the total number of visits for patients on antipsychotic medication.

RESULTS
Between January 2016 and January 2017, the digital data collection system recorded 2,445 unique mental health patients across ZL sites. Only a handful of these patients attended multiple facilities concurrently. The digital system was only missing 5 (3.5%) of 143 possible monthly reports across
this period. In comparison, between January 2013 and December 2015, the paper data collection system was missing 45 (11.0%) of 409 possible monthly reports.

When examining concordance between the digital system and paper archives, of 74 forms searched for at the first sampling site, there was concordance for 55 forms (74.3%). Eighteen (24.3%) forms could not be found in the facility archives, and 1 (1.4%) form was found but did not match. For the 50 forms sampled at the second site, there was concordance between originals and the digital system for 49 forms (98.0%). One (2.0%) form was found that did not match the paper original.

Regarding the system’s ability to calculate indicators, all 4 indicators could be calculated. A ZLDSI score was recorded for 1,551 (63.4%) of first encounters and 1,240 (89.7%) visits for depression. Of the encounters for patients with epilepsy, 3,000 (82.5%) documented past month seizure frequency. An AIMS score was recorded for 28 (2%) of visits for patients on antipsychotic medications. These findings led to the identification of 2 new initiatives. The lower proportion of depression screen completion at first encounter for a mental health concern, relative to depression screen completion at follow-up visits for a person with a known depressive disorder, suggested that the role of the depression screen within the ZL health system needed clarification, which was done via retraining integrated into mental health program meetings. Additionally, use of the AIMS for patients prescribed antipsychotic medication was very low, suggesting that this tool was not being used appropriately in clinical encounters and needed retraining, which was done via clinician refresher trainings on medication management of psychotic disorders.

### IMPLEMENTATION CHALLENGES AND STRATEGIES

The team encountered several implementation challenges in deploying the digital data collection system. Psychologists reported concerns that the digital system, which was substantially more detailed than the prior paper-based system, had been built to monitor their work and to assign blame if they did not perform well. Additionally, psychologists initially took an average of 17 minutes to complete a digital form for a single patient encounter. As a result, psychologists reported that they perceived that the digital data collection system would substantially increase their workload. Having retained paper records alongside the digital system to be able to evaluate the validity of the digital system further contributed to this concern, as psychologists and other providers were recording data during patient encounters on paper and then entering summary data at the end of the day digitally. One option would have been to transition to a more efficient point of care digital system, but ZL did not yet have the necessary infrastructure. Psychologists and other providers also continued to benefit from being able to use paper forms during sessions as new staff were hired due to turnover and as the scope of mental health care expanded at ZL to include new clinical skills. As a result, paper forms were retained longer than originally intended, despite the duplication.

To increase psychologists’ buy-in, we took an approach consistent with both change management best practices and training providers in new clinical areas in global health.29,30 Project team members traveled to health facilities to help psychologists with data entry and to provide technical support for several months while providing ongoing supervision and refresher training as one would with a new clinical intervention. The project team also framed data presentations back to psychologists around the system’s strengths, using digitally collected data to reward high-performing individuals at an annual ZL meeting. The emerging ability to systematically examine clinical data, such as the ZLDSI or the AIMS, further demonstrated the utility of the new data collection system to both supervisors and psychologists by enabling them to identify areas in which targeted retraining was needed (e.g., when to use the AIMS). Additional training then helped providers become clearer, more confident, and more skilled in their roles. Over several months, psychologists’ speed of data entry and buy-in increased. The project team also made clear to psychologists from the beginning that this system could and would evolve and psychologists began to share suggestions for future versions. A key piece of psychologist feedback that emerged was to add decision support prompts directly into the data collection system to support in-service training and help remove the need for paper tools and the program team began to work toward this goal.

Another key challenge was created by the rapid increase in patient demand for mental health services at ZL facilities. In 2016, ZL recorded 8,100 mental health patient visits across sites, an increase from 4,696 in 2015, as services became more widely known in the area. As psychologists...
provide care for the majority of patients with mental health concerns at ZL, it became increasingly challenging for them to keep up with clinical duties and also manage the digital data collection system. Though psychologists’ speed in entering data had improved, at the end of 2016, psychologists reported to the project team that they were experiencing difficulty keeping pace with both growing clinical caseloads and data collection. As a result, psychologists were working longer hours and monthly reports were being submitted later than scheduled. The project team became concerned that, even with removing paper forms, managing a growing clinical caseload alongside data collection would lead to psychologist burnout and undermine patient care, as well as missing data and data loss.

Starting in early 2017, a series of conversations were held with key stakeholders from the PIH and ZL mental health teams to begin to generate support for a shift to data clerks, identify funding for these additional staff, and develop job descriptions and training materials. Data clerks were hired in mid-2018 and deployed to each facility to take over digital data collection of mental health data from psychologists.

LESSONS LEARNED

Despite facing implementation challenges, ZL psychologists were able to consistently and electronically collect accurate data about mental health patient encounters at ZL health facilities that could be used to calculate priority indicators that informed decision making. These findings, which are among the first for routine mental health data collection in a low-resource setting, suggest that digital data collection systems can be effective even in very low-resource settings and are consistent with the findings of other implementers.20,31 The challenges experienced, including that the digital data collection system increased workload for what was already a small and resource-limited staff, are consistent with those that have been reported by the few other mental health HMIS projects in LMICs.32–34 The implementation challenges this project faced helped inform several key lessons learned.

Build Provider Buy-In and Capacity With Recognition and Supportive Supervision

The ongoing presence of the project team at health facilities and use of data to recognize high-performing psychologists were key strategies to building psychologist buy-in for and skill using the digital data collection system as initially deployed. Ongoing supportive supervision, while time-consuming, and opportunities for reward to users should be planned from the initial project stages to minimize challenges.

Determine the Role of Maintaining Paper Records

Despite the greater data validity offered by a digital data collection system, systems for paper records may also need to be maintained in low-resource settings. This could be just in the short term to establish the accuracy of a new digital system, as we initially intended with this project, or possibly because there is no other way for patients to access their own records. In this project, it became clear the paper forms helped providers who were new or who were learning new interventions feel more supported. There was a training benefit to maintaining the paper forms longer than initially intended alongside the digital data collection system, just as there was a data quality benefit to introducing the digital data collection system in addition to the paper forms. In the short term, duplicate data entry was shifted to data clerks to help reduce the negative effects of this duplication on psychologists. In the longer term, the integration of decision support prompts directly into the digital data collection system offered a way to remove duplication while still maintaining support for in-service training for task-shared providers. Maintaining paper records for any period of time when introducing a digital data collection system increases workload, and the advantages and disadvantages should be carefully considered by program managers.

Address Staffing Needs

Our experience supports the importance of implementers being realistic about the time needed for data collection and the potentially large and growing caseloads that providers may be taking on in mental health care systems in contexts with otherwise limited access to mental health care.35 Within the ZL system, when introducing the electronic data collection system, there was simultaneously an 83% annual increase in service demand. The decision to shift data collection responsibilities to mental health data clerks was feasible due to existing grants and was essential to prevent psychologist burnout and ensure quality data collection at the time.36 Such a decision may not be needed in other health systems, depending on available staffing and how quickly service demand is growing. Additionally, such a decision to add data
clerks may not be feasible in other settings and may not be sustainable at a larger scale or without external funding. A key lesson for program managers regardless of setting is that it is important to identify who is responsible for collecting mental health data in a given context and ensure that this does not interfere with their other existing clinical duties and other responsibilities. Directly integrating mental health data collection within broader data collection systems that exist or are being developed—which was not possible in our context except for in 1 example where internet was available—would leverage existing resources for mental health and may help address this issue of sustainable staffing.

Offset Financial Costs by Integrating With Existing Data Collection Systems

In addition to the costs of staff time to develop the digital data collection system and enter and manage data, this project also had other costs. Primarily, these were the costs of computers (US $1,300 each) as OpenMRS is free. For the relatively low cost of approximately US$15,000, it was possible to substantially improve mental health data collection. This, in turn, allowed better clinical and programmatic decision making within the ZL care system, enabled ZL to much more clearly describe its impact internally and externally, and facilitated ZL to generate more funding. However, the additional expense of the computers, while manageable at ZL due to existing grant funding, would likely not have been sustainable without external funding and would likely not scale across an entire country due to limited financial resources for mental health.37 We could have used lower-priced tablets or scanner-supported data collection in which paper forms are digitized to help further reduce costs and improve project sustainability and scalability.38,39 Digital data collection innovations developed and deployed by necessity during the coronavirus disease (COVID-19) pandemic may help guide the way in better understanding the effectiveness, feasibility, and acceptability of newer technologies for data collection within mental health care in rural LMICs. Again, integration of mental health data collection directly within other data collection systems and innovations may offer the most financially sustainable and scalable option.

CONCLUSIONS

We have described the development, implementation, and evaluation of a digital data collection system for mental health data in rural Haiti led by psychologists. This is the first data collection system of this type for mental health data in Haiti and represents one of the few routine digital mental health data collection systems tested in an LMIC globally. The primary goal for this system was to improve data collection so that it could facilitate decision making, which was achieved. However, the need to eventually introduce data clerks to ensure both quality psychological care and data collection occurred reveals an important ongoing staffing challenge in mental health data collection in LMICs. Moreover, task-shared providers may need access to paper forms or decision support tools to structure patient interactions. Leveraging lessons learned to identify and test more sustainable and scalable models for mental health data collection that can also support in-service training for task-shared providers represents an important future area of work in global health implementation.

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Author contributions: ALR and DF led the development of the data collection system, evaluation process of the data collection system, and manuscript writing. WD and SFCS led data extraction from health centers to be able to evaluate the data collection system. JRFA, WD, SFCS, SS, GJ, EE, and GR provided substantive contributions to the design process of the data collection system and substantive edits to the manuscript.

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A key lesson is to identify who is responsible for collecting data and ensure that data collection does not interfere with their other responsibilities.
Mental Health Data Collection in Haiti

Développement d’un système innovant de collecte de données numériques dans la prestation de soins routiniers de santé mentale en région rurale haïtienne

En Français

Introduction. Les systèmes de gestion de l’information sanitaire (SGIS) sont reconnus efficaces quand ils étayent la validité des données de santé permettant ainsi aux soignants de prendre des décisions programmatiques et des résolutions nationales au regard des objectifs internationaux de développement. En 2015, la santé mentale a été incluse dans les Objectifs de Développement Durable (ODD), pourtant il existe peu d’applications de SGIS de quelque type que ce soit dans la pratique des soins de santé mentale dans les milieux à ressources limitées. Zanmi Lasante (ZL), l’un des plus grands fournisseurs de soins de santé mentale en Haïti, a développé un système de collecte de données numériques pour la santé mentale à travers 11 établissements sanitaires ruraux. Intervention du programme. Nous décrivons le développement, la mise en œuvre et l’évaluation du système numérique de collecte de données de santé mentale à ZL. Pour évaluer la fiabilité du système, nous avons déterminé le nombre de rapports mensuels manquants. Pour évaluer la validité des données, nous avons calculé la concordance entre le système numérique et les dossiers papier dans deux établissements. Pour évaluer la capacité du système à éclairer la prise de décision, nous avons spécifié et calculé quatre indicateurs prioritaires. Résultats. Il manquait au système numérique 5 des 143 rapports mensuels dans tous les établissements et la concordance avec les dossiers papier était de 74,3% (55/74) et 98% (49/50). Il a été possible de calculer les quatre indicateurs, ce qui a entraîné des changements programmatiques dans deux cas. En réponse aux défis de la mise en œuvre, il a été nécessaire d’utiliser des stratégies pour stimuler la participation des prestataires dans un premier temps et finalement d’introduire des officiers de données dédiés à la saisie régulière des données permettant ainsi aux prestataires de consacrer plus de temps aux activités cliniques. Leçons apprises. Tout en démontrant le potentiel de la collecte de données numériques sur la santé mentale dans un milieu rural à faibles ressources, nous avons constaté qu’il était nécessaire de prendre en compte le rôle continu que joue parallèlement les dossiers papier. Nous avons également identifié le défi d’établir un juste équilibre entre les responsabilités cliniques et celles correspondantes à la saisie des données compte tenu du nombre restreint de personnel. Des efforts réguliers sont nécessaires afin de développer des modèles réellement durables et évolués pour la collecte de données sur la santé mentale dans les milieux à ressources limitées.

Principales conclusions:

- L’équilibre entre le temps consacré aux tâches cliniques et le celui alloué à la saisie des données a été un défi majeur quand les prestataires de soins y sont impliqués.

- L’apport de commentaires sur les données à l’intention des utilisateurs, la supervision continue et les primes de reconnaissance aux acteurs performants peuvent contribuer à augmenter l’adhésion aux nouveaux systèmes de collecte de données.

- Le maintien des supports papier en plus des systèmes de collecte de données numériques ou l’inclusion d’outils d’aide à la décision directement dans les systèmes de collecte de données numériques peut être nécessaire pour soutenir pleinement l’apprentissage des prestataires dans un système de partage de tâches au sein du personnel de santé mental.

Principaux enseignements:

- Les gestionnaires de programme doivent soigneusement considérer une dotation durable en personnel dès la conception des projets de collecte de données numériques.

- Les gestionnaires de programme doivent envisager comment les systèmes de collecte de données numériques peuvent intégrer des outils d’aide à la décision pour soutenir l’apprentissage continu des prestataires partageant des tâches communes.

- Les décideurs devraient intégrer la collecte de données de santé mentale dans d’autres systèmes de données afin de s’assurer de l’infrastructure et des ressources en faveur de la santé mentale.

Peer Reviewed

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Health System Redesign to Shift to Hospital Delivery for Maternal and Newborn Survival: Feasibility Assessment in Kakamega County, Kenya

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Key Findings

- Maternal and newborn health service delivery redesign (MNH redesign) is a policy to shift all deliveries to or close to hospitals.
- Current system assets that support MNH redesign in Kakamega County are the adequate geographic spread of hospitals, close proximity of women to these hospitals, and high provider and user support for the concept.
- Before MNH redesign is implemented in Kakamega County, prevailing health system deficits, like health provider shortages and transportation challenges for mothers, would need to be addressed.

Key Implications

- The county, in partnership with health system researchers, should rigorously evaluate the process of implementing MNH redesign and its impact on health, to learn and test the model and to serve as a base for generalizing uptake across the country.
- Countries that seek to implement MNH redesign would need to similarly assess feasibility to determine the assets and gaps for implementation.

ABSTRACT

Maternal and newborn health (MNH) service delivery redesign aims to improve maternal and newborn survival by shifting deliveries from poorly equipped primary care facilities to adequately prepared designated delivery hospitals. We assess the feasibility of such a model in Kakamega County, Kenya, by determining the capacity of hospitals to provide services under the redesigned model and the acceptability of the concept to providers and users. We find many existing system assets to implement redesign, including political will to improve MNH outcomes, a strong base of support among providers and users, and a good geographic spread of facilities to support implementation. There are nonetheless health workforce gaps, infrastructure deficits, and transportation challenges that would need to be addressed ahead of policy rollout. Implementing MNH redesign would require careful planning to limit unintended consequences and rigorous evaluation to assess impact and inform scale-up.

INTRODUCTION

Maternal and newborn mortality remain high in many low- and middle-income countries (LMICs), with these countries accounting for more than 90% of the global burden. At their current rates of decline, most high-burden countries are unlikely to achieve the Sustainable Development Goals (SDGs) for maternal and child health despite remarkable increases in facility deliveries. Recent studies demonstrate that giving birth in a facility does not necessarily translate to improved outcomes, a phenomenon likely attributable to poor quality. More than half of preventable maternal and neonatal deaths in LMICs are estimated to be due to poor quality care during childbirth rather than lack of facility utilization.

Up to 45% of facility deliveries in LMICs occur in primary care facilities. Many of these primary care facilities lack basic requirements to manage complications arising during delivery, including experienced and specialized staff, supplies, and access to surgical and emergency services, which tend to be available in hospitals. Primary care facilities may also be located far away from advanced care, with limited referral...
options. Thus, improving processes of care in primary care facilities alone is not enough to reduce maternal and newborn mortality. Against this background, the Lancet Global Health Commission on High Quality Health Systems in the SDG Era (the Quality Commission) proposed service delivery redesign, a reorganization of health systems, to optimize outcomes by ensuring that the right care is provided at the right level of the system and by the right provider. For maternal and newborn health service delivery redesign (MNH redesign), this reorganization means all births would occur in hospitals that provide dignified, patient-centered care and immediate, definitive care for complications (including capacity for cesarean deliveries, blood transfusion, and care for sick mothers and newborns), or in nearby affiliated birthing facilities. In this model, primary care facilities would focus on providing quality antenatal and postnatal care and would be linked to hospitals where women would deliver. In addition, physical access to facilities would be improved through better transport or upgrading primary care centers to support women in remote communities, and communities would be included in the design of the reorganized system. Details about the components of MNH redesign, benefits, potential risks, and key implementation considerations have been previously described.

Assessing feasibility is a critical step before embarking on MNH redesign, not only because redesign is a complex health reform but also because its components must be tailored to the specific needs of the local health system and population. In this article, we describe a feasibility assessment conducted in Kakamega County, in western Kenya, to determine the capacity of hospitals to provide services under the redesigned model and the acceptability of the concept to providers and users. Kakamega County is the first setting to embark on service delivery redesign as recommended by the Quality Commission.

## ASSESSMENT PROCESS

### Understanding the Context

Kenya has operated a devolved system of governance since 2010, with 47 semiautonomous counties. Kakamega County is one of the most populous, with a population of approximately 2 million people. Both the maternal mortality ratio in Kakamega, at 316 per 100,000 live births, and the neonatal mortality rate, at 19 per 1,000 live births, are just below Kenya’s average (362 for maternal mortality ratio and 22 for neonatal mortality rate) but well above the SDG targets. Kakamega County is among the top 15 counties with the highest burden of maternal mortality in the country. Kenya will miss the SDG targets for mothers and children at the current rates of decline.

Against this background, the Lancet Global Health Commission on High Quality Health Systems in the SDG Era (the Quality Commission) proposed service delivery redesign, a reorganization of health systems, to optimize outcomes by ensuring that the right care is provided at the right level of the system and by the right provider. For maternal and newborn health service delivery redesign (MNH redesign), this reorganization means all births would occur in hospitals that provide dignified, patient-centered care and immediate, definitive care for complications (including capacity for cesarean deliveries, blood transfusion, and care for sick mothers and newborns), or in nearby affiliated birthing facilities. In this model, primary care facilities would focus on providing quality antenatal and postnatal care and would be linked to hospitals where women would deliver. In addition, physical access to facilities would be improved through better transport or upgrading primary care centers to support women in remote communities, and communities would be included in the design of the reorganized system. Details about the components of MNH redesign, benefits, potential risks, and key implementation considerations have been previously described.

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## Stakeholder Consultations

Given the different stakeholders involved in maternal and newborn care, we used a broad and participatory approach for the feasibility assessment. The core study team consisted of individuals from the Kakamega County Department of Health, Kenya Council of Governors, Kenya Ministry of Health, and Harvard University. Consultations were held with health system managers, health care providers, development and implementing partners, health system researchers, and health care users before the start of the assessment to inform its content and strategy. After the analysis stage, we held discussions with the same stakeholder groups to discuss and interpret the findings, identify additional analysis needs, and determine potential strategies for implementation.

### Feasibility Assessment Components

Through consultation, the study team identified 2 broad domains for the feasibility of MNH redesign in Kakamega County: capacity and acceptability. First, the capacity assessment estimated the geographic proximity of women to delivery care,
assessed the infrastructure and human resource capacity, and identified potential barriers to care in hospitals. Since the relocation of the place of birth is the biggest change in MNH redesign, these analyses focused on hospital capacity. Second, we aimed to assess the acceptability of MNH redesign among health care providers and health care users.

There were 5 major components of data collection and analysis, using a mix of primary and secondary data sources.

1. Geographic analysis: We performed a geographic analysis using the following secondary data: facility geocations were obtained from the Kenya Master Health Facilities List:25 distribution of pregnancies came from WorldPop 2015 projection:25; roads and road classification came from OpenStreetMap:26 publicly available shapefiles were used to map out the landcover, road characteristics, and the administrative boundaries of the county. The geographic analysis was conducted using the WHO’s AccessMod tool.27 We estimated the proportion of pregnancies that were within 2 hours, 1 hour, and 30 mins of a delivery facility (now and under redesign) using motorized transport. Details on the assumptions used in the geographic analysis are included in the Supplement.

2. Facility survey: We conducted a facility survey to assess current facility infrastructure and human resource capacity for maternal and newborn care. Data were collected on administration, infrastructure, health workforce, management and data, clinical services, equipment, materials and supplies, and medicines. All 19 hospitals in the county and a stratified random sample of 30 health centers and dispensaries were selected for inclusion in the survey. This analysis focused on the hospitals since they are the key determinants of the feasibility of the MNH redesign program.

3. Self-administered health care provider survey: We conducted a self-administered health care provider survey to assess knowledge and confidence in the management of key maternal and newborn complications and collect provider perspectives on MNH redesign. A previously validated 60-item survey for testing knowledge on maternal and newborn care formed the base of the knowledge test—recommended pass score: 80%.28 The survey was adapted to fit the Kenyan context. All doctors, clinical officers, and nurses/midwives providing maternal and newborn care on the day of the facility survey were eligible to take part in the survey. A total of 151 providers completed the survey of 160 eligible (response rate=94%).

4. Gap analysis: Descriptive statistics were calculated on infrastructure and human resource capacity, and we conducted gap analyses to determine future needs under redesign. The estimated number of deliveries was projected for the year 2021 using average year-on-year increase between 2014 and 2019 and holding subcounty delivery proportions constant (Supplement). We assessed 2 scenarios for each item of interest. The “near-term” scenario assumed that all facility deliveries would shift to the designated hospitals, but no home deliveries are shifted. The “long-term” scenario assumed that all deliveries in the county (facility and home births) would shift to the designated hospitals. These gap analyses were done at the facility level, and the assumptions used in estimating the human resource and other needs were based on international guidelines, Kenyan national guidelines, and consultations with subject matter experts in Kenya.29–34 (full list of assumptions included in the Supplement).

5. Focus group discussions (FGDs): We held 16 community FGDs with 119 participants across 4 sites (details included in the Supplement) to explore practical barriers to receiving quality care, opportunities for better health system utilization, and to obtain perceptions on MNH redesign. At each site, 1 FGD was held with each of the following groups: (1) women with a recent home delivery; (2) women with a recent facility delivery and other women of reproductive age who have never delivered; (3) mothers-in-law, grandmothers, and traditional birth attendants/birth companions; and (4) husbands and other male community members. A rapid thematic analysis of the discussion notes was done to summarize the FGD findings.

The feasibility assessment, including initial consultations, data collection and analyses, and final consultations, lasted 7 months, from August 2019 to February 2020. As this was a health system quality improvement project, it was deemed exempt from human subject considerations by the Institutional Ethics Review Board of the Masinde
Muliro University of Science and Technology Department of Public Health and by the Harvard University Office of Human Research Administration. All data used for the assessment were deidentified.

**FINDINGS: HOSPITAL CAPACITY IN KAKAMEGA COUNTY**

In consultation with the county health team, the assessment team identified 16 public and faith-based hospitals that could serve as designated delivery hospitals if MNH redesign is implemented in the county. The county decided to focus on these facilities for planning purposes since they already had oversight or contractual relationships with these facilities. As such 3 private for-profit hospitals, along with their 13 surveyed health care providers, were excluded from this initial analysis. However, exclusion of the 3 private for-profit hospitals in the analysis did not significantly change the results. The 16 hospitals together currently conduct more than half of facility deliveries in Kakamega County and are geographically spread among the 12 subcounties (Figure 1).

**Accessibility**

The geographic analysis found that all pregnant women (100%) live within 1 hour of travel of current delivery facilities in Kakamega County and 98% live within 30 minutes. Under MNH redesign, 100% of pregnant women would live within 2 hours of travel of a designated hospital, 99% would live within 1 hour, and 85% within 30 minutes.

The FGDs identified transportation availability and cost as barriers to reaching hospitals. Lack of transportation was worse at night when motorbike riders feared to respond to calls due to the risk of being robbed (motorbikes being the most common means of transportation in the county). When transportation was available, the prices were sometimes prohibitive at night: a trip that would typically cost 100 KES (~US$1) during the day may cost 6 times that at night. A few participants indicated that there was sometimes a preference for home deliveries due to the care and attention provided by traditional birth attendants or for cultural reasons, like the need to bury the placenta in the family home. In these few cases, facility access was limited by cultural and social acceptability rather than by distance, cost, or availability of transportation.

**Infrastructure**

Table 1 displays the existing infrastructure, gaps, and needs under MNH redesign in the 16 designated hospitals. Based on standard occupancy rates and average length of stay (Supplement), we estimated that for the current volume of deliveries in the 16 designated facilities, there are currently 120 excess maternity beds, but that 137 additional beds would be required under the near-term service delivery redesign scenario. The 13 currently functional operating rooms are in 7 of the 16 designated hospitals, and 1 operating room for cesarean deliveries would be required in each of the other designated hospitals under both redesign scenarios. Additional blood transfusion and newborn units would also be required. Additional results on infrastructure are provided in the Supplement.

**Human Resources**

There are currently substantial gaps in the number of health care providers (Table 1). The prevailing human resource gap suggests a heavy workload for health care providers, and only 63% of them thought their current workload was manageable. The number of doctors would need to more than triple under the near-term scenario of MNH redesign and the number of nurses/midwives and clinical officers would need to increase 2.5 times to be able to provide care without being overworked. The findings for anesthetists and pediatricians are included in the Supplement.

Beyond the number of staff, we found that health care providers in hospitals had significantly more experience with managing maternal and newborn complications and expressed greater confidence in managing these complications. For example, only 18% of health care providers in primary care facilities reported managing severe pre-eclampsia/eclampsia in the preceding 12 months, compared to 82% of providers in the designated hospitals. However, scores on the knowledge assessment were low across the board. Doctors, who were only found in the hospitals, performed better, with an average score of 68%, albeit still less than the passing score of 80%. Table 2 reports the findings on provider knowledge, experience, and confidence in managing obstetric and newborn complications.

**FINDINGS: ACCEPTABILITY OF MNH REDESIGN**

Community members (including mothers and other family members) and health workers expressed high support for service delivery redesign.

From the FGDs with community members, the main potential benefit of redesign identified was that delivery in an improved higher-level facility would improve outcomes by reducing the need for referrals.
would improve outcomes by reducing the need for referrals. Another potential benefit mentioned was that improving the quality of maternal and newborn care could have a spillover effect on other facility users, e.g., for surgical care. The main challenge identified was transportation because the nearest designated hospital may now be farther away from women. Other concerns were that there may be overcrowding in the designated hospitals, leading to poor-quality care. Many focus group participants identified disrespect, abuse, and lack of patient-centered care as current problems in health facilities, which was sometimes cited as a reason for some mothers preferring to deliver at home (Box).

From the health care provider surveys, approximately 85% of respondents either strongly agreed or somewhat agreed that MNH redesign would be more effective in reducing maternal and newborn mortality than the current approach in Kakamega County (Figure 2). Most also believed it would be feasible to implement service delivery redesign in the county.

**INTERPRETING THE FINDINGS**

This feasibility assessment found that Kakamega County has a good base of system assets to facilitate a transition to birth in hospitals for all women. There is an adequate distribution of hospitals, health care providers in hospitals demonstrate higher experience with and greater confidence in managing maternal and newborn complications than their counterparts in primary care facilities, and providers and health care users support the idea of MNH redesign. Bottlenecks for MNH redesign include health care provider deficits, health facility infrastructure inadequacies, and transportation challenges.

This assessment shows that hospitals are not distant for most women in Kakamega County, but some women may be excluded from access if concerns about the cost, safety, and ease of reaching a hospital are not addressed.
### TABLE 1. Current Infrastructural and Human Resource Capacity and Gaps for Redesign Across 16 Designated Hospitals, Kakamega County, Kenya

<table>
<thead>
<tr>
<th></th>
<th>Current Available</th>
<th>Current Gap</th>
<th>Gap in Near-Term Redesign Scenario&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Gap in Long-Term Redesign Scenario&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infrastructure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total maternity beds</td>
<td>419</td>
<td>–120&lt;sup&gt;b&lt;/sup&gt;</td>
<td>137</td>
<td>457</td>
</tr>
<tr>
<td>(including delivery beds)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional operating rooms</td>
<td>13</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Facilities providing blood</td>
<td>10</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>transfusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facilities with functional</td>
<td>3</td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>newborn units</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Human resources</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctors&lt;sup&gt;c&lt;/sup&gt;</td>
<td>32</td>
<td>25</td>
<td>110</td>
<td>183</td>
</tr>
<tr>
<td>Clinical officers and</td>
<td>204</td>
<td>183</td>
<td>511</td>
<td>881</td>
</tr>
<tr>
<td>nurses/midwives</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Near-term scenario is the case where deliveries that would have occurred in a facility (45,440 deliveries) are shifted to the 16 designated hospitals, while long-term scenario is the situation in which all deliveries in Kakamega County, both home and facility (72,552 deliveries) are shifted to the 16 redesign facilities. Both scenarios are set in 2021.

<sup>b</sup>This indicates excess capacity of 120 beds.

<sup>c</sup>Includes medical officers (general practitioners) and obstetrician/gynecologists.

### TABLE 2. Health Care Provider Knowledge, Experience, and Confidence in Designated Delivery Hospitals and Sampled Primary Care Facilities, Kakamega County, Kenya

<table>
<thead>
<tr>
<th>Health Care Providers in Primary Care Facilities&lt;sup&gt;a&lt;/sup&gt; (n=65)</th>
<th>Health Care Providers in Designated Hospitals&lt;sup&gt;b&lt;/sup&gt; (n=73)</th>
<th>Comparison (P Value)&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average knowledge scores</td>
<td>54%</td>
<td>57%</td>
</tr>
<tr>
<td>Managed complication in past 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe pre-eclampsia/eclampsia</td>
<td>18%</td>
<td>82%</td>
</tr>
<tr>
<td>Post-partum hemorrhage</td>
<td>57%</td>
<td>89%</td>
</tr>
<tr>
<td>Obstructed labor</td>
<td>38%</td>
<td>67%</td>
</tr>
<tr>
<td>Newborn resuscitation</td>
<td>62%</td>
<td>89%</td>
</tr>
<tr>
<td>All 4 complications</td>
<td>11%</td>
<td>59%</td>
</tr>
<tr>
<td>Very confident in ability to manage complication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe pre-eclampsia/eclampsia</td>
<td>49%</td>
<td>79%</td>
</tr>
<tr>
<td>Postpartum hemorrhage</td>
<td>77%</td>
<td>92%</td>
</tr>
<tr>
<td>Obstructed labor</td>
<td>51%</td>
<td>68%</td>
</tr>
<tr>
<td>Newborn resuscitation</td>
<td>71%</td>
<td>74%</td>
</tr>
<tr>
<td>All 4 complications</td>
<td>28%</td>
<td>45%</td>
</tr>
</tbody>
</table>

<sup>a</sup>Health care providers in primary care facilities include 11 clinical officers and 54 nurses/midwives.

<sup>b</sup>Health care providers in the designated hospitals include 9 doctors, 12 clinical officers, and 52 nurses/midwives.

<sup>c</sup>A 2-sided student t-test was used for the comparison of the knowledge scores and a chi square test was used for the comparison of all the other variables.

<sup>d</sup>A P value < .05 indicates statistical significance.
However, there is still a risk of leaving some women behind if concerns about the cost, safety, and ease of reaching a designated hospital are not addressed. Strategies like voucher programs, which are known to increase utilization in similar settings, could be used to improve access for remote communities. Such a program could be layered on Kakamega’s existing conditional cash transfer program for pregnant women, Oparanyacare, to maximize efficiency and reach.

There is substantial inefficiency in current delivery care in Kakamega County, with the majority (58%) of the 205 delivery facilities each conducting fewer than 1 delivery per week. Aside from quality implications of such low volumes, this represents an inefficient use of scarce health system resources. However, these facilities provide an important primary care function, and antenatal and postnatal care should be enhanced in these facilities as part of the redesign process. The excess of maternity beds suggests other hospital

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**Key Participant Quotations in Focus Group Discussions on Maternal and Newborn Service Delivery Redesign in Kakamega, Kenya**

When you deliver in the hospital you are more “digital”; you are not “analogue”. You are seen to be of high status, and people therefore want to deliver in the facility. —Mother, aged 36 years, with recent home delivery

You would have saved us; it would be very good. If this hospital is set up for delivery, then there would be no delays in accessing care. —Mother, aged 37 years, with a recent home delivery

If that hospital has everything, then you know that you will not be referred to another facility. Every problem will be managed there. You go to [Level 3 facility], there are no drugs, then you go to [non-surgical Level 4 facility] you cannot be helped and then you are sent to CGH (Level 5 facility), and this could take a very long time. —Traditional birth attendant, aged 57 years

Health workers may be a challenge. The health provider may be careless due to overworking. —Mother, aged 39 years, with recent home delivery

Some hope to deliver at home, because at home when you are screaming someone would hold you and support you, but in the facility if you scream no one would come and help you. You do not know anyone in the facility and no one is there to support you. —Mother, aged 28 years, with recent facility delivery

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**FIGURE 2. Health Care Provider Perceptions on Maternal and Newborn Health Service Delivery Redesign, Kakamega County, Kenya**

MNH redesign can reduce maternal and newborn mortality more effectively than current approach in Kakamega County

- Strongly agree: 74%
- Somewhat agree: 11%
- Somewhat disagree: 3%
- Strongly disagree: 9%

MNH redesign is feasible to implement in Kakamega County

- Strongly agree: 58%
- Somewhat agree: 25%
- Somewhat disagree: 7%
- Strongly disagree: 11%

Abbreviation: MNH, maternal and newborn health.

*Percentages may not add up to 100% due to rounding.
departments may also have similar excesses. If this is the case, a reallocation of these excess beds could reduce the need for new investments with MNH redesign. Beyond this, most hospitals would require an infusion of critical inputs, including the construction of new or improvements to existing operating theaters and newborn units before MNH redesign can be rolled out.

Our assessment found significant health worker deficits, both currently and for MNH redesign. Potential sources of new personnel may be to engage doctors on a part-time basis and reassign some of the nurses/midwives in underused primary care facilities, bearing in mind that some may be performing other functions beyond delivery care. MNH redesign would also result in higher economies of scale for designated hospitals, thus relatively fewer health care providers would be needed. Based on the low scores observed, provider knowledge and competence would need to be improved. Expert refresher training, specialist supervision, and linkages with obstetric and pediatric training programs may offer a competence boost in the short turn. Since short-term trainings are less durable in sustaining quality and are difficult to scale, longer-term strategies like reforms to pre-service education would be needed to ensure consistent delivery of quality care.

The FGDs revealed patient concerns about respectful and dignified care in hospitals—a problem that has been highlighted in studies in many LMICs—which is associated with a decreased likelihood of future desire for delivery in the same facility. Respectful, patient-centered care requires policies, training, and investment ahead of the rollout of MNH redesign to enhance user confidence in the health system.

Two key constituents in the Kakamega health system, health care users and health care providers, demonstrated strong support for MNH redesign. Interestingly, the health care providers at the primary care level were as equally supportive of MNH redesign as their counterparts in the hospitals, irrespective of the fact that the critical, and in some sense prestigious, function of providing birth care would be shifted away from them. This may be due to well-documented stresses of providing delivery care without sufficient backup.

**TAKING A DECISION AND NEXT STEPS**

Upon review of the findings of the feasibility assessment, the Kakamega County government has decided to move forward with planning for and implementing MNH redesign. The county plans to roll out the reform in a phased and deliberate manner, starting with 3 of the 12 subcounties. The decision is primarily driven by the county’s ambition to improve outcomes for mothers and newborns, as already demonstrated by the county-level initiative, OparanyaCare. National policies on free maternal care and the push toward universal health coverage are also important supportive contextual factors.

With the decision taken to implement redesign, the next phase of the process is a thorough planning phase. Through this highly participatory planning phase, which includes health system administrators, health care providers, and health care users, and employs a human-centered design approach, the county is outlining the policies, care models, and investments needed to permit the safe rollout of MNH redesign. This includes developing strategies to increase provider numbers and competence within allowed civil service and county budgeting rules and strategies on how to raise funds internally and align development partner funding for the program. Another key consideration at this stage is how the county can ensure that potential risks of this program, including the risk of overmedicalization of births or reducing access for the very remote, can be prevented. Potential strategies that could reduce the risk of overmedicalization include the utilization of midwife-led birthing centers, which are incorporated in or adjacent to designated delivery hospitals. Strategies to address problems with access could include the provision of free transportation, voucher programs, or the establishment of people-centered maternity waiting homes where applicable. With the intended improvement of facilities, another risk is the influx of women from neighboring counties to seek quality birth care in Kakamega county, a situation that can overstretch the infrastructure and health care providers. The county would need to closely monitor delivery volumes when the program is rolled out and prepare a plan to address overutilization. Program costing will also occur at this planning stage; the costing has been completed for the first phase (first 3 subcounties) of implementation. After this planning phase, there will be an improvement phase to address quality, access, and capacity gaps. In this phase, actual health system improvements (in infrastructure, human resource capacity, access, and other sectors) will be undertaken to ensure that the system is ready to support the service delivery redesign program. Only then, after the system has been adequately prepared, would the redesign be implemented.
There is political goodwill to improve maternal and newborn health outcomes, a strong base of stakeholder support, and a good spread of facilities to support implementation. There are nonetheless a health workforce gap, infrastructure deficits, and transportation challenges that would need to be addressed ahead of policy rollout.

This feasibility assessment also shows that there is latent capacity in LMICs to institute systems-level change to accelerate progress toward achieving the SDGs. However, redesign is not a one-size-fits-all policy and will look different in different settings. This makes a feasibility assessment a necessary first step. The feasibility assessment methodology presented in this article provides a blueprint for adaptation for countries that seek to embark on MNH redesign.

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Mid-Upper Arm Circumference Tapes and Measurement Discrepancies: Time to Standardize Product Specifications and Reporting

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Key Messages

- There is no standard mid-upper arm circumference (MUAC) tape specification. Alerted by programmers in Ethiopia, we found using tapes of varied design results in measurement discrepancies and potential for systematic bias.
- This impacts case identification and the number of children eligible for treatment. At-risk children may be excluded from receiving the critical treatment they need.
- While some organizations use corrected tapes to account for design differences, many do not. Tapes used to validate current MUAC thresholds are not reported.
- We propose practitioners report on tape specifications used and call for global standardization of MUAC tape design and examination of possible implications for current MUAC thresholds.

ABSTRACT

In recent years, community-based management of acute malnutrition (CMAM) has revolutionized the care for children by increasing treatment coverage. Critical to the success of CMAM is early case identification. Mid-upper arm circumference (MUAC) measurement is a widely used, practical anthropometric measure used at the community level for the identification and admission of cases to appropriate treatment services. Globally, many organizations and government services use MUAC tapes for early case detection. However, there is no one universal MUAC tape specification, and it has been observed that using different MUAC tapes results in different measurements. In this article, we aim to: (1) present the measurement discrepancies; (2) discuss design specifications and their effect on case identification and admissions; (3) present a call to action to agree on common design specifications and standardized reporting. We hope this article will catalyze discussion and practical actions among nutrition and health stakeholders to ensure we have common MUAC tape design specifications so that all eligible at-risk children will get an equal chance to be identified early for critical treatment.

BACKGROUND

Globally, an estimated 47 million children under age 5 years are wasted and are at increased risk of mortality, morbidity, poor development, and long-term adverse effects (noncommunicable diseases). In recent years, community-based management of acute malnutrition (CMAM) has revolutionized the care for children (aged 6–59 months) by increasing treatment program coverage. Critical to the success of CMAM is early and effective case identification. Combining speed, low cost, ease of use, portability, and strong prognostic performance in identifying children at high risk of mortality/morbidity, mid-upper arm circumference (MUAC) measurement is a common anthropometric measure and is especially useful at the community level to identify and admit cases to appropriate health and nutrition services. MUAC is also recommended as a “reduced physical contact” approach in the context of coronavirus disease (COVID-19). In general, children with a MUAC of less than 115 mm are identified as severely wasted; those with MUAC between 115 mm and 125 mm are moderately wasted.
Globally, many ministries of health, international and national nongovernmental organizations are using MUAC tapes for early case detection in the community. However, there is not one MUAC tape specification, and it has been observed that using different MUAC tapes results in different measurements. In this article, we aim to: (1) present the measurement discrepancies; (2) discuss design specifications and their effect on case identification and admissions; (3) present a call to action to agree on common design specifications and standardized reporting.

### Different Types of MUAC Tapes and Systematic Bias

GOAL, an international humanitarian organization working in 13 countries across Africa, Latin America, and the Middle East, with headquarters in Ireland, is supporting a community-based program that uses MUAC to screen and admit children for wasting treatment in the Gambella refugee camps in Ethiopia. In Gambella, there are multiple screening opportunities (quarterly mass screening led by other organizations and monthly program screening by GOAL). Two types of MUAC (insertion) tapes are being used: type A and type B (Figure 1). A chance observation led us to note that health workers are sometimes faced with the problem of a child recording a MUAC measurement of 126 mm with one tape and the other measures 124 mm. Such cases create a dilemma: should a child be admitted to treatment services or not?

To confirm this measurement discrepancy, researchers at GOAL measured a solid cylindrical object using both type A and type B MUAC tapes. The findings showed a difference of 2 mm (as observed in the community), with type A giving measurement of 167 mm and type B of 165 mm (Figure 2).

Teams at GOAL suspected this discrepancy in measurement was due to the thickness of some tapes not being corrected for during the design process. This prompted a closer examination, which we elaborate on here.

The MUAC measurement is taken around the upper arm and thus, tapes made of thicker material add to the circumference. This leads to systematic bias/differences in MUAC measurements taken using different tapes (Table), unless this is corrected for in tape design—which currently is not the case.

This systematic bias has implications for case identification and admissions to appropriate treatment services. We present the following hypothesized example to simulate possible consequences.

Applying an error-free tape to a population of 10,000 children with a mean MUAC of 142 mm with a standard deviation of 14.5 mm, we would expect (using the PROBIT approach to estimating prevalence) to identify:

\[
\text{PROBIT (115, 142, 14.5)} \div 10000 = 313 \text{ cases}
\]

If we do this using a tape with a 2 mm error, we expect to identify:

\[
\text{PROBIT (115 - 2, 142, 14.5)} \div 10000 = 228 \text{ cases}
\]

This means that the 2 mm error excludes 313 \(- 228 = 85 \text{ children (or 85/313 = 27% of “true” cases) with true MUAC less than 115 mm. This example shows that a 2 mm error, which introduced underestimation of malnutrition, excluded a considerable proportion of children who are at elevated risk of mortality but would be likely to respond rapidly (and with reduced cost) to treatment from which they are excluded due to MUAC tape.

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**Figure 1.** Two Mid-Upper Arm Circumference Tapes. Top: Type A (thickness: 180 microns; width: 17 mm; measurement: the scale measures the outside circumference of the tape); Bottom: Type B (thickness: 280 microns; width: 25 mm; measurement: the scale measures the inside circumference of the tape)
error. These issues indicate the need for global standardization of MUAC tape design. Toward such common global design specifications and standardized reporting, we propose the following recommendations.

1. There should be a fixed thickness of MUAC tape material with this accounted for in the ruler.
2. If organizations choose to use different tape thicknesses than the common recommendation, they should shift the ruler to account for this, ensuring measurement of the true MUAC.

3. Before use, MUAC tapes should be checked against known circumference solid cylinders, preferably ranging from 110 mm–130 mm. This calibration check should be a standard practice as per other medical-grade anthropometric tools.

4. All future work should document which tapes were used, as already reported with weight and length/height measurement scales in research.

5. Finally, since it is not reported which tapes many original MUAC validation studies used,
we also note a need for broader examination of implications for current MUAC thresholds.

**Limitations**

We acknowledge the following limitations. The technical aspects presented in this note are results of observations reported by GOAL staff who spotted the measurement discrepancies in the field. With the observations we had, we could only explore thickness and the position of the measurement scale/ruler. Effects of other design aspects, such as large/small tab, number of “buckles,” tape width, and measuring points/arrows, were not explored. However, some information on these design aspects is presented elsewhere.7

A few organizations (Médecins Sans Frontieres, Action Against Hunger, and GOAL) have developed, tested, and used corrected MUAC tapes that adjust the position of the ruler to account for material thickness and measure the inside circumference of the tape (which is the circumference of the arm being measured). The adjustment is easily calculated using circle geometry (circumference of circle = \(\pi \times \text{diameter}\)).

Since 2019, GOAL has been using a corrected MUAC tape design, with the ruler adjusted to account for material thickness. However, at the time of writing, MUAC tapes produced and distributed by several organizations remain uncorrected.

**CONCLUSION**

We hope this article will catalyze discussions and practical actions among nutrition and health stakeholders with leadership by the relevant United Nations agencies to ensure all eligible at-risk children will get an equal chance to be admitted to timely, appropriate treatment.

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