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Cover caption: Head antenatal nurse Margie Harriet Egessa providing antenatal counseling and checkups for a group of pregnant women at Mukujju clinic in Kenya. © 2014 Jonathan Torgovnik/Getty Images/Images of Empowerment

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COMMENTARY

Health for the People: Past, Current, and Future Contributions of National Community Health Worker Programs to Achieving Global Health Goals

Henry B. Perry,^a Stephen Hodgins^b

Key Messages

- After almost a century of experience, innovation, adaptation, and evidence, national community health worker (CHW) programs are now recognized as one of the most valuable assets for reaching global health goals, including achieving universal health coverage and ending preventable child and maternal deaths by 2030.
- In 2019, the United Nations General Assembly called urgently to accelerate progress in achieving these global health goals recognizing that, at the current pace, these goals will not be achieved for up to one-third of the world's population.
- There is rapidly growing interest not only in CHWs but in community health more broadly, in engagement with communities for improving their own health, and in community-based surveillance for infectious disease outbreaks, especially now that the world is struggling to combat COVID-19 and is likely to face similar pandemics in the future.
- Training more professionalized CHWs with better and longer training, better supervision, improved logistical support, and well-defined career paths, and linking them to lower-level volunteer workers, each serving a small number of households, will help strengthen program effectiveness and improve CHW morale and long-term retention.

INTRODUCTION

The year targeted for achieving the United Nations (UN) Sustainable Development Goals (SDGs)—2030—is now less than a decade away. The health-related SDG3 includes both universal health coverage (UHC) and ending preventable child and maternal

deaths. But, at the current pace, the UN predicts that UHC will not be achieved for up to one-third of the world's population.¹ In 2019, the UN General Assembly unanimously passed a resolution stating that “measurable acceleration is urgently needed” to reach the health-related targets of the SDGs by 2030.¹ The United Nations also estimates that half the world's population (3.8 billion people) lacks access to essential health services.¹ The UN High-Level Commission on Health Employment and Economic Growth estimates a shortfall of 18 million health workers to reach SDG targets.²

Without a major expansion of support for national community health worker (CHW) programs, such an acceleration is unlikely. The Director-General of the World Health Organization (WHO), Dr. Tedros Adhanom Gebreyesus, has affirmed “there will be no UHC without primary health care” (PHC).³ And we would add: in low-income settings, there can be no effective PHC without CHWs. Indeed, the coronavirus disease (COVID-19) epidemic has undermined PHC and health-related development work more generally, making more robust CHW programs that much more important to achieving health and development goals. This has been recognized by the new administration in the United States, with President Biden calling for hiring 100,000 new CHWs as part of his response to the epidemic.⁴

For many decades, governments and their partners—at national and global levels—have been trying to extend health care services and interventions to better reach the whole population, particularly those segments poorly served by existing health services. Clearly, health priorities and available resources vary across settings, but there have been common challenges:

- How to effectively (and efficiently) *make key lifesaving interventions available to the whole population* (e.g., immunizations, insecticide-treated mosquito nets, micronutrient supplementation, among many others)?
- How to overcome the challenges of *distance and geographic barriers* to extend services to segments of the population that cannot easily reach better equipped and staffed health centers and hospitals?

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The COVID-19 epidemic has undermined PHC and health-related development work more generally, making more robust CHW programs that much more important to achieving health and development goals.

- How to *bridge cultural gaps* that may exist between educated health professionals—many originally hailing from urban settings—and those they are to serve?

In many settings, over the years, it has been evident that our current systems and approaches have not been fully able to meet these challenges and that there is a need for some kind of lower-level provider to bridge the gap at the community level.

THE POTENTIAL CONTRIBUTION OF BROADER AND STRONGER NATIONAL CHW PROGRAMS FOR HELPING ACCELERATE PROGRESS TOWARD GLOBAL HEALTH GOALS

For achieving the health-related targets of the SDGs, there are 3 important reasons why CHWs are a better option, in many instances, than relying only on services provided at health facilities.

1. CHWs can be trained and deployed quickly. Although building more PHC facilities and training and deploying physicians, nurses, and other health care professionals is certainly needed, in many cases this by itself will not accelerate progress, in the near term, simply because of the lag time required for training and deploying higher-level workers and building the PHC facilities where they can work.
2. Since CHWs are based in the community, the challenges of geographical access are greatly reduced. Many lower-income countries with dispersed populations have insufficient transportation infrastructure to enable all their citizens to readily access health facilities; people in many rural settings still travel mostly by foot. In such countries, achieving equitable access for all to PHC centers will require the construction and staffing of an extraordinary number of additional facilities. Given the markedly lower use of health facilities among those living more than 45 minutes from a health facility,⁵ in most low- and middle-income countries it will not be feasible, over the short- to medium- term, to achieve 90% population coverage using only PHC center and hospital platforms. Furthermore, even with a marked increase in the number of such facilities, it will remain challenging to recruit and retain the needed medical and nursing staff needed in more isolated areas in low-income countries. In contrast, CHW programs use locally

available human resources; supporting and improving availability of appropriately-trained CHWs would cost less and result in quicker and more significant improvements in access to basic care and to preventive and promotive services.

3. Given current disease burden, more lives of mothers and children can be saved by comparatively simple, community-based interventions than those requiring a PHC center or a hospital. According to recent modeling,⁶ expanding and increasing coverage of services that can be provided by CHWs in the community could avert 2.3 million maternal and child deaths per year. Contrast this with the 0.8 million averted deaths achieved by increasing coverage of services requiring higher-level workers in a PHC facility and 0.9 million by scaling up services requiring hospital-level care.⁶ These estimates do not take into account the additional impact that could be achieved by having CHWs providing family planning services in the community and at household level. Given the well-documented capability of well-supported and supervised CHWs to competently provide family planning services, extending services in this way reduces the unmet need for contraception, with many benefits not only for health but also for other areas of development.⁷

Aside from the well-established role of CHW programs in maternal and child health, it is becoming increasingly evident that CHWs can play an important role in screening and managing non-communicable diseases, such as hypertension and diabetes,⁸ and identifying and following up patients needing basic and essential surgical care, increasingly recognized as a major global health priority.⁹ Task shifting and extending care beyond facilities are critical for increasing health coverage. Furthermore, including CHWs as integral members of PHC teams can potentially strengthen the PHC system and improve quality of care by facilitating access to higher levels of care and following up patients after treatment at a higher-level facility.

The Joint United Nations Program on HIV/AIDS (UNAIDS) has called for urgent new investments to be made in recruiting, training, and deploying 2 million additional CHWs to ensure Africa’s success in ending AIDS as a public health threat and in attaining sustainable health for all of Africa.¹⁰

In a 2018 report,¹¹ the Lancet Global Health Commission on High Quality Health Systems

Including CHWs as integral members of PHC teams can potentially strengthen the PHC system and improve quality of care by promoting more effective use of higher levels of care.

points out that deficiencies in the quality of care provided to patients currently using the health care system are responsible for 5.2 million deaths each year that could be prevented by high-quality health care. Appropriately, the Commission concludes that improving the quality of care in existing health systems is an urgent priority for resource-constrained settings. The Commission did not, however, address the question of how health systems can reduce the 3.2 million deaths that it documents are due to nonutilization of the health system. It is important to recognize that adverse outcomes associated with nonuse are disproportionately concentrated among the poor.¹² Improving the quality of care provided by the existing hospital-centric health system is unlikely, on its own, to be sufficient to ensure universal access or achieve optimal population health outcomes. In most resource-constrained settings, today, facilities are too far away for a significant portion of the population. In low-income settings, recourse to health facility services diminishes exponentially with distance from the facility and declines precipitously at 3 kilometers, or more than a 45-minute walk from the facility.^{5,13} So, equity considerations call for attention to access; CHWs represent an effective and cost-efficient strategy for addressing this challenge.

Numerous studies have documented that those making use of health facility services are better off financially and educationally than the population as a whole¹⁴; prioritizing public investment at health facility-level, particularly if focused on hospitals, disproportionately benefits the better-off. Persisting disparities, by household level of wealth, in coverage of essential maternal-child interventions (as well as other basic health services, including family planning, that CHWs can provide) call for attention not only to the quality of services but also to access, for the poorest segments of society.

With appropriate support, CHWs are able to provide competent lifesaving prevention and treatment services for many conditions (including malaria, postpartum hemorrhage, childhood pneumonia, diarrhea, and acute malnutrition, among many others).¹⁵ They can also direct patients and their families to appropriate sources of care and accompany them to the health facility¹⁶ or facilitate engagement with health services in other ways. CHWs can thus help create greater community trust in the health system.

As Gwatkin et al.¹⁷ observed more than 40 years ago:

Unless services reaches those most in need, even the best-conceived programs can ... have little impact on

mortality. Thus, ... the development of plans for getting services to the people is as important as are decisions concerning which services should be offered.

One might add ... getting basic and essential services to people as important as the quality of those services. In summary, although there is now a well-recognized need for improving the quality of existing services in health systems, improving health outcomes at the scale of whole populations will also require improved access, which can be achieved through robust CHW programs.

■ THE NEED TO INVEST MORE IN NATIONAL CHW PROGRAMS

The UN has determined that UHC will be required to achieve all the SDGs by 2030, not just health-related SDG3, and that to achieve UHC, governments will need to invest an additional 1% of their GDP in expanding and strengthening their PHC systems.¹⁸ The UHC conceptual framework focuses on financial “coverage” of the costs of clinical services. However, the concept of UHC also needs to be understood to include the provision of essential preventive, promotive, and curative services to everyone requiring them, particularly those with the greatest needs. To expand access to essential services a significant proportion of the investment at the PHC level needs to be directed to strengthening national CHW programs, generally with free provision of services. These services need to specifically target the poor and socially vulnerable and those living in more remote locations. CHWs represent a key strategy to reduce health inequities.

However, despite robust evidence of the effectiveness of CHWs in delivering high-impact interventions,¹⁵ country investments in such programs, to date, are only a small fraction of what has been spent on PHC more broadly. Furthermore, only 2.5% of official development assistance for health over the past decade has specifically targeted CHW programs and fully two-thirds of this has been for vertical programs related to HIV/AIDS, malaria, TB, reproductive health, or family planning.¹⁹ A recent report from the Center for Accelerating Innovation and Impact and the Financing Alliance for Health estimated that an additional US\$2 billion is needed annually to build and strengthen CHW programs in sub-Saharan Africa, alone.²⁰

Finally, national CHW programs are beginning to garner the attention and recognition they deserve, as an integral component of PHC.²¹ In

To expand access to essential services, a significant proportion of the investment at the PHC level needs to be directed to strengthening national CHW programs, generally with free provision of services.

Over the years, important lessons from earlier national CHW program experiences had often been ignored.

2018, the WHO adopted the *WHO Guideline on Health Policy and System Support to Optimize Community Health Worker Programs*.^{22,23} The following year, the World Health Assembly passed an historic resolution on CHWs, highlighting their role in ensuring “that UHC and comprehensive health services reach difficult-to-access areas and vulnerable populations,” and in “advancing equitable access to safe, comprehensive health services.” The Assembly called on member states to “optimize” community health worker programs as part of the global strategy to achieve UHC and SDG3.²⁴

■ THE NEED FOR MORE INFORMATION ABOUT NATIONAL CHW PROGRAMS

Despite their importance, information currently available on national CHW programs is sparse and not easily accessed. In 2010, the Global Health Workforce Alliance and the WHO released a comprehensive report on the global experience with national CHW programs, which included a systematic review of literature on this topic and a set of 8 case studies, 3 from Africa, 3 from Asia, and 2 from Latin America.²⁵ In 2014, a group of experts produced a guide on developing and strengthening CHW programs at scale, which drew heavily on lessons from large-scale CHW programs.²⁶ In 2017, this group produced a set of 13 case studies of national CHW programs.²⁷ The program Advancing Partners and Communities subsequently produced a series of case studies of 25 national CHW programs, with a particular focus on family planning and HIV/AIDS services.²⁸ More recently, informative case studies have been developed on several national CHW programs.²⁹

Over the years, many countries have made use of community-level providers to extend the reach of their health services. Through the 1960s and 1970s, the largest-scale program efforts in global health focused on specific infectious diseases—malaria, smallpox, and TB—and it was common to employ locally recruited outreach workers who were quickly trained and deployed for program-specific, community-level work; there were few large-scale examples of integrated CHW programs (China’s barefoot doctor program being a notable case).³⁰ In various regions of the world there were, however, small-scale, NGO-run programs (e.g., Jamkhed^{31,32} and SEARCH/Gadchiroli^{33–35}, both in India) that were having notable health impact and exemplified key principles that could inform larger-scale efforts. A vital insight was that community-level workers needed to be: (1) accepted and respected by the community; and (2) well-connected to and

supported by the PHC system, including reliably supplied with needed commodities.

The 1978 Declaration of Alma-Ata marked a global-level recognition of the potential for CHWs to serve as a foundation for PHC. Inspired by this vision, beginning in the early 1980s, many countries established national CHW programs. However, over the years, important lessons from earlier national CHW program experiences were often ignored. Instead, many saw CHWs as a panacea, a way of delivering PHC on the cheap. As a result, many programs were inadequately supported and experienced high attrition.³⁶ By the late 1980s, the pendulum had swung away from CHW programs. Two seminal books—*The Community Health Worker: Effective Programs for Developing Countries*³⁷ and *Community Health Workers in National Programs*³⁸—cast a sharp critical eye, drawing lessons from large-scale CHW programs implemented over the preceding decade. Both books drew attention to systems support needed for CHW programs to be effective as a part of robust PHC services operating at scale.

In the following decades, there have been further cycles of waxing and waning of enthusiasm for CHW programs. Today, it is recognized that CHWs have potential to play an important role in PHC and to contribute to more rapid progress in population health status improvements. Certainly, as we have seen in the past, shifting tasks or functions typically assumed by physicians or other highly trained professionals to auxiliary health workers and CHWs can make such services available to segments of the population that otherwise have considerable difficulty accessing care. CHW and health auxiliary programs have played and will continue to play an important role in delivering key interventions to rural populations, including: immunization, antenatal and postnatal care, family planning, management of childhood illness, malaria prevention and treatment, and nutrition-related services. However, with urbanization, rising levels of education, technological innovations (notably the now nearly universal use of cell phones), and an epidemiologic shift toward a proportionally greater burden of noncommunicable diseases, the needs of the population and optimal strategies to address those needs will continue to evolve.

CHWs should not be seen as a stopgap; they can and should be a key strategy for strengthening PHC. Although we may think of these programs as a strategy for low-income countries, there are many examples of CHWs playing helpful roles in high-income countries, as brokers between the community and health services.^{39,40} CHWs can

CHWs should not be seen as a stopgap; they can be part of strategies for the future of PHC.

be part of strategies for the *future* of PHC. The need for community-level workers for the response to the current COVID-19 pandemic is a case in point. As we noted earlier, this has been recognized at the highest levels, with U.S. President Joseph Biden having recently called for the hiring of 100,000 CHWs to support the COVID-19 response in the US.⁴

In global health, we see ourselves as making evidence-based decisions, but an important type of evidence is often neglected: evidence arising from past (and current) *program experience*. As a consequence of this blind spot, we fail to apply insights garnered from analogous experiences in other settings, and we unnecessarily repeat mistakes or struggle, reinventing the wheel.

■ RECENTLY RELEASED COMPENDIUM OF NATIONAL CHW CASE STUDIES

A recently-released resource, *Health for the People: National Community Health Worker Program from Afghanistan to Zimbabwe*,⁴¹ provides insights into national CHW programs—their structure, their achievements, and the challenges they face. This book comprises 29 case studies of national CHW programs from: Afghanistan, Bangladesh (BRAC's world-renowned CHW program being the 1 non-governmental organization program included), Brazil, Ethiopia, Ghana, Guatemala, India, Indonesia, Iran, Kenya, Liberia, Madagascar, Malawi, Mozambique, Myanmar, Nepal, Niger, Nigeria, Pakistan, Rwanda, Sierra Leone, South Africa, Tanzania, Thailand, Uganda, Zambia, and Zimbabwe. Each case study has at least 1 author who has personal in-country experience with the program described and follows a common format, helping facilitate comparisons across cases. The case studies look at a mix of CHW types, from the more professionalized end of the spectrum to less formalized community health volunteer programs. The programs described are drawn from diverse regions and both low- and middle-income countries. The publication is timely, given the growing interest not only in CHWs but also in community health services more broadly, in engaging communities for improving their own health, and in community-based surveillance and other forms of support for priority infectious disease outbreaks (especially now as we struggle to combat COVID-19).

Insights From Country Program Experiences

As is evident on review of these program case studies, the circumstances across these 29 countries vary considerably regarding:

- Geographic and demographic factors
- Responsibilities assumed by CHWs
- Robustness of government health services and their support systems
- Role of private providers

There is no single, one-size-fits-all model for CHW programs. Some employ full-time paid CHWs, others offer allowances and other incentives and expect only part-time service, and yet others engage volunteers having only intermittent functions (e.g., as mobilizers or distributors in twice-annual child health days). In almost all the programs reviewed, part of the role the CHW serves is as an intermediary between the community and the government PHC system, encouraging and supporting use of these services as well as adoption of healthy practices (e.g., exclusive breastfeeding and use of insecticide-treated nets). In some programs, CHWs play a role dispensing or resupplying health-related commodities (e.g., oral contraceptive pills, sachets of oral rehydration salts, or micronutrient supplements). In other programs, CHWs have assumed responsibility for functions—under task shifting⁴²—that are normally performed by more highly trained health workers, including assessing for and treating childhood illness and administering injectable contraceptives. Especially for communities lacking easy access to facility-based services, provision of such services through CHW outreach can help close an important coverage gap. Also, offering comparatively simple services at the community level (for example, resupplying oral contraceptive pills or antenatal iron supplements) can relieve some of the volume of clients who could otherwise overburden health centers.

Program experience has shown, nevertheless, that even simple community-based services provided by volunteers or very modestly compensated CHWs can only be reliably delivered if there are functional support systems, and these require a significant financial commitment.

Review of the programs documented in this set of case studies reveals that all of these programs exist in dynamic, evolving health systems, many of which are quite pluralistic. As education levels rise, in many countries there are increasing numbers of credentialed health workers available that can be deployed to peripheral-level health services where, previously, only minimally trained CHWs were serving. Necessarily, this has resulted in evolving roles of the various categories of health workers and CHWs present. Epidemiologic and

Program experience has shown that even simple community-based services provided by CHWs can only be reliably delivered if they are adequately supported, requiring functional systems and significant financial commitment.

demographic transitions have also resulted in new roles for such workers, including important, previously neglected conditions such as noncommunicable diseases and mental health. As we have noted, private providers are now an important source of health services in many countries where CHW programs are active. In some countries, there are private sector providers, recognized as “village doctors,” “rural medical practitioners,” “patent medicine vendors,” or “medicine shop providers,” who may have the same training and credentials as government CHWs or auxiliary health workers, and may—in fact—be engaged in dual practice, working both in the private sector and in government PHC services. Effective strategies at the community level need to take into account the real situation on the ground rather than be based on an assumed, hypothetical situation. In some countries, ministries of health and development partners have actively engaged with private and informal sector providers, often complementing efforts undertaken through CHW programs. Under social-marketing and social-franchising schemes, for example, the presence of such providers has been leveraged for a range of programs.^{43,44}

■ TOWARD A FUTURE AGENDA

There are many reasons to be optimistic that large-scale CHW programs are at the dawn of a new era. Drawing lessons from programs documented in the recently released compendium of national CHW case studies, and others, we and our broader team have developed a soon-to-be published journal supplement that identifies important challenges to be overcome for these programs to reach their full potential. The summary article⁴⁵ calls for:

1. Broader recognition of the value of CHW programs as the foundation of effective health system function and greater respect for CHWs as indispensable members of the PHC team
2. Funding that is steady, growing, sustainable and progressively less donor-dependent
3. Better remuneration for CHWs
4. Stronger supervision and logistical support
5. Rigorous ongoing monitoring and evaluation and independent academic research to support continuous improvement
6. Allocation of broader CHW roles and tasks that CHWs can competently perform (as confirmed by rigorous evaluation), including for

noncommunicable diseases as well as for surveillance, detection of disease outbreaks, vital events registration, and care navigation (by accompanying patients for services at facilities) and expansion of the number of CHWs to prevent work overload and ensure population coverage

7. Greater flexibility in programming to respond to local health needs that are identified by working in partnership with communities

Achieving these conditions for optimal program effectiveness will require the cultivation of strong leadership within countries as well as greater recognition within the global health community that the expansion and strengthening of CHW programs are critical for achieving the SDGs and other global health goals, including “Health for All.”

Given that CHWs have long been seen as a promising resource for strengthening health care in resource-constrained settings, on what basis do we propose that we are on the threshold of a new era for CHW programs? We argue that several historical trends are now converging that will enable CHW programs to cross the threshold.

There is extensive research evidence¹⁵ and national experience from exemplar countries, such as Bangladesh, Brazil, Ethiopia,²⁹ and Nepal,⁴⁶ demonstrating that CHWs can and, in fact, do make important contributions to population health improvement. Furthermore, given persisting inequities in health outcomes and service utilization between and within countries, fundamental health systems changes are needed for current and future global health goals to be achieved. CHW programs should not be dismissed as merely a temporary solution for a problem in low-income settings that will go away (i.e., to reduce the burden of disease among mothers and children and from communicable disease). Instead, such programs must be recognized as an important permanent element needed for any health system anywhere to achieve its full potential. Indeed, this acknowledgement is reflected in the growing use of CHWs in middle-income countries such as Brazil⁴⁷ and high-income countries such as the United States.⁴⁸ Finally, the COVID-19 pandemic has made it abundantly clear—as did the 2013–2016 Ebola outbreak in West Africa⁴⁹—that CHWs have a critical role to play in surveillance, case detection and effective frontline response.⁵⁰ They will have a critical role to play in COVID-19 vaccination efforts. National CHW programs are being proposed for Great Britain and the United States in part to respond to the current crisis but also to provide a

permanent new cadre of health workers to address other unmet health needs.^{4,51}

CONCLUSION

Small, innovative, proof-of-concept programs can certainly generate rich and important lessons; indeed, such programs served as inspiration for the 1978 Declaration of Alma-Ata. However, programs at national scale face a different set of challenges. For that reason, case studies of such programs—providing useful information on CHW roles and performance, as well as on context and systems support—can be particularly relevant and useful for national-level policy makers and program managers concerned about delivery of services to whole populations.

Although there has been increased attention to CHW programs over the past several years, challenges remain in ensuring adequate systems support for CHWs. Despite nearly a century of experience, we continue to struggle with how to define, deploy, and support such health workers. Almost 30 years ago, in his introduction to a series of case studies of national CHW programs, Stephen Frankel wrote³⁶:

There is no longer any place for discussion of whether CHWs can be key actors in achieving adequate health care. The question is how to achieve their potential.

His statement is equally true today.

CHWs count. It is time, now, for governments and UN agencies to: enumerate CHWs—together with doctors, nurses, and allied health personnel—in their official health statistics; ensure they are reflected in national planning for human resources for health, including provision of adequate numbers of CHWs; and give priority to supervisory, logistical, and other needed support for these programs.

Despite the obstacles these programs have often faced, the future for CHW programs appears to be bright. Finding new sources for financing will be important for building stronger programs. Training more professionalized CHWs, providing better supervision, strengthening logistical support, offering well-defined career paths, and (in some settings) linking them to lower-level volunteer workers, each serving a small number of households, will result in more effective programs and improved CHW morale and retention.

The time for national CHW programs as an underfunded afterthought has passed. Millions of lives are at stake.

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REFERENCES

1. United Nations General Assembly. Resolution adopted by the General Assembly on 10 October 2019: Political declaration of the high-level meeting on universal health coverage. 2019. Accessed January 22, 2021. <https://undocs.org/en/A/RES/74/2>
2. High-Level Commission on Health Employment and Economic Growth. *Working for Health and Growth: Investing in the Health Workforce*. World Health Organization; 2016. Accessed January 22, 2021. <https://apps.who.int/iris/bitstream/handle/10665/250047/9789241511308-eng.pdf>
3. Ghebreyesus T. Address by Dr. Tedros Adhanom Ghebreyesus, Director-General. 2019. Accessed January 22, 2021. http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_3-en.pdf
4. Cohen J, Wadman M. Biden proposes a science-led New Deal to end pandemic suffering. *Science*. January 15, 2021. [CrossRef](#)
5. Tanser F, Gijsbertsen B, Herbst K. Modelling and understanding primary health care accessibility and utilization in rural South Africa: an exploration using a geographical information system. *Soc Sci Med*. 2006;63(3):691–705. [CrossRef](#). [Medline](#)
6. Black RE, Taylor CE, Arole S, et al. Comprehensive review of the evidence regarding the effectiveness of community-based primary health care in improving maternal, neonatal and child health: 8. summary and recommendations of the Expert Panel. *J Glob Health*. 2017;7(1):010908. [CrossRef](#). [Medline](#)
7. Scott VK, Gottschalk LB, Wright KQ, et al. Community health workers' provision of family planning services in low- and middle-income countries: a systematic review of effectiveness. *Stud Fam Plann*. 2015;46(3):241–261. [CrossRef](#). [Medline](#)
8. Mishra SR, Neupane D, Preen D, Kallestrup P, Perry HB. Mitigation of non-communicable diseases in developing countries with community health workers. *Global Health*. 2015;11(1):43. [CrossRef](#). [Medline](#)
9. Meara JG, Leather AJM, Hagander L, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. *Lancet*. 2015;386(9993):569–624. [CrossRef](#). [Medline](#)
10. United Nations Joint Programme on HIV/AIDS (UNAIDS). *2 Million African Community Health Workers*. UNAIDS; 2017. Accessed January 22, 2021. https://www.unaids.org/sites/default/files/media_asset/African2mCHW_en.pdf
11. Kruk ME, Gage AD, Arsenault C, et al. High-quality health systems in the Sustainable Development Goals era: time for a revolution. *Lancet Glob Health*. 2018;6(11):e11196–e1252. [CrossRef](#). [Medline](#)
12. Gilson L, Doherty J, Loewenson R, Francis V. *Challenging Inequity Through Health Systems: Final Report*. Knowledge Network on Health Systems. WHO Commission on the Social Determinants of Health and Equinet; 2007. Accessed January 22, 2021. https://www.researchgate.net/publication/242476124_Challenging_Inequity_Through_Health_Systems
13. Wong KLM, Benova L, Campbell OMR. A look back on how far to walk: systematic review and meta-analysis of physical access to skilled care for childbirth in sub-Saharan Africa. *PLoS One*. 2017;12(9):e0184432. [CrossRef](#). [Medline](#)
14. Barros AJD, Ronsmans C, Axelson H, et al. Equity in maternal, newborn, and child health interventions in Countdown to 2015: a retrospective review of survey data from 54 countries. *Lancet*. 2012;379(9822):1225–1233. [CrossRef](#). [Medline](#)

15. Perry HB, ed. *Engaging Communities for Improving Mothers' and Children's Health: Reviewing the Evidence of Effectiveness in Resource-Constrained Settings*. Edinburgh University Global Health Society; 2017. Accessed January 22, 2021. https://issuu.com/laser-plus/docs/engaging_communities_for_improving_m
16. Carrasco H, Napier H, Giber D, et al. Accompanimeter 1.0: creation and initial field testing of a tool to assess the extent to which the principles and building blocks of accompaniment are present in community health worker programs. *Glob Health Action*. 2019;12(1):1699348. [CrossRef](#). [Medline](#)
17. Gwatkin DR, Wilcox JR, Wray JD. *Can Health and Nutrition Interventions Make a Difference?* Overseas Development Council; 1980.
18. World Health Organization (WHO). Countries must invest at least 1% more of GDP on primary health care to eliminate glaring coverage gaps. News release. September 22, 2019. Accessed January 22, 2021. <https://www.who.int/news-room/detail/22-09-2019-countries-must-invest-at-least-1-more-of-gdp-on-primary-health-care-to-eliminate-glaring-coverage-gaps>
19. Lu C, Palazuelos D, Luan Y, et al. Development assistance for community health workers in 114 low- and middle-income countries, 2007–2017. *Bull World Health Organ*. 2020;98(1):30–39. [CrossRef](#). [Medline](#)
20. U.S. Agency for International Development (USAID). *Strengthening Primary Health Care through Community Health Workers: Closing the \$2 Billion Gap*. USAID; 2018. Accessed January 22, 2021. https://www.usaid.gov/sites/default/files/documents/1864/USAID_FAH_Report_digital_version_nov21-508.pdf
21. Schneider H, Okello D, Lehmann U. The global pendulum swing towards community health workers in low- and middle-income countries: a scoping review of trends, geographical distribution and programmatic orientations, 2005 to 2014. *Hum Resour Health*. 2016;14(1):65. [CrossRef](#). [Medline](#)
22. World Health Organization (WHO). *WHO Guideline on Health Policy and System Support to Optimize Community Health Worker Programmes*. WHO; 2018. Accessed January 22, 2021. <https://apps.who.int/iris/bitstream/handle/10665/275474/9789241550369-eng.pdf>
23. Cometto G, Ford N, Pfaffman-Zambruni J, et al. Health policy and system support to optimise community health worker programmes: an abridged WHO guideline. *Lancet Glob Health*. 2018;6(12):e1397–e1404. [CrossRef](#). [Medline](#)
24. World Health Assembly. Community health workers delivering primary health care: opportunities and challenges. World Health Assembly; 2019. Accessed January 22, 2021. https://apps.who.int/gb/ebwha/pdf_files/EB144/B144.R4-en.pdf
25. Bhutta ZA, Lassi ZS, Pariyo G, Huicho L. *Global Experience of Community Health Workers for Delivery of Health Related Millennium Development Goals: A Systematic Review, Country Case Studies, and Recommendation for Integration into National Health Systems*. World Health Organization and the Global Health Workforce Alliance; 2010. Accessed January 22, 2021. <https://chwcentral.org/wp-content/uploads/2013/07/Global-Experience-of-Community-Health-Workers-for-Delivery-of-Health-Related-Millennium-Development-Goals.pdf>
26. Perry H, Crigler L, Hodgins S. *Developing and Strengthening Community Health Worker Programs at Scale: A Reference Guide and Case Studies for Program Managers and Policy Makers*. Maternal and Child Health Integrated Program; 2014. Accessed January 22, 2021. http://www.mchip.net/sites/default/files/mchipfiles/CHW_ReferenceGuide_sm.pdf
27. Perry H, Zulliger R, Scott K, et al. *Case Studies of Large-Scale Community Health Worker Programs: Examples from Afghanistan, Bangladesh, Brazil, Ethiopia, India, Indonesia, Iran, Nepal, Niger, Pakistan, Rwanda, Zambia, and Zimbabwe*. Maternal and Child Health Integrated Program; 2017. Accessed January 22, 2021. https://www.mcsprogram.org/resource/case-studies-large-scale-community-health-worker-programs-2/?_sfm_resource_topic=community-health
28. Advancing Partners & Communities. Community Health Systems Catalog. 2019. Accessed January 22, 2021. <https://www.advancingpartners.org/resources/chsc>
29. Exemplars in Global Health. Community Health Workers. 2020. Accessed January 22, 2021. <https://www.exemplars.health/topics/community-health-workers>
30. Sidel VW. The barefoot doctors of the People's Republic of China. *N Engl J Med*. 1972;286(24):1292–1300. [CrossRef](#). [Medline](#)
31. Perry HB, Rohde J. The Jamkhed Comprehensive Rural Health Project and the Alma-Ata vision of primary health care. *Am J Public Health*. 2019;109(5):699–704. [CrossRef](#). [Medline](#)
32. Jamkhed Comprehensive Rural Health Project. Accessed January 22, 2021. <http://jamkhed.org/>
33. Society for Education and the Advancement of Research in Connected Health. 2020. Accessed January 22, 2021. <https://searchsociety.org/>
34. Bang AT, Bang RA, Tale O, et al. Reduction in pneumonia mortality and total childhood mortality by means of community-based intervention trial in Gadchiroli, India. *Lancet*. 1990;336(8709):201–206. [CrossRef](#). [Medline](#)
35. Bang AT, Bang RA, Reddy HM. Home-based neonatal care: summary and applications of the field trial in rural Gadchiroli, India (1993 to 2003). *J Perinatol*. 2005;25 Suppl 1:S108–S122. [CrossRef](#). [Medline](#)
36. Strodel RJ, Perry HB. The National Village Health Guide Scheme in India: lessons four decades later for community health worker programs today and tomorrow. *Hum Resour Health*. 2019;17(1):76. [CrossRef](#). [Medline](#)
37. Frankel S, ed. *The Community Health Worker: Effective Programmes for Developing Countries*. Oxford University Press; 1992.
38. Walt G. *Community Health Workers in National Programmes: Just Another Pair of Hands?* The Open University Press; 1990.
39. Perry HB, Zulliger R, Rogers MM. Community health workers in low-, middle-, and high-income countries: an overview of their history, recent evolution, and current effectiveness. *Annu Rev Public Health*. 2014;35(1):399–421. [CrossRef](#). [Medline](#)
40. Task Force on Global Advantage. *The Task Force on Global Advantage Report*. Arnhold Institute for Global Health; 2018. Accessed January 22, 2021. <https://icahn.mssm.edu/files/ISMMS/Assets/Research/Arnhold/TheTaskForceonGlobalAdvantageReport.pdf>
41. Perry H. *Health for the People: National Community Health Programs from Afghanistan to Zimbabwe*. Maternal and Child Survival Program; 2020. Accessed January 22, 2021. https://pdf.usaid.gov/pdf_docs/PA00WKKK.pdf
42. World Health Organization (WHO). *WHO Recommendations: Optimizing Health Worker Roles to Improve Access to Key Maternal and Newborn Health Interventions through Task Shifting*. WHO; 2012. Accessed January 22, 2021. http://apps.who.int/iris/bitstream/10665/77764/1/9789241504843_eng.pdf
43. Awor P, Miller J, Peterson S. Systematic literature review of integrated community case management and the private sector in Africa: relevant experiences and potential next steps. *J Glob Health*. 2014;4(2):020414. [CrossRef](#). [Medline](#)
44. Montagu D, Goodman C. Prohibit, constrain, encourage, or purchase: how should we engage with the private health-care sector? *Lancet*. 2016;388(10044):613–621. [CrossRef](#). [Medline](#)
45. Perry H, Crigler L, Kok M, et al. Community health workers at the dawn of a new era: 11. Leading the way to “Health for All”. *Health Res Policy Syst*. 2020; (forthcoming).

46. Ban B, Shrestha A, Khanal L, Perry H, Hodgins S. Nepal's community health worker system. In: Perry H, ed. *National Community Health Programs: Descriptions from Afghanistan to Zimbabwe*. USAID/Jhpiego/Maternal and Child Survival Program; 2020. Accessed January 22, 2021. <https://chwcentral.org/national-community-health-worker-programs-descriptions-from-afghanistan-to-zimbabwe/>
47. Macinko J, Harris MJ. Brazil's family health strategy—delivering community-based primary care in a universal health system. *N Engl J Med*. 2015;372(23):2177–2181. [CrossRef](#). [Medline](#)
48. Lapidus A, Lapedis J, Heisler M. Realizing the value of community health workers — new opportunities for sustainable financing. *N Engl J Med*. 2019;380(21):1990–1992. [CrossRef](#). [Medline](#)
49. Perry HB, Dhillon RS, Liu A, et al. Community health worker programmes after the 2013–2016 Ebola outbreak. *Bull World Health Organ*. 2016;94(7):551–553. [CrossRef](#). [Medline](#)
50. Ballard M, Bancroft E, Nesbit J, et al. Prioritising the role of community health workers in the COVID-19 response. *BMJ Glob Health*. 2020;5(6):e002550. [CrossRef](#). [Medline](#)
51. Haines A, de Barros EF, Berlin A, Heymann DL, Harris MJ. National UK programme of community health workers for COVID-19 response. *Lancet*. 2020;395(10231):1173–1175. [CrossRef](#). [Medline](#)
52. World Health Organization, United Nations Children's Fund. Declaration of Alma-Ata. 1978. Accessed January 22, 2021. http://www.who.int/publications/almaata_declaration_en.pdf

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Global Access to Technology-Enhanced Medical Education During the COVID-19 Pandemic: The Role of Students in Narrowing the Gap

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Key Messages

- The COVID-19 pandemic has severely affected medical education worldwide. With clinical placements suspended and social distancing rules in place, medical education institutions transitioned to online education to compensate for canceled in-person teaching.
- Although some institutions in high-income countries had the residual capacity to shift their education model to eLearning, educational institutions in low- and middle-income countries may have struggled to fully implement novel solutions due to obstacles such as slow and unstable bandwidth, limited access to computer facilities, and insufficient funding to develop online platforms.
- Some solutions have been postulated, but this issue has yet to be addressed. We argue that medical students have the responsibility to advocate for national and international collaboration to accelerate the adoption of technology-enhanced learning and hybrid teaching models globally.

IMPACT OF COVID-19 PANDEMIC ON MEDICAL EDUCATION

The coronavirus disease (COVID-19) pandemic caused global disruption across all industries, resulting in nearly 72 million cases worldwide and more than 1.6 million deaths as of this writing.¹ Due to the rapid spread of the illness in teaching hospitals and shortages in personal protective equipment, medical education was severely impacted. Clinical rotations were suspended, electives were canceled, and pre-clinical teaching had to be delivered remotely. In a survey distributed among final year medical students in the United Kingdom, more than 70% of respondents reported having their clinical placements canceled, and almost 50% had their final exams conducted in an altered format.² Moreover, both international and national electives were called off, and pre-clinical teaching moved online.³ The General Medical Council, British Medical Association, and Medical Schools Council have expressed their concerns over the disruptions that the COVID-19 pandemic has caused for medical students in progressing through their studies and qualifying as doctors.

The disruptive effect of COVID-19 has been particularly severe for senior medical students whose teaching takes place mostly in clinical settings. The COVID-19 pandemic created a demand for digital resources to compensate for in-person teaching that was canceled due to social distancing requirements and the unavailability of clinical faculty.⁴ However, the technological transformation of medical education requires significant human and financial resources, which can be difficult to aggregate and mobilize when faced with a challenge like the COVID-19 pandemic.

Despite the limitations caused by the COVID-19 pandemic, a vast array of technology-enhanced learning (TEL) solutions was successfully introduced in high-income countries (HICs) in a very short time frame. Webinars conducted via Zoom, Skype, Google Hangouts, or WebX; online learning platforms; mobile applications; 3-dimensional anatomy models; and online question banks were implemented within the pre-existing infrastructure, thus facilitating their adoption.

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Examinations were altered to comply with the social distancing guidelines and were carried out as online tests, oral tests via teleconferences, and assessments of simulated tasks using video recordings. Moreover, novel approaches were developed to compensate for the lack of direct patient contact, including online video libraries of patient encounters and virtual consultation rooms.⁶

It is important to note that the majority of research on the implementation of TEL during the COVID-19 pandemic has been based on HIC experiences, and as such, solutions described might not be applicable in low-resource settings.⁷ An analysis of articles about medical education that were published during the first wave of the pandemic has revealed that of 28 articles that discussed TEL, only 2 had a first author based in a low- and middle-income country (LMIC). Thus, the overall positive conclusions of the HIC-focused articles might not be applicable to other settings. However, it is worth remembering that TEL is not devoid of limitations and poses challenges to both students and faculty in any setting. Although implementing TEL proves demanding in HICs, such a rapid adjustment can be extremely difficult in LMICs.⁵

Some institutions in HICs had the residual capacity to effectively shift to an online education model on short notice, but institutions in LMICs might struggle to implement these solutions. Infrastructural barriers including unstable bandwidth that results in low quality of audio and video outputs and slow download speed, as well as frequent electrical power failures, limit reliable access to TEL in real-time. Limited computer facilities and financial resources for the development of eLearning platforms and insufficient time available from the teachers to create digital content further hinder the transfer to remote education. Moreover, the successful delivery of teaching through online platforms depends on having technical support personnel available for teachers and students, which is also limited in LMICs.⁸

Also, because of the significant differences among LMICs and medical schools based there, there are unique challenges to be addressed by each university and its student community. In some institutions, before the COVID-19 pandemic, there were pre-existing online learning environments for students to use. However, many of these had limited interactivity, only allowed for administrative purposes like communicating test results, and were not regularly used for sharing educational resources. At the

same time, many medical schools only relied on face-to-face and email communication. Considering the current medical crisis, the already present differences between these institutions were aggregated, as the development of pre-existing platforms was boosted by the needs created by the pandemic. At the same time, it was very difficult to build up the infrastructure without foundations.

We were able to witness some of these differences in capability in making technological adaptations between institutions in HICs and LMICs firsthand while undertaking clinical research electives in China and Thailand. We identified potential obstacles to the transfer of TEL solutions from HICs including restricted Internet access to certain search engines and social media portals that could be used for disseminating resources and incompatibility of computer systems with some eLearning platforms. Also, the clinical teachers were not accustomed to using digital assistance; instead, they relied on pen and paper. Additional technological training time may be required to prepare medical school faculty for TEL content delivery, making the process even more difficult.

Despite the aforementioned challenges, due to the COVID-19 pandemic, institutions based in LMICs were forced to transition to TEL with mixed results. Intermittent Internet connectivity and lack of infrastructure for students to reliably access online teaching rendered the initial transition challenging both for students and educators.^{9,10} Maintaining stable Internet connections, which is essential for effective access to real-time remote teaching for students staying at home, is achievable, but due to the high cost of mobile data packages, it is not affordable for everyone. Further, although pre-clinical medicine courses are well-suited to be taught through webinars, clinical medicine, which relies on hands-on patient examination and acquiring practical skills, may require more advanced TEL solutions (e.g., virtual or mixed reality) to deliver high-quality education, most of which are not currently accessible in LMICs.¹¹ Similar challenges also apply to the assessment of student competencies, which are an integral part of medical education.¹²

However, this does not mean that supplementing clinical education with online learning in LMICs should not be pursued. As medical students, we believe that it is our responsibility to be actively involved in fostering global collaboration to promote and implement medical education technology.

We witnessed firsthand some of the differences in capability in making technological adaptations between medical schools in HICs and LMICs.

As medical students, it is our responsibility to be actively involved in fostering global collaboration to promote and implement medical education technology.

Successful implementation of these solutions depends on collecting feedback from medical students who are arguably the most important stakeholders.

■ SOLUTIONS FOR MAINTAINING ELEARNING

Effective hybrid teaching delivery models that combine in-person teaching with online pre-reading material are needed globally to maintain continuity of medical education. Implementing solutions that have the potential to mitigate issues with Internet speed and connectivity in LMICs include focusing on eLearning content that can be delivered and accessed asynchronously, such as lecture recordings and other downloadable content (e.g., videos of dissections, patient examinations, clinical skills, animations, podcasts, eModules, or transcripts).

Additionally, learning platform developers need to optimize their products for functioning on mobile devices and in data saver mode to ensure affordability and accessibility for students who do not own a personal computer. Teaching students self-directed learning skills, for which they may not have received training before, has the potential to increase knowledge retention even in the absence of in-person education.⁹

Utilizing social media to disseminate educational resources and to share best practices of adapting them to local conditions could allow for a bottom-up approach in which the medical students from HICs and LMICs could empower each other in overcoming adversities of the current situation.

Transferring existing eLearning platforms and resources from HICs to LMICs is another potential solution. Nevertheless, the software cannot be directly implemented without adjusting for language, cultural, and country-specific needs.⁸ As such, if TEL solutions are to be transferred from HICs to LMICs and successfully implemented, they need to be designed using principles of frugal and responsible innovation (e.g., capacity and needs assessment and consideration of local environmental factors).¹³

■ ENCOURAGING MEDICAL STUDENTS' COLLABORATION TO IMPLEMENT BOTTOM-UP SOLUTIONS

Even though all these ideas have been suggested, their implementation proves to be challenging, and the problem has yet to be resolved. Due to the limited preparation, most of the effort to introduce TEL in LMICs has been top-down and did not involve students, who are arguably the most important stakeholders.⁹ We are convinced that medical students in both HICs and LMICs should

actively seek opportunities to engage in the process of improving TEL. Successful implementation depends on collecting feedback on novel teaching methods, engaging in medical education research, and advocating for the establishment of international collaborations and reciprocal exchange programs.

This notion can be supported by the recent emergence of local social media initiatives originating from the United Kingdom to have a global reach. Social media platforms, including Facebook, Instagram, Slack, WhatsApp, and especially Twitter, showed the effectiveness of students' and junior doctors' networks in the United Kingdom during the COVID-19 pandemic. Networks such as SMILE (Sustaining Medical education In a Lockdown Environment) Medical Education (@Lockdown_MedEd) or COVID Medical Education (@EdCovid) helped supplement teaching lost due to the pandemic and helped in developing much needed self-regulated learning skills with free webinars and peer tutorials. These networks have been created using a bottom-up approach and continuous feedback to tailor content to students' needs. The use of social media and online webinars allows for such resources to be disseminated and accessed globally, democratizing access to high-quality teaching (the SMILE Medical Education Facebook group has approximately 13,800 members as of early October 2020). We think that this bottom-up approach could be emulated on a global scale, as connecting students and junior doctors who have a passion for medical education has been shown to be a valuable complementary resource during the pandemic, largely dependent on using technology. Moreover, introducing technology into medical education creates an opportunity for students to develop collaborative skills, improve adaptability, and prepare them for future clinical practice, which will likely rely on technological literacy of doctors to a greater extent.¹⁴

Another way to catalyze international partnerships of students can be by following a model developed by research collaboratives such as GlobalSURG, a global academic network of practicing surgeons from around the world that conducts international research into surgical outcomes.¹⁵ GlobalSURG is open not only to doctors, but also nurses, medical students, and researchers, allowing them to participate in multicenter, prospective cohort studies regardless of their previous experience and expertise.^{16,17} The current network includes over 5,000 collaborators from more than 100 countries, creating an inclusive environment. To

ensure easy delivery in diverse local conditions, each study is designed so that it does not require additional resources or funding. Moreover, GlobalSURG offers their study documents translated into several languages to facilitate local dissemination and adoption. By creating an inclusive environment, such initiatives empower grass-root academics and build research capacity locally.

We propose a similar framework to foster cooperation for improving eLearning delivery in LMICs by creating opportunities for exchanging study materials, discussing ideas on delivery methods, and sharing best practices. However, this new platform, while driven by medical students, should also bring together academics, teaching fellows, and lecturers. By exchanging experiences and sharing knowledge of locally available infrastructure, collaborators could brainstorm ideas and tailor the eLearning content to the needs of LMIC institutions. Results of these discussions should be summarized and published, making them available to the academic community worldwide. Outcomes of this cooperation could also apply to other fields and serve as guidelines for creating online resources. For example, Abidi et al.¹⁸ drew from their experience in Pakistan and described a roadmap for offering a massive open online course at an LMIC institution. Similar articles would have a crucial role in accelerating the creation of widely available eLearning platforms and online educational content. Moreover, a transfer of technological know-how, both between institutions and students, would help with efficient administration of learning environments and maximize their usefulness.

Disruption of medical education globally, caused by the burden of COVID-19, is likely to continue through the coming months or even years. TEL is going to play a crucial role as a supplement to conventional learning methods in preparing medical students for the challenges of our profession. Tailored hybrid teaching methods must be developed and implemented to prevent further broadening of the gap in access to high-quality education between HICs and LMICs. Medical students of our generation across the world have an instrumental role to play. It is our responsibility to cooperate with university faculty members to drive changes to get the education necessary to provide the highest standard of care for our future patients globally during the COVID-19 pandemic and in the future.

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REFERENCES

1. World Health Organization Coronavirus Disease (COVID-19) Dashboard. Accessed December 16, 2020. <https://covid19.who.int/>
2. Choi B, Jegatheeswaran L, Minocha A, Alhilani M, Nakhoul M, Mutengesha E. The impact of the COVID-19 pandemic on final year medical students in the United Kingdom: a national survey. *BMC Med Educ.* 2020;20(1):206. [CrossRef](#). [Medline](#)
3. Wayne DB, Green M, Neilson EG. Medical education in the time of COVID-19. *Sci Adv.* 2020;6(31):eabc7110. [CrossRef](#). [Medline](#)
4. Sandhu P, de Wolf M. The impact of COVID-19 on the undergraduate medical curriculum. *Med Educ Online.* 2020;25(1):1764740. [CrossRef](#). [Medline](#)
5. Newman NA, Lattouf OM. Response to COVID-19 pandemic: beyond medical education in Brazil. *J Card Surg.* 2020;35(6):1176. [CrossRef](#). [Medline](#)
6. Dedeilia A, Sotiropoulos MG, Hanrahan JG, Janga D, Dedeilias P, Sideris M. Medical and surgical education challenges and innovations in the COVID-19 era: a systematic review. *In Vivo.* 2020;34(3 Suppl.):1603–1611. [CrossRef](#). [Medline](#)
7. Hays R, Jennings B, Gibbs T, Hunt J, McKay K. Impact of the COVID-19 pandemic: the perceptions of health professions educators. *Med Ed Publish.* 2020;9(1):4. [CrossRef](#)
8. Frehywot S, Vovides Y, Talib Z, et al. E-learning in medical education in resource constrained low- and middle-income countries. *Hum Resour Health.* 2013;11:4. [CrossRef](#). [Medline](#)
9. Cecilio-Fernandes D, Parisi MCR, Santos TM, Sandars J. The COVID-19 pandemic and the challenge of using technology for medical education in low and middle income countries. *Med Ed Publish.* 2020;9(1). [CrossRef](#)
10. Parisi MCR, Frutuoso L, Benevides SSN, et al. The challenges and benefits of online teaching about diabetes during the COVID-19 pandemic. *Diabetes Metab Syndr.* 2020;14(4):575–576. [CrossRef](#). [Medline](#)
11. Nepal PR. Role of webinars in medical educations during pandemic of COVID 19. *Eastern Green Neurosurg.* 2020;2(2):1–2. [CrossRef](#)
12. Pattanshetti VM, Pattanshetti SV. The impact of COVID-19 on medical education in India. *J Sci Soc.* 2020;47(1):1. [CrossRef](#)
13. Bolton WS, Aruparayil N, Quyn A, et al. Disseminating technology in global surgery. *Br J Surg.* 2019;106(2):e34–e43. [CrossRef](#). [Medline](#)
14. Ferrel MN, Ryan JJ. The impact of COVID-19 on medical education. *Cureus.* 2020;12(3):e7492. [CrossRef](#). [Medline](#)
15. Global Surg & the NIHR Global Health Research Unit on Global Surgery. Accessed October 2, 2020. <https://globalsurg.org/>
16. Bhangu A, Ademuyiwa AO, Aguilera ML, et al; Global Surg Collaborative. Surgical site infection after gastrointestinal surgery in high-income, middle-income, and low-income countries: a prospective, international, multicentre cohort study. *Lancet Infect Dis.* 2018;18(5):516–525. [CrossRef](#). [Medline](#)
17. Global Surg Collaborative. Mortality of emergency abdominal surgery in high-, middle- and low-income countries. *Br J Surg.* 2016;103(8):971–988. [CrossRef](#). [Medline](#)
18. Abidi SH, Pasha A, Moran G, Ali S. A roadmap for offering MOOC from an LMIC institution. *Learn Media Technol.* 2017;42(4):500–505. [CrossRef](#)

We propose an international networking framework to foster cooperation for improving eLearning delivery in LMICs by creating opportunities for exchanging study materials, ideas, and best practices.

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ORIGINAL ARTICLE

Pathways to Care for Patients With Type 2 Diabetes and HIV/AIDS Comorbidities in Soweto, South Africa: An Ethnographic Study

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Key Findings

- Health systemic challenges such as the lack of medication, untrained nurses, and limited number of doctors at primary health care clinics necessitated patient referrals to a tertiary hospital in Soweto, South Africa.
- At the tertiary hospital, patients with multimorbidities received fragmented and uncoordinated care for their conditions.
- Little to no collaboration occurred among health care providers due to poor communication, noncentralized patient information, and staff shortage, leading to poor quality of care provided to patients.

Key Implications

- Policy makers must consider primary health care clinics and providers as key actors for implementation of integrated care models. This demands more investment in the clinics in terms of equipment, medication supply, and human resources.
- Public health practitioners need to develop stronger links with communities to promote awareness on chronic diseases prevention strategies.
- More research is needed to inform the development of context-specific strategies that may enhance successful implementation of integrated care models.

ABSTRACT

Background: South Africa is experiencing colliding epidemics of HIV/AIDS and noncommunicable diseases. In response, the National Department of Health has implemented integrated chronic disease management aimed at strengthening primary health care (PHC) facilities to manage chronic illnesses. However, chronic care is still fragmented. This study explored how the health system functions to care for patients with comorbid type 2 diabetes (T2DM) and HIV/AIDS at a tertiary hospital in Soweto, South Africa.

Methods: We employed ethnographic methods encompassing clinical observations and qualitative interviews with health care providers at the hospital (n=30). Data were transcribed verbatim and thematically analyzed using QSR NVivo 12 software.

Findings: Health systemic challenges such as the lack of medication, untrained nurses, and a limited number of doctors at PHC clinics necessitated patient referrals to a tertiary hospital. At the hospital, patients with T2DM were managed first at the medical outpatient clinic before they were referred to a specialty clinic. Those with comorbidities attended different clinics at the hospital partly due to the structure of the tertiary hospital that offers specialized care. In addition, little to no collaboration occurred among health care providers due to poor communication, noncentralized patient information, and staff shortage. As a result, patients experienced disjointed care.

Conclusion: PHC clinics in Soweto need to be strengthened by training nurses to diagnose and manage patients with T2DM and also by ensuring adequate medical supplies. We recommend that the medical outpatient clinic at a tertiary hospital should also be strengthened to offer integrated and collaborative care to patients with T2DM and other comorbidities. Addressing key systemic challenges such as staff shortages and noncentralized patient information will create a patient-centered as opposed to disease-specific approach to care.

INTRODUCTION

Nokuthula [pseudonym], seeking care at a specialty diabetes clinic in a large urban hospital, left her doctor's office with a confused look. In her mid-sixties, she had been to the clinic many times for her type 2 diabetes and other comorbid conditions, including hypertension. But this time, she had several physical complications that she needed to deal with. When she left the clinical encounter, she held a file, which she handed to the clerk at the reception, while she scrambled to manage

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The Integrated Chronic Disease Management (ICDM) model aims to improve the convenience and quality of chronic disease care for patients in PHC at a single delivery point, thereby integrating PHC into the health system.

several loose papers in her other hand. These loose papers were several referrals to other clinics, which she eventually placed on the reception desk. As the clerk was busy working on her file, Nokuthula lifted one of her loose paper, read it, and asked, "Where is the podiatrist clinic?" The clerk, without looking up, pointed to the far end, right side of clinic. Nokuthula did not understand what the clerk meant and asked again. The clerk said this time, "That room labeled Podiatry!" She then picked up the second sheet of paper and asked, "Where is the dietician clinic?" The clerk answered, "Use the stairs up to the second floor." Then she picked up the third sheet of paper, read it, and asked; "Where is the St. Johns eye clinic?" The clerk, looking irritable, answered, "You have to walk up on the bridge from the hospital to the taxi rank just outside Bara then ask from there. The eye clinic is outside Bara. Looking confused, Nokuthula reassembled her papers and walked out. —EB notes on the diabetes/endocrine clinic at a tertiary hospital, 2018

Living with a chronic condition such as type 2 diabetes (T2DM) and other multimorbidities—the coexistence of 2 or more chronic conditions in the same individual¹—can pose extraordinary social and medical costs for people residing in cities such as Johannesburg, South Africa. These costs arise in part because multimorbidity is now considered a global health care priority and has become a fundamental challenge for health systems.² In South Africa, a middle-income country, noncommunicable diseases (NCDs) such as T2DM have risen swiftly among communities experiencing a heavy burden of HIV as well as other infections, such as TB.^{3–5} For instance, T2DM was found to be nearly as common as HIV, TB, and hypertension in a peri-urban settlement in Cape Town, representing 45% of all consultations.⁵ In this context, patients receiving antiretroviral therapy are more likely to have T2DM than low-income people without HIV,⁶ and this risk increases exponentially the longer the patient receives antiretroviral therapy.⁷ Concurrently, the individuals most affected by this double burden of disease largely depend exclusively upon the public health system for detection, treatment, and care for both acute and chronic conditions in South Africa.⁸ Yet, public hospitals in South Africa are weak and under-resourced compared with private hospitals,⁹ and they are characterized by staff shortages, inadequate equipment, and drug stock-outs,¹⁰ leading to longer waiting times, fewer screenings,⁹ under-treatment, and poor disease control.¹¹

As a response to the disease burden, the National Department of Health in South Africa initiated the

Integrated Chronic Disease Management (ICDM) model, which uses a diagonal approach to health systems strengthening.¹² The diagonal approach integrates the vertical HIV program with the horizontal general health system.¹³ The ICDM model aims to improve the convenience and quality of chronic disease care for the majority of patients in primary health care (PHC) at a single delivery point, thereby integrating PHC into the health system.

Few studies have evaluated the quality of ICDM in South Africa. Despite ICDM having a greater potential to deal with the barriers experienced by patients with multiple chronic diseases, a recent study found that it has been more useful to patients with HIV because of reduced stigma, but it did not show benefits for patients with NCDs, such as hypertension.¹⁰ Other studies have also reported that infrastructure limitations have negatively affected the sustainability and scale-up of the model.¹⁴ Recently, a study conducted in Cape Town revealed that the ICDM model has not been implemented in most public PHC clinics.¹⁵ This has necessitated patient referral to higher levels of care that are overutilized, congested, and overburdened, leading to an escalation of health care cost.^{8,16}

Care pathways are often part of integrated care and may help to guide the delivery of integrated care for patients while clarifying roles and responsibilities in the care process.¹⁷ In addition, due to overstretched health system, health policy makers have recommended delegation of duties, popularly known as task shifting,¹⁸ from physicians to other health care professionals, including nurses, pharmacists, or community health workers.¹⁹ As a result, tasks that have traditionally been thought of as solely within the scope of specialist practice (such as prescribing medications) can often be performed by health care workers without specialist training¹⁸ or occur in settings where no specialists are available. More recently, task sharing or collaborative care between different professionals, such as primary care physicians, hospital specialists, nurses, and social workers, has been considered a more appropriate strategy for managing patients with multiple chronic conditions^{20,21} and mental illnesses.²² This strategy is particularly important in highly skilled areas because it is difficult to shift tasks entirely to new cadres of health care workers.²³ In this article, the terms task sharing and collaborative care are used interchangeably. We conceptualize task sharing not as a referral to other providers, such as from tertiary specialists to primary care providers, but instead a sharing of care among providers in tertiary hospitals or between tertiary hospital and primary care

clinics.¹⁹ A good example can be drawn from a task-sharing outreach intervention program called Primary Care 101 that was implemented in South Africa to increase the capacity of nurses at primary care levels to not only take on assessment and prescribing roles for HIV and TB, but also NCDs and mental illnesses.¹¹

Collaborative care has the potential to make it easier to work as a team with colleagues from other professions when managing patients, allowing better provision of patient-centered care.²⁴ However, building effective partnerships requires relationships, procedures, and structures that can be different from the usual ways of working.²⁵ These structures seem to be lacking in most public health care facilities in South Africa due to insufficient financial and human resources to manage the health care system.^{9,11} In addition, the failure to use electronic health records or a centralized system for patient's information in most public hospitals in South Africa^{26–28} poses a huge challenge to integrated and collaborative care for patients. But why is the ICDM model not functioning as expected?

We draw from the Atun et al. conceptual framework of integration of targeted health interventions into health systems.²⁹ This framework proposes that each situation uniquely affects the adoption and diffusion of new health interventions and the extent to which they are integrated into critical health system functions. Atun and colleagues identified variants as the nature of the problem being addressed, the intervention, the adoption system, the health system characteristics, and the broad context.²⁹ The implementation of the ICDM model in South Africa has been slow, and it has not been scaled up to most PHC spaces. As a result, patients bypass the PHC clinics to attend hospitals for the initial contact visit, thereby increasing the cost of the service.³⁰ In addition, patients with T2DM are mostly managed at secondary or tertiary levels, while HIV is managed at PHC clinics. This is partly due to limited and untrained providers at PHC clinics to properly diagnose and manage diabetes. Integrating care for chronic diseases such as T2DM into PHC clinics in South Africa can only be feasible if systemic challenges in management are addressed.³¹

We use a case study of 2 clinics that provide care for patients with T2DM, HIV/AIDS, or both at a public tertiary hospital in Soweto, South Africa, to investigate care pathways and explore how the health system functions to care for such patients. We interviewed 30 health care providers who care for patients with T2DM, HIV, or both, to better understand the challenges and opportunities within the current system for care of these conditions alone and together.

■ METHODS

Study Setting

This tertiary hospital-based study was conducted in Soweto, a peri-urban neighborhood, located about 15 km southwest of Johannesburg's central business district and with a population of approximately 1.3 million.³² Soweto has no designated secondary (regional or level 2) hospitals because a tertiary hospital, Chris Hani Baragwanath Academic Hospital (commonly known as Bara), provides district (level 1) and regional (level 2) hospital services, in addition to tertiary (level 3) referral services. Patients accessing care at the tertiary hospital are referred from regional, district, or PHC clinics or community clinics from outside or within Soweto. This study focuses on 2 clinics within the tertiary hospital: the medical outpatient clinic (MOPD) and the diabetes/endocrine clinic.

The MOPD covers all specialized clinics at a tertiary hospital. Apart from patients who enter the hospital through the emergency department, other patients accessing the hospital pass through the MOPD. Most patients are first managed at the MOPD and then systematically referred to specialty clinics within the hospital if specialized care is needed. The diabetes/endocrine clinic is situated opposite the MOPD. It is a specialty clinic for patients with all endocrine conditions, including diabetes.

Study Design and Data Collection

This ethnographic study was conducted between April 2018 and December 2018 and comprised observation and semistructured interviews. All observations were conducted after obtaining consent from health care providers and patients. Observations (by EB) were conducted in different spaces of the 2 clinics: the triage room, the doctor's room, the reception area, patient queuing space, and diabetic education class. EB's role fluctuated between an observer and participant observer; she participated in everyday life of staff in the clinic by helping, watching, listening, and asking questions pertaining to care for patients. However, she did not participate in helping to manage patients clinically. She engaged in informal conversations with different people in the clinics (patients, health care providers, or caregivers). Sometimes, EB asked unstructured questions during the observations. She recorded a summary of field notes in a small jotting notebook and wrote up a full ethnographic account before the end of the day.

Collaborative care has the potential to make it easier to work as a team, allowing provision of patient-centered care, but building effective partnerships requires changing the usual ways of working.

Thirty semistructured interviews, lasting between 30 and 60 minutes were conducted in English with health care providers to understand their experiences in managing patients with T2DM and HIV/AIDS comorbidities. The interviews included doctors, endocrinologists, dietitians, podiatrists, nurses, hospital administrators, data managers, and social workers. Initially, purposive sampling was used to select health care providers across the disciplines in the diabetes/endocrine clinic; this involved approaching existing contacts to interview and follow from within the clinic. Later, a snowball method was used to recruit more health care providers from each discipline within the diabetes/endocrine clinic (n=25). As the first author uncovered how patients navigated care in the hospital, it became apparent that some patients with T2DM were first managed at the MOPD and were only referred to the diabetes/endocrine clinic when experiencing complications. This necessitated understanding care pathways from the MOPD to the diabetes/endocrine clinic. One provider from the diabetes/endocrine clinic recommended a provider working at the MOPD, and this snowballing method facilitated recruitment of other health care providers at the MOPD (n=5) until saturation was reached. A semistructured interview guide included questions about care for patients with T2DM and HIV/AIDS, referral system, integrated and collaborative care, barriers to care, and opportunities for care. Interviews were transcribed verbatim.

Data Analysis

Qualitative data were thematically analyzed using Qualitative Solutions for Research (QSR) NVivo 12 software. A combined deductive and inductive approach was used for data analysis. The deductive analysis was based on the pre-identified themes focusing on the research questions and literature reviews.^{4,5,10,12,15,33} These themes included care provision for patients with chronic diseases; experience managing patients with multimorbidities; availability of resources for managing patients with multimorbidities; understanding of integrated care; collaborative care; patient-centered care; and opportunities and challenges experienced when managing patients with multimorbidities. Inductive analysis was undertaken for all themes emerging from the transcripts. EB read all transcripts repeatedly as they were developed after each interview. This process was systematic, and it facilitated re-evaluating data that were already categorized and creating new categories.³⁴ These categories were

refined by the constant comparative method,³⁵ which involved concurrent systematic data collection and analysis. EB compared new data with previously collected data. Making comparisons facilitated challenging data that were already grouped with new categories, and this process helped in integrating the different categories and provided a holistic understanding of the phenomena under study. These categories were then reviewed by 3 other researchers involved in the study (SAN, JG, and EM) and any identified discrepancies were solved at this level. Consequently, discussions between the researchers facilitated a collaborative agreement on key emerging themes. EB then developed a codebook that was reviewed by EM. The final codebook was uploaded in QSR Nvivo 12 software where coding was done, and emerging codes were added throughout analysis. Initially, 40 parent nodes were identified, discussed, and defined. This led to reducing the parent nodes to 15, with several child nodes. Subsequent reading enabled the splitting of the parent nodes to child nodes, which provided a fast snapshot of similarities, differences, patterns, and relationships from the data. Nodes were summarized in analytical memos, and verbatim excerpts were used to report the dominant themes. The following key themes were identified: (1) organizational care pathways and the referral system; (2) managing patients with T2DM and HIV/AIDS comorbidities; and (3) patient support and involvement of family members or caregivers in care (Table 1). Case stories were developed based on observations at the clinics.

In our analysis, we used the Atun et al. framework²⁹ as a diagnostic tool. This process allowed a detailed mapping and understanding of how the health care system functioned in terms of care provision. Specifically, we looked at the health care intervention, which in this case was integrated care, while identifying its purpose, extent, or implementation, as well as gaps and recommendations. In other words, the framework provided a detailed mapping of chronic care at a tertiary hospital in Soweto while evaluating the purpose, extent, and nature of ICDM integration in Soweto. It also enabled us to explore what works and what does not work within the health system.

Ethical Considerations

Written informed consent was obtained from the study participants after reading out the content of the information sheet and explaining the purpose of the study. A research committee at the tertiary hospital and the human research and ethics

TABLE 1. Key Themes to Care for Patients With Type 2 Diabetes and HIV/AIDS Comorbidities, Soweto, South Africa

Theme	Expectations	Working	Not Working
Organizational— Care pathways and referral system	Multidisciplinary team working together to manage patients with comorbidities	Most patients are referred to a tertiary hospital. Most go through the medical outpatient clinic before they are referred to specialty clinics.	Limited collaboration among providers due to poor communication, staff shortage, lack of resources, and so forth.
Managing patients with type 2 diabetes and HIV/AIDS comorbidities	Efficient communication, electronic health record system	Communication is mostly done manually through a patient’s file. Diabetes/endocrine clinic has implemented electronic system that captures patients’ biometric data.	Due to workload and staff shortage, rarely do health providers communicate with colleagues, especially when they are in different buildings. Most other clinics use manual data capture in patient’s files. Having noncentralized patient records further challenges proper communication.
Patient support and involvement of family members or caregivers in care.	Fully involve patients and their family/caregivers in care or decision making.	Mostly, patient are supported in group forums, such as during diabetes education sessions. Social workers visited patients at home.	Doctors rarely involved patients or caregivers in health care. Patient were supported in groups rather than individually. Some caregivers failed to collaborate with social workers during home visits.

committee at one of the largest universities in Johannesburg approved this study (M171125).

RESULTS

Table 2 describes the 30 health care providers who were recruited from the diabetes/endocrine unit (n=25) and the MOPD (n=5). Participants’ median age was 40 years (interquartile range=15). The majority of providers had worked for more than 20 years and were trained in diverse disciplines. We discuss the 3 emergent themes in turn.

Organizational Care Pathways and the Referral System

Health care providers described how most patients used 2 main structured channels in accessing the tertiary hospital: (1) a referral from PHC clinics, or (2) patient who came directly through the emergency department (Figure). One nurse described this process as follows:

There is a referral system, patient need to start there [PHC clinics]. The doctor must write a referral letter for them to come here [tertiary hospital]. Some will come in through the emergency department. Once they are treated here, they are down referred for management and collection of pills at the community clinics. —Provider 1, nurse

Limitations in the Current System

Health care providers reported that the current referral system design failed to meet patient needs for various reasons. First, providers often referred patients from the PHC clinic to tertiary hospitals because of health systemic challenges (such as lacking medication, equipment, untrained nurses, and limited number of doctors) as opposed to patients needing the specialist care often associated with such referrals:

Due to lack of necessities at primary clinics, sometimes the GP understand it’s pointless to write the letter to send this patient to PHC, only for the patient to be sent back to us [a tertiary hospital]. —Provider 2, doctor

Primary health care clinics have got limited resources; they can’t do the blood tests required for diabetic care. —Provider 3, doctor

Many argued that because the PHC clinics in Soweto were managed by nurses, as opposed to doctors who only worked in the clinics on rotational basis, many nurses were overburdened by their patient load, or untrained to manage patients with diabetes, which caused them to initiate more up-referrals from PHC to the tertiary hospital:

Doctors come on a specific day, let’s say on Wednesday. If a patient comes on Monday and it’s beyond the sister’s scope, they will refer the patient to tertiary hospital. —Provider 4, nurse

Health care providers reported that the current referral system design failed to meet patient needs for various reasons.

TABLE 2. Sociodemographic Characteristics of Study Health Care Providers in the Medical Outpatient Clinic and Diabetes/Endocrine Clinic, Soweto, South Africa

	No. (%) N=30
Gender	
Male	12 (40)
Female	18 (60)
Age, years	
25–35	9 (30)
36–45	10 (33)
46–55	8 (27)
>56	3 (10)
Profession	
Administrator	3 (10)
Data manager	3 (10)
Dietician	4 (13)
General doctor	6 (20)
Endocrinologist	3 (10)
Nurse (professional nurse, diabetes educator)	6 (20)
Podiatrist	3 (10)
Social worker	2 (6)
Years of service	
<5	5 (17)
6–10	6 (20)
11–20	9 (30)
>20	10 (33)

Some nurses at PHC are not well trained to diagnose patients with diabetes early enough. They only suspect that a patient is diabetic when patients are already experiencing complications, and this makes them refer them to tertiary hospital. —Provider 11, endocrinologist

As a way of increasing nurse capacity in PHC clinics in Soweto, one doctor explained why an outreach program was important yet challenging to implement in this context:

Our clinics at the tertiary hospital are overwhelmed by new cases of diabetes and diabetes complications because, nothing is happening at the community – where we expect prevention strategies to be taking place [. . .]. I started an outreach program which I conduct alone, and

on a voluntary basis. It entails educating patients at the community and, capacity building nurses who work in the PHC clinics in Soweto. I have done this exercise for a couple of years now, though it is challenging because I don't have any support in terms of finances, logistics and facilitations. Again, because there are many clinics in Soweto, I sometimes end up seeing one clinic maybe two times in a year. Therefore, we still have many patients being referred from PHC clinics to the tertiary hospital. —Provider 2, doctor

Some opined that patients' self-referrals from PHC to the tertiary hospital were simply due to geographic convenience or perceived better quality there:

Some patients will walk in because Bara is very close to where they live compared to a primary clinic in Soweto. —Provider 5, hospital administrator

They [patients] don't want to go to the local clinic, they will say there are no medication. —Provider 6, nurse

This pattern of skipping the PHC clinic and therefore not following the traditional referral process was described as common negligence because a patient who walked in without a referral would still be allowed to access the hospital:

The problem is that here [tertiary hospital], they cannot turn the patient away. The person at registration will give them a number and allow them in. —Provider 2, doctor

Many providers suggested that such deference to protocol was central to reinforcing these structural factors, such as overwhelming workloads, that played a primary role in creating bottlenecks at the tertiary hospital, thus compromising patients' quality of care.

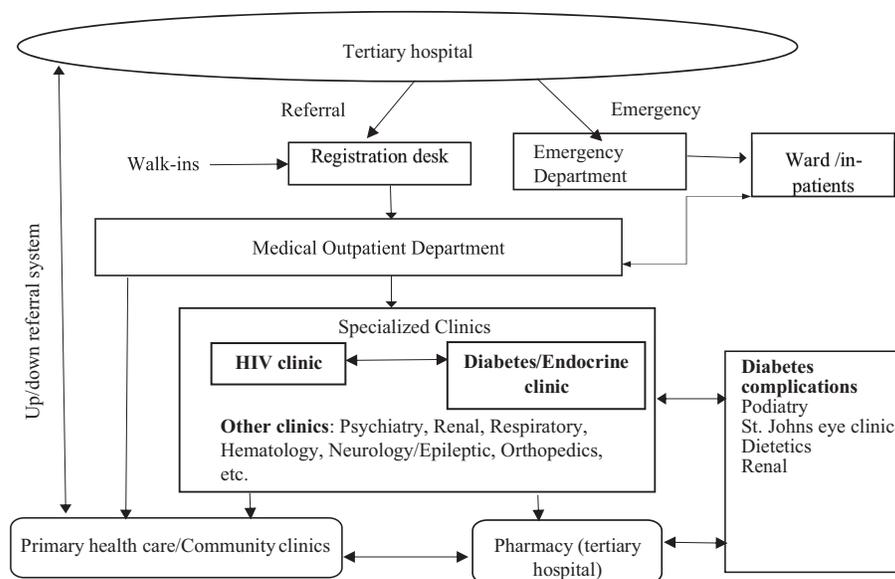
Down-Referral, Medication, and Challenges

The existing referral system design requires that once patients have received treatment and are stable at the tertiary hospital, they are down-referred to community or PHC clinics for management and continuous collection of their medications:

We have a down referral form, this is what we use to send them back to the community clinics. —Provider 1, nurse

A MOPD doctor also described how prepackaged medication is sent to local clinics:

FIGURE. Up and Down Referral System From Primary Health Care to a Tertiary Hospital in Soweto, South Africa



Medication is prepared at the chemist here [tertiary hospital] and then sent to the local clinic. Then at the local clinic, there is a chemist staff who just takes the medication out of the shelf and dispenses to the patient. — Provider 16, doctor

Most providers reported that 6 main clinics in Soweto were selected to be central for medical supplies and refilling to patients with chronic conditions. These clinics were Lilian Ngoyi, Chiawelo, Mofolo, Stretford, Laneshia South, and Zola. Medications were distributed to these clinics and patients could select any of the 6 clinics based on which was closest to them for repeat medical supplies. This plan did not work as expected because of drug stock-outs:

Patients will always complain that they missed their medications at the primary clinics due to drug stock-outs. —Provider 8, nurse

Drug stock-outs at PHC clinics were attributed to various reasons. First, stock-outs were said to be a trickledown effect of drug stock-outs at the tertiary hospital, which in turn influenced nonsupply of medications to PHC clinics:

The hospital does not pay the drug suppliers on time. If you want to confirm this, they keep on changing the suppliers because, some have stopped supplying the drugs. —Provider 9, data manager

Oversupplying medication to patients was also linked to drug stock-outs at the tertiary hospital:

They will issue extra medication to patient and at some point, you will be told this and that is missing from the pharmacy. This affects supply to primary clinics too — Provider 10, doctor

In addition, the system of prepackaging medication and sending it to PHC clinics was said to be failing as described below:

There are so many steps in the system; it could be that the courier dropped the parcel, could be someone stole the medication and so on. —Provider 11, endocrinologist

The challenges experienced in the referral system were majorly attributed to poor communication between different providers at different levels of care:

You imagine the patient coming here, from Orange farm to say, “I didn’t get medication.” Already they are in turmoil [. . .], poor communication is the biggest challenge in the referral process. —Provider 12, nurse

Managing Patients With Comorbid T2DM and HIV/AIDS

This study revealed limited integration of chronic services at the tertiary hospital. This limitation was partly because of the design of the tertiary hospital, which is specialized into different clinics.

Patients with comorbid T2DM and HIV received care in 2 separate clinics: at the MOPD or diabetes/endocrine clinic for their diabetes, while those with HIV would receive care at the Nthabiseng (HIV/AIDS) clinic—a separate stand-alone clinic that was 3 minutes' walk from the building housing the diabetes/endocrine clinic. One doctor explained this:

We don't do the HIV treatment itself here, they go to HIV clinic. Then they will come back here [diabetes/endocrine clinic] on the same day or different days for diabetes care. —Provider 2, doctor

Another doctor said that:

Patients go in the morning in one clinic and as soon as they are done with that clinic, they'll go and queue in the other clinic. —Provider 10, doctor

The diabetes/endocrine clinic only managed patients with endocrine conditions:

We only manage patients with endocrine conditions in this clinic. Patients with HIV must be managed at HIV clinic. —Provider 2, doctor

Not unsurprisingly, individuals with both T2DM and hypertension often received care in tandem; however, for every other physical and psychiatric condition, patients would visit specific clinics. Patients with diabetes complications, such as neuropathy of the hands and feet and nephropathy, visited other, specific clinics (as illustrated in Nokuthula's case). Some of these clinics were situated outside a tertiary hospital. Although they were a very short walk from the hospital, the distance could be difficult for someone with a disability. Health care providers emphasized that collaboration and coordination of care were imperative in such instances, but they rarely occurred.

Nevertheless, providers acknowledged that collaboration or task sharing between different professionals, such as primary care providers, specialists at a tertiary hospital, nurses, and social workers, would be a good thing and would improve patients' quality of care:

Working together means we are treating the patient well by providing what we are thinking is best for the patient. If she's amputated and she's the bread winner for example, then nothing else will be happening at home. So, with that consideration we might motivate the surgeon to do amputation that is not so intrusive. —Provider 14, Podiatrist

They also gave examples on instances where they collaborated in caring for patients:

Yeah, we work as a team. We [educators] will teach them about the disease, the dietician teaches about what they need to eat, then the podiatrist will teach them on the foot care. —Provider 15, diabetes nurse educator

However, providing integrated and collaborative care for patients with HIV and T2DM was said to be difficult due to poor communication, noncentralized patient information, staff shortage, and limited resources, among other reasons (Table 3).

Poor Communication

Poor communication affected both vertical and horizontal collaboration. This occurred at 2 levels: between providers at the tertiary hospital and those at PHC, and among health care providers in different specialty clinics at the tertiary hospital. For instance, nurses reported that some doctors at a tertiary hospital down-referred patients to PHC clinics in Soweto, without a detailed report on further management at the PHC level. This led to most patients being referred back to a tertiary hospital, especially when nurses at PHC did not know how to manage the patients. In addition, providers at the tertiary hospital rarely communicated with each other when managing patients with multimorbidity; some providers would provide a double prescription to patients with comorbid conditions especially those that cluster together (such as T2DM and hypertension) without realizing that the patients had already received similar prescriptions in a different specialty clinic. This led to cases of oversupply of medication, drug duplication, and mismanagement of patients.

Ethnographic case observation of communication problems. Patients with T2DM and other comorbidities came to the clinic with unused medications. There were empty drawers at the clinic reception where all unused medication were kept. Sometimes, patients would return the unused medication to the pharmacy when they came to collect new supplies. Nurses would shout at the patients for being nonadherent to their treatment. After a series of observations and informal conversations with patients, it became clear that patients were given extra medications especially when they attended other clinics for comorbidities.

One nurse expressed her amazement when she said:

When they come to the clinic, you will be surprised that they still have enough medication for another month or so. —Provider 4, nurse

Providers acknowledged that collaboration or task sharing between different professionals would be a good thing and would improve patients' quality of care.

TABLE 3. Challenges to Collaborative and Integrated Chronic Care for Patients With HIV and Type 2 Diabetes in Soweto, South Africa

Theme	Excerpts
Poor communication	<p>“There is no consistent communication between a tertiary hospital and these community clinics. Sometimes, if they [patients] see that medication is running out, they will walk to the nearest clinics, some of the clinics give them medication even without any down referral letter.” —Provider 4, nurse</p> <p>“This is something that happened last week [...] at respiratory the doctor prescribed medication for her respiratory problem and diabetes as well. She went to the pharmacy and collected medication for diabetes twice in a day” —Provider 6, nurse)</p>
Noncentralized patient information	<p>“It’s frustrating for them, isn’t it? the files get lost every now and then. Patients have to queue for opening of new files, they have to figure out what medication they were on to tell the doctor...” —Provider 22, endocrinologist</p> <p>“Look, honestly until we have an electronic record keeping system in the whole hospital, record keeping is going to be in shambles and working as a team will only be a dream. Look, I only see diabetes patients twice a month which means I only use the Intellovate system twice a month, the rest of the other time I am using manual paper recording in other departments.” —Provider 23, doctor</p>
Staff shortage, workload, and unavailability of doctors	<p>“It is difficult because doctors have a lot on their hands [...] they are expected to see a number of patients here [diabetes clinic], expected to do this and that and by the time they come back here, the queue has build up again. They will not have time for collaboration with others.” —Provider 1, nurse</p>
Lack of resources such as medication	<p>“The problem is not the model [ICDM] but lack of resources. [...] I treated the patient and when he got well, I designed a chronic medication plan, I referred the patient to the local clinic but the patient came back and said there are no medications there.” —Provider 2, doctor</p>
Proximity of clinics	<p>“Collaboration is difficult. All these clinics are isolated from each other. So now, we have interprofessional communication where I write my own recommendations, you write your own recommendations, somebody writes their own without involving the patient.” —Provider 26, endocrinologist</p>
Interprofessional conflicts	<p>“Most of the time, surgeons will override anyone’s decision. I don’t know why it’s like that, but sometimes they do. So [...] we will screen the patient and find a wound, write our notes and say that we want to manage this patient with wound care. Then the following day when you go, the surgeons have taken over the patient and maybe the patient is already prepared for theatre. This makes me feel they think we don’t know our work.” —Provider 21, podiatrist</p>

Probing further, a doctor revealed circumstances in which oversupply of medication occurred:

The patient has a file in dermatology, he gets his medication and then when he come for his diabetic clinic, it’s a different file that they have and there is no communication between the two clinics. In such cases, double prescriptions may occur. —Provider 10, doctor

Poor communication also led to treating diseases in isolation from the other conditions among individuals with comorbidities:

We try to ask if they have any other diseases but with workload, and if the other diseases are not indicated in the file, I just treat the disease I know of. —Provider 3, doctor

Noncentralized Patient Information System
Ethnographic case observations of unlinked medical records. The MOPD clinic had computers, but they were typically not linked to other departments due to network connectivity challenges. In

most cases, data were captured manually. The diabetes/endocrine clinic is one of the 3 specialty clinics at the tertiary hospital that has implemented an electronic health record system (the Intellovate system). This system captures patient’s information through biometrics. The system also scans through the patient’s file every time they have a clinical encounter with the doctor. The up-to-date information captured in this clinic cannot be shared with other clinics because this system has not been rolled out to other clinics.

This case observation reveals that the lack of a centralized patient records system in a tertiary hospital challenged collaborative care efforts. This led to manual capture of patient’s information through their files. Thus, providers complained of spending more time checking patient’s files and the poor quality of care provided for patients requiring more than one clinic. In addition, some patients’ files were lost at the hospital registry (Table 3).

Staff shortage and workload were reported to negatively affect care collaboration across disciplines.

Staff Shortage

Staff shortage and workload were reported to negatively affect care collaboration across disciplines:

Collaboration is not that easy. If you find there is something urgent you have to address, and you have other patients in the queue waiting, this makes it difficult . . . —Provider 3, doctor

Another provider shared the same sentiments when she said:

The problem is we have few doctors and many patients. —Provider 1, nurse

In addition, integrating services and working as a team was also a challenge due to the existing professional hierarchical structures for managing patients:

A podiatrist is not exactly authorized to prescribe antibiotics. When the doctor is not around maybe once they've left the clinic when they finish, you find that it becomes a challenge. Because I always need a medical doctor to prescribe certain drugs for me. —Provider 14, Podiatrist

Interprofessional conflicts were also highlighted as another reason why collaborative care was not working well (Table 3).

Proximity to other clinics was also reported to negatively influence collaborative care. For example, HIV, renal, and psychiatric clinics were said to be meters away from the diabetes/endocrine clinic:

Some clinics like psychiatric are far away [. . .] It is difficult to start looking for a psychologist when they cannot be reached by telephone. —Provider 7, doctor

Patient Support and Involvement in Care

Patient support was said to be imperative especially for those who managed more than one chronic condition. However, it was mentioned that due to workload, providers never had enough time to provide personalized care to patients:

We try to involve them [patients], but the workload is too much, we have not much time for this. —Provider 16, doctor

Support was mostly done in group forums, such as during the diabetes education sessions. Yet, this support was not always accessed, especially when some patients had attended such sessions before or when they were in a hurry to join queues in other clinics.

They are always in a hurry to leave the education class. They will complain that they are getting late for other clinics.—Provider 6, nurse

They [patients] feel it is a waste of time because they have been in the sessions before. —Provider 17, diabetes nurse educator

Another key challenge for patient support was a language barrier. Elsewhere, we have extensively described how language barriers hinder health care providers from managing patients and providing patient-centered care.³⁶

Ethnographic observation during an ongoing diabetes class. In a diabetes class, the dietician was busy educating patients about the permissible and nonpermissible foods, monitoring blood glucose, and self-care. Seven patients were seated around a large table that was positioned at the center of the room. Three patients were very active, asking questions and discussing their experiences managing diabetes. Three others were partly engaged, while 2 patients were very quiet and seemed disinterested. Suddenly the dietician pointed at 1 quiet patient and asked, “Mama [mother], why are you not saying anything?” The woman did not answer, but only stared at the dietician. One other woman seated next to the quiet woman quickly said, “She is from Mozambique and does not understand either English or the local languages.” The dietician, sounding empathetic turned to me and said, “This is so sad. Language barrier is a key challenge that we experience especially with patients from Mozambique.” The dietician paused for a few minutes, then proceeded with educating the other patients. The patient from Mozambique stared at the pictures and charts hanging on the wall.

Moreover, although patients' family or caregivers were invited to join diabetes education sessions, this was challenging for patients who live alone or who don't have family.

Similarly, social workers reported some of the challenges they experienced while involving family members in patient's care:

Sometimes, we don't receive a good welcome from the patient's relatives or other caregivers. —Provider 19, social worker

We make all the family and patient sit down and talk about the patient's condition [. . .] the problem comes when they [family] abandon the patient and don't want to be involved in the care. —Provider 20, social worker

DISCUSSION

This ethnographic study investigated integrated and collaborative chronic care at a tertiary hospital in Soweto to examine how the health care system functions to manage patients with comorbid T2DM and HIV. We found that patients with

comorbid T2DM and HIV visited different clinics with limited collaboration among health care providers within the different clinics at the tertiary hospital and with PHC clinics in Soweto. This situation did not arise because of a lack of will from health care providers; rather, it reflected health system deficiencies such as staff shortage, noncentralized record keeping, poor communication, and medication stock-outs. Lack of communication impeded people from addressing major health concerns. In addition, patients with more advanced T2DM symptoms who arrived at the MOPD at the tertiary hospital were required to seek care at this level first. Then, they were referred to the diabetes/endocrine clinic only when their condition worsened. This process often delayed more specialized care for about 2 months and arguably made them sicker. In what follows, we address some of the major findings around care provision for patients, and we make recommendations for improving the care of patients with multimorbidities in Soweto and in similar settings in low-and middle-income countries (LMICs).

Patients with co-occurring chronic illnesses require complex models of care, involving integration and collaboration of services among professions and institutions. South Africa has already implemented the ICDM model to strengthen PHC facilities to care for patients with chronic multimorbidities.¹² However, this model has not been implemented in most PHC clinics in Soweto. Although patients with HIV can be managed at PHC clinics, those with T2DM are mostly referred to a tertiary hospital.³⁷ This is because of systemic challenges such as staff shortages, untrained nurses at PHC clinics, lack of equipment and medical supplies, and poor outcomes. Such systemic barriers were also found in a Cape Town study that reported 2 separate clinics for patients with T2DM and HIV even within PHC clinics.¹⁵ In addition, our findings may provide useful insights into why a task sharing program that aimed to increase nurses' capacity to manage and offer prescriptions for NCDs did not result in intensification of treatment for these diseases.¹¹ Thus, it is clear that reorganization of PHC according to the ICDM model is still experiencing challenges throughout the country.

Furthermore, the spaces in which chronic care is differentially provided matters. Atun et al.²⁹ argued that these clinical arrangements are essential to the health system and the context where interventions are being implemented. It is therefore

important to recognize that integration of chronic care models is impeded at the level of the health system in public health facilities in South Africa. Studies conducted in other low-resource settings have found that the readiness of health services scale-up for the management of chronic conditions through an integrated chronic care approach failed due to lack of staff, lack of access to treatment protocols, inconsistent supply of essential drugs, and other systemic barriers.^{38–40} Such findings align with what was found at the tertiary hospital in Soweto.^{36,37} To bolster integration of chronic care through the health system therefore requires more investment in detection, diagnosis, treatment of NCDs alongside and in tandem with HIV care at the PHC level.¹¹ This will reduce cost, improve care, and enhance patient outcomes.

Care pathways through a well-structured referral system are required for integrated care for patients with multimorbidities.¹⁷ The current study revealed several limitations in both up- and down-referral. For instance, some patients walked into the tertiary hospital without a referral letter, while some doctors and nurses referred patients who did not qualify for a referral to the tertiary hospital. All these gaps and frequent bypassing of a structured referral system led to congestion and long queues at the tertiary hospital, contributing to overextending its services. Indeed, most health care providers revealed that some of the patients seen at the tertiary hospital could have easily been managed at the PHC clinics, further emphasizing the point that more investment in human resources is needed for PHC. Mojaki et al.⁴¹ have reported similar findings, whereby most patients seen at the MOPD and casualty had bypassed the referral system. More than half of the patients seen at these units could have been managed at the PHC facilities, a finding similar to a report from King Edward VIII Hospital in Durban⁴² and a factor that is overburdening tertiary care and leading to high cost.⁴³ In addition, our findings are in line with an ethnographic study conducted in Guatemala that found that health system challenges, including hospital bureaucracies, communication breakdowns, and fragmented care, were key restricting factors that hindered patients from accessing care.⁴⁴ Atun et al.²⁹ similarly describe concern for how these communication networks break down to influence the rate at which an intervention is integrated into the general health system. Thus, targeted focus on identifying and addressing referral cogs in the health system may lead to improved and integrated NCD-HIV care, as well as improved health outcomes of vulnerable populations.

Care pathways for patients through a well-structured referral system are required for integrated care for those with comorbidities.

Patients with co-occurring chronic illnesses require complex models of care, involving integration and collaboration of services among professions and institutions.

The ICDM model is patient-centered, proactive, and well-coordinated multidisciplinary care, using new technologies to improve collaboration between patients, providers, and caregivers.

Integrated care at the PHC level may alleviate many of the challenges patients with multiple chronic conditions face at the tertiary hospital. Because most clinics were specialized, collaboration of services or task sharing¹⁹ was limited and care was focused on only one disease at a time. These findings are similar to other studies in low-resource settings that revealed how service provision for T2DM remains very limited at PHC, with services being offered in isolation in hospitals and at higher levels of care.^{33,39,40} Yet, important management issues impeded a more integrated chronic care approach for many patients: poor communication between clinicians and patients, poor communication among health care providers, and interprofessional conflicts and competition among specialized clinics. Some providers were not aware that patients had comorbidities alongside the immediate disease for which they were being treated. As such, the providers treated one condition in isolation from any others. Importantly, although diseases that cluster together such as T2DM and hypertension were managed together, patients had to visit separate clinics for any other additional conditions that they had. This finding concurs with recent studies among patients with multimorbidities in South Africa that have revealed that patients with concordant conditions (similar in risk profile and management) were more likely to progress further along the care continuum, while those with discordant multimorbidities (not directly related in pathogenesis or management) tended not to progress beyond diagnosis.^{45,46} We also found that even in cases in which clinicians were aware of other comorbidities, some ended up giving a double prescription to patients. Lack of a centralized patient information led to parallel care, drug duplications, and disjointed care between providers and patients, similar to other reports.⁴⁷⁻⁴⁹

Ultimately, health care providers rarely provided personalized support to patients or their caregivers due to workload, language barriers, and time constraints, similar to what we have reported elsewhere.^{36,37} This situation occurred despite many health care providers recognizing the need for personalized support; health systems inherently contained barriers that impeded this integrated care. Patient support was provided apart from clinical interactions and primarily in group forums. The most common type of forum was diabetes education sessions, with many patients attending only one session. Patient activation in groups was limited given the lack of personalized engagement with providers that would facilitate interactions and partnership in care.³⁶ These findings may explain why a randomized

controlled trial that evaluated the effectiveness of group education sessions in Cape Town, found no significant improvement in any of the primary or secondary outcomes after 12 months, apart from a significant reduction in mean systolic and diastolic blood pressure.⁵⁰ Social workers also experienced challenges with families who were uncomfortable, disengaged, or absent. A growing body of research highlights the importance of meaningful engagement with families in clinical practice and a refocus on the providers' contribution in supporting families.⁵¹ Other studies in South Africa have also attributed low motivation to attend diabetes education sessions to poor patient-provider interaction, fear, dishonesty, and provider burn-out.⁵² Chronic conditions such as T2DM, however, require significant participation by informed patients, which may necessitate an ongoing collaborative process between patients and professionals to optimize long-term outcome. Yet, it is imperative to note that while the rationale for group education remains strong, such sessions must take into consideration the contexts in which they are implemented. Thus, future interventions on education forums for patients should be adapted for the infrastructural limitations and logistical barriers to patient retention.⁵⁰

The ICDM model is proactive and well-coordinated multidisciplinary care, designed to improve collaboration between patients, providers, and caregivers.¹² To achieve this goal in Soweto, PHC clinics must be strengthened in terms of providing adequate equipment and medication and training nurses to manage patients with T2DM and other chronic comorbidities. Only should the most severe cases be referred up to the tertiary level. Enhancing PHC interventions within the health system, especially within this context, can save time for the patient, enhance engagement in clinical visits for the patient and their family members, and ensure that further symptoms or health conditions are diagnosed early and cared for holistically.⁵¹ Even as chronic care escalates,⁵³ the ICDM model must incorporate the complexities associated with multimorbidity, especially HIV and NCD co-occurrence, to meet the emerging needs of the burgeoning number of patients with the concurrent diagnoses.

Policy and Research Implications

As South Africa's health care sector undergoes important reforms,⁹ numerous health systemic challenges remain, hindering the implementation of integrated and collaborative care models. In particular, integrating diabetes care into HIV care

programs has yet to be fully achieved due to health systemic challenges. Walt and Gilson⁵⁴ have argued that most health policies wrongly focus attention on the content of reform and neglect the actors involved in policy reform; the processes are contingent on developing and implementing change and on the context within which policy is developed. Atun et al.²⁹ have similarly emphasized that new interventions should be viewed with caution or circumspection by multiple potential adopters, affecting the extent, pattern, and rate of their adoption. Thus, when thinking about how to integrate care for patients with HIV and NCDs in South Africa and other LMICs, we suggest that PHC clinics and providers must be considered as key actors of implementation for ICDM models. Without addressing major issues of detection, diagnosis, and integrated care at the PHC level, higher levels of care such as secondary or tertiary hospitals will continue to face enormous patient burden in the everyday management of multiple conditions that can and should be relegated to the PHC. Greater investment is needed in PHC clinics in terms of equipment, medication, and staff who can deliver the consistent, careful, integrated, and patient-centered care patients deserve.

The MOPD is the centralized clinic through which patients first initiate care at a tertiary hospital in Soweto. We recommend strengthening the MOPD to offer integrated and collaborative care to patients with T2DM and other chronic comorbidities, especially HIV. Moreover, a key feature of task sharing or collaborative care is a team-based approach to care,¹⁹ whereby specialists at tertiary hospital engage and communicate among themselves and with providers at PHC clinics to improve patient outcomes.⁵⁵ In the context of this study, clinicians at the tertiary hospital rarely communicated with providers in different clinics within the hospital or at PHC clinics, largely due to staff shortages, limited time for meetings, and poor communication. Strengthening the MOPD and enhancing a proper collaborative care require training and increasing the number of staff, as well as implementing a centralized electronic data capture system at the tertiary hospital that will ease communication and task sharing among providers and patients across different levels of care. Further, addressing key systemic issues especially at PHC clinics will enable early screening, detection and management of comorbidities, ease workload at tertiary levels of care, and create a patient-centered as opposed to disease-specific approach.

Findings reported from our study have implications for other LMICs that are poorly prepared to

manage multimorbidity, partly due to inadequacies in the health system infrastructure (shortages of trained health care providers, equipment, and medication).^{56,57} For effective implementation and sustainability of the integrated care models, countries must adapt such models to fit their context. This tailoring calls for research into how countries are operationalizing and implementing integrated care and what challenges and opportunities exist. Such research may facilitate creating context-specific interventions or strategies that would enhance successful implementation of integrated care models. It may include assessing issues of human resources for health, equipment and medication, sustained decision support, developing comorbidity guidelines and checklists, and so forth.⁵⁸ Importantly, the term *multimorbidity* does not seem to have a universally accepted definition.² It is imperative to develop a standardized definition that can be incorporated into research agendas to identify the evidence gaps and to inform the organization of health systems.

Moreover, health care providers working with chronic care patients in LMICs must align chronic care to meet the needs of the patients and the population at large. This alignment will require a properly functioning patient information system to facilitate care coordination and effective communication between providers and patients. Establishing community linkages in care is one of the key tenets of integrated and collaborative care. Thus, a need exists to develop stronger links with communities to promote awareness on chronic comorbidity or multimorbidity prevention strategies through approaches such as outreach programs, early screening, self-management, and self-care.

Lastly, the coronavirus 2019 (COVID-19) pandemic has illustrated the need to understand how multimorbidities create vulnerabilities and interact with new infections (for example HIV and TB and immunosuppressed population groups). Thus, a need exists for more research to understand the complexities around multimorbidities and health systems to be better prepared to provide more effective care.

Limitations

This study did not involve PHC facilities in Soweto and thus excludes what happens in these settings. Yet, our ethnographic interviews encompassed observations and informal conversations with different actors in the health care system that inform what challenges and opportunities are present within these settings. This information is especially relevant regarding patients who had been

For proper and sustainable implementation of the integrated care models, countries must adapt such models to fit their context.

referred from PHC to tertiary hospital and provided insights about their experiences with PHC. Further, findings from this study concur with other qualitative studies^{10,14,15} that have focused on care provisions for patients with T2DM, HIV/AIDS, and other comorbidities in PHC in South Africa. This being an ethnographic study, issues around reflexivity and subjectivity were considered. First, being an outsider (non-South African) may have influenced the primary researcher's views on care provision. Second, the researcher relied on her own interpretation which could be biased. However, a constant thoughtful process in reviewing field notes, observations, and interviews with the participants and other researchers involved in this study allowed flexibility in data collection, analysis, and reporting of study findings.⁵⁹ In this way, reporting of research finding was objective, which increased scientific rigor.

CONCLUSIONS

Challenges experienced by patients with T2DM, HIV, and other chronic comorbidities in Soweto call for new ways to improve patient care by thinking and acting among policy makers, health care organizations, and health care professionals—as well as patients and caregivers. In addition to investing in and strengthening PHC-level disease detection, diagnosis, and care, we recommend strengthening the MOPD at the tertiary hospital to offer integrated and collaborative care to patients with T2DM and other comorbidities. The MOPD should also work with PHC clinics to ensure that patients can receive reliable care closer to their homes and families. To achieve this, health policy makers must address health system challenges such as lack of medical supplies, staff shortages, and a centralized patient information system in the public health care system. Improving the information that health care providers have from the level of the PHC clinic to the MOPD and specialty clinics is imperative, not only to improve the implementation of policies aimed at strengthening the health care system in South Africa but also to ensure the sustainability of such policies.

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REFERENCES

- World Health Organization (WHO). *Multimorbidity: Technical Series on Safer Primary Care*. WHO; 2016. Accessed January 15, 2021. <https://apps.who.int/iris/bitstream/handle/10665/252275/9789241511650-eng.pdf>
- The Lancet. Making more of multimorbidity: an emerging priority. *Lancet*. 2018;391(10131):1637. [CrossRef](#). [Medline](#)
- Chang AY, Gómez-Olivé FX, Payne C, et al. Chronic multimorbidity among older adults in rural South Africa. *BMJ Glob Health*. 2019; 4(4):e001386. [CrossRef](#). [Medline](#)
- Mendenhall E, Kohrt BA, Norris SA, Ndeti D, Prabhakaran D. Non-communicable disease syndemics: poverty, depression, and diabetes among low-income populations. *Lancet*. 2017; 389(10072):951–963. [CrossRef](#). [Medline](#)
- Oni T, Youngblood E, Boule A, McGrath N, Wilkinson RJ, Levitt NS. Patterns of HIV, TB, and non-communicable disease multi-morbidity in peri-urban South Africa—a cross sectional study. *BMC Infect Dis*. 2015;15(1):20. [CrossRef](#). [Medline](#)
- Clark SJ, Gómez-Olivé FX, Houle B, et al. Cardiometabolic disease risk and HIV status in rural South Africa: establishing a baseline. *BMC Public Health*. 2015;15(1):135. [CrossRef](#). [Medline](#)
- Sobieszczyk ME, Werner L, Mlisana K, et al. Metabolic syndrome after HIV acquisition in South African women. *J Acquir Immune Defic Syndr*. 2016;73(4):438–445. [CrossRef](#). [Medline](#)
- Coovadia H, Jewkes R, Barron P, Sanders D, McIntyre D. The health and health system of South Africa: historical roots of current public health challenges. *Lancet*. 2009;374(9692):817–834. [CrossRef](#). [Medline](#)
- Fusheini A, Eyes J, Goudge J. The state of public hospital governance and management in a South African hospital: a case study. *Int J Healthc*. 2017;3(2):68–77. [CrossRef](#)
- Ameh S, Klipstein-Grobusch K, D'ambrosio L, Kahn K, Tollman SM, Gómez-Olivé FX. Quality of integrated chronic disease care in rural South Africa: user and provider perspectives. *Health Policy Plan*. 2017;32(2):257–266. [CrossRef](#). [Medline](#)
- Fairall LR, Folb N, Timmerman V, et al. Educational outreach with an integrated clinical tool for nurse-led non-communicable chronic disease management in primary care in South Africa: a pragmatic cluster randomised controlled trial. *PLoS Med*. 2016;13(11): e1002178. [CrossRef](#). [Medline](#)
- Mahomed OH, Asmal S, Freeman M. An integrated chronic disease management model: a diagonal approach to health system strengthening in South Africa. *J Health Care Poor Underserved*. 2014;25(4):1723–1729. [CrossRef](#). [Medline](#)
- Knaul FM, Bhadelia A, Atun R, Frenk J. Achieving effective universal health coverage and diagonal approaches to care for chronic illnesses. *Health Aff*. 2015;34(9):1514–1522. [CrossRef](#). [Medline](#)
- Mahomed OH, Asmal S, Voce A. Sustainability of the integrated chronic disease management model at primary care clinics in South Africa. *Afr J Prim Health Care Fam Med*. 2016;8(1):e1–e7. [CrossRef](#). [Medline](#)
- Matima R, Murphy K, Levitt NS, BeLue R, Oni T. A qualitative study on the experiences and perspectives of public sector patients in Cape Town in managing the workload of demands of HIV and type 2 diabetes multimorbidity. *PLoS One*. 2018;13(3):e0194191. [CrossRef](#). [Medline](#)

16. Atun R, Jaffar S, Nishtar S, et al. Improving responsiveness of health systems to non-communicable diseases. *Lancet*. 2013;381(9867):690–697. [CrossRef](#). [Medline](#)
17. Pinder R, Petchey R, Shaw S, Carter Y. What's in a care pathway? Towards a cultural cartography of the new NHS. *Social Health Illn*. 2005;27(6):759–779. [CrossRef](#). [Medline](#)
18. World Health Organization (WHO), PEPFAR, UNAIDS. *Task Shifting: Rational Redistribution of Tasks Among Health Workforce Teams: Global Recommendations and Guidelines*. WHO; 2007. Accessed January 15, 2021. <https://apps.who.int/iris/handle/10665/43821>
19. Anand TN, Joseph LM, Geetha AV, Prabhakaran D, Jeemon P. Task sharing with non-physician health-care workers for management of blood pressure in low-income and middle-income countries: a systematic review and meta-analysis. *Lancet Glob Health*. 2019;7(6):e761–e771. [CrossRef](#). [Medline](#)
20. Nuño R, Coleman K, Bengoa R, Sauto R. Integrated care for chronic conditions: the contribution of the ICCF Framework. *Health Policy*. 2012;105(1):55–64. [CrossRef](#). [Medline](#)
21. Boulton C, Green AF, Boulton LB, Pacala JT, Snyder C, Leff B. Successful models of comprehensive care for older adults with chronic conditions: evidence for the Institute of Medicine's "retooling for an aging America" report. *J Am Geriatr Soc*. 2009;57(12):2328–2337. [CrossRef](#). [Medline](#)
22. Spedding M, Stein D, Sorsdahl K. Task-shifting psychosocial interventions in public mental health: a review of the evidence in the South African context. *South African Heal Rev*. 2015;2014/2015(1):73–87. <https://hdl.handle.net/10520/EJC189295>
23. Bergström S. Training non-physician mid-level providers of care (associate clinicians) to perform caesarean sections in low-income countries. *Best Pract Res Clin Obstet Gynaecol*. 2015;29(8):1092–1101. [CrossRef](#). [Medline](#)
24. Petersen I, Bhana A, Fairall LR, et al. Evaluation of a collaborative care model for integrated primary care of common mental disorders comorbid with chronic conditions in South Africa. *BMC Psychiatry*. 2019;19(1):107. [CrossRef](#). [Medline](#)
25. Lasker RD, Weiss ES, Miller R. Partnership synergy: a practical framework for studying and strengthening the collaborative advantage. *Milbank Q*. 2001;79(2):179–205, III-IV. [CrossRef](#). [Medline](#)
26. Bantom SA. Retha de la Harpe NR. Accessibility to patients' own health information: a case in rural Eastern Cape, South Africa. Paper presented at: SAICSIT '16: Proceedings of the Annual Conference of the South African Institute of Computer Scientists and Information Technologists; September 2016. [CrossRef](#)
27. Marutha S. *Records Management in Support of Service Delivery in the Public Health Sector of the Limpopo Province in South Africa*. Thesis, University of South Africa; 2011. Accessed January 15, 2021. <http://hdl.handle.net/10500/5737>
28. Raff M, James MFM. An audit of anaesthetic record keeping. *Southern Afr J Anaesthesia Analgesia*. 2003;9(3):7–9. [CrossRef](#)
29. A'jun R, de Jongh T, Secci F, Ohiri K, Adeyi O. Integration of targeted health interventions into health systems: a conceptual framework for analysis. *Health Policy Plan*. 2010;25(2):104–111. [CrossRef](#). [Medline](#)
30. National Department of Health. *Integrated Support Team Consolidated Report of the Integrated Support Team: Review of Health Overspending and Macro-Assessment of the Public Health System in South Africa*. National Department of Health; 2009.
31. Mahomed O, Asmall S. Development and implementation of an integrated chronic disease model in South Africa: lessons in the management of change through improving the quality of clinical practice. *Int J Integr Care*. 2015;15(4):e038. [CrossRef](#). [Medline](#)
32. Statistics South Africa. *Statistical Release (Revised), Census 2011*. Statistics South Africa; 2011. Accessed January 21, 2021. <https://www.statssa.gov.za/publications/P03014/P030142011.pdf>
33. Bosire E, Mendenhall E, Omondi GB, Ndeti D. When diabetes confronts HIV: biological sub-citizenship at a public hospital in Nairobi, Kenya. *Med Anthropol Q*. 2018;32(4):574–592. [CrossRef](#). [Medline](#)
34. Braun V, Clarke V. To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales useful concept for thematic analysis and sample-size rationales. *Qual Res Sport Exerc Health*. 2019. [CrossRef](#)
35. Kolb SM. Grounded theory and the constant comparative method: valid research strategies for educators. *J Emerg Trends Educ Res Policy Stud*. 2012;3(1):83–86.
36. Bosire EN, Mendenhall E, Norris SA, Goudje J. Patient-centred care for patients with diabetes and HIV at a public tertiary hospital in South Africa: an ethnographic study. *Int J Heal Policy Manag*. 2020. [CrossRef](#). [Medline](#)
37. Bosire EN. Patients' experiences of comorbid HIV/AIDS and diabetes care and management in Soweto, South Africa. *Qual Health Res*. 2021;31(2):373–384. [CrossRef](#). [Medline](#)
38. Leung C, Aris E, Mhalu A, et al. Preparedness of HIV care and treatment clinics for the management of concomitant non-communicable diseases: a cross-sectional survey. *BMC Public Health*. 2016;16(1):1002. [CrossRef](#). [Medline](#)
39. Katende D, Mutungi G, Baisley K, et al. Readiness of Ugandan health services for the management of outpatients with chronic diseases. *Trop Med Int Health*. 2015;20(10):1385–1395. [CrossRef](#). [Medline](#)
40. Peck R, Mghamba J, Vanobberghen F, et al. Preparedness of Tanzanian health facilities for outpatient primary care of hypertension and diabetes: a cross-sectional survey. [published correction appears in *Lancet Glob Health*. 2014;2(9):511]. *Lancet Glob Health*. 2014;2(5):e285–e292. [CrossRef](#). [Medline](#)
41. Mojaki ME, Basu D, Letshokgohla ME, Govender M. Referral steps in district health system are side-stepped. *S Afr Med J*. 2011;101(2):109. [CrossRef](#). [Medline](#)
42. Rutkove SB, Abdool Karim SS, Loening WE. Patterns of care in an overburdened tertiary hospital outpatients department. *S Afr Med J*. 1990;77(9):476–478. [Medline](#)
43. Kamau KJ, Osuga BO, Njuguna S. Challenges facing implementation of referral system for quality health care services in Kiambu County, Kenya. *Health Syst Policy Res*. 2017;4(1):48. [CrossRef](#)
44. Chary A, Flood D, AUSTAD K, et al. Navigating bureaucracy: accompanying indigenous Maya patients with complex health care needs in Guatemala. *Hum Organ*. 2016;75(4):305–314. [CrossRef](#)
45. Chang AY, Gómez-Olivé FX, Manne-Goehler J, et al. Multimorbidity and care for hypertension, diabetes and HIV among older adults in rural South Africa. *Bull World Health Organ*. 2019;97(1):10–23. [CrossRef](#). [Medline](#)
46. Manne-Goehler J, Siedner MJ, Montana L, et al. Hypertension and diabetes control along the HIV care cascade in rural South Africa. *J Int AIDS Soc*. 2019;22(3):e25213. [CrossRef](#). [Medline](#)
47. Atun R, Davies JI, Gale EAM, et al. Diabetes in sub-Saharan Africa: from clinical care to health policy. *Lancet Diabetes Endocrinol*. 2017;5(8):622–667. [CrossRef](#). [Medline](#)
48. Jaffar S. Diabetes and other non-communicable diseases in Africa: a potential disaster in the waiting. *Lancet Diabetes Endocrinol*. 2016;4(11):875–877. [CrossRef](#). [Medline](#)
49. Manne-Goehler J, Atun R, Stokes A, et al. Diabetes diagnosis and care in sub-Saharan Africa: pooled analysis of individual data from 12 countries. *Lancet Diabetes Endocrinol*. 2016;4(11):903–912. [CrossRef](#). [Medline](#)
50. Mash RJ, Rhode H, Zwarenstein M, et al. Effectiveness of a group diabetes education programme in under-served communities in South Africa: a pragmatic cluster randomized controlled trial. *Diabet Med*. 2014;31(8):987–993. [CrossRef](#). [Medline](#)
51. Deek H, Hamilton S, Brown N, et al; FAMILY Project Investigators. Family-centred approaches to healthcare interventions in chronic

- diseases in adults: a quantitative systematic review. *J Adv Nurs*. 2016;72(5):968–979. [CrossRef](#). [Medline](#)
52. van der Does AMB, Mash R. Evaluation of the “Take Five School”: an education programme for people with type 2 diabetes in the Western Cape, South Africa. *Prim Care Diabetes*. 2013;7(4):289–295. [CrossRef](#). [Medline](#)
53. Boehmer KR, Abu Dabrh AM, Gionfriddo MR, Erwin P, Montori VM. Does the chronic care model meet the emerging needs of people living with multimorbidity? A systematic review and thematic synthesis. *PLoS One*. 2018;13(2):e0190852. [CrossRef](#). [Medline](#)
54. Walt G, Gilson L. Reforming the health sector: the central role of policy analysis. *Health Policy Plan*. 1994;9(4):353–370. [CrossRef](#). [Medline](#)
55. Shaw J, Sethi S, Vaccaro L, et al. Is care really shared? A systematic review of collaborative care (shared care) interventions for adult cancer patients with depression. *BMC Health Serv Res*. 2019; 19(1):120. [CrossRef](#). [Medline](#)
56. Academy of Medical Sciences (UK) and Academy of Science of South Africa (ASSAf). *Improving the Prevention and Management of Multimorbidity in Sub-Saharan Africa*. ASSAf; 2020. Accessed January 15, 2021. <http://hdl.handle.net/20.500.11911/139>
57. Beaglehole R, Epping-Jordan J, Patel V, et al. Improving the prevention and management of chronic disease in low-income and middle-income countries: a priority for primary health care. *Lancet*. 2008;372(9642):940–949. [CrossRef](#). [Medline](#)
58. Ku GMV, Kegels G. Adapting chronic care models for diabetes care delivery in low-and-middle-income countries: a review. *World J Diabetes*. 2015;6(4):566–575. [CrossRef](#). [Medline](#)
59. Reeves S, Peller J, Goldman J, Kitto S. Ethnography in qualitative educational research: AMEE Guide No. 80. *Med Teach*. 2013;35(8): e1365–e1379. [CrossRef](#). [Medline](#)

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ORIGINAL ARTICLE

Inpatient Point-of-Care HIV Early Infant Diagnosis in Mozambique to Improve Case Identification and Linkage to Antiretroviral Therapy

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Key Findings

- Monthly virologic testing volume in HIV-exposed infants increased 97% with introduction of point-of-care early infant diagnosis testing.
- There was a 29.7% positivity rate for inpatient point-of-care tests performed.
- Antiretroviral therapy initiation for infants with positive tests improved 64% with introduction of point-of-care early infant diagnosis.

Key Implications

- Pediatric inpatient wards are high-yield sites for HIV case identification, and inpatient early infant diagnosis is an important backstop to outpatient follow-up of exposed infants for prevention of mother-to-child transmission.
- Point-of-care testing improves inpatient early infant diagnosis performance, facilitating more timely initiation of antiretroviral in HIV-infected infants, and point-of-care early infant diagnosis expansion plans should prioritize high-volume pediatric wards.

ABSTRACT

Introduction: Novel approaches to case identification and linkage to antiretroviral therapy (ART) are needed to close gaps in early infant diagnosis (EID) of HIV. Point-of-care (POC) EID is a recent innovation that eliminates the long turnaround times of conventional EID that limit patient management in the inpatient setting. The initial deployment of POC EID in Mozambique focused primarily on outpatient clinics; however, 2 high-volume tier-4 pediatric referral hospitals were also included.

Methods: To assess the impact of inpatient POC EID, a retrospective review of testing and care data from Hospital Central de Beira (HCB) and Hospital Central de Maputo (HCM) was performed for the period September 2017 to July 2018, with comparison to the 8-month pre-POC period when dried blood spots were used for conventional EID.

Results: Monthly testing volume increased from 8.5 tests pre-POC to 17.6 tests with POC ($P < .001$). Among 511 children with POC testing, the median age was 5 months, there was ongoing breastfeeding in 326 (63.8%), and 136 (26.6%) of mothers and 146 (28.6%) of infants had not received ART or antiretroviral prophylaxis, respectively. POC tests were positive in 152 (29.7%) infants, and 52 (37.5%) had a previous negative DNA polymerase chain reaction through the conventional outpatient EID program. Linkage to ART for infants with HIV-positive tests improved 64% during the POC period ($P = .002$). Inpatient mortality for infected infants during the POC period was 28.2%. Excluding these deaths, 61.2% of eligible infants initiated ART as inpatients, but only 29.8% of those discharged without ART were confirmed to have initiated as outpatients.

Conclusions: Inpatient wards are a high-yield site for EID and ART initiation that have historically been overlooked in programming for prevention of mother-to-child transmission. POC platforms represent a transformative opportunity to increase inpatient testing, make definitive diagnoses, and improve timely linkage to ART. Scale-up plans should prioritize pediatric wards.

INTRODUCTION

Despite massive scale-up over the past decade, pediatric antiretroviral therapy (ART) coverage rates in sub-Saharan Africa remain low. In Mozambique, only an estimated 50% of HIV-infected children were on ART at the end of 2018, compared with a 55% coverage rate in adults.^{1,2} Low pediatric coverage rates can, in part, be attributed to significant challenges with retention of

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Conventional EID programs do not adequately serve pediatric inpatient wards and represent a missed opportunity to reduce the impact of HIV in children.

mother–infant pairs in prevention of mother-to-child transmission (PMTCT) services with only 62% of exposed infants of women living with HIV enrolled in antenatal care having an early infant diagnosis (EID) virologic test by 2 months of age in 2018.¹ For HIV-exposed infants (HEI) retained in care, the complexity of establishing the HIV status of children under 18 months of age likely also contributes to low pediatric ART coverage. Definitive diagnosis in HEIs requires a virologic EID test, which until recently was only available in centralized reference laboratories, with delayed result delivery due to transport times and the need to process samples from many health facilities.³ Slow delivery of EID results and subsequent delayed ART initiation lead to higher mortality rates among HIV-infected children.⁴

Point-of-care (POC) testing for EID is a recent innovation that permits health care systems to decentralize testing and bypass the inefficient networks needed for centralized testing platforms.³ POC EID has well-documented impact and success, virtually eliminating turnaround times and therefore permitting a same-day testing and treatment paradigm for HIV-infected infants.^{5–8} In Mozambique, a cluster randomized trial showed that 90% of participants accessing POC EID were linked to timely ART compared with 13% in the standard of care.⁹

POC EID testing in Mozambique uses the Abbott mPIMA platform, which gives results in approximately 1 hour, and was scaled up from 2017 and 2018 in a strategic rollout that prioritized deployment to high-volume outpatient services at public primary health care facilities, consistent with international implementation recommendations.^{10,11} In recognition of the opportunity to also reach hospitalized infants who are more likely to have advanced HIV and need urgent ART to prevent mortality, pediatric wards in 2 large referral hospitals, Hospital Central de Maputo (HCM) and Hospital Central de Beira (HCB), were included in the implementation plan. Despite their perceived ease of access to reference laboratories with conventional molecular testing equipment, inpatient wards in hospitals in Mozambique historically face similar long turnaround times for EID results compared with outpatient health facilities, with an average of 36 days for the 11 largest hospitals in the country in 2016 compared with 47 days for health centers.¹² These settings represent considerable wastage of conventional EID resources because patient discharge usually occurs before results are available, and post-discharge follow-up is complicated by long distances between patients' homes

and the referral hospital. Furthermore, the national EID program does not use a unique patient identifier to facilitate tracking results across health facilities. As such, conventional EID programs do not adequately serve pediatric inpatient wards and represent a missed opportunity, especially since these settings are known to have high yields of HIV-positive tests when EID testing is part of provider-initiated testing and counseling (PITC) is operationalized.^{13–17}

We conducted an early assessment of the impact of POC EID deployment in the pediatric wards of HCM and HCB.

METHODS

Study Design, Setting, and Participants

This study was a retrospective review of routine EID testing and patient care data from HCM and HCB, tier-4 reference hospitals providing the highest level of care in the public sector in the southern and central regions of Mozambique, respectively. In 2018, HCM admitted an average of 866 children per month, and HCB admitted an average 536 children per month. In both hospitals, the median age of admission is below 2 years old. The POC study period began from the time of POC implementation at each site (February 2017 for HCB and September 2017 for HCM) through July 2018. Eight months of pre-POC data, when testing was performed via dried blood spots (DBSs), were included from each site for comparison. Per national guidelines, HEIs aged 1 to 18 months who underwent inpatient EID testing were included.¹⁸ Patients with nonvalid EID results and those referred from other health facilities for EID testing (i.e., infants not admitted to the hospital but accessing the POC EID platform) were excluded. Patients who were known to be HIV infected at the time of admission were not eligible for EID testing and were not included.

National PITC and EID Guidelines

Infants already known to be HIV exposed at the time of admission (identified through review of maternal and child health documents and caregiver medical history) were routinely offered initial EID testing if standard testing at 1 month of age had been missed. They were also generally offered repeat EID testing if they had outdated previous negative outpatient EID test results or presenting conditions suggestive of HIV infection. For infants whose mothers had unknown serostatus or whose last negative test was more than 3 months prior to admission, national policy was to conduct routine

opt-out ward-based PITC of mothers using rapid antibody tests to newly identify HEIs eligible for EID testing.¹⁸ The national EID algorithm during the time period of this study called for virologic testing at enrollment in the HEI clinic (recommended at 1 month of age), at 9 months if rapid antibody testing was positive, and at any time infants had signs and symptoms suggestive of HIV infection. For inpatient EID, guidelines are not specific about when to repeat virologic testing for HEIs who previously tested negative, but generally speaking, EID testing is repeated in children with malnutrition, developmental delay, or infectious illness that could be associated with immune suppression, or if previous testing was more than 2 months prior to admission. Active phone tracing of infected patients identified through hospital-based EID to confirm their continuity of care after discharge to primary health centers was recommended, but it was more routinely done at HCM than HCB during the period of this study.

Data Collection

For the pre-POC period, DBS EID data were collected for each site from a national EID data database that contains test results, demographic information, and clinical information from standard national EID requisition forms which include PMTCT information on maternal ART, infant prophylaxis, breastfeeding status, and previous EID testing. ART information for the pre-POC period was obtained from site ART registers. A more comprehensive set of data were collected for the POC EID period from sources including onsite EID logbooks, EID requisition forms, 2 web-based databases (POC connectivity and the national online EID portal), ART registers, and call logs from a patient follow-up program (HCM only). A trained team of data collectors reviewed all available data sources to populate an anonymous, structured database that recorded patient demographics, EID testing dates and results, ART information, and follow-up status for all patients with POC EID testing in the study period.

Data Analysis

Data were collected and organized into Microsoft Excel (2003), and data analysis was conducted using STATA v12 (StataCorp©, 2011). Descriptive summary statistics were produced for testing volumes and positivity rates. Chi-square and Fisher's exact tests were applied to investigate differences in pre- and post-POC implementation results in addition to POC positivity rates for a set of patient characteristics

including age, sex, PMTCT regimens, and previous access to conventional DNA polymerase chain reaction (PCR) results. All statistical analyses used *P*-values and 5% significance level for inference.

Ethical Considerations

Ethical approval for this assessment was obtained from Mozambique's National Health Bioethics Committee reference 80/CNBS/14. The Scientific Directorates of HCM and HCB also approved the study. These boards did not require the study to obtain consent from caregivers for use of the routine EID and ART data included in the analysis.

RESULTS

POC Study Population Characteristics

A total of 511 HEIs were tested with POC at both hospitals during the study period (330 patients over 18 months at HCB, and 181 patients over 11 months at HCM). The median age was 5 months, and 232 patients (45.4%) were girls. A previous negative DNA PCR performed at the primary health facility level of care as part of routine EID was documented for 219 (42.9%) infants. No history of antiretroviral prophylaxis or ART for PMTCT was available for 136 (26.6%) of mothers, 146 (28.6%) of infants had not received nevirapine prophylaxis, and 326 (63.8%) of infants were still being breastfed (Table 1).

POC Test Results and ART Initiation

POC tests were positive in 152 (29.7%) of the HEIs tested. Of these HIV positive infants, 74 (48.7%) initiated ART during their hospitalization. A total of 43 inpatient deaths (28.2%) occurred among infants with confirmed HIV infection, including 12 who initiated ART in the hospital. Excluding the 31 infants who died in the hospital prior to ART initiation, 61.2% (74/121) of eligible patients initiated ART while admitted. For the 109 infected infants who were discharged, 66.1% (41/62) of those who initiated ART as inpatients were confirmed to be active on ART on follow-up, and only 29.8% (14/47) of those who did not initiate ART as inpatients were confirmed to be active on ART (Figure).

Clinical and Demographic Variables Associated With POC Positivity

Infants whose mothers were on ART had a 27.4% positivity rate compared with 38.2% when there was no maternal ART ($P=.047$). Infants who had received nevirapine prophylaxis had a

TABLE 1. Clinical and Demographic Characteristics of HIV-Exposed Infants in Point-of-Care Early Infant Diagnosis Study From Inpatient Wards of 2 Pediatric Referral Hospitals, Mozambique

Variable	Patients, n (%)		
	HCB	HCM	Total
Age, months			
1–2	101 (30.6)	45 (24.9)	146 (28.6)
3–5	67 (20.3)	54 (29.8)	121 (23.7)
6–8	73 (22.1)	33 (18.2)	106 (20.7)
9–11	40 (12.1)	27 (14.9)	67 (13.1)
≥12	48 (14.5)	20 (11.0)	68 (13.3)
Missing	1 (0.3)	2 (1.1)	3 (0.6)
Sex			
Female	148 (44.8)	84 (46.4)	232 (45.4)
Male	182 (55.2)	97 (53.6)	279 (54.6)
Previous DNA PCR			
Yes	138 (41.8)	81 (45.0)	219 (42.9)
No ^a	192 (58.2)	99 (55.0)	292 (57.1)
Maternal PMTCT			
Prophylaxis	2 (0.6)	4 (2.2)	6 (1.2)
Full ART	210 (63.6)	133 (73.5)	343 (67.1)
None	105 (31.8)	31 (17.1)	136 (26.6)
Missing	13 (3.9)	13 (7.2)	26 (5.1)
Infant PMTCT			
NVP prophylaxis	207 (62.7)	130 (71.8)	337 (65.9)
None	113 (34.2)	33 (18.2)	146 (28.6)
Missing	10 (3.0)	18 (9.9)	28 (5.5)
Current breastfeeding			
Yes	233 (70.6)	93 (51.4)	326 (63.8)
No	78 (23.6)	73 (40.3)	151 (29.5)
Missing	19 (5.8)	15 (8.3)	34 (6.7)
Total	330 (100)	180 (100)	511 (100)

Abbreviations: ART, antiretroviral therapy; HCB, Hospital Central de Beira; HCM, Hospital Central de Maputo; NVP, nevirapine; PCR, polymerase chain reaction; PMTCT, prevention of mother-to-child transmission.

^a Includes infants with unknown or undocumented previous testing.

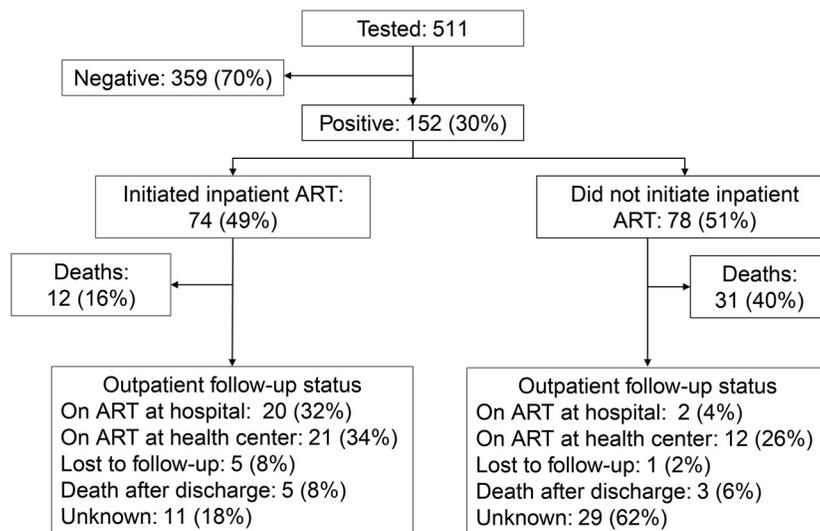
26.4% positivity rate compared to 37.0% in those who had not ($P=.018$). Infants who were still breastfeeding at the time of testing had a 33.1% positivity rate compared with 22.5% in those who were not ($P=.019$). No significant differences in positivity were found based on age, sex, and previous negative DNA PCR (Table 2). Of children who tested positive,

37.5% (52/152) had a documented previous negative DNA PCR test performed prior to admission.

POC Positivity by Ward

Significant differences in POC test positivity were found based on the ward from which patients were referred for inpatient testing, with malnutrition

FIGURE. Point-of-Care Early Infant Diagnosis Testing and Linkage to Antiretroviral Therapy, Among HIV-Exposed Infants From Two Pediatric Referral Hospitals, Mozambique



Abbreviation: ART, antiretroviral therapy.

(41.1%), the pediatric intensive care unit (40.0%), and the breastfeeding ward (38.3%) having the highest rates (Table 3).

Utilization, Positivity, and Linkage to ART Compared With Pre-POC DBS Testing

In combined analysis from both hospitals, testing volume increased 97% from an average of 8.9 inpatient tests per month with DBSs in the pre-POC period to 17.6 tests per month with POC ($P<.001$). The median age of tested infants was 4 months for the pre-POC period and 5 months for the POC period. Test positivity decreased from 45.5% pre-POC to 29.7% with POC ($P<.001$). Documentation of successful linkage to ART (inpatient or outpatient) increased from 35.4% pre-POC to 57.9% with POC ($P=.002$).

DISCUSSION

This study shows that inpatient POC EID is both feasible and effective. Not only did the placement of POC technology in these hospital settings increase overall testing volume and newly identify a high number of children with HIV-positive tests, but the immediate onsite POC test results also permitted much improved linkage to ART for these children compared with the pre-POC period.

A highly significant 97% increase in testing volume per month occurred after allocation of POC, which we believe is best explained by clinicians being more likely to order EID testing when timely results were available. Improved inpatient PITC at both hospitals during the time period of the study could have contributed to more newly identified HEIs, but PITC testing data were not included in this study and the large majority of EID tests are performed in infants already known to be HIV exposed. No dramatic changes in maternal antenatal HIV prevalence, annual admission volumes, or EID eligibility criteria occurred during the time period of the study that would otherwise explain this large increase in testing volume. Yet, despite the large increase in testing volume, the POC platforms still may have been underutilized. This circumstance is of particular concern at HCM, which is in a higher-HIV prevalence province and has approximately 60% more admissions per month, but had fewer inpatient POC tests performed per month than did HCB (16.5 versus 18.3).¹⁹ Increased POC EID testing is needed in wards that admit HEIs 12–18 months of age, which represented only 36.6% of the test requests in this study. This finding is important in light of new EID algorithm recommendations from the World Health Organization that call for virologic

The immediate onsite POC test results permitted much improved linkage to ART for children with HIV infection compared with the pre-POC period.

TABLE 2. Point-of-Care Early Infant Diagnosis Positivity by Clinical and Demographic Variables Among HIV-Exposed Infants From Inpatient Wards of 2 Pediatric Referral Hospitals, Mozambique

Variable	Negative Test, n (%)	Positive Test, n (%)	Chi-Square P Value
Age, months			
1–2	113 (77.4)	33 (22.6)	0.127
3–5	77 (63.6)	44 (36.4)	
6–8	70 (66.0)	36 (34.0)	
9–11	48 (71.6)	19 (28.4)	
≥12	49 (72.1)	19 (27.9)	
Missing	2 (66.7)	1 (33.3)	
Sex			
Female	160 (69.0)	72 (31.0)	0.561
Male	199 (71.3)	80 (28.7)	
Previous DNA PCR			
Yes	162 (74.0)	57 (26.0)	0.106
No	196 (67.4)	95 (32.6)	
Maternal PMTCT			
Prophylaxis	5 (83.3)	1 (16.7)	0.047 ^a
Full ART	249 (72.6)	94 (27.4)	
None	84 (61.8)	52 (38.2)	
Missing	21 (80.8)	5 (19.2)	
Infant PMTCT			
NVP prophylaxis	248 (73.6)	89 (26.4)	0.018
None	92 (63.0)	54 (37.0)	
Missing	19 (67.9)	9 (32.1)	
Current breastfeeding			
Yes	218 (66.9)	108 (33.1)	0.019
No	117 (77.5)	34 (22.5)	
Missing	24 (70.6)	10 (29.4)	
Total	359 (70.3)	152 (29.7)	

Abbreviations: ART, antiretroviral therapy; NVP, nevirapine; PCR, polymerase chain reaction; PMTCT, prevention of mother to child transmission.

^aFisher’s exact test.

testing in HEIs >9 months of age given the possibility of false-negative rapid HIV test results.^{11,20–22}

Concerningly, a study of pediatric inpatient PITC from wards in Mozambique reported that coverage rates are low.¹³ Routine opt-out rapid antibody testing of breastfeeding mothers is a crucial first step to newly identify HEIs who need EID testing, and this step can help improve POC EID platform utilization. The same study also showed that hospitals that relied on DBSs for EID often

did not test or retest exposed infants and presumptive HIV diagnosis was rarely made.¹³ POC platforms bypass the inherent delays that come with DBS-based EID; eliminate the need for inpatient presumptive HIV diagnosis, which has been consistently underutilized; and have the potential to strengthen pediatric inpatient PITC and improve case detection. Inpatient POC EID can also serve as an important backstop to traditional outpatient HEI-clinic EID, as 37.5% of the infants with

TABLE 3. Point-of-Care Early Infant Diagnosis Positivity Among HIV-Exposed Infants From Inpatient Wards of 2 Pediatric Referral Hospitals, Mozambique, by Referral Ward

Ward	Negative Test, n (%)	Positive Test, n (%)	Fisher’s Exact Test P Value
Nursery	12 (100.0)	0 (0)	0.002
Breastfeeding ^a	108 (61.7)	67 (38.3)	
General ward ^b	32 (82.1)	7 (17.9)	
Infectious diseases	130 (74.7)	44 (25.3)	
Malnutrition	33 (58.9)	23 (41.1)	
Pediatric intensive care unit	15 (60.0)	10 (40.0)	
Other ^c	5 (83.3)	1 (16.7)	
Missing	24 (100.0)	0 (0)	
Total	359 (70.3)	152 (29.7)	

^aWard for all admission diagnoses in patients aged 1–12 months at Hospital Central de Maputo. During the study, Hospital Central de Beira changed admission criteria to breastfeeding ward from 1–6 months to 1–12 months.

^bPatients aged 12 months or older.

^cIncludes pediatric surgery, respiratory, and other subspecialty wards.

positive POC tests had a previous negative outpatient PCR and were presumably infected during breastfeeding.

The 29.7% overall positivity rate for POC EID from this study is significantly higher than other results reported from the region. A POC EID evaluation from 8 African countries reported a 15.2% prevalence in pediatric inpatients (hospitalized children represented only 2.9% of the total cohort), and a study from Malawi, where 48.9% of the infants tested with POC came from inpatient wards, had an overall positivity rate of 5.7% (no inpatient/outpatient disaggregation provided).^{5,7}

The EID positivity rate was even higher before POC implementation, at 45.5%. Although some of this difference could be explained by improved PMTCT coverage in the later POC period, it is also likely that DBS testing was only performed in HEIs with more advanced signs and symptoms of HIV infection.¹ Not all admitted HEIs need repeat virologic testing with POC, but the ease of use and timely results seem to lower the clinical threshold for testing to include more subtle early signs of infection, thereby allowing for more timely diagnosis of HIV with better treatment outcomes.

The PMTCT program in Mozambique continues to struggle to reduce vertical transmission, with an estimated rate of 15% (much of which occurs via breastfeeding), challenges with maternal ART adherence and retention, and high rates of maternal seroconversion during pregnancy and lactation.^{23–26} Undiagnosed infants will often

become ill and require hospitalization, and this study showed the high toll of such late presentation in terms of inpatient mortality at 28.2%. This rate was higher than the 22% mortality rate reported in a recent pediatric inpatient study from Kenya that included infants and older children, and it highlights the importance of strengthening serial maternal HIV testing throughout pregnancy and the breastfeeding period, as well as outpatient EID, so diagnoses can be made before children develop advanced disease requiring hospitalization.²⁷

Confirmed ART initiation for infants with positive inpatient EID tests was 64% higher in the POC period, facilitated by same-day actionable results. Despite previous efforts to prioritize central laboratory testing of DBS samples from inpatient wards, the turnaround times for conventional DNA PCR (36-day average for the 11 largest hospitals in Mozambique in 2016) meant that most hospitalized patients had been discharged before their results were returned, despite being expedited.¹² Furthermore, posthospitalization follow-up often occurs at primary health care centers closer to patients’ homes, and the resources needed for routine active tracing of infected infants via phone or home visits are generally lacking. Consequently, these conventional results never reached the children’s caregivers, contributing to reduced linkage to ART. This study shows that such hurdles to timely ART initiation for infants with HIV infection

The PMTCT program in Mozambique struggles to reduce vertical transmission.

diagnosed during hospitalization can be addressed with the use of POC EID.

With the exclusion of infants who died during hospitalization prior to ART initiation, 61.2% of those with positive tests initiated as inpatients. Our data set did not allow for analysis of why some infants did not initiate ART as inpatients, but anecdotally the most common reason was inpatient tuberculosis diagnosis with guidelines recommending 2 weeks of treatment before ART should be started. An additional 29.8% of HIV-infected infants who were discharged without ART were confirmed to have initiated as outpatients. These numbers compare unfavorably to other POC studies, which reported ART linkage rates of 86.3% and 91%, but did not disaggregate inpatient versus outpatient timing.^{5,7} A large difference was found in confirmed ART post discharge in patients who initiated as inpatients versus those who did not (66.1% vs. 29.8%), suggesting that an ideal model would promote ART initiation during admission to the extent possible. A recent clinical trial showed no early mortality benefit to urgent inpatient ART initiation in children, but the findings from this study suggest that initiation after stabilization but before discharge may help improve access to and retention on ART.²⁷ A clear need exists to improve active follow-up of infants diagnosed during hospitalization at these sites to ensure successful linkage to ongoing ART.

The results from this study suggest that POC EID can further improve access to EID and pediatric ART by broadening the considerations for potential placement scenarios. Our findings suggest there is clear benefit to deploying POC testing to hospitals with subsequent establishment of context-appropriate ART initiation models that readily decentralize back to primary care. However, this consideration for further deployment of POC testing to inpatient settings does not need to be limited to large pediatric hospitals; the dynamics of inpatient reality (late presentation, incomplete EID testing history, admission duration shorter than conventional DNA PCR turnaround times) are applicable to smaller wards throughout the country whose patients would also benefit from inpatient POC EID. The ability to now multiplex on POC instruments, such as the HIV viral load assays that are now also being performed at HCM and HCB on the Abbott mPIMA analyzer used in this study, the advent of birth EID testing opportunities, and combined inpatient/outpatient testing at sites with both EID clinics and pediatric wards can generate testing volumes that justify deployment to settings such as

district hospitals that previously may not have met POC allocation criteria. Indeed, there remain deployment opportunities to further reach HEIs across the health care system, and POC consistently proves to be an effective and feasible solution—one that will be needed to help reach national and global targets.

Limitations

This study had limitations that need mention. A smaller set of data variables was available for the pre-POC period, and we were not able to perform a comparison of hospital outcomes from before and after the implementation of inpatient POC EID. The number of HIV-exposed children who were admitted and would need EID testing during the pre-POC and POC periods was also not part of the data available for this study, so our conclusions about availability of POC driving increased testing demand come with qualifications. Phone follow-up to verify outpatient ART status did not occur at a standard time interval post hospital discharge, and systems were lacking for timely and routine phone follow-up of discharged patients at HCB, possibly leading to an underestimation of ART linkage. Given the retrospective methodology, several clinical and demographic variables had missing data that could not be captured. The data presented here are from a 2017–2018 period, but the results reflect the inpatient EID realities in Mozambique and are useful for ongoing programmatic planning.

CONCLUSIONS

Inpatient wards are a high-yield site for case identification and ART initiation that have historically been overlooked in PMTCT programming. POC platforms can increase inpatient EID testing volume and represent a transformative opportunity to improve the diagnosis and treatment of HIV in hospitalized infants. POC EID scale-up plans should include pediatric wards as priority sites for future expansion.

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There is clear benefit to deploying POC testing to hospitals with subsequent establishment of context-appropriate ART initiation models.

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REFERENCES

1. Republic of Mozambique Ministry of Health (MISAU). *2018 Annual Report on HIV/AIDS Activities*. MISAU; 2019. Accessed February 16, 2021. <https://www.misau.gov.mz/index.php/relatorios-anuais>
2. Joint United Nations Programme on HIV/AIDS (UNAIDS) *AIDS Data*. UNAIDS; 2016. Accessed February 11, 2021. https://www.unaids.org/sites/default/files/media_asset/2016-AIDS-data_en.pdf
3. Jani IV, De Schacht C. Innovations and challenges in early infant diagnosis of HIV. *Curr Opin HIV AIDS*. 2019;14(1):55–59. [CrossRef](#). [Medline](#)
4. Violar A, Cotton MF, Gibb DM, et al.; CHER Study Team. Early antiretroviral therapy and mortality among HIV-infected infants. *N Engl J Med*. 2008;359(21):2233–2244. [CrossRef](#). [Medline](#)
5. Bianchi F, Cohn J, Sacks E, et al.; EGPAP POC EID Study Team. Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries. *Lancet HIV*. 2019;6(6):e373–e381. [CrossRef](#). [Medline](#)
6. Frank SC, Cohn J, Dunning L, et al. Clinical effect and cost-effectiveness of incorporation of point-of-care assays into early infant HIV diagnosis programmes in Zimbabwe: a modelling study. *Lancet HIV*. 2019;6(3):e182–e190. [CrossRef](#). [Medline](#)
7. Mwenda R, Fong Y, Magombo T, et al. Significant patient impact observed upon implementation of point-of-care early infant diagnosis technologies in an observational study in Malawi. *Clin Infect Dis*. 2018;67(5):701–707. [CrossRef](#). [Medline](#)
8. Spooner E, Govender K, Reddy T, et al. Point-of-care HIV testing best practice for early infant diagnosis: an implementation study. *BMC Public Health*. 2019;19(1):731. [CrossRef](#). [Medline](#)
9. Jani IV, Meggi B, Loquiha O, et al. Effect of point-of-care early infant diagnosis on antiretroviral therapy initiation and retention of patients. *AIDS*. 2018;32(11):1453–1463. [CrossRef](#). [Medline](#)
10. United Nations Children's Fund (UNICEF). *Key Considerations for Introducing New HIV Point-of-Care Diagnostic Technologies in National Health Systems*. UNICEF; 2018. Accessed February 11, 2021. <https://www.who.int/hiv/pub/vct/point-of-care-hiv-diagnostic/en/>
11. World Health Organization (WHO). *HIV Diagnosis and ARV Use in HIV-Exposed Infants: A Programmatic Update*. WHO; 2018. Accessed February 11, 2021. <http://apps.who.int/iris/bitstream/handle/10665/273155/WHO-CDS-HIV-18.17-eng.pdf>
12. Mozambique EID Web Portal. Instituto Nacional de Saúde. Accessed February 11, 2021. <https://www.portaldpi.com/pentaho/Login>
13. Nhabomba C, Chicumba S, Muquingue H, et al. Clinical and operational factors associated with low pediatric inpatient HIV testing coverage in Mozambique. *Public Health Action*. 2019;9(3):113–119. [CrossRef](#). [Medline](#)
14. Kankasa C, Carter RJ, Briggs N, et al. Routine offering of HIV testing to hospitalized pediatric patients at university teaching hospital, Lusaka, Zambia: acceptability and feasibility. *J Acquir Immune Defic Syndr*. 2009;51(2):202–208. [CrossRef](#). [Medline](#)
15. McCollum ED, Preidis GA, Golitko CL, et al. Routine inpatient human immunodeficiency virus testing system increases access to pediatric human immunodeficiency virus care in sub-Saharan Africa. *Pediatr Infect Dis J*. 2011;30(5):e75–e81. [CrossRef](#). [Medline](#)
16. Mutanga JN, Raymond J, Towle MS, et al. Institutionalizing provider-initiated HIV testing and counselling for children: an observational case study from Zambia. *PLoS One*. 2012;7(4):e29656. [CrossRef](#). [Medline](#)
17. Wanyenze RK, Nawavvu C, Ouma J, Namale A, Colebunders R, Kanya MR. Provider-initiated HIV testing for paediatric inpatients and their caretakers is feasible and acceptable. *Trop Med Int Health*. 2010;15(1):113–119. [CrossRef](#). [Medline](#)
18. Republic of Mozambique Ministry of Health (MISAU). *National Guidelines for Implementation of Counseling and Testing*. MISAU; 2015.
19. Instituto Nacional de Estatística (INE), Instituto Nacional de Saúde (INS). *Study of Immunization, Malaria, and HIV/AIDS in Mozambique (IMASIDA) 2015: Report on Basic HIV Indicators*. INE, INS; 2018. Accessed February 16, 2021. <https://dhsprogram.com/pubs/pdf/AIS12/AIS12.pdf>
20. Ojikutu B, Higgins-Biddle M, Greeson D, et al. The association between quality of HIV care, loss to follow-up and mortality in pediatric and adolescent patients receiving antiretroviral therapy in Nigeria. *PLoS One*. 2014;9(7):e100039. [CrossRef](#). [Medline](#)
21. Urlick B, Fong Y, Okiira C, et al. Rapid serological tests ineffectively screen for HIV exposure in HIV-positive infants. *J Acquir Immune Defic Syndr*. 2018;77(3):331–336. [CrossRef](#). [Medline](#)
22. Wagner AD, Njuguna IN, Andere RA, et al. Infant/child rapid serology tests fail to reliably assess HIV exposure among sick hospitalized infants. *AIDS*. 2017;31(11):F1–F7. [CrossRef](#). [Medline](#)
23. De Schacht C, Hoffman HJ, Mabunda N, et al. High rates of HIV seroconversion in pregnant women and low reported levels of HIV testing among male partners in Southern Mozambique: results from a mixed methods study. *PLoS One*. 2014;9(12):e115014. [CrossRef](#). [Medline](#)
24. De Schacht C, Mabunda N, Ferreira OC Jr, et al. High HIV incidence in the postpartum period sustains vertical transmission in settings with generalized epidemics: a cohort study in Southern Mozambique. *J Int AIDS Soc*. 2014;17(1):18808. [CrossRef](#). [Medline](#)
25. Mabunda NMC, Mutsaka D, Loquiha O, Buck WC, Nhachigule C, Meggi B. Positivity trends among HIV-exposed children tested on point-of-care early infant diagnosis in Mozambique. Poster presented at: IAS 2019; 2019; Mexico City, Mexico.
26. Republic of Mozambique Ministry of Health (MISAU). *2019 Annual Report on HIV/AIDS Activities*. MISAU; 2020. Accessed February 16, 2021. <https://www.misau.gov.mz/index.php/relatorios-anuais?download=367:relatorio-anual-hiv-2019-final-pdf>
27. Njuguna IN, Cranmer LM, Otieno VO, et al. Urgent versus post-stabilisation antiretroviral treatment in hospitalised HIV-infected children in Kenya (PUSH): a randomised controlled trial. *Lancet HIV*. 2018;5(1):e12–e22. [CrossRef](#). [Medline](#)

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Test and Prevent: Evaluation of a Pilot Program Linking Clients With Negative HIV Test Results to Pre-exposure Prophylaxis in Zimbabwe

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Key Findings

We implemented and monitored an intervention, called Test and Prevent, to intentionally link clients with a negative HIV test result to oral pre-exposure prophylaxis (PrEP).

- Most clients (98%) who were referred for PrEP immediately after their negative test result completed their referrals and started PrEP.
- The rate of screening for PrEP eligibility was low (61%). Among those screened, only 6% were deemed eligible for PrEP via the national PrEP screening tool.
- Although the subsequent referral rate (3%) was low, both clients and providers reported satisfaction with the intervention and its importance in connecting clients who test negative to PrEP.

Key Implications

- Intentionally linking clients who receive a negative HIV test result to PrEP using methods from the test and treat literature could help increase PrEP uptake.
- Screening approaches for PrEP eligibility need further examination and validation to ensure they don't unintentionally screen out clients who could benefit from prevention.
- As PrEP scale-up continues, staff shortages and training needs should be addressed.

ABSTRACT

Background: As HIV testing increases worldwide, programs are reaching individuals without HIV infection who are at risk of exposure and may be candidates for oral pre-exposure prophylaxis (PrEP). Although linkage of individuals with HIV infection to treatment is a global priority (referred to as “test and treat”), less attention is given to individuals with negative HIV test results. We developed the “Test and Prevent” pilot program to intentionally link at-risk clients with negative HIV test results to PrEP services. The intervention included risk assessment of all clients with a negative result from HIV testing (with national risk assessment tool), accompanied referral, fast-tracking, and targeting follow-up.

Methods: The intervention was conducted in Bulawayo, Zimbabwe, at 6 public sector sites from October 2019 to February 2020. We collected routine monitoring data from all study sites and tracked referral completion and PrEP initiation among clients who enrolled. We conducted in-depth interviews with providers (n=12), facility managers (n=5), and female clients (n=17) to explore acceptability.

Results: Among clients referred for PrEP (n=206), 98% completed their referrals and started PrEP. However, only 3% of clients who received a negative test result during the study period were referred. Low referrals stemmed from lack of screening (39% of clients with negative HIV test results were not screened) and lack of eligibility among clients who were screened (only 6% of those screened qualified as candidates for PrEP per the national screening tool). Qualitative results indicate that some providers purposefully did not complete screening with clients they felt were not at risk and that workload could have contributed to low screening uptake.

Qualitative interviews showed that Test and Prevent was acceptable among both providers and clients. Clients were happy to learn about PrEP following HIV testing, and the additional support of accompanied referrals and fast-tracking encouraged them to access PrEP and made them feel valued. Providers were burdened by workload constraints but felt that Test and Prevent was important and should be scaled to other sites.

Conclusion: Intentionally linking clients with negative results to PrEP immediately following HIV testing was found to be acceptable from both provider and client perspectives, yet screening procedures need closer examination and reinforcement for the program to realize a larger impact.

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■ INTRODUCTION

Provision of antiretroviral therapy (ART) as treatment for HIV has increased markedly in the past 15 years. In 2017, the World Health Organization (WHO) estimated that 59% of people living with HIV (PLHIV) globally were on ART, an increase from just 7% in 2005.^{1,2} One important strategy for initiating more PLHIV on ART is “test and treat,” which recommends that treatment start immediately following HIV diagnosis.¹ As these approaches to HIV treatment scale up and programs prioritize intensified HIV testing, greater numbers of high-risk clients with negative test results who may be good candidates for prevention services are being identified. To date, however, little attention has been given to immediately linking clients with negative test results to prevention services, or “Test and Prevent.”^{3,4} More aggressive Test and Prevent efforts are especially warranted with an expanded range of HIV prevention options, including oral pre-exposure prophylaxis (PrEP).^{5–7} WHO recommends that oral PrEP be offered to populations at substantial risk of HIV infection, defined as having >3% HIV incidence.⁵ Since 2016, countries in sub-Saharan Africa have begun introducing oral PrEP, yet studies have shown that uptake is low among PrEP-eligible individuals.^{6–8}

Evidence-based strategies that successfully link clients with positive HIV test results to treatment^{9–11} could also be effective in linking clients with negative test results to prevention, including oral PrEP. One study demonstrated that referral slips facilitate access to care among clients with HIV and reduce registration time,¹² and many studies have shown that reminder messages sent via short message service (SMS) can be a low-cost method of promoting retention in care.^{13–15} Collocation of testing and treatment services in Zambia and Haiti have shown increases in ART initiation rates.^{16,17} Fast-tracking, a method that allows clients to bypass queues when accessing certain services, also shows promise. In Mozambique, fast-tracked clients with a positive result from HIV testing were more than twice as likely to start ART within 1 week than those offered standard care.¹⁸

These approaches linking clients from HIV testing to follow-up services hold potential for Test and Prevent interventions, but there are complexities unique to prevention services that require attention. While clients receiving an HIV-positive result may be motivated to act immediately,^{19,20} individuals with an HIV-negative result

may feel less urgency to seek prevention services. Some research has even shown an association between HIV-negative test results and subsequent increased risky behavior.^{4,21,22} Further, no single solution exists for clients with HIV-negative results, and the appropriate prevention option may change over time.²³ Adaptation is required and more evidence is needed on the feasibility and acceptability of Test and Prevent programs.

The Ministry of Health and Child Care (MOHCC) in Zimbabwe is among the HIV program leaders seeking evidence about linking clients with HIV-negative test results to prevention. The goal of the current evaluation was to assess the feasibility of a Test and Prevent program to intentionally link such clients to oral PrEP. Given the lack of evidence around Test and Prevent, we aimed to assess the percentage of clients referred for PrEP who completed the referral as well as to examine qualitatively the acceptability and feasibility of Test and Prevent strategies from both clients' and providers' perspectives.

■ INTERVENTION

We designed the Test and Prevent pilot intervention in consultation with the MOHCC and United States Agency for International Development mission in Zimbabwe. We aimed to identify a package of highly effective linking interventions that could be affordably implemented at scale within the national program, assuming the package proved to work effectively. We aligned the intervention with national guidelines for HIV testing and PrEP delivery.²⁴ Components of the intervention are summarized in Table 1.

Briefly, providers were asked to complete a risk assessment using the national Risk Assessment Screening Tool (RAST) with all clients who had negative HIV test results. Additional information about the RAST and other risk assessment tools used in Zimbabwe are included in the Box. Clients deemed potential candidates for PrEP based on the RAST were provided with more information about the study, and those who were interested completed informed consent and were enrolled. Clients who were not considered at risk or chose not to enroll could still receive counseling and prevention services. However, they were not offered accompanied referrals, fast-tracking, or follow-up messages, and no data were collected about them to inform study outcomes. After enrollment, participants were counseled about PrEP and given referrals. After referral, women were offered accompanied referrals and fast-tracking.

The goal of the current evaluation was to assess the feasibility of a Test and Prevent program to intentionally link clients without HIV to oral PrEP.

TABLE 1. Components of the Test and Prevent Pilot Intervention in Zimbabwe

Intervention Component	Current National Guidelines for PrEP ²⁴	Test and Prevent Pilot Intervention
Risk assessment	Clients with negative HIV test results who are at substantial risk of HIV should be screened for PrEP eligibility using the RAST (see Box)	Use the RAST to screen all clients with negative HIV test results immediately after delivering results
Counseling and referral	Clients with negative HIV test results should be proactively linked to prevention services	All clients who are determined to be at risk based on the RAST receive <ul style="list-style-type: none"> • Detailed counseling about oral PrEP using the national PrEP fact sheet • Referral to oral PrEP services, including referral slip • A prevention services card, detailing the prevention services available at the facility
Accompanied referrals with fast tracking	Not part of national guidelines for PrEP	<ul style="list-style-type: none"> • Women referred for PrEP are given the option of having a provider immediately accompany them to PrEP services at the time of referral. • When accompanying a client, the provider facilitates fast tracking, allowing the client to skip the queue.
Follow-up	Not part of national guidelines for PrEP	<ul style="list-style-type: none"> • Clients not completing their PrEP referral in 2 weeks receive reminder messages via phone call, WhatsApp, or SMS (based on client preference at enrollment).

Abbreviation: PrEP, pre-exposure prophylaxis; RAST, Risk Assessment Screening Tool; SMS, short message service.

Additional barriers exist for women accessing prevention services, so the more time-consuming accompanied referrals and fast-tracking intervention were provided only to women.

Finally, clients who did not complete referrals were given reminders via phone or messaging.

While the study enrolled both men and women, we recognized that additional barriers exist for women accessing prevention services. Given budget and workload constraints, we provided the more time-consuming accompanied referrals and fast-tracking intervention only to women. We also chose to only conduct in-depth interviews with female clients because they received the most intensive intervention and could therefore provide insights on Test and Prevent.

METHODS

Setting

Zimbabwe began PrEP delivery in 2015, initially offering PrEP in nongovernmental organization clinics, then expanding to government-supported sites. Unlike some countries that targeted PrEP rollout only to specific populations, PrEP was available in Zimbabwe to all individuals without HIV who were at substantial risk of exposure.

This study was conducted in Bulawayo, Zimbabwe. As the second largest city in Zimbabwe, Bulawayo is an urban center with HIV prevalence estimated at 17.9%, which is higher than the national average of 14.6%.²⁵

The intervention was implemented in 6 public sector sites in Bulawayo: 5 clinics and 2 HIV testing points within a central hospital (the antenatal care [ANC] clinic and the outpatient department). Sites were purposely selected based on availability of PrEP services and client volume for HIV testing. Although we originally intended that the intervention be delivered approximately 2 months after PrEP was first introduced to these facilities, delays in the PrEP supply chain resulted in PrEP and the intervention being rolled out simultaneously. The pilot intervention was implemented and evaluated at these sites from October 2019 to February 2020. Due to concerns around the availability of medicines and sustainability, PrEP demand creation activities in Bulawayo did not take place until October 2020, well after the study period.

The location of HIV testing and PrEP services varied across study sites. Most sites, with the exception of the ANC service delivery point, deliver PrEP services in the opportunistic infections (OI) unit, which is in a separate part of the health facility compound from HIV testing. As such, clients referred to PrEP from HIV testing needed to walk to the OI unit to learn more about PrEP and receive their drugs. Alternatively, at the ANC service delivery point, PrEP services were integrated into

the ANC department, and clients received HIV testing and PrEP at the same location. Clients at this site did not require accompanied referrals.

Outcome Measures

The primary outcome measure was the percentage of clients referred for PrEP who completed that referral. The secondary outcome was the percentage of clients given a PrEP referral who initiated PrEP. We also qualitatively explored intervention feasibility and the facilitators and barriers clients experienced regarding PrEP access and provision.

Data Collection and Data Analysis

We used a prospective cross-sectional design, comprising collection of both qualitative and quantitative data. To assess the primary and secondary outcomes, we asked providers to complete study forms, introduced through a 1-day training, to track client referrals and completion of referrals. We limited the number and length of these study forms to simulate real-world service delivery as much as possible, and we therefore collected limited information about participants, including age, gender, name, contact information, whether they received a referral, whether they completed the referral, and whether they accepted the offer of PrEP (initiated PrEP). We also collected routine monitoring data on the number of HIV tests performed and number of positive HIV tests, to serve as the denominator for measuring PrEP uptake. The study team provided supportive supervision for completion of study forms to improve data quality.

We conducted in-depth interviews with clients and providers to assess their perceptions of the intervention. Providers were selected purposively to include 1 facility-in-charge per facility as well as providers who were most involved in administering the intervention. Since we were particularly interested in the experiences of women accessing PrEP services, qualitative interviews with clients were only with female clients who received a PrEP referral. Women that participated in the intervention were selected for qualitative interviews using stratified random sampling by site and referral completion status. We attempted to interview 3–5 women from each site who were given a PrEP referral and completed that referral, and another 3–5 women from each site who were given a referral but did not complete the referral.

Trained qualitative interviewers conducted in-depth interviews following a structured guide. Interviews covered topics including feasibility

and acceptability of intervention components, impact on provider workload (for providers), overall impressions of intervention implementation (for facility managers), and recommendations for future improvements. Interviews also included close-ended questions about time allocated to each intervention component (for providers), and prior knowledge of PrEP and experiences with HIV prevention and intervention components (for clients). Interviews were held in private locations (generally in study facilities) and were conducted in Shona, Ndebele, or English (the 3 most common languages in Zimbabwe) depending on the preference of the respondent. Interviews lasted on average 34 minutes with providers, 19 minutes with facility managers, and 12 minutes with clients. Interviews were audio recorded, transcribed, translated to English (if necessary), and reviewed for accuracy.

Transcripts were uploaded into NVivo v.12 for coding and analysis.²⁶ Research analysts coded the data using a codebook developed according to the interview guide. To assess intercoder agreement, analysts coded 11% of transcripts independently and then compared results, discussed, and updated the codebook to reflect agreed-upon coding approaches. After coding, code reports were analyzed into memos around key study themes.

Ethics

Ethical approval for the study was obtained from the Protection of Human Subjects Committee at FHI 360 (IRBnet number 1447486) and the Medical Research Council of Zimbabwe in Zimbabwe (approval number MRCZ/A/2488). All providers and study staff who collected study data were trained in research ethics. Participants provided written consent to participate in the study.

RESULTS

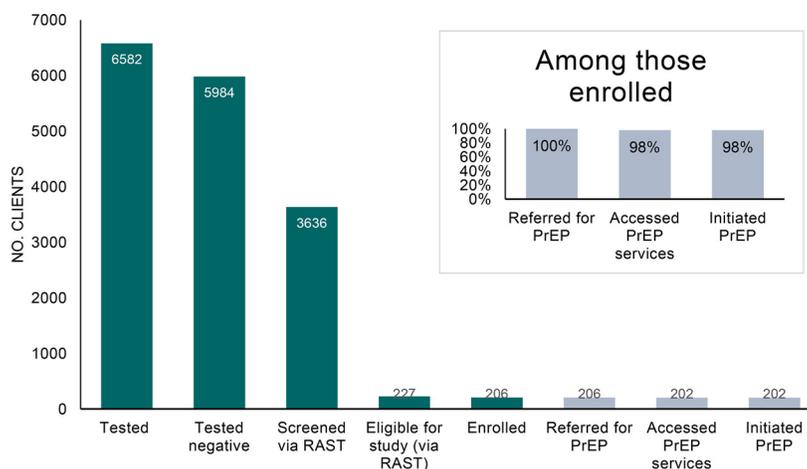
PrEP Screening, Referrals, and Uptake

Data were collected from November 4, 2019, to February 29, 2020. A total of 6,582 individuals underwent HIV testing at the study sites during the 17-week study period (Figure 1). Of these, 91% received negative results. Only 61% of the individuals with negative results were screened for HIV risk using the RAST, and of these, only 6% were deemed at risk of HIV, and thus invited to enroll in the study.

Of those deemed eligible via the RAST, 91%, or 206 individuals, agreed to participate in the study and were enrolled. Reasons for declining enrollment included being interested in PrEP, but

Unlike some countries that targeted PrEP rollout only to specific populations, in Zimbabwe, PrEP was available to all individuals without HIV who were at substantial risk of exposure.

FIGURE 1. Number of Clients at Each Stage of the HIV Test and Prevent Intervention, Zimbabwe



Abbreviations: PrEP, pre-exposure prophylaxis; RAST, Risk Assessment Screening Tool.

BOX. HIV Risk Assessment Tools in Use in Zimbabwe

National guidelines in Zimbabwe promote 2 risk screening tools, the Risk Assessment Screening Tool (Figure 2) and the Adult Screening Tool (Figure 3). Neither tool was developed for the pilot intervention. Rather, they are standard components of HIV services in Zimbabwe, but provide important context to understand the HIV testing population and pre-exposure prophylaxis (PrEP) referrals.

Before testing, per national guidelines, eligibility for HIV testing should be assessed using the Adult Screening Tool. This tool uses a series of questions to determine whether a client is eligible for HIV testing. A client is considered eligible if they meet any of the following criteria:

- Reports experiencing poor health in the past 3 months
- Considers their own risk of HIV to be mild, moderate, or severe
- Has experienced symptoms of a sexually transmitted infection
- Has a partner or parent living with HIV

In addition to the Adult Screening Tool, national guidelines also promote the use of the RAST after an HIV-negative test result to determine whether a client should be offered PrEP or postexposure prophylaxis or be considered at risk for acute HIV infection. The RAST also assesses HIV risk but uses different criteria. Based on the RAST, a client is a candidate for PrEP if they meet any of the following criteria:

- Has had vaginal or anal sex with 2 or more people in the past 6 months
- Has not used a condom every time they had sex in the past 6 months
- Has had a sexually transmitted infection in the past 6 months
- Has a partner living with HIV

Of the 206 participants who received referrals, 202 accessed PrEP services, and all participants who accessed PrEP services accepted the offer of PrEP.

not the study; wanting more time to think about the study; being too busy; and wanting to discuss enrollment first with their husband or partner.

Among the 206 clients who enrolled, 77% identified as cisgender women, 23% cisgender men, and <1% transgender women (Table 2). The mean age was 32 (SD: ± 11) years old. Of those enrolled, 50 were adolescent girls and young women (i.e.,

female and between the ages of 15–24). Most clients were from sites delivering PrEP at the OI unit (n=167); 39 clients were from the ANC service delivery point that offered PrEP onsite.

After enrollment, all participants were told about PrEP immediately at the site of HIV testing and referred to PrEP services. Of the 206 participants who received referrals, most (n=202)

accessed PrEP services, and all participants who accessed PrEP services accepted the offer of PrEP. Among the 4 individuals who did not complete the referral, 2 were from sites that offered PrEP at the OI unit, and 2 were from the ANC service delivery point. They were all women aged 21–30.

Qualitative Sample Characteristics

Qualitative interviews were conducted with 12 providers, 5 facility managers, and 17 female clients. Providers were mostly women (n=11), and the sample was composed of registered nurses (n=7), primary counselors (n=4), and 1 clinic referral facilitator. Facility managers were all women. Clients had a mean age of 35 years old (range 20–64). All had received PrEP counseling, accepted a referral, and completed their referrals. While we tried to interview the 4 female clients who did not complete their referrals, all declined.

The results below are structured by clinical step involved in the PrEP process and incorporate both qualitative and quantitative findings to provide a more holistic understanding of the intervention.

Risk Assessment Screening Tool

Although monitoring data indicate that a third of the clients with negative HIV test results were not screened using the RAST, just over half of the providers interviewed described completing the RAST with every client with a negative result. Others noted that they used the RAST with a subset of clients: those who asked for PrEP or those presumed to be at risk because they are in a serodiscordant relationship or identify as a member of a key population. One provider explained:

Those patients who are saying the partner is positive and [they are] negative . . . that is where I would want to use the risk assessment tool. —Registered nurse, acting Sister-in-Charge

In interviews, many providers expressed concerns about the sensitivity of RAST questions. They felt that clients were uncomfortable answering questions about their sexual activity—especially the first question of the tool, which asks about anal sex—and were not always forthcoming. Providers described utilizing counseling skills and their own judgment, instead of following the RAST questionnaire directly. As explained by one provider:

When you are conducting the risk assessment, some of the clients will be shy to tell you. Especially the first question: “How many people did you have vaginal sex

with?” So, you try to put it in a way that they can understand so they are free to share. “Sister, here you can tick 2 plus.” Especially for elderly people . . . I just create a good rapport with the client before doing anything. Just try to be friendly. Then if it’s an elderly person, I humble myself. If it’s a young person in their mid-twenties, I bring myself to their level. Then I try to ask. —Registered nurse and midwife

Some providers were concerned that the RAST may miss some clients who are at risk, including clients with a partner who is not monogamous. Others described needing to probe to identify risk not covered in the tool.

Despite these challenges, every provider and facility manager interviewed said they would recommend that other facilities use the RAST, with one provider qualifying that counselors needed to use their own “assessment” not just the questionnaire. Most described the RAST as a helpful guide to administer and document a risk assessment, and some expanded that it would be more difficult to determine who is appropriate for PrEP without this kind of guidance.

I think out of all the things, [the RAST] will make life easy when administering PrEP because after you have done the screening you know everything about the patient, such that when you are now prescribing the tablets, the client won’t ask other questions that will lead you back to deciding whether I should give PrEP or not. —Registered nurse

Use of the RAST and the Adult Screening Tool

Results showed a disconnect between results of the Adult Screening Tool and the RAST. Presumably, all clients who received HIV testing were determined to be at risk based on the Adult Screening Tool prior to testing. In qualitative interviews with facility managers we confirmed that all sites were using the Adult Screening Tool, with the exception of the ANC site where HIV testing is offered to all pregnant women. Yet among HIV testing clients who were later screened with the RAST, only 6% (227 clients) were deemed at risk, suggesting that 94% of these clients were considered at risk from the Adult Screening Tool, but not at risk based on the RAST.

PrEP Counseling and Referral

Providers reported that counseling about PrEP often happened in conjunction with conducting risk assessment via the RAST. When asked how they determine which clients to counsel on PrEP, most

Despite challenges, every provider and facility manager interviewed said they would recommend that other facilities use the RAST.

FIGURE 2. Risk Assessment Screening Tool Used in Zimbabwe for HIV Risk Screening

**Screening Form for PrEP
Start Up or Follow-Up Visits**

Date of Birth (DD/MM/YYYY) _____/_____/_____

What is your sex? Male [] Female []

Tick what is applicable.

*** Consider offering PrEP**

1. In the past 6 months: How many people did you have vaginal or anal sex with?

	0	1	2+*
Men			
Women			

2. In the past 6 months: Did you use a condom every time you had sex?

Yes	No*	Don't Know*

3. In the past 6 months: Did you have a sexually transmitted infection?

Yes*	No	Don't Know*

4. Do you have a sexual partner who has HIV? Yes* [] No [] Don't Know* []

	Yes	No*	Don't Know*
a. If "Yes, has he or she been on therapy for 6 or more months?			
b. If "Yes," has the therapy suppressed viral load?			

**** Consider offering PEP**

5. In the past 3 days: Have you had sex without a condom with someone with HIV who is not on treatment?

Yes**	No	Don't Know

***** Consider acute HIV**

6. Have you had a "cold" or "flu" such as sore throat fevers, sweats, swollen glands, mouth ulcers, headache, or rash?

Yes***	No	Don't Know

Abbreviations: PEP, postexposure prophylaxis; PrEP, pre-exposure prophylaxis.

FIGURE 3. Adult Screening Tool Used in Zimbabwe for HIV Risk Screening

1	What is the service/purpose of your visit? Medical <input type="checkbox"/> Surgical <input type="checkbox"/> Visitor <input type="checkbox"/> Other <input type="checkbox"/>	
2	Have you experienced poor health in the past three months? Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes offer HIV testing
3	When was the last time you were tested for HIV? Never <input type="checkbox"/> Past 3 Mnts <input type="checkbox"/> Past 12 Mnts <input type="checkbox"/> Beyond 12 Mnts <input type="checkbox"/>	Refer to testing/retesting algorithm
4	What was the result? Positive <input type="checkbox"/> Negative <input type="checkbox"/> Inconclusive <input type="checkbox"/>	
5	If negative, how do you consider your HIV risk? Not at all <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/>	Refer/offer for HIV test for those at risk.
6	If inconclusive	Refer to testing/retesting algorithm
7	If Positive, are you currently on ART? Yes <input type="checkbox"/> No <input type="checkbox"/>	If No, refer for OI/ART services
8	Have you experienced any symptoms and/or signs of an STI, such as vaginal/urethral discharge or genital sores? Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes offer HIV testing
9	Any partner, parent HIV positive? Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes offer HIV testing
*Follow the colour codes from 4 to 7.		

Abbreviations: ART, antiretroviral therapy; OI, opportunistic infections unit; STI, sexually transmitted infection.

TABLE 2. Age and Sex of Enrolled Participants in Test and Prevent Pilot Intervention in Zimbabwe (n=206)

Characteristics	No. (%)
Age, years	
15–18	13 (6.3)
19–24	46 (22.3)
25–29	49 (23.8)
30–39	50 (24.3)
40–49	31 (15.0)
≥50	17 (8.3)
Sex	
Female	158 (76.7)
Male	47 (22.8)
Transgender	1 (0.5)

providers noted that they primarily counseled serodiscordant couples or clients in serodiscordant relationships, although some mentioned that they provided PrEP counseling to all clients who have HIV-negative test results and/or perceived themselves to be at risk of HIV. Tracking results indicated that not all clients with negative test results were being informed about PrEP, however, nor was the RAST used systematically to determine which clients to inform about PrEP.

Providers described that while counseling clients after HIV testing and receipt of negative results, they informed clients about PrEP, discussed clients’ HIV risk, and addressed fears and concerns. Some mentioned that clients typically had low pre-existing knowledge or awareness of PrEP, and the counseling process was consequently more challenging or time intensive than standard counseling about HIV risk reduction. Others noted that clients may have concerns about PrEP, particularly due to the fact that it was a novel product in Bulawayo, or that clients may be reticent to share information about HIV risk

Echoing provider accounts, several interviewed clients stated that they learned about PrEP for the first time through the counseling following HIV testing.

behaviors during PrEP counseling. Echoing provider accounts, several interviewed clients stated that they learned about PrEP for the first time through the counseling following HIV testing.

Most providers reported they were successful in addressing clients' questions and concerns and in improving clients' knowledge about PrEP, noting that clients "didn't know anything" about PrEP before but "are now knowledgeable." One provider described the importance of tailoring PrEP counseling to clients' specific situations, noting that no single strategy may work well across all clients:

... you should treat each client differently because as clients come they have different presentations, they have different scenarios, so what works well is what the clients presents you with and should act the way the client presents to you. If it's a sex worker, you counsel according to their sex work. If they are in a serodiscordant relationship you counsel according to that... So, you can't really say this [single strategy] works well in counseling.
—Registered nurse

All providers responded favorably to the idea of recommending that other facilities implement PrEP counseling after HIV testing and described that it should be "a priority," noting that it is an "important" and "beneficial" service that could "empower" and inform clients. Likewise, all clients interviewed said receiving PrEP counseling and referral immediately following their test results was acceptable, and many spoke of it being a relief to find out PrEP was an option.

I felt very happy knowing that I am going to get help, so that I do not get this disease... Knowing my husband's [HIV] status, I was just happy knowing that at least one of us can be safe and look after the kids in case anything happens to him. —Client

Accompanied PrEP Referrals and Fast-Tracking

Providers who were responsible for accompanied referrals indicated that they offered accompanied referrals to female clients that they referred; however, some mentioned that they did not do this consistently with all female clients as prescribed. Likewise, providers stated that fast-tracking of PrEP clients did not occur universally across facilities or clients but did take place in most cases.

Some providers shared apprehensions about accompanied referrals, including concerns about leaving other clients waiting and spending a long time guiding clients from one location to the next. At the same time, providers noted that

collaboration between providers, especially of different cadres, and short distances between referral locations eased these challenges. Likewise, providers had concerns about the interruption of service delivery when having to prioritize a PrEP client, and the lack of fairness to other patients who may be waiting for equally important services. Clients who did not receive fast-tracking noted that the wait time and queue were relatively short.

Some providers indicated that being accompanied to the location of PrEP services at the OI unit may incite stigma and deter clients from completing referral, explaining that:

You see someone frowning saying, I have to go to OI now, if they see me there they will assume I'm infected.

Despite some providers' concerns, no clients mentioned this issue.

Most clients who received accompanied referral recalled having a positive experience. They appreciated having help to "know where to go" and assistance with communication. Some noted that accompanied referral made them "happy," and one participant explained that,

If you have someone with you it helps you to confidently go through the whole process without turning away. —Client

Likewise, clients remarked that fast-tracking made them feel valued. One participant admitted experiencing negative treatment from other patients whom she was allowed to bypass, but she nevertheless appreciated the service.

Providers highlighted that accompanied referrals and fast-tracking help ensure that PrEP clients are prioritized and gives clients the "support and encouragement" they need. Both providers and clients overwhelmingly agreed that accompanied referrals decreased loss to follow-up. One provider explained that it "helps you not lose the clients in the process." Many clients who received accompanied referral directly stated that they would not have gone to the PrEP services to complete their referral without this assistance. They identified numerous barriers that accompanied referral helped them overcome, including fear of the medication, anxiety expressing oneself to providers, lack of understanding the counselor, not knowing where to go, long queues, and negative partner attitudes. Even clients who felt they would have completed the referral on their own expressed that "the accompaniment made it much better,"

Providers highlighted that accompanied referrals and fast-tracking help ensure that PrEP clients are prioritized and gives them needed "support and encouragement."

highlighting the support this service can provide across clients.

At the same time, clients who were initiated in the same room where HIV testing was conducted (at the ANC clinic where PrEP was integrated into HIV testing) considered this the ideal scenario, explaining that,

You do fall out along the way. Then you go to the other place, that side there's a queue and you end up meeting people you don't want to see. So it's best you put the two of them in the same room and the process is just done. — Client

Workload

We asked providers how the intervention's additional tasks affected their workload. Just over half of providers reported “a little” impact on workload, while the remaining providers reported a large increase in workload. We also asked providers to report the amount of time it took to complete each study component. Quantitative responses are summarized in Table 3.

Providers reported the RAST taking an average of 10 minutes to complete. Some felt extra time required for the RAST was minimal, as counseling and risk assessment were already taking place, stating, “It’s just an added prevention tool to the HIV prevention program, which is already existing.” Other providers felt it did increase the time spent with each client significantly. One provider described:

Conducting risk assessment? It's like I'm a PC [Primary Counselor]. I've got a queue of people waiting to be tested . . . So, by the time I finish with that client conducting the risk assessment, they will start sharing, and you can't stop the patient. They will start sharing their story and at the same time answering the risk assessment tool.

TABLE 3. Reported Time to Complete Different Components of Test and Prevent Intervention, Zimbabwe

Study Component	Average Time (Range), Min
RAST	10 (3–30)
Counseling and referral following HIV testing	17 (5–30)
Accompanied referral and fast tracking	13 (5–45)

Abbreviation: RAST, Risk Assessment Screening Tool.

Then I tell them about PrEP . . . but my queue is stuck. —Primary Counselor

Providers reported counseling and PrEP referral taking an average of 17 minutes. Most providers felt counseling is time consuming because clients are not well informed about PrEP and had questions.

. . . I think it [PrEP counseling] needed a little bit of extra time than the normal counseling. 'Cause it depended on the client, 'cause some clients had fears so you really had to go out of your way to explain and address those fears . . . [but] when you start it was actually flowing and we were able to do everything. —Registered nurse

A few providers felt counseling did not require additional time, because they were already counseling clients on other prevention options, stating, “Counseling is counseling.” A provider at one site that implemented group PrEP education sessions in the waiting room described that such sessions helped reduce the time needed for individual counseling.

Time to complete accompanied referrals varied. Most sites were clinics and therefore did not have a large distance between HIV testing and the OI unit where PrEP was delivered. This contributed to shorter times: all sites except one reported times of 4–5 minutes. One provider explained:

Being a clinic set up, well the services wouldn't be really far apart so it wouldn't really take much of your time to move from one room to give the patient to the next service provider. —Registered nurse

The provider reporting that accompanied referrals require more time explained that the process involves more than simply walking to the site of services. Fast-tracking can take additional time if a provider is not ready to receive the client. This participant said:

So, it's about 45 [minutes] because it's going there and coming back. There you are not just going to say here it is, you make sure that you have handed the patient to the right person. —Registered nurse

Most providers mentioned workload challenges, often reiterating this concern. When asked if there were times when they were unable to complete the risk assessment, some providers described feeling rushed because of workload constraints, stating, “some clients were not screened.” Others mentioned not probing as much as they would have liked, explaining that,

When asked if they were sometimes unable to complete the risk assessment, some providers described feeling rushed because of workload constraints.

The queue will be very long, so sometimes, like the risk assessment, you have to shorten it depending on the first answers you had during the pretest counseling For some it will be a disadvantage, because you won't be able to probe enough. Somebody would have given you shallow answers. You wouldn't have time to go deeper because of the queue outside and you will be doing everything by yourself. —Primary counselor

Providers and some clients suggested that integrating PrEP services within the same room as HIV testing could save time moving between these services, reduce patient volume, and decrease client stigma.

Similarly, when discussing counseling challenges, providers said that their facilities are “overwhelmed” and are dealing with a “shortage of staff.” When asked about how to improve PrEP counseling following HIV testing, providers had few suggestions about modifying the content or process of PrEP counseling, but rather suggested that additional staff be allocated to the task. Likewise, when providers were asked about challenges related to referrals and fast-tracking, most providers responded that they were short-staffed. Providers highlighted that having insufficient staff at any point in the PrEP referral chain—from counselors, to providers who do accompanied referrals, to nurses initiating PrEP—causes a backlog of clients, increases wait times and client frustration, and hinders the facility’s ability to carry out the full PrEP referral process.

Compounding the challenge of general workforce shortages, only a few providers per site were trained on the study procedures, and few were trained to deliver PrEP services. Consequently, no providers were available to replace trained providers who were on leave, went out to lunch, or were not scheduled to work. In interviews, providers described these constraints as directly affecting patient care, even resulting in some PrEP clients leaving without being seen.

PrEP Acceptability and Participant Recommendations

Clients were overwhelmingly in support of PrEP delivery, describing it as “a good thing” and “a good idea.” Clients described feeling “happy” and having “a peaceful feeling inside my heart” in response to learning about or using PrEP. Others described feelings of reassurance, saying, “my life is safe” and that “[PrEP will] help me stay negative.”

Despite general acceptance, both clients and providers discussed recommendations to improve PrEP delivery. The most common recommendation among both clients and providers was the need for community sensitization. Clients felt there was little knowledge about PrEP in the community, and outreach could help reach more people as well as make disclosure easier for PrEP users. Providers

felt that community sensitization was important to legitimize PrEP, ensure clients have heard of PrEP, and increase reach.

Providers shared multiple recommendations around workload. In addition to requesting more staff, providers felt hiring one person who could be responsible for all stages of PrEP delivery could help streamline Test and Prevent, reduce waiting times and stigma, and ensure all interested clients receive PrEP services. Along those lines, providers and some clients suggested that integrating PrEP services within the same room as HIV testing could eliminate time moving between these services, reduce patient volume at the OI unit, and decrease the stigma of clients with negative HIV test results accessing services with PLHIV.

DISCUSSION

Effective, scalable interventions are needed to link at-risk individuals with negative HIV test results to PrEP. As rates of HIV testing have grown, such individuals are increasingly being identified. Some countries, including Zimbabwe, already have guidelines for screening clients immediately following HIV testing and providing referrals for PrEP, yet the rates of referral and completion of referrals are not well documented. Building on the “test and treat” literature, we designed and evaluated an intervention to proactively link clients with negative HIV test results to the site of PrEP services, immediately after they receive their result.

This study identified high rates of completed PrEP referrals (98%) and PrEP uptake (98%) among clients with negative results referred to PrEP after testing. These findings suggest that when a referral was made, linkage to PrEP services using the Test and Prevent approach piloted in this study was highly successful. However, we found that very few clients were offered PrEP overall; as such, these outcomes could reflect selection bias in PrEP referrals. While Test and Prevent is a rather new concept, a similar intervention to intentionally link HIV testing clients to PrEP was recently conducted as part of the SEARCH study, among a much larger population.⁷ They found that only 27% of those referred initiated within 90 days. More evidence is needed to confirm that the referral rates and outcomes documented in our small-scale study in Zimbabwe can be sustained at scale, particularly when higher volumes of clients are offered PrEP referrals. Further, while high PrEP uptake is promising, PrEP effectiveness is contingent upon adherence and continuation. This study did

Despite general acceptance, both clients and providers noted the need for community sensitization about PrEP.

not measure adherence or continuation and therefore we cannot determine whether high uptake led to continued use or sustained HIV prevention among study participants.

In contrast to the high rates of linkage to PrEP that we observed, our results indicate a substantial gap in screening and referrals. Only 3.4% of clients with negative HIV test results were referred to PrEP during the study period. Per Zimbabwe's national guidelines, the RAST should be used to determine if a client is appropriate to refer for PrEP. However, more than one-third of clients with negative HIV tests were not screened using the RAST during the study. Interviews suggest that some providers purposefully avoided screening clients who they felt were not at risk, and that some providers did not screen when their workload was too heavy. Perceived barriers such as clients' potential discomfort with the content of the RAST could have biased selection of clients for screening and counseling. In the context of national workforce shortages, gaps in implementation are not surprising.²⁷

More surprising, of those clients screened with the RAST, only 6% were considered at risk for HIV and appropriate for PrEP referral. Most of the study sites (with the exception of the ANC site) used the Adult Screening Tool to screen clients prior to HIV testing. Our findings demonstrate a disconnect between the results of these 2 tools. Presumably, most clients who received HIV testing were determined to be at risk based on the Adult Screening Tool, yet among those who were later screened with the RAST, only 6% were deemed at risk. This finding has major implications for PrEP provision because it means most clients with negative HIV test results may not be identified as eligible for PrEP referral per Zimbabwe guidelines.

Approaches for screening clients prior to offering PrEP require further study. Judicious provision of PrEP services requires accurate risk identification; accordingly, a variety of assessment tools have been developed to attempt to identify individuals at greatest risk.^{28–30} However, the content of these tools varies widely. In 2018, a review of existing risk assessment tools found that among 24 tools currently used to assess risk, only 3 were validated.³¹ As such, it is difficult to understand whether unvalidated tools appropriately quantify and predict risk. While quantitative tools are appealing, some oral PrEP stakeholders have suggested that risk tools should not define strict cutoffs for eligibility, but rather should serve as a process to initiate a conversation around the potential benefits of oral PrEP.³¹ This sentiment was

echoed by providers in this study who felt that adhering too strictly to the questions defined in the RAST could lead to a lack of identification of at-risk clients. The RAST requires further examination, as well as validation, to improve its use as a tool for channeling clients from HIV testing to PrEP services.

We also identified provider concerns that clients were not comfortable discussing sensitive risk assessment questions that are part of the RAST. Other studies have shown that some clients have challenges communicating with providers about sexual behaviors,³² and that conversely, providers too can be uncomfortable and will avoid taking sexual histories.^{33,34} Further refinement of the RAST to address the sensitivity of some questions, as well as encouraging providers to administer it in a more conversational manner, could help address this. However, given the low rate of utilization of the RAST, provider training to address discomfort and bias in discussing risk behaviors may be necessary. The number of times clients have to discuss risk could also be reduced. Clients accessing PrEP through study sites needed to discuss risk before testing while completing the Adult Screening Tool, after HIV testing while completing the RAST, and after completing the referral before being given PrEP. Centralizing PrEP services could be explored to reduce the burden on clients of having to discuss risk multiple times.

Despite challenges with the overall number of referrals, our qualitative findings demonstrate high acceptability of the pilot Test and Prevent program among clients who were referred. While much of the positive response in interviews can be attributed to the availability of PrEP in general, and not necessarily the linkage intervention, most clients did express support for accompanied referrals and fast-tracking. This complements other studies that have demonstrated acceptability of accompanied or "escorted" referrals among clients accessing HIV treatment or family planning services.^{12,35} Little evidence is available on the use of "fast-tracking" in clinic settings, and while clients in this evaluation found it acceptable, some providers expressed concerns that it would unfairly result in other clients having longer wait times. Further assessment of the equity of fast-tracking may be needed before considering offering the service at scale.

Despite the acceptability of Test and Prevent among providers, those interviewed did raise concerns with workload, often citing pre-existing staff shortages. Of note, Zimbabwe's persistent national shortage of health care workers was particularly

Despite challenges with the overall number of referrals, the pilot Test and Prevent program was deemed highly acceptable by clients who were referred.

acute during the study period.³⁶ Stemming from the economic crisis that devalued their salaries, health care workers in the country had come to an agreement with the MOHCC to only work a limited number of days a week until their salaries increased. As a result, during the study, many staff were working reduced hours or a reduced number of days. Nonetheless, our results show that additional cascading of the national PrEP training would be needed to ensure that adequate numbers of staff were trained at each site to provide coverage. These human resource challenges directly affected PrEP delivery, resulting in some clients not being screened and others leaving without accessing PrEP. To prevent staff burnout and ensure quality services for clients, staff shortages and training needs should be addressed before further scale-up.

Both providers and clients felt that further community sensitization of PrEP was necessary. Targeted community sensitization can improve PrEP awareness and reduce misinformation.³⁷ Community sensitization should not target just potential PrEP users, but also partners and family members to foster support.^{38,39} While community sensitization has the potential to make it easier for providers to counsel on PrEP, higher PrEP demand has workload implications that need to be considered in this context.

Limitations

We recognize important limitations of this work. Most significantly, the lack of an experimental design prevents us from making conclusions about the effectiveness of Test and Prevent because we do not know how many individuals would have completed their PrEP referrals without the added support. We did not track PrEP continuation and therefore cannot determine whether PrEP initiations using the Test and Prevent approach led to long-term PrEP use or HIV prevention. As sustained PrEP use is ultimately needed for PrEP to be effective, continuation is an important metric to assess in future Test and Prevent studies. Results suggest that some providers only screened individuals for PrEP eligibility if they perceived them to be at high risk, and this selection bias limits the generalizability of these findings by not necessarily capturing perspectives of all HIV test clients who could benefit from PrEP. This intervention was implemented when PrEP was first being introduced in these facilities and community sensitization in Bulawayo was minimal. We acknowledge that provider and client perspectives

about the Test and Prevent intervention might be different if PrEP was a well-established prevention service. Many participants first learned about PrEP during the study, making it difficult to determine whether opinions expressed in interviews reflect positive attitudes towards the intervention, or positive opinions about PrEP in general. We interviewed only female PrEP clients and therefore can only comment on the acceptability of the intervention among women. Further, all 4 individuals who did not complete their PrEP referrals declined interviews; as a result, qualitative results are limited to the experiences of those who completed their PrEP referrals and may be favorably biased. The intervention took place at a small number of sites that were already experiencing workforce shortages, which makes it difficult to conclude which challenges were a result of the intervention versus a result of existing constraints on providers' time.

Despite these limitations, this study highlights the potential of the Test and Prevent program to link at-risk clients who have received negative HIV test results to PrEP and to ultimately lead to PrEP uptake. It also identifies important considerations from the perspectives of clients and providers for PrEP scale-up as a whole. The study is timely. Given that many countries are expanding PrEP delivery to the general population, this work highlights important considerations for stakeholders at multiple levels of PrEP planning.

CONCLUSION

Intentionally linking clients who have received negative HIV test results to PrEP immediately following testing was found to be acceptable from both provider and client perspectives. Results show that the intervention was successful in encouraging clients who were given a PrEP referral to access PrEP services (98%) and those that completed the referral all initiated PrEP. Yet the screening procedures to identify good candidates for PrEP use need closer examination. Questions in the national screening tool should be reviewed for sensitivity, and repetitiveness between PrEP screening and risk screening prior to HIV testing should be addressed. Training should reinforce that screening for PrEP needs to be conducted consistently with all clients, and clients should not be excluded due to providers' perceptions of their risk. Improved screening for HIV risk will be essential for Test and Prevent to realize a larger impact on PrEP uptake in this setting.

Community sensitization should not target just potential PrEP users, but also partners and family members to foster support.

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REFERENCES

- World Health Organization (WHO). *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach*. WHO; 2016. Accessed January 12, 2021. <https://apps.who.int/iris/handle/10665/208825>
- Floyd S, Ayles H, Schaap A, et al.; HPTN 071 (PopART) Study Team. Towards 90-90: findings after two years of the HPTN 071 (PopART) cluster-randomized trial of a universal testing-and-treatment intervention in Zambia. *PLoS One*. 2018;13(8):e0197904. [CrossRef](#). [Medline](#)
- Baggaley R, Dalal S, Johnson C, et al. Beyond the 90-90-90: refocusing HIV prevention as part of the global HIV response. *J Int AIDS Soc*. 2016;19(1):21348. [CrossRef](#). [Medline](#)
- Doll M, Fortenberry JD, Roseland D, McAuliff K, Wilson CM, Boyer CB. Linking HIV-negative youth to prevention services in 12 U.S. cities: barriers and facilitators to implementing the HIV prevention continuum. *J Adolesc Health*. 2018;62(4):424-433. [CrossRef](#)
- World Health Organization (WHO). *Guideline on When to Start Antiretroviral Therapy and on Pre-exposure Prophylaxis for HIV*. WHO; 2015. Accessed January 12, 2021. <https://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>
- Mayer CM, Owaraganise A, Kabami J, et al. Distance to clinic is a barrier to PrEP uptake and visit attendance in a community in rural Uganda. *J Int AIDS Soc*. 2019;22(4):e25276. [CrossRef](#). [Medline](#)
- Koss CA, Charlebois ED, Ayieko J, et al.; SEARCH Collaboration. Uptake, engagement, and adherence to pre-exposure prophylaxis offered after population HIV testing in rural Kenya and Uganda: 72-week interim analysis of observational data from the SEARCH study. *Lancet HIV*. 2020;7(4):e249-e261. [CrossRef](#). [Medline](#)
- Poteat T, van der Merwe LA, Cloete A, et al. Low PrEP awareness and willingness among transgender women in South Africa. *Lancet HIV*. 2020;7(12):e825-e834. [CrossRef](#). [Medline](#)
- Higa DH, Crepaz N, Mullins MM; Prevention Research Synthesis Project. Identifying best practices for increasing linkage to, retention, and re-engagement in HIV medical care: findings from a systematic review, 1996-2014. *AIDS Behav*. 2016;20(5):951-966. [CrossRef](#). [Medline](#)
- Govindasamy D, Ford N, Kranzer K. Risk factors, barriers and facilitators for linkage to antiretroviral therapy care. *AIDS*. 2012;26(16):2059-2067. [CrossRef](#). [Medline](#)
- Sharma M, Ying R, Tarr G, Barnabas R. Systematic review and meta-analysis of community and facility-based HIV testing to address linkage to care gaps in sub-Saharan Africa. *Nature*. 2015;528(7580):S77-S85. [CrossRef](#). [Medline](#)
- Nsigaye R, Wringe A, Roura M, et al. From HIV diagnosis to treatment: evaluation of a referral system to promote and monitor access to antiretroviral therapy in rural Tanzania. *J Int AIDS Soc*. 2009;12(1):31. [CrossRef](#). [Medline](#)
- Mugo PM, Wahome EW, Gichuru EN, et al. Effect of text message, phone call, and in-person appointment reminders on uptake of repeat HIV testing among outpatients screened for acute HIV infection in Kenya: a randomized controlled trial. *PLoS One*. 2016;11(4):e0153612. [CrossRef](#). [Medline](#)
- Ammassari A, Trotta MP, Shalev N, et al. Timed short messaging service improves adherence and virological outcomes in HIV-1-infected patients with suboptimal adherence to antiretroviral therapy. *J Acquir Immune Defic Syndr*. 2011;58(4):e113-e115. [CrossRef](#). [Medline](#)
- Pop-Eleches C, Thirumurthy H, Habyarimana JP, et al. Mobile phone technologies improve adherence to antiretroviral treatment in a resource-limited setting: a randomized controlled trial of text message reminders. *AIDS*. 2011;25(6):825-834. [CrossRef](#). [Medline](#)
- Okeke NL, Ostermann J, Thielman NM. Enhancing linkage and retention in HIV care: a review of interventions for highly resourced and resource-poor settings. *Curr HIV/AIDS Rep*. 2014;11(4):376-392. [CrossRef](#). [Medline](#)
- LINKAGES. *Differentiated Care for Antiretroviral Therapy for Key Populations*. Case Examples from the LINKAGES Project. LINKAGES; 2017. Accessed January 12, 2021. <https://www.fhi360.org/sites/default/files/media/documents/resource-linkages-differentiated-art-delivery.pdf>
- Elul B, Lamb MR, Lahuerta M, et al. A combination intervention strategy to improve linkage to and retention in HIV care following diagnosis in Mozambique: a cluster-randomized study. *PLoS Med*. 2017;14(11):e1002433. [CrossRef](#). [Medline](#)
- Hult JR, Maurer SA, Moskowitz JT. "I'm sorry, you're positive": a qualitative study of individual experiences of testing positive for HIV. *AIDS Care*. 2009;21(2):185-188. [CrossRef](#). [Medline](#)
- Maughan-Brown B, Smith P, Kuo C, et al. Readiness for antiretroviral therapy: implications for linking HIV-infected individuals to care and treatment. *AIDS Behav*. 2018;22(3):691-700. [CrossRef](#). [Medline](#)
- Ottens MW Jr, Zaidi AA, Wroten JE, Witte JJ, Peterman TA. Changes in sexually transmitted disease rates after HIV testing and posttest counseling, Miami, 1988 to 1989. *Am J Public Health*. 1993;83(4):529-533. [CrossRef](#). [Medline](#)
- Leaity S, Sherr L, Wells H, et al. Repeat HIV testing: high-risk behaviour or risk reduction strategy? *AIDS*. 2000;14(5):547-552. [CrossRef](#). [Medline](#)
- OPTIONS. *Test-And-Prevent Analysis: Key Findings*. OPTIONS; 2019. Accessed January 12, 2021. <https://www.prepwatch.org/resource/test-prevent-analysis-key-findings/>
- National Medicines and Therapeutics Policy Advisory Committee (NMTPAC), The AIDS and TB Directorate, Ministry of Health and Child Care, Zimbabwe. *Guidelines for Antiretroviral Therapy for the Prevention and Treatment of HIV in Zimbabwe*. NMTPAC; 2016. Accessed January 21, 2021. https://depts.washington.edu/edgh/zw/vl/project-resources/ZIM_ART_Guidelines_2016_-_review_final.pdf
- Zimbabwe. Ministry of Health and Child Care (MOHCC). *Zimbabwe Population-Based HIV Impact Assessment*. MOHCC; 2017. Accessed January 21, 2021. https://phia.icap.columbia.edu/wp-content/uploads/2017/11/ZIMPHIA_First_Report_FINAL.pdf
- NVivo. Version 11. QSR International Pty Ltd; 2015.
- Venter WDF, Cowan F, Black V, Rebe K, Bekker LG. Pre-exposure prophylaxis in Southern Africa: feasible or not? *J Int AIDS Soc*. 2015;18(4)(Suppl 3):19979. [CrossRef](#). [Medline](#)
- Kahle EM, Hughes JP, Lingappa JR, et al. An empiric risk scoring tool for identifying high-risk heterosexual HIV-1 serodiscordant couples

- for targeted HIV-1 prevention. *J Acquir Immune Defic Syndr*. 2013;62(3):339–347. [CrossRef](#). [Medline](#)
29. Balkus JE, Brown E, Palanee T, et al. An empiric HIV risk scoring tool to predict HIV-1 acquisition in African women. *J Acquir Immune Defic Syndr*. 2016;72(3):333–343. [CrossRef](#). [Medline](#)
 30. Pintye J, Drake AL, Kinuthia J, et al. A risk assessment tool for identifying pregnant and postpartum women who may benefit from pre-exposure prophylaxis. *Clin Infect Dis*. 2017;64(6):751–758. [CrossRef](#). [Medline](#)
 31. Dunbar M. *Risk Assessment Tools and the Identification of Individuals at High-Risk of HIV Infection in the Delivery of Oral PrEP*. AVAC; 2018. Accessed January 12, 2021. https://www.prepwatch.org/wp-content/uploads/2019/03/Risk_assessment_tools_and_analysis.pdf
 32. Goparaju L, Praschan NC, Jeanpiere LW, Experton LS, Young MA, Kassaye S. Stigma, partners, providers and costs: potential barriers to PrEP uptake among US women. *J AIDS Clin Res*. 2017;08(09):730. [CrossRef](#). [Medline](#)
 33. Loeb DF, Lee RS, Binswanger IA, Ellison MC, Aagaard EM. Patient, resident physician, and visit factors associated with documentation of sexual history in the outpatient setting. *J Gen Intern Med*. 2011;26(8):887–893. [CrossRef](#). [Medline](#)
 34. Wimberly YH, Hogben M, Moore-Ruffin J, Moore SE, Fry-Johnson Y. Sexual history-taking among primary care physicians. *J Natl Med Assoc*. 2006;98(12):1924–1929. [Medline](#)
 35. Shamu S, Slabbert J, Guloba G, et al. Linkage to care of HIV positive clients in a community based HIV counselling and testing programme: a success story of non-governmental organisations in a South African district. *PLoS One*. 2019;14(1):e0210826. [CrossRef](#). [Medline](#)
 36. Haley CA, Vermund SH, Moyo P, et al. Impact of a critical health workforce shortage on child health in Zimbabwe: a country case study on progress in child survival, 2000–2013. *Health Policy Plan*. 2017;32(5):czw162. [CrossRef](#). [Medline](#)
 37. Mack N, Odhiambo J, Wong CM, Agot K. Barriers and facilitators to pre-exposure prophylaxis (PrEP) eligibility screening and ongoing HIV testing among target populations in Bondo and Rarieda, Kenya: Results of a consultation with community stakeholders. *BMC Health Serv Res*. 2014;14(1):231. [CrossRef](#). [Medline](#)
 38. Lanham M, Stankevitz K, Ridgeway K, et al., eds. Healthcare providers' attitudes and experiences delivering oral PrEP to adolescent girls and young women: implementation research to inform PrEP scaleup in Kenya, South Africa, and Zimbabwe. IAS 2019. July 21–24, 2019, Mexico City, Mexico. Accessed January 25, 2021. <http://programme.ias2019.org/Abstract/Abstract/1207>
 39. Stankevitz K, Schwartz K, Hoke T, et al. Reaching at-risk women for PrEP delivery: what can we learn from clinical trials in sub-Saharan Africa? *PLoS One*. 2019;14(6):e0218556. [CrossRef](#). [Medline](#)

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Bugs in the Bed: Addressing the Contradictions of Embedded Science with Agile Implementation Research

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Key Findings

- Embedding research into host program management and policy processes fostered the utilization of evidence for community-based health service development in Bangladesh, Ghana, and Tanzania. However, in each of these cases, strategies were required to offset challenges to the application of the embedded science approach.
- Research designs that maximize statistical rigor can be inconsistent with optimizing utilization. Achieving evidence-driven organizational change required phases for sequential learning to support systems development decision making.

Key Implications

- Agile science methods can address the inherent contradictions of embedded science health systems development in low- and middle-income country settings without compromising scientific rigor.
- Research aims should target the goal of achieving programmatic improvement as an endpoint that supplements demographic and health goals. To that end, phases of agile implementation research can overlap and curate knowledge, facilitating the institutionalization of evidence-based learning.
- The principles of agile development are potentially relevant to health systems strengthening in low- and middle-income country settings.

ABSTRACT

Implementation research often fails to have its intended impact on what programs actually do. Embedding research within target organizational systems represents an effective response to this problem. However, contradictions associated with the approach often prevent its application. We present case studies of the application of embedded implementation research in Bangladesh, Ghana, and Tanzania where initiatives to strengthen community-based health systems were conducted using the embedded science model. In 2 of the cases, implementation research standards that are typically embraced without question were abandoned to ensure pursuit of embedded science. In the third example, statistical rigor was sustained, but this feature of the design was inconsistent with embedded science. In general, rigorous statistical designs employ units of observation that are inconsistent with organizational units that managers can control. Structural contradictions impede host institution ownership of research processes and utilization of results. Moreover, principles of scientific protocol leadership are inconsistent with managerial leadership. These and other embedded implementation science attributes are reviewed together with contradictions that challenged their pursuit in each case. Based on strategies that were effectively applied to offsetting challenges, a process of merging research with management is proposed that is derived from computer science. Known as “agile science,” this paradigm combines scientific rigor with management decision making. This agile embedded research approach is designed to sustain scientific rigor while optimizing the integration of learning into managerial decision making.

INTRODUCTION

Implementation science is often applied to developing health policies.^{1–3} In a recent review of the expanding application of this paradigm, Peters et al.⁴ defined implementation research as:

... the scientific inquiry into questions concerning implementation—the act of carrying an intention into effect, which in health research can be policies, programmes, or individual practices (collectively called interventions).

As they noted, research utilization is critical to ensuring that implementation science results have their intended impact. Various strategies have been advanced to foster implementation research utilization, such as “action research,”^{5,6} “participatory planning,”⁷ “applied research,”⁸ “operations research,”⁹ and “organization development.”¹⁰ Common to this body of literature are

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recommendations for establishing host organization ownership of research processes and outcomes.^{11–13} This focus on optimizing strategic ownership is termed “embedded science,”^{14–17} an implementation science strategy with a long history of development.⁴ Spanning several decades of methodological refinement,¹⁸ the study of research utilization has consistently shown that evidence-based decision making is enhanced by establishing a partnership of policy makers, implementers, and researchers in the design, conduct, interpretation, and dissemination of health systems research.^{17,19–21}

This article reviews programs from Bangladesh, Ghana, and Tanzania that applied embedded implementation science to community-based primary health care systems development. Case studies identify challenges constraining the use of embedded science and strategies that each case employed to offset their effects on the integrity of implementation research results and utilization. The contradictions and challenges experienced in these case examples have also constrained the pursuit of embedded science elsewhere.^{22–24} All 3 case examples concerned the need for evidence-driven national community-based primary health care programs.²⁵ Each case involved convening a partnership of a research team with a public program to configure embedded research designs, results, and procedures for translating results into action.

Although lessons emerge from the case studies, gaps in resolving contradictions are evident. We have identified a body of theory and action that has addressed these contradictions and could extend embedded implementation science in ways that could bridge these gaps. Developed by computer engineers and organizational scientists to simultaneously optimize systems performance and compliance with client needs, this application of implementation research is termed “agile science”²⁶:

... a specific approach to project management for developing products rapidly and iteratively. Teams using an agile approach use principles and tools that involve inputs from end users, iterations on an idea, and frequent structured communication among all team members. Work is delivered more quickly with more appeal to end users and, ultimately, more value.

We extract lessons from our case studies that resolve contradictions of embedded science, supplement these lessons with tenets of agile science that expand upon these lessons, and posit a synthesis of case lessons with agile implementation science that could address the full range of challenges that the 3 case examples portray.

■ THREE EXAMPLES OF EMBEDDED RESEARCH SCIENCE

Bangladesh: Evidence-Guided Community-Based Primary Health Care Development

The Matlab field station of the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr, b) was founded in 1964 to provide a demographic platform for testing vaccines against cholera.²⁷ Pursuing this goal required detailed information on a large population and longitudinal records of births, deaths, and migration.²⁸ Termed a “demographic surveillance system” (DSS), this capability not only provided a basis for randomized trials of vaccine efficacy, but also permitted investigation of a wide range of sociodemographic topics, as well as the conduct of quasi-experimental studies of health systems issues.²⁹

In the 1970s, such investigations were urgently needed. Having recently experienced a catastrophic typhoon followed by a devastating war of liberation and subsequently one of the most severe famines in the recorded history of South Asia, Bangladesh was widely regarded as a case example of the development challenges confronting the world’s most impoverished settings. Matlab not only hosted a large population that exemplified the pervasive poverty and adversity of deltaic Bangladesh, its population dynamics were being continuously monitored by the DSS.

Bangladesh was particularly prominent in the global debate on population policy. Some commentators advanced the view that family planning service systems could not succeed in such a setting without prior development progress that would alter the demand for children.³⁰ A contrasting perspective was advanced by health scientists who advocated the utilization of family planning programs as a core strategy of development assistance,³¹ a perspective derived from survey evidence that respondents who were not using contraception often stated that they wanted to space or limit childbearing. This finding suggested that “latent demand” for contraception was widespread even in settings where development challenges were pronounced. Matlab was deemed to be an ideal setting for testing the latent demand hypothesis by evaluating a project that would provide convenient access to modern contraceptive methods.

A 2-celled plausibility trial, the Contraceptive Distribution Project (CDP), was launched in 1977. Oral contraceptives and condoms were made freely available by traditional midwives who were trained to dispense supplies to women in their homes. Although initial results provided

We have identified a body of theory and action that addresses the gaps in resolving contradictions and could extend embedded implementation science to bridge these gaps.

evidence of demand for contraception,³² adoption and continuation rates declined with time.³² The CDP had no lasting fertility impact.³³

A series of qualitative appraisals were conducted during the CDP that informed the design of a follow-on study, the Family Planning Health Services Project (FPHSP). In response to community comments, the service provision role of traditional birth attendants was replaced with young literate women, called family welfare assistants (FWAs), who were trained and equipped to provide a wider range of contraceptive methods, treat common childhood illnesses, and purvey comprehensive childhood immunization services.³⁴ FWAs provided fortnightly rounds of clinical and community outreach with backstopping at subdistrict health centers.

The total fertility rate of 6.8 births declined by nearly 2 births in the initial 18 months of FPHSP operation, and a rapid decline in childhood mortality followed.^{33,35,36} Matlab research was embedded in government operations to the extent that its design was developed collaboratively with the Planning Commission. However, its management, supervision, and monitoring omitted any discernable provision for governance by Ministry of Health and Social Welfare (MOHSW) officials (Box 1). This strategic gap was nonetheless essential to achieving the flexibility needed for developing and testing operational innovation.

In 1982, the donor for this initiative, the United Nations Population Fund (UNFPA), sponsored a “tripartite review” of policy implications of these results. Participation included all institutions responsible for Matlab research, service, or policy development roles in maternal and child health. Despite their appreciation of Matlab results, senior MOHSW officials initially rejected the relevance of Matlab results to national programming because of fundamental staffing differences distinguishing Matlab from the national program. FPHSP frontline workers were icddr,b project employed FWAs, and existing MOHSW frontline workers were all male family welfare workers (FWWs). The FWWs had been deployed in the Pakistan era as smallpox eradication campaign workers and “encadere” into the civil service by the postliberation Bangladesh government as a large frontline primary health care workforce. In the view of MOHSW officials, civil service rules prevented any action that would replace FWWs.

Diplomacy prevailed. Tripartite review discussions successfully identified 7 themes that would guide future collaboration. First, the Maternal

and Child Health–Family Planning Extension Project would test the transfer of Matlab service strategies to MOHSW district operations elsewhere in the country. Second, FWWs would be retained as “encadere” civil servants and deployed as health promotional workers. However, FWAs would be added to the system as temporary project employees of the MOHSW system and deployed with job descriptions and supervisory arrangements that were modeled on FPHSP operations. Third, the geographic density of FWA deployment would be consistent with MOHSW resources. The salaries of FWAs would be commensurate with government compensation scales. Fourth, all implementation activities would be MOHSW supervised, while all research components would be conducted by the icddr,b.³⁷ Fifth, the extension project would be located in more than one district, with sites to be selected by the MOHSW. Frequent operational process reports would be channeled directly to MOHSW and the Planning Commission. Sixth, Matlab FPHSP operations would be sustained to permit research plans to be completed. Seventh, Matlab supervisors would serve as temporary advisors to MOHSW counterparts, but ongoing operations would be managed and supervised by MOHSW staff.

Early extension project results replicated the FPHSP impact. Contraceptive use in extension districts increased dramatically,³⁸ and health service indicators improved as well. But most importantly, implementation demonstrated the feasibility of scaling up operations and process documentation was embedded in the MOHSW program monitoring operations.³⁹ Because start-up activities coincided with national 5-year plan development processes, extension project field activities, costing data, and performance reports provided lessons that could be inserted into the strategic design of the World Bank’s Third Health and Population lending agreement.³⁸ This agreement, in turn, financed the hiring, training, and national deployment of 28,000 FWAs over the World Bank’s Third Project 5-year implementation cycle. In this manner, extension project process experience was embedded into national program implementation plans well before final demographic results were attained.^{40–42} The program that emerged was inefficient,⁴³ with staffing that included the continuing deployment of large numbers of unproductive FWWs. Yet it worked. The program was associated with dramatic improvements in reproductive and child health indicators and the onset of one of the most rapid demographic transitions ever recorded.^{43–45}

Matlab research was embedded in government operations; however, its management, supervision, and monitoring omitted any provision for governance by Ministry of Health and Social Welfare officials.

The Extension Project process experience was embedded into national program implementation plans well before final demographic results were attained.

BOX 1. Does Success Always Matter?

Community health service outreach session in Ghana with a Matlab family welfare assistant. © 1981 James F. Phillips/Population Council

The initial official reaction to the Matlab Family Planning Health Services Project results was decidedly negative, despite its impressive statistical and demographic evidence of success. In the view of stakeholders, statistical results provided no evidence that its operational staffing design and management system could be replicated by the Bangladesh Government program. To the official audience for Matlab results, its scientific results initially mattered less than the Maternal-Child Health-Family Planning Extension Project demonstration of the feasibility of replicating its strategies.

The Ghana Community-Based Health Planning and Services Initiative

Ghana embraced the 1978 Alma Ata Declaration with policies that aimed to develop a community-based worker cadre. However, economic and political turmoil in the 1980s severely constrained progress. By 1990, nearly 2,000 “community health nurses” had been hired by the Ministry of Health (MOH) and trained to provide community-based primary health care. However, these nurses had been posted to inaccessible subdistrict clinics and hospitals because funds were unavailable for the construction of community health posts. Consequently, evidence compiled in the early 1990s consistently showed that “health for all by the year 2000” was unachievable unless reform was instituted.⁴⁶ In response, MOH extended a mandate to the Navrongo Health Research Centre (NHRC), in Kassena-Nankana District of the Upper East Region (UER), to develop and test means of implementing community-based primary health care.⁴⁷ The UER was known to have high mortality, prevalent morbidity of nutritional and infectious diseases,^{48,49} and other health development challenges.⁵⁰

In 1992, a 6-week exchange visit to Bangladesh was convened for senior MOH officials and NHRC scientists⁵¹ to work with Matlab counterparts on the design of a DSS for evaluating research and a protocol for testing the transfer of the Matlab FPHSP service model to Ghana.⁴⁷ General strategies of the Bangladesh program were potentially relevant to Ghana. However, operational details were not wholly transferable owing to profoundly contrasting cultural and organizational contexts of Ghana and Bangladesh (Box 2). Nonetheless, the Bangladesh phased progression of research was relevant to developing Ghana’s community-based primary health care program. From its onset, community-based primary health care development in Ghana was a planned process of guiding organizational change with implementation research. A 3-community, 18-month participatory pilot phase was followed by a 4-celled district-wide plausibility trial that tested the fertility and mortality impact of alternative strategies for providing community-based primary health care.⁴⁷

When preliminary evidence emerging from Navrongo was promising, MOH convened a national health forum for deliberating on scaling up the

BOX 2. What Was Transferable From Bangladesh to Ghana?

International Centre for Diarrheal Disease scientists in Bangladesh hosting Navrongo Health Research Centre counterparts in Matlab. © 1992 James F. Phillips/Population Council

A 1993 exchange between the Navrongo service implementation and research teams and Matlab counterparts aimed to transfer the Matlab system to northern Ghana. Since social institutions, the health systems context, and the resource base in Navrongo were fundamentally different from the Matlab context, transferring the strategic details of the Matlab program to Africa did not make sense. What was transferable, however, was the process of developing a program that would work. In both examples, a diagnostic phase was followed by a plausibility trial and then by replication research. In both settings, this phased approach to systems development set the stage for scaling up evidence-based systems improvements.

Navrongo model. However, most participants were decidedly negative about taking this action because the NHRC resource base was believed to be nonreplicable and the cultural context atypical of other regions.

In the course of forum discussions, the Nkwanta District Director of Health Services advocated testing the transferability of the Navrongo system to his district where social characteristics contrasted markedly with the Navrongo setting. Within a year, a Nkwanta replication pilot generated promising implementation experience that was presented in a repeat forum. Based on consensus, MOH adopted the

Navrongo service model and the Nkwanta replication strategy as a national policy known as Community-based Health Planning and Services (CHPS).⁵²

CHPS implementation commenced in 2000. In the decade that followed, external donor support focused on expanding in-service and preservice training for frontline workers, promotional activities in donor-selected districts, and other topics of interest to donors. Imbalances ensued. This commitment to developing components of CHPS was implemented by contracting with international

technical assistance agencies who engaged in operational management activities that bypassed the newly constituted Ghana Health Service (GHS). Budgetary support for bridging implementation gaps was peripheral to this type of commitment because international contracting agency technical assistance consumed most of the external revenue earmarked for CHPS. Most critically, no available mechanism paralleled the World Bank's sector-wide health and population lending that had enabled scale-up in Bangladesh. Lacking an overarching implementation plan with associated financing arrangements, CHPS implementation was decentralized to district management teams where its start-up financing depended upon volunteer labor and contributions from communities to be served. Lack of resources and the paucity of district leadership experience with community mobilization constrained the pace of CHPS scale-up during its first decade of operation. By 2008, GHS program monitors estimated that achieving total population coverage would require 49 years.

CHPS implementation was decentralized to district management teams; its start-up financing depended upon volunteer labor and contributions from communities to be served.

An organic process within districts in Ghana contrasted with the “top-down” financing in Bangladesh—scaling-up eventually worked, covering all targeted communities.

Workshops on donor-financed technical components of CHPS proliferated without implementation-based leadership training or financing for incremental start-up costs. Unlike Bangladesh, personnel availability was not a problem. The hiring and technical training of CHPS workers was expanded far more rapidly than MOH could expand community facilities and procure equipment that was essential for their deployment. Coverage achieved by 2008 was concentrated in the 32 districts where implementation teams had experienced on-site orientation visits in Nkwanta and had received start-up grants for launching CHPS in 1 or 2 demonstration communities.⁵³ By establishing demonstration communities, equipped with seed revenue, district managers could undertake activities that catalyzed the diffusion of implementation within their districts. Although this approach was successful in participating districts, the Nkwanta CHPS development exchange strategy was terminated in 2004 because contracting mechanisms of donor agencies were inconsistent with the Nkwanta embedded research model.

In 2009, the MOH convened a qualitative appraisal to determine why some districts had implemented CHPS in nearly all communities, while most other districts had achieved hardly any progress at all.⁵⁴ Leadership and financing were found to be the key factors. Resources for CHPS start-up

costs were often available from district development financing mechanisms, but district health officials tended to rely upon internal GHS budgets rather than to explore means of seeking revenue elsewhere. When grassroots political leaders were properly engaged with CHPS community demonstration activities and were fully aware of its popularity, they tended to commit development revenue to community health post construction. Often this permitted community volunteer construction of interim facilities that could be used for CHPS until permanent facilities could be constructed. Investment in this approach enabled the program to commence without delay. Participants in Nkwanta exchanges understood the process of community engagement that generated this political support. With creative engagement of traditional leaders and grassroots politicians, managers were able to mobilize resources for rolling out CHPS sequentially, community by community, by linking leaders from communities that had not yet implemented CHPS with start-up activities in communities where CHPS milestones were progressing. This process of “guided diffusion” catalyzed spontaneous scaling up of CHPS operations from a few start-up communities to district-wide implementation.⁵⁵

This organic process within districts contrasted with the World Bank financed “top-down” engagement of the health bureaucracy in Bangladesh. Scaling-up has eventually worked, covering all targeted communities in Ghana. As many studies of social diffusion have demonstrated, catalytic inputs are critical to getting started. Where diffusion was organized, with catalytic revenue provided for demonstration activities, district teams could implement CHPS. But, for the first decade of CHPS implementation, investment in the process and agile leadership for making it happen were typically lacking.

To develop and test mechanisms for reforming the CHPS implementation process, the GHS launched the Ghana Essential Health Interventions Program (GEHIP) in 2009 in 4 UER districts.⁵⁶ Areas associated with prior NHRC research were excluded, while 7 other districts of the UER were comparison areas. In treatment districts, leadership exchanges were supplemented with flexible financing of US\$0.85 per capita per year for 3 years. Existing leadership training was augmented with community-based participatory planning that included district health

management team (DHMT) and district political and development personnel.

The impact of GEHIP on the pace of CHPS implementation was immediate, accelerating coverage from 20% of the target population to 100% in less than 4 years.⁷ Treatment district coverage at the end of GEHIP was achieved at twice the levels as in comparison districts. This coverage expansion was combined with development of an emergency referral and acute care system.⁵⁷ Mortality declined in all UER districts, but GEHIP districts experienced a more pronounced mortality transition than comparison districts.⁵⁸ GEHIP fertility effects were also evident.⁵⁹

Evidence of GEHIP affordability and impact justified the adoption of its strategies as policy, and inspired an ongoing 5-year replication project in 2 other regions of Ghana, known as CHPS+. ^{53,60} Designed to provide continuous knowledge of the replication process, CHPS+ has implemented 4 “system learning districts” where GEHIP capacity is fully functional and where visiting district implementation teams observe operations, learn from the process, and return to their home districts with small grants for financing the roll-out of lessons learned.

The Tanzania Connect Project

In 2008, the President of Tanzania pledged to develop a “dispensary in every community” through a policy known by its Swahili acronym MMAM for Mpango wa Maendeleo wa Afya ya Msingi, translated as the Primary Health Services Development Program.⁶¹ This commitment coincided with the proliferation of community-based primary health care programs throughout Africa,⁶²⁻⁶⁵ often in response to international advocacy of the deployment of community health workers (CHWs).⁶⁶⁻⁶⁸ But MMAM was controversial. At the time of the proclamation of MMAM, Tanzania had the highest geographic density of primary health care fixed facilities in Africa.⁶⁹ The added value of adding several thousand CHWs was questionable in a setting where accessible fixed-facility services were already functioning. A project was developed to respond to the need for a trial of the MMAM policy, while also addressing international policy questions concerning the health and survival benefits of CHW deployment. This project, known as Connect, would develop procedures for MMAM implementation and test the health and survival impact of this policy.

Unlike district systems development interventions in Bangladesh and Ghana, Tanzanian policy questions concerned the value of adding community-level door-step care in an existing community-based system of fixed-facility dispensary services. In this instance, research advisors to MOHSW believed that a randomized controlled trial of CHW deployment would be appropriate because randomization of community catchment areas was both organizationally and statistically feasible. Moreover, addressing policy questions concerning CHW effects with statistically rigorous randomized designs remained rare.^{70,71} Since Tanzania had a long legacy of public investment in community dispensary care, the existing system provided a platform for testing the proposition that CHW household outreach could have incremental benefits, even in the context of accessible fixed-facility care.

The Ifakara Health Institute (IHI) was an appropriate institution for undertaking this trial (Box 3). The IHI DSS had functioned for over a decade in households located in 101 communities of 3 rural districts.⁷² The DSS operations provided a statistical platform for testing the hypothesis that CHW deployment saves lives in the context of accessible dispensary-based care.⁷³

To implement the Connect trial, an interdisciplinary team was constituted, in which a systems learning exchange with Navrongo and Nkwanta implementers convened a participatory planning process to clarify requirements of adapting the Navrongo model to Tanzanian circumstances.⁷⁴ CHWs were recruited from communities where they would be assigned, provided with a 6-month regimen of CHPS-like training, and then deployed to 49 randomly selected communities. A sample of 51 correspondingly randomized communities were selected where CHWs were not deployed.⁷⁵ Legacy DSS data were marshalled for the decade prior to Connect permitting cause-specific mortality analyses⁷⁶ and social determinants research that established preproject statistical balance of treatment and comparison conditions.⁷⁷

For the initial 2 years, Connect operations proceeded as planned. A cadre of workers had been hired, trained for 6 months, paid a modest salary, and deployed to their home communities. Their primary health care regimen resembled the Matlab and Navrongo models. In year 3, however, problems ensued that were unrelated to project research hypotheses. Dispensaries served a catchment area typically composed of 3 or more communities. With communities specified as the primary unit of statistical randomization, Connect CHW deployment was misaligned with the operational design of the service system. Supervisors based in the

BOX 3. Rigor as a Barrier to Success



Ifakara Health Institute demographic surveillance system interview, Rufiji District, Tanzania. © 2012 James F. Phillips/Columbia University

The Tanzania Connect experiment was a randomized controlled trial that conformed to conventional standards of statistical rigor. Its use of demographic surveillance permitted community randomization of the assignment of community health workers (CHWs). While this was statistically appropriate, the relevant unit of program governance was the hierarchy defined by dispensary catchment area, ward, and district. Lack of congruence of randomization with bureaucratic context spuriously weakened prospects that the investigation of the CHW deployment hypothesis would succeed.

Although initial Connect results were impressive, the policy impact of the project was compromised by subsequent failure.

dispensaries were responsible for both treatment and comparison communities. Moreover, district authorities were organizationally disconnected from the trial of CHWs, because both treatment and comparison conditions fell within the leadership domain. Managing experimental operational variance was contrary to managerial norms. So long as service operations were managed by the IHI research team, this structural anomaly did not detract from Connect implementation. But, in midstream, after

2 years of operation, the National Steering Committee requested the transfer of all frontline logistics operations from the IHI project team to local MOHSW authorities. The provision of essential supplies immediately broke down Connect because the national program logistics system was unprepared for the management of Connect CHW supply requirements. CHWs soon lacked essential supplies, causing their community credibility to evaporate and their impact on health and survival to atrophy in the final 2 project years.⁷⁷ Although initial

Connect results were impressive, the policy impact of the completed project was compromised by subsequent failure (Box 4). A planned phase 3 replication trial never emerged and systematic utilization of Connect for national scale-up was suboptimal. The premature embedding of Connect in a fragile health system undercut its utilization. Connect has contributed learning to the national program, but its operational design has not been scaled up.

DISCUSSION

The 3 cases represent a common commitment to applying embedded research to a phased process for developing community-based primary health care systems (Figure 1).⁷⁸ Despite common endpoints, theory, and embedded science methods, implementation outcomes differed because contrasting challenges were encountered, each requiring distinct strategies to address them. Fielding phase 1 investigations addressed the need for a program implementation strategy. Phase 2 experiments

tested the operational model that emerged from phase 1. Phase 3, in Bangladesh and Ghana, transitioned research from testing impact to investigating the appropriate replication processes for achieving operational change. Phase 4 research monitored scale-up, either by supporting implementation processes or by indicating need for redirection and reform. Yet, all 3 examples encountered unresolved challenges.

Tables 1 to 3 cite attributes of implementation science design together with contradictions that each of the 3 embedded science initiatives encountered. Table 1 focuses on planning, Table 2 on operations, and Table 3 the utilization of results.

Planning implementation research in collaboration with a host organization is a fundamental principle of embedded science.

Contradictions Associated With Embedded Implementation Research Planning

Planning implementation research in collaboration with a host organization is a fundamental principle of embedded science. Yet, the process of collaborative planning is challenged by contrasting goals of

BOX 4. The Value of Strategic Isolation

Connect was a test of the hypothesis that community health worker (CHW) deployment could save childhood lives. It was not a test of district Ministry of Health and Social Welfare (MOHSW) leadership capacity to manage a community program.

The Connect protocol was an emerging success story that was disrupted by a premature shift of logistics management to a national MOHSW system that was experiencing serious organizational malaise. Embedding a district-level trial into this dysfunctional context disrupted the routine supply of essential medicines to CHWs, compromising their effectiveness and the statistical elegance of the Connect design. Without continuous supplies for essential services, CHWs lost credibility and Connect lost effectiveness in its final 2 years of operation. If Connect had functioned as an autonomous project, its final outcome would have been consistent with its successful first 2 years of operation. However, when final results were available, the project lost credibility. Replication research was never attempted. Impact on scale-up was marginal rather than central to program planning.

FIGURE 1. Research Phases Associated With Developing Community-Based Primary Health Care in Bangladesh and Ghana

	1	2	3	4
Phase:	Diagnosis and formative research	Experimental trial	Replication and validation	Scale-up
Questions:	• What is appropriate?	• Does it work?	• Is it replicable? • If so, how?	• Is scaling up progressing? • Is fidelity sustained?
Approach:	Qualitative appraisal and pilot	Factorial trial with quantitative endpoints	Mixed methods operations research	Health systems monitoring
Product:	Candidate system	Successful system model	Model for achieving systems change	Improved system

Adapted from Nyonator et al.⁷⁸ and Awoonor-Williams et al.⁷⁹

TABLE 1. Contradictions Associated With the Planning of Embedded Implementation Science and Case Study Examples of Strategies for Resolving Contradictions

Attribute	Core Strategies of Implementation Science	Strategic Adjustments of Embedded Science	Contradictions Associated With Strategic Adjustments	Case Study Resolution of Contradictions
Goal	Problems are identified <i>a priori</i> and resolved through researcher controlled hypothesis testing and dissemination.	Organizational change and development requires joint researcher and host agency goal setting.	Goals are defined in terms of endpoint hypotheses to be tested rather than host agency goals for testing means of achieving system change.	Retain, but subordinate, primary health and demographic impact research to implementation research as an integrated and continuous process. ⁴
Outcome evaluation	Statistical inference is based on observation of treatment and counterfactual endpoints, with units of observation conforming to power requirements.	Improved host agency functionality and impact	Protocols define project start and end dates, endpoints, and hypotheses, whereas organizational change is a continuous, open-ended, and multi-faceted process. ¹⁰	Phase in research as a process that fosters continuous utilization and action. ⁴⁴ Avoid ending learning processes just because a protocol has been completed. ²
Leadership	Researchers in directive, independent, and autonomous roles with outreach to decision makers and managers at the end of investigation.	Collaboration of host agency and research partner leadership	Researchers assume directive, independent, and autonomous roles and episodically communicate health and demographic outcomes to host agency counterparts. Managers' roles are defined by bureaucratic and organizational norms.	Host agency managers representing each level of the investigative process are appropriately teamed with research counterparts at each system level.
Ownership	Host agency audience through "steering committees" and end of the project dissemination.	Subordination of research leadership to host agency governance. Joint dissemination.	Leadership malaise in the host agency can permeate an embedded research system, diluting rigor and compromising research implementation. ^{54,80}	Develop a partnership of research leadership with host agency institutional structures, but maintain an autonomous research operation.
Scientific rigor	Study designs conform to conventional criteria for statistical inference.	Studies embrace process research, mixed methods research designs, and multi-level analyses in concert with the norms of statistical inference.	Constructing the counterfactual is essential but inconsistent with management operations that span all organizational levels. ⁹⁰ Acquiring meaningful numbers of randomized organizational units for observation and statistical inference is impossible. ⁹²	Intervene with treatment and counterfactual conditions that conform to the host organizational structure. Use plausibility trials ^{56,85} with statistical methods for non-experimental designs. ⁶⁰
System relevance	Systems thinking provides frameworks for data capture and analysis. Optimize costing for achieving clear and unequivocal results for hypothesis testing.	Systems thinking includes partnership arrangements and research activities that reflect units of the host agency organization. Establish researcher and host agency collaboration on operational costing and costing research.	Contexts where implementation science is needed most are settings where systems research is most challenging to conduct. ⁹² Systems research requires multilevel longitudinal data that are complex to capture, manage, and analyze. ^{90,92} Prospects for utilization are enhanced if costs are clear, but organizational change often incurs costs that are impossible to predict.	Utilize replication studies to disperse research in all relevant cultural and ecological contexts. Configure learning localities that are consistent with program organizational units at each level of the system. ⁴⁴ Restrict implementation financing to affordable and replicable activities. Prioritize costing analyses for replication and scale-up phases. ^{100,101}

TABLE 2. Contradictions Associated With the Process of Conducting Embedded Implementation Science and Case Study Examples of Strategies for Resolving Contradictions

Attribute	Core Strategies of Implementation Science	Strategic Adjustments of Embedded Science	Contradictions Encountered by Embedded Implementation Science	Implications for Resolving Contradictions
Teamwork	Constitute teams according to technical functions.	Delineate implementation and research teams.	Research teams and implementation teams have contrasting skills, orientations, and roles.	Configure at each level of the system “learning localities” where the pursuit of excellence is a collaborative endeavor that integrates implementation with investigation.
Simplicity	Develop measurable indicators of endpoints and possible confounders.	Focus on indicators that are commensurate with host organizational data capture, analysis, and communication capabilities.	Research and implementation integration is complex to undertake, but simplicity is often essential for fostering organizational change. ^{105,106}	Employ mixed methods research and knowledge management to promote understanding of essential processes and outcomes. ^{44,45,98}
Replicability	End of project terminates further research on replication or scale-up.	Design projects to facilitate subsequent replication and scale-up.	Developing learning systems requires focused inquiry in localities where interventions can be tractably managed. Managers often seek investigation that is immediately relevant to large-scale operations. ^{44,45}	Plan phases in advance ⁹⁹ that (i) diagnose systems requirements, (ii) test impact, (iii) test replication, and (iv) scale up based on replication lessons.
Fidelity	Fidelity of interventions to themes appearing in the scientific literature.	For longitudinal research on scaling up, develop communication mechanisms that ensure widespread host agency understanding of the evidence justifying change.	Primary science generates knowledge about impact without providing knowledge about change processes. ⁹⁰ Adapting to unanticipated changes is essential to scale-up. ¹⁰⁰ Fidelity to research outcomes is often incompatible with flexibility.	Develop “learning localities” for catalyzing the geographic spread of implementation. Integrate learning into national systems planning processes. Avoid advocacy focusing solely on “success” without also publicizing challenges and failure. ⁸⁸

researchers and implementers and alternative perspectives on process. Rows of Table 1 summarize challenges to embedded research planning. The goal of joint leadership for establishing host agency ownership is challenged by contrasting professional leadership norms of researchers and managers. Moreover, differing criteria for defining scientific rigor can be associated with contrasting perspectives on the relevance of results.

Precisely Defined and Measurable Goals

In each case, research achieved demographic and health impact for each phase in the research process. While this contributed to the credibility of each initiative, primary goals, as defined by host agency leaders, were more focused on demonstrating the feasibility of changing operations, the practicality of intervention components, and the

operational integrity and quality of community health services. This focus on achieving systems change contrasts with conventional project-based fixed-duration health research whereby designs, protocol execution, and dissemination of outcomes are preplanned and governed by protocol. Amplifying this contradiction is the tendency for project completion to terminate further thinking about organizational change implications. Utilization of results is a research afterthought rather than an explicit objective worthy of investigation. Operational change may be fortuitous under such circumstances, but more typically, large-scale change does not occur or is not included as a topic of explicit research focus. Fully embedded science connotes a process of continuous institutionalized learning and action that never ends, just as effective management is an interminable goal.

TABLE 3. Contradictions Associated With Utilizing Embedded Implementation Science for Policy and Action

Attribute	Core Strategies of Implementation Science	Strategic Adjustments of Embedded Science	Contradictions Encountered by Embedded Implementation Science	Implications for Resolving Contradictions
Curation of knowledge	Publish results and disseminate findings to host agency and research audiences.	Develop knowledge-sharing mechanisms.	Science is disseminated by modes of communication that have limited currency among donors, decision makers, implementers, and managers.	Develop a multimethod knowledge management system for research advocacy, ¹⁰⁵ and build participatory learning and exchanges into research operations. ^{71,74}
Sustainability	Recommend utilization of research findings in the course of end-of-project dissemination activities.	Collaboration of researchers and host agency counterparts on research utilization strategic planning.	Planning research utilization is challenged by the institutionalization of dysfunction. Failure is therefore more sustainable than improvement. Research results may contradict existing organizational norms and policies.	Utilize research phase 3 replication research to investigate the determinants of sustainability.

Overarching research goals to change organizational structure or functioning differ from goals that concern biomedical experimental outcomes.

Overarching research goals to change organizational structure or functioning differ from goals that concern biomedical experimental outcomes. In Bangladesh, organizational change was conducted in phases that were informed by continuous learning that was integrated into leadership activities and planning processes. Activities involved in setting up the Maternal and Child Health–Family Planning Extension Project were documented in ways that provided operational plans for the World Bank’s lending agreement. Rolling out the extension project simultaneously rolled out the World Bank’s plan well before project demographic and health outcomes were known. This process of integrated knowledge management and curation was also characteristic of the Ghana case,⁸⁰ where the process of launching Navrongo and Nkwanta operations led to the 1999 CHPS policy. Navrongo completed its protocol in 2003, and Nkwanta replication activities continued until 2004. Yet national CHPS scale-up commenced in 2000. This anomalous timing of action was done for a reason: The focus in each case was achieving systems change rather than testing hypotheses on health and demographic outcomes. If phase 3 results had showed that replication failed to achieve phase 2 results, a new round of phase 1 diagnostic learning would have commenced with the goal of developing phase 4 reform.

Decision-Making Processes

A manager assessing the impact of implementation research is focused on improving operations rather than the health or demographic outcomes that are external to direct management control. The integration of research operations with host agency organizational structure contributes directly to research credibility. Procedural monitoring with multi-method research is critical to the conduct of embedded science. Contradictions arise, however. Temporal congruence can be inconsistent with the continuous provision of information for program planning and decision making.⁸¹ Research timelines may encounter delays or adjustments in order to align technical activities with counterpart planning cycles. This adjustment process can cause projects to overrun timelines and deplete resources before final analyses or dissemination activities can be conducted. Moreover, abandoning temporal congruence to ensure compliance with protocol timelines can detract from official interest in research operations.

In Bangladesh, this problem was addressed by integrating project information generation cycles into the national planning cycle, so that project communication could provide direct input into the World Bank lending agreement. But, in Ghana and Tanzania, temporal integration of research-based learning cycles with the timing of national planning and donor agreement cycles

was never possible. In Ghana and Bangladesh, health authorities addressed this problem by integrating project reporting into routine communication mechanisms. In Ghana, however, delays were associated with temporal discordance of mechanisms that provided resources for implementation research with timing cycles that funded CHPS implementation.

Host Agency Ownership

Establishing host agency ownership involves collaboration in the process of research management, project implementation, and dissemination.^{82–84}

In each of the 3 case examples, integration of scientific leadership into planning units of the host government was facilitated by host agency research skills that were commensurate with leading protocols, conducting investigations, and interpreting results for national program utilization. Despite this potential for joint ideational development, leadership sharing is alien to most health bureaucracies, which require leadership to be singular, directive, and decisive. However, external research support often involves external technical advisors who depend upon funding, professional recognition, and achievement criteria. A totally embedded academic or research agency partner will have career goals that are at odds with ceding ownership and ideational leadership to program implementers. Indeed, even the scholars who promote embedded science only rarely practice embedded science in the course of their work. Some degree of strategic isolation of research is appropriate. Independent ideational leadership is critically important, totally justified, and essential to the advancement of implementation science. Such capabilities are often unavailable in the institution that implementation research has targeted for change. Researchers are often obligated to defy embedded ownership goals and take charge of some operations that research is testing, as in the Matlab and Ifakara examples.

Disengagement of researchers with host agency institutions can be particularly critical to developing innovations during the initial phases of implementation research. In many instances, research associated with discovery and organizational diagnosis would not survive if bureaucratic scrutiny was embedded with research operations. This differentiation of roles also applies to host agency leaders. Administrative issues that they, as owners, recognize as meriting investigation may be of little perceived importance to researchers. While the pursuit of joint ownership may be critical to

embedded science, not all phases in the development process benefit from joint leadership.

Embedded science ownership assumes that all essential partners are included in the vital system of decision making. If donors are positioned to shape policy, action, and the research itself, they must be embedded in the systems development process, just as the World Bank was a systems investor in Bangladesh. But, if donor agreements that fund research or implementation impose mechanisms that extract ownership, leadership, or ideational integrity from embedded processes, no amount of embeddedness among other players will matter.

Statistical Rigor

The pursuit of statistical rigor can confound embedded project designs. For example, Ghana's GEHIP project failed to have an impact the survival of children aged 1–4 years because the mortality decline in comparison areas was equivalent to trends in treatment areas. This pronounced improvement in child health was the outcome of successful strengthening of the Integrated Management of Childhood Illness care system throughout the UER. In the embedded science paradigm, the Regional Director of Health Service was a co-investigator, whose successful and fully appropriate leadership led to health systems improvements in comparison districts that spuriously introduced statistical failure when comparison area trends were found to match progress in treatment areas.^{56,58}

Connect in Tanzania also illustrates challenges. Randomization of community units of observation complied with the criteria of rigorous randomized cluster trials. Yet, this feature of the design was its major shortcoming. Achieving organizational congruence for decision making that is evidence based is more critical to embedded science than optimizing observational congruence with criteria for statistical decision making.⁸⁵

System Relevance

The institutional context of trials influences the credibility of results.⁸⁶ Health systems research is often implemented as a project that is optimized for achieving endpoint success. Resources, site location selection, staffing, and organizational arrangements are configured in ways that ensure that objectives are achieved⁸⁷ since scientific credibility and donor support usually require evidence of endpoint success. Failure as a theme in the health systems science literature is rare.⁸⁸ This

Despite the potential for joint ideational development, leadership sharing is alien to most health bureaucracies, which require leadership to be singular, directive, and decisive.

Health systems research is often implemented as a project that is optimized for achieving endpoint success.

Conducting joint embedded science operations is challenged by complications from integrating teamwork, investigating problems that are complex, and maintaining flexibility.

emphasis on achieving endpoint success can be particularly dysfunctional in Africa where contextual variance in organizational, cultural, linguistic, and ecological circumstances can be pronounced. In any country setting, findings emerging from a single location and provided with unusual features and resources can be dismissed as being irrelevant to national policy.^{86,87} In response to this challenge in Bangladesh and Ghana, interregional dispersion of embedded replication projects ensured that geographic context would not overshadow the programmatic relevance of results.⁶⁰

The relevance of embedded science is also enhanced if units of inquiry span levels of the host agency system. Although systems thinking gained currency with the dissemination of the World Health Organization (2007) systems strengthening framework^{89,90} apart from a few examples, systems strengthening trials remain rare in Asia and Africa^{37,73,91} because of the high cost, complexity, and organizational challenges of systems research.⁹²

In all 3 cases, investment in innovation incurred incremental costs. Establishing cost compatibility with host agency budgets and generating host agency knowledge of these costs was important to deliberations on the utilization of results.^{93–95} Once operational impact had been demonstrated, prospects for utilization were enhanced. Contradictions arose, however, when budgeting and financial procedures of the host agency contrasted with the financial procedures associated with embedded research projects. Costs of innovation were affordable and yet procedurally awkward to undertake. However, in Bangladesh, costing information facilitated financing by the World Bank and offset the political risk of adding the FWA cadre to the system. But, in Ghana, the start-up costs of CHPS implementation was not the focus of external investment. Reforms instituted in 2009 specified budget lines that permitted district directors to plan the costing of health posts, equipment, and supplies. Congruence between research recommendations and capacity to act was enhanced. Politically embedded CHPS catchment areas enabled district directors to align revenue negotiations with domains of responsibility of local development officials. In Tanzania, costs were financed externally, but resources were managed by local government mechanisms. Connect was not only affordable, but its financial requirements were manageable within the host organizational system.⁹⁵

Contradictions Associated With Conducting Embedded Implementation Research

Conducting research and operational leadership as a partnership represents a fundamental principle of

embedded science. Dual leadership is fundamentally challenging in any formal organization. In particular, conducting joint embedded science operations is challenged by the complications associated with integrating teamwork, by the challenge of simplifying investigation of problems that are complex, and by maintaining flexibility when sustaining fidelity is vital to maintaining compliance with evidence. Table 2 summarizes these contrasts and corresponding case study outcomes.

Teamwork

As the 3 cases have demonstrated, the delineation of research from implementation functions can structure task autonomy rather than foster embedded collaborative task implementation. This dysfunction can be offset with multi-method interdisciplinary teamwork involving collaborative extraction of lessons spanning each level of the system,^{94,95} thereby facilitating investigation of hierarchy, structure, and function and fostering host agency stakeholder consensus that results are relevant to the system at large.^{96,97} But, total research integration is tantamount to contamination because managers are both the subject of research and the purveyors of implementation insights. Moreover, managing operations can be inconsistent with ceding authority to researchers, even if trials are testing ways to improve program performance. Partnership is possible if leadership focuses on mechanisms for achieving interdisciplinary teamwork, but more commonly, functional diversity constrains embedded management and research thinking.

Simplicity

Evidence-based change is an application of complexity science.⁹⁸ Phases, milestones, and implementation processes are complex to understand, document, and explain. Complexity was addressed in Bangladesh by embedding research outcomes into routine government orders, plans, training guidelines, and internal memoranda. In Ghana, simplicity was achieved when field demonstration was combined with catalytic financing that enabled participants to pilot the system they were learning how to manage. Mixed methods research was used in all 3 case examples to integrate implementation process knowledge into managerial utilization of outcomes.^{44,45} However, this integration process is often too complex for donors and senior officials to embrace unless political action drives the integration process. Organized units were created,

in each case, to create a bridge between research project teams and planning units. In Ghana, for example, a national order rearranged CHPS catchment areas to coincide with grassroots electoral areas, thereby aligning popular support for CHPS with District Assembly member electoral aspirations. This simplified district health leadership actions required building political support for defraying CHPS start-up costs with district development revenue. And, to achieve organizational congruence, the national office responsible for health planning, known as GHS Policy Planning Monitoring and Evaluation Division, was charged with the task of monitoring all CHPS-related research in Ghana. In Bangladesh, a World Bank-financed management development unit was convened to support the communication of project results to planners. In Tanzania, a planning unit of the MOHSW was charged with the task of monitoring project progress.

Flexibility and Replicability

Scalability is often an afterthought rather than a process that is antecedent to research.⁹⁹ This was the principal limitation of the Matlab phase 2 FPSP that the phase 3 extension project was convened to address. Phase 3 was crucial to catalyzing utilization of Phase 2 outcomes. Program planners at the World Bank had assembled the initial draft of Population and Health Plan Three in Washington without review of extension project results. This procedural isolation was perceived by the World Bank's officials to be essential to organizing lending, because World Bank procedures were complex, requiring careful compliance with preparation timelines. Co-financing arrangements that added critically needed resources also added complexity. Nearly 60% of the \$243 million agreement was foreign aid contributed to the lending agreement by European governments and Canada. Procedural momentum for configuring a large and complex agreement required fidelity to pre-arranged timelines rather than fidelity to research findings. As a result, the text of the initial agreement was voluminous, yet imported from afar, and tangential to health development needs.

In response to the World Bank's procedural agenda, the Bangladesh MOHSW deliberations focused on sustaining the program and complying with the World Bank's leadership with extension project lessons initially assuming the character of a disruption of the process of developing the vitally important World Bank agreement. But, the products of extension project implementation soon provided the Bangladesh government with

content to use in negotiating terms specified in the World Bank's agreement. By providing the Bangladesh government with documented evidence that supported its procedural ownership of the borrowing process, the extension project catalyzed national program adoption of the Matlab service model well before the extension project demographic results were attained.

In Ghana, general policy and programmatic decisions to scale up results were taken prior to the launching of Navrongo research. However, the full range of considerations for financing scale-up lacked the strategic integration of research outcomes with donor processes that had supported scale-up in Bangladesh. In fact, throughout the CHPS development process, donors were only peripherally embedded in the initial planning process. Based on donor understanding of the potential impact of CHPS, but insufficiently engaged with implementation processes, donors engaged contracting mechanisms for supporting CHPS that extracted ownership from GHS-embedded partnership arrangements. Scaling down operations to tractable levels of district managerial learning had catalyzed scaling up at the district level,⁶⁰ where effective scaling-up progressed if district managers developed 1 or 2 learning communities. By utilizing their functional CHPS operations as demonstration zones, leadership action could spread CHPS implementation.⁵³ Lacking mechanisms for centralizing this fundamentally decentralized process, embedded science failed to foster appropriate donor investment.

Scaling-up in each district was confronted with a fundamental contradiction represented by the requirement of flexibility and fidelity. Utilization of research implies fidelity to the evidence, while managerial flexibility is equivalently essential to the process of achieving change. Flexibility to permit district leadership to progress is essential to CHPS development. However, maintaining balance between fidelity and flexibility requires ensuring an element of research autonomy that is somewhat at odds with the tenets of embedded science.

In all 3 case examples, project steering committees were constituted to ensure that activities were both compliant with protocols and adaptable to changing operational needs. To protect fidelity, mechanisms insulated research teams from bureaucratic constraints; yet, corresponding mandates permitted managers to engage in change that implementation research required. In Bangladesh, the institutional autonomy of the icddr,b insulated extension project research from bureaucratic constraints and district managers in extension project

Scalability is often an afterthought rather than a process that is antecedent to research.

Utilization of research implies fidelity to the evidence, while managerial flexibility is equivalently essential to the process of achieving change.

areas were permitted to alter training, supervision, and worker deployment schemes. Similarly, in Tanzania, the IHI field research stations were essentially autonomous from MOHSW oversight and managers were provided with mandates to support CHW deployment and supervision. In Ghana, research units of the GHS are separated from directorates responsible for implementation, but when implementation research is undertaken, the existing GHS management system retains control of operations. In all 3 settings, research projects had autonomous accounts, technical research staffing, and logistics capabilities that permitted operational independence and flexibility of research operations that regional and district management teams lacked. Yet, care was taken to ensure communication, reporting, and accountability to the organizational hierarchy of the host agency system.

Contradictions Constraining the Institutionalization of Results

Research establishing that implementation can improve health or well-being contributes little to understanding how utilization of such findings can proceed. This contradiction was addressed by the cases, each requiring the pursuit of implementation flexibility in conjunction with fidelity to research lessons. Knowledge was not just created by research; learning was institutionalized. Initiatives evolved as continuous and iterative learning capabilities rather than projects that ended, with their termination also ending knowledge curation (Table 3).

Curation of Knowledge

Mechanisms for scientific dissemination are typically designed to communicate with other researchers rather than to optimize evidence-driven decision making.¹⁰⁰ Efforts to address this problem were pursued in each case (Table 3). In Bangladesh, extension project communication was integrated into MOHSW circulars. In Ghana, international responsibility for the dissemination of science was not only shared with policy makers, but was also generated as a participatory process involving policy makers who had responsibility for using this knowledge for program development. In Tanzania, cell phone technology was used to foster knowledge sharing among frontline workers. In each example, community stakeholders contributed material to a series of documents, news articles, web traffic, site visits, and other forms of awareness building for institutionalizing knowledge emerging from research operations.⁷

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Sustainability

The pursuit of sustainability is an important goal of embedded implementation science. Yet, researching sustainability is typically impossible within the timeframe of research projects. Since failure is more sustainable than success, sustainability per se should be researched in the final phase of embedded implementation research. In each case, phase 3 permitted costing studies, staff responses, and other practical considerations such as implementation milestone clarification.

A process of continuous temporal congruence of research with program planning is critical to ensuring embedded science decision making.⁸⁴ Researchers may be required to adjust plans and activities to be commensurate with counterpart planning and activity cycles. But such an adjustment process can overrun timelines and divert resources from final analyses or dissemination activities. If temporal and task congruence is ignored, official interest in research operations can wane before results are available.

In Bangladesh, this problem was addressed by integrating project information generation into the national planning cycle, so that the Third Population and Health lending agreement was supported by output from project activities. But, in Ghana and Tanzania, temporal integration of research-based learning cycles with the timing of national planning and donor agreement cycles was never possible. In Ghana, the GHS attempted to address this problem by integrating project reporting into routine communication mechanisms. Temporal discordance of mechanisms that provide resources for research represents a challenge for embedded science. Timing of evidence production can be inconsistent with cycles associated with the utilization of results for organizational change.

A Synthesis: Agile Science

In 2001, a computer engineering working group convened a review of innovations that could improve software development compliance with user needs. Together they constructed an “Agile Manifesto” that has had a transformative impact on best practices in software engineering and has influenced innovations in agile science.¹⁰¹ Table 4 illustrates how an agile science perspective can contribute to resolving methodological challenges and contradictions encountered by the case studies. The table aligns the key attributes of embedded implementation science with the 12 principles of agile development to suggest ways in which the

TABLE 4. Implications of Lessons From the Principles of Agile Science and Case Example for an Agile Paradigm for Embedded Implementation Research

Attribute	The Agile Working Group’s 12 Principles of Agile Science ^{101,a}	Agile Embedded Science Implications
Goal	“Our highest priority is to satisfy the customer through early and continuous delivery of valuable software [program improvements].”	Problem identification is a continuous process. Owing to contextual complexity and uncertainty, problem details and solutions cannot always be identified in advance.
Outcome evaluation	“Continuous attention to technical excellence and good design enhances agility.”	<ul style="list-style-type: none"> • Monitor compliance with implementation goals continuously with evaluation criteria that continuously shift, as needed. • Subordinate demographic and health hypothesis testing to implementation process evaluation.
Leadership	“The best architectures, requirements, and designs [research strategies] emerge from self-organizing teams.”	<ul style="list-style-type: none"> • Problem identification and candidate solutions can be defined by anyone in the research or host agency teams. • Peer leadership is encouraged. • Project leadership is systemic and multileveled, and it is the outcome of collaborative investigation of appropriate system development needs.
Ownership	“Business people [Host agency participants] and developers must work together daily throughout the project.”	<ul style="list-style-type: none"> • Establish host agency and research joint ownership. • Participatory decision making throughout the process of organizational development.
Scientific rigor	[Not relevant]	Develop credible results that focus on implementation processes and outcomes.
System relevance	Working software is the primary measure of progress“Deliver working software [or research products] frequently, from a couple of weeks to a couple of months, with a preference to the shorter timescale.”	<p>Achieve concordance of research operations with host agency structure and functions. Assess costs and design research to demonstrate affordability.</p> <ul style="list-style-type: none"> • Open-ended, iterative, and continuous sharing of information and review of progress. • Timing of phases governed by host agency planning and decision processes.
Teamwork	“At regular intervals, the team reflects on how to become more effective, then tunes and adjusts its behavior [or strategies] accordingly.”	<ul style="list-style-type: none"> • At regular intervals, program managers review feedback to implementers and researchers to detect departures from quality or the need to adjust research or implementation strategy. • Roles are integrated for research and host agency counterparts by implementation function.
	“Build projects around motivated individuals. Give them the environment and support they need, and trust them to get the job done.”	<ul style="list-style-type: none"> • Build teams around champions who are successful communicators of innovation. • Foster peer leadership through exchanges.
Simplicity	“Simplicity—the art of maximizing the amount of work not done—is essential.”	<ul style="list-style-type: none"> • Simple solutions are preferred over more complex interventions. • Complexity determined by host agency targeted changes to be investigated.
Replicability	“Welcome changing requirements, even late in development.”	Intervention targets, processes for monitoring, and evaluation procedures can be changed by evolving host agency priorities.
Fidelity	[Not relevant]	Intervention targets, processes for monitoring, and evaluation procedures can be changed by evolving host agency priorities.

Continued

TABLE 4. Continued

Attribute	The Agile Working Group’s 12 Principles of Agile Science ^{101,a}	Agile Embedded Science Implications
Curation of knowledge	“The most efficient and effective method of conveying information to and within a [software] development team is face-to-face conversation.”	<ul style="list-style-type: none"> • Direct communication between host agency and research team is essential. • Integrate the process of generating evidence and outcomes with the process of utilizing evidence for decision making.
Sustainability	“Agile processes promote sustainable [software] development. The sponsors, developers, and users should be able to maintain a constant pace indefinitely.”	<ul style="list-style-type: none"> • Research activities and processes are pursued at a pace that can be maintained indefinitely. • Outcomes are delivered continuously as a regular part of research operations. • Investigation is embedded in change processes that are continuous and never ending.

Adapted from similar tables by Nerur et al.¹⁰⁷ and by Flood et al.¹⁰⁹

Agile and embedded scientists alike share a recognition of the importance of employing phased stages in system development.

contradictions identified in the case studies were or can be resolved.

The agile principles attest to ways of improving embedded science, beyond the strategies that the 3 case studies provide. The overarching goal of applying agile science to health systems development is summarized by Kessler and Glasgow.¹⁰²

Randomized controlled efficacy trials using precisely defined interventions and highly selected participants . . . when applied to the other major issues facing health care today . . . are limited in their ability to address the complex populations and problems we face . . . Pragmatic, transparent, contextual, and multilevel designs that include replication, rapid learning systems and networks, mixed methods, and simulation and economic analyses to produce actionable, generalizable findings that can be implemented in real-world settings is suggested. This shift would include greater focus on the needs of practitioners, patients, payers, and policy-makers and generate more relevant evidence.

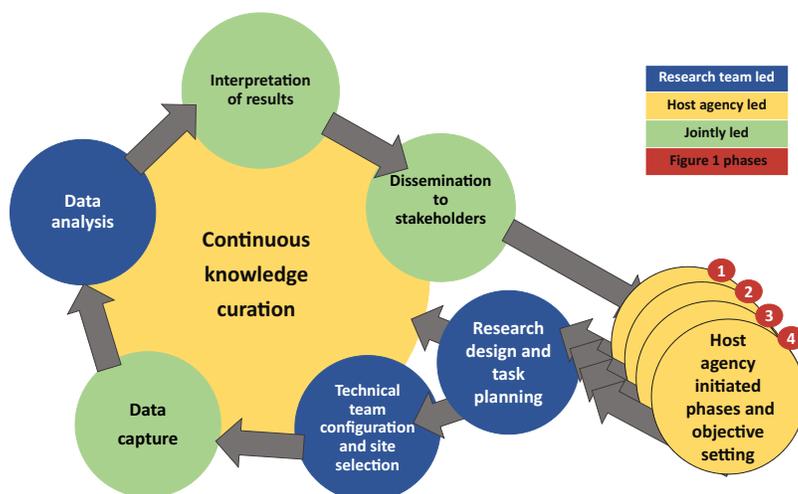
Five themes of agile software engineering could contribute to improving the application of embedded implementation science to health system strengthening.¹⁰³ First, the goal of focusing on implementation objectives would be enhanced by methodologies that include the estimation of scales and composite indices of service readiness, leadership acumen, or other indicators of implementation functionality.¹⁰⁴ Second, agile leadership respects the importance of peer leadership and recognizes that strong leadership is an outcome of the successful efforts of capable and creative subordinates. Third, continuous team evaluation and

review is emphasized in the agile paradigm. Fourth, establishing functioning systems that can be continuously improved is of greater importance than awaiting achievement of optimum endpoints. Fifth, timing is critical. In the linear approach shown in Figure 1, each phase can be needlessly prolonged if protocol completion governs the duration of phases.

The coterminous implications of case examples with the Table 4 tenets of agile science invites consideration of an amalgamation of strategies and implications. An overarching research design could replace the piecemeal approach of the case studies, build upon engineering agility ideas, and obviate the tendency of some implementation researchers to reject embedded science altogether. Agile and embedded scientists alike share a recognition of the importance of employing phased stages in system development.^{105,106}

Figure 2 highlights elements of the process implied by such an amalgamation. It portrays the iterative application of agile principles for inference, decision making, and action. These agile cycles commence with the host agency identifying objectives for change and improvement. Launching deliberations can be informed by previous research activities, tacit system knowledge, the scientific literature, or advisory support from research partners. The agile research team then proceeds to design studies that refine the design of interventions, test the effectiveness of interventions, and clarify requirements of achieving organizational change that address host agency objectives for large-scale implementation. Dissemination is a

FIGURE 2. The Agile Science Process of Health Systems Strengthening



continuous component of the process, with options for taking many alternative mechanisms based on the needs of the host agency.

Figure 2 can serve as a supplement to the linear phased processes shown in Figure 1. Each phase can have multiple iterations of discovery, investigation, and results generation until the objectives of the phase are satisfied. As in Figure 1, formative research is associated with phase 1. Phase 2 corresponds to trial, experimentation, or quantitative appraisal of prospects that formative knowledge gained in phase 1 could actually work, as intended. Phases 3 and 4 have corresponding agile cycles, with knowledge curation as the outcome of each recurrent cycle. But irrespective of phases, the Figure 2 cycle applies within each phase. This iteration, with larger phases is analogous to the Agile Unified paradigm, a software development process that has phases of product conceptualization, elaboration and trial, refinement, and deployment.¹⁰⁷

Taken as a system of work, the Figure 2 cycle of ideational development, evaluation, and change could form the basis for embedded implementation science.^{26,106–110} Doing so would optimize the pursuit of embedded science goals while sustaining the overarching need for rigorous science.

The centrality of knowledge curation in Figure 2 portrays the institutionalization of system learning. In the agile paradigm, the combination of documenting learning, responding to learning, and disseminating learning to relevant stakeholders converts knowledge management processes into

interactive and institutionalized system learning. If all stakeholders are aware of curated knowledge and informed by each round of problem solving, then knowledge curation is possible. By maintaining agile team field investigators who have a mandate to engage in regular dialogues with host agency counterparts, each cycle diagnoses problems, tests solutions, and advises the agile team leaders on appropriate responses to emerging lessons. Whether the process represents an agile acquisition of discrete decision-making guidance or a multi-year process of institutional reform is determined by the user in concert with the agile research generated evidence.

As Table 4 suggests, agile investigation and action can serve multiple purposes that include the introduction of new organizational strategies or processes that are focused on organizational reform. Agile embedded implementation science is not a project; rather, it is a process of evidence-driven organization development. By sustaining the agile process, knowledge curation and continuous action are recurrent, securing systemic organizational learning about implementation challenges and successes.

Agile embedded implementation science is not a project; rather, it is a process of evidence-driven organization development.

CONCLUSION

The embedded science that guided community-based primary health care development in Bangladesh, Ghana, and Tanzania attests to the value of subordinating the generation of research results to researching the process of changing the

way that programs work. Doing so requires a system of action and decision making that integrates the tools of science into the process of managerial planning and decision making.^{14,15,100,105} Although the pursuit of this goal will encounter intrinsic contradictions, strategies that case examples pursued piecemeal could be assembled into a combined approach that would strengthen the application of embedded science. Agile science has functioned well to that end for organizations engaged in developing software, medical technologies, and engineering innovations. As our case examples illustrate, the elements of agile science are also feasible in settings that are not yet equipped with advanced technologies. Assembling these elements as an agile extension of embedded research could sustain scientific rigor while optimizing the prospects for results to be put to use.

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REFERENCES

1. Sanders D, Haines A. Implementation research is needed to achieve international health goals. *PLoS Med*. 2006;3(6):e186. [CrossRef](#). [Medline](#)
2. Peters DH, El-Saharty S, Siadat B, Janovsky K, Vujcic M, von Haeseler A. *Improving Health Service Delivery in Developing Countries: From Evidence to Action*. The World Bank; 2009.

- Accessed January 9, 2021. <https://openknowledge.worldbank.org/handle/10986/12335>
3. Alonge O, Rodriguez DC, Brandes N, Geng E, Reveiz L, Peters DH. How is implementation research applied to advance health in low-income and middle-income countries? *BMJ Glob Health*. 2019;4(2):e001257. [CrossRef](#). [Medline](#)
 4. Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Republished research: implementation research: what it is and how to do it. *Br J Sports Med*. 2014;48(8):731–736. [CrossRef](#). [Medline](#)
 5. Lewin K. Action research and minority problems. *J Soc Issues*. 1946;2(4):34–46. [CrossRef](#)
 6. Peters M, Robinson V. The origins and status of action research. *J Appl Behav Sci*. 1984;20(2):113–124. [CrossRef](#)
 7. Awoonor-Williams JK, Phillips JF, Bawah AA. Catalysing the scale-up of community-based primary health care in a rural impoverished region of northern Ghana. *Int J Health Plann Manage*. 2015;31(4):e273–e289. [CrossRef](#). [Medline](#)
 8. Gouldner AW. Explorations in applied social science. *Soc Probl*. 1956;3(3):169–181. [CrossRef](#)
 9. Brandeau ML, Sainfort F, Pierskalla WP. *Operations Research and Health Care: A Handbook of Methods and Applications*. Kluwer Academic Publishers; 2004.
 10. French W, Bell C. *Organization Development: Behavioral Science Interventions for Organization Improvement*. Prentice Hall; 1999.
 11. Golden-Biddle K, Reay T, Petz S, et al. Toward a communicative perspective of collaborating in research: the case of the researcher-decision-maker partnership. *J Health Serv Res Policy*. 2003;8(2_suppl):20–25. [CrossRef](#). [Medline](#)
 12. Boog BWM. The emancipatory character of action research, its history and the present state of the art. *J Community Appl Soc Psychol*. 2003;13(6):426–438. [CrossRef](#)
 13. Kemmis S, McTaggart R. Participatory action research. In: Denzin NK, Lincoln YS, eds. *The Handbook of Qualitative Research*. 2nd ed. Sage Publications; 2000:567–605.
 14. Ghaffar A, Tran NT, Reddy KS, et al. Changing mindsets in health policy and systems research. *Lancet*. 2013;381(9865):436–437. [CrossRef](#). [Medline](#)
 15. Koon AD, Nambiar D, Rao KD. *Embedding of Research Into Decision-Making Processes*. Alliance for Health Policy and Systems Research; 2012. Accessed January 14, 2021. https://www.who.int/alliance-hpsr/alliancehpsr_backgroundpaperembedding_research.pdf
 16. Ghaffar A, Langlois EV, Rasanathan K, Peterson S, Adedokun L, Tran NT. Strengthening health systems through embedded research. *Bull World Health Org*. 2017;95:87. [CrossRef](#). [Medline](#)
 17. Rasanathan K, Tran N, Johnson HL, Hafeez A, Peterson S, Ghaffar A. Realizing the potential of embedded implementation research: lessons from Pakistan. *J Glob Health*. 2020;10(2):020104. [CrossRef](#). [Medline](#)
 18. Johnson RB. Toward a theoretical model of evaluation utilization. *Eval Program Plann*. 1998;21(1):93–110. [CrossRef](#)
 19. World Health Organization (WHO). *Changing Mindsets: Strategy on Health Policy and Systems Research*. WHO; 2012. Accessed January 9, 2021. https://www.who.int/alliance-hpsr/alliancehpsr_changingmindsets_strategyhpsr.pdf
 20. Porras JI, Silvers RC. Organization development and transformation. *Annu Rev Psychol*. 1991;42(1):51–78. [CrossRef](#). [Medline](#)
 21. Varallyay NI, Bennett SC, Kennedy C, Ghaffar A, Peters DH. How does embedded implementation research work? Examining core features through qualitative case studies in Latin America and the Caribbean. *Health Policy Plan*. 2020;35(2)(Suppl 2):ii98–ii111. [CrossRef](#). [Medline](#)

22. Albert MA, Fretheim A, Maiga D. Factors influencing the utilization of research findings by health policy-makers in a developing country: the selection of Mali's essential medicines. *Health Res Policy Syst.* 2007;5(1):2. [CrossRef](#). [Medline](#)
23. Jung C, Lippitt R. The study of change as a concept—in research utilization. *Theory Pract.* 1966;5(1):25–29. [CrossRef](#)
24. Nutley S, Walter I, Davies HTO. From knowing to doing: a framework for understanding the evidence-into-practice agenda. *Evaluation.* 2003;9(2):125–148. [CrossRef](#)
25. Hanney SR, Gonzalez-Block Miguel A, Buxton MJ, Kogan M. The utilisation of health research in policy-making: concepts, examples and method of assessment. *Health Res Policy Syst.* 2003;1(1):2. [CrossRef](#). [Medline](#)
26. Nelson LA, Threatt AL, Martinez W, Acuff SW, Mayberry LS. Agile science: what and how in digital diabetes research. In: *Diabetes Digital Health.* Elsevier; 2020:51–63. [CrossRef](#)
27. Aziz KMS, Mosley WH. The history, methodology, and main findings of the Matlab Project in Bangladesh. In: Das Gupta M, Aaby P, Garenne M, Pison G, eds. *Prospective Community Studies in Developing Countries.* Clarendon Press; 1997:28–53.
28. D'Souza S, Bhuiya A, Zimicki S, Sheikh K. *Mortality and Morbidity: The Matlab Experience.* International Development Research Centre; 1988. Accessed January 9, 2021. <https://idl-bnc-idrc.dspacedirect.org/bitstream/handle/10625/8318/IDL-8318.pdf>
29. Menken J, Phillips JF. Population change in a rural area of Bangladesh, 1967–87. *Ann Am Acad Pol Soc Sci.* 1990;510(1):87–101. [CrossRef](#)
30. Demeny P. Observations on population policy and population program in Bangladesh. *Popul Dev Rev.* 1975;1(2):307–321. [CrossRef](#)
31. Ravenholt RT. The A.I.D. Population and Family Planning Program—goals, scope, and progress. *Demography.* 1968;5(2):561–573. [CrossRef](#)
32. Huber DH, Khan AR. Contraceptive distribution in Bangladesh villages: the initial impact. *Stud Fam Plann.* 1979;10(8/9):246–253. [CrossRef](#). [Medline](#)
33. Stinson WS, Phillips JF, Rahman M, Chakraborty J. The demographic impact of the contraceptive distribution project in Matlab, Bangladesh. *Stud Fam Plann.* 1982;13(5):141–148. [CrossRef](#). [Medline](#)
34. Bhatia S, Mosley WH, Faruque ASG, Chakraborty J. The Matlab family planning-health services project. *Stud Fam Plann.* 1980;11(6):202–212. [CrossRef](#). [Medline](#)
35. LeGrand TK, Phillips JF. The effect of fertility reductions on infant and child mortality: evidence from Matlab in rural Bangladesh. *Popul Stud.* 1996;50(1):51–68. [CrossRef](#)
36. Phillips JF, Simmons R, Koenig MA, Chakraborty J. Determinants of reproductive change in a traditional society: evidence from Matlab, Bangladesh. *Stud Fam Plann.* 1988;19(6):313–334. [CrossRef](#). [Medline](#)
37. Phillips JF, Simmons R, Simmons GB, Yunus M. Transferring health and family planning service innovations to the public sector: an experiment in organization development in Bangladesh. *Stud Fam Plann.* 1984;15(2):62–73. [CrossRef](#). [Medline](#)
38. Phillips JF. *The World Bank and the Bangladesh Population Program.* Operations Evaluation Division, International Bank for Reconstruction and Development/The World Bank; 1991.
39. Haaga JG, Maru RM. The effect of operations research on program changes in Bangladesh. *Stud Fam Plann.* 1996;27(2):76–87. [CrossRef](#). [Medline](#)
40. Simmons R, Phillips JF, Rahman M. Strengthening government health and family planning programs: findings from an action research project in rural Bangladesh. *Stud Fam Plann.* 1984;15(5):212–221. [CrossRef](#). [Medline](#)
41. Phillips JF, Simmons R, Chakraborty J, Chowdhury AI. Integrating health services into an MCH-FP program: lessons from Matlab, Bangladesh. *Stud Fam Plann.* 1984;15(4):153–161. [CrossRef](#). [Medline](#)
42. Simmons R, Baeqe L, Koenig MA, Phillips JF. Beyond supply: the importance of female family planning workers in rural Bangladesh. *Stud Fam Plann.* 1988;19(1):29–38. [CrossRef](#). [Medline](#)
43. Cleland J, Phillips JF, Amin S, Kamal GM. *The Determinants of Reproductive Change in Bangladesh: Success in a Challenging Environment.* The International Bank for Reconstruction and Development/The World Bank; 1994. Accessed January 9, 2021. <http://documents1.worldbank.org/curated/en/991321468768584526/pdf/multi0page.pdf>
44. Simmons R, Shiffman J. Scaling-up reproductive health service innovations: a conceptual framework. In: Simmons R, Fajans P, Ghiron L, eds. *Scaling Up Health Service Delivery: From Pilot Innovations to Policies and Programmes.* World Health Organization; 2007:1–30. Accessed January 14, 2021. https://www.who.int/immunization/hpv/deliver/scalingup_health_service_delivery_who_2007.pdf
45. Fajans P, Simmons R, Ghiron L. Helping public sector health systems innovate: the strategic approach to strengthening reproductive health policies and programs. *Am J Public Health.* 2006;96(3):435–440. [CrossRef](#). [Medline](#)
46. Nyongator F, Kutzin J. Health for some? The effects of user fees in the Volta Region of Ghana. *Health Policy Plan.* 1999;14(4):329–341. [CrossRef](#). [Medline](#)
47. Binka FN, Nazzar A, Phillips JF. The Navrongo Community Health and Family Planning Project. *Stud Fam Plann.* 1995;26(3):121–139. [CrossRef](#). [Medline](#)
48. Armar-Klemesu M, Rikimaru T, Kennedy DO, Harrison E, Kido Y, Takyi EEK. Household food security, food consumption patterns, and the quality of children's diet in a rural northern Ghana community. *Food Nutr Bull.* 1995;16(1):1–7. [CrossRef](#)
49. Abdulai A, Delgado CL. Determinants of nonfarm earnings of farm-based husbands and wives in northern Ghana. *Am J Agric Econ.* 1999;81(1):117–130. [CrossRef](#)
50. Ngom P, Debpuur C, Akweongo P, Adongo P, Binka FN. Gate-keeping and women's health seeking behaviour in Navrongo, northern Ghana. *Afr J Reprod Health.* 2003;7(1):17–26. [CrossRef](#). [Medline](#)
51. Binka FN, Ngom P, Phillips JF, Adazu K, Macleod BB. Assessing population dynamics in a rural African society: the Navrongo Demographic Surveillance System. *J Biosoc Sci.* 1999;31(3):375–391. [CrossRef](#)
52. Ghana Health Service. *The Community-Based Health Planning and Services (CHPS) Initiative.* Ghana Health Service; 1999.
53. Awoonor-Williams JK, Phillips JF, Bawah AA. Scaling down to scale-up: Ghana's strategy for achieving health for all at last. *J Glob Health Sci.* 2019;1(1):e9. [CrossRef](#)
54. Binka FN, Aikins M, Sackey SO, et al. *In-Depth Review of the Community-Based Health Planning Services (CHPS) Programme: A Report of the Annual Health Sector Review, 2009.* School of Public Health, University of Ghana; 2009.
55. Nyongator FK, Awoonor-Williams JK, Phillips JF, Jones TC, Miller RA. The Ghana Community-based Health Planning and Services Initiative for scaling up service delivery innovation. *Health Policy Plan.* 2005;20(1):25–34. [CrossRef](#). [Medline](#)
56. Awoonor-Williams JK, Bawah AA, Nyongator FK, et al. The Ghana Essential Health Interventions Program: a plausibility trial of the impact of health systems strengthening on maternal & child survival. *BMC Health Serv Res.* 2013;13(S2)(Suppl 2):S3. [CrossRef](#). [Medline](#)
57. Patel S, Koku Awoonor-Williams J, Asuru R, et al. Benefits and limitations of a community-engaged emergency referral system in a

- remote, impoverished setting of northern Ghana. *Glob Health Sci Pract.* 2016;4(4):552–567. [CrossRef](#). [Medline](#)
58. Bawah AA, Awoonor-Williams JK, Asuming PO, et al. The child survival impact of the Ghana Essential Health Interventions Program: a regional health systems strengthening initiative in northern Ghana. *PLoS One.* 2019;14(6):e0218025. [CrossRef](#). [Medline](#)
 59. Phillips JF, Jackson EF, Bawah AA, Asuming PO, Awoonor-Williams JK. The fertility impact of achieving universal health coverage in an impoverished rural region of Northern Ghana. *Gates Open Research.* 2019;3:1537. [CrossRef](#)
 60. Phillips JF, Awoonor-Williams JK, Bawah AA, et al. What do you do with success? The science of scaling up a health systems strengthening intervention in Ghana. *BMC Health Serv Res.* 2018;18(1):484. [CrossRef](#). [Medline](#)
 61. United Republic of Tanzania. *The Primary Health Care Improvement Programme (MMAAM).* United Republic of Tanzania; 2007.
 62. El Arifeen S, Christou A, Reichenbach L, et al. Community-based approaches and partnerships: innovations in health-service delivery in Bangladesh. *Lancet.* 2013;382(9909):2012–2026. [CrossRef](#). [Medline](#)
 63. Black RE, Taylor CE, Arole S, et al. Comprehensive review of the evidence regarding the effectiveness of community-based primary health care in improving maternal, neonatal and child health: 8. summary and recommendations of the Expert Panel. *J Glob Health.* 2017;7(1):010908. [CrossRef](#). [Medline](#)
 64. Freeman P, Perry HB, Gupta SK, Rassekh B. Accelerating progress in achieving the millennium development goal for children through community-based approaches. *Glob Public Health.* 2012;7(4):400–419. [CrossRef](#). [Medline](#)
 65. Perry HB, Dhillon RS, Liu A, et al. Community health worker programmes after the 2013–2016 Ebola outbreak. *Bull World Health Organ.* 2016;94(7):551–553. [CrossRef](#). [Medline](#)
 66. Singh P, Sachs JD. 1 million community health workers in sub-Saharan Africa by 2015. *Lancet.* 2013;382(9889):363–365. [CrossRef](#). [Medline](#)
 67. Baatiema L, Sumah AM, Tang PN, Ganle JK. Community health workers in Ghana: the need for greater policy attention. *BMJ Glob Health.* 2016;1(4):e000141. [CrossRef](#). [Medline](#)
 68. Brownstein JN, Bone LR, Dennison CR, Hill MN, Kim MT, Levine DM. Community health workers as interventionists in the prevention and control of heart disease and stroke. *Am J Prev Med.* 2005;29(5)(Suppl 1):128–133. [CrossRef](#). [Medline](#)
 69. Masanja H, de Savigny D, Smithson P, et al. Child survival gains in Tanzania: analysis of data from demographic and health surveys. *Lancet.* 2008;371(9620):1276–1283. [CrossRef](#). [Medline](#)
 70. Waiswa P, Peterson SS, Namazzi G, et al. The Uganda Newborn Study (UNEST): an effectiveness study on improving newborn health and survival in rural Uganda through a community-based intervention linked to health facilities—study protocol for a cluster randomized controlled trial. *Trials.* 2012;13(1):213. [CrossRef](#). [Medline](#)
 71. Horwood C, Butler L, Barker P, et al. A continuous quality improvement intervention to improve the effectiveness of community health workers providing care to mothers and children: a cluster randomised controlled trial in South Africa. *Hum Resour Health.* 2017;15(1):39. [CrossRef](#). [Medline](#)
 72. Geubbels E, Amri S, Levira F, Schellenberg J, Masanja H, Nathan R. Health & Demographic Surveillance System Profile: the Ifakara Rural and Urban Health and Demographic Surveillance System (Ifakara HDSS). *Int J Epidemiol.* 2015;44(3):848–861. [CrossRef](#). [Medline](#)
 73. Ramsey K, Hingora A, Kante M, et al. The Tanzania Connect Project: a cluster-randomized trial of the child survival impact of adding paid community health workers to an existing facility-focused health system. *BMC Health Serv Res.* 2013;13(Suppl 2):S6. [CrossRef](#)
 74. Steyn PS, Cordero JP, Gichangi P, et al. Participatory approaches involving community and healthcare providers in family planning/contraceptive information and service provision: a scoping review. *Reprod Health.* 2016;13(1):88. [CrossRef](#). [Medline](#)
 75. Kanté AM, Nathan R, Jackson EF, et al. Trends in socioeconomic disparities in a rapid under-five mortality transition: a longitudinal study in the United Republic of Tanzania. *Bull World Health Organ.* 2016;94(4):258–266A. [CrossRef](#). [Medline](#)
 76. Kanté AM, Nathan R, HELLERINGER S, et al. The contribution of reduction in malaria as a cause of rapid decline of under-five mortality: evidence from the Rufiji Health and Demographic Surveillance System (HDSS) in rural Tanzania. *Malar J.* 2014;13(1):180. [CrossRef](#). [Medline](#)
 77. Kanté AM, Exavery A, Jackson EF, et al. The impact of a randomized cluster trial of paid community health workers deployment on child survival in rural Tanzania. *BMC Health Serv Res.* 2019;19(19):492. [CrossRef](#). [Medline](#)
 78. Nyonator FK, Akosa AB, Awoonor-Williams JK, Phillips JF, Jones TC. Scaling up experimental project success with the Community-based Health Planning and Services Initiative in Ghana. In: Simmons R, Fajans P, Ghiron L, eds. *Scaling Up Health Service Delivery: From Pilot Innovations to Policies and Programmes.* World Health Organization; 2008:89–112. Accessed January 14, 2021. https://www.who.int/immunization/hpv/deliver/scalingup_health_service_delivery_who_2007.pdf
 79. Awoonor-Williams JK, Sory EK, Nyonator FK, Phillips JF, Wang C, Schmitt ML. Lessons learned from scaling up a community-based health program in the Upper East Region of northern Ghana. *Glob Health Sci Pract.* 2013;1(1):117–133. [CrossRef](#). [Medline](#)
 80. Awoonor-Williams JK, Vaughan-Smith MN, Phillips JF, Williams JKA, Vaughan-Smith MN, Phillips JF. Scaling up health system innovations at the community level: a case-study of the Ghana experience. In: Malarcher S, ed. *Social Determinants of Sexual and Reproductive Health: Informing Future Generations.* The World Health Organization; 2010:51–70. Accessed January 14, 2021. https://apps.who.int/iris/bitstream/handle/10665/44344/9789241599528_eng.pdf
 81. Campbell B. Applying knowledge to generate action: a community-based knowledge translation framework. *J Contin Educ Health Prof.* 2010;30(1):65–71. [CrossRef](#). [Medline](#)
 82. Goldberg J, Bryant M. Country ownership and capacity building: the next buzzwords in health systems strengthening or a truly new approach to development? *BMC Public Health.* 2012;12(1):531. [CrossRef](#). [Medline](#)
 83. Remme JHF, Adam T, Becerra-Posada F, et al. Defining research to improve health systems. *PLoS Med.* 2010;7(11):e1001000. [CrossRef](#). [Medline](#)
 84. Winther-Schmidt E. Projects and programmes: a development practitioner's critique of the transition to a sector-wide approach to educational development in Nepal. *Globalisation, Societies Educ.* 2011;9(1):51–65. [CrossRef](#)
 85. Victora CG, Habicht JP, Bryce J. Evidence-based public health: moving beyond randomized trials. *Am J Public Health* 2004; 94(3):400–405. [CrossRef](#). [Medline](#)
 86. Crewe E, Young J. *Bridging Research and Policy: Context, Evidence and Links.* Overseas Development Institute; 2002. Accessed January 14, 2021. <https://www.odi.org/sites/odi.org.uk/files/odi-assets/publications-opinion-files/184.pdf>
 87. Carr ER. The millennium village project and African development: problems and potentials. *Prog Dev Stud.* 2008;8(4):333–344. [CrossRef](#)

88. Phillips JF, Sheff M, Boyer CB. The astronomy of Africa's health systems literature during the MDG era: where are the systems clusters? *Glob Health Sci Pract*. 2015;3(3):482–502. [CrossRef](#). [Medline](#)
89. World Health Organization (WHO). *Everybody's Business-Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action*. WHO; 2007. Accessed January 9, 2021. https://www.who.int/healthsystems/strategy/everybodys_business.pdf
90. DeSavigny D, Adam T. *Systems Thinking for Health Systems Strengthening*. Alliance for Health Policy and Systems Research, World Health Organization; 2009. Accessed January 14, 2021. https://apps.who.int/iris/bitstream/handle/10665/44204/9789241563895_eng.pdf
91. DeSavigny D, Kasale H, Mbuya C, Reid G. *Fixing Health Systems*. 2nd ed. International Development Research Centre; 2008. Accessed January 9, 2021. <https://www.idrc.ca/sites/default/files/openebooks/411-6/index.html>
92. Bloom G. History, complexity and health systems research. *Soc Sci Med*. 2014;117:160–161. [CrossRef](#). [Medline](#)
93. Attanayake N, Fauveau V, Chakraborty J. Cost-effectiveness of the Matlab MCH-FP Project in Bangladesh. *Health Policy Plan*. 1993;8(4):327–338. [CrossRef](#)
94. Kanmiki EW, Akazili J, Bawah AA, et al. Cost of implementing a community-based primary health care strengthening program: the case of the Ghana Essential Health Interventions Program in northern Ghana. *PLoS One*. 2019;14(2):e0211956. [CrossRef](#). [Medline](#)
95. Tani K, Exavery A, Baynes CD, et al. Unit cost analysis of training and deploying paid community health workers in three rural districts of Tanzania. *BMC Health Serv Res*. 2016;16(1):237. [CrossRef](#). [Medline](#)
96. Krumholz AR, Stone AE, Dalaba MA, Phillips JF, Adongo PB. Factors facilitating and constraining the scaling up of an evidence-based strategy of community-based primary care: management perspectives from northern Ghana. *Glob Public Health*. 2015;10(3):366–378. [CrossRef](#). [Medline](#)
97. Baynes C, Semu H, Baraka J, et al. An exploration of the feasibility, acceptability, and effectiveness of professional, multitasked community health workers in Tanzania. *Glob Public Health*. 2017;12(8):1018–1032. [CrossRef](#). [Medline](#)
98. Plsek PE, Greenhalgh T. Complexity science: the challenge of complexity in health care. *BMJ*. 2001;323(7313):625–628. [CrossRef](#). [Medline](#)
99. Ghiron L, Shilling L, Kabiswa C, et al. Beginning with sustainable scale up in mind: initial results from a population, health and environment project in East Africa. *Reprod Health Matters*. 2014;22(43):84–92. [CrossRef](#). [Medline](#)
100. Curran JA, Grimshaw JM, Hayden JA, Campbell B. Knowledge translation research: the science of moving research into policy and practice. *J Contin Educ Health Prof*. 2011;31(3):174–180. [CrossRef](#). [Medline](#)
101. Beck K, Beedle M, van Bennekum A, et al. Twelve Principles of Agile Software. Manifesto for Agile Software Development. 2001. Accessed January 9, 2021. <http://agilemanifesto.org/>
102. Kessler R, Glasgow RE. A proposal to speed translation of health-care research into practice: dramatic change is needed. *Am J Prev Med*. 2011;40(6):637–644. [CrossRef](#). [Medline](#)
103. Augustine S, Payne B, Sencindiver F, Woodcock S. Agile project management: steering from the edges. *Assoc Comput Mach*. 2005;48(12):85–89. Accessed January 9, 2021. [CrossRef](#)
104. Sherr K, Fernandes Q, Kanté AM, Bawah A, Condo J, Mutale W; AHI PHIT Partnership Collaborative. Measuring health systems strength and its impact: experiences from the African Health Initiative. *BMC Health Serv Res*. 2017;17(S3)[Suppl 3]:827. [CrossRef](#). [Medline](#)
105. Varallyay NI, Langlois EV, Tran N, Elias V, Reveiz L. Health system decision-makers at the helm of implementation research: development of a framework to evaluate the processes and effectiveness of embedded approaches. *Health Res Policy Syst*. 2020;18(1):64. [CrossRef](#). [Medline](#)
106. Hidalgo ES. Management of a multidisciplinary research project: a case study on adopting agile methods. *J Res Pract*. 2018;14(1). Accessed January 25, 2021. <http://jrp.icaap.org/index.php/jrp/article/view/588/489>
107. Nerur S, Mahapatra R, Mangalaraj G. Challenges of migrating to agile methodologies. *Comm ACM*. 2005;48(5):72–78. [CrossRef](#)
108. Keen P, Tan M. Knowledge fusion: a framework for extending the rigor and relevance of knowledge management. *Int J Knowl Manage*. 2007;3(4):1–17. [CrossRef](#)
109. Flood D, Chary A, Austad K, et al. Insights into global health practice from the agile software development movement. *Glob Health Action*. 2016;9(1):29836. [CrossRef](#). [Medline](#)
110. Hekler EB, Klasnja P, Riley WT, et al. Agile science: creating useful products for behavior change in the real world. *Transl Behav Med*. 2016;6(2):317–328. [CrossRef](#). [Medline](#)

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Levels, Trends, and Inequalities in Using Institutional Delivery Services in Low- and Middle-Income Countries: A Stratified Analysis by Facility Type

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Key Findings

- Progress toward improving the utilization of institutional delivery services was not uniform across low- and middle-income countries (LMICs) and across subpopulations within LMICs irrespective of public and private health facilities.
- Wealth, place of residence, and education-based inequalities in the utilization of institutional delivery services are widening in many LMICs, which warrants the attention of policy makers for further investments and policy reviews.

Key Implications

- Program managers and policy makers should give special priority to people who are poorest, live in rural areas, and have low education when designing appropriate interventions for increasing institutional delivery service coverage, irrespective of public and private facilities.
- Appropriate and tailored interventions covering the disadvantaged countries and marginalized populations within countries may help countries to achieve the global target of “leaving no one behind” for the utilization of institutional delivery services by 2030.

ABSTRACT

Introduction: To ensure equitable and accessible services and improved utilization of institutional delivery it is important to identify what progress has been achieved, whether there are vulnerable and disadvantaged groups that need specific attention and what are the key factors affecting the utilization of institutional delivery services. In this study, we examined levels, trends, and inequalities in the utilization of institutional delivery services in low- and middle-income countries.

Methods: We used nationally representative cross-sectional data from Demographic and Health Surveys (DHS) conducted during 1990–2018. Bayesian linear regression analysis was performed.

Results: Among 74 countries, the utilization of institutional delivery services ranged from 23.7% in Chad to 100% in Ukraine and Armenia (with >90% in 19 countries and <50% in 13 countries) during the latest DHS rounds. Trend analysis in 63 countries with at least 2 surveys showed that the utilization of institutional delivery services increased in 60 countries during 1990–2018, with the highest increase being in Cambodia (18.3%). During this period, the utilization of institutional delivery services increased in 90.3% of countries among the richest, 95.2% of countries in urban, and 84.1% of countries among secondary+ educated women. The utilization of institutional delivery services was higher among wealthiest, urban, and secondary+ educated women compared to their counterparts. Greater utilization of private facilities for delivery was observed in women from the highest income group and urban communities, whereas highest utilization of public facilities was observed for women from the lowest income group and rural communities.

Conclusions: The utilization of institutional delivery services varied substantially between and within countries over time. Significant disparities in service utilization identified in this study highlight the need for tailored support for women from disadvantaged and vulnerable groups.

INTRODUCTION

Institutional delivery is a necessary intervention to reduce delivery-related avoidable maternal and infant mortality.¹ Between 1990 and 2015, more than 10 million women died globally due to pregnancy and childbirth-related complications.² Globally, 2.6 million newborns died in 2016, approximately 7,000 per day,³ and almost all (99%) of these potentially preventable deaths occurred in low- and middle-income countries

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(LMICs).⁴ Pregnancy-related complications that lead to maternal mortality may occur during or shortly after childbirth.⁵ In LMICs, direct obstetric complications during childbirth were responsible for 70% of maternal deaths.⁶ Timely access to facility-based births save the lives of many mothers and newborns.⁷ In high-income countries, maternal mortality can be further reduced with increased rates of institutional delivery.⁸ In many LMICs, due to the geographical barriers in accessing services and the presence of cultural issues, women are accustomed to delivering babies at home, which leads to low utilization of institutional delivery services. To ensure equitable and accessible institutional delivery services, identifying vulnerable groups and populations within countries is crucial so that customized interventions can be developed and delivered.

The United Nations' Millennium Development Goals (MDGs) had a priority to improve maternal health and had set a target of reducing maternal mortality by three-quarters between 1990 and 2015 (MDG 5, target 5.A).⁹ Several initiatives have been introduced to achieve this target, including increased utilization of institutional delivery services.⁴ Earlier evidence showed improvements in the coverage of institutional delivery services in LMICs during the MDG era.¹⁰ During the same period, the world made remarkable progress in reducing maternal mortality by 43.9% from 385 deaths per 100,000 live births in 1990 to 216 in 2015.² However, this progress was uneven across countries and different populations within countries, and significant progress gaps consequently exist between populations.

To reduce such gaps, the global agenda shifted from MDGs to Sustainable Development Goals (SDGs). The highest priority of the SDG targets (target 3.8) is achieving universal health coverage (UHC), which means "all individuals and communities receive the health services they need without suffering financial hardship."¹¹ Given the role of financial hardship in service utilization, it is also important to know which facility services (public or private) are increasing in LMICs and whether all people, irrespective of sociodemographic conditions, have equal access to these facilities. At the global level, evidence suggests an increasing trend in the utilization of institutional delivery services in sub-Saharan Africa,^{12,13} notably higher utilization by women from high-income groups residing in urban areas,¹⁴ as well as increasing use of private facilities for institutional delivery.¹⁵

However, comprehensive information is lacking on how socioeconomic and demographic disparities

are associated with access to institutional delivery services, which limits the design of effective interventions/strategies required for equitable services. In addition, the extent to which these disparities are prevalent in public and private facilities remains unclear. Trend analysis at national and subpopulation levels helps policy makers and program managers assess overall progress, quantify gaps, and identify priority groups to guide strategies/interventions, further accelerating progress toward saving millions of lives of mothers and newborns. Therefore, this study aimed to examine the levels and trends in the utilization of institutional delivery services between LMICs and across subpopulations within LMICs.

METHODS

Data

This study used secondary data from large-scale, population-based, nationally representative repeated cross-sectional surveys conducted between 1990 and 2018 under the Demographic and Health Surveys (DHS) program.¹⁶ We extracted data from 74 LMICs across 5 DHS regions: sub-Saharan Africa (37 countries), South and Southeast Asia (12 countries), Central Asia (4 countries), North Africa-West Asia-Europe (10 countries), and Latin America and Caribbean (LAC; 11 countries). A detailed description of the surveyed country, survey year, and sample size is presented in the [Supplement](#) (Table S1).

Outcome Variable

The outcome variable in our study was institutional delivery. We used DHS standard recode files (KR files) to construct the variable for institutional delivery based on the responses of participants. The DHS provided information for institutional delivery for children born in the past 5 years in most of the countries. However, for some countries such as Bangladesh, the information on institutional delivery services was only available for children born in the past 3 years. Therefore, to allow cross-country comparison, we defined institutional delivery services as the proportion of live births delivered in health facilities in the 3 years preceding the survey. We compared deliveries conducted in different types of health facilities (public versus private), and we particularly evaluated the proportion of deliveries that occurred in a public facility and those in a private facility. All calculations were conducted for live births.

Statistical Analyses

We estimated the weighted prevalence of institutional delivery services as proportions from the original survey data for all survey years of each

A lack of information on how socioeconomic and demographic disparities affect access to institutional delivery services limits the design of effective interventions and strategies.

study country. The rates of delivery in public and private facilities were estimated using the same method. However, we examined the geographical variation in the utilization of institutional delivery services during the latest DHS round. We calculated the variation in the utilization of institutional delivery services across subgroups in terms of place of residence, education of women, age of women, and wealth quintiles that the DHS constructed based on household assets by principal component analysis.¹⁷

For this study, we dichotomized education as below secondary (no or primary education) and secondary+ (secondary or higher) education. Similarly, we categorized age as 15–19 years (adolescents) and 20–49 years (adults). Also, we used place of residence (categorized as rural and urban) and wealth quintiles (categorized as poorest [first quintile], poorer, middle, richer, and richest [fifth quintile]) that the DHS provided with the survey data. Notably, we restricted our analysis to the country level but not at a regional level for 2 reasons. First, some regions (e.g., Central Asia) had data for a limited number of countries and heterogeneity between survey years (arbitrary). Second, we were interested in assessing progress across individual countries so that country-level programs and policies could be implemented.

To examine trends, a Bayesian linear regression model that used a Markov Chain Monte Carlo algorithm of multiple imputations for missing data was applied to estimate the institutional delivery rates and trends from 1990 to 2018 (Supplement). We reported 95% credible intervals (CrI) drawn from Bayesian analysis along with these estimates. We used the same technique to examine trends in the utilization of institutional delivery services across various sociodemographic groups to explore the changes in the utilization of institutional delivery services across sociodemographic subpopulations. We also validated our estimates drawn from regression models with those drawn from the original microdata (Supplement, Table S2).

To measure inequalities in the utilization of institutional delivery services, we applied both absolute and relative measure of inequalities. We estimated absolute inequality by subtracting the rate of the institutional delivery services in the poorest quintile from the rate of the institutional delivery services in the richest quintile, of rural from urban, of below secondary education from secondary+ education, and of adolescent mothers 15–19 years of age from adult mothers 20–49 years of age. We calculated rate ratio by dividing the rate of the institutional delivery services in the richest

quintile by the rate of the institutional delivery services in the poorest quintile, and similarly the rate in urban by rural, in secondary+ education by below secondary education, and in adult mothers by adolescent mothers. To quantify the changes in inequalities over time, we measured changes in absolute and relative inequalities in the utilization of institutional delivery services from the earliest and latest rounds of DHS for countries that had at least 2 survey data points.

We used Stata (version 15.1) and R (version 3.5) statistical software to analyze the data.

RESULTS

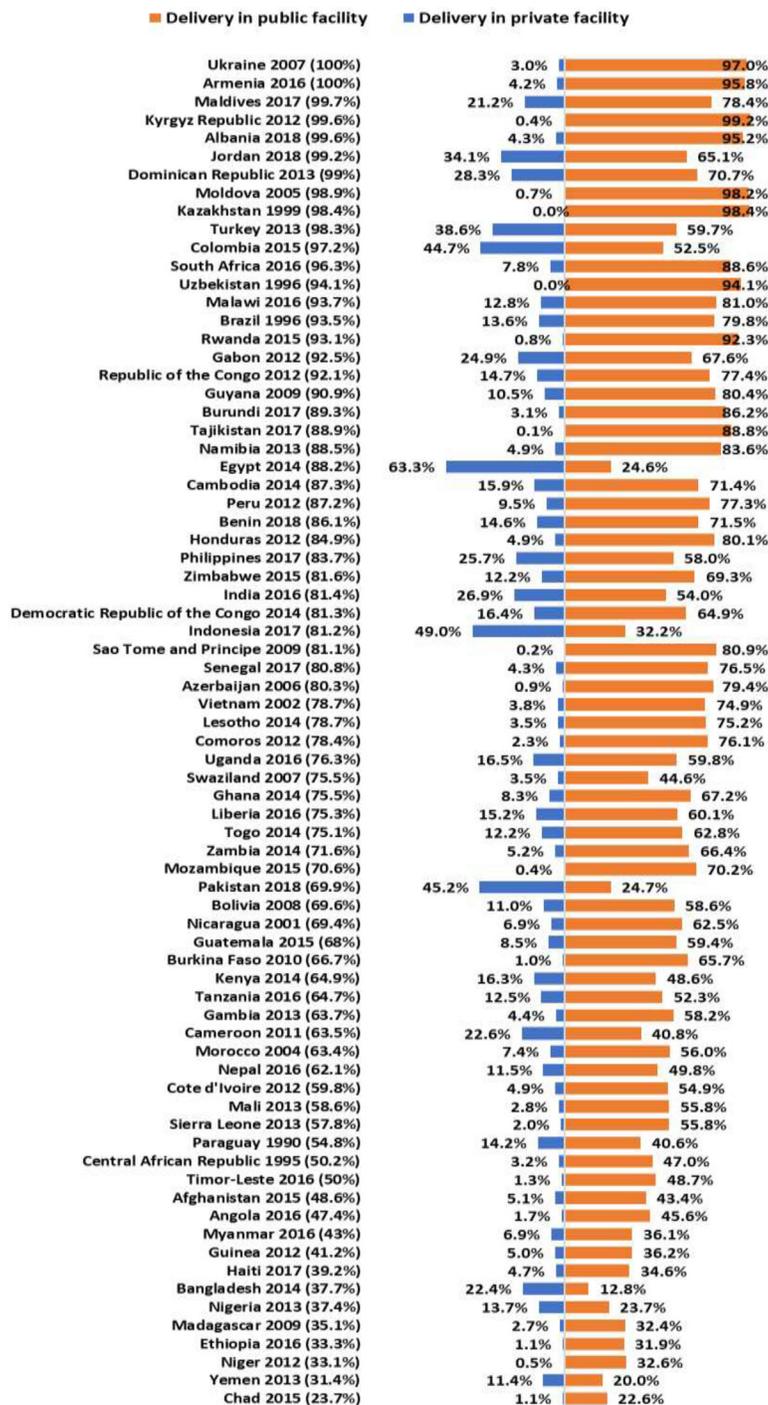
Sample Characteristics

We included a total of 1,538,486 live births, from 256 surveys conducted in 74 countries, to assess whether these births took place at a health facility or at home. For trend analysis, we considered a total of 245 surveys conducted in 63 countries that had data on institutional delivery for at least 2 DHS rounds (Supplement, Table S1). Overall, 23.1% of all live births were reported for women from the lowest quintile of wealth (poorest). The majority of birth data came from women living in rural areas (67.5%) and women with below secondary education (65.2%).

Coverage in the Utilization of Institutional Delivery Services

Our results show that the coverage of institutional delivery services varied between study countries (Figure 1). During 1990–2018, 19 of 74 countries reported that more than 90% of all deliveries were conducted at health facilities, with Armenia and Ukraine having universal coverage of institutional delivery services. In contrast, 13 countries had <50% coverage of institutional delivery services, with the lowest in Chad (23.7%) followed by Yemen (31.4%) and Niger (33.1%). Among all live births, the place of delivery (i.e., public or private health facilities) also varied across countries. In 52 of 74 countries, more than 50% of all live births took place in public health facilities. In comparison, 71 of 72 countries reported less than 50% of deliveries in private health facilities. The rate of public facility-based delivery was highest in the Kyrgyz Republic (99.2%) and lowest in Bangladesh (12.8%). On the other hand, Egypt had the highest rate of private facility-based deliveries (63.3%), whereas Tajikistan had the lowest (0.1%). The rate of delivery in public health facilities was greater than delivery in private

FIGURE 1. Geographical Variations in the Utilization of Institutional Delivery Services in Low- and Middle-Income Countries During Latest Demographic and Health Survey Rounds^a



^a Country and year listed indicate the latest survey year of the respective country. Percentage listed is the country's overall institutional delivery service rate during the latest survey.

During 1990–2018, the utilization of institutional delivery services increased in 60 of 63 countries, but the progress varied across countries.

health facilities in all countries, except Bangladesh, Egypt, Indonesia, and Pakistan.

Trends in the Utilization of Institutional Delivery Services

During 1990–2018, the utilization of institutional delivery services increased in 60 of 63 study countries (Figure 2). The progress in the utilization of institutional delivery services varied across countries. The highest increase in the utilization of institutional delivery services was observed in Cambodia (an 18.3% annual increase from 0.6% in 1990 to 94.0% in 2018) followed by Sierra Leone (16.2%) and Timor-Leste (13.7%). At the same time, utilization decreased in Angola (−0.9%), Kazakhstan (−0.3%), and Madagascar (−1.4%). The increase in the utilization of institutional delivery services steadily decreased after 1990–1999 in most LMICs (Figure 2). Based on this trend, 31 of 63 countries were estimated to have <80% utilization of institutional delivery services in 2018, with the highest in Armenia (100%, 95% CrI 100%–100%) and lowest in Chad (26.1%, 95% CrI 15.3%–38.7%) (Figure 3).

Trends in the utilization of institutional delivery services varied across wealth, residence, education,

and age of mother over time. From 1990 to 2018, the utilization of institutional delivery services in the lowest income group increased in 90.3% of countries (56 of 62 countries), with the highest in Cambodia (27.7% increase). In comparison, utilization declined in 9.7% of countries (6 of 62 countries), with the largest decline being −6.1% in Nigeria. Over 90.3% of countries (56 of 62 countries) reported increasing utilization of institutional delivery services by the highest income group, with the highest increase seen in Sierra Leone (14.4%), and 9.7% of countries (6 of 62 countries) showed a decline in the utilization of institutional delivery services with the largest decline in Angola (−0.6%) (Supplement, Table S3). If this trend continues, Nigeria (4.7%, 95% CrI 1.9%–9.6%) and Yemen (47.0%, 95% CrI 0.0%–95.8%) are estimated to have the lowest utilization of institutional delivery services in the lowest and highest income groups, respectively (Supplement, Table S4).

During the same time in rural areas, the utilization of institutional delivery services increased in 93.7% of countries (59 of 63 countries), with the highest increase by 20.5% in Cambodia, and 6.3% of countries (4 of 63 countries) reported a decline in utilization, with the largest decline

FIGURE 2. Change Rates of Institutional Delivery Services in Low- and Middle-Income Countries

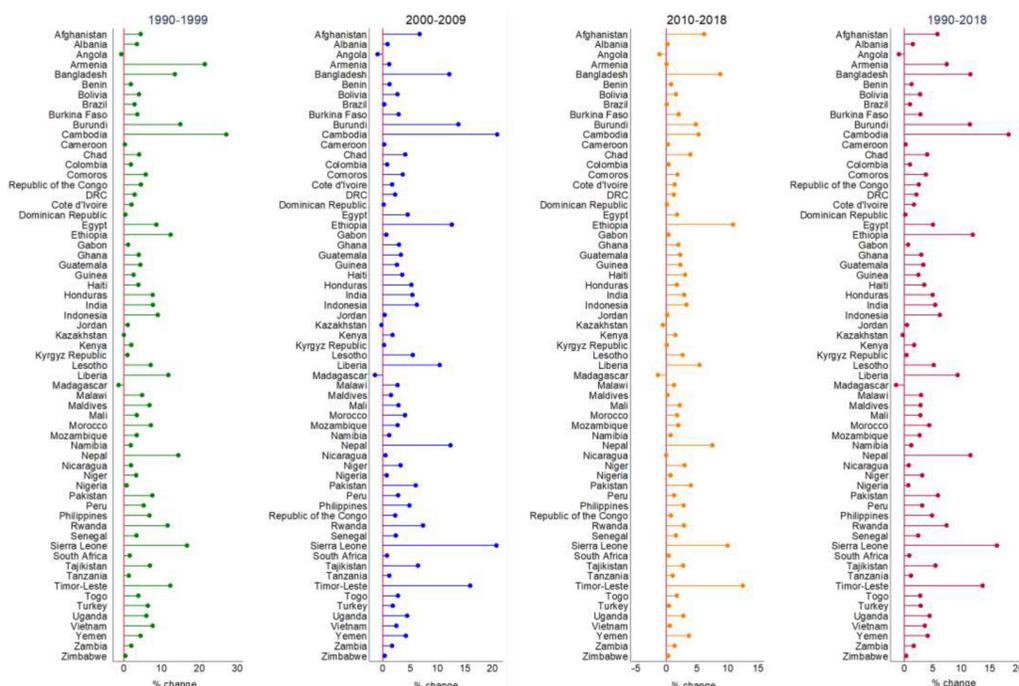
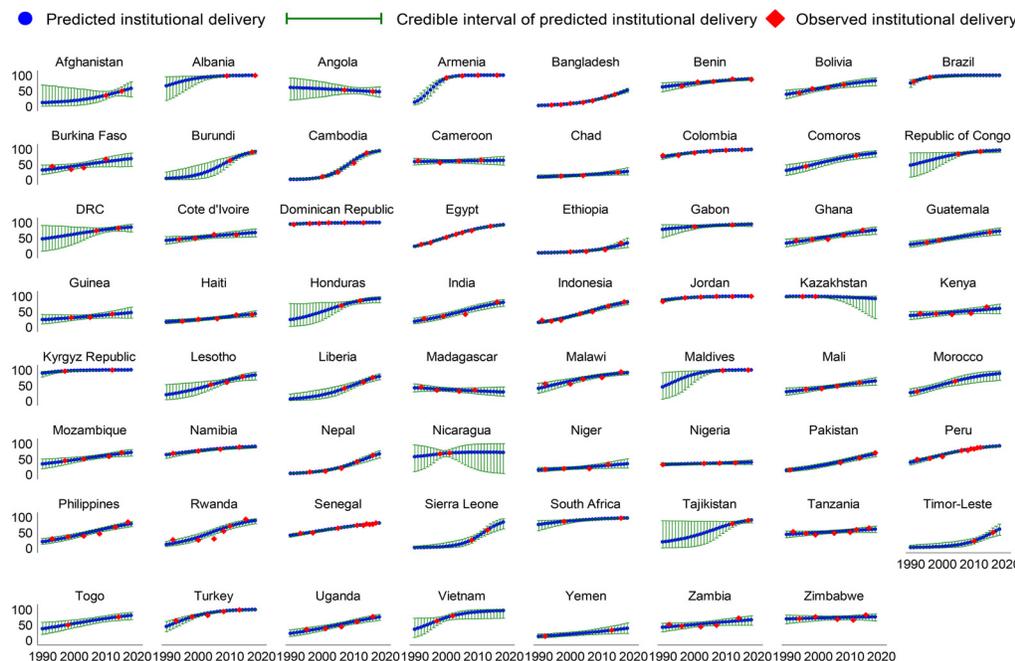


FIGURE 3. Trends in the Utilization of Institutional Delivery Services in Low- and Middle-Income Countries



observed in Angola (−2.1%). In contrast, in urban areas, 95.2% of countries (60 of 63 countries) experienced an increasing rate of institutional delivery services, with the highest increase in Cambodia (14.5%), and 4.8% of countries (3 of 63 countries) showed a decline in the utilization of institutional delivery services, with the largest decline in Angola by −1.4% (Supplement, Table S5). Similar to trends related to wealth and place of residence, the utilization of institutional delivery services also varied over time across women’s education (Supplement, Tables S7 and S8) and age (Supplement, Tables S9 and S10).

Changes in Inequalities in the Utilization of Institutional Delivery Services

Among 60 countries, inequalities in the utilization of institutional delivery services increased in relation to wealth, place of residence, age, and education. Wealth-related inequalities widened in 16 countries during the latest DHS round compared with the earliest, with the highest increase of 41.4% occurring in Ethiopia (earliest round: poorest 0.8%, richest 22.9%; latest round: poorest 13.9%, richest 77.5%) (Figure 4). In terms of place of residence, 10 of 63 countries experienced

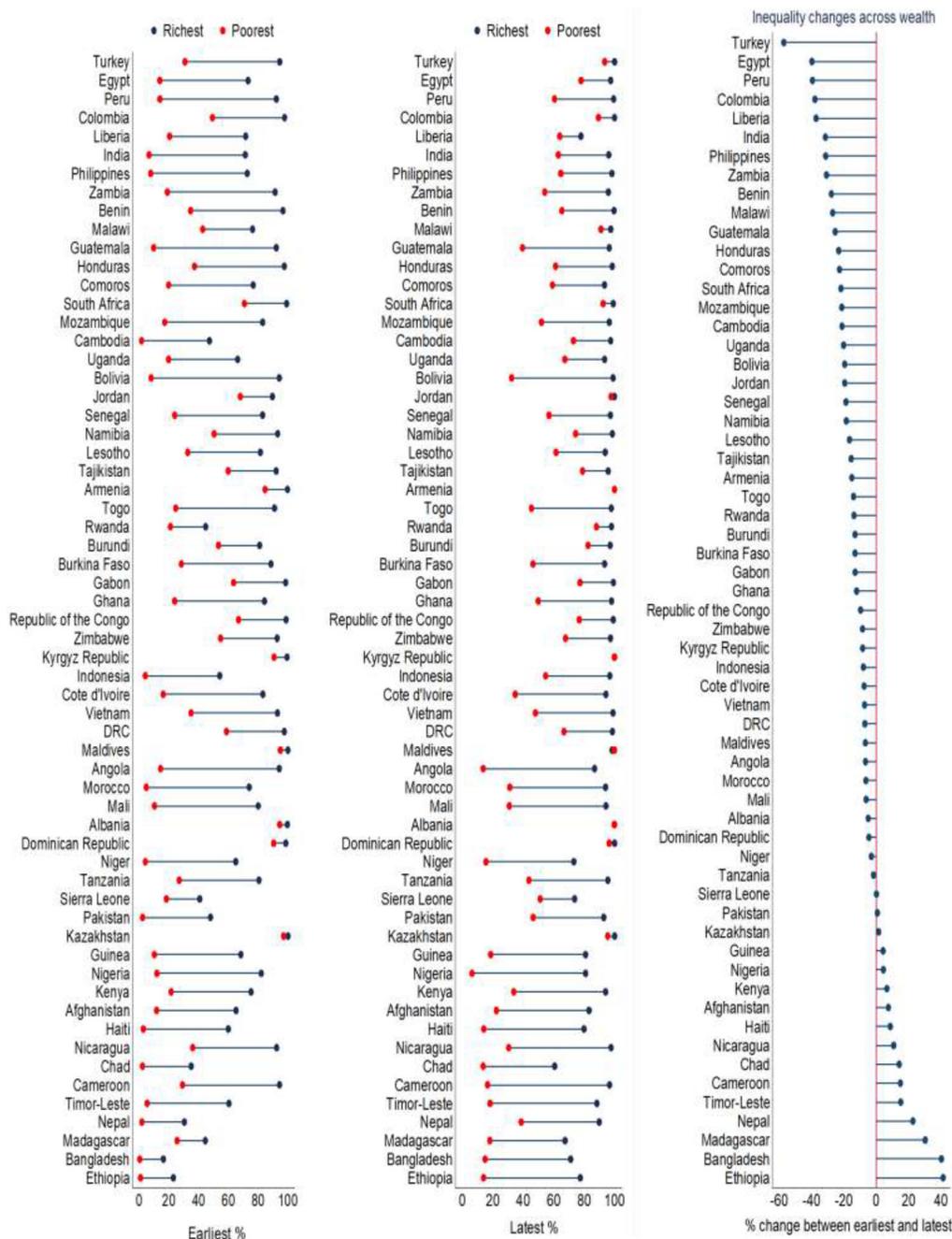
a growing gap in this inequality, with the highest increase of 29.4% occurring in Ethiopia (earliest round: rural 1.8%, urban 32.5%; latest round: rural 26.3%, urban 86.3%) (Supplement, Figure S1). Among these countries, a widening in the inequality of institutional delivery service utilization was seen in 10 countries in terms of education, with the highest increase of 20.2% in Madagascar (Supplement, Figure S2), and in 36 countries in terms of age, with the highest increase of 13.9% in Burundi (Supplement, Figure S3). In some countries, utilization of institutional delivery services increased among the advantaged groups and decreased among the disadvantaged groups during the latest round of surveys (Supplement, Figures S1–S3). Relative inequalities in the utilization of institutional delivery services also changed during the earliest and latest DHS rounds across wealth, place of residence, education, and age of women (Supplement, Tables S11–S14).

Changes in Institutional Delivery Between Public and Private Facilities

We explored the variations in the utilization of institutional delivery services by the type of facilities (i.e., public and private health facilities) to understand

In many study countries, inequalities in the utilization of institutional delivery services increased in relation to wealth, place of residence, age, and education.

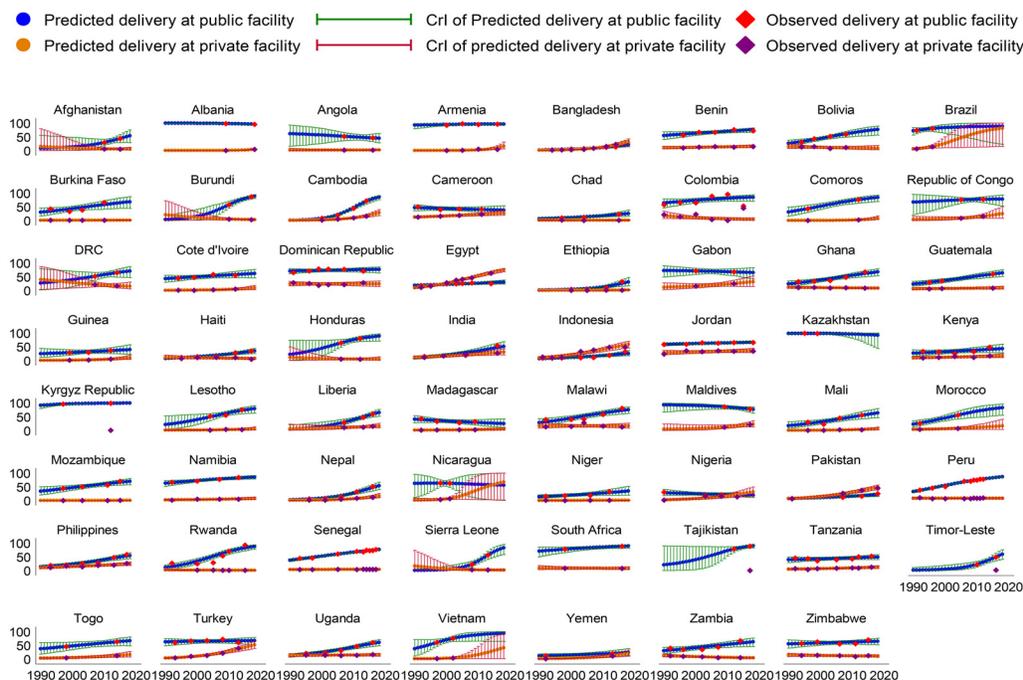
FIGURE 4. Changes of Inequalities in the Utilization of Institutional Delivery Services Between Earliest and Latest Time Points in Low- and Middle-Income Countries by Wealth Quintiles



the differences in service provision (Supplement, Table S15 and Figure 5). Although an increase in the utilization of institutional delivery services was observed, this increase was common across public

facilities in 54 countries and private facilities in 43 countries. During 1990–2018, the highest increase in the utilization of institutional delivery services was observed in Sierra Leone (16.8%) in public facilities

FIGURE 5. Trends in the Utilization of Delivery Services Facilitated by Public and Private Sectors in Low- and Middle-Income Countries



and Albania (30.2%) in private facilities. During the same period, the utilization of institutional delivery services decreased in some countries in both public and private facilities, with the largest declines in Madagascar (−1.7%) in public facilities and Sierra Leone (−8.1%) in private facilities.

Significant disparities exist in the utilization of delivery services in public and private facilities between countries and across wealth quintiles, residence, education, and age of women within countries. In most of the countries, the delivery in both public and private facilities was mostly dominated by the richest rather than the poorest women (Supplement, Tables S16 and S17). However, these gaps across residence, education, and age are minimal in most countries. (Supplement, Tables S18–S23).

Change rates in the utilization of delivery services in public and private facilities varied between countries, between periods within countries, and between countries and periods across wealth quintiles, residence, education, and age. In public facilities, the increase in the utilization of delivery services was highest in Cambodia (27.9%) among the poorest, and in Sierra Leone (17.2%) among the richest (Supplement, Table S24). Whereas,

Cambodia (24.0%) and Albania (33.6%) had the highest increase in the utilization of delivery services in private facilities among the poorest and the richest groups, respectively (Supplement, Table S25). Variations in the utilization of delivery services were also apparent across the place of residence, education, and age in both public and private facilities (Supplement, Tables S26–S31).

DISCUSSION

During the latest DHS round, the utilization of institutional delivery services varied substantially across countries and over time. The utilization across public and private health facilities was not uniform across countries. Among study LMICs, 16 countries had ≥80% utilization of delivery services in public facilities, whereas no countries had ≥80% utilization of this service in private facilities during the latest DHS rounds. Trend analysis showed a sustained increase in the utilization of institutional delivery services in most countries. Our findings showed a significant influence of wealth quintile, place of residence, and education of women in the utilization of institutional

Significant disparities exist in the utilization of delivery services in public and private facilities between countries and across specific populations within countries.

Our results highlight uneven progress in the utilization of institutional delivery services between countries and across subpopulations within countries.

delivery services. In many countries, the service utilization gaps observed in the earliest DHS rounds were found to be persistent and widened further in the latest DHS rounds.

Geographical variations in the utilization of institutional delivery services were expectedly common and were in agreement with previous studies.¹⁸ During the latest DHS rounds, in nearly 20% of countries included in our analysis, less than half of deliveries took place at a health facility. This finding highlights that still more than half of the babies are delivered at home in many countries such as Chad, Yemen, and Niger. Traditional and familial influences, distance to the facility, cost of delivery, perceptions of low quality of care, and fear of discrimination play a key role in inadequate utilization of facility-based delivery.¹⁹

Our findings on increasing trends in the utilization of institutional delivery services are consistent with previous studies.¹² However, our results also highlight uneven progress in the utilization of institutional delivery services between countries and across subpopulations within countries. The utilization of institutional delivery services decreased by nearly 1.5 percentage points in Madagascar.

The presence of disparities in the utilization of institutional delivery services across income and education levels is supported by previous research.^{14,20} We found lower utilization of institutional delivery services among women of the poorest quintile (lowest income group). Similar to previous research, we also found that compared with their counterparts, women from the lowest income group have lower access to private facilities for delivery.^{13,15,21} We also identified countries such as Bangladesh where inequality in the utilization of institutional delivery services is further increased. In particular, wealth-based inequalities in the utilization of institutional delivery services widened in 19 countries, while residence- and education-based inequalities grew further in 10 countries each. This finding highlights the need of revisiting strategies and implementing appropriate interventions to reduce the inequalities in the utilization of institutional delivery services across various sociodemographic groups.

Our study demonstrates an increasing trend in the majority of countries toward greater utilization of public health facilities for delivery. The predominant role of public facilities in increased utilization of institutional delivery services was proven in previous studies.¹³ The reasons for using

public facilities for delivering births could be multifaceted. The lower delivery cost is reported to greatly influence the use of this service.^{22,23} Also, increasing the number of health care providers through recruitment and improving the quality of care by training frontline health service providers are the key factors driving the growing rates of delivery in public facilities.^{24–27} However, compared with public facility-based deliveries, the rate of deliveries in private facilities was greater in Egypt, Indonesia, Pakistan, and Bangladesh by 38.6, 29.4, 20.5, and 9.6 percentage points respectively. The higher rate of deliveries in private facilities could be due to better quality of services, shorter wait time, higher availability of health care providers, greater privacy, and the visualization of social status.²⁸ Affordability and availability of private services are also increased due to the growth of gross domestic product per capita in these countries.²⁹ In general, an increase in awareness about the benefit of facility-based delivery might be the key to the increased utilization of institutional delivery services.¹² This may further result in the reduction of maternal and newborn mortality. However, we acknowledge that merely moving births to health facilities does not eliminate maternal and child mortality.

Our analysis has shown that most LMICs have reported remarkable improvement in the utilization of institutional delivery services. For example, the LAC countries showed the highest utilization of institutional delivery services. Innovative strategies have helped reduce financial barriers to access maternal health care in LAC countries; these include national health insurance (Brazil, Chile, Colombia, Jamaica, Mexico, and Peru), free health insurance scheme for lower-income families (Bolivia, Mexico, and Peru), incorporating UHC as a constitutional right (Brazil and Chile), and public-private partnerships (Colombia).³⁰ Reducing the gap in provisioning institutional delivery services for a particular demographic group, such as the one for indigenous and African origin women, was also considered there.³⁰ Some vertical approaches can also be attributed to the growing rates of institutional delivery services utilization in Asian countries. For example, conditional cash incentives in India³¹ and demand-side financing in Bangladesh³² are linked with higher utilization of institutional delivery services.

Higher rates of home delivery assisted by a traditional birth attendant are common in many settings. Restricting the services from a traditional birth attendant backed up by hospital readiness increased facility-based births from <30% during the start of MDG era to the current rate of >90% rate in

Malawi and Rwanda.^{33–36} In contrast, countries with slower progress or decreasing trends of utilizing institutional delivery services such as Angola, Kazakhstan, and Madagascar have shown higher inequality in the utilization of institutional delivery services. Distance to health facilities, lower educational level, and rural residence were the major determinants of poor utilization of this service in sub-Saharan African countries.⁷ Moreover, the current coronavirus disease (COVID-19) pandemic situation can aggravate the poor utilization of institutional delivery services because people may not be accessing health facilities as they would have before COVID.

The major strength of this study is the use of population-based nationally representative samples covering both rural and urban areas of 74 LMICs and the identification of population subgroups within LMICs. Analysis at the subpopulation level is particularly helpful to design interventions for target populations.

Limitations

The use of the same standard methodology across countries allows cross-country comparison of the estimates. However, older and fewer data points created wider credible intervals of the estimates in some countries (e.g., Kazakhstan). Credible intervals could be smaller for countries with many data points (e.g., Bangladesh). Estimates drawn from authentic representative data collected from multiple sources may better predict the indicators with lower uncertainty. Moreover, the DHS data are mostly self-reported and hence are prone to recall bias. However, the DHS has followed a standard methodology and questionnaire for more than 3 decades to provide population-based data that are comparable and representative not only at the national level but also subnational and subpopulation levels.

CONCLUSIONS

Although the utilization of institutional delivery services varied substantially across LMICs, the utilization of health facilities for delivery overall increased in most of the countries between 1990 and 2018. However, this increase was not uniform across countries and sociodemographic subpopulations (e.g., poorest and richest, and rural and urban) within countries. Unfortunately, inequalities in the utilization of institutional delivery services are widening in some countries. These findings warrant the development of appropriate and tailored interventions covering the disadvantaged

and marginalized populations identified in this study to achieve the global target of “leaving no one behind” for the utilization of institutional delivery services by 2030.

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REFERENCES

1. Moyer CA, Adanu RM, Engmann CM. The relationship between facility-based delivery and maternal and neonatal mortality in Sub-Saharan Africa. *Int J Gynaecol Obstet.* 2013;122(3):263–265. [CrossRef](#). [Medline](#)
2. Alkema L, Chou D, Hogan D, et al. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. *Lancet.* 2016;387(10017):462–474. [CrossRef](#). [Medline](#)
3. United Nations Children’s Fund (UNICEF), World Health Organization, World Bank, United Nations. *Levels & Trends in Child Mortality: Report 2017.* UNICEF; 2017. Accessed January 7, 2021. <https://childmortality.org/wp-content/uploads/2018/10/UN-IGME-Child-Mortality-Report-2017.pdf>
4. World Health Organization (WHO). *Trends in Maternal Mortality: 1990 to 2015: Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division.* WHO; 2015. Accessed January 7, 2021. <https://www.who.int/reproductive-health/publications/monitoring/maternal-mortality-2015/en/>
5. Ronsmans C, Graham WJ; Lancet Maternal Survival Series steering group. Maternal mortality: who, when, where, and why. *Lancet.* 2006;368(9542):1189–1200. [CrossRef](#). [Medline](#)
6. Ronsmans C, Campbell OMR, McDermott J, Koblinsky M. Questioning the indicators of need for obstetric care. *Bull World Health Organ.* 2002;80(4):317–324. [Medline](#)
7. Rosário EVN, Gomes MC, Brito M, Costa D. Determinants of maternal health care and birth outcome in the Dande Health and Demographic Surveillance System area, Angola. *PLoS One.* 2019;14(8):e0221280. [CrossRef](#). [Medline](#)
8. Koblinsky MA, Campbell O, Heichelheim J. Organizing delivery care: what works for safe motherhood? *Bull World Health Organ.* 1999;77(5):399–406. [Medline](#)
9. United Nations. *The Millennium Development Goals Report 2015.* United Nations; 2015. Accessed January 7, 2021. <https://www.un.org/en/development/desa/publications/mdg-report-2015.html>
10. ICF. DHS final reports. Accessed January 7, 2021. <https://dhsprogram.com/publications/publication-search.cfm?type=5>
11. World Health Organization (WHO). Universal health coverage (UHC). Accessed January 7, 2021. <https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-uhc>

12. Doctor HV, Nkhana-Salimu S, Abdulsalam-Anibilowo M. Health facility delivery in sub-Saharan Africa: successes, challenges, and implications for the 2030 development agenda. *BMC Public Health*. 2018;18(1):765. [CrossRef](#). [Medline](#)
13. Doctor HV, Radovich E, Benova L. Time trends in facility-based and private-sector childbirth care: analysis of Demographic and Health Surveys from 25 sub-Saharan African countries from 2000 to 2016. *J Glob Health*. 2019;9(2):020406. [CrossRef](#). [Medline](#)
14. Joseph G, da Silva ICM, Wehrmeister FC, Barros AJD, Victora CG. Inequalities in the coverage of place of delivery and skilled birth attendance: analyses of cross-sectional surveys in 80 low and middle-income countries. *Reprod Health*. 2016;13(1):77. [CrossRef](#). [Medline](#)
15. Benova L, Macleod D, Footman K, Cavallaro F, Lynch CA, Campbell OMR. Role of the private sector in childbirth care: cross-sectional survey evidence from 57 low- and middle-income countries using Demographic and Health Surveys. *Trop Med Int Health*. 2015;20(12):1657–1673. [CrossRef](#). [Medline](#)
16. Rutstein SO, Rojas G. *Guide to DHS Statistics*. Demographic and Health Surveys, ORC Macro; 2006. Accessed January 7, 2021. https://dhsprogram.com/pubs/pdf/DHSG1/Guide_to_DHS_Statistics_29Oct2012_DHSG1.pdf
17. Rutstein SO, Johnson K. *DHS Comparative Reports No. 6 The DHS Wealth Index*. ORC Macro; 2004. Accessed January 7, 2021. <https://dhsprogram.com/publications/publication-cr6-comparative-reports.cfm>
18. Kanyangarara M, Chou VB, Creanga AA, Walker N. Linking household and health facility surveys to assess obstetric service availability, readiness and coverage: evidence from 17 low- and middle-income countries. *J Glob Health*. 2018;8(1):010603. [CrossRef](#). [Medline](#)
19. Bohren MA, Hunter EC, Munthe-Kaas HM, Souza JP, Vogel JP, Gülmezoglu AM. Facilitators and barriers to facility-based delivery in low- and middle-income countries: a qualitative evidence synthesis. *Reprod Health*. 2014;11(1):71. [CrossRef](#). [Medline](#)
20. Lohela TJ, Nesbitt RC, Pekkanen J, Gabrysch S. Comparing socioeconomic inequalities between early neonatal mortality and facility delivery: cross-sectional data from 72 low- and middle-income countries. *Sci Rep*. 2019;9(1):9786. [CrossRef](#). [Medline](#)
21. Victora CG, Joseph G, Silva ICM, et al. The inverse equity hypothesis: analyses of institutional deliveries in 286 national surveys. *Am J Public Health*. 2018;108(4):464–471. [CrossRef](#). [Medline](#)
22. Meessen B, Hercot D, Noirhomme M, et al. Removing user fees in the health sector: a review of policy processes in six sub-Saharan African countries. *Health Policy Plan*. 2011;26(Suppl 2):ii16–ii29. [CrossRef](#). [Medline](#)
23. Nabyonga Orem J, Mugisha F, Kirunga C, Macq J, Criel B. Abolition of user fees: the Uganda paradox. *Health Policy Plan*. 2011;26(Suppl 2):ii41–ii51. [CrossRef](#). [Medline](#)
24. Nyonator FK, Awoonor-Williams JK, Phillips JF, Jones TC, Miller RA. The Ghana Community-based Health Planning and Services Initiative for scaling up service delivery innovation. *Health Policy Plan*. 2005;20(1):25–34. [CrossRef](#). [Medline](#)
25. Doctor HV, Findley SE, Ager A, et al. Using community-based research to shape the design and delivery of maternal health services in Northern Nigeria. *Reprod Health Matters*. 2012;20(39):104–112. [CrossRef](#). [Medline](#)
26. Ramsey K, Hingora A, Kante M, et al. The Tanzania Connect Project: a cluster-randomized trial of the child survival impact of adding paid community health workers to an existing facility-focused health system. *BMC Health Serv Res*. 2013;13(S2)(Suppl 2):S6. [CrossRef](#). [Medline](#)
27. Sherr K, Cuembelo F, Michel C, et al. Strengthening integrated primary health care in Sofala, Mozambique. *BMC Health Serv Res*. 2013;13(S2)(Suppl 2):S4. [CrossRef](#). [Medline](#)
28. Wong KLM, Radovich E, Owolabi OO, et al. Why not? Understanding the spatial clustering of private facility-based delivery and financial reasons for homebirths in Nigeria. *BMC Health Serv Res*. 2018;18(1):397. [CrossRef](#). [Medline](#)
29. The World Bank. DataBank: World Development Indicators. World Bank; 2020. Accessed January 7, 2021. <https://databank.worldbank.org/source/world-development-indicators#>
30. Montagu D, Sudhinaraset M, Diamond-Smith N, et al. Where women go to deliver: understanding the changing landscape of childbirth in Africa and Asia. *Health Policy Plan*. 2017;32(8):1146–1152. [CrossRef](#). [Medline](#)
31. Randive B, Diwan V, De Costa A. India's conditional cash transfer programme (the JSY) to promote institutional birth: is there an association between institutional birth proportion and maternal mortality? *PLoS One*. 2013;8(6):e67452. [CrossRef](#). [Medline](#)
32. Anwar I, Nababan HY, Mostari S, Rahman A, Khan JAM. Trends and inequities in use of maternal health care services in Bangladesh, 1991–2011. *PLoS One*. 2015;10(3):e0120309. [CrossRef](#). [Medline](#)
33. Cammack D. Local governance and public goods in Malawi. *IDS Bull*. 2011;42(2). [CrossRef](#)
34. Bucagu M, Kagubare JM, Basinga P, Ngabo F, Timmons BK, Lee AC. Impact of health systems strengthening on coverage of maternal health services in Rwanda, 2000–2010: a systematic review. *Reprod Health Matters*. 2012;20(39):50–61. [CrossRef](#). [Medline](#)
35. Campbell OMR, Calvert C, Testa A, et al. The scale, scope, coverage, and capability of childbirth care. *Lancet*. 2016;388(10056):2193–2208. [CrossRef](#). [Medline](#)
36. Chitsa Banda E. *Stakeholders' Perceptions of the Changing Role of Traditional Birth Attendants in The Rural Areas of Central West Zone, Malawi: A Mixed Methods Study*. PhD thesis. University of the Witwatersrand, Johannesburg; 2013.

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ORIGINAL ARTICLE

Expanding Contraceptive Method Choice With a Hormonal Intrauterine System: Results From Mixed Methods Studies in Kenya and Zambia

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Key Messages

- Making the hormonal intrauterine system (IUS) available in public facilities in low-income countries could increase uptake of long-acting contraception because it appeals to some women who would not otherwise choose a long-acting method; 30% of hormonal IUS adopters would have chosen a short-acting method if the hormonal IUS had not been available.
- Satisfaction and continuation rates were high among interviewed hormonal IUS adopters. Providers also reported that most hormonal IUS adopters were satisfied and rarely returned with complaints that could not be addressed with additional counseling.
- Providers reported that many women were not willing to try a method they were hearing about for the first time.

Key Implications

- When taking steps to increase the availability of the hormonal IUS, donors and policy makers must fund demand-creation efforts to increase awareness of a new long-acting contraceptive option that has characteristics that are distinctly different from other long-acting and short-acting methods.
- Program managers should develop introduction and scale-up plans that allow for ongoing support and mentorship of providers in offering a new long-acting contraceptive method.

ABSTRACT

Introduction: Few women in low- and middle-income countries have access to the hormonal intrauterine system (IUS). Past research from a small number of facilities and the private sector suggest the IUS could be an important addition to the contraceptive method mix because it is the only long-acting method some women will adopt and users report high satisfaction and continuation. We aimed to determine whether these promising results were applicable in public facilities in Kenya and Zambia.

Methods: We used a mixed-methods approach with program monitoring data, interviews with women who received an IUS, and qualitative focus group discussions with providers. Data were collected in 2017–2019.

Results: Facilities in Kenya and Zambia reported 1,985 and 428 IUS insertions, respectively. If the IUS had not been available, 30% of adopters would have chosen a short-acting method. Women and providers gave diverse reasons for adopting the IUS, with the desire for fewer side effects being frequently mentioned in focus group discussions. Many IUS adopters first heard of the method on the day it was inserted (70% in Kenya, 47% in Zambia), yet providers reported that many women were unwilling to try a method they were just hearing about for the first time. Satisfaction and continuation were high: 86% of adopters in Kenya were still using the method 3–6 months after insertion and 78% were in Zambia (average 10 months post insertion). Providers also reported that most IUS adopters were satisfied; they rarely returned with complaints that could not be addressed with additional counseling.

Conclusion: Expanding IUS access through the public sector shows promise to increase contraception use and continuation in low- and middle-income countries. Efforts to strengthen availability should consider demand and engage directly with various communities, including youth, around availability of a new long-acting option.

BACKGROUND

The hormonal intrauterine system (IUS) is a highly effective, long-acting reversible contraceptive (LARC) method with numerous noncontraceptive benefits.^{1–3} The hormonal IUS has been very successful in high-income countries; in the United States, it is more widely used than all other contraceptive methods introduced in recent decades.⁴ However, the hormonal IUS has limited availability

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in low- and middle-income countries (LMICs), primarily due to the cost of branded products. Accessibility in LMICs could increase in the near future with the introduction of new low-cost hormonal IUS products, such as Avibela from Medicines360, plus increasing awareness of a generic product available for donation through the International Contraceptive Access (ICA) Foundation.^{5,6}

The hormonal IUS has the potential to be an important addition to the method mix in LMICs. Generally, increasing the number of available methods increases contraceptive use, although adding a method that is a variation of existing methods may have a greater effect on continuation than uptake.⁷ The hormonal IUS is a small, flexible T-shaped plastic frame with a white cylinder-shaped, hormone-filled vertical stem with 2 nylon threads at the end, and it has specific attributes that make it attractive. Use of a hormonal IUS often reduces menstrual bleeding and cramping (nonhormonal copper-containing intrauterine devices [IUDs] can have the opposite effect), and it releases less hormone into the bloodstream than other hormonal methods.⁸ These features are important because the most common reasons that women in LMICs cite for discontinuing contraception or not using it at all are side effects and health concerns.^{9,10}

Past research on the hormonal IUS in LMICs suggests women will choose it when it is offered as part of a mix of methods.^{11–13} For some women, it may be the only long-acting method they will adopt when given the option of IUDs and implants.^{11,13} Hormonal IUS users also report high satisfaction and continuation of the method.^{13–15} Although these results suggest the hormonal IUS could be an important addition to the contraceptive method mix, the evidence has limited generalizability to the public health care sector, which remains an important source of contraception in LMICs.¹⁶ Participants in past hormonal IUS studies in LMICs were mostly recruited from clinics run by nongovernmental organizations, social franchises, or outreach services or from a very small number of public facilities. Two studies involved the same cohort recruited from 1 public facility in Kenya.^{11,14} A recent study in Nigeria gathered data on the hormonal IUS provided via social franchise, mobile outreach, and 20 public sector providers, but the latter inserted too few hormonal IUSs to be included in the analysis.¹³ A study in Ghana involved 12 providers operating in 6 hospitals where IUD acceptance was already high.¹⁵ Providers that did counseling and insertion

in these studies were usually experienced in IUD provision. Provider knowledge, experience, and comfort with contraceptive methods affect the quality of counseling, which in turn affects women's contraceptive choice and continuation.^{17,18} Evidence for the viability of the hormonal IUS in public sector health facilities, including lower level facilities, in LMICs is not yet sufficient.

The U.S. Agency for International Development (USAID) flagship Maternal and Child Survival Program (MCSP) aimed to fill this evidence gap by introducing the hormonal IUS into public facilities in 2 counties in Kenya and 4 provinces in Zambia. MCSP used donated products from the ICA Foundation with implementation activities executed in partnership with the USAID-funded Afya Hali project¹⁹ in Kenya and Safe Motherhood 360+ project (SM360+)²⁰ in Zambia. Introduction started in late 2016 in Kenya and early 2017 in Zambia.

This article explores characteristics of women adopting the hormonal IUS at public facilities with comparison to IUD adopters, reasons women chose the hormonal IUS, sources of information about the method, user satisfaction, and continuation rates. Data collected from women were triangulated with provider perspectives. MCSP's intent was to learn whether promising results from earlier studies on the hormonal IUS in LMICs hold true when the method is introduced in the public sector under “real-world” conditions. This evidence contributes to the learning agenda developed by a global Hormonal IUS Consultative Group of donors, implementers, and suppliers.²¹

PROGRAM DESCRIPTION

In Kenya and Zambia, MCSP consulted with Ministry of Health (MOH) stakeholders to plan and design the program, including tools for on-the-job training with ongoing mentorship, an approach shown to be cost efficient for building provider skills.^{22,23} MCSP used its LARC Learning Resource Package, a modular set of training materials that focuses on hands-on practice for developing clinical LARC skills (Box).²⁴ The training approach and materials align with the current or anticipated national MOH plans for expanding LARC access in both countries.

To implement cascade training, MCSP trained providers (mainly nurses and midwives) who had been identified as MOH mentors to support other providers in building their clinical skills. The first step of the process was to train the mentors in hormonal IUS counseling and insertion and removal

This study investigated whether promising results from earlier studies hold true when the hormonal IUS is introduced in the public sector under “real-world” conditions.

BOX. Capacity-Building Approach Used by the Maternal and Child Survival Program for Hormonal Intrauterine System Training

Traditional training through extended, off-site, group-based workshops often fails to improve health care provider performance.^{25,26} Sustained improvements are better achieved through interactive techniques, simulated practice, immediate feedback, and ongoing learning opportunities delivered at appropriate doses and frequencies.²⁶

In light of this evidence, and to ensure hormonal intrauterine system (IUS)/long-acting reversible contraceptive (LARC) training translated into performance, the Maternal and Child Survival Program (MCSP) used an on-the-job, modular (no session longer than 3 hours) approach to help build and strengthen the competency and confidence of providers to learn and perform essential job skills with minimal disruption to services. Training was interactive and held at health care facilities with special attention given throughout to learning and practicing skills through role plays and simulations (i.e., with anatomical models) with family planning clients. Training content was tailored at each site based on identified learning needs of providers, using the appropriate modules from MCSP's LARC Learning Resource Package as needed. For example, in Kenya, the copper intrauterine device (IUD) module was used in addition to the hormonal IUS and postpartum modules when LARC providers were not sufficiently proficient in IUD counseling and insertion, so providers could confidently and competently provide both the IUD and hormonal IUS. The LARC Learning Resource Package contains 5 clinical modules plus modules on family planning counseling and assessing medical eligibility (with activities designed to help providers strengthen their communication skills to enable clients to make well informed and voluntary decisions), infection prevention, and quality care.

Mentoring complements on-the-job-training by supporting skill transfer and service implementation after training, ensuring that remaining skill gaps of learners are addressed during post-training mentorship sessions. MCSP defined mentoring as "the process through which an experienced and empathetic person who is proficient in her/his content area (a mentor) teaches and coaches another individual (mentee) or group of individuals (mentees), in person and/or virtually, to ensure competent workplace performance and provide ongoing professional development."²⁷ As part of hormonal IUS introduction, mentors supported ongoing practice and quality improvement activities to reinforce learning and facilitate application of new skills during clinical practice. When needed (particularly if mentors offered training at a facility where they were not based), mentors sometimes identified high-performing mentees who served as peer practice coordinators within their facilities, supporting their peers in learning and practice between clinical mentorship sessions. Groups of mentors and mentees also established WhatsApp groups to facilitate communication at a distance and rapid response to questions. As a result, mentees received continuous feedback and reinforcement on their performance even when a mentor was not present. Once mentees were confident in providing hormonal IUS services, they could then be assessed and certified. In addition, in Zambia, district-level supervisors provided general technical supervision.

techniques and to review the process for training and mentoring other providers. After mentors conducted 10 insertions in Kenya (as many as possible under observation during training and mentorship and the remainder done independently and logged) and 4 insertions in Zambia (2 while being coached and 2 under observation during training or mentorship), they underwent assessment to become certified hormonal IUS providers. After becoming certified, mentors were then expected to train and provide ongoing support for other providers (mentees) in facilities where they worked and/or nearby facilities, as well as continue to conduct insertions. Mentees were other providers (also mainly nurses and midwives) selected collaboratively by MOH coordinators, the project team, and facility in-charges. On-site training of mentees was spread over 4 consecutive days and lasted no more than 3 hours per day. Mentors then developed a follow-up mentoring plan based on the performance of the mentees. The criteria

for becoming a certified hormonal IUS provider were the same for mentees as for mentors (Box).

In Kenya, the mentors had been previously trained by MCSP in other LARCs (implants and IUDs) in 2016 but were inexperienced in hormonal IUS. With hormonal IUS introduction, MCSP led additional training for mentors on hormonal IUS plus postpartum insertion (for the IUS and IUD) in December 2016, using the appropriate modules from the Learning Resource Package. Additional mentors were trained in 2017 on all LARCS under the Afya Halisi project. As of mid-2019, 65 mentors were trained in hormonal IUS with 48 certified plus 190 mentees trained by mentors, although none were certified due to delays in rolling out the assessments. (The assessments were costly because they involved travel for 3 assessors to each site, so the process was delayed waiting for more providers to reach the 10-insertion threshold for certification. In the meantime, providers continued to offer the service, even if they exceeded the threshold.)

In Zambia, the SM360+ project trained maternity care providers to become LARC providers and mentors from February to August 2017, with MCSP contributing materials and trainers to incorporate the hormonal IUS into the training. The mentors had previous training in maternal and newborn health and mentorship skills, but were often inexperienced with LARCs. They were expected to start integrating LARC counseling and provision into their maternity clinical work and mentorship of other providers of maternity services. (Although the project targeted maternity providers, facilities rotated providers and some reported working in different departments during the study period.) As of mid-2019, 68 mentors were trained in all LARCs including hormonal IUS (17 in Luapula, 20 in Eastern, 8 in Central, 23 in Southern Province) with 49 certified plus 134 mentees trained by mentors with 91 certified. In both countries, the number of trained and certified providers continues to rise as cascade training is ongoing.

Mentors and mentees worked in facilities that offered short-acting contraceptive methods as well as IUDs and implants (some also provided sterilizations), although temporary stock-outs or staffing disruptions sometimes limited availability of certain methods. Hormonal IUS was offered free of charge, as are all contraceptive methods in the public sector in these countries. MCSP distributed donated ICA Foundation commodities directly to facilities. Providers in both countries gave information on the hormonal IUS during group talks at facilities and one-on-one counseling. Information on the hormonal IUS was incorporated into discussions or counseling on family planning and the various methods available, and not done separately. Providers had been trained to give a woman more information on the characteristics of a method once she made her choice, including expected side effects, bleeding changes, and noncontraceptive benefits. Providers also explained to the woman that she could have it removed at any time and what she could expect before, during, and after insertion. Information about the hormonal IUS was also shared through community outreach. In Kenya, community health volunteers work with facilities to promote health behaviors and care-seeking; facilities where the hormonal IUS was available were responsible for orienting community health volunteers on the method so they could share information in communities as part of their general efforts to promote family planning. In Zambia, SM360+ oriented existing Safe Motherhood Action Groups on LARCs including the hormonal IUS, although orientations happened late in the study period. MCSP did not track data on these demand-creation activities.

■ METHODS

We used a mixed-methods approach that included analysis of program monitoring data, interviews with women who received a hormonal IUS or an IUD, and qualitative focus group discussions (FGDs) with providers. IUD adopters were interviewed for comparison since adopters of hormonal IUS and IUD were both presumed to desire long-acting contraception and to be undeterred by having a device in the uterus, so we could compare other factors that influence women's decision making and experiences.

Ethical approval was received from the ethics review committees at the Johns Hopkins University School of Public Health (USA), Maseno University (Kenya), and ERES Converge (Zambia).

Quantitative Data

In Kenya, women were enrolled in the study immediately after hormonal IUS or IUD insertion beginning in April 2017 (approximately 5 months after the initial training for mentors). All women receiving a hormonal IUS or an IUD at participating facilities were eligible for the study. Providers received training on research ethics and were given informed consent scripts to read to women after insertion. After providers obtained oral consent, they completed a short paper-based questionnaire collecting sociodemographic characteristics and contact information for follow-up. This questionnaire also collected reasons for choosing the method, what method they would have chosen if the hormonal IUS or IUD was not available, and when and how they heard about the hormonal IUS, which are questions implementers in the global hormonal IUS consultative group all agreed to collect.²¹ Consent was obtained immediately following insertion in Kenya due to initial plans to conduct follow-up interviews via short message service survey; however, the study team later opted for phone interviews instead. All women who gave a phone number were contacted for follow-up interviews. At the start of the call, women were reminded they could drop out at any point or decline to answer questions. Multiple attempts were made to call women who did not answer their phone. Phone interviews were conducted by 2 trained LARC mentors hired as temporary consultants by the study; a mentor in Migori called women in Kisumu, and a mentor in Kisumu called women in Migori to avoid the possibility of a provider interviewing her own client. RedCap v9.6.0 was used to enter data collected on the day of insertion and via phone; a single

database was used to store data collected at both time points.

In Zambia, providers completed a paper-based questionnaire immediately after insertion as part of program monitoring and study recruitment. Data were collected on all women who received a hormonal IUS or IUD in participating facilities and were willing to answer the questions. Data collection started during the initial training for mentors. The questionnaire collected information similar to the one used in Kenya, but contact information was documented only for women that expressed interest in learning about the research study. The study consent process and interview were done sequentially via phone by MCSP staff. In Zambia, phone interviews were limited to women who received the hormonal IUS or IUD within 1 year after giving birth or after receiving postabortion care. The population was restricted due to the programmatic focus on maternity providers and because Society for Family Health was simultaneously introducing the hormonal IUS and collecting similar data in other public facilities in Zambia without a postpartum focus.²⁸ Multiple attempts were made to call women who received a hormonal IUS or IUD postpartum or postabortion and did not answer the phone. Separate and unlinked databases were kept in Zambia for program data collected immediately after insertion and research data collected via phone. Firebase web application and Google forms were used for program and research data, respectively.

We present results based on data collected by providers at 42 facilities in Kenya from April 2017 to March 2019 and 41 facilities in Zambia from February 2017 to September 2019, although program expansion continued into additional sites after these dates. Follow-up phone interviews were conducted over 2 time periods—September 2017 and March 2019 in Kenya, and March–December 2018 and April–July 2019 in Zambia. These periods were selected based on availability of consultants and staff conducting interviews. To meet reporting requirements from the ICA Foundation, MCSP also collected the number of hormonal IUS commodities distributed to facilities and contacted facilities semiannually to obtain the total number of hormonal IUS insertions according to facility records. Data were extracted from these reports for the purpose of assessing overall uptake of hormonal IUS in program-supported facilities.

Qualitative Data

FGDs were held with providers, with separate groups for mentors and mentees to allow different

questions about the training and mentorship approach. Participants were selected by MOH staff. Each participant worked in a different facility to increase the representativeness of the sample. FGDs were conducted in English, recorded, and transcribed. In all, 2 FGDs were done with mentors (23 participants) and 4 with mentees (36 participants) in Kenya and 4 with mentors (23 participants) and 3 with mentees (15 participants) in Zambia. FGDs were held in February 2019 in Kenya and August 2018 in Zambia. Providers did not receive compensation for participation.

Analysis

Quantitative analysis was done using Stata v14. Using data collected on the day of insertion, we ran cross-tabulations to compare hormonal IUS and IUD adopters in terms of sociodemographic characteristics, timing of insertion relative to last birth, and the method nonpostpartum adopters were switching from. We used the Pearson chi-squared test with Rao-Scott correction to adjust for clustering by facility. We also explored reasons hormonal IUS adopters chose the method; what method they would have chosen if hormonal IUS were unavailable; and where they first heard about the hormonal IUS. Using follow-up phone interviews, we cross-tabulated side effects or physical changes that hormonal IUS and IUD adopters reported providers mentioned to them on the day of insertion. In Kenya, we also examined whether the time lapse from insertion to interview seemed to affect the side effects women mentioned by restricting the analysis to women who received the hormonal IUS or IUD within 6 months before the phone call. We could not do the same in Zambia due to the small number of women participating in phone interviews. As markers of satisfaction, we looked at whether hormonal IUS adopters would recommend or have recommended the method (the question was asked differently in Kenya and Zambia) and what benefits they would mention to other women. Finally, we examined continuation rates for hormonal IUS adopters. Since there was a wide range in the time lapse from insertion to phone interviews, we restricted analysis to women interviewed 3–6 months (92–183 days) after insertion in Kenya to make the sample more homogenous. Due to the small sample size in Zambia, we were unable to restrict the sample.

FGDs were explored for information to enhance the quantitative findings, namely provider perspectives on the reasons women chose the

hormonal IUS, information women received on the method, challenges to providing counseling, and client satisfaction with the method. Transcripts were coded using these themes; codes were then analyzed using principles from the One Sheet of Paper method.²⁹

RESULTS

Totals of 1,985 and 428 insertions of the hormonal IUS were reported by facilities in Kenya and Zambia, respectively, by mid-2019.

In Kenya, 37% of women chose the hormonal IUS because they desired fewer side effects. In Zambia, 55% of women chose the method because of the ability to space pregnancies.

MCSP Kenya and Zambia received 2,930 and 1,205 hormonal IUSs from ICA Foundation, respectively, with 1,985 and 428 insertions reported by facilities in Kenya and Zambia, respectively, by mid-2019. In Kenya, 289 adopters of the hormonal IUS were interviewed on the day of insertion (14.6% of hormonal IUS insertions in program-supported facilities), of which 182 (63%) participated in phone interviews. Additionally, 143 copper IUD adopters were interviewed on the day of insertion, with 87 (61%) participating in follow-up phone interviews. In Zambia, 395 adopters of the hormonal IUS were interviewed on the day of insertion (92.3% of hormonal IUS insertions); 246 were postpartum or postabortion clients, of which 40 (16%) participated in phone interviews. Additionally, 359 IUD adopters were interviewed on the day of insertion; 183 were postpartum or postabortion clients, of which 42 (23%) participated in follow-up phone interviews. Day-of-insertion interviews ranged from 1 to 47 per facility in Kenya (0–37 IUS adopters, 0–24 IUD adopters) and from 1 to 121 in Zambia (0–45 IUS adopters, 0–76 IUD adopters). The average time lapse between insertion to follow-up interview was 5 months (range 43–668 days) in Kenya and 10.4 months (range 52–773 days) in Zambia.

Characteristics of Adopters

In Kenya, no statistically significant differences were observed in the characteristics examined between hormonal IUS and IUD adopters (Table 1), although a larger proportion of hormonal IUS adopters were under age 25 (41.2% vs. 30.8%). In Zambia, statistically significant differences were apparent—more hormonal IUS adopters were under age 25 (20.8% vs. 10.3%), were never married (12.7% vs. 6.7%), and had a primary education level or less (52.7% vs. 34.0%). The proportion of high-parity (≥ 5 children) hormonal IUS adopters was larger in Zambia than in Kenya, but not different by method within each country. In Zambia, more adopters had given birth within 48 hours before insertion than in Kenya, although the proportion of adopters within 1 year postpartum was similar between the countries. Within

Zambia, more hormonal IUS adopters received immediate postpartum insertion compared with IUD adopters (27.9% vs. 17.6%), but the difference was not statistically significant.

Among nulliparous and interval adopters (women whose last birth was more than 1 year prior), around half in Kenya and two-thirds in Zambia were switching from a short-acting method. In both countries, around 10% of hormonal IUS and IUD adopters were not switching from another method (Table 2).

Reasons for Choosing a Hormonal IUS

Women were allowed to give multiple reasons for choosing the hormonal IUS; answers were unprompted. Women had diverse reasons for adopting the hormonal IUS. The most commonly mentioned reasons in Kenya were each mentioned by less than 40% of adopters and included the desire for fewer side effects (37%) and the facts that it is reversible (31%), can be used for spacing (30%), and is long-lasting (29%). In Zambia, the ability to use the hormonal IUS for spacing was the only reason mentioned by over half of women (55%); other top reasons included it is long-lasting (36%) and reduces bleeding (36%) (Figure 1). The ability to use it while breastfeeding was not a popular reason, but it was unsurprisingly more often mentioned by postpartum than nonpostpartum adopters (12% vs. 1% in Kenya, 15% vs. 2% in Zambia). Additional statistically significant differences for postpartum versus nonpostpartum adopters were that postpartum adopters in Kenya were more likely to mention reversibility (36% vs. 22%) and less likely to mention reduced bleeding (16% vs. 34%) and postpartum adopters in Zambia were more likely to mention spacing (60% vs. 44%).

If the hormonal IUS had not been available in Kenya, 48% of hormonal IUS adopters would have opted for an implant, 15% an IUD, 30% a short-acting method, and 4.5% a traditional method or no contraception. In Zambia, 37% would have chosen an implant, 15% an IUD, 30% a short-acting method, and 3% a traditional method or no contraception (Figure 2).

When asked why clients chose the hormonal IUS, providers mentioned many of the same reasons as the interviewed women. The desire for fewer side effects came out strongly in the focus groups. Providers explained that women's desire for fewer side effects were, at times, tied to negative experiences using other hormonal methods, and some hormonal IUS adopters had come to

TABLE 1. Sociodemographic Characteristics and Timing of Insertion for Adopters of a Hormonal Intrauterine System or Copper-containing Intrauterine Device in Kenya and Zambia

	Kenya			Zambia		
	Hormonal IUS Adopters (N=289)	Copper IUD Adopters (N=143)	P Value Comparing IUS vs. IUD	Hormonal IUS Adopters (N=395)	Copper IUD Adopters (N=359)	P Value Comparing IUS vs. IUD
Age, years	No. (%)	No. (%)		No. (%)	No. (%)	
<20	25 (8.7)	16 (11.2)	.189	30 (7.6)	11 (3.1)	.029
20–24	94 (32.5)	28 (19.6)		52 (13.2)	26 (7.2)	
25–29	63 (21.8)	33 (23.1)		64 (16.2)	58 (16.2)	
30–34	49 (17.0)	32 (22.4)		88 (22.3)	86 (24.0)	
≥35	48 (16.6)	29 (20.3)		133 (33.7)	137 (38.2)	
Missing	10 (3.5)	5 (3.5)		28 (7.1)	41 (11.4)	
Marital status						
Married	248 (85.8)	122 (85.3)	.569	326 (82.5)	317 (88.3)	.029
Never married	32 (11.1)	19 (13.3)		50 (12.7)	24 (6.7)	
Widowed/divorced	7 (2.4)	2 (1.4)		12 (3.0)	7 (2.0)	
Missing	2 (0.7)	0 (0.0)		7 (1.8)	11 (3.1)	
Education						
None/primary	120 (41.5)	64 (44.8)	.710	212 (53.7)	122 (34.0)	.001
Secondary	98 (33.9)	41 (28.7)		127 (32.2)	137 (38.2)	
Postsecondary	66 (22.8)	34 (23.8)		49 (12.4)	69 (19.2)	
Missing	5 (1.7)	4 (2.8)		7 (1.8)	31 (8.6)	
Parity						
0	12 (4.2)	8 (5.6)	.254	9 (2.3)	11 (3.1)	.333
1–2	141 (48.8)	61 (42.7)		110 (27.9)	89 (24.8)	
3–4	87 (30.1)	42 (29.4)		103 (26.1)	118 (32.9)	
≥5	44 (15.2)	31 (21.7)		159 (40.3)	129 (35.9)	
Missing	5 (1.7)	1 (0.7)		14 (3.5)	12 (3.3)	
Timing of insertion						
Postpartum (<48 hours)	25 (8.7)	13 (9.1)	.725	110 (27.9)	63 (17.6)	.362
Postpartum (48 hours to 1 year)	152 (52.6)	71 (49.7)		119 (30.1)	102 (28.4)	
Postabortion	1 (0.4)	2 (1.4)		17 (4.3)	18 (5.0)	
Not postpregnancy	108 (37.4)	54 (37.8)		143 (36.2)	157 (43.7)	
Missing	3 (1.0)	3 (2.1)		6 (1.5)	19 (5.3)	

Abbreviations: IUD, intrauterine device; IUS, intrauterine system.

the facility with the intent of switching to a method with fewer side effects. Although there was not extensive conversation about the specific side effects women sought to avoid, providers mentioned

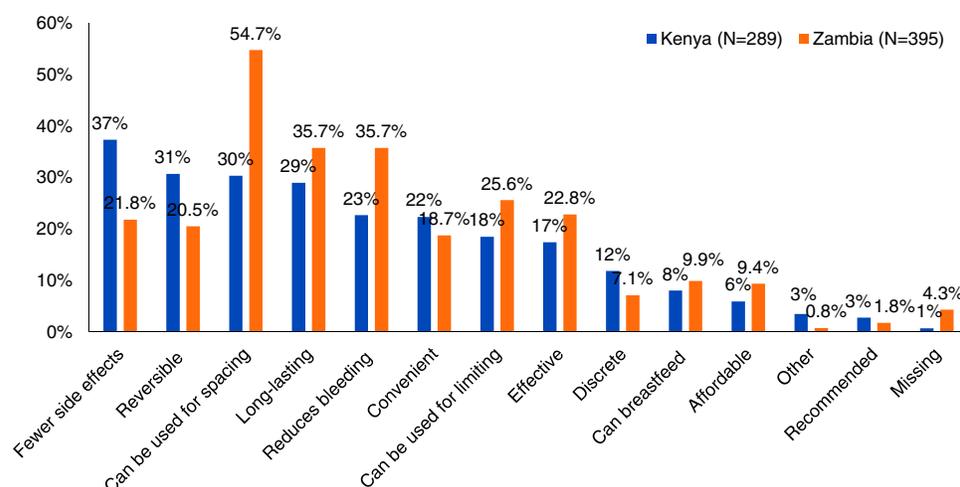
weight changes, reduced sexual desire, and cardiac effects (hypertension or palpitations). Providers reported that clients found it appealing that the hormonal IUS releases less hormone than other

TABLE 2. Interval/Nulliparous Adopters of a Hormonal Intrauterine System or Copper-containing Intrauterine Device in Kenya and Zambia Switching From Other Contraceptive Methods

		Kenya		Zambia	
		Hormonal IUS Adopters (N=108)	Copper IUD Adopters (N=54)	Hormonal IUS Adopters (N=143)	Copper IUD Adopters (N=157)
		No. (%)	No (%)	No. (%)	No. (%)
Long-acting methods	Implant	38 (35.2)	20 (37.0)	24 (16.8)	29 (18.5)
	Other IUD	4 (3.7)	0 (0.0)	7 (4.9)	11 (7.01)
Short-acting methods	Injectable	33 (30.6)	22 (40.7)	74 (51.8)	70 (44.6)
	Pills	10 (9.3)	0 (0.0)	16 (11.2)	24 (15.3)
	Condoms only	3 (2.8)	1 (1.9)	1 (0.7)	4 (2.6)
	Emergency contraceptive pills	1 (0.9)	1 (1.9)	0 (0.0)	2 (1.3)
	CycleBeads	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
	Traditional	1 (0.9)	0 (0.0)	3 (2.1)	0 (0.0)
	LAM	1 (0.9)	1 (1.9)	1 (0.7)	1 (0.6)
Other categories	None	10 (9.3)	4 (7.4)	15 (10.5)	15 (9.6)
	Other	0 (0.0)	0 (0.0)	2 (1.4)	1 (0.6)
	Missing	6 (5.6)	1 (1.9)	0 (0.0)	0 (0.0)

Abbreviations: IUD, intrauterine device; IUS, intrauterine system; LAM, lactational amenorrhea method.

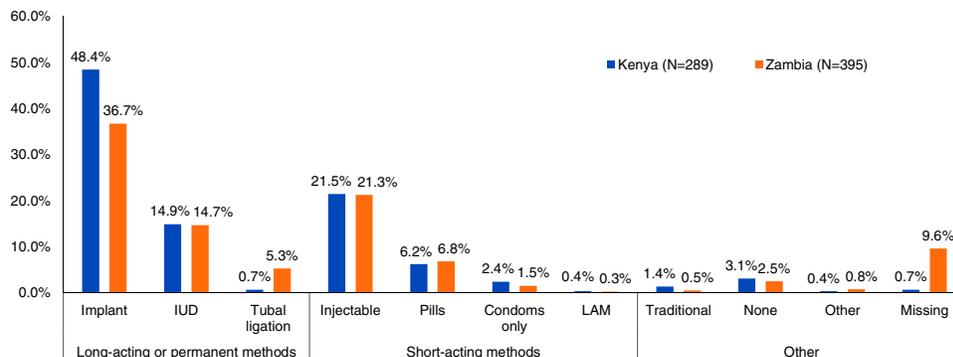
FIGURE 1. Reasons for Choosing the Hormonal Intrauterine System



hormonal methods and that the hormone is localized to the uterus. These features eased women's concerns about side effects and using a hormonal method. Providers also reported women desired

less bleeding to avoid discomfort, inconvenience, and disruption to their lives. The appeal of bleeding reductions came up more frequently in the Kenya interviews. There was no mention of

FIGURE 2. Method That Hormonal Intrauterine System Adopters Would Have Chosen if Hormonal Intrauterine System Had Not Been Available



Abbreviations: IUD, intrauterine device; LAM, lactational amenorrhea method.

negative reactions to reduced bleeding in any focus group.

Maybe the hormonal level in hormonal [IUS] where the hormonal is less and it is concentrated in the uterus most of the time. Personally, as a user of hormonal I have gone into amenorrhoea and that is an advantage. The hormone level is okay with me, I don't feel any palpitations, I don't have any other problem. That is the reason why I choose hormonal. So if you counsel, because with many women they tend to fear hormones, so even when you counsel and tell them that it is a 5-year and it is hormonal, unless you elaborate further that it is a hormone that concentrates mostly in the uterus and very little can be released into the system which will not affect [them], they will go for it. —Kenya, Migori County mentor

Providers mentioned that some women like that the hormonal IUS is long-lasting but not as long-lasting as the IUD (commonly called a “copper T” in reference to the IUD’s shape). This preference implies women are unaware that IUDs can be removed by choice before their full effective period. This lack of awareness may be due to inadequate counseling, misinterpreted marketing, or even difficulty experienced in accessing removals (providers in an FGD in Zambia said women reported resistance from providers when attempting to have an IUD removed before full duration). Whatever the reason, providers shared it can be challenging to overcome the perception that the IUD is only appropriate for women who want 10 years of protection, and some women still feel more comfortable with a method intended for removal within 5 years (the maximum effectiveness for the hormonal IUS at the time these programs

were implemented). The 5-year duration may be especially appealing to adolescents because it aligns well with their reproductive intentions—that is, to finish school and start childbearing soon thereafter.

The other reason is because it takes a shorter period, some women would want to have an [intrauterine device] that does not go up to 12 years like the copper T, so during the counseling when you discuss with them then they tell you, I would rather have this one because previously with the one that takes long, the copper IUD, I realized that because of ineffective counseling sometimes women are not told that whenever you want to have it removed they can just come back, that part sometimes misses that you find clients coming back to you with IUDs that were inserted 20 years ago, so for them if you talk about this, most of them say I would rather have the one with a shorter period. —Kenya, Kisumu County, mentor

Providers also mention that the hormonal IUS can appeal to women who desire fewer visits to a facility, for convenience, cost saving, or, as 1 provider mentioned, to hide the use of contraception from her partner. Few women mentioned the ability to use the method discretely as a reason for choosing it and this reason was likewise only mentioned by a few providers. Still, it could be an important reason for a minority of women.

I have a certain group of clients who don't want their spouses to know that they are using family planning methods yet they want the method. I have a mother who [had 10 previous births]. She just delivered yesterday and the husband is very cruel that he doesn't allow

the mother to take any method. She has twelve children because she had a twin delivery previously. And all these children are alive and the spacing between them is not that good. So we counseled this mother at [antenatal care] so when she was coming for delivery, she just opted up for that method so that the husband will not know but will not take a long time as copper T.
—Kenya, Migori County, mentee

Providers mentioned additional attractive qualities that were not recorded in interviews with women, although discussion was not extensive and these may not be driving reasons for many women. These factors included a bias some women have in favor of a new method, believing it would be superior to methods that have been around a long time; the hormonal IUS does not require an incision; and removal is less painful compared with subcutaneous implants.

Sources of Information and Content of Counseling

Among adopters of the hormonal IUS, 70% in Kenya and 47% in Zambia heard of the method for the first time on the day it was inserted.

Most hormonal IUS adopters in Kenya heard of the method for the first time on the day it was inserted (70%), and 22.5% had heard about it from a provider during a previous visit to the facility. In Zambia, 47% heard about the method for the first time on the day of insertion, and 36% had heard about it from a provider previously (Table 3).

During follow-up interviews, women were asked, without prompting, what physical changes or side effects the provider mentioned at the time

of insertion, and all answers were recorded. In Kenya, most women recalled the provider telling them about potential physical changes or side effects; only 3% of hormonal IUS adopters and 10% of IUD adopters reported the provider did not mention any or could not recall if the provider had mentioned any. The majority of hormonal IUS (76%) and IUD adopters (60%) said the provider mentioned changes in menstrual bleeding and 38% of hormonal IUS adopters and 39% of IUD adopters mentioned abdominal discomfort or pain. Other side effects were mentioned by a small number of women. The majority of women were told what to do if they experienced side effects (93% of hormonal IUS and 85% of IUD adopters). When restricting the analysis to women interviewed within 6 months after insertion, results did not materially change (data not shown). In Zambia, a larger proportion of women reported the provider did not mention any side effects or could not recall if the provider mentioned side effects than in Kenya (30% of hormonal IUS and 21% of IUD adopters). The difference between IUS and IUD adopters within Zambia was not statistically significant in this small sample. Similar to the results in Kenya, the most common side effects women recalled providers discussing were changes in bleeding (43% of hormonal IUS and 31% of IUD adopters) and the majority were told what to do if they experienced side effects (75% of hormonal IUS and 83% of IUD adopters), although the levels were not as high as in Kenya (Table 4).

Although a large proportion of hormonal IUS adopters had not previously heard of the method, a common theme across FGDs with providers was that many women are not willing to try a method they are hearing about for the first time.

Okay, for me, the challenge is just lack of information. The clients are not aware of the method, so when you try to tell them about the method, they will just tell you let me go and think about it, then I will come later.
—Kenya, Kisumu County, mentee

Providers shared that they found it difficult to counsel women who have no baseline awareness of the method and to overcome pervasive rumors about IUDs and contraception, including that IUDs do not stay in place and that contraception can cause cancer or infertility. The providers also shared that some women appeared interested in the method, but were unwilling to start the method that day, needing time to think and to consult their husbands. And a few providers shared stories of women who did receive the method, but then

TABLE 3. Sources of Information on Hormonal Intrauterine System Among Adopters in Kenya and Zambia

	Kenya (N=289) No. (%)	Zambia (N=395) ^a No. (%)
First heard of IUS today	201 (69.6)	187 (47.3)
Health worker another day	65 (22.5)	143 (36.2)
Community health worker	2 (0.7)	24 (6.1)
Family/friend	16 (5.5)	35 (8.9)
Other	3 (1.0)	10 (2.5)
Missing	2 (0.7)	27 (6.8)

Abbreviation: IUS, intrauterine system.
^aIn Zambia, more than 1 answer option was allowed.

TABLE 4. Information Women Reported Receiving From Provider at the Time of Insertion of Hormonal Intrauterine System or Copper-containing Intrauterine Device in Kenya and Zambia

	Kenya		Zambia	
	Hormonal IUS Adopters (N=182) No. (%)	Copper IUD Adopters (N=87) No. (%)	Hormonal IUS Adopters (N=40) No. (%)	Copper IUD Adopters (N=42) No. (%)
Physical changes/side effects mentioned				
Changes in menstrual bleeding	139 (76.4)	52 (59.8)	17 (42.5)	13 (31.0)
Vaginal discharge or infection	8 (4.4)	10 (11.5)	1 (2.5)	2 (4.8)
Headache/migraine	8 (4.4)	3 (3.4)	5 (12.5)	9 (21.4)
Nausea/vomiting	5 (2.7)	1 (1.1)	0 (0.0)	2 (4.8)
Abdominal discomfort/pain	69 (37.9)	34 (39.1)	11 (27.5)	18 (42.9)
Breast tenderness/pain	3 (1.6)	0 (0.0)	0 (0.0)	1 (2.4)
Pelvic discomfort/pain	9 (4.9)	2 (2.3)	1 (2.5)	3 (7.1)
Pain during sex	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.8)
Weight gain or loss	4 (2.2)	1 (1.1)	0 (0.0)	1 (2.4)
Backache	3 (1.6)	1 (1.1)	2 (5.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	8 (20.0)	10 (23.8)
Don't know or no side effects mentioned	6 (3.3)	9 (10.3)	12 (30.0)	9 (21.4)
Missing	22 (12.1)	15 (17.2)	1 (2.5)	0 (0.0)
Told what to do if side effects occurred				
Yes	169 (92.9)	74 (85.1)	30 (75.0)	35 (83.3)
No	8 (4.4)	12 (13.8)	9 (22.5)	6 (14.3)
Missing	5 (2.7)	1 (1.1)	1 (2.5)	1 (2.4)

Abbreviations: IUD, intrauterine device; IUS, intrauterine system.

returned requesting a removal because their husbands did not like the method or did not approve of them using it. Because of these experiences, providers across most of the focus groups appealed for investments in spreading accurate information on the hormonal IUS in the community through mass media, community health workers or volunteers, or community groups so women come to facilities with awareness of the hormonal IUS, openness to using long-acting contraception, and support from their partners.

Although the content of counseling was infrequently discussed, in a couple of instances, providers made a direct link between counseling on side effects and women’s willingness to initiate or continue using contraception. They explained that truthful conversations about side effects meant women were better prepared and were more

trusting of providers if they experienced unwelcomed effects.

Just to add-on to what she has said, like in the counseling there are times when you discover that when people are given counseling at first, the side effects never used to come out. So now we would concur with people as they are mentoring them, you come in the audience without people noticing you and listen to the on-going counseling. They will talk about the benefits as she put it but side effects are not talked about. So mothers would start shunning out family planning, but when you tell the mothers the truth of what they are going to face or to experience the first 3 months of the hormonal IUS and other IUCDs they will understand that this is what I was told and afterwards the side effects go. At least this time it’s coming up bit by bit. —Zambia, Central Province, mentor

Providers appealed for investments in spreading accurate information on the hormonal IUS in the community so women come to facilities with greater awareness of it.

These FGDs cannot be used to assess the quality of counseling, but it should be noted that providers often discussed feeling overworked and complained that facilities were understaffed. A few times during the discussions, providers mentioned that this situation contributed to inadequate counseling.

Not adequately because of lack of personnel so a client will come but I'll feel I am not giving them enough time for counseling.—Kenya, Kisumu County, mentor

In Kenya, 79% of hormonal IUS users had recommended the method to other women and 95% in Zambia would recommend the method.

Satisfaction and Continuation Rates

In Kenya, 79% of hormonal IUS users had recommended the method to other women and 95% in Zambia would recommend the method. In terms of willingness to recommend their method, no difference was found between IUS and IUD adopters. The top benefits that IUS users in Kenya would mention to other women were reduced bleeding (49%), fewer side effects (33%), and the fact that it is long-lasting (29%). The top benefits IUS users in Zambia would mention to other women were convenience (63%), fewer side effects (34%), and high effectiveness (29%) (Table 5).

Among hormonal IUS adopters in Kenya interviewed 3–6 months after insertion, 128 women (86%) were still using the method, 7 (5%) experienced an expulsion, and 11 (7%) had the method removed, and 2 responded “I don’t know” to the question “Is the same IUD still in place, as far as you know?” (plus 1 with missing data). In Zambia, where the average time lapse from insertion to interview was over 10 months with a wide range for a small sample size, 31 women (79%) reported still using the method, 4 (10%) experienced an expulsion, and 4 (10%) had the method removed (plus 1 with missing data). In both countries, continuation rates were slightly higher among IUD users (94% in Kenya, 90% in Zambia) and there were fewer expulsions among IUD users, but the difference between IUS and IUD users was not statistically significant.

Continuation was very high among women who did not report experiencing a “major” problem with the hormonal IUS.

Continuation was very high among women who did not report experiencing a “major” problem with the hormonal IUS (93% in Kenya, 95% in Zambia) and was lower among women who did (60% in Kenya and 56% in Zambia). Among the 11 women who had the hormonal IUS removed in Kenya, 4 did not report having a major problem, and the remaining 7 women reported the following problems: cramping or pain (4), too much bleeding (2), husband disapproval (2), strings were too long

TABLE 5. Hormonal Intrauterine System Users That Have Recommended or Would Recommend the Method to Other Women

	Kenya, No. (%)	Zambia, No. (%)
Recommend Hormonal IUS ^a	N=182	N=40
Yes	144 (79.1)	38 (95.0)
No	34 (18.7)	1 (2.5)
Don’t know	1 (0.5)	1 (2.5)
Missing	3 (1.6)	0 (0.0)
Benefits to mention ^b	N=103	N=38
Reduces bleeding	50 (48.5)	7 (18.4)
Reversible	6 (5.8)	4 (10.5)
Convenient	16 (15.5)	24 (63.2)
Fewer side effects	34 (33.0)	13 (34.2)
Discreet	4 (3.9)	1 (2.6)
Can breastfeed	5 (4.9)	1 (2.6)
Affordable	14 (13.6)	1 (2.6)
Long-lasting	30 (29.1)	8 (21.1)
Highly effective	110 (10.7)	11 (28.9)
Provider recommended	1 (1.0)	0 (0.0)
None	8 (7.8)	0 (0.0)
Other	1 (1.0)	3 (7.9)
Don’t know/missing	30 (29.1)	9 (23.7)

Abbreviation: IUS, intrauterine system.

^a In Kenya, women were asked *have you recommended the method*. In Zambia, women were asked *would you recommend the method*.

^b In Kenya, the question was added midstudy, so the denominator includes only the women who were asked this question. The women were asked what benefits they would mention, regardless of whether they had recommended the method (yes, no, don’t know, or missing to above question). In Zambia, the question was limited to women who would recommend the method (yes to above question).

(2), and irregular bleeding (1). Among 4 removals in Zambia, women reported the following problems: too much bleeding (4), dizziness (2), and cramping or pain (1). For comparison, 15 women still using the IUS in Kenya (12%) reported cramping or pain (8), too much bleeding (2), discharge (2), reduced bleeding (1), irregular bleeding (1), or husband disapproval (1). Ten women still using the IUS in Zambia (32%) reported cramping or pain (6), too much bleeding (3), too little bleeding (2), fever (2), or irregular bleeding (1).

Women were asked about amenorrhea separately. In Kenya, 40 women still using the IUS (31%) reported experiencing amenorrhea, with 7 saying it was a negative change. None who had the IUS removed experienced amenorrhea. In Zambia, 5 women still using the IUS (16%) reported amenorrhea, with 3 saying it was a negative change, and 1 of the 4 who had the IUS removed experienced amenorrhea saying that was a positive change (she reported dizziness as a problem).

In the focus groups, providers frequently expressed confidence that most hormonal IUS adopters were satisfied with the method because they did not return with complaints. Occasionally, providers contrasted the absence of complaints among hormonal IUS adopters with grievances heard from users of other methods.

I feel they are satisfied because so far no one has approached me with any complaint. I have removed copper T, I have removed Implanon and Jadelle, but not hormonal [IUS]. Even those that I meet, when I ask them about the method they tell you they are comfortable. —Zambia, Southern Province, mentor

Providers also reported hearing positive feedback from hormonal IUS users, who said they did not have any problems or were pleased to have fewer side effects than previously experienced with other methods.

We have had interactions with them through other services that they come to seek. Maybe they have come for under-5, maybe they are sick with other ailments then you tend to interact with them and say how are you finding the hormonal [IUS] that you had received from here? They say it's just okay, I thought it would give me problems but there is nothing. Such things, so some of the women are coming out openly to say that there is no problem. And we are just encouraging them also to help us by sensitizing the women in the community because the community believes more their fellow community members than us the health practitioners. —Zambia, Eastern Province, mentee

Providers talked about the powerful influence satisfied users can have within their circle of friends, family, and neighbors when they share their experiences using the method. Some providers reported that satisfied users in their communities led to increased interest among other women. And some providers said they had invited satisfied users to talk to other women with the intention of garnering more demand for the method.

Providers also told stories of women returning with complaints and how they were able to successfully address them with counseling and occasionally through treatment of side effects such as

bleeding. With additional counseling to assuage concerns, providers reported that many women opted to continue using the method and found that the side effects eventually faded. However, a few providers gave examples of women who had bad experiences with the hormonal IUS and actively discouraged other women from using the method.

Providers also recounted cases of hormonal IUS removals. In many of the accounts mentioned, providers believed the male partners were driving the decision to have the method removed and the woman was not necessarily unhappy with the method. In 1 case, the woman even had the provider secretly reinsert the method. Providers also shared examples of women wanting or needing to have the method removed, each for a different reason, including undesired bleeding changes (spotting or excessive bleeding were mentioned), discharge, infection, and diagnosis of hypertension.

■ DISCUSSION

This study provides information on characteristics of women who adopted the hormonal IUS in public facilities in 2 low-income countries. Generally, these characteristics are likely correlated with the profile of the typical family planning clientele of these facilities, which probably accounts for many differences in hormonal IUS adopters across countries and studies. A large proportion of Kenyan adopters in this study and a prior study of postpartum adopters at a public facility in Kenya¹¹ were young (41% under 25 years in this study and 51% in the previous study) and had low educational attainment (41.5% with primary level or less in this study and 61.5% in the previous study). In this study, adopters were older in Zambia (47% were ≥35 years) and educational attainment was lower (54% with primary or less). Adopters recruited at hospitals in a prior study in Ghana were older than those in either Kenya study, with a similar age distribution to our population in Zambia (31% age ≥35 years) but were more highly educated than adopters in Kenya or Zambia.¹⁵ Adopters recruited from social franchise and outreach sites in a prior study in Nigeria were even older (47% age ≥35 years) and highly educated (70% had secondary or higher education).¹³ Adopters were mostly married in both countries in this study as well as in the previous studies in Kenya, Ghana, and Nigeria, suggesting that specific outreach may be necessary to increase use among unmarried women in many contexts.

Providers talked about the powerful influence satisfied users can have within their circle of friends, family, and neighbors.

Comparisons of hormonal IUS to IUD adopters at the same facilities allows additional insight into whether hormonal IUS appeals to a different set of women. The results from this study suggest that hormonal IUS may appeal more to young women than the IUD since a greater proportion of hormonal IUS adopters were under age 25 in both countries (although the differences was not statistically significant in Kenya). More adopters of the hormonal IUS in Zambia were never married and had lower educational attainment, which may be attributable to the differences in the age profile. Provider testimonies that shorter duration of effectiveness is a favorable attribute of the hormonal IUS could explain why the method may be more appealing to younger women than IUDs, as they may want to become pregnant in the near to intermediate term.

Many adopters would have opted for a short-acting or traditional method or none at all, if the hormonal IUS had not been an option.

A substantial proportion of women choosing the hormonal IUS (35% in Kenya and 33% in Zambia) would have opted for a short-acting or traditional method or none at all, if the hormonal IUS had not been an option. This finding is similar to what Hubacher et al.¹¹ found among postpartum adopters in Kenya (30.5% would have chosen a short-acting method instead) and higher than what Eva et al.¹³ found among social franchise and outreach clients in Nigeria (20% would have chosen a short-acting, traditional, or no method). Both previous studies concluded that some women are willing to try the hormonal IUS because of its features and do not see it as interchangeable with other long-acting methods. We reached the same conclusion, among a broader population of hormonal IUS adopters accessing contraception at public facilities, adding to the evidence that the hormonal IUS has features that appeal to women that they may not find in other LARCs. Adding hormonal IUS to the method mix could increase the proportion of women opting for a LARC. At the same time, some adopters were already using a long-acting method (39% of non-postpartum adopters in Kenya and 22% in Zambia were switching from another long-acting method, mainly implants), suggesting that some women using LARCs are not completely satisfied with their methods and would prefer to try a LARC with different features.

Women gave diverse reasons for choosing the method, suggesting that it can appeal to women wishing to adopt contraception for a broad range of reasons.

As in other studies, women gave a range of reasons for choosing the hormonal IUS. A desire for fewer side effects emerged at the top. Among adopters we interviewed, 37% in Kenya mentioned hormonal IUS having fewer side effects than other methods and 23% specifically mentioned reduced bleeding. In Zambia, 22% mentioned fewer side

effects and 36% specifically mentioning reduced bleeding. Users of the hormonal IUS also reported that fewer side effects and reduced bleeding were benefits they would mention to other women when recommending the method. A desire for fewer side effects was also a popular reason for women in past studies.^{11,13,15,30} The fact that it can be used discretely was not mentioned as frequently by women in this study (12% in Kenya, 7% in Zambia) compared with past studies in Kenya (23%)¹¹ or Nigeria (42%).¹³ However, it may be an important reason for a minority of women based on stories shared by providers during FGDs. Given that some women like the long, but not too long, duration of effectiveness and that reversibility was a popular reason, the immediate return to fertility after IUS removal may be an important consideration to emphasize during counseling and marketing, especially with younger clients. Overall, women gave diverse reasons for choosing the method in this study and previous ones, suggesting that it can appeal to women wishing to adopt contraception for a broad range of reasons.

Many hormonal IUS adopters had never previously heard of the method. Providers reported that lack of awareness of the method among their clients handicapped uptake, but they saw potential for further growth in interest in hormonal IUS if information on the method could be disseminated through community channels. Although few adopters reported hearing about the method from family or friends, providers believed that satisfied users can be powerful assets to encourage other women to try the method. The critical role of satisfied users to increasing demand for IUDs has been shown in past research.^{13,31} The qualitative interviews also reinforce the importance of educating and engaging male partners, since they often influence or even determine women's decision to adopt or continue using contraception. Yet we recognize the need for nuance in male engagement. For a subset of women, it may be important to be able to use contraception covertly and counseling couples together could have unintended consequences.³²

Most women reported being told what to do if they experienced side effects, and many recalled being told about bleeding changes and abdominal pain, although other side effects were rarely recalled and may not have been emphasized or mentioned at all. Providing clients with information about contraceptive methods in general and their chosen method in particular is associated with improved continuation.³³ A few providers talked about this link during FGDs, while at the

same time, providers suggested counseling may not have always been as high quality as they thought was ideal.

Despite some indications that the quality of counseling before insertion was not always optimal, user satisfaction levels were high, as evidenced by the high proportion of users who would recommend the hormonal IUS to other women. We also found a high level of continuation among women in Kenya 3–6 months after insertion (86%), on par with the rate seen in a previous study in Kenya at 12 months (89%).¹⁴ Continuation was slightly lower in Zambia (78%), but the sample was extremely small and some women were interviewed close to 2 years after insertion. Even among women that reported experiencing what they perceived to be a major problem, the majority continued to use the method. Additionally, only a minority of women experiencing amenorrhea felt negatively about that change (in Kenya; the numbers were very small in Zambia). Earlier studies also showed that amenorrhea or reduced bleeding may be welcomed by many users, but be an unwelcome change for some.^{13,34} Good counseling before insertion is critical to ensure that a woman selects a method that aligns with her preferences, and it is also an important aspect of follow-up care to reduce discontinuation. Providers shared experiences with successfully addressing concerns among women returning to facilities citing problems with the method. However, we did not collect data from women who experienced problems on why they continued to use the method and how interactions with providers contributed to that decision.

Uptake of the hormonal IUS was higher in Kenya than Zambia. Two prolonged health care worker strikes (December 2016 to March 2017 and June–November 2017) disrupted services in Kenya during the study period, but demand quickly recovered after each strike ended. The difference between countries may be partially explained by general trends in contraceptive use in each country. The modern contraceptive prevalence rate (mCPR) was 34.1% in Zambia in 2018.³⁵ In Kenya, mCPR was 39.1% in 2014³⁶ and seems to have increased in the intervening years, with mCPR being 44.6% across 11 counties included in the Performance Monitoring and Accountability 2020 Survey conducted in 2018.³⁷ IUD use is low in both countries, but higher in Kenya (2.3% in 2014³⁶) than in Zambia, where it declined from 0.9% in 2014³⁸ to 0.5% in 2018.³⁵ The difference in uptake between countries may also be explained by implementation factors, including the focus on

training maternity providers in Zambia and the wide geographic spread of implementation sites in Zambia across 4 provinces, presenting challenges to managing commodities and monitoring the mentorship process. Assessing the contribution of these factors to uptake, however, is beyond the scope of this article.

For context, we compared the number of IUS insertions in project-supported facilities to MOH data from the same facilities over the same period. In Kenya, we reported 1,985 IUS insertions over a period when approximately 8,000 total intrauterine insertions (IUS + IUDs) and 37,000 implant insertions were reported by the same facilities. In Zambia, we reported 428 IUS insertions over a period when approximately 2,700 total intrauterine insertions (IUS + IUDs) and 16,000 implant insertions were reported by the same facilities. (MOH numbers in Zambia are underreported because we were unable to get data from 7 facilities, plus 6 facilities reported fewer intrauterine insertions than the number interviewed for this study.)

We found wide variation in uptake across facilities. In some participating facilities, no IUS insertions were reported. We know from project reports and focus groups that some trained providers were transferred to different facilities and some did not yet feel comfortable in their skills. As mentioned above, providers reported challenges in offering a new method that women were not familiar with. From the MOH data, we also see a wide range across participating facilities in terms of total LARC insertions. Adoption of new practices is often uneven, although it could be improved with careful tracking and by quickly responding when providers are transferred or are found to not be adequately skilled. Investments in widespread demand creation could also support more even adoption.

Limitations

Study limitations include that findings may not be representative of all women receiving a hormonal IUS; in Kenya, only around 15% of women receiving the IUS were interviewed at the time of insertion, either because women refused to participate or providers did not take the time to enroll all eligible women. We do not know if interviewed adopters were different from those not interviewed in ways that might affect the results presented in this article. In both countries, the study conducted follow-up phone interviews with a minority of adopters because many women were unable or unwilling to share phone numbers or did

User satisfaction levels were high, as evidenced by the high proportion of users who would recommend the hormonal IUS to other women.

not answer their phones after multiple attempts to reach them. Data from follow-up interviews are thus likely biased toward women who have greater phone access, including women with a higher income. We did not track how many insertions were done by providers who were still in training, but it is likely to be many because there was a long training and mentorship process before certification. It is possible that clients' experience of care, satisfaction, and continuation may shift over time as the number of more experienced providers increases. In Kenya, we conducted fewer interviews with IUD adopters than IUS adopters, which affected our ability to detect statistically significant differences between the groups. Results from follow-up interviews are subject to recall bias. In addition, women were interviewed at very different time points after insertion, so data on continuation have to be interpreted cautiously. Qualitative interviews were conducted with providers only, and there may have been a social desirability bias, especially since program staff were in attendance to assist the qualitative interviews and interviews were conducted on project premises. Also, MOH may have identified providers that were high performing or held more positive views on the training and mentorship experience to participate in the interviews.

CONCLUSION

Expanding access to the hormonal IUS through the public sector as part of a range of contraceptive choices shows promise to increase overall use of contraception and continuation in both Kenya and Zambia. Supporting providers to acquire skills in both counseling and insertion is essential and efficiencies can be gained if integrated within efforts to fill LARC competency gaps, rather than offering stand-alone hormonal IUS training, although proficient LARC providers only need tailored support to add this method to their skillset. Ensuring that training includes skills for insertion in interval, postabortion, and immediate postpartum services can improve the diversity of clients who benefit from this method and requires only a marginal additional investment. Efforts to strengthen availability of the services should not ignore demand-related efforts and engaging directly with various communities around the availability of a new LARC option with its own method characteristics. These communities could include youth groups and channels for unmarried women as well as men. With global donors and multilateral agencies planning to introduce hormonal IUS as part of offerings

for commodity donations to countries, there will be more opportunities for women in LMICs to access and voluntarily opt for this method.

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REFERENCES

- Fraser IS. Added health benefits of the levonorgestrel contraceptive intrauterine system and other hormonal contraceptive delivery systems. *Contraception*. 2013;87(3):273–279. [CrossRef](#). [Medline](#)
- Fraser IS. Non-contraceptive health benefits of intrauterine hormonal systems. *Contraception*. 2010;82(5):396–403. [CrossRef](#). [Medline](#)
- Hubacher D. The levonorgestrel intrauterine system: reasons to expand access to the public sector of Africa. *Glob Health Sci Pract*. 2015;3(4):532–537. [CrossRef](#). [Medline](#)
- Hubacher D, Finer LB, Espey E. Renewed interest in intrauterine contraception in the United States: evidence and explanation. *Contraception*. 2011;83(4):291–294. [CrossRef](#). [Medline](#)
- Jacobstein R, Shelton JD. The levonorgestrel intrauterine system: a pragmatic view of an excellent contraceptive. *Glob Health Sci Pract*. 2015;3(4):538–543. [CrossRef](#). [Medline](#)
- Rademacher KH, Solomon M, Brett T, et al. Expanding access to a new, more affordable levonorgestrel intrauterine system in Kenya: service delivery costs compared with other contraceptive methods and perspectives of key opinion leaders. *Glob Heal Sci Pract*. 2016; 4(Suppl 2):S83–S93. [CrossRef](#). [Medline](#)
- Ross J, Stover J. Use of modern contraception increases when more methods become available: analysis of evidence from 1982–2009. *Glob Health Sci Pract*. 2013;1(2):203–212. [CrossRef](#). [Medline](#)
- Bednarek PH, Jensen JT. Safety, efficacy and patient acceptability of the contraceptive and non-contraceptive uses of the LNG-IUS. *Int J Womens Health*. 2010;1(1):45–58. [CrossRef](#). [Medline](#).
- Sedgh G, Ashford LS, Hussain R. *Unmet Need for Contraception in Developing Countries: Examining Women's Reasons for Not Using a Method*. Guttmacher Institute; 2016. Accessed February 15, 2021. https://www.guttmacher.org/sites/default/files/report_pdf/unmet-need-for-contraception-in-developing-countries-report.pdf
- Bradley SE, Schwandt HM, Khan S. *Levels, Trends, and Reasons for Contraceptive Discontinuation*. DHS Analytical Studies No. 20. ICF Macro; 2009. Accessed February 15, 2021. <https://www.dhsprogram.com/pubs/pdf/AS20/AS20.pdf>
- Hubacher D, Masaba R, Manduku CK, Veena V. Uptake of the levonorgestrel intrauterine system among recent postpartum women in

- Kenya: factors associated with decision-making. *Contraception*. 2013;88(1):97–102. [CrossRef](#). [Medline](#)
12. Hubacher D, Akora V, Masaba R, Chen M, Veena V. Introduction of the levonorgestrel intrauterine system in Kenya through mobile outreach: review of service statistics and provider perspectives. *Glob Health Sci Pract*. 2014;2(1):47–54. [CrossRef](#). [Medline](#)
 13. Eva G, Nanda G, Rademacher K, et al. Experiences with the levonorgestrel intrauterine system among clients, providers, and key opinion leaders: a mixed-methods study in Nigeria. *Glob Health Sci Pract*. 2018;6(4):680–692. [CrossRef](#). [Medline](#)
 14. Hubacher D, Masaba R, Manduku CK, Chen M, Veena V. The levonorgestrel intrauterine system: cohort study to assess satisfaction in a postpartum population in Kenya. *Contraception*. 2015;91(4):295–300. [CrossRef](#). [Medline](#)
 15. Nyarko P, Adohinzin C, Tapsoba P, et al. *Acceptability and Promotion Strategies for LNG-IUS in Ghana: A Public Health Assessment*. Population Council; 2009. Accessed February 15, 2021. https://knowledgecommons.popcouncil.org/cgi/viewcontent.cgi?article=2161&context=departments_sbsr-rh
 16. Bradley SEK, Shiras T. *Sources for Family Planning in 36 Countries: Where Women Go and Why It Matters*. Sustaining Health Outcomes through the Private Sector Plus Project, Abt Associates; 2020. Accessed February 15, 2021. <https://www.shopsplusproject.org/resource-center/sources-family-planning-36-countries>
 17. Neukom J, Chilambwe J, Mkwandawire J, Mbewe RK, Hubacher D. Dedicated providers of long-acting reversible contraception: new approach in Zambia. *Contraception*. 2011;83(5):447–452. [CrossRef](#). [Medline](#)
 18. Dehingia N, Dixit A, Averbach S, et al. Family planning counseling and its associations with modern contraceptive use, initiation, and continuation in rural Uttar Pradesh, India. *Reprod Health*. 2019; 16(1):178. [CrossRef](#). [Medline](#)
 19. U.S. Agency for International Development (USAID). *Kenya: Afya Halisi*. USAID; 2020. Accessed February 15, 2021. https://www.usaid.gov/sites/default/files/documents/Afya_Halisi_fact_sheet.pdf
 20. U.S. Agency for International Development (USAID)/Zambia Health Office. *Safe Motherhood 360+*. Fact Sheet. USAID; 2020. Accessed February 15, 2021. <https://www.usaid.gov/zambia/fact-sheets/usaidzambia-health-office-safe-motherhood-360-1>
 21. Rademacher KH, Sripipatana T, Pfitzer A, et al. A global learning agenda for the levonorgestrel intrauterine system (LNG IUS): addressing challenges and opportunities to increase access. *Glob Health Sci Pract*. 2018;6(4):635–643. [CrossRef](#). [Medline](#)
 22. Willcox M, LeFevre A, Mwebaza E, Nabukeera J, Conecker G, Johnson P. Cost analysis and provider preferences of low-dose, high-frequency approach to in-service training programs in Uganda. *J Glob Health*. 2019;9(1):010416. [CrossRef](#). [Medline](#)
 23. Willcox M, Harrison H, Asiedu A, Nelson A, Gomez P, LeFevre A. Incremental cost and cost-effectiveness of low-dose, high-frequency training in basic emergency obstetric and newborn care as compared to status quo: part of a cluster-randomized training intervention evaluation in Ghana. *Global Health*. 2017;13(1):88. [CrossRef](#). [Medline](#)
 24. Maternal and Child Survival Program (MCSP). *Long-acting Reversible Contraceptives Learning Resource Package*. MCSP; 2017. Accessed February 15, 2021. <https://www.mcsprogram.org/resource/providing-long-acting-reversible-contraception-larc-learning-resource-package/>
 25. Rowe AK, Rowe SY, Peters DH, Holloway KA, Chalker J, Ross-Degnan D. Effectiveness of strategies to improve health-care provider practices in low-income and middle-income countries: a systematic review. *Lancet Glob Health*. 2018;6(11):e1163–e1175. [CrossRef](#). [Medline](#)
 26. Bluestone J, Johnson P, Fullerton J, Carr C, Alderman J, BonTempo J. Effective in-service training design and delivery: evidence from an integrative literature review. *Hum Resour Health*. 2013;11(1):51. [CrossRef](#). [Medline](#)
 27. Maternal and Child Survival Program (MCSP). *Mentoring for Human Capacity Development: Implementation Principles and Guidance*. MCSP; 2018. Accessed February 15, 2021. <https://www.mcsprogram.org/resource/mentoring-human-capacity-development-implementation-principles-guidance/>
 28. Danna K, Jackson A, Mann C, Harris D. *Lessons Learned From the Introduction of the Levonorgestrel Intrauterine System (LNG-IUS) in Zambia and Madagascar*. PSI; 2020. Accessed February 15, 2021. https://www.psi.org/wp-content/uploads/2020/02/IUSCaseStudy_d7-digital.pdf
 29. Ziebland S, McPherson A. Making sense of qualitative data analysis: an introduction with illustrations from DIPEx (personal experiences of health and illness). *Med Educ*. 2006;40(5):405–414. [CrossRef](#). [Medline](#)
 30. Nanda G, Rademacher K, Solomon M, Mercer S, Wawire J, Ngahu R. Experiences with the levonorgestrel-releasing intrauterine system in Kenya: qualitative interviews with users and their partners. *Eur J Contracept Reprod Health Care*. 2018;23(4):303–308. [CrossRef](#). [Medline](#)
 31. Gottert A, Jacquin K, Rahaivondrafahitra B, Moracco K, Maman S. Influences on women’s decision making about intrauterine device use in Madagascar. *Contraception*. 2015;91(4):289–294. [CrossRef](#). [Medline](#)
 32. Ashraf N, Field E, Lee J. Household bargaining and excess fertility: an experimental study in Zambia. *Am Econ Rev*. 2014;104(7):2210–2237. [CrossRef](#)
 33. Jain A, Aruldas K, Tobey E, Mozumdar A, Acharya R. Adding a question about method switching to the method information index is a better predictor of contraceptive continuation. *Glob Health Sci Pract*. 2019;7(2):289–299. [CrossRef](#). [Medline](#)
 34. Polis CB, Hussain R, Berry A. There might be blood: a scoping review on women’s responses to contraceptive-induced menstrual bleeding changes. *Reprod Health*. 2018;15(1):114. [CrossRef](#). [Medline](#)
 35. Zambia Central Statistical Agency (CSO), Zambia Ministry of Health (MOH), ICF International. *Zambia Demographic and Health Survey 2018: Key Indicators*. CSO, MOH, ICF; 2019. Accessed February 15, 2021. <https://www.zamstats.gov.zm/phocadownload/Demography/ZDHS%20Key%20Indicator%20Report%202018.pdf>
 36. Kenya National Bureau of Statistics (KNBS) Kenya Ministry of Health (MOH), Kenya National AIDS Control Council, Kenya Medical Research Institute, Kenya National Council for Population and Development, ICF International. *Kenya Demographic and Health Survey 2014*. KNBS, ICF; 2015. Accessed February 15, 2021. <https://dhsprogram.com/pubs/pdf/FR308/FR308.pdf>
 37. International Centre for Reproductive Health Kenya (ICRHK) and the Bill & Melinda Gates Institute for Population and Reproductive Health at the Johns Hopkins Bloomberg School of Public Health. *Performance Monitoring and Accountability 2020 (PMA2020) Survey Round 7, PMA2018/Kenya R-7 Snapshot of Indicators*. ICRHK, Johns Hopkins Bloomberg School of Public Health; 2018. Accessed February 15, 2021. <https://www.pmadata.org/countries/kenya/kenya-indicators/pma2017kenya-round-7-indicators>
 38. Zambia Central Statistical Agency (CSO), Zambia Ministry of Health (MOH), ICF International. *Zambia Demographic and Health Survey 2013–14*. CSO, MOH, ICF; 2014. Accessed February 15, 2021. <https://dhsprogram.com/pubs/pdf/FR304/FR304.pdf>

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Economic Evaluation of Provision of Postpartum Intrauterine Device Services in Bangladesh and Tanzania

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Key Findings

- Delivering family planning counseling and offering the immediate postpartum intrauterine device (PPIUD) was found to be cost-effective compared to the standard PFP practice.
- The PPIUD program resulted in an incremental cost-effectiveness ratio of US\$14.60 per couple years of protection (CYP) and US\$91.13 per disability-adjusted life year (DALY) averted in Bangladesh and US\$54.57 per CYP and US\$67.67 per DALY averted in Tanzania.
- It is likely that national rollout of PFP counseling and PPIUD delivery will save costs to the health care system in both countries.

Key Implications

- There is a strong case for governments and donors to invest in providing high-quality family planning counseling during antenatal care and around the time of delivery and to include PPIUD within PFP provision immediately following delivery.
- National provision of PPIUD could produce long-term savings in health care costs due to the decrease in unplanned pregnancies resulting from increased PFP uptake.
- PPIUD could be even better value if health care providers receive preservice training in this method and if PPIUD delivery was rolled out nationally.

ABSTRACT

Introduction: Postpartum family planning is an effective means of achieving improved health outcomes for women and children, especially in low- and middle-income settings. We assessed the cost-effectiveness of an immediate postpartum intrauterine device (PPIUD) initiative compared with standard practice in Bangladesh and Tanzania (which is no immediate postpartum family planning counseling or service provision) to inform resource allocation decisions for governments and donors.

Methods: A decision analysis was constructed to compare the PPIUD program with standard practice. The analysis was based on the number of PPIUD insertions, which were then modeled using the Impact 2 tool to produce estimates of cost per couple-years of protection (CYP) and cost per disability-adjusted life years (DALYs) averted. A micro-costing approach was used to estimate the costs of conducting the program, and downstream cost savings were generated by the Impact 2 tool. Results are presented first for the program as evaluated, and second, based on a hypothetical national scale-up scenario. One-way sensitivity analyses were conducted.

Results: Compared to standard practice, the PPIUD program resulted in an incremental cost-effectiveness ratio (ICER) of US\$14.60 per CYP and US\$91.13 per DALY averted in Bangladesh, and US\$54.57 per CYP and US\$67.67 per DALY averted in Tanzania. When incorporating estimated direct health care costs saved, the results for Bangladesh were dominant (PPIUD is cheaper and more effective versus standard practice). For Tanzania, the PPIUD initiative was highly cost-effective, with the ICER (incorporating direct health care costs saved) estimated at US\$15.20 per CYP and US\$18.90 per DALY averted compared to standard practice. For the national scale-up model, the results were dominant in both countries.

Conclusions/Implications: The PPIUD initiative was highly cost-effective in Bangladesh and Tanzania, and national scale-up of PPIUD could produce long-term savings in direct health care costs in both countries. These analyses provide a compelling case for national governments and international donors to invest in PPIUD as part of their family planning strategies.

INTRODUCTION

Postpartum family planning (PFP) is widely recognized as an important approach to achieving progress towards improved health outcomes for women and children.¹⁻³ The World Health Organization (WHO) advises a minimum of 24 months between a live birth and trying for the next pregnancy⁴ owing to the

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Provision of immediate PPIUD leads to a lower risk of future unintended pregnancies and higher continued use at 6 months, versus IUD provided later.

This economic evaluation of the PPIUD initiative in Bangladesh and Tanzania aims to inform efforts to increase access to PPFPP counseling and PPIUD provision.

increased risks to the mother and child of short interpregnancy intervals (the definition of which differs across studies), including miscarriage, induced abortion, stillbirth, preterm birth, low birth weight, infant mortality, and child malnutrition.⁵⁻⁹ Many contraceptive methods are now considered safe to use postpartum, even among breastfeeding women.^{10,11} In addition, the increasing number of women in low- and middle-income countries (LMICs) attending antenatal care and delivering in health facilities means that discussing PPFPP during antenatal care and at the time of delivery and offering effective postpartum contraception immediately postpartum are now key ways to reduce the risk of unintended pregnancies.^{3,5,7,12}

Although many women who give birth do not want another pregnancy within 12 months,¹³ births at short interpregnancy intervals are not uncommon, especially in LMICs.¹⁴ PPFPP use remains low and is mostly unchanged over the last decade, particularly across Africa,¹⁵ resulting in high unmet need among postpartum women for both spacing and limiting births.^{13,14,16} Institutional delivery and child immunization are the factors most correlated with voluntary uptake of modern PPFPP,^{15,17} and several studies have demonstrated the importance of good-quality counseling and community involvement to increasing PPFPP acceptance.¹⁸⁻²⁰ Challenges identified for PPFPP uptake include perceived low risk of pregnancy during the postpartum period among both providers and women, low rates of facility deliveries, and (perceived or real) cultural resistance to family planning, particularly during the postpartum period.^{2,21} The latest WHO Medical Eligibility Criteria (MEC) guidance in 2015 included several additional methods that can be initiated immediately postpartum.¹⁰ Before this guideline change, PPFPP was often not discussed until the 6-week follow-up visit, which many women do not attend and which comes after the return of fertility for women who are not exclusively breastfeeding.

Long-acting reversible contraceptives (LARCs) have the potential to be an important component of PPFPP programs, especially because they have very low failure rates, do not require resupply visits, and can be reversed. Women who do use PPFPP mostly use short-acting methods, and very few use a postpartum intrauterine device (PPIUD).^{13,14} The WHO MEC guidance states that long-acting methods (intrauterine devices [IUDs], intrauterine systems [IUSs], and implants), can be used immediately postpartum.¹⁰ They are also appropriate for breastfeeding women; IUDs can be used without

restrictions, and implants and IUSs are methods for which the advantages of use generally outweigh the risks.¹⁰ IUSs and implants have high costs, which means that IUSs are rarely available in LMICs, and the availability of implants frequently depends on subsidies or donor supplies rather than national government purchasing.²²⁻²⁴

The copper IUD has been available in both LMICs and high-income countries for decades as an interval method (after 6 weeks postpartum), but it has not been routinely used immediately postpartum.²⁵ Provision of immediate PPIUD leads to a lower risk of future unintended pregnancies and higher continued use at 6 months, compared with IUD provided at a later time.²⁶ Although previous studies reported higher expulsion rates for immediate PPIUD compared with insertions at other times,²⁶⁻²⁸ 2 recent studies showed that when Kelly forceps are used to ensure correct placement at the fundus of the uterus, expulsion rates of immediate PPIUD insertion are comparable to interval insertion (<5%).^{29,30} Several programs in both high- and low-income countries have demonstrated that immediate PPIUD is a safe method with low expulsion and discontinuation rates and high acceptance among providers and clients.^{11,27,31-34} Immediate PPIUD also offers cost and time savings to women since they do not have to return to the facility to receive their PPFPP method and can combine their follow-up visit with their routine postpartum checkup.

Recent global efforts have focused on expanding family planning access, including PPFPP, through programs such as FP2020.^{12,35} However, the funding landscape is changing, with uncertainty in the continuity of donor funding and increasing expectation for LMICs to financially sustain their own health services, such as through national health insurance schemes.^{36,37} Advocating for sufficient investment for widescale provision of PPFPP counseling and PPIUD provision is hindered by a limited number of studies and a consequent gap in the evidence base on the cost-effectiveness of these approaches.

The International Federation of Gynecology and Obstetrics (FIGO) conducted a PPIUD initiative between 2013 and 2020 across 6 countries in Africa and Asia. Published analyses from the initiative have demonstrated the feasibility and safety of immediate PPIUD provision, with almost 37,000 PPIUDs inserted between May 2014 and September 2017 in the 6 countries, a low expulsion rate of 2.6% overall, and no cases of uterine perforation.²⁹ Our study presents an economic evaluation based on the implementation of the PPIUD initiative in Bangladesh and Tanzania,

which was led by FIGO and its national member societies—the Obstetrical and Gynaecological Society of Bangladesh, the Association of Gynaecologists and Obstetricians of Tanzania, and the Tanzanian Midwifery Association. The aim of the evaluation is to inform future national and global efforts to increase access to PPFPP counseling and PPIUD provision.

METHODS

Target Population, Setting, and Location

The target population was women in Tanzania and Bangladesh attending the facilities participating in the FIGO PPIUD initiative for delivery (6 facilities in each country). All the participating facilities were large tertiary teaching and referral hospitals. In both countries, counseling on postpartum contraception was offered when women were admitted for delivery, as well as during antenatal care at these facilities. In Tanzania, it was also offered during antenatal care at 26 satellite facilities linked to the participating hospitals.

Intervention (PPIUD Initiative and Context)

The most recent Demographic and Health Surveys (DHS) found that in Bangladesh, 12% of married women of reproductive age have an unmet need for family planning and 52% use modern

contraception.³⁸ In Tanzania, 22% of married women have an unmet for family planning and just 32% use a modern contraceptive method.³⁹ In both countries, less than 1% of women choose to use an IUD (Table 1).^{38–42} Most women in both countries receive at least one antenatal care visit, and almost half of women in Bangladesh and two-thirds of women in Tanzania deliver at a health facility.

The economic evaluation focused on the second phase of the FIGO PPIUD initiative, which ran from January 2015 to June 2018. Full details of the FIGO PPIUD initiative were published previously.³³ In short, the PPIUD initiative included training on and the provision of PPFPP counseling (on all postpartum methods), PPIUD insertion (if eligible and voluntarily chosen), and follow-up at 6 weeks. Each country established a central project team at national professional societies to develop and roll out the PPIUD initiative at 6 large tertiary teaching and referral hospitals. In both countries the national teams consisted of 6 project staff, although not all were employed full-time by the PPIUD project. One facility coordinator and one deputy facility coordinator, both clinicians, oversaw the project at each participating facility in each country.

Based on shared lessons learned among the 6 countries involved in the PPIUD initiative, an

TABLE 1. Country Demographic and Health Data^a

	Bangladesh ³⁸	Tanzania ³⁹
2018 population, millions ⁴⁰	161.4	56.3
2018 population density, people/km ² of land area ⁴⁰	1,240	64
Total fertility rate, births per woman	2.3	5.2
Use of modern method of contraception, ^b %	51.9	32
Family planning uptake at 1–2 months postpartum, % ⁴¹	13.2	9.2 ^c
Unmet need for family planning, ^b %	12.0	22.1
Use of intrauterine device, ^b %	0.6	0.9
Received antenatal care at least once from a medically trained provider, ^{d,e} %	81.9	98.0
Delivered at a health facility, ^{d,e} %	49.4	62.6
Deliveries attended by a skilled provider, ^d % ⁴²	52.7	63.6

^a Source: Demographic and Health Survey, unless otherwise stated.

^b Among currently married women aged 15–49 years.

^c Tabulations based on use of family planning obtained from the reproductive calendar (average of use in time span postpartum), births 12–23 months preceding the interview, based on Bangladesh DHS 2011 and Tanzania DHS 2010.

^d Among women aged 15–49 years who had a live birth within 3 years of the survey.

^e Medically trained providers include qualified doctor, nurse, midwife, family welfare visitor, and community skilled birth attendant. For antenatal care, medically trained providers also include paramedics, medical assistants, or subassistant community medical officer.

Immediate PPFp, including provision of IUDs at or around the time of delivery, is not currently standard practice in government health facilities in Bangladesh or Tanzania.

initial “training of trainer” session was held, after which all training of trainer and cascade trainings were conducted by national staff on the PPIUD project team. Existing clinical staff at the participating facilities were trained on PPFp counseling and immediate PPIUD insertion. In Bangladesh, 1,160 providers (predominantly doctors) were trained in PPIUD insertion and training lasted 1 day (note this number includes some providers who were trained more than once). Due to the high flow of clients in the Bangladesh facilities, 28 dedicated postpartum contraceptive counselors were also recruited and received an initial 2.5-day training followed by a half-day refresher training the following year. In Tanzania, 1,113 providers received a 3-day PPIUD insertion training, and 1,515 received a 3-day PPFp counseling training. The health care providers trained in PPIUD insertion in Tanzania were a mix of doctors, nurses, and nurse-midwives, and the training content was adapted to suit all cadres and to align with national requirements.

No community-level demand generation activities were included as part of the initiative in these 2 countries, although leaflets and informative videos were produced as an adjunct to counseling in the hospitals as part of the PPIUD initiative. Voluntary insertion of a Copper T 380A IUD was available to any woman who was medically eligible, voluntarily consented to receive an IUD, and attended a PPIUD initiative facility for delivery.

For the initiative and this evaluation, a PPIUD was defined as an IUD inserted immediately following delivery, before the woman was discharged. This could be within 10 minutes of delivery of the placenta (post placental) or between 10 minutes and 48 hours following placental delivery (immediately postpartum).

Ethical approval for the overall FIGO PPIUD initiative was obtained in both countries and from the London School of Hygiene and Tropical Medicine for overall analysis of the data.

Comparator (Standard Practice)

Standard practice PPFp in both countries was assumed to be no provision of immediate PPFp. The only immediate postpartum contraceptive method available at the facilities during the timeframe of the initiative was tubal ligation during cesarean delivery, which was not routinely available to all women (and very rare in Tanzania). Where PPFp counseling was provided, it typically occurred at the 6-week follow-up postnatal care visit (i.e.,

outside the defined period of immediate postpartum contraception).

The governments of both countries have expressed official support for increasing access to postpartum contraception, for example, through the 2017 National Action Plan for Family Planning in Bangladesh⁴³ and the 2015 Postpartum Family Planning Action Plan and 2019 National Family Planning Costed Implementation Plan in Tanzania.^{44,45} However, a shortage of trained providers, inconsistent availability of products, and poor infrastructure limit the extent to which these services can be accessed. Immediate PPFp, including provision of IUDs at or around the time of delivery, is not currently standard practice in government health facilities in either country.

Although no immediate PPFp (within 48 hours of delivery) is routinely available in either country, PPFp from 6 weeks onwards is offered and it is likely that some of the women who adopted a PPIUD would otherwise have taken up an alternate method during the extended postpartum period. Due to the lack of direct comparators and a lack of available data on uptake of other PPFp in the extended postpartum period, we did not include any alternate methods as the comparator in our main analysis. We have instead included a sensitivity analysis testing the impact of different proportions of women taking up alternate PPFp methods, based on the national uptake rate of PPFp. See the [Supplement](#) for full details.

Economic Evaluation Perspective, Design, and Time Horizon

The economic evaluation involved a decision analysis that compared the new PPIUD initiative with standard practice. A decision analysis was used because it was able to reflect whether women voluntarily accept contraception provided in the immediate postpartum period. The economic evaluation was composed of the incremental costs of the PPIUD initiative (relative to standard practice) and uptake of the PPIUD. This included costs for recruitment; project staff; meetings; equipment; training; development of information, education, and communication materials; clinical supervision; and sharing of data and learning. Full details can be found in the [Supplement](#).

For each country we defined an initial setup period of 4 months; March to June 2015 in Bangladesh and December 2015 to March 2016 in Tanzania. The setup period included 3 months of initial project establishment and 1 month in which the first training of trainers was conducted. The setup period thus included fixed

costs but no impact (no PPIUDs inserted). The implementation period, based on the actual timing of the PPIUD initiative, was July 2015 to June 2018 for Bangladesh (36 months) and April 2016 to June 2018 for Tanzania (27 months); the implementation period included ongoing costs of implementation as well as impact (number of PPIUDs inserted).

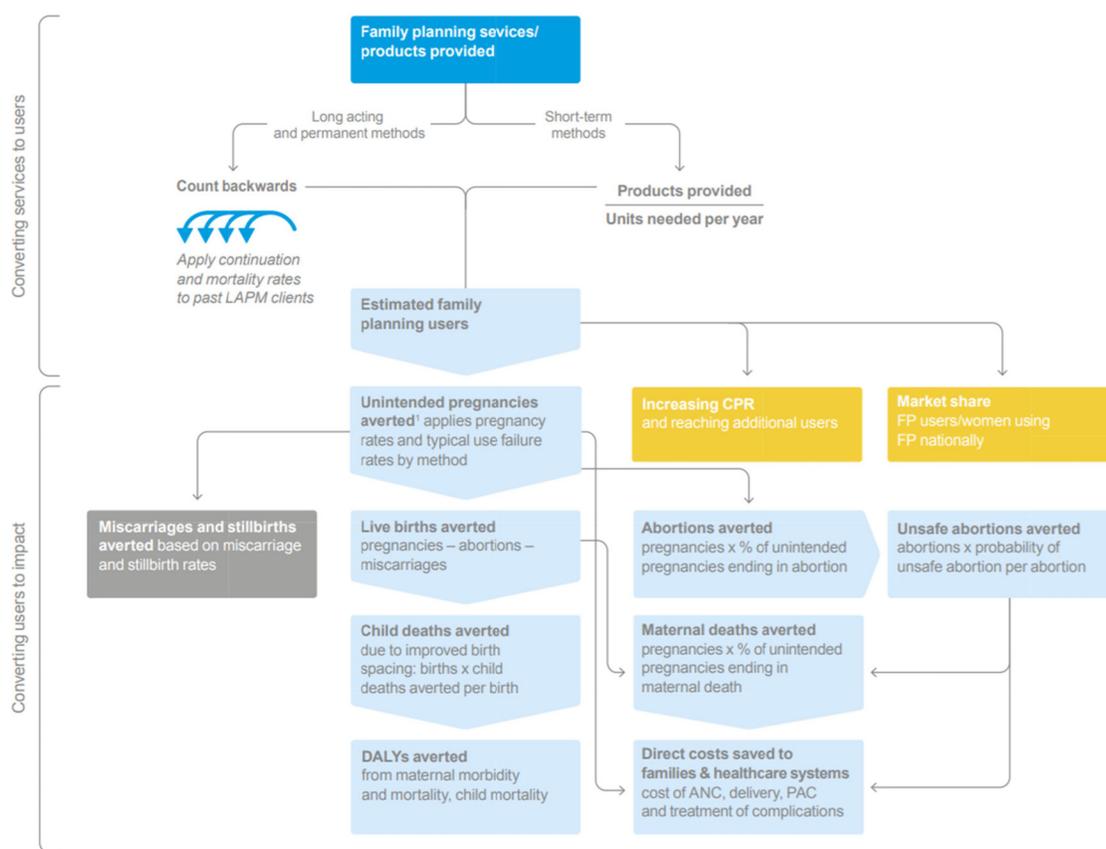
The analyses were conducted from the government’s perspective. Cost-effectiveness was reported within the time frame of program operation and was also modeled using the existing Impact 2 tool (Figure 1).^{46,47} In brief, the Impact 2 tool uses national- and regional-level data on typical pregnancy rates and rates of maternal deaths, unsafe abortions, child deaths, and similar outcomes to estimate the impact on key health outcomes of contraceptive services delivered,

based on the number of pregnancies and pregnancy-related deaths or illnesses that are averted because a woman is using contraception (Figure 1). The Impact 2 tool also estimates the direct cost savings to the health care system as a result of these health outcomes being averted, based on cost of antenatal care, delivery, postabortion care, and treatment of complications that are averted. The estimated impact of the services will occur over the lifetime of the contraceptive method provided.

To maximize the usefulness of the evaluation for national governments, we repeated the economic evaluation based on a hypothetical national scale-up. In Bangladesh, we modeled the cost of scaling up the PPIUD initiative to all 36 Government Medical College Hospitals nationally.⁴⁸ In Tanzania, we modeled the cost of scaling

The economic analyses were conducted from the government’s perspective.

FIGURE 1. Overview of Impact 2 Tool Used to Assess Cost-Effectiveness of Postpartum Intrauterine Device Initiative



Abbreviations: ANC, antenatal care; CPR, contraceptive prevalence rate; DALYs, disability-adjusted life years; FP, family planning; LAPM, long-acting permanent method; PAC, postabortion care; PPIUD, postpartum intrauterine device.

Source: Weinberger et al.⁴⁷

up the PPIUD initiative to all 28 Regional Referral Hospitals nationally,⁴⁹ as well as to 140 satellite facilities (assuming an average of 5 per hospital). PPIUD insertion rates for the national scale-up model were based on the insertion rates during the PPIUD initiative. Full details of the adjustments and assumptions made for this analysis can be found in the [Supplement](#).

This manuscript has been prepared in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS).⁵⁰

Effectiveness Measures

The measure of effectiveness of the PPIUD initiative was based on the number of immediate PPIUDs inserted, taken directly from the recorded data in the 2 countries, during implementation of the initiative. This measure is relevant for family planning and as an input to the existing Impact 2 tool, which quantifies the relationship between number of insertions, couple-years of protection (CYP), health outcomes, and future costs averted. The primary outcomes for this economic evaluation are cost per PPIUD inserted, cost per CYP,⁵¹ and cost per disability-adjusted life year (DALY) averted.

Estimating Resources and Costs

Costs that were provided in local currencies were first adjusted to 2018 local currency costs based on available national inflation data.^{52,53} The resulting 2018 local currency costs were then converted to US\$ using the average exchange rate for the year. Costs that were provided in US\$ were adjusted to 2018 US\$ using the annual average US inflation rates.⁵⁴ No discount rate was applied to the costs of conducting the PPIUD program or its associated uptake due to the short timeframe of the initiative.

A bottom-up, micro-costing approach was used with inputs as described in the [Supplement](#). Data on costs and PPIUD insertions were primarily sourced from existing project narrative and financial reports, with additional cost data collected as needed from the national project teams. The economic evaluation included the following costs:

- Training of providers in PPIUD insertion and PPFPP counseling;
- Staff salary and honorarium payments for facility level staff;
- Reusable clinical equipment;

- Lifetime direct PPIUD service delivery costs: cost of insertion, follow-up visit (if any), and removal; and
- Costs of supporting activities: behavior change materials, advocacy, project management, and monitoring.

A 10% overhead rate was applied, as per the overhead rate used by the government in each country. See the [Supplement](#) for further information on costs included.

We included costs for all postpartum contraception counseling sessions delivered at the participating facilities during the initiative, regardless of whether the counseled woman adopted a PPIUD, because more women will need to receive counseling than eventually receive a PPIUD. We included costs for people to attend 1 follow-up visit at a health facility, using an attendance rate of 25%, based on follow-up rates achieved during the initiative.

The Government of Bangladesh pays reimbursements for uptake of LARCs; part of the reimbursement is paid to the woman and part to the provider. For IUDs (including PPIUD), up to US\$6.24 is available as reimbursement (email communication, July 13, 2020). However, due to administrative challenges, payment of these reimbursements was not consistent during the evaluation timeframe. No reimbursements are paid to women or providers for attendance at follow-up visits in either country.

Costs associated with the initiative being an international, donor-funded project and the costs of the research component of the initiative were excluded from the analysis since these are not reflective of the true cost of government-led introduction of PPIUD. Costs to the women or to society were not included, other than where fees charged to women offset the cost to the government. Consistent with sector standards, costs to treat complications are not included in the analysis.⁵⁵

Analysis

Incremental cost-effectiveness ratios (ICERs) were generated for the PPIUD initiative as it was conducted in the 6 facilities in each country compared with standard practice using the formula below. The PPIUD initiative was considered as standard postpartum practice *plus* PPFPP counseling and PPIUD service delivery, meaning that the cost of standard practice can be estimated as 0 for both the initiative and for standard practice alone.

ICERs are reported both with and without the estimated direct health care savings from the Impact 2 tool factored in; when these estimated savings from the Impact 2 tool are factored in, we refer to “ICER with cost offset.”

$$\text{ICER} = \frac{\text{Cost PPIUD} - \text{Cost of Standard Practice}}{\text{Outcomes PPIUD} - \text{Outcomes of Standard Practice}}$$

The incremental costs and incremental benefits (outcomes) of the PPIUD initiative can be interpreted through a cost-effectiveness plane representing the 4 potential outcomes of the analyses (Figure 2).⁵⁶

One-way sensitivity analyses were conducted to test the robustness of estimates included in the economic evaluations and describe the impact of uncertainty on parameter values (costs of direct service delivery and training costs, and varying the proportion of government reimbursements paid in Bangladesh).

RESULTS

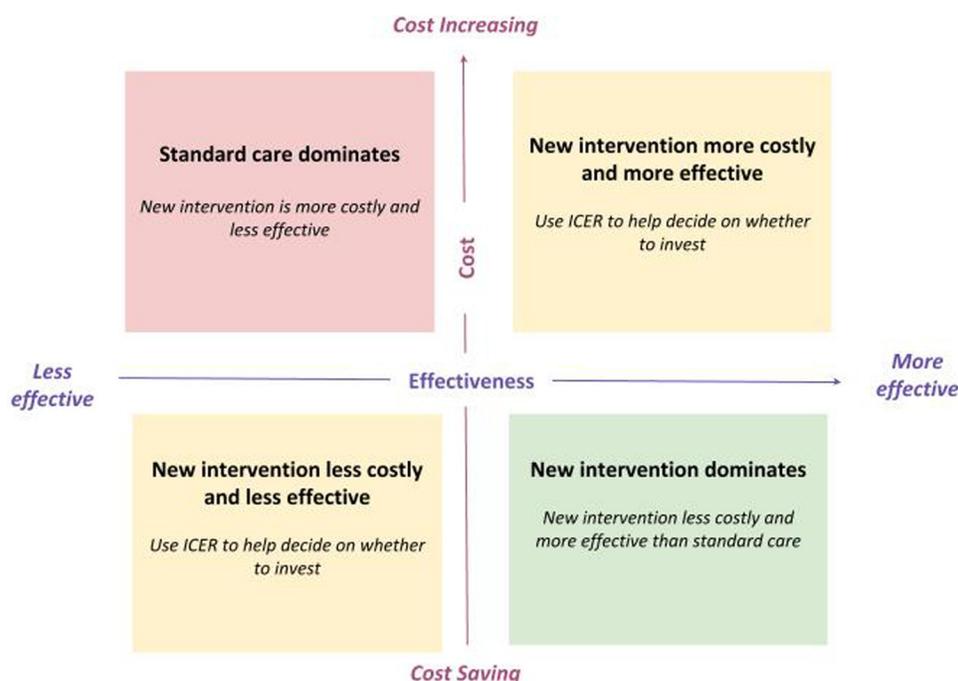
Outcomes

In Bangladesh, the 6 participating facilities delivered 8,031 PPIUDs over the 36-month implementation period; in Tanzania the 6 participating facilities delivered 7,448 PPIUDs over the 27-month implementation period (Table 2).

Service Provision and Total Cost

Table 2 displays the main results of the costing analysis. The direct service costs of a PPIUD include cost of insertion, follow-up visit, and removal. In Bangladesh, the counselors were employed full-time, so their costs were included in staff costs not direct services costs, whereas for Tanzania counseling was done by existing staff, so costs were calculated per PPIUD and are included here. The cost of direct service provision was estimated to be US\$1.71 per PPIUD in Bangladesh (excluding government reimbursements) and US\$2.05 in

FIGURE 2. Cost-Effectiveness Plane Representing 4 Potential Outcomes of Cost-Effectiveness Analyses of Postpartum Intrauterine Device Initiative



Abbreviation: ICER, incremental cost-effectiveness ratio. Source: Cost-effectiveness plane figure adapted from Cohen et al.⁵⁶

Tanzania. It was estimated that the reimbursement paid by the Government of Bangladesh (see above) would be paid 50% of the time during the implementation period, thus US\$3.12 was added to the base cost, resulting in a cost per PPIUD with reimbursements included of US\$4.83 in the Bangladesh analysis. In Bangladesh, the main cost driver was facility-level staffing, followed by national-level staffing. In Tanzania the main cost driver was training.

The direct health care costs saved by the PPIUD initiative were estimated to be US\$802,368 in Bangladesh and US\$1,348,744 in Tanzania.

The direct health care costs saved by the PPIUD initiative, based on estimates from the Impact 2 tool, were US\$802,368 in Bangladesh and US\$1,348,744 in Tanzania (Table 2).

National Scale-Up Model

In the analysis for the national scale-up model, a 36-month implementation period was used for both countries. For Bangladesh it was estimated that the 36 facilities would deliver 26,507 PPIUDs, while for Tanzania it was estimated that the 28 facilities (plus 140 satellite facilities) would deliver

43,928 PPIUDs (Table 2). The analysis for the national scale-up model estimated direct health care costs saved of US\$2,648,284 in Bangladesh, and US\$7,954,649 in Tanzania (as estimated by the Impact 2 tool) (Table 2).

Cost-Effectiveness

Table 3 displays ICER results for the PPIUD initiative presented both with and without the cost offset of the estimated direct health care savings from the Impact 2 tool.

In both countries, the PPIUD initiative was found to be more expensive and more effective than standard practice, before offsetting the direct cost savings to the health care system. In Bangladesh, the cost per outcome was estimated to be US\$14.60 per CYP and US\$91.13 per DALY averted, while in Tanzania the cost per outcome was estimated to be US\$54.57 per CYP and US\$67.67 per DALY averted compared with standard practice. When the cost offset generated from the Impact 2 tool was incorporated (from estimated

TABLE 2. Results of Costing Analysis in Bangladesh and Tanzania

	Bangladesh		Tanzania	
	PPIUD Initiative	National Scale-Up Model	PPIUD Initiative	National Scale-Up Model
Program design				
Number of facilities ^a	6	36	6	28
Setup period, months	4	4	4	4
Implementation period, months	36	36	27	36
Number of PPIUDs inserted	8,031	26,507	7,448	43,928
Costing analysis				
Estimated total cost	US\$539,285	US\$1,979,140	US\$1,869,507	US\$6,910,494
Estimated cost of direct PPIUD service provision ^b	US\$1.71	US\$1.71	US\$2.05	US\$2.05
Cost per facility per year	US\$27,986	US\$17,373	US\$130,697	US\$79,223
Main cost driver	Facility staff ^c (58% total cost)	Facility staff ^c (53% total cost)	Training (76% total cost)	Training (80% total cost)
Estimated direct health care costs saved (Impact 2)	US\$802,368	US\$2,648,284	US\$1,348,744	US\$7,954,649
Estimated total costs after including estimated health care costs saved (Impact 2)	−US\$263,083	−US\$669,144	US\$520,763	−US\$1,044,156

Abbreviation: PPIUD, postpartum intrauterine device.

^aNote the facilities included in the national scale-up model include the facilities in the PPIUD initiative plus additional facilities at the equivalent level of the public health care system. For Tanzania, each hospital in the scale-up model is assumed to have 4–6 associated satellite facilities that are trained in postpartum family planning counseling and given IEC materials to distribute and that refer clients to the hospitals, as was done in the PPIUD initiative.

^bIncludes cost of initial insertion, follow-up visit, and eventual removal using weighted averages. Cost of counseling is included for Tanzania but not for Bangladesh (cost of counselors in Bangladesh is included in staff costs, not direct service costs). Government reimbursements paid in Bangladesh are not included here.

^cFacility staff in Bangladesh include counselors and honorariums in the PPIUD initiative. Counselors only are included in the national scale-up model.

TABLE 3. Cost-Effectiveness of PPIUD Initiative

Outcome of interest ^a	Bangladesh			Tanzania		
	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset ^c
PPIUDs inserted	8,031	67.2	PPIUD dominates	7,448	251.1	69.9
CYPs	36,943	14.6	PPIUD dominates	34,261	54.6	15.2
Unintended pregnancies averted	16,683	32.3	PPIUD dominates	15,471	120.8	33.7
Maternal deaths averted	11	50,731.0	PPIUD dominates	30	62,316.9	17,358.8
Child deaths averted	63	8,613.0	PPIUD dominates	306	6,109.5	1,701.8
Total DALYs averted (maternal + child DALYs)	5,918	91.1	PPIUD dominates	27,626	67.7	18.9

Abbreviations: CYP, couple-years of protection; DALYs, disability-adjusted life years; ICER, incremental cost-effectiveness ratio; PPIUD, postpartum intrauterine device.

^a Outcomes are the estimated service lifespan impacts from the Impact 2 tool.

^b The ICER without cost offset is equivalent to the cost per outcome because the cost of standard practice is estimated as zero cost in both study groups without any impact on the ICER.

^c When neither the intervention nor standard care “dominates,” the ICER should be used to decide whether or not to invest (see Figure 2).

direct cost savings to the health care system), in Bangladesh PPIUD “dominated” (i.e., PPIUD is cheaper and more effective). For Tanzania, the ICER with cost offset was estimated to be US\$15.20 per CYP and US\$18.90 per DALY averted compared with standard practice, meaning it remained more effective and more costly than standard care.

Table 4 displays ICER results for the national scale-up model. In Bangladesh, the cost per outcome was estimated to be US\$16.23 per CYP and US\$106.64 per DALY averted, while in Tanzania the results were estimated to be US\$34.20 per CYP and US\$43.31 per DALY averted. Once the estimated savings from direct health care costs averted were factored in (as estimated by the Impact 2 tool) PPIUD dominated for all outcomes in both countries, meaning that it would be both cheaper and more effective to provide the PPIUD intervention compared with standard care. Full results of the national scale-up model can be found in the Supplement.

Sensitivity Analyses for Cost Adjustments

In Bangladesh, the ICER was most sensitive to the rate of payment of government reimbursements (Figure 3). With all the parameters and scenarios tested, the PPIUD intervention remained cheaper and more effective than standard practice,

indicating it was the dominant strategy. In Tanzania, the ICER was most sensitive to variations in costs of training (Figure 3). For both scenarios tested, the PPIUD intervention remained highly cost-effective. The scenario with the highest cost per DALY was an increase of 10% of training costs, which resulted in a cost per DALY of US \$72.83 before estimated health savings were factored in.

For the national scale-up analysis, the models were most sensitive to changes in rate of payment of government reimbursements (Bangladesh) and training costs (Tanzania). However, the models remained cheaper and more effective than standard care, indicating the PPIUD intervention was the dominant strategy in all scenarios tested. Details can be found in the Supplement.

Sensitivity Analyses for Uptake of Alternate PPF

A number of scenarios were tested to estimate the effect on the ICER of different proportions of PPIUD adopters taking up an alternate family planning method during the extended postpartum period (see Figure 4). The scenarios tested were based on the national PPF uptake rate at either 1–2 months or 9–11 months postpartum. Details of the different scenarios and assumptions made can be found in the Supplement.

TABLE 4. Cost-Effectiveness of National Scale-Up Model

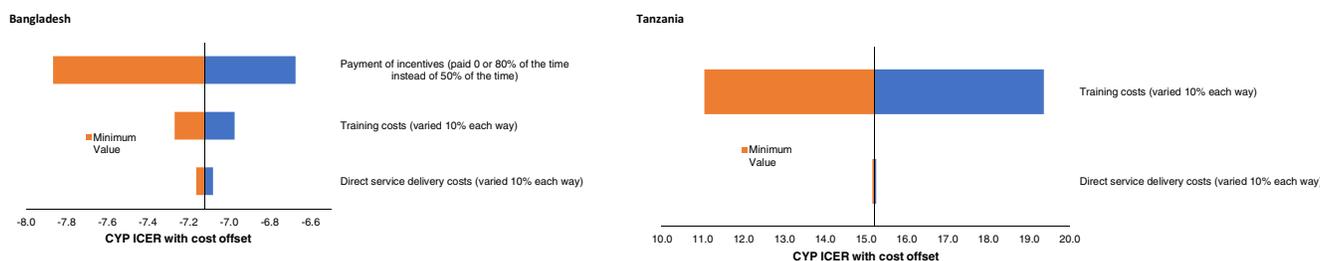
Outcome of Interest ^a	Bangladesh			Tanzania		
	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset
PPIUDs inserted	26,507	74.7	PPIUD dominates	43,928	157.31	PPIUD dominates
CYPs	121,932	16.2	PPIUD dominates	206,064	34.2	PPIUD dominates
Unintended pregnancies averted	55,062	35.9	PPIUD dominates	91,248	75.73	PPIUD dominates
Maternal deaths averted	18	107,057.9	PPIUD dominates	120	57,587.45	PPIUD dominates
Child deaths averted	207	9,576.2	PPIUD dominates	1,804	3,830.65	PPIUD dominates
Total DALYs averted (maternal + child DALYs)	18,558	106.6	PPIUD dominates	159,561	43.31	PPIUD dominates

Abbreviations: CYP, couple-years of protection; DALYs, disability-adjusted life years; ICER, incremental cost-effectiveness ratio; PPIUD, postpartum intrauterine device.

^a Outcomes are the estimated service lifespan impacts from the Impact 2 tool.

^b The ICER without cost offset is equivalent to the cost per outcome because the cost of standard practice is estimated as zero cost in both study groups without any impact on the ICER.

FIGURE 3. Sensitivity Analyses for Cost Adjustments Showing Incremental Cost-Effectiveness Ratio for Postpartum Intrauterine Device Initiative in Bangladesh and Tanzania



Abbreviations: CYP, couple-years of protection; ICER, incremental cost-effectiveness ratio.

For all scenarios in both countries, the PPIUD intervention remained more costly and more effective than standard care (before estimated direct cost savings to the health care system were factored in), and is likely cost-effective. Even in the most extreme scenarios (the 9–11 month PPFU uptake rate in Bangladesh, and 4 times the 1- to 2-month PPFU uptake rate in Tanzania), the ICER did not change substantially from the base case results (14.6 in Bangladesh, 54.6 in Tanzania). Details can be found in the Supplement.

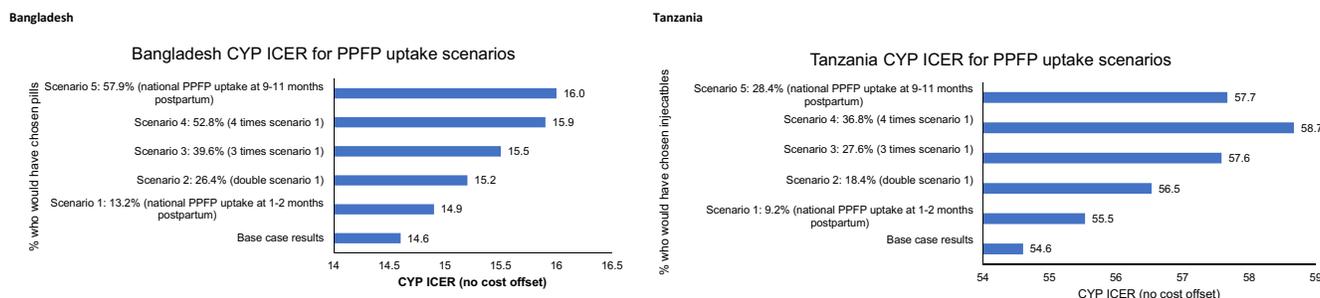
DISCUSSION

Summary of Key Findings

The cost per CYP of the PPIUD initiative was US\$14.60 in Bangladesh and US\$54.57 in

Tanzania before considering longer-term cost savings. In both countries, the PPIUD initiative was found to be more effective than standard PPFU practice. In Bangladesh, once the costs savings for the health care system were factored in, the PPIUD initiative was also found to be cheaper than standard practice. Despite the overall higher costs in Tanzania, cost per outcomes related to deaths averted and DALYs averted were less in Tanzania compared with Bangladesh because overall maternal health outcomes in Tanzania were much poorer,³⁹ thus the estimated impact of averting a pregnancy was much greater. In both countries, when PPIUD insertion was modeled to national-level scale-up, the estimated direct health care savings to the government exceeded the estimated

FIGURE 4. Sensitivity Analyses for Uptake of Alternate Postpartum Family Planning Methods During the Extended Postpartum Period in Bangladesh and Tanzania



Abbreviations: CYP, couple-years of protection; ICER, incremental cost-effectiveness ratio; PPFU, postpartum family planning.

cost of rolling out PPIUD services. In other words, these analyses suggest that rolling out PPIUD services nationally would save costs in the long run.

International thresholds state that interventions that avert 1 DALY for less than the average per capita GDP for a given country are considered very cost-effective (see the limitations to these thresholds outlined below),⁵⁷ while country-specific cost-effectiveness thresholds for Bangladesh and Tanzania range from 3% to 77% and from 4% to 86% of GDP per capita, respectively.⁵⁸ Our cost per DALY estimates are cost-effective under all proposed thresholds. In Bangladesh, the cost per DALY averted was US\$91.13 (5.4% of the 2018 GDP per capita of US\$1,698), and in Tanzania the cost per DALY averted was US\$67.67 (6.4% of the 2018 GDP per capita of US\$1,501).

Assumptions and Limitations

Due to the lack of direct comparability between immediate PPFU and family planning in the extended postpartum period, as well as the lack of necessary data, we did not factor into our analysis the proportion of PPIUD adopters who would otherwise have taken up an alternate PPFU method at a later date. As such, we may have overestimated the impact of the PPIUD initiative. We ran sensitivity analyses to test the impact of different proportions of women taking up alternate methods (see the [Supplement](#) for details). In all scenarios, when the estimated direct cost savings to the health care system from the PPIUD initiative were not factored in, the PPIUD initiative remained more expensive and more effective than standard practice and was likely cost-effective. The change

in ICER was not substantial from our base ICER, suggesting only a small impact from women taking up alternate methods in the extended postpartum period. This outcome is because the most commonly used family planning methods in both countries are short-acting (and so lead to fewer CYPs) and are more expensive per CYP than the PPIUD.

Additional limitations of the evaluation include reliance on self-reported data and estimates for some measures, for example, time spent on the PPIUD initiative by project management staff and time spent on PPIUD delivery by clinical staff. We minimized reporting error by collecting multiple estimates, removing outliers, and reporting averages. We used sector standard CYP factors that do not account for services being delivered postpartum, when fertility may be lower than at other times due to abstinence or lactational amenorrhea,⁵¹ although this effect is dependent on women breast-feeding exclusively and only applies for the first 6 months postpartum.

The WHO guidance from 2001 to determine cost-effectiveness thresholds based on a country’s per capita GDP has been criticized for not reflecting opportunity cost⁵⁸ and lacking country specificity. It should be used alongside other country-specific information, such as the overall budget available for health.⁵⁹ To address this issue, we also compared our findings with available country-specific thresholds (Summary of key findings above).

Certain costs, such as costs of demand generation activities and costs of treating complications, were not included in the analysis, which may have led to an underestimate of the true cost of scaling up PPIUD. Demand generation activities

National introduction and scale-up of PPIUD in Bangladesh and Tanzania are expected to be highly cost-effective or even cost saving.

were not included because they were not part of the PPIUD initiative. Costs of treating complications were not included because there are insufficient data on the rate, type, and severity of PPIUD complications; however, these costs are not likely to be substantial and therefore likely would not impact the final analysis significantly. Similarly, there may have been additional benefits to the PPIUD initiative that were not captured in this evaluation. These possible benefits include increased uptake of other contraceptive methods during the immediate postpartum period and increased uptake of any contraceptive method after the immediate postpartum period due to improved PPFPP counseling, uptake of PPIUD at non-participating facilities by providers trained through the initiative, and personal cost and time savings to women that take up a PPIUD. For the national scale-up model we needed to make several assumptions regarding costs and activities, which are described in full in the [Supplement](#).

A further limitation of our analysis is that we only considered what was done in the PPIUD initiative, and this may differ if PPIUD rollout is run by the government or if the national context changes. For example, government-run PPIUD training might be longer than that used during the initiative, staff may already be in place and trained to provide PPFPP counseling, and if different types of facilities were included, these would likely have different levels of uptake and costs. To explore these possibilities, we repeated the analyses with some adjustments to the intervention design. Details of this analysis and the results are in the [Supplement](#).

Comparison With Existing Literature

Although LARCs have been consistently demonstrated to be more cost effective than short-acting methods in high-income countries,^{60,61} there are few comparable studies on the cost-effectiveness of delivering postpartum contraception and even fewer specifically on immediate postpartum IUD.⁶² In addition, comparisons with other studies are of limited use due to different implementation approaches, different methodology for calculating cost, and different costs in different countries.

Previous studies comparing contraceptive methods have consistently found IUD to have a lower cost per CYP compared with other methods of contraception. One study in Kenya (not of postpartum contraception) reports an estimated cost of US\$1.37 per CYP for IUD, US\$1.60 for female sterilization, US\$4.06–US\$6.17 for implants, US\$6.34 for IUS, US\$6.88 for oral contraceptives,

and US\$7.07–US\$12.47 for injectables (ranges represent different types of implant and injectables).⁶³ A study from Rwanda reports an estimated cost of US\$6 per CYP for PPIUD compared with US\$21 per CYP for postpartum implant.⁶⁴

The only known studies to have considered the cost-effectiveness of immediate PPIUD provision are Wall et al.⁶⁴ in Rwanda and Washington et al.⁶⁵ in the United States. The latter found that immediate PPIUD results in cost savings of US\$282,540 per 1,000 women and a gain of 10 quality adjusted life years. Wall et al.⁶⁴ used a micro-costing approach similar to our analyses to estimate the incremental cost of PPIUD and postpartum implants compared with standard methods, from the perspective of the health system, in Kigali, Rwanda. The authors included and excluded similar costs as our analyses, but unlike the PPIUD initiative, they conducted and included the costs of promotional activities. The resulting cost per PPIUD inserted was US\$25 and cost per CYP for PPIUD was US\$5, lower than the results in our analyses. However, the Rwanda initiative did include reimbursements paid directly to providers and community health workers referring women to providers and had a higher uptake rate of PPIUDs of 16% (compared with 5%–8% uptake in our analyses), making direct comparisons difficult.

Significance of Results

Compared with previous analyses, our estimates of cost per PPIUD inserted and cost per CYP for PPIUD were generally higher than those reported in peer-reviewed publications, which could reflect our very detailed micro-costing approach as well as differing costs between countries. Nonetheless, our results indicate that even with these higher costs, national introduction and scale-up of PPIUD in Bangladesh and Tanzania are expected to be highly cost-effective or even cost saving. Both the cost-effectiveness and the impact of PPIUD may improve over time as some costs will decrease (for example, no repeat setup costs, and all facilities having trained providers in place), while the impact may increase as awareness and acceptability of the method improve among providers, women and their families, and communities. In addition, potential future national rollout of the PPIUD initiative may be positively affected by ongoing efforts in both countries to encourage births in facilities and improve the capacity of lower-level facilities, as well as efforts to increase awareness and availability of a range of postpartum contraceptive methods.^{42,45}

While the PPIUD initiative was found to be cost-effective in both countries, the main cost drivers and actual costs differed. In Bangladesh, the largest cost driver was the staff employed at the facility level to counsel women on PPF. Although more costly to the government, the inclusion of dedicated counselors was a highly effective way of providing quality counseling, which contributed to the success of the initiative,¹⁹ and has now been incorporated into the latest Bangladesh Costed Implementation Plan (2020–2022).⁴² Alternatively, this counseling role could be taken over by the new midwifery cadre of health worker, which could increase access to PPIUD services, while simultaneously reducing salary costs. In Tanzania, the main cost driver was training, partly because the training course was several days longer than in Bangladesh and also due to higher associated travel and meeting costs. PPIUDs in Tanzania are predominantly inserted by midwives, as opposed to doctors in Bangladesh,⁶⁶ and so a longer training period was deemed necessary. The practice of frequently rotating providers to different clinical departments also meant that training had to be repeated frequently; the same challenge of high rotation of providers was also observed in a program to introduce PPIUD in Malawi.⁶⁷ In the future, approaches such as on-the-job training could be used to reduce costs while maintaining quality, as has been demonstrated in other countries.⁶⁸

FIGO shared the findings of the PPIUD initiative with the national societies of obstetricians and gynecologists and key government departmental heads in both countries, and they were received with much interest. In Bangladesh, there is an in-principle agreement to engage with the Obstetrical and Gynaecological Society of Bangladesh in the national rollout of PPIUD as part of a broader PPF package, although the costs of this have not yet been ascertained. The Tanzanian government is currently seeking donor funding to progress national rollout of PPIUD. Furthermore, in both countries the PPIUD initiative has instigated changes to the preservice training curriculum of midwives and doctors; over time, this will lead to decreased need for detailed in-service training specifically for PPIUD provision.

It is estimated that making family planning widely accessible could reduce maternal mortality by one-third globally.⁶⁹ As well as the health benefits arising from reduced risks to subsequent pregnancies, the newborn, and the wider family,^{5–9} there are additional benefits such as an increase in productivity and the economic value women can contribute to their societies when

able to control their fertility.^{70,71} Offering immediate PPF is an efficient way of giving women the choice to space or limit their pregnancies. Following the change in WHO MEC criteria, there are now more methods potentially available to women postpartum, each of which has advantages and disadvantages. Making available a broad contraceptive method mix allows women to choose the method most appropriate for them, increasing uptake and reducing the chances of discontinuation.⁷² The FIGO PPIUD initiative and many others have demonstrated that IUD insertion immediately postpartum is safe and feasible to implement.²⁹ However, in practice many countries cannot consistently supply all LARC methods, and difficult cost-benefit decisions have to be made by governments when allocating resources. Information on cost-effectiveness can help guide government and policy resource allocation decisions to maximize value and impact. This economic evaluation estimated that from an implementation perspective, the provision of quality PPF counseling and insertion of immediate PPIUD if chosen, is highly cost-effective in 2 LMICs, including when modeled to a national scale.

CONCLUSION

The PPIUD initiative was found to be highly cost-effective in Bangladesh and Tanzania, with national scale-up of PPIUD estimated to produce long-term savings in health care costs. The true benefits to national governments are likely to be even greater than our analysis suggests owing to additional likely benefits not quantified. These analyses provide a compelling case for national governments and international donors to invest in the provision of quality contraceptive counseling before and around the time of delivery and for the routine inclusion of PPIUD within the suite of contraceptive methods made available during the immediate postpartum period in Bangladesh and Tanzania.

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societies of Bangladesh and Tanzania. AM conceived the idea of an economic evaluation of the initiative in Bangladesh and Tanzania, and FIGO contracted GE, JG, and KD to conduct the economic evaluation. All authors contributed to the design of the evaluation. With support from SB, EAT and KD, FP and AY collated the data required from Bangladesh and PM and GK from Tanzania. The data were analyzed and the economic evaluation constructed by GE, JG and KD. The paper was written by GE, JG and AM with direction for the economic analysis from KD, and then reviewed by all authors.

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REFERENCES

- World Health Organization (WHO). *Programming Strategies for Postpartum Family Planning*. WHO; 2013. Accessed February 25, 2021. https://www.who.int/reproductivehealth/publications/family_planning/ppfp_strategies/en/
- Gaffield ME, Egan S, Temmerman M. It's about time: WHO and partners release programming strategies for postpartum family planning. *Glob Health Sci Pract*. 2014;2(1):4–9. [CrossRef](#). [Medline](#)
- High Impact Practices in Family Planning. Immediate postpartum family planning: a key component of childbirth care. 2017. Accessed February 25, 2021. <http://www.fphighimpactpractices.org/overview>
- World Health Organization (WHO). *Report of a WHO Technical Consultation on Birth Spacing*. WHO; 2007. Accessed February 25, 2021. https://www.who.int/maternal_child_adolescent/documents/birth_spacing05/en/
- Cleland J, Conde-Agudelo A, Peterson H, Ross J, Tsui A. Contraception and health. *Lancet*. 2012;380(9837):149–156. [CrossRef](#). [Medline](#)
- Rutstein SO. *Further Evidence of the Effects of Preceding Birth Intervals on Neonatal, Infant, and Under-Five-Years Mortality and Nutritional Status in Developing Countries*. DHS Working Papers, no. 41. Macro International; 2008. Accessed February 25, 2021. <https://dhsprogram.com/pubs/pdf/WP41/WP41.pdf>
- Kozuki N, Lee ACC, Silveira MF, et al; Child Health Epidemiology Reference Group Small-for-Gestational-Age-Preterm Birth Working Group. The associations of birth intervals with small-for-gestational-age, preterm, and neonatal and infant mortality: a meta-analysis. *BMC Public Health*. 2013;13(Suppl 3):S3. [CrossRef](#). [Medline](#)
- DaVanzo J, Hale L, Razzaque A, Rahman M. Effects of interpregnancy interval and outcome of the preceding pregnancy on pregnancy outcomes in Matlab, Bangladesh. *BJOG*. 2007;114(9):1079–1087. [CrossRef](#). [Medline](#)
- Conde-Agudelo A, Rosas-Bermúdez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. *JAMA*. 2006;295(15):1809–1823. [CrossRef](#). [Medline](#)
- World Health Organization (WHO). *Medical Eligibility Criteria for Contraceptive Use*, 5th ed. WHO; 2015. Accessed February 25, 2021. https://apps.who.int/iris/bitstream/handle/10665/181468/9789241549158_eng.pdf
- Makins A, Cameron S. Post pregnancy contraception. *Best Pract Res Clin Obstet Gynaecol*. 2020;66:41–54. [CrossRef](#). [Medline](#)
- Shah IH, Santhya KG, Cleland J. Postpartum and post-abortion contraception: from research to programs. *Stud Fam Plann*. 2015;46(4):343–353. [CrossRef](#). [Medline](#)
- Pasha O, Goudar SS, Patel A, et al. Postpartum contraceptive use and unmet need for family planning in five low-income countries. *Reprod Health*. 2015;12(S2)(Suppl 2):S11. [CrossRef](#). [Medline](#)
- Moore Z, Pfitzer A, Gubin R, Charurat E, Elliott L, Croft T. Missed opportunities for family planning: an analysis of pregnancy risk and contraceptive method use among postpartum women in 21 low- and middle-income countries. *Contraception*. 2015;92(1):31–39. [CrossRef](#). [Medline](#)
- Hounton S, Winfrey W, Barros AJD, Askew I. Patterns and trends of postpartum family planning in Ethiopia, Malawi, and Nigeria: evidence of missed opportunities for integration. *Glob Health Action*. 2015;8(1):29738. [CrossRef](#). [Medline](#)
- Borda M, Winfrey W. *Postpartum Fertility and Contraception: An Analysis of Findings From 17 Countries*. Jhpiego; 2010. Accessed February 25, 2021. http://reprolineplus.org/system/files/resources/ppfp_17countryanalysis.pdf
- Cleland J, Shah IH, Daniele M. Interventions to improve postpartum family planning in low- and middle-income countries: program implications and research priorities. *Stud Fam Plann*. 2015;46(4):423–441. [CrossRef](#). [Medline](#)
- Makins A, Taghinejadi N, Sethi M, et al. Factors influencing the likelihood of acceptance of postpartum intrauterine devices across four countries: India, Nepal, Sri Lanka, and Tanzania. *Int J Gynaecol Obstet*. 2018;143(S1)(Suppl 1):13–19. [CrossRef](#). [Medline](#)
- Fatima P, Antora AH, Dewan F, Nash S, Sethi M. Impact of contraceptive counselling training among counsellors participating in the FIGO postpartum intrauterine device initiative in Bangladesh. *Int J Gynaecol Obstet*. 2018;143(S1)(Suppl 1):49–55. [CrossRef](#). [Medline](#)
- Thapa K, Dhital R, Rajbhandari S, et al. Improving post-partum family planning services provided by female community health volunteers in Nepal: a mixed methods study. *BMC Health Serv Res*. 2020;20(1):123. [CrossRef](#). [Medline](#)
- Rossier C, Bradley SEK, Ross J, Winfrey W. Reassessing unmet need for family planning in the postpartum period. *Stud Fam Plann*. 2015;46(4):355–367. [CrossRef](#). [Medline](#)
- Hubacher D. The levonorgestrel intrauterine system: reasons to expand access to the public sector of Africa. *Glob Health Sci Pract*. 2015;3(4):532–537. [CrossRef](#). [Medline](#)
- Jacobstein R, Shelton JD. The levonorgestrel intrauterine system: a pragmatic view of an excellent contraceptive. *Glob Health Sci Pract*. 2015;3(4):538–543. [CrossRef](#). [Medline](#)
- UNFPA. UNFPA contraceptives price indicators year 2018. UNFPA; 2018. Accessed February 25, 2021. https://www.unfpa.org/sites/default/files/resource-pdf/UNFPA_Contraceptive_Price_Indicators_2018_V3_-_EXTERNAL.pdf
- Averbach SH, Ermias Y, Jeng G, et al. Expulsion of intrauterine devices after postpartum placement by timing of placement, delivery type, and intrauterine device type: a systematic review and meta-analysis. *Am J Obstet Gynecol*. 2020;223(2):177–188. [CrossRef](#). [Medline](#)
- Lopez LM, Bernholm A, Hubacher D, Stuart G, Van Vliet HAAM. Immediate postpartum insertion of intrauterine device for contraception. *Cochrane Database Syst Rev*. 2015;2015(6):CD003036. [CrossRef](#). [Medline](#)
- Hooda R, Mann S, Nanda S, Gupta A, More H, Bhutani J. Immediate postpartum intrauterine contraceptive device insertions in caesarean and vaginal deliveries: a comparative study of follow-up outcomes. *Int J Reprod Med*. 2016;2016:7695847. [CrossRef](#). [Medline](#)
- Sonalkar S, Kapp N. Intrauterine device insertion in the postpartum period: a systematic review. *Eur J Contracept Reprod Health Care*. 2015;20(1):4–18. [CrossRef](#)
- Makins A, Taghinejadi N, Sethi M, et al. FIGO postpartum intrauterine device initiative: complication rates across six countries. *Int J Gynaecol Obstet*. 2018;143(S1)(Suppl 1):20–27. [CrossRef](#). [Medline](#)
- Pfitzer A, Mackenzie D, Blanchard H, et al. A facility birth can be the time to start family planning: postpartum intrauterine device experiences from six countries. *Int J Gynaecol Obstet*. 2015;130(Suppl 2):S54–S61. [CrossRef](#). [Medline](#)

31. Pleah T, Hyjazi Y, Austin S, et al. Increasing use of postpartum family planning and the postpartum IUD: early experiences in west and central Africa. *Glob Health Sci Pract*. 2016;4(Supplement 2):S140–S152. [CrossRef](#). [Medline](#)
32. FHI 360. Assessing the feasibility of postpartum IUD provision in Rwanda. FHI 360; 2013. Accessed February 25, 2021. <https://www.fhi360.org/sites/default/files/media/documents/assessing-feasibility-postpartum-iucd-rwanda-2013.pdf>
33. Makins A, Arulkumar S. Institutionalization of postpartum intrauterine devices. *Int J Gynaecol Obstet*. 2018;143(S1)(Suppl 1):1–3. [CrossRef](#). [Medline](#)
34. Cooper M, Cameron S. Successful implementation of immediate postpartum intrauterine contraception services in Edinburgh and framework for wider dissemination. *Int J Gynaecol Obstet*. 2018;143 Suppl:56–61. [CrossRef](#). [Medline](#)
35. FP2020. Home page. Accessed February 25, 2021. <http://www.familyplanning2020.org/>
36. Appleford G, Ramarao S. *Health Financing and Family Planning in the Context of Universal Health Care: Connecting the Discourse*. Population Council; 2019. Accessed February 25, 2021. https://knowledgecommons.popcouncil.org/cgi/viewcontent.cgi?article=1553&context=departments_sbsr-rh
37. World Health Organization (WHO). Universal health coverage. Accessed February 25, 2021. <https://www.who.int/data/gho/data/major-themes/universal-health-coverage-major/GHO/universal-health-coverage>
38. National Institute of Population Research and Training (NIPORT), ICF. *Bangladesh Demographic and Health Survey 2017–18*. NIPORT, ICF; 2020.
39. Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) [Tanzania Mainland], Ministry of Health (MOH) [Zanzibar], National Bureau of Statistics (NBS), Office of the Chief Government Statistician (OCGS), ICF. *Tanzania Demographic and Health Survey and Malaria Indicator Survey (TDHS-MIS) 2015–16*. MOHCDGEC, MOH, NBS, OCGS, and ICF; 2016:172–173. Accessed February 25, 2021. <https://dhsprogram.com/pubs/pdf/fr321/fr321.pdf>
40. World Bank. Population density estimates 2018. Accessed May 18, 2020. <https://data.worldbank.org/indicator/EN.POP.DNST>
41. Winfrey W, Rakesh K. *Use of Family Planning in the Postpartum Period*. DHS Comparative Report No. 36. ICF International; 2014. Accessed February 25, 2021. <https://dhsprogram.com/pubs/pdf/CR36/CR36.pdf>
42. Hamid SA, Sultana N, Shimul SN, et al. *Policy Guideline: Costed Implementation Plan for National Family Planning Program in Bangladesh (2020–2022)*. Pathfinder International; 2020. Accessed February 25, 2021. http://familyplanning2020.org/sites/default/files/Bangladesh_FP-CIP_2020-2022_Policy-Guideline.pdf
43. Medical Education and Family Welfare Division, Ministry of Health and Family Welfare Bangladesh. *Bangladesh National Action Plan for Post-Partum, Post-Menstrual Regional and Post-Abortion Care Family Planning*. Ministry of Health and Family Welfare Bangladesh; 2017.
44. United States Agency for International Development, Maternal and Child Survival Program (USAID MCSP). *Accelerating Access to Postpartum Family Planning (PPFP) in Sub-Saharan Africa and Asia PPFP Country Programming Strategies Worksheet - Tanzania*. USAID MCSP; 2015. Accessed February 25, 2021. <https://www.familyplanning2020.org/sites/default/files/Tanzania-Worksheet.pdf>
45. Ministry of Health, Community Development, Gender, Elderly, and Children (MOHCDGEC). *Tanzania National Family Planning Costed Implementation Plan 2019–2023*. MOHCDGEC; 2019. Accessed February 25, 2021. https://www.familyplanning2020.org/sites/default/files/Tanzania_CIP_2019-2023.pdf
46. Weinberger MB, Fry K, Boler T, Hopkins K. Estimating the contribution of a service delivery organisation to the national modern contraceptive prevalence rate: Marie Stopes International's Impact 2 model. *BMC Public Health*. 2013;13(Suppl 2):S5. [CrossRef](#). [Medline](#)
47. Weinberger M, Fry K, Hopkins K. *Impact 2 Version 5: An Innovative Tool for Estimating the Impact of Reproductive Health Programmes*. Methodology Paper. Marie Stopes International; 2018. Accessed February 25, 2021. https://www.mschoices.org/media/2191/methodology-paper_july-2018.pdf
48. Government of the People's Republic of Bangladesh, Ministry of Health and Family Welfare. *Bangladesh Health Bulletin 2018*. Accessed March 5, 2021. <https://dghs.gov.bd/images/docs/Publications/HB%202018%20final.pdf>
49. United Republic of Tanzania. Ministry of Health, Community Development, Gender, Elderly and Children; President Office Regional Administration and Local Government. *Guideline for Regional Referral Hospital Advisory Board (RRHAB)*. 2016. Accessed February 25, 2021. http://www.tzdp.org.or.tz/fileadmin/documents/dpg_internal/dpg_working_groups_clusters/cluster_2/health/Key_Sector_Documents/Tanzania_Key_Health_Documents/Ver_08_07_2016_RRHAB_-_JICA_BOOK.PDF
50. Husereau D, Drummond M, Petrou S, et al.; CHEERS Task Force. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. *BMJ*. 2013;346:f1049. [CrossRef](#). [Medline](#)
51. United States Agency for International Development (USAID). Couple years of protection (CYP). USAID; 2019. Accessed February 25, 2021. <https://www.usaid.gov/global-health/health-areas/family-planning/couple-years-protection-cyp>
52. Central Bank of Bangladesh. Home page. Accessed February 25, 2021. <https://www.bb.org.bd/>
53. International Monetary Fund. World economic outlook database. Accessed February 26, 2021. <https://www.imf.org/external/pubs/ft/weo/2019/01/weodata/weorept.aspx?sy=2017&ey=2024&scsm=1&ssd=1&sort=country&ds=.&br=1&pr1.x=51&pr1.y=10&c=738&s=PCPIPCH&grp=0&a=>
54. U.S. Inflation Calculator. Accessed February 25, 2021. <https://www.usinflationcalculator.com/inflation/current-inflation-rates/>
55. Darroch JE. *Adding It Up: Investing in Contraception and Maternal and Newborn Health, 2017. Estimation Methodology*. Guttmacher Institute; 2018. Accessed February 25, 2021. https://www.guttmacher.org/sites/default/files/report_pdf/adding-it-up-2017-estimation-methodology.pdf
56. Cohen DJ, Reynolds MR. Interpreting the results of cost-effectiveness studies. *J Am Coll Cardiol*. 2008;52(25):2119–2126. [CrossRef](#). [Medline](#)
57. Hutubessy R, Chisholm D, Edejer T. Generalized cost-effectiveness analysis for national-level priority-setting in the health sector. *Cost Eff Resour Alloc*. 2003;1(1):8. [CrossRef](#). [Medline](#)
58. Woods B, Revill P, Sculpher M, Claxton K. Country-level cost-effectiveness thresholds: initial estimates and the need for further research. *Value Health*. 2016;19(8):929–935. [CrossRef](#). [Medline](#)
59. Bertram MY, Lauer JA, De Joncheere K, et al. Cost-effectiveness thresholds: pros and cons. *Bull World Health Organ*. 2016;94(12):925–930. [CrossRef](#). [Medline](#)
60. Mavranzeouli I; LARC Guideline Development Group. The cost-effectiveness of long-acting reversible contraceptive methods in the UK: analysis based on a decision-analytic model developed for a National Institute for Health and Clinical Excellence (NICE) clinical practice guideline. *Hum Reprod*. 2008;23(6):1338–1345. [CrossRef](#). [Medline](#)
61. Trussell J, Lalla AM, Doan QV, Reyes E, Pinto L, Gricar J. Cost effectiveness of contraceptives in the United States. *Contraception*. 2009;79(1):5–14. [CrossRef](#). [Medline](#)

62. Lynch M, De Abreu Lourenco R, Flattery M, Haas M. Reviewing the cost-effectiveness of long-acting reversible contraceptive methods in an Australian context. *Aust N Z J Obstet Gynaecol*. 2019;59(1):21–35. [CrossRef](#). [Medline](#)
63. Rademacher KH, Solomon M, Brett T, et al. Expanding access to a new, more affordable levonorgestrel intrauterine system in Kenya: service delivery costs compared with other contraceptive methods and perspectives of key opinion leaders. *Glob Health Sci Pract*. 2016;4(Suppl 2):S83–S93. [CrossRef](#). [Medline](#)
64. Wall KM, Ingabire R, Allen S, Karita E. Cost per insertion and couple year of protection for postpartum intrauterine devices and implants provided during service scale-up in Kigali, Rwanda. *Gates Open Research*. 2018;2:39. [CrossRef](#). [Medline](#)
65. Washington CI, Jamshidi R, Thung SF, Nayeri UA, Caughey AB, Werner EF. Timing of postpartum intrauterine device placement: a cost-effectiveness analysis. *Fertil Steril*. 2015;103(1):131–137. [CrossRef](#). [Medline](#)
66. Muganyizi PS, Kimario G, Ponsian P, Howard K, Sethi M, Makins A. Clinical outcomes of postpartum intrauterine devices inserted by midwives in Tanzania. *Int J Gynaecol Obstet*. 2018;143(S1)(Suppl 1):38–42. [CrossRef](#). [Medline](#)
67. Tang JH, Kamtwanje N, Masepuka P, et al. Implementation of postpartum intrauterine device (PPIUD) services across 10 districts in Malawi. *Malawi Med J*. 2018;30(3):205–210. [CrossRef](#). [Medline](#)
68. Thapa K, Dhital R, Karki YB, et al. Institutionalizing postpartum family planning and postpartum intrauterine device services in Nepal: role of training and mentorship. *Int J Gynaecol Obstet*. 2018;143 Suppl:43–48. [CrossRef](#)
69. Arulkumaran S, Hediger V, Manzoor A, May J. *Saving Mothers' Lives: Transforming Strategy Into Action. Report of the Maternal Health Working Group 2012*. The Global Health Policy Summit; 2012. Accessed February 25, 2021. <https://www.imperial.ac.uk/media/imperial-college/institute-of-global-health-innovation/public/Mothers-lives.pdf>
70. Bernstein A, Jones KM. *The Economic Effects of Contraceptive Access: A Review of the Evidence*. Institute for Women's Policy Research; 2019. <https://iwpr.org/iwpr-issues/reproductive-health/the-economic-effects-of-contraceptive-access-a-review-of-the-evidence-fact-sheet/>
71. Sonfield A, Hasstedt K, Kavanaugh ML, Anderson R. *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children*. Guttmacher Institute; 2013. Accessed February 25, 2021. https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf
72. Ross J, Stover J. Use of modern contraception increases when more methods become available: analysis of evidence from 1982–2009. *Glob Health Sci Pract*. 2013;1(2):203–212. [CrossRef](#) [Medline](#)

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ORIGINAL ARTICLE

Implementing a Social Accountability Approach for Maternal, Neonatal, and Child Health Service Performances in Ethiopia: A Pre-Post Study Design

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Key Findings

- The average community scorecard measurements on health workforce behavior toward patients, availability of services, patient waiting time, facility infrastructure, ambulance service, and cleanliness and safety of the health facility significantly improved over 1 year at primary health care units.
- Of the 10 key maternal neonatal and child health performance indicators measured, 9 were found to improve as a result of implementing the community scorecard approach.

Key Implications

- The implementation of a community scorecard approach enhances a culture of social accountability, transparency, and engagement of citizens in planning, implementing, and evaluating maternal, neonatal, and child health services. In addition, it improves the negotiation capacities and involvement of both community members and health workers, resulting in increased availability and utilization of health service.
- Program managers and development partners should continue their support for the government-led social accountability interventions to ensure the sustainability of improvements in maternal, neonatal, and child health outcomes.

ABSTRACT

Background: Social accountability approaches, such as the community scorecard (CSC), can improve the performance of health systems in low-income countries by providing a mechanism for obtaining and incorporating community input. This longitudinal study assessed the effects of CSCs implemented by primary health care units (PHCUs) on health system performance in Ethiopia.

Methods: This study used a pre-post design and was conducted from October 2018 to September 2019 in 159 PHCUs in 31 districts in Amhara and Southern, Nations, Nationalities and Peoples' regional states. The data were extracted from a routine health information management system database at baseline, midterm, and endline stages over 12 months for statistical analysis. The effects of implementing CSCs on health system performance were evaluated against selected key performance indicators (KPIs).

Results: The CSC measurement results were based on input from 38,556 community representatives. The mean CSC score with standard deviation (\pm SD) was $60.8\% \pm 12.5\%$, $66.3\% \pm 10.8\%$, and $70.6\% \pm 10.0\%$ at baseline, midterm, and endline, respectively. The mean KPI score was $54.9\% \pm 17.4\%$, $61.9\% \pm 15.1\%$, and $67.6\% \pm 14.6\%$ at baseline, midterm, and endline, respectively. The average CSC and KPI values were positively correlated ($r > 0.37$). Using a nonparametric Friedman's test, we found a statistically significant difference in CSC and KPI scores at baseline, midterm, and endline ($P = .001$). Post hoc analysis with Wilcoxon signed-rank tests was conducted with a Bonferroni correction and the results showed higher CSC and KPI values from baseline to midterm and from midterm to endline ($P < .017$).

Conclusions: The use of CSCs in Ethiopia contributed to the health system's performance in terms of maternal and child health services. The responsiveness of health workers and utilization of basic health services by community members were found to increase significantly with CSC use. We recommend continued implementation of the CSC intervention at PHCUs.

BACKGROUND

The World Development Report of 2004 highlighted the benefits of listening to citizens to improve pro-poor targeted service delivery.¹ Following this report, the global community showed an eagerness to institutionalize social accountability approaches to help improve the performance of health systems in developing countries.²⁻⁴ Accountability includes the obligation of individuals or

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agencies to provide information about and/or justification for their actions to other actors, along with the imposition of sanctions for failure to comply and/or to engage in appropriate action.^{5–9} One of the key interventions to ensure the sustainability of gains in the health sector is to promote community ownership and engagement in health care. The community scorecard (CSC) process allows communities and service providers to engage in a dialogue on the delivery of services under a government program or a project, often in rural areas. To this end, CSCs have been most commonly used in health sectors in different African countries as a way for communities and service providers to work together on the planning and monitoring of specific health services and to jointly gear efforts toward improving service equity, quality, and access to services in resource-limited settings.^{4,10–15}

Since 2006, the Ethiopian Social Accountability Program led by the Ministry of Finance and Economic Commission has been implementing CSCs in 223 districts (woredas)—third-level administrative divisions of Ethiopia covering 60,000–100,000 people—to improve the citizens' participation in public services including education, health, water and sanitation, agriculture, and rural roads.¹⁰ The Ethiopian Ministry of Health and regional health bureaus, along with development partners, aim to promote the involvement and engagement of community members in the planning, development, implementation, and monitoring and evaluation processes of health service delivery.¹⁶

During the health sector transformation plan period (2015–2020), a guide for promoting and implementing CSC approaches in the health sector was introduced. The national implementation guide dictates that community groups (i.e., client councils, health service providers, development partners, and local government officials) work together to make basic health services equitable, effective, efficient, transparent, responsive, and accountable.¹⁷ The guide recommends a 6-phase implementation process (Figure 1).

The exercise of developing a national strategy led to the development of a theory of change. The goal of implementing CSCs is to contribute to the prevention of maternal and child deaths.^{16–18} The long-term outcomes strategize increasing utilization of quality maternal and child health services under well-functioning primary health care entities.^{18,19} Figure 2 illustrates the preconditions and assumptions of the CSC theory of change led by the Ethiopian health sector.²⁰ The preconditions are expected to enable the achievement of higher scores on (1) compassionate, respectful,

and caring health workforce; (2) patient waiting time; (3) availability of services, biomedical equipment, and pharmaceutical supplies; (4) health facility infrastructure; (5) ambulance service and management; and (6) clean and safe health facility. Higher-level community scores on these standards lead to enhanced positive results on immediate expected outcomes, which include improving knowledge of entitlements and/or rights to increase health-seeking behavior of community members and subsequently improve their equitable access to quality health services. Similarly, it improves the responsiveness of health service providers or duty bearers for varied changes within the community, making the system resilient.

The U.S. Agency for International Development (USAID) Transform: Primary Health Care is a bilateral project, implemented by a consortium of international and local development partners, in collaboration with communities and the public health sector in 4 regional states in Ethiopia.¹⁸ The project has been providing technical, financial, and other resource support on leadership, management, and governance; health information systems; health care financing; maternal, neonatal, and child health; immunization; reproductive health; adolescent health and development; and performance and quality improvement initiatives to the public health sector to prevent avoidable maternal and child deaths.¹⁸

The primary health care system of Ethiopia is the foundation of the country's 3-tier health system. It is composed of a district hospital and 3 or 4 health centers, each overseeing about 5 health posts. A PHCU includes 1 health center and 5 satellite health posts, serving an average of 25,000 people.¹⁶ Between October 2018 and September 2019, the project initiated the CSC approach and has scaled up the initiative to 159 PHCUs in 31 districts within the Amhara and Southern Nations, Nationalities and Peoples' (SNNP) regional states. The project has been providing technical support through building the capacity of community members and health care providers, enhancing the use of data for evidence-based decision making, adopting and printing job aids, and ensuring the responsiveness of the health system to community needs.¹⁸ The CSC process is considered by the Ministry of Health to be a set of evidence-based tools and resources that will promote performance and quality improvement and has been endorsed for implementation by all PHCUs.

To date, to our knowledge, no studies have assessed the effects of CSCs on health system performance in Ethiopia in terms of service utilization

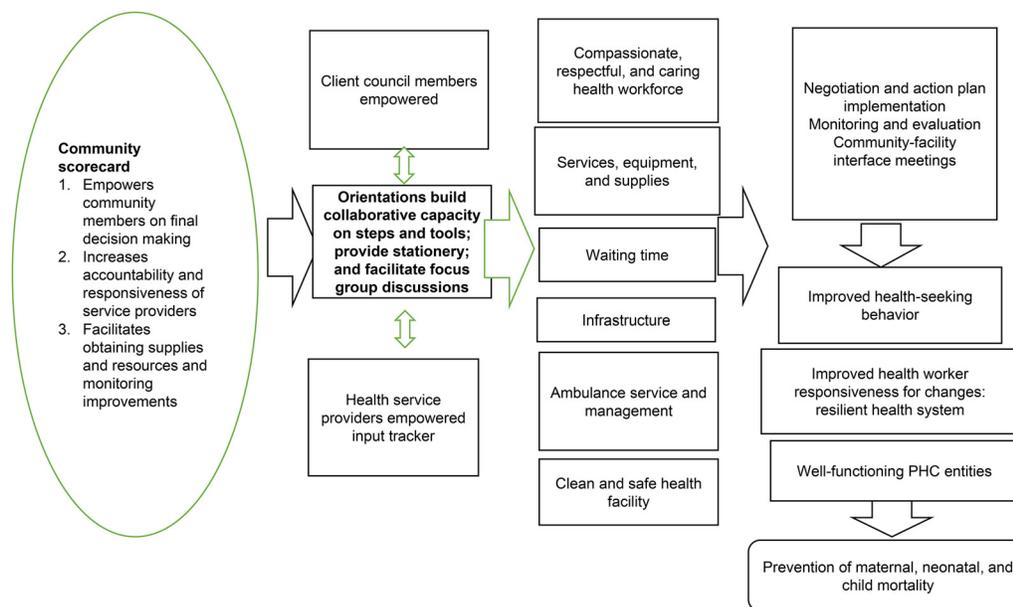
To our knowledge, no studies have assessed the effects of CSCs on health system performance in Ethiopia in terms of service utilization using longitudinal data.

FIGURE 1. Six Phases of Implementation of a Community Scorecard Approach in Ethiopia



Abbreviations: CSC, community scorecard; PHCU, primary health care unit.

FIGURE 2. Illustration of the Ethiopian Health Sector Community Scorecard Theory of Change Developed by USAID Transform: Primary Health Care and the Ethiopian Ministry of Health



Abbreviations: PHC, primary health care; USAID, United States Agency for International Development.

using longitudinal data. Despite the shortage of rigorous evidence on the inputs, process, and outcomes of implementing CSCs in Ethiopia, wide use of CSCs by the public health sector for performance improvement has continued based on the global evidence. Therefore, the results of this longitudinal pre-post interventional study present the effect of CSCs on maternal and child service performance in 2 administrative zones of Ethiopia.

■ METHODS

Study Setting

This study was conducted in South Wollo and Kembata Tembaro administrative zones of Amhara and SNNP regional states, respectively. The USAID Transform: Primary Health Care project provides technical, financial, and other resource support to 91 districts in Amhara and 84 in SNNP, as well as to districts in other regional states.²⁰ The project supported 31 districts and 159 PHCUs to start and implement the CSC intervention for over 12 months as a social accountability tool for performance management.²¹

Ethiopia has a 3-tier health care delivery system. Level 1 is the district (woreda) level, composed of primary hospitals that cover 60,000–100,000 people, health centers serving 15,000–25,000 people, and their satellite health posts covering 3,000–5,000 people, connected to each other through a referral system. The primary hospitals, health centers, and health posts form PHCUs. Districts are subdivided into kebeles (villages), the lowest administrative units. Level 2 includes general hospitals covering 1–1.5 million people. Level 3 includes specialized hospitals covering 3.5–5 million people.¹⁶

In the last 3 decades, the country has expanded access to primary health care through 17,187 health posts; 7,245 private health facilities; 3,724 health centers; and 266 hospitals. In addition, more than 151,053 health professionals are serving communities.²⁰

Implementation of the CSC Intervention

To institutionalize accountability and transparency as a tool for performance management in the health system in both Amhara and SNNP regional states of Ethiopia, 632 participants attended the CSC training of trainers, including 155 from district health offices and 477 from PHCUs. A 3-day classroom theoretical orientation and practical sessions were facilitated in July 2018 at the respective capital cities of the regional states. The CSC orientations were given to 4,053 client councils within the targeted 159 health centers in South

Wollo and Kembata Tembaro administrative zones in August 2018.²¹ The client councils were informed of the 6 standards of the CSC: (1) compassionate, respectful, and caring health workforce; (2) patient waiting time; (3) availability of services, biomedical equipment, and pharmaceutical supplies; (4) health facility infrastructure; (5) ambulance service and management; and (6) clean and safe health facility, citizens' rights, service providers' duties, facilitation techniques, counting and organizing scores, observation skills, verification tools, report submission, and provision of feedback. In addition, every 3 months, the client councils were actively engaged in facility-community interface meetings, presented the results of the CSCs and feedback of community members, addressed issues raised by town hall meeting participants, and closely monitored the implementation of developed action plans. The project supported all client councils with 1-page job aids, reporting forms, and a minute book.

From September 2018 to December 2019, USAID Transform: Primary Health Care provided technical, financial, and other resource support to its targeted districts. Some forms of this support were providing team-based strategic problem-solving trainings for health care providers with the formation of performance improvement and quality improvement projects, enhancing the capacity of performance management team members through offering the use of data for decision-making trainings, providing performance improvement subgrant funding for primary health care entities, and organizing and facilitating community-facility interface meetings.

In addition, the project's staff and experts from zone health departments provided follow-up visits and on-site coaching for all PHCUs and district health offices on a quarterly basis. During facility visits, the coaching team facilitated the exploration of CSC measurements with feedback and gave opportunities for PHCU management staff to systematically analyze the root causes of any issues, propose prioritized solutions, and develop doable action plans. In addition, the coaches revised the concepts of social accountability, provided feedback on performance, and supported the client councils and health care providers. The coaches then submitted a copy of agreed measurement reports, identified gaps, and developed action plans with district health offices and to zone health departments. Baseline data were extracted from the period of October 10–20, 2018. At 6 and 12 months after the intervention periods, secondary data were collected during April 10–20, 2019, as midterm

assessments, and during October 10–22, 2019, as endline measurements by the data collection teams.²¹

Study Design

For this study, the investigators used a longitudinal pre-post interventional study design.²² The necessary data were collected from October 2018 to September 2019. We used quantitative methods to measure the effects of CSC implementation on health-seeking behavior, health service utilization, and responsiveness of health care providers.

Sample Size

The study participants were identified from the Amhara and SNNP regional states in Ethiopia. Two administrative zones where the project had provided technical and other resource support for 12 months or more were purposively selected. All 31 districts (woredas) and 159 PHCUs were included in selected zone administrations. Documents and records from each primary health care entity were reviewed at the 3 points of the assessment.

Data Collection Procedures

The required routine health management information system data on CSC and on maternal and child health services were extracted from 159 PHCUs' RHIMS database. To ensure data completeness, accuracy, consistency, and reliability, 8 data managers and 2 supervisors were trained for 3 days. The training covered the objective of the pre-post interventional study, ethical issues, quantitative data extraction methods, and piloting all tools and ethical principles. During the real data collection, all investigators actively monitored completeness and consistency of data on a daily basis. Data were extracted using structured and pretested forms.

Dependent variables: The average measures, from 0% to 100% on 10 key performance indicators (KPIs) were reviewed and collated: (1) contraceptive acceptance rate, (2) syphilis screening among antenatal care (ANC) clients, (3) skilled delivery services coverage, (4) postnatal care coverage, (5) full immunization coverage, (6) under 2 years growth monitoring coverage, (7) proportion of available essential or tracer drugs, (8) proportion of clean and safe health facility standards met, (9) proportion of available laboratory and diagnostic services, and (10) patient flow and service organization (Table 1).^{18,21} The effects of CSC implementation on the health system's performance were measured at baseline,

midterm (after 6 months), and endline (after 12 months).

Independent variables: The data extraction forms dedicated to capture information on CSCs were adopted from the nationally endorsed CSC reporting tools. The forms captured the summary of the following 6 standards: (1) compassionate, respectful, and caring health workforce; (2) patient waiting time; (3) availability of services, biomedical equipment, and pharmaceutical supplies; (4) health facility infrastructure; (5) ambulance service and management; and (6) clean and safe health facility, reported as an average score from a 5-point Likert scale measurement (Supplement 1), that is, 5=very good to 1=very low. The overall summary of CSCs was reported as a percentage from 0% to 100.0% on 3 occasions¹⁷ (Table 1). The data were collated using a Microsoft Excel sheet and exported to Statistical Program for Social Science (SPSS IBM V 20) software for analysis. To ensure consistency and reliability, the data were double entered by experienced data encoders.

Data Analysis

The PHCU scores of CSCs and KPIs were reviewed for completeness and consistency. Quantitative data analysis methods were used, which included descriptive statistic frequencies, mean, median, interquartile ranges, and standard deviations. To determine the presence of a linear relationship between baseline, midterm, and endline scores, a Pearson Product-Moment Correlation technique was employed. After checking the assumption of the nonparametric test, we used the Friedman²³ test, which includes (1) a single group measured on 3 or more different occasions, (2) a group that is a random sample from population, (3) use of a continuous level of dependent variables, and (4) samples that do not need to be normally distributed. Post hoc analysis with the Wilcoxon signed-rank tests was conducted with a Bonferroni correction applied and a statistical test result with a *P*-value of <.017, indicating presence of a significant difference between CSCs and KPIs at baseline, midterm, and endline measurements.

Ethical Considerations

The ethical clearances of this study were granted by the JSI Institutional Review Board (IRB), and the Amhara Public Health Institute and SNNP Regional State Health Bureaus' IRBs.

The research protocol of this pre-post interventional study was granted certification from the Amhara Public Health Institute (reference

TABLE 1. Description of Key Performance Indicators and Community Scorecard Scoring Standards to Assess Effects of Implementing a Social Accountability Approach on Improving Health System Performance in Maternal and Child Health Services in 2 Regional States in Ethiopia^a

I. Key Performance Indicators	
Contraceptive acceptance rate	
Number of women of reproductive age who use family planning	
Number of women eligible for modern family planning methods	×100%
Syphilis screening among pregnant women attending antenatal care (ANC)	
Number of pregnant women tested for syphilis	
Total number of pregnant mothers attended at least 1 ANC visit	×100%
Skilled delivery service coverage	
The number of births attended by skilled health personnel	
Total number of expected deliveries	×100%
Postnatal care service coverage	
Number of postnatal visits within 7 days of delivery	
Total number of expected deliveries	×100%
Fully immunization coverage	
Number of children who received all vaccine doses before first birthday	
Total number of surviving infants	×100%
Under 2 years growth monitoring service coverage	
Number of children less than 2 year weighed during growth monitoring session	
Total estimated children under 2 years	×100%
Availability of essential (tracer drugs)	
Sum of tracer drugs × months available in the time period	
Sum tracer drugs × sum total number of months in time period	×100%
Clean and safe facility	
Number of clean and safe facility minimum standards met	
Total number of clean and safe facility minimum standards (met and unmet)	×100%
Availability of laboratory and diagnostic services	
Number of laboratory services minimum standards met	
Total number of laboratory services minimum standards (met and unmet)	×100%
Patient flow and service organization	
Number of patient flow and service organization minimum standards met	
Total number of patient flow and service organization minimum standards (met and unmet)	×100%
II. Community Scorecard Facilitation and Scoring	
Indicator 1: Compassionate, respectful, and caring health workforce	
Consider patients as human beings, and provide person-centered care with empathy; effective communication with health care teams and in interactions with patients; and respect for and facilitation of patients’ and families’ participation in decisions and care	
Indicator 2: Patient waiting time for health care services	
Waiting time refers to the time from the patient’s arrival at the health facility to the time the patient receives services	

Continued

TABLE 1. Continued

Indicator 3: Availability of services, biomedical equipment, and pharmaceutical supplies
Availability of services, biomedical equipment, and pharmaceutical supplies
Indicator 4: Health facility infrastructure
Health facility has adequate infrastructure, such as appropriate building, electricity, and water, and the infrastructure is functional for patient care.
Indicator 5: Ambulance service and management
Ambulance service is readily available whenever it is required, and transparent and appropriate ambulance car service management is in place.
Indicator 6: Clean and safe health facility
Health facility compound is clean, green, and pleasing; clinical service areas, such as the outpatient rooms, inpatient beds, and laboratory service area, are safe, hygienic, and odor free; and waste disposal mechanism managed without risk to the health workers, patients, and community members.

^oTen selected maternal, neonatal, and child health indicators were rated from 0.0% to 100.0% and the average scores were extracted. Similarly, the community scorecards were measured against 6 minimum standards developed by the Ministry of Health, regional health bureaus, and development partners. The overall score was rated from 0.0% to 100.0% and extracted from the database.

number: M/T/SH/D/03/435) and the SNNP Regional State Health Bureau Research and Ethics Review Committees (reference number NS 12/36/22). In addition, the study protocol was reviewed at the JSI Research & Training Institute, Inc. IRB, which determined that this activity was exempt from human subjects’ oversight (reference number IRB no. 19-16E). To maintain the confidentiality of collected data, anonymity was maintained throughout the research process.

Permission to use data from zone health departments and PHCUs were obtained through formal written requests. Informed individual written consent was taken from each study subject. Both quantitative and qualitative data were collected in aggregate forms. All PHCUs were encouraged to use the data for evidence-based

decision making and to be responsive to the demands of rights holders. The summary of CSCs and KPIs were submitted to district health offices, zone health departments, and regional health bureaus at the 3 points of the assessment. Throughout the research process, the investigators maintained national and international ethical principles.

RESULTS

In this study, a total of 31 districts from 2 regional states of Ethiopia were enrolled. Table 2 depicts the characteristics of the study areas. Two-thirds (67.7%) of the districts and the majority (128; 80.5%) of PHCUs were located in South Wollo administrative zones of Amhara region. About

TABLE 2. Characteristics of 2 Regions in Ethiopia Where the Study Assessed the Effects of Implementing a Social Accountability Approach on Improving Health System Performance in Maternal and Child Health Services

	SNNP Region No. (%)	Amhara Region No. (%)	Total
Districts	10 (32.3)	21 (67.7)	31
Primary health care units	31 (19.5)	128 (80.5)	159
Population	814,564 (21.2)	3,022,075 (78.8)	3,836,639
Number of villages (kebeles)	166 (22.6)	568 (77.4)	734
Client councils	31 (5.4)	548 (94.6)	579
Villages that implemented community scorecard	93 (14.5)	548 (85.4)	641
Client council members participated in focus group discussions	217 (5.3)	3,836 (94.7)	4,053
Community members participated in focus group discussions	2,604 (6.7)	35,952 (93.3)	38,556

Abbreviation: SNNP, Southern, Nations, Nationalities and Peoples.

3.8 million inhabitants reside in the study area there. A total of 38,556 community representatives participated in focus group discussions and measurements.

Positive Changes in Overall Average CSC and KPI Scores

Table 3 presents the summary score of CSCs and KPI values. The percentage of CSC and standard deviation (\pm SD) achieved at the 3 points in time

were 60.8% (\pm 12.5%), 66.3% (\pm 10.8%), and 70.6% (\pm 10.0%) for baseline, midterm, and endline measurements, respectively. The mean CSC measurement improvement was observed from 68.7% to 74.4% and 58.9% to 69.7% in Kembata Tembaro and South Wollo administrative zones, respectively. Availability and utilization of services were higher at 3 points in time, that is, 54.9 ± 17.4 , 61.9 ± 15.1 , and 67.6 ± 14.6 at baseline, midterm,

TABLE 3. Key Performance Indicator and Community Scorecard Scores of the Study Assessing the Effects of a Social Accountability Approach on Improving Health System Performance in Maternal and Child Health Services in 2 Regional States in Ethiopia, October 2018 to September 2019^a

	Baseline		Midterm		Endline	
	SNNP	Amhara	SNNP	Amhara	SNNP	Amhara
Social accountability						
Compassionate, respectful, and caring health work force	3.78 \pm 0.50	3.07 \pm 0.72	3.56 \pm 0.53	3.41 \pm 0.68	3.77 \pm 0.45	3.66 \pm 0.60
Patient waiting time	3.31 \pm 0.97	2.95 \pm 0.80	3.39 \pm 0.60	3.25 \pm 0.72	3.61 \pm 0.57	3.47 \pm 0.77
Availability of services, biomedical equipment, and pharmaceutical supplies	3.40 \pm 0.61	2.92 \pm 0.68	3.74 \pm 0.45	3.15 \pm 0.70	3.83 \pm 0.52	3.40 \pm 0.67
Health facility infrastructure	3.44 \pm 0.70	2.86 \pm 0.74	3.69 \pm 0.53	3.15 \pm 0.82	3.71 \pm 0.57	3.47 \pm 0.71
Ambulance service and management	3.11 \pm 0.55	2.57 \pm 0.81	3.29 \pm 0.51	3.06 \pm 0.81	3.58 \pm 0.48	3.14 \pm 0.80
Clean and safe health facility	3.53 \pm 0.50	3.28 \pm 0.88	3.67 \pm 0.79	3.50 \pm 0.78	3.84 \pm 0.78	3.75 \pm 0.68
Overall summary of community scorecard	68.7 \pm 6.6	58.9 \pm 12.8	71.2 \pm 5.8	65.2 \pm 11.5	74.4 \pm 6.4	69.7 \pm 10.5
	60.8% \pm 12.5%		66.3% \pm 10.8%		70.6% \pm 10.0%	
Key performance indicators						
Contraceptive acceptance rate	80.7 \pm 22.0	85.2 \pm 28.4	82.7 \pm 25.0	93.4 \pm 22.0	88.9 \pm 22.3	95.1 \pm 28.7
Syphilis screening among antenatal care clients	82.9 \pm 17.7	58.6 \pm 37.3	84.2 \pm 17.5	67.4 \pm 36.5	87.8 \pm 22.6	78.4 \pm 43.1
Skilled delivery service coverage	64.7 \pm 23.4	40.6 \pm 21.5	66.3 \pm 23.3	45.0 \pm 22.0	66.9 \pm 23.5	54.9 \pm 28.0
Postnatal service coverage	76.1 \pm 23.3	52.7 \pm 25.9	88.6 \pm 18.6	56.6 \pm 24.0	84.5 \pm 23.1	67.4 \pm 31.4
Fully immunization coverage	98.2 \pm 15.2	78.5 \pm 25.9	94.3 \pm 7.8	76.8 \pm 18.7	97.7 \pm 14.7	83.0 \pm 20.4
Growth monitoring coverage	84.3 \pm 29.6	13.9 \pm 7.1	87.9 \pm 25.4	14.5 \pm 8.5	92.8 \pm 18.8	17.0 \pm 10.9
Proportion of available essential or tracer drugs	63.2 \pm 16.7	51.3 \pm 32.0	72.5 \pm 14.3	63.3 \pm 24.8	76.5 \pm 13.5	69.6 \pm 20.1
Proportion of available diagnostic services	74.2 \pm 20.4	37.0 \pm 37.7	83.2 \pm 17.0	50.4 \pm 35.8	86.5 \pm 12.9	51.0 \pm 36.2
Proportion of clean and safe health facility standards met	77.0 \pm 18.2	49.4 \pm 33.8	80.9 \pm 15.1	63.1 \pm 26.1	85.0 \pm 11.0	70.4 \pm 21.8
Waiting time/ patient flow/responsiveness health center–health post linkage	54.8 \pm 25.1	31.7 \pm 30.1	56.9 \pm 26.4	45.1 \pm 30.5	69.3 \pm 27.1	50.0 \pm 29.2
Overall key performance indicators summary score	75.6 \pm 19.1	49.9 \pm 15.1	79.7 \pm 7.5	57.6 \pm 13.1	83.6 \pm 7.1	63.7 \pm 13.2
	75.6% \pm 9.1%		79.7% \pm 7.5%		80.9% \pm 8.7%	

Abbreviation: SNNP, Southern, Nations, Nationalities and Peoples.

^a Average community scorecard and key performance indicators with standard deviation.

and endline, respectively. The mean KPI (\pm SD) scores of 31 health centers in Kembata Tembaro zone were 75.6% (\pm 19.1%), 79.7% (\pm 7.5%), and 80.9% (\pm 8.7%) at baseline, midterm, and endline measurements, respectively. Similarly, the mean KPI scores (\pm SD) of 128 health centers in South Wollo zone were 49.9% (\pm 15.1%), 57.6% (\pm 13.1%), and 63.7% (\pm 13.2%) at baseline, midterm, and endline measurements, respectively. The results revealed the presence of significant positive changes in syphilis screening tests among ANC clients (58.6% to 78.4%), skilled delivery attendance (40.6% to 54.9%), full immunization services (78.5% to 83.0%), and availability of essential or tracer drugs (51.3% to 69.6%) in South Wollo zone. There were also improvements in the Kembata Tembaro zone within the SNNP region, including syphilis screening tests among ANC clients (82.9% to 87.8%), skilled delivery attendance (64.7% to 66.9%), growth monitoring services (84.3% to 92.8%), and availability of essential or tracer drugs (63.2% to 76.5%).

Difference in CSC Values Over Time

At baseline, the mean score of CSCs was 60.8; at midterm, it was 66.3; and at endline, it was 70.6. A statistically significant difference was found in CSC ratings at baseline, midterm, and endline measurements, $\chi^2(2)=252.642$, $P=.000$. Post hoc analysis using the Wilcoxon signed-rank tests was conducted with a Bonferroni correction applied, resulting in a significance level set at $P<.017$. Median (interquartile range) CSC measurements at baseline, midterm, and endline were 60.4 (52.9–70.3), 66.9 (58.3–73.9), and 71.0 (61.1–77.6), respectively. There were statistically significant positive differences between CSC at midterm and baseline ($Z=-9.049$, $P=.00$); endline and baseline ($Z=-10.235$, $P=.000$), and endline and midterm ($Z=-9.667$, $P=.000$). Therefore, it can be concluded that long-term community engagement elicits a significant rise in perceived CSC measurement values.

Difference in KPIs Over Time

At baseline, the mean score of KPIs was 54.94; at midterm, it rose to 61.93; and at endline, it increased even further to 67.61. A statistically significant difference was found in KPIs at baseline, midterm and endline measurements, $\chi^2(2)=267.142$, $p=0.001$. Post hoc analysis with Wilcoxon signed-rank tests was conducted with a Bonferroni correction applied, resulting in a significance level set

at $P<.017$. Median (interquartile range) KPI measurements at baseline, midterm, and endline were 53.6 (42.0–68.5), 60.1 (51.6–74.5), and 66.3 (56.7–80.0), respectively. There were statistically significant positive differences between KPI at midterm and baseline ($Z=-10.203$, $P=.001$), endline and baseline ($Z=-10.889$, $P=.001$), and endline and midterm ($Z=-10.026$, $P=.000$). Therefore, it can be concluded that long-term community engagement brings a significant increase in KPI measurement values.

Table 4 shows that the summary result of each CSC and average KPIs have a positive correlation, as CSC at midterm and average KPI at endline had a moderate degree relationship ($r>0.377$). The highest correlation was seen between KPI at midterm and endline ($r>0.924$), which was followed by KPI at baseline and midterm ($r>0.882$). These findings also indicate a statistically significant correlation between CSC and KPIs.

DISCUSSION

This longitudinal, pre-post CSC interventional study in 31 districts and 159 PHCUs documented the establishment of 579 client councils and the participation of 38,556 community members. The support of the project, which included capacity building of health workers and community members, as well as provision of job aids, reporting forms, and performance improvement subgrants, helped the PHCUs to increase their performance. The baseline, midterm, and endline data showed statistically significant ongoing increases. The results revealed positive correlations between the CSC average values and the average KPI achievements. Therefore, it can be concluded that building the capacity of community members and health workers on the implementation of social accountability interventions can help to improve service availability and utilization of primary health care services.

The measurement results of CSCs were positively correlated and had statistically significant higher differences, which may have occurred due to the responsiveness of the health system to the needs and demands of community members in terms of health worker behavior, availability of services, and improvements in supplies, infrastructure, and waiting time. This finding was in line with an article by Ho et al.²⁴ on CSC implementation in the DRC, which showed improved patient and health provider relationships as well as improved quality of and access to primary health care services.²⁴ Tabish²⁵ and Herrera et al.²⁶ confirmed that changing governance arrangements had an

The support of the project, including health worker capacity building, job aids, and reporting forms, helped the PHCUs to increase their performance.

TABLE 4. Correlation Summary Analysis of Each Community Scorecard With Average Key Performance Indicators Score of the Study Assessing the Effects of a Social Accountability Approach on Improving Health System Performance in Maternal and Child Health Services in 2 Regional States in Ethiopia, October 2018 to September 2019

		CSC Baseline	CSC Midterm	CSC Endline	KPI Baseline	KPI Midterm	KPI Endline
CSC baseline	Pearson Correlation	1					
	Sig. (2-tailed)						
	N	159					
CSC midterm	Pearson Correlation	.718 ^a	1				
	Sig. (2-tailed)	.000					
	N	159	159				
CSC endline	Pearson Correlation	.662 ^a	.874 ^a	1			
	Sig. (2-tailed)	.000	.000				
	N	159	159	159			
KPI baseline	Pearson Correlation	.504 ^a	.489 ^a	.533 ^a	1		
	Sig. (2-tailed)	.000	.000	.000			
	N	159	159	159	159		
KPI midterm	Pearson Correlation	.448 ^a	.412 ^a	.446 ^a	.882 ^a	1	
	Sig. (2-tailed)	.000	.000	.000	.000		
	N	159	159	159	159	159	
KPI endline	Pearson Correlation	.398 ^a	.377 ^a	.429 ^a	.815 ^a	.924 ^a	1
	Sig. (2-tailed)	.000	.000	.000	.000	.000	
	N	159	159	159	159	159	159

Abbreviations: CSC, community scorecard; KPI, key performance indicator.

^aCorrelation is significant at the 0.01 level (2-tailed). Perfect: If the value is near ± 1, then it said to be a perfect correlation: as one variable increases, the other variable tends to also increase (if positive) or decrease (if negative). High degree: If the coefficient value lies between ±0.50 and ± 1, then it is said to be a strong correlation. Moderate degree: If the value lies between ±0.30 and ±0.49, then it is said to be a medium correlation. Low degree: When the value lies below + 0.29, then it is said to be a small correlation. No correlation: When the value is zero.

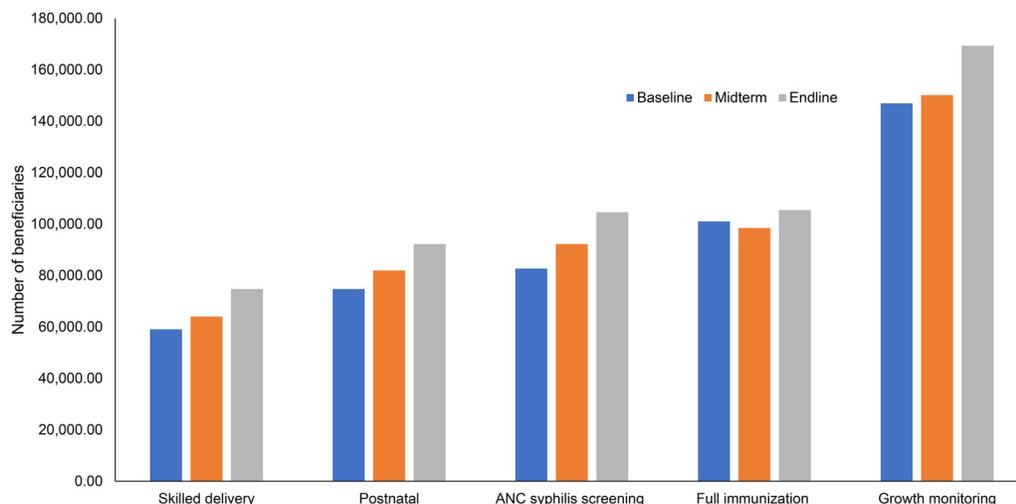
effect on health outcomes. Similarly, in Afghanistan, Edward et al.²⁷ attested that the implementation of CSCs helped to enhance governance and health system accountability for people-centered health care.

Maternal and child health service utilization increased, specifically for skilled delivery (from 45.3% to 57.3%), postnatal care services (from 57.3% to 70.7.0%), syphilis screening (from 63.4% to 80.2%), full immunization for infants under 1 year (from 82.3% to 85.9%), and growth monitoring for children under 3 years (from 27.0% to 31.8%) (Figure 3). These results could have been achieved through negotiations between community members and health workers in which detailed action plans were developed, implemented, and evaluated (Supplement 2). This finding was in line with Gullo

et al.,¹⁴ Schaaf et al.,⁴ and Gullo et al.,¹⁵ who found that service utilization was significantly higher among CSC intervention groups than among nonintervention community members. Similarly, Blake et al.²⁸ attested that after a 1-year implementation of scorecards in 37 health facilities in Ghana, there was a significant improvement on maternal and newborn health services through better access to essential drugs, improved infrastructures, and availed essential equipment.

The implementation of CSCs at the PHCU level was aligned with the performance measurement and enhancing accountability, transparency, and engagement of public and civil societies and duty holders (citizens) to achieve the strategic objectives of the Ethiopian Health Sector Transformation Plan

FIGURE 3. Increased Utilization of Maternal and Child Health Services in Ethiopia, October 2018 to September 2019



Abbreviation: ANC, antenatal care.

(HSTP 2015-2020) of the Ethiopian government.^{16,29} This finding was in line with Argaw et al.,¹⁹ who reported that measurements against minimum standards and developing improvement plans helped to improve primary health system performance. In addition, this social accountability tool is implemented by creating pools of trainers, orienting health care providers and community members on the principles and guiding steps, and providing job aids. However, to improve the performance of the health system, costs associated with close follow-up on action plans by the next higher-level institution in the system and performance improvement funds should be a part of the CSC intervention.

This longitudinal pre-post interventional study revealed that the implemented CSC intervention, which is a nationally recommended citizen measurement, engagement, and accountability tool, helps health workers and community members to contribute to the improvement of the performance of the health system.

Limitations

This study has some limitations. The main limitation is related to the pre-post study design; unlike a randomized study design, it is difficult to conclude the causal association between the CSC intervention and the KPI improvements with a pre-post design. The other limitation of this study

is the lack of literature on government-led large-scale implementation of CSC. Hence, this study uses results from projects implemented by civic society organizations in limited areas. As the study targeted 2 zone administrations, before generalizing the findings, the context should be noted.

CONCLUSIONS AND RECOMMENDATIONS

Based on this study’s results, implementing CSCs as a tool to enhance accountability, transparency, and community engagement could help to contribute to improvements in the performance of the health system regarding maternal and child health services. Ensuring continuity of the implementation of the CSC intervention by orienting client councils on the principles of CSCs, providing reporting forms and job aids, and providing sub-grants for PHCUs is recommended. In addition, a qualitative study to document the process of CSC implementation and experiences of community representatives is recommended.

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REFERENCES

- World Bank. *World Development Report 2004: Making Services Work for Poor People*. Oxford University Press/World Bank; 2003. Accessed February 25, 2021. <http://hdl.handle.net/10986/5986>
- Malena C, Forster E, Singh J. *Social Accountability—An Introduction to the Concept and Emerging Practice*. World Bank Group; 2004. Accessed February 25, 2021. <http://documents.worldbank.org/curated/en/327691468779445304/Social-accountability-an-introduction-to-the-concept-and-emerging-practice>
- Gullo S, Galavotti C, Altman L. A review of CARE's CSC experience and evidence. *Health Policy Plan*. 2016;31(10):1467–1478. [CrossRef](#). [Medline](#)
- Schaaf M, Topp SM, Ngulube M. From favours to entitlements: community voice and action and health service quality in Zambia. *Health Policy Plan*. 2017;32(6):847–859. [CrossRef](#). [Medline](#)
- Brinkerhoff DW. Accountability and health systems: toward conceptual clarity and policy relevance. *Health Policy Plan*. 2004;19(6):371–379. [CrossRef](#). [Medline](#)
- Brinkerhoff DW, Wetterberg A. Gauging the effects of social accountability on services, governance, and citizen empowerment. *Public Adm Rev*. 2016;76(2):274–286. [CrossRef](#)
- Jacobs A. Creating the missing feedback loop. *IDS Bull*. 2010;41(6):56–64. [CrossRef](#)
- Danhoundo G, Nasiri K, Wiktorowicz ME. Improving social accountability processes in the health sector in sub-Saharan Africa: a systematic review. *BMC Public Health*. 2018;18(1):497. [CrossRef](#). [Medline](#)
- Rad MH, Handalo DM, Debela TF, Siraneh Y, Worku F, Yesuf EA. Practice and associated factors of health professionals towards citizens' charter at Jimma University Medical Center. *Ethiop J Health Sci*. 2019;29(5):535–542. [CrossRef](#)
- Federal Democratic Republic of Ethiopia, Ministry of Finance and Economic Commission (MOFEC). Ethiopia Protection of Basic Services Social Accountability Program: Internal Assessment. MOFEC; 2016.
- Addai E, Dery M. *The Community Scorecard Approach for Performance Assessment*. WaterAid Ghana; 2004. Accessed February 28, 2021. <https://namati.org/resources/community-scorecard-approach-performance-assessment-a-wateraid-ghana-briefing-paper/>
- Claasen M, Alpin-Lardiés C, eds. *Social Accountability in Africa: Practitioners' Experiences and Lessons*. African Books Collective; 2010.
- CARE Malawi. *The Community Score Card (CSC): A Generic Guide for Implementing CARE's CSC Process to Improve Quality of Services*. CARE Malawi; 2013. Accessed February 25, 2021. http://www.care.org/sites/default/files/documents/FP-2013-CARE_CommunityScoreCardToolkit.pdf
- Gullo S, Galavotti C, Sebert Kuhlmann A, Msiska T, Hastings P, Marti CN. Effects of a social accountability approach, CARE's Community Score Card, on reproductive health-related outcomes in Malawi: a cluster-randomized controlled evaluation. *PLoS One*. 2017;12(2):e0171316. [CrossRef](#). [Medline](#)
- Gullo S, Kuhlmann AS, Galavotti C, Msiska T, Nathan Marti C, Hastings P. Creating spaces for dialogue: a cluster-randomized evaluation of CARE's Community Score Card on health governance outcomes. *BMC Health Serv Res*. 2018;18(1):858. [CrossRef](#). [Medline](#)
- Federal Democratic Republic of Ethiopia, Ministry of Health (MOH). *Health Sector Transformation Plan*. EFMOH; 2015. Accessed February 27, 2021. https://www.globalfinancingfacility.org/sites/gff_new/files/Ethiopia-health-system-transformation-plan.pdf
- Federal Democratic Republic of Ethiopia, Ministry of Health (MOH). *Creating Accountability Through Community Scorecard: Implementation Guidelines*. EFMOH; 2017. Accessed February 28, 2021. http://repository.iifphc.org/bitstream/handle/123456789/642/Implementation%20Manual-Community%20Scorecard%2005_9_18.pdf?sequence=1&isAllowed=y
- U.S. Agency for International Development (USAID) Transform: Primary Health Care Project. *Theory of Change in Practice* 2017. USAID Transform Primary Health Care; 2017.
- Argaw MD, Desta BF, Bele TA, Ayne AD. Improved performance of district health systems through implementing health center clinical and administrative standards in the Amhara region of Ethiopia. *BMC Health Serv Res*. 2019;19(1):127. [CrossRef](#). [Medline](#)
- Federal Democratic Republic of Ethiopia, Ministry of Health (MOH). *Health and Health Related Indicators*. MOH; 2017. Accessed February 27, 2021. <http://repository.iifphc.org/bitstream/handle/123456789/395/Health%20and%20Health%20Related%20Indicator%202017.pdf?sequence=1&isAllowed=y>
- U.S. Agency for International Development (USAID) Transform: Primary Health Care Project. *Theory of Change in Practice* 2019. USAID Transform Primary Health Care; 2019.
- Thiese MS. Observational and interventional study design types; an overview. *Biochem Med (Zagreb)*. 2014;24(2):199–210. [CrossRef](#). [Medline](#)
- Scheff SW. *Fundamental Statistical Principles for the Neurobiologist: A Survival Guide*. Academic Press; 2016.
- Ho LS, Labrecque G, Batonon I, Salsi V, Ratnayake R. Effects of a community scorecard on improving the local health system in Eastern Democratic Republic of Congo: qualitative evidence using the most significant change technique. *Confl Health*. 2015;9(1):27. [CrossRef](#). [Medline](#)
- Tabish SA. Healthcare: from good to exceptional governance. *JIMSA*. 2012;25(3):147–150.
- Herrera CA, Lewin S, Paulsen E, et al. Governance arrangements for health systems in low-income countries: an overview of systematic reviews. *Cochrane Database Syst Rev*. 2017;9(9):CD011085. [CrossRef](#). [Medline](#)
- Edward A, Osei-Bonsu K, Branchini C, Yarghal T, Arwal SH, Naeem AJ. Enhancing governance and health system accountability for people centered healthcare: an exploratory study of community scorecards in Afghanistan. *BMC Health Serv Res*. 2015;15(1):299. [CrossRef](#). [Medline](#)
- Blake C, Annorbah-Sarpei NA, Bailey C, et al. Scorecards and social accountability for improved maternal and newborn health services: a pilot in the Ashanti and Volta regions of Ghana. *Int J Gynaecol Obstet*. 2016;135(3):372–379. [CrossRef](#). [Medline](#)
- Manroth A, Hernandez Z, Masud H, et al. *Strategic Framework for Mainstreaming Citizen Engagement in World Bank Group*

Operations: Engaging With Citizens for Improved Results. World Bank Group; 2014. Accessed February 25, 2021. <http://documents.worldbank.org/curated/en/266371468124780089/>

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ORIGINAL ARTICLE

The Evolving Landscape of Medical Device Regulation in East, Central, and Southern Africa

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Key Findings

- Although 11 of 14 member countries of the College of Surgeons of East, Central, and Southern Africa have legislation mandating the regulation of medical devices, only half are currently developing medical device regulatory processes and half do not have a formal process.
- A country's gross domestic product had a strong correlation to level of medical device regulation.
- The number of years that had elapsed from the country's independence to the present had a strong correlation to the status of the country's regulatory processes.

Key Implications

- To expand regulatory capacity and minimize resource expenditure when developing or creating new medical device regulations, policy makers should facilitate adopting or amending existing harmonized regulations.
- Ministries of health should prioritize local capacity building in the form of well-trained personnel, tools, and facilities to improve regulatory standards.
- Medical technology companies with a charitable division should consider investment in capacity building and innovation to harmonize regulatory standards across African countries.

ABSTRACT

Effective regulatory frameworks, harmonized to international standards, are critical to expanding access to quality medical devices in low- and middle-income countries. This review provides a summary of the state of medical device regulation in the 14 member countries of the College of Surgeons of East, Central, and Southern Africa (COSECSA) and South Africa. Countries were categorized according to level of regulatory establishment, which was found to be positively correlated to gross domestic product (GDP; $r_s=0.90$) and years of freedom from colonization ($r_s=0.60$), and less positively correlated to GDP per capita ($r_s=0.40$). Although most countries mandate medical device regulation in national legislation, few employ all the guidelines set forth by the World Health Organization. A streamlined regulatory process across African nations would simplify this process for innovators seeking to bring medical devices to the African market, thereby increasing patient access to safe medical devices.

INTRODUCTION

Medical devices are essential to the diagnosis and treatment of many diseases, particularly within surgical specialties, radiology, and critical care.¹ A medical device is any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material, or related article used for a specific medical purpose.² Most existing medical devices were built for the demands and resources available in high-income countries and are not adapted to the challenges often present in many countries in Africa.³ Therefore, there is an urgent need to develop medical devices that are specifically designed to address these challenges to improve African patients' access to medical care.⁴ The medical device regulatory processes in many African countries are not well-defined, and countries may rely on clearance from the European Medicines Agency⁵ or the U.S. Food and Drug Administration (FDA).⁶ Although these regulatory processes are stringent with excellent safety standards,⁷ these processes are expensive and may be prohibitive to nonprofit organizations or local device developers in Africa. In addition, the regulatory processes of high-income countries are not designed to meet the needs and safety issues present in Africa. Further, it can be challenging to obtain regulatory approval or clearance in multiple African countries since regulatory processes vary or can be challenging to navigate.⁸

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Well-established regulatory systems for medical devices are essential to ensuring device safety and efficacy.⁹ In 1993, the Global Harmonization Task Force (GHTF), now known as the International Medical Device Regulators Forum (IMDRF), was founded in association with multiple national regulatory authorities. The IMDRF encourages convergence of regulatory standards for medical devices and facilitates information access for countries in the development phase of their regulatory process.¹⁰ Despite these efforts, very few African countries have established regulatory systems. A 2017 World Health Organization (WHO) report found that 40% of countries in the WHO-defined African region have no regulations for medical devices, 32% have some regulations, and the remaining 28% have no available data. In contrast, medical device regulation is present in 58% of all WHO member countries.¹¹ This gap in medical device regulation between the African region and the global average is important to address as it may translate to lower quality medical devices and limited access to health care technology for patients.

The importance of medical device regulation is magnified by the prevalence and economic cost of substandard medicines and medical devices. According to the WHO, in 2017, the approximate failure rate of substandard and falsified medical products in low- and middle-income countries was 10.5%, which translates to an economic loss of around \$30.5 billion in medical expenditures. Strong medical device regulation is therefore an important, needed step toward achieving higher-quality and more affordable medical care for countries already working within tight economic constraints.¹²

Underdeveloped regulatory processes present challenges for businesses and manufacturers of new medical devices interested in entering the African market,¹³ as regulatory processes are country-dependent but generally modeled after the European Union and the Medical Device Directive.¹⁰ As a result, introducing a new medical device in the African region requires evaluating local laws and regulations on a country by country basis.

Previous evaluations of regulatory work have been published.^{8,14–17} We provide an updated review with a focus on medical device regulation in the 14 member countries of the College of Surgeons of East, Central, and Southern Africa (COSECSA).¹⁸ COSECSA is the largest surgical training institution in sub-Saharan Africa, with a diverse international surgical membership who commonly use a wide range of medical devices. This summary is essential

to understanding the state of medical device regulations in this region of Africa, examining how regulatory systems could be further developed and harmonized, and developing best approaches for increasing access to new medical devices in COSECSA countries and surrounding regions.

■ METHODS

Search Strategy and Selection Criteria

We completed a literature review to understand the status of medical device regulation in COSECSA countries and South Africa. The following databases were searched for peer-reviewed journal articles up to December of 2019: SCOPUS, PubMed, and Google Scholar. Search terms included “medical device regulation,” “device regulation,” “Africa,” and “sub-Saharan Africa,” as well as the individual countries under consideration. Literature detailing regulation of medical devices outside of the African countries of interest were excluded from this review. Literature that discussed only the regulation of medicines and pharmaceuticals and not medical devices was also excluded. The relevant literature was agreed upon by 2 reviewers and examined. Additional sources were identified within the reference lists of literature compiled during this initial search. A Google search was conducted for non-peer-reviewed gray literature, including government legislation and reports by both governmental and nongovernmental organizations. This search provided access to country-specific information, legislation from national regulatory authority websites, and reports from nongovernmental organizations and the United Nations.

Key information was extracted from relevant literature and organized by country. Data included: national regulatory authorities or regulatory bodies; regulatory legal framework; medical device definition; device classification system; essential principles and standards; conformity assessment; registration and listing requirements; import controls; and postmarket controls. These key areas were adapted from WHO guidelines.¹¹

A classification scheme was developed to categorize the level of medical device regulation. Level 1 was designated for countries with the most well-established regulatory processes. These may closely resemble those of the FDA or European Medicines Agency in both complexity and level of establishment. Level 2 was designated for countries with developing regulatory processes where such processes are not yet well-established or implemented. Lastly, level 3 was designated for countries with no defined regulatory approval process for medical

This review is essential to understanding the state of medical device regulations in this region of Africa, examining how regulatory systems could be further developed and harmonized, and developing best approaches for increasing access to new medical devices.

devices. This included countries that have legislation mandating the regulation of medical devices but have no defined system for pursuing implementation. It also included countries that use informal systems of regulation or regulate medical devices according to the same policies that govern the import of all commercial goods.

Country regulatory levels were correlated to gross domestic product (GDP), GDP per capita,¹⁹ and years since freedom from colonization by calculating the Spearman correlation coefficient in Microsoft Excel (Office 365 version 16.41). A correlation coefficient of 0 indicates no correlation, while a coefficient of 1 indicates perfect correlation between variables. Ethical review by an institutional review board was not sought as all information was accessed from publicly available sources.

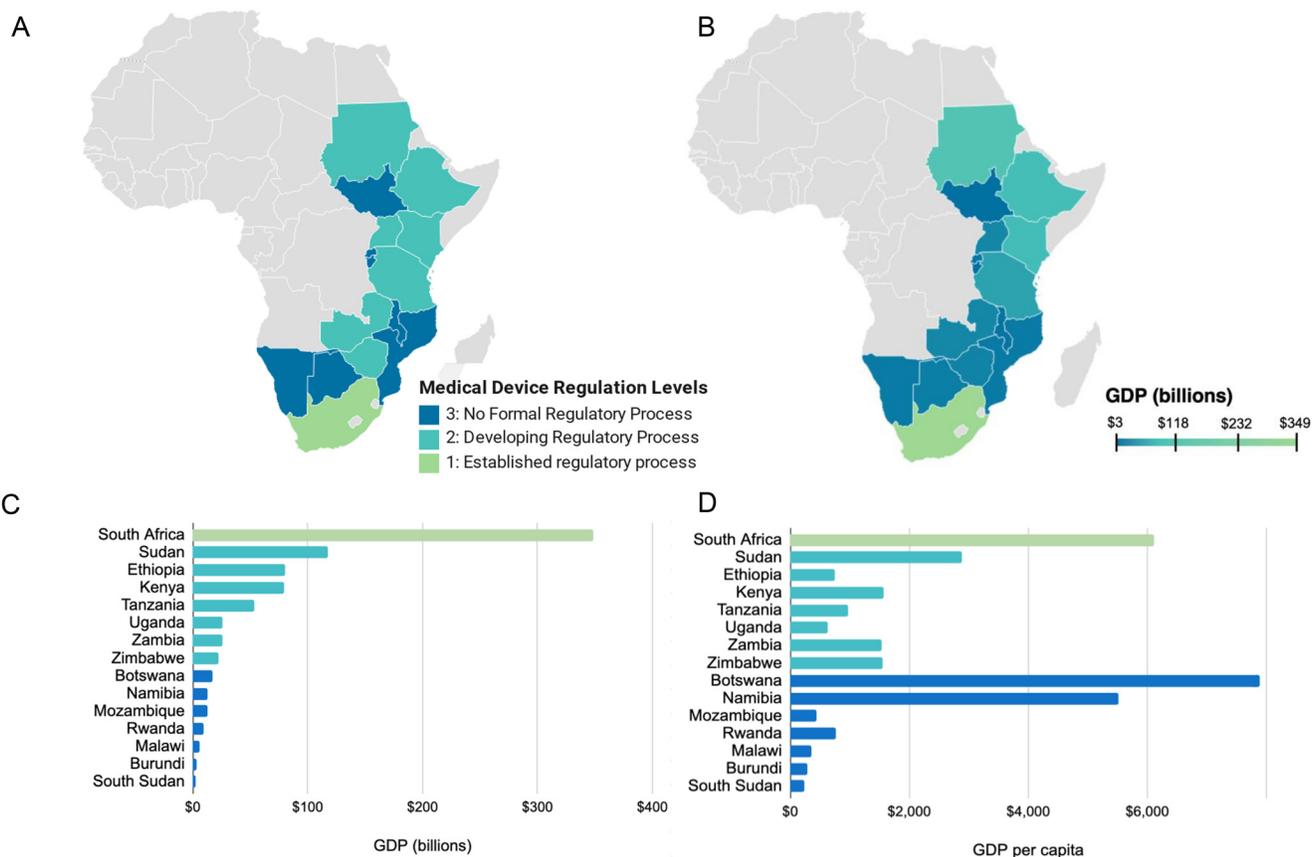
RESULTS

The literature search returned 6,138 articles, of which 11 were determined to be relevant and were reviewed. Additional sources included 10 government websites, 16 nongovernmental organization websites, and 4 publicly available, non-peer-reviewed websites.

GDP, Colonization, and Regulatory Processes

All COSECSA countries and South Africa were evaluated to determine their respective levels of medical device regulation (Figure 1A). South Africa, though not a COSECSA member country, was included in analysis as a point of comparison. Half of all COSECSA countries (n=7, 50%) are currently developing regulatory processes for medical devices (Level 2) while the remaining

FIGURE 1. (A) Map of Africa showing the levels of medical device regulation in selected countries. (B) Map of Africa showing the GDP in selected countries in 2020. (C) The level of medical device regulation is correlated to gross domestic product (Spearman correlation coefficient of 0.90). (D) The level of medical device regulation is not significantly correlated to the 2020 gross domestic product per capita (Spearman correlation coefficient of 0.40).



half (n=7, 50%) do not have a formal regulatory process in place for medical devices (Level 3). South Africa has an established, formal regulatory process for medical devices that includes all essential regulatory components as recommended by the WHO (Level 1).

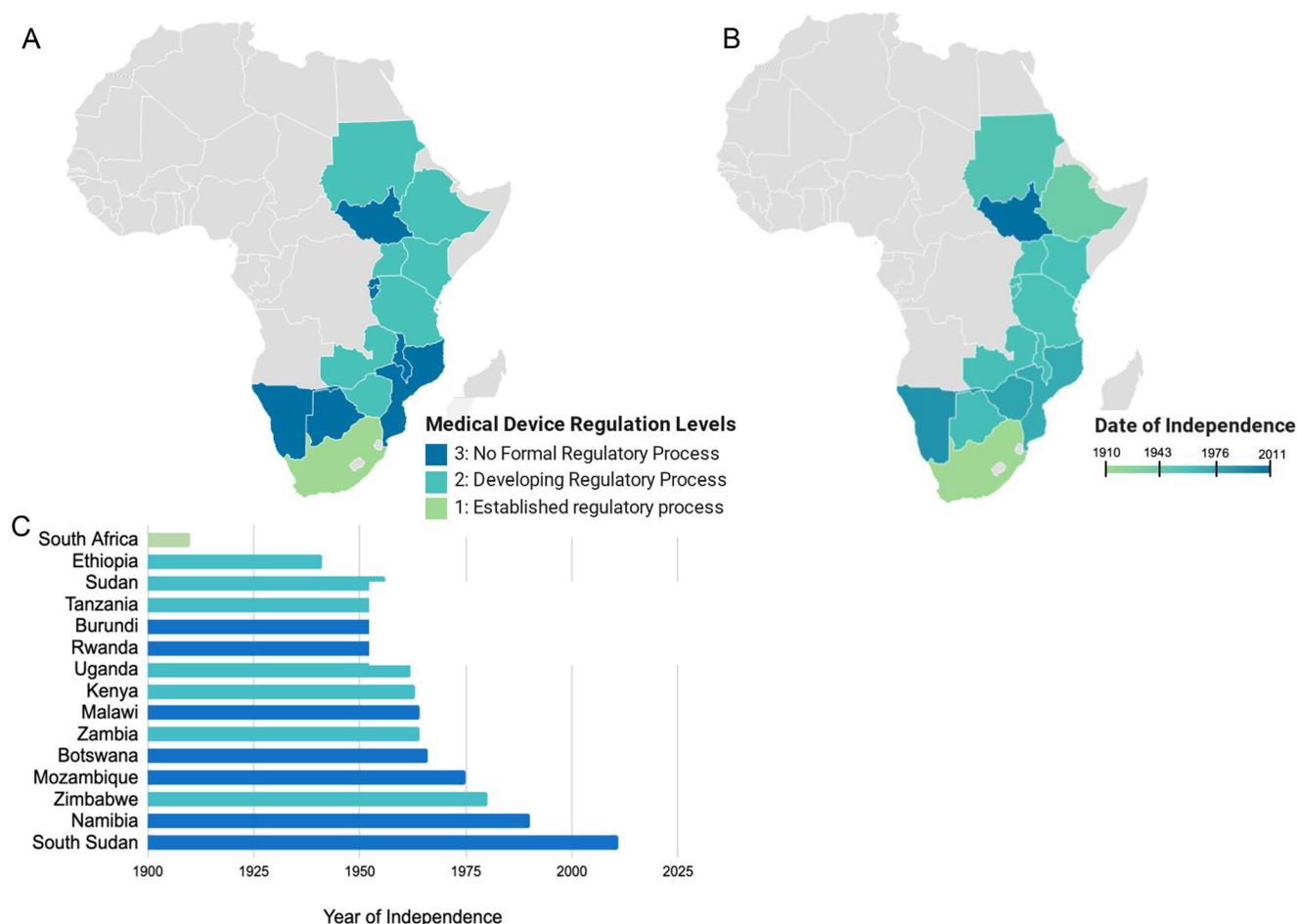
Levels of medical device regulation were examined with respect to GDP (Figure 1B, C) and GDP per capita (Figure 1D) as these metrics are descriptive of the size of the economy and income per person. GDP was found to have a strong positive association with the level of medical device regulation, yielding a Spearman correlation coefficient of 0.90. South Africa, with the highest GDP of \$349 billion,¹⁹ has the greatest establishment of medical device regulation. All countries with a GDP between \$20 and \$120 billion fell under Level 2. All countries with a GDP lower than \$20 billion fell under Level 3.

Interestingly, the same trend was not as prominent for GDP per capita, where the Spearman correlation coefficient was 0.40, indicating a weak association. Botswana and Namibia, with the highest and third highest GDP per capita respectively, both fall under Level 3. South Africa has the second highest GDP per capita and falls under Level 1. In summation, GDP has a strong correlation with medical device regulation while GDP per capita shows a less clear association.

Due to a history of colonization in sub-Saharan Africa, and its negative sequelae,²⁰ we examined years of country independence and compared it to the status of medical device regulation (Figure 2). Years of independence was defined as the number of years elapsed from the date of the country's independence to the present. In general, the longer a country has existed as

GDP has a strong correlation with medical device regulation, but GDP per capita shows a less clear association.

FIGURE 2. (A) Map of Africa showing the levels of medical device regulation in selected countries. (B) Map of Africa showing dates of country independence. (C) The level of medical device regulation is correlated to the year of independence (Spearman correlation coefficient of 0.60).



an independent state, the more advanced the regulatory process. The correlation coefficient between regulatory status and years of independence was 0.60, indicating a strong correlation.

Critical Components of the Regulatory Process

An overview of the regulatory processes of the COSECSA countries and South Africa is presented in the Table. This includes information

regarding the existence of certain premarket controls, placing on the market, and postmarket controls recommended within the 2017 WHO Global Model Regulatory Framework for Medical Devices.¹¹

1. Legal Framework

The establishment of medical device regulation must have a sound legal basis. Although the legal foundation can vary, the WHO recommends legislation to define the scope of regulation. This

TABLE. Existence of Critical Components of the Regulatory Process for Medical Devices in COSECSA Countries and South Africa

	Regulatory Complexity 1-3	Regulatory Body	Legal Framework	Medical Device Defined	Risk-based Classification System	Essential Principles	Conformity Assessment	Registration Required	Import Controls	Post-Market Controls
South Africa	1	South African Health Products Regulatory Authority	✓	✓	A-D	✓	✓	✓	✓	✓
Sudan	2	National Medicine and Poisons Board	✓	✓	A-D	✓	✓	✓	X	✓
Ethiopia	2	Food, Medicine and Healthcare Administration and Control Authority	✓	✓	I-IV	✓	X	✓	X	✓
Kenya	2	The Pharmacy and Poisons Board	✓	✓	A-D	✓	✓	✓	✓	✓
Tanzania	2	Tanzania Food and Drugs Authority	✓	✓	A-D	✓	✓	✓	✓	✓
Uganda	2	National Drug Authority	✓	✓	X	X	✓	✓	✓	✓
Zambia	2	Zambia Medicines Regulatory Authority	✓	✓	X	X	X	✓	✓	✓
Zimbabwe	3	Medical Devices Unit, Medicines Control Authority	✓	X	X	X	✓ ^a	✓ ^a	✓ ^a	✓ ^a
Botswana	3	Botswana Medicines Regulatory Authority	✓	✓	X	X	X	X	X	X
Namibia	3	Medicines Regulatory Council	✓	✓	X	X	X	X	X	X
Mozambique	3	None	X	X	X	X	X	X	X	X
Rwanda	3	Rwanda Food and Drug Administration	✓	✓	✓	X	X	✓	✓	✓
Malawi	3	Pharmacy, Medicines & Poisons Board	X	X	X	X	X	X	X	X
Burundi	3	Directorate of Pharmacies, Medicines and Laboratories	X	X	X	X	X	X	X	X
South Sudan	3	Drug and Food Control Authority	✓	✓	X	X	X	X	X	X

Abbreviation: COSECSA, College of Surgeons of East, Central and Southern Africa.

^a Only for gloves and condoms.

should include a formalized definition of a medical device, one that is ideally harmonized to the WHO definition. It should also require that only medical devices that are safe, of acceptable quality, and perform as intended can be marketed. Additionally, it should mandate the formation of a regulatory authority and establish the responsibilities and enforcement capabilities of that agency.¹¹

All COSECSA member countries and South Africa with the exception of Burundi,²¹ Malawi,²² and Mozambique²³ have legislation mandating the regulation of medical devices. The specificity of this legislation varies with the level of regulatory establishment. South Africa, for example, regulates medical devices according to 3 distinct pieces of legislation and guidelines most closely resembling those of the IMDRF founding members.²⁴ Level 3 countries including Botswana,²⁵ Burundi,²¹ Rwanda,²⁶ South Sudan,²⁷ and Zimbabwe²⁸ use a legal framework for the regulation of medical devices but in a more limited capacity. This legislation is restricted to the mention of medical devices and definitions of medical devices in legislative acts establishing national medicines regulatory authorities. It does not assign specific responsibilities or guidelines for regulation.

The South Sudanese *Drug and Food Control Authority Act, 2012*, for example, states²⁹:

The purpose of this act is to provide for the establishment of an independent Drug and Food Control Authority in South Sudan and to provide an appropriate and effective independent regulatory mechanism to control and regulate the manufacture, supply, promotion, marketing, advertising, distribution and use of drugs, poisons, chemicals, cosmetics, medical devices, and food for human or animal use.

The legislation goes on to define “medical device” and states that it is necessary to apply for authorization for all medical products including devices but does not provide any further guidance on the registration process.

2. Regulatory Bodies

Regulatory authorities provide initial infrastructure to implement medical device law and prioritize the inclusion of national regulatory strategies. With the exception of Mozambique, all COSECSA member countries and South Africa have established national medicines regulatory authorities responsible for regulating medical devices.³ Mozambique uses the Pharmaceutical Department within its Ministry of Health as its regulatory authority but only mandates the regulation of drugs, not devices.²³ The practical enforcement capacity of country regulatory

authorities remains limited, particularly within Level 2 and Level 3 designated countries. Botswana’s Medicines Regulatory Authority, for example, only has regulatory procedures in place for drugs and related substances but not devices.³⁰

3. Risk-Based Device Classification System

The most well-established regulatory systems classify devices according to risk. Medical devices vary in level of invasiveness, duration of use, and other technical elements that necessitate they be regulated according to stringent controls.¹¹ A stethoscope, for example, poses a significantly lower risk to patients than a pacemaker. An understanding of the internationally harmonized risk-based classification system is necessary for governments seeking to develop regulatory strategies and for manufacturers seeking to enter markets in this region.

South Africa and most Level 2 designated countries use risk-based classification systems. South Africa,²⁴ Kenya,³¹ Sudan,³² Tanzania,³³ and Ethiopia³⁴ employ a system that designates 4 levels of risk. South Africa is the only country included in this analysis that includes specific guidelines governing the regulation of in vitro diagnostic devices.³⁵

4. Essential Principles and Standards

A legal framework for regulatory processes should require that device manufacturers and importers present evidence of conformity to safety and performance standards. The IMDRF established a list of essential principles for medical devices including in vitro diagnostic devices.¹¹ These principles included: (1) design and production processes should ensure that a medical device when used according to the intended purpose is safe and does not compromise the clinical condition of the patient or the health of the user; (2) the manufacturer should perform a risk assessment to identify known and foreseeable risks and to mitigate these risks in the design, production and use of the medical device; (3) under normal conditions, devices should perform as intended by the manufacturer; (4) performance and safety should not be affected during the lifetime of a medical device in a way that affects the safety of the user or patient; (5) performance and safety should not be affected by transport, packaging and storage; and (6) known and foreseeable risks should be weighed against the benefits of the intended purpose.

The regulatory processes for medical devices in South Africa²⁴ and a number of Level 2 designated countries including Ethiopia,³⁴ Kenya,³⁶ Sudan,³²

The practical enforcement capacity of country regulatory authorities varies and remains limited, particularly within Level 2 and Level 3 designated countries.

and Tanzania³³ mandate conformity to these principles or an adaption within their guiding regulatory legislation. Ethiopia, for example, includes medical device essential safety and performance requirements within the *Guideline for Registration of Medical Devices*.³⁷

5. Conformity Assessment

The WHO maintains that the legal framework for medical devices should include a requirement that organizations seeking to market a medical device within the jurisdiction of a national regulatory authority must submit a declaration of conformity. A declaration of conformity corroborates that the device complies with the law or with certain accredited international standards. This should include a device description, adherence to a quality management system, and the presentation of technical documentation of safety and performance testing.¹¹

Conformity assessment requirements vary among South Africa and Level 2 designated countries including Kenya,³¹ Sudan,³² Tanzania,³³ and Uganda.³⁸ Uganda, for example, requires that medical devices not licensed in 1 of the 5 IMDRF founding members (United States, European Union, Canada, Japan, or Australia) demonstrate conformity to WHO guidelines or to a quality management system used in IMDRF countries.³⁹ Zimbabwe²⁸ is the only Level 3 country that requires conformity assessment but does so only for gloves and condoms and not all medical devices.²⁸ The Medicines Control Authority of Zimbabwe performs control assessments of gloves and male condoms in accordance with international standards and WHO guidelines due largely to their role in preventing the transmission of HIV/AIDS.

6. Required Registration and Listing

There must be effective oversight of medical devices and those organizations responsible for bringing those devices to market. This is particularly relevant to COSECSA countries as many rely almost entirely upon imported medical devices.⁸ Many countries require devices, manufacturers, importers, and distributors to be registered with the national medicines regulatory authorities. This provides a greater potential for monitoring and postmarket inspection of medical devices to maintain adherence to quality standards over time. Registration and listing are required by all Level 1 and Level 2 countries. Zimbabwe requires registration and listing but only for parties who sell condoms or gloves as mentioned previously.²⁸

7. Import Controls

Imported medical devices must be approved before their shipment and entry. These controls provide regulators with advanced notice to verify if these devices have been previously marketed in the country and whether they conform to regulatory standards. Import controls are especially important in countries where most medical devices are imported. In South Africa, for instance, imported medical devices make up an estimated 90% of the market.⁴⁰ South Africa and the majority of Level 2 countries have import controls. Rwanda and Zimbabwe are the only Level 3 countries with import controls.^{26,28}

8. Postmarket Controls

Regulatory authorities must address problems with registered medical devices as they arise. Medical devices do not always perform as expected, and there must be mechanisms to manage problems in design, manufacturing, performance, labeling, storage, distribution, or use.⁴¹ Controls can include a system for reporting complaints, inspection, procedures to withdraw from the market medical devices deemed unsafe, and market surveillance.¹¹

South Africa employs extensive postmarket controls including inspection per quality management systems procedures and guidelines, the seizure of devices that are unregistered or expired, reporting of adverse events, and controls of labeling and advertising.⁴² All Level 2 countries (Kenya, Ethiopia, Sudan, Tanzania, Uganda, and Zambia) likewise have postmarket controls in place, to varying degrees.^{31–34,38,43} Zambia, for example, has controls in place for the inspection, advertising, and labeling of devices but does not have a formal avenue for reporting adverse events. Rwanda is the only Level 3 country that employs postmarket control for all medical devices, but they are restricted to inspection, advertising, and labeling.²⁶ However, inspection operates under the same guiding principles as all pharmaceuticals and food.

Case Studies in Categorization Levels 1, 2, and 3

To gain a greater understanding of the unique regulatory processes and categorization schemes within East, Central, and Southern Africa, 3 countries (1 from each level) and their regulatory processes are reviewed in depth below.

Medical devices don't always perform as expected. Postmarket controls can help identify and manage problems in design, manufacturing, performance, labeling, storage, distribution, or use.

Level 1: South Africa

In South Africa, medical devices are regulated by the South African Health Products Regulatory Authority under the *Medicines and Related Substances Act of 2015, Act No.1417*;⁴⁴ *General Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices*;⁴⁵ and *Hazardous Substances Act No. 15 of 1973*.²⁴ Specific guidelines for medical device standards are outlined in *General Information on Medical Devices and IVDs and Medical Devices and IVDs Essential Principles*.⁴⁶

South Africa uses a risk-based classification system ranging from Class A (low risk) to Class D (high risk) to determine the premarket approval process. All pathways require appointing an authorized representative in South Africa. For Class A, devices demonstrate conformity by passing a Conformity Assessment Body and Declaration of Conformity. For Classes B-D, devices are required to meet the *Essential Principles* and demonstrate conformity by passing a Conformity Assessment Body and Declaration of Conformity. Passing the conformity assessment may require clinical testing, ensuring risk management, and outlining provisions for quality assurance techniques and sterility.³⁵ Lastly, all medical devices, except custom-made devices, must be registered with the South African Health Products Regulatory Authority. All importers and manufacturers importing or exporting medical devices must also obtain a license from South African Health Products Regulatory Authority.⁴⁶

Postmarket controls include inspections and certification of a quality management system. If medical devices fail to comply with postmarket requirements or are not registered, they can be seized under *General Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices, Art. 16*.³⁵ Advertising is permitted for certain audiences, such as health professionals. All medical device labels are in English. Applicants or holders of a device registration certificate are obligated to report detrimental effects associated with that device. Effective postmarket surveillance will require an avenue for consumers, providers, and distributors to report this information, and for the information to reach the device manufacturer. The institution and operationalization of this kind of reporting system will demand high enforcement capacity.

Level 2: Uganda

Within Uganda, the National Drug Authority (NDA) regulates medical devices according to the

mandate presented in the *National Drug Policy and Authority Act, Cap. 206*.⁴⁷ Standards and regulatory procedures including the definition of medical devices are outlined in the *Guideline for Registration of Medical Devices for Human Use In Uganda*.³⁹ All medical devices manufactured, imported, and distributed in Uganda must be registered with the NDA. This excludes devices for which specific guidelines exist, namely malaria rapid diagnostic tests. In addition, the Uganda National Bureau of Standards, under the Ministry of Trade, formulates and enforces the use of standards.⁴⁸

Registration does not require devices to be classified according to a risk-based system, but the NDA does offer 3 tracks that vary in complexity. Track 1 applications are reserved for devices already licensed in IMDRF countries and require less rigorous documentation. Track 2 applications are used for devices that are not licensed by IMDRF member countries. They can demonstrate evidence of conformity to a quality system standard from a certification body in 1 of the IMDRF founding member countries, WHO Prequalification, or other international organizations recognized by NDA. Lastly, Track 3 applications are required for devices that do not have certification of compliance to quality system standards. These applications require a Declaration of Conformity to IMDRF Essential Principles of Safety and Performance and information regarding preclinical design verification and validation. Maintenance of registration is reliant upon consistent quality, satisfactory performance of the device, and a 5-yearly registration review process. The NDA performs physical inspection of locally manufactured medical diagnostics annually. Imported devices are subject to inspection by the NDA at the port of entry.

In total, Uganda's process for the regulation of medical devices includes most components detailed in the [Table](#), but the practical implementation of regulations remains limited. Efforts to control the safety and efficacy of imported medical devices prioritize malaria, HIV, and tuberculosis control programs.⁸ These disease areas remain at the apex of the Western global health agenda and tend to receive significant levels of global health assistance funding.

Level 3: Botswana

Botswana's National Regulatory Authority for medical devices is the Botswana Medicines Regulatory Authority, which was established under the *Medicines and Related Substances Act of*

2013.⁴⁴ However, this legislation is still general and has not translated to the creation of formal avenues for device regulation. Botswana does not have a formal premarket approval process or post-market surveillance. The Botswana Medicines Regulatory Authority is primarily focused on working toward implementing quality management systems to oversee the use of medical devices.²⁵ Botswana does not have formal import regulations.

■ DISCUSSION

Availability of Literature

Peer-reviewed literature relating to regulatory processes for medical devices in Africa is very limited. This stands in stark contrast to the body of research around the FDA (U.S. Food and Drug Administration) approval process and the CE mark (European conformity mark). A simple literature search revealed 6,138 articles related to the regulatory process in Africa (of which most were not relevant). In contrast, 1.3 million articles related to the FDA process and 2.5 million articles related to the CE mark appear in a simple literature search. Considering this dearth in the literature, increased efforts should be directed toward developing the regulatory processes of African nations.

Inadequate Regulatory Capacity and Enforcement

The majority of COSECSA member countries currently do not effectively regulate medical devices, due in part to both underdeveloped regulatory frameworks and a lack of downstream enforcement. Failure to successfully implement basic controls for the regulation of medical devices poses serious challenges for countries who wish to pursue more expanded controls and harmonize to international standards.⁴³ Numerous political and socioeconomic conditions have restricted the ability of countries within East, Central, and Southern Africa to pursue the effective regulation of medical devices.^{14,44,45} As it stands, there are conflicting recommended approaches to build state capability and subsequently expand the capacity of COSECSA member countries to regulate the marketing of medical devices. These include the institutional approach and the problem-driven approach.¹¹

The institutional approach has largely been the preferred approach of major international bodies, such as the World Bank Group and the World Trade Organization.⁴⁹ The institutional approach

encourages the implementation of “best practices” with a focus on improving regulatory capacity. In theory, this empowers countries to expand regulatory capacity in a way that is sustainable, enforceable, and responsive to national public health priorities and resource availability.^{20,50,51} On the other hand, critics of this approach have raised concerns about its efficacy, especially in terms of what Andrews call “isomorphic mimicry.” By trying to implement “best practices,” the institutional approach could discourage experimentation and the prioritization of country-specific issues.⁴⁹ The presence of regulatory processes that resemble those of IMDRF member states may in actuality mask the inability of institutions within many countries in the region to effectively carry out any regulatory processes.

The problem-driven approach diverges from the institutional approach by prioritizing country-specific issues and enforcement over the blanket implementation of “best practices.” This approach allows for feedback loops and greater policy experimentation as issues arise.⁴⁹

In considering the potential for strengthened regulatory systems to expand access to quality medical devices in East, Central, and Southern Africa, it is salient to also understand that many states within the region currently lack the capacity to effectively carry out these reforms. As Andrews et al. wrote⁵²:

... articulating a reasonable policy is one thing; actually implementing it successfully is another.

Significant effort must be directed toward the practical implementation of the critical components of these regulatory frameworks.

The Effects of Colonialism and Economic Status

From 1881 to 1914, several European nations formed colonies in Africa that made a lasting imprint on the development of these countries.⁵¹ This is reflected in the correlation found between the date of independence and the status of regulatory processes for medical devices. The legacy of colonialism has persisted despite the majority of COSECSA countries gaining independence in the 1960s.^{20,51} Arbitrary postcolonial borders negotiated by European powers failed to consider competing ethnic groups within newly formed states, which resulted in instability as a result of civil conflict and separatist movements.²⁰ The First and Second Sudanese Civil Wars, for example, were waged for nearly 40 years, and resulted in the

Numerous political and socioeconomic conditions have restricted the ability of countries within East, Central, and Southern Africa to pursue the effective regulation of medical devices.

eventual formation of an independent South Sudan in 2011, which continues to be plagued by civil conflict.⁵⁰ South Sudan currently has no formal regulatory process in place for medical devices.

Additionally, a history of economic exploitation has manifested in the form of economic inequality, poverty, and class polarization. The instability within African nations, particularly those who have become independent in more recent years, has produced conditions which reduce the effectiveness of governance structures.⁵³ Country governments may prioritize other health goals including poverty alleviation, the expansion of access to health care and the reduction of communicable diseases, which may be viewed as less consequential to the health and well-being of citizens.⁵⁴

GDP and GDP per capita are both measures of economic conditions. GDP showed a strong positive correlation with the development of regulatory processes for medical devices, but GDP per capita was not as strongly correlated. GDP per capita is often used as a measure of prosperity and income inequality.⁵⁵ The lack of correlation of GDP per capita with the development of regulatory processes could exist because GDP per capita is more telling of individual wealth. The total wealth available within a country is more accurately measured by the GDP and represents the resources that are available for community-wide investment, such as medical device regulation.

Innovative medical devices are needed to address the burden of disease, economic challenges, and infrastructure of African nations rather than just using medical devices that were designed for the needs and resources of high-income countries. Those seeking to develop such devices, both within and outside of Africa, face many challenges including clearing the regulatory processes of several countries and developing business models that provide sustainability.⁵⁶

Many grants and awards for medical device innovations in Africa do not pay close attention to adherence to regulations—maybe due to their absence—but it leads many innovators to not value the importance of regulations in the early stages. Medical device regulation is not only needed to ensure patient safety but also to provide clarity, direction, and industry protection especially when substantial resources are invested into the development of a device. However, cumbersome regulatory processes and the risk of uncertain markets may prohibit medical device companies

from developing technology suited to these regions.⁵⁷

In many cases, innovation may stagnate because poor regulations and other factors result in an unreliable business environment. Better regulations around intellectual property protection would encourage local innovators as well as international business people to invest in the field.¹⁷ If African nations were to come together to develop a unified regulatory process, this would allow for pooling of resources, and relieve the economic and infrastructural burdens on individual countries.⁵⁸ It would also simplify the process for device companies seeking to enter African markets, and therefore encourage innovation and provide an attractive market. Some efforts have been made to harmonize the regulatory process in Africa, but this has focused heavily on medications and less so on medical devices.¹⁵ There are many fragmented systems in Africa, representing large challenges. Investment in harmonization may be an opportunity to provide synergy for other fragmented systems to grow together.

One could argue that African nations could just accept the CE Mark or FDA approval, which is effectively what many countries are currently doing. However, this is not ideal as the FDA and CE mark processes were designed for the needs of high-income countries. The review process may not consider infrastructural limitations currently present in many African nations. Many medical devices designed to meet the standards of other countries have been observed to easily malfunction due to such factors. In addition, cultural and economic barriers may prohibit African medical device companies from obtaining approval through these entities.

Limitations and Complexities

Although an understanding of the extent to which COSECSA member countries have a regulatory framework is valuable, it is crucial to recognize that the mere presence of a regulatory framework for medical devices does not predict more effective government oversight of the provision of health-related goods and services. Likewise, classification as Level 3 does not inherently mean that a country has similarly weak health infrastructure. The stringency of required regulatory processes may serve as a helpful proxy for the efficacy of government measures for the oversight of health-related goods and services, but it is not a steadfast rule. For example, although we classified Botswana as Level 3, it has a significantly more robust health

Country governments may prioritize other health goals over the medical device regulation, which may be viewed as less consequential to the health and well-being of citizens.

care system than many other COSECSA member states.

Despite a long colonial history, an independent Botswana has achieved what many scholars call an “exceptional” record of functioning institutions and consistently favorable economic growth.⁵⁹ The breadth of health services provision in Botswana is consistent with this claim. The nation relies on integrated primary health care as the basis of the health delivery system. The Ministry of Health is predominantly responsible for national health policy and strategies for health development and delivery whereas 27 decentralized health districts are responsible for the provision of public sector services. Public health services which are nearly free for citizens emphasize preventative over curative medicine and have allowed for steady increases in equitable access to health care for the citizens of Botswana.⁶⁰ Additionally, the U.S. International Trade Administration reports that in recent years, Botswana’s government has prioritized human resources development, technology, and supply chain capacity.⁶¹ These factors in combination with a higher national GDP and a national policy on health technology demonstrate that the government of Botswana may be more likely to ensure access to quality medical devices than some COSECSA counterparts despite the country’s lack of a formal regulatory framework.

Cases like Botswana indicate that the mechanism for expanding access to medical devices is more complex than the sole existence of a regulatory framework. Future work must also consider the interplay between regulatory frameworks, political, and socioeconomic institutions and existing health infrastructure.

RECOMMENDATIONS

With these challenges in mind, several strategies may be pursued to build state capability and mitigate the economic and health effects of weak regulatory systems for medical devices. We propose recommendations that may prove useful to policy makers and other stakeholders to improve regulatory systems within COSECSA member countries and beyond.

Policy makers may choose to employ an institutional approach toward expanding regulatory capacity by adopting and amending existing harmonized regulations, rather than formulating new ones. The IMDRF facilitates the adoption of regulations for medical devices developed by member countries. It grants low- and middle-income countries the opportunity to participate

in and observe well-established regulatory development processes and take advantage of recent medical advancements. Therefore, it is advisable for low- and middle-income countries to use this platform to minimize resource expenditure during the development and formulation of new regulations.

This strategy may, however, fail to consider country-specific barriers to enforcement. Thus, it is crucial to also prioritize local capacity building. Local capacity in the form of well-trained personnel, tools, and facilities is an essential driver of efficient and effective medical technology regulatory bodies in all countries. Locally trained, capable professionals with sufficient financial and technical support will be more capable of responding with authority to distinctively local challenges.

Capacity building requires resources. As non-communicable diseases are increasingly recognized as a major source of morbidity and mortality globally, medical devices that address these issues must be prioritized. Grant funding from government and nongovernmental agencies should be used to promote innovation and capacity building in medical device regulation and harmonization. Specifically, many medical technology companies (primarily based in high-income countries) have a charitable arm and should consider investment in efforts that seed and encourage Pan-African harmonization. Currently existing African medical and engineering societies are instrumental in connecting professionals across country borders and should play an increased role in galvanizing these changes.

CONCLUSION

The current landscape for regulation of medical devices within East, Central, and Southern Africa is complex and often underdeveloped, despite a legal mandate for regulation in most countries. Higher GDP and years of freedom from colonization were positively correlated with a country’s regulatory capacity. A streamlined regulatory process, harmonized across African nations would simplify the regulatory process for companies and possibly make it less expensive and more efficient to bring medical devices to the African market, thereby increasing patient and physician access to medical devices and improving health outcomes.

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REFERENCES

- Sabet Sarvestani A, Sienko KH. Medical device landscape for communicable and noncommunicable diseases in low-income countries. *Global Health*. 2018;14(1):65. [CrossRef](#). [Medline](#)
- World Health Organization (WHO). Medical device – full definition. Accessed March 4, 2021. https://www.who.int/medical_devices/full_definition/en/
- Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo A, Kaale E. Medicines regulation in Africa: current state and opportunities. *Pharmaceut Med*. 2017;31(6):383–397. [CrossRef](#). [Medline](#)
- Velazquez Berumen A, Jimenez Moyao G, Rodriguez NM, Ilbawi AM, Migliore A, Shulman LN. Defining priority medical devices for cancer management: a WHO initiative. *Lancet Oncol*. 2018;19(12):e709–e719. [CrossRef](#). [Medline](#)
- Wilkinson B, van Bostel R. The medical device regulation of the European Union intensifies focus on clinical benefits of devices. *Ther Innov Regul Sci*. 2019;2168479019870732. [CrossRef](#). [Medline](#)
- Sastry A. Overview of the US FDA medical device approval process. *Curr Cardiol Rep*. 2014;16(6):494. [CrossRef](#). [Medline](#)
- Sorenson C, Drummond M. Improving medical device regulation: the United States and Europe in perspective. *Milbank Q*. 2014;92(1):114–150. [CrossRef](#). [Medline](#)
- Rugera SP, McNerney R, Poon AK, et al. Regulation of medical diagnostics and medical devices in the East African community partner states. *BMC Health Serv Res*. 2014;14(1):524. [CrossRef](#). [Medline](#)
- Gilman BL, Brewer JE, Kroll MW. Medical device design process. *Annu Int Conf IEEE Eng Med Biol Soc*. 2009;2009:5609–5612. [CrossRef](#). [Medline](#)
- Lissel A, Ottenberg F, Bracio BR, et al. Status and solutions to medical device regulations for improving the healthcare landscape in Africa. *Annu Int Conf IEEE Eng Med Biol Soc*. 2016;2016:4329–4332. [CrossRef](#). [Medline](#)
- World Health Organization (WHO). WHO Global Model Regulatory Framework for Medical Devices Including in vitro Diagnostic Medical Devices. WHO; 2017. Accessed March 4, 2021. https://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/
- World Health Organization (WHO). A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products. 2017. Accessed March 4, 2021. https://www.who.int/medicines/regulation/ssfc/publications/SE-Study_EN_web.pdf
- Deloitte. Research to guide the development of strategy for the medical devices sector of South Africa. Deloitte; 2014.
- Arik M, Bamenyekanye E, Fimbo A, et al. Optimizing the East African Community's Medicines Regulatory Harmonization initiative in 2020–2022: a roadmap for the future. *PLoS Med*. 2020;17(8):e1003129. [CrossRef](#). [Medline](#)
- Ndomondo-Sigonda M, Moit J, Naidoo S, Ambali A, Dodoo A, Mkwandawire H. The African Medicines Regulatory Harmonization Initiative: progress to date. *Med Res Arch*. 2018;6(2). [CrossRef](#)
- Mashingia JH, Ahonkhai V, Aineplan N, et al. Eight years of the East African Community Medicines Regulatory Harmonization initiative: implementation, progress, and lessons learned. *PLoS Med*. 2020;17(8):e1003134. [CrossRef](#). [Medline](#)
- Peeling RW. *Update on Regional Harmonization of Diagnostic Regulation in Africa*. Accessed March 4, 2021. https://www.who.int/hiv/amds/202_Peelin-Update-on-Regulatory-harmonization.pdf
- College of Surgeons of East, Central, and Southern Africa. Accessed March 4, 2021. www.cosecsa.org
- GDP (current US\$). The World Bank; 2020. Accessed March 4, 2021. <https://data.worldbank.org/indicator/NY.GDP.MKTP.CD>
- Ocheni S, Nwankwo BC. Analysis of colonialism and its impact in Africa. *Cross-Cultural Communication*. 2012;8(3):46–54. Accessed March 4, 2021. https://www.tralac.org/images/News/Documents/Analysis_of_Colonialism_and_Its_Impact_in_Africa_Ocheni_and_Nwankwo_CSCanada_2012.pdf
- Medical devices regulatory systems at country level: Burundi. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/bdi.pdf
- Medical devices regulatory systems at country level: Malawi. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/mwi.pdf
- Medical devices regulatory systems at country level: Mozambique. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/moz.pdf
- Medical devices regulatory systems at country level: South Africa. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/zaf.pdf
- Medical devices regulatory systems at country level: Botswana. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/bwa.pdf
- Medical devices regulatory systems at country level: Rwanda. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/rwa.pdf
- Medical devices regulatory systems at country level: South Sudan. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/ssd.pdf
- Medical devices regulatory systems at country level: Zimbabwe. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/zwe.pdf
- Drug and food control act. Ministry of Justice Republic of South Sudan; 2012. Accessed March 4, 2021. https://www.wto.org/english/thewto_e/acc_e/ssd_e/wtaccsd6_leg_15.pdf
- Dhami D. List of countries without formal regulatory approval process. *Regdesk*. January 25, 2017. Accessed March 4, 2021. <http://www.regdesk.co/countries-no-medical-device-regulations/>
- Medical devices regulatory systems at country level: Kenya. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/ken.pdf
- Medical devices regulatory systems at country level: Sudan. World Health Organization; 2016. Accessed March 15, 2021. https://www.who.int/medical_devices/countries/regulations/sdn.pdf
- Medical devices regulatory systems at country level: United Republic of Tanzania. Geneva: World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/tza.pdf
- Medical devices regulatory systems at country level: Ethiopia. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/eth.pdf
- South Africa Medical Device Regulations. *Regdesk*. Accessed March 4, 2021. <https://www.regdesk.co/resource-library/south-africa/>
- Republic of Kenya. Ministry of Health (MOH). Pharmacy and Poisons Board. *Guidelines on Submission of Documentation for Registration*

- of Medical Devices. MOH; 2018. Accessed March 4, 2021. <https://pharmacyboardkenya.org/files/?file=Final%20Guidelines%20for%20Medical%20Devices%20and%20IVDs.pdf>
37. Ethiopian Food and Drug Authority. Guidelines for registration of medical devices or supplies. Accessed March 4, 2021. <http://www.fmhaca.gov.et/publication/guidelines-for-registration-of-medical-devices-or-supplies>
 38. Medical devices regulatory systems at country level: Uganda. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/uga.pdf
 39. Uganda National Drug Authority. *Draft Guideline for Registration of Medical Devices for Human Use in Uganda*. Uganda National Drug Authority; 2009. Accessed March 4, 2021. <http://www.rfa.co.za/wp-content/uploads/2014/01/Guidelines-for-Medical-Devices-090901.pdf>
 40. Maharaj I, Sunjka BP. A strategic framework for start-up medical device manufacturers in South Africa. *S Afr J Industrial Eng*. 2019; 30(3):30. [CrossRef](#)
 41. Kramer DB, Tan YT, Sato C, Kesselheim AS. Ensuring medical device effectiveness and safety: a cross-national comparison of approaches to regulation. *Food Drug Law J*. 2014;69(1):1–23. [Medline](#)
 42. Saidi T, Douglas TS. Medical device regulation in South Africa: The Medicines and Related Substances Amendment Act 14 of 2015. *S Afr Med J*. 2018;108(3):168–170. [CrossRef](#). [Medline](#)
 43. Medical devices regulatory systems at country level: Zambia. World Health Organization; 2016. Accessed March 4, 2021. https://www.who.int/medical_devices/countries/regulations/zmb.pdf
 44. Medicines and related substances. In: *Revised Principal and Subsidiary Legislation of Botswana*. Blackhall Publishing; 2013. Accessed March 4, 2021. <https://botswanalaws.com/alphabetical-list-of-statutes/medicines-and-related-substances>
 45. Regulations relating to medical devices and in vitro diagnostic medical devices. Government Gazette. December 9, 2016. Accessed March 4, 2021. <https://www.emergobyul.com/sites/default/files/south-africa-regulations-medical-devices-ivds.pdf>
 46. South African Health Products Regulatory Authority (SAHPRA). *Medical Devices and IVDs: Essential Principles of Safety & Performance*. SAHPRA; 2019. Accessed March 4, 2021. https://www.sahpra.org.za/wp-content/uploads/2020/01/Medical_Device_IVD_Essential_Principles_Nov19_v2.pdf
 47. Uganda National Drug Authority. National Drug Policy and Authority Act. Uganda National Drug Authority; 2016. Accessed March 4, 2021. <https://www.unhro.org/ug/assets/images/resources/nationaldrugpolicy&authorityactcap206.pdf>
 48. Uganda National Bureau of Standards. Accessed March 4, 2021. www.unbs.go.ug
 49. Andrews M, Pritchett L, Woolcock M. *Escaping capability Traps Through Problem Driven Iterative Adaptation (PDIA)*. Center for Global Development; 2012. Accessed March 4, 2021. https://www.cgdev.org/sites/default/files/1426292_file_Andrews_Pritchett_Woolcock_traps_FINAL_0.pdf
 50. Civil war in South Sudan. Council on Foreign Relations; 2020. Accessed March 4, 2021. <https://www.cfr.org/global-conflict-tracker/conflict/civil-war-south-sudan>
 51. Barasa F. Colonialism in Africa. World Atlas. 2019. Accessed March 4, 2021. <https://www.worldatlas.com/articles/colonialism-in-africa.html>
 52. Andrews M, Pritchett L, Woolcock M. *Building State Capability: Evidence, Analysis, Action*. Oxford University Press; 2017.
 53. Premkumar R, Tebandeke A. Political and socio-economic instability: does it have a role in the HIV/AIDS epidemic in sub-Saharan Africa? *SAHARA J*. 2011;8(2):65–73. [CrossRef](#). [Medline](#)
 54. Meara JG, Leather AJM, Hagander L, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. *Lancet*. 2015;386(9993):569–624. [CrossRef](#). [Medline](#)
 55. Lepenies P. *The Power of a Single Number: A Political History of GDP*. New York: Columbia University; 2016.
 56. Makobore P, Kamugasha D, Rolfe P, Ssekitoleso R. Medical device electronics development in resource limited settings: a Ugandan perspective. *Canadian Medical and Biological Engineering Society Proceedings*. 2016;39(1). Accessed March 4, 2021. <https://proceedings.cmbes.ca/index.php/proceedings/article/view/55/53>
 57. Matovu B. Regulation and standards of medical devices in Uganda. Presented at: East African Health Scientific Conference; November 17, 2018; Nairobi, Kenya. Accessed March 4, 2021. <https://www.slideshare.net/matovubrian/regulation-and-standards-of-medical-devices-in-uganda>
 58. De Maria C, Di Pietro L, Díaz Lantada A, et al. Safe innovation: on medical device legislation in Europe and Africa. *Health Policy Technol*. 2018;7(2):156–165. [CrossRef](#)
 59. Seidler V. Why did Botswana end up with good institutions: the role of culture and colonial rule. SSRN. Posted online October 11, 2017. [CrossRef](#)
 60. Tapera R, Moseki S, January J. The status of health promotion in Botswana. *J Public Health Africa*. 2018;9(1):699. [CrossRef](#). [Medline](#)
 61. Healthcare resource guide: Botswana. Export.gov. Accessed March 4, 2021. https://2016.export.gov/industry/health/healthcare-resourceguide/eg_main_108566.asp

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Curbing the Rise of Noncommunicable Diseases in Uganda: Perspectives of Policy Actors

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Key Findings

- Inadequate government funding for noncommunicable diseases (NCDs) has elevated the role of external partners in shaping the development and implementation of NCD policies and programs in Uganda.
- Limited recruitment of technical experts and managers for NCDs in the Ministry of Health (MOH) has been a barrier to the effective coordination and communication across multiple government and nongovernmental actors in the NCD space.
- Financial, technical, and managerial constraints have contributed to external actors spearheading several NCD program activities with the MOH playing a more supportive role.

Key Implications

- Policy makers and public health practitioners should prioritize building the MOH's financial, managerial, and technical capacity to oversee and lead the development and implementation of NCD programs and policies.
- Government leadership is critical in developing and executing a comprehensive strategic plan for NCDs that all actors can agree upon and adopt as the guiding framework for action.

ABSTRACT

Background: Uganda faces a complex policy landscape as it simultaneously addresses infectious diseases and noncommunicable diseases (NCDs). The health system has been overwhelmed by the growing burden of NCDs across all socioeconomic strata. In this study, we sought to understand the policy context around NCDs in Uganda, the roles of actors both within and external to the government, and the factors shaping the development and implementation of NCD policies and programs in Uganda.

Methods: We conducted in-depth interviews with 30 policy actors from the Ugandan Ministry of Health (MOH), nongovernmental organizations, and academia to understand the roles of different actors in the Ugandan NCD space, the programs and policy measures in discussion, and how to bridge any identified gaps. A thematic data analysis was conducted.

Results: All national actors viewed funding constraints as a critical barrier to developing and executing an NCD strategic plan and as a barrier to leading and coordinating NCD prevention and control efforts in Uganda. The crowding of nongovernment actors was found to fragment NCD efforts, particularly due to the weak implementation of a framework for action among NCD actors. Relatedly, limited recruitment of technical experts on NCDs within the MOH was viewed to further diminish the government's role in leading policy and program formulation and implementation. Though recent MOH efforts have aimed at addressing these concerns, some skepticism remains about the government's commitment to increase budgetary allocations for NCDs and to address the technical and human resources gaps needed to achieve NCD policy aims in Uganda.

Conclusions: This study highlights the immediate need to mobilize more resources, reduce fragmented efforts in the NCD space, and prioritize investment in NCD prevention and management in Uganda.

INTRODUCTION

The rising prevalence of noncommunicable diseases (NCDs) is a growing concern globally, particularly in low- and middle-income countries, where the burden of disease is transitioning from infectious diseases to NCDs. Every year, NCDs kill 41 million people, and contribute to 74% of the global mortality burden.¹ NCDs are also the principal causes of morbidity and loss of disability-adjusted life years globally.^{2,3} Four modifiable behavioral risk factors—unhealthy diet, physical inactivity, excess alcohol consumption, and tobacco use—contribute to roughly 67% of all NCD deaths worldwide.^{4,5} Globally,

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nearly two-thirds of NCD-related deaths are caused by cardiovascular disease, cancer, diabetes, and chronic lung diseases.^{6,7}

NCDs are likely to become a major health system challenge in Africa as they are predicted to become the leading cause of death in the region by 2030.⁸ Of the 97,600 deaths in Uganda in 2016, NCDs accounted for 1 in 3.⁹ The estimated risk of mortality from NCDs was 22%, primarily due to cardiovascular disease and cancer, along with underlying risk factors of hypertension, tobacco use, and alcohol.⁹ Across metabolic, environment/occupational, and behavioral risk factors, high blood pressure and high fasting plasma glucose respectively were the sixth and seventh most correlated with death and disability among Ugandans in 2019.¹⁰ A nationally representative household survey conducted in 2014 further revealed that nearly 80% of Ugandans diagnosed with NCDs were unaware of their own status; for example, only 7.7% of individuals with hypertension were aware of their condition, and among those who had hypertension, 76% were not being treated for their condition.^{11,12}

Population-based interventions, such as mass media campaigns or taxes, may help mitigate the effects of modifiable NCD risk factors. To reduce dietary risk factors, the World Health Organization (WHO) recommends several “best-buy” interventions, such as limiting salt and sugar intake and implementing front-of-pack labelling and taxation on sugar-sweetened beverages.¹³ Implementing mass awareness campaigns and providing counseling during routine primary health care visits about the importance of physical activity for well-being also have been identified as effective NCD interventions.¹³ The successful implementation of these “best buys” requires clear policy guidelines and strategies by governments and a concomitant increase in financial and technical investments to support their development.

Locally generated data on NCD risk factors shows a rise in NCDs in Uganda and underscores the need to increase investment in and allocation of resources to NCDs.¹¹ The 2015–2020 Ugandan Health Sector Development Plan emphasizes the need to develop national NCD management policy and guidelines, strengthen surveillance systems for NCDs, and expand access to prevention, diagnosis, and treatment services for NCDs, among other related priorities.¹⁴ The Ugandan government also has expressed commitment to allocate 17% of the total health budget to NCDs and 60% of the NCD budget to prevention services.¹⁴

At the national level, additional efforts aimed at addressing NCDs include the development of a Multisectoral Health Action Plan for NCDs and several related collaborations with local and global nongovernmental organizations (NGOs) and development partners who support the government in developing trainings, implementing public awareness on NCDs and their risk factors, and strengthening the capacity of the health system to prevent and manage NCDs. In the Ugandan Ministry of Health (MOH), NCD-related policy and program activities have been coordinated by an NCD unit (also known as the NCD Desk at the time of this study). Several promising initiatives are aimed at specific NCDs and their underlying risk factors. These initiatives require identifying unmet needs, understanding the roles of actors both within and outside government working on heterogeneous NCD policy and programs, and identifying the factors driving their development and implementation.¹⁴

It is particularly critical to explore the views of external actors who provide substantial health funding in Uganda (Table 1),¹⁵ and who may be influential in affecting policy and program development and implementation,¹⁶ including those for NCDs.¹⁷ In this context, we aimed to understand the current NCD policy landscape in Uganda, including the role of actors within and external to the government, and then examine the factors shaping the country’s development and implementation of NCD policies and programs.

METHODS

Study Design

Our qualitative study followed an emergent research design using in-depth interviews as our primary data source.¹⁸ To better understand the NCD policy landscape, we conducted in-depth interviews with 3 types of NCD actors: (1) officials from national government (MOH and Ministry of Finance) with authority to make programmatic and policy decisions for their relevant work areas; (2) researchers from local universities in Uganda working on health policy or familiar with the NCD space; and (3) individuals from NGOs and development partners working in the NCD space. We selected these actors because they made decisions about funding NCD programs; developed, implemented, or evaluated NCD programs in Uganda; or provided technical support to high-level government policy actors. During interviews, we also requested that respondents introduce us to other relevant NCD actors in their networks, including

We aimed to understand Uganda’s current NCD policy landscape and examine the factors shaping the development and implementation of policies and programs.

TABLE 1. Overview of Key Health Systems and Financial Indicators of Uganda¹⁵

Indicator	Value	Year
Total population (millions)	42.72	2018
Urban population (% total population)	23.8	2018
Net official development assistance received (constant 2015 US\$)	1,976,190,000	2017
Net official development assistance received (% of central government expense)	57.9	2017
Domestic general government health expenditure (% of general government expenditure)	5.14	2016
Domestic general government health expenditure (% of current health expenditure)	16.6	2016
Current health expenditure (% of gross domestic product)	6.16	2016
Out-of-pocket health expenditure (% of total expenditure on health)	40.31	2016
External resources for health (% of total expenditure on health)	40.37	2016

other sectors involved in NCD-related activities, so that we could request interviews with them.

The in-depth interview guide covered NCD programs and policy priorities in Uganda and existing gaps, actors involved in the NCD policy space in Uganda, and factors influencing the development or implementation of NCD policies and programs (Supplement). To inform the development of a semistructured, in-depth interview guide, we read key policy documents pertaining to the national government's strategic plans for health and health financing. These documents included the 2015–2020 Uganda Health Sector Development Plan,¹⁴ the 2016 Health Financing Strategy,¹⁹ and the 2019–2020 National Budgetary Framework,²⁰ as well as other documents about preventive and curative services for NCDs in Uganda.^{21–23} We piloted the in-depth interview guide with 4 health policy researchers working in the NCD space who were not selected to participate in the study.

Data Collection

In-depth interviews were conducted from February to July 2018 by 3 research staff of the Makerere University School of Public Health who were trained qualitative researchers with several years of experience conducting policy-level interviews in Uganda. Prior to data collection, interviewers completed a 2-day training session on research methods for qualitative data collection and principles of research ethics. Written informed consent was obtained from each participant prior to conducting the interview. All interviews were conducted in English and audio-recorded. Interviews lasted between 45 minutes and 1 hour. Study staff transcribed all audio-recorded interviews verbatim immediately following each interview.

During the interview process, the study team met weekly to reflect on the interviews, identify potential problems and areas of improvement, revise the interview guide, and discuss the focus of future interviews. This iterative process aligned with the emergent nature of our study design, as analysis of early interviews informed the selection of topics for subsequent interviews. Throughout this process, we triangulated responses from different NCD actors to develop a comprehensive understanding of the policy context, to identify any areas of consensus and divergence, and to examine factors affecting NCD policy/program development and implementation in Uganda.

All participants we identified agreed to participate in an in-depth interview. Overall, we conducted 30 in-depth interviews with NCD actors from the MOH, Ministry of Finance, academia, and local and international NGOs, as well as development partners working in the NCD space in Uganda (Table 2).

Analysis

A thematic analysis was used to analyze the in-depth interview data, primarily using deductive coding.²⁴ We grouped textual data according to elements of the policy analysis triangle²⁵ (context, actors, process), and drew from the 4-stage policy heuristic (problem identification, policy formulation, policy implementation, and policy evaluation). Actors were identified as specific individuals, groups, or organizations currently or potentially involved in the NCD space in Uganda, including national-level actors from government, academia, and international development partners. Context was viewed as situational, cultural, and international factors that could influence policy or

TABLE 2. Policy Actors in Uganda Involved With Noncommunicable Diseases Who Participated in In-depth Interviews

Type of Respondent	Number	Corresponding Identification Number
Academics	7	A1-A7
National government officials (ministries of health and finance)	10	G1-G10
Members of civil society organizations, nongovernmental organizations, and semi-autonomous agencies and development partners	13	C1-C13
Total	30	

program perspectives around NCDs. Processes were the steps involved in different stages of policy development, from problem identification to policy formulation, implementation, and evaluation. Focusing on these elements provided a conceptualization of the existing landscape around NCD programs and policies in Uganda. We also inductively coded data not captured through our deductive approach to identify factors shaping the development or implementation of NCD policies and programs in Uganda.²⁶

Initially, 2 co-authors analyzed the first set of 6 transcripts to review and reconcile the codes, which then informed the final codebook. The codes were organized into 3 main categories: context, actors, and process. The process category was further divided into problem identification, policy formulation, policy implementation, and policy evaluation, for which additional codes emerged related to the factors shaping these processes (e.g., technical, financial, and managerial). Codes were analyzed for each category, and memos were written to summarize emerging themes. Atlas Ti.8.0 was used to manage the textual data and support coding.

Ethical Approval

We received ethical approval from the institutional review boards at Makerere University School of Public Health (protocol 526) and the Uganda National Council of Science and Technology (registration number SS 4477). The institutional review board at Johns Hopkins University Bloomberg School of Public Health provided an institutional review board exemption for this study.

RESULTS

The Current Landscape: Actors and Platforms for Engagement in the NCD Policy Space Overview of Actors

The NCD policy space in Uganda is diverse and includes a multitude of government, nongovernment,

and development actors involved in developing and implementing various programs and policies across the country. Respondents identified several departments, divisions, and units within the MOH that are involved in NCD programming and policy making, such as the Division of Mental Health and Substance Abuse, Division of Tobacco and Alcohol, Policy and Planning Unit, Health Services Directorate, and Public Health and Preventive Unit. However, all respondents agreed that the NCD Desk, now the NCD Department, is a critical coordinating body because of its perceived convening power to bring together actors within and outside the government.

In contrast, respondents viewed external actors as largely providing the MOH with technical assistance in developing policies, strategies, plans, and guidelines for NCDs, and in many instances, supporting the implementation of pilot projects and programs. In particular, semi-autonomous government agencies, such as the Uganda Cancer Institute and Uganda Heart Institute, were seen as advisers to the MOH on matters related to their disease specialty. These 2 institutes and WHO were identified as having close partnerships with NGOs, such as a research partnership with the Ugandan Initiative for NCDs to support implementation of disease prevention and management programs at the community level.²⁷ Respondents highlighted several projects aimed at improving management of NCD services among lower-tier health centers, training health workers on NCDs, and implementing sensitization campaigns to increase NCD awareness among communities, district councils, and parliamentarians.

In addition to being program implementers, NGOs also were seen as NCD advocates who encourage the development of government programs and policies that expand access to preventative care and treatment for NCDs. As part of this role, NGO actors reflected on their past engagements with policy makers, which included hosting NCD

Awareness Days in the parliamentary offices and funding visits for parliamentarians to learn about the types of policies and programs being implemented to address NCDs in other countries.

Platform for Engagement

Respondents identified multiple platforms that facilitated engagement between government and external partners, such as steering committees for specific NCDs and, more recently, a multisectoral committee comprised of representatives from different government ministries (e.g., agriculture, transport, education, health) and external stakeholders. The NCD Parliamentarian Forum was seen as a platform to engage with parliamentarians, to understand their views on NCDs and related policies, and to share information about addressing NCDs for the better health of their constituents.

The NCD Technical Working Group, which is housed in the MOH but coordinated by the NCD Desk, was seen as an important knowledge-sharing and policy-making forum where both programmatic and research activities could be disseminated and shared with the MOH and its external partners, such as researchers, civil society, and development partners. Respondents felt this forum facilitated discussion about the latest evidence on NCDs in Uganda that could inform MOH guidelines, policies, and programs for NCD prevention and care.

Factors Affecting the Development and Implementation of NCD-Related Policies

Our interviews with policy actors suggested that the level of financial, managerial, and technical resources available to them affected what roles they could play in developing and implementing policies for NCDs in Uganda (Table 3).

Financial Resources

Policy actors felt that insufficient funds were allocated for NCD-related activities by the government and that this deficiency affected the formulation, implementation, and subsequent monitoring and evaluation of NCD programs and policies. The 2015–20 Uganda Health Sector Development Plan describes the importance of providing a comprehensive package of essential health services encompassing NCD prevention, control, and management. In this plan, 17% of the health budget is allocated to NCDs, and of that, 60% is directed toward prevention activities. However, a funding gap of 29% was identified as a challenge for achieving Uganda's health agenda.¹⁴

According to the National Budget Framework 2019–20, the health sector received 8.9% of the total government budget.²⁰ Both government and external actors reported that the proportion of this budget dedicated to NCDs was insufficient, particularly given the need to develop an NCD infrastructure that includes primary and specialized health care.

Policy Formulation. The most recent National Health Policy of 2010 recognizes the growing burden of NCDs. However, respondents felt that policy discourse was not enough. Respondents universally expressed the need for an overall strategic plan for NCDs to provide both government and external actors with a cohesive and coordinated blueprint for the prevention and management of NCDs in Uganda.²⁸ Such efforts require additional funding, as a government official noted:

When you go to the National Health Policy, you will find that NCDs are prioritized in the Health Sector Development Planning document, but this unfortunately does not lead to increased funding for NCDs.—Government official, G5

Respondents also felt that the lack of financial resources available to the NCD Desk constrained its ability to lead and coordinate the efforts necessary for developing the NCD strategic plan.

Things need money, the staff and the implementation at least. They [MOH] have started to talk about it . . . but still, in terms of the money, it is still lacking. It is a very scanty program, but they had promised to upgrade the department.—Civil society organization member, C7

Specifically, respondents felt that limited funding resulted in inadequate recruitment of technical and programmatic staff to manage and coordinate processes within the MOH to move the agenda for NCDs forward. Consequently, external partners, such as WHO, filled the gaps. These external partners were viewed as playing pivotal roles in helping to develop guidelines and plans for different NCD areas and in collaborating with government and civil society organizations to develop clinical guidelines for managing NCD care at different levels of the health system.

At the time of our interviews, there were discussions within the MOH about converting the NCD Desk into the NCD Department, which became official in July 2019. Many respondents expressed that as members of a full-fledged government department, NCD program officers would have the necessary funding, power, and decision-making ability to facilitate the development, implementation, and expansion of appropriate NCD

Both government and external actors reported that the proportion of the health budget dedicated to NCDs was insufficient, particularly given the need to develop an NCD infrastructure that includes primary and specialized health care.

TABLE 3. Financial, Managerial, and Technical Barriers to the Noncommunicable Disease Policy and Program Processes in Uganda

	Financial (control and allocation of funds to NCD-related activities; overall funding in the health sector)	Managerial (ability to lead on policy issues, coordinate efforts among government & partners, oversee implementation)	Technical (ability to produce, analyze, interpret, and influence policy/programming)
Policy/Program Formulation	<ul style="list-style-type: none"> NCD Department (previously Desk) has limited ability to mobilize resources, including human resources, necessary for the finalization and execution of the NCD Strategic Plan Government unable to commission studies to fill NCD knowledge gaps 	<ul style="list-style-type: none"> Inadequate recruitment of techno-managerial human resources limits the NCD Department’s ability to manage and coordinate processes within the Ministry of Health to move the agenda for NCDs forward Reliance on external partners to address gaps in coordinating efforts around policy/program development 	<ul style="list-style-type: none"> Primary study on NCDs done in 2014 was donor-funded/partner-led; need more evidence; limited role of government in driving research efforts Reliance on external partners for technical assistance and policy formulation based on evidence they generate
Policy/Program Implementation & Monitoring	<ul style="list-style-type: none"> Limited funding for implementing established guidelines Lack of public sector funding has elevated the role of partners and non-government organizations that are leading implementation Due to limited funding, the government’s role is limited to supervising activities funded and implemented by external partners 	<ul style="list-style-type: none"> Program implementation activities are largely done by external partners with minimal government oversight Inadequate government oversight and coordination results in duplication of programs implemented by different actors Fragmentation of efforts results in external partners working in silos 	
Cross-cutting Issues	<ul style="list-style-type: none"> Inertia to change existing funding practices, particularly if cuts are made to other disease areas Absorptive capacity of the government may be limited after partner-run programs end External actors provide significant financial and techno-managerial support in policy/program formulation and implementation processes 		

Note: Table structure adapted from Khan (2018).
 Abbreviation: NCD, noncommunicable disease.

Respondents felt that the lack of government funding for NCDs elevated the role of external actors in the NCD space in Uganda.

programs and policies. Furthermore, the graduation from a desk to a department would mean more funding, which respondents felt would reflect the MOH’s prioritization of NCDs. As a government official noted:

We have elevated the NCD Desk to a Department. That shows, first of all, that the Ministry [of Health] is determined to implement that strategy.—Government official, G7

Aside from slowing the development of the NCD strategic plan, some respondents indicated that a lack of financial resources limited the government’s ability to commission new studies to understand the prevalence and distribution of NCDs and their risk factors across the population. For example, respondents felt that studies were needed to assess NCD risk factors among young people, such as childhood obesity. Respondents also felt that financial constraints limited the government’s ability to formulate appropriate NCD

policies and guidelines, leaving such efforts to actors with access to financial resources, namely development partners or NGOs.

Implementation and Monitoring of Policies and Programs. Respondents felt that the lack of government funding for NCDs elevated the role of external actors in the NCD space in Uganda. As such, WHO, civil society actors, and NGOs played more active roles in the development and implementation of different programs to address their own mandates for cancer, heart disease, tobacco control, and so on. One MOH respondent described the diminishing role of the MOH as follows:

The Ministry, because of the little funding we have, most of the programs are run by partners. We just come, maybe to monitor and to support those programs.—Government official, G5

Though respondents from the MOH felt that the lack of funding did not limit their ability to

discuss government priorities with donors, they still felt that funders tended to be more influential in deciding how programs should be implemented. They described how funders' priorities and plans needed to be followed most of the time:

Mostly, the funders' influence how the things should be done, because if they come up with their plan of implementation, you have to follow it if you are to implement this kind of project or program. You must follow their priorities and their plans most of the time. If the Ministry is . . . going to implement, we also have to discuss with them our mandate and our priorities, so that we all benefit. . . . They come with their priorities. We also have ours. So, sometimes we have to discuss and say, "Let us maybe do this and this," depending on what we want to implement . . . —Government official, G3

Respondents felt that planning, programming, and implementation would be different if the MOH had more funding. As such, senior leaders of civil society organizations operating in the NCD space felt that funding constraints shifted the balance of power toward nongovernment actors and thus limited the government's ability to set priorities and the agenda. Appropriate funding allocation by local governments to support the implementation of national NCD programs and policies was highlighted as a critical factor, as indicated by one senior government official:

The local governments have to deliver. The local governments have to make sure that the facilities are there to diagnose and treat the patients, so we need to see that more money is earmarked, for example, to provide the drugs that are critical or vital in the management of NCDs.—Government official, G7

Managerial and Technical Expertise

Respondents felt that building the technical and management capacity of the MOH to lead and coordinate the work around NCDs was critical for (1) coordinating different NCD program activities conducted by different actors; (2) strengthening existing policy processes, such as facilitating workshops with stakeholders to develop guidelines and policies for different NCD programmatic areas; and (3) improving the implementation of NCD guidelines, including the NCD component of the Health Sector Development Plan. Respondents also felt that hiring staff with technological and managerial skills for the NCD Desk would increase its presence and awareness of NCD-related issues within the government.

First, several respondents, including actors from the government, civil society, and NGOs, expressed frustration over the perceived lack of leadership from the MOH in coordinating this effort. Specifically, respondents found the managerial and technical capacity of the MOH to be inadequate and incomplete. Respondents both within and outside the government felt that involvement from multiple actors without adequate coordination by the MOH created silos and fragmentation in policy and program implementation efforts in the country. Without clear agreement on how best to manage NCD prevention and care in Uganda, respondents felt resources were not being used effectively. One respondent described the lack of communication as follows:

We could be strategic in leveraging resources and getting the most out of our investment, because now I don't know much about what is happening in other areas of NCDs, other than what I am leading . . . —Civil society organization member, C4

Lack of communication from the MOH often resulted in information about new policies and programs reaching only those who attended meetings and not reaching policy implementers or beneficiaries who, according to a civil society organization member, "may not even know what is in it."

Second, in a context where most actors operate outside of the MOH, senior policy actors within the MOH felt that programs were being developed and implemented to meet the funder's mandate rather than to address an overarching strategic plan. One government official put it this way:

There are different people doing different things. It just depends on where someone gets their money—Government official, G1

Another respondent echoed this sentiment, further highlighting how the absence of technical and managerial leadership, including internal agreement on NCD strategy and priorities, diminished the government's ability to control and influence the implementation of NCD programs.

Third, respondents felt that inadequate recruitment of managers and technical experts within the MOH limited the government's technical role in policy and program formulation. Some respondents felt that the government did not actively drive the research agenda on NCDs, leaving such effort to external partners, who also produced the evidence. At the time of this study, other than the 2014 NCD survey conducted by the

Respondents felt MOH technical and management capacity needed to be strengthened to lead and coordinate the work around NCDs.

MOH with technical support and funding from WHO,¹¹ respondents were not aware of any other government-commissioned study. Although they felt that this report's findings could form a strong basis for developing an NCD strategic plan, they also emphasized that additional areas required more research, such as identifying risk factors affecting adolescent health and predispositions to NCDs.

In sum, respondents universally emphasized the important managerial and technical roles of the NCD Desk while also recognizing that mobilizing actors is a particularly large challenge due to understaffing and inadequate financing.

Cross-cutting Issues

The inertia to change existing funding practices and the limited absorptive capacity of the government were identified as cross-cutting issues affecting the availability of financial resources and appropriate staffing of technical experts and managers by the MOH. Respondents felt that the declining government expenditure on health reflected a lack of prioritization of the health sector. Without an increase in overall funding for the health sector, respondents felt areas like NCDs would remain underfunded.

According to one academic interviewed, changing budget allocations within the MOH from areas that historically received the "lion's share of funding" to other underfunded areas was viewed as particularly challenging for 3 reasons. First, respondents recognized that reallocating funds within the limited resources of the current budget would result in funding cuts to existing areas that are already underfunded:

If they [MOH] are to move money from infectious disease control to put it in NCDs, it will mean that they have managed and controlled infectious disease to a level where they can go on to another disease area, but they haven't done that yet. —Academic, A1

Second, some respondents acknowledged the powerful role of lobbyists in Uganda who maintain the status quo and protect NGO interests. One respondent from the MOH noted that compared to issues like HIV and family planning, NCD-related issues receive less government funding and less interest from the donor community to fund civil society organizations and other networks. Third, a couple of respondents felt that funding for NCDs would remain low as long as politicians and elites in power do not directly experience NCD consequences. As one respondent explained, access to health insurance shields

politicians from the adverse consequences of NCDs, and funding for NCDs thus remains a barrier.

DISCUSSION

In this study, we aimed to understand the policy context for NCDs in Uganda by eliciting the views and experiences of a wide range of stakeholders within and external to the MOH. In addition, we sought to identify the factors influencing the development and implementation of policies and programs for NCDs within Uganda. From the in-depth interviews, it became clear that the NCD space has multiple actors, such as NGOs, alliances for specific NCDs, and development partners, who play major roles in shaping the development and implementation of NCD policies and programs. Although these activities by external partners serve as valuable stopgap measures, respondents noted several challenges facing the government.

First, many respondents expressed that the allocation of financial resources toward the development and implementation of existing NCD programs remains a challenge. Though the overall health budget has increased in recent years in Uganda, resources available for NCD policy implementation have not met needs.¹⁷ A recent evaluation examining priority settings for NCDs in Uganda similarly noted delays or failure to implement relevant NCD priorities due to insufficient resources and stated a need for leadership and greater accountability to support these processes.¹⁶ The mismatch between the disease burden of and response to NCDs is not unique to Uganda. It has also been observed in other countries in sub-Saharan African, where efforts to address NCD prevention and burden has been inadequate.^{29–31} Additional funds will be required to target the changing trends in NCDs and their underlying risk factors. For example, tobacco use among adults has declined, but incidences of obesity and high blood pressure have increased.⁹ Expanding annual health budgets and earmarking funds for NCDs will be critical. However, traditional funding approaches (e.g., domestic tax revenues), though a common source of health funding in low- and middle-income countries, have been described as inadequate to close the funding gap required for NCDs.³² In this context of limited resources, the role of innovative financing mechanisms (e.g., pooled funding) to mobilize alternative financing strategies to support the prevention and management of NCDs may be useful to consider.³³

Second, the limited recruitment of managerial and technical expertise for the NCD Desk (at the time of the study) was viewed as a barrier to the coordination and communication across actors within the NCD space. Platforms such as the NCD Technical Working Group and Parliamentary Forum on NCDs allow different stakeholders to engage with one another. Yet, external partners often lead policy and program development, with the MOH playing more of a supportive role. This situation is not unique to Uganda. Studies in other low- and middle-income settings have similarly noted diminished roles of local policy actors in the policy process, particularly when they lack sufficient “control” of financial and technical resources^{34,35} and when collaboration and coordination between the government and partners is weak.^{35,36}

Respondents felt the presence of multiple external actors led to a perceived vacuum in government leadership and alluded to a need for stronger government leadership in developing a comprehensive strategic plan that both government and external actors can agree upon and adopt as the guiding framework for action. If the activities of actors in the NCD space are well-coordinated and channeled to implement a clear strategic plan, then the presence of different actors could be advantageous. Strengthening platforms such as the Health Policy Advisory Committee; conducting regular joint reviews between the government, NGOs, and funders; and documenting priority areas for action may be mechanisms for strengthening the government’s stewardship role in a multi-partner and multi-stakeholder environment for NCDs in Uganda. Developing a policy vision and strategy, building a coalition of relevant actors in the space, and creating accountability for action have been identified as additional ways to strengthen stewardship.³⁷

Third, respondents raised concerns about the government’s absorptive capacity and ability to take on financial, managerial, and technical responsibilities for overseeing various NCD programs initiated by external partners. In 2015, a benchmarking exercise conducted by the East Africa NCD Alliance Initiative described a need for greater alignment between development partners and national governments, more robust implementation frameworks, and stronger health system capacity to manage NCDs and address the growing burden of NCDs in low- and middle-income countries, including Uganda.³⁸ A recent assessment in Uganda found that only 34% to 48% of the country’s public health facilities offer

services for diabetes, cardiovascular disease, and chronic respiratory diseases.¹⁴

This study highlights the immediate need to mobilize more resources, reduce fragmented efforts in the NCD space, and prioritize investment in NCD prevention and management in Uganda. Since this study was completed, the MOH elevated the NCD Desk to a full NCD Department headed by a commissioner. The expansion is expected to increase funding and staffing of human resources dedicated to the prevention and control of NCDs. The NCD Department at the MOH, in partnership with health partners, has begun training health workers, including community health workers in NCD prevention and control, at the facility and community levels. The MOH also has supplied health facilities with new blood pressure machines and weighing scales to improve NCD control and management. There have been discussions about adding new NCD drugs to Uganda’s list of essential medicines, which would facilitate their procurement by the National Medical Stores and increase their distribution to lower-level facilities. In addition, the MOH engaged with the pharmaceutical industry through public and private partnerships to increase access to NCD drugs at lower costs.

Despite these achievements, a strong policy is still needed to guide prevention, screening, treatment, and management of NCDs. In August 2019, the MOH launched the Non-Communicable Diseases and Injuries Commission with the goal of reframing NCD and injury care in Uganda. The Commission has been tasked with collecting, analyzing, and reporting information to demonstrate the national burden related to NCDs, assess the health system’s readiness, and propose mechanisms to strengthen health system capacity.³⁹ Proceedings from the Commission are expected to bring greater attention to the policy and funding needs to strengthen NCD prevention and management in Uganda.

Limitations

Our study has several limitations. First, despite trying to interview a broad range of actors from different organizations, we were unable to interview some key policy actors, such as parliamentarians and actors from other sectors outside of health whose insights would have contributed to shaping our narrative. As a result, we captured a subset of views that may not represent all views on these issues. Second, because we conducted interviews with national-level actors, we were unable to completely explore factors that affect

The MOH elevated the NCD Desk to a department, begun health worker training in NCD prevention and control, and provided new equipment and supplies to facilities.

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policy implementation at the sub-national levels. Third, conducting interviews with policy actors often requires insider access to information and resources, as well as trust. Although the study team consisted of Makerere University School of Public Health faculty, it is possible that respondents might not have been fully transparent with the interviewer, thus preventing a more nuanced narrative.⁴⁰ Relatedly, differences arising from the investigator's ability to establish and maintain rapport with respondents, their interviewing styles, as well as the time respondents could dedicate to the interview, affected the type of data collected and the depth of discussions. Finally, our work was specific to Uganda, and thus we recognize that our findings may not be widely generalizable. However, we anticipate that some of our findings may be relevant to governments and partners working in other countries that are trying to address the growing double burden of disease in the face of limited resources.

CONCLUSIONS

Awareness about the importance of addressing NCDs is increasing in Uganda, as reflected in Uganda's policy discourse, the development of an NCD Department within the MOH, and efforts to engage with partners, researchers, and other stakeholders, such as the NCD Technical Working Group. Funding constraints continue to hamper the government's ability to lead in the NCD space and contribute to an imbalance, with external actors spearheading several NCD program activities in the country. Despite recent improvements, respondents remain skeptical about the government's commitment to adequately increase budgetary allocations to meet NCD-related needs and to invest in strengthening health system capacity by addressing technical and human resources constraints.

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REFERENCES

- Roth GA, Abate D, Abate KH, et al. Causes of Death Collaborators. Global, regional, and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980–2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet*. 2018;392(10159):1736–1788. [CrossRef](#). [Medline](#)
- Kyu HH, Abate D, Abate KH, et al. Global, regional, and national disability-adjusted life-years (DALYs) for 359 diseases and injuries and healthy life expectancy (HALE) for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet*. 2018;392(10159):1859–1922. [CrossRef](#). [Medline](#)
- James SL, Abate D, Abate KH, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet*. 2018;392(10159):1789–1858. [CrossRef](#). [Medline](#)
- Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012;380(9859):2224–2260. [CrossRef](#). [Medline](#)
- World Health Organization (WHO). *Global Health Risks: Mortality and Burden of Disease Attributable to Selected Major Risks*. WHO; 2009. Accessed February 28, 2021. <https://apps.who.int/iris/handle/10665/44203>
- World Health Organization (WHO). NCD mortality and morbidity. WHO; 2017. Accessed February 28, 2021. http://www.who.int/gho/ncd/mortality_morbidity/en/
- Bygbjerg IC. Double burden of noncommunicable and infectious diseases in developing countries. *Science*. 2012;337(6101):1499–1501. [CrossRef](#). [Medline](#)
- Marquez PV, Farrington JL. *The Challenge of Non-Communicable Diseases and Road Traffic Injuries in Sub-Saharan Africa: An Overview*. The World Bank; 2013 June. Working Paper Africa Human Development Sector Unit. Accessed February 28, 2021. https://www.researchgate.net/profile/Patricio_Marquez/publication/255721580_The_Challenge_of_Non-communicable_Diseases_and_Road_Traffic_Injuries_in_Sub-Saharan_Africa_An_Overview/links/5592c30508ae1e9cb42977aa.pdf
- World Health Organization (WHO). Uganda: Noncommunicable Diseases (NCD) Country Profiles, 2018. WHO; 2018. Accessed February 28, 2021. https://www.who.int/nmh/countries/uga_en.pdf
- Institute of Health Metrics and Evaluation. Health Data, Uganda. University of Washington; 2017. Accessed February 28, 2021. <http://www.healthdata.org/uganda>
- Republic of Uganda, Ministry of Health (MOH). *Non-Communicable Disease Risk Factor Baseline Survey*. MOH; 2014. Accessed February 28, 2021. http://www.who.int/chp/steps/Uganda_2014_STEPS_Report.pdf
- Guwatudde D, Mutungi G, Wesonga R, et al. The epidemiology of hypertension in Uganda: findings from the national non-communicable diseases risk factor survey. *PLoS One*. 2015;10(9):e0138991. [CrossRef](#). [Medline](#)
- World Health Organization (WHO). "Best Buys" and Other Recommended Interventions for the Prevention and Control of Noncommunicable Diseases. WHO; 2017. Accessed February 28, 2021. https://www.who.int/ncds/management/WHO_Appendix_BestBuys.pdf
- Republic of Uganda, Ministry of Health (MOH). *Health Sector Development Plan 2015/16–2019/20*. MOH; 2015. Accessed February 28, 2021. <http://library.health.go.ug/sites/default/files/>

- resources/Health%20Sector%20Development%20Plan%202015-16_2019-20.pdf
15. World Bank Databank. Uganda. Accessed March 8, 2021. <https://data.worldbank.org/country/uganda>
 16. Essue BM, Kapiriri L. The unfunded priorities: an evaluation of priority setting for noncommunicable disease control in Uganda. *Global Health*. 2018;14(1):22. [CrossRef](#). [Medline](#)
 17. Republic of Uganda, Ministry of Finance, Planning and Economic Development. Approved budgets over time. Tableau Software; 2019. Accessed February 28, 2021. https://public.tableau.com/views/BudgetOverTheYears/ApprovedBudgets?:embed=y&:display_count=yes&publish=yes&:showVizHome=no
 18. Creswell JW. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. Sage Publications; 2013.
 19. Republic of Uganda. Health Financing Strategy 2015/16-2024/25. Republic of Uganda; 2016. Accessed February 28, 2021. <http://library.health.go.ug/sites/default/files/resources/Health%20Financing%20Strategy%202016.pdf>
 20. Republic of Uganda, Ministry of Health (MOH). *National Budget Framework Paper FY2019/20-FY 2023/24*. MOH; 2018. Accessed February 28, 2021. <https://budget.go.ug/sites/default/files/National%20Budget%20docs/National%20Budget%20Framework%20Paper%20FY%202019-20.pdf>
 21. Republic of Uganda, Ministry of Health (MOH). *Child and Adolescent Mental Health Policy Guidelines*. MOH; 2017. Accessed February 28, 2021. https://health.go.ug/sites/default/files/CAMH%20POLICY%20-%20%20Final%201%20%281%29_0.pdf
 22. Republic of Uganda, Ministry of Health (MOH). *Ugandan Clinical Guidelines 2016*. MOH; 2016. Accessed February 28, 2021. http://library.health.go.ug/sites/default/files/resources/Uganda%20Clinical%20Guidelines%202016_FINAL.pdf
 23. Republic of Uganda, Ministry of Health (MOH). *Essential Medicines and Health Supplies List for Uganda*. MOH; 2016. Accessed February 21, 2021. https://health.go.ug/sites/default/files/Essential%20Medicines%20and%20Health%20Supplies%20List_EMHSLU_2016_FINAL_0.pdf
 24. Miles MB, Huberman AM, Huberman MA, et al. *Qualitative Data Analysis: An Expanded Sourcebook*. Sage; 1994.
 25. Walt G, Shiffman J, Schneider H, et al. "Doing" health policy analysis: Methodological and conceptual reflections and challenges. *Health Policy Plan*. 2008;23(5):308–317. [CrossRef](#). [Medline](#)
 26. Glaser B, Strauss A. *The Discovery of Grounded Theory: Strategies for Qualitative Research*. Aldin Pub Co; 1967.
 27. Uganda Initiative for Integrated Management of Non-Communicable Diseases. Accessed February 28, 2021. <https://www.uincd.org>
 28. Republic of Uganda, Ministry of Health (MOH). *National Health Policy*. MOH; September 1999. Accessed February 28, 2021. http://library.health.go.ug/sites/default/files/resources/National_Health_Policy_1999_1.pdf
 29. Dalal S, Beunza JJ, Volmink J, et al. Non-communicable diseases in sub-Saharan Africa: what we know now. *Int J Epidemiol*. 2011; 40(4):885–901. [CrossRef](#). [Medline](#)
 30. Yeates K, Lohfeld L, Sleeth J, et al. A global perspective on cardiovascular disease in vulnerable populations. *Can J Cardiol*. 2015; 31(9):1081–1093. [CrossRef](#). [Medline](#)
 31. Nyaba GN, Stronks K, de-Graff Aikins A, et al. Tracing Africa's progress towards implementing the Non-Communicable Diseases Global action plan 2013–2020: a synthesis of WHO country profile reports. *BMC Public Health*. 2017;17(1):297. [CrossRef](#). [Medline](#)
 32. Reeves A, Gourtsoyannis Y, Basu S, et al. Financing universal health coverage—effects of alternative tax structures on public health systems: cross-national modelling in 89 low-income and middle-income countries. *Lancet*. 2015;386(9990):274–280. [CrossRef](#). [Medline](#)
 33. Meghani A, Basu S. A review of innovative international financing mechanisms to address noncommunicable diseases. *Health Aff*. 2015;34(9):1546–1553. [CrossRef](#). [Medline](#)
 34. Buse K, Mays N, Walt G. *Making Health Policy*. 2nd ed. McGraw-Hill Education (UK); 2012.
 35. Khan MS, Meghani A, Liverani M, et al. How do external donors influence national health policy processes? Experiences of domestic policy actors in Cambodia and Pakistan. *Health Policy Plan*. 2018;33(2):215–223. [CrossRef](#). [Medline](#)
 36. Parkhurst J. *The Politics of Evidence: From Evidence-Based Policy to the Good Governance of Evidence*. Routledge; 2016.
 37. World Health Organization (WHO). Regional Office for Africa. Accessed February 28, 2021. <https://www.afro.who.int>
 38. The East Africa NCD Alliance Initiative. *A Civil Society Benchmark Report*. The East Africa NCD Alliance Initiative; 2014. Accessed February 28, 2021. <https://ncdalliance.org/sites/default/files/rfiles/East%20Africa%20NCD%20Alliance%20Civil%20Society%20Survey%20Report.pdf>
 39. Republic of Uganda, Ministry of Health (MOH). *Uganda Launches Non-Communicable Diseases and Injuries Commission*. MOH; 2019. Accessed February 28, 2021. <https://www.health.go.ug/2019/12/02/uganda-launches-non-communicable-diseases-and-injuries-commission/>
 40. Creswell JW, Poht CN. *Qualitative Inquiry and Research Design: Choosing Among Five Approaches*. Sage Publications; 2017. Accessed February 27, 2021. <http://bit.ly/2YW1rGe>

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Human Resources for Health-Related Challenges to Ensuring Quality Newborn Care in Low- and Middle-Income Countries: A Scoping Review

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Key Messages

- We mapped the evidence of human resources for health (HRH)-related challenges to providing quality facility-based newborn care into 10 categories:
 - Lack of HRH data and monitoring
 - Poor health worker (HW) preservice education
 - Lack of HW access to evidence-based guidelines, continuing education, and continuing professional development
 - Insufficient and inequitable distribution of HWs and heavy workload
 - Poor retention, absenteeism, and rotation of experienced staff
 - Poor work environment, including low salary
 - Limited and poor supervision
 - Low morale, motivation, and attitude, and job dissatisfaction
 - Weaknesses of policy, regulations, management, leadership, governance, and funding
 - Structural and contextual barriers
- Mapping the evidence provided useful insight to inform recently published World Health Organization strategies to systematically address the challenges and strengthen HRH for newborn care globally and nationally.
- The thematic analysis process also underscored the complicated interactions between different types of HRH challenges.
- Findings support new strategies for action to address these challenges.

➔ *Resumen en español al final del artículo. El texto completo del artículo también está disponible en español.*

➔ *Le texte complet de l'article est aussi disponible en français.*

ABSTRACT

Background: A critical shortage of health workers with needed maternal and newborn competencies remains a major challenge for the provision of quality care for mothers and newborns, particularly in low- and middle-income countries. Supply-side challenges related to human resources for health (HRH) worsen shortages and can negatively affect health worker performance and quality of care. This review scoped country-focused sources to identify and map evidence on HRH-related challenges to quality facility-based newborn care provision by nurses and midwives.

Methods: Evidence for this review was collected iteratively, beginning with pertinent World Health Organization documents and extending to articles identified via database and manual reference searches and country reports. Evidence from country-focused sources from 2000 onward was extracted using a data extraction tool that was designed iteratively; thematic analysis was used to map the 10 categories of HRH challenges.

Findings: A total of 332 peer-reviewed articles were screened, of which 22 met inclusion criteria. Fourteen additional sources were added from manual reference search and gray literature sources. Evidence has been mapped into 10 categories of HRH-related challenges: (1) lack of health worker data and monitoring; (2) poor health worker preservice education; (3) lack of HW access to evidence-based practice guidelines, continuing education, and continuing professional development; (4) insufficient and inequitable distribution of health workers and heavy workload; (5) poor retention, absenteeism, and rotation of experienced staff; (6) poor work environment, including low salary; (7) limited and poor supervision; (8) low morale, motivation, and attitude, and job dissatisfaction; (9) weaknesses of policy, regulations, management, leadership, governance, and funding; and (10) structural and contextual barriers.

Conclusion: The mapping provides needed insight that informed new World Health Organization strategies and supporting efforts to address the challenges identified and strengthen human resources for neonatal care, with the ultimate goal of improving newborn care and outcomes.

BACKGROUND

Newborns are extremely vulnerable; globally, about 2.5 million babies die during their first 28 days of

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life (the neonatal period), with about 77% of those deaths occurring during the first week of life.^{1,2} Additionally, almost 2 million stillbirths occur in the last 3 months of pregnancy or during childbirth each year,^{3,4} and millions of infants develop short- and long-term morbidities and neurocognitive problems.^{5,6} Most newborns can survive and thrive with access to quality health care, yet reductions in neonatal mortality remain slow and unequal due to variable coverage of essential interventions and quality care delivery by health workers (HWs).^{7,8} Universal access to quality care could prevent 1.7 million neonatal deaths each year or 68% of the deaths that will otherwise occur by 2030.⁵

Skilled birth attendants and midwives capable of providing high-quality childbirth, essential newborn, and referral-level care are critical because early neonatal deaths are inextricably linked to maternal health and to the quality of care a mother and her baby receive during labor, childbirth, and the immediate postpartum period.⁷ In addition, competent newborn workers—primarily composed of nurses and midwives with support from medical doctors and other health specialists—are needed to provide facility-based care to an estimated 30 million newborns every year who require care in a hospital setting.^{5,9} As the majority of women choose institutional delivery and neonatal mortality declines below 30/1,000 live births globally, interventions delivered in facilities across primary (basic), secondary (“special care”), and tertiary (neonatal intensive care) levels become increasingly important to achieve further declines.¹⁰ Facility-based maternal and newborn care refers to round-the-clock clinical services provided by skilled personnel at health care facilities, focused on routine care and management of complications.^{11,12} Together, nurses and midwives compose the largest percentage of HWs worldwide and are critical to achieving not only improved maternal and newborn health outcomes, but also stronger health systems that ensure all newborns not only survive but also thrive and realize their rights to the highest attainable standards of health and well-being.^{5,13–15}

However, a critical shortage of HWs with needed maternal and neonatal competencies remains an impediment to scaling up the provision of skilled care for mothers and newborns, particularly in low- and middle-income countries (LMICs). Currently, high-income countries have on average 10.9 nurses and midwives per 1,000 population, compared with 2.5 and 0.9 in LMICs and low-income countries, respectively.¹⁶ Supply-side human resources for health (HRH)-related challenges worsen shortages and can negatively affect HW performance and

quality of care.^{17,18} As the coronavirus disease (COVID-19) pandemic overburdens health systems in many countries, newborns—although less likely to die from COVID-19—are at increased risk for mortality from other preventable and treatable conditions as access to and availability of health services are disrupted.¹⁹

Despite increased attention to the issue of HRH since the 2006 World Health Report and World Health Assembly, and the creation of the Global Health Workforce Alliance, which spearheaded World Health Organization (WHO) HRH efforts from 2006 to 2016, specific attention to HRH for newborn care is more recent, as is a focus on the quality of care provided.^{20,21} It is now essential to address the critical shortage of competent HWs to attain the ambitious newly released Every Newborn Action Plan 2025 health targets and new WHO standards for improving the quality of care for small and sick newborns in health facilities, as part of progress toward attaining the Sustainable Development Goals (SDGs).^{22,23}

This scoping review responds to the call for timely information for WHO’s Year of the Nurse and Midwife to ensure that this relatively neglected topic has a place in the discussion. It scopes the literature to identify and map country-focused evidence on HRH-related challenges to quality facility-based newborn care provision by nurses and midwives in LMICs and provides the evidence base for recently published WHO strategies to address these challenges.^{9,24} While community-based care is also critical to reducing maternal and neonatal mortality and morbidity, this article focuses on newborn care provided in health care facilities.

METHODS

Approach

A scoping methodology was selected for this review because the approach allows for expeditious large-scale accumulation of literature and mapping of the evidence therein and determining the extent of the evidence and gaps requiring additional research.²⁵ The approach applied in this scoping review uses a 5-stage process: (1) identifying the research question, (2) identifying relevant studies, (3) selecting studies, (4) charting the data, and (5) collating, summarizing, and reporting the results.²⁶ Evidence for this review was collected iteratively, beginning with pertinent WHO documents and topical published series and extending to articles identified via database searches and manual reference searches, as well as country and organizational reports.

HWs with maternal and neonatal competencies are critically needed to scale up the provision of skilled care for mothers and newborns.

This review investigated what evidence is available on HRH-related challenges to provision of quality newborn care by nurses and midwives in LMICs.

Database Searches

This review investigated the following research question: what evidence is available on HRH-related challenges to provision of quality newborn care by nurses and midwives in LMICs. The database searches aimed to find peer-reviewed articles, commentaries, and reports from LMICs that addressed the topic of inquiry and were published starting in 2000, with the inception of the Millennium Development Goals.

Search Strategy and Selection Criteria

Data for this review were identified by searches of PubMed, EMBASE, CENTRAL, Cumulative Index of Nursing and Allied Health Literature (CINAHL), African Journals Online (AJOL), Latin American & Caribbean Health Sciences Literature (LILACS), and references from relevant articles using the following search terms: nurses, nursing, midwives, midwifery, nurse-midwives, neonates, newborns, infants, premature, preterm, low birth weight, developing countries, low-income countries, middle-income countries, inpatient, hospitals, health care facilities, health centers, clinics, neonatal care units, newborn care units, neonatal intensive care units, health human resources, human resources for health, workforce, health personnel, policies, education, employment, deployment, distribution, retention, shortages, salaries, motivation, performance, supervision combined using Boolean operators AND and OR and limited to humans. Grey literature was sought through Open Grey (www.opengrey.eu), Grey Literature Report (www.greylit.org), and Healthy Newborn Network. Searches were conducted in English, without language restrictions. Only articles published from 2000 were included.

The complete search strategy is provided in a Supplement.

Inclusion and Exclusion Criteria

Search results were entered into Covidence software (www.covidence.org), and 2 reviewers (NEB and KDC) independently screened study titles and abstracts against inclusion and exclusion criteria. The articles selected for full-text review met inclusion criteria consistent with manuscripts examining HRH challenges for newborn care by nurses and midwives at the facility level in LMICs.

Specific inclusion criteria were:

1. Topic: addressed HRH challenge
2. Providers: nurses and/or midwives
3. Patient Population: from birth to 28 days of life (neonatal period) and caregiver

4. Setting: health care facilities at primary, secondary, or tertiary level in LMICs: country included on World Bank list for LMICs²⁷
5. Country-focused; evidence from the national, regional, district, or facility-level in country
6. Years: 2000 to present

Reasons for exclusion were sources that were community-based only (not facility-based) or that described initiatives with traditional birth attendants, community HWs, or medical doctors only; policy initiatives that were theoretical but not implemented; or research carried out in refugee settings (since these settings often face unique challenges). Each reviewer independently screened each full-text document to determine whether the source should be included or excluded, and disagreements were resolved through discussion. The search and review results are shown (Figure).

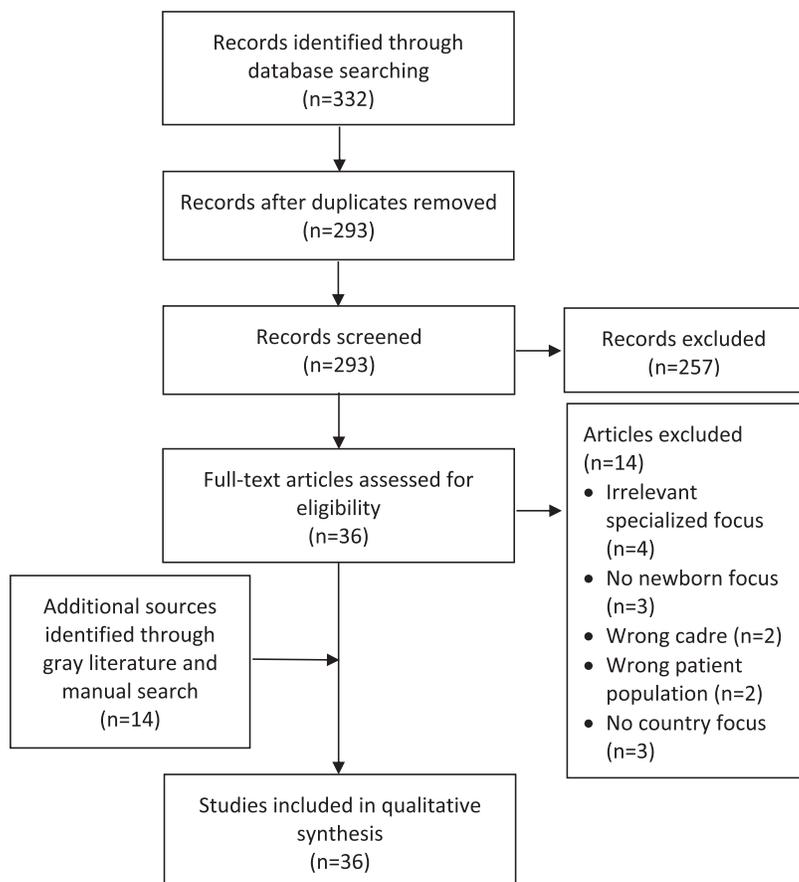
Data Extraction and Management

The primary author (NEB) read and coded each full-text document using a data extraction form that was created iteratively as we reviewed the full texts. Data fields were the following: HRH challenge, example (detail) of challenge, country, setting, research methods, type of document (peer-reviewed or gray), type of provider, year of publication, source, and any additional notes. The extracted data were used to create a concept map or chart of HRH challenges and then were grouped into categories by similar themes via inductive thematic analysis described by Braun and Clarke.²⁸ Categories of challenges were reviewed by 2 authors (NEB and OL), collapsing the themes based on the volume of evidence in each category and using an iterative and inductive process to reach consensus on the final 10 categories of challenges.

RESULTS

A total of 332 peer-reviewed articles, including 39 duplicates, were retrieved. The 293 abstracts were then reviewed using pre-identified inclusion and exclusion criteria. Of these sources, 22 met the inclusion criteria (Figure). Fourteen additional records were added from manual reference search and gray literature sources, bringing the total number of included articles to 36. Sources meeting the inclusion criteria covered 20 of 138 LMICs. With 8 peer-reviewed articles, India had the highest representation, and the remaining 19 countries were represented by 1 or 2 publications each. One publication covered 4 countries (Cambodia, Lao PDR, Vietnam, and Malaysia).²⁹

FIGURE. Flow Diagram of Search and Review Results of Evidence on Human Resources for Health-Related Challenges to Quality Newborn Care in Low- and Middle-Income Countries



Most sources included were peer-reviewed publications (n=33). Year of publication ranged from 2005 to 2019, and sources relied primarily on evidence about nurses (including obstetric and neonatal nurses, neonatal intensive care unit [NICU] nurses, and student nurses), midwives (including auxiliary nurse midwives), and to a lesser extent medical doctors, medical officers, district health officers, facility managers, and policy makers. Research methods utilized in the reviewed articles were both qualitative (interviews and focus groups) and quantitative (surveys, audits, multiple-choice and skills tests, questionnaires); articles also employed document review, record review, and observation to collect data. One article relied on data from a national multistakeholder group³⁰ and another on secondary data analysis.³¹ Most studies reported on data from NICUs, health centers, hospitals, or district hospitals from specified regions. Four articles used national-

level data for their analysis (Ethiopia, Indonesia, Ghana, and Uganda).^{30,32-34}

The thematic analysis of the data resulted in 10 categories of HRH-related challenges faced by nurses and midwives in providing quality facility-based newborn care. A summary of data, classified by HRH challenge, is provided in the Table. Data from each source were often mapped to more than 1 challenge (Table).

Categories of HRH Challenges

1. Lack of Data and Monitoring on HRH Required for Maternal and Newborn Health

Reviewed sources reported a lack of HRH data on personnel availability, distribution, trends, and requirements.^{35,36} For example, Nigeria has a critical shortage of HWs, particularly for health facilities in rural areas, and the problematic task of

A thematic data analysis yielded 10 categories of HRH-related challenges faced by nurses and midwives in providing quality facility-based newborn care.

TABLE. Mapped Human Resources for Health-Related Challenges With Review Sources

HRH Challenge	Examples	Country	Source Type	Source	
1. Lack of data on HRH	Scarce HRH data as a barrier to HRH planning	Nigeria	PR	Adegoke et al. ³⁵	
	Few workforce indicators for midwifery	Mongolia	PR	Kildea et al. ³⁶	
2. Poor HW preservice education/insufficient newborn content	Lack of qualified instructors and clinical preceptors for midwives	Democratic Republic of the Congo	PR	Bogren et al. ³⁷	
	Basic neonatal component in nursing preservice insufficient	Ghana	PR	Elikplim Pomevor and Adomah-Afari ³⁸	
	Bachelor’s-level nurse curriculum and performance poor compared to other providers (including diploma nurses)	Ethiopia	Report	Getachew et al. ³²	
	HWs receive limited preservice instruction on neonatal care in their basic training	Kenya	PR	Aluvaala et al. ¹⁰	
	NB care not a core competency in general nursing education	India	PR	Campbell-Yeo et al. ³⁹	
3. Lack of access for HWs to evidence-based practice guidelines and protocols, CE, and CPD	Nonavailability of ENC and NR guidelines/protocols	Ethiopia	PR	Haile-Mariam et al. ⁴¹	
	Lack of guidelines/posted protocols NR	Malawi	PR	Bream et al. ⁴²	
	Few protocols for care of sick neonates available	Ghana	PR	Elikplim Pomevor and Adomah-Afari ³⁸	
	Helping Babies Breathe guidelines in 25% of health facilities	Malawi	PR	Kozuki et al. ⁴³	
	Nonavailability of NB protocols	Tanzania	PR	Nyamtema et al. ⁴⁷	
	Poor dissemination of practice protocols to NICU nurses	Thailand	PR	Jirapaet et al. ⁴⁴	
	Little in-service training on NB, NR, and small and sick newborn care		Ghana	PR	Elikplim Pomevor and Adomah-Afari ³⁸
			India	PR	Malhotra et al. ⁴⁰
	75% of health centers studied had no trained clinician in basic emergency obstetric and newborn care	Malawi	PR	Kozuki et al. ⁴³	
	Variable CE opportunities for neonatal nurses	India	PR	Campbell-Yeo et al. ³⁹	
	Limited access to CE for nurses and midwives	DR Congo	PR	Bolan et al. ⁶⁶	
	Lack of policy on CE/renewal of skills	Malawi	PR	Bream et al. ⁴²	
	Little CE for HWs on managing NR or newborn emergencies	The Gambia	PR	Cole-Ceesay et al. ⁴⁵	
	No CE for midwives	Mongolia	PR	Kildea et al. ³⁶	
	Lack of coordination of CPD of HWs, in past CPD not mandatory for MWs and absence of quality control over CPD	Liberia	PR	Michel-Schuldt et al. ⁴⁶	
4. Insufficient and inequitable distribution of HWs, heavy workload	Insufficient HWs in general	Nigeria	PR	Adegoke et al. ³⁵	
		Malawi	PR	Bream et al. ⁴²	
		Tanzania	PR	Nyamtema et al. ⁴⁷	
	Lack of HWs in primary health care/district hospitals	Nepal	PR	Allen and Jeffrey ⁵⁴	

Continued

TABLE. Continued

HRH Challenge	Examples	Country	Source Type	Source
	Insufficient NICU staff	Thailand	PR	Jirapaet et al. ⁴⁴
	Lack of specialized nursing staff for neonatal care and sick newborns	SE Asia (4 countries)	PR	Martinez et al. ²⁹
		Solomon Islands	PR	Tosif et al. ⁵⁵
		India	PR	Neogi et al. ³¹
	Acute nursing shortage in newborn units	Kenya	PR	Nzinga et al. ⁴⁸
		Kenya	PR	Aluvaala et al. ¹⁰
	Shortage of HWs with neonatal training	Rwanda	PR	Ntigurirwa et al. ⁴⁹
	Low number of HWs compounded by uneven distribution.	Indonesia	Report	National Research Council ³³
	Poor distribution in rural/remote areas	Nepal	PR	Allen and Jeffrey ⁵⁴
		Nigeria	PR	Adegoke et al. ³⁵
		India	PR	Fischer et al. ⁵⁰
	Heavy workload for existing staff	India	PR	Amin et al. ⁵¹
		Cambodia	PR	Ith et al. ⁵²
		India	PR	Morgan et al. ⁵⁸
	Gap filling with lower-level staff	Tanzania	PR	Prytherch et al. ⁵³
5. Poor retention, rotation out, absenteeism	Poor retention of HWs due to (examples) - Deaths of HWs from HIV - Rural-urban migration - External brain drain - Attrition to private sector and non-governmental organizations	Tanzania	PR	Nyamtema et al. ⁴⁷
		Rwanda	PR	Ntigurirwa et al. ⁴⁹
		India	PR	Neogi et al. ¹¹
		Gambia	PR	Cole-Ceesay et al. ⁴⁵
	Absenteeism	India	PR	Neogi et al. ¹¹
		Tanzania	PR	Nyamtema et al. ⁴⁷
		Tanzania	PR	Prytherch et al. ⁵³
	Rotation /transfer of neonatal nurses - To other units - To other facilities	India	PR	Dewez et al. ⁵⁷
		Ghana	PR	Elikplim Pomevor and Adomah-Afari ³⁸
		Rwanda	PR	Ntigurirwa et al. ⁴⁹
6. Poor work environment including: low salary; bad housing; lack of supplies, medications, equipment, electricity, and water; and poor safety and infrastructure	Low salary and irregular payment	Nigeria	PR	Adegoke et al. ³⁵
		Cambodia	PR	Ith et al. ⁵²
		Tanzania	PR	Prytherch et al. ⁵³
	Poor accommodations	Gambia	PR	Cole-Ceesay et al. ⁴⁵
	Lack of safety on the job - Lack of protective equipment - Fear theft, assaults, gender-based violence, assault by families	Nigeria	PR	Adegoke et al. ³⁵
		Gambia	PR	Cole-Ceesay et al. ⁴⁵
		India	PR	Morgan et al. ⁵⁸
		Tanzania	PR	Prytherch et al. ⁵³
	Lack of equipment, essential drugs, supplies	Nigeria	PR	Adegoke et al. ³⁵

Continued

TABLE. Continued

HRH Challenge	Examples	Country	Source Type	Source
		Southeast Asia (4 countries)	PR	Martinez et al. ²⁹
		Ethiopia	PR	Haile-Mariam et al. ⁴¹
		India	PR	Morgan et al. ⁵⁸
	Lack of tech support, delays in repair	Solomon Islands	PR	Tosif et al. ⁵⁵
	Ward setup as barrier to care	India	PR	Neogi et al. ⁵⁶
		Malawi	PR	Bream et al. ⁴²
7. Limited and poor supervision	Limited capacity for routine supervision	Lao PDR	PR	Horiuchi et al. ⁵⁹
	No on-site mentors or technical support for MWs with limited skills	Nigeria	PR	Adegoke et al. ³⁵
	Lack of clinical supervision in NICU	Thailand	PR	Jirapaet et al. ¹²
	Supervision punitive, no feedback given, lack of confidentiality	Tanzania	PR	Prytherch et al. ⁵³
	Problems remain unsolved after supervisory visits	Lao PDR	PR	Horiuchi et al. ⁵⁹
8. Low morale, poor motivation and attitude, dissatisfaction	Poor conditions, salaries, lack of incentives	Gambia	PR	Cole-Ceesay et al. ⁴⁵
	Lack of career ladder and promotion opportunities for HWs	Nigeria	PR	Adegoke et al. ³⁵
		Mongolia	PR	Kildea et al. ³⁶
		Tanzania	PR	Prytherch et al. ⁵³
	Burnout and stress, overwhelmed by workload and patient numbers	India	PR	Amin et al. ⁵¹
		India	PR	Dewez et al. ⁵⁷
	Powerless over work environment, lack of control over transfers	Tanzania	PR	Prytherch et al. ⁵³
		India	PR	Dewez et al. ⁵⁷
	Low morale from high mortality of patients and inability to provide good care due to poor conditions	Gambia	PR	Cole-Ceesay et al. ⁴⁵
		India	PR	Dewez et al. ⁵⁷
		Tanzania	PR	Prytherch et al. ⁵³
9. Weaknesses of policy, regulations, management, leadership, governance, and funding	Lack of policy and regulatory frameworks for neonatal care and clinical protocols	Ghana	PR	Elikplim Pomevor and Adomah-Afari ³⁸
		Cambodia	PR	Ith et al. ⁵²
	Limited scope of practice for MWs, not in line with international scope of practice	Mongolia	PR	Kildea et al. ³⁶
	No nationally accepted competency standards for MWs and nurses	Mongolia	PR	Kildea et al. ³⁶
		Indonesia	Report	National Research Council ³³
	Lack of parity between public and faith-based workers' salaries	Tanzania	PR	Prytherch et al. ⁵³
	Absence of staffing norms by facility level	Ghana	Report	Ministry of Health Ghana ³⁰
	Nonrecognition by management of need for ICU-like ratios in neonatal care units	India	PR	Dewez et al. ⁵⁷

Continued

TABLE. Continued

HRH Challenge	Examples	Country	Source Type	Source
	Lack of support by hospital management team, facility leadership, or authorities	India	PR	Dewez et al. ⁵⁷
		India	PR	Fischer et al. ⁵⁰
	Lack of job descriptions, neonatal guidelines, or orientation in newborn units	Kenya	PR	Nzinga et al. ⁴⁸
		Tanzania	PR	Prytherch et al. ⁵³
		India	PR	Campbell-Yeo et al. ³⁹
	Low productivity by HWs	Tanzania	PR	Nyamtema et al. ⁴⁷
	Unsupportive management, inflexible work schedules	Tanzania	PR	Prytherch et al. ⁵³
	HR deficiencies at management level resulting in inefficient management, particularly related to budgeting	Lao PDR	PR	Sychareun et al. ⁶⁰
	Nonprioritization of newborn health by policy makers in past	Ghana	Report	Ministry of Health Ghana ⁵⁰
	Weak professional associations that do not improve conditions of HWs	Tanzania	PR	Prytherch et al. ⁵³
	Inadequate funding in national budgets for neonatal care (public sector)	Uganda	PR	Mbonye et al. ³⁴
		Tanzania	PR	Nyamtema et al. ⁴⁷
		Gambia	PR	Cole-Ceesay et al. ⁴⁵
10. Structural and contextual barriers	Lack of recognition of newborn specialty care requirements	India	PR	Campbell-Yeo et al. ³⁹
	Lack of community perception of neonatal disease burden	Nepal	PR	Allen and Jeffrey ⁵⁴
	Neglect of female newborns	India	PR	Morgan et al. ⁵⁸
	Child-bearing women lack power to determine care-seeking behavior in emergencies	Nepal	PR	Brunson ⁶¹

Abbreviations: CE, continuing education; CPD, continuing professional development; ENC, essential newborn care; HRH, human resources for health; HW, health worker; ICU, intensive care unit; MW, midwife; NB, newborn; NICU, neonatal intensive care unit; NR, neonatal resuscitation; PR, peer-reviewed.

planning workforce hiring and distribution is rendered more difficult by lack of critical HRH data.³⁵ Similarly, in Mongolia, Kildea et al.³⁶ noted that in addition to an overall shortage of nurses, midwives, and allied health professionals for maternal and newborn care, it is difficult to determine the needed numbers of different HW cadres, linked to lack of metrics for measuring those cadres.

2. Poor HW Preservice Education and Insufficient Newborn Content

Sources support that HW preservice training is often weak, particularly as it pertains to newborn knowledge and skills training across all cadres, and few programs exist for training specialized neonatal nurses in LMICs.^{10,32,37-39} For example, HWs in Kenya receive limited preservice instruction on

neonatal care in their basic training, gaining most practical experience during clinical placements or internships in hospitals.¹⁰ Similarly, newborn care was observed not to be a core competency in general nursing education in India³⁹; in Ghana, newborn content was noted to be insufficient in nursing pre-service education.³⁸

3. Lack of Access for HWs to Evidence-Based Practice Guidelines and Protocols, Continuing Education, and Continuing Professional Development

Unavailability or lack of access to current evidence-based practice guidelines or protocols, continuing education, and continuing professional development for newborn care is a common complaint in

the sources from LMICs.^{36,38–47} Jirapaet et al.⁴⁴ reported on a study conducted in 4 NICUs in Thailand where researchers noted a lack of dissemination of practice protocols to nurses. Similarly, a study in Ethiopia in all hospitals and health centers with deliveries reported a lack of availability of guidelines and protocols on essential newborn care and neonatal resuscitation.⁴¹ Continuing education, defined as an ongoing process of learning, is a cornerstone of continued competence and is closely connected to the quality of care and patient safety.²¹ Continuing professional development refers to the process of tracking and documenting the skills, knowledge, and experience that the HW gains both formally and informally beyond any initial training. Michel-Schuldt et al.⁴⁶ noted that continuing professional development is not mandatory for midwives in Liberia and, more generally, there is a lack of coordination of continuing professional development for health professionals as well as an absence of quality control over the training for midwives. In the Gambia, Cole-Ceesay et al.⁴⁵ found little continuing education for HWs on managing neonatal resuscitation or newborn emergencies; Ghana reported limited in-service training on newborn care, neonatal resuscitation, or care of small and sick newborns.³⁸

4. Insufficient and Inequitable Distribution of HWs and Heavy Workload

Sources gave numerous examples of lack of sufficient and equitable distribution of HWs—specifically lack of skilled birth attendants and skilled neonatal nurses—with resulting heavy workloads for existing staff and unacceptable staffing ratios.^{10,29,33,35,42,44,47–56} A study in 2 newborn units in Nairobi public hospitals reported staffing ratios of 1 nurse to 15 babies.⁴⁸ Aluvaala et al.¹⁰ found that of 22 hospital-based newborn units surveyed in Kenya, 6 had such severe personnel shortages that they were not able to allocate even 1 nurse specifically for each newborn unit. Similarly, a study across 9 NICUs in India reported inequitable staffing ratios that ranged from 1:4 to 1:8 in private facilities, but 1:25 to 1:35 in government facilities.⁵¹ A multi-country study in Southeast Asia reported that Hanoi neonatal units routinely cared for 50% more patients than allocated beds and staffing and that they were thus obliged to put 2 patients to a bed.²⁹ Neogi et al.⁵⁶ evaluated 8 special newborn care units in rural district hospitals throughout India and found that the nurse-to-newborn ratio appeared to play a critical role in improving newborn survival in these units: almost 15% of the variation in the neonatal mortality rate across the units could be explained by the nurse-to-

newborn ratio. In addition to heavy workload for existing staff in rural facilities, Tanzania reported an imbalance between the proportion of skilled health staff and lower-level cadres in rural maternal-newborn workers, with 43% of the workforce made up of lower-level cadres (e.g., maternal and child health aides, assistant clinical officers, and attendants).⁵³

5. Poor Retention, Absenteeism, and Rotation of Experienced Staff

Poor retention of maternal and newborn workers was described in many sources.^{11,38,45,47,49,53,57} Absenteeism was reported¹¹ due to HWs from the public sector also working in private practice in India. A study carried out in 2 rural health centers in Tanzania reported that HWs often have parallel income-generating activities, such as agriculture, commerce, or other health work, to complement their salaries, which can lead to distraction at work and absenteeism.⁵³ Many articles included in this review also cited rotation within the facility or transfer to another facility as a major concern. In a study of 6 health facilities in Ghana, many HWs interviewed were concerned about yearly rotation of neonatal staff, as this hampered quality of care given the loss of experienced staff and the time required to get new staff up to speed.³⁸ Dewez et al.⁵⁷ described that when nurses trained in India in neonatal care and were rotated to other wards they lost confidence and neonatal skills.

6. Poor Work Environment

Poor salaries, inconsistent payment, and substandard accommodations are often reported.^{29,31,35,41,42,45,52,53,55,58} A qualitative study carried out with HWs in Cambodia⁵² reported low salaries for skilled birth attendants, such that they only provide postnatal care to the mother and newborn if additional payments are made by family members. As noted in HRH challenge 5, HWs often create additional income-generating activities to supplement their incomes.⁵³ Lack of equipment, supplies, medications, electricity, and water are often reported in the literature.^{29,35,41,58} A lack of supplies and protective equipment, such as gloves and masks, can affect HW safety. It can be exacerbated during outbreaks such as the current COVID-19 pandemic and contributes to poor quality of care.¹⁹ Additionally, lack of HW security due to blame and assault appears in the literature; an article from India noted that providers refer complicated cases out so as not to be assaulted by family members in the case of poor maternal and neonatal outcomes.⁵⁸

7. Limited and Poor Supervision

Poor supervision is cited as a problem leading to poor HW retention, low morale and motivation, and poor-quality care provision.^{35,44,53,59} Horiuchi et al.⁵⁹ noted that although external supervisory visits are a common approach to promote behavioral change among newborn HWs, reinforce skills, and maintain quality of care, these visits are often not feasible in resource-limited settings, such as Lao PDR, due to both high cost and human resource demands. The authors note that there is minimal capacity to implement routine supervision; however, when supervision visits occur, problems identified often remain unsolved.⁵⁹ Similarly, maternal and newborn HWs interviewed in Tanzania reported supervision and performance appraisal to be punitive and to lack confidentiality.⁵³

8. Low Morale, Motivation, and Attitude, and Job Dissatisfaction

Morale and motivation were frequently referenced in the sources.^{35,36,45,51,53,57} Low motivation and job dissatisfaction were linked to a variety of factors, including low salaries, poor working conditions, lack of career and promotion opportunities, lack of control over being transferred, insufficient training and technical guidance, burnout and stress linked to heavy workload, and demoralizing supervision.^{36,45,51,53} Several articles reported high stress and low morale due to high maternal and newborn mortality^{45,51} and HW guilt and feelings of powerlessness linked to not being able to provide better care to patients.⁵⁷ Stress and burnout were reported among NICU workers in India and Thailand.^{44,51} Low morale and poor attitudes were also noted to affect care provision; for example, provider passivity in attending life-threatening emergencies in Tanzania was noted to contribute to poor outcomes.⁴⁷

9. Weaknesses of Policy, Regulations, Management, Leadership, Governance, and Funding

Sources documenting weaknesses in the policy and management arena were varied in nature.^{30,33,34,36,38,39,47,48,50,52,53,57,60} A study conducted in Tanzania concluded that factors discouraging maternal newborn providers could be divided into those that pertain to conditions of employment (e.g., related to policy), and those that pertain to the organization of work processes (e.g., related to facility management).⁵³ Leadership, governance, and funding references pointed to a lack of prioritization of newborn care and lack of funding for it in national budgets.³⁴

10. Structural and Contextual Barriers

A variety of potential structural and contextual barriers to the provision of high-quality newborn care augment the aforementioned HRH challenges.^{39,54,58,61} A study in rural Nepal reported that a significant barrier to improving neonatal care was a lack of perception of the neonatal disease burden in the community from which health providers originate and that without the perception of a problem, providers have little incentive to improve job performance.⁵⁴ A report from Bihar, India observed a preference for male children and neglect of female newborns, to the extent that families sometimes threaten HWs who attempt to resuscitate female newborns.⁵⁸ Gender biases affect newborn care in a variety of additional ways—from power dynamics for majority female midwifery and nursing professions to gender-based power dynamics related to birthing decisions such as emergency care-seeking behavior—as reported in Nepal.⁶¹

DISCUSSION

To our knowledge, this review is the first to comprehensively look at HRH challenges to providing quality newborn care in LMICs. In conducting this scoping review, we sought to better understand HRH-related challenges to quality facility-based neonatal care provision by nurses and midwives in LMICs by identifying tangible thematic areas to address at national, regional, and international levels. We aimed to synthesize evidence identified in country-focused sources and to provide needed insight to inform strategies for strengthening HRH for newborn care globally and nationally, reinforcing country capacity and capability to meet new WHO standards for the care of small and sick newborns, ENAP 2025 targets, and SDGs. The goals of addressing this pressing set of challenges are to improve quality care and to reduce mortality, stillbirths, and short-and-long term morbidity of newborns.

Weak HRH data and monitoring make workforce decision making and planning particularly difficult.^{5,18} Essential data on availability of HWs, especially nurses and midwives, are often missing.³⁶ Data showing the necessary facility mix of staff skills are lacking, which adds to planning challenges.⁷ To improve quality care for newborns and to facilitate advocacy, data are needed on who, where, and how HWs care for newborns.⁶² Research on HRH metrics and monitoring frameworks to guide national planning is a global priority.⁵

The goals of addressing HRH challenges are to improve quality care and to reduce mortality, stillbirths, and short-and-long term morbidity of newborns.

Evidence from multiple countries shows that the preservice education of physicians, nurses, and midwives is often low; additionally, the rapid mushrooming of nonaccredited private sector schools raises questions about their quality.⁶³ Neonatal care content is often limited in preservice curricula of relevant cadres.⁶⁴ Bottleneck analysis for inpatient care of small and sick newborns revealed a dearth of skills-based training in top high-burden neonatal mortality countries, and indicated that related education is inconsistent and poorly structured.^{12,17} Part of the difficulty stems from lack of trained faculty and qualified clinical preceptors for teaching neonatal care, resulting in limited opportunities to acquire newborn care skills during the preservice period.^{37,64} The means of fast-tracking faculty training in neonatal content and assuring faculty retention is not addressed in the literature and is an area where research is needed.

Access to relevant, up-to-date guidelines, protocols, and continuing education and continuing professional development opportunities for nurses and midwives is often difficult or impossible, especially in rural areas.^{21,65,66} For care specific to small and sick babies, research in 12 countries with high neonatal mortality rates reported that there was inadequate or no competency-based training or continuing education, including in-service and refresher training, particularly at lower-level facilities.¹² Guidelines change regularly and thus dissemination and methods of updating HWs on new knowledge are essential; however, simple dissemination of written guidelines is ineffective.⁶⁷ Most obstetric and neonatal emergencies take place in peripheral health facilities, which are difficult to reach with conventional training programs and require innovative learning strategies.⁶⁸ Opportunities to address these challenges are now available through evidence-based and competency-based learning packages that incorporate simulation training and mentoring, digital e- and m-learning initiatives, and other innovative learning tools that utilize technology such as virtual reality training tools, clinical decision, and point-of-care learning and support tools.^{66,69,70} However, additional research is needed on e- and m-learning, particularly in LMICs, that measures newborn outcomes as a primary outcome.⁷⁰

Shortages of HWs (theme 4) is one of the main factors behind persistent high mortality rates for women and newborns in many countries.^{5,71} Fewer than 1 in 6 countries with the highest burden of maternal and neonatal mortality reaches the minimum benchmark necessary to provide a

basic package of care, identified as 23 doctors, midwives, and nurses per 10,000 population.⁹ An insufficient number of HWs, combined with poor working conditions and few incentives for staff to live and work in remote areas or among disadvantaged populations, leads to unequal distribution. Imbalances exist not only in the number and geographical distribution of available HWs, but also in the employment sector (public/private)⁷² and in the range of HW skills. Most countries still have too few specialists relative to the health needs of their population; shortages are particularly evident for specialist doctors (e.g., neonatologists, surgeons, obstetricians, and anesthetists) and neonatal nurses, with few available programs for training these cadres in low-income settings.^{64,71} In contrast, in high-income countries neonatal nurses are the backbone of newborn facility-based care to the newborns and their families, including through extended roles such as advanced neonatal nurse practitioners.^{12,73}

HW shortages and unequal distribution increase the workload of existing staff, leading to high staff-to-patient ratios and increased stress, impeding the ability to provide high quality care, and directly influencing patient outcomes.^{31,40} Research on NICU nurse staffing and workload in high-income countries showed that understaffing relative to national guidelines was associated with an increased risk for nosocomial infection in very low-birth-weight babies.^{74,75} In contrast, 1:1 NICU nursing staffing reduces in-hospital mortality.^{76,77} There are no globally accepted recommendations for staffing ratios at the different levels of newborn care provision, but we can contrast ratios in LMICs with recommended ratios in the United Kingdom of 1 specialized neonatal nurse to 1 patient for neonatal intensive care and 1 registered nurse or midwife to 4 patients for special care.⁷⁸

Poor retention, absenteeism, and rotation of experienced nurses out of neonatal units can both create the dynamics above and contribute to their worsening (theme 5). The majority of countries (81%) show a workforce strongly favoring urban areas, which can be related to many factors, such as greater possibilities of private practice and unattractiveness of rural and remote areas due to poor working conditions, inadequate housing, limited opportunities for professional development, and limited educational opportunities for children.^{72,79}

Additionally, even the best trained and motivated HW needs a supportive, enabling environment to work effectively, including well-maintained infrastructure and a reliable supply of medicines,

supplies, and technologies (theme 6). Poor salaries and work environments contribute to other challenges, such as poor retention, especially in remote areas, and also to low morale and attitude.¹⁷ A systematic mapping of barriers to the provision of quality midwifery care reported routine absence of safe working conditions, such as availability of sharps disposal, water for handwashing, and basic protective supplies such as gloves.⁸⁰ Similarly, a survey conducted in 364 health facilities throughout Africa, Asia, and Latin America found that essential supplies and equipment were widely unavailable and concluded that staff are often unable to perform key procedures, and that women, stillborn, and newborns die unnecessarily as a result.⁸¹

Supportive supervision (theme 7) is another tool that is used in most settings to support HWs and improve job performance. If done correctly, supervision can be a mechanism for providing professional development, improving job satisfaction, and increasing motivation.⁶⁷ However, the reality is that supervisory visits often fall short of their goal. Supervisors may lack skills, tools, and transport to provide quality supervision.^{17,67} Planned studies to evaluate self-managed continuous monitoring by peer reviews and feedback sessions as a more sustainable way to improve quality of care may prove an alternative to current supervision approaches.⁵⁹

Quality care provision is dependent on HW motivation—a critical driver for HWs' willingness to maintain their professional competence, apply themselves to their jobs, and continue in the workforce.^{67,82–85} Low levels of HW morale and high levels of stress and burnout have been identified in the literature as an often-neglected problem (theme 8) and have been widely documented among NICU nurses, nurses, and midwives.^{51,80,86} Researchers suggest that motivation can both influence performance directly and mediate the effect of other factors; thus, motivation—and interventions that improve job satisfaction (e.g., salaries, work conditions)—are likely to be important determinants of job performance and retention.⁶⁷

Challenges related to weak or absent policies, regulations, management, leadership, governance, and funding (theme 9) are critical to quality newborn care provision.^{30,33,34,36,38,39,47,48,50,52,53,57,60} Examples include lack of alignment between national policy defining the legal scope of practice for various cadres and regulation of the cadres, job descriptions, preservice education, or actual practice.⁷² There is also a lack of regulation of private-sector educational institutions and health providers,⁸⁷ and lack of needed policies, such as well-defined staff-to-

patient ratios, referral systems, discharge criteria, and standardized levels of care.¹² All health programs—whether funded by governments, development partners, civil society, or the private sector—must contribute to government-driven national priorities; achieving this goal requires improved governance and better coordination between national and subnational systems.⁸⁷ National-level advocates are needed for advancement of high-quality care for newborns, including policymakers, key individuals within professional bodies, academics, and national institutions. In terms of health financing, lack of sustained, coordinated newborn funding remains a challenge,³⁴ and mobilization of sufficient financing with better cash flow is needed.⁸⁷

Finally, the literature describes structural and contextual barriers that exacerbate other HRH-related challenges, particularly the low social status of caring professions and gender inequality in a predominantly female workforce. For example, a mapping of barriers to the provision of quality midwifery care identified gender inequality and lack of female empowerment as the most significant barriers leading to stress and burnout, which in turn lead to disempowerment, diminishing self-esteem, and ultimately adoption of negative behaviors.^{80,88} Disempowerment has also been widely reported in nursing, a profession similarly dominated by women, along with high stress and burnout as noted above.^{21,89}

Campbell⁹⁰ wrote that the only route to achieve quality of care is “through the health worker,” and that effective universal coverage—with HRH ensuring both availability and quality coverage of needed health services—is the grand challenge for all countries. This finding was echoed by the Lancet Global Health Commission on High Quality Health Systems, which proposes a “reboot” of health systems given the extent of quality deficits.²⁰ Competent human resources and necessary physical resources are needed at all times to avoid preventable mortality of women, stillbirths, and newborns.⁸¹ These principles, elevating the importance of the global health workforce, were articulated in the 2006 World Health Report and with the creation of the Global Health Workforce Alliance. Global strategies to address HRH challenges were reinforced by WHO in the Global Strategy on Human Resources for Health: Workforce 2030.⁶⁹ Given new 2025 newborn health targets and standards for the care of small and sick, newborn-specific HRH strategies, informed by the challenges identified in this article, have recently been published by WHO to address the accessibility and

quality of care of this most-vulnerable population.⁹ Challenges to the provision of high-quality care to mothers and newborns in countries are complex, interrelated, and intertwined with broader social and structural challenges and will require ongoing attention and prioritization at all levels of the health system if we are to succeed in reaching the SDGs by 2030.

Limitations

Narrowing and focusing the research question was a challenge and the broad definition of newborn care resulted in a large amount of information. While an iterative, inductive thematic analysis process was used to identify HRH-related challenges to delivering quality newborn care, some overlaps existed in conceptual areas, which may have masked some of the importance, nuance, or interconnectedness of the categories of challenges. Additionally, our analysis is not representative of all LMICs, given that many countries do not have data on their respective HRH-related challenges, which may be unique and context specific.

CONCLUSIONS

With only 10 years to reach the SDGs, it is critical to ensure access to quality care for all newborns in need of facility-based care. However, lack of a sufficient number of HWs with neonatal care competencies is a critical gap. This review scoped country-focused articles to explore HRH-related challenges to quality facility-based neonatal care provision by nurses and midwives in LMICs. The review identified and mapped evidence into 10 HRH-related challenges and interpreted the data. The mapping provides needed insight informing new WHO strategies and supporting efforts to address the challenges identified and strengthen human resources for neonatal care, with the ultimate goal of improving newborn care and outcomes.

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REFERENCES

1. United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). *Levels & Trends in Child Mortality: Report 2019, Estimates Developed by the United Nations Inter-Agency Group for Child Mortality Estimation*. UN IGME; 2019. <https://www.unicef.org/media/60561/file/UN-IGME-child-mortality-report-2019.pdf>
2. Sankar MJ, Natarajan CK, Das RR, Agarwal R, Chandrasekaran A, Paul VK. When do newborns die? A systematic review of timing of overall and cause-specific neonatal deaths in developing countries. *J Perinatol*. 2016;36(S1)(Suppl 1):S1–S11. [CrossRef](#). [Medline](#)
3. Lawn JE, Blencowe H, Oza S, et al.; Lancet Every Newborn Study Group. Every Newborn: progress, priorities, and potential beyond survival. *Lancet*. 2014;384(9938):189–205. [CrossRef](#). [Medline](#)
4. United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). *A Neglected Tragedy: The Global Burden of Stillbirths*. UN IGME; 2020. Accessed December 22, 2020. <https://www.unicef.org/reports/neglected-tragedy-global-burden-of-stillbirths-2020>
5. World Health Organization (WHO). *Survive and Thrive: Transforming Care for Every Small and Sick Newborn*. WHO; 2019. Accessed December 22, 2020. <https://www.unicef.org/media/58076/file>
6. Lawn JE, Blencowe H, Darmstadt GL, Bhutta ZA. Beyond newborn survival: the world you are born into determines your risk of disability-free survival. *Pediatr Res*. 2013;74(S1)(Suppl 1):1–3. [CrossRef](#). [Medline](#)
7. Bhutta ZA, Salam RA, Lassi ZS, Austin A, Langer A. Approaches to improve Quality of Care (QoC) for women and newborns: conclusions, evidence gaps and research priorities. *Reprod Health*. 2014;11(S2)(Suppl 2):S5. [CrossRef](#). [Medline](#)
8. United Nations Inter-agency Group for Child Mortality Estimation (UN IGME). *Levels and Trends in Child Mortality: Report 2018*. UN IGME; 2018. Accessed December 22, 2020. <https://childmortality.org/wp-content/uploads/2018/12/UN-IGME-Child-Mortality-Report-2018.pdf>
9. World Health Organization (WHO). *Roadmap on Human Resource Strategies to Improve Newborn Care in Health Facilities in Low and Middle-Income Countries*. WHO; 2020. Accessed December 22, 2020. <https://apps.who.int/iris/bitstream/handle/10665/336677/9789240015227-eng.pdf>
10. Aluvaala J, Nyamai R, Were F, et al.; SIRACLE/Ministry of Health Hospital Survey Group. Assessment of neonatal care in clinical training facilities in Kenya. *Arch Dis Child*. 2015;100(1):42–47. [CrossRef](#). [Medline](#)
11. Neogi SB, Khanna R, Chauhan M, et al. Inpatient care of small and sick newborns in healthcare facilities. *J Perinatol*. 2016;36(S3)(s3): S18–S23. [CrossRef](#). [Medline](#)
12. Moxon SG, Lawn JE, Dickson KE, et al. Inpatient care of small and sick newborns: a multi-country analysis of health system bottlenecks and potential solutions. *BMC Pregnancy Childbirth*. 2015;15(S2)(Suppl 2):S7. [CrossRef](#). [Medline](#)
13. Every Woman Every Child (EWEC). *The Global Strategy for Women's, Children's, and Adolescents' Health (2016–2030): Survive, Thrive, Transform*. EWEC; 2015. Accessed December 22, 2020. <http://www.everywomaneverychild.org/global-strategy/>
14. World Health Organization (WHO). *Global Strategic Directions for Strengthening Nursing and Midwifery 2016–2020*. WHO; 2016.

- https://www.who.int/hrh/nursing_midwifery/global-strategy-midwifery-2016-2020/en/
15. Bell SA, Rominski S, Bam V, Donkor E, Lori J. Analysis of nursing education in Ghana: priorities for scaling-up the nursing workforce. *Nurs Health Sci.* 2013;15(2):244–249. [CrossRef](#). [Medline](#)
 16. World Bank. World Development Indicators. Data Bank. Accessed December 22, 2020. <https://databank.worldbank.org/reports.aspx?source=2&series=SH.MED.NUMW.P3&country=>
 17. Sharma G, Mathai M, Dickson KE, et al. Quality care during labour and birth: a multi-country analysis of health system bottlenecks and potential solutions. *BMC Pregnancy Childbirth.* 2015;15(S2)(Suppl 2):S2. [CrossRef](#). [Medline](#)
 18. World Health Organization (WHO). *2018 Progress Report: Reaching Every Newborn National 2020 Milestones.* WHO; 2018. Accessed December 22, 2020. <https://www.healthynetwork.org/hnn-content/uploads/Final-Country-Progress-Report-v9-low-res.pdf>
 19. Robertson T, Carter ED, Chou VB, et al. Early estimates of the indirect effects of the COVID-19 pandemic on maternal and child mortality in low-income and middle-income countries: a modelling study. *Lancet Glob Health.* 2020;8(7):e901–e908. [CrossRef](#). [Medline](#)
 20. Kruk ME, Pate M. The Lancet Global Health Commission on High Quality Health Systems 1 year on: progress on a global imperative. *Lancet Glob Health.* 2020;8(1):e30–e32. [CrossRef](#). [Medline](#)
 21. World Health Organization (WHO). *The World Health Report 2006: Working Together for Health.* WHO; 2006. Accessed December 22, 2020. <https://www.who.int/whr/2006/en/>
 22. World Health Organization (WHO), UNICEF. *Ending Preventable Newborn Deaths and Stillbirths by 2030.* WHO, UNICEF; 2020. Accessed December 22, 2020. <https://www.healthynetwork.org/hnn-content/uploads/Final-draft-Every-Newborn-Coverage-target-Milestones-to-2025.pdf>
 23. World Health Organization (WHO). *Standards for Improving the Quality of Care for Small and Sick Newborns in Health Facilities.* WHO; 2020. Accessed December 22, 2020. <https://www.who.int/publications/i/item/9789240010765>
 24. Tunçalp Ö, Were WM, MacLennan C, et al. Quality of care for pregnant women and newborns—the WHO vision. *BJOG.* 2015;122(8):1045–1049. [CrossRef](#). [Medline](#)
 25. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci.* 2010;5(1):69. [CrossRef](#). [Medline](#)
 26. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol.* 2005;8(1):19–32. [CrossRef](#)
 27. The World Bank. World Bank country and lending groups. Accessed December 23, 2020. <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>
 28. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol.* 2006;3(2):77–101. [CrossRef](#)
 29. Martinez AM, Khu DTK, Boo NY, Neou L, Saysanasongkham B, Partridge JC. Barriers to neonatal care in developing countries: parents' and providers' perceptions. *J Paediatr Child Health.* 2012;48(9):852–858. [CrossRef](#). [Medline](#)
 30. Ministry of Health Ghana. *Ghana National Newborn Health Strategy and Action Plan 2014–2018.* Accessed December 23, 2020. https://www.healthynetwork.org/hnn-content/uploads/FINAL_Ghana-Newborn_Strategy_2014July10.pdf
 31. Neogi SB, Malhotra S, Zodpey S, Mohan P. Challenges in scaling up of special care newborn units—lessons from India. *Indian Pediatr.* 2011;48(12):931–935. [CrossRef](#). [Medline](#)
 32. Getachew A, Ricca J, Cantor D, et al. *Quality of Care for Prevention and Management of Common Maternal and Newborn Complications: A Study of Ethiopia's Hospitals.* Jhpiego; 2011. Accessed December 23, 2020. https://www.healthynetwork.org/hnn-content/uploads/Ethiopia_Quality-of-Care-Assement-report_MCHIP_final-1.pdf
 33. National Research Council. *Reducing Maternal and Neonatal Mortality in Indonesia: Saving Lives, Saving the Future.* National Academies Press; 2013. [CrossRef](#)
 34. Mbonye AK, Sentongo M, Mukasa GK, et al.; Uganda Decade of Change and Future Implications Analysis Group. Newborn survival in Uganda: a decade of change and future implications. *Health Policy Plan.* 2012;27(suppl_3):iii104–iii117. [CrossRef](#). [Medline](#)
 35. Adegoke AA, Atiyaye FB, Abubakar AS, Auta A, Aboda A. Job satisfaction and retention of midwives in rural Nigeria. *Midwifery.* 2015;31(10):946–956. [CrossRef](#). [Medline](#)
 36. Kildea S, Larsson M, Govind S. A review of midwifery in Mongolia utilising the 'Strengthening Midwifery Toolkit'. *Women Birth.* 2012;25(4):166–173. [CrossRef](#). [Medline](#)
 37. Bogren M, Ndela B, Toko C, Berg M. Midwifery education, regulation and association in the Democratic Republic of Congo (DRC)—current state and challenges. *Glob Health Action.* 2020;13(1):1717409. [CrossRef](#). [Medline](#)
 38. Eliklim Pomevor K, Adomah-Afari A. Health providers' perception of quality of care for neonates in health facilities in a municipality in Southern Ghana. *Int J Health Care Qual Assur.* 2016;29(8):907–920. [CrossRef](#). [Medline](#)
 39. Campbell-Yeo M, Deorari A, McMillan DD, et al. Educational barriers of nurses caring for sick and at-risk infants in India. *Int Nurs Rev.* 2014;61(3):398–405. [CrossRef](#). [Medline](#)
 40. Malhotra S, Zodpey SP, Vidyasagar AL, et al. Assessment of essential newborn care services in secondary-level facilities from two districts of India. *J Health Popul Nutr.* 2014;32(1):130–141. [CrossRef](#). [Medline](#)
 41. Haile-Mariam A, Tesfaye N, Otterness C, Bailey PE. Assessing the health system's capacity to conduct neonatal resuscitation in Ethiopia. *Ethiop Med J.* 2012;50(1):43–55. [Medline](#)
 42. Bream KDW, Gennaro S, Kafalafula U, Mbweza E, Hehir D. Barriers to and facilitators for newborn resuscitation in Malawi, Africa. *J Midwifery Womens Health.* 2005;50(4):329–334. [CrossRef](#). [Medline](#)
 43. Kozuki N, Oseni L, Mtimuni A, et al. Health facility service availability and readiness for intrapartum and immediate postpartum care in Malawi: a cross-sectional survey. *PLoS One.* 2017;12(3):e0172492. [CrossRef](#). [Medline](#)
 44. Jirapaet V, Jirapaet K, Sopajaree C. The nurses' experience of barriers to safe practice in the neonatal intensive care unit in Thailand. *J Obstet Gynecol Neonatal Nurs.* 2006;35(6):746–754. [CrossRef](#). [Medline](#)
 45. Cole-Ceasay R, Cherian M, Sonko A, et al. Strengthening the emergency healthcare system for mothers and children in The Gambia. *Reprod Health.* 2010;7(1):21. [CrossRef](#). [Medline](#)
 46. Michel-Schuldt M, Billy Dayon M, Toft Klar R, et al. Continuous professional development of Liberia's midwifery workforce—a coordinated multi-stakeholder approach. *Midwifery.* 2018;62:77–80. [CrossRef](#). [Medline](#)
 47. Nyamtema AS, Urassa DP, Massawe S, Massawe A, Lindmark G, Van Roosmalen J. Staffing needs for quality perinatal care in Tanzania. *Afr J Reprod Health.* 2008;12(3):113–124. [Medline](#)
 48. Nzinga J, McKnight J, Jekposgei J, English M. Exploring the space for task shifting to support nursing on neonatal wards in Kenyan public hospitals. *Hum Resour Health.* 2019;17(1):18. [CrossRef](#). [Medline](#)
 49. Ntigurirwa P, Mellor K, Langer D, et al. A health partnership to reduce neonatal mortality in four hospitals in Rwanda. *Global Health.* 2017;13(1):28. [CrossRef](#). [Medline](#)
 50. Fischer EA, Jayana K, Cunningham T, et al. Nurse mentors to advance quality improvement in primary health centers: lessons from a

- pilot program in Northern Karnataka, India. *Glob Health Sci Pract.* 2015;3(4):660–675. [CrossRef](#). [Medline](#)
51. Amin AA, Vankar JR, Nimbalkar SM, Phatak AG. Perceived stress and professional quality of life in neonatal intensive care unit nurses in Gujarat, India. *Indian J Pediatr.* 2015;82(11):1001–1005. [CrossRef](#). [Medline](#)
 52. Ith P, Dawson A, Homer CSE, Klinken Whelan A. Practices of skilled birth attendants during labour, birth and the immediate postpartum period in Cambodia. *Midwifery.* 2013;29(4):300–307. [CrossRef](#). [Medline](#)
 53. Prytherch H, Kakoko DCV, Leshabari MT, Sauerborn R, Marx M. Maternal and newborn healthcare providers in rural Tanzania: in-depth interviews exploring influences on motivation, performance and job satisfaction. *Rural Remote Health.* 2012;12(3):2072. [Medline](#)
 54. Allen CW, Jeffery H. Implementation and evaluation of a neonatal educational program in rural Nepal. *J Trop Pediatr.* 2006;52(3):218–222. [CrossRef](#). [Medline](#)
 55. Tosif S, Nasi T, Gray A, Sadr-Azodi N, Ogaoga D, Duke T. Assessment of the quality of neonatal care in the Solomon Islands. *J Paediatr Child Health.* 2018;54(2):165–171. [CrossRef](#). [Medline](#)
 56. Neogi SB, Malhotra S, Zodepy S, Mohan P. Assessment of special care newborn units in India. *J Health Popul Nutr.* 2011;29(5):500–509. [CrossRef](#). [Medline](#)
 57. Dewez JE, Chellani H, Nangia S, et al. Healthcare workers' views on the use of continuous positive airway pressure (CPAP) in neonates: a qualitative study in Andhra Pradesh, India. *BMC Pediatr.* 2018;18(1):347. [CrossRef](#). [Medline](#)
 58. Morgan MC, Dyer J, Abril A, et al. Barriers and facilitators to the provision of optimal obstetric and neonatal emergency care and to the implementation of simulation-enhanced mentorship in primary care facilities in Bihar, India: a qualitative study. *BMC Pregnancy Childbirth.* 2018;18(1):420. [CrossRef](#). [Medline](#)
 59. Horiuchi S, Rattana S, Saisanasongkham B, et al. Study protocol of a cluster randomized controlled trial to evaluate effectiveness of a system for maintaining high-quality early essential newborn care in Lao PDR. *BMC Health Serv Res.* 2018;18(1):489. [CrossRef](#). [Medline](#)
 60. Sychareun V, Phommachanh S, Soysouvanh S, et al. Provider perspectives on constraints in providing maternal, neonatal and child health services in the Lao People's democratic republic: a qualitative study. *BMC Pregnancy Childbirth.* 2013;13(1):243. [CrossRef](#). [Medline](#)
 61. Brunson J. Confronting maternal mortality, controlling birth in Nepal: the gendered politics of receiving biomedical care at birth. *Soc Sci Med.* 2010;71(10):1719–1727. [CrossRef](#). [Medline](#)
 62. Moxon SG, Ruysen H, Kerber KJ, et al. Count every newborn; a measurement improvement roadmap for coverage data. *BMC Pregnancy Childbirth.* 2015;15(S2)(Suppl 2):S8. [CrossRef](#). [Medline](#)
 63. World Health Organization (WHO). *Transforming and Scaling Up Health Professional Education and Training. Policy Brief on Regulation of Health Professions Education.* WHO; 2013. Accessed December 23, 2020. https://apps.who.int/iris/bitstream/handle/10665/93635/9789241506502_eng.pdf?sequence=1
 64. Kalyan G, Vatsa M. Neonatal nursing: an unmet challenge in India. *Indian J Pediatr.* 2014;81(11):1205–1211. [CrossRef](#). [Medline](#)
 65. Hudspeth J, Curry CL, Sacks Z, Surena C. Continuing professional development in low-resource settings: Haiti as example. *Ann Glob Health.* 2015;81(2):255–259. [CrossRef](#). [Medline](#)
 66. Bolan NE, Shreshley L, Ngoy B, et al. mLearning in the Democratic Republic of the Congo: a mixed-methods feasibility and pilot cluster randomized trial using the safe delivery app. *Glob Health Sci Pract.* 2018;6(4):693–710. [CrossRef](#). [Medline](#)
 67. Rowe AK, de Savigny D, Lanata CF, Victora CG. How can we achieve and maintain high-quality performance of health workers in low-resource settings? *Lancet.* 2005;366(9490):1026–1035. [CrossRef](#). [Medline](#)
 68. Nilsson C, Sørensen BL, Sørensen JL. Comparing hands-on and video training for postpartum hemorrhage management. *Acta Obstet Gynecol Scand.* 2014;93(5):517–520. [CrossRef](#). [Medline](#)
 69. World Health Organization (WHO). *Global Strategy on Human Resources for Health: Workforce 2030.* WHO; 2016. Accessed December 23, 2020. <https://www.who.int/hrh/resources/globstrathrh-2030/en/>
 70. Bolan NE, Newman SD, Nemeth LS. Technology-based newborn health learning initiatives for facility-based nurses and midwives in low-and middle-income countries: a scoping review. *Int J Childbirth.* 2018;8(4):252–268. [CrossRef](#)
 71. World Health Organization (WHO). *Every Newborn: An Action Plan to End Preventable Deaths.* WHO; 2014. Accessed December 23, 2020. https://www.who.int/maternal_child_adolescent/documents/every-newborn-action-plan/en/
 72. Gupta N, Maliqi B, França A, et al. Human resources for maternal, newborn and child health: from measurement and planning to performance for improved health outcomes. *Hum Resour Health.* 2011;9(1):16. [CrossRef](#). [Medline](#)
 73. Smith SL, Hall MA. Advanced neonatal nurse practitioners in the workforce: a review of the evidence to date. *Arch Dis Child Fetal Neonatal Ed.* 2011;96(2):F151–F155. [CrossRef](#). [Medline](#)
 74. Rogowski JA, Staiger D, Patrick T, Horbar J, Kenny M, Lake ET. Nurse staffing and NICU infection rates. *JAMA Pediatr.* 2013;167(5):444–450. [CrossRef](#). [Medline](#)
 75. Küng E, Waldhör T, Rittenschöber-Böhm J, Berger A, Wisgrill L. Increased nurse workload is associated with bloodstream infections in very low birth weight infants. *Sci Rep.* 2019;9(1):6331. [CrossRef](#). [Medline](#)
 76. Watson SI, Arulampalam W, Petrou S, et al.; Neonatal Data Analysis Unit (NDAU) and the Neonatal Economic, Staffing, and Clinical Outcomes Project (NESCO) Group. The effects of a one-to-one nurse-to-patient ratio on the mortality rate in neonatal intensive care: a retrospective, longitudinal, population-based study. *Arch Dis Child Fetal Neonatal Ed.* 2016;101(3):F195–F200. [CrossRef](#). [Medline](#)
 77. Hamilton KE, Redshaw ME, Tarnow-Mordi W. Nurse staffing in relation to risk-adjusted mortality in neonatal care. *Arch Dis Child Fetal Neonatal Ed.* 2007;92(2):F99–F103. [CrossRef](#). [Medline](#)
 78. BLISS. The chance of a lifetime? BLISS Baby Report 2010. *BLISS.* 2010;(8):8–10. Accessed January 21, 2021. https://issuu.com/bliss-charity/docs/baby_report_2010_web
 79. Buchan J, Shaffer FA, Catton H. *Policy Brief: Nurse Retention.* International Centre on Nursing Migration; 2018. Accessed December 23, 2020. https://www.icn.ch/sites/default/files/inline-files/2018_ICNM%20Nurse%20retention.pdf
 80. Filby A, McConville F, Portela A. What prevents quality midwifery care? A systematic mapping of barriers in low and middle income countries from the provider perspective. *PLoS One.* 2016;11(5):e0153391. [CrossRef](#). [Medline](#)
 81. Manasyan A, Saleem S, Koso-Thomas M, et al.; EmONC Trial Group. Assessment of obstetric and neonatal health services in developing country health facilities. *Am J Perinatol.* 2013;30(09):787–794. [CrossRef](#). [Medline](#)
 82. Franco LM, Bennett S, Kanfer R. Health sector reform and public sector health worker motivation: a conceptual framework. *Soc Sci Med.* 2002;54(8):1255–1266. [CrossRef](#). [Medline](#)
 83. Dieleman M, Toonen J, Touré H, Martineau T. The match between motivation and performance management of health sector workers in Mali. *Hum Resour Health.* 2006;4(1):2. [CrossRef](#). [Medline](#)
 84. Thi Hoai Thu N, Wilson A, McDonald F. Motivation or demotivation of health workers providing maternal health services in rural areas in

- Vietnam: findings from a mixed-methods study. *Hum Resour Health*. 2015;13(1):91. [CrossRef](#). [Medline](#)
85. Fonn S, Ray S, Blaauw D. Innovation to improve health care provision and health systems in sub-Saharan Africa—promoting agency in mid-level workers and district managers. *Glob Public Health*. 2011;6(6):657–668. [CrossRef](#). [Medline](#)
86. Inoue KC, Gomes da Silva Versa GL, Misue Matsuda L. Stress level among intensive care nurses in the municipality of Paraná (Brazil). *Invest Educ Enferm*. 2014;32(1):69–77. [CrossRef](#). [Medline](#)
87. Campbell J, Cometto G, Rasanathan K, et al. Improving the resilience and workforce of health systems for women's, children's, and adolescents' health. *BMJ*. 2015;351:h4148. [CrossRef](#). [Medline](#)
88. World Health Organization (WHO). *Midwives' Voices Midwives' Realities*. WHO; 2016. Accessed December 23, 2020. https://www.who.int/maternal_child_adolescent/documents/midwives-voices-realities/en/
89. Gallagher A. Moral distress and moral courage in everyday nursing practice. *Online J Issues Nurs*. 2011;16(2):8. <http://ojin.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Vol-16-2011/No2-May-2011/Articles-Previous-Topics/Moral-Distress-and-Courage-in-Everyday-Practice-.html>. [Medline](#)
90. Campbell J. The route to effective coverage is through the health worker: there are no shortcuts. *Lancet*. 2013;381(9868):725. [CrossRef](#). [Medline](#)

En español

Desafíos de los recursos humanos en el área de salud para garantizar atención neonatal de calidad por parte en países con ingresos bajos y medianos: una revisión exploratoria

Mensajes clave

- Se mapeó evidencia de los desafíos de los recursos humanos en el área de la salud (RHS) y el poder brindar atención neonatal de calidad en centros hospitalarios. Esta evidencia se clasificó en 10 categorías:
 - Falta de seguimiento y datos de los RHS
 - Formación deficiente previa al ejercicio de las funciones de los trabajadores de la salud y escaso material de contenido acerca de la salud del recién nacido
 - Falta de acceso a material dirigido a trabajadores de la salud, como guías de práctica clínica basadas en evidencia, educación continua y desarrollo profesional continuo
 - Distribución insuficiente e inequitativa del personal de salud y cargas de trabajo extenuantes
 - Mala retención del personal, ausentismo y rotación del personal experimentado
 - Mal ambiente laboral, así como salarios bajos
 - Supervisión limitada y deficiente
 - Baja moral, falta de motivación y de actitud, así como insatisfacción laboral
 - Debilidades en políticas, regulaciones, administración, liderazgo, gobernanza y financiamiento
 - Barreras estructurales y contextuales
- El mapeo de la evidencia proporcionó información útil para poder presentar las estrategias de la Organización Mundial de la Salud publicadas recientemente, las cuales describen el abordaje sistemático de los desafíos y el fortalecimiento de los RHS para la atención del recién nacido, tanto a nivel mundial como a nivel nacional.
- El proceso de análisis temático también resalta las complicadas interacciones entre los diferentes tipos de desafíos de los RHS.
- Los hallazgos sugieren nuevas estrategias de acción para abordar estos desafíos.

RESUMEN

Antecedentes: La escasez crítica de trabajadores de la salud que a su vez cuentan con las competencias necesarias para atender a la madre y al recién nacido sigue siendo un desafío importante en la prestación de servicios de atención de calidad, especialmente, en países con ingresos bajos y medianos. La problemática de la oferta de los recursos humanos para la salud (RHS), agrava la falta de estos y puede afectar negativamente el desempeño de los trabajadores de la salud y la calidad de la atención. Esta investigación utiliza fuentes centralizadas en cada país para identificar y mapear la evidencia de los desafíos del campo de los RHS para la prestación de atención neonatal de calidad en centros hospitalarios por parte de enfermeras y parteras.

Métodos: La evidencia de esta revisión fue recopilada de forma iterativa, comenzando con documentos pertinentes de la Organización Mundial de la Salud y extendiéndose a los artículos identificados a través de bases de datos y búsquedas manuales en listas de referencias e informes de los países incluidos en el estudio. La evidencia se obtiene de fuentes enfocadas en cada país y se considera la información a partir del año 2000. La extracción de datos fue realizada utilizando una herramienta diseñada de forma reiterativa; además, se hizo uso de un análisis temático para mapear las 10 categorías de los desafíos de los RHS.

Resultados: Se examinaron un total de 332 artículos y fueron revisados por pares, 22 de estos cumplieron los criterios de inclusión. Se agregaron catorce fuentes adicionales de búsqueda manual de listas de referencias y fuentes de literatura de carácter no científico. La evidencia se ha mapeado en 10 categorías de desafíos relacionados con los RHS: (1) falta de datos y monitoreo de los trabajadores de la salud; (2) deficiencia en educación previa al servicio como trabajador de la salud; (3) falta de acceso a material dirigido a trabajadores de la salud, como guías de práctica clínica basadas en evidencia, educación continua y desarrollo profesional continuo; (4) distribución insuficiente y desigual de los trabajadores de la salud y

extenuantes cargas de trabajo; (5) mala retención del personal, ausentismo y rotación del personal experimentado; (6) mal ambiente laboral, así como bajos salarios; (7) supervisión limitada y deficiente; (8) baja moral, falta de motivación y de actitud, así como insatisfacción laboral; (9) debilidades en políticas, regulaciones, administración, liderazgo, gobierno y financiamiento; y (10) barreras estructurales y contextuales.

Conclusión: El mapeo proporciona la información necesaria y muestra las nuevas estrategias de la Organización Mundial de la Salud y los esfuerzos para apoyar el abordaje de los desafíos identificados y fortalecer los recursos humanos para la atención neonatal, con el objetivo final de mejorar la atención y los resultados en el recién nacido.

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FIELD ACTION REPORT

Remote Interviewer Training for COVID-19 Data Collection: Challenges and Lessons Learned From 3 Countries in Sub-Saharan Africa

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Key Findings

- Remote interviewer training for large-scale surveys can be an effective replacement to in-person learning in low-resource contexts when data are urgently needed and in-person learning is impossible.
- An intermittent Internet connection, distribution of physical materials to interviewers, and interviewer experience and social cohesion are critical to the success of remote training.

Key Implications

- Training designers need to balance streamlining design choices for efficiency and the importance of contextual adaptation to improve training quality.
- In-person learning still conveys significant advantages over remote learning. Training designers should evaluate local context and a project's unique circumstances before proceeding with remote training.

➔ [Résumé en français à la fin de l'article.](#)

ABSTRACT

There is an urgent need for data to inform coronavirus disease (COVID-19) pandemic response efforts. At the same time, the pandemic has created challenges for data collection, one of which is interviewer training in the context of social distancing. In sub-Saharan Africa, in-person interviewer training and face-to-face data collection remain the norms, requiring researchers to think creatively about transitioning to remote settings to allow for safer data collection that respects government guidelines. Performance Monitoring for Action (PMA, formerly PMA2020) has collected both cross-sectional and longitudinal data on key reproductive health measures in Africa and Asia since 2013. Relying on partnerships with in-country research institutes and cadres of female interviewers recruited from sampled communities, the project was well-positioned to transition to collecting data on COVID-19 from the onset of the pandemic. This article presents PMA's development of a remote training system for COVID-19 surveys in the Democratic Republic of the Congo, Kenya, and Nigeria, including challenges faced and lessons learned. We demonstrate that remote interviewer training can be a viable approach when data are critically needed and in-person learning is not possible. We also argue against systematic replacement of in-person trainings with remote learning, instead recommending consideration of local context and a project's individual circumstances when contemplating a transition to remote interviewer training.

INTRODUCTION

Since the coronavirus disease (COVID-19) pandemic began, researchers have repurposed ongoing survey platforms to provide timely data and inform COVID-19 response efforts.¹⁻⁸ Transitioning toward COVID-19 research is particularly important for countries in sub-Saharan Africa, where the limitations of disease surveillance systems were well known even before the pandemic.^{9,10} Existing survey platforms can offer critical support to COVID-19 monitoring efforts; however, rapid repurposing of survey infrastructure is not without challenges.

In much of sub-Saharan Africa, in-person interviewer training and face-to-face data collection remain the norms

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Comprehensive interviewer training impacts data quality, so it's important to consider remote training options during the COVID-19 pandemic.

for population-based surveys, largely due to inconsistent Internet connectivity and barriers to technological literacy.^{11,12} However, during the COVID-19 pandemic, in-person activities may violate government restrictions and put respondents at risk of infection. As a result, some surveys have shifted to abbreviated remote trainings or have forgone formal interviewer training altogether.^{2-4,6,13,14} Comprehensive interviewer training impacts data quality, so it is important to consider remote training options under the current circumstances.¹⁵⁻²⁰ To date, little has been published on remote interviewer training in low-resource contexts, and what does exist lacks detail or is largely anecdotal.^{2-4,6,13} Comprehensive documentation is necessary to better understand when remote training may be feasible and to establish best practices for remote learning in these settings.

■ PERFORMANCE MONITORING FOR ACTION

Performance Monitoring for Action (PMA, formerly PMA2020) has collected rapid-turnaround data on family planning and other reproductive health indicators across Africa and Asia since 2013. Universities and research institutes lead implementation in each country (referred to as “country teams” in this article), recruiting female interviewers from sampled communities to conduct mobile phone-based population and facility surveys annually. Data are representative at the national or subnational level and provide timely information to policy makers on key indicators in sexual and reproductive health. The Johns Hopkins Bloomberg School of Public Health (JHSPH) and Jhpiego provide technical and coordination support. Beginning in late 2019, PMA transitioned to a panel design, with annual, in-person follow-up surveys planned over 3 years.

Preparing for PMA’s baseline survey begins with a 2-week in-person training for the country team project staff and field supervisors, followed by a 2-week training of interviewers. Before each subsequent survey round, teams hold shorter refresher trainings, typically between 3 and 5 days, to review challenges from the previous round and train on new survey topics. Facilitators employ a variety of formats, including lecture, small group activities, individual assessments, and field exercises.

In late 2019 and early 2020, teams in 4 of the 8 PMA countries—Burkina Faso, the Democratic Republic of the Congo (DRC), Kenya, and Nigeria—collected baseline survey data in-person, obtaining consent and phone numbers from women willing to

participate in follow-up surveys. These teams also had previous experience with conducting remote surveys over the phone as part of PMA Agile, a separate project within the PMA platform.²¹

Given this background, PMA was well-poised to collect COVID-19 data remotely through phone interviews and attempt remote interviewer trainings. In March 2020, PMA developed a COVID-19 survey and began preparing for remote training. In this article, we present PMA’s remote interviewer training approach implemented in 3 of the 4 countries: the Democratic Republic of the Congo (DRC), Kenya, and Nigeria. We also describe key challenges faced and provide recommendations for others considering remote interviewer training.

We describe here the PMA COVID-19 survey, the key features of PMA’s approach to remote interviewer training, an interviewer’s typical training experience, and country-specific adaptations to the training system.

The PMA COVID-19 Survey

PMA’s COVID-19 survey consisted of a short phone-based questionnaire administered to women of reproductive age (15–49 years) who consented to follow-up at baseline. The survey contained 6 sections: COVID-19 awareness and information sources; perception of personal infection risk; knowledge of COVID-19 symptoms, transmission, and prevention; social consequences of COVID-19-related restrictions; and the impact of COVID-19 on accessing health services as well as reproductive health outcomes. Data are representative of Kinshasa province in the DRC, nationally representative in Kenya, and representative of Kano and Lagos States in Nigeria. PMA is led by the Kinshasa School of Public Health (KSPH) in the DRC; the International Centre for Reproductive Health (ICRH) in Kenya; the Centre for Research, Evaluation Resources, and Development (CRERD) in Nigeria; and the *Institut Supérieur des Sciences de la Population* in Burkina Faso.

PMA’s Remote Training System

As we began planning for PMA’s COVID-19 survey, we considered our options for interviewer training. Country teams weighed the feasibility of interviewers participating in training from their homes against the practicality and safety of in-person trainings during the pandemic. We recognized the health risks of in-person trainings, while also acknowledging the risk of poor data quality if we chose to conduct minimal or no training at all. We knew data quality issues would extend the

Country teams weighed the feasibility of remote interviewer training from home against the practicality and safety of in-person trainings during the pandemic.

cleaning phase for urgently needed data, thus limiting the survey’s overall utility. Ultimately, teams in the DRC, Kenya, and Nigeria elected to conduct training remotely, with technical support from JHSPH staff and an independent learning consultant.

As training approached in Burkina Faso, new COVID-19 cases waned, and government restrictions relaxed. As such, the *Institut Supérieur des Sciences de la Population* proceeded with in-person, socially distanced training following PMA’s standard training procedures. We do not present information here on this latter approach.

Recognizing that interviewers had limited familiarity with online learning, our goal was to develop a training system that mimicked the in-person experience. This included sharing content through video lectures, reinforcement through small group activities, evaluation through electronic assessments, and active monitoring via one-on-one phone calls between facilitators and interviewers. Interviewers accessed all training materials from PMA smartphones also used for data collection. To reduce interviewers’ learning burden, we relied on platforms with which they were already familiar, namely WhatsApp, Google Drive, Open Data Kit, and YouTube.

Each country team had its own distinct training system, based around 3 types of WhatsApp groups, named, “Info,” “My Group,” and “Q&A,” for information-sharing, small group work, and asking questions, respectively (Figure 1). The WhatsApp “Info” group served as the “training room,” or the central location where interviewers could follow along with the training agenda and

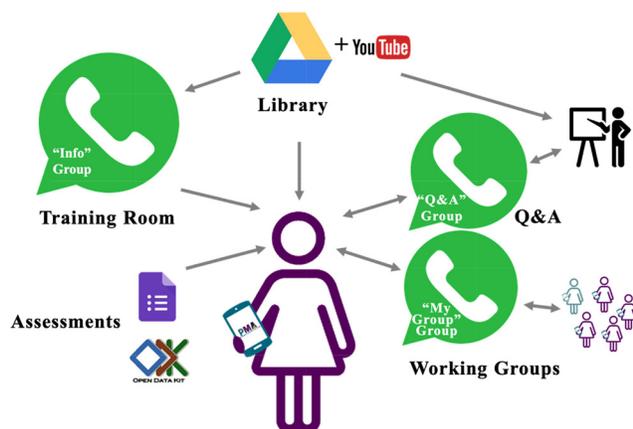
access training content. It was designed as a unidirectional group, where only the lead trainer and facilitators could post. This made the group the centralized place for information-sharing, whereas the “Q&A” and “MyGroup” WhatsApp groups were designed for bidirectional exchange and interaction between interviewers and facilitators.

At the start of each training day, lead facilitators began with a virtual roll call in the “Info” group and posted an image of the day’s agenda. They then shared links to the training content for each session, which video lectures previously recorded and uploaded to the PMA YouTube channel, as well as activity instructions, and links to individual assessments. They posted training content to the “Info” group in the order given in the agenda, with time between each post for interviewers to watch the videos or complete the activity. If interviewers had questions, they posted them to the “Q&A” WhatsApp group. Small group activities were completed in their assigned “My Groups” WhatsApp group. Interviewers completed assessments using Open Data Kit or GoogleForms that facilitators then graded. The lead trainer moderated the “Q&A” group and coordinated with facilitators moderating the “MyGroups” and grading assessments to post any information that was relevant to all interviewers to the “Info” group.

Knowing that Internet connectivity would pose a challenge, country teams downloaded backup copies of training content to the interviewers’ smartphones via the Google Drive app before distributing the smartphones to interviewers. We also did not include any live sessions

Because Internet connectivity would pose a challenge, country teams distributed print manuals, adapted training to include recorded, not live, sessions, and designed training lectures to be 20 minutes or less.

FIGURE 1. The Remote Interviewer Training System for the Performance Monitoring for Action COVID-19 Survey, March 2020



in the original training design, though some country teams chose to add group video calls as their Internet connection permitted. We distributed printed training manuals to ensure that interviewers had a reference text while watching videos and completing activities, and as a final backup option if all technology failed. Given the pressing need for these data, we accelerated training material development by having JHSPH staff and the independent consultant create ready-to-implement training lectures and activities, with options for country-specific adaptation. We designed training lectures to be no longer than 20 minutes and made them as interactive and participatory as possible, given the virtual setting. Remote trainings in all 3 countries took place over 3 consecutive days between May and July 2020. Details of the training experience from an interviewer's perspective are shown in the [Box](#).

Country-Specific Adaptations

While adhering to the general training system described above, each country team adapted aspects of this remote approach to make it more effective in their context. In Kenya, ICRH recruited all available interviewers who participated in the baseline survey (n=282). They sent preloaded smartphones and training manuals via courier service to reduce infection risk. Given the large team, ICRH developed a cascading training approach, starting with a remote training of trainers (TOT) that included participation from experienced

PMA Agile interviewers and field supervisors. The TOT followed the general remote training model as described. For interviewer training, each county organized separate trainings with its own WhatsApp groups "Info," "MyGroup," and "Q&A." Field supervisors who had participated in the TOT moderated the county-specific groups and sent questions they could not answer to the TOT "Q&A" group. They relayed responses back to interviewers via the county groups, thus standardizing training content for all interviewers.

In the DRC, KSPH recruited a subset of 25 interviewers who had participated in the baseline survey and/or PMA Agile. To translate the COVID-19 questionnaire into Lingala, a language not widely written, the team invited interviewers to participate in a pretraining competition. Interviewers submitted audio files of their questionnaire translations in Lingala. The central team reviewed submissions and sent the most accurate and specific translations to all interviewers as the standard translation for each question.

In Nigeria, CRERD recruited a subset of 10 interviewers in Kano State and 21 in Lagos State, all of whom participated in baseline data collection. They also recruited 2 supervisors from Kano State and 4 from Lagos State to manage teams of interviewers during training and data collection. Field coordinators for each state distributed preloaded smartphones and training manuals, rather than asking interviewers to come to a central location and risk infection. The team translated the COVID-19 questionnaire into Pidgin, Hausa, and Yoruba. Daily, live group video

BOX. An Interviewer's Typical Experience with Remote Training for the Performance Monitoring for Action COVID-19 Survey

1. **Receive physical materials:** Included a printed training manual and configured smartphone, with copies of training materials synced locally for offline viewing on Google Drive. For ease of access, we added shortcuts of the Google Drive training folder and other relevant applications to the home screen of each phone.
2. **Orient to remote training system:** Facilitators shared the day's agenda in the unidirectional WhatsApp "Info" group, pushing content for each session in chronological order throughout the training day. Training tools had unique identification numbers corresponding to the day and sequence of the session. Interviewers accessed tools from links shared by WhatsApp group or by searching by identification numbers in Google Drive.
3. **Learn content:** Interviewers watched videos, pausing for pop quizzes and reminders to review their training manual.
4. **Apply content and evaluate understanding:** Facilitators shared pre-designed activities in the WhatsApp "Info" group, such as practicing survey introduction with a member of the interviewer's household or another interviewer over the phone. Interviewers completed activities and took daily Google Forms or Open Data Kit quizzes and received automatic grading and individualized feedback.
5. **Ask questions and receive support:** Interviewers asked questions and received responses via multidirectional exchange on the WhatsApp "Q&A" group. They communicated in smaller WhatsApp groups called "MyGroup [#]" for direct support from facilitators. Field supervisors tracked progress and comprehension via a shared spreadsheet that centralized data on homework completion and quiz scores. Supervisors followed up with interviewers by phone as needed.

calls enabled interviewers to socialize and discuss training content further. CRERD continued using the WhatsApp “Q&A” group during data collection to reinforce learning and enhance general communication.

■ CHALLENGES TO REMOTE TRAINING

In the implementation of our remote training system, we encountered 3 central challenges. We describe these challenges and our attempts to address these issues in real-time.

How Do We Rapidly Prepare Remote Training Facilitators in Each Country?

Country teams already had extensive experience leading in-person interviewer trainings, but facilitating a virtual training required additional skills. Given the urgent need for the data, we knew we had limited time to support this learning. Acknowledging the time constraints, how could we help build facilitators’ confidence with virtual training?

In an attempt to reduce the learning burden on facilitators from the beginning, we designed a training system that leveraged participants’ existing technological knowledge, using applications like WhatsApp that most interviewers and facilitators already used. In Kenya, the ICRH team built in additional experience by having interviewers who had conducted remote surveys under PMA Agile participate in the TOT and then serve as lead facilitators for the remote, county-level trainings. In the DRC, where the KSPH team was particularly concerned about interviewers’ comfort using WhatsApp, facilitators pretested a prototype of the remote training system even before deciding to adopt a remote approach. This increased facilitators’ confidence in using the training system while improving the overall design.

Still, we acknowledge that the preparation process was not perfect, and we omitted steps that could have helped country teams better prepare their trainings. Country teams expressed post-training that they would have benefited from an introductory webinar presenting the training system in its entirety and how we envisioned it being used. Due to time constraints, we instead provided this information in piecemeal, usually over email. This created confusion about the intended order of training sessions, which training sessions we envisioned country teams’ adapting or creating, and duplication of efforts between JHSPH staff and country teams. We also did not provide sufficient training on new tools introduced as part of the remote training approach. For

example, we introduced Google Forms for virtual assessments but did not offer guidance on how to use it. As a result, some country teams did not know about key features that made it ideal for remote learning, such as automatic grading and immediate question-by-question feedback, until later in the training.

How Do We Ensure That Interviewers Are Able to Fully Participate in the Training?

We were uncertain of the extent to which interviewers would be able to participate in training from their homes. We were particularly worried about Internet connectivity, which ranged from generally stable with sufficient bandwidth to frequent outages and low bandwidth. We were also concerned about interviewer availability, given other household obligations for which women are often responsible.

In response to Internet connectivity concerns, we invested early in testing the technology necessary for remote training, while also preparing several backup options for when the Internet inevitably failed. In the overarching training system, country teams downloaded offline copies of all training materials to the smartphones ahead of distribution. In Nigeria, the team conducted a 2-stage verification by ensuring that videos were playing offline before and after delivering phones to interviewers. Interviewers could also view videos via PMA’s YouTube channel, which automatically adjusts streaming quality based on available bandwidth. Hard copies of the training manuals served both as a reference text and an additional low-tech option for learning.

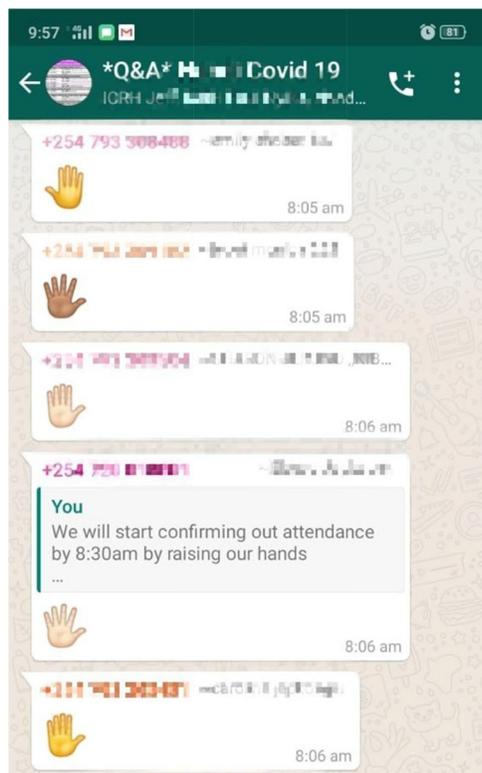
Recognizing that competing household priorities was also not an insignificant challenge for a group of female interviewers, all teams adopted a strategy developed by ICRH. This approach allowed interviewers to go through a day’s training at their own pace, while requiring everyone to finish all sessions for the day by a designated time. Interviewers thus had the flexibility to fit training around household responsibilities, while still benefitting from synchronous learning. ICRH also implemented a roll call to start each training day, where a facilitator asked interviewers to virtually raise their hand by sending a hand emoji to the WhatsApp “Q&A” group, acknowledging they were online and ready to start training (Figure 2).

How Do We Ensure Interviewers Are Actually Learning?

Beyond basic participation, we saw evaluation of interviewer performance as another central

To try to reduce the facilitators’ learning burden, we designed a training system that leveraged participants’ existing technological knowledge by using apps that most interviewers and facilitators already used.

FIGURE 2. Screenshot of the Virtual RollCall Implemented by the International Centre for Reproductive Health in Kenya to Assess if Interviewers Were Present and Following the Remote Training



challenge. How could we ensure that interviewers understood and retained the material they accessed remotely?

As part of the training system, we created quizzes in Google Forms and Open Data Kit and tracked performance with a shared spreadsheet. In addition, country teams developed ways to routinely gauge interviewer comprehension. The CRERD team used the small-group format of the WhatsApp “MyGroups” to delve deeper into confusing topics. Live evening debriefs over video call covered lingering issues that could not be resolved in these small groups. The review meetings served both to clarify content for interviewers and also to verify comprehension. For example, when interviewers raised questions, the facilitator randomly chose another interviewer to respond before providing further clarity.

In the DRC, the KSPH team announced at the beginning of training that 2 interviewers would be selected at the end of each training day to provide

a daily summary the following morning. This created an incentive for interviewers to complete the day’s training on time, clarify any confusing points, and be prepared if they were selected to report out the next day. Finally, all teams acknowledged that despite the numerous options for tracking learning virtually, the best way to support struggling interviewers was often still to call them and provide one-on-one support.

LESSONS LEARNED

We share our approach and the challenges we faced in implementing remote interviewer trainings for a COVID-19 survey in the DRC, Kenya, and Nigeria. We hope this information will assist other groups planning data collection activities during the pandemic. To this effect, we discuss below 2 overarching lessons learned from the experience.

Acknowledge Trade-offs Between Country Ownership and Timelines

Given that the data were urgently needed, we struggled with the tension between (1) fostering local ownership over training design and (2) meeting timelines for data collection. Centralized decision making by JHSPH staff in the name of efficiency led to some confusion that impacted training quality. An incomplete understanding of why we chose certain training tools made it difficult for country teams to decide which approaches to implement and how best to adapt them to their contexts. When there was time for country adaptation, it was also evident that teams’ additions improved interviewer participation and knowledge retention. Daily virtual roll calls, random interviewer selection to provide daily summaries, and live video calls all enhanced the overall training experience by ensuring participation, assessing comprehension, and building a sense of in- and cross-country comradery. Although we have little information on remote interviewer trainings, we know from the literature on interviewer training more generally that these factors are associated with better interviewer performance and improved data quality.^{16–18}

Given this, we wished we had invested more time upfront toward greater inclusivity in the training design process. A core tenet of PMA’s design centers on promoting country team autonomy in survey implementation over time. We approached remote training development with this goal in mind, and yet still struggled. Ideally, JHSPH staff and the learning consultant would have cocreated the training system with country

Country teams developed different ways to gauge interviewers’ comprehension, including small group discussions via Whatsapp and recorded, live debriefs via video call.

team facilitators. We would have taken more time to coach country teams on the proposed approach and the logic behind the design choices, and we would have created more space for feedback and new design options by country teams.

We recognize that this polarity is not unique to PMA nor is it unique to remote learning. However, circumstances like the COVID-19 pandemic that necessitate remote learning in low-resource contexts will likely only exacerbate this common tension further. As such, we recommend that others facing similar constraints model the importance of a minimal viable product for content creation.²² The minimal viable product concept originated in business, as a way for technology startups to bring new technology to market faster by introducing a product once it met minimal useability and functionality standards. This process accelerated users' access to a functional product while allowing designers to collect user data to make iterative product improvements. Promoting the concept of a minimal viable product in the context of remote training design is helpful because it demonstrates that imperfect, unpolished materials can be created in less time, while still being effective for learning. We also suggest that training system designers invest their time engaging with country teams earlier in the planning, specifically by organizing a facilitator orientation

session to introduce the system and get feedback before getting into the details of content creation. When data are urgently needed, an honest and collaborative assessment of the trade-off between local ownership and efficiency is even more critical, along with creative solutions to strike a balance between the 2 sides of the polarity.

Thoughtful Consideration Over a Uniform Approach

We summarize our identified advantages and limitations of remote compared to in-person trainings, along with factors to consider when deciding on an approach (Table). Remote training conveys some advantages over in-person training under specific circumstances. Most fundamentally, it allows for some level of interviewer training with minimal added infection risk. Secondary benefits of remote learning among our global team included increased confidence in using the tools of remote learning and easier cross-country and cross-language collaboration to improve the overall training design. Having training content recorded also meant that interviewers could watch training lectures multiple times to increase retention.

Nonetheless, it is important to acknowledge the limitations of remote trainings and that in-

Promoting the concept of a minimal viable product in the context of remote training design is helpful because it demonstrates that imperfect, unpolished materials can be created in less time, while still being effective for learning.

TABLE. Advantages and Limitations of Implementing Remote Interviewer Trainings and Factors to Consider When Deciding on Approach

Remote Training Advantages	Remote Training Limitations
<ul style="list-style-type: none"> • Allows some interviewer training safely during a global pandemic • Builds confidence, skills, and familiarity with remote training, to leverage future remote learning if necessary • Enables cross-country and cross-language knowledge sharing to create standardized materials • Enables participants to watch prerecorded content multiple times and on their own schedule 	<ul style="list-style-type: none"> • Requires preparing multiple back up options in anticipation of Internet connectivity or technology issues • Necessitates additional training in remote facilitation for training facilitators • Limits opportunities for organic learning from discussion or practical application • Demands significant human resources to design, develop, and deploy the training system • Requires group tolerance for the risks and potential delays
Ideal Circumstances for Remote Training	Circumstances That Do Not Favor Remote Training
<ul style="list-style-type: none"> • Access to at least an intermittent Internet connection • Ability to distribute select materials to interviewers, such as a training manual and smartphone, to engage in remote learning • An established and cohesive field team, enabling an environment conducive to attempting new ways of learning • Experienced interviewers, with sufficient background knowledge on protocols and survey content to minimize training time • Simple survey content that builds on interviewers' previous experiences • Familiarity across the study team with at least a few common applications that could be used for remote learning 	<ul style="list-style-type: none"> • Internet connection is unavailable or unreliable for large portions of training time • Printed materials and common familiar applications cannot be ensured • Field team is new, or trust and familiarity are still being developed across a team • Training content is lengthy or significantly complex • In-person practical application is essential to learning

person learning has significant pedagogical advantages. These include easier observation of learner engagement, greater flexibility to address learners' needs throughout training, more opportunities for organic discussion and practical exercises, and greater socialized learning alongside other learners.^{15–17,23} Other groups implementing COVID-19 surveys with remote interviewer training have also noted disadvantages to self-directed learning in the home environment compared to in-person trainings.^{6,14} Finally, others considering implementing a remote approach should be aware of the extensive time investments needed to develop an effective virtual training, especially if aiming for standardization across geographies.

In terms of factors that enable successful remote learning, our ability to effectively mitigate many of the challenges above was largely due to PMA's structure and history as a project. We have invested considerable time and resources into interviewer training and fostering an environment of collaboration across the project. Most interviewers remain with the project over many survey rounds, meaning those who participated in the COVID-19 survey had substantial existing knowledge of PMA survey protocols, research ethics, and phone-based data collection. Country teams have also made significant efforts to develop a strong sense of community among field teams, which undoubtedly contributed to interviewer confidence in attempting a new way of learning. Guidelines on conducting remote interviewer trainings from the World Bank, Innovations for Poverty Action, and Abdul Latif Jameel Poverty Action Lab likewise note the importance of having an experienced and cohesive field team as well as familiar, easily accessible technology.^{4,6,13,14} Though critical to PMA's success with remote learning, these factors may not be present or feasible for other large-scale surveys.

For these reasons, we do not advocate for systematically replacing in-person trainings with remote learning. Instead, thoughtful consideration of the specific circumstances and the project's available resources are needed when deciding on the feasibility of conducting interviewer trainings remotely. Indeed, JHSPH staff and principal investigators in each country discussed the above considerations early in the planning process, and colleagues in Burkina Faso ultimately decided to hold an in-person training. The team explained that Internet connectivity was not consistent or reliable enough even in the capital of Ouagadougou for remote training to be a viable option. In their case, an in-person training with strict safety and infection protocol measures was feasible and still safe. Everyone

who attended training was given masks and hand sanitizer and instructed to remain appropriately spaced. Instead of large plenaries, the team held training in small groups and worked outdoors whenever possible. Survey teams implementing in similar settings during the COVID-19 pandemic may want to consider such an approach. Under more typical circumstances, teams implementing a survey for the first time or with entirely new interviewers should also think about extending in-person trainings with remote learning, rather than replacing them entirely.

■ CONCLUSION

This article demonstrates that when data are urgently needed and in-person interviewer trainings are not possible, a well-designed remote training can be an effective replacement in low-resource contexts in sub-Saharan Africa. Development of our remote training approach was not without challenges, including difficulties rapidly preparing for remote facilitation, and ensuring interviewer participation and comprehension from home. Critical factors to the success of our design include an experienced and cohesive team of facilitators and interviewers, the ability to rapidly distribute select physical training materials, and interviewer access to an intermittent Internet connection at a minimum. Although we do not advocate for systematic replacement of in-person trainings with remote learning, demonstrating that a remote approach is possible in these settings is an important step toward ensuring the availability of high-quality data during the COVID-19 pandemic.

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Author contributions: ST led the conceptualization and drafting of the manuscript and revision process, including coordinating feedback and input from the other authors. SA led the design of the global remote training system and drafted key sections of the manuscript, including the box and table. SOA led the design of remote training in Nigeria and codrafted the section on Nigeria's country-specific adaptations to the system along with II. He also provided specific examples of training design innovations from Nigeria presented in the manuscript. PA led the design of remote training in the DRC and drafted in French the section on the DRC's country-specific adaptations to the system before ST translated into English. He also provided specific examples of training design innovations from the DRC that are presented throughout the manuscript. II co-led the design of remote training in Nigeria and contributed to the section on Nigeria's country-specific adaptations. AM led the design of remote training in Kenya and contributed to the section on Kenya's country-specific adaptations, providing detailed examples of training

design innovations from Kenya. EL provided technical support in standing up the remote training system across all three countries. She also provided edits to the overall structure, flow, and logic of the manuscript over multiple reviews, including heavy editing for overall clarity. CM provided technical support in standing up the remote training system across all three countries. She also provided guidance on overall conceptualization, structure, and flow of the manuscript and participated in multiple rounds of review. PA provided technical support in standing up the remote training system across all 3 countries. He also provided guidance on overall conceptualization, structure, and flow of the manuscript and participated in multiple rounds of review.

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REFERENCES

- Asanov I, Flores F, Mckenzie DJ, Mensmann M, Schulte M. *Remote-Learning, Time-Use, and Mental Health of Ecuadorian High-School Students During the COVID-19 Quarantine*. World Bank; 2020. Accessed August 25, 2020. <https://www.poverty-action.org/sites/default/files/publications/Remote-learning-Time-Use-and-Mental-Health-of-Ecuadorian-High-School-Studentsduring-the-COVID-19-Quarantine.pdf>
- Austrian K, Pinchoff J, Tidwell JB, et al. COVID-19 related knowledge, attitudes, practices and needs of households in informal settlements in Nairobi, Kenya. Preprint. Posted online April 6, 2020. *Bull World Health Organ*. 2020;6. [CrossRef](#)
- Banda J, Dube A, Brumfield S, et al. Knowledge and behaviors related to the COVID-19 pandemic in Malawi. Preprint. medRxiv Posted online June 29, 2020. 2020;29. [CrossRef](#)
- Delius A, Himelein K, Pape UJ. *Conducting Rapid Response Phone Surveys to Fill Data Gaps*. World Bank; 2020. Accessed August 25, 2020. <http://hdl.handle.net/10986/34300>
- Geopoll. *Coronavirus in Sub-Saharan Africa: How Africans in 12 Nations Are Responding to the COVID-19 Outbreak*. Geopoll; 2020. Accessed August 25, 2020. https://cdn2.hubspot.net/hubfs/325431/COVID%20Report_April152020.pdf
- Jones M, Khincha R, Kondylis F, Uwamariya L. Practical tips for implementing remote surveys in the time of the Great Lockdown. *World Bank Blogs*. Accessed August 25, 2020. <https://blogs.worldbank.org/impactevaluations/practical-tips-implementing-remote-surveys-time-great-lockdown>
- Le Nestour A, Mbaye S, Moscoviz L. *Phone Survey on the Covid Crisis in Senegal*. Center for Global Development; 2020. Accessed August 25, 2020. [CrossRef](#)
- Lopez-Pena P, Austin Davis C, Mushfiq Mobarak A, Raihan S. Prevalence of COVID-19 symptoms, risk factors, and health behaviors in host and refugee communities in Cox's Bazar: a representative panel study. Preprint. Posted online May 11, 2020. *Bull World Health Organ*. 2020;11. [CrossRef](#)
- Fall IS, Rajatonirina S, Yahaya AA, et al. Integrated Disease Surveillance and Response (IDSR) strategy: current status, challenges and perspectives for the future in Africa. *BMJ Glob Health*. 2019;4(4):e001427. [CrossRef](#). [Medline](#)
- Phalkey RK, Yamamoto S, Awate P, Marx M. Challenges with the implementation of an Integrated Disease Surveillance and Response (IDSR) system: systematic review of the lessons learned. *Health Policy Plan*. 2015;30(1):131–143. [CrossRef](#). [Medline](#)
- Ahmed A, Nwagwu WE. Challenges and opportunities of e-learning networks in Africa. *Development*. 2006;49(2):86–92. [CrossRef](#)
- Sife AS, Lwoga ET, Sanga C. New technologies for teaching and learning: challenges for higher learning institutions in developing countries. *Int J Educ Dev Inf Communication Tech*. 2007;3(2):57–67. Accessed January 7, 2021. <http://ijedict.dec.uwi.edu/viewarticle.php?id=246&layout=html>
- Gupta P. *Best Practices: Remote Field Staff Training*. J-PAL South Asia at IFMR; 2020. Accessed August 25, 2020. https://drive.google.com/file/d/1M3rj_Hgc_Ha6FFSGW2y3nL25gkxRAAN5/view
- Mezghbe B. 7 ways to conduct a COVID-19 phone survey like IPA. Survey CTO. Accessed August 25, 2020. <https://www.surveyccto.com/case-studies/ipa-recovr-phone-survey/>
- Groves RM, McGonagle KA. A theory-guided interviewer training protocol regarding survey participation. *J Off Stat*. 2001;17(2):249. Accessed January 7, 2021. <http://www.sverigeisiffror.scb.se/contentassets/ca21efb41fee47d293bbec5bf7be7fb3/a-theory-guided-interviewer-training-protocol-regardingsurvey-participation.pdf>
- Jansen HAFM, Watts C, Ellsberg M, Heise L, García-Moreno C. Interviewer training in the WHO multi-country study on women's health and domestic violence. *Violence Against Women*. 2004;10(7):831–849. [CrossRef](#)
- Jaszczak A, Lundeen K, Smith S. Using nonmedically trained interviewers to collect biomeasures in a national in-home survey. *Field Methods*. 2009;21(1):26–48. [CrossRef](#). [Medline](#)
- Link MW. Predicting the persistence and performance of newly recruited telephone interviewers. *Field Methods*. 2006;18(3):305–320. [CrossRef](#)
- Meitinger K, Stadtmüller S, Silber H, et al. Fieldwork monitoring in practice: insights from 17 large-scale social science surveys in Germany. *Survey Methods: Insights from the Field*. 2020;1–13. [CrossRef](#)
- O'Brien EM, Black MC, Carley-Baxter LR, Simon TR. Sensitive topics, survey nonresponse, and considerations for interviewer training. *Am J Prev Med*. 2006;31(5):419–426. [CrossRef](#). [Medline](#)
- Tsui A, Anglewicz P, Akinlose T, et al. Performance monitoring and accountability: The Agile Project's protocol, record and experience. *Gates Open Res*. 2020;4(30):30. [CrossRef](#). [Medline](#)
- Rancic Moogk D. Minimum viable product and the importance of experimentation in technology startups. *Tech Innovation Manage Rev*. 2012;23–26. [CrossRef](#)
- Ali S, Uppal MA, Gulliver SR. A conceptual framework highlighting e-learning implementation barriers. *Inf Technol People*. 2018;31(1):156–180. [CrossRef](#)

En Français

Formation à distance des enquêteurs pour la collecte de données sur la COVID-19: Défis et leçons tirées de 3 pays d'Afrique subsaharienne

Messages clés: La formation à distance des enquêteurs dans des environnements à faibles ressources peut être une approche efficace pendant la pandémie de la COVID-19 lorsque les données sont absolument nécessaires et que l'apprentissage en personne n'est pas possible. Nous démontrons que la formation à distance des enquêteurs est possible lorsque les enquêteurs: disposent au moins d'une connexion Internet intermittente, disposent de matériels de supports spécifiques, sont expérimentés et font partie d'une équipe soudée.

ABSTRACT

Il y a un besoin urgent de données pour informer les efforts de réponse à la pandémie de coronavirus (COVID-19). En même temps, la pandémie a créé des défis pour la collecte de données, dont l'un est la formation des enquêteurs dans le contexte de la distanciation sociale. En Afrique subsaharienne, la

formation des enquêteurs en personne et la collecte de données en face à face restent la norme, ce qui oblige les chercheurs à réfléchir de manière créative à la transition vers des cadres de travail à distance afin de permettre une collecte de données plus sûre et respectant les directives gouvernementales. Depuis 2013, Performance Monitoring for Action (PMA, anciennement PMA2020) a permis de recueillir des données transversales et longitudinales sur les principaux indicateurs de la santé reproductive en Afrique et en Asie. S'appuyant sur des partenariats avec des instituts de recherche nationaux et des équipes d'enquêtrices recrutées dans les communautés échantillonnées, le projet était bien positionné dès le début de la pandémie pour passer à la collecte de données sur la COVID-19. Cet article présente le développement par PMA d'un système de formation à distance pour les enquêtes COVID-19 en République Démocratique du Congo, au Kenya et au Nigéria, y compris les défis rencontrés et les leçons apprises. Nous démontrons que la formation des enquêteurs à distance peut être une approche viable lorsque les données sont absolument nécessaires et que l'apprentissage en personne n'est pas possible. Nous argumentons également contre le remplacement systématique des formations en personne par l'apprentissage à distance, et recommandons plutôt de prendre en compte le contexte local et les circonstances individuelles d'un projet lorsque l'on envisage une transition vers la formation à distance des enquêteurs.

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PROGRAM CASE STUDY

Egypt’s Ambitious Strategy to Eliminate Hepatitis C Virus: A Case Study

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Key Messages

- Despite the modest success of Egypt’s first national control program for chronic hepatitis C virus in 2008, subsequent control and elimination campaigns between 2014 and 2020 successfully screened more than 50 million individuals and treated 4 million people for chronic hepatitis C.
- The campaign’s success was driven by: (1) a robust public health care infrastructure and surveillance system; (2) political commitment to sustainable chronic hepatitis C virus elimination; (3) inclusive care that reached all sectors of society; and (4) use of information technology and innovative scientific research.

ABSTRACT

Introduction: Chronic hepatitis C virus (HCV) infection is a major public health problem in many low- and middle-income countries. In 2015, Egypt’s HCV infection prevalence of 7% among adults was among the highest in the world and accounted for 7.6% of the country’s mortality. In 2014, Egypt embarked on an aggressive screening and treatment program that evolved into a national strategy to eliminate HCV as a public health threat by 2021.

Methods: In this qualitative case study, we analyzed Egypt’s HCV control strategy using the Kingdon framework to understand how the problem, policy, and political streams merged to create an opportunity to achieve an ambitious elimination goal. We describe key aspects of the implementation, identify lessons learned, and provide recommendations for other low- and middle-income countries aiming to eliminate HCV.

Results: Between 2014 and 2020, Egypt screened more than 50 million and treated more than 4 million residents for HCV. Five key elements contributed to Egypt’s successful HCV elimination program: (1) sufficient and reliable epidemiologic data to quantify and monitor public health threats; (2) a robust public health care infrastructure; (3) inclusive care that reached all sectors of society; (4) political commitment to public health through increased health care spending and a comprehensive long-term national control strategy; and (5) innovative scientific research and use of information technology.

Conclusion: Egypt conducted a successful HCV screening program that covered more than 50 million residents and treated more than 4 million. It is poised to be the first country in the world to eliminate HCV within its borders. The lessons learned from this experience can inform the elimination plans of other low- and middle-income countries with high HCV burden.

INTRODUCTION

Context and Goals of Egypt’s Hepatitis C Virus Elimination Program

Chronic hepatitis C is a liver infection that is caused by the hepatitis C virus (HCV). In 2015, an estimated 71 million people globally were living with HCV, 1.75 million people were newly infected, and the epidemic was responsible for an estimated 399,000 deaths.¹ HCV-related deaths are primarily due to chronic (or end-stage) liver disease and liver cancer. Low- and middle-income countries accounted for about 75% of people living with HCV globally in 2016.¹

Egypt, a lower middle-income country with a population of 100 million, had one of the highest burdens of

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A community health worker educates a group of women about hepatitis C virus in a village in Assiut. © 2018 Tahsin Bakr

HCV infections globally.² In 2008, 15% of the population had antibodies to HCV (seropositive), indicating they had been exposed to the virus, and 1 in 10 Egyptians aged 15–59 years had chronic HCV infection.³ Faced with this major health and economic burden, Egypt established its first national control program for HCV in 2008, focused on expanding access to treatment. In 2014, Egypt issued its second national program for mitigating HCV, with emphasis on prevention, education, and improved patient care for those living with HCV.

By 2018, the program had evolved into a national strategy to eliminate HCV as a public health threat. This new strategy aligned with the first Global Health Sector Strategy on Viral Hepatitis 2016–2021 agenda that was unanimously adopted by the 194 World Health Organization (WHO) member states, including Egypt.⁴ WHO signatories committed to eliminating viral hepatitis as a public health threat by 2030. Elimination was defined by WHO as a 65% reduction in mortality and a 90% reduction in incidence, compared with the 2015 baseline.⁴

Purpose Statement

This case study examined Egypt's HCV control strategy from 2006 to the present, particularly 2014–2020. We aimed to describe Egypt's HCV control strategy using the Kingdon framework⁵ to understand how the problem, policy, and political streams merged to create the window of opportunity for a successful HCV elimination program. We

examined the factors and challenges associated with the HCV elimination program's creation, implementation, and results. We then summarized the lessons learned from the program. These lessons can inform HCV elimination plans in other low- and middle-income countries.

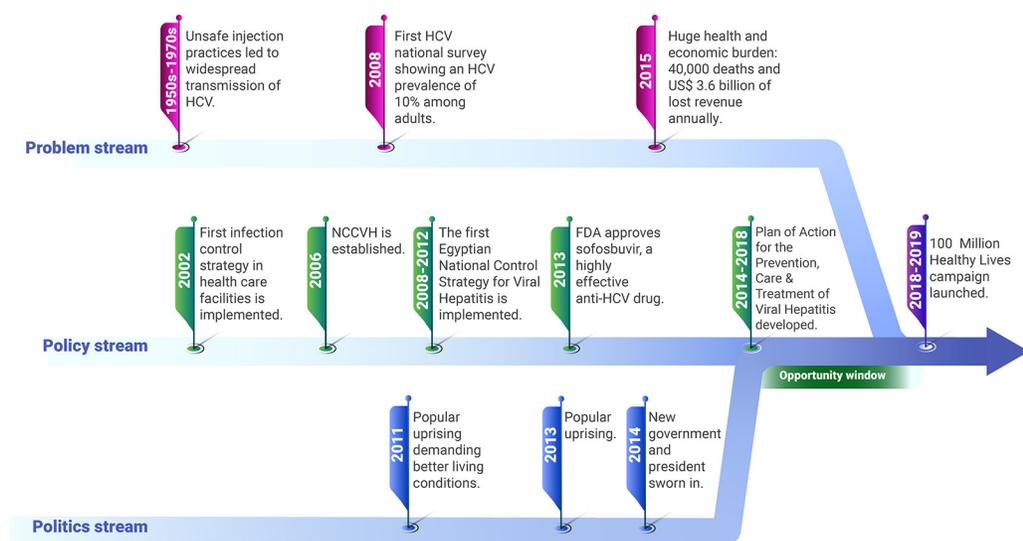
We conducted an extensive review of documents published from 2006 to 2020 and supplemented this review by consulting key stakeholders. Data sources included World Bank reports; World Health Organization documents; official Egyptian governmental publications; National Committee for Control of Viral Hepatitis (NCCVH) strategy and action plans; published statements by key stakeholders involved with the program, including the Ministry of Health and Population (MOHP), NCCVH members, WHO director-general, and frontline workers; and peer-reviewed publications (Box 1). To identify peer-reviewed publications, we conducted a PubMed search using the search terms "Egypt" and "Hepatitis C." We used an iterative process to review official and peer-reviewed publications, in which newly collected data were extracted, discussed, and categorized by the coauthors. We discussed the pertinence of specific events and data points as they related to the 3 streams of the Kingdon framework and to the lessons learned from the Egyptian experience until consensus was reached.

Figure 1 presents a summary of the key moments in each of the 3 streams that led to defining elimination as a goal in 2018 and 2019. The following sections describe these streams in detail.

Box 1. Key Stakeholders Involved in Egypt's Hepatitis C Virus Elimination Program, 2016–2021

- National Committee for Control of Viral Hepatitis (NCCVH): Established in 2006, the NCCVH's goals include monitoring hepatitis C virus (HCV) incidence and prevalence, developing a strategy to combat the spread of HCV, and establishing a wide network of specialized centers to provide integrated care for HCV patients. The NCCVH comprises hepatology and public health experts from Egypt and abroad and is divided into an advisory board and an executive working group.
- Egyptian government and political leadership: The Ministry of Health and Population played a major role in rolling out HCV prevention and treatment strategies, as well as establishing training and education activities for thousands of health care personnel.
- Egyptian public: HCV has been a mainstream health concern for many Egyptians since the late 1900s. A serologic survey conducted as part of the 2008 Demographic and Health Survey showed that 1 in 10 Egyptian adults aged 15–59 years had chronic HCV infection.³
- Nongovernmental organizations (NGOs) and media: Several NGOs contributed to HCV screening efforts, community-based education, and supporting the treatment costs for uninsured patients. The local media played a major role in raising awareness about HCV and promoting screening and treatment efforts.
- Foreign organizations: The U.S. Centers for Disease Control and Prevention, the U.S. Naval Medical Research Unit 3 based in Cairo, and the Pasteur Institute of France provided technical support in drafting the national HCV control strategies.
- World Health Organization: The Global Health Sector Strategy on Viral Hepatitis 2016–2021 document⁴ endorsed by the World Health Assembly served as a blueprint for Egypt's HCV elimination strategy starting in 2017.
- World Bank: The World Bank played 2 key roles in support of Egypt's HCV control program: (1) assisting with feasibility studies of various HCV elimination programs^{6,7}; and (2) providing monetary assistance in the form of loans to the health care sector.⁸
- Pharmaceutical and medical device companies: The Egyptian government worked closely with several local and international companies to ensure adequate supply of HCV testing supplies and therapeutic drugs.

FIGURE 1. Timeline of the 3 Streams of the Kingdon Framework That Led to Defining Elimination of Hepatitis C Virus Goal



Abbreviations: FDA, U.S. Food and Drug Administration; HCV, hepatitis C virus; NCCVH, National Committee for Control of Viral Hepatitis.

Problem Stream

The origins of the HCV epidemic in Egypt can be traced back to the 1950s–1980s, during a mass treatment campaign for the parasitic illness schistosomiasis, or bilharzia. The use of inadequately sterilized, reusable needles during this campaign led to widespread transmission of HCV.^{9,10} Over the last 2 decades, the majority of new HCV cases in Egypt were attributed to HCV transmission in health care facilities related to blood transfusions and suboptimal infection control techniques.^{11–13} Until 2007, no large nationwide HCV prevalence studies had been conducted. Government insurance schemes did not cover the cost of HCV therapy, and infection control policies were limited. In a 2012 presentation, NCCVH board member Dr. Gamal Esmat stated¹⁴:

Unfortunately, till 2007, we did not have a national control program for control of viral hepatitis.

The 2008 Demographic and Health Survey revealed that 15% of Egypt's adult population had antibodies to HCV (seropositive), indicating they had been infected with the virus, and 1 in 10 Egyptians aged 15–59 years had chronic HCV infection.³ A second survey in 2015 estimated that 7% of Egypt's population aged 19–65, roughly

4.1 million people, had chronic HCV infection.¹⁵ This number included 750,000 previously diagnosed individuals who were on a waitlist pending access to treatment.¹⁶ That year, the burden of HCV accounted for 40,000 deaths,⁷ or 7.6% of all deaths, and a loss in life expectancy of approximately 1.8 years for men and 1.0 year for women. The World Bank estimated the total economic burden of HCV in Egypt to be US\$3.81 billion, equivalent to 1.4% of the country's total GDP, in 2015.^{7,17}

Medical and public health experts recognized the HCV epidemic in Egypt as of the early 2000s. Yet, several studies suggest a poor understanding of HCV modes of transmission and therapeutic options among Egyptians.^{18,19} By the end of 2011, only 2.8% of patients with HCV had started treatment, and only 1.67% of the total number achieved sustained virologic response (cure).⁹ Early on, the NCCVH faced several challenges, including high costs, extensive adverse effects, and low cure rates of therapies available at the time.

Policy Stream

Although Egypt's response to HCV as a public health crisis intensified significantly in 2014, much of the experience and physical infrastructure of the



Advertisements in Arabic used in communication strategy for hepatitis C virus that conveyed 5 messages. “It is either us, or hepatitis virus C: (1) Don’t use personal items that are not yours; (2) It is ok to have contact with HCV patients; (3) Pills are safer than injections; (4) Consult with a physicians and test for HCV; and (5) HCV treatment is available and effective.” © World Health Organization Regional Office for the Eastern Mediterranean

HCV control program had been established nearly a decade earlier. The NCCVH was established in 2006 to combat the spread of HCV and establish the National Network of Treatment Centers (NNTC) to provide specialized, integrated care for HCV patients. In 2008, the NCCVH published the first Egyptian National Control Strategy for Viral Hepatitis.¹⁴ The strategy comprised several main goals for 2008–2012:

- Detect the prevalence and incidence of HCV and hepatitis B virus (HBV) infections.
- Reduce the prevalence of chronic HCV and HBV infections in the 15–30 age group by 20% of 2008 levels by 2012.
- Expand access to treatment to within 100 km for all Egyptians and treat 50% of individuals needing treatment by 2012.
- Continue to produce high-quality scientific research.
- Ensure programmatic sustainability.

The plan achieved several of its goals:

- The government acknowledged the magnitude of the HCV problem in Egypt, as supported by publishing the 2008 Demographic and Health Survey, which showed an HCV prevalence of 10% among Egyptians aged 15 to 59 years.
- National guidelines for the treatment of chronic HCV were established.
- Between 2007 and 2010, 21 specialized HCV treatment centers were established.
- Governmental funding for HCV treatment programs exceeded 90%.

The strategic plan was a modest success—only about 191,000 Egyptians had started treatment.²⁰ At the time, treatment modalities included a combination of pegylated interferon and ribavirin given over an extended period. These treatments were expensive, with extensive adverse effects and a low cure rate of about 60%. The underlying investment of US\$80 million in subsidized HCV treatment over 4 years was inadequate.²¹ From 2008 to 2012, the MOHP emphasized HCV treatment more than prevention of transmission among high-risk groups.²²

In December 2013, the panorama of HCV treatment changed dramatically when the U.S. Food and Drug Administration approved sofosbuvir, a new class of HCV direct-acting antiviral drug. Sofosbuvir in combination with other antivirals offered up to a 90–95% sustained virologic

response, or cure rate, using a simple and well-tolerated 12-week oral regimen.²³ However, the retail price of this treatment was US\$84,000 per individual case. Gilead, the pharmaceutical company that owned the patent for sofosbuvir, applied for a proprietary license in Egypt. The application was initially rejected, forcing the company to enter negotiations with the Egyptian government. These negotiations resulted in a voluntary licensing agreement in March of 2014. Sofosbuvir would be sold to the Egyptian government at a 99% discount, or US\$900 per treatment course.²⁴ Eventually, sofosbuvir was licensed to several Egyptian pharmaceutical companies. Between 2015 and 2018, it cost just under US\$84 for the typical 12-week treatment course.²⁵

Egypt's second HCV national strategy, covering 2014–2018, is referred to as the Plan of Action for the Prevention, Care & Treatment of Viral Hepatitis.²⁶ The plan aimed to build on the success of clinical trials for direct-acting antiviral drugs, to overcome the limitations of the previous strategy by emphasizing reduced HCV transmission via increased prevention and education, and to ensure access to safe and effective care and treatment for all Egyptians. The 2 main goals of this plan were to: (1) prevent HCV transmission and treat HCV patients on the treatment waitlist, and (2) offer treatment to 300,000 patients annually. These goals were implemented along 5 predefined axes (Table).^{27–33}

Political Stream

Egypt experienced popular uprisings in 2011 and 2013, leading to changes in the political regimen, including a new government and president in 2014. The prospect of significantly reducing the burden of HCV in Egypt was seen by the new administration as a means to galvanize the country around a common goal of improving public health. At the time, elimination of HCV seemed far-fetched, so the administration's emphasis was on offering treatment to previously confirmed HCV patients who were still awaiting treatment and limiting HCV transmission.

In 2016, the 194 WHO member states, including Egypt, committed to eliminating viral hepatitis as a public health threat by 2030. The same year, the Egyptian government consulted with the World Bank to model several scenarios. One such scenario—the “current path”—screened 5% of the population per year in addition to continuing demand-driven treatment. An HCV elimination scenario screened 20% of at-risk individuals per

TABLE. Five Axes for Implementing Egypt's Viral Hepatitis Plan of Action, 2014–2018

Axis	Actions
Axis 1: Strengthening surveillance to detect viral hepatitis transmission and disease	The Demographic and Health Survey conducted in 2015 updated the HCV prevalence estimate in adults aged 15–59 years from 10% to 7%, or approximately 4.1 million Egyptians. The survey provided a detailed breakdown of HCV prevalence in rural versus urban areas, between various administrative governorates, and across different socioeconomic strata.
Axis 2: Improving blood products safety to reduce transmission of viral hepatitis	Transmission of HCV via blood product transfusion is among the most common modes of HCV infection in Egypt. Policies to prevent such transmission were implemented, and nucleic-acid testing for all blood products in Egypt became mandatory in private and public health care facilities. Screening for HCV for all pregnant women also became mandatory.
Axis 3: Promoting infection control practices to reduce transmission of viral hepatitis	MOHP, WHO, CDC, and the biomedical research lab of the U.S. Navy located in Cairo, Egypt, updated national infection control policies and guidelines and launched a national training and auditing campaign with health care workers and facilities to ensure adherence to infection control policies. ²⁵ This comprehensive plan launched in 2002 and included policies for prevention of transmission in health care facilities and dialysis centers. It was relaunched in 2014 as part of the Plan of Action for the Prevention, Care & Treatment of Viral Hepatitis. It had a significant impact on hospital-acquired HCV transmission. Among dialysis patients, the annual HCV incidence rate declined from 28% in 2001 to 6% in 2012 ²⁶ and just 1.6% in 2015. ²⁷
Axis 4: Educating providers and communities to increase awareness about viral hepatitis and its prevention	Nongovernmental organizations contributed to community-based education and test-and-treat projects seeking to raise awareness and promote behavioral changes that reduce HCV transmission. ²⁸ WHO provided technical support to the MOHP in drafting a 5-year communication strategy and implementation plan to combat HCV. ²⁹ The communication strategy focused on 5 main messages, and 5 television outlets, 5 radio outlets, and online social media were used to spread the message. A library of the visual advertisements and messaging is available on the MOHP-sponsored YouTube channel. ³⁰
Axis 5: Improving care and treatment to prevent liver disease and cancer	In September 2014, the NCCVH debuted an online portal for people living with HCV to register for treatment. Using this portal, people could register for treatment by inputting basic demographic data, their national identification number, and a call-back number. Within 24 hours, an operator from the call center would call to set up an appointment and give an overview of expectations for the upcoming visit. In the first month after opening the online portal, over 500,000 people registered to receive HCV treatment. To manage this influx of patients, the number of comprehensive treatment centers across the 27 administrative governorates was increased from 21 centers in 2010 to 54 centers in 2014, with less than 50 km between any two centers. By 2018, the number of centers expanded to 121. ³¹ The treatment centers, which formed the NNTC for HCV, were integrated care units that provide all required services for HCV management. A well-trained, multidisciplinary team of medical doctors, pharmacists, nurses, and administrative staff participated in the assessment and follow-up of each patient. By September 2018, 2.4 million people with HCV had been treated using various sofosbuvir-based direct-acting antiviral drug combinations for 12 or 24 weeks, depending on the presence or absence of cirrhosis (liver failure). ^{22,32} The number of patients treated reflected the number of previously recognized cases awaiting access to treatment and newly diagnosed cases due to expanded screening.

Abbreviations: CDC, U.S. Centers for Disease Control and Prevention; HCV, hepatitis C virus, MOHP, Ministry of Health and Population; NCCVH, National Committee for Control of Viral Hepatitis; NNTC, National Network of Treatment Centers; WHO, World Health Organization.

year, positive cases would be offered treatment, and the entire population would be covered by 2022.^{6,7} The elimination scenario would cost US \$530 million more in the short term, but it eventually would reduce the health budget by an

estimated \$60 million every year between 2023 and 2030 by preventing HCV-related complications. Building on the success of the 2014–2018 HCV national strategy the government shifted its strategy from HCV control to elimination.

■ THE 3 STREAMS MERGE: 100 MILLION HEALTHY LIVES CAMPAIGN

In late 2018, the government launched the 100 Million Seha (100 Million Healthy Lives) campaign under the patronage of Egyptian President Abdel-Fattah ElSisi. The campaign aimed to eliminate HCV as a public health threat.³⁴ It included free voluntary HCV screening to all residents of Egypt aged 18 years and older, or about 62 million people, and offered free treatment for confirmed cases. Between October 2018 and April 2019, more than 60,000 health care personnel (e.g., doctors, nurses, pharmacists, lab technicians, and data entry employees) participated in the campaign at more than 5,000 HCV screening or treatment sites.³⁵

Implementation

Funding Sources

The Egyptian government has substantially increased health care spending over the past decade. Between 2010 and 2017, governmental health care spending increased from 4.3% to 5.2% of total government spending, a per-capita increase from US\$141 to US\$205.³⁶ The main funds for the HCV elimination program involved governmental funding for the MOHP to support screening and treatment of uninsured individuals. The Transforming Egypt's Healthcare System Project, a 5-year project that commenced in 2018, is a US\$992.5 million government plan targeting improvement in the quality of primary, secondary, and family planning health care services, as well as the prevention and treatment of HCV.⁸ From the total budget of the project, US\$129.6 million was assigned to HCV screening, US\$130.6 million to HCV treatment, and US\$50 million to the National Blood Transfusion Services system to improve screening of blood products for transmissible infections. Later the same year, the World Bank approved a US\$530 million loan to support the Transforming Egypt's Healthcare System Project.⁸

Monitoring and Quality Assurance Mechanisms

One of the accomplishments of the first Egyptian National Control Strategy for Viral Hepatitis between 2008 and 2012 was the establishment of a closed virtual private network to connect the NNTC to the NCCVH head office to collect real-time patient data from a unified case report. The virtual private network facilitated clinical and operational monitoring by NCCVH in real time so that case volume and treatment quality could be

monitored at the regional and center levels.³⁷ Additionally, it allowed for instant troubleshooting to overcome logistical challenges. The integration of health information systems reduced paperwork costs, which accounted for 65% of patients' out-of-pocket costs.³⁵

The NCCVH treatment regimens have changed over time to reflect the most recent data, availability, and cost-effectiveness of various treatment regimens. A study covering all HCV patients in Egypt treated between October 2014 and March 2016 compared and contrasted the treatment regimens of more than 330,000 patients to identify the most effective ones.²³ The data aided in choosing the most effective regimens for use when HCV elimination became a stated goal.

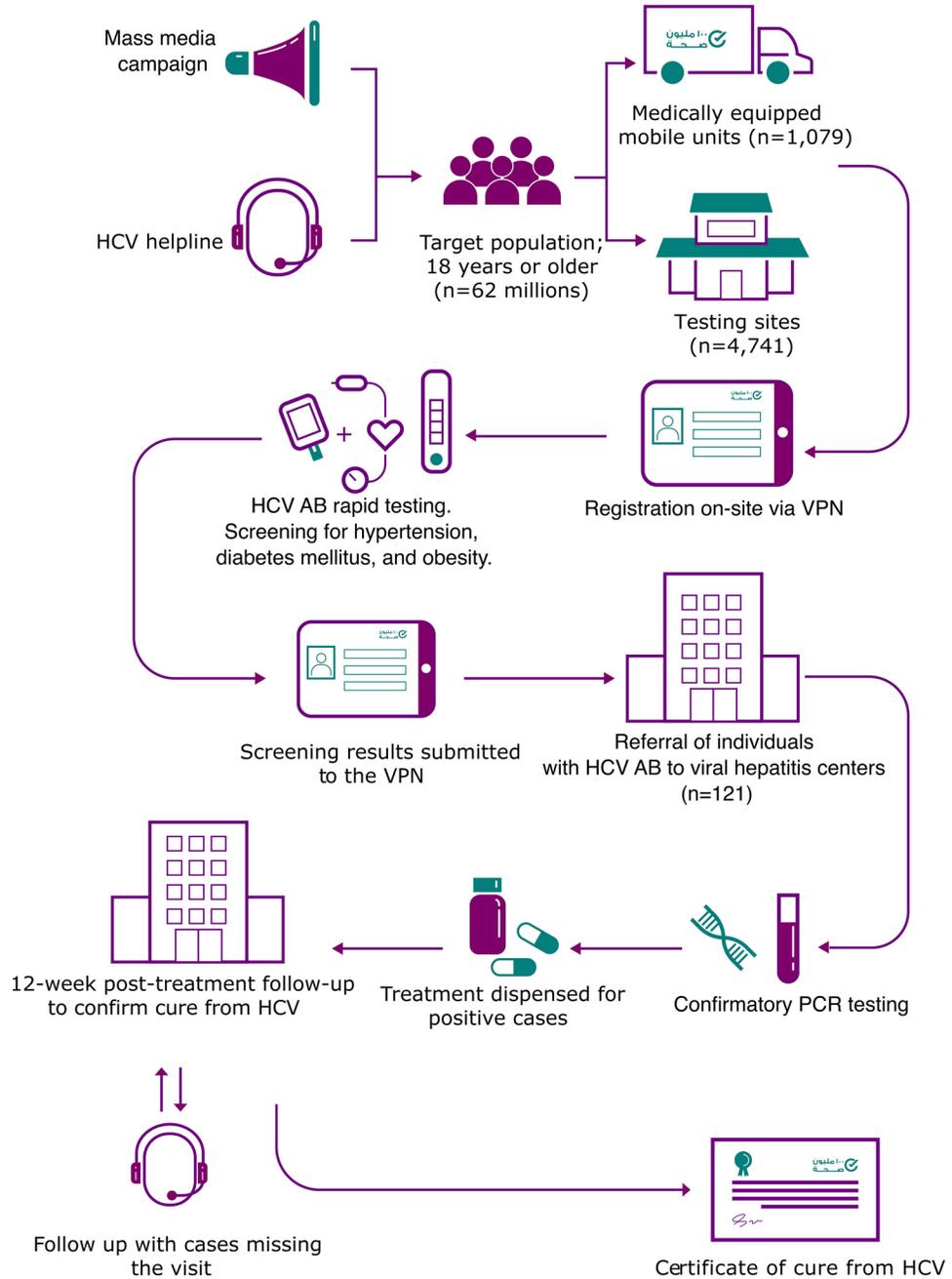
Coverage

Figure 2 illustrates the flow of individuals reached by the 100 Million Health Lives Campaign. Patients diagnosed with but not treated for HCV registered at a website (stophcv.org). Within 24 hours of registering, the person received a call from an operator to schedule an appointment at a nearby care center within the NNTC. Individuals with no known history of HCV also could be screened for HCV without an appointment at any of the 5,820 testing sites (including 1,079 mobile units) throughout the country.³⁵ These individuals were tested onsite and typically received their results within 20 minutes. Individuals with positive screening tests were referred to the nearest NNTC member for confirmatory testing. Confirmed HCV cases were referred for treatment, which was typically approved within 1 week. All patients who were treated for HCV were asked to return to the treatment center after completing the 12-week therapy to evaluate their sustained virologic response (cure status) of HCV.

Adaptations

An important lesson learned between 2014 and 2016 was that prioritization based on the presence of advanced liver fibrosis (damage), which required patients to undergo a liver biopsy, caused significant backlogs and impaired enrollment in the treatment program.²³ Initially, the limited supplies of medication, high costs, and capacities of treatment centers made prioritization necessary. As the availability of drugs and treatment centers increased, however, individuals with HCV at all stages of fibrosis, including no evidence of fibrosis, were treated. At that time, Egypt became

FIGURE 2. Flow of Individuals Screened for Hepatitis C Virus Through by the 100 Million Health Lives Campaign in Egypt



Abbreviations: AB, antibody; HCV, hepatitis C virus; PCR, polymerase chain reaction; VPN, Virtual Private Network.



A medically equipped vehicle used for screening individuals for hepatitis C virus near a construction site in South Sinai, Egypt. © 2018 Tahsin Bakr

the first country globally to treat all people with HCV, regardless of their fibrosis stage.

Egypt's HCV elimination efforts intensified with the inauguration of the 100 Million Healthy Lives campaign. Efficiency became a priority. To screen 60 million eligible Egyptians, the campaign was divided into 3 phases, each comprising 7 to 11 administrative governorates, at 5,820 testing sites throughout the country.³⁵ To serve the 57% of Egyptians who live in rural areas,³⁸ 1,079 medically equipped vehicles were used to reach remote and underserved areas.

The overall rate of compliance with post-treatment follow-up visits increased from 28% in 2014 to 75.4% in 2016.²³ Compliance reached 85% during the 100 Million Health Lives Campaign. Several methods were adopted to encourage return visits to evaluate patients' sustained virologic response. These methods included issuing a "certificate of cure" to those who had a negative viral load test at 12-weeks post-treatment. To encourage patients to return for evaluation of their sustained virologic response, the HBV vaccine was offered free of cost at the end of HCV treatment. Patients with HCV but no history of HBV were given the first dose of the HBV vaccine at their last HCV treatment appointment. They were asked to return 12 weeks later for the second HBV vaccine dose as part of the HCV post-treatment follow-up visit intended to confirm sustained virologic response. A professional call center was contracted to contact patients who did not show up for treatment appointments and treated patients who did not

show for their 12-week post-treatment evaluation. The call center recorded the reason for their "no-show" and set new appointments if needed.

To encourage HCV screening among low-risk young adults who might be reluctant to get tested, the screening sites additionally offered screening for diabetes, hypertension, and obesity to attract individuals who desired a general health check. All screening data were electronically recorded. Individuals with abnormal blood pressure or blood glucose levels were referred to the nearest primary care unit.

Acceptability

The 100 Million Health Lives campaign was widely accepted by the public for several reasons:

- The high magnitude of effort was perceived by the public as a serious attempt to eliminate HCV as a public health threat.
- Conducting the program under the patronage of Egyptian President Abdel-Fattah El-sisi signaled that it was a national priority.
- Major political figures participated in the screening campaign, which had mass media coverage.
- Screening sites offered widespread availability, operating 12 hours per day 7 days per week, to overcome logistical challenges that many individuals who were interested in screening might face.
- The mass media campaign that accompanied the launch of the 100 Million Healthy Lives campaign focused on educating the public on

HCV and reducing the stigma associated with HCV diagnosis.

- Screening and treatment for HCV, as well as follow-up visits, were free for participants.

Program Evaluation Results of the Campaign

When the 100 Million Health Lives campaign concluded, the Egyptian MOHP announced that nearly 50 million Egyptians and 36,000 foreign residents of the intended 62 million were screened for HCV.³⁵ Of those, 2.2 million individuals were seropositive, indicating HCV exposure or chronic infection, and referred for confirmatory testing. Of those referrals, 1.6 million patients had confirmed chronic HCV infection. Many were unaware of their status, as noted by a 47-year-old patient from Alexandria who tested positive:

I didn't know I was infected with hepatitis C. I had no symptoms.

Over the course of the 7-month campaign, 900,000 confirmed cases received treatment.³⁹ An additional 700,000 confirmed cases were treated after the conclusion of the campaign. The rate of sustained virologic response (cure) was 98%.²³ In February 2020, Dr. Hala Zayed of the Ministry of Public Health announced that between March

2014 and January 2020, 4 million Egyptians had been treated for HCV through the NNTC.⁴⁰ Figure 3 shows the care cascade describing patient retention across sequential stages of the 100 Million Health Lives campaign and the subsequent continuum of care for diagnosed HCV cases.

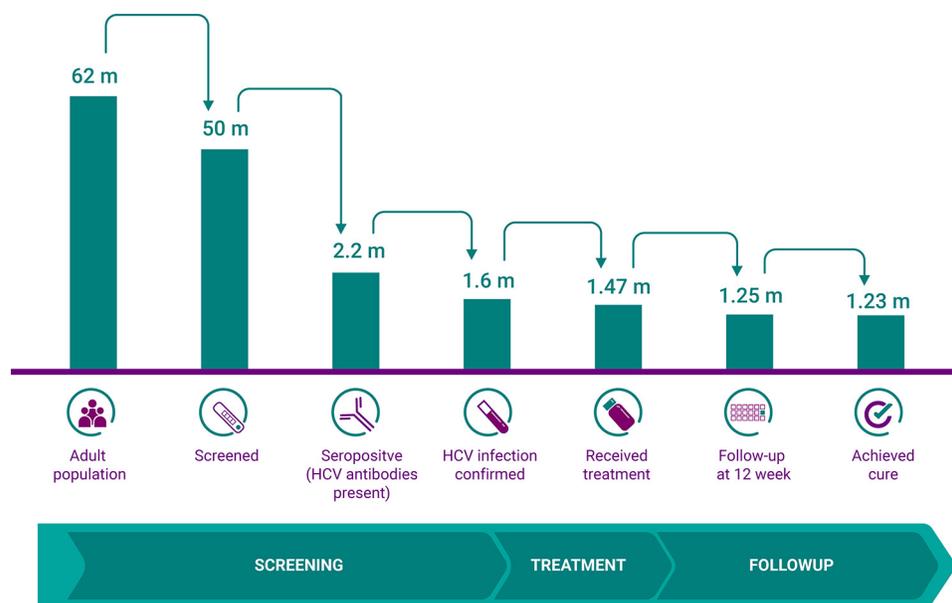
After screening all willing adults for HCV, the 100 Million Healthy Lives campaign shifted its attention to HCV screening of students aged 6 to 18, after obtaining consent from their legal guardians. Khaled Megahed, spokesperson for the MOHP, stated that 3.8 million students across Egypt were screened between May 2019 and January 2020.⁴¹ In June 2020, Dr. Hala Zayed announced that Egypt had become the first country in the world to overcome hepatitis C⁴²:

Egypt proved that community-based screening of hepatitis viruses is not impossible.

Costs

The Egyptian government procured a license to locally manufacture direct-acting antiviral drugs, reducing the price for a typical 12-week treatment course to US\$84 between 2015–2018 and then further to US\$54 in 2018. The government also purchased HCV screening kits (SD Bioline HCV Abbott) at costs as low as US\$0.60 per kit and real-time quantitative polymerase-chain reaction

FIGURE 3. Hepatitis C Virus Screening and Case Cascade Used by Egypt's 100 Million Health Lives Campaign



Abbreviation: HCV, hepatitis C virus.

assays (Cobas AmpliPrep/CobasTaqMan HCV Test, Roche Diagnostics) at US\$4.80 per test.⁴³ This decreased the total cost of identifying a patient with HCV viremia to US\$85.41 and the cost of identifying and curing a patient to US\$130.62.⁴³ Testing and treatment were fully funded by the state, irrespective of one's financial ability or insurance coverage. Of all patients treated, 58% were covered by the NCCVH, 24% by the Egyptian Health Insurance Organization, and 15% paid out-of-pocket to secure brand name direct-acting antiviral drug combinations.³² The testing and treatment component of the 100 Million Healthy Lives campaign had a direct total cost of US\$207.1 million.⁴³ The total cost of the HCV elimination effort since 2014 has not been made public, but 2017 World Bank projections estimate the excess cost of HCV elimination incurred by the Egyptian health care sector at US\$530 million.⁷

■ SYNTHESIS

Lessons Learned

The main lessons gleaned from Egypt's HCV control program over the past decade and a half can be viewed through the lens of WHO's Global Health Sector Strategy on Viral Hepatitis 2016–2021 to achieve the 2030 elimination target (Box 2). WHO Director-General Dr. Tedros Adhanom Ghebreyesus visited the command center for the 100 Million Healthy Lives campaign. In response to that visit, he tweeted in August 2019⁴⁴:

During my visit to #Egypt I saw three things that are key to success: speed, scale and quality. This is a great example to follow on the way to achieve #HealthForAll!

- **Speed:** A central-level commitment to swift elimination of HCV helped make this achievement possible. Over 7 months, nearly 50 million Egyptians were screened. Between 2014 and 2020, more than 4 million Egyptians were treated for HCV. This rapidity helped galvanize governmental agencies and the public around a common goal with a target date.
- **Scale:** The Egyptian government capitalized on a strong public health infrastructure and a highly centralized command system to scale up the campaign on a national level, mobilizing all of its resources to that end. It also took advantage of mass purchasing to drive prices down.
- **Quality:** The NCCVH used an evidence-based, adaptable approach to HCV elimination built on locally and internationally produced scientific research. The MOHP used information software systems to ensure equity and efficacy of HCV screening and treatment across the population.

The Egyptian experience with HCV elimination can serve as a model for other low- and middle-income countries with high HCV burdens. The Coalition for Global Hepatitis Elimination, launched in July 2019, provides services and resources to assist in the planning, implementation, and evaluation of national and sub-national programs to eliminate HCV transmission and disease.⁴⁵

At the 2019 African Hepatitis Summit, Egyptian Minister of Health and Population Dr. Hala Zaid announced that Egypt would provide HCV testing and treatment for 1 million people in 14 African countries⁴⁶:

Box 2. Key Lessons Gleaned From Egypt's Hepatitis C Virus Control Program, 2014–2020

- **Information for focused action:** National disease surveys are key to understanding the magnitude and progression of public health problems. Use of information technology systems is essential for accurate monitoring and success of implemented care policies.
- **Interventions for impact:** A strong public health system infrastructure and steadfast political commitment are essential for providing a package of high-impact interventions based on local and international expertise.
- **Delivering for equity:** A commitment to reaching out to the sectors of society that are most likely to be overlooked and to adapting the approach to those sectors is essential to ensure quality.
- **Financing for sustainability:** Increasing governmental health care spending and the support of international organizations concerned with health are important steps for the sustainability of national-level healthcare programs. Mass purchasing can reduce costs. Upfront spending can translate to downstream savings in healthcare spending and economic revenue.
- **Innovation for acceleration:** Locally produced scientific research, evidence-based decisions, and program adaptability are essential in any large health care program.

Egypt has pledged to provide technical support, expertise and screening software, as well as free treatment for 1 million of our African sisters and brothers with hepatitis C for 3 months as part of our role on the continent.

In a June 2020 news report, the Egyptian MOHP announced that since the inception of the program, 30,632 African citizens from South Sudan, Chad, and Eritrea had been tested for hepatitis C, and 376 citizens had received free treatment.⁴⁷

Program Weaknesses

Some challenges to the success of the elimination effort included low post-treatment follow-up testing rates and people not getting screened. Nearly 12.5 million Egyptian adults (20% of eligible individuals) were not screened. Although the reason for this non-participation is unknown, a potential explanation is that 10 million Egyptians live and work abroad. Additionally, although infection control measures in health care settings have significantly improved over the past decade, several areas in the domain of primary prevention have not been adequately addressed, such as limiting HCV transmission via IV drug use, sex workers, and barbershops.

Sustainability

The NCCVH plans to sustain HCV-related gains by instituting the following strategies (email communication with NCCVH board, December 11, 2021):

- Screening of all pregnant women for HCV and HBV
- HCV screening of all first graders in preparatory school and students commencing university education over the next 5 years
- HCV and HBV rescreening and treatment for at-risk individuals who missed the national screening program, including persons who inject drugs, who are incarcerated, and who are on dialysis
- Establishment of a harm-reduction program for persons who inject drugs, including syringe distribution
- Establishment of a national follow-up program for the nearly 400,000 people who have cirrhosis or history of cirrhosis to promote early detection of liver cancer and decompensation, as HCV among these individuals can be more difficult to cure.

CONCLUSION

Between 2014 and 2020, Egypt screened more than 50 million and treated 4 million residents for chronic HCV, with the goal of eliminating HCV as a public health threat. Five key elements led to the success of this elimination program: (1) a reliable epidemiologic surveillance to quantify and monitor public health threats; (2) a robust public health care infrastructure; (3) inclusive care that reached all sectors of society; (4) political commitment to public health through increased health care spending and a comprehensive long-term national control strategy; and (5) innovative scientific research and use of information technology. Egypt is poised to be the first country in the world to eliminate HCV within its borders. The lessons learned from this experience will inform the elimination plan of other low- and middle-income countries with high HCV burden.

REFERENCES

1. World Health Organization (WHO). *Global Hepatitis Report 2017*. Accessed March 1, 2021. <https://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/>
2. Blach S, Zeuzem S, Manns M, et al. Polaris Observatory HCV Collaborators. Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study. *Lancet Gastroenterol Hepatol*. 2017;2(3):161–176. [CrossRef](#). [Medline](#)
3. El-Zanaty F, Way A. *Egypt Demographic and Health Survey 2008*. Egypt Ministry of Health, El-Zanaty and Associates, Macro International; 2009. Accessed March 1, 2021. <https://dhsprogram.com/pubs/pdf/FR220/FR220.pdf>
4. World Health Organization (WHO). *Global Health Sector Strategy on Viral Hepatitis, 2016–2021*. Accessed March 1, 2021. <https://www.who.int/hepatitis/strategy2016-2021/ghss-hep/en>
5. Kingdon J. *Agendas, Alternatives, and Public Policies*. Little Brown; 1984.
6. World Bank. *Eliminating Hepatitis C from Egypt: 2017 Update on Current Trends and Policy Recommendations*. 2017. World Bank; 2017. Accessed March 1, 2021. <http://documents1.worldbank.org/curated/en/164381517333701631/pdf/123068-WP-P157533-PUBLIC-Eliminating-Hepatitis-C-from-Egypt-2017-Update.pdf>
7. World Bank. *Burden and Response: An Economic Analysis 2017*. World Bank; 2017. Accessed March 1, 2021. <http://documents.worldbank.org/curated/en/972381517328583384/Burden-and-response-an-economic-analysis-2017>
8. World Bank. *Transforming Egypt's Healthcare System Project*. Accessed March 1, 2021. <https://projects.worldbank.org/en/projects-operations/project-detail/P167000>
9. Rao MR, Naficy AB, Darwish MA, et al. Further evidence for association of hepatitis C infection with parenteral schistosomiasis treatment in Egypt. *BMC Infect Dis*. 2002;2(1):29. [CrossRef](#). [Medline](#)
10. Frank C, Mohamed MK, Strickland GT, et al. The role of parenteral antischistosomal therapy in the spread of hepatitis C virus in Egypt. *Lancet*. 2000;355(9207):887–891. [CrossRef](#). [Medline](#)
11. Arafa N, El Hoseiny M, Rekecewicz C, et al. Changing pattern of hepatitis C virus spread in rural areas of Egypt. *J Hepatol*. 2005; 43(3):418–424. [CrossRef](#). [Medline](#)

12. Mostafa A, Taylor SM, el-Daly M, et al. Is the hepatitis C virus epidemic over in Egypt? Incidence and risk factors of new hepatitis C virus infections. *Liver Int.* 2010;30(4):560–566. [CrossRef](#). [Medline](#)
13. Paez Jimenez A, Sharaf Eldin N, Rimlinger F, et al. HCV iatrogenic and intrafamilial transmission in Greater Cairo, Egypt. *Gut.* 2010;59(11):1554–1560. [CrossRef](#). [Medline](#)
14. Esmat G. *Evaluation of the National Program for Treatment of Chronic HCV in Egypt.* 2012. Accessed March 1, 2021. <http://www.hepbcpa.org/wp-content/uploads/2012/08/Esmat-A-nation-prog-for-treating-chronic-HCV-in-Egypt.pdf>
15. El-Zanaty F. *Egypt Health Issues Survey 2015.* Ministry of Health and Population, ICF; 2016. Accessed March 1, 2021. <https://dhsprogram.com/pubs/pdf/FR313/FR313.pdf>
16. Gomaa A, Allam N, Elsharkawy A, et al. Hepatitis C infection in Egypt: prevalence, impact and management strategies. *Hepat Med.* 2017;9:17–25. [CrossRef](#). [Medline](#)
17. Estes C, Abdel-Kareem M, Abdel-Razek W, et al. Economic burden of hepatitis C in Egypt: the future impact of highly effective therapies. *Aliment Pharmacol Ther.* 2015;42(6):696–706. [CrossRef](#). [Medline](#)
18. Sultan NY, YacoubMayet A, Alaqeel SA, et al. Assessing the level of knowledge and available sources of information about hepatitis C infection among HCV-infected Egyptians. *BMC Public Health.* 2018;18(1):747. [CrossRef](#). [Medline](#)
19. Saleh DA, Amr S, Jillson IA, et al. Knowledge and perceptions of hepatitis c infection and pesticides use in two rural villages in Egypt. *BMC Public Health.* 2014;14(1):501. [CrossRef](#). [Medline](#)
20. Elgharably A, Gomaa AI, Crossey MME, et al. Hepatitis C in Egypt—past, present, and future. *Int J Gen Med.* 2016;10:1–6. [CrossRef](#). [Medline](#)
21. Egyptian Initiative for Personal Rights. *HCV Treatment in Egypt – Why Cost Remains a Challenge.* Economic and Social Justice Unit; 2014. Accessed March 1, 2021. http://www.eipr.org/sites/default/files/pressreleases/pdf/hcv_treatment_in_egypt.pdf
22. Abdel-Wahab MF, Esmat G, Strickland GT, et al. High seroprevalence of hepatitis C infection among risk groups in Egypt. *Am J Trop Med Hyg.* 1994;51(5):563–567. [CrossRef](#). [Medline](#)
23. Elsharkawy A, El-Raziky M, El-Akel W, et al. Planning and prioritizing direct-acting antivirals treatment for HCV patients in countries with limited resources: Lessons from the Egyptian experience. *J Hepatol.* 2018;68(4):691–698. [CrossRef](#). [Medline](#)
24. Hill A, Simmons B, Gotham D, et al. Rapid reductions in prices for generic sofosbuvir and daclatasvir to treat hepatitis C. *J Virus Erad.* 2016;2(1):28–40. [CrossRef](#). [Medline](#)
25. Iyengar S, Tay-Teo K, Vogler S, et al. Prices, costs, and affordability of new medicines for hepatitis C in 30 Countries: an economic analysis. *PLoS Med.* 2016;13(5):e1002032. [CrossRef](#). [Medline](#)
26. Ministry of Health and Population. *Plan of Action for the Prevention, Care & Treatment of Viral Hepatitis, Egypt 2014–2018.* 2014. Accessed March 1, 2021. http://www.emro.who.int/images/stories/egypt/VH_Plan_of_Action_FINAL_PRINT1.pdf
27. Centers for Disease Control and Prevention (CDC). Progress toward prevention and control of hepatitis C virus infection—Egypt, 2001–2012. *MMWR Morb Mortal Wkly Rep.* 2012;61(29):545–549. [Medline](#).
28. Egypt: Significant increase in the rate of application of infection control methods. [Webteb](#).
29. Shiha G, Metwally AM, Soliman R, et al. An educate, test, and treat programme towards elimination of hepatitis C infection in Egypt: a community-based demonstration project. *Lancet Gastroenterol Hepatol.* 2018;3(11):778–789. [CrossRef](#). [Medline](#)
30. World Health Organization (WHO). Egypt launches national communication campaign on hepatitis C. Accessed March 1, 2021. <http://www.emro.who.int/egy/egypt-events/hepatitis-c-campaign.html>
31. 100 Million Seha. YouTube page. Accessed March 1, 2021. <https://www.youtube.com/channel/UCDkFTuNFCG-Crz8N7NvqYUQ>
32. Hepatitis C Treatment Centers. Ministry of Health and Population. Accessed March 8, 2021. <http://www.stophcv.eg>
33. Abdel-Razek W, Hassany M, El-Sayed MH, et al. Hepatitis C virus in Egypt: interim report from the world's largest national program. *Clin Liver Dis.* 2019;14(6):203–206. [CrossRef](#). [Medline](#)
34. 100 Million Healthy Lives. Ministry of Health and Population. Accessed March 1, 2021. <http://www.stophcv.eg/>
35. Zaid H, Salaheldeen A, Othman MM, Hassany, M et al. *Life Is Too Short With HCV and NCDS—100 Million Healthy Lives Initiative.* 2019:157–160. Accessed March 1, 2021. https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019-chapter12.pdf
36. World Bank. Domestic general government health expenditure (% of GDP) - Egypt, Arab Rep. World Bank. Accessed March 1, 2021. <https://data.worldbank.org/indicator/SH.XPD.GHED.GD.ZS?locations=EG>
37. Shousha HI, Said M, ElAkel W, et al. Assessment of facility performance during mass treatment of chronic hepatitis C in Egypt: enablers and obstacles. *J Infect Public Health.* 2020;13(9):1322–1329. [CrossRef](#). [Medline](#)
38. World Bank. Rural population (% of total population) - Egypt, Arab Rep. Accessed March 1, 2021. <https://data.worldbank.org/indicator/SP.RUR.TOTL.ZS?locations=EG>
39. Esmat G, El-Sayed MH, Hassany M, et al. National Committee for the Control of Viral Hepatitis. One step closer to elimination of hepatitis C in Egypt. *Lancet Gastroenterol Hepatol.* 2018;3(10):665. [CrossRef](#). [Medline](#)
40. Zayed DH. Egypt's 100 million lives campaign inspires the world. *Egypt Today.* February 9, 2020. Accessed March 1, 2021. <https://www.egypttoday.com/Article/1/81438/Egypt-s-100-Million-Healthy-Lives-Campaign-inspires-the-world>
41. 1.75 million prep. students examined as part of 100 Million Health Initiative: ministry. *Daily News Egypt.* January 13, 2020. Accessed March 1, 2021. <https://dailynewsegypt.com/2020/01/13/1-75-million-prep-students-examined-as-part-of-100-million-health-initiative-ministry/>
42. Egypt celebrates becoming hepatitis-free. *Ahram online.* July 29, 2020. Accessed March 1, 2021. <http://english.ahram.org.eg/NewsContent/1/64/375627/Egypt/Politics-/Egypt-celebrates-becoming-Hepatitisfree.aspx#:~:text=%E2%80%9CWe%20proved%20that%20community%2Dbased,the%20100%20Million%20Health%20initiative>
43. Waked I, Esmat G, Elsharkawy A, et al. Screening and treatment program to eliminate hepatitis C in Egypt. *N Engl J Med.* 2020;382(12):1166–1174. [CrossRef](#). [Medline](#)
44. @DrTedros. This is an incredible commitment from the President & an enormous [sic] public health campaign. During my visit to #Egypt I saw three things that are key to success: speed, scale and quality. This is a great example to follow on the way to achieve #HealthForAll! August 23, 2019. Accessed March 1, 2021. <https://twitter.com/DrTedros/status/1164891100907286528>
45. Coalition for Global Hepatitis Elimination. The Task Force for Global Health. Accessed March 1, 2021. <https://www.globalhep.org/>
46. World Health Organization (WHO). WHO welcomes Egypt's support to 14 African countries in their fight against hepatitis C. Accessed March 1, 2021. <http://www.emro.who.int/media/news/who-welcomes-egypts-support-to-14-african-countries-in-their-fight-against-hepatitis-c.html>
47. Egypt helps test 30K African citizens for Hepatitis C. *Egypt Today.* January 7, 2020. Accessed March 1, 2021. <https://www.egypttoday.com/Article/1/79411/Egypt-helps-test-30K-African-citizens-for-Hepatitis-C>

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PROGRAM CASE STUDY

Blended Learning Using Peer Mentoring and WhatsApp for Building Capacity of Health Workers for Strengthening Immunization Services in Kenya

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Key Messages

- We piloted peer mentoring with WhatsApp for immunization capacity building of maternal and child health (MCH) nurses in the Lari and Machakos subcounties of Kenya.
- Each mentor was assigned 4 mentees and provided on-site mentoring and hands-on training for 1 year. WhatsApp networking groups supported peer-mentoring efforts.
- In both subcounties, we observed positive changes in mentees' immunization knowledge, skills, and practices.
- The WhatsApp platform improved mentees' engagement with peers and promoted discussion and learning.

ABSTRACT

Evidence from available studies suggests that peer mentoring is a useful tool to build health workers' knowledge, skills, and practices. However, there is a dearth of research on use of this method of learning in immunization programs. Although WhatsApp has been used as a networking platform among health care professionals, there is limited research on its potential contribution to improving the immunization competencies of health workers. This study showed that peer mentoring and WhatsApp networking are useful blended learning methods for need-based and individualized capacity building of health workers providing immunization services. Future research to assess the comparative cost-benefit between classroom-based training and peer mentoring (along with WhatsApp networking) will be useful.

INTRODUCTION

A skilled workforce is an important determinant for a successful public health program to achieve universal health coverage.¹ However, the health workforce is not always empowered to address current and future population health issues.² Health systems in many countries often lack adequate and equitable support systems for health workers.^{3,4}

Training for health care providers has traditionally been provided within the health system in the form of classroom-based methods, usually conducted at the capital or district levels.^{1,5} Immunization training has until recently been predominately via classroom-based lectures using guidance such as the World Health Organization (WHO) immunization modules.⁶ Increasingly, however, learner-centered education methods are being utilized to encourage active participation and learning, with the traditional lecture method complemented by coaching and discussion.^{7,8} Nursing education has used peer learning to help develop skills, critical thinking, and self-confidence.^{9,10} In the conventional mentoring approach, a trainee is assisted by senior staff for their professional development.^{11,12} However, relationships with peers offer important alternative benefits compared to conventionally defined mentors.¹³

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Mentoring has been used widely in health programs to build health worker capacity. It has been used for quality improvement of clinical care,^{14–16} laboratory services,¹⁷ sexual and reproductive health and HIV/AIDS care,^{18–20} clinical nutrition,²¹ and health research.²² Evidence on use of mentoring for immunization capacity building of health workers is limited, as immunization training is traditionally classroom based. Standardized immunization competencies for health workers have more recently been established for workforce development.²³ Despite the common practice of classroom-based training, peer training for routine immunization was found to improve skills and practices.²⁴

With the availability of smartphones, social media applications are increasingly used for networking and learning among health care professionals.^{25,26} WhatsApp is a popular platform among health care professionals to network, communicate, and learn from each other.^{27,28} WhatsApp is easy to use, allows users to send text messages to a maximum of 256 people at once, and provides free video and image sharing.^{29,30} Evidence on the use of WhatsApp in the field of immunization is limited. However, WhatsApp use was documented during measles supplemental immunization activities for communication and coordination among health workers³¹ as well as for social networking with parents to promote seasonal influenza vaccination among young children.³²

In this case study, we piloted peer mentoring with WhatsApp for immunization capacity building of maternal and child health (MCH) nurses in the Lari and Machakos subcounties of Kenya. We

aimed to document the processes and outcomes of using these training tools for immunization capacity building of MCH nurses. We included WhatsApp as the learning platform to be used in conjunction with face-to-face peer mentoring because all MCH nurses reported already having a personal smartphone and using WhatsApp. Additionally, WhatsApp has been used by the subcounty health managers for administrative communication with health workers. This study was implemented from November 2017 to June 2019.

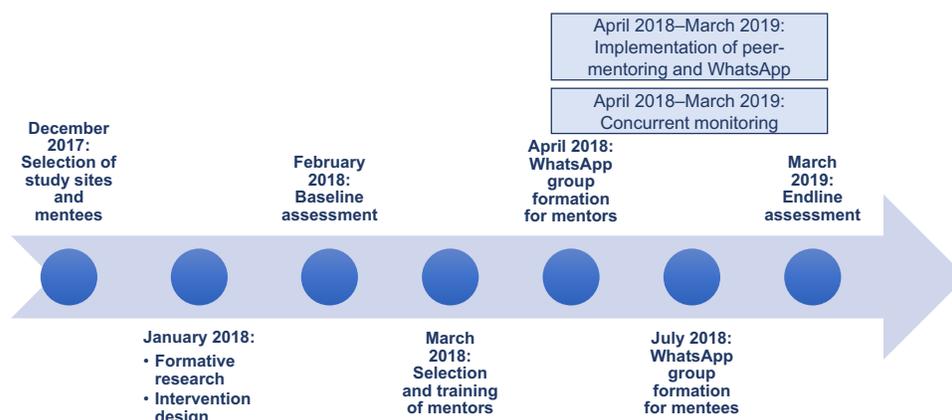
■ PEER MENTORING PROGRAM DESCRIPTION

The peer mentoring and WhatsApp study for immunization capacity building of MCH nurses consisted of the following steps: site selection, participant (mentee and mentor) selection, formative research, training of mentors, on-site mentoring, and networking using the WhatsApp platform (Figure 1).

1. Study Site Selection

In December 2017, using 2016 pentavalent-3 immunization coverage data extracted from the health management information system (with 60% vaccine coverage rate as the cutoff), Lari subcounty (58% coverage) in Kiambu County and Machakos subcounty (53% coverage) in Machakos County were selected. Lari and Machakos represent typical Kenyan rural and urban subcounties, respectively. In Lari, some health facilities lacked electricity and water supply, whereas in Machakos all health

FIGURE 1. Timeline of Peer-mentoring and WhatsApp Intervention Plan for Building Capacity of Immunization Workers in 2 Subcounties in Kenya



facilities had urban amenities (paved road, electricity, and water supply).

A total of 40 health facilities (20 in each sub-county) were selected to study the peer mentoring and WhatsApp capacity-building program. The criteria used for selecting health facilities were pentavalent-3 immunization coverage (60% vaccine coverage rate as the cutoff) and dropout rate of pentavalent vaccine from first dose to third dose (>10% as cutoff). The selected sites in Lari were 12 (60%) public health facilities, 4 (20%) faith-based organizations (FBOs), and 4 (20%) private health facilities; and in Machakos, 15 (75%) were public health facilities, 2 (10%) FBOs, and 3 (15%) private health facilities (Table 1).

2. Study Participant Selection (December 2017)

Study participants were selected in December 2017. In each subcounty, with the support of sub-county health officials, the MCH nurse who was responsible for providing the immunization services at each target health facility was identified and selected as a mentee. A total of 40 MCH nurses (20 in each subcounty) were selected to participate as mentees in the intervention. In Lari, 17 of the selected mentees were female (85%) and 3 (15%) were male, and in Machakos, 15 (75%) mentees were female and 5 (25%) were male (Table 1).

A total of 10 MCH nurses (5 in each subcounty) were selected to be peer mentors. Criteria for mentor selection were: (1) belonged to a health

facility that was high performing in immunization, (2) willing to work as a peer mentor, and (3) had prior experience as a mentor in other health programs. All 5 mentors in Lari were female, and all but 1 mentor in Machakos were female.

3. Formative Research Using a Human-Centered Design Approach

In January 2018, formative research was conducted using a human-centered design (HCD) approach in 19 low- and high-performing health facilities selected conveniently (10 in Lari and 9 in Machakos). The HCD methodology was used to understand how existing capacity among MCH nurses and available communication resources could be utilized to build peer-to-peer immunization competencies and to co-design the peer mentoring and WhatsApp networking approach with the primary users. In-depth interviews were conducted with 16 MCH nurses (mentors and mentees) and supervisors in Lari and 15 MCH nurses (mentors and mentees) and supervisors in Machakos to gain insights on contextual and systemic factors, health care context, and supervision and training, structure and knowledge, and culture and communication. We asked the following key questions: how can immunization knowledge of MCH nurses be increased and barriers to performance be decreased; how can technical awareness be increased; how can dialogue be initiated among MCH nurses; and how can the cultural norms be shifted to improve adherence to immunization policy. Models of archetype MCH nurses

We used HCD methodology to understand how existing capacity among MCH nurses and available communication resources could be used to build peer-to-peer immunization competencies.

TABLE 1. Facility and Participant Characteristics for Peer Mentoring and WhatsApp Intervention for Building Capacity in Immunization in Lari and Machako Subcounties, Kenya

Subcounty	Facility Type and Ownership Lari: N=20; Machakos: N=20				Age Group	Mentor Lari: N=5; Machakos: N=5		Mentee Lari: N=20; Machakos: N=20		Mentoring Visits Lari: N=19; Machakos: N=15	
	Facility Type	Public	FBO	Private		Male	Female	Male	Female	Visits	No.
Lari	Hospital	1	1	0	<30	0	2	0	4	<4	0
	Health Center	1	1	1	30–60	0	3	3	9	4–8	0
	Dispensary	10	2	3	60+	0	0	0	4	>8	19
Total, No. (%)		12 (60%)	4 (20%)	4 (20%)		0	5 (100%)	3 (15%)	17 (85%)		19 (100%)
Machakos	Hospital	1	0	2	<30	0	0	2	2	<4	1 (7%)
	Health Center	1	0	0	30–60	1	4	2	12	4–8	6 (40%)
	Dispensary	13	2	1	60+	0	0	1	1	>8	8 (53%)
Total, No. (%)		15 (75%)	2 (10%)	3 (15%)		1 (20%)	4 (80%)	5 (25%)	15 (75%)		15 (100%)

Abbreviation: FBO, faith-based organization.

were created to represent their needs, values, and behaviors. Based on the findings, prototyped intervention concepts of peer mentoring and use of WhatsApp were created and tested. Important take-aways from the formative research were:

1. Peer mentorship must be built on a foundation of trust. This allows nurses to feel comfortable having conversations with peers, leading to open exchanges of knowledge and skills.
2. Moderators of the WhatsApp networking groups must demonstrate an open-forum dialogue to make members feel comfortable to participate and create an environment that is conducive to free discussion while also enhancing the mentees' knowledge.

4. Mentor Training

A 2-day orientation training in March 2018 was conducted for the mentors in each subcounty to introduce the processes, steps, and challenges of peer mentoring and the use of WhatsApp networking to enhance learning beyond face-to-face mentoring. Mentor training did not include technical aspects of immunization with the assumption that they had the required immunization knowledge.

5. On-site Peer Mentoring

From April 2018 to March 2019, mentors met with mentees in their health facilities at least monthly. Each mentor was assigned 4 mentees. During the first mentoring visit, the mentor reviewed the baseline assessment findings with the mentee. The pair then discussed and prioritized the learning agenda and mentoring goals for the peer-mentoring sessions. The learning agenda for the mentoring sessions in both subcounties were: monitoring and data use, record keeping and reporting, problem solving, supply chain, increasing immunization coverage, cold chain management, administering vaccines, and interpersonal communication with caregivers. During subsequent mentoring visits, mentors provided hands-on training to mentees in the designated immunization technical areas. On-site peer mentoring occurred for 1 year (April 2018–March 2019).

6. Networking Using WhatsApp

To support peer-mentoring efforts, WhatsApp groups were formed in both subcounties. The mentors' group was formed in April 2018 and was cofacilitated by the research coordinator with

support from the subcounty Expanded Program on Immunization (EPI) focal person. The mentees' group was formed in July 2018, with both mentees and mentors participating, and was facilitated by the mentors on a rotating basis (with initial support from the research coordinator).

Each mentor was provided 1,000 Kenyan Shilling (US\$10) for transport costs and 500 Kenyan Shilling (US\$5) per mentoring visit for lunch. In addition, each mentor was given 500 Kenyan Shilling (US\$5) monthly for mobile phone airtime. Mentees were given 300 Kenyan Shilling (US\$3) monthly for mobile phone airtime for participation in the WhatsApp group.

■ DATA COLLECTION METHODS

Baseline Assessment

In February 2018, baseline data collection was conducted to assess current immunization knowledge, skills, and practices of the 20 selected MCH nurses (mentees) at the 20 selected health facilities in each subcounty (total 40 in both subcounties). Data collection was done by 2 research coordinators (consultants) using an electronic data collection tool (Survey CTO) consisting of a one-on-one interview with the MCH nurse and an observation portion where the research team assessed the nurse's immunization skills and practices during a facility immunization session. The research coordinators were oriented on the survey tool by the principal investigator. The baseline assessment included: health facility type and ownership; demographic information; human resources; immunization strategy and plan; cold chain management; availability of vaccines; availability of vaccination logistics; and availability of financial resource, supervision, and immunization program monitoring.

Concurrent Monitoring

Starting in April 2018, during each mentoring visit, mentors recorded each mentee's learning progress using a CommCare digital checklist (a mobile application). This app was used for real-time tracking of mentees' progress on the learning agenda. Additionally, postings in the WhatsApp groups of mentors and mentees were transcribed for review of the key themes of discussions within the network. Mentors shared mentoring experiences and challenges in their WhatsApp group. Mentees shared immunization technical questions, challenges, and systemic issues in their WhatsApp group.

Endline Assessment

The endline assessment was conducted in March 2019 by the same consultants who conducted the baseline assessment. It was conducted in 34 of the 40 initially selected health facilities (19 in Lari and 15 mentees in Machakos). Six private and faith-based health facilities (1 in Lari and 5 in Machakos) dropped out of the mentoring program. A total of 6 mentees in these facilities were furloughed by the facility management due to economic conditions. All 34 remaining mentees (19 in Lari and 15 in Machakos) were assessed for immunization knowledge in the endline assessment. However, immunization skills and practices were assessed in only 30 of the mentees (17 in Lari and 13 in Machakos). The skills of 2 mentees in each sub-county could not be assessed because the facilities did not have immunization sessions on the day that the data collectors visited. The survey tool (Survey CTO) that was used in the baseline was also used in the endline assessment. In addition to the interviews for knowledge assessment and skill observations, the endline assessment also included a qualitative component in the form of focus group discussions (FGDs). Four FGDs (1 with mentors in each sub-county and 1 with 10 randomly selected mentees in each sub-county) were conducted to gather the perceptions of mentees and mentors on peer mentoring and WhatsApp as methods of learning. The key FGD questions focused upon effectiveness of peer mentoring and WhatsApp in improving the knowledge, skills, and practices of mentees for immunization services; how different peer mentoring was from other methods of capacity building; what the challenges in the process of peer mentoring were, and how useful WhatsApp was as a complement to peer mentoring for building immunization capacity.

Ethical Review

The research protocol was reviewed by JSI Research and Training Institute institutional review board, exempted from human subject oversight, and approved by the Ministry of Health in Kenya. Written consent was obtained from all study participants before administering the study questionnaires. In addition, written consent was received from both mentors and mentees before forming WhatsApp groups for networking. Participants' names were not collected in the data collection forms, and the information they provided was kept confidential during data collection, storage, and analysis.

Data Analysis

The CommCare checklist data were analyzed in Microsoft Excel using a scoring system. Points

were given by researchers based on the observed competency of the mentees in each immunization technical area during the mentor's visit: 0 points, if the mentee was not observed to be performing in the technical area; 1 point, if the mentee needed substantial support and on-site training in the technical area; 2 points, if the mentee showed progress but still needed on-site support in the technical area; 3 points, if the mentee could perform without support in the technical area but still needed to be observed to confirm the proficiency; and 4 points, if the mentee demonstrated proficiency and could be fully independent. The scores were averaged for all technical areas and for all mentees quarterly for each sub-county.

Baseline and endline quantitative data on knowledge, skills, and practices of mentees were entered and analyzed using Microsoft Excel, and frequency tables were generated. McNemar's test was used with paired proportions of baseline and endline data to examine the improvement in mentees' immunization knowledge and skills, and practices. Risk ratio (RR) was computed with probabilities of gaps in mentees' knowledge, skills, and practices at endline and baseline assessment.

The postings in WhatsApp groups were transcribed quarterly into an electronic database to assess the participation of mentors and mentees in the groups and to identify immunization technical areas of discussion. The endline qualitative data were transcribed into an electronic database and analyzed based on emergent themes on perception of mentees and mentors regarding peer mentoring and WhatsApp networking as methods of immunization learning.

RESULTS

On-site Mentoring Visits

Concurrent monitoring (CommCare) data indicated that the mentoring visits varied between the 2 sub-counties. In Lari, most mentees (95%) had between 9 and 12 mentoring visits and 1 received more than 12 visits over the course of the study. In Machakos, slightly more than half (53%) of mentees had between 9 and 12 visits, 40% received 5–8 visits, and 1 mentee had less than 4 visits over the course of the study (Table 1). Turnover of the mentees in some health facilities affected the number of mentoring visits received by mentees.

Mentoring Visit Technical Content

CommCare data indicated that immunization technical content covered during mentoring visits

was similar in both Lari and Machakos; however, prioritization of the content areas by the mentees differed. In Lari, prioritized content areas (ranked from highest to lowest) were: record keeping and reporting, reaching every district strategy, monitoring and use of data, vaccine supply management, increasing immunization coverage, cold chain management, interpersonal communication with caregivers, and administering vaccines. In Machakos, ranking of content areas (highest to lowest) were: recording and reporting, vaccine supply management, cold chain management, monitoring and use of data, administering vaccines, interpersonal communication with caregivers, increasing immunization coverage, and reaching every district strategy.

Mentees’ Capacity-Building Progress

Analysis of CommCare data showed a steady increase of mentees’ average scores in capacity building across all technical areas in both subcounties between the launch in April 2018 and the end of the peer mentoring program in March 2019 (Figure 2). However, the average score in Lari dipped in October 2018, since mentors were not able to complete the assessment of all mentees’ progress in all technical areas by the October 2018 cutoff point.

Networking Using WhatsApp

Analysis of transcribed WhatsApp data showed that both mentors and mentees actively

participated in the WhatsApp groups and posted knowledge questions, opinions, and experiences in their respective groups. The total number of postings in the mentors’ group (April 2018–March 2019) in Lari was 239 (average 20 postings/month) and in Machakos was 220 (average 18 postings/month). Posting in the mentors’ groups in both subcounties dropped steadily from approximately August 2018 onward as mentors shifted to sharing their postings in the mentees’ groups after their formation in July 2018 (Figure 3).

The total number of postings in the mentees’ group (July 2018–March 2019) in Lari was 292 (average 32 postings/month) and in Machakos was 345 (average 38 postings/month). There was a decline in postings in the mentees’ groups in November 2018–January 2019 quarter in both subcounties due to the holidays; however, postings in both the subcounties increased in the following quarter (Figure 3). The discussion topics ranged from technical areas of administering vaccines and cold chain management to interpersonal communication with caregivers and increasing immunization coverage (Box).

Mentee Knowledge Acquisition

In Lari, comparing baseline with endline assessment data, positive changes in mentees’ knowledge were found in 11 of 12 immunization technical areas (Table 2). Highly statistically

Mentors and mentees actively participated in the WhatsApp groups and posted knowledge questions, opinions, and experiences in their respective groups.

FIGURE 2. Change in Average Scores in Nurse Knowledge Across All Technical Areas of Immunization Between April 2018 and May 2019 in 2 Subcounties in Kenya

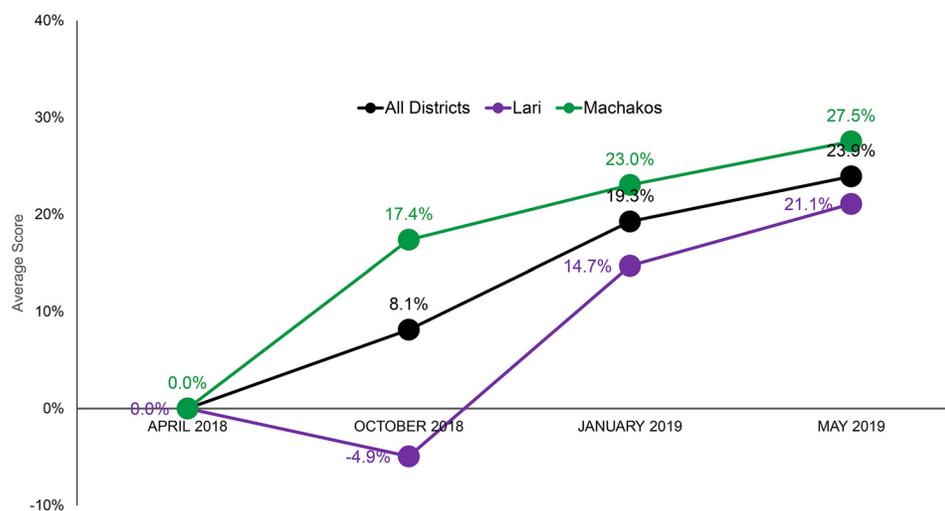
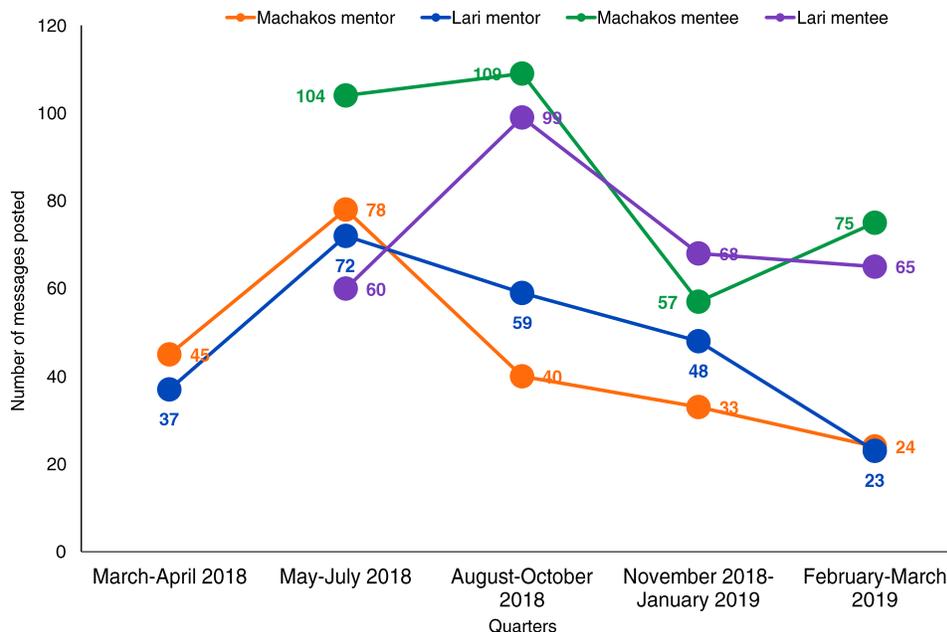


FIGURE 3. Average Number of Messages Posted per Quarter in Mentor and Mentee WhatsApp Groups in 2 Subcounties in Kenya



BOX. Examples of Mentee Messages Shared in the WhatsApp Group on Capacity Building on Immunization

- What information does a caregiver need to know about the child’s vaccination before she leaves the immunization site?
- What is the meaning of missed opportunity of vaccination?
- What is the meaning of multidose vial, multidose vial policy, and multidose antigen vaccine?
- What is the latest time during pregnancy that a woman should take tetanus toxoid vaccine to protect her newborn baby?
- A health center received 200 doses of BCG vaccine and vaccinated 150 children. What is the wastage rate?

significant changes in knowledge were found for: contraindication of vaccination ($P<.0001$, $RR=0.13$); forecasting vaccine requirement ($P<.0001$, $RR=0.23$); vaccination coverage rate calculation ($P=.0039$, $RR=0.46$); dropout rate calculation ($P<.0001$, $RR=0.27$); and preparation of coverage monitor chart ($P=.0004$, $RR=0.37$). In addition, significant change was found on knowledge of EPI target estimation ($P=.0104$, $RR=0.55$).

In Machakos, positive changes in mentees’ knowledge were found in 10 of 12 immunization technical areas (Table 3). Highly significant changes were found for: contraindication of vaccination

($P<.0001$, $RR=0.15$); forecasting vaccine requirement ($P<.0001$, $RR=0.22$); EPI target estimation ($P=.0068$, $RR=0.55$); coverage rate calculation ($P<.0023$, $RR=0.44$); dropout rate calculation ($P<.0001$, $RR=0.27$); and preparation of coverage monitoring chart ($P=.0007$, $RR=0.36$).

Mentee Skills Acquisition

In Lari, mentees were found to have positive changes in skills and practices for 11 of 17 activities observed (Table 4). The gains were highly significant for: marking the tally sheet after each

TABLE 2. Mentees' Immunization Knowledge Improvement From Baseline to Endline During Peer Mentoring and WhatsApp Intervention for Building Capacity in Immunization in Lari Subcounty, Kenya^a

	Baseline, February 2018 (N=20) No. (%)	Endline, March 2019 (N=19) No. (%)	Net Percentage Gain	P Value p(2-tailed)	Risk Ratio
Missed opportunity of vaccination	7 (33%)	5 (26%)	-7%	.7488	1.14
Side effect of pentavalent vaccine	17 (85%)	18 (95%)	10%	.7488	0.33
Contraindications of vaccination	3 (15%)	17 (89%)	74%	<.0001	0.13
Forecasting vaccine requirement	2 (10%)	15 (79%)	69%	<.0001	0.23
Stages of vaccine vial monitor	16 (80%)	15 (84%)	4%	1.0000	1.05
Fridge tag	9 (45%)	11 (58%)	13%	.5218	0.76
Defaulter tracking	18 (90%)	18 (95%)	5%	1.0000	0.50
EPI target estimation	1 (5%)	9 (47%)	42%	.0104	0.55
Coverage rate calculation	2 (10%)	11 (58%)	48%	.0039	0.46
Dropout rate calculation	1 (5%)	14 (74%)	69%	<.0001	0.27
Preparation of coverage monitor chart	2 (10%)	13 (68%)	58%	.0004	0.34
Multidose vial policy	4 (20%)	5 (26%)	6%	.7488	0.91

Abbreviation: Expanded Program on Immunization (EPI).

^a Net percentage gain was calculated from the percentage of mentees who answered correctly the knowledge questions at baseline and endline. Significance (*P* value) was computed using McNemar's test with paired proportion of mentees' with correct knowledge on the topics at endline and baseline. Risk ratio was computed with probabilities of mentees' knowledge gap on the topics at endline and baseline.

Mentees reported that constant support, tracking progress, and positive feedback from mentors were instrumental in building their knowledge and skills.

vaccination ($P=.0085$, $RR=0.09$); providing measles and rubella vaccination daily ($P=.0085$, $RR=0.18$); providing BCG vaccination daily ($P=.0010$, $RR=0.43$); and availability of mother and child card ($P<.0001$, $RR=0.06$). Changes in hand-washing practices were not observed in Lari, most likely due to lack of running water or hand sanitizer in the health facilities. No changes were expected at endline on correct diluent use for BCG and measles and rubella vaccines, as this practice was found to be 100% at baseline. Negative changes for vaccine vial monitor checking before vaccination and completing the mother and child card accurately were due to new or replaced mentees who did not have adequate mentoring visits. Negative changes on availability of vaccines and vaccination materials (e.g., syringe and needles) were due to inadequate supply from sub-county offices.

In Machakos, positive gains in skills and practices were found in 11 of 17 observed activities (Table 5). Highly significant changes were found for: handwashing before vaccination ($P=.0053$, $RR=0.44$); maintaining the temperature chart of the vaccine fridge ($P=.0005$, $RR=0.33$); daily BCG

vaccination ($P=.0053$, $RR=0.30$); and providing daily measles and rubella vaccination ($P=.0148$, $RR=0.32$). No change was expected for completing the mother and child card accurately, as this was found to be 100% in the baseline assessment. Negative changes for checking vaccine vial monitor before vaccination and marking the tally sheet after each vaccination were due to new or replaced mentees who did not receive adequate mentoring visits. Significant negative changes on availability of vaccines and mother and child health card were due to inadequate supply from subcounty health offices.

Perception on Using Peer Mentoring

Most mentees indicated that peer mentorship was useful in building their individualized capacity in providing routine immunizations services. Mentees reported that constant support, tracking progress, and positive feedback from mentors during peer mentoring sessions were instrumental in building knowledge and skills.

I really benefited from mentoring and gained knowledge and skills in the technical areas of immunization—

TABLE 3. Mentees' Immunization Knowledge Improvement From Baseline to Endline During Peer Mentoring and WhatsApp Intervention for Building Capacity in Immunization in Machakos Subcounty, Kenya^a

Immunization Knowledge	Baseline, February 2018 (N=20) No. (%)	Endline, March 2019 (N=15) No. (%)	Net Percentage Gain	P Value (two tailed)	Risk Ratio
Missed opportunity of vaccination	7 (35%)	4 (27%)	-8%	1.0000	1.12
Side effect of pentavalent vaccine	17 (85%)	14 (93%)	8%	1.0000	0.40
Contraindications of vaccination	3 (15%)	13 (87%)	72%	<.0001	0.15
Forecasting vaccine requirement	2 (10%)	12 (80%)	70%	<.0001	0.22
Stages of vaccine vial monitor	16 (80%)	12 (80%)	0	.7353	1.0
Fridge tag	9 (45%)	9 (60%)	15%	.4990	0.72
Defaulter tracking	18 (90%)	14 (93%)	3%	.7353	0.60
EPI target estimation	1 (5%)	7 (47%)	42%	.0068	0.55
Coverage rate calculation	2 (10%)	9 (60%)	50%	.0023	0.44
Dropout calculation	1 (5%)	11 (73%)	68%	<.0001	0.27
Preparation of monitor chart	2 (10%)	10 (67%)	57%	.0007	0.36
Multi-dose vial policy	4 (20%)	4 (27%)	7%	.4990	0.91

Abbreviation: Expanded Program on Immunization (EPI).

^aNet percentage gain was calculated from the percentage of mentees who answered correctly the knowledge questions at baseline and endline. Significance (P value) was computed using McNemar's test with paired proportion of mentees' with correct knowledge on the topics at endline and baseline. Risk ratio was computed with probabilities of mentees' knowledge gap on the topics at endline and baseline.

thanks to my committed mentor who was always available for me. —Mentee in Machakos

Mentees added that peer mentoring was different from classroom-based training. Mentors addressed the individual training needs of mentees and helped them with skills development. They also noted the benefit of not needing to close the clinic for training because mentoring was done at the mentees' facilities and mentoring did not disrupt working hours.

I am the only nurse in this health facility providing immunization services. My facility did not need to close the services for attending peer-mentoring session. —Mentee from Lari

Upon request from the hospital management, mentees in larger health facilities also mentioned that they informally began mentoring other MCH nurses in the same facility. Mentors indicated that during mentoring visits, they were able to identify gaps in knowledge, skills, and practices that the mentees themselves were unaware of but that were necessary for providing quality routine immunization services.

On-site mentoring allowed me to identify skill gaps in mentees and to practically demonstrate the

procedures to mentees to build capacity. —Mentor in Machakos

Mentors also indicated that initiating mentoring for peers was a challenge; however, they were able to do it through building relationships with the mentees. Challenges to mentoring included turnover of mentees and supply issues with vaccines and vaccinating materials, which prevented the mentees from putting the new knowledge and skills into practice for improving routine immunization services.

Mentees older than me were initially ambivalent to accept me as a mentor; however, I was able to overcome this issue through building relationship with my mentees. —Mentor in Lari

Mentees' and Mentors' Perception of Using WhatsApp

Both mentees and mentors indicated that WhatsApp provided a platform for sharing technical questions, systemic challenges, and opinions among MCH nurses. The platform allowed increased interaction among mentees themselves and with their mentors on addressing routine immunization-related questions

TABLE 4. Mentees' Immunization Skill and Practice Improvement From Baseline to Endline in Peer Mentoring and WhatsApp Intervention for Building Capacity in Immunization in Lari Subcounty, Kenya^a

Skills and Practices	Baseline, February 2018 (N=20) No. (%)	Endline, March 2019 (N=17) No. (%)	Net Percentage Gain	P Value (2-tailed)	Risk Ratio
Wash hands before vaccination	6 (30%)	5 (30%)	0	1.0000	1.0
Explain procedure to caregivers	12 (60%)	15 (88%)	28%	0.1884	0.27
Check Vaccine Vial Monitor (VVM) before vaccination	20 (100%)	16 (94%)	-6%	0.5108	0.00
Keep BCG, measles, and rubella diluents cold	18 (90%)	16 (94%)	4%	1.0000	0.50
Use correct diluent to reconstitute BCG, measles, and rubella	20 (100%)	17 (100%)	0	0.5108	0.00
Use nontouch injection technique	13 (65%)	15 (88%)	23%	0.3239	0.31
Dispose of used needle and syringe immediately	18 (90%)	16 (94%)	4%	1.0000	0.50
Marking each vaccination in the tally sheet	9 (45%)	16 (94%)	49%	0.0085	0.09
Complete mother and child health card accurately	20 (100%)	16 (94%)	-6%	0.5108	0.00
Complete permanent register after each vaccination	18 (90%)	16 (94%)	4%	1.0000	0.50
Correct arrangement of vaccine in the fridge	12 (60%)	16 (94%)	34%	0.1002	0.12
Temperature chart for the vaccine fridge	16 (80%)	16 (94%)	14%	0.7423	0.25
Provide measles and rubella vaccination daily	8 (40%)	15 (79%)	39%	0.0085	0.18
Provide BCG vaccination daily	1 (5%)	10 (53%)	48%	0.0010	0.43
Availability of all vaccines	19 (95%)	16 (94%)	-1%	0.7423	1.0
Availability of all vaccination materials	14 (70%)	7 (41%)	-29%	0.1002	1.93
Availability of mother and child health card	4 (20%)	16 (94%)	74%	<0.0001	0.06

^a Net percentage gain was calculated from the percentage of mentees who demonstrated correct skills and practices at baseline and endline. Significance (p value) was computed using McNemar's test with paired proportion of mentees' with correct skills and practices at endline and baseline. Risk Ratio (RR) was computed with probabilities of mentees' skill and practice gaps at endline and baseline.

and challenges they encountered day-to-day in immunization service delivery.

WhatsApp platform provided me opportunity to ask questions or share a scenario that I encountered in between the face-to-face mentoring visit of my mentor. —Mentee in Lari

Mentees added that discussion in the WhatsApp group acted as a reminder of what they learned and as method to get further clarification of any questions and issues related to routine immunization.

My mentor shared a lot of information during the mentoring visit, and at times, I forgot some of those. However, discussions in the WhatsApp group worked as a reminder of information my mentor provided. —Mentee in Machakos

Interaction in the WhatsApp platform was helpful in building confidence among MCH nurses

in sharing issues related to routine immunization services.

Discussion in WhatsApp built my morale and self-confidence. It realized that I was not the only one having issues in delivering immunization services. —Mentee in Lari

The WhatsApp platform was useful for sharing national immunization policy guidelines or other relevant reference documents to mentees on certain immunization standards.

In case of difference of opinion among mentees in the group on certain technical areas, the group facilitator resolved the issues by providing reference from the national policy guidelines. —Mentee in Machakos

Mentors' perception was that mentees' participation in the WhatsApp groups may have been negatively affected if the direct supervisor was

TABLE 5. Mentees' Immunization Skill and Practice Improvement From Baseline to Endline in Peer Mentoring and WhatsApp Intervention for Building Capacity in Immunization in Machakos Subcounty, Kenya^a

Skills and Practices	Baseline, February 2018 (N=20) No. (%)	Endline, March 2019 (N=13) No. (%)	Net Percentage Gain	P Value (2-tailed)	Risk Ratio
Wash hands before vaccination	3 (15%)	8 (62%)	47%	.0053	0.44
Explain procedure to caregivers	12 (60%)	12 (92%)	32%	.2963	0.17
Check Vaccine Vial Monitor prior vaccination	20 (100%)	12 (92%)	-8%	.1637	0.00
Keep BCG, measles, and rubella diluents cold	18 (90%)	12 (92%)	2%	.4862	0.70
Use correct diluent to reconstitute BCG, measles, rubella	18 (90%)	12 (92%)	2%	.4862	0.70
Use nontouch injection technique	14 (70%)	12 (92%)	22%	.7277	0.23
Dispose of used needle and syringe immediately	19 (95%)	12 (92%)	-3%	.2963	1.40
Marking each vaccination in the tally sheet	14 (70%)	9 (69%)	-1%	.7277	1.53
Complete mother & child health card accurately	20 (100%)	13 (100%)	0	.2963	0.00
Complete permanent register after each vaccination	15 (75%)	11 (85%)	10%	1.0000	0.60
Correct arrangement of vaccine in the fridge	11 (55%)	9 (69%)	14%	.7277	0.66
Temperature chart for the vaccine fridge	4 (20%)	11 (85%)	65%	.0005	0.33
Provide measles and rubella vaccination daily	6 (30%)	10 (67%)	47%	.0148	0.32
Provide BCG vaccination daily	5 (25%)	10 (67%)	42%	.0053	0.30
Availability of all vaccines	19 (95%)	8 (62%)	-33%	.0148	7.60
Availability of all vaccination materials	16 (80%)	12 (92%)	12%	1.0000	0.35
Availability of mother and child health card	17 (85%)	4 (31%)	-54%	.0017	4.60

^a Net percentage gain was calculated from the percentage of mentees who demonstrated correct skills and practices at baseline and endline. Significance (p value) was computed using McNemar's test with paired proportion of mentees' with correct skills and practices at endline and baseline. Risk Ratio (RR) was computed with probabilities of mentees' skill and practice gaps at endline and baseline.

nominated as the group facilitator, rather than a mentor who was not the mentee's supervisor.

DISCUSSION

Peer Mentoring: A Nonconventional Effective Learning Approach

The peer-mentoring program was designed to build individual immunization capacity of MCH nurses while also fostering cross learning in a less hierarchical manner.

Mentors worked with mentees to identify their individual training needs at the outset of peer mentoring, considering gaps identified during baseline assessment and challenges shared by the mentees. They worked to address gaps in mentees' knowledge and provided practical support in developing skills, and improving practices. Mentors also kept track of individual mentee's learning progress during each mentoring visit, reinforcing

knowledge, skills and practices during subsequent visits and with WhatsApp discussions until the required competencies were achieved.

Mentees' positive perceptions of peer mentoring was attributed to its individualized method of learning at the facility, rather than the previous didactic lecture methods (which were conducted in classrooms rather than at the health facility). Mentees also noted that on-site peer mentoring did not disrupt their routine activities, and health facilities did not have to close facility activities for the MCH nurse to participate in the training sessions. Ndwiga et al. also reported that mentors and mentees perceived peer mentoring as an acceptable method of training.¹⁹ Luck et al. found that peer mentoring is a relatively cost-effective strategy requiring minimal resources and negligible disruption to clinical services.³³

Peer training was found to be a cost-effective method for increasing immunization coverage in health centers.²⁵ However, the main objectives of

Mentees noted that on-site peer mentoring did not disrupt their routine activities.

our study were to document the processes and outcomes in terms of knowledge, skills/practices improvement with peer mentoring and WhatsApp. The increases in immunization coverage that arose from improved knowledge, skills, and practices could not be documented credibly in this study as stock-out of vaccines and shortage of vaccination materials affected coverage during the implementation period. During formative research, we found that MCH nurses were less likely to reach out to their supervisors either face-to-face or electronically for support related to immunization services. This may be due to the perception of the supervisor as having a position of power that is intimidating to MCH nurses. The MCH nurse mentees were found more likely to seek help from an experienced peer in gaining new knowledge, addressing a challenge, or learning an immunization skill. Mentors were nonjudgmental with mentees, creating a nonthreatening environment for mentees' learning. Mentees noted their comfort in sharing their needs and challenges. The peer-mentoring approach is an alternative to conventional mentoring in which peers are actively involved and take responsibility for their own learning.^{13,34}

Preparing Mentors for Mentoring Visits

Mentoring is not natural for everyone and is considered a reciprocal relationship process.³⁵ As such, our training for mentors helped to prepare them for peer mentoring as an important first step. We oriented them on the processes, steps, and phases of peer mentoring; listening and feedback skills; and how to do on-the-job training and provide support for performance improvement. The 5 phases of peer mentoring are⁹: (1) seeding, time of relationship building potential; (2) opening, initiation and progression of mentoring relationship; (3) laddering, period of reciprocal interaction; (4) equalizing, mentee and mentor become equal; and (5) reframing, reflection and recognition. We trained and equipped the mentors on each phase and ways to overcome potential challenges with peer mentoring. At the seeding phase, younger mentors in our program had challenges with older mentees; however, they were able to build mentees' trust by establishing a relationship. Mentees in larger health facilities even felt empowered enough to informally start mentoring other MCH nurses.

Factors Influencing the Success of Peer Mentoring

A key to success of peer mentoring was relationship building between mentors and mentees. To build a relationship, mentors in our program

presented themselves to the mentees as a helper, not as a supervisor or monitor. They created trust and a nonthreatening environment in which mentees felt comfortable sharing their challenges, with mentors listening with empathy. They provided mentees with positive feedback and avoided critiquing mentees' faults in the immunization session in front of the caregivers. In busy clinics, mentors even provided on-site support to mentees to help the mentees finish their routine work in order to free up time for mentoring sessions. One mentee stated during an FGD:

Peer mentoring created a conducive environment in which we were comfortable to learn and share our capacity gaps and challenges.

A mentorship based on mutual trust and respect empowers a partnership between 2 people who have a shared set of learning objectives.^{9,36} The use of the CommCare tool was useful for real-time tracking of mentees' progress.

On-site mentoring in a real-life situation (i.e., at the mentees' place of work) resulted in mentees feeling comfortable, and mentors were able to see and understand mentees' work challenges. However, support from supervisors and facility managers are critical to plan and implement on-site peer mentoring. In our program, the subcounty managers supported the selection of mentors and mentees and communicated with the facility managers regarding the peer mentoring. Support from facility managers enabled mentors to be released once a week from their regular work to participate in the mentoring activity. To avoid any interruption of immunization work in their own facilities, mentors diligently planned the mentoring visits to be on the days when there was no immunization session in the facilities. In addition, in the larger health facilities (hospitals) where immunization sessions were usually more frequent, the facility manager deputed another MCH nurse to manage the immunization sessions to allow the mentor to go for mentoring visits. Managers at the target health facilities allowed mentees to attend the mentoring sessions. County managers' support was needed to ensure that mentors and mentees were not transferred during the peer-mentoring period. In addition, support from county and subcounty managers was required to ensure that routine immunization supplies were available; however, there were instances during our study in which staff transfers and lack of vaccines and vaccination supplies negatively affected the peer-mentoring application of knowledge and skills into practices. Similar to our findings, Ndwiga et al. found successful mentorship conditional upon facility management support,

sufficient supplies, a positive work environment, and mentor selection.¹⁹

WhatsApp as a Networking and Learning Platform

The use of the WhatsApp platform improved MCH nurses' engagement with peers and promoted discussion and learning through sharing challenges and experiences in providing immunization services. This was consistent with other studies on WhatsApp networking among health care professionals.^{37,38} Henson et al. found difficulty in the use of social media among older age health workers and reported it to be a limiting factor for its use in other health programs.³⁸ However, we found both mentors and mentees were able to participate in the WhatsApp group discussion regardless of their age in both subcounties. The research coordinators supported participants initially for logging in, and after a while, they were comfortable using it. Consistent with Amry et al.³⁹ we found that the presence of a moderator in the WhatsApp group facilitated the learning process. Johnston et al. reported that WhatsApp networking helps "flatten hierarchy" among students, residents, and experienced consultants in a clinical setting by enabling all to actively contribute to discussion without inhibition.⁴⁰ However, we found that although the role of a group moderator was important, the inclusion of a supervisor as moderator in the mentees' group could introduce power imbalances that might hinder participation of mentor and mentees. Moderation of the mentees' groups by the mentors (who were not direct supervisors) in our study created an open and nonjudgmental environment for mentees that encouraged their active participation and comfort in posting questions in the group.

Preserving patient privacy in the WhatsApp group is important for health care professionals.⁴¹ Both mentors and mentees in our study complied with patient privacy during WhatsApp group discussions, neither identifying by name nor adding pictures of the clients or caregivers in the WhatsApp group.

Institutionalization, Sustainability, and Scalability of Peer Mentoring and WhatsApp

Mentoring was considered as an integral part of the continuing education process.²⁰ Consistent with the findings of Ndwiga et al.¹⁹ the mentees and mentors in our study perceived peer-mentoring as an effective and sustainable method of capacity building to improve immunization

services. We found that some mentees informally started mentoring the peers in their own health facilities. Hale indicated that in the reframing phase of peer mentoring, the mentees gain recognition of their improved knowledge and skills from the management and peers in their work place and may serve as a mentor for their peers.⁹ The capacity of the existing and newly positioned nurses can be built and updated periodically with peer mentoring backed by WhatsApp group discussions as new vaccines and technologies are added to the immunization system.

During progress update meetings with the county/subcounty health officials, we discussed the continuation of the peer mentoring and WhatsApp groups beyond the life of the project. We shared the gain in competencies of mentees and improvement in the quality of immunization services through peer-mentoring and WhatsApp. Both counties decided to continue the peer-mentoring process and WhatsApp groups. Machakos decided to scale up the initiatives to other subcounties and also decided to use peer mentoring for capacity building of health workers for other health program (e.g., family planning) using their own funds. Both subcounties decided to increase the number of mentors graduating some of the existing mentees into mentors to expand peer mentoring in all the health facilities providing immunization services. To address the performance gaps in other health facilities, supervisors in Lari were utilizing the trained mentors to improve the immunization capacity of nurses. Manzi et al. reported that integrating trained nurse mentors into the district supervision system was instrumental for quality of care improvement through providing ongoing, on-site individual mentorship to health workers in the health facilities.¹⁴ The WhatsApp groups in both subcounties continued after the project phased out, and group members remained active and continued to participate in the discussions.

Limitations

1. The small sample size of the study limited precise measurement of improvement in mentees' knowledge, skills, and practices in some immunization areas with peer mentoring and WhatsApp.
2. The turnover of mentees was a limiting factor in the study. The new and replaced mentees did not receive enough peer mentoring opportunities in all immunization technical areas identified in the learning agenda.
3. The short supply and stock-out of vaccines and vaccination materials negatively affected

the practices of MCH nurses (mentees) in both subcounties.

- The increases in immunization coverage as outcome of improved knowledge, skills, and practices of mentees was not documented in this study due to performance issues related to short supply of vaccines and vaccination materials.

CONCLUSION

The Global Vaccine Action Plan underscored the importance of building health worker capacity to support immunization programs.⁴² Innovative learning strategies outside of formal classroom trainings are needed to improve frontline health workers' competencies for achieving immunization coverage goals that have become more important now during the COVID-19 pandemic as large gatherings for face-to-face trainings are restricted. Using peer mentoring and WhatsApp for adult learning is new in immunization programs. Evidence from this study suggests that peer mentoring and WhatsApp networking could be effective methods for improving frontline health workers' on-the-job performance in immunization at minimal cost. However, to generate further evidence, a cost-benefit study would be useful to compare peer mentoring (along with WhatsApp networking) with classroom-based training for health workers.

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REFERENCES

- Anatole M, Magge H, Redditt V, et al. Nurse mentorship to improve the quality of health care delivery in rural Rwanda. *Nurs Outlook*. 2013;61(3):137–144. [CrossRef](#). [Medline](#)
- Sobel HL, Huntington D, Temmerman M. Quality at the centre of universal health coverage. *Health Policy Plan*. 2016;31(4):547–549. [CrossRef](#). [Medline](#)
- Gebbie K, Merrill J, Tilson HH. The public health workforce. *Health Aff*. 2002;21(6):57–67. [CrossRef](#). [Medline](#)
- Moran AM, Coyle J, Pope R, Boxall D, Nancarrow SA, Young J. Supervision, support and mentoring interventions for health practitioners in rural and remote contexts: an integrative review and thematic synthesis of the literature to identify mechanisms for successful outcomes. *Hum Resour Health*. 2014;12(1):10. [CrossRef](#). [Medline](#)
- Iwasiw CL, Andrusyszyn MA, Goldenberg D. *Curriculum Development in Nursing Education*. 4th ed. Jones & Bartlett; 2020.
- World Health Organization (WHO). *Immunization in Practice: A Practical Guide for Health Staff*. WHO; 2015. https://apps.who.int/iris/bitstream/handle/10665/193412/9789241549097_eng.pdf?sequence=1
- Banning M. Approaches to teaching: current opinions and related research. *Nurse Educ Today*. 2005;25(7):502–508. [CrossRef](#). [Medline](#)
- Moore CL, Manyibe EO, Aref F, Washington AL. Research capacity building: a historically black college/university-based case study of a peer-to-peer mentor research team model. *Rehabil Res Policy Educ*. 2017;31(3):283–308. [CrossRef](#)
- Hale R. Conceptualizing the mentoring relationship: an appraisal of evidence. *Nurs Forum*. 2018;53(3):333–338. [CrossRef](#). [Medline](#)
- Stone R, Cooper S, Cant R. The value of peer learning in undergraduate nursing education: a systematic review. *ISRN Nurs*. 2013; 2013:930901. [CrossRef](#). [Medline](#)
- Higgins MC, Kram KE. Reconceptualizing mentoring at work: a developmental network perspective. *Acad Manage Rev*. 2001;26(2): 264–288. [CrossRef](#)
- Nickitas DM. Mentorship in nursing: an interview with Connie Vance. *Nurs Econ*. 2014; 32(2):65–69. https://www.nursing.economics.net/necfiles/news/MA_14_p65.pdf
- Kram KE, Isabella LA. Mentoring alternatives: the role of peer relationships in career development. *Acad Manage J*. 1995;28(1):110–132. [CrossRef](#)
- Manzi A, Megge H, Redditt V, et al. Nurse mentorship to improve the quality of health care delivery in rural Rwanda. *Nurs Outlook*. 2013; 61(3):137–144. [CrossRef](#). [Medline](#)
- Manzi A, Magge H, Hedt-Gauthier BL, et al. Clinical mentorship to improve pediatric quality of care at the health centers in rural Rwanda: a qualitative study of perceptions and acceptability of health care workers. *BMC Health Serv Res*. 2014;14(1):275. [CrossRef](#). [Medline](#)
- Schwerdtle P, Morphet J, Hall H. A scoping review of mentorship of health personnel to improve the quality of health care in low and middle-income countries. *Global Health*. 2017;13(1):77. [CrossRef](#). [Medline](#)
- Donovan G, Ong SK, Song S, et al. Remote mentorship using video conferencing as an effective tool to strengthen laboratory quality management in clinical laboratories: lessons from Cambodia. *Glob Health Sci Pract*. 2020;8(4):689–698. [CrossRef](#). [Medline](#)
- Bertman V, Petracca F, Makunike-Chikwinya B, et al. Health worker text messaging for blended learning, peer support, and mentoring in pediatric and adolescent HIV/AIDS care: a case study in Zimbabwe. *Hum Resour Health*. 2019;17(1):41. [CrossRef](#). [Medline](#)
- Ndwiga C, Abuya T, Mutemwa R, et al. Exploring experiences in peer mentoring as a strategy for capacity building in sexual reproductive health and HIV service integration in Kenya. *BMC Health Serv Res*. 2014;14:98. [CrossRef](#). [Medline](#)
- World Health Organization (WHO). *WHO Recommendations for Clinical Mentoring to Support Scale-up of HIV Care, Antiretroviral Therapy and Prevention in Resource-Constrained Settings*. WHO; 2005. <http://www.who.int/hiv/pub/guidelines/clinicalmentoring.pdf>

21. Palermo C, McCall L. The role of mentoring in public health nutrition workforce development. Perspectives of advanced-level practitioners. *Public Health Nutr.* 2008;11(8):801–806. [CrossRef](#). [Medline](#)
22. Hamer DH, Hansoti B, Prabhakaran D, et al. Global health research competencies for individuals and institutions in low-and middle-income countries. *Am J Trop Med Hyg.* 2019;100(1_Suppl):15–19. [CrossRef](#). [Medline](#)
23. Traicoff D, Pope A, Bloland P, et al. Developing standardized competencies to strengthen immunization systems and workforce. *Vaccine.* 2019;37(11):1428–1435. [CrossRef](#). [Medline](#)
24. Robinson JS, Burkhalter BR, Rasmussen B, Sugiono R. Low-cost on-the-job peer training of nurses improved immunization coverage in Indonesia. *Bull World Health Organ.* 2001;79(2):150–158. [Medline](#)
25. Scott N, Goode D. The use of social media (some) as a learning tool in health care education: An integrative review of the literature. *Nurse Educ Today.* 2020;87:104357. [CrossRef](#). [Medline](#)
26. Korda H, Itani Z. Harnessing social media for health promotion and behavior change. *Health Promot Pract.* 2013;14(1):15–23. [CrossRef](#). [Medline](#)
27. Nardo B, Cannistrà M, Diaco V, et al. Optimizing patient surgical management using WhatsApp application in the Italian health care system. *Telemed J E Health.* 2016;22(9):718–725. [CrossRef](#). [Medline](#)
28. Khanna V, Sambandam SN, Gul A, Mounasamy V. “WhatsApp”ing in orthopedic care: a concise report from a 300-bedded tertiary care teaching center. *Eur J Orthop Surg Traumatol.* 2015;25(5):821–826. [CrossRef](#). [Medline](#)
29. Boulos MNK, Giustini DM, Wheeler S. Instagram and WhatsApp in health and health care: an overview. *Future Internet.* 2016;8(3):37. [CrossRef](#)
30. Astarcioglu MA, Sen T, Kilit C, et al. Time-to-reperfusion in STEMI undergoing interhospital transfer using smartphone and WhatsApp messenger. *Am J Emerg Med.* 2015;33(10):1382–1384. [CrossRef](#). [Medline](#)
31. Masresha B, Nwankwo O, Bawa S, et al. The use of WhatsApp group messaging in the coordination of measles supplemental immunization activity in Cross Rivers State, Nigeria, 2018. *Pan Afr Med J.* 2020;35(1):6. [CrossRef](#). [Medline](#)
32. Liao Q, Fielding R, Cheung YTD, Lian J, Yuan J, Lam WW. Effectiveness and parental acceptability of social-networking interventions for promoting seasonal influenza vaccination among young children: a randomized control trial. *J Med Internet Res.* 2020;22(2):e16427. [CrossRef](#). [Medline](#)
33. Luck L, Ng Chok H, Wilkes L. Peer buddy mentoring project for nurses’ career development. *Clin Nurs Stud.* 2017;5(4):82. [CrossRef](#)
34. Stewart BM, Krueger LE. An evolutionary concept analysis of mentoring in nursing. *J Prof Nurs.* 1996;12(5):311–321. [CrossRef](#). [Medline](#)
35. Mccloughen A, O’Brien L, Jackson D. Positioning mentorship within Australian nursing contexts: a literature review. *Contemp Nurse.* 2006;23(1):120–134. [CrossRef](#). [Medline](#)
36. Hale RL, Phillips CA. Mentoring up: A grounded theory of nurse-to-nurse mentoring. *J Clin Nurs.* 2019;28(1–2):159–172. [CrossRef](#). [Medline](#)
37. Martyn-Hemphill CM, Sarkar S, Withington J, et al. MP16-06 “WhatsApp Doc?” Evaluating a novel modality of communication amongst urology team members to promote patient safety. *J Urol.* 2015;193(4S):169–170. [CrossRef](#)
38. Hanson C, West J, Neiger B, Thackeray R, Barnes M, McIntyre E. Use and acceptance of social media among health educators. *Am J Health Educ.* 2011;42(4):197–204. [CrossRef](#)
39. Amry AB. The impact of WhatsApp mobile social learning on the achievement and attitude of female students compared with face to face learning in the classroom. *Eur Sci J.* 2014;10(12):116–136. [CrossRef](#)
40. Johnston MJ, King D, Arora S, et al. Smartphones let surgeons know WhatsApp: an analysis of communication in emergency surgical teams. *Am J Surg.* 2015;209(1):45–51. [CrossRef](#). [Medline](#)
41. Bernhardt JM, Alber J, Gold RS. A social media primer for professionals: digital dos and don’ts. *Health Promot Pract.* 2014;15(2):168–172. [CrossRef](#). [Medline](#)
42. World Health Organization (WHO). *Global Vaccine Action Plan*. WHO; 2013. https://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/

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