



## GLOBAL HEALTH: SCIENCE AND PRACTICE

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Front cover: GHSP celebrates its 5-year publication anniversary in 2018. © GHSP 2018.

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Ruwaida M Salem, Steve Hodgins

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James D Shelton

Glob Health Sci Pract. 2018;6(2):232–236 https://doi.org/10.9745/GHSP-D-18-00193

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Michael B Macdonald

Glob Health Sci Pract. 2018;6(2):237–241 https://doi.org/10.9745/GHSP-D-18-00158

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Shannon L Silkensen, Mark Schiffman, Vikrant Sahasrabuddhe, John S Flanigan

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Glob Health Sci Pract. 2018;6(2):247–248 https://doi.org/10.9745/GHSP-D-18-00192

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Alexandra C Vrazo, David Sullivan, Benjamin Ryan Phelps

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Irene Koek, Marianne Monclair, Erin Anastasi, Petra ten Hoope-Bender, Elizabeth Higgs, Rafael Obregon

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Elisabeth Paul, Fabienne Fecher, Remo Meloni, Wim van Lerberghed

Glob Health Sci Pract. 2018;6(2):260–271 https://doi.org/10.9745/GHSP-D-18-00001

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Angela Acosta, Emmanuel Obi, Richmond Ato Selby, Iyam Ugot, Matthew Lynch, Mark Maire, Kassahun Belay, Abidemi Okechukwu, Uwem Inyang, Jessica Kafuko, George Greer, Lilia Gerberg, Megan Fotheringham, Hannah Koenker, Albert Kilian

Glob Health Sci Pract. 2018;6(2):272–287 https://doi.org/10.9745/GHSP-D-17-00350

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Yacouba Ouedraogo, Gahan Furlane, Timothee Fruhauf, Ousmane Badolo, Moumouni Bonkoungou, Tsigue Pleah, Jean Lankoande, Isabelle Bicaba, Eva S Bazant

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Steven A Harvey

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Tekou B Koffi, Karen Weidert, Eralakaza Ouro Bitasse, Marthe Adjoko E Mensah, Jacques Emina, Sheila Mensah, Annette Bongiovanni, Ndola Prata

Glob Health Sci Pract. 2018;6(2):317–329 https://doi.org/10.9745/GHSP-D-17-00471

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Laura Subramanian, Callie Simon, Elkan E. Daniel

Glob Health Sci Pract. 2018;6(2):330–344 https://doi.org/10.9745/GHSP-D-17-00440

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Shohinee Sarma, Bennett Nemser, Heather Cole-Lewis, Nadi Kaonga, Joel Negin, Patricia Namakula, Seth Ohemeng-Dapaah, Andrew S. Kanter

Glob Health Sci Pract. 2018;6(2):345–355 https://doi.org/10.9745/GHSP-D-16-00290

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The majority of countries with mandatory grain fortification requirements document the technical specifications for grain fortification, such as allowable food vehicles and fortification levels required. Most document systems for monitoring. However, detailed protocols, descriptions of roles and responsibilities, means to support the cost of regulation, enforcement strategies, and methods for reporting monitoring results to stakeholders are generally lacking.

Kristin J Marks, Corey L Luthringer, Laird J Ruth, Laura A Rowe, Noor A Khan, Luz María De-Regil, Ximena López, Helena Pachón

Glob Health Sci Pract. 2018;6(2):356–371 https://doi.org/10.9745/GHSP-D-17-00427

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Khadidiatou Ndiaye, Erin Portillo, Dieneba Ouedraogo, Allison Mobley, Stella Babalola

Glob Health Sci Pract. 2018;6(2):372–383 https://doi.org/10.9745/GHSP-D-17-00417

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Soy Ty Kheang, May Aung Lin, Saw Lwin, Ye Hein Naing, Phyo Yarzar, Neeraj Kak, Taylor Price

Glob Health Sci Pract. 2018;6(2):384–389 https://doi.org/10.9745/GHSP-D-17-00318

#### **METHODOLOGIES**

## Monitoring Progress in Equality for the Sustainable Development Goals: A Case Study of Meeting Demand for Family Planning

As demand for family planning has increasingly been satisfied, disparities between groups within a country have also generally declined but persist. To monitor disparity across countries and over time, we recommend comparing met demand by wealth quintile because it is most comparable to interpret and highly correlated with disparity by education, residence, and region. Within country, comparing disparity in met demand across geographic region can identify populations with greater need for programmatic purposes.

Yoonjoung Choi, Madeleine Short Fabic

Glob Health Sci Pract. 2018;6(2):390–401 https://doi.org/10.9745/GHSP-D-18-00012

#### **EDITORIAL**

### Global Health: Science and Practice . . . 5 Years In

Ruwaida M. Salem, a Steve Hodginsb

Five years after launching Global Health: Science and Practice, we are seeing signs that we are helping to fill an important gap in program-related evidence. Looking forward, we seek to offer better coverage for topics that are relatively neglected in the global health literature and to publish more papers by authors based in low- and middle-income countries. We invite authors to submit manuscripts on global health programs grounded in evidence from research, evaluation, monitoring data, or experiential knowledge, and encourage readers to access and share our free articles to find scalable approaches and important lessons to inform programs and policy.

See also related infographic.

n the face of wide disparities in population health out-Lcomes between high-income and low- and middleincome countries, there is a strong imperative to achieve and sustain large gains in population health. "Science," in the sense of context-free evidence for the efficacy of clinical interventions that is typically reported in the peer-reviewed health literature, is certainly an important input to strategies to achieve such population impact. But even if we've identified an intervention for which there is sound evidence of efficacy, how can we ensure the effectiveness of delivery of such an intervention at scale, under real-world conditions? Such questions are addressed to some degree in the gray literature, but more often than not project reports lack rigor. This can result in global health program managers, policy makers, and donors reinventing the wheel, and failing to draw lessons from relevant experience elsewhere.

#### ■ FILLING THE PROGRAM EVIDENCE GAP

We launched *Global Health: Science and Practice* (GHSP) 5 years ago because the United States Agency for International Development and the Johns Hopkins Center for Communication Programs recognized an important gap in program-relevant evidence. Our vision was to enable the global health community to better share important lessons arising from their program experience, and to do so with sufficient rigor. We also wanted to contribute to the development of new norms

on how to study and document program implementation issues, with a view to informing global health policy and practice.

One of the ways that GHSP differs from most other journals is that we encourage authors not only to share the overall results or impact of their programs on health outcomes, but also to provide detail on *how* they implemented their programs and important contextual factors that may have interacted with features of their program efforts (Box). With such information, readers in other settings can make more fully informed judgements on the possible relevance of findings to their own settings and populations.

Another characteristic that differentiates us from most other journals serving the global health community is that we prioritize offering program implementers themselves a platform to share their valuable program experience. Such on-the-ground program practitioners often have less publishing experience than most of those submitting to scholarly journals, so we provide mentorship at different stages to coach them through the publication process. With no article-processing fees, we offer this support free of charge for authors, and we also provide readers free full-text access to all our articles—thus eliminating financial barriers to sharing and accessing important lessons from programs. In a GHSP reader survey conducted in 2017, 60% of respondents identified themselves as program managers, providers, technical advisors, teachers, or trainers, suggesting we are reaching our main audience of program practitioners (Figure 1). Furthermore, approximately 1 in 5 lead authors of GHSP published articles and 2 in 5 of our readers come from low- and middle-income countries (Figure 2).

#### ■ WHAT IS THE JOURNAL ACHIEVING?

Since launching 5 years ago, GHSP has published 45 editorials and 273 original articles, commentaries,

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viewpoints, field action reports, and other types of articles, as well as 2 supplements. In total, these articles have been accessed 1.2 million times, with our most popular articles covering a range of global health topics including digital health, 1,2 adolescent sexual and reproductive health,3 tuberculosis, 4 immunization, 5 family planning, 6 health promotion,<sup>7</sup> and health systems.<sup>8</sup> The number of readers accessing our articles has increased each year, from about 60,000 full-text accesses when we launched in 2013 to nearly 375,000 in 2017. And many of our articles are being cited in the peer-reviewed literature. Scopus calculates that each GHSP article receives, on average, 1.24 citations (using data from May 31, 2017). In comparison, each article in Global Public Health receives, on average, 1.60 citations, and in the Bulletin of the World Health Organization 3.09 citations—these journals were launched in 2006 and 1948, respectively.<sup>9</sup>

Clearly, for any journal, citations are an important measure of impact. However, citations in the peer-reviewed literature are also something of an echo chamber; the literature references itself, whether or not it is having useful impact in the real world. A central part of our ambition at GHSP is to serve the policy and program community, providing them with rigorously grounded but practical lessons arising from global public health program work, i.e., "practice-based evidence." More important to us than number of citations in the peer-reviewed literature is seeing lessons documented through GHSP picked up and influencing policy and practice.

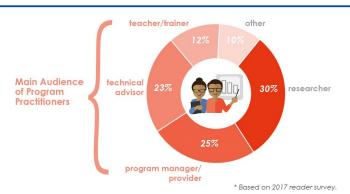
#### Impact on Practice

We have some indication that insight captured in GHSP authors' work is being picked up and applied in other contexts. In a recent survey of our readers, about two-thirds reported they've applied lessons from GHSP articles in their own public health practice (Figure 3). Of those, 42% said they used lessons from GHSP to design new programs or improve existing ones. For example, a technical advisor in Nigeria made use of an article from GHSP on task-shifting provision of contraceptive implants to community health extension workers<sup>12</sup> to advocate to the national reproductive health technical working group to allow lower-level health workers to perform family planning procedures. In Rwanda, a teacher used lessons drawn from an article on trends in HIV prevalence and sexual behaviors in Burkina Faso<sup>13</sup> to develop an approach to sex and drug

#### **BOX.** Attributes of GHSP

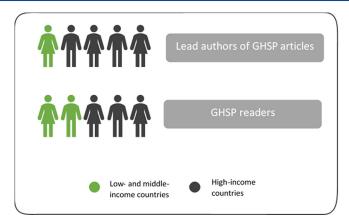
- Focus on programs implemented under real-world conditions, with specifics on the "how" of implementation
- Details on the context in which the program was implemented that might influence implementation elsewhere
- Emphasis on scalable approaches with high-impact potential
- Insightful analysis grounded in evidence—whether from research studies, program evaluations, monitoring data, or observational and experiential knowledge

#### FIGURE 1. Job Function of GHSP Readers



Source: "Celebrating 5 Years of Success" infographic: http://www.ghspjournal.org/ 5year-anniversary.

FIGURE 2. Current Reach of GHSP Into Low- and Middle-Income Countries



Source: Data on lead authors from administrative data and on GHSP readers from Google Analytics data (total sessions from March 2013 through April 2017).

5 Years of GHSP www.ghspjournal.org

FIGURE 3. Use of GHSP Lessons by Readers



Source: 2017 GHSP reader survey.

abuse-related behavior change communication work with youth. A quarter of our surveyed readers who report having used GHSP articles to inform their programs said they used the articles to create or revise training or educational materials. For instance, a clinician in India used a GHSP article on operational challenges to Ebola case investigation in Sierra Leone<sup>14</sup> to develop a mock exercise for university students to explore how to investigate an Ebola case.

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webinars, online journal clubs, and translation of

on what we set out to do 5 years ago-"to

find principles and lessons learned that are sys-

tematic, replicable, and applicable in other settings"<sup>15</sup> to contribute to stronger, more effective

health programs delivered at scale and to accelerate improvements in population health status.

Most importantly, we will keep our eye

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#### LOOKING AHEAD

In the coming years, we are looking to attract more readers and authors across a broad range of global health topics, including non-communicable diseases and injury, malaria, nutrition, water and sanitation, mental health, and HIV/AIDS, who share our common goal of improving global health programs and population health outcomes. We especially want to continue expanding our reach into low- and middle-income countries, to help people on the ground who are actually designing and implementing programs share what they've been learning with each other and develop more effective programs. To facilitate that, we seek to build partnerships with institutions in low- and middle-income countries to learn from their experiences while helping to strengthen their capacity in scholarly publishing. We will also continue to expand our reach by, for example, linking with other major indexing services beyond MEDLINE, PubMed, and Scopus, in which we're already included, and to explore adding new high-value features and services, such as

We seek to build partnerships with institutions in low- and middle-income countries to learn from their experiences while helping to strengthen their capacity in scholarly publishing.

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**EDITORIAL** 

## At Last! Universal Health Coverage That Prioritizes Health Impact: The Latest Edition of Disease Control Priorities (DCP3)

James D. Shelton<sup>a</sup>

Sadly, we face a vast sea of health problems in global health. Universal health coverage programming should prioritize interventions with the most health impact, but instead largely succumbs to emphasizing less impactful clinical curative services. In contrast, DCP3 provides an evidence-based template that prioritizes impact. Yet even the most basic and realistic DCP3 package comes at a formidable price.

See related article by Paul.

Faced by the vast numbers of health problems of mankind, one immediately becomes aware that all of them cannot be attacked simultaneously.

- Julia Walsh and Kenneth Warren, 1979<sup>1</sup>

#### HEALTH OR HEALTH SERVICES?

Universal health coverage (UHC) has become a major focus of global health, embedded in Sustainable Development Goal (SDG) 3 (ensure healthy lives and promote well-being) and a major priority for the World Health Organization (WHO). Thus, according to WHO<sup>2</sup>:

UHC means that all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, quality health services from health promotion to prevention, treatment, rehabilitation, and palliative care.

Certainly, this objective sounds laudable. But notice that health impact is not explicit in the definition. Rather, emphasis is indirect, on a potential *means* to better health—"health services." And only by mention of the phrase "they need" is impact implied.

Of course, "services" can encompass any health intervention. But many highly effective health interventions such as tobacco taxation, community distribution of long-acting insecticide-treated nets, clean air regulation, and promotion of healthy lifestyle lie outside the clinical realm entirely. And conceptually most people don't tend to think of them as "health services."

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Moreover, many high-priority preventive clinical services such as immunization, contraception, and prenatal care can be lost in the shuffle within the vast panoply of curative services.

## THE INEXORABLE PULL TOWARD CURATIVE SERVICE

To most of the public and to politicians "health coverage" means having a doctor or other health care provider available when they need or want one, which generally means after some problem develops. And policy decisions are heavily influenced by physicians, whose main professional orientation is curative practice. Elite decision makers themselves may have personal felt needs for specialized clinical care. Moreover, nascent health insurance systems, which often serve as a core part of UHC, are oriented toward specific, mainly curative, procedures. Thus, UHC, as it has been commonly rolled out, has a primary emphasis on curative clinical, sometimes even highly specialized, care.<sup>3,4</sup> And it quickly gets enmeshed in the dense quagmire of issues related to coverage and payment schemes. Yet, ironically, high expenditures on clinical service show scant effect on population-level health indicators.<sup>5</sup>

#### ENTER THE DCP'S LATEST EDITION, WITH EVIDENCE-BASED PRIORITY UHC PACKAGES

The prestigious pedigree of the *Disease Control Priorities* (DCP) extends back for decades, convening world-class expertise and using the best available evidence to do exactly what its name conveys—provide guidance on priorities for health programming. After years in the making, its third edition (DCP3) has now blossomed forth.<sup>6</sup> It aims directly at UHC priorities, using solid criteria of (1) value for money, (2) burden addressed, and (3) implementation feasibility.

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#### DCP3's Adept Methodology

As befits the complex issue of UHC, the methodology is thoughtfully complex. It starts by laying out interventions like tobacco tax that lie outside the conventional concept of a health system, with 71 "intersectoral" interventions including 29 proposed for early adoption. Then, within the conventional health system, it includes 218 health interventions labeled Essential Universal Health Coverage (EUHC), of which a subset of 71 are included in a Highest Priority Package (HPP). In essence, the HPP is aimed at lower-income countries (LICs) and the larger EUHC at lower-middle-income countries (LMICs).

In addition to looking at interventions individually, DCP3 examines 18 "cluster packages" (such

as child health and tuberculosis) as well as 5 "platforms" (such as population, community, and first-level hospital). Interventions are also categorized as urgent, chronic, and time-bound but not urgent. Lastly, the interventions within the EUHC and the HPP subset are evaluated for cost and health impact in the context of the clusters and platforms. (The intersectoral interventions are *not* included in this component of the analysis.)

### The Packages Are Well Prioritized. Yet Very Much Is Not Included Even in EUHC

To help you grasp a sense of what is included or not in the packages, Box 1 shows some examples of what interventions are included in the pack-

#### BOX 1. Illustrative Examples of Health Interventions Included in DCP3

#### **Intersectoral Interventions for Health**

- Outdoor air pollution restriction (transport, power, industrial)
- Tax on tobacco, alcohol, and other addictive substances
- Ban on trans fat
- Reduced salt in food products
- Traffic calming mechanisms in road construction
- Infrastructure conducive to walking, cycling

#### **HPP Interventions**

- Mass media promotion of healthy eating and physical activity
- Routine childhood vaccination
- Contraception
- Labor and delivery (multiple levels)
- · Rapid tests and ACTs for malaria
- Management of childhood illness (iCCM and IMCI)
- Management of severe childhood infections
- TB diagnosis and treatment (multiple levels)
- Mass treatment of NTDs (e.g., lymphatic filariasis)
- Condoms for key at-risk populations
- Antiretroviral therapy for HIV
- Postabortion care
- Basic management of depression
- Drainage of superficial abscess
- Adult febrile illness, management (multiple levels)
- Diabetes among adults, basic management
- Selected cardiovascular disease, basic management

- Pain management and palliative care (multiple levels)
- Diagnosis and treatment of early cervical, breast, and colorectal cancer
- Hernia repair
- Cleft palate repair
- Cataract removal and replacement
- Selected urgent surgery (e.g., appendectomy, perforated ulcer)

#### Other EUHC Interventions Not in the HPP

- Mass media to reduce tobacco and alcohol use
- Breastfeeding promotion by lay health workers
- Life skills education
- Hepatitis B vaccination for high-risk adults
- Insecticide-treated nets for children and pregnant women.
- Preexposure prophylaxis with antiretroviral therapy for high HIV risk
- Flu vaccine for those with underlying lung disease
- Suturing of lacerations
- Hypertension, opportunistic screening and basic treatment for high risk
- Asthma and obstructive pulmonary disease, simple and some advanced treatment
- Dental caries and extraction
- Gallbladder removal
- Prosthetics, orthotics, and splints
- · Repair club feet
- Specialized TB care (e.g., treatment of drug-resistant TB failure)

Abbreviations: ACTs, artemisinin-based combination therapies; DCP3, Disease Control Priorities, 3rd edition; EUHC, Essential Universal Health Coverage; HPP, Highest Priority Package; iCCM, integrated community case management; IMCI, integrated management of childhood illness; NTDs, neglected tropical diseases; TB, tuberculosis.

### **BOX 2.** Examples of Health Services and Conditions <u>Not</u> Included in EUHC

- Routine physical exams
- Low back pain (except some basic physical management)
- Allergies
- Shingles vaccine
- Common viral infections<sup>a</sup>
- Routine urinary tract infection<sup>a</sup>
- Juvenile diabetes
- Gastric reflux and heartburn
- Colonoscopy/mammography
- Prostatic hypertrophy
- Infertility
- Inflammatory bowel disease
- Hemorrhoids
- Cosmetic surgery
- Fibromyalgia
- Lupus
- Multiple sclerosis
- Alzheimer's disease
- Parkinson's disease
- Joint replacement
- Treatment of all cancer except early cervical, breast, and colorectal
- Medium and advanced treatment of most cardiovascular disease

Abbreviation: EUHC, Essential Universal Health Coverage.

<sup>a</sup> The HPP does include management of febrile illness but is oriented toward severe disease like malaria.

ages. And Box 2 shows revealing examples that are not. (In some cases, I've condensed and combined categories for simplification.)

- Intersectoral set and HPP (Box 1). Many of these interventions will be familiar to those working in global health, featuring interventions (often preventive in nature) well known to be effective—for example, tobacco tax in the intersectoral group and childhood vaccination in the HPP. A modest modicum of fairly basic clinical curative and palliative services are also included in the HPP such as management of childhood illness.
- EUHC interventions, beyond those in the HPP (Box 1). Included here are a number of important but less cost-effective preventive interventions such as flu vaccine for high-risk individuals and a larger list of clinical services like suturing of lacerations and limited approach to hypertension.

Much not included, even in EUHC (Box 2). Perhaps most revealing, this list demonstrates the vast expanse of the health arena that such a practical essential package does not include. Virtually everyone reading this list will see several, and probably multiple, interventions or conditions for which they themselves or close friends and family have sought care. Notably with respect to the huge and growing burden of chronic disease, treatment of cancer in the EUHC is limited to just early treatment for cervical, breast, and colorectal cancer, leaving the many other cancers, from leukemia to brain cancer, untouched. Likewise most advanced therapy for other major chronic diseases like myocardial infarction, obstructive pulmonary disease, stroke, and heart failure is excluded.

#### Most Impact Comes With the HPP, but Even It Requires Substantial Boost in Health Spending

The Figure shows the projected reduction in premature deaths and the annual cost in percent of gross national income (GNI) for the HPP and the EUHC, assuming 80% population coverage at 2030. (The intersectoral interventions were not included in this analysis.) Notice that for both LICs and LMICs, the HPP would provide 80% of the death reduction but at about half the incremental cost of the EUHC. The increased costs beyond what countries are currently spending just for the HPP, however, are substantial and would require more than a doubling of the percent of GNI dedicated to health by 2030. And the additional cost of the EUHC is even more formidable at about twice that of the HPP. Not surprisingly, the populationbased and community platforms had the lowest costs.

### Implementation of Even the More Expensive EUHC Would Fall Far Short of 2030 SDGs

The SDGs translate into a decline in premature mortality of 40%, or 7.0 million lives, annually by 2030 in LMICs. However, as shown in the Figure, the projected impact of EUHC is a reduction of only 4.2 million lives annually—about 40% short of the objective.

On a more positive note, substantial additional impact could come from implementing a good portion of the intersectoral approaches, which were not included in the impact and cost analysis. And some approaches, like tobacco and alcohol taxes, can actually generate substantial funding.

LOWER-INCOME COUNTRIES LOWER-MIDDLE-INCOME COUNTRIES Premature Death Reduction Premature Death Reduction EUHC = 2.0 million EUHC = 4.2 million fewer premature deaths fewer premature deaths 20% 24% HPP HPP = 3.2 million HPP = 1.6 million fewer premature deaths ■ EUHC fewer premature deaths Annual Costs **Annual Costs** (% GNI per person) (% GNI per person) 9.1% total 5.1% 5.2% total total 2.9% incremental 2.8% total 2.3% current EUHC EUHC

FIGURE. Health Impact and Annual Cost of HPP and EUHC in Lower-Income and Lower-Middle-Income Countries

Abbreviations: HPP, Highest Priority Package; EUHC, Essential Universal Health Coverage; GNI, gross national income.

However, others like improved outdoor air quality and safer highway design would come at additional cost. To reach the SDGs, we may also benefit from the tailwind of advancing economic development wherein much of the gains in health indictors historically have come from incompletely understood effects through such means as improved nutrition, sanitation, housing, communication, transportation, and health literacy. On the other hand, economic development can lead to increases in many chronic diseases, which are becoming increasingly important.

#### Avoiding Extreme Poverty

Avoiding extreme poverty is an integral UHC objective. Such poverty can come from high out-of-pocket expenditures as well as time lost from work from either sustained illness or a catastrophic episode. Still it is not at all clear that purely subsidizing clinical services, as UHC is too often conceived, is the best remedy for this problem. Rather, a strong emphasis on preventing severe and chronic disease through interventions like tobacco control, clean air, bed nets, and

traffic safety, along with some key therapeutic components such as those laid out in DCP3, may well be a better approach.

# ■ FACING THE HARSH REALITY OF ENORMOUS HEALTH NEEDS BUT VERY LIMITED RESOURCES — INFORMED PRIORITIZING IS CRUCIAL

We would all like to live in a world where all health need could be satisfied. Of course, like any overarching exercise of its kind, DCP3 surely entails some inaccuracies and is subject to necessary assumptions and simplifications. Still there is no escaping the conclusion, that health needs across the board vastly outstrip realistic resources. Proper prioritizing is thus imperative.

## Public Health Leadership Should Frame UHC Around Actual Health Impact

Given our current reality where health need vastly outstrips resources, where many decision makers are mostly oriented toward curative services, and where decision making takes place on the uncertain political stage, what should public health leadership do? Serious health advocates should weigh in to make the case for the most cost-effective health interventions, adapted to country context and subject to political realities. That includes advocacy with political leaders and the public for intersectoral health promoting interventions like clean air initiatives, taxes on tobacco and alcohol, and traffic calming as well as clinical services like a full set of childhood immunizations—not just as having access to a health care provider when a person may want or need one. Encouragingly, WHO has recently weighed in advocating a more largely "intersectoral" preventive approach to non-communicable diseases.7

Clearly, undertaking UHC under these circumstances is a difficult and uncertain process. No wonder then in the current issue of GSHP, Paul and colleagues find very diverse views from informed health experts about how to go about UHC, even in the fairly homogeneous context of francophone Africa.8 That appears to be at least partly because the evidence for how to implement UHC is very weak, even once the decision is made as to what it should consist of. Nevertheless, some serious efforts are underway to try to rationalize the UHC process—for example, the recent volume from the Center for Global Development, What's In, What's Out: Designing Benefits for Universal Health Coverage. But the authors of DCP3 have now given us a concrete, robust evidence-based template to turn the attention of UHC to interventions that will benefit health the most.

#### CONCLUSION

The authors of DCP3 have done a great service by identifying, with painstaking effort and expertise, key interventions that will have the most health impact for the universe of people in LMICs. Their

priority packages do respond to the felt need for clinical services at the facility level. But the most impactful priority interventions are at the population, community, and intersectoral levels. The rest of the global health community should follow the leadership of DCP3, get beyond the mentally constraining framework around "health services," and emphasize true health impact in UHC. The people we serve deserve nothing less.

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#### **EDITORIAL**

# Long-Lasting Insecticidal Nets for Malaria Control in Myanmar and Nigeria: Lessons From the Past, Tools for the Future

Michael B. Macdonalda

While having saved many lives over the past decade, continued dependence on mass distribution of free long-lasting insecticidal nets (LLINs) is not sufficient and may not be sustainable. Programs must be enabled with flexible policy and technical options to place LLINs within a larger context of multisectoral partnerships and integrated vector management, avoiding what happened in the DDT era, where there was overreliance implementing a uniform solution to a complex problem.

See also related articles by Acosta and by Kheang.

Two articles appearing in this issue of GHSP illustrate the diverse challenges—and limitations—of malaria vector control that has become heavily reliant on mass distributions of free insecticide-treated nets (ITNs). On the surface, the 2 contexts could not seem more different. Acosta et al. describe a school-based distribution scheme in Cross River State, Nigeria, and Kheang et al. service delivery strategies for mobile and migrant populations in Myanmar: two vastly different scenarios with unique tactical problems, but with options limited by the common strategic solution being implemented.

Mass distribution of free ITNs has shown proven success across many contexts. Between 2000 and 2015, reported malaria cases dropped from 271 million to 212 million, and deaths from 864,000 to 429,000<sup>3</sup>; 68% of the decline was attributed to ITNs, 19% to availability of artemisinin-based combination therapy, and 13% to indoor residual spraying (IRS). However, according to the latest data from the World Health Organization (WHO), there were an estimated 216 million cases of malaria in 2016, marking a return to 2012 levels, and deaths stood at about 445,000, similar to the previous year. Speaking at a Malaria Summit during the recent 2018 Commonwealth Heads of Government Meeting in London, Dr. Tedros Ghebreyesus, WHO Director-General, said<sup>6</sup>:

The latest data show that we are now at crossroads. If we relax our efforts, we know that malaria will come roaring back—and with a vengeance.

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Dr. Pedro Alonzo, Director of the WHO Global Malaria Programme, struck a similar note in a World Malaria Day interview<sup>7</sup>:

We are at a real crossroads. We've seen great progress, we're now stalling. Why are we stalling? Possibly because funding has plateaued for the last five or six years. With population growth, that means that per capita investment in the fight against malaria is decreasing in a great number of countries, and we haven't had any new transformative tools come onto the market so it doesn't seem hard to imagine that with the same level of funding, with the same tools we are seeing the limit to what we can do.

If we are to succeed in our malaria elimination efforts, we need to remember the words of Dr. José Nájera, former director of the WHO malaria program<sup>8</sup>:

Before DDT, malariologists were trained as problems solvers, after DDT, malariologists were trained as solution implementors.

DDT (dichlorodiphenyltrichloroethane) was the first modern synthetic insecticide that initially had great success and broad use but was later greatly reduced after evidence emerged that its benefits were declining due to development of resistance by many insect species and because of its harmful environmental effects. We need to move beyond the current "solution" of exclusive reliance on public-sector free mass LLIN distributions. Instead, under the context of integrated vector management that recognizes that effective vector control is not the sole preserve of the health sector but requires the collaboration of various public and private agencies and community participation,9 we should enable program managers to engage all available resources to "solve the problem" of malaria vector control in their unique circumstances.

We need to enable program managers to engage all available resources to "solve the problem" of malaria vector control in their unique circumstances.

After the initial waves of episodic free mass LLIN distributions, the need for "between campaign" continuous distributions became apparent.

## We need to enable A SIMPLE SOLUTION TO A COMPLEX program PROBLEM

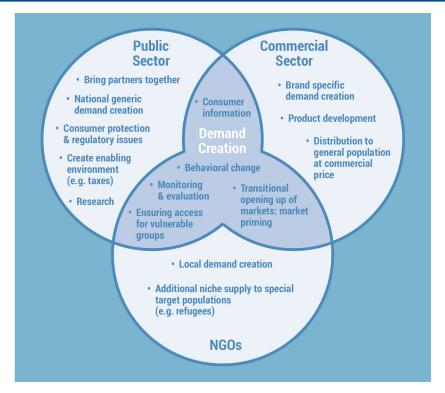
ITN distribution strategies narrowed for several years and are just now modestly expanding. Prior to support from the Global Fund to Fight AIDS, Tuberculosis and Malaria, the WHO/Roll Back Malaria ITN distribution strategy focused on building partnerships among the public sector, the commercial sector, and NGOs, as illustrated in the Figure. 10 Considerable efforts were made through the United States Agency for International Development-supported NetMark project, the UK Department for International Development (DfID), the Canadian International Development Research Centre (IDRC), the Swiss Agency for Development and Cooperation, and others to develop these partnerships and strategies, with one of the larger examples being the Tanzania National Voucher Scheme. 11

In the mid-2000s, two things happened. First, there was recognition that just protecting "vulner-

able groups" (i.e., pregnant women and children and people living with HIV/AIDS) had less impact than "universal coverage" for all populations at risk and that in addition to personal protection, ITNs would have a "mass effect" and reduce vectoral capacity of the local mosquito vector population. 12

Second, the expansion of resources through the Global Fund and the President's Malaria Initiative (PMI), and examples from Cambodia and Ghana of free mass distribution campaigns linked with immunization campaigns, shifted strategies toward exclusive reliance on public-sector distribution. Now with the commercial sector as vendor rather than partner, the focus became producing uniform ITNs, and later long-lasting insecticidal nets (LLINs), that were able to meet minimum specifications at the lowest possible price in order to win the large tenders for mass distribution. This limited opportunities for product innovation that could add even the most modest price per unit to the LLIN. Moreover, this

**FIGURE.** Roles of the Public Sector, NGOs, and the Commercial Sector in Creating an Enabling Environment for ITN Distribution



Abbreviation: ITN, insecticide-treated net.

Source: WHO (2003).10

created a profound division between local commercial net makers and retailers and large producers for the international procurement market.

After the initial waves of episodic free mass LLIN distributions, the need for "betweencampaign" continuous distributions became apparent. The 2017 WHO guidance considers antenatal care (ANC), Expanded Programme on Immunization (EPI), and other child health clinics as high-priority continuous LLIN distribution channels where these services are used by a large proportion of the population at risk of malaria. The guidance makes brief mention of private- and commercial-sector channels "as long as these are well-regulated to ensure product quality in line with WHO recommendations."14

#### EXPANDING PUBLIC-SECTOR **CHANNELS FOR CONTINUOUS** DISTRIBUTION

Working within these constraints of centrally procured LLINs distributed through the public sector, Acosta and her team in Nigeria lay out a school-based distribution scheme to 4 grade levels, in addition to the standard ANC distribution, to maintain equitable coverage of nearly 80% of households with at least ITN for the 3 years postcampaign in 3 local government areas (LGAs) of Cross River State, Nigeria. A comparison LGA with only ANC distribution showed a steady decline from 64% to 43% despite availability of ITNs thorough ANC services. The school-based distribution in addition to the standard ANC distribution provided a potential replacement for subsequent mass campaigns in this setting with high rates of school enrollment. Expanding to additional grades may increase the proportion of households with access to a net.

#### LLINS, NECESSARY BUT NOT **SUFFICIENT**

Myanmar presents a different problem. Here, the at-risk population described by Kheang et al. are mobile and migrant workers entering forested areas where they are exposed to the highly efficient malaria vectors Anopheles dirus and Anopheles minimus. There are several challenges. Many of the mobile population are new to the area with limited knowledge of malaria prevention as well as of public health services in the area. Moreover, some may be engaged in illegal forest activities and reluctant to approach government services. Some work at night or sleep in

small temporary shelters where ITNs and IRS are not practical. Kheang found that village malaria workers, mobile teams, and screening points each have strengths and weaknesses in access, cost, and efficiency, and there needs to be a combination of approaches to engage these hard-toreach populations.

While in general ITNs are effective for malaria prevention in the Greater Mekong Subregion<sup>15</sup> and free mass ITN distributions in settled villages continue, 16 there is a long tradition of net use, albeit with untreated nets from the market. The 2016 Myanmar Demographic and Health Survey found that although 97% of households possessed a mosquito net, the vast majority were untreated nets from the market; only 19% of children under 5 and 18% of pregnant women slept under an ITN the previous night. 17 Cambodia piloted a project for "bundling" untreated nets with insecticide treatments at the wholesale level, 18 but the IconMaxx and K-O Tab 1-2-3 formulations are no longer being produced. Vietnam continues insecticide retreatment campaigns for the untreated conventional nets, but this is not currently practiced by other programs in the region that continue to rely strictly on standard free mass distribution. 19

"Outdoor transmission" among mobile and migrant populations present additional challenges. There is nascent work on supplementary vector control tools, including treated shelters, treated clothing and blankets, and topical and spatial repellents. 20 Recognizing that the market for these new tools may be too small and unstable for serious industry investment, there is an initiative through Roll Back Malaria to link these needs to the much larger needs for vector control in humanitarian emergencies where ITNs and IRS may not be practical.<sup>21</sup>

Taken together, the 2 examples from Myanmar and Nigeria illustrate the risk and limitations of reliance on mass distribution of free LLINs. Cross River State in Nigeria has the advantage of high school attendance enabling an integrated vector additional channel for continuous distribution. Still, the "solution" remains solely within the public sector and entirely dependent on continued donor support. Risk of supply chain failure can be mitigated through a reconsideration of the partnerships developed in the early days of ITNs. before the Global Fund and PMI, and as recommended in the Multisectoral Action Framework for Malaria.<sup>22</sup> The LLIN distribution should also be seen in the context of integrated vector management, where larval source management,

**LLIN** distribution should be seen in the context of management.

We are now at a crossroads in malaria vector control whereby the current "solution" of mass distribution of free LLINs is not sufficient and may not be sustainable.

housing improvements, IRS where appropriate, and new tools such as attractive targeted sugar baits may play a role, including for insecticide resistance management.<sup>23</sup> Myanmar has these challenges, and more. Insecticide treatment strategies for the commonly used untreated market nets and new tools for "outdoor transmission" beyond the reach of traditional ITNs and IRS are required. Linked to the needs for vector control in humanitarian emergencies, there is growing interest and investment that we hope will enable some of these new tools to come to the market.<sup>24</sup>

## LESSONS FROM THE PAST, TOOLS FOR THE FUTURE

As Dr. Tedros and Dr. Alonzo said, we are now at a "crossroads" in malaria vector control. Implementing the current "solution" of mass distribution of free LLINs is not sufficient and may not be sustainable. To reduce risk and optimize use of available resources, we need to learn from the past and revitalize the partnerships and the strategies for multisectoral actions and integrated vector management. We also need to look to the future, beyond LLINs, for tools and processes to prevent outdoor transmission, for the mobile forest worker in Myanmar as well as for displaced families throughout much of the malaria-endemic world. As Dr. Nájera suggests, we need to enable programs with the flexible policy and technical options to move from being "solution implementors" to "problem solvers."8

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**EDITORIAL** 

## Is It Time to Move Beyond Visual Inspection With Acetic Acid for Cervical Cancer Screening?

Shannon L. Silkensen, a Mark Schiffman, b Vikrant Sahasrabuddhe, John S. Flanigan

Newly emerging low-cost molecular assays and improved visual tests for cervical cancer screening call into question the role of visual inspection with acetic acid (VIA). VIA-based screening continues to offer a low-cost, single-visit approach for screening. However, VIA is highly rater-dependent and has problematic accuracy. RNA, DNA, and protein tests are now available. They offer greater accuracy and the option for self-sampling, but the testing kits are expensive. As these new options continue to improve, the time to move beyond VIA is fast approaching.

See related article by Ouedraogo.

In this issue of GHSP, Yacouba Ouedraogo and colleagues describe successes and lessons from a limited scaling up of a cervical cancer prevention program in Burkina Faso based on visual inspection with acetic acid (VIA). Is now the time to ramp up cervical cancer screening and, if so, should VIA be included? Ouedraogo et al.'s commitment to measuring the impact of the program provides data to examine this question.

## WHAT IS THE BURDEN OF CERVICAL CANCER?

Cervical cancer is highly prevalent in sub-Saharan Africa; the disease can strike women young, prompting the decision to start screening at age 25 in Burkina Faso. The median age for associated mortality is in the early 50s, often during women's most productive years when family and community depend on them.

Cervical cancer mortality is stubbornly persistent in many low- and middle-income countries. The striking progress seen in decreasing maternal-fetal mortality and infectious disease deaths is not seen for this disease. In fact, the Global Burden of Disease models show that we are at a crossover point with cervical cancer mortality exceeding maternal deaths during child-birth (Figure 1).

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#### WHAT IS THE ROLE OF PERSISTENT HPV INFECTION IN DEVELOPMENT OF CERVICAL CANCER?

Human papillomavirus (HPV) is a highly prevalent virus and efficiently transmitted through sexual and skin-to-skin contact. Therefore, promoting abstinence or delay of sexual debut are not effective preventative strategies. Persistence of carcinogenic genotypes of HPV infection leads to virtually all cases of invasive cervical cancer. The long interval between persistence of infection with associated precancers and the development of invasive cancers affords the long-time window for screening and early detection of lesions (Figure 2).

## WHAT STRENGTHS CONTRIBUTED TO THE SCREENING PROGRAM'S EXPERIENCE IN BURKINA FASO?

Ouedraogo and colleagues used a VIA-based detection strategy to reach nearly 14,000 women in Burkina Faso. Of those, 985 (8.9%) screened positive and 649 (65.9%) of those were treated with cryotherapy in a single visit. In addition, 200 women required referral for loop electrosurgical excision procedure (LEEP). Because Ouedraogo and colleagues nested their study within Burkina Faso's health care delivery system, women at community hospitals who needed a more extensive cervical excision procedure were referred to nearby district and teaching hospitals. <sup>1</sup>

The strengths of this cervical cancer screening program include:

- 1. Organized efforts, offering more efficiencies than sporadic or opportunistic screening
- 2. Single-visit approach, minimizing loss to follow-up

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- Patient education and outreach, a critical determinant of broader community-level acceptance of prevention programs
- Health workforce education, vital for success of rater-dependent screening approaches such as VIA

There is growing consensus that these strengths are the basis for building impactful screening programs, but are they enough to recommend the broad uptake of VIA-based screening? Considering the pace achieved, 20 million people live in Burkina Faso; approximately 3.3 million are women ages 25-59 years. Ouedraogo and colleagues required 4 years to cover 14,000 women, underscoring the fact that significant additional resources and manpower commitment will be needed to achieve nationwide coverage. The existing program has achieved a great deal, but one can question whether a quality-assured, practically implemented VIA program of the necessary scale could be established and maintained.

#### WHAT CAN BE DONE TO ADDRESS THE SCALING CHALLENGE?

VIA screening followed by treatment ("screenand-treat") is currently recommended by the World Health Organization (WHO)<sup>4</sup> as a cervical cancer screening strategy when more accurate approaches are not available. In our opinion, successful VIA programs, while laudable, will face

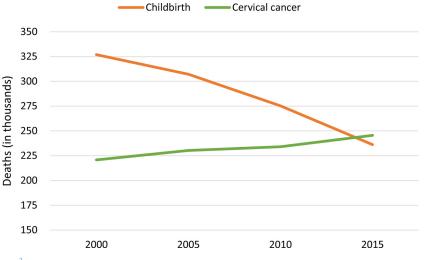
significant scale-up challenges. VIA has the advant- We are now at a age of being inexpensive with a limited supplychain burden and results that are apparent at the time of exam. Yet unaided VIA has problematic accuracy and is not reliably reproducible for the identification of precancerous lesions. Additionally, other differences in screened populations such as age, parity, and underlying cervical disease burden affect the positive predictive value of VIA. It is also highly dependent on the skill and judgment of the observer. 5-7 For example, in a 2017 study by Raifu and colleagues in the Democratic Republic of the Congo, positivity rates of VIA performed by nurses and physicians differed significantly (36.3% versus 30.2%, respectively).8 In contrast, in a large study in India conducted by Shastri and colleagues, the positivity rate of VIA performed by trained high schoollevel educated public health workers was less than 5%.9 Although the utility of VIA in downstaging of invasive cancers in previously unscreened women has been demonstrated in large randomized trials, 9,10 its utility for scaling up of screening programs for detecting and treating cervical precancers is limited due to the need for intensive quality assurance efforts and ensuring adequate provider training and re-training.<sup>11</sup> The strengths and limitations of VIA are illustrated in Table 1.

Given the substantial limitations of VIA, it is important to consider implementing alternative approaches that can overcome its limitations<sup>6</sup> and

crossover point with cervical cancer mortality exceeding maternal deaths during childbirth.

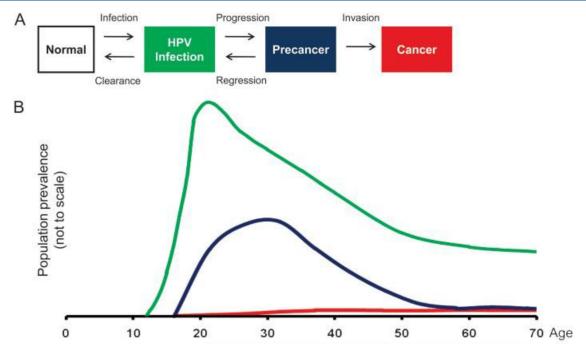
Successful VIA programs, while laudable, will likely face significant scaleup challenges.

FIGURE 1. Deaths From Childbirth and Cervical Cancer, 2000–2015



Source: IHME (2016).2

FIGURE 2. Long-Time Course of Progression From HPV Infection to Cancer



Abbreviation: HPV, human papillomavirus.

Source: Schiffman (2011).<sup>3</sup>

**TABLE 1.** VIA Strengths and Limitations

VIA Strengths	VIA Limitations
Affordable; low per-capita screening costs	High inter-operator variability
Point-of-care results; treatment or referral decisions can be taken in the same visit	Problematic sensitivity, especially for older women with endocervical lesions
Useful for downstaging of cancers in previously unscreened women	Need for investments in high-intensity quality assurance efforts

Abbreviation: VIA, visual inspection with acetic acid.

permit redirecting resources to reach greater numbers of patients.

#### IS IT TIME TO SWITCH TO HPV DNA TESTING AND COMPUTER-ASSISTED VISUAL ASSESSMENT?

There are now at least 5 approved, commercially available HPV tests in the United States, <sup>12</sup> with more in Europe and many more marketed in Asia. This marketplace is competitive and is starting to improve prices and availability of

consumables and testing platforms globally. One test has already received WHO prequalification, an important and necessary step for improving access and bulk purchasing for low-income countries that rely on such multilateral mechanisms for regulatory approvals. <sup>13</sup> Additional tests are on the near horizon and can further improve on affordability and availability in austere practice settings.

The utility of HPV testing in reducing both incidence and mortality due to cervical cancer has been demonstrated in a large community randomized trial in India. <sup>14</sup> Several head-to-head

TABLE 2. H	HPV Testing	Strengths	and	Limitations
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HPV Testing Strengths	HPV Testing Limitations
Point-of-care testing or centralized testing, dependent on testing platform and local needs	Majority of HPV infections (especially in young women) are transient and clinically non-significant
Simplicity and potential scalability of self-collection of samples	Lack of specificity for precancer
Reproducible results; not rater-dependent	Higher per-capita tests costs than VIA
Economical due to longer screening intervals possible for HPV-negative women	

Abbreviations: HPV, human papillomavirus; VIA, visual inspection with acetic acid.

comparisons in cross-sectional studies and field demonstration projects in settings as diverse as India,<sup>5,6</sup> Uganda,<sup>5</sup> Zambia,<sup>15</sup> Tanzania,<sup>16</sup> South Africa, <sup>17</sup> Nicaragua, <sup>5</sup> Brazil, <sup>18</sup> and Argentina <sup>18</sup> have shown that HPV testing has better overall test performance characteristics than VIA or cytology (Pap smears). The ability to self-collect specimens is a unique advantage of HPV testing as a screening strategy and can be gainfully employed for expanding the reach of screening programs (Table 2). Testing platforms for HPV are often repurposed from those already utilized for testing for HIV, tuberculosis, and other infectious diseases. One example, the Cepheid GeneXpert HPV cartridge test, can correctly identify women with significant cervical neoplasia 90.8% of the time and provides a point-of-care testing format.<sup>19</sup> Several of these platforms (e.g., the Cepheid GeneXpert) are already in use in low- and middleincome countries although there might be underutilization challenges that are setting-specific (M. Bates, Cepheid, personal communication, 2018). Nonetheless, the potential to scale-up HPV testing using such platforms is not yet proven. 19

We conclude that neither VIA nor the currently priced HPV tests can scale to solve the cervical cancer problem. Screening systems will require alternative approaches that are highly accurate yet cost-effective. The expanding platforms for HPV testing, as well as other emerging screening modalities, especially computer-assisted visual evaluation, will undoubtedly lead to increased options to implement cervical cancer screening programs. Increased usage of self-collected samples will ensure wider coverage. Advanced technologies will also reduce the variable interpretation of subjective clinical exams and limit the chances of over- and under-treatment. It bears mentioning that management of positive cervical cancer

screening test results virtually always requires a tri- **HPV testing has** age test to prevent over-treatment. While VIA, par- better overall test ticularly with low-tech adaptations like digital cervicography, can be used for such triage, novel developments in machine learning/artificial intelligence<sup>20</sup> and novel imaging techniques<sup>21</sup> are on the horizon and can dramatically improve on performance of current visual inspection approaches. Additionally, improvements in cut-points for sensitivity and specificity of HPV DNA tests and the development of alternative biomarkers for cervical cancer screening could be other approaches to improve accuracy of protocols relying on primary HPV screening.

Overall, we applaud current high-quality VIAbased programs but believe that the future role for VIA is limited. We are confident that using contemporary, high-quality, reproducible tests will soon provide women, researchers, and clinicians with the accurate screening approaches needed for efficient cervical cancer prevention. As we consider the future, we envision successful cervical cancer screening programs will incorporate modern tests into their current health care systems. The quality of these health care systems informs the likelihood of the patient receiving safe, effective, and timely treatment for their disease. Thus, the platform of VIA programs might survive, but the switch to better screening methods will improve the outcomes for women worldwide.

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performance characteristics than VIA or cytology.

We believe the future role for VIA is limited and that contemporary, high-quality, reproducible tests will soon provide us with the accurate screening approaches needed for efficient cervical cancer prevention.

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**EDITORIAL** 

## Evidence-Based Programs, Yes—But What About More Program-Based Evidence?

Policy makers and program managers are better enabled to draw relevant lessons from implementation research and program experience elsewhere when there is richer documentation on what was done and what key contextual factors may have influenced outcomes. Newly developed Program Reporting Standards from WHO provide helpful guidance on what is needed for optimally useful documentation.

See related article by Koek.

#### STANDARDS FOR RESEARCH

An important development over the past couple of decades has been the emergence of reporting standards for various types of research. In the early 1990s, journal editors and investigators agreed on standards for reporting randomized controlled trials, issuing the Standardized Reporting of Trials statement. Over the years since, this has evolved to the Consolidated Standards of Reporting Trials (CONSORT)<sup>2</sup> and numerous reporting standards have been developed for other types of study and evidence synthesis, many of which can be found on the website of the EQUATOR Network (Enhancing the Quality and Transparency of Health Research) (http://www.equator-network.org/). These standards have not only helped improve reporting of research results but also both raised the bar on quality of the research itself and strengthened guidelines based on evidence synthesis. Nevertheless, this development has been largely driven in response to felt needs of investigators and journal editors rather than those of program managers and policy makers.

#### WHY NEW GUIDANCE IS NEEDED FOR PROGRAMMATIC EVIDENCE

Certainly, much is gained from translation of research evidence to practice. But achieving important gains in the complex, messy, real world of programs requires also that we draw evidence from practice.<sup>3</sup> The World Health Organization (WHO) plays a crucial role providing guidance to country level with regard to both evidence-based interventions addressing key health problems and strategies for delivering them. When guidance is offered on specific biomedical interventions, often we are well served by evidence from randomized controlled trials, and a research-to-practice translation

model is helpful. However, for complex interventions and lessons drawn from program experiences, factors other than intervention efficacy also come into play. For policy makers and program managers considering evidence arising from particular program experiences, context and specific details on how an intervention was delivered are crucial in trying to determine to what other circumstances or settings that finding might generalize. Rigorous though their requirements may be in other respects, many research-oriented journals give short shrift to these crucial elements.

Hales et al. (2016)<sup>4</sup> describe the process and results of a recent effort to specify reporting standards that more adequately capture the kind of information needed by program managers who are trying to draw actionable lessons from implementation and operations research results. A related effort on reporting standards for complex interventions has carried this further, resulting in Standards for Reporting Implementation Studies (StaRI).<sup>5</sup> Checklists developed for these standards now include explicit logic pathways, how the tension between fidelity and adaptation is resolved, and adequately rich description of context and its interplay with delivery of the intervention.

## THE WORLD HEALTH ORGANIZATION WEIGHS IN

For policy makers and program managers seeking to draw on what has been learned from programs in other settings that might be relevant to their own, published studies can be ahelpful source of such insights, *providing there is sufficient information on context and how the interventions were delivered*. In addition to studies published in the peer-reviewed literature, good gray literature documentation of such program experiences can be a valuable resource. But to date, although StaRI is a very helpful addition, there hasn't been similar attention to elaborating reporting standards for gray literature. As discussed in the article by Koek et al.<sup>6</sup> in this issue of GHSP, WHO has recently released a new guidance document,

Achieving important gains in the complex, messy, real world of programs requires us to draw evidence from practice.

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Program Reporting Standards for Sexual, Reproductive, Maternal, Newborn, Child and Adolescent Health (PRS), which helps address this gap. These standards cover both peer-reviewed and gray literature reports documenting implementation and scale up of reproductive, maternal, newborn, child, and related health programs and are intended to result in reporting that can better facilitate crossprogram learning on what works (and what doesn't), and under what circumstances. Such learning can aid in decision making on adoption, adaptation, and scale up across diverse settings.

Koek et al. acknowledge the value of current research reporting standards but they also point out that for program managers and decision makers existing standards have given insufficient attention to documentation needed on context and implementation details. The new PRS give appropriate attention to issues including:

- · Implementation design and logic model
- Context
- The time dimension
- The actors involved in delivery
- Resource requirements
- The planning, piloting, and scale-up process
- Specific activities
- Quality assurance, monitoring, and evaluation
- Coverage and reach achieved
- Adaptations (fidelity vs. flexibility)
- Sustainability
- Strengths and weaknesses
- Lessons learned and implications

More systematic attention to such issues in gray literature reports can make them considerably richer, more useful learning documents for decision makers in other settings who are trying to draw lessons that could be relevant for their own programs.

## ■ GHSP SUPPORTS THE PROGRAM REPORTING STANDARDS

At GHSP, we believe these new standards are also useful in specifying the kind of information that

can make peer-reviewed implementation and operations research more valuable to program managers. In the Internet age, even hard-copy journals can offer their authors the option of online annexes, to provide richer detail on context and implementation. At the end of the day, we are better able to deliver effective programs and achieve improved population-level health outcomes if we can draw lessons from each other's program experiences.

We fully realize that the PRS represents something of an idealized model. Much useful evidence is developed that does not comprise every element in the standards. And the real world of program implementation can be messy and challenging. Still the elements in the PRS are to a very large extent what we look for in considering what papers to publish. We encourage colleagues in the global health community to use the PRS with vigor.—*Global Health: Science and Practice* 

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The new WHO
Program
Reporting
Standards can
help make
program
documentation
richer and more
useful for decision
makers in other
settings.

#### **VIEWPOINT**

## Eliminating Mother-to-Child Transmission of HIV by 2030: 5 Strategies to Ensure Continued Progress

Alexandra C. Vrazo, a David Sullivan, Benjamin Ryan Phelpsa

To keep up momentum in preventing mother-to-child transmission we propose: (1) advocating for greater political and financial commitment; (2) targeting high-risk populations such as adolescent girls and young women; (3) implementing novel service delivery models such as community treatment groups; (4) performing regular viral load monitoring during pregnancy and postpartum to ensure suppression before delivery and during breastfeeding; and (5) harnessing technology in monitoring and evaluation and HIV diagnostics.

#### ENORMOUS PROGRESS IN PMTCT

ver the last 3 decades, prevention of mother-tochild transmission (PMTCT) of HIV programs have been at the forefront of HIV care and treatment innovation. The Global Plan Towards Eliminating New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive, launched in 2011, set a series of ambitious targets for 2015 including the reduction of new HIV infections among children by 90% and AIDSrelated maternal mortality by 50% from 2009 through 2015. The successful global movement to start all pregnant and breastfeeding women on antiretroviral therapy (ART) regardless of CD4 T-cell count or clinical staging (known as Option B+)<sup>2,3</sup> set the stage for the World Health Organization's (WHO's) aptly named "Treat All" guidelines, which eliminated many longstanding barriers to HIV treatment.4 Meanwhile, data from several clinical trials—PROMISE, TEMPRANO, START, and HPTN 052—further demonstrated how outcomes improve with ART initiation at any CD4 T-cell count.<sup>5–8</sup> These studies demonstrated lower morbidity and mortality, increased linkages to care, faster immune system reconstitution, and decreased HIV transmission in those starting ART sooner. The rapid scale up of Option B+ to more than 21 countries has demonstrated that programs designed to test and then quickly start treatment in all pregnant and breastfeeding women with HIV lead to increased enrollment, infections averted, and lives saved.9 The elimination of mother-tochild transmission of HIV in Armenia, Belarus, the Caribbean, Cuba, and Thailand is encouraging and historic. This multinational milestone provides a clear example of how a strategic approach can succeed when access to services is coupled with strong public health infrastructure, committed political leadership, coordinated engagement of multiple partners, sufficient funding, and a robust monitoring system. <sup>10,11</sup>

The increasing awareness of the ART regimens and program strategies that best prevent vertical transmission of HIV has led to a dramatic increase in access to ART among pregnant and breastfeeding women over the last decade. Global ART coverage is now estimated at 77% of pregnant women living with HIV, while ART coverage of all people living with HIV is lower, at approximately 53%. In 22 of the countries with the highest HIV burden-which together account for 90% of the global unmet PMTCT need—ART coverage has almost doubled for pregnant women, with 7 of these countries reaching 90% ART coverage rates among pregnant women living with HIV.12 Moreover, motherto-infant transmission rates are now below 5% in several countries, including Ethiopia, South Africa, and Tanzania, moving toward the criteria for elimination of MTCT, defined in part by lowering new HIV cases to fewer than 50 per 100,000 live births.9

These advances in PMTCT may signal to some that the mother-to-child transmission battle is won, or soon will be. This is unfortunately not the case. An estimated 90% of the new annual incident infections in children under 15 are still due to mother-to-child transmission, likely due to undiagnosed incident infection during the pregnancy or breastfeeding period, <sup>13</sup> and an estimated 2 million additional children under 15 will be living with HIV by 2020. <sup>14</sup> To eliminate new HIV infections among children by 2030, we will need to build upon the successes and investments that have carried us this

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far. Below, we outline 5 actionable strategies that will consolidate the gains earned by PMTCT programs and help avoid reversals in progress already made.

## 5 STRATEGIES TO PROTECT AND BUILD ON PMTCT GAINS

### Strategy #1: Advocate for Intensified Political and Financial Commitment for PMTCT

The key take-home message from this article is this: Providers, policy makers, programmers, and communities must continue to advocate strongly for PMTCT, a platform that cost effectively saves 2 lives simultaneously (mother and infant) while preventing HIV and promoting family health. After the much-needed initial scale up of funding for global PMTCT programming and achievements in the earlier years of this decade, both funding and progress have slowed. The year 2015 saw the first global decrease in PMTCT funding since 2010, and further cuts are planned. 15 As an example, PMTCT funding declined by 65% between 2013 and 2017 within the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). 16 While progress in antiretroviral (ARV) coverage for pregnant women showed rapid global scale up in the early part of the decade, increasing from the previous year by 17% in 2011 and by 13% in 2012, progress has slowed more recently, increasing by just 1.4% and 2.7% in 2016 and 2017, respectively.9

Advocates for sustaining PMTCT funding must frequently remind policy makers that PMTCT is cost-effective and protects not just 1 but 2 lives. 17-19 Besides keeping mothers well, PMTCT protects HIV-exposed children from infection and decreases infant morbidity and mortality, thus reducing the need for infant ART and limiting HIV resistance.<sup>20,21</sup> Leveraging the PMTCT platform to improve access to services to improve the health of mothers, infants, and children living with or at risk from HIV infection can help extend services efficiently in an era of increasingly limited resources. Family planning, nutrition, and maternal, neonatal, and child health services are often integrated, such as combining visits for immunizations with infant virological tests for HIV during the breastfeeding period. 22,23 Other PMCT services can be integrated into immunization platforms, including rapid HIV testing of mothers who may have seroconverted during pregnancy, of those who did not come to antenatal care, or of those who did not receive an HIV test at antenatal care. Service integration is feasible across a variety of contexts, both in health facilities and in community settings, and can help protect recent hard-fought gains in child survival. <sup>24,25</sup> With family planning, modeling exercises have shown that simple interventions such as the inclusion of contraceptives as part of the PMTCT package can have a greater impact on reducing the number of infants born with HIV infection than ARV drugs for PMTCT alone. <sup>26,27</sup>

Finally, PMTCT platforms can catalyze access to other HIV services, including HIV case finding for men and siblings through family-based models. Successful family-based interventions, such as "MTCT-Plus," enrolled family members into care and treatment in countries including Côte d'Ivoire, Kenya, Malawi, and Thailand. 28-31 MTCT-Plus is a comprehensive approach, linking PMTCT programs with HIV-specific primary and preventive care for the whole family.<sup>32</sup> Conceptualized as a suite of services reaching entire families, the cost-effectiveness of PMTCT is compelling: Averting 90% of new pediatric infections alone would significantly reduce expenditures on pediatric care and treatment by country governments and donors. In addition to averting thousands of pediatric infections, a 90% decrease in PEPFAR's pediatric care and treatment costs could represent over \$100 million in annual savings (based on PEPFAR planned expenditures in fiscal year 2017).

## Strategy #2: Continue Focused Innovation to Target High-Risk Populations

PMTCT program innovation ushered in an era of "Treat All" and family-based care. Building on PMTCT programs that have redefined the HIV landscape, future innovations in PMTCT policy frameworks and program design must sensitively target populations that bear the highest burden of the epidemic, including adolescent girls and young women ages 10–24 and female sex workers.

Adolescent girls and young women. The "youth bulge" in Africa, where 61% of the population is under the age of 24, has made adolescent girls and young women a major at-risk population for HIV infection, <sup>33</sup> where they now account for nearly 75% of new HIV infections in sub-Saharan Africa. <sup>34</sup> Besides new incident infections, a substantial number of new HIV-positive diagnoses are made in perinatally infected adolescents. <sup>35,36</sup> Together, these new and previously undiagnosed adolescent infections could represent a large contribution to new infant infections.

Providers, policy makers, programmers, and communities must continue to advocate strongly for PMTCT, a platform that saves the lives of both mother and infant while preventing HIV and promoting family health.

**MTCT-Plus** provides integrated services for the entire family, including clinical care and prevention, nutrition, family planning, counseling, and other supportive care, in both clinical and community settings.

Female sex workers. HIV prevalence is an estimated 13.5 times higher among female sex workers than the general female population.<sup>37</sup> The majority of female sex workers worldwide are mothers, and PMTCT platforms represent a unique opportunity to reach and retain these women and their infants in HIV care. 38-40 However, due to criminalization, stigma, discrimination, and violence, access to respectful antenatal and postnatal care remains elusive for them, and poor HIV-related outcomes for mothers who identify as female sex workers and their infants are sadly all too common. 39,41–43 Programmers can use innovative approaches such as differentiated service delivery models that simplify and adapt HIV services to better meet the needs of people while reducing burdens on the health system<sup>44</sup> and stigma measurement tools for key populations<sup>45</sup> to inform the design of respectful, sensitive, and stigma- and discrimination-free services to ensure that pregnant and breastfeeding female sex workers are not marginalized from PMTCT programs. Since a substantial proportion of incident HIV infections will occur in high-risk women who are pregnant and breastfeeding, to truly eliminate mother-to-child transmission and to achieve the 90-90-90 HIV treatment goals (by 2020, 90% of all people living with HIV will know their HIV status, 90% of all those diagnosed with HIV will receive ART, and 90% of those on ART will have viral suppression), it will be critical to incorporate periodic HIV retesting and PMTCT programming into both adolescent- and female sex worker-friendly sexual and reproductive health services.

#### Strategy #3: Refine Novel Service Delivery Modalities for the PMTCT Context

Novel HIV service delivery approaches are crucial to reducing the burden on health facilities in the era of universal treatment, and programmers must advocate that pregnant and breastfeeding women living with HIV are included in these approaches. WHO recently outlined key considerations for promoting differentiated service delivery for pregnant and breastfeeding women living with HIV.44 Under a differentiated service delivery model, people living with HIV who are clinically stable on treatment would need to make less frequent clinic visits than people who are ill and need intensive follow-up. As delivery models evolve to incorporate these considerations specifically for pregnant and breastfeeding women living with HIV, the package of PMTCT services should

be deliberately developed to maximize the advantages of these models. Numerous studies have reported on the barriers for pregnant and breastfeeding women-including travel time, cost, and disclosure—that impact both access to and retention in care. 46-51 Many of these barriers are being addressed by bringing services closer to where women live. For example, in South Africa, almost 90,000 stable individuals belong to community ART groups implemented by Médecins Sans Frontières. 52 These groups have promoted adherence among stable patients with enhanced viral load suppression and higher CD4 T-cell counts, and they have also improved linkages to other supportive services and retention in care. 53,54 Appointment spacing and fast-track drug refills have also saved costs and increased retention by reducing clinical visits, the amount of time spent at the clinic, and staff workloads.<sup>55</sup> Expanding the use of proven lay cadre platforms, such as mentor mothers and patient advocates, is another strategy to bring differentiated care models to pregnant and breastfeeding women. 25,56,57

During development of differentiated models of ART delivery, it will be crucial for programmers to address the distinct needs of women in the pregnancy and breastfeeding periods, and to consider integration with maternal, neonatal, and child health services, including child health visits. To ensure increased uptake and scale up of the recent WHO considerations for differentiated service delivery in PMTCT programs, programmers should seek out opportunities to innovate and to publicize any resulting successes.

#### Strategy #4: Recognize the Importance of **Viral Load Monitoring During Pregnancy** and Postpartum

Despite the promise held by new ARV formulations like dolutegravir for pregnant and breastfeeding women, current first-line ARV regimens have great potential to eliminate mother-to-child transmission as long as regular viral load monitoring is performed to identify challenges with ART adherence or clinical failure. The pregnancy and breastfeeding period represents a time-limited window in which reduced adherence and spikes in maternal viremia, even with ART usage, put the mother and infant at risk.<sup>58</sup> However, there has been inadequate attention to viral load monitoring in pregnancy and the postpartum period. Recent considerations suggest that the frequency of viral load testing should be increased during **pregnancy or** pregnancy and breastfeeding, with the goal of breastfeeding.

**Recent WHO** guidance for differentiated service delivery for pregnant or breastfeeding women highlights distinct considerations for clinically stable women who are accessing ART care at conception compared with women initiating **ART during** 

Innovative approaches to reporting and visualizing program and laboratory data online have helped PMTCT programs track results in near real-time in Kenya, Malawi, Nigeria, Tanzania, and Uganda.

achieving suppression before delivery and maintaining suppression during breastfeeding.<sup>59</sup> Proposed interventions include viral load testing 4 weeks prior to delivery to set the stage for postpartum interventions in the event of high maternal viral load, including targeted birth testing and enhanced ARV birth prophylaxis.<sup>59,60</sup>

Much additional research remains on viral load monitoring in pregnancy and postpartum that cuts across clinical, programmatic, and behavioral areas. As a simple step, health cadres already in use in PMTCT programs, such as mentor mothers, can be employed to create demand for viral load monitoring; sensitize and inform mothers about the prolonged risk that incomplete adherence carries; and provide adherence support to mothers. For breastfeeding mothers, the clinical visits for the infant (including newborn visits, immunization visits, and well-child visits) can be leveraged as opportunities to provide access to maternal viral load testing throughout the period of infant exposure.

## Strategy #5: Harness Technology to Advance PMTCT's Impact

Technological advances in monitoring and evaluation and HIV diagnostics have the potential to further drive PMTCT program success. The Global Plan brought significant improvements to measuring PMTCT program outcomes, including lowtech longitudinal registers to track mother-infant pairs and an updated monitoring framework as countries moved to providing lifelong ART for women under Option B+.<sup>61,62</sup> Despite these advances, ongoing core challenges to monitoring and evaluation include tracking women who move between general ART and PMTCT programs, monitoring maternal viral suppression, and assessing final infant HIV status. The individual medical record data needed to accurately determine these PMTCT outcomes are challenging to track in settings where health infrastructure is limited and electronic systems are not available.<sup>63</sup> Several technologies have been used in PMTCT applications to complement paper-based systems to improve the collection and reporting of patient, facility, subnational, and national data to help programmers identify gaps in PMCT programming. Below are a few examples.

SMS-based reporting and messaging algorithms: Short message service (SMS) technology has been used widely for mobile health (mHealth) initiatives. Many of these initiatives, including MomConnect in South Africa, have

been used to provide bidirectional information to pregnant mothers and to health facility staff.64 Other SMS innovations in use for PMTCT include Uganda's nationwide weekly reporting system. 65 Each registered PMTCT site reports weekly on 9 indicators by using mobile phones to text data, including on ARV and test kit stock-outs. In 2015, an average of 79% of the 1,687 registered PMTCT sites reported their data, which is received in a central database. This "small data" is analyzed and shared via an electronic dashboard to stakeholders including program managers, district health officials, and implementing partners to allow decisions on targeted technical assistance to sites. The online dashboard program is available publicly at http://dashboard. mets.or.ug, and a smartphone app is also available (B+Track). In Kenya, the HIV Infant Tracking System (HITSystem) uses algorithmbased computer and text messaging alerts. It was first demonstrated to improve the quality and efficiency of early infant diagnosis services in Kenyan hospitals and has been expanded to Malawi, Nigeria, and Tanzania.66 The tool links key stakeholders—clinicians, laboratory staff, and mothers-through web-based and SMS notifications with the goal of improving mother-infant retention in care and health outcomes. Lessons from SMS technologies have demonstrated that for successful use in PMTCT programs, early and sustained engagement with stakeholders, including mothers, health staff, and policy makers, is critical to effectively impact PMTCT outcomes.

Laboratory dashboards: A key challenge in monitoring mother-infant health outcomes in PMTCT programs has been ineffectively used paper-based systems, which hamper the timely return of maternal viral load and infant virological test results, including early infant diagnosis. Lengthy turnaround times also contribute to delays in clinical management and represent a major challenge to managing viremia in mothers and infants living with HIV alike. Dashboards to support the review of national viral load and infant virological test program data have been created in Kenya (http://eid. nascop.org/) and Uganda (https://edash. cphluganda.org/) by integrating open-source laboratory information systems with cloudbased servers. These dashboards allow customizable data views for metrics at the national and subnational level, including viral load

suppression rates for pregnant and breastfeeding mothers; infant positivity rate; infant ART initiation rate; early infant diagnosis and viral load turnaround times; and district- and facility-level data disaggregation. Providers and program managers can monitor progress in real time at the site and lab levels using these dashboards to complement patient-level data, and make adjustments to laboratory or clinical processes to ensure that women with high viral load and HIV-exposed infants receive care in a timely manner.

Novel point-of-care instruments: One of the greatest challenges of the PMTCT cascade is the infant diagnostic test. In high-burden HIV settings, it can be very challenging to get samples from the patient to the laboratory and back, and then to communicate those results to the parent.<sup>67</sup> Point-of-care (POC) instruments have the potential to be used at birth or later for infant diagnosis per recent WHO guidelines. Though POC instruments require unique maintenance, reagents, and provider training,68,69 field evaluations have shown that POC instruments are feasible for use in infant diagnosis, 70-73 where they increase infant retention in care.<sup>74</sup> When coupled with effective clinical and community linkage processes, POC infant testing promises to increase access to testing and improvements in retention among those diagnosed.75

#### CONCLUSION

PMTCT programs have made significant strides over the last 2 decades, but global funding for HIV is in decline while new pediatric infections persist. To continue to advance PMTCT programs, advocates, public health practitioners, and policy makers have promising options, including the ones outlined in this article. Strategies such as these will help ensure continued progress toward the elimination mother-to-child transmission of HIV, one of the key global health challenges of our time.

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**Integration of POC** instruments into the conventional **laboratory** diagnostic network and coordination of procurements and trainings are critical considerations for planners to ensure POC technology adds value to PMTCT programs for infant diagnosis.

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#### **COMMENTARY**

# Doing What We Do, Better: Improving Our Work Through Systematic Program Reporting

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WHO has recently published program reporting standards to guide the type of information that reproductive, maternal, newborn, child, and related health programs should document to promote cross-program learning. We strongly encourage our partners and key stakeholders to make use of the new standards as part of their routine program reporting.

The world's 2030 Sustainable Development Goals (SDGs) put forth a broad, visionary, and ambitious agenda, including targets that require efficient, effective programs in communities and populations implemented at scale. Collectively, our organizations invest significantly in global health science and practice.

We all emphasize evidence-based learning, design, and implementation to improve the programs we support. There are several paths to improving the efficiency, effectiveness, and sustainability of programs; one path to improvement is cross-program learning. We often find, however, that program reports, when accessible, lack critical information necessary for reproducibility and adaptation to context. They also often lack information on key insights generated in the field that could be invaluable to other programs struggling with similar issues or seeking to implement similar interventions in a different context. Having accessible, systematic, comprehensive, and easily comparable data on program implementation—the how, why, who, and what would facilitate learning, replication, validation, and scale up of interventions for different populations and environments.

For these reasons, we welcome the World Health Organization's (WHO's) recent publication on Program Reporting Standards (PRS) for sexual, reproductive, maternal, newborn, child, and adolescent health (SRMNCAH) programs. The objective of the PRS is "to

provide guidance for complete and accurate reporting on the design, implementation, monitoring, and evaluation processes of SRMNCAH programs." The PRS are intended for program managers and other staff who design, implement, and/or evaluate SRMNCAH programs, as well as implementation researchers who need to document important details of implementation and context. The PRS are comprised of 24 reporting items across 5 sections (Box). For example, the PRS indicate that implementation monitoring should include a description of the monitoring mechanisms; coverage/reach and drop-out rate; adaptations to programming; acceptability of programming; feasibility of programming; and factors affecting implementation.

Gaps identified in program reporting between "what is learned in the field and what is communicated in scientific publications" and gray literature are longstanding. For example, the 2013 Population-Level Behavior Change Evidence Summit for Child Survival and Development, led by the United States Agency for International Development (USAID) and the United Nations Children's Fund (UNICEF), found systematic reporting gaps for social and behavior change programming and evidence for impact on child health.<sup>3</sup> More than 100 experts reviewed hundreds of peer-reviewed articles and gray literature published since 1990 in order to develop recommendations for policy, programs, and research. They concluded that the basic information needed to assess the quality and context of much of the evidence they reviewed was lacking. Additionally, they concluded more broadly that the field of social and behavior change needs "to improve the way it reports successes and failures and collectively learns."3 Systematic reviews and global guidance carried out by WHO<sup>4</sup> in other program areas have reached similar conclusions. The United Nations Population Fund (UNFPA) also learned this through its efforts to review the availability and quality of emergency obstetric and newborn

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Program reports often lack critical information necessary for reproducibility and adaptation to context.

**WHO's Program** Reporting Standards provide guidance for complete and accurate reporting on the design, implementation, monitoring, and evaluation process of reproductive, maternal, newborn, child, and related health programs.

care and to determine the drivers for successful implementation of policies and programs.<sup>5</sup>

WHO's extensive and collaborative process to develop these PRS originated in a shared understanding of the need for more "action-oriented" information in the peer-reviewed and gray literature. Kågesten et al.<sup>2</sup> identified and reviewed several other existing reporting guidelines in their work developing the PRS. While the existing reporting guidelines are considered relevant and have some overlap in reporting items with the new WHO PRS, they were mostly developed for translation or synthesis of research findings and fail to include key aspects of context; details of intervention or program design, the development process, implementation, or delivery; and evaluation processes and outcomes of particular relevance to policymakers, program implementers, and their partners.2 The new PRS provide guidance on achieving more complete and accurate documentation of those processes and outcomes, including important factors such as context, sustainability, scalability, and stakeholder involvement.

The new PRS place emphasis on context, which is needed to understand how programs are delivered, key factors accounting for observed performance, and issues that may be important in its potential replication and/or scale up, including factors that can vary over the program's planned timeframe. Currently, contextual factors such as norms, behaviors, social networks, existing policies, and health system capacity are not included in routine reporting, though implementation success often depends on such factors. With organizations supporting and implementing programs across a wide range of different contexts, this information is critical to better understand both successful and failed programming; replicate and/or adapt programs as needed; and scale up effective interventions. Reporting items on sustainability and scalability can help ensure that these aspects are considered, as appropriate, from the beginning of implementation and are continually reflected upon throughout implementation. The process of stakeholder involvement and local ownership of programs needed for sustainability is considered vital by donors and United Nations (UN) agencies supporting governments; however, very little is reported on the success or failure of these processes. Use of PRS would allow for a consistent documentation of these experiences.

From an implementation perspective, these standards are practical and easily applicable, though some adaptation may be required for **BOX.** WHO's Program Reporting Standards for Sexual, Reproductive, Maternal, Newborn, Child, and Adolescent Health: Reporting Items by Section

- 1. Program overview
  - a. Rationale and objectives
  - b. Start and end date
  - c. Setting and context
  - d. Stakeholders
  - e. Funding source(s)
  - f. Theory of change and/or logic model
  - g. Human rights perspectives
- 2. Program components and implementation
  - a. Program planning
  - b. Piloting
  - c. Components/activities
  - d. Quality assurance mechanisms
- 3. Monitoring of implementation
  - a. Monitoring mechanisms
  - b. Coverage/reach and drop-out rate
  - c. Adaptations
  - d. Acceptability
  - e. Feasibility
  - f. Factors affecting implementation
- 4. Evaluation and results
  - a. Evaluation
  - b. Results
  - c. Costs
- Synthesis
  - a. Lessons learned
  - b. Sustainability
  - c. Scalability
  - d. Possibilities for implementation in other settings

larger programs.<sup>3</sup> Widespread use of these standards for reports and publications should much improve the usefulness of program reporting, adding essential information on context and facilitating more relevant cross-country learning. The new PRS have the advantage of bringing all of the reporting items together in a single document and providing guidance on definitions and quality standards of the reporting items. In other words, what WHO is proposing is facilitating a more

coherent and more systematic way of reporting, with the specific goal of better serving program learning needs.

WHO's PRS ensure a comprehensive approach to documentation of the program development cycle, from design to evaluation and results. The ability to find all the needed information in a single document—and to be able to compare or collate this information across programs—represents a relatively modest change in existing processes that could, nevertheless, result in significant benefits, not only for program managers and implementers but also for program participants/beneficiaries and the larger global health research, policy, and practice communities.

One key consideration that Kågesten et al. highlight in their article is the importance of uptake and use of the PRS. Given that the PRS are intended for use by any implementing partner, dissemination will be important through a range of channels and through different partners such as donors, UN, international NGOs, and the private sector, among others. Agencies and organizations could help in its uptake by incorporating PRS as a strong recommendation or as a standard element of contractual agreements and programming guidance provided to partners, country offices, and other stakeholders. A second but no less important piece will be ensuring the availability of the reports so the information can be widely accessed and shared. Many agencies and organizations already do this.

Global Health: Science and Practice is an important venue for sharing programmatic experiences with sufficient space for discussion of context, implementation, and experiences. A key consideration moving forward is how to make sure that this tool for improving the way we report on and communicate about programs—for providing more thorough and accurate information on program successes and failures—is widely available, shared in other publications, and, ultimately, used. Progress in global public health depends on

the ability of the field to share, learn from, and build on each other's programs, including understanding what did or did not work as well as why and in what contexts. Accurate, complete, and comparable reporting will help make this possible.

We are pleased that WHO is taking concrete steps to address these gaps and to harmonize and strengthen reporting across the broad field of SRMNCAH programming. The new standards apply beyond the field of SRMNCAH and are an important contribution to document progress and achievements toward the SDGs. We strongly recommend our partners and key stakeholders in the field of global health and development take ownership and systematically make use of the new reporting standards as part of their routine program reporting.

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Agencies and organizations can help with uptake of the Program Reporting Standards by incorporating them into contractual agreements and programming guidance provided to partners and country offices.

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#### **ORIGINAL ARTICLE**

### Universal Health Coverage in Francophone Sub-Saharan Africa: Assessment of Global Health Experts' Confidence in Policy Options

Elisabeth Paul, a,b Fabienne Fecher, Remo Meloni, Wim van Lerberghed

Even within the fairly homogenous context of francophone Africa, among 18 options presented to experts on how to proceed toward universal health coverage (UHC), consensus was reached on only 1 with respect to effectiveness and another with respect to feasibility. The complexity and challenges of UHC as well as the weak evidence base likely contribute to this uncertainty.

Résumé en français à la fin de l'article. Le texte complet de l'article est aussi disponible en français.

#### ABSTRACT

Many countries rely on standard recipes for accelerating progress toward universal health coverage (UHC). With limited generalizable empirical evidence, expert confidence and consensus plays a major role in shaping country policy choices. This article presents an exploratory attempt conducted between April and September 2016 to measure confidence and consensus among a panel of global health experts in terms of the effectiveness and feasibility of a number of policy options commonly proposed for achieving UHC in low- and middle-income countries, such as fee exemptions for certain groups of people, ring-fenced domestic health budgets, and public-private partnerships. To ensure a relative homogeneity of contexts, we focused on French-speaking sub-Saharan Africa. We initially used the Delphi method to arrive at expert consensus, but since no consensus emerged after 2 rounds, we adjusted our approach to a statistical analysis of the results from our questionnaire by measuring the degree of consensus on each policy option through 100 (signifying total consensus) minus the size of the interquartile range of the individual scores. Seventeen global health experts from various backgrounds, but with at least 20 years' experience in the broad region, participated in the 2 rounds of the study. The results provide an initial "mapping" of the opinions of a group of experts and suggest interesting lessons. For the 18 policy options proposed, consensus emerged only on strengthening the supply of quality primary health care services (judged as being effective with a confidence score of 79 and consensus score of 90), and on fee exemptions for the poorest (judged as being fairly easy to implement with a confidence score of 66 and consensus score of 85). For none of the 18 common policy options was there consensus on both potential effectiveness and feasibility, with very diverging opinions concerning 5 policy options. The lack of confidence and consensus within the panel seems to reflect the lack of consistent evidence on the proposed policy options. This suggests that experts' opinions should be framed within strengthened inclusive and "evidence-informed deliberative processes" where the trade-offs along the 3 dimensions of UHC-extending the population covered against health hazards, expanding the range of services and benefits covered, and reducing out-of-pocket expenditures—can be discussed in a transparent and contextualized setting.

#### INTRODUCTION

uring the past decade, universal health coverage (UHC) has progressively become global health's number one goal. Progress toward UHC is measured along 3 dimensions: (1) extending the population

covered by a mechanism of financial protection against health hazards; (2) expanding the range of services and benefits covered; and (3) reducing out-of-pocket expenditure for the services and benefits that are provided. 1-3 However, evidence on the impact of specific UHC design features is scarce and inconclusive, 4 and it is acknowledged that there is no one-size-fits-all approach to achieving UHC. 2,5-8 Therefore, the choice between the dimension(s) of UHC to be privileged in the first place and the policy options to implement to achieve that implies trade-offs and requires a context-dependent balancing act. 6 In practice, however, key

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stakeholders and agencies often tend to sidestep the difficult trade-off decisions by relying on standardized policy heuristics that may override contextualization and negotiation. The influence of global health experts may be very important in this respect.

This article presents exploratory research attempting to measure global health experts' confidence in, and possible consensus on, the effectiveness and feasibility of a number of policy options commonly proposed for achieving UHC in low- and middle-income countries (LMICs). We first present our objectives and the methodological approach we used, and then draw general lessons from our results.

#### METHODS

Our research question emanated from the observation that many countries rely on standard recipes for accelerating progress toward UHC. We aimed to test the following hypothesis: only those policy options that are judged by a majority of experts to be both effective (that is, likely to achieve their intended objective) and feasible (that is, with a reasonable degree of ease in implementation) should be implemented in a vast range of contexts; the others would be used only in favorable, specific contexts. That is why we intended to assess the degree of confidence among a sample of global health experts on the potential effectiveness and feasibility of a set of common policy options, to allow us to move toward UHC in typical African contexts. To do so, we opted for the Delphi method with the hope that we could reach some degree of consensus on at least some policy options that countries could focus on or, alternatively, avoid.

Based on the World Health Report 2010 on health systems financing, 2 we identified a number of policy options recommended on the path to UHC and grouped them along the 3 dimensions of the UHC "cube." We selected the most frequently recommended and implemented in French-speaking sub-Saharan Africa based on our field experience (Table 1). We then performed a selective review of the literature on these policies, in search for systematic evidence when available and non-systematic evidence otherwise.

We designed a simple questionnaire comprising explanations about the research's purpose and 2 tables requiring respondents to rate the potential degree of "effectiveness" and "feasibility" of the policy options along a 5-point Likert scale. To limit variability of contexts and ensure coherence, we focused the study on typical con- This article texts of French-speaking sub-Saharan African countries; and to limit ideological biases, we selected a number of global health experts working in various types of organizations (multilateral organizations, bilateral donors, consulting firms or freelance consultants, academia, recipient Ministries of Health) who had experience in this broad region. Experts were selected on an ad hoc basis to represent various profiles, but 2 inclusion criteria were that they had to have (1) at least 20 years' experience in supporting health reforms in LMICs in general, with substantive experience in francophone (Western and/or Central) Africa, and (2) a sufficiently generalist profile in order to be able to assess the effectiveness and feasibility of policies relative to the service provision and the financing dimensions of UHC.

We intended to lead the survey across 2 panels: one composed of 15 experts originating from Europe and Northern America (representing 8 nationalities) (the Northern panel), and one composed of 16 experts from Northern, Western, and Central Africa (representing 11 nationalities) (the Southern panel). We contacted experts individually by email and proposed a discussion of the questionnaire through the use of Skype if they were willing to do so. The experts were blind to each other's scoring and did not interact during the survey. All participants were informed about the study's objectives and methods and consented freely to participate. Anonymity was guaranteed until the last step when we shared results in the aggregate with participating experts. We planned to pursue the Delphi process until a consensus was reached, and to also compare experts' responses with the available evidence on policy options. The 2 rounds of the study were conducted between April and September 2016.

#### Adaptations to the Delphi Method

Unexpectedly, our research attempt confronted several issues. First, the participation rate was lower than expected. Of the 31 persons contacted, 23 participated in the first round (13 from the Northern panel, 10 from the Southern panel) and 21 participated in the second round (10 Northern/11 Southern). However, we had to dismiss 4 respondents from the second round who had not participated in the first round, so only 17 experts completed the 2 survey rounds: 9 from Europe (representing 5 nationalities) and 8 from Northern, Western, and Central Africa (representing attempts to measure global health experts' confidence in and consensus on the effectiveness and feasibility of policy options commonly proposed for achieving universal health coverage.

TABLE 1. Common of its rolley opinions beletied for the beight but very	<b>TABLE 1.</b> Common UHC	Policy Options	Selected for	the Delphi Survey
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UHC Dimension	Policy Options
Diminish financial barriers to access	B1 Fee exemptions for children and pregnant women B2 Fee exemptions for the poorest B3 Fee exemptions for priority services (e.g., cesarean deliveries, malaria, HIV) B4 Mandatory health insurance with subsidization of the poor B5 Voluntary community-based health insurance B6 Vouchers for the poor
Improve health care funding	F1 Ring-fenced domestic health budgets F2 Innovative financing for health (e.g., sin tax, bonds) F3 Pooling and defragmentation of existing financing mechanisms F4 Reducing inefficiencies and wastage F5 Performance-based aid funding F6 Creation of a global UHC fund
Improve the supply and management of services	S1 Start with a package of essential services for the whole population and progressively expand the package ("universalist" approach) S2 Start with a full package of services for some categories of population or geographic areas, and progressively extend UHC coverage to other types of populations or areas ("sequenced" approach) S3 Strengthen the supply of quality primary health care services S4 Develop public-private partnerships S5 Results- or performance-based payment of providers S6 Separate provider and purchaser functions through creation of autonomous health services or agencies

Abbreviations: B, barriers; F, funding; S, supply; UHC, universal health coverage.

8 nationalities). No substantial differences were observed between the 2 panels, so we merged them into a single panel in order to analyze the results. See Table 2 for characteristics of the 17 experts included in our panel.

Second, after the first round of the exercise, several experts mentioned the difficulty of granting a score in abstracto for each strategy considered in an isolated manner. As happens in the literature, 2,6,7 they commented on the need to contextualize, to consider how strategies interact with each other, and to differentiate between strategies that may be effective at the micro level but might not be easily scaled up at the country level (the "micro-macro" paradox<sup>9</sup>). For instance, while there is strong evidence that community-based health insurance (CBHI) schemes improve service utilization and protect members financially by reducing their out-ofpocket expenditure, and that CBHI improves resource mobilization, <sup>10</sup> both theory and evidence suggest that a CBHI model, relying only on voluntary, small-scale schemes and small pools with little or no subsidization of poor and vulnerable groups, can play only a very limited role in helping countries move toward UHC.11

Therefore, per the participants' request, we converted the initial questionnaire to include

2 sets of 2 questions for the second round. The first set of questions focused on confidence in the effectiveness of each policy option. These questions were broken down into 2 items and thus scored twice, once for its potential effectiveness as a stand-alone intervention, and once for its potential as part of a UHC reform package. The second set of questions focused on confidence in feasibility of each policy option. These questions were scored once for operational and technical feasibility, and once for political feasibility. Yet when asked to differentiate between standalone and part-of-package effectiveness, and between technical and political feasibility, the differences in scores were negligible. Consequently, we merged these when analyzing the results.

Third, during the first round, experts gave a "moderate" response to the majority of policy options, thus not clearly positioning themselves in favor for or against proposed policy options. To allow for more clear-cut answers, we converted the Likert scale's results into a nominal scale from 0 to 100, and asked the second round's respondents to use the nominal scale to position themselves in the range between their previous response and the average response. However, during the second round, most policy options kept scoring in the "moderately effective" range, and

**TABLE 2.** Characteristics of the Delphi Study Panel of Experts

				Experience in:		
Expert No.	Country of Origin	LMIC MOH Staff or Technical Assistant	Multilateral Organization	Bilateral Agency	Consultancy Firm or Freelance	Academia and/ or Civil Society
1	Belgium	Х	Х		Х	Х
2	Belgium	Х		Х		Х
3	Belgium				X	Х
4	France				X	
5	Germany	Х		Х	Х	
6	Germany	X		Х		
7	Germany	X	Χ	Х	Х	
8	Italy		Χ		Х	Χ
9	Netherlands	Х	X		Х	
10	Burundi	Х			X	
11	Democratic Rep. of the Congo	Х	Х	Х	Х	
12	Guinea	Х	X	Х	Х	Х
13	Côte d'Ivoire	Х			X	Х
14	Mali	Х	Х			
15	Morocco	Х	Х			
16	Senegal	Х			Х	Х
17	Tunisia	Х	X			

Abbreviations: LMICs, low- and middle-income countries; MOH, Ministry of Health.

no consensus emerged as we hoped would be possible.

Therefore, we changed our analytical approach: since no consensus seemed to emerge through the use of the Delphi method, instead, we statistically analyzed the results from our 17 questionnaires. We measured the degree of consensus on each policy option through 100 minus the size of the interquartile range (IQR) of the individual scores, with 100 signifying total consensus. 12 This indicates an important methodological limitation of our study, due to a lack of representativeness of the expert sample. Our panel was initially designed in a purposive way, fit for the initial qualitative approach chosen, in order to represent a wide range of experiences; however, it is not representative of all global health experts. Therefore, our quantitative results must be interpreted with caution. While providing an indication of tendencies, they certainly should not to be thought of as being generalizable. Other limitations of our study deal with the focus on French-speaking Africa, which is quite homogeneous in some respects—notably the epidemiological profile and main features of health systems and policies—but which also gathers, under the same umbrella, very different contexts, notably in terms of wealth and political regimes. Experts' opinions might also have been biased by their personal experience, be it positive or negative, in specific countries.

#### FINDINGS

## Statistical Analysis of Delphi Survey Responses

Regarding potential effectiveness, only 8 policy options received a consensus rating of 80% or

**TABLE 3.** Average Scores of Delphi Study Participants for Confidence in and Degree of Consensus<sup>a</sup> on Effectiveness and Feasibility of Common UHC Policy Options, Classified by Increasing Confidence in Effectiveness

		Effectiveness		Feasibility	
UHC Dimension Code	Policy Option	Confidence	Consensus	Confidence	Consensus
B5	Community-based health insurance	40	75	49	60
F5	Performance-based aid funding	43	72	48	72.5
S5	Performance-based payment of providers	48	67.5	49	80
F1	Ring-fenced budgets	48	80	56	73.75
S2	Expansion of population covered	49	80	54	70
F2	Innovative financing	51	80	59	65
S4	Public-private partnerships	54	80	58	72.5
B2	Fee exemption for poorest	55	80	66	85
B6	Vouchers	56	80	63	75
F4	Reduction of inefficiencies	59	75	60	75
B1	Fee exemption for children and pregnant women	60	80	64	77.5
F3	Pooling of schemes	60	75	57	65
S6	Purchaser-provider split	60	75	60	68.75
В3	Fee exemption for specific services	61	75	65	77.5
F6	Global fund for UHC	64	75	67	67.5
S1	Expansion of package of services	64	76.25	68	75
B4	Mandatory health insurance	67	75	68	70
\$3	Strengthen supply of quality primary health care	79	90	78	73.75

Abbreviations: B, barriers; F, funding; S, supply; UHC, universal health coverage.

above, but 7 of them were in the "moderately effective" range (confidence scores between 48% and 60%), indicating "soft consensus" (Table 3). Only the policy option "strengthen the supply of quality primary health care services" was consensually judged as being clearly effective by our panel (confidence score of 79 with a consensus rating of 90).

Regarding feasibility, the degree of consensus was even lower. Only 2 policy options received a consensus rating of 80 or above (performance-based payment of providers and fee exemption for the poorest), but one of them was judged moderately feasible (with a confidence score of 49), so that only the policy option "fee exemption for the poorest" was consensually judged as being fairly easy to implement by our panel (confidence score for feasibility of 66, consensus rating of

85). On the other hand, for 5 policy options, the consensus rating was below 70, indicating very diverging opinions among the experts.

#### **Review of Key Evidence on Policy Options**

To deepen our analysis, we attempted to compare responses from our panel of experts with the available evidence (not especially related to French-speaking sub-Saharan Africa), in order to assess whether or not each corresponded with the other. We therefore opted to search for systematic evidence with regard to each of the 18 proposed policy options and completed the literature review with non-systematic evidence when needed.

Regarding the path toward UHC, overall, the existing literature concludes that the effect of UHC schemes on access, financial protection,

Strengthening the supply of primary health care services was the only policy option that the panel of experts agreed was effective for achieving UHC.

<sup>&</sup>lt;sup>a</sup> Degree of consensus measured through 100 (total consensus) minus the interquartile range of individual scores.

and health status varies across contexts, UHC scheme design, and the implementation processes. In most countries and regions, a number of UHC schemes coexist although they demonstrate heterogeneity in terms of design and organization. Evidence on the impact of specific UHC design features on their intended outcomes is scarce and inconclusive, so that several pathways may be appropriate. 4-7,13,14 Yet, there are indications that a progressive expansion of a package of essential services for the whole population (sometimes called progressive universalism) is preferable to sequential extension of the share of the population covered with a full package of services. 14-17 However, to our knowledge, no systematic evidence is available to back this opinion. The literature is also consensual on the fact that no country has attained UHC by relying mainly on voluntary contributions to insurance schemes 18,19 and progress toward UHC requires compulsion and cross-subsidization.6,19,20

Regarding specific policy options, we found that the lack of confidence and consensus among our experts, with large inter-expert variability (ranging from 0 to 100 in the case of fee exemption for the poorest) and many policy options lying in the "woolly" consensus area, often matches the lack of consistent evidence on the proposed policy options. Indeed, the literature is often scanty, inconclusive, and inconsistent, or may challenge the implementation of the proposed policy options. This is the case for:

- *Fee exemptions*: They are shown to entail many implementation challenges while robust evidence quantifying their impact remains scant. <sup>21–26</sup>
- *Ring-fenced domestic budgets for health*: The effectiveness of earmarking taxes or revenue for health appears to be mixed in terms of increasing overall funding, improving its stability, or increasing expenditure for the target program. <sup>5,27–29</sup>
- *Innovative financing mechanisms*: These fall in various categories, but their potential impact on efficiency and equity depend on each country context. <sup>30,31</sup>
- *Mandatory health insurance*: A systematic review of the impact of state-subsidized or social health insurance schemes found no strong evidence of any impact on utilization, protection from financial risk, or health status.<sup>32</sup> Moreover, the real issue is more about the feasibility of the

strategy, in terms of ensuring enrollment in a health insurance mechanism, because the willingness to pay for health insurance in LMICs is low,<sup>33</sup> and even subsidized schemes for the non-poor informal sector face low participation and retention issues.<sup>32</sup>

- Performance-based financing: There is no consistent evidence of the effectiveness, efficiency, and equity of the approach, and there are indications of possible perverse effects on health care providers' behavior and weakening of health systems.<sup>34–41</sup>
- Public-private partnerships: Despite the scale and significance of the phenomenon, there is relatively limited conceptualization and in-depth empirical investigation of such partnerships. Evidence about their effect on clinical quality, coverage, equity, and cost-effectiveness is inadequate, and other challenges concern scalability and scope, indicating the limitations of such interventions as a basis for universal health coverage, though interventions can address focused problems on a restricted scale.
- *Purchaser-provider splits:* No systematic review or coherent literature has been found on this matter, probably due to the extreme diversity in approaches.
- Performance-linked aid: Its alleged advantages are flawed theoretically and poorly backed by empirical research.

On the whole, the quality of the evidence is low and/or non-systematic. The panel's relative confidence in mandatory health insurance, purchaser-provider split, and the creation of a global fund for UHC contrasts with the lack of documented evidence for these options.

On the other hand, the literature does provide evidence that several policy options, with regard to which our experts had mixed opinions, **can contribute positively to UHC**. This is the case for:

- *Community-based health insurance*: There is systematic but weak evidence of a moderate effect with improved service utilization and financial protection by reducing out-of-pocket spending; yet, schemes serve only a limited section of the population. <sup>10,49</sup>
- Vouchers: A systematic review of the impact of vouchers on the use and quality of health care in developing countries found modest evidence that vouchers effectively target specific populations, but there is insufficient evidence to available.

Despite the scale and significance of public-private partnerships, there is relatively limited conceptualization and indepth empirical evidence of such partnerships.

Progressive
expansion of a
package of
essential services
for the whole
population may
be preferable to
sequential
extension of the
share of the
population
covered with a full
package, but no
systematic
evidence is
available.

None of the 18 common UHC policy options received sufficient consensus on both potential effectiveness and feasibility.

Our findings suggest UHC policy options should be implemented only in favorable contexts, following a careful analysis and trade-off process. determine whether vouchers deliver health care efficiently. There is robust evidence that vouchers increase utilization, and modest evidence that vouchers improve quality, 50 in particular for reproductive health services. Another systematic review concluded that all identified evaluations reported some positive findings, indicating that voucher programs increase the utilization of reproductive services, improve quality of care, and improve population health outcomes.<sup>51</sup> A related strategy is the use of conditional cash transfers: Overall the evidence suggests that they are effective in increasing the use of preventive services and sometimes improving health status.<sup>52</sup> A recent systematic review focusing on sub-Saharan Africa found that cash transfers can be effective in tackling structural determinants of health such as financial poverty, education, household resilience, child labor, social capital, and social cohesion. The review further found that cash transfers modify intermediate determinants such as nutrition, dietary diversity, child deprivation, sexual risk behaviors, teen pregnancy, and early marriage. There is moderate evidence from the review that cash transfers impact health and quality-of-life outcomes.<sup>53</sup>

- Pooling/defragmentation: There is anecdotal evidence of a positive effect, even if experience suggests that once established, different pools are politically difficult to integrate or harmonize because integration involves the redistribution of resources across organized interest groups. 15,17,19,54–56
- Reduction of inefficiencies: There is nonsystematic evidence of a positive effect,<sup>57</sup> and systematic evidence of cost savings and efficiency gains in HIV services in LMICs.<sup>58</sup>
- Strengthening primary health care: The experts on our panel were quite confident with regard to the potential of this policy option, which is also supported by existing evidence (mainly non-systematic evidence, 5,55,59,60 but also by systematic evidence in high-income countries, and limited systematic evidence in LMICs). For instance, a systematic review found that although a majority of primary care programs had multiple components—thus making it difficult to attribute effects to the primary care component alone given this integration and the variable quality of the available research—primary care-focused health initiatives in LMICs have improved access to health care, including among the poor, at reasonably

low cost. There is also evidence that primary care programs have reduced child mortality and, in some cases, wealth-based disparities in mortality.<sup>64</sup>

#### DISCUSSION

First, note that since our panel of experts was built on an ad hoc basis in order to involve a wide range of experienced, generalist global health experts, it cannot be characterized as an epistemic community, that is "a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policyrelevant knowledge within that domain or issue-area."65 Indeed, if the inclusion criteria were aimed to guarantee shared knowledge base about UHC and possibly shared principled beliefs, their actual heterogeneity in terms of personal and professional experience—which was desired in the first place—might have led to different causal beliefs and possibly different interests or ideological values. This might have led to the impossibility of reaching a consensus through the Delphi method.

Our study provides an initial "mapping" of the opinions of a group of experts, which offers interesting lessons. It shows that among a panel of 17 experienced global health experts coming from varied countries and backgrounds, none of the 18 common policy options recommended on the path toward UHC received sufficient consensus regarding both its potential effectiveness and its feasibility. This lack of clarity and consensus of opinions regarding UHC policy options in a relatively homogeneous region like French-speaking sub-Saharan Africa is itself an important piece of information. According to our basic premise, this suggests that we should be cautious when it comes to implementing these policy options and that they should be implemented only in favorable contexts, following a careful analysis and trade-off process. But this is not the case in practice, since we observe the concomitant implementation of many of the proposed options in most sub-Saharan African countries and the trend of some donor agencies to "sell" preferred policy options whatever the context. The most striking example is probably that of performanceor results-based financing: This is the one policy option that received the least consensus among our panel of experts, which contrasts with its rapid donor-funded expansion in LMICs. For example, since its inception in 2007, the Health Results Innovation Trust Fund managed by the World

Bank has committed \$385.6 million for 35 results-based financing programs in 29 countries, with the bulk of disbursements taking place in the past 3 years (https://www.rbfhealth.org/projects). This was done despite the fact that in 2014, the Independent Evaluation Group of the World Bank raised a flag by pointing out that the Bank had promoted results-based financing with insufficient empirical support on the soundness of the approach, even proclaiming that "... decisions were made to scale up regardless of weak, inconclusive, or incomplete pilot results." 66

When comparing our results with findings in the literature, we were struck by the lack of consistent, systematic evidence on the effectiveness of most policy options. Most worrying, even supposedly systematic evidence may not be entirely trusted when applied to complex issues. For instance, Coarasa et al. (2017) examined 2 systematic reviews of the literature on the quality of private-sector primary care in LMICs, published in the same journal within a year and reaching conflicting conclusions. They found that weaknesses in the underlying evidence, rather than the rigor of the reviews themselves, led to reasonable disagreements, and therefore called for high-quality empirical evidence on reforms aimed at reaching UHC.<sup>67</sup> Given the broadness of the UHC objective and the complexity and difficulty of implementing policy reforms—especially in low-resource environments such as in Frenchspeaking sub-Saharan Africa—and given the lack of robust evidence on possible policy options, it may therefore be considered very rational for experts to differ widely in terms of what they might recommend. This stresses the **importance** of contextualized policy advice.

We were also struck by the weak differentiation on the part of the experts between policy options that are isolated vs. part-of-package effectiveness on the one hand, and between technical vs. political feasibility on the other hand (as explained above, the differences in scores were negligible, so that we merged these 2 sets of questions when analyzing the results). We hypothesize that there is a disjunction between experts' professional rationality (they are intellectually convinced of the need to contextualize and to differentiate between effectiveness and feasibility in complex systems) and a rather heuristic appraisal when asked to judge a strategy. This has long been recognized, <sup>68,69</sup> and shows the difficulty of formulating objective recommendations in a complex system. It might also raise doubts as to how vulnerable to biases knowledgeable and

experienced experts may be when making policy recommendations.

On this issue, Cairney and Oliver (2017) identify 2 important dilemmas for scientists and researchers—that we can extrapolate to advisers—contributing to an "evidence-policy gap." First, effective actors combine evidence with manipulative emotional appeals to influence the policy agenda. Second, when adapting to multilevel policymaking, experts should not necessarily prioritize "evidence-based" policymaking above other governance principles such as the "coproduction" process of policy between local public bodies, interest groups, and service users, which may be based primarily on values. They conclude that successful engagement in evidence-based policymaking requires pragmatism, combining scientific evidence with governance principles, and persuasion to translate complex evidence into simple stories. To maximize the use of scientific evidence with regard to public health policy, experts should recognize the tendency of policy makers to base judgements on their beliefs and shortcuts based on their emotions and familiarity with information; be prepared to engage in long-term strategies to be able to influence policy; and, in both cases, decide how far they are willing to go to persuade policy makers to act and secure a hierarchy of evidence underpinning policy. These are value-driven and political, not just "evidence-based," choices. 70

Finally, we wondered why international organizations often continue to promote a number of strategies ("donor fads"), the effectiveness of which lack consistent evidence. Wane (2004) establishes both theoretically and empirically that the quality of aid is endogenous to the incentive system that prevails in the aid agency (career concerns) and the capacity and accountability of the recipient country to gauge the quality of aid. He shows that a mix of factors (recipient governments' incentives to accept projects if they bring personal benefits, a donor agency culture of "pushing money," low-capacity and/or lowaccountability recipient governments) leads to recipient governments accepting poorly designed projects to the detriment of their population.<sup>71</sup>

#### CONCLUSIONS

Despite the limitations pointed out above, and even when limiting the focus to the relatively homogeneous contexts of French-speaking sub-Saharan Africa, this exploratory study shows that global health experts' opinions on policy options with regard to achieving UHC diverge a great deal, they are often only moderately supportive or not in support of the standard UHC recipes prevalent in today's global health and development rhetoric, and that most policy options are not backed by systematic and coherent evi**dence**. This conveys implications for the development community. Development agencies are understandably tempted to promote "magic bullet" approaches to UHC. Notably due to a culture of "pushing money" and low-capacity recipient governments,<sup>71</sup> incentives on both the donor and the recipient side favor simple, easily budgeted, single-instrument or isolated solutions, which can then rapidly proliferate, even with little evidence. This may do more harm than good.<sup>20</sup> Expert opinion has a large role to play in justifying policy choices, but it would be dangerous to take their opinion for granted—all the more because, despite a discourse of evidence-based decision making, development actors may have opinions based primarily on personal values and may combine evidence with manipulative emotional appeals to influence the policy agenda. 70 This makes expert policy advice value-driven and political, not just "evidence-based."

Therefore, there is clearly a need for a better understanding of the interactions between the multiple stakeholders-including not only the experts but also the domestic actors—their agendas, and their hierarchy of values. While progress toward UHC has taken various forms around the globe, a common feature emerging from experience is that adopting UHC is primarily a political rather than a technical issue. 72,73 Hence, the need to strengthen inclusive and "evidenceinformed deliberative processes" enabling stakeholders to discuss the trade-offs along the 3 dimensions of UHC in a transparent way, to make the set of values and decision criteria used more explicit, and to take decisions in a coherent and contextualized way. 74–77 This might also promote more actively the respect for domestic political ownership.

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#### En français

La couverture santé universelle en Afrique francophone au Sud du Sahara : Évaluation de la confiance d'un panel d'experts en santé mondiale quant à une série d'options stratégiques

Même dans le contexte assez homogène de l'Afrique francophone, parmi 18 options stratégiques présentées à des experts permettant de progresser vers la couverture santé universelle (CSU), un consensus n'a été atteint que pour une option quant à son efficacité, et pour une autre quant à sa faisabilité. La complexité et les défis liés à la CSU ainsi que la faiblesse de la base de données probantes contribuent probablement à cette incertitude.

#### RÉSUMÉ

De nombreux pays s'appuient sur des recettes standards pour accélérer les progrès vers la couverture santé universelle (CSU). Les données empiriques généralisables étant limitées, la confiance des experts et leur consensus jouent un rôle majeur dans les choix politiques des pays. Cet article présente une ventative exploratoire menée entre avril et septembre 2016 pour mesurer la confiance et le consensus parmi un panel d'experts en santé mondiale quant à l'efficacité et la faisabilité d'un certain nombre d'options stratégiques communément proposées pour atteindre la CSU dans les pays à revenus faibles et intermédiaires, telles que les exemptions de frais pour certains groupes de personnes, les recettes affectées pour la santé et les partenariats publicprivé. Pour assurer une relative homogénéité des contextes, nous nous sommes concentrés sur l'Afrique subsaharienne francophone. Nous comptions d'abord utiliser la méthode Delphi pour arriver à un consensus entre les experts, mais comme aucun consensus ne s'est profilé après deux cycles, nous avons ajusté notre approche pour passer à une analyse statistique des résultats de notre questionnaire. Nous avons mesuré le degré de consensus sur chaque option stratégique à travers 100 (signifiant le consensus total) moins l'intervalle interquartile des scores individuels attribués aux options stratégiques. Dix-sept experts en santé mondiale de divers horizons, mais ayant au moins 20 ans d'expérience dans la vaste région, ont participé aux deux cycles de l'étude. Les résultats fournissent une première « cartographie » des opinions d'un groupe d'experts et suggèrent des leçons intéressantes. Pour les 18 options stratégiques proposées, un consensus s'est seulement dégagé en faveur du renforcement de l'offre de services de soins de santé primaires de qualité (jugé efficace avec un score de confiance de 79 et un score de consensus de 90) et quant à la faisabilité des exemptions de frais pour les plus pauvres (jugées assez faciles à mettre en œuvre avec un score de confiance de 66 et un score de consensus de 85). Aucune des 18 options stratégiques communément rencontrées n'a fait l'objet d'un consensus à la fois quant à son efficacité potentielle et à sa faisabilité. Des opinions très divergentes ont été observées pour cinq options stratégiques. Le manque de confiance et de consensus au sein du groupe d'experts semble refléter le manque de preuves cohérentes sur les options proposées. Cela suggère que les opinions des experts devraient être formulées dans le cadre de processus délibératifs renforcés, inclusifs et fondés sur des données probantes, où les compromis quant aux trois dimensions de la CSU – étendre la population couverte contre les risques de santé, élargir la gamme des services et des avantages couverts, réduire les dépenses directes de santé – peuvent être discutés dans un cadre transparent et contextualisé.

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#### **ORIGINAL ARTICLE**

## Design, Implementation, and Evaluation of a School Insecticide-Treated Net Distribution Program in Cross River State, Nigeria

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Three years following a mass bed net distribution campaign, the addition of school-based distribution to antenatal care (ANC) distribution in Cross River State, Nigeria, increased household ownership of any net to nearly 80%, whereas ownership in the comparison area was below 50%. School distribution was nearly equitable among rich and poor, and very few households obtained nets from both ANC and schools, suggesting complementary reach.

#### ABSTRACT

**Background:** In 2013, the World Health Organization recommended distribution through schools, health facilities, community health workers, and mass campaigns to maintain coverage with insecticide-treated nets (ITNs). We piloted school distribution in 3 local government areas (LGAs) of Cross River State, Nigeria.

Methods: From January to March 2011, all 3 study sites participated in a mass ITN campaign. Baseline data were collected in June 2012 (N=753 households) and school distribution began afterward. One ITN per student was distributed to 4 grades once a year in public schools. Obubra LGA distributed ITNs in 2012, 2013, and 2014 and Ogoja LGA in 2013 and 2014 while Ikom LGA served as a comparison site. Pregnant women in all sites were eligible to receive ITNs through standard antenatal care (ANC). Endline survey data (N=1,450 households) were collected in March 2014. Data on ITN ownership, population access to an ITN, and ITN use were gathered and analyzed. Statistical analysis used contingency tables and chi-squared tests for univariate analysis, and a concentration index was calculated to assess equity in ITN ownership.

Results: Between baseline and endline, household ownership of at least 1 ITN increased in the intervention sites, from 50% (95% confidence interval [CI]: 44.7, 54.3) to 76% (95% CI: 71.2, 81.0) in Ogoja and from 51% (95% CI: 35.3, 66.7) to 78% (95% CI: 71.5, 83.1) in Obubra, as did population access to ITN, from 36% (95% CI: 32.0, 39.5) to 53% (95% CI: 48.0, 58.0) in Ogoja and from 34% (95% CI: 23.2, 45.6) to 55% in Obubra (95% CI: 48.4, 60.9). In contrast, ITN ownership declined in the comparison site, from 64% (95% CI: 56.4, 70.8) to 43% (95% CI: 37.4, 49.4), as did population ITN access, from 47% (95% CI: 40.0, 53.7) to 26% (95% CI: 21.9, 29.9). Ownership of school ITNs was nearly as equitable (concentration index 0.06 [95% CI: 0.02, 0.11]) as for campaign ITNs (-0.03 [95% CI: -0.08, 0.02]), and there was no significant oversupply or undersupply among households with ITNs. Schools were the most common source of ITNs at endline and very few households (<2%) had nets from both school and ANC.

Conclusion: ITN distribution through schools and ANC provide complementary reach and can play an effective role in achieving and maintaining universal coverage. More research is needed to evaluate the cost-effectiveness of such continuous distribution channels in

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combination with, or as a potential replacement for, subsequent mass campaigns.

#### BACKGROUND

Insecticide-treated nets (ITNs) are an effective means of preventing malaria. Over the past 10 years, hundreds of millions of ITNs have been distributed throughout sub-Saharan Africa. Most of these have been through either targeted or universal mass campaigns, which have been found to raise coverage rapidly and equitably. However, maintaining these gains can be a challenge. Household ITN ownership and

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population access to ITNs start to decrease immediately after mass campaigns due to births, migration, and net loss (through repurposing of or damage to the nets). In response, countries have used mass campaigns to replenish ITN coverage every few years. These "top-up" and repeated universal coverage campaigns can be challenging and costly, given the burden of conducting registration visits to every household and the potential for oversupply. Moreover, most households cannot obtain ITNs between mass campaigns.<sup>6,7</sup> Although antenatal care (ANC) clinics, the Expanded Program on Immunization (EPI), and retailers also distribute or sell ITNs, the volumes are too low to maintain universal coverage.8

In 2013, the World Health Organization's (WHO's) Malaria Policy Advisory Committee recommended the combined use of mass campaigns and continuous distribution channels to maintain universal coverage. Universal coverage is defined as universal access to and use of ITNs by populations at risk of malaria and is usually interpreted as the broad goal of distributing 1 net for every 2 people. 9,10 Examples of continuous distribution channels include ANC and EPI as well as community-based platforms, religious networks, agricultural and food-security support schemes, the private and commercial sector, and schools. 11

Schools have long been used as platforms for public health interventions related to nutrition, personal and environmental hygiene, deworming, vaccination, and malaria treatment and surveillance. 12-16 While the primary target beneficiaries for school distribution are household members, students can serve as conduits to households. They can transport ITNs from school to home, where household members can allocate the ITN as needed. Students can also share messages on the importance of using nets with household members. 16

Schools are a promising channel for ITN distribution for several reasons. First, many countries have high rates of school enrollment, particularly at the primary school level. 17 Second, schools' reach into communities is often as good as, if not better than, the reach of the health sector; in many cases, schools outnumber health facilities in the same area. Third, the number of grades receiving ITNs can be increased or decreased based on the number of ITNs required to maintain desired coverage levels. 18 This level of flexibility and reach is not possible with ANC and EPI distribution channels. Fourth, schools have existing structures that make ITN distribution feasible. For example, they have student registers, eliminating the time and costs of household registration visits. They also have lockable storage areas that can temporarily store ITNs. Furthermore, teachers are literate and numerate personnel who can complete basic reports and pass information on to students. Teachers may also value preventive health behaviors and care deeply about students' health and its implications on absenteeism and education outcomes.

Because of these advantages, several countries (Ghana, Nigeria, Senegal, Tanzania, Uganda, Zambia, and Zimbabwe) have piloted schoolbased distribution while several others have included it in their national malaria strategic plans. However, there is little published evidence on the impact of school distribution of ITNs. This article reports on a proof-of-principle study to assess whether adding the distribution of ITNs to a few school grades to the existing ANC channel could sustain household ownership of at least 1 ITN and population ITN access 3 years after a mass campaign in Cross River State, Nigeria.

#### METHODS

#### Settina

This study was conducted in Cross River State in the South-South zone of Nigeria, a region that is highly endemic for malaria. In consultation with the State Ministries of Education and Health, we selected Obubra, Ogoja, and Ikom local government areas (LGAs) as they have similar populations and are equally accessible. The populations for Obubra, Ogoja, and Ikom were projected to be 205,000, 204,000, and 193,000 respectively, in 2012 based on the 2006 national census and an estimated growth rate of 3.2%.19

#### **Study Design**

This study was a before-after assessment of Schools are a intervention areas with a comparison area using promising cross-sectional household surveys. Cross River channel for bed State distributed nets to all 3 study sites during the first wave of the mass ITN campaign, which ran from January to March 2011. The study sites did not participate in the second wave of the mass ITN campaign, which issued nets to several other LGAs in Cross River State from October 2011 to February 2012. We collected baseline data in June 2012 (peak of the rainy season; 15 months after the mass campaign) and implemented the first school distribution in Obubra LGA immediately afterward. During these distributions, schools distributed nets to students in

recommends the combined use of mass bed net campaigns and continuous distribution to maintain universal coverage.

net distribution.

4 grades during a 1-week period. In late February 2013 and March 2014, nets were distributed in both Obubra and Ogoja LGAs. The endline surveys were fielded a few days after the last distribution in March 2014 (end of the dry season). Ikom LGA served as a comparison site and did not receive nets for school distribution. However, all 3 sites received ITNs for distribution to pregnant women at their first ANC visit as standard practice in Cross River State (Figure 1).

The baseline also served as an evaluation of the statewide mass campaign, while the endline was used only to evaluate the continuous (school + ANC) distribution program. For these reasons, the sample size and stratification approach differed between baseline and endline. The 2 primary strata for the baseline survey were the 2 waves of the mass campaign, and the 2 schooldistribution LGAs were oversampled as part of the wave 1 stratum (Figure 2, left panel). The baseline survey covered the whole state with a total of 75 clusters across 10 LGAs; 45 for areas covered by the first wave of the mass campaign (15 for Obubra LGA, 15 for Ogoja LGA, and 15 for the rest of wave 1), and 30 clusters for the second wave (the remaining LGAs). In contrast, the endline survey was limited to the school distribution pilot area (Figure 2, right panel) with a total of 90 clusters, 30 in each of the 3 strata across the 3 LGAs. Because the baseline survey covered a larger group of LGAs than the endline, we ran a sensitivity analysis to assess the comparability between the endline and baseline samples.

Our target sample size for the school baseline and endline assessment was 765 and 1,530 households, respectively. The target sample size of the endline survey was calculated to detect a 12 percentage-point difference in ITN coverage between implementation and comparison sites assuming 5% non-response, a design effect of 1.75, power of 80%, and a 95% confidence interval (CI) for the 2-sided assessment.

The baseline and endline surveys used a stratified, multistage cluster sampling design. First, using population data from the 2006 census, 75 (baseline) and 90 (endline) wards were selected using probability proportionate to size. Thereafter, 1 community (settlement) per ward was selected using simple random sampling from a complete list of settlements for that ward, and served as the cluster. Within each cluster, all households were eligible for selection. A list of households was prepared by the survey team on the day of the survey and the households for interview were selected using simple random number lists. If a cluster had more than 200 households, an equal-size section approach was used and 1 section was randomly chosen from the household list. Households were defined as "people eating from the same pot," which was the definition used in the mass campaign. The target for household-level interviews was the head of household or his/her spouse.

The questionnaire was based on the 2010 *Malaria Indicator Survey* and focused on household ownership, access to, and use of ITNs.<sup>20</sup> Additional questions were added to capture several processes specific to the school distribution such as number of ITNs received through school and sources of information about net use or hanging.

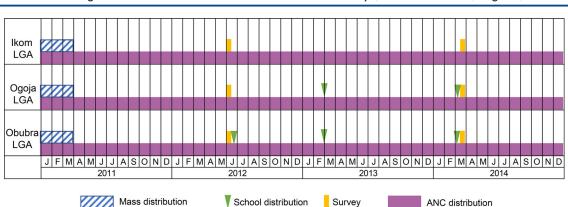


FIGURE 1. Modes and Timing of ITN Distribution and Baseline and Endline Surveys, Cross River State, Nigeria, 2011–2014

Abbreviations: ANC, antenatal care; ITN, insecticide-treated net; LGA, local government area

Baseline

Endline

Wave 1: Jan-Mar 2011

Wave 1: School distribution

Wave 2: Oct 2011-Feb 2012

Akamkpa

Obukpani

Calabar South

Akamkpa

Calabar South

Bakassi

Abbreviations: ITN, insecticide-treated net; LGA, local government area.

FIGURE 2. Maps of Baseline and Endline Survey Strata by Mode of ITN Distribution per LGA, Cross River State, Nigeria

## Program Description Design, Coordination, and Planning

We used the population-based NetCALC modeling tool to estimate the number of nets and grades needed for the pilot. The model assumed that at least 80% of households would own at least 1 ITN after the mass campaign (Supplement). Input data included demographic characteristics from the 2006 census and ANC and school attendance rates from the 2008 Demographic and Health Survey (a gross attendance ratio of 110% was used for primary schools and 95% for secondary schools as well drop-out rates of 20% and 25%, respectively). 22

We met jointly with health and education officials at the state and LGA levels to coordinate planning. Together, we conducted field visits and in-depth interviews with teachers and head teachers to develop the guidelines. Samples of implementation materials from the pilot can be found at www.continuousdistribution.org.

Stakeholders preferred the month of March for school distribution for several reasons. First, it was before the high malaria transmission (rainy) season. Second, it was relatively soon (within 1 year) after the mass distribution in those LGAs, preventing a prolonged gap between distributions. Finally, it did not conflict with school exams. They chose grade levels that were 1 to 3 years apart to ensure most households with children could receive at least 1 ITN every 2 to 3 years: primary

year 1, primary year 4, junior secondary school year 1 (7th year of education), and senior secondary school year 1 (10th year of education). Heads of schools and teachers of the selected grades also received ITNs as incentives for participation. Only public schools were included in the pilot.

#### ITN Quantification

We used second-term attendance numbers from school records to calculate the number of ITNs required. The second term was chosen because attendance usually stabilizes by this time. A buffer stock was considered unnecessary.

#### Training and Microplanning

A cascade training model was used. Heads of schools traveled to the LGA level for an orientation on distribution, completion of forms, supervision, and social and behavior change communication (SBCC) messages. Heads of schools then returned to their schools and trained their teachers. During trainings, heads of schools brought enrollment data, which we used to allocate nets to schools and grades. Microplans for ITN transport and storage were also created during these workshops.

#### **ITN Transport and Storage**

We hired a private transport company to deliver ITNs from the state warehouse (to which they Instead of conducting household registration visits, school attendance records were used to calculate the number of ITNs required. were directly shipped after arrival at port) to the LGA warehouse once school microplanning data were verified, and then from the LGA warehouse to schools. Nets were in storage for a minimal amount of time to reduce the potential for leakage; they arrived at the LGA warehouse 3 days before distribution and at the school 1 to 2 days before distribution. Schools kept ITNs in store rooms or in the head of school's office.

**ITN Distribution** 

Each year, we distributed 1 ITN per student to 4 grades, which were 1 to 3 years apart to ensure most households with children could receive at least 1 ITN every 2 to 3 years.

One ITN per student was distributed to 4 grades once a year in public schools. Nets were distributed during the school break (30-45 minutes) to minimize disruption. Teachers in target grades first taught students about the benefits of ITN use and net maintenance, then each student was called forward to receive an ITN and sign the register. Students received Olyset or DawaPlus 2.0 ITNs. Teachers opened the packaging before handing ITNs over to discourage resale. Since there were concerns about other people taking nets from primary school 1 students, schools asked their parents or their representatives to come and pick up the net on the child's behalf. A total of 50,138 ITNs were distributed during the pilot; 8,444 in Obubra LGA in 2012; 20,545 in Obubra and Ogoja in 2013, and 21,149 in Obubra and Ogoja in 2014.

#### **Supervision**

Heads of schools supervised teachers as ITNs were distributed. In addition, pairs of external monitors, composed of state and LGA health and education officials, NGO representatives, and local consultants, visited selected schools on distribution days. Supervisors sought to ensure that ITNs were distributed to the right grades and that registered students were in the classroom, received education on malaria prevention, received an ITN, and signed the register.

#### Social and Behavior Change Communication

New SBCC activities were added each year and they were implemented only in Obubra and Ogoja shortly before, during, and after each school distribution period. In 2012, stakeholder meetings were held with ward, LGA, and community opinion leaders. The school distribution program was also discussed at parent-teacher association meetings and in class by teachers. Key messages included who is eligible to get a net, how to obtain a net, how to use the net, and how to care for it. In 2013, a teacher's guide was developed, containing

key messages and suggestions for classroom and assembly activities. In 2014, teachers used additional materials, including a poster, a comic strip, and a malaria protection pledge.

#### Monitoring

Waybills and stock cards were used to track the flow of ITNs from the state to the school level. Each school had an allocation list and a distribution register. One head of school collected forms from other schools in his or her ward and handed them over to the LGA education executive officer.

#### **Data Collection and Analysis**

The study goal was to assess household ITN ownership, access, use, and equity in each of the 3 sites over time by using definitions from the Roll Back Malaria Monitoring and Evaluation Reference Group (MERG).<sup>23</sup> Key indicators included:

- ITN ownership (proportion of households that owned at least 1 ITN)
- Proportion of households with at least 1 ITN for every 2 people
- Proportion of the population with access to an ITN within their household (the proportion of the population that could be protected by an ITN, assuming that each ITN in a household can be used by 2 people)
- Net use (the percentage of a given population group that slept under an ITN the night before the survey)
- Equity (access to any ITNs across economic quintiles)

A question on the source of each net was added to the ITN roster at endline to assess the contribution of each channel and the degree of overlap in the reach of the channels. Answer options included mass campaign, ANC, health facility, community drug distributors, schools, mosque or church, pharmacy, shop or supermarket, market, hawker, school, and other. Respondents were asked if they had a child in the selected grades during each of the last 3 years and if the household had received a net from school or from ANC.

Data were entered using EpiData 3.1 software (EpiData Association, Odense, Denmark) with double entry and record validation. Cleaned data sets were then transferred to Stata 13.1 software package (Stata Corp., College Station, Texas, USA) for further consistency checks and cleaning before data processing and analysis. Sampling

weights (inverse of the probability of cluster and household selection) were used to reflect the unbalanced sampling strategy for the baseline survey. In addition, all analyses for baseline and endline survey accounted for the cluster survey design by using the appropriate commands in the statistical software package.

A wealth index was computed at the household level using principal component analysis (PCA), using variables for household amenities, assets, livestock, and other characteristics that are related to a household's socioeconomic status. Quintiles were calculated separately for each stratum. Lorenz concentration curves were produced by plotting the cumulative distribution of wealth quintiles among households with the outcome of interest (e.g., ITN ownership from school distribution) against the respective distribution among all sampled households as described by O'Donnell et al.<sup>24</sup> A concentration index was used to analyze outcome differences by wealth quintile. Standard errors and confidence intervals for the concentration indices were calculated using the formula suggested by Kakwani et al.<sup>23</sup>

Data on sources of ITN information were obtained by asking respondents if they had heard or seen any messages about net hanging or use in the past 6 months, and if so, where they had seen or heard the message and what types of messages were recalled. The latter two were then summarized as mean number of sources of information and mean number of messages recalled. Additional questions included whether the respondent had discussed net use with family members, and whether he or she intended to use a net every night. Respondents from households with children in school were asked if they knew whether the child learned about malaria or ITNs at school.

Statistical analysis used contingency tables and chi-squared tests for univariate analysis. A difference-in-difference approach was also used to assess the treatment effect between intervention and comparison groups over time. Statistical significance was defined at the *P*<.05 level.

#### **Ethical Clearance**

Ethical clearance was obtained for conducting human subject research from the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (IRB #4073 baseline; #5553 endline), as well as from the National Health Research Ethics Committee of Nigeria. All participants provided informed consent.

#### RESULTS

This study ran from 2012 to 2014 in Cross River State, Nigeria. Obubra LGA implemented its first round of school ITN distribution in mid-2012, 15 months after the mass campaign, and then again in March 2013 and March 2014. Ogoja LGA implemented its first round in March 2013, 23 months after the mass campaign, and then again in March 2014. Ikom LGA served as a comparison area. The quality of implementation was good since almost all (98%) targeted school children received an ITN.

The final sample size obtained for analysis for the baseline survey was 753 households (98% of the target), with 502 households in the 2 school implementation groups and 251 in the comparison group. The sample obtained for the endline evaluation was 1,450 (95% of the target) with rates of 94%, 96%, and 95%, respectively, for Obubra, Ogoja, and Ikom LGAs. At the population level, the baseline survey included 3,593 de-facto household members, of which 96% were usual household members (de-jure population). For the endline survey, the de-facto population was 8,186, of which 97% were de-jure.

## Household Characteristics at Baseline and Endline

Key demographic characteristics at baseline are shown in Table 1. With a few exceptions, neither of the 2 school distribution LGAs differed significantly from the surrounding LGAs in the first wave of the ITN mass distribution campaign. Household demographics and access to safe drinking water and latrines were similar in all sites and so was the main type of house construction. A lower percentage of the heads of households in Obubra LGA was literate than the other LGAs, a lower percentage had a secondary education, and a significantly lower percentage owned a radio or mobile phone, suggesting that this LGA was overall socioeconomically somewhat worse off than the rest. Interestingly, ownership of a means of transport was similar between the 2 school distribution LGAs but higher in the comparison group. Although the baseline survey did not have a large enough sample for the comparison LGA (Ikom) to allow precise estimates of key household characteristics, the results from this LGA alone did not suggest a deviation from the average of the LGAs in the rest of wave 1 (data not shown).

Registration rates for the mass campaign were not very high (range, 37.8% to 48.0%) but did not differ significantly between sites (Table 1).

TABLE 1. Baseline Characteristics of Survey Households, by Comparison<sup>a</sup> and School-Based Distribution Intervention Sites (N=753)

	Comparison	Intervention		
	Rest of Wave 1 (N=251)	Ogoja LGA: 2 Rounds (N=286)	Obubra LGA: 3 Rounds (N=216)	<i>P</i> Value
No. of de-jure household members, mean	4.7	4.5	4.9	.33
No. of persons per sleeping room	2.2	2.4	2.3	.07
Households with any children under 5, %	33.1%	38.5%	37.1%	.56
Households with a pregnant woman, %	8.6%	9.6%	12.3%	.51
Households with any eligible school children, %	_	36.7%	42.8%	.19 <sup>b</sup>
Age of head of household, years, mean	41.3	43.4	41.4	.24
Female-headed households, %	18.4%	23.5%	22.5%	.57
Educational achievement of head of household, %				.09
Non-literate	10.7%	11.8%	21.4%	
Primary	22.6%	22.1%	31.3%	
Secondary	48.5%	48.2%	29.3%	
Tertiary	18.1%	18.0%	18.1%	
Household access to safe water, %	41.2%	35.8%	23.6%	.47
Household access to any latrine, %	72.0%	66.0%	59.8%	.33
Houses with modern roof (e.g., sheets, tiles), %	89.7%	92.2%	91.2%	.81
Household ownership of radio, %	86.4%	81.8%	68.9%	.02
Household ownership of mobile phone, %	83.7%	80.3%	66.7%	.06
Household ownership of any means of transport, %	73.8%	58.2%	55.7%	.007
Households registered by ITN campaign, %	48.0%	37.8%	44.9%	.36
Household received any net from campaign, %	65.8%	47.0%	47.6%	.006
No. of ITNs received, if any, mean	1.88	1.73	1.83	.61

Abbreviations: ITN, insecticide-treated net; LGA, local government area.

However, in the baseline comparison group, more households received ITNs from the campaign compared with the intervention LGAs; as a result the overall reach of the campaign was somewhat higher in the comparison group. Among households that received nets, the number of nets per household was similar across all sites.

Because the baseline comparison group comprised 8 LGAs (Ikom, Etung, Yakurr, Abi, Obanliku, Obudu, Bekwarra, and Yala Cross) and the comparison group at endline sampled in Ikom LGA only, further analyses were conducted to evaluate whether the larger group (labeled "Rest of Wave 1" in the tables) was appropriate to use as a comparison area. Table 2 shows that the

larger group and Ikom LGA were similar in composition and socioeconomic status. While somewhat fewer households in Ikom LGA were registered for the campaign (32.8% vs. 48.0%, respectively), there were no statistically significant differences in their ability to own an ITN from the campaign or in the number of ITNs received.

## Household ITN Ownership and Population Access

Household ownership of ITNs before and after the school distribution is presented in Table 3. Improvements in ownership were seen at both intervention sites. In Obubra LGA, the proportion

Household ownership of and population access to ITNs increased in the intervention areas after school distribution was implemented.

<sup>&</sup>lt;sup>a</sup> The rest of the LGAs (8 total) in the wave 1 distribution served as the comparison group at baseline.

<sup>&</sup>lt;sup>b</sup> Comparing Ogoja to Obubra LGA.

TABLE 2. Baseline Characteristics for All Non-School Intervention LGAs in the Wave 1 Distribution (Baseline Comparison Group) and Ikom LGA Alone (Endline Comparison Group)

	Rest of Wave 1 (N=251)	Ikom LGA (N=34)	P Value
No. of de-jure household members, mean	4.7	4.8	.98
No. of persons per sleeping room	2.2	2.4	.20
Households with any children under 5, %	33.1%	26.0%	.16
Households with a pregnant woman, %	8.6%	7.5%	.86
Households with any eligible school children, %	_	-	
Age of head of household, years, mean	41.3	43.6	.38
Female-headed households, %	18.4%	15.2	.50
Educational achievement of head of household, %			.14
Non-literate	10.7%	13.5%	
Primary	22.6%	16.8%	
Secondary	48.5%	36.2%	
Tertiary	18.1%	33.5%	
Household access to safe water, %	41.2%	28.5%	.31
Household access to any latrine, %	72.0%	50.3%	.06
Houses with modern roof (e.g., sheets, tiles), $\%$	89.7%	96.6%	.37
Household ownership of radio, %	86.4%	82.4%	.38
Household ownership of mobile phone, %	83.7%	89.9%	.44
Household ownership of any means of transport, %	73.8%	69.0%	.50
Households registered by ITN campaign, %	48.0%	32.8%	.02
Household received any net from campaign, %	65.8%	52.2%	.13
No. of ITNs received, if any, mean	1.88	1.88	.94

Abbreviations: ITN, insecticide-treated net; LGA, local government area.

of households with any ITN increased by 27 percentage points (from 51% to 78%) while the proportion of households with enough ITNs to cover all household members (at least 1 ITN for 2 people) increased by 13 percentage points (from 17% to 30%). Interestingly, Ogoja LGA, which had waited 2 years after the mass distribution campaign to start school distribution, experienced similar levels of improvement, with ITN ownership increasing from 50% to 76% and ownership of 1 ITN for 2 people increasing from 18% to 30%. In contrast, rates in the comparison group at endline were significantly lower (P<.05) than the 2 school distribution LGAs with only 43% of households owning any ITN and 14% owning at least 1 ITN for 2 people.

Table 3 also shows that there was no major increase of oversupply (1 ITN or more per person)

nor of severe undersupply (less than 1 ITN per 3 people) in the intervention LGAs, meaning that gains in coverage were mainly in the "enough" (1 ITN per 2 people) and "almost enough" (1 ITN per 3 people) categories. Similar trends were also seen in population access to an ITN within the household. At endline, population ITN access had increased from 34% to 55% in Obubra LGA and from 36% to 53% in Ogoja LGA. ITN access decreased over time in the comparison areas (from 47% in the baseline comparison group to 26% in Ikom LGA at endline). Trends for ITN indicators are shown in Figure 3.

Table 3 also presents ITN use by the general oversupply nor of population at baseline and endline. Results clearly show the influence of seasonality on ITN use in ITNs in the this context. While use rates among those who intervention had access to an ITN within the household were **gregs**.

There was no major increase of undersupply of

TABLE 3. ITN Ownership, Access, and Use (%) at Baseline and Endline, by Comparison<sup>a</sup> and Intervention Sites

	Baseline (N=753)			Endline (N=1,450)		
	Rest of Wave 1	Ogoja LGA	Obubra LGA	Ikom LGA	Ogoja LGA	Obubra LGA
	(Comparison)	(2 Rounds)	(3 Rounds)	(Comparison)	(2 Rounds)	(3 Rounds)
Household level						
Owns at least 1 ITN	63.9	49.5	51.1	43.3	76.4	77.9
	(56.4, 70.8)	(44.7, 54.3)	(35.3, 66.7)	(37.4, 49.4)	(71.2, 81.0)	(71.5, 83.1)
Owns at least 1 ITN per 2 people	24.4	17.7	17.4	13.9	29.9	30.3
	(17.8, 32.5)	(13.0, 23.7)	(11.8, 25.0)	(10.7, 17.8)	(25.1, 35.2)	(26.1, 34.8)
ITN supply						
Less than 1 ITN per 3 people	21.1	16.8	20.8	20.5	23.2	23.6
	(16.2, 27.2)	(13.1, 21.5)	(15.1, 27.9)	(15.8, 26.2)	(19.8, 26.9)	(20.5, 27.0)
1 ITN per 3 people	18.4	15.0	12.9	8.9	23.4	24.0
	(14.3, 23.2)	(10.5, 20.9)	(7.8, 20.6)	(6.5, 12.0)	(19.3, 27.9)	(20.3, 28.1)
1 ITN per 2 people	21.1	13.5	14.5	12.2	23.8	22.8
	(16.7, 26.2)	(9.7, 18.6)	(9.5, 21.6)	(9.1, 16.2)	(19.6, 28.5)	(19.0, 27.0)
1 ITN or more per person	3.3	4.2	2.9	1. <i>7</i>	6.2	7.5
	(1.2, 9.2)	(2.3, 7.6)	(1.1, 7.5)	(0.9, 16.2)	(4.1, 9.2)	(5.2, 10.8)
Population level						
Population access to ITN <sup>b</sup>	46.8	35.7	33.5	25.7	53.1	54.7
	(40.0, 53.7)	(32.0, 39.5)	(23.2, 45.6)	(21.9, 29.9)	(48.0, 58.0)	(48.4, 60.9)
ITN use previous night	41.8	28.9	28.5	16.8	24.0	31.6
	(35.6, 48.3)	(26.1, 31.8)	(17.9, 42.0)	(13.7, 20.4)	(20.6, 27.7)	(26.1, 37.6)
ITN use previous night among population with access to ITN	92.5	84.7	88.3	66.7	45.7	61.2
	(86.3, 99.0)	(81.4, 88.5)	(77.9, 99.8)	(63.6, 70.3)	(42.3, 49.4)	(55.3, 66.7)

Abbreviations: ITN, insecticide-treated net; LGA, local government area.

All data shown as % (95% confidence interval).

generally high at baseline (85% to 93%), which had been done at the peak of the rains, they were much lower at the endline survey (46% to 67%), which was conducted at the end of the dry season. Between the 2 school distribution LGAs, Obubra showed better use rates than Ogoja (61% vs. 46%, respectively; P < .05), but Ikom LGA (comparison) had similarly high rates (67%) as Obubra LGA. However, even with the increased "use gap" at endline, overall ITN use was highest in Obubra LGA, followed by Ogoja LGA and Ikom LGA (comparison), and this trend was statistically significant (P<.001). There was no indication that ITNs from school distribution were used less or more the previous night than ITNs from other sources both in univariate comparison and multivariate regression analysis (P>.05).

The result from the difference-in-difference analysis is shown in Table 4. The changes in ITN coverage between baseline and endline surveys as shown in Table 3 are expressed as a percentage-point difference comparing the intervention sites (3 or 2 rounds of school distributions) against the comparison group. This difference-in-differences can be interpreted as the overall percentage-point gain in ITN coverage compared with the comparison group combining the decrease observed in the comparison areas with the increases in the intervention areas. This result or "treatment effect" is then tested against the hypothesis that there is no difference between intervention and control. As one would expect, the largest gains of 59 percentage-point increases were seen for the indicator "households owning at least 1 ITN" followed by a 47 to

<sup>&</sup>lt;sup>a</sup>The rest of the LGAs (8 total) in the wave 1 distribution served as the comparison group at baseline, while Ikom LGA served as the comparison at endline.

b Proportion of the population with access to an ITN within their household (assuming each ITN in a household can be used by 2 people).

Household owns any net Household owns any ITN 100 6 06 80 80 20 2 Percent 10 50 60 Percent 10 50 60 4 40 30 9 20 20 10 10 2013 2014 2015 2013 2014 2015 2012 2012 Time Point Time Point Control ····· Control 3 Rounds 3 Rounds 2 Rounds - 2 Rounds Population with access to ITN Household owns enough ITN for all members 100 100 06 90 8 80 2 20 Percent 40 50 60 9 20 40 30 30 20 20 10 9 2012 2013 2014 2015 2012 2013 2014 2015 Time Point Time Point Control ..... Control 3 Rounds 3 Rounds -- 2 Rounds = 2 Rounds

FIGURE 3. Trends in ITN Indicators From Baseline to Endline

Abbreviation: ITN, insecticide-treated net.

50 percentage-point gain in population access and 28 to 29 percentage-point gain in households with enough ITNs for all members. Consistently, the comparison between the 2 intervention arms showed no difference in impact of 3 versus 2 rounds of distributions. Using the Ikom LGA subset as the comparison group at baseline rather than the rest of wave 1 did not change the magnitude of the effects, and differences were still statistically significant at the .05 level (data not shown).

#### Sources of ITNs

Sources of ITNs at endline for all surveyed households are shown in Table 5. The school channel was the most common source of ITNs at endline, with 44% (Obubra) and 43% (Ogoja) of all surveyed households reporting owning ITNs from the school distribution. In comparison,

29% (Obubra) and 18% (Ogoja) of households owned any campaign net and 9% and 10%, respectively, owned any net from ANC.

At baseline, the overall proportion of households that owned any ITNs from the campaign was only slightly higher in the comparison group than the intervention groups, but it was the main source of ITNs at endline for the comparison group. Antenatal care was the least common source of ITNs; only 2.5% of households in Ikom LGA had any ITNs from ANC. There was very little overlap between the continuous distribution channels. Less than 2% of households had an ITN from both ANC and schools.

Equity of the public distribution channels at the endline survey is shown in Figure 4. Access to campaign ITNs based on recall of the respondent of having received any ITNs from the campaign was highly equitable with a tendency toward a ANC.

The most common source of ITNs in the intervention areas at endline was schools, followed by mass campaigns and ANC

**TABLE 4.** Difference-in-Difference Analysis on Core ITN Indicators

Comparison	Difference-in-Differences	P Value
HH owns any ITN		
Obubra (3 rounds) vs. Comparison <sup>a</sup>	58.8%	<.001
Ogoja (2 rounds) vs. Comparison <sup>a</sup>	58.9%	<.001
Obubra (3 rounds) vs. Ogoja (2 rounds)	-0.01%	.99
HH owns at least 1 ITN per 2 people		
Obubra (3 rounds) vs. Comparison <sup>a</sup>	28.2%	<.001
Ogoja (2 rounds) vs. Comparison <sup>a</sup>	28.8%	<.001
Obubra (3 rounds) vs. Ogoja (2 rounds)	-0.6%	.91
Population access to ITN within HH <sup>b</sup>		
Obubra (3 rounds) vs. Comparison <sup>a</sup>	49.6%	<.001
Ogoja (2 rounds) vs. Comparison <sup>a</sup>	47.2%	<.001
Obubra (3 rounds) vs. Ogoja (2 rounds)	2.4%	.42

Abbreviations: HH, household; ITN, insecticide-treated net.

pro-poor distribution (curve above the equity line), but the concentration index of -0.03 (95% CI: -0.08, 0.02) shows that it was not statistically different from perfect equity. School distribution was slightly pro-rich, with a concentration index of 0.06 (95% CI: 0.02, 0.11). Ownership of ANC ITNs was also not statistically different from perfect equity, with a concentration index of 0.04 (95% CI: -0.06, 0.15).

#### Social and Behavior Change Communication

Endline data on exposure to any net-related messages in the past 6 months based on the recall of household respondents and the sources of those messages are presented in Table 6. The percentage of households reporting exposure to any message varied between the LGAs and was significantly higher in Obubra (51%) and Ogoja (45%) than in the comparison area (32%) (P<.001). Radio was the dominant source of messages reported by households in the comparison group at 75% while schools played an increasing role as the duration of school distribution increased (comparison group 4%, Ogoja 17%, Obubra 34%).

The most frequently recalled message was "use the net" or "use the net every night," which was recalled by 85% of respondents reporting exposure to any messages, with higher exposure in the intervention sites and in the site with the longer pilot (comparison group 29%, Ogoja 35%, Obubra 45%; P<.001). A similar trend was also seen for discussing net use in the family (P=.001) and the intention to use ITNs most or all nights (P=.005). Among households with school going children, the proportion whose children had mentioned learning about malaria in class was much higher in the school distribution LGAs (64% to 74%) than the comparison group (38%) (P<.05), indicating that schools outside school distribution also discussed or taught about malaria but not as intensively.

#### DISCUSSION

Our study found that 3 years after the last mass campaign, ITN ownership and access increased in areas where 2 or 3 rounds of school distribution were implemented. During the same period, ITN ownership and access fell in the comparison area. Oversupply did not significantly increase as a result of the pilot, and school, ANC, and campaign distributions were all very equitable. Very few households obtained ITNs from both ANC and schools, suggesting that the 2 continuous distribution channels have complementary reach. About 40% of all households had an eligible student during the pilot period, and a similar

Very few households obtained ITNs from both ANC and schools, suggesting they have complementary reach.

<sup>&</sup>lt;sup>a</sup>The rest of the LGAs (8 total) in the wave 1 distribution served as the comparison group at baseline, while Ikom LGA served as the comparison group at endline.

b Proportion of the population with access to an ITN within their household (assuming each ITN in a household can be used by 2 people).

<b>TABLE 5.</b> Source of ITNs (	%) Among All Households at Enc	lline (N=1,450)
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HH Source of ITN	Ikom LGA (Comparison)	Ogoja LGA (2 Rounds)	Obubra LGA (3 Rounds)
Any source			
No ITN	56.3 (50.5, 62.0)	22.1 (17.5, 27.6)	20.9 (15.9, 27.0)
At least 1 net from school	0.0	43.0 (35.9, 50.5)	44.2 (35.9, 53.0)
At least 1 net from campaign	31.5 (26.2, 37.3)	18.0 (12.3, 25.6)	29.0 (22.3, 36.8)
At least 1 net from ANC	2.5 (1.4, 4.4)	9.8 (6.9, 13.6)	9.4 (7.1, 12.3)
Other (family, private)	1.9 (0.7, 5.0)	2.5 (1.3, 4.5)	1.7 (0.8, 3.4)
Unknown	8.1 (5.4, 11.9)	11.5 (8.2, 15.8)	6.9 (4.0, 11.6)
1 Source			
Campaign only	31.3 (26.0, 37.1)	11.9 (7.2, 19.0)	19.4 (13.8, 26.6)
ANC only	2.3 (1.2, 4.2)	8.4 (5.5, 12.7)	5.6 (4.1, 7.7)
School only	0.0	36.7 (29.9, 44.1)	34.2 (26.4, 43.0)
2 or more sources			
Campaign and ANC	0.2 (0.03, 1.5)	0.6 (0.2, 1.9)	1.3 (0.6, 2.6)
Campaign and school	0.0	5.5 (3.6, 8.4)	7.5 (4.9, 11.3)
ANC and school	0.0	0.8 (0.3, 2.1)	1.7 (0.7, 7.7)
Campaign, ANC, and school	0.0	0.0	0.8 (0.3 - 2.1)

Abbreviations: ANC, antenatal care; CI, confidence interval; HH, household; ITN, insecticide-treated net; LGA, local government area. All data shown as % (95% confidence interval).

proportion of all households had received a school ITN. Schools were the largest source of ITNs in the intervention LGAs.

At endline, household ownership of at least 1 ITN in the intervention areas was just under the target level of 80% (78% in Obubra and 76% in Ogoja). However, just over half of the population in the intervention areas had access to an ITN. While below the 80% target, population ITN access in the intervention LGAs was within the range observed in post-campaign surveys in other countries.26 Although Ogoja (where school distribution started 24 months after the mass campaign) was able to achieve nearly the same coverage rates as the site that started at 15 months post-campaign (Obubra), Obubra benefited immediately from its first round of school distribution, since school ITNs filled some gaps from the mass campaign, which had barely reached half of all households. Ogoja's results, however, show that strong outcomes are possible even when a school distribution program starts late. There may also be a ceiling for ITN ownership and access in a school distribution program with this set of selected grades (4 grades 3 years apart, of which

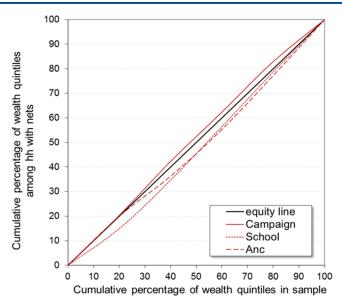
2 were in secondary school). To reach target levels of population ITN access, future programs may need to use more school grades to reach a broader cross-section of households.

Interventions to treat and prevent schistosomiasis and soil-transmitted helminths have long been implemented at schools,<sup>27</sup> in addition to educational curricula for a wide variety of health interventions, 28 and malaria programs have implemented intermittent treatment of malaria in school-age children,<sup>29</sup> school parasitemia survevs, 30,31 and school ITN coverage surveys. 32,33 WHO recommendations include school distribution of ITNs as part of a comprehensive strategy to maintaining universal coverage, but the most effective combinations of channels are still under study. Other types of distribution (such as through community volunteers and traditional leaders) have been or are being tested in Madagascar,<sup>34</sup> South Sudan,<sup>35</sup> and Zanzibar (Mwinyi Khamis, written communication, 2016). An assessment conducted in Tanzania hypothesized that school distribution might be able to replace mass campaigns entirely: A pilot was subsequently conducted, and recent data show that ITN ownership

Household ownership of at least 1 ITN was just under the target level of 80% in the intervention areas at endline.

To reach target levels of population ITN access, programs may need to distribute ITNs to more school grades.

**FIGURE 4.** Lorenz Concentration Curve Assessing Equity in Household ITN Ownership by Source of Net



Abbreviations: Anc, antenatal care; hh, household; ITN, insecticide-treated net.

and access were maintained up to 4 years post-campaign. Even households without eligible school children benefited, since 7% of recipient households donated nets to others during the last round of school distribution. <sup>36</sup> These findings are promising. More work is needed to determine whether these types of programs can maintain ITN coverage over the longer term and whether more consistent coverage year-to-year provides better protection than rising and falling coverage provided by mass campaigns.

Schools offer a practical logistical and administrative platform for ITN distribution. Quantification of ITN needs is based on student enrollment; teachers are by profession literate and able to read and fill out necessary instructions and forms; and school health administration offers a feasible supervision and reporting structure. School distribution is scalable in areas with high school enrollment rates, because it allows countries to leverage existing structures and avoid the time and cost of household registration, and may be particularly useful in places where mass campaigns have been especially challenging. It offers the flexibility to add or subtract grades depending on ITN ownership and access levels achieved.

Equity of school enrollment determines equity of school ITN distribution; less equitable school

enrollment rates in Cross River State would likely have resulted in less equitable access to school ITNs. Planners should take enrollment equity into account when planning school distribution programs. Similarly, class selection was based on using primary, junior secondary, and senior secondary school grades to spread out the age ranges of students benefiting from the distribution. Adding or subtracting grades requires more ongoing monitoring than in mass campaigns. Having enough nets was associated with donating nets in the Tanzania study. 36 Increasing the number of eligible grades could increase levels of sufficient access among school going households and, consequently, redistribution. Furthermore, program planners must weigh the costs of additional transport and training in secondary schools against the benefits of reaching what is usually a smaller number of students (and, consequently, households) in places where secondary school enrollment is low.

As expected, SBCC exposure was much higher in the intervention sites and highest in the site with the longer pilot. Aside from schools themselves, leading sources of information were radio and health workers, indicating that there were malaria SBCC activities beyond the school distribution program. However, more households in the intervention sites had discussed net use and were more likely to have the intention to use nets most nights. Moreover, twice as many households with schoolchildren had a child who learned about malaria in school in the intervention sites than the comparison site. These findings suggest that schools are willing partners in malaria SBCC activities.

#### **Limitations**

This study did have limitations. First, this was not a randomized controlled trial. Though Table 1 suggests that the study groups had similar baseline characteristics, a few slight differences remained that could have influenced the results, such as ownership of a radio, campaign nets, or a means of transport.

Second, while nesting the baseline in a post-campaign survey was necessary to conserve financial resources, the resulting sampling methods for the comparison group varied slightly since the endline was designed solely to assess the coverage achieved by the school distribution pilot, so it was not strictly an intervention-control assessment. While Ikom LGA was merely one in a group of 8 LGAs used in the baseline comparison group,

	Ikom LGA (Comparison)	Ogoja LGA (2 Rounds)	Obubra LGA (3 Rounds)
Exposed to information about nets past 6 months	31.5 (24.1, 39.9)	44.5 (37.6, 51.6)	50.7 (45.9, 55.6)
Source of information if exposed			
Radio	75.0 (64.6, 83.1)	40.1 (30.9, 50.0)	35.0 (25.8, 45.4)
Health worker (facility or community)	54.6 (46.1, 62.9)	54.4 (45.2, 63.2)	43.2 (33.4, 53.6)
School	4.0 (2.0, 7.6)	17.1 (11.8, 24.0)	33.7 (24.0, 45.1)
Community leader	7.9 (4.5, 13.4)	21.7 (13.7, 32.5)	11.1 (5.6, 20.7)
Town announcer	24.3 (16.1, 35.0)	18.0 (10.0, 30.2)	8.6 (4.9, 14.9)
Family or friends	20.4 (13.5, 29.6)	14.3 (10.0, 20.1)	14.0 (8.0, 23.2)
Pharmacy or shop attendant	10.5 (5.3, 19.8)	0.9 (0.2, 3.5)	0.0
Mosque or church	2.0 (0.6, 6.2)	3.7 (1.8, 7.3)	11.5 (4.7, 25.8)
Newspaper or TV	9.2 (5.3, 15.6)	1.8 (0.7, 4.8)	1.2 (0.3, 5.2)
Mean number of information sources mentioned	2.6 (2.2, 3.0)	2.2 (1.7, 2.7)	1.9 (1.6, 2.2)
Mean number of messages recalled if exposed	3.1 (2.7, 3.5)	2.6 (2.0, 3.3)	3.9 (3.5, 4.3)
Message on net use recalled (all households)	29.0 (21.8, 37.5)	35.0 (29.4, 41.2)	45.3 (39.7, 51.0)
Discussed net use with family	46.8 (40.3, 53.4)	59.0 (53.5, 64.4)	64.1 (57.1, 70.5)
Intention to use nets regularly (most or all nights)	66.1 (59.1, 72.4)	73.4 (67.9, 78.2)	79.3 (74.1, 83.7)
Child learned about malaria and/or nets at school if any schoolchild in household	37.8 (23.1, 55.3)	73.6 (66.5, 79.7)	64.2 (54.1, 73.2)

Abbreviations: ITN, insecticide-treated net; LGA, local government area. All data shown as % (95% confidence interval).

the comparison group at endline comprised households from Ikom LGA only. Table 2 implies it is possible that Ikom LGA was not significantly different from the other LGAs used in the baseline comparison group. However, the baseline Ikom sample size was only 34 (and it was not drawn to be representative of the LGA population as a whole), so this comparison had inadequate statistical power to make any definitive conclusions about comparability.

Third, during the planning stage for school distribution, we assumed that the mass campaign had achieved its targets of 80% of households owning at least 1 ITN, but our baseline survey revealed much lower levels (range, 50.0% to 63.9%). Had this been known earlier, we would have tried to distribute more ITNs through schools during the pilot to make up for the gap. However, this limitation may have been counterbalanced by a longer-than-expected median ITN lifespan. Recent data has shown that median net survival is 4.7 years in Cross Rivers State, much longer than the 3 years we had used in the planning model.<sup>37</sup>

Fourth, the proportion of ITN users among those with access decreased between baseline (rainy season) and endline (dry season). This reflects the potential influence of seasonality (Table 3) on attitudes toward using a net, which has been reported in other net use studies in Nigeria.<sup>38</sup> It would have been ideal to compare the net use using surveys that had been conducted during the same season. Finally, the study was subject to recall or misclassification bias due to the use of retrospective cross-sectional surveys; families who acquired nets in earlier years may have had more difficulty remembering the source of nets at the time of the surveys.

#### CONCLUSION

The addition of school distribution to standard antenatal clinic distribution in Cross River State, Nigeria, increased ownership of at least 1 ITN to nearly 80% and population ITN access to over 50% in the 3 years following a mass campaign; rates fell in the comparison area to 43% and

26%, respectively. School ITN ownership was nearly as equitable as the mass campaign and did not oversupply households. Very few households had ITNs from both school and ANC, indicating that the 2 channels had complementary reach. These results suggest that school and ANC distribution combined can play an effective role in achieving and maintaining universal coverage. Though the proportion of the population with access to an ITN remained similar at baseline and endline, these levels were short of universal coverage. Future programs should consider increasing the number of eligible grades to increase the proportion of the population with access to a net. They should also ensure that ANC distribution programs are functional, to protect biologically vulnerable groups such as pregnant women and infants and contribute to population-level coverage. One of our key learnings is that policy makers should consider school distribution as an option in high school enrollment areas. One size does not need to fit all, and in a vast and very diverse country like Nigeria, having ANC and school distribution in some states and universal coverage campaigns or other forms of continuous distribution programs in other states may be appropriate. More research is underway to evaluate the costeffectiveness of continuous distribution channels in combination with, or as a potential replacement for, subsequent mass campaigns.

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#### **ORIGINAL ARTICLE**

# Expanding the Single-Visit Approach for Cervical Cancer Prevention: Successes and Lessons From Burkina Faso

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The single-visit approach was implemented with strong attention to systems in 14 health facilities. In the 2 largest facilities, nearly 14,000 women screened for cervical cancer over 4 years. Of approximately 9% who screened positive, about 66% received same-day cryotherapy. Attention is needed to ensure local technicians can repair cryotherapy equipment, supplies are consistently in stock, and user fees are not prohibitive to accessing care.

Résumé en français à la fin de l'article.

#### ABSTRACT

**Background:** Cervical cancer accounts for 23% of cancer incidence and 22% of cancer mortality among women in Burkina Faso. These proportions are more than 2 and 5 times higher than those of developed countries, respectively. Before 2010, cervical cancer prevention (CECAP) services in Burkina Faso were limited to temporary screening campaigns.

**Program Description:** Between September 2010 and August 2014, program implementers collaborated with the Ministry of Health and professional associations to implement a CECAP program focused on coupling visual inspection with acetic acid (VIA) for screening with same-day cryotherapy treatment for eligible women in 14 facilities. Women with larger lesions or lesions suspect for cancer were referred for loop electrosurgical excision procedure (LEEP). The program trained providers, raised awareness through demand generation activities, and strengthened monitoring capacity.

**Methods:** Data on program activities, service provision, and programmatic lessons were analyzed. Three data collection tools, an individual client form, a client registry, and a monthly summary sheet, were used to track 3 key CECAP service indicators: number of women screened using VIA, proportion of women who screened VIA positive, and proportion of women screening VIA positive who received same-day cryotherapy.

Results: Over 4 years, the program screened 13,999 women for cervical cancer using VIA; 8.9% screened positive; and 65.9% received cryotherapy in a single visit. The proportion receiving cryotherapy on the same day started at a high of 82% to 93% when services were provided free of charge, but dropped to 51% when a user fee of \$10 was applied to cover the cost of supplies. After reducing the fee to \$4 in November 2012, the proportion increased again to 78%. Implementation challenges included difficulties tracking referred patients, stock-outs of key supplies, difficulties with machine maintenance, and prohibitive user fees. Providers were trained to independently monitor services, identify gaps, and take corrective actions.

**Conclusions:** Following dissemination of the results that demonstrated the acceptability and feasibility of the CECAP program, the Burkina Faso Ministry of Health included CECAP services in its minimum service delivery package in 2016. Essential components for such programs include provider training on VIA, cryotherapy, and LEEP; provider and patient demand generation; local equipment maintenance; consistent supply stocks; referral system for LEEP; non-prohibitive fees; and a monitoring data collection system.

#### BACKGROUND

Globally, cervical cancer has the third highest incidence rate of all cancers in women, with more than 500,000 new cases per year, and causes an estimated 265,672 deaths per year. In Burkina Faso, the cervical cancer incidence and related mortality exceeds that of any other cancer in women, accounting for 23% of cancer incidence and 22% of cancer mortality. While these proportions are comparable with

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those of sub-Saharan Africa generally (25% incidence and 23% mortality) and Western Africa specifically (24% and 22%, respectively), they represent more than 2 times the incidence rate and 5 times the mortality rate of developed countries.1

In many developing countries, few skilled professionals are trained for cytology-based cervical cancer screening and surgical treatment of lesions, and the resources to sustain these costly services are also absent.2 Highly sensitive diagnostic and treatment tools including human papilloma virus testing and thermal coagulation require advanced health infrastructure and remain costly and vulnerable to loss of patients to follow-up. 3-5 Visual inspection with diluted acetic acid (VIA) coupled with cryotherapy treatment for precancerous lesions is recommended by the World Health Organization (WHO)<sup>6</sup> as an alternative, low-cost screening and treatment method. This single-visit approach (SVA) requires minimal infrastructure and can be practiced by nonphysician health care providers following targeted training.<sup>2,7,8</sup> In Burkina Faso, the Ministry of Health (MOH), professional associations, and various organizations have organized cervical cancer screening campaigns using VIA since the mid-2000s. However, treatment for precancerous lesions, including cryotherapy, had remained unavailable, leaving Burkina Faso's 1.7 million women ages 30-59 years without access to secondary prevention of cervical cancer. 9,10

SVA has been implemented in several lowresource settings and its documented effectiveness has the potential to reduce cervical cancer mortality.11,12 Scale-up efforts are now underway in a number of countries, bridging screening and treatment services for cervical cancer prevention (CECAP). 12-14 SVA is feasible, well-accepted, and safe despite initial concerns. 2,15,16 However, debate remains regarding the best implementation approach for training providers, 2,14,17 retaining providers, 14,18–20 minimizing attrition through task shifting, 12,21 and ensuring sustainability and integration of CECAP services into the health system. 2,7,12,20-22 The wide spectrum of experiences in introducing SVA in several locations underlines the importance of adapting the implementation approach to the local context. In the interest of South-South collaboration, all experiences implementing SVA need to be widely shared so that programs can benefit from practical learning and CECAP services can be offered at scale. 2,7,23

We describe the implementation of an integrated CECAP program in 14 health facilities, the challenges encountered, how they were overcome, and the outcomes of the program in the 2 teaching hospitals. Lessons for implementation and advocacy are drawn with the aim of benefiting other countries similarly expanding CECAP services.

#### PROGRAM DESCRIPTION

Between September 2010 and August 2014, the project aimed to expand CECAP services in The single-visit 14 health facilities at different levels in the health system throughout Burkina Faso by introducing VIA screening coupled with cryotherapy for precancerous lesions in a single visit. A second aim was to develop program monitoring skills among providers to foster independent and local improvement in service provision. The project's activities, described in the Table, encompassed training health care providers, demand generation, and capacity building in monitoring and evaluation.

The CECAP program was started in 5 facilities as a collaborative project between the MOH and the implementing organization, Jhpiego, an American nonprofit organization focused on improving health systems and operating in more than 30 low-income countries. Through a partnership between Jhpiego and the Burkinabe Society of Gynecology and Obstetrics (SOGOB), additional resources were later leveraged from the Society of Obstetricians and Gynecologists of Canada and SEMAFO, a Canadian-based mining company, to expand CECAP services to all 9 regional hospitals. In total, 14 facilities were included in the program: 2 teaching hospitals (or Centre Hospitalier Universitaire, CHU), all 9 regional hospitals, and 3 district hospitals.

The CECAP program provided individual counseling to women ages 25 to 59. While cervical cancer screening programs typically start at age 30, local gynecologists favored the inclusion of women as young as 25 years old in this intervention because median age at sexual initiation is 17.7 in Burkina Faso.<sup>24</sup> The program used a standard clinical protocol for VIA and cryotherapy based on the WHO guidelines for screening and treatment of precancerous cervical lesions and adapted to Burkina Faso's context through expert consultation.<sup>25</sup> Women who screened negative by VIA received counseling and instructions to schedule a follow-up appointment in 3 years, unless they were living with HIV in which case they scheduled a follow-up appointment for repeat screening in 1 year. Women who screened 2014.

approach to cervical cancer prevention requires minimal infrastructure and can be practiced by non-physician health care providers.

The single-visit approach was implemented in 14 health facilities in Burkina Faso between 2010 and

Objectives	Intervention	Activities	Challenges	Solutions
To strengthen institutional and provider capacity to provide CECAP services	Training	<ul> <li>Provision of initial equipment for VIA, cryotherapy, and LEEP including parts and supplies</li> <li>Training of providers in counseling, VIA, cryotherapy, and LEEP</li> <li>Supportive supervision visits to mentor and support providers</li> </ul>	maintenance was performed abroad, reducing availability of services  Shortage of supplies for VIA and cryotherapy	<ul> <li>Training local technicians to perform maintenance of cryotherapy machines internally</li> <li>Charging user fees to finance some of the costs of the procedures</li> </ul>
To increase awareness about cervical cancer and CECAP services among providers and patients	Demand generation	<ul> <li>Group education in facilities about cervical cancer and CECAP services</li> <li>Television programs about cervical cancer and CECAP services</li> </ul>	Prohibitive user fees deterred demand for cryotherapy services at the same visit as screening	The implementing organization and SOGOB used a costing analysis to advocate for a reduced user fee in line with patients' financial capacity
To build local capacity to monitor program progress, identify shortcomings, and take corrective actions	Monitoring	Development of data collection tools: individual client form, client registry, and monthly summary sheet     Training of data managers on data extraction and crosscheck methodology to improve data quality     Training of providers on utilization of data to track program progress     Routine review and dissemination of program results	twice in program statistics	Tracking error was identified by providers and rectified in subsequent years to improve data quality

Abbreviations: CECAP, cervical cancer prevention; LEEP, loop electrosurgical excision procedures; SOGOB, Burkinabe Society of Gynecology and Obstetrics; VIA, visual inspection with acetic acid.

positive by VIA and were eligible for cryotherapy received it at the time of the screening upon consenting to the procedure.

Eligibility for cryotherapy was based on WHO guidelines<sup>6</sup>:

- 1. The lesion is not suspicious of cancer.
- 2. The lesion does not extend into the endocervical canal.
- 3. The lesion occupies less than 75% of the
- 4. The cryotherapy machine tip (cryotip) covers the lesion (or less than 2 millimeters of the lesion extends beyond the edge of the cryotip).
- 5. The client is not pregnant.
- 6. The client is more than 12 weeks postpartum.

Women found to have larger lesions or lesions suspect for cancer were referred to the 2 university hospitals for loop electrosurgical excision procedure (LEEP) as part of the program's comprehensive secondary prevention services.

#### **Training**

We first trained 10 providers on VIA and cryotherapy in Malawi and Côte d'Ivoire during a 6-day training that gathered national training experts. Sessions were adapted to focus on the trainees' weaknesses identified through an initial assessment of baseline knowledge and skills. Training covered the general gynecologic exam, recognition of cervical landmarks and lesions, and interpretation of VIA results using photographic images. It also included practical training on

Women with larger lesions or lesions suspect for cancer were referred to the 2 university hospitals for LEEP. conducting VIA and cryotherapy using anatomical models. These trained trainers then received technical assistance from Jhpiego to introduce SVA in their respective hospitals and train additional providers using the same 6-day training curriculum. The new trainers trained an additional 21 gynecologists, 2 general practitioners, and 27 nurse-midwives. Newly trained providers worked in pairs with a seasoned gynecologist or nurse-midwife who supervised their practice of VIA and cryotherapy for a minimum of 1 month. Eleven gynecologists were also trained to perform LEEP through a dedicated training organized by experts from Jhpiego.

#### **Demand Generation**

Demand for cervical cancer prevention services was generated through organized educational activities. Every morning, trained midwives would facilitate informal educational discussions in the waiting areas for family planning and antenatal care services. Topics covered the female genital tract, the presentation of cervical cancer, cervical cancer screening, and available services. Service providers at the same facilities that were not trained in CECAP were also targeted with messages about the benefits of cancer screening and the introduction of SVA. In addition, trained providers received supportive supervision visits reinforcing SVA and CECAP service delivery standards, and a dedicated team of gynecologists and data managers ensured the quality of services through quarterly monitoring visits that followed Jhpiego's CECAP Monitoring and Evaluation Strengthening Guidelines. As part of the quality verification system, the gynecologists and data managers monitored inter-provider variation and reviewed pathology for some patients who underwent LEEP. Quality monitoring was particularly useful to identify providers over-diagnosing precancerous lesions and to define further training needs.

## Capacity Building in Monitoring and Evaluation

Besides service provision and demand generation, the program also built local capacity for CECAP service monitoring. Providers at the 2 highest-volume sites, the CHUs, were engaged in collecting data and improving data quality to monitor service delivery outcomes. Midwives designated as data managers were trained to extract data, crosscheck values, and make corrections using tools developed by the program. Jhpiego and

SOGOB organized a quarterly review of service statistics and data quality checks: client forms, registries, and monthly summary sheets were crosschecked and discrepancies were discussed and corrected. Advice to improve data quality was shared with data managers. Providers were also trained to graph data on a laminated poster to display key indicators related to CECAP services. They used these charts to track the progress of program activities and disseminate results to program staff.

Program results were shared at national meetings that brought together program managers, SOGOB, other partners working in the realm of cervical cancer, and key decision makers including the MOH and the First Lady of Burkina Faso. Following these dissemination events, the government integrated CECAP into its national guidelines on cancer, *Plan stratégique de la lute contre le cancer 2013–2017*, <sup>26</sup> thereby strengthening some of the program's achievements and sustainability.

#### **METHODS**

The program collected 3 types of data: (1) program reports describing activities undertaken to introduce SVA and monitor results, (2) service records describing the number of clients reached by the program, and (3) implementation lessons learned via discussions with key stakeholders.

First, program reports were used to collect results of CECAP activities in the 14 health facilities between September 2010 and August 2014. Program reports, written each quarter, described progress against program objectives.

Second, the program developed 3 tools for monitoring service data: an individual client form, a client registry in which each client was listed, and a monthly summary sheet. Individual client forms completed by providers at each visit included client identification information, HIV status, VIA results, relevant treatment information, and follow-up plans. Program data managers extracted data from individual forms to populate client registries. Facility staff aggregated the registry data on the monthly summary sheet. These tools collecting individual- and facility-level data were used to track progress of 3 indicators:

- The number of women screened using VIA.
- The proportion of women who screened VIA positive.
- The proportion of women screening VIA positive who received same-day cryotherapy in a single visit approach ("proportion SVA").

These indicators were disaggregated by HIV status according to Jhpiego's standard practice. HIV status was self-reported and extracted from the patient's medical booklet or assessed when the patient requested a voluntary HIV test. While this disaggregation was of interest for this program because of the increased risk for cervical cancer in women living with HIV, these numbers are not shown because Burkina Faso's HIV prevalence among women 15–49 years is 1.2%. 24 Program staff and clinical providers reviewed data compiled every quarter. The authors collected and reviewed monitoring data from the 2 larger health facilities. SOGOB collected and reviewed monitoring data from the other 12 facilities and those data are not shown.

Third, formative lessons about the implementation of CECAP services were drawn from program experiences through discussions among program staff and with key stakeholders at the dissemination and advocacy events in Burkina Faso.

This program does not constitute a research study. Data collection and monitoring activities were carried out for quality improvement purposes and therefore were not subject to approval by an institutional review board. Privacy and confidentiality of personal information was maintained throughout data collection and analysis. All data kept by the program were de-identified.

#### RESULTS

#### **Trained Providers**

As mentioned previously, the program trained providers in VIA and cryotherapy through a partnership with programs in Malawi and Côte d'Ivoire. These trainers then trained 21 gynecologists, 2 general practitioners, and 21 nurse-midwives in Burkina Faso. In addition, 11 providers in the 2 CHUs were trained to provide LEEP for cases ineligible for cryotherapy. All providers continued to provide CECAP services over the course of the 4 years; no attrition was recorded. All SVA-trained providers were inclu-ded in program monitoring workshops conducted throughout the 4-year implementation period; supportive supervision visits decreased in frequency over that time. Demand generation activities were conducted in all 14 facilities.

Over 4 years, nearly 14,000 women were screened for cervical cancer and 9% screened positive.

Of those who

66% received

treatment with

cryotherapy.

same-day

screened positive,

#### **Screened Clients**

Over the course of 4 years, 13,999 women were screened for cervical cancer using VIA. On average, 8.9% of the women screened positive by VIA. Several trends can be noted. First, the

number of screened women increased dramatically with demand generation efforts in the first full year (2011) and second year (2012), from 2,713 to 4,662 (Figure 1a). The end of the initial funding phase led to a decrease in the number of women screened in the second quarter of the third year because there were fewer supportive supervision visits and several facilities experienced stockouts of key supplies, including acetic acid, carbon dioxide, swabs, and gauze. Supportive supervision visits were less frequent but continued with assistance from SOGOB, the professional association.

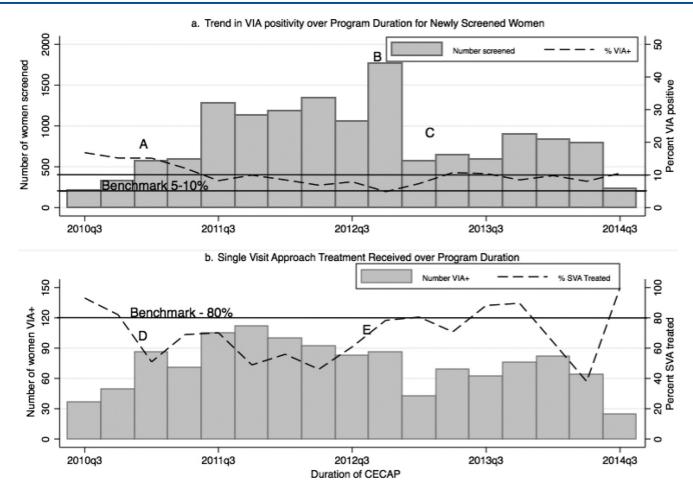
Each quarter, 5% to 17% of women screened VIA positive (dotted line in Figure 1a). This proportion was in line with the international standard benchmark of 5% to 10%.<sup>27</sup> The percentage was higher at the beginning of the program because some health centers did not offer cryotherapy and referred VIA-positive clients to CHUs where women were retested. These repeated screening results were recorded as though they were first diagnoses. This tracking error was rectified in the second year: these clients were logged as referrals from other health centers rather than new clients.

#### **Treated Clients**

Of the 985 women who screened positive at first screening, 65.9% (649) received same-day cryotherapy treatment (Figure 1b). Additionally, 200 women received LEEP on a later date and 176 of these occurred in the 2 CHUs. Moreover, 151 women were referred for surgical management of suspected cancer. The proportion of VIA positive women who were treated with cryotherapy varied between 38% and 100% by quarter. This proportion was high (82% to 93%) at the start of the program when sites offered free cryotherapy because carbon dioxide gas was provided free of charge for the procedure. Later, when facilities were expected to support these costs, the SVA rate declined to 51% when a user fee for VIA and cryotherapy was charged to cover the cost of supplies. The prohibitively expensive fees (approximately \$10 in a country where 44.5% of the population was living on less than \$1.25 per day in 2009<sup>28</sup>) led many women to postpone cryotherapy.

The increase in the proportion of VIA positive women treated with cryotherapy in late 2012 may have been linked to two changes. First, program implementers and SOGOB advocated for lower prices to the MOH and facilities management teams. In November 2012, after the cryotherapy fee was reduced to \$4 in CHUs, the proportion of women receiving cryotherapy increased again to 78%.

**FIGURE 1.** Trends in Cervical Cancer Screening, VIA Positivity, and Treatment, 2 Teaching Hospitals in Burkina Faso, September 2010–August 2014



Abbreviations: CECAP, cervical cancer prevention; SVA, single-visit approach; VIA, visual inspection with acetic acid.

#### Notes:

A. February 2011: Revision to the data collection tools to differentiate between clients referred for cryotherapy from other centers and clients making initial visits.

- B. October 2013: Television broadcast on cervical cancer by University Hospital Sorou Sanon.
- C. January–June 2013: Period without financial resources for supervision and procurement of consumables.
- D. January 2011: Facilities begin requiring payment for VIA and cryotherapy.
- E. November 2012: Cost reduction for cryotherapy.

Second, the capacity to repair cryotherapy machines improved locally. Treatment services had typically been intermittently halted when broken cryotherapy machines were sent out of the country for repairs. In 2012, the program hired the cryotherapy machine manufacturer to train 12 onsite technicians from the health facilities to repair machines. Maintenance and repairs were then conducted onsite reducing hiatuses in treatment provision.

#### Midcourse Corrections Based on Use of Program Monitoring Data

Providers collected data on services through the 3 tools—client forms, the client registry and monthly summary sheets—allowing the onsite managers and providers themselves to visualize progress, analyze trends, and identify potential bottlenecks in service provision. Displaying key indicators on posters meant providers had the

tools to evaluate themselves and take corrective actions in real time. For instance, providers noticed that the proportion of women who screened positive by VIA was higher than expected and identified the source to be the incorrect recording of referred patients. Women with positive VIA tests at outside facilities who were referred for cryotherapy had a repeat VIA test prior to cryotherapy leading referred patients to be counted twice as having positive VIA tests. By tracking indicators, they also realized that the fees charged to patients were too high and gathered evidence to effectively convince facility managers to reduce these costs.

#### DISCUSSION

The program introduced comprehensive CECAP services through same-day VIA screening and cryotherapy treatment for eligible women in 14 health facilities in Burkina Faso through the combined efforts of several institutions. The program had several components: (1) training providers to engage in same-day screening using VIA and cryotherapy for treatment, and referral for and performance of LEEP for women with larger lesions or lesions suspect for cancer, (2) generating demand for cervical cancer prevention services among patients and providers, and (3) building capacity among providers to collect and use monitoring data to track progress and take corrective actions locally. Over 4 years, this approach allowed the program to screen 13,999 women for cervical cancer, detect 8.9% of VIA-positivity among women screened, and treat 65.9% of the women testing VIApositive in a single visit. The 80% treatment target set by the program was reached at the start of the program when services were provided free of charge, but once the program started charging treatment fees to cover the cost of supplies, the proportion treated in a single visit dropped to 51% because the user fees were prohibitive. Once the fees were lowered from \$10 to \$4, the proportion treated in a single visit increased again to 78%.

Overall, the program increased awareness of cervical cancer prevention services among patients, leading to service uptake from previous levels of zero (as services were not offered before this program). Program uptake suggests the acceptability and feasibility of such a program in Burkina Faso in the context of donor funding. Following the dissemination of the program's results, the MOH integrated CECAP services into its strategic planning document, laying the way forward for possible future expansion of

comprehensive CECAP services in Burkina Faso. Since then, all health districts have included CECAP services in their annual action plans, especially with regard to provider training. The MOH is developing strategies to overcome gaps in availability of cryotherapy equipment.

Challenges related to implementation occurred. First, referred women who received a repeat screening were initially counted twice when tracking the provision of services; this was later corrected by including referral status in the registries. Second, some facilities could not provide CECAP services continuously because there were shortages of supplies necessary for VIA and cryotherapy. In addition, sometimes cryotherapy machines were unavailable when they were being repaired in other countries. Training local technicians to perform maintenance internally in the facilities and charging fees to finance some of the costs of the procedure addressed some of these issues. Third, fees were initially set at a prohibitive level for the patient population and deterred use of the services. SOGOB negotiated a lowering of these fees to an appropriate level.

This program experience confirms many aspects of SVA implementation detailed in the literature. For example, data monitoring and quality checks have been beneficial to CECAP service provision in published experiences. 12,20,21,29-31 However, only this Burkina Faso program has integrated that aspect in a framework of capacity building and placed local providers at the center of using that data for problem and solution identification. Other programs also noted the importance of continued supervision to guarantee quality outcomes<sup>8,12,32</sup> and access to consistent supplies and operational equipment.<sup>5,12,30,33</sup> The literature also reports on the difficulty of maintaining the screen-and-treat continuum by minimizing loss to follow-up and ensuring that women return for cryotherapy if the SVA is not possible for a patient. 14,22,33 This program identified user cost as a key barrier to follow-up and successfully addressed it. Finally, support from the MOH was also found to be instrumental in incorporating CECAP services into the health agenda and scaling up services in Botswana, Guyana, Mozambique, Tanzania, and Zambia. 20,21,32,34–36

#### **Essential Components and Lessons Learned**

In light of these challenges faced by the Burkina Faso program and those recounted in the literature, essential components for the establishment of a national CECAP program include:

Once the program started charging treatment fees, the proportion of patients treated in a single visit dropped, from over 80% to 51%. When the fees were lowered, this proportion increased to 78%.

The MOH integrated cervical cancer prevention services into its strategic planning document, laying the way forward for possible future expansion in the country.

- 1. Adequate training of physicians and midlevel providers, including nurses and nurse-midwives, accompanied by a quality assurance protocol.
- 2. Effective demand generation campaigns targeting patients and providers.
- 3. Local cryotherapy equipment maintenance.
- 4. Consistent stocks of VIA and cryotherapy supplies.
- 5. A referral system for large lesions that need LEEP and suspect cancer cases.
- 6. Non-prohibitive fees that allow access to services.
- 7. A robust routine monitoring data collection system used to identify and address service delivery gaps.

Some components are likely setting-specific and should be adapted to consider local contexts.

Three key lessons can be drawn from the implementation of this CECAP program. First, fostering champions of cervical cancer prevention was essential to influence stakeholders and decision makers to increase their commitment to CECAP services. This program nurtured these reproductive health champions and trained them to adopt and promote SVA for cervical cancer. They trained additional providers, which expanded the reach of the program. Their leadership led to increased interest in CECAP services not only among other medical professionals, including obstetricians-gynecologists, nurses and midwives, and SOGOB generally, but also among political figures and experts at the MOH.

Second, the collection, visualization, and display of routine monitoring data in real time by the providers themselves empowered them to track progress, identify gaps, and take corrective actions to remedy any shortcomings, thereby reaching more successful outcomes. The program's focus on strengthening the monitoring capacity of local providers enabled them to become participants in the program's success and essential players in not only identifying issues themselves but also conceptualizing innovative solutions. For instance, through these monitoring data, providers were actively engaged in brainstorming solutions about tracking women referred to other facilities to report accurate indicators, reducing the cost of cryotherapy for patients, and improving internal machine maintenance capacity.

Third, stakeholder coordination under the umbrella of national guidelines is essential to ensure the growth and sustainability of a cervical cancer prevention program focused on increasing the provision of services. Prior to 2013, there was no national program dedicated to CECAP and different stakeholders lacked coordination: local associations conducted separate outreach campaigns for cervical cancer screening without linking screening to timely and appropriate treatment in a facility. Providers did not have the technical support they needed to introduce comprehensive CECAP services. Supportive supervision from district management teams to health facilities did not include CECAP, and the health management information system did not collect data on CECAP. Through training of trainers, technical assistance, and capacity building on monitoring, this program began to coordinate the different players with a role in the provision of CECAP services among the 14 facilities where it was implemented.

Gathering key decision makers for the dissemination of the program's results and engaging them in the successes, shortcomings, and revisions of the experience illustrated not only the importance of cervical cancer prevention services in Burkina Faso but also the acceptability, feasibility, and impact of providing these services. This process is believed to be essential to the sustainability of providing CECAP services. Since the program's end, CECAP services have continued to be offered routinely in the 14 sites and supplies and materials for these activities have been included in the facilities' budgets.

These dissemination efforts were also crucial for sustainability at the national level. Advocacy activities conducted with SOGOB lent support to CECAP services and promoted the integration of VIA-based screening and cryotherapy in the national plan for cancer control. In March 2016, the MOH issued a decree making cervical and breast cancer screening and basic treatment free of charge. In April 2016, CECAP became part of the minimum package of services offered to women in facilities in Burkina Faso. Through these commitments, Burkina Faso has progressively become a model for the successful integration of cervical cancer prevention efforts in resource-limited settings and illustrated a path toward implementing a part of the global cancerfree agenda.

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#### En français

#### Etendre l'approche de la visite unique pour la prévention du cancer du col de l'utérus : succès et leçons apprises du Burkina Faso

L'approche de la visite unique a été mise en œuvre avec une attention particulière au renforcement du système dans 14 formations sanitaires. Dans les deux plus grandes structures sanitaires, près de 14 000 femmes ont bénéficié d'un dépistage des lésions précancéreuses du col de l'utérus en quatre ans. Sur environ 9% de cas positifs, environ 66% ont reçu la cryothérapie le jour même. Une attention particulière est nécessaire pour s'assurer que les techniciens locaux peuvent réparer les équipements de cryothérapie, que les produits sont disponibles et que les tarifs pratiqués pour l'offre de service ne constituent pas une barrière a l'accès aux soins.

#### RÉSUMÉ

Contexte: Le cancer du col de l'utérus représente 23% de l'incidence du cancer et 22% de la mortalité par cancer chez les femmes au Burkina Faso. Ces proportions sont respectivement plus de 2 et 5 fois plus élevées que celles des pays développés. Avant 2010, les services de prévention du cancer du col de l'utérus (CECAP) au Burkina Faso se limitaient à des campagnes de dépistage sporadiques.

Description du programme : Entre septembre 2010 et août 2014, une équipe de Jhpiego a collaboré avec le ministère de la Santé et les associations professionnelles pour mettre en œuvre un programme CECAP axé sur le couplage de l'inspection visuelle du col a l'acide acétique pour le dépistage et le traitement par cryothérapie des lésions précancéreuses chez des femmes éligibles dans 14 formations sanitaires. Les femmes avec des lésions plus grandes ou des lésions suspectes de cancer ont été référées pour la résection a l'anse diathermique (RAD). Le programme a formé des prestataires, conduit des activités de sensibilisation pour la création de la demande et renforcé la capacité en suivi.

Méthodes: Les données sur les activités de programme, les prestations de services et les leçons programmatiques ont été analysées. Trois outils de collecte de données à savoir un formulaire individuel client, un registre client et une fiche de synthèse mensuelle ont été utilisés pour suivre trois principaux indicateurs de service CECAP: nombre de femmes dépistées à l'aide de l'IVA, proportion de femmes dépistées positives à l'IVA qui a reçu la cryothérapie le jour même du dépistage.

Résultats: En 4 ans, le programme a dépisté 13 999 femmes pour les lésions précancéreuses du col de l'utérus en utilisant l'IVA; 8,9% ont été dépistés positives; et 65,9% d'entre elles ont reçu une cryothérapie au cours de la même visite. La proportion de patients recevant la cryothérapie le même jour est passée de 82% à 93% lorsque les services étaient fournis gratuitement, mais est tombée à 51% lorsque des tarifs d'environ 10 \$ ont été appliqués pour couvrir le coût des prestations. Après avoir réduit les frais à environ 4 \$ en novembre 2012, la proportion a encore augmenté pour atteindre 78%. Les difficultés de mise en œuvre comprenaient celles du suivi des patients référés, les ruptures de stock de produits essentiels, les difficultés de maintenance des machines de cryothérapie et les tarifs prohibitifs appliqués pour les prestations de service. Les prestataires ont été formés pour assurer de manière autonome le suivi des indicateurs d'offre de services, identifier les lacunes et prendre des mesures correctives.

Conclusions: Après la diffusion des résultats démontrant l'acceptabilité et la faisabilité du programme CECAP, le ministère de la Santé du Burkina Faso a inclus les services CECAP dans son paquet de prestation de services minimum en 2016. Les composantes essentielles de ces types de programmes comprennent la formation des prestataires sur l'IVA, la cryothérapie et la résection a l'anse diathermique; la création de la demande des services au niveau des prestataires et des clients; la maintenance des équipements au niveau local; un approvisionnement adéquat en produits; un système de réference pour la RAD; des tarifs non prohibitifs et un système de collecte de données performant.

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#### **ORIGINAL ARTICLE**

## Observe Before You Leap: Why Observation Provides Critical Insights for Formative Research and Intervention Design That You'll Never Get From Focus Groups, Interviews, or KAP Surveys

Steven A. Harvey<sup>a</sup>

Four case studies show how observation can uncover issues critical to making a health intervention succeed or, sometimes, reveal reasons why it is likely to fail. Observation can be particularly valuable for interventions that depend on mechanical or clinical skills; service delivery processes; effects of the built environment; and habitual tasks that practitioners find difficult to articulate.

#### ABSTRACT

Formative research is essential to designing both study instruments and interventions in global health. While formative research may employ many qualitative methods, focus group discussions and in-depth interviews are the most common. Observation is less common but can generate insights unlikely to emerge from any other method. This article presents 4 case studies in which observation revealed critical insights: corralling domestic poultry to reduce childhood diarrhea, promoting insecticide-treated bed nets (ITNs) to prevent malaria, evaluating skilled birth attendant competency to manage life-threatening obstetric and neonatal complications, and assessing community health worker (CHW) ability to use malaria rapid diagnostic tests (RDTs). Observation of Zambian CHWs to design malaria RDT training materials revealed a need for training on how to take finger-stick blood samples, a procedure second nature to many health workers but one that few CHWs had ever performed. In Lima, Peru, study participants reported keeping their birds corralled "all the time," but observers frequently found them loose, a difference potentially explained by an alternative interpretation of the phrase "all the time" to mean "all the time (except at some specific seemingly obvious times)." In the Peruvian Amazon, observation revealed a potential limitation of bed net efficacy due to the built environment: In houses constructed on stilts, many people sleep directly on the floor, allowing mosquitoes to bite from below through gaps in the floorboards. Observation forms and checklists from each case study are included as supplemental files; these may serve as models for designing new observation guides. The case studies illustrate the value of observation to clearly understanding clinical practices and skills, details about how people carry out certain tasks, routine behaviors people would most likely not think to describe in an interview, and environmental barriers that must be overcome if an intervention is to succeed. Observation provides a way to triangulate for social desirability bias and to measure details that interview or focus group participants are unlikely to recognize, remember, or be able to describe with precision.

#### INTRODUCTION

et's play a quick game of word association: If I say "formative research," what's the first word or phrase that comes to mind? Some of you, thinking of purpose, might say that formative research is what you do before designing a behavior change campaign. Others, thinking of methods, might say "focus groups." Both would be wrong. Well, at least partially wrong.

Formative research *is* important to the design of behavior change campaigns, but it serves many other purposes as well. It is essential to developing research

instruments and global health interventions of many kinds. <sup>1–4</sup> It can provide the basis for assessing clinical practice, determining how to measure intervention outcomes, planning quality improvement initiatives, and understanding many other aspects of global health programming. <sup>5–14</sup> As medical anthropologist Margaret Bentley explains <sup>15</sup>:

The purpose [of formative research] is to provide input into the design of a research study or intervention, including the identification of target populations and appropriate recruitment, retention or consent strategies, development of assessment or evaluation measures, and refinement of intervention components. Formative research allows community participation in the design of research and program protocols, which leads to greater community acceptance.

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So formative research is about much more than just behavior change interventions.

Now, what about methods? If you want to do formative research, how should you go about it? Formative research can incorporate many methods, both qualitative and quantitative. Focus groups tend to be the most common, perhaps because they are most familiar. Interviews and knowledge, attitude, and practice (KAP) surveys are also popular. However, as you've probably gathered by now, I'm going to argue that those methods are often insufficient. If you're doing formative research, you should also consider observation.

Researchers seem more hesitant about observation than other methods, perhaps because they don't know how to do it, consider it too laborintensive or costly, feel uncomfortable with the idea of watching other people, or worry about reactivity—the phenomenon where those being observed change their behavior due to the observer's presence. But observation can generate insights you won't get using any other method. And those insights can often prove critical.

In this article, I present 4 case studies on different global health topics, from corralling domestic poultry to measuring the competency of skilled birth attendants (SBAs). 19-21 These examples illustrate some of the scenarios in which observation—both structured and unstructured can be useful, and they highlight the types of insights it can provide. In each case study, observation vielded critical information that would have been difficult or impossible to obtain any other way. For each case study, I provide a brief description of the research and the context from which it was drawn, then focus more extensively on the observational methods used and the unique insights they generated. Complete descriptions of the original research can be found elsewhere. 22-28 I've provided the observation instruments used for each case study as supplemental files.

#### **Ethics Review**

The research cited in case studies #1 and #2 was reviewed and approved by the Institutional Review Board of the Johns Hopkins Bloomberg School of Public Health in Baltimore, MD, USA, and by the Ethics Committee of the Asociación Benéfica PRISMA in Lima, Peru. The research cited in case study #3 was reviewed for compliance with the ethics guidelines of the Quality Assurance Project funded by the United States Agency for International Development and ap-

proved by Ministry of Health ethics committees or their equivalent in each study country. The research cited in case study #4 received ethics approval from the World Health Organization Special Programme for Research and Training in Tropical Diseases (WHO/TDR) and by the Tropical Disease Research Centre Ethics Committee – Ndola, Zambia.

#### CASE STUDY #1: CORRALLING DOMESTIC POULTRY TO REDUCE CHILDHOOD DIARRHEA IN LIMA, PERU

#### **Background**

Campylobacter jejuni is a common bacterial contributor to diarrheal disease worldwide. The bacteria is found almost universally in the intestinal tracts of chickens and can be transmitted to humans from contact with chicken feces or consumption of undercooked chicken. And I not the shanty town outside Lima, Peru, where this study took place, the link between C. jejuni in domestic poultry and childhood diarrhea has been established for decades and confirmed repeatedly. And the state of the state

#### **Study Context and Observation Methods**

The observations described here took place as formative research for a trial to test whether corralling free-range chickens and other domestic poultry would reduce Campylobacter-associated diarrhea by minimizing contact between children and birds. 23 The research team recruited 12 local families raising domestic poultry, built corrals for the poultry at each household, and asked each family to test the corral for 8 weeks. A study team member made weekly visits to each household to complete a 19-item structured observation form (Supplement 1) with space to record variables such as number of birds present; number inside and outside each corral; visual evidence that birds might have been outside the corral recently (e.g., feathers or bird droppings in the yard or inside the house); interaction, if any, between birds and children; cleanliness and structural soundness of each corral; and presence and cleanliness of food and water. The weekly visits were carried out at preselected random times during daylight hours Monday-Saturday. Participants were not notified of visits in advance. This unannounced random schedule made it possible to observe the natural state of each household and corral on different days of the week and at different times of day. In

should consider observation.

If you're doing

research, you

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addition, the project sociologist made 3–4 random semi-structured spot checks per household over the 8-week period (30 total across the 12 participating households) noting whether, at the moment of arrival, birds were corralled, children were interacting with birds, birds had adequate food and water, and corrals were in good condition. The sociologist took unstructured notes on anything he judged relevant to feasibility or acceptability of corralling.

## Critical Findings Extent of Corralling

In interviews, participants stated that they kept their birds corralled "all the time." However, observers found birds loose during 13% of observation visits and 33% of spot checks. Asked about this difference, participants clarified that they let the birds out at certain times such as while cleaning the corrals or to give them time to play (recrearse)—an activity owners considered essential to their birds' well-being.

Why did participants say they kept their birds corralled all the time when they really didn't? One possible reason is courtesy bias: The project had built them corrals, and so participants may have felt they would disappoint us or seem ungrateful by admitting they didn't always use them. Another possible reason is that they meant something different than we did by "all the time." Participants took for granted that—like themselves—everyone would understand the need to let birds loose at certain times for practical or health reasons, a "fact" seemingly so obvious as to be unworthy of mention. "All the time" really meant "all the time except at certain (presumably obvious) specific times." Had we relied solely on interviews (reported behavior), we might never have known that birds were sometimes loose or might never have thought to ask why. Triangulation between what people told us and what we observed revealed critical information about why the intervention might not work.

#### **Sufficient Food and Water**

For the local population, one advantage of raising loose poultry was that the birds could find their own food and water. With a corral, the household needed to provide a constant supply of food and water and maintain hygienic conditions. As shown in Figure 1, both structured observations and spot checks revealed that over the 8-week surveillance only 46% of corrals had food and only 43% had water. Further, corral floors were

often wet after birds overturned their water dishes, and food was often rotting. In earlier interviews, participants had expressed concern that corralling would be unhealthy for their birds. Observations made clear that a corralling intervention might validate these concerns unless participants received training on how to keep corrals clean and corralled birds healthy. The data also showed that corralling took more time and effort since someone had to clean the corrals regularly and ensure availability of food and water.

#### Contact Between Poultry and Children

The primary objective of corralling was to break the Campylobacter transmission cycle by separating birds from children. Observations demonstrated that children took a keen interest in the new corrals, often swinging on the doors, sticking their fingers through the mesh, or entering to play with the birds. Attempts to childproof corrals with latches or convince parents to keep children away were largely ineffective: Observers continued to encounter children inside. Parents explained that this was natural and appropriate: They wanted their children to grow up around animals. Children as young as 3 were assigned to collect eggs every day. Instead of isolating children from C. jejuni, observations suggested that corralling actually concentrated exposure. This may help explain the finding from a later study that rates of Campylobacter-associated diarrhea among children under 6 were 2 to 7 times higher in corralling households than non-corralling households with the same number of chickens.<sup>3</sup> Without observation, we might have missed the child-bird contact.

#### **Handling of Poultry Manure**

One contributor to child *Campylobacter* exposure not revealed in interviews was household handling of chicken manure. With manure now concentrated in a smaller space, poultry-raising households began to collect it to use as fertilizer. Observers documented that manure removed from coops was often stored in tin cans or buckets outside the coop within easy reach of children. Uncovered storage also allowed the wind to scatter dried manure around the outside of the living area, thus increasing potential contact.

#### Contrast Between Human and Bird Habitation

Though not part of formal data collection, observers also noted the contrast between human and animal living space. Residents of this area had

Participants took for granted that—like themselves— everyone would understand the need to let birds loose at certain times for practical or health reasons, a "fact" seemingly so obvious as to be unworthy of mention.

Mean 46% corrals have food

Mean 43% corrals have water

Mean 43% corrals have water

40%

1 2 3 4 5 6 7 8

Observation Week

**FIGURE 1.** Percentage of Domestic Poultry Corrals Containing Food or Water During Weekly Random Observations, Lima, Peru (N=122 Observations)

settled outside Lima as squatters, often after fleeing rural terrorism in the 1980s. Most worked as casual laborers, domestic servants, or textile piece-workers earning the equivalent of \$4.00 to \$5.00 per day. Many lived in houses cobbled together from discarded materials, often scavenged from construction sites or garbage dumps. Corrals, though built as cheaply as possible, were made from new material at an average cost of \$60.00 per household. Figure 2 shows a projectconstructed corral to the left with the human habitation in the center. After receiving their corrals, more than 1 participant joked that their birds now enjoyed a higher standard of living than the human members of the family. Documenting this contrast offered a perspective beyond that likely to be achieved through interviews or focus groups alone.

#### CASE STUDY #2: BED NETS FOR MALARIA PREVENTION IN THE PERUVIAN AMAZON

#### **Background**

Malaria was virtually eliminated from the Peruvian Amazon during the 1970s and 1980s but began to reappear sporadically in the mid-1990s, culminating in an epidemic outbreak in 1997.<sup>39</sup> In response that year, the Peruvian Ministry of Health began distributing ITNs to affected communities. This

case study involves observations carried out to evaluate the social acceptability of ITNs and to assess their potential efficacy based on human behavior during the peak biting hours of local malaria-transmitting mosquitoes.

#### **Study Context and Observation Methods**

The study took place in 1 peri-urban community and 3 rural villages, all within 30 km of Iquitos, the Peruvian Amazon's largest city. Over 9 months, 4 observers carried out 1 dusk-to-dawn observation in each of 60 households. Upon arrival, the observer used a structured form (Supplement 2) to collect information about the number, ages, and relationships of household occupants; the number and types of sleeping spaces; and the number and types of bed nets. The observer then took unstructured notes at 5-minute intervals throughout the night, recording the location and activities of each household member. Most households consisted of a wooden platform on stilts raised about 2 meters off the ground and covered with a thatched roof. These structures had few rooms or interior dividers. so observers could follow most household activities from a single vantage point. 17,40

## Critical Findings Net Use During Peak Biting Hours

A key concern about ITN effectiveness in the Americas is whether people are likely to be inside

FIGURE 2. Contrast Between Human and Animal Living Spaces Documented Through Observation, Las Pampas de San Juan de Miraflores, Peru

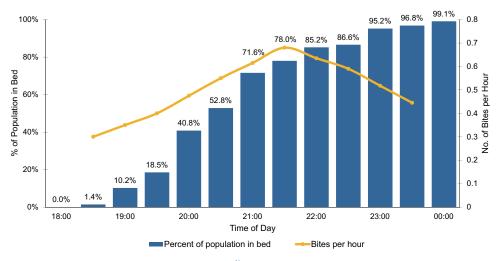


Project-constructed poultry corral (left foreground) vs. human habitation (center background). Project participants sometimes joked that the birds in the project enjoyed a better standard of living than the people. © 1999 Steven Harvey.

a net during the hours when local malariatransmitting mosquitoes bite. Observation allowed us to systematically document net use. As shown in Figure 3, people began to enter their nets for the night as early as 7:00 p.m., but only about half the population was inside a net by 8:30 p.m. and slightly less than 80% by 9:30 p.m., the peak biting

hour for *Anopheles darlingi*, the Amazon's most important malaria vector. <sup>42</sup> This suggests that ITNs might be somewhat effective, but not as effective as in Africa where principal vector species feed later at night. Rather than observing all night, we might have simply asked people what time each member of the household went to bed the previous night,

**FIGURE 3.** Percentage of the Population in Bed by Half-Hour (N=60 Observations) Compared With *Anopheles darlingi* Feeding Behavior, <sup>a</sup> Department of Loreto, Peru



<sup>&</sup>lt;sup>a</sup> Data on mosquito feeding behavior come from Vittor (2003).

but in a setting where few people had watches or clocks, it would have been hard for them to respond with much precision. Social desirability bias might also have affected people's reports about their own behavior: At the time, the Ministry of Health was running a campaign encouraging people to enter their nets at dusk—a practice unlikely to be feasible in an area near the equator where the sun sets around 6:30 p.m. throughout the year.

#### **Multiple Entries and Exits**

One unanticipated finding was the number of times people enter and exit ITNs during the night. He had been share an opportunity to enter. Parents who share nets with children may spend considerable time outside the net unprotected after their children have gone to sleep. The Table shows an example of a single sleeping space occupied by a 23-year-old mother and her 2-year-old son. The net was lifted a total of 20 times between 7:00 p.m. and 6:30 a.m. The mother spent 195 minutes outside the net between the first time she entered with her son at 7:00 p.m. and the time both of them got out of bed at 6:30 the next morning.

#### Additional Potential Risk Factors

Observations revealed other phenomena that would have been difficult to capture with interviews or focus groups. For instance, observers took detailed notes on sleeping spaces in participating households. These notes revealed that many people slept directly on cane flooring rather than on a bed. The flooring had gaps between the cane staves. Since many houses were built on stilts, this meant mosquitoes could enter the sleeping space from below. A net alone could not provide adequate protection in this setting: An effective malaria prevention intervention would need to help at-risk individuals find a way to protect themselves from below as well as from above. Observers also documented other practices that might increase exposure risk: attending evening church services during peak biting hours, bathing after dark, running small home-based stores where community members came to buy food or basic necessities in the evening hours, and other nighttime activities such as hunting, fishing, or charcoal production. While study participants reported some of these activities during interviews, direct observation allowed the study team to document them more systematically.

An unanticipated finding from an observational study of bed net use was the number of times people enter and exit their bed nets during the night—as many as 20 times for 1 mother with a young son.

While knowledge can be measured using a written exam, the only way to assess manual skill is by watching someone perform a task.

#### CASE STUDY #3: ASSESSING THE COMPETENCY OF SKILLED BIRTH ATTENDANTS IN 7 COUNTRIES

#### Background

About 90% of the 300,000-350,000 annual maternal deaths worldwide are caused by 5 common obstetric complications: postpartum hemorrhage, pregnancy-induced hypertension, obstructed labor, perinatal sepsis, and postabortion complications. 44,45 Risk for experiencing one of these life-threatening complications cannot be reliably predicted in advance, but most can be treated successfully if the woman experiencing them has access to basic or comprehensive essential obstetric care delivered by an SBA. For this reason, the World Health Organization (WHO) recommends that all pregnant women be assisted by an SBA during labor and delivery.<sup>46</sup> Several international organizations have defined the competencies necessary to manage these complications. The observations described below were carried out as part of developing a method to assess these competencies among practicing SBAs in low- and middle-income countries.

### **Study Context and Observation Methods**

Testing a clinician's competency to manage a complication according to standards requires assessing not only abstract knowledge but also physical or manual ability. Knowledge can be measured using a written exam, but the only way to assess manual skill is by watching someone perform a task to see whether she or he does it correctly. Assessing skills on actual patients, however, is problematic. Ethically, an observer qualified to evaluate clinical competency would need to stop observing and intervene before allowing an insufficiently skilled provider to endanger a patient's life or well-being. Moreover, even common obstetric complications are relatively rare. This makes it impossible to assess the skill of more than a handful of providers using actual patients.

The observations discussed here were designed to test SBA competency at performing 4 critical procedures. The first 3 procedures—active management of the third stage of labor (AMTSL), manual removal of the placenta, and bimanual uterine compression—are performed to prevent or control postpartum hemorrhage in a mother who has just given birth. The fourth, neonatal resuscitation with an Ambu bag, is used to treat neonatal asphyxia. The project, eventually carried out in Benin, Ecuador, Jamaica, Kenya, Nicaragua,

**TABLE.** Observational Bed Net Entry and Exit Data From a Single Sleeping Space With 2 Occupants, a 23-Year-Old Mother and Her 2-Year-Old Son, Peruvian Amazon

Time	Entry (+)/Exit (-) [Minutes Outside Net Before Reentering]		
	Mother (P1)	Child (P2)	Comments
19:00	+/- [145 min]	+	P1 gets into net with P2, then gets back out, does housework, cares for pigs, chickens.
20:50			P1 straightens up kitchen, talks with observer.
21:25	+/- [37 min]	-/+[1 min]	P1 removes P2 from net, takes him to urinate. Both get back into net. P1 gets back out of net.
21:30		- [17 min]	P2 gets back out of net, sits with P1.
21:47		+	P2 gets back into net.
21:55		- [7 min]	P2 gets back out of net, goes to find P1.
22:02	+	+	P1 & P2 get into net.
22:06	-/+ [1 min]		P1 gets out of net to look for socks for P2, finds socks, gets back in.
22:10	-/+[1 min]		P1 gets out of net to close bedroom door, gets back in.
01:45	-/+[1 min]		P1 gets out of net to get juice for P2, then gets back in & helps P2 drink juice.
01:47	- [5 min]	- [5 min]	P1 takes P2 out of net to urinate.
01:52	+	+	P1 and P2 get back into net.
06:05	— [5 min]		P1 gets out of net, goes outside, opens door to chicken coop to let chickens out.
06:10	+		P1 gets back into net.
06:22			P2 wakes up, looks at P1, sees she is still asleep, stays inside net sitting up.
06:30	-	_	P1 and P2 both get out of net.
Total minutes outside net from first entry (after 18:30)	195 (225)	30 (60)	
Total number of times net lifted	;	20	

Rwanda, and Tanzania, used expert obstetrician/gynecologists and pediatricians from host countries as observers. SBAs being assessed performed each procedure on an anatomical model (Gaumard S500 Advanced Childbirth Simulator and Simulaids Sani-Baby CPR mannequin or Gaumard S320 Newborn Airway Trainer); observers assessed competency using a structured step-by-step checklist (Supplement 3). <sup>27,28</sup>

#### **Critical Findings**

Correct hand position and movement are essential to successfully performing all 4 tasks. Controlled cord traction, an elective component of AMTSL, requires exerting a gentle downward pull on the umbilical cord with one hand while

using the other to prevent uterine inversion by applying counter-traction just above the pubic bone.47 In case of retained placenta, manual removal requires inserting the hand through the vaginal canal and using a gentle lateral motion to detach the placenta intact, leaving no fragments that could provoke continued bleeding or cause sepsis. Figure 4 shows an expert observer demonstrating manual removal with the Gaumard Advanced Childbirth Simulator. The open abdominal cavity allows the observer to assess the technique of the SBA being observed. Some SBAs might be able to describe these or similar procedures, but even a precise detailed description would not necessarily indicate ability to perform them.

FIGURE 4. Demonstration of the Correct Hand Position for Manual Removal of a Retained Placenta on an Anatomical Model



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Observations across the 7 study countries revealed the following:

- Though AMTSL is commonly included in national standards for managing uncomplicated delivery, most SBAs did not know how to perform controlled cord traction.
- Similarly, most SBAs could not demonstrate the correct hand positions for carrying out the manual removal of a retained placenta. Although bimanual uterine compression is a relatively simple procedure requiring no instruments or equipment, virtually no SBA was familiar with it.
- Neonatal resuscitation with an Ambu bag—in addition to requiring a neonatal-sized bag, valve, and mask, which many health facilities lack—requires the person performing it to place the mask over the newborn's mouth and nose

and position his or her hand over the mask correctly to achieve a proper seal. Failure to do so can result in air escaping out the sides of the mask rather than entering the newborn's lungs. Proper head position is also critical to ensuring that the newborn's airways are open, not blocked. In Figure 5, the left image shows correct positioning of the bag, mask, and head while the right image shows incorrect positioning: Placing the bag vertically with respect to the newborn's body makes it more difficult to achieve a good seal. Both newborn mannequins used in the study were designed so that the mannequin's chest would rise when ventilated properly, similar to the chest of an actual newborn receiving correct ventilation. This allowed both the observer and the SBA to determine if the SBA was performing the procedure correctly.

Using checklists adapted to each country's norms, observation also enabled the study team to assess whether SBAs followed prescribed infection prevention guidelines including handwashing, gloving, and post-procedure decontamination. Participating SBAs were provided with all necessary supplies and equipment. At the beginning of each assessment, the observer instructed each participant to "begin by preparing yourself, the equipment, and the patient," then noted if the SBA proceeded in accordance with norms. At the end, the observer similarly instructed each participant to "please tell me what more you would do or ask someone else to do once you have finished the procedure."

It's tempting to classify this research as *summative* since its initial objective was to assess existing health worker skills. But it was also *formative*, because the results helped shape interventions: In the short term, observers offered feedback and retraining to each participant, and sometimes—when many participants had a particular weakness in common—to the entire group. In the longer term, findings have influenced training programs and assessment methods in participating countries and around the globe.

#### CASE STUDY #4: ASSESSING CHW ABILITY TO USE MALARIA RAPID DIAGNOSTIC TESTS IN ZAMBIA

#### **Background**

For decades leading up to the early 2000s, malaria in sub-Saharan Africa was diagnosed presumptively: Anyone with a fever was presumed to have malaria and treated with antimalarials. This

FIGURE 5. Neonatal Resuscitation With an Ambu Bag: Correct vs. Incorrect Positioning





Left: Correct positioning of mask, bag, and newborn's head to achieve a good seal, with bag perpendicular to the newborn's body. © 2006 Steven Harvey.

Right: Incorrect positioning, with bag parallel with the newborn's body, making it more difficult to achieve a good seal. © 2002 Steven Harvey.

practice developed because the supply of both microscopes and trained microscopists was too limited to diagnose more than a tiny fraction of febrile patients. In addition, first-line antimalarial drugs were cheap and adverse effects negligible, so presumptive treatment involved minimal cost and risk. After introduction of artemisinin combination therapy as first-line treatment for malaria starting around 2004, WHO recommended parasite-based diagnosis first for adults and older children, then for all suspected cases of malaria regardless of age. 48 Malaria rapid diagnostic tests (RDTs) make parasite-based diagnosis possible even at health facilities with no laboratory, microscope, or microscopist. In many areas, however, febrile patients seek treatment at the community level without ever visiting a health facility. The observations described in this case study were carried out to determine whether volunteer community health workers (CHWs) could use RDTs safely and accurately and, if so, what sort of training materials they needed.

#### Study Context and Observation Methods

Based on focus group discussions with Zambian CHWs, the study team designed a job aid and brief training curriculum. We used structured

observation to pilot test these materials. Study team members observed 79 CHWs prepare 3 RDTs each and recorded the results on a 16-item checklist (Supplement 4). 24,25

#### **Critical Findings**

Malaria RDTs require using a sterile lancet to draw a finger-stick blood sample, a procedure that is second nature to many professional health workers. Due to concerns about HIV and other blood-borne diseases, however, most African CHWs were prohibited from taking finger-stick blood samples. The Zambian Medical Council authorized the practice for this study, but few participating CHWs had ever taken a sample or used a lancet. During training, observers noticed that instead of drawing blood with a quick stab—the preferred approach—many CHWs set the point of the lancet on the patient's fingertip, then pushed it into the skin. Participants explained they were doing this for fear that stabbing would cause the patients too much pain, but the effect was just the opposite: Pushing was more painful. In addition, it often produced too little blood, thus necessitating a second, third, or even fourth finger prick. Observing this made clear

- that CHWs needed specific training on proper lancet technique. The study team subsequently developed a training module demonstrating how to extract sufficient blood with a single prick. Improved CHW technique reduced patient discomfort and increased testing quality.
- Watching CHWs transfer blood from fingertip to test cassette yielded a similar revelation. The project RDT came packaged with a loop-shaped blood transfer device designed to collect a 5 µl film of blood across the width of the loop. CHWs did the finger prick with the ball of the patient's finger facing up, then tried to collect the drop from above. This often conveyed too little blood to the test cassette even after multiple tries. Noting this, an experienced observer suggested pricking the finger, rotating the patient's hand 180°, then collecting the drop from underneath with the ball of the finger facing down. In most cases, this made it possible to collect and transfer the precise volume of blood required on the first attempt.
- A key concern related to blood safety was correct disposal of the blood-contaminated lancet. To minimize danger to patients, CHWs, and the community, the research team distributed sharps boxes to all participating CHWs and instructed them to deposit the used lancet into the sharps box immediately after pricking the patient's finger. Setting down the used lancet prior to disposal heightens risk of finger-stick injuries. Observers noticed that positioning the sharps box appropriately made immediate disposal convenient: For a right-handed CHW, this meant placing the sharps box on the right side of the work space, and vice versa for a lefthanded CHW. Placing the box on the opposite side of the CHW's dominant hand forced the CHW to reach across both his or her own body and that of the patient. This made handling the used lancet more risky and immediate disposal more difficult.
- Assembling supplies prior to conducting a test revealed a similar issue. Most CHWs work from home. Lacking permanent work space, they take out their supplies and then put them away again for each patient. In pilot testing, observers noticed that CHWs would often forget one or more items prior to starting a test. In some cases, this posed only minor inconvenience: CHWs might open a test kit, realize they had forgotten to bring a pen or pencil, and ask the patient to wait while they retrieved one. Other cases presented greater risk: CHWs might

- open a sterile lancet, realize they had forgotten an alcohol swab or the sharps box, and set the open lancet down on a table while going to retrieve the missing item. This finding led the team to modify the job aid by listing all necessary supplies and equipment at the top and adding an instruction to assemble everything before starting the procedure (Figure 6).
- Watching CHWs provide services from home led to another observational finding: Many CHW homes lack electricity and thus have poor-quality artificial lighting. This fact can affect the accuracy of test interpretation when RDTs are prepared inside, especially after dusk or during inclement weather. The RDT's positive test line—indicating that a patient is infected with malaria—can often be quite faint. With inadequate artificial lighting inside and insufficient natural light outside, a CHW could easily misread a faint positive result as negative, thus leaving an infected patient untreated. Realizing this led to added emphasis during training that positive lines are sometimes quite faint and that CHWs should read results in the brightest light possible to avoid missing a faint positive.

#### DISCUSSION

Observation produced novel insights in the case studies just described, but how do you decide when observation might be valuable or even essential for your intervention or study? To answer this, it's useful to think in terms of categories of events or processes. Among others, these might include mechanical skills, health service delivery processes, effects of the built environment, and habitual practices that people would have difficulty articulating, sometimes known as "tacit knowledge." <sup>49,50</sup>

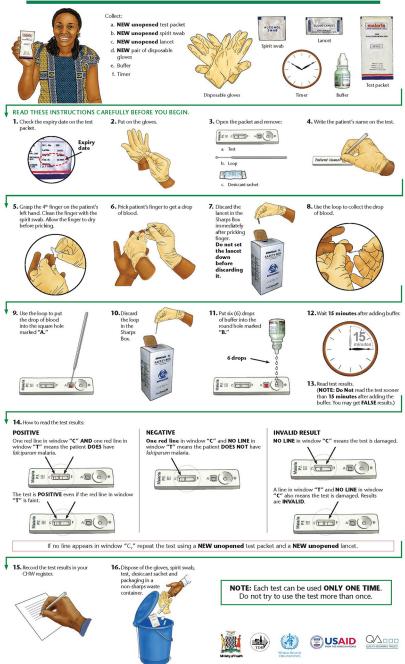
#### **Mechanical Skills**

The SBA and RDT case studies both illustrate the value of observation to understanding mechanical skills, including critical details such as the correct hand position needed to effectively carry out a lifesaving obstetric or neonatal intervention. Manual removal of a retained placenta or resuscitation of an asphyxiated newborn are two examples. Although lancet technique, sharps box position, or collecting blood with the fingertip facing up or down might seem like minute details when preparing an RDT, they can make the difference between effective, efficient, safe practices

Observation can produce novel insights, but how do you decide when it might be valuable or even essential for your intervention or study?

#### FIGURE 6. Malaria Rapid Diagnostic Test Job Aid

## How To Do the Rapid Test for Malaria



A job aid for community health workers lists at the top all supplies and equipment that the worker needs to assemble prior to conducting a rapid diagnostic test for malaria.

and practices that lead to incorrect results or endanger the patient, the health worker, or the community. Observation in these cases is critical not only to diagnose lapses but also to identify interventions that can address them. Observation thus led to additional practical training for SBAs and to development of specific training modules and revised job aid illustrations for malaria RDTs. Beyond their specific substantive findings, these two studies highlight the value of observation to understanding both health worker and community behavior.

#### **Sequential Processes**

Many public health interventions involve sequential processes: Not only must each step be performed properly, it must also be performed in the proper order. Again, the RDT case study offers an illustrative example: The study team identified 16 discrete steps necessary to correctly prepare and interpret the test; performing them in the wrong order (e.g., opening the sterile lancet before cleaning the finger with an alcohol swab) or the wrong way (depositing the blood drop where the buffer solution is supposed to go) could compromise test accuracy or patient or health worker safety. The observation checklist (Supplement 4) enabled the team to determine the proportion of health workers who completed all steps correctly, identify specific steps where health workers had problems, and modify training to address the problems observed. Greenland et al. used a similar approach in Zambia to determine what proportion of caregivers of young children with diarrhea could prepare oral rehydration solution correctly.<sup>51</sup> Hurley et al. used a combination of structured and unstructured observations to track the flow of pregnant women through antenatal care in Mali and better understand why many completed their visits without receiving intermittent preventive treatment for malaria in pregnancy (IPTp) or received it without any information about the purpose of IPTp.52 Hermida et al. found observation to be more accurate than patient exit interviews or medical record review for assessing facility-based provider adherence to standards of care for acute lower respiratory infection, diarrheal disease, and family planning counseling.<sup>53</sup> For this reason, observation is often a key component of quality improvement research. 53,54 In sum, observation can be an invaluable tool for documenting the necessary steps in a process, identifying where breakdowns occur, and thus pinpointing where intervention is needed. This type of analysis can be useful at the household, community, and health facility levels.

#### **Understanding the Built Environment**

The built environment—and sometimes its relationship to the natural environment—can significantly affect disease risk, health service delivery, and the feasibility of health interventions. The Campylobacter study setting consists of dusty desert hills where water is scarce and rain nonexistent (natural environment). Since the poorest people live at the top of those hills with neither wells nor piped water (built environment), many families struggle to provide water for themselves. Water for corralled birds becomes, at best, a secondary priority. Observing the difficulty of obtaining water helped study team members better understand owners' concerns about the effect of corralling on birds' health. Wind (natural environment) combined with open storage of concentrated chicken manure cleaned from the corrals (built environment) turned out to be one form of continued contact between humans and Campylobacter despite corralling.

The built environment was likewise a critical aspect of the bed net study. The structure of a typical bed in the study setting-no mattress and gaps between the wooden or bamboo slats that allowed mosquitoes to bite from underneathmight never have occurred to public health practitioners, most of whom presumably sleep in beds with mattresses. Even had it occurred to them, they would not have been able to collect systematic data on bed configurations without observation. Thus, observation revealed one potential limitation of bed net efficacy in the study setting. This, in turn, revealed a necessary component of any improvement intervention: figure out how to block the gaps between flooring that allowed mosquitoes to enter.

Systematically observing the built environment can be revealing in many settings. By documenting patient flow at health centers and hospitals, maternal health researchers from the Quality Assurance Project helped explain why women arriving with an obstetric complication might encounter significant, sometimes lifethreatening, delays before seeing a clinician. 55–58 Observing both the size of rooms in a house and their use for multiple purposes (sleeping at night, running a small retail shop during the day) helped explain why some households in Ghana were reluctant to permanently install bed nets over

their sleeping spaces and why, in some cases, residents preferred conical nets to rectangular.<sup>59</sup> Observing the dim lighting in CHWs' houses helped explain why CHWs might miss weak positive RDT results and why training programs needed to emphasize the importance of reading test results under bright light.<sup>25</sup> Many U.S. researchers have used observation to study the relationships between built environment, physical activity, available food choices, and chronic diseases such as obesity and diabetes. 60-63 As with the discussion of sequential processes above, it is worth reiterating that observations related to the built and natural environments can be useful at the household, community, and health facility levels.

#### **Habitual Practices and Tacit Knowledge**

In any setting, people perform a variety of routine activities, the procedures for which they learned at some point in the past, committed to memory, and carry out automatically, almost as if by instinct. Because these activities are habitual, those who perform them often have difficulty articulating the step-by-step process and even come to think of that process as self-evident. Collecting a fingerstick blood sample is a case in point. A health care provider who has done it many times considers it second nature and wonders why a novice finds it so difficult. Observation reveals that the process involves numerous steps: assemble all the supplies before starting, swab the fingertip with alcohol, wait for it to dry, massage the finger to work the blood up into the fingertip, open the sterile lancet, puncture the fingertip with a quick stab, orient the fingertip with the blood drop in the optimum position for the particular blood collection device being used, etc. The experienced provider has internalized all this and performs it without needing to think. The novice may fail to massage the finger, stab too timidly and thus extract too little blood, or orient the fingertip in a less than optimal position and thus collect too little blood, or too much. Observing both expert and novice helps distinguish the differences and thus determine what training the novice requires.

The *Campylobacter* study provides additional examples: Interview or focus group participants might fail to mention the many points of contact between children and birds either because they knew the intervention was meant to separate the two (courtesy bias) or because the types of contact were so commonplace as to seem unworthy of mention. Observing children play with birds, feed

and water them, collect eggs, and clean corrals provides tangible evidence that those designing public health interventions should take into account both human nature (children like to play with animals) and economic and cultural practices (even a very young child may be assigned household chores; parents may view learning to raise animals as a key life skill). Cumulative findings from these observations contributed to a conclusion that the intervention was unlikely to succeed, a conclusion confirmed by subsequent research demonstrating that corralling, instead of decreasing risk of *Campylobacter*-associated diarrhea in children, actually doubled it. <sup>38</sup>

The bed net study also provides examples: Absent observation, as noted above, public health practitioners might not have thought to ask about bed design. Conversely, mentioning bed design—an aspect of daily existence so routine as to pass virtually unperceived—might never have occurred to a member of the at-risk population. Had interviewers thought to ask, net occupants might also have mentioned that they enter and exit their nets more than once per night, but it is unlikely that they could have reported very precisely the number of entries and exits, the amount of time the net was lifted, or the amount of time different occupants spend outside the net. Observation made it possible to quantify this phenomenon much more systematically. 43

After validating the method, Gittelsohn used structured mealtime observations to estimate differences in caloric and micronutrient intake between men, women, and children in lowland south-central Nepal. 64–66 It is unlikely that parents would have been able to provide such detailed information about intra-household food allocation. Bentley et al. used structured observation during formative research to document child feeding practices prior to a nutritional intervention to improve infant growth and development in Andhra Pradesh, India. 10 Brummell used observation to discover tacit knowledge related to the prognosis of patients suffering cardiac arrest and whether to attempt resuscitation in 2 UK hospital emergency departments.<sup>67</sup> Huot and Laliberte Rudman, who used participant observation to learn about the daily routines of refugees in Canada, explain why observation can be so important for understanding habitual phenomena<sup>68</sup>:

The tacit nature of daily occupation can make the details involved in participation difficult to verbalize because respondents may not have reflected upon their occupational engagement in such detail, or

People who perform habitual activities often have difficulty articulating the step-by-step process and even come to think of that process as self-evident. may assume that such "minutia" may not be relevant for research.

This statement could be extended to many areas of health at individual, household, community, and facility levels. Often observation, used together with more common methods like interviews or focus groups, is the only way to make such tacit knowledge explicit.

## Triangulating Observation Data With Data From Other Methods

In both the case studies described here and many of the examples cited, researchers used observation together with other methods to achieve a more complete picture of a setting, practice, or intervention. Using observation to triangulate information gathered from interviews or focus group discussions can bring to light differences between what people say they do (reported behavior) and what people actually do (observed behavior). In some cases, this may reveal social desirability bias: People over- or underreport a particular behavior because it violates what they perceive to be social norms. Hygiene studies, for instance, have often found that people over-report handwashing at critical times; observation shows much lower levels. 69,70

There is no Peruvian data on reported ITN use that we can compare to the case study #2 observation. But there is at least a plausible basis for comparison in Ghana: Nighttime observation of net use in Northern and Upper West Regions found that only 17% of the population used a net at any time during the night. 71 In a malaria indicator survey of the same 2 districts, 51% and 54% of the population reported sleeping under a net.<sup>72</sup> The numbers are not directly comparable for many reasons, so these differences should be interpreted with caution. The observation study is based on a small purposive sample, the survey on a population-based representative sample; the data were collected in different years and at different times of year. But the wide gap suggests a considerable difference between reported and actual net use. Also, for the observation sample, we know when each individual entered and exited his or her net and how long individuals spent protected versus unprotected. All we know from the survey is that the individual reported sleeping under the net at some point during the night—we have no idea for how long.

Triangulation may also reveal that a word, phrase, or concept means something different to participants than to the researcher. The possibility,

in the *Campylobacter* study, that participants who reported keeping their birds in the corral "all the time," really meant "all the time except for certain specific seemingly obvious times" is one example. Had we employed only interviews in that study, we would likely have concluded—incorrectly—that birds were never loose. Had we employed only observation, we would likely have concluded that birds were loose 20% of the time—more accurate, but not the whole story. Only the *combination* revealed the differences in meaning and their conflicting unspoken assumptions.

#### **Observation and Reactivity**

A key objection to observation is that it leads to reactivity: Those under observation may change their behavior because they know they are being observed. However, this problem is not unique to observation: People also change their behavior when they are being studied in other ways. Survey and interview respondents may answer questions based on what they think society (social desirability bias) or the interviewer (courtesy bias) expect of them. Observer expectancy effect refers to how an observer can shape behavior—deliberately or subconsciously—by providing subtle nonverbal cues such as slight changes in facial expression. The Hawthorne effect was named for a study in which factory workers from both intervention and control groups became more productive because they knew that researchers were testing possible interventions (such as better lighting) to improve productivity. More detailed definitions are beyond the scope of this article but can be found in many social science references. 73-76

In one example of reactivity, P.V. Ram and colleagues found evidence of a 35% increase in handwashing when an observer was present compared with when there was no observer and handwashing was detected by a motion sensor hidden within a bar of soap.7<sup>77</sup> But while reactivity often does occur, researchers can measure and adjust for it. 17 Reactivity also diminishes with time: The longer amount of time or the greater number of times people are observed, the less likely they are to react to an observer's presence. Ram's study concluded that their findings "call into question the validity of structured observation details because it appears that a majority of participating caregivers substantially altered their behavior in the presence of an observer." But the study included only 1 observation per household. Had Ram's team observed each household multiple

Using observation to triangulate information from interviews or focus group discussions can bring to light differences between what people say they do and what they actually do.

times and waited until household members became accustomed to the observer's presence, their results might have been different.

Ram and her colleagues have a point that in some cases a less invasive technological method might be preferable to observation. For example, studies exploring household use of cleaner cookstoves to reduce indoor air pollution often use temperature sensors (called stove use monitors or SUMs) to track which stove is being used when and for how long. 81,82 At least one recent study reports that combining observation and SUMs data provides a more accurate picture than SUMs data alone. 83

Moreover, reactivity is often unrelated to the focus behavior. In the bed net study, we identified 339 instances of reactivity across 60 observations using the broadest possible definition: any interaction whatsoever between the observer and any member of the observed household. Of these 339 instances, only 2 were directly related to the behavior of interest: protecting against mosquito bites. <sup>17</sup> In a similar way, John Schnelle and colleagues found that observations did not change provider treatment of nursing home residents in the United Kingdom. <sup>84</sup>

Another way to control reactivity is through unannounced spot checks similar to those we used in case study #1. Nazmul Chaudhury and colleagues used this method to chronicle the degree of health worker and teacher absenteeism in health facilities and primary schools in Bangladesh, Ecuador, India, Indonesia, Peru, and Uganda. In his classic article about nighttime observations among the Samukundi Abelam, Richard Scaglion describes how he used spot checks to document time allocation within this Papua New Guinea ethnic group. Scaglion admits, however, that he was not always able to maintain the element of spontaneity that spot check observations are meant to provide:

... it is not easy for an anthropologist in the field to come upon an Abelam unawares. Since I did not want to record "greeting anthropologist" as a frequent activity when people were first observed, I often had to reconstruct what they were doing immediately before I arrived.

#### CONCLUSION

In sum, observation can be an essential tool in formative research. As a stand-alone method, it can measure phenomena not measurable by any other method. In combination with interviews or focus groups, it can suggest questions to be posed through these other methods. It can also triangulate findings from other methods, reveal potential differences between reported and observed behavior, and thus help assess social desirability bias. Given these benefits, observation—either alone or in combination with other methods—is something both investigators and program managers should consider when undertaking formative research.

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#### **ORIGINAL ARTICLE**

# Engaging Men in Family Planning: Perspectives From Married Men in Lomé, Togo

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Men in the study generally supported couples' use of contraception, especially citing socioeconomic reasons. Some had reservations stemming from perceptions that family planning could facilitate infidelity and promiscuity. They also thought family planning decisions should be made jointly. All men expressed interest in learning more about family planning, preferring dissemination from community health workers, trusted men, and current family planning users.

Résumé en français à la fin de l'article.

#### ABSTRACT

Family planning programs have made vast progress in many regions of sub-Saharan Africa in the last decade, but francophone West Africa is still lagging behind. More emphasis on male engagement might result in better outcomes, especially in countries with strong patriarchal societies. Few studies in francophone West Africa have examined attitudes of male involvement in family planning from the perspective of men themselves, yet this evidence is necessary for development of successful family planning projects that include men. This qualitative study, conducted in 2016, explored attitudes of 72 married men ages 18-54 through 6 focus groups in the capital of Togo, Lomé. Participants included professional workers as well as skilled and unskilled workers. Results indicate that men have specific views on family planning based on their knowledge and understanding of how and why women might use contraception. While some men did have reservations, both founded and not, there was an overwhelmingly positive response to discussing family planning and being engaged with related decisions and services. Four key findings from the analyses of focus group responses were: (1) socioeconomic motivations drive men's interest in family planning; (2) men strongly disapprove of unilateral decisions by women to use family planning; (3) misconceptions surrounding modern methods can hinder support for family planning; and (4) limited method choice for men, insufficient venues to receive services, and few messages that target men create barriers for male engagement in family planning. Future attempts to engage men in family planning programs should pay specific attention to men's concerns, misconceptions, and their roles in family decision making. Interventions should educate men on the socioeconomic and health benefits of family planning while explaining the possible side effects and dispelling myths. To help build trust and facilitate open communication, family planning programs that encourage counseling of husbands and wives in their homes by community health workers, trusted men, or couples who have successfully used or are currently using family planning to achieve their desired family size will be important.

#### INTRODUCTION

**D**uring the last decade, family planning activities have resulted in increased voluntary uptake of family planning in many regions of sub-Saharan Africa,

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yet high fertility and low contraceptive prevalence persist in francophone West Africa. Recognizing this lag, representatives from francophone West African countries gathered in Ouagadougou, Burkina Faso, in February 2011 to discuss initiatives that address population growth, climate, and family planning. Participating countries, which included Benin, Burkina Faso, Côte d'Ivoire, Guinea, Mali, Mauritania, Niger, Senegal, and Togo, formed the Ouagadougou Partnership, with a call to action through the Ouagadougou Declaration to strengthen family planning services, mobilize political commitment and resources, and coordinate actions. The Ouagadougou Partnership paved the way forward

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in francophone Africa at the same time that Family Planning 2020 (FP2020) was gaining momentum. Member countries of the Ouagadougou Partnership agreed to reach at least 1 million additional women in the region with voluntary family planning services by 2015. All member countries also worked with FP2020 to develop Costed Implementation Plans (CIP), which are multiyear roadmaps to help governments achieve their family planning goals by prioritizing interventions, engaging stakeholders around one strategy, forecasting costs, and mobilizing resources to meet any gaps.

Given the success of the Ouagadougou Partnership in reaching its target of an additional 1 million contraceptive users by 2015, ministers of health from the member countries reconvened to develop an accelerated plan for 2016-2020, which included a new target of reaching an additional 2.2 million women with voluntary contraceptive services. The member countries also agreed to review and revise their action plans, taking into account scientific evidence and promising innovations. There is a general acknowledgment that these revisions posed both opportunities and challenges, given limited availability of research and evidence on family planning programs in francophone West Africa.<sup>6</sup> That said, given the primary role of men in decision making in francophone West Africa, engagement of men in family planning should be a critical component of the revised action plans.

Male engagement should be a critical component of francophone West African countries' family planning programs.

#### **Togolese Context**

The latest Togo Demographic and Health Survey (DHS), conducted in 2013-14, reported a total fertility rate (TFR) of 4.8.7 FP2020, in its 2016-17 annual report, measured low modern contraceptive prevalence among all women at 23.2% and high unmet need among married women at 34.6%.8 Meanwhile, in the 2013-14 DHS, 57% of women reported their husband was the main decision maker for their own health care, whereas 82% of men reported they solely made decisions surrounding their own health care. At the same time, 52% and 71% of women and men, respectively, reported that men make most decisions surrounding major household purchases. Ninetyfive percent of men reported having final say in making both types of decisions.

As part of repositioning family planning between 2012 and 2015, Togo improved access to family planning services by implementing a number of activities, including free family planning

services through mobile strategies and special days, community-based distribution of contraceptives including injectables with the support of NGOs and associations, and authorization for setting up mobile clinics through NGOs and associations. The Government of Togo also committed to the following targets after the Family Planning Summit in July 2017 in London 10:

- 1. Develop a new plan to accelerate family planning access in Togo with the aim of increasing modern contraceptive prevalence among women in union from 23% in 2017 to 35.5% in 2022
- Quadruple the annual state subsidy for the purchase of contraceptive products between 2016 and 2022
- 3. Ensure the implementation of comprehensive sex education for adolescents and young people in all schools by 2022
- 4. Improve the supply chain of family planning products by reducing stock-outs of contraceptives at service delivery points by 50% between 2017 and 2022

While these commitments and ongoing efforts are important and necessary, the role of men is not fully addressed. The engagement of married men in family planning will be critical to achieving the ambitious national goals, particularly in light of the decision-making power yielded by men in Togo combined with their historically low engagement in family planning.<sup>9</sup>

#### **Male Engagement in Family Planning**

Because women are the ones who face the risks associated with pregnancy and childbirth, they are often the focus of family planning programs. Furthermore, most contraceptive methods are female-controlled, giving women better control over their fertility. Programs presume that women have greater motivation than men to use family planning services, and they usually interact more with health care services in general than men. Yet this targeted programming often overlooks the gender-related power dynamics that position men at the head of the household with decision-making power, including whether and when sex occurs and if contraception is used. <sup>11</sup>

There are several proven, promising, and emerging strategies to engage men as contraceptive users. Male motivators, social marketing, and mHealth have been identified as proven strategies, whereas comprehensive sexual education,

community dialogue, and clinic provision of information are designated as promising strategies. 12 The Ministry of Health in Togo has reported achievements with their Committees of Men project, 9 which was inspired by the Husband Schools project in Niger<sup>13</sup> where men are engaged to promote reproductive health and behavioral change in their communities. In fact, the ministry planned to scale up this project between 2013 and 2017.9 The success of this project was likely highlighted by participants in another recent study assessing how to best engage men in Togo who mentioned that exchanges with "Papa Champions," men who are already strongly engaged in the health of their families and recognized in the community, was a strategy for improving male involvement in family planning. 14

In the realm of male motivators, positive deviance has also emerged as a preferable approach to increase awareness of family planning among men, including in another study from Togo. 14 This is a bottom-up approach that focuses on the individuals in every community who behave differently—their uncommon (positive) practices, such as using contraception consistently or communicating with his spouse about family planning-enable success in areas where their neighbors fail. The approach seeks out these "positive deviants" in the community and uses their existing solutions to bring about sustainable behavioral and social change. 15 While the positive deviance approach has had limited application in family planning programs to date, it is feasible and logical in the context of using community-based approaches to increase awareness and use of modern methods, particularly among men with unfounded concerns.

Engaging religious leaders, which is considered an emerging strategy, has had success in francophone West Africa. In 2013, the Senegal Ministry of Health and Social Action launched the first-ever national family planning communication campaign addressing men as a primary target audience. Muslim religious leaders were included among the messengers and influencers represented in the campaign. After the campaign, a survey was conducted with 1,800 men responding. The findings showed that more than 68% initiated a discussion with their partner about family planning and more than 12% reported that their partner now practices family planning as a result of the campaign. 16 This case is not unique, as across the region, religious leaders are emerging as champions and speaking in favor of family planning to ensure the healthy timing and spacing of pregnancies. In fact, Togo, in its 2013-2017 plan to reposition family planning, committed to training religious leaders on the advantages of family planning,9 enabling them to deliver sermons on family planning and also establishing a cadre of family planning champions who could train their peers of other religious leaders.

Though the examples above provide evidence of promising interventions, there is a continued need for evidence on how to engage men in family planning in francophone West Africa. Failure to involve men in family planning can have important implications, even when women are educated and motivated to use contraception. 17 It is also well documented that men's general knowledge and attitudes related to family size, spacing between children, and contraceptive methods affect women's family planning preferences and opinions. 18-20 DHS data from 7 African countries, including Togo, revealed that the percentage of women who used modern contraceptives was higher among those who had discussed family planning with their spouses than among those who did not.<sup>21</sup> A 1996 study in Togo found the likelihood of spousal communication about family planning and modern contraceptive use was significantly higher among women who exercised complete control over the selection of their partner than among those with arranged marriages. Additionally, women who worked for cash were significantly more likely than those who did not to communicate with their spouses about family planning, particularly if they participated in rotating credit or savings schemes. Such participation also significantly increased the likelihood of ever using traditional or modern methods of contraception.<sup>22</sup>

Many scholars have argued that the inability to engage men in family planning is impeding progress to increase uptake of contraception. 19,23-26 The role of men in family planning has been seen as crucial for optimizing family planning services. A review of existing studies of male involvement in family planning in sub-Saharan Africa found that among the reasons for poor male involvement in family planning were cultural barriers, such as embarrassment with visiting family planning service delivery points.<sup>20</sup> The review also found that poor male involvement in family planning was associated with poor communication between men and their female partner, although a majority of men disagree that they should be the sole family planning decision makers. Finally, it was found that definitions of male involvement francophone West in family planning have varied, making it difficult **Africa**.

There is continued need for evidence on how to engage men in family planning in

to compare the results and efficacy of the few interventions that have been implemented.<sup>20</sup> These challenges point to the need for further evidence generation on male engagement in family planning. Few studies have been carried out to understand the barriers to male involvement in family planning from the male perspective in francophone West Africa. This is in spite of policy trends in the region, which encourage men to take more responsibility for family planning and parenting.

#### Purpose of the Study

The purpose of this study was to gain insights on how to best engage men in future family planning programs in Lomé, Togo. Through male perspectives, we assessed their experiences, perceptions, and preferences, specifically with regard to spousal use of contraception, family planning discussions, and how men would like to receive family planning information and services. Results from this study might have implications for a broader audience in urban and peri-urban Togo, as well as for similar settings in francophone West Africa.

#### DATA AND METHODS

#### **Study Design**

A qualitative study was conducted in 2016 using focus group discussions with men ages 18-54 in urban and peri-urban areas of Lomé, Togo. Data used in this study were collected as part of operations research conducted in Lomé to assess the effectiveness of an ongoing family planning service delivery model of the Agir pour la Planification Familiale (AgirPF) program of the U.S. Agency for International Development (USAID)/West Africa and EngenderHealth.<sup>27</sup> The goal of AgirPF is to enable women of reproductive age to make, and voluntarily act on, informed decisions about family planning, saving women's lives in selected urban and peri-urban areas of 5 francophone West African countries: Burkina Faso, Côte d'Ivoire, Mauritania, Niger, and Togo. AgirPF incorporates many high-impact practices in its technical approach, 28 including a range of program activities from addressing quality of clinic services and provider training to the availability of mobile services and community-based distribution.<sup>27</sup> More specifically, to bring family planning services to underserved communities, AgirPF supports mobile outreach services, brings health fairs to industries and community sites, offers "citybased services," an adaptation of EngenderHealthmanaged community-based distribution in Togo, and supports community leaders with family planning advocacy activities.<sup>27</sup>

#### **Participant Selection**

Men who were married or cohabiting and residing in AgirPF program catchment areas were eligible to participate. Advertising and recruitment were carried out by local development organizations and NGOs working with the AgirPF program. Participants were recruited from 3 health districts (District II, District III, and District V) and Maritime Health District (Golfe). Site selection for the focus group discussions was based on the site selection for the larger study to assess AgirPF program. We conducted 2 focus group discussions in District III and Golfe District and 1 focus group discussion each in Districts II and V. No personal information in the form of names or other identifying data was obtained. All participants gave informed consent and the study was approved by the Republic of Togo Ministry of Health and Social Protection, Bioethics Committee for Research in Health (AVIS NO 017/2016/CBRS du 30 Juin 2016) and the University of California Berkeley Committee of Protection of Human Subjects (CPHS #2016-04-8614).

#### Data Collection

A total of 6 focus groups were conducted in August 2016. Each focus group consisted of 12 men and averaged about 1 hour and 45 minutes. Openended, semi-structured question guides were used to explore perceptions regarding preferences and barriers to male involvement in family planning. Focus group discussions were conducted in French or a combination of French and a local language, and were audio-recorded with permission from the participants. They were led by a local team (men and women) of experienced qualitative investigators. All study participants were encouraged and given opportunities to openly discuss their opinions in confidence.

#### Data Analysis

All discussions and interviews were recorded and transcribed verbatim in French and local languages and translated to English using thematic content analyses. A thematic analysis was conducted using deductive coding process. First, 2 coders reviewed the transcripts several times to identify major themes and develop a broad coding scheme based on the research questions. The

FIGURE. Three Categories of Male Focus Group Participants Based on General Views of Family Planning, Lomé, Togo, 2016



#### Believe in family planning



#### Believe in family planning with reservations



codes were refined and emerging themes discussed and confirmed with the local research team. The coding team met regularly to discuss any discrepancies in code definitions and in the application of codes, ensuring the reliability of coded data and consistent coding of transcripts.

Focus group participants were asked their occupation and age during a sign-in procedure when they provided consent to participate. The participants were also assigned a number at check-in for which they would be referred to in transcripts, rather than their names. The transcripts included a key that indicated the age and occupation associated with each participant number. This allowed the coding team to assign an age and occupation when including quotations. However, there were not enough cases to stratify the analysis based on age and occupation.

#### RESULTS

Among the 72 married men included in the focus groups, 20% were 30 years of age or younger, 53% were between ages 31 and 45, and the remaining 26% were over 45 years of age. They encompassed qualified professional workers (including a university professor, computer scientist, and journalist) and skilled and unskilled workers (including a driver, mason, and hairdresser). Major themes that emerged from the data were related to explanations for positive or negative views of family planning; views on spousal communication about family planning; interest in learning about family planning; views of current family planning services; and the

role of male-controlled contraceptive methods including perceived barriers to male involvement in family planning.

#### **General Views on Family Planning**

There were 3 groups of men in the sample based on their perceptions about family planning: (1) those who believed in family planning; (2) those who believed in family planning but had reservations about it; and (3) those who did not believe in family planning (Figure). Focus groups were mixed vis-àvis these 3 categorizations and we specifically did We conducted not assign values related to number of men that focus group fell into each category due to the purposive nature of the sample and our desire for the categories to be 72 married men to illustrative of the range of perceptions.

The men who believed in family planning often stated socioeconomic reasons associated with raising children, including the cost of their education, and the maternal and child health benefits of birth spacing as their main reasons for supporting family planning.

Birth spacing is a good thing; this means when we bring a child into this world, the period of spacing between the second and third birth allows the mother and the child to recover to its [her] initial health. In addition, the mother is a bit free for other chores. - 48-year-old teacher

Reservations about family planning seemed to stem from men's lack of trust of women and their views that family planning could potentially facilitate infidelity, promiscuity, and/or lead to commercial sex work. As one respondent put it:

Men who believed in family planning often stated socioeconomic reasons for supporting it.

discussions with aain insiahts on how to best engage men in future family planning programs in Lomé, Togo.

... this means that there are certain women whose husbands have left the country to immigrate to the West. Because they [the women] have sexual desire, they go to a provider to benefit from a contraceptive method with the intention not to get pregnant, this way they practice prostitution. – 28-year-old merchant

Other reservations were linked to health concerns associated with specific contraceptive methods. Fear of side effects, threats to future fertility, risks to maternal and child health after contraceptive use, and misconceptions regarding the dispensing of contraceptive methods were all cited as reasons why one may avoid using family planning methods. Many men in this group believed that laboratory tests, including various blood tests, must be carried out before a contraceptive method is prescribed. There was a general perception that without specific tests, women will get the wrong method, which might end up affecting their health and their future children's health. This concern was best explained by one participant:

... we notice that after the use of a method, when the method expires, women develop many health problems. When the method is removed, the same we find that the children born after the use of a method are not really in good health. – 35-year-old entrepreneur

Non-believers in family planning often suggested that periodic abstinence could be practiced to avoid unintended pregnancies. They believed that was what their ancestors practiced in the absence of modern family planning. They associated sex only with reproduction, consequently believing that if a couple is not trying to conceive they should not have sex at all. Therefore, modern family planning methods were unnecessary, these men expressed.

... our parents did not use any product. The understanding among couples is to practice birth spacing. If, as a man, there is no consent between the woman, and the man lays with the woman because of desire, that will only bring unintended pregnancies. Our grandparents themselves used this consent as the reason why they did not have unintended children. — 37-year-old merchant

Most men had positive views of couples who used contraception to space or limit pregnancies.

Views Related to Use of Contraception

Independent of the categorization of participants mentioned above, the majority of men participating in the focus group discussions responded positively when asked about their views on couples who used contraceptive methods to space or limit pregnancies, noting it was the "good" and

"responsible" thing to do. Though men were asked specifically about using contraceptive methods, they often responded with more general perspectives surrounding family planning. Common themes that arose during these discussions were that by practicing family planning, couples could make better use of limited resources and improve overall family wealth. Participants often cited that spacing and limiting births resulted in happier, healthier families and better relationships within the family. Other less prevalent benefits mentioned were maternal health and child wellbeing. More specifically, some men noted that birth spacing gives women appropriate time to recover between children. They also mentioned that birth spacing gives parents more opportunity to focus on their child and results in better prospects for education.

A planned family is a happy family since we do not see them go into debt, running back and forth looking for a way out. They are free and always go about their activities. It is a model family. – 40-year-old psychosocial counselor

Let me say that couples who use contraceptive methods are healthy even if they do not have money. Their children grow well and they are content with the few resources they have. — 30-year-old mobile phone repairman

However, not all responses were positive. Some men mentioned concerns with side effects of contraceptive methods and occasionally repeated a common misconception about long-term negative health impacts of contraception.

[referring to perceived side effects of implant, earlier noting infertility and early menopause.]... expenditures for its treatment in the hospital and the treatment of other long-term side effects may exceed the costs related to the care of 10 children. Those couples, who today are victims due to contraceptive methods, will suffer more in the long term from other diseases. — 42-year-old teacher

## Views on Spousal Communication About Family Planning

While men largely spoke favorably about couples' use of contraception, the majority had negative, and often animated, responses when asked about a woman who uses contraception without the knowledge or authorization of her spouse. Many men noted that a woman does not have the right to make this decision alone and it would be

Many men noted that a woman does not have the right to make the decision to use family planning on her own and that it would be grounds for divorce. grounds for divorce, explaining their suspicion of infidelity when a woman is using a family planning method secretly. In addition, some men had the perception that a law exists that prevents providers from distributing contraceptives to women without spousal consent.

There are many risks. Women who individually take the initiative to go for family planning methods without the knowledge of their partners are exposed to risks such as divorce, for example. Why not seek the advice of their husbands before going? The issue of procreation is decided by both partners. A woman has the right to do whatever she wants with her body; however, from the moment she gets married, the issue of having children or not, spacing births or not, should be consensually decided with the husband. - 35-year-old PhD student

Such things always lead to divorce in households in our community here. It is the man who is the head of the family. The law does not normally authorize the service provider to administer a method to a woman without consent of her husband. - 48-year-old teacher

Despite a general sentiment supporting spousal consent for a woman's contraceptive use, some men did mention cases whereby such behavior would be justified by women. During the focus groups, men discussed understanding a woman's motivation for using contraception without the knowledge of her husband. A small number of participants felt it was appropriate if the woman had a psychological or medical reason or was responsible for all the household expenses.

In reality, my wife had the implant without my knowledge and I only found out after two years. Indeed I was traveling, and after a sensitization session in the neighborhood, she opted for the implant. And when I discovered this, I was really angry with her before calming myself down. [But] after investigations [it was] revealed there was not hidden motive [in my wife's decision to use *the implant*]. – 30-year-old printer

Yes, I don't blame the woman who used contraception without the knowledge of her husband. There is always a beginning [reason] for everything. We should try to understand whether the woman has enough children and doesn't want more. - 37-year-old communicator

While less prominent, the theme of infidelity as a reason for covert contraceptive use also came up in discussions. A few men proposed that a woman covertly using contraception suggested promiscuity. Several men agreed that a women's covert use of contraception justified infidelity on the part of the man who is seeking more children.

I have personally been a victim of this situation. As I insisted on making another child, I began to have another partner and my wife finally left the marital home. - 28-year-old trader

Several men also stated that it was the provider's fault in cases where women were using contraception without the knowledge of their husbands.

First of all, the error comes from the provider because this must be included in the information or sensitization [about contraception]; since there must be consensus between the man and the woman before the woman uses contraception. The provider should be sure of the husband's agreement before offering this service to the woman. – 30-year-old barber

It was clear that the participants' general opin- Men generally ion was that family planning should be a decision thought family made by a husband and wife. When asked how they felt about men who discuss family planning with their wives, most participants spoke positively of these men referring to them as "wise," "thoughtful," and "responsible."

He is a responsible man and a model for society because not all men will like to discuss such issues with their wives. - 37-year-old communicator

They felt that having such discussions demonstrates strong and open relationships, whereas an inability to discuss family planning signals greater marital discord.

The fact that the man discusses the issue with the wife is an indication of the good dialogue and communication which already exists between them. - 29-year-old sociologist

I think the couple is really solid. Sitting and making decisions together will make them strong and help them address many issues in the family. - 34-year-old teacher

Moreover, the responses were overwhelmingly positive when participants were asked about discussing family planning with other people outside of the marriage. Most men suggested that such conversations occur when they are already discussing problems with friends and family, because these conversations provide an opportunity to give advice or elaborate on personal experience, which can include family planning. Some men mentioned bringing up birth spacing when

planning decisions should be made jointly by a husband and wife.

having a discussion with someone who mentions their financial woes.

If I am well informed about family planning and I practice it and it suits me, I can talk to my friend and suggest that he tries it too. In doing so, I train him and indirectly train society. – 49-year-old printer

However, some participants remarked they would need training to feel comfortable discussing family planning, while others felt these discussions should be initiated by health care providers or peer educators who have been trained and have comprehensive, accurate information about family planning.

Only those who have been trained can have relevant information about family planning since they are familiar with all the issues relating to it. - 38-year-old evangelist

Men expressed a desire to talk with couples who had successfully used or were currently using family planning.

All the men wanted to learn more about family planning.

All of the men were opposed to vasectomy, mostly because it was irreversible.

#### Interest in Learning About Family Planning

Regardless of their initial views on family planning, all men participating in the focus groups said they wanted to learn more about it. When probed on how, when, and where they would prefer to learn more about family planning, their suggestions spanned from identifying who should be providing information, venues for sharing information, and different channels through which information could be shared.

The majority of participants mentioned that the best way to share information would be door to door. Trained community health workers were considered a reliable source of initial information that would be disseminated by word of mouth in communities. Many venues were cited as important points where information could be disseminated including community gatherings, markets, clubs, popular community celebrations, the work place, and other media outlets. Men emphasized the importance of the credibility of those providing the information and accuracy of information. An organization considered credible for informing men on family planning issues was the Togolese Association for Family Wellbeing (ATBEF), an International Planned Parenthood Federation affiliate, as well as AgirPF. Although less frequently, participants also mentioned village development committees as avenues to spread information and football matches as a potential venue where information on family planning could be shared. Some men questioned the value and effectiveness of using health facilities as a means to inform men about family planning. Many reasons were cited including that many men do not go to the health facility; facilities are usually busy with providing care to sick patients; information is provided in sessions designed for women at facilities; and most providers are female, which may inhibit men's ability to comfortably ask questions and/or have an open discussion on contraceptive methods.

Focus group participants said they would like family planning messages to emphasize contraceptive side effects and the importance of smaller families for the health and well-being of the family. Overall, participants seemed to appreciate learning about family planning through sketches or cartoons, including those that resemble comic books. More importantly, they expressed a desire to talk with couples who had successfully used or were currently using family planning to achieve their desired family size—that is, positive deviant case studies—as well as those who did not use family planning resulting in a higher-thandesired family size.

For me, I prefer to go with my wife to couples whose family planning practices have succeeded because I do not know if the provider himself has already used a family planning method, so I prefer to contact someone who has already practiced it. – 38-year-old evangelist

#### **Views on Current Family Planning Services** and the Role of Existing Male-Controlled **Methods**

Men discussed their views on current family planning services, including information campaigns, in part to justify their limited engagement in family planning thus far. Limited availability and understanding of male-controlled methods, as well as the way they perceived the family planning campaign in Lomé, were all critical themes to the conversation. Male condoms, vasectomy, and abstinence were identified by all focus group participants as male-controlled methods. Only one focus group also identified withdrawal as a malecontrolled method. Male condoms were discussed as an important method but also "not for all"; some men remarked that women did not like condoms, while others did support their use. All participants were opposed to vasectomy, with the most notable reason for opposition being its irreversibility. Some believed that male performance would be negatively impacted.

... I will say that this male method [vasectomy] is not good at all because we can no longer father a child. However, the ones [contraceptives] for women allow her to have a child when she wants. I cannot use this method of contraception, it will prevent me from having children. That is why I can never opt for this method. – 30-year-old mobile phone repairman

Abstinence was positively mentioned by all participants (irrespective of their views on family planning) and associated with encouraging good spousal communication. However, their appreciation of abstinence as a method seemed to be more in theory than practice, as many men also mentioned the difficulty in using this method to prevent pregnancies. Withdrawal, a method less frequently mentioned, was deemed "too difficult to apply." Overall, men felt that male methods were too limited. Of the current 4 choices available to men, vasectomy was not considered a possibility; abstinence and withdrawal were too difficult to apply consistently and accurately; and male condoms had limited use, given lack of preference for this method in the community.

The fact that there are fewer contraceptive methods for men was mentioned by participants as part of the explanation for poor male engagement in family planning. Men thought that development of other male-controlled methods could encourage their involvement in family planning. Thus, if there was a disagreement between a husband and wife and the method was controlled by men, men would be in a better position to convince their disagreeing spouse. As one participant put it:

... men can convince their wives to accept a method better than wives can convince their husbands.

All men also had very strong opinions on current family planning services, including how the Togolese family planning campaign is run. The majority of participants believed that the campaign was not really for, nor did it target, men. They felt that although men are often the primary decision makers about family size and health services, family planning services and campaigns almost exclusively target women. They thought the family planning campaign had no specific information for men; awareness and education was mostly provided during antenatal care, which men do not attend; and the overall communication strategies employed were not directed at men. Some men cited existing work in their communities with community health workers but felt it was also largely directed at women.

#### DISCUSSION

There is strong evidence to suggest that involving men in sexual and reproductive health programs can improve spousal communication, genderequitable attitudes, and family planning use.<sup>29–32</sup> Previous studies have also found that spousal communication is useful to foster contraceptive practice among couples.33,34 Given the significance of the man's role in deciding family size in sub-Saharan Africa, especially in francophone West Africa, there is a dearth of studies examining male engagement in family planning. Meanwhile, Ouagadougou Partnership member countries have aimed to reach 2.2 million additional modern contraceptive users by 2020, as well as revised action plans that incorporate scientific evidence from the region. Consequently, the findings from this study provide important insights into how men view family planning and how programs can further involve them in family planning efforts. Analyses highlighted 4 keys findings:

- 1. Socioeconomic motivations drive men's interest in family planning.
- 2. Men strongly disapprove of unilateral decision by women to use family planning.
- 3. Misconceptions surrounding modern methods can hinder support for family planning.
- 4. Limited method choice for men, insufficient venues to receive services, and few messages that target men all create barriers for male engagement in family planning.

Additionally, participants' views on family planning provide insights on how to tailor future family planning programs and campaigns to engage men. For example, the reasons cited by men who "believed in family planning" were consistent with the child's quantity-quality theory. This model assumes that parents' psychological satisfaction from their children is likely dependent on the investment parents make in the quality of children, in terms of their lifetime well-being, the quality of education received, and the quality of future job prospects. Therefore, belief in family planning is proportional to level of awareness of the high cost of raising quality children and the effect of the number of children on the quality of those children.

Men who had reservations about family planning comprised a segment of the population that is likely the most uninformed about modern methods, including side effects and implications for future fertility. From a programmatic perspective, focusing behavior change communication activities on this segment of the population would likely be extremely beneficial. The finding that all men wanted to be better informed about all methods is very encouraging. Interventions should

possible side effects and dispelling the myths around long-term negative health effects to the mother and child associated with use of modern contraceptive methods. More awareness on the value of contraceptive methods for both spacing and limiting would also be important.

The findings from the focus group discussions not only highlighted the family planning informa-

educate men on the socioeconomic and health

benefits of family planning while explaining the

The findings from the focus group discussions not only highlighted the family planning information that should be included in messaging and campaigns but also the best channels for delivering family planning information. Door-to-door dissemination of information was preferred, particularly with incorporation of "positive deviants," a communication method that was also identified in another Togo study. <sup>14</sup> Using positive deviance as an approach could be particularly beneficial to addressing misconceptions about infidelity and contraception that arose during the focus group discussions.

On the other hand, it is not clear from the analysis of the focus group discussions whether there is an opportunity to influence the men considered nonbelievers in family planning, as this group included men with fundamental differences of opinion specifically related to sex, sexuality, and sexual desire, and they refuted the need for modern methods to exercise control over sexual desire. Among some men's perspectives, sex is intended for procreation only. This group of men could potentially be reached by religious leaders, male motivators, or trained male peers, a strategy that has had some success in francophone West Africa. 9,16,37

In addition to the importance of reaching men with information, the focus group findings highlighted the need to engage men as family planning clients, not just as the partners of women. A recent review of programming showed that men are not well served by current family planning programs, but when male-controlled methods were made available through interventions, uptake typically increased.<sup>37</sup> The review also highlighted the need for more male-controlled methods. Focus group participants in this study found current methods, namely, male condoms and vasectomy, to be unsatisfactory, which is consistent with previous studies. 34,38 Although using condoms is an effective means of birth control and protects against sexually transmitted infections, some couples claim that condoms create a barrier, which reduces pleasure during sexual intercourse.<sup>38</sup> Likewise, although vasectomy is effective for birth control, its irreversibility constituted a principal barrier for men in this study.

Participants also linked the limited choices of effective and acceptable methods for men to the low level of male engagement in family planning. In addition, their opinion of the current national family planning campaign was negative and perceived as exclusive of men. From a gender norms perspective, this finding could be interpreted in two ways. Men might want to have more control over fertility regulation and having more malecontrolled methods could be a way to achieve this control. Alternatively, they might simply feel excluded, given their perception that the family planning campaign is currently only targeting women in Togo, but also feel that if more male methods were available, the nature of the campaign would also focus on men. These findings were similar to the results from a rapid formative assessment of male engagement in family planning conducted in Togo as part of ongoing efforts around expanding no-scalpel vasectomy services. 14 Themes from that assessment included the perceptions that family planning is only for women, there is a lack of methods available for men, services are not meeting men "where they are" (i.e., not at hours or locations convenient to men's schedules), there is a perceived lack of male providers offering family planning services for men, there is lack of communication about family planning among couples in the community, and social norms do not support use of family planning.14

It is important to note that program planners and policy makers must be sensitive to the former case where men's negative perception of family planning programs derives from a desire to be more in control of fertility. Engaging men in family planning requires addressing the norms that leave them thinking they are—and should be—in control. For example, as in the case of some of the responses during the focus group discussions, approval of leaving your wife or taking on another partner if she uses contraception is a sign of control. It is critical that male engagement in family planning should not come at the expense of women's agency for decision making.

Findings from this study, as well as other studies looking at male involvement in family planning, confirm the need for increased efforts to directly engage men in family planning discussions, campaigns, and services. It is clear that family planning interventions that target men provide an opportunity to improve progress in reaching goals surrounding contraception and fertility, particularly in countries where men retain decision-making power.

Men preferred door-to-door dissemination of information about family planning.

#### Limitations

This study was not representative of Togo and focused on peri-urban and urban neighborhoods of Lomé, a capital city where family planning services are relatively available to women. There are also general limitations to qualitative research methods related to validity, reliability, and subjectivity.<sup>39</sup> Translation of transcripts to English, a language common to the entire research team, may have resulted in details lost in translation; validity of the data may have been compromised in this process. Nonetheless, focus group discussions allowed us to better capture details and understand the nuances of engaging men in family planning in Togo, which might have been missed with more rigorous forms of quantitative data collection.

#### CONCLUSION

Improving family planning programming to better involve men is imperative to increasing voluntary uptake of family planning among couples. This is particularly important in francophone West Africa, where men's influential role in family decision making is coupled with accelerated national goals of reaching new modern contraceptive users with services by 2020. Meeting these targets will not be possible without engaging men. Our theory of change for male engagement in family planning is based on the premise that involving men will lead to higher contraceptive use and better gender equality, as men are not only partners of contraceptive users but also family planning clients themselves and agents of change. However, many programs exclude men, thus failing to address their need for joint decision making in family planning choices.

Existing literature shows that there are many challenges to increasing male involvement in family planning. 20 Attempts to address these challenges need to start by listening to men's concerns, misconceptions, and their views of their roles in family planning decision making, which this study provides insights on. To help build trust and facilitate open communication, family planning programs that encourage counseling of husbands and wives in their homes by community health workers, trusted men, or couples that have successfully used or are currently using family planning to achieve their desired family size will be important. Family planning campaigns should be tailored to also encompass men and be accompanied by increased availability of male methods to the extent possible. The integration of gender

equity in family planning in Togo needs to be done, but in a careful manner. Finally, future studies should qualitatively explore the practices, characteristics, perceptions, and motivation that help men successfully engage in family planning, and then incorporate the findings in family planning programs and campaigns.

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#### En français

#### Engagement des hommes dans la planification familiale : « Perspectives des hommes mariés dans la ville de Lomé, Togo »

Les hommes participants à l'étude étaient en général favorable à l'utilisation de la contraception moderne dans le couple, en particulier pour des raisons socioéconomiques. Cependant, certains hommes ont manifesté des réserves, dues essentiellement à la perception que la planification familiale pourrait faciliter l'infidélité et la promiscuité. Ces mêmes hommes ont indiqué leur préférence pour que la décision en matière de planification familiale soit prise de commun accord entre les partenaires. Tous les hommes ayant participé à l'étude ont exprimé le désir d'apprendre davantage sur la planification

familiale, avec une préférence pour les activités de sensibilisation menées par les agents de santé communautaires, d'autres hommes de confiance ainsi que par des utilisateurs actuels de la planification familiale.

#### RÉSUMÉ

Les programmes de planification familiale ont fait de grands progrès dans de nombreuses régions d'Afrique subsaharienne au cours de la dernière décennie, même si l'Afrique de l'Ouest francophone reste encore « à la traîne ». L'accent mis sur l'engagement des hommes pourrait aboutir à de meilleurs résultats, en particulier dans les pays structurés autour de sociétés patriarcales fortes. Peu d'études en Afrique de l'Ouest francophone ont examiné les attitudes des hommes en matière de planification familiale du point de vue des hommes eux-mêmes. Pourtant ces preuves sont nécessaires pour le développement de projets de planification familiale incluant des activités ciblant les hommes. Cette étude qualitative, menée en 2016 par USAID/WA-Evidence for Development, a exploré les attitudes de 72 hommes mariés âgés de 18 à 54 ans à travers 6 groupes de discussions dans la capitale du Togo, Lomé. Les participants à l'étude incluaient des travailleurs professionnels ainsi que d'autres travailleurs « qualifiés » et « non qualifiés ». Les résultats indiquent que les hommes ont des points de vue spécifiques sur la planification familiale ; lesquels points de vue sont basés sur eurs connaissances et de leur compréhension du « comment et du pourquoi » les femmes pourraient utiliser une méthode moderne de contraception. Alors que certains hommes ont indiqué avoir des réserves, fondées ou non, il y avait une réaction extrêmement favorable pour discuter de la planification familiale et même de participer à la prise de décisions et la mise en óuvre des services connexes. Les quatre principales conclusions des analyses des groupes de discussions ont été les suivantes : (1) les motivations socioéconomiques poussent les hommes à s'intéresser à la planification familiale ; (2) les hommes désapprouvent fortement les décisions unilatérales de leurs femmes d'adopter une méthode de planification familiale ; (3) les idées fausses entourant les méthodes modernes peuvent entraver les efforts de soutien à la planification familiale ; et (4) un choix limité de méthodes pour les hommes, l'insuffisance de sources et lieux pour recevoir des services, et peu de messages spécifiques ciblant les hommes sont autant de barrières pour leur engagement dans la planification familiale. Les futures initiatives engageant les hommes dans les programmes de planification familiale devraient accorder une attention particulière à leurs préoccupations spécifiques, aux « idées fausses » et à leurs rôles dans la prise de décision familiale. Les interventions devraient permettre aux hommes de mieux appréhender les avantages socio-économiques et sanitaires de la planification familiale tout en expliquant les effets secondaires possibles et en dissipant les mythes. Pour aider à établir la confiance et faciliter la communication ouverte dans la famille, les programmes de planification devraient encourager le counseling des maris et leurs épouses dans leur foyer par les agents de santé communautaires, les hommes de confiance ou les couples qui utilisent ou ont utilisé avec succès les services de planification familiale pour atteindre leurs objectifs en matière de famille.

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#### **ORIGINAL ARTICLE**

# Increasing Contraceptive Use Among Young Married Couples in Bihar, India: Evidence From a Decade of Implementation of the PRACHAR Project

Laura Subramanian, a Callie Simon, b Elkan E. Daniela

Critical program elements to improving voluntary contraceptive use among married youth included: (1) use of a socioecological intervention model of behavior change; (2) engaging both women and men; and (3) calibrating interventions to different moments in the life cycle of adolescents and youth. Trade-offs between intensive NGO-led models and less intensive government-led models occurred in effectiveness, scale of interventions, and sustained behavior changes.

#### ABSTRACT

**Background:** Evidence on effective behavior change programming for sexual and reproductive health among married youth aged 15–24 in developing countries is lacking. To address this gap, we examined monitoring, evaluation, and special study data from the Promoting Change in Reproductive Behavior of Adolescents (PRACHAR) Project, which was implemented between 2001 and 2012 in Bihar, India, over 3 phases using 2 different implementation models (NGO- and government-led).

**Methods:** We conducted a synthesis of evidence from multiple PRACHAR studies to identify key findings on intervention effectiveness, scalability, and sustained effects on behaviors. Data were triangulated from quantitative population-based quasi-experimental evaluations from each project phase; the project's performance monitoring database; and qualitative studies with beneficiaries.

Results: PRACHAR's original comprehensive NGO-led model, which included behavior change elements and multiple overlapping communication channels (including home visits and small-group meetings), increased contraceptive use among young married couples, and these outcomes were sustained 4–8 years after project interventions ended. Several program elements were critical to the effectiveness of PRACHAR, including use of a socioecological intervention model with emphasis on behavior change efforts; use of a gender-synchronized approach that engages both male and female partners; and intensity of interventions calibrated to different moments in the life cycle of adolescents and youth. While the hybrid government-NGO model of PRACHAR implementation reached greater scale than the original NGO-led model, comparison of results suggests trade-offs in effectiveness of interventions and sustained impacts.

Conclusions: A decade of learning from the PRACHAR Project in Bihar, India, finds that comprehensive programming with gender-synchronized interventions tailored to specific life stages and aimed at different levels of the socioecological model can effectively increase contraceptive use among married young people in a conservative context. Shifting from a more intensive NGO-led model to less intensive government implementation enhances scalability but may have diminished impact on reach and long-lasting effectiveness.

#### INTRODUCTION

In many low- and middle-income countries, early marriage followed by early and closely spaced births results in elevated risk for maternal and infant morbidity and mortality and limited opportunities for educational and economic advancement among young married

women.<sup>1–3</sup> By age 18, 28% of young women living in developing regions are married or in union, and 90% of the approximately 12 million annual adolescent births in developing regions occur in the context of marriage.<sup>4,5</sup> Early and rapid repeat pregnancies and births among young married women (under age 24) are driven by a number of factors, including gendered social norms that require women to demonstrate fertility to prove their value, young women's lack of agency to seek health care, and limited access to contraceptive information and a full range of methods.<sup>3,6,7</sup>

In response to persistently low use of contraception and high rates of early and rapid repeat childbearing

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among young married women, there is a growing call to address the drivers of low contraceptive use and to increase young married couples' access to contraception.<sup>7–9</sup> Doing so would address critical unmet need for family planning and contribute to achievement of national and global goals and priorities, such as Family Planning 2020 (FP2020) and the Sustainable Development Goals. 10,11 Some efforts have been made to increase contraceptive use among married adolescents and youth and to prevent rapid repeat pregnancies, and recent papers have synthesized the primary strategies used in these programs.<sup>7,8,12</sup> However, there remains little published evidence from low- and middle-income countries to inform critical program design decisions related to intervention intensity and duration, effective combinations of interventions, and scale up. This makes it critical to learn from the few rigorously documented and evaluated projects that have worked with married young women and their partners to address the social and behavioral constraints to contraceptive use. The Promoting Change in Reproductive Behavior of Adolescents (PRACHAR) Project, implemented in Bihar, India, has amassed a wealth of monitoring and evaluation data on its interventions with young married couples, much of which is unpublished. By synthesizing these data and implementation experiences from more than a decade of PRACHAR implementation, this article seeks to contribute to the growing body of evidence around behavior change approaches for contraceptive use by married youth.

#### PROGRAM DESCRIPTION

The PRACHAR Project was designed and led by Pathfinder International and implemented in Bihar, India, from 2001 through 2012. At the time PRACHAR began, Bihar had few programs to address the contraceptive needs of the population, including adolescents and youth. The modern contraceptive prevalence rate was low (22%) for all women of reproductive age, with almost no contraceptive use among married adolescents aged 15-19 (1%) and young women aged 20–24 (5%). 13 Bihar also had the highest prevalence of early marriage in India, with 84% of young women married by age 18. 13 To address this situation, PRACHAR aimed to delay the age at first birth by delaying the age at marriage and increasing voluntary contraceptive use among young nulliparous married women, and to space second and subsequent births by at least 3 years among young married women in Bihar.

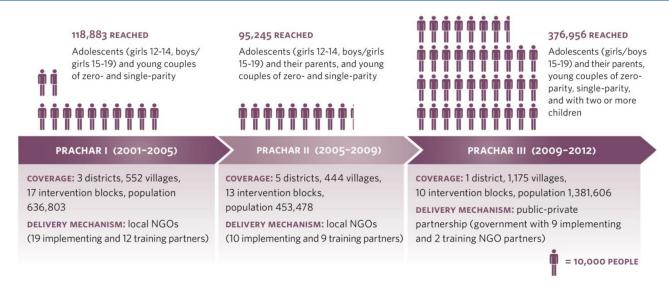
PRACHAR was designed using a life-stage tailored social and behavior change approach, based on the socioecological framework. 14 PRACHAR interventions targeted individuals (young men and women ages 12-24), their family members and other gatekeepers (husbands, fathers, mothers, and mothers-in-law), community members (religious leaders, community elders), and the health service delivery system. Young women and men in PRACHAR areas could have been exposed to PRACHAR at multiple life stages (before marriage, as newlyweds, and at different parities). For unmarried adolescents, PRACHAR conducted training on sexual and reproductive health and life skills with age-appropriate content for 12-14 and 15-19 age groups, delivered separately to males and females. For newlywed couples, PRACHAR hosted "newlywed ceremonies" that combined education and entertainment. For married young women with up to 2 children, female lay health workers (called "change agents") conducted home visits and group meetings to counsel and refer women for services at planned intervals timed with life events such as marriage, pregnancy, and newly parenting a child. Male change agents reached husbands of young women through regular small-group meetings, which included dialogue and discussion on sexual and reproductive health This article seeks and gender. Mothers-in-law were reached with home visits and small groups, and the wider community was engaged through community meetings, street theater performances, wall paintings, puppet shows, and information, education and communication (IEC) materials. Government and private-sector contraceptive services were mapped and received small enhancements (e.g., training) from PRACHAR, with referrals to these services made by the change agents. All activities were mutually reinforcing and used dialogic and narrative content to promote reflection and dialogue that aimed to change attitudes and behaviors related to early marriage, immediate childbearing, birth spacing, and contraceptive use. (See the Supplement for a detailed description of how PRACHAR activities were implemented.)

PRACHAR was implemented in 3 phases with different coverage levels, intervention combinations, and durations (Figure 1 and Table). Phase I was implemented for 3 years in Nalanda, Nawada, and Patna districts of Bihar, using a comprehensive model including all the interventions described above. Phase II was implemented in 5 districts: the original 3 districts plus Gaya and Shikhpura. Phase II included different intervention arms to compare the effectiveness of the comprehensive PRACHAR and durations.

to contribute to the growing body of evidence around behavior change approaches for contraceptive use by married youth.

**The PRACHAR Project was** implemented in 3 phases between 2001 and 2012 with different coverage levels, intervention combinations,

FIGURE 1. PRACHAR Phases, Intervention Delivery Mechanisms, and Coverage



Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

model over different durations (2 and 5 years) with 3 "single intervention" models. The "singleintervention" models were: trained couples only (where young married couples were trained to provide reproductive health information), home visits only, and volunteers only (where community resource people were available for reproductive health questions and dialogue without a formal home visit or group meeting structure). All the arms in Phase II included communitylevel enabling environment activities. Phases I and II were implemented through local NGOs with referrals to government and private-sector service delivery sites. Phase III was implemented for 3 years in Gaya district and aimed to test a streamlined government-NGO model that had greater potential for scale up than the Phase I and II models. Government community-based health workers (Accredited Social Health Activists [ASHAs]) assumed the role of female change agents conducting home visits. Local NGOs maintained responsibility for male engagement and training unmarried adolescents. Engagement with husbands, gatekeepers, and the broader community was diminished. The Phase I, II, and III districts were chosen because they were representative of Bihar from a demographic perspective (the majority of the population was of low socioeconomic status and belonged to the Scheduled and Backward

castes) and were within 2–4 hours of the city of Patna (the state capital) by car or bus.

#### METHODS

From 2014 to 15, Pathfinder International staff conducted a review of existing PRACHAR Phases I, II, and III evaluation reports, special studies, presentations, and project monitoring data to synthesize evidence related to the following research question: "What is the evidence from PRACHAR around programming to increase contraceptive use among young married women and men?". The studies we reviewed are briefly described here, and their methodologies are described in the source files referenced. First, we reviewed reports of quasi-experimental studies conducted for each project phase, i.e. population-based surveys among young married women and men in intervention and control areas at baseline and endline.15-17 In addition, we reviewed reports of special studies conducted to further assess effectiveness of interventions. These included the Adolescent Follow-up Survey with youth in PRACHAR Phase I intervention areas who participated in adolescent trainings and other enabling environment interventions, as well as a comparable control group; a qualitative study on gender norms, attitudes, and practices related to sexual and reproductive health outcomes in PRACHAR

TABLE.	PRACHAR	Activities.	by Pro	iect Phase
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			Phase I		Phase II				Phase III
PRACHAR Strategies and Interventions	Target Level	Implementer(s)	Comprehensive 3-year model	Comprehensive 5-year model (continued for 2 years beyond Phase I)	Comprehensive 2-year model	Home visits only	Volunteers only	Trained couples only	2-year model with ASHAs
Interventions with adolescents,	young couples,	key influencers, and cor	mmunities to increa	se support for RH practices	and use of services	;			
Small-group education on RH with adolescent girls (aged 12–14 years), and unmarried girls and boys aged 15–19 years	Individual	Trainers from NGO training partner	Х	Х	Х	-	-	-	Х
Counseling on RH/FP and referrals to FP services through regularly scheduled home visits to married young women with no children, married young women with first pregnancy, married postpartum young women who delivered their first child, married young women with 1 child	Individual	Phase I and II: Female Change Agent Phase III: ASHA	Х	х	х	Х	-	-	Х
Home visits to women and men (whenever possible, without a regular schedule) and referral by female and male volunteers (rather than paid change agents), respectively	Individual	Male and female community volunteers	-	-	-	-	X	-	-
Outreach to young couples by other trained young couples (rather than change agents, peer-to-peer outreach approach)	Individual, young couples	Male and female members of young couples	-	-	-	-	-	Х	-
Newlywed couple ceremony/ infotainment parties	Young cou- ples, Group	NGO training partner	Х	Х	-	-	-	-	-
Small-group discussion and dialogue on RH and contra- ception, and referrals to health services, separately to young married women and married men	Group	Phase I and II: Female Change Agent, Male Communicator Phase III: ASHA, Male Communicator	Х	Х	Х	-	-	-	Х
Orientation and training of community leaders and influ- encers on RH for young people	Community	NGO intervention partner	Х	Х	Х	-	-	-	-
Group meetings and infotain- ment programs for mothers and fathers of young married men (the mothers-in-law and fathers-in-law of young mar- ried women)	Community	NGO intervention partner	Х	Х	Х	X	Х	Х	-
Street theater performances	Community	NGO intervention partner	Х	Х	Х	-	-	-	-
Wall paintings	Community	NGO intervention partner	Х	Х	Х	Х	Х	Х	Х

TABLE. Continued

			Phase I		Phase II				Phase III
PRACHAR Strategies and Interventions	Target Level	Implementer(s)	Comprehensive 3-year model	Comprehensive 5-year model (continued for 2 years beyond Phase I)	Comprehensive 2-year model	Home visits only	Volunteers only	Trained couples only	2-year model with ASHAs
Improving access to RH services									
Support to monthly MCH clinics by providing government ANMs with training and sup- port, essential instruments, and recordkeeping tools.	Community	Phase I and II: NGO intervention partner, Anganwadi Worker, ANM (Government)	Х	X	Х	Х	Х	Х	-
Training of rural health practi- tioners on RH and FP issues	Community	NGO training partner	X	Χ	Х	Х	Χ	Х	-
Training of TBAs on safe deliv- ery, counseling on postpartum contraceptives, and referral of pregnant women with complications	Community	NGO training partner	Х	Х	Х	Х	Х	Х	-
Training of chemist outlets and village convenience shops on FP and connecting them with social marketing agencies to encourage regular stocks of condoms and pills	Community	NGO intervention partner	Х	Х	Х	X	Х	Х	-

Abbreviations: ANM, auxiliary nurse-midwife; AHSA, accredited health social activist; FP, family planning; MCH, maternal and child health; PRACHAR, Promoting Change in Reproductive Behavior of Adolescents; RH, reproductive health; TBA, traditional birth attendant.

intervention and comparison areas; a survey conducted by the Population Council to evaluate the effectiveness of Phase III in building ASHAs' capacity to offer reproductive health services; and a population-based survey conducted by the Population Council to evaluate if the reproductive health outcomes observed in PRACHAR Phases I and II were sustained among new cohorts of women 5–8 years after PRACHAR ended. 18–21 We also reviewed analyses of individual-level routine project monitoring data on contraceptive uptake among young married beneficiaries.

Following the review of existing PRACHAR evaluation and monitoring reports, we identified key gaps in knowledge that would be important to address for program design purposes and conducted secondary analyses of PRACHAR evaluation data to answer specific questions around effectiveness, intensity, and duration of program interventions. We generated bivariate frequency distributions and conducted multivariate logistic regressions with contraceptive use as the outcome variable and a variety of independent variables (demographic characteristics such as age, education,

wealth index, and parity; exposure to PRACHAR interventions).

The findings from our review and the secondary analysis were categorized according to key program learning themes as described in the Results below.

#### RESULTS

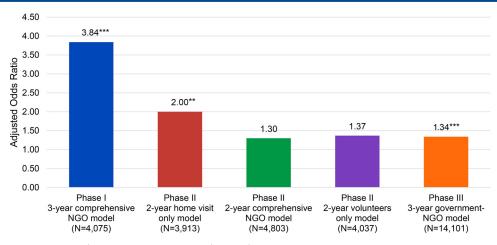
Through our review of the PRACHAR evaluation studies, special studies, and our secondary analysis, we identified evidence around 4 key themes: (1) project effectiveness in achieving attitudinal and behavioral outcomes; (2) effectiveness of selected program components and the intensity required to produce effects; (3) scalability and effectiveness at scale; and (4) sustained project impact.

#### PRACHAR's Effectiveness in Achieving Attitudinal and Behavioral Outcomes

The results of our analyses indicate that comprehensive intervention models of longer duration are most effective in increasing contraceptive use among married youth. The 3-year comprehensive

Comprehensive intervention models of longer duration are most effective in increasing contraceptive use among married youth.

**FIGURE 2.** Adjusted Odds Ratios for Current Contraceptive Use Among Young Married Women Aged 15–24 (Phase I and II) and Aged 15–34 (Phase III) in PRACHAR Intervention Models



Reference groups are comparison areas where PRACHAR was not implemented.

Adjusted odds ratios are from multivariate logistic regressions comparing baseline-endline changes in intervention and comparison areas for each PRACHAR model. These adjusted odds ratios are from different studies/designs so direct comparison should be taken with limitations.

\*P<.05; \*\*P<.01; \*\*\*P<.001.

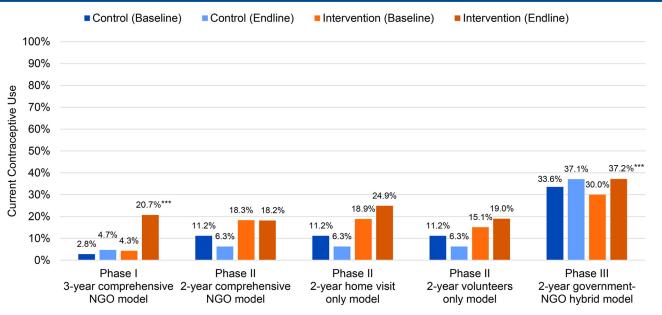
Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

NGO-led PRACHAR model in Phase I. which included behavior change elements and multiple overlapping communication channels, had the greatest magnitude of effect on contraceptive use. As published in Daniel et al. (2008), the odds of current contraceptive use increased nearly 4 times as much from baseline to endline among young married women in Phase I intervention areas than among those in comparison areas (adjusted odds ratio [aOR]=3.84; P < .001, adjusted for age, education, caste, and parity) (Figure 2). 15 The adjusted effect size for Phase I is larger than that of PRACHAR's 2-year "single-intervention" models in Phase II (i.e., the 2-year "home visit only" model with an aOR of 2.00, P<.01, adjusted for age, parity, education, caste, and standard of living index; the 2-year comprehensive model [not statistically significant]; and the 2-year "volunteers only" model [also not statistically significant]), 16 as well as the Phase III government-NGO model of similar duration (aOR=1.34; P<.001, adjusted for age, education, and caste). 17 The lack of significant effect on contraceptive use in the comprehensive 2-year model (aOR=1.30) offers suggestive evidence of a minimum duration of comprehensive interventions required to achieve effects in this context.

Bivariate findings on current contraceptive prevalence rate from all 3 PRACHAR Phases also show the greatest baseline-endline increase in the 3-year Phase I model, from 4% to 21% in intervention areas (Figure 3). <sup>15–17</sup> While the contraceptive prevalence rate findings from Phases I and II are not directly comparable with Phase III due to different study populations (ages 15–24 in the former vs. ages 15–34 in the latter), the relative baseline-endline increase is still greatest in the 3-year Phase I model.

Contraceptive method mix remained relatively consistent in Phases I and II, reflecting the limited availability of several methods in Bihar at that time, particularly for young married women. Condoms and pills were the most commonly used contraceptive methods among young married women aged 15-24 of zero and single parity in the intervention and comparison areas. Condoms ranged from 62% to 85% of the method mix, and pills from 11% to 27% of the method mix. Use of IUDs was negligible (less than 1%), and there was virtually no use of female or male sterilization as expected with a young population (Figure 4). In Phase III, contraceptive method mix among women aged 15-34 of zero or single parity remained heavily focused on short-acting

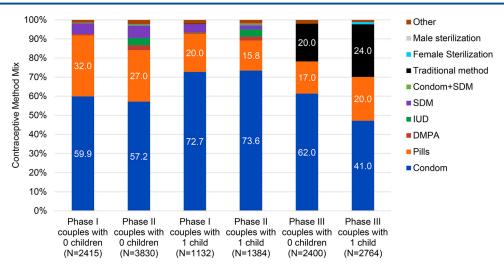
FIGURE 3. Current Contraceptive Use Among Married Women Aged 15–24 (Phases I and II) and Aged 15–34 (Phase III) in PRACHAR Intervention Models



\*P<.05; \*\*P<.01; \*\*\*P<.001.

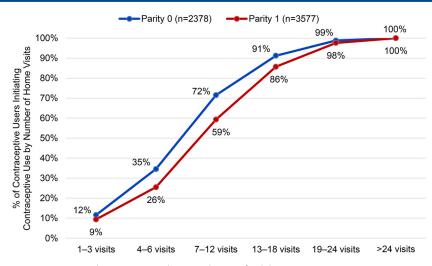
Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

**FIGURE 4.** Contraceptive Method Mix Among Young Married Contraceptive Users Aged 15–24 in the PRACHAR 5-Year Comprehensive Model (Phases I and II), and Aged 15–34 in Phase III Intervention Areas (Baseline + Endline)



Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

**FIGURE 5.** Number of Home Visits Required for Contraceptive Initiation Among Young Married Contraceptive Users Aged 15–24 in PRACHAR Phase I, by Parity



Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

methods (condoms and pills), with minimal use of female sterilization and some use of traditional methods. <sup>17</sup>

# Effectiveness of Selected Program Components and the Intensity Required to Produce Effects

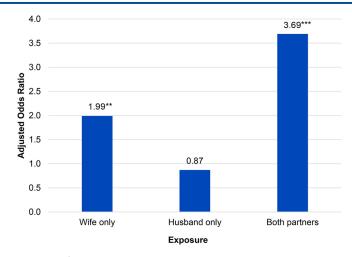
Phase I evidence also sheds light on the relative contributions of specific PRACHAR interventions, as well as the intervention timing and intensity required to influence contraceptive use. Home visits by NGO change agents conducting interpersonal communication were found to be effective in increasing contraceptive use among young married women when implemented in tandem with community-level activities that aimed to change attitudes and behaviors. In the Phase I comprehensive model, young married women in PRACHAR intervention areas who were exposed to home visits had 2 times higher odds of currently using contraception than those who did not receive home visits (aOR=2.30; P<.001, adjusted for education, caste, and standard of living index). Among the Phase II "single-intervention" models, the home visit model (plus service linkages and community-level interventions) had the highest magnitude of effect for current contraceptive use (aOR=2.00 as noted above; P < .01). <sup>16</sup> No effect was seen in the other "single-intervention" 2-year models. Additionally, bivariate analyses showed that couples reached with both adolescent

training and home visits in Phase I had higher rates of ever using contraception than couples reached with only one of these interventions, suggesting a multiplicative effect of these interventions. There is also some evidence of effectiveness of small-group meetings. Phase I and II data show that married women in PRACHAR intervention areas who were exposed to group meetings (and potentially other interventions as well) had 3 times higher odds of currently using contraception than those not exposed (aOR=3.16; *P*<.001, adjusted for education, caste, and standard of living index).

PRACHAR Phase I monitoring data show that intensity and timing of home visits matter. Women reached with home visits at multiple life cycle stages (newlywed, before pregnancy, during pregnancy, and after first birth) had the highest ever use of contraception after their first birth and initiated contraception more quickly compared with women reached at fewer life cycle stages. In addition, a relationship was observed between the number of home visits and ever use of contraception among young married women, with 7 to 12 visits as the "tipping point" where more than half of contraceptive users had initiated use (Figure 5). While multiple factors affect initiation of contraception, these data suggest that among young women who eventually used contraception, repeated home visits were required to stimulate contraceptive initiation.

Home visits by NGO change agents, when implemented in tandem with community-level activities, were found to be effective in increasing contraceptive use among young married women.

**FIGURE 6.** Adjusted Odds Ratios for Current Contraceptive Use Among Young Married Women Aged 15–24 With 1 Child, According to Exposure to PRACHAR Phase I Interventions (Wife, Husband, or Both) (N=1779)



Reference group: neither partner exposed.

Odds ratios adjusted for parity, education, and standard of living index.

\*P<.05; \*\*P<.01; \*\*\*P<.001.

Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

Contraceptive initiation earlier in life is correlated with future contraceptive use.

We also found that contraceptive initiation earlier in life is correlated with future contraceptive use. Results from the Adolescent Follow-up Survey show that married young women with 1 or more children (in both intervention and comparison areas) who had used contraception before their first birth had nearly 14 times higher odds of using contraception after their first birth compared with women who had not previously used contraception (aOR=13.70; *P*<.001).<sup>21</sup> This further underscores the importance of reaching young married women to promote contraceptive initiation early in their reproductive life.

Phase I results suggest that a gender synchronized approach in which both male and female partners are engaged—both together and separately—was associated with stronger results than working with only young men or only young women. Couples in which both the woman and her partner were exposed to PRACHAR had the highest odds of contraceptive use (aOR=3.69; *P*<.001), whereas couples in which only the woman was exposed to PRACHAR had lower odds of contraceptive use (aOR=1.99; *P*<.01), and there was no significant effect on contraceptive use for couples in which only the husband was exposed (aOR=0.87; *P*>.05) (Figure 6). Similarly, Phase I and II data show that couples

had higher odds of contraceptive use when wives participated in decision making about contraceptive use vs. when they did not participate (aOR=1.5 for couples without children and aOR=1.2 for couples with 1 child).

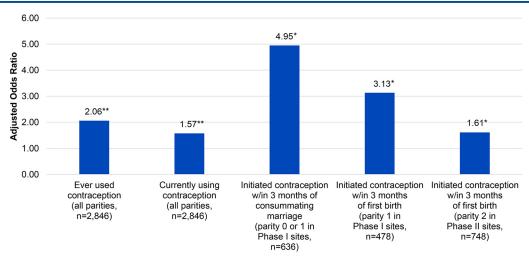
The PRACHAR data do not shed light on the effectiveness of the other PRACHAR intervention components. No significant associations were found between exposure to newlywed ceremonies or cultural programs and current use of contraception by young married women. The added impact of engaging mothers-in-law and other key gatekeepers could not be determined, as young married respondents were not asked if other family members besides their partner (i.e., parents, parents-in-law) participated in PRACHAR activities, and gatekeeper and community engagement to shift attitudes occurred across all Phase I and II intervention arms.

#### Scalability and Effectiveness at Scale

As per an internal evaluation report by the Population Council, the scalable PRACHAR Phase III hybrid government-NGO model (using ASHAs instead of change agents and reducing or eliminating other activities) had significant but smaller contraceptive use gains than Phases I and II.<sup>17</sup>

The hybrid government-NGO model, while scalable, had significant but smaller contraceptive use gains than the NGO-led model.

FIGURE 7. Adjusted Odds Ratios for Current Contraceptive Use Among Married Women Aged 15-34 in Areas Where PRACHAR Phase I, Phase II, or Phases I + II Were Implemented 4-8 Years Earlier



Reference group is women in comparison areas where PRACHAR was not implemented.

Adjusted odds ratios are from multivariate logistic regressions comparing baseline-endline changes in intervention and comparison areas. Odds ratios are adjusted for age, education, caste, and wealth quintile.

\*P<.05: \*\*P<.01: \*\*\*P<.001.

Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

From PRACHAR Phase III baseline to endline, the odds of currently using contraception increased 34% more among young married women in PRACHAR intervention areas than in comparison areas (aOR=1.34; P<.01, adjusted for age, education, and caste). Effect sizes varied by parity: aOR=1.89 among women with 1 child (P<.05), aOR=1.67 among women with more than 2 children (all P < .01), and no significant effect among women with zero or 2 children. The smaller effect sizes in Phase III may reflect several implementation factors. First, women in comparison and intervention areas had comparable rates of exposure to ASHAs (74% and 77%, respectively, in the 3 years prior to the survey). Second, among women contacted by ASHAs, only 28% of women in intervention areas and 17% of women in comparison areas reported that the ASHA discussed family planning. (For reference, 78% of women in intervention areas and 79% of women in comparison areas reported that the ASHA discussed child immunization.) Third, ASHAs had lower coverage rates for zero-parity women, which was a key target population for PRACHAR. Only 43% of zero-parity women were reached at least once in both intervention and comparison groups,

compared with 78% to 86% of women of parity 1 or higher. Only 44% of zero-parity women visited by ASHAs received 13 or more visits in the past 3 years, compared with 61% to 74% of women of parity 1 or higher. Finally, Phase III also lacked significant behavior change interventions with gatekeepers such as mothers-in-law and other community influencers.

#### **Sustained Project Impact**

As published in Jejeebhoy et. al (2015), the The contraceptive current contraceptive use gains achieved in use gains PRACHAR Phases I and II persisted several years achieved under after the interventions ended, both among those directly exposed to PRACHAR as well as those living in the intervention areas at the time of the survey but not directly exposed to PRACHAR.<sup>20</sup> Married women aged 15-34 in areas where Phases I and/or II were implemented 4-8 years earlier had 2 times higher odds of ever using contraception (aOR=2.06) and 57% higher odds of currently using contraception (aOR=1.57) than women in comparison areas where PRACHAR was not implemented (both P < .001) (Figure 7). Bivariate findings showed the highest current contraceptive use of 43% among married women

the NGO-led **PRACHAR** model persisted several years after the interventions ended.

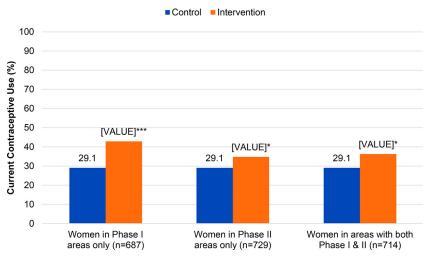
living in areas where PRACHAR Phase I was implemented (Figure 8). Sustained effects were also seen for initiation of contraceptive use immediately after marriage and after first birth among specific parity groups. Married women with zero or 1 child living in former PRACHAR Phase I areas had nearly 5 times higher odds of initiating contraceptive use within 3 months of consummating marriage than women in comparison areas (aOR=4.95; P<.05), with 4.1% of women with zero children and 5.9% of women with 1 child initiating contraception in this time frame (vs. 0% and 2.1% in comparison groups, respectively). Married women with 1 child in former Phase I areas had 3 times higher odds of initiating contraceptive use within 3 months of their first birth (aOR=3.13), with 10.2% of women with 1 child initiating contraception during this time frame (vs. 2.9% in comparison areas). Married women with 2 children in former PRACHAR Phase II areas had 61% higher odds of initiating contraception within 3 months of their first birth (aOR=1.61) than women in comparison areas (both P < .05), with 15.1% of women with 2 children initiating contraception during this time frame (vs. 9.8% in comparison areas).

In addition to the contraceptive behavior changes sustained after the intervention ended, there is some evidence that PRACHAR led to sustained attitudinal shifts around healthy timing and spacing of pregnancies. Women in former PRACHAR intervention areas had significantly greater odds of preferring an ideal age at first birth of 21 or older (aOR=1.60) and preferring a birth interval of at least 36 months (aOR=1.46) than women in comparison areas (both *P*<.001). Several years after Phase I and II ended, qualitative data from program participants indicated that PRACHAR had played a role in shifting community perceptions on girls' sexual and reproductive health, specifically the use of contraception by adolescents and youth for healthy timing and spacing of pregnancies. <sup>18</sup>

#### DISCUSSION

The evidence and learning generated from a decade of PRACHAR implementation have important implications for the design of future programming both in India and in a range of other contexts that face similar challenges of early marriage, early and rapid repeat pregnancies among young married women, and inequitable social and gender norms. The evidence and learning also raise critical questions around scale up and sustainability that should be explored in future programming for married youth.

FIGURE 8. Current Contraceptive Use Among Married Women Aged 15–34 in Areas Where PRACHAR Phase I, Phase II, or Phases I + II Were Implemented 4–8 Years Earlier



\*P<.05; \*\*P<.01; \*\*\*P<.001.

Abbreviation: PRACHAR, Promoting Change in Reproductive Behavior of Adolescents.

#### Comprehensive Programming Can Increase Contraceptive Use Among Married Young People

PRACHAR Phase I results demonstrate that a comprehensive program with multiple reinforcing interventions tailored to specific life stages and aimed at different levels of a socioecological model can effectively increase contraceptive use among married young people in a conservative context.

PRACHAR evaluations and implementation experience also demonstrate the importance of several other design features, particularly gender synchronization and the life cycle approach for adolescents and youth. When both young married women and their male partners were exposed to project interventions, contraceptive use was greater. This quantitatively demonstrates what the literature has long suggested—that changing behaviors related to contraception and fertility requires engagement of both members of the couple.<sup>22</sup> While PRACHAR effectively engaged both members of the couple, the gender content of the intervention was somewhat limited, focusing primarily on enhancing young women's participation in household decision making. The social and behavior change interventions at the community level focused on norms related to marriage, contraception, and fertility, rather than underlying inequitable gender norms. As gender inequality is a primary driver of early marriage and early and rapid repeat childbearing among young women, future programs aiming to increase contraceptive use among young married women should more robustly address the gender inequitable attitudes, behaviors, and norms underlying contraceptive behavior and the intersectional vulnerabilities, such as poverty and lack of educational opportunities, that young married women face.

PRACHAR included interventions that targeted adolescents and youth at different life stages, including before marriage, right after marriage, and before and after childbirth. The findings from the monitoring and evaluation data suggest that this approach—intervening at multiple points along the life cycle—had powerful impacts on the uptake of contraception. Young women who received home visits at multiple life stages as per the intervention design had the highest use of contraception, and women who had used contraception before their first birth were more likely to use contraception after their first birth than those who had not previously used contraception. This finding has relevance to a range of contexts and quantitatively reinforces the importance of interventions across the life cycle, including prior to the first birth.<sup>23</sup>

#### Shifting From NGO to Government Workers **Enhances Scalability but May Have Reduced Effectiveness**

Though Phase I and Phase III evaluations did not use the same methodology so caution should be taken in direct comparison, the smaller magnitude of effect of PRACHAR Phase III (the government-NGO hybrid model) relative to the effect size of Phase I (the full comprehensive model) raises important considerations for program design and scale up.

First, the shift from NGO change agent (in married women Phases I and II) to ASHA (in Phase III) enhanced scalability. ASHAs are a scalable platform through which interventions can potentially reach many people and be sustained through government funding, whereas local NGOs have limited geographic reach and depend on external funding sources. However, the shift to ASHAs resulted in reduced quality and reach of interpersonal communication during home visits under Phase III. There are several possible reasons for this. Like community health workers in many other countries, ASHAs are responsible for promoting a wide range of maternal and child health care practices and are regularly tasked with additional priorities. During PRACHAR implementation, incentivization schemes that encouraged ASHAs to seek out pregnant women and refer them for institutional delivery diverted ASHAs from reaching young nulliparous women and inadvertently disincentivized discussion of family planning. Some states in India have explored incentivization of community health workers for helping couples to achieve outcomes related to delaying and spacing births, but ASHAs—like community health workers worldwide—remain a cadre with many responsibilities and competing incentives covering the gamut of maternal and child health. The PRACHAR experience under Phase III demonstrates the challenges of relying on governmentsupported multipurpose community health workers to conduct intensive behavior change focused on young married women, amidst their other competing priorities.

In addition, PRACHAR further demonstrates that shifting the main intervention to government implementation resulted in less funding and diminished prioritization of the other elements of the intervention, including reduced engagement of male partners and key gatekeepers. Consi-

When both young and their male partners were exposed to project interventions, contraceptive use was areater.

dering the quantitative and qualitative evidence from Phases I and II of PRACHAR that points to the importance of the engagement of male partners and the broader community, it is possible that the reduced engagement of men and limited community social norm change interventions under Phase III contributed to the reduced magnitude of impact. This finding aligns with behavior change theory and reinforces existing evidence from a range of contexts that suggests that the use of a socioecological framework with multiple reinforcing interventions at different levels can change behavior related to contraceptive use among young married couples.<sup>6,7</sup>

The PRACHAR experience suggests that there are trade-offs for behavior change approaches when moving from a more intensive, NGOimplemented approach to an approach that may be more easily scaled but relies on overburdened government workers or systems. These trade-offs are not unique to PRACHAR and are likely to be found when seeking to scale up behavior change programs across a range of target groups and outcomes.<sup>24</sup> Behavior change often requires more intensive interpersonal and community-level efforts, which do not fit naturally into the mandate and scope of most government community workers or existing government systems, such as health facilities. For example, in India as in many other countries, there are no clear government workers or systems to take up interpersonal behavior change efforts with adolescents and youth and community-wide social and behavior change activities, which poses further challenges to scaling up through government-only systems. The Rashtriya Kishor Swasthya Karyakram (RKSK) program in India, launched in 2014, is the current national initiative to promote the health of adolescents and youth through interpersonal communication strategies, health services, and several other school- and communitybased channels.25 However, RKSK uses unpaid youth peer educators, rather than a formal government system or cadre, as the primary implementer of the program component that aims to reach young people with interpersonal communication to catalyze behavior change. Governments, donors, and practitioners must think critically and creatively about the appropriate scaleup pathways for behavior change interventions that rely on interpersonal communication and analyze potential trade-offs between quality, impact, and scale. These considerations also suggest that practitioners could explore and rigorously evaluate methodologies for behavior change that require less intensive interpersonal and community-level interventions.

### Comprehensive Programming Can Have Sustained Effects on Behaviors

The PRACHAR experience also raises important questions on potential tensions between less intensive implementation approaches that can reach more people in the context of constrained funding but may have diminished impact on intractable behaviors, and intervention models that may be more intensive but catalyze change in behaviors with long-lasting and intergenerational effects. The PRACHAR long-term studies indicate that the more intensive interventions of PRACHAR Phases I and II had sustained impacts for 4 to 8 years after the program ended. While the PRACHAR studies did not include normative measures, the sustained behavior change and corresponding attitudinal changes regarding healthy timing and spacing of pregnancies suggest that norms surrounding use of contraception and fertility among young married couples may also have shifted due to PRACHAR. While direct comparison of the sustained impact of Phases I and II with Phase III is not possible (because no long-term study has been done following Phase III), it is important to consider whether the intensity and/or quality of Phase I and II interventions might have contributed to the sustained effects observed. Would we see the same sustained effects from the less intensive ASHA-led intervention with limited community engagement, especially given that the immediate effects on contraceptive use at endline were modest (and negligible among zero-parity women)? We hypothesize that we would not. This begs the question of whether a more intensive model that creates sustained impacts after 3 years of implementation may offer better value for money than a less intensive model that reaches more people but must continue for many more years to create long-lasting effects.

#### CONCLUSION

PRACHAR represents a decade of investment in implementation, learning, and evaluation of social and behavior change efforts to increase voluntary contraceptive use for married adolescents and youth. It is essential that we use the learning from PRACHAR to inform the design and implementation of current and future programs for married youth. In addition, to advance the field and better meet the needs and rights of married adolescents and youth, future programs should seek to answer the questions that PRACHAR raises in relation to

effective models to scale up multilevel behavior change efforts and around potential trade-offs between intensity, quality, and sustainability of impacts over time. Answering these questions will require implementation of thoughtfully designed programs for married youth that draw on the learnings from PRACHAR and improve upon the PRACHAR model. In addition, it will require robust and mixed-method evaluations and thoughtful implementation science approaches that assess not only effectiveness but also how programs are implemented, why programs are or are not impactful, and what the scale-up pathways and processes are. Furthermore, as the use of social norm measurement and theory advances in global public health, programs for married youth will benefit from more theory-driven normative change interventions and measurement.<sup>26</sup>

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#### **ORIGINAL ARTICLE**

### Effectiveness of SMS Technology on Timely Community Health Worker Follow-Up for Childhood Malnutrition: A Retrospective Cohort Study in sub-Saharan Africa

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In Ghana, Rwanda, Senegal, and Uganda, we found positive association between community health workers (CHWs) using SMS data entry with reminder alerts and timely follow-up for childhood malnutrition screening visits compared with paper forms. This association was strongest when CHWs used SMS data entry consecutively over multiple visits than when they switched between SMS and paper forms.

#### ABSTRACT

**Background:** The Millennium Villages Project facilitated technology-based health interventions in rural under-resourced areas of sub-Saharan Africa. Our study examined whether data entry using SMS compared with paper forms by community health workers (CHWs) led to higher proportion of timely follow-up visits for malnutrition screening in under-5 children in Ghana, Rwanda, Senegal, and Uganda.

**Methods:** Children under 5 years were screened for malnutrition every 90 days by CHWs using mid-upper arm circumference (MUAC) readings. CHWs used either SMS texts or paper forms to enter MUAC data. Reminder texts were sent at 15 days before follow-up was needed. Chi-square tests assessed proportion of timely follow-up visits within 90 days between SMS and paper groups. Logistic regression analysis was conducted in a step-wise multivariate model. Post-hoc power calculations were conducted to verify strength of associations.

**Results:** SMS data entry was associated with a higher proportion of timely malnutrition follow-up visits compared with paper forms across all sites. The association was strongest with consistent SMS use over consecutive visits. SMS use at the first of 2 consecutive visits was most effective, highlighting the importance of SMS reminder alerts.

**Conclusions:** SMS technology with reminders increased timely CHW malnutrition screening visits for under-5 children in Ghana, Rwanda, Senegal, and Uganda, highlighting the importance of such technology for improving health worker behavior in low-resource settings.

#### INTRODUCTION

In 2000, the world committed to achieving the measurable targets set by the Millennium Development

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Goals (MDGs) to combat extreme poverty by 2015. Goal No. 1 targeted halving the proportion of people suffering from hunger globally and Goal No. 4 aimed to cut the global under-5 mortality rate by two-thirds.<sup>2</sup> In 2015, more than 99 million children under 5 years of age remained undernourished, with two-thirds of this number in Asia and one-third in Africa.3 The pace of progress has not been consistent or equal across regions. The global prevalence of underweight children decreased from 25% (1990) to 15% (2013),<sup>3</sup> but Africa experienced the smallest relative decrease compared with other regions.<sup>3</sup> These regional inequalities persist due to complex and multifaceted socioeconomic and political variables. Child health remains a priority in the post-2015 agenda, as evidenced by the targets included in the Sustainable Development Goals (SDGs) 1, 2, and 3 to end poverty, prevent hunger, and improve health, respectively.4

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The Millennium Villages Project (MVP) was initiated in 2005 to meet these MDGs in rural sub-Saharan Africa with a series of integrated interventions spanning multiple sectors including health, education, agriculture, and infrastructure. By 2006, MVP operated across 10 countries and 14 community sites in sub-Saharan Africa, covering approximately 500,000 people. 5,6 An opensource information and communication system called the Millennium Villages Global Network (MVG-Net) was designed and deployed to assist with health systems monitoring and evaluation and to communicate between sites. 7

The open-source components of this system used for community health worker (CHW) support were comprised of ChildCount+, a mobile platform used to collect data, and OpenMRS, an electronic medical record in which patient health information was stored. These 2 components of MVG-Net interacted with each other to collect health information at household visits, store data in a central system, and send CHWs follow-up reminders for pending visits (Figure). Included in these interventions was the equipping of CHWs with mobile technology (SMS, or short message service) for data collection, reporting, communications, and point-of-care support.

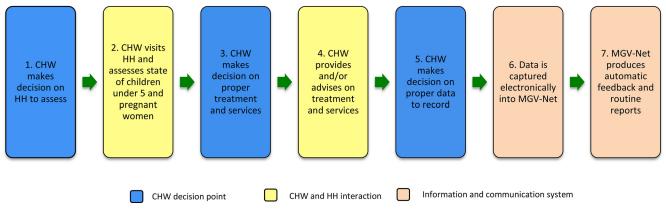
A cluster randomized control trial (RCT) of mobile text message reminders in Kenya evaluated health worker adherence to malaria treatment and counseling. When health workers received daily text message reminders, there was a 23.7% improvement in correct management immediately and 24.5% improvement at 6 months. Additional evidence from Western Kenya's MVP

site found improved adherence to antenatal care and postpartum visits among CHWs receiving ChildCare+ text reminders. Similarly, mobile phone use had a positive effect on malaria surveillance, case reporting, and follow-up in rural South Africa. Quality of SMS reporting by health workers remains a concern; the SMS for Life study across 5 rural Kenyan districts showed variable accuracy of surveillance data.

The field of mHealth has itself burgeoned recently and the use of mobile phones for health interventions has become increasingly sophisticated. The World Health Organization (WHO) describes mHealth as "the practice of medicine and public health assisted by mobile technologies, such as mobile phones, patient monitoring personal digital assistants (PDAs) and other wireless technologies.<sup>13</sup> In high-income countries, examples include point-of-care monitoring for blood glucose levels in diabetes management<sup>14</sup> or running a 2-lead electrocardiogram (ECG) for point-of-care cardiac investigations. 15,16 In lowand middle-income countries, mobile phones offer a low-cost tool for data collection. The WHO Global Observatory for eHealth (electronic health) reports that the majority (83%) of WHO member states offer at least 1 type of mHealth service within their countries and 70% of mobile phone users reside in low- and middle-income countries.13

A systematic review on the use of SMS in health programs identified 31 projects in developing countries in 2012.<sup>17</sup> The majority of these programs were in Africa (Kenya and South Africa) followed by Asia (India). Within Africa, programs





Abbreviations: CHW, community health worker; HH, households; MVG-Net, Millennium Villages Global Network.

were concentrated in the Great Lakes region, particularly Kenya, Tanzania, and Uganda, where the mobile phone market has recently expanded. 17 The purpose of these interventions included disease prevention, surveillance, self-management, treatment adherence, 17 and improved health worker behavior. 18 Despite this interest, academic research in the field is minimal and mixed, 19,20 particularly in Africa.<sup>21</sup> Studies are mainly single observational data points rather than multinational or regional research.<sup>22</sup>

The purpose of this article is to examine whether SMS patient data entry with text message reminders influenced CHW follow-up visits compared with paper data entry. Our study uniquely shows evidence from multiple MVP country sites across sub-Saharan Africa.

#### INTERVENTION

The MVG-Net system's purpose was to gather health information in order to provide a feedback mechanism to inform patient management. Standard mobile phones with SIM cards were provided to CHWs.8 These phones included the ChildCount+ platform, an open-source system built on Django web framework and Python language. 8 CHWs used these phones to send SMS formatted texts to register patients during home visits and enter their individual and household data into a central database.8 Household heads, children under 5 years, and all pregnant women in a household were registered using a unique patient identifier (Patient ID) with a linked household identifier (Household Head ID) at the first home visit. Malnutrition screening for children under 5 years occurred at 90-day intervals.<sup>23</sup>

After performing a nutritional screen that included checking mid-upper arm circumference (MUAC) and signs of edema for all under-5 children in a household, CHWs sent a formatted SMS text message into the ChildCount+ system. The ChildCount+ system then sent a reminder text message to the CHW's phone 75 days after the previous MUAC screen. 23 If the CHW did not conduct a follow-up MUAC screen within 90 days, then the system would send weekly text reminders until follow-up was achieved.23 CHWs using paper forms for data entry did not receive these reminder alerts. CHWs were also responsible for ad hoc visits to follow-up if a child was malnourished or after a recent discharge from clinic. These ad hoc visits were prioritized over regular follow-ups when needed.

#### **CHW Training**

Integral to MVP's focus on health systems was integrated community case management. CHWs played a large role in regular home visits and the patient referral process. CHWs were generally chosen by the communities and given initial training on community health including maternal and child health.<sup>24</sup> Scope of practice involved clear tasks during household visits including registering individuals, identifying sick individuals, following up on young children and pregnant women, and reporting visits to CHW supervisors. A defined management structure with regular remuneration was in place, including necessary resources such as medical supplies, mobile phones, and bicycles, among others.<sup>24</sup> As per the Earth Institute's Technical Task Force Report on CHW scale-up and management, the average estimated cost of funding CHWs per head per year for the covered rural population was \$6.56.25

CHWs scheduled a total of 30 home visits per week with 5 visits per day over a 6-day work week. These visits included a mix of follow-up and regular visits, which prioritized pregnant women and infants. Sick individuals were referred to the nearby primary health care facility. At the end of each month, weekly logbooks outlining each visit were presented to CHW supervisors. The supervisor analyzed visit history and redistributed caseloads as necessary. CHW supervisors were generally experienced senior CHWs with supervisory training, who then reported to CHW managers at the primary health care facility. There was an approximate minimum ratio of 150 households per CHW across MVP sites.<sup>25</sup>

The purpose of this article is to examine whether **SMS** patient data entry with text message reminders influenced CHW follow-up visits compared with paper data entry.

#### Implementation Challenges

There were 2 components to data collection involved in this study: CHWs entered patient and household data and tracked their home visits during an initial 3- to 6-month period using only paper forms followed by 3 to 6 months of using only SMS entries. During the transition from paper only SMS entry for forms to mobile phones, data collection was validated using both paper and SMS for at least a 1-month period in order to ensure operational effectiveness and data accuracy. The date of visit on the paper forms was the actual date visited, whereas the date of visit on SMS entries was not entered but assumed to be the date of SMS transmission. There were no major server outages or SMS coverage disturbances during this study period that could have offset consistent reporting.

For 3 to 6 months, **CHWs** entered data using only paper forms, followed by using another 3 to 6 months but some CHWs switched between paper and SMS for the same patients. Variations in implementation did occur across sites and was likely due to unfamiliarity with the tool or CHW-related factors. These variations allowed for concomitant use of paper forms and SMS data entry outside the prescribed overlap period. CHWs switched between paper and SMS entries for follow-up visits for the same patients. This switching created 4 comparison groups for evaluation over consecutive visits:

- SMS entry at initial visit followed by paper form at follow-up visit
- 2. Paper form at initial visit followed by SMS entry at follow-up visit
- 3. SMS entries at both visits
- 4. Paper forms at both visits

When CHWs used SMS at the first of 2 consecutive visits (groups 1 and 3), a reminder text would still be sent after 75 days. This text would not be sent when using paper forms at the first visit (groups 2 and 4).

#### METHODS

#### **Study Design**

The study design is a retrospective observational study with follow-up over 30 months, from February 1, 2010, through July 31, 2012. The 2 comparison groups were SMS for data entry versus paper forms.

#### **Study Sites**

Four MVP sites were selected for this study: Ruhiira (Uganda), Bonsaaso (Ghana), Potou (Senegal), and Mayange (Rwanda). These sites were chosen based on the continuity of accurate data available over the study period. These sites represent a collection of villages with a total catchment

population of approximately 155,740 people.<sup>6</sup> Ruhiira is the largest of the 4 sites with 8 villages and more than 10,000 households (Table 1). Bonsaaso is a group of 6 villages with about 5,700 households. Potou, similarly, has 6 villages with approximately 3,200 households. Lastly, Mayange is made up of 4 villages with about 5,500 households.

#### Study Population and Inclusion Criteria

The study population across the 4 sites included children aged 6–60 months<sup>26</sup> who received an MUAC screen from a CHW between February 1, 2010, and July 31, 2012. Only patient data entries that could be linked to MUAC readings were included. Participants with missing MUAC readings or missing information on type of data entry (SMS or paper) were excluded. Children with MUAC screens who turned 5 during the course of follow-up were included. Children under 6 months of age were excluded because they do not receive regular MUAC screens as per WHO growth monitoring standards.<sup>27</sup>

#### **Study Follow-Up Period**

Appropriate follow-up by CHWs was defined as an MUAC reading within 90 days from previous measurement (during the relevant age range). Prior research demonstrated that MUAC measurements were independently comparable predictors of child mortality compared with weight-for-age *z* score indices. <sup>28</sup> Risk of childhood mortality was shown to significantly increase when MUAC measurements fell below 115 mm and it is one of the WHO diagnostic criteria for severe acute malnutrition. <sup>26,29</sup> The 90 days maximum for follow-up MUAC readings was chosen since MUAC measurements were previously shown to predict mortality within 30- and 90-day intervals. <sup>30</sup>

**TABLE 1.** Snapshot of MVP Sites Catchment Data<sup>a</sup>

Site	No. of Villages	Population	No. of Households	No. of Health Centers
Ruhiira, Uganda	8	50,000	10,385	6
Bonsaaso, Ghana	6	35,000	5769	7
Potou, Senegal	6	32,000	3249	5
Mayange, Rwanda	4	23,000	5500	1

Abbreviation: MVP, Millennium Villages Project.

<sup>&</sup>lt;sup>a</sup> Catchment data represent baseline data from the MVP midterm analysis conducted in 2009.

## Variables Exposure Variable

The exposure variable was a dichotomous variable representing MUAC data entries using either SMS (1) or paper forms (0) for children aged 6–60 months over the entire study period.

#### **Outcome Variable**

The outcome variable captured each follow-up MUAC entry after the first MUAC entry for a unique child. The outcome variable was coded as a dichotomous variable: proportion of follow-up MUAC entries within 90 days (1) or after 90 days (0).

#### **Covariates**

Six explanatory variables were selected *a priori* and included age of child, gender of child, age of household head, gender of household head, number of children per household, and number of children per CHW. Each of these covariates was created as a continuous variable initially. In order to assess subgroup differences, the variables were then transformed into categorical variables.

#### **Data Selection**

The method of selecting study participants was non-randomized; there was no participant sampling because the entire study site was evaluated. All children between 6–60 months who received a household visit between February 1, 2010, and July 31, 2012, and an MUAC assessment at any point in this duration were automatically enrolled.

#### **Power and Sample Size Calculation**

We conducted post-hoc power and sample size calculations to guide interpretation of our findings (Supplement 1).<sup>31</sup> We used 5% alpha level and a 2-sample comparison of proportion of timely follow-up visits between data and SMS entry.

#### **Data Analysis**

Household-level data were reformatted and merged to patient-level data by matching Household Head IDs with Patient IDs in order to group patients who belonged to a unique household together. Duplicates were removed from each variable separately before merging all observations together by Patient ID.

Chi-square tests at 5% significance level were conducted between exposure and outcome variables, and also between all covariates and exposure

and outcome variables. Logistic regression was used to examine the strength of the association between exposure and outcome in both crude and adjusted models. All covariates were included in the multivariate regression models regardless of associated *P* values. The final adjusted multivariate model included analysis of the switch between paper and SMS entries to elicit whether using SMS even at 1 visit had a benefit in timely follow-up due to the 75-day text reminder. This relationship between type of data entry switching and proportion of timely visits was coded as following:

- (0) Paper forms over 2 consecutive visits
- (1) SMS at first visit, paper forms at second visit
- (2) Paper forms at first visit, SMS at second visit
- (3) Only SMS over 2 consecutive visits

All statistical tests were conducted using STATA v.10 (STATACorp, Texas, USA).

#### **Patient Confidentiality and Ethics**

All MVG-Net personnel received training on patient confidentiality and data access. Only health care providers had access to primary identified data. The data were de-identified and stored in the OpenMRS system using secure, confidential, password-protected means. The de-identified data were retrospectively accessed by the research analysis team at the Earth Institute at Columbia University. All de-identified retrospective raw data are available in Supplements 2–5.

This study was approved by the Columbia University Institutional Review Board (IRB) under protocol number IRB AAAF1647.

#### RESULTS

#### **Descriptive Statistics**

The number of children with MUAC data entries ranged across the study sites from 1,970 in Ghana, to 10,256 in Uganda (Table 2). The median number of under-5 children per household was 1 in Ghana and Rwanda, and 2 in Uganda and Senegal. CHWs in Uganda and Senegal saw more children (median of 177 and 162, respectively) than CHWs in Ghana and Rwanda (median of 60 and 35, respectively).

#### **Bivariate Analyses**

Two-sided bivariate analyses with chi-square tests of SMS versus paper entry including all covariates was conducted at 5% level of significance (Table 3). All covariates had a statistically

TABLE 2.	Descriptive	Statistics by	/ Study	Site,	2010-2012
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	Bonsaaso, Ghana	Ruhiira, Uganda	Mayange, Rwanda	Potou, Senegal
Under-5 Children	N=2563	N=13,404	N=2398	N=5765
No. of children (6–60 months) with MUAC data entries	N=1970	N=10,256	N=2250	N=5038
Median age of under-5 children, years (IQR)	2.1 (2.5)	2.3 (2.3)	2.9 (2.5)	2.5 (2.5)
Age groups for under-5 children, months, No. (%)				
0–6°	310 (14)	1860 (14)	238 (10)	631 (12)
6–12	283 (13)	1442 (11)	286 (12)	599 (11)
12–18	235 (11)	1308 (10)	147 (6)	557 (11)
18–24	272 (13)	1190 (9)	216 (9)	563 (11)
24–30	262 (12)	1262 (9)	261 (11)	631 (12)
30–36	208 (10)	1125 (8)	246 (11)	520 (10)
36–42	212 (10)	1241 (9)	342 (15)	557 (11)
42–48	171 (8)	1157 (9)	248 (11)	528 (10)
48–54	189 (9)	1443 (11)	325 (14)	651 (12)
54–60	-	1444 (10)	-	_
Gender of under-5 children, No. (%)				
Male	1250 (49)	6643 (50)	1247 (52)	2918 (51)
Female	1313 (51)	6761 (50)	1151 (48)	2847 (49)
Households	N=4956	N=11,703	N=4631	N=4146
Median age of household head, years (IQR)	35.5 (14.3)	32.0 (13.0)	33.0 (12.0)	40.5 (15.8)
Median number of under-5 children in each household (IQR)	1 (1.0)	2 (1.0)	1 (1.0)	2 (1.0)
Gender of household head, No. (%)				
Male	3900 (79)	8529 (73)	3467 (75)	3980 (96)
Female	1056 (21)	3174 (27)	1164 (25)	166 (4)
Community Health Workers	N=78	N=70	N=155	N=40
Median number of under-5 children per community health worker (IQR)	60 (63)	177 (50)	35 (35)	162 (107)

Abbreviations: IQR, interquartile range; MUAC, mid-upper arm circumference.

significant association with the outcome except gender of the child and of the household head.

The percentage of follow-up visits occurring within 90 days by SMS entry and paper forms is displayed in Table 4. In all sites, a greater proportion of follow-up visits occurred within 90 days when CHWs entered data through SMS versus paper forms. For example, in Uganda 92% of follow-up visits occurred within 90 days when data were entered through SMS compared with 78% when data were entered using paper

forms. Similarly, in Ghana the percentages were 85% and 46%, respectively. Associated chi-square tests demonstrated P values <.001 across all sites.

# Multivariate Analyses Ruhiira, Uganda

At the Uganda site, there was a strong positive crude association between SMS data entry and timely MUAC follow-up visits within 90 days of

<sup>&</sup>lt;sup>a</sup> Not included in analysis as MUAC readings are conducted in children ages >6 months and <5 years.

TABLE 3. Chi-Square Analysis of Paper Versus SMS Follow-Up by Study Population Characteristics

	Uga	ında	Ghana		Sen	egal	Rwanda	
Characteristic	MUAC >90 days (%)	P Value						
Under-5 Children								
Age, months		<.001***		<.001***		<.001***		<.001***
6-12 (1 year)	64	REF	67	REF	26	<.001***	64	.11
12–18	70	<.001***	80	<.001***	34	<.001***	79	.001***
18–24 (2 years)	72	<.001***	77	<.001***	36	<.001***	76	.03*
24–30	72	<.001***	70	<.001***	36	<.001***	69	.96
30–36 (3 years)	73	<.001***	77	<.001***	32	<.001***	75	REF
36–42	73	<.001***	80	<.001***	35	<.001***	68	.67
42-48 (4 years)	74	<.001***	73	<.001***	33	<.001***	78	.002***
48–54	71	<.001***	71	<.001***	30	<.001***	75	.045*
54–60 (5 years)	62	<.001***	62	<.001***	20	.30	76	.02*
Gender		.006**		.25		.98		.76
Male	70	.006**	73	REF	32	REF	73	REF
Female	71	REF	74	.25	32	.98	74	.76
Households								
No. of under-5 children in each house- hold categorized		<.001***		.002**		.05*		.047*
1	56	REF	72	REF	33	REF	74	REF
2	60	.03*	76	<.001***	33	.94	74	.75
3	60	<.001***	78	.001***	31	.16	71	.61
4	61	.63	72	.88	31	.33	63	.20
5	71	.03*	30	.01**	32	.67	11	.003**
6	68	.37	NA	NA	30	.28	NA	NA
7	NA	NA	NA	NA	14	.04*	NA	NA
8	NA	NA	NA	NA	41	.20	NA	NA
9	NA	NA	NA	NA	40	.28	NA	NA
10	NA	NA	NA	NA	16	.09	NA	NA
11	NA	NA	NA	NA	NA	NA	NA	NA
Age groups for household heads, years		<.001***		<.001***		.82		.02*
0–15	66	.11	67	.30	NA	NA	NA	NA
15–25	48	<.001***	41	<.001***	27	REF	NA	NA
25–35	56	REF	55	REF	26	.49	54	<.001***
35–45	59	<.001***	54	.20	28	.74	67	REF
45–55	59	<.001***	61	<.001***	27	.98	68	.45
55–65	60	<.001***	58	.33	26	.50	66	.80
≥65	60	<.001***	55	.99	26	.61	70	.31

**TABLE 3.** Continued

	Uga	nda	Gh	ana	Sen	egal	Rwe	anda
Characteristic	MUAC >90 days (%)	P Value						
Gender of household head		.05*		.88			.26	<.001***
Male	56	REF	55	REF	27	REF	69	REF
Female	57	.05*	54	.88	29	.26	54	<.001***
CHWs								
No. of under-5 children per CHW		<.001***		<.001***		<.001***		<.001***
1 (range: 0–1 <i>5</i> 0)	71	REF	76	REF	NA	REF	64	REF
2 (range: 150-177)	72	.56	77	.66	NA	NA	70	<.001***
3 (range: 177–200)	72	.005**	81	.002**	17	.45	80	<.001***
4 (range: ≥200)	67	<.001***	63	<.001***	32	<.001***	NA	NA

Abbreviations: CHW, community health worker; MUAC, mid-upper arm circumference; NA, not applicable.

\* P≤.05; \*\* P≤.01; \*\*\* P≤.001.

**TABLE 4.** MUAC Follow-Up Within and After 90 Days by Paper Entry Versus SMS Entry and Reminders

	No.	(%)
Country	Paper Entry	SMS Entry + Reminders
Uganda		
≤90 days	67,374 (78)	9,885 (92)
>90 days	18,796 (22)	914 (8)
Ghana		
≤90 days	487 (46)	5,123 (85)
>90 days	583 (54)	921 (15)
Senegal		
≤90 days	1,248 (22)	3,576 (40)
>90 days	4,509 (78)	5,376 (60)
Rwanda		
≤90 days	1,253 (59)	1,651 (92)
>90 days	869 (41)	135 (8)

Abbreviations: MUAC, mid-upper arm circumference; SMS, short message service. Chi-square tests demonstrated *P* values < .001 across all sites.

previous visit (odds ratio [OR]=3.02; 95% confidence interval [CI]: 2.82, 3.24) compared with paper entry. This association was stronger after adjusting for confounding in the logistic regression analysis (OR=3.23; 95% CI: 2.90, 3.59). Compared with only paper entries as a reference, the adjusted association was strongest with consistent SMS use over consecutive visits (OR=18.14; 95% CI: 12.99, 25.32) (Table 5). The adjusted association was significantly weaker when paper entry was used at the first and SMS entry at the second of 2 consecutive visits (OR=1.98; 95% CI: 1.81, 2.15), whereas the strength of the association remained when using SMS first across 2 consecutive visits (OR=3.23; 95% CI: 2.91, 3.60).

#### Bonsaaso, Ghana

At the Ghana site, the crude association between using SMS entry versus paper entry and MUAC follow-up visits within 90 days was strongly positive (OR=6.66; 95% CI: 5.79, 7.65). However, when adjusted for confounding, this association was not significant (OR=1.78; 95% CI: 0.39, 8.04). The adjusted association did not become statistically significant regardless of SMS entry at the first consecutive visit (OR=2.02; 95% CI: 0.44, 9.34) or at the second consecutive visit (OR=0.17; 95% CI: 0.12, 0.23) (Table 5). There was, however, a statistically significant adjusted

**TABLE 5.** Association Between Timely Follow-up and Switching Between SMS and Paper Forms Over 2 Consecutive Visits (Multivariate Model)

	Uga	ında	Gho	ina	Sen	egal	Rwe	anda
SMS-Paper	Crude OR	Adjusted OR	Crude OR	Adjusted OR	Crude OR	Adjusted OR	Crude OR	Adjusted OR
Switching	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)	(95% CI)
Paper-Paper (0 0)	REF	REF	REF	REF	REF	REF	REF	REF
Paper-SMS	2.04	1.98	0.16	0.17	0.24	0.25	1.30	1.31
(0 1)	(1.88, 2.23)	(1.81, 2.15)	(0.12, 0.22)	(0.12, 0.23)	(0.21, 0.27)	(0.22, 0.29)	(1.02, 1.65)	(1.02, 1.67)
SMS-Paper	3.34	3.23	2.52	2.02	1.91	2.00	5.43	5.33
(1 0)	(3.01, 3.71)	(2.91, 3.60)	(0.58, 10.97)	(0.44, 9.34)	(1.63, 2.23)	(1.71, 2.35)	(3.14, 9.40)	(3.06, 9.27)
SMS-SMS	18.54	18.14	2.99	3.01	1.38	1.43	10.52	9.89
(1 1)	(13.34, 25.76)	(12.99, 25.32)	(2.34, 3.83)	(2.32, 3.91)	(1.24, 1.54)	(1.28, 1.60)	(7.39, 14.97)	(6.91, 14.14)

Abbreviations: CI, confidence interval; OR, odds ratio; SMS, short message service.

association between SMS entry over consecutive visits and timely MUAC follow-up (OR=3.01; 95% CI: 2.32, 3.91).

#### Potou, Senegal

The Senegal site also had positive crude (OR=2.40; 95% CI: 2.23, 2.59) and adjusted (OR=2.03; 95% CI: 1.73, 2.38) associations between SMS data entry and timely MUAC follow-up within 90 days compared with paper entry. Similar to Uganda and Ghana, the adjusted dose-dependent association was stronger when SMS was used at the first consecutive visit followed by paper entry at the second visit (OR=2.00; 95% CI 1.71, 2.35) (Table 5). There was a negative association between using paper entry at the first visit and SMS at the second consecutive visit (OR=0.25; 95% CI: 0.22, 0.29). Consistent SMS use over consecutive visits had an improved association with timely follow-up (OR=1.43; 95% CI: 1.28, 1.60), but not as strong as the Uganda and Ghana sites.

#### Mayange, Rwanda

Between all study sites, the crude association between SMS versus paper entry and timely 90-day MUAC follow-up was the strongest for Rwanda (OR=8.48; 95% CI: 6.97, 10.31). There was still a strong positive association when adjusted for confounding (OR=5.09; 95% CI: 2.92, 8.87). The adjusted association grew stronger with SMS use at the first visit (OR=5.33; 95% CI: 3.06, 9.27) compared with paper entry at the first visit (OR=1.31; 95% CI: 1.02, 1.67) (Table 5). The adjusted association was strongest

with consistent SMS use over consecutive visits (OR=9.89; 95% CI: 6.91, 14.14).

#### DISCUSSION

The results of our study show a clear positive association between SMS data entry with reminder alerts and timely CHW follow-up for malnutrition screening visits. This finding is consistent with other studies that show improvement in case reporting, follow-up, and treatment by CHWs using SMS text reminders. Our study focused on the process indicator of proportion of timely malnutrition follow-ups using SMS versus paper data entry. This analysis does not comment on what program evaluation literature describes as outcome or impact indicators to describe adequacy of child nutritional support. 32 Mitchell et al. recently published the endline evaluation of 40 outcomes across 10 MVP-scaled sites in categories including nutrition and child health.<sup>5</sup> We refer readers to this evaluation for end outcomes that are overall positive for the study duration.

Across all study sites, the association with Across all study timely follow-up was strongest when SMS data entry was used consecutively over multiple visits compared with switching between SMS and paper entry. Using SMS entry at the first of 2 consecutive visits still showed benefits, likely due to the reminder alerts sent at 75 days. The poorer results in some sites are difficult to explain without qualitative field data. Future qualitative research including interviews with CHWs and site administrative staff would help to explain differences in SMS implementation. This knowledge would help improve implementation in the future and

**Between all** 4 study sites, the association between SMS vs. paper entry and timely follow-up was strongest for Rwanda.

sites, the association with timely follow-up was strongest when SMS data entry was used consecutively than when CHWs switched between SMS and paper.

prevent switching between SMS and paper entry. Our analysis reflects what occurred on the ground across sites during program implementation and shows benefit of using SMS consistently over follow-up visits.

Additionally, SMS use may be largely dependent on individual CHW characteristics and patient demographics. In our study, CHWs were more likely to use SMS entry when there were more than 200 children per CHW (Senegal and Uganda). Similarly, other factors may influence CHW adherence to mobile phones including CHW age, gender, and training duration. Future analyses could explore patient and CHW characteristics associated with SMS use behavior.

#### Limitations

According to post-hoc power calculations, the study was highly powered across all 4 sites (Supplement 1), which could reflect the large effect sizes. A multilevel regression model combining all 4 sites was initially considered, but this analysis was underpowered and difficult to achieve due to variations in site implementation. The lack of a clear comparison group in this study makes it difficult to control for unknown factors that influence patient follow-up. Without qualitative data, it is difficult to know why CHWs sometimes switched between paper and SMS data entry. This switching could occur due to various reasons such as poor cellular reception, short battery life, or lack of adequate training. More qualitative data about the study sites may help understand why Uganda had such a low proportion of SMS use compared with Ghana, Rwanda, and Senegal. There were no reported power outages or natural reasons causing poor SMS use in Uganda, but it is possible that an administrative challenge led to disruptions in service. Delays in follow-up visits could also be related to difficult and hilly terrains specifically in Ruhiira, Uganda, impacting both SMS and paper entry groups.

#### CONCLUSION

Using SMS for patient data entry with reminder alerts led to more timely CHW follow-up visits for malnutrition screening across multiple countries. The study highlights the importance of SMS technology in improving community-based health care delivery in low-income countries.

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#### **ORIGINAL ARTICLE**

# Review of Grain Fortification Legislation, Standards, and Monitoring Documents

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The majority of countries with mandatory grain fortification requirements document the technical specifications for grain fortification, such as allowable food vehicles and fortification levels required. Most document systems for monitoring. However, detailed protocols, descriptions of roles and responsibilities, means to support the cost of regulation, enforcement strategies, and methods for reporting monitoring results to stakeholders are generally lacking.

#### ABSTRACT

Objective: Analyze the content of documents used to guide mandatory fortification programs for cereal grains.

**Methods:** Legislation, standards, and monitoring documents, which are used to mandate, provide specifications for, and confirm fortification, respectively, were collected from countries with mandatory wheat flour (n=80), maize flour (n=11), and/or rice (n=6) fortification as of January 31, 2015, yielding 97 possible country-grain combinations (e.g., Philippines-wheat flour, Philippines-rice) for the analysis. After excluding countries with limited or no documentation, 72 reviews were completed, representing 84 country-grain combinations. Based on best practices, a criteria checklist was created with 44 items that should be included in fortification documents. Two reviewers independently scored each available document set for a given country and food vehicle (a country-grain combination) using the checklist, and then reached consensus on the scoring. We calculated the percentage of country-grain combinations containing each checklist item and examined differences in scores by grain, region, and income level.

Results: Of the 72 country-grain combinations, the majority of documentation came from countries in the Americas (46%) and Africa (32%), and most were from upper and lower middle-income countries (73%). The majority of country-grain combinations had documentation stating the food vehicle(s) to be fortified (97%) and the micronutrients (e.g., iron) (100%), fortificants (e.g., ferrous fumarate) (88%), and fortification levels required (96%). Most (78%) stated that labeling is required to indicate a product is fortified. Many country-grain combinations described systems for external (64%) monitoring, and stated that industry is required to follow quality assurance/quality control (64%), though detailed protocols (33%) and roles and responsibilities (45%) were frequently not described.

Conclusions: Most country-grain combinations have systems in place for internal, external, and import monitoring. However, documentation of other important items that would influence product compliance to national standard, such as roles and responsibilities between agencies, the cost of regulating fortification, and enforcement strategies, are often lacking. Countries with existing mandatory fortification can improve upon these items in revisions to their documentation while countries that are beginning fortification can use the checklist to assist in developing new policies and programs.

#### INTRODUCTION

arge-scale fortification of staple foods is a costeffective and sustainable strategy for substantially reducing micronutrient malnutrition.<sup>1</sup> The fortification of cereal grains with folic acid, iron, zinc, vitamin B12, niacin,

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riboflavin, thiamin, vitamin A, and other micronutrients has gained global traction as a strategy to improve human health. Fortification has led to reduced incidence of neural tube defects<sup>2,3</sup> and nutritional anemia,<sup>4</sup> among other health outcomes. According to the Food Fortification Initiative, in 2016, 34% of industrially milled wheat flour, 57% of industrially milled maize flour, and 1% of industrially milled rice was fortified (71%, 29%, and 45% of wheat flour, maize flour, and rice, respectively, was industrially milled), and 87 countries mandated the fortification of at least one of these cereal grains.<sup>5</sup>

For governments to ensure effective food fortification, enactment of laws and regulations provide legal

<sup>&</sup>lt;sup>b</sup> Emory University, Atlanta, GA, USA.

<sup>&</sup>lt;sup>c</sup>Global Alliance for Improved Nutrition, Geneva, Switzerland.

<sup>&</sup>lt;sup>d</sup>U.S. Centers for Disease Control and Prevention, Atlanta, GA, USA.

<sup>&</sup>lt;sup>e</sup> Project Healthy Children, Cambridge, MA, USA.

<sup>&</sup>lt;sup>f</sup>Nutrition International, Ottawa, Canada.

<sup>&</sup>lt;sup>g</sup> Granotec, Santiago, Chile.

authority and a regulatory framework. 1 Mandatory fortification, as compared to voluntary, is more likely to achieve and sustain the desired health benefits of fortification.<sup>3,6</sup> The regulatory framework specific to food fortification provides the basis for ensuring the quality and safety of products and for meeting public health nutrition objectives. 7,8 Practical implementation of fortification is challenging though, as evidenced by global insufficient compliance against fortification standards.<sup>7</sup> Therefore, periodic government monitoring will help determine whether program objectives are being met.

Given the challenges of implementing largescale, cereal-grain fortification, effective legislation, standards, and monitoring documents can provide clear guidance on key program decisions, activities, and milestones such as the micronutrients/premix required; financial responsibility of implementing and monitoring and enforcing fortification; labeling of fortified products; internal, external, commercial, and import monitoring procedures; incentives and penalties; laboratory methods; and reporting guidelines. 1,8-23 The objectives of this review are to assess the content of legislation, standards, and monitoring documents used to guide mandatory cereal grain fortification programs in countries and to identify areas of strength and areas needing improvement. To the best of our knowledge, there has never been a review of cereal-grain legislation, standards, and monitoring documents' content conducted at global scale. Previous work has looked at individual regions or a handful of countries, has been limited to one food vehicle, and has rarely included monitoring documents.8,10,21,24

#### METHODS

#### **Document Inclusion Criteria**

Any country that had mandatory fortification of wheat flour, maize flour, or rice as of January 31, 2015, was included in this review. We defined mandatory fortification of cereal grains as "country has legislation that has the effect of mandating fortification of one or more types of wheat or maize flour or rice with at least iron or folic acid." 5 Under this definition, as of January 2015, 80 countries mandated wheat flour fortification, 11 mandated maize flour fortification, and 6 mandated rice fortification. This yielded a maximum of 97 possible country-grain combinations for the analysis (e.g., Philippines-wheat flour was one combination and Philippines-rice was another).

Documents included in our study consist of legislation and statutory instruments, standards, technical regulations and specifications, and monitoring guidelines (Box). Legislation and statutory instruments typically mandate national or regional fortification of the specified cereal grain and include initial legislation such as the food act As of January (may also be known as the food and drug act or food control act)<sup>1,17</sup>; hereafter, we refer to these as legislation documents. Standards, technical regulations, and specifications typically provide any implementing rules, regulations, or guidelines, such as dictating which vitamins and minerals to include in fortification and the levels of each nutrient to be added, as well as packaging and labeling requirements<sup>1,17</sup>; hereafter, we refer to these as standards documents. Monitoring guidelines ensure that quality control measures are followed routinely and problems are corrected so that fortified products consistently abide by relevant standards and fortification achieves its maximum health impact<sup>1,17</sup>; hereafter, we refer to these as **The purpose of** monitoring guidelines.

Four monitoring categories were included in this analysis: internal, external, commercial, and import level. As part of internal monitoring, food processors use quality assurance and quality control procedures to ensure consistent production of quality fortified food. 11 In external and import monitoring, government authorities periodically inspect and audit processes and test products at production and import sites, respectively, to

**2015, 80 countries** mandated wheat flour fortification, 11 mandated maize flour fortification, and 6 mandated rice fortification.

this article is to assess cerealgrain legislation, standards, and monitoring documents among countries with mandatory grain fortification programs.

BOX. Description of Legislation, Standards, and Monitoring Documents<sup>a</sup> Legislation: establishes the legal framework and broad principles for fortification Examples include:

- Statutory instruments
- Food law

**Standards:** mandate the specific legal requirements for food fortification Examples include:

- Technical regulations
- **Specifications**

Monitoring documents: provide instructions to track the operational performance of a fortification program Examples include:

- Manuals
- Guidelines
- **Procedures**
- <sup>a</sup> Adapted from Allen et al. (2006)<sup>1</sup> and Nathan (1999).<sup>17</sup>

We completed 72 reviews representing 84 country-grain combinations. ensure that fortification meets the country's specifications.<sup>1</sup> As part of commercial monitoring, food safety inspectors check retail outlets to be sure the fortified product is in the marketplace and complies with regulations on packaging and labeling.<sup>21</sup>

In addition to the 3 main types of documents included (legislation, standards, and monitoring guidelines), we included the following document types when applicable: updates or amendments to legislation or standards; documents that are referenced by the legislation, standards, or monitoring guidelines; and reports of monitoring results. We recognize that countries have different legal systems, resulting in laws and regulations taking different forms; therefore, this review examines legislation, standards, and monitoring documents collectively and uses broad inclusion criteria for documents.<sup>17</sup>

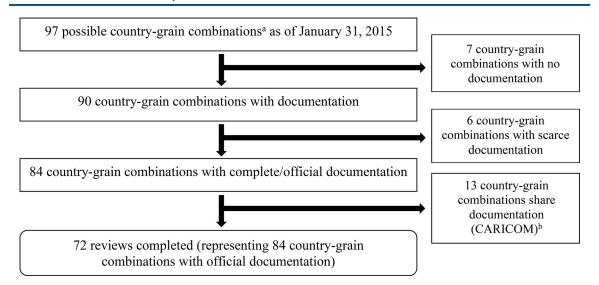
Of the 97 possible country-grain combinations, there were 7 countries with no documentation available (Benin, Guinea, Iran, Mali, Mauritania, Niger, and Saudi Arabia) (Figure 1). In 6 countries (Bahrain, Iraq, Jordan, Nepal, Oman, and Yemen), very limited documents were available so they were also excluded. Thirteen Caribbean countries follow the Caribbean Community and Common Market (CARICOM) standard<sup>25</sup> and have no

additional documentation; therefore, we reviewed these countries as a whole (Antigua and Barbuda, Bahamas, Barbados, Dominica, Grenada, Guyana, Haiti, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, and Trinidad and Tobago). In summary, we completed 72 reviews representing 84 country-grain combinations (Supplement Table 1).

#### **Document Collection**

Documents included in the analysis were primary sources collected in a variety of ways. First, we gathered documents from internal databases within partner agencies, such as the Food Fortification Initiative (FFI), the Global Alliance for Improved Nutrition (GAIN), Project Healthy Children (PHC), and Nutrition International, that support countries with their fortification programs. Second, we sent requests for documents to contacts for all countries mandating grain fortification in September 2014 and September 2015 to fill any known gaps. 4,26 We also emailed and called Ministries of Health and other relevant agencies within countries to procure documents. If documents were in a language other than English or Spanish, they were translated to English.

**FIGURE 1.** Flowchart of Country-Grain Combination Exclusions



<sup>&</sup>lt;sup>a</sup> Country-grain combination refers to the unit of analysis; countries that mandate the fortification of multiple cereal grains will contribute more than one country-grain combination (e.g., Philippines-wheat and Philippines-rice).

<sup>&</sup>lt;sup>b</sup> Thirteen Caribbean countries follow the Caribbean Community and Common Market (CARICOM) standard (Caribbean Community Secretariat, 1995): Antigua and Barbuda, Bahamas, Barbados, Dominica, Grenada, Guyana, Haiti, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, and Trinidad and Tobago.

#### Framework Development

To evaluate the contents of a set of documents, where a set is the legislation, standards, and/or monitoring guidelines for a given country-grain combination, we developed a checklist of items that should be ideally included in a set of fortification documents. 1,8-23 We determined the checklist items through a literature review conducted in February and March 2015 using PubMed and Google Scholar (keywords included combinations of food fortification, legislation, standards, monitoring, evaluation, framework). The checklist was then revised by content experts, who also suggested pertinent studies for consideration. As part of the literature review, studies of legislation surrounding mandatory or voluntary fortification of any food vehicle were included, specifically studies of legislation for industrial fortification (as opposed to home-based fortification, which employs the use of a supplement, not fortified food). Legislative frameworks for fortification and case studies of legislation development or monitoring procedures were also included. Manuals for legislation, standards, and enforcement of food law and fortification, as well as manuals developed for implementing components of a fortification program, were also included in the literature review. Lastly, we included any studies that contained suggestions for model laws or any studies on monitoring of fortification programs.

We piloted the criteria checklist with a subset of 11 country-grain combinations. Following the pilot, we pared down the checklist and focused on items relevant to fortification (as opposed to general food control measures). The final version of the criteria checklist contained 44 items categorized as general, micronutrients/premix, costing, labeling, internal monitoring, external monitoring, commercial monitoring, import monitoring, enforcement/penalties, laboratory testing, and reporting (Table 1).

#### **Document Review**

Two reviewers independently reviewed a set of documents for a given country-grain combination and came to a consensus on the scoring of the 44 items. All coauthors conducted the reviews (8 reviewers in total); the 3 reviewers involved in the development of the checklist and the pilot (KJM, CLL, HP) were paired with the other 5 reviewers to ensure consistency across reviews. Three reviewers (XL, LMD-R, HP) reviewed the Spanish-language sets in Spanish. Reviewers completed the checklist by scoring each item using "does not contain item" or "contains item in its totality." About one-third of items on the checklist (n=15) also had "contains item to some degree" as an option. One-quarter of items on the checklist (n=10) had "not applicable" as an option. There was a comment field adjacent to each item for qualitative observations. If there was a discrepancy in the scoring between reviewers that the pair could not come to consensus on, a third-person arbiter resolved it.

#### Country Outreach

After we completed reviews in June 2016, we reached out to in-country contacts, particularly National Fortification Alliance members, via email for all countries included in the review to confirm that all appropriate documentation was included in the review and that preliminary reviews seemed accurate for the given documentation. If documentation was missing and then sent by contacts, we completed a second review including the additional documentation.

#### **Data Analysis**

For each item in the checklist, we calculated the percentage of countries with documentation that fully contained that item. Country-grain combinations receiving a score of "not applicable" for an item were removed from the denominator for that item. We also examined differences in scores by grain, by region,<sup>27</sup> and by income level.<sup>28</sup> We conducted a sensitivity analysis, using chi-square tests, to gauge whether the completeness of the documentation reviewed differed between those countries that responded to the country outreach We developed a efforts and verified completeness of documentation versus those that did not. Qualitatively, we extracted clear and flexible passages from documents that illustrated language that fully contained each item of interest.

#### RESULTS

Of the 72 country-grain combinations reviewed, 55 (76%) were of wheat flour, 11 (15%) of maize flour, and 6 (8%) of rice. The majority of documentation came from countries in the Americas (46%, n=33) and Africa (32%, n=23). Among those with wheat flour documentation, the countries were mainly from the Americas (42%, n=23) and Africa (33%, n=18), with Europe (13%, n=7), the Pacific (5%, n=3), Asia (4%, n=2), and the Middle East (4%, n=2) contributing a smaller proportion. Among those with maize flour documentation, 55% was from the Americas (n=6) and 45% from

checklist of 44 items that should be ideally included in a set of fortification documents.

Most of the documentation we reviewed came from countries in the Americas and Africa.

TABLE 1. Checklist of Key Items<sup>a</sup> and All Possible Scoring Options in Fortification Legislation, Standards, and Monitoring Documents

ltem	Scoring Options	References
General		
1. States that legislation applies to at least one food vehicle fit for human consumption (types/grades to be fortified)	(2) States at least one type fit for human consumption (0) Does not state	10, 12, 17, 22
2. States the public health objective; purpose and scope of legislation	<ul><li>(2) States the public health objective or general purpose of legislation</li><li>(0) Does not state</li></ul>	10, 13, 17, 22
3. References latest available science or accepted international norms and recommendations, particularly for items that may not be covered in the country's documents	<ul><li>(2) States the documents referenced</li><li>(0) Does not state</li></ul>	12, 17, 21
4. Provides definitions that include terms that are specific to fortification (e.g., fortified food, premix, fortificant, food vehicle)	(2) States at least one term related to fortification (0) Does not state	17, 22
5. Provides repeals (if there is at least one prior document about fortification)	<ul><li>(2) States repeals</li><li>(0) Does not state</li><li>(N/A) No prior documents about fortification</li></ul>	12, 17
6. Provides effective date or gives grace period for when fortification is to begin (e.g., effective 6 months from signing)	<ul><li>(2) States effective date or grace period for when fortification is to begin (e.g., effective 6 months from signing)</li><li>(0) Does not state</li></ul>	12, 17
Micronutrients/Premix		
7. States nutrients required	(2) States nutrients (0) Does not state	8, 10, 12, 13, 21
8. States fortificants (chemical compounds) to be used (including fortificants that are allowable as options)	(2) States fortificants for at least one nutrient (0) Does not state	8, 10, 12, 13, 21
9. States fortification levels	<ul><li>(2) States a range or number with +/-</li><li>(1) States one number only</li><li>(0) Does not state</li></ul>	8, 10, 13, 21
10. States consideration of bioavailability/biological activity of fortificants	<ul><li>(2) States some consideration of bioavailability (mentions these or related terms)</li><li>(0) Does not state any consideration</li></ul>	9
11. States consideration of nutrient stability	(2) States consideration of nutrient stability (0) Does not state any consideration	11
Costing		
12. States that the cost of fortification is regulated through cost-sharing schemes (between government, industry, consumers) or tax measures (to assist industry)	<ul><li>(2) States consideration of either cost regulation method</li><li>(0) Does not state any consideration</li></ul>	10, 12, 13
13. States consideration of the financial responsibility (of the government) of monitoring and enforcing fortification (schedule of fees, budget)	(2) Shows consideration that monitoring costs money (0) Does not state any consideration	10, 13, 19, 21, 22
Labeling		
14. Includes some sort of statement/label/logo that makes it clear that the product is fortified	(2) Includes a statement, label, or logo (0) Does not include statement, label, or logo	8, 10, 12, 13, 18
15. Provides guidance on health claims that can be made for this product (specific to micronutrients added through fortification)	(2) Provides guidance on health claims specific to micronutrients added through fortification (0) Does not provide	12, 15, 20

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ltem	Scoring Options	References
Internal Monitoring (Conducted by Industry)		
16. States requirement for sampling as part of internal monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	<ul> <li>(2) States that samples should be taken as part of internal monitoring</li> <li>(1) States that samples should be taken (generally)</li> <li>(0) States that samples should not be taken</li> <li>(N/A) Does not describe the sampling process</li> </ul>	1, 8, 12, 22, 23
17. States that industry is required to follow quality assurance/quality control in regards to fortification	(2) States requirement of quality assurance/quality control for fortification (0) Does not state requirement	1, 8, 12, 22, 23
18. States applicability of using qualitative testing (e.g., spot tests, iChecks) to determine the presence or absence of a vitamin or mineral	(2) States applicability of spot test to determine presence/absence of vitamin or mineral specific to internal monitoring (1) States applicability of spot test to determine presence/absence of vitamin or mineral generally (0) Does not state	11, 21
External Monitoring (Conducted by Government)		
19. States requirement for external monitoring at the production site to assure compliance with standards and regulations	<ul><li>(2) States requirement for external monitoring or the need for audits/inspections</li><li>(0) Does not state requirement</li></ul>	1, 9, 10, 12, 15, 17, 18, 21, 22, 23
20. Describes protocols and systems for regulatory monitoring	<ul> <li>(2) Includes checklists or provides detailed description of regulatory monitoring procedures</li> <li>(1) Does not explicitly describe, but references protocols and systems for regulatory monitoring</li> <li>(0) Does not describe</li> </ul>	1, 13, 21
21. If there are two or more government agencies involved in external monitoring, clarifies the roles and responsibilities between different government agencies in external monitoring	<ul> <li>(2) Clarifies roles and responsibilities for more than one agency</li> <li>(1) Clarifies roles and responsibilities for one agency</li> <li>(0) Clarifies roles and responsibilities for no agencies</li> <li>(N/A) Only one government agency involved</li> </ul>	12, 21, 23
22. Allows for monitoring to be conducted often enough that problems can be identified and addressed on a timely basis; specifies a timeline for inspections (e.g., once every 6 months, increasing to once every 2 months if a discrepancy is found)	<ul> <li>(2) Describes frequency and how it is responsive to the needs of industry or the stage of fortification implementation</li> <li>(1) Makes mention of a timeline</li> <li>(0) Does not state</li> </ul>	1, 16, 18, 23
23. States requirement for sampling as part of external monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	<ul> <li>(2) States that samples should be taken as part of external monitoring</li> <li>(1) States that samples should be taken (generally)</li> <li>(0) States that samples should not be taken</li> <li>(N/A) Does not describe the sampling process</li> </ul>	1, 8, 12, 22, 23
24. States applicability of using qualitative testing (e.g., spot tests, iChecks) to determine the presence or absence of a vitamin or mineral	<ul> <li>(2) States applicability of spot test to determine presence/absence of vitamin or mineral specific to external monitoring</li> <li>(1) States applicability of spot test to determine presence/absence of vitamin or mineral generally</li> <li>(0) Does not state</li> </ul>	21
25. States registration is required in order to use a logo/be licensed to produce fortified foods	<ul><li>(2) Describes some type of registration or licensing</li><li>(0) Does not state that registration or licensing is required</li></ul>	17, 18

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tem	Scoring Options	References
Commercial Monitoring (Conducted by Government)		
26. Provides justification for commercial monitoring at retail stores	(2) Provides justification for commercial monitoring (0) Does not provide justification for commercial monitoring	21
27. Describes protocols and systems for commercial monitoring	<ul> <li>(2) Includes checklists or provides detailed description of commercial monitoring procedures</li> <li>(1) Does not explicitly describe, but references protocols and systems for commercial monitoring</li> <li>(0) Does not describe</li> </ul>	1, 13, 21
28. If there are two or more government agencies involved in commercial monitoring, clarifies the roles and responsibilities between different government agencies in commercial monitoring	<ul> <li>(2) Clarifies roles and responsibilities for more than one agency</li> <li>(1) Clarifies roles and responsibilities for one agency</li> <li>(0) Clarifies roles and responsibilities for no agencies</li> <li>(N/A) Only one government agency involved</li> </ul>	12, 21, 23
29. Allows for monitoring to be conducted often enough that problems at the production site or import companies can be identified and addressed on a timely basis; specifies a timeline for inspections (e.g., once every 6 months) or works with production companies to correct noncompliance	<ul> <li>(2) Describes frequency and how it is responsive to the needs of industry or the stage of fortification implementation</li> <li>(1) Makes mention of a timeline</li> <li>(0) Does not state</li> <li>(N/A) No commercial monitoring occurs</li> </ul>	1, 16, 18, 23
30. States requirement for sampling as part of commercial monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	<ul> <li>(2) States that samples should be taken as part of commercial monitoring</li> <li>(1) States that samples should be taken (generally)</li> <li>(0) States that samples should not be taken</li> <li>(N/A) Does not describe the sampling process</li> </ul>	1, 8, 12, 22, 23
Import Monitoring (Conducted by Government)		
31. Provides justification for import monitoring at points of entry	(2) Provides justification for import monitoring (0) Does not provide justification for import monitoring	21
32. Describes protocols and systems for import monitoring	<ul> <li>(2) Includes checklists or detailed description of import monitoring procedures</li> <li>(1) Does not explicitly state, but references protocols and systems for import monitoring</li> <li>(0) Does not state</li> </ul>	1, 13, 21
33. If there are two or more government agencies involved in import monitoring, clarifies the roles and responsibilities between different government agencies in import monitoring	<ul> <li>(2) Clarifies roles and responsibilities for more than one agency</li> <li>(1) Clarifies roles and responsibilities for one agency</li> <li>(0) Clarifies roles and responsibilities for no agencies</li> <li>(N/A) Only one government agency involved</li> </ul>	12, 21, 23
34. States requirement for sampling as part of import monitoring (e.g., describing number of samples, amount, frequency, individual vs. composite, where samples are taken in the process, and percent considered passing)	<ul> <li>(2) States that samples should be taken as part of import monitoring</li> <li>(1) States that samples should be taken (generally)</li> <li>(0) States that samples should not be taken</li> <li>(N/A) Does not describe the sampling process</li> </ul>	1, 8, 12, 22, 23
Enforcement/Penalties		
35. Indicates roles and responsibilities in enforcing the legislation	(2) States the role and responsibilities of government in enforcement (0) Does not state	14, 17, 22

TABLE	<ul> <li>Continued</li> </ul>
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tem	Scoring Options	References	
36. States incentives to start fortification	<ul> <li>(2) States any incentives to encourage fortification initiation (e.g., tax incentives for new equipment or premix)</li> <li>(0) Does not state</li> </ul>		
37. States incentives to continue fortification, including ensuring compliance	(2) States any incentives to encourage the continuation of fortification (e.g., transport priority, favorable tax or tariff treatment, or patent rights) (0) Does not state	13, 17, 22	
38. States penalties to compel compliance	(2) States any penalties (0) Does not state	12, 13, 14, 17, 22	
39. Penalties are objectively defined (e.g., first penalty=\$100, second penalty=\$300)	(2) Penalties are objectively laid out in the document (e.g., first penalty=\$100, second penalty=\$300) (0) Penalties are not objectively laid out (N/A) No penalties are stated (answered 0 to previous question)	10	
40. States that enforcement is required to include feedback and support to improve performance and correct noncompliance	(2) Requires any feedback/support to improve per- formance (0) Does not require	1, 10, 17, 18, 21, 23	
Laboratory			
41. References required analytical assays for nutrients (e.g., liquid chromatography-mass spectrometry for folic acid, atomic absorption for iron and zinc)	(2) References required assays (0) Does not state requirements	8	
42. States recognition that laboratory results are subject to several sources of variation and do not provide conclusive evidence of compliance or noncompliance	<ul><li>(2) States recognition that lab results are subject to variation</li><li>(0) Does not state recognition</li></ul>	21	
43. Focuses on the quantitative analysis of marker micronutrients such as iron	<ul><li>(2) Focuses on quantitative analysis of marker micronutrient such as iron</li><li>(0) Does not state</li></ul>	12, 21, 23	
Reporting			
44. States how government monitoring results are shared with stakeholders	(2) States how results are shared with stakeholders (0) Does not state how results are shared	17	

<sup>&</sup>lt;sup>a</sup> As identified in the literature and by content experts.

Africa (n=5). The majority of rice documentation was also from the Americas (67%, n=4), though the Asia and Pacific regions also contributed documentation (17%, n=1 each). The majority of documentation came from upper middle-income countries (33%, n=24) and lower middle-income countries (40%, n=29), with low-income countries contributing 13% (n=9) and high-income countries contributing 14% (n=10) of documentation (based on World Bank classification of countries by income<sup>28</sup>). Most documentation was originally in English (42%, n=30) or Spanish (35%, n=25).

On average, 46% of checklist items were fully present in reviews. When examining median scores by grain, maize flour scores were higher (58%) than rice (45%) and wheat flour (44%) scores (Figure 2). The median scores by region showed some variability, with Asia scoring the highest (63%), followed by Africa (50%), Europe (50%), the Pacific (48%), the Americas (45%), and the Middle East (17%) (Figure 3). Comparing scores by income classification, the median scores for high income (45%), upper middle-income (43%), and lower middle-income (48%) were very similar, while low-income countries had a notably higher median score (80%) (Figure 4).

Documentation for every country-grain com- items were fully bination (100%, N=72) stated the nutrients present in our required to be added through fortification (Table 2). document review.

On average, 46% of checklist

70% 58% 60% 50% 45% 44% **Median Score** 30% 20% 10% 0% Wheat flour (n=55) Maize flour (n=11) Rice (n=6) IQR: 29-60% IQR: 42-47% IQR: 45-63%

**FIGURE 2.** Median Country-Grain Combination Scores<sup>a</sup> by Cereal Grain in Countries With Mandatory Cereal-Grain Fortification

Abbreviation: IQR, interquartile range.

While 64% of country-grain combinations documented the requirement for external monitoring at the production site, only 33% provided a detailed description of the monitoring protocols and systems.

The fortification levels of those nutrients were stated by 96% of country-grain combinations; 54% stated one number, whereas 42% stated an allowable range. The majority (88%) of country-grain combinations stated at least one fortificant to be used for fortification (e.g., type of iron compound). Documentation for country-grain combinations was also relatively abundant for other general items commonly found in legislation and standards documents: stating the food vehicle to be fortified (97%), labeling as fortified food (78%), providing definitions to terms specific to fortification (76%), and providing the effective date or giving a grace period for when fortification is to begin (72%).

Documentation of monitoring procedures among country-grain combinations was less common (Table 2). About two-thirds (64%) of country-grain combinations stated that industry is required to conduct quality assurance/quality control as part of internal monitoring and 29% described the applicability of qualitative (spot) tests. Of countries that included a sampling

protocol, 71% of country-grain combinations clearly outlined a sampling process for internal monitoring. The requirement for external monitoring at the production site was documented for 64% of country-grain combinations; 33% of country-grain combinations provided a detailed description of external monitoring protocols and systems. The same pattern held for commercial and import monitoring: while 47% and 64% of country-grain combinations stated a requirement for commercial and import monitoring, respectively, 19% and 35% described the protocols for commercial and import monitoring in detail.

Similarly, 68% of country-grain combinations stated there were penalties to compel compliance, yet of these, only 31% laid out objectively defined penalties (e.g., first penalty=\$100, second penalty=\$300) (Table 2). Furthermore, only 18% of country-grain combinations stated that enforcement should include feedback and support to improve performance and correct noncompliance. Very few (14%) country-grain combinations

<sup>&</sup>lt;sup>a</sup> Country-grain combination refers to the unit of analysis; countries that mandate the fortification of multiple cereal grains will contribute more than one country-grain combination (e.g. Philippines-wheat and Philippines-rice). Scores based on number of checklist items fully documented out of total applicable checklist items.

70% 63% 60% 50% 50% 48% 50% 45% **Median Score** 40% 30% 20% 17% 10% 0% Africa **Americas** Asia Europe Middle East **Pacific** (n=3)(n=2)(n=23)(n=33)(n=7)(n=4)IQR: --IQR: 34-70% IQR: 29-58% IQR: 52-63% IQR: 38-60% IOR: 41-52%

**FIGURE 3.** Median Country-Grain Combination Scores<sup>a</sup> by Geographic Region in Countries With Mandatory Cereal-Grain Fortification

Abbreviation: IQR, interquartile range.

<sup>a</sup> Country-grain combination refers to the unit of analysis; countries that mandate the fortification of multiple cereal grains will contribute more than one country-grain combination (e.g. Philippines-wheat and Philippines-rice). Scores based on number of checklist items fully documented out of total applicable checklist items.

stated that they provide incentives to start fortification (e.g., reduction of taxes for fortification equipment) and fewer (10%) provided incentives to continue fortification (e.g., reduction of taxes for fortification premix).

Other gaps in documentation existed in regards to the cost of monitoring fortification and laboratory procedures (Table 2). For example, only 35% stated consideration of the financial responsibility of monitoring and enforcing fortification (e.g., cost of laboratory testing; explicit budget for monitoring activities). Furthermore, only 19% of country-grain combinations stated that the cost of fortification is regulated through cost-sharing schemes between government and industry or reduced taxes for fortification inputs. Regarding laboratory procedures, while 60% of country-grain combinations referenced the required analytical assays for measuring nutrients in food, only 36% of country-grain combinations focused on the quantitative analysis of a marker micronutrient(s) such as iron, which limits the amount of laboratory analysis required but accurately assesses fortification since fortificants are typically added together in premix. Even fewer (11%) explicitly recognized that laboratory results are subject to several sources of variation and do not alone provide conclusive evidence of compliance. Lastly, results showed that less than one-third (31%) stated how government monitoring results are shared with stakeholders, including consumers.

A sensitivity analysis investigated differences between reviews that were considered complete (i.e., country representatives confirmed that all relevant documents were included in the reviews) versus those that were unconfirmed in regards to completeness (Supplement Table 2). We observed few differences between the subset of 23 reviews that were confirmed by country representatives and those that were not. Differences were noted for 5 of 44 items: stating the food vehicle to be fortified, describing the sampling process for internal

Less than onethird of countrygrain combinations stated how government monitoring results are shared with stakeholders.

80% 80% 70% 60% 48% 50% 45% **Median Score** 43% 40% 30% 20% 10% 0% High Upper Middle Lower Middle Low (n=29)(n=10)(n=24)(n=9)IQR: 29-82% IQR: 35-48% IQR: 29-60% IQR: 40-58% Income Level

**FIGURE 4.** Median Country-Grain Combination Scores<sup>a</sup> by Income Level in Countries With Mandatory Cereal-Grain Fortification

Abbreviation: IQR, interquartile range.

<sup>a</sup> Country-grain combination refers to the unit of analysis; countries that mandate the fortification of multiple cereal grains will contribute more than one country-grain combination (e.g. Philippines-wheat and Philippines-rice). Scores based on number of checklist items fully documented out of total applicable checklist items.

monitoring, stating the applicability of qualitative testing in internal monitoring, clarifying roles and responsibilities in external monitoring, and requiring enforcement to include feedback to those monitored.

We identified what we considered excellent examples of each of the 44 checklist items from English-language and English-translated documents (Supplement Table 3). We compiled completed checklists for each country-grain combination, including extracted sample language from the documents reviewed (Supplement Table 4).

Most countries lack documentation around the areas that would influence product compliance to national standard.

#### DISCUSSION

To our knowledge, this is the first comprehensive review of legislation, standards, and monitoring documents for any fortified food, and specifically for fortified grains. Our study provides a standardized checklist of 44 key criteria that the literature suggests are important components of fortification legislation, standards, and monitoring documents, which was in turn employed on a global level to

systematically measure the documentation of each country-grain combination and to evaluate country policies against these criteria. We found that countries document the technical specifications for fortification, such as allowable food vehicles and nutrients required, and most document systems for internal, external, and import monitoring. However, documentation is lacking in some areas, such as describing the roles and responsibilities for monitoring between governmental agencies, providing detailed descriptions of protocols and systems for monitoring, addressing the costs of fortification and fortification monitoring, outlining enforcement strategies, and describing how government monitoring results are reported to stakeholders. Lack of documentation persisted largely around the areas that would influence product compliance to national standard, while sufficient documentation existed around areas that establish a mandatory program. This is important to highlight, as it is a more complex piece that needs to be carefully outlined (e.g., assigning clear roles and responsibilities for regulatory monitoring,

**TABLE 2.** Percentage of Country-Grain Combinations<sup>a</sup> With Documented Items in Fortification Legislation, Standards, and Monitoring Documents (N=72)

ltem	Eligible (N)	% (n) Fully Meeting	% (n) Partly Meeting	% (n) Not Meeting
General				
1. Food vehicle stated in legislation	72	97% (70)	_	3% (2)
2. Public health objective/purpose	72	69% (50)	_	31% (22)
3. Accepted international norms	72	54% (39)	-	46% (33)
4. Definitions specific to fortification	72	76% (55)	-	24% (17)
5. Repeals of prior documentation <sup>b</sup>	59	71% (42)	-	29% (17)
6. Effective date/grace period	72	72% (52)	-	28% (20)
Micronutrients/Premix				
7. Nutrients required	72	100% (72)	-	0% (0)
8. Fortificants (chemical compounds)	72	88% (63)	-	13% (9)
9. Fortification levels	72	42% (30)	54% (39)	4% (3)
10. Bioavailability of fortificants	72	31% (22)	-	69% (50)
11. Nutrient stability	72	54% (39)	-	46% (33)
Costing				
12. Cost sharing of fortification	72	19% (14)	_	81% (58)
13. Financial responsibility of monitoring and enforcement	72	35% (25)	-	65% (47)
Labeling				
14. Labeling required	72	78% (56)	-	22% (16)
15. Guidance on health claims	72	50% (36)	_	50% (36)
Internal Monitoring (conducted by industry during production)				
16. Sampling process outlined <sup>b</sup>	31	71% (22)	29% (9)	0% (0)
17. Industry QA/QC justified/required	72	64% (46)	_	36% (26)
18. Applicability of qualitative tests	72	29% (21)	1% (1)	69% (50)
External Monitoring (conducted by government at production sites)				
19. External monitoring justified	72	64% (46)	_	36% (26)
20. Protocols and systems described	72	33% (24)	28% (20)	39% (28)
21. Roles and responsibilities clarified <sup>b</sup>	56	45% (25)	7% (4)	48% (27)
22. Timeline for inspections outlined	72	26% (19)	13% (9)	61% (44)
23. Sampling process outlined <sup>b</sup>	45	67% (30)	33% (15)	0% (0)
24. Applicability of qualitative tests	72	19% (14)	1% (1)	79% (57)
25. Registration requirements	72	38% (27)	_	63% (45)
Commercial Monitoring (conducted by government at market or distribution sites)				
26. Commercial monitoring justified	72	47% (34)	_	53% (38)
27. Protocols and systems described	72	19% (14)	21% (15)	60% (43)
28. Roles and responsibilities clarified <sup>b</sup>	63	32% (20)	0% (0)	68% (43)
29. Timeline for inspections outlined <sup>b</sup>	44	14% (6)	25% (11)	61% (27)
30. Sampling process outlined <sup>b</sup>	28	71% (20)	29% (8)	0% (0)

Continued

**TABLE 2.** Continued

ltem	Eligible (N)	% (n) Fully Meeting	% (n) Partly Meeting	% (n) Not Meeting
Import Monitoring (conducted by government at ports/points of entry)				
31. Import monitoring justified	72	64% (46)	_	36% (26)
32. Protocols and systems described	72	35% (25)	26% (19)	39% (28)
33. Roles and responsibilities clarified <sup>b</sup>	59	42% (25)	2% (1)	56% (33)
34. Sampling process outlined <sup>b</sup>	29	62% (18)	38% (11)	0% (0)
Enforcement/Penalties				
35. Enforcement roles and responsibilities clarified	72	69% (50)	-	31% (22)
36. Incentives to start fortification	72	14% (10)	_	86% (62)
37. Incentives to continue fortification	72	10% (7)	-	90% (65)
38. Penalties to compel compliance	72	68% (49)	_	32% (23)
39. Penalties objectively defined <sup>b</sup>	49	31% (15)	-	69% (34)
40. Enforcement includes feedback	72	18% (13)	_	82% (59)
Laboratory				
41. Analytical methods identified	72	60% (43)	-	40% (29)
42. Recognition of laboratory variation	72	11% (8)	-	89% (64)
43. Quantitative analysis of "marker" micronutrients such as iron	72	36% (26)	-	64% (46)
Reporting				
44. Dissemination of monitoring results described	72	31% (22)	-	69% (50)

Abbreviations: QA/QC, quality assurance/quality control.

establishing detailed protocols for conducting regulatory monitoring) if a program is going to be monitored for long-term adherence and impact.<sup>7,21</sup> Given these gaps, our checklist could be used as a guide to strengthen existing documentation or assist in developing new documentation, as this would ensure important areas, such as product compliance, are outlined.

Our study found similar results as a review of legislative frameworks for corn flour and maize meal fortification. Similar to our study, Makhumula and colleagues found that legislative and standards documents commonly describe fortificants used, fortification labeling, reference analytical assays, and sampling procedures. In our review, 100% (n=11) of maize flour countries documented the fortificants to be used and 91% (n=10) of maize flour countries clearly labeled their maize flour as fortified. Of the 4 maize flour countries that stated the use of sampling

in external and import monitoring, 3 provided details on sampling procedures for external and import monitoring. The majority of maize flour countries referenced the required analytical assays for nutrients (73%, n=8) in our review. Differences observed might be because the checklist for our study was specific to fortification, whereas Makhumula and colleagues' review was not limited to fortification. In particular, this might explain any differences observed in sampling procedures and analytical assays; sampling and laboratory testing could include food safety parameters in Makhumula and colleagues' review.

One notable conclusion from Makhumula and colleagues was that countries fortifying maize flour take a variety of approaches to setting fortification levels, such as specifying the minimum amount required or an allowable range.<sup>8</sup> In our study, a slight majority (55%, n=6) of maize flour countries provide a range or a

<sup>&</sup>lt;sup>a</sup> Country-grain combination refers to the unit of analysis; countries that mandate the fortification of multiple cereal grains will contribute more than one country-grain combination (e.g., Philippines-wheat and Philippines-rice).

<sup>&</sup>lt;sup>b</sup>The number eligible differs for these items due to a "not applicable" option on the scoring checklist.

single number within an allowable range, while 45% (n=5) of countries provide a single number only. Opposing results were found for wheat flour and rice in this study: 40% (n=22) of wheat flour and 33% (n=2) of rice countries provide a range or single number within an allowable range, while 53% (n=29) of wheat flour and 67% (n=4) of rice countries provide a single number only (the remaining 7% (n=4) of wheat flour countries did not state fortification levels). These results confirm Makhumula's maize flour findings and suggest there are inconsistencies between food vehicles and countries in stating fortification levels, and clarity is needed on this issue.

A 2015 survey by Luthringer and colleagues highlights the gap between legislation, standards, and monitoring documents and barriers in the monitoring of fortified foods identified by regulatory agencies and the food industry. Gaps identified in the documentation reviewed in our study support the survey results reported by Luthringer et al. For example, when asked in the survey to prioritize regulatory monitoring elements needing improvement to ensure compliance against national fortification standards, industry respondents prioritized incentives and penalties for enforcement, both areas of weakness in the documentation reviewed in our study (only 10% of documentation stated incentives are offered to continue fortification and 21% objectively defined penalties). While incentives are rarely documented, Luthringer and colleagues' study suggests that both regulatory agency and industry respondents believed that incentives could encourage compliance with fortification regulations. Survey results also indicated that only slightly more than half of regulatory agencies report regularly sharing their data with stakeholders. In the documentation reviewed in our study, only 31% of country-grain combinations require government monitoring results to be reported. Together, these results suggest that few countries require results to be reported, while slightly more claim to report results. The benefits of a requirement to report results could be written into official documentation, compelling the reporting of results to stakeholders and creating an accountability structure. Lastly, Luthringer et al.'s study identified the lack of clarity in the roles of government authorities as a barrier to effective monitoring; our study found a similar lack of clarity in the documentation.<sup>7</sup> When two or more agencies were involved, roles and responsibilities were only clarified in 32% to 45% of documentation, dependent on monitoring type, indicating that this is an area of documentation that could be strengthened. On the whole, the opinions expressed by regulatory agency and industry respondents in the survey conducted by Luthringer et al. are confirmed by the present study. Not only do the survey respondents think that documentation is unclear but also our study confirms that documentation is generally lacking in the areas identified by the survey respondents.

While our study aligns with previous studies of fortification legislation, standards, and monitoring documents, it also highlights concerns that previous studies have not raised. <sup>7,8,10,21,23,24</sup> For instance, the majority of previous studies have not reviewed the content of monitoring documents. 7,8,10,24 Our study found that the details included in monitoring documents vary widely-some countries do not have any monitoring procedures in their dossier of documentation, while other countries have a unique manual for each type of monitoring. In particular, our study identifies the lack of documented protocols and systems in external, commercial, and import monitoring (39%, 60%, and 39%, respectively). Our study corroborates a previous study by van den Wijngaart et al. (2013)<sup>21</sup> that identified the issue of poorly established or weakly designed protocols and systems for regulatory monitoring of salt and wheat flour fortification in countries of the Association of Southeast Asian Nations (ASEAN); our study found that for the 3 types of regulatory monitoring, 21% to 28% of country-grain combinations did not explicitly describe their monitoring protocols (scored as "partly meeting"). While the van den Wijngaart et al. study and our study are in agreement about the variable quality of monitoring procedures, our study notes the complete lack of documentation. This finding emphasizes the opportunity to improve upon existing monitoring procedures and the opportunity to implement well-designed monitoring procedures for the first time. Additionally, our study shows infrequent documentation requiring qualitative (spot) tests in internal (29%) and external monitoring (19%). While it is possible that spot tests are used but not documented in monitoring procedures, this result shows an opportunity to expand the use of this simple, fast, and inexpensive method.11

# Strengths and Limitations

First, an important strength of our study is that such a comprehensive review for any cereal grain and for any fortified food has not previously been

There is a lack of documented protocols and systems in external, commercial, and import monitoring. done. Previous efforts have focused on reviewing legislation and/or standards, while few have included monitoring documents; our study included all 3 types of documents for a more complete sense of content. Furthermore, each country in our study was objectively scored using a standardized checklist of key items in official fortification legislation, standards, and monitoring documents by two separate reviewers. Other strengths of our study are the inclusion of documents from 84% of countries (68 of 81 countries) that mandated cereal-grain fortification as of January 31, 2015, regardless of the language of the document, and the examination of multiple food vehicles within the cereal-grain family. The checklist we created for this study can be used by countries as a framework for starting a new fortification program or assessing a current fortification program. An additional strength is that this methodology presents a model with which to expand this research to other food vehicles, such as salt and vegetable oils.

The main limitation of our study is the possibility of missing documentation. However, attempts were made to collect missing documentation from country representatives, and a sensitivity analysis showed few differences between those countries where country representatives confirmed documentation and those who did not. It was assumed that the knowledge of and access to documents was complete and up to date for the country representatives that were reached. Furthermore, selection bias may be an issue, as those countries that were excluded due to a lack of documentation likely have less comprehensive legislation, standards, and/or monitoring guidelines than those included. This bias may be particularly problematic when comparing scores by region, as there were 7 excluded countries from the Middle East region (78% of countries in the region), 5 from Africa (22%), and 1 from Asia (25%). It is possible that some details were lost in the translation of the documents into English from some languages, but few documents were not already in English or Spanish. Furthermore, it is possible that the checklist was incomplete and did not include some important items that countries prioritize in their documents. However, this risk is low and was mitigated through an inclusive process of listing, refining, and prioritizing the items by considering the existing literature, expert opinion, and through pilot testing for other items that were in reviewed documents. Lastly, our study only addresses documentation, not implementation; while it seems plausible that countries with good documentation also have good implementation of that documentation (and vice-versa), our study did not address implementation of the documentation reviewed.

#### CONCLUSION

In conclusion, our comprehensive review of 72 country-grain combinations found that the majority adequately document the required food vehicles, nutrients, and amounts of fortificants for fortification. Most countries have documented justification of the need for monitoring, but detailed protocols, roles and responsibilities for monitoring between agencies, and systems are not well defined. Furthermore, few countries document strategies for paying for the cost of fortification or alleviating the burden on industry through tax exemption or other economic incentives, which can be important in ensuring the sustainability and success of a fortification program. By identifying areas that are often weak or absent in legislation, standards, and monitoring documents, countries with existing mandatory fortification can improve upon these items in revisions to their documents, while countries that are new to fortification will have a better sense of what to include in their policies and programs from the beginning.

Going forward, this study's checklist can be used by many stakeholders. The in-country representatives of private, civic, and public sectors who oversee fortification activities can use the checklist to assess and revise the documents that guide their country's programs. Organizations that provide technical assistance to countries can use the checklist to find common themes across countries and offer technical assistance through regional workshops, for example, or targeted technical assistance based on countries' specific needs.

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# FIELD ACTION REPORT

# High-Risk Advanced Maternal Age and High Parity Pregnancy: Tackling a Neglected Need Through Formative Research and Action

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Harmful social norms and lack of knowledge contribute to risky pregnancies in older and high-parity women in low- and middle-income countries. A social and behavior change communication resource combining technical guidance with tangible client and provider materials was designed to address and prevent such pregnancies in Niger and Togo.

Résumé en français à la fin de l'article.

# ABSTRACT

Pregnancy among women of advanced maternal age (those 35 years or older) or among women of high parity (those having had 5 or more births) is linked to maternal and infant mortality. Yet little is known about the drivers of these pregnancies as they are often neglected in existing family planning and reproductive health programs. To better understand the context in which advanced maternal age and high parity pregnancies occur and the acceptability of discussing associated pregnancy risks, the Health Communication Capacity Collaborative (HC3) conducted formative qualitative research between January and March 2015 on the perception and determinants of such pregnancies in rural and urban areas of Niger and Togo. We supplemented this research with secondary analyses of data from Demographic and Health Surveys and a 2014 Niger survey. Our formative research showed that urban Togolese participants demonstrated more knowledge about advanced maternal age and high parity pregnancy risks than did participants in Niger as a whole. We found that such pregnancies were generally seen as part of reproductive norms in situations where fertility rates remain exceptionally high, especially in Niger. Social, gender, and religious norms, including competition between co-wives, also drove women into high parity and advanced maternal age situations, particularly in Niger, highlighting the need to bring men and community and religious leaders into family planning conversations to increase acceptance. The study also provided important insights needed to address these high-risk pregnancies through culturally appropriate health communication interventions. A main insight was that providers often had incomplete information about advanced maternal age and high parity pregnancies and lacked communication skills, protocols, and tools to appropriately discuss such pregnancy risks with clients. HC3 used these and additional findings to create an Implementation Kit (I-Kit) for family planning and maternal and child health program managers with guidance and tangible tools to address advanced maternal age and high parity pregnancy through social and behavior change communication. The I-Kit includes health communication materials to engage women, men, decision makers, communities, health care providers, journalists, and others. In 2016 and 2017, one organization each in Niger and Togo piloted the I-Kit, integrated selected I-Kit tools into their unique programs, and documented their experiences. Both organizations credited the I-Kit with expanding the scope of their programs to now address advanced maternal age and high parity pregnancy and provided concrete suggestions for adapting the materials according to activity and intended audience.

#### INTRODUCTION

Pamily planning remains a key aspect of the global health agenda. Following a decline in global funding in the late 2000s, family planning has regained momentum and international attention in recent years. This funding resurgence has been coupled with renewed governmental commitments and global advocacy. For

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example, building upon the 2012 London Summit on Family Planning, the Family Planning 2020 (FP2020) movement was established to champion global advocacy and drive country-level support for family planning. Furthermore, while Goal 3 of the Sustainable Develop-ment Goals (SDGs) includes a specific target to "ensure universal access to sexual and reproductive health services, including for family planning,"2 the argument has also been made that investing in family planning will accelerate achievement across all 5 SDG themes.3

While these efforts have increased family planning programs in developing countries, there remain distinct neglected needs, risk factors, and population segments. For example, while much attention is given to preventing pregnancy among women before age 18, increasing voluntary contraceptive uptake, and establishing healthy spacing intervals between pregnancies, 4-6 less focus is typically placed on addressing pregnancies among women of advanced maternal age (those 35 years or older) or high parity (having had 5 or more births)—even though these pregnancies are high risk and linked to maternal and infant mortality.

Advanced maternal age and high parity pregnancies are prevalent in sub-Saharan African countries where parity rates are high and childbearing often continues until menopause.<sup>7</sup> A 29-country study found that advanced maternal age pregnancies "significantly increased the risk of maternal adverse outcomes, including MNM [maternal near miss], MD [maternal death], and SMO [severe maternal outcome], as well as the risk of stillbirths and perinatal mortalities."8 "Maternal near miss" refers to cases "in which women present potentially fatal complications during pregnancy, delivery or during the puerperium, and who survive merely by chance or by good hospital care." High parity complications include anemia in the mother, postpartum hemorrhage, and fetal malpresentation. It is important to also consider that a high parity pregnant mother may also be of advanced maternal age, and hence her risks are compounded—and may be made graver still if her pregnancies are spaced too closely.

A review of the literature shows that while advanced maternal age- and high parity-specific research exists, much is from high-income settings in the West. Only a few studies from sub-Saharan Africa exist, 10,11 and most of this work focuses on establishing risks with little to no research on knowledge, attitudes, and behaviors relating to such pregnancy. 12 Understanding how a country's culture and context influence individuals' and communities' beliefs and practices relating to these pregnancies is also crucial in developing effective interventions to address them.

Given the risks and region-specific information gaps, the Health Communication Capacity Collaborative (HC3) project of the Johns Hopkins Center for Communication Programs conducted formative research and created and piloted a Healthy Timing and Spacing of Pregnancies: Addressing Advanced Maternal Age and High Parity in Family Planning Programs Implementation Kit (I-Kit) (https://sbccimplementationkits. org/htsp/) to help program managers address these high-risk pregnancies in their programs using social and behavior change communication. high parity.

**Family planning** programs typically place less attention on addressing pregnancies among women of advanced maternal age or

#### RESEARCH GOALS AND OBJECTIVES

To understand what drives these high-risk pregnancies, we conducted formative research in 2 countries with considerable advanced maternal age and high parity rates: Niger and Togo. The countries represent 2 different contexts. Niger, with a largely Muslim population, generally has more conservative social and religious norms and a larger rural population than Togo, and women in Niger desire more children than they have. This is the opposite of the situation in Togo (Table 1).

We focused on Niger and Togo for several reasons. First, for more than a decade, Niger has had the highest total fertility rate in the world, currently at 7.6—an increase from 7.0 and 7.2 in past Demographic and Health Survey (DHS) reports. 13 On average, women in urban Niger think having 7.4 children is ideal while their rural counterparts aspire to have 9.6 children. The mean ideal number of children for women in Niger has increased over the years, from 8.2 in 1992 to 9.2 in 2012. 14 Although Togo's fertility rate is lower than Niger's and is showing a steady decrease from 6.4 over the past 25 years, Togo's most recent total fertility rate of 4.8 still demonstrates high parity risk for women in the country, especially in rural areas.<sup>14</sup> Women in Togo have on average 3.7 children in urban areas and 5.7 in rural locations, and in both urban and rural areas women say their ideal number of children is fewer than the actual number of children they have, at 3.6 and 4.9, respectively. 15 The mean ideal number of children for women in Togo has decreased over the years, from 5.3 in 1988 to 4.3 in 2013/2014. 14 Per each country's most recent DHS, 43% and 22% of women had 5 or more births in Niger and Togo, respectively

**TABLE 1.** Key Indicators for Niger and Togo

	Niger	Togo
Urban population (% of population living in urban areas)	18%	40%
Polygamy (% of married women in polygamous marriage)	36%	32%
Total fertility rate	7.6	4.8
Urban	5.6	3.7
Rural	8.1	5.7
Ideal number of children (among women)	9.2	4.3
Urban	7.4	3.6
Rural	9.6	4.9
Advanced maternal age (% of all women 35–49 who had a child at 35 years or older)	60%	46%
High parity (% of all women who had 5 or more births)	43%	22%

Source: Enquête Démographique et de Santé et à Indicateurs Multiples du Niger 2012<sup>13</sup>; Enquête Démographique et de Santé au Togo 2013–2014. <sup>15</sup>

(Table 1). These same reports show the ideal number of children is higher among men than women in each country: currently married men in Niger desire 12.4 children, and in Togo, 5.4 children. This, too, has been increasing in Niger and decreasing in Togo over the past 25 years. High fertility rates and high parity status are also coupled with early childbearing in both countries, which carries with it its own significant maternal and infant morbidity and mortality risks. Early childbearing is more common in Niger, where 40.4% of women ages 15 to 19 are mothers or pregnant with their first child. This statistic is much lower in Togo, where 16.5% of women between ages 15 and 19 have begun childbearing.14

Another reason we focused on Niger and Togo is that both countries have critical family planning needs. Contraceptive use is relatively low in both Niger (14% of married women)<sup>13</sup> and Togo (20% of married women). 15 In Niger, the percentage of women with an unmet need for modern contraceptive methods has increased over the past 5 years from 18.7% to 20.8%; 41.9% of women's demand is satisfied with a modern contraceptive method. 16 In Togo, 34.6% of women have an unmet need for a modern method of family planning—a rate that has decreased over the past 5 years, and 40.9% of women's family planning demand is satisfied with a modern method.<sup>17</sup> Advanced maternal age is particularly common in both countries. According to each country's most recent DHS, 60% of women in Niger and 46% of women in Togo had a child at age 35 or older. <sup>13,15</sup>

Finally, both countries have NGO and government support for family planning programs. In addition to being FP2020 focus countries, both Niger and Togo are members of the Ouagadougou Partnership. The Government of Niger has committed to increase the contraceptive prevalence rate to 50% in 2020, from 10.8% in 2012. The Niger government plans to achieve this by increasing contraceptive availability (e.g., through mobile and community-based distribution), strengthening demand for family planning methods and services (e.g., through social marketing and information and education communication efforts), and creating a more favorable family planning environment through policy and other structural efforts. 18 The Government of Togo has committed to increase contraceptive prevalence to 35.5% in 2022, primarily by creating demand for family planning, increasing availability of and access to services, strengthening contraceptive commodity procurement to avoid stock-outs, and creating an enabling finance and policy environment.<sup>19</sup> The contraceptive prevalence rate in Togo has increased from 13.2% in 2012 to 23.2% in 2017, which was the highest prevalence among all 9 Ouagadougou Partnership countries.<sup>20</sup>

The overall goals of the formative research were to: (1) understand the knowledge, attitudes, and behaviors that contribute to advanced maternal age and high parity pregnancy incidence/ prevalence, and (2) understand how the findings

could be used to improve maternal and child health and family planning programs through a pilot intervention focused on social and behavior change communication.

# METHODS

The formative, qualitative research took place between January and March 2015 in 1 urban and 2 rural locations in Niger and Togo (Table 2). The selection of study sites was based on several factors including fertility rate, prevalence of advanced maternal age pregnancies, cultural diversity, and level of contraceptive use as well as accessibility from the capital. Selecting sites closer to capital cities is one limitation of the study, as knowledge, attitudes, and behaviors prevalent among populations living near a capital city may not be representative of those of more remote communities. Further, participants in each site were presumed to live in each location, rather than having traveled to research sites to participate in the study. As such, findings should be interpreted as specific to populations living in each site and cannot be assumed to be representative of prevailing knowledge, attitudes, and behaviors throughout each country.

In Niger, we conducted the study in Niamey (urban), Koygoro (rural), and Mokko (rural) in the Dosso region, which is approximately 130 km from the capital city of Niamey. Villages in the north of the Dosso region were selected due to safety concerns. In Togo, we conducted the study



A woman in West Africa with her 6 children. High parity pregnancies can lead to complications including anemia in the mother, postpartum hemorrhage, and fetal malpresentation. © 2014 Dieneba Ouedraogo.

in Lomé (urban), Aouda (rural), and Adjengre (rural) in the Plateaux region, located 169 km from the capital Lomé. This region was chosen because of its mix of religions (Muslim, Christian, and indigenous religions). We conducted focus group discussions, case studies, and in-depth interviews with 285 (174 female, 111 male) health care service providers, women of advanced maternal age and/or high parity, male partners of

**TABLE 2.** Number of Participants (and Groups) by Qualitative Research Method and Location

	Niger				Togo			
	Niamey (urban)	Koygoro (rural)	Mokko (rural)	Lomé (urban)	Aouda (rural)	Adjengre (rural)	Total	
Focus group discussions								
Women	36 (4)	8 (1)	8 (1)	31 (4)	19 (2)	25 (2)	127 (14)	
Male partners	24 (3)	8 (1)	8 (1)	25 (3)	8 (1)	9 (1)	82 (10)	
Mixed (men and women)	8 (1)	_	-	8 (1)	-	_	16 (2)	
Case studies	2	1	1	2	1	1	8	
In-depth interviews								
Service providers	3	2	1	3	2	2	13	
Couples	8 (4)	4 (2)	4 (2)	4 (2)	4 (2)	4 (2)	28 (14)	
Community leaders	2	2	1	2	2	2	11	
Total							285	

women in these risk categories, and community leaders. In each study site:

- Focus group discussions were conducted with women of advanced maternal age and/or high parity and with male partners of women in these risk categories to gather data about collective perceptions and attitudes that influence choices about reproduction, particularly advanced maternal age and/or high parity pregnancies.
- Case studies were collected from individual women of advanced maternal age and/or high parity who had difficult pregnancies or deliveries. These histories highlighted knowledge and attitudes of these women about risks with such pregnancies and how these impacted their pregnancies and deliveries.
- **In-depth interviews** were conducted with:
  - Advanced maternal age and high parity couples to understand how marriage, gender dynamics, and individual, cultural, economic, and other factors impacted fertility desires and reproductive health decision making regarding advanced maternal age and high parity pregnancies.
  - Maternal and infant health service providers to understand their perception and knowledge of advanced maternal age and high parity pregnancies, and how they communicated with their clients about these types of pregnancies.
  - Community leaders to understand their maternal health and family planning perspectives, as well as their view of advanced maternal age and/or high parity pregnancies.

We supplemented the qualitative research with data from the "Customer Insights Research for Family Planning Demand Generation in Niger," a nationwide survey of 2,000 women between the ages of 15 and 49, conducted in 2014 by Hope Consulting (which merged with SwitchPoint to form Camber Collective in July 2015).<sup>21</sup> We analyzed a subset of this survey data, the responses of the advanced maternal age and high parity women (n=760), to examine specific knowledge, attitudes, and behaviors related to advanced maternal age and high parity pregnancies. In this article, we refer to this subset analysis as the Niger survey. Additionally, we performed secondary analyses on select DHS indicators from Niger<sup>13</sup> and Togo.<sup>15</sup>

Participants in Niger recognized pregnancy as a perilous situation for women but did not perceive age or parity to compound the risk. The research protocol was approved by the Johns Hopkins University Institutional Review Board (IRB) and by local IRBs in Niger and Togo. We conducted focus group discussions and in-depth interviews in Zharma and Hausa languages in Niger and in Mina and Kabiye languages in Togo; all were recorded and transcribed in the field into French. A resource person (often the main facilitator who spoke the language in which the interview was conducted) checked and evaluated the transcripts. Finally, we conducted content analysis using Microsoft Word and coded responses thematically.

# FINDINGS

# Perceived Prevalence of Advanced Maternal Age and High Parity Pregnancies

Participants in both rural and urban Niger believed advanced maternal age pregnancies were common in their communities. In Togo, responses were mixed; while most viewed such pregnancies as a "rural problem." others reported they were also prevalent in cities.

In Niger, most participants reported high parity was common in both urban and rural settings. One man from urban Niger explained in an in-depth interview:

Personally, 5 children is good. But if God arranged for us to have more, that would not be a problem.

The Niger survey confirmed the participants' perceptions that high parity was common, showing 42% of women between the ages of 15 and 49 in a relationship at the time of the survey were high parity. Among these, 71% said they wanted more children. In Togo, participants generally acknowledged the high number of high parity pregnancies in their country, but were divided about high parity pregnancy frequency in urban areas.

# **Risk Perceptions**

In Niger, participants saw pregnancy itself as a perilous situation for women but did not perceive age or parity to compound the risk. Those who did associate dangers with advanced maternal age and high parity pregnancies did so generally, and referred mostly to the death of the mother and, secondarily, to that of the baby. These 2 risks were perceived as the most common and the most serious. Togo participants were somewhat more aware of age- and parity-related risks and were also concerned about advanced maternal

age and high parity women dying as a result of pregnancies. They mentioned infant mortality, the likelihood of genetic defects, and even social consequences of such pregnancies.

# **Religious Beliefs and Cultural Norms**

We found that religious beliefs contributed to advanced maternal age and high parity pregnancy, particularly among Muslim participants in both countries, and more prominently in Niger than in Togo. Many believed Islam forbids any interference with reproduction and mandates that women have the number of children "God gave them," regardless of their desired fertility. Religion was scarcely mentioned as a factor among non-Muslim participants.

In both countries, male and female participants reported an unfavorable cultural norm toward limiting births or did not feel it was their place to prevent births. These norms were stronger in Niger and in rural Togo. One man from urban Niger, who did not use family planning, explained:

Really it's not good to limit births to 3, 4, or 5 children. It's not our culture. So those of us who have 4 wives—and if we only want 4 children? So every woman will stop after a single child? (Hum!) In any case, we would like every woman to have 16 children . . . . Really, [limiting births] is not normal, [and] not just in Niger.

# **Perceived Benefits of Large Families**

In Niger, and to a lesser extent in Togo, participants felt having a large family helped them to be perceived positively and as "blessed by God" in their community. Participants also felt that having more children added to a family's monetary wealth, ensuring that parents would be cared for in their old age. Finally, participants in both countries favored large families because of perceived high infant mortality rates; the thought is to give birth to many children in the hopes of always having some children should others succumb to illness or death. According to each country's DHS, however, infant mortality rates have decreased sizably from 123 per 1,000 live births in 1998 to 51 in 2012 in Niger, and from 80 in 1998 to 49 in 2013/ 2014 in Togo. 14 In comparison, fertility rates in Niger increased from 7.2 to 7.6 between 1998 and 2012, and have dropped only slightly in Togo from 5.2 to 4.8 between 1998 and 2013/2014. In urban Togo, we did see evidence that norms are shifting toward acceptance of and desire for using family planning to have smaller families.

# Role of Polygamy, Early Marriage, and Marital Instability

More common in Niger than in Togo, our research revealed women in polygamous situations feared real consequences if they had too few children—fears that some men confirmed. One man from urban Togo explained in a focus group discussion:

If you do not want to raise your hands to implore God because your husband wants to take another wife, you must agree to lift your legs. Yes, if the woman wants to close her legs instead of providing all the children she can have, the man will want to take a second wife. If she doesn't want him to take a second wife, she is forced to open her legs. That's why instead of raised hands "alolédji" it's instead lifted legs "afolédji," you see?

Having many children therefore served to (1) prevent the husband from attempting to take another wife or (2) have a competitive edge over co-wives for the husband's attention, resources, and eventual social status and inheritance should the husband die.

Niger has the highest rate of child marriage in the world, with 76% of girls marrying by age 18, <sup>22</sup> and DHS lists the median age at first marriage at 16. In Togo, 22% of girls are married by age 18, <sup>23</sup> and the median age at first marriage per the DHS is 20. In both countries, our research showed early entry into a relationship increased the number of children a woman had when limiting births was not allowed. Once married, women lacked acceptable grounds to delay childbearing. In addition to early marriage, participants reported that divorce and remarriage also put women in circumstances where, regardless of age or parity, they had to provide children to their new spouse.

# **Health Care Provider Practices**

Interviews with maternal and infant health care professionals in both countries revealed inconsistent and unstructured communication with clients about advanced maternal age and high parity pregnancy risks. Providers had low or very general knowledge about age- and parityrelated complications, though knowledge levels were acceptable among midwives compared with community health workers and other lower-level cadre providers, who demonstrated a poor understanding of advanced maternal age and high parity pregnancy risks. Further, providers reported that no guidelines existed on when or how to discuss advanced maternal age and high parity pregnancy with clients, and lamented a lack of materials to support such counseling. Finally, providers

Participants in Niger and Togo favored large families because of perceived infant mortality rates, yet infant mortality has decreased sizably in both countries.

Providers in Niger and Togo had low or very general knowledge about age- and parityrelated pregnancy complications. seemed to lack the skills needed to communicate risk in culturally appropriate ways. This sometimes led clients to fear or mistrust providers. One service provider in rural Togo told of a particular health center where women no longer wanted to visit. Women believed that when a particular midwife at the facility discussed potential pregnancy complications with women, she was wishing misfortune on them, which would then surely come true.

# PROGRAMMATIC IMPLICATIONS

Overall, the study showed that urban locations had more accepting cultural norms about family planning use compared with rural locations and that urban participants in Togo demonstrated more knowledge about advanced maternal age and high parity pregnancy risks than Niger participants as a whole. We found such pregnancies are generally seen as part of reproductive norms, and limiting is forbidden in contexts where fertility rates remain exceptionally high, such as in Niger. In some urban settings, however, particularly in Togo, these norms were shifting as some "positive deviant" men and women were recognizing the social, health, and economic value of planning pregnancies and having smaller families. Pregnancy risks, such as the death of the mother or the child, were key fears among men and women in both countries. In Togo, these were already understood by some to be elevated risks in advanced maternal age and high parity pregnancy. However, these risks were inconsistently or poorly communicated at the service delivery level.

Health communication is an indispensable tool for increasing understanding about advanced maternal age and high parity pregnancy prevalence and risks, and it is key to catalyzing improved behaviors and strengthening existing family planning programs. The study findings suggest clear opportunities to:

 Advocate for addressing advanced maternal age and high parity pregnancy risks in national health agendas and developing data-driven, comprehensive communication strategies accordingly. Such strategies and associated messaging should be designed to address a country's specific context—for example, according to attitudes about spacing and limiting pregnancies, prevailing marriage dynamics (such as polygamy), and prevalence of advanced maternal age compared with high parity. Increase capacity among providers who interact with clients on maternal and child health and family planning matters, including community health workers, midwives, and facility-based providers, to communicate advanced maternal age and high parity pregnancy risks by improving counseling and clinical skills during pre- and in-service trainings.

- Include advanced maternal age and high parity pregnancy information in maternal, newborn, and child health programs, including child health and immunization visits, and in family planning programs, including postpartum family planning programs. This way, programs can better reach clients at a time when they may be thinking about current family size and a future pregnancy, or family health, respectively.
- Work with local organizations and structures, including religious leaders, to develop community-centered programs that address social, religious, and cultural norms that perpetuate advanced maternal age and high parity pregnancy (e.g., polygamy and early marriage), and emphasize positive, existing norms (e.g., prioritizing the health of the mother and spacing births) through proven communication strategies.
- Engage male partners (e.g., through counseling and community activities) to understand advanced maternal age and high parity pregnancy risks and help prevent such pregnancies in their households, where strict gender roles elevate men as family planning decision makers.
- Develop health communication tools specific to advanced maternal age and high parity pregnancy for women's health gatekeepers to promote awareness, change attitudes (e.g., regarding risk factors, modern contraceptive methods, and the decline in infant mortality), and catalyze lifesaving behavior change among key audiences.

### TURNING RESEARCH INTO PRACTICE

With many of these implications in mind, we created the Healthy Timing and Spacing of Pregnancies I-Kit, focused exclusively on addressing advanced maternal age and high parity pregnancy risks. The I-Kit is adaptable, with source files (in Microsoft Word, InDesign, etc.) available upon request. The I-Kit is designed to save program managers the time and money of creating materials on advanced maternal age and high

We developed the Healthy Timing and Spacing of Pregnancies Implementation Kit to address advanced maternal age and high parity pregnancy risks.

parity from scratch and to enable them to expand their projects' breadth and impact by including communication activities on such pregnancies in their existing family planning and maternal and child health work. The I-Kit is grounded in the formative research findings described in this article, and includes a guide for program managers that explains how to integrate risk information, key messages, and calls to action into existing relevant projects using social and behavior change communication theories and processes. It also includes a collection of ready-to-use or adaptable health communication tools including client brochures, a community mobilization guide, counseling assessment guides, a provider poster, a guide for researchers, a guide for journalists, and infographics.

In 2015, the I-Kit was pretested in Niger and Togo with advanced maternal age and high parity women, male partners, community and facility health workers, journalists, program implementers, and other NGO and government representatives to gauge the materials' clarity, cultural appropriateness, and usefulness. We conducted focus groups, working sessions, user observations, and interviews. Based on participant feedback, we revised resources to trim text, add or adjust images for more conservative audiences, and adjusted translations to use preferred and more common or regionally acceptable terminology. We also expanded certain resources to be more inclusive of men, youth, religious leaders, community health workers, and TV and print (rather than just radio) journalists. The I-Kit was finalized in 2016. We then contracted with Marie Stopes International (MSI) in Niger and the Association Togolaise pour le Bien-Être Familiale (ATBEF) in Togo to pilot selected I-Kit elements and tools and identify opportunities to adapt the I-Kit's materials based on on-the-ground use.

MSI, active in Niger since 2013, provides quality reproductive health services in and around Maradi, Niamey, and Tillaberi. MSI operates primarily through its Niamey clinic and a series of mobile outreach workers, including mobile clinic teams, social mobilization agents, and community-based promoters. ATBEF is a member of the International Planned Parenthood Federation and has been delivering sexual and reproductive health services throughout Togo since 1975. ATBEF operates through 5 clinics, 2 mobile teams, and a cadre of community health workers.

To prepare for the pilot, each organization reviewed the entire I-Kit and chose specific tools to incorporate into existing project activities to share advanced maternal age and high parity information with their clients and communities. Table 3 outlines each organization's selections and their implementation periods, which ranged from 4 to 7 months based on each organization's staff availability and activity schedules. We provided modest financial support and delivered technical assistance via phone, Skype, and email. The technical assistance culminated with 1 inperson country visit each. Time and financial The resources allowed each organization to print, organize trainings, and disseminate the I-Kit materials as is, and we asked that MSI-Niger and ATBEF follow each material's use closely, documenting successes and challenges along the way.

Both MSI and ATBEF initiated the pilot by holding a staff and stakeholder workshop to review the program manager guide, and orient their teams on advanced maternal age and high parity pregnancy, why it should be a priority, and how to address it through social and behavior change communication. These types of communication activities were somewhat new to both organizations, arguably more so to ATBEF. Despite this initial challenge—surmounted through virtual technical support sessions and additional French-language social and behavior change communication references—each organization successfully employed the I-Kit tools into their work.

Overall, MSI reached 12,757 women and men with the pilot activities through mobile clinic outreach, community discussions, individual counseling, and workshops with journalists. ATBEF reached 3,337 individuals through client counseling and community education sessions and provider and community health worker training sessions. These numbers are impressive both considering the short implementation period, but particularly when considering that for most, if not all, beneficiaries, this was the first time receiving complete and correct information about advanced maternal age and high parity pregnancy risks (Supplements 1 and 2).

Specific achievements in Niger included 2 news stories, one each on local television and print outlets, spurred by a workshop with radio, TV, and print journalists on reporting on bringing advanced maternal age and high parity into focus in Niger. Other workshop participants expressed interest reporting on the topic, noting advanced maternal age and high parity presented a new avenue for inquiry and mass sensitization. The I-Kit also helped MSI providers expand the topics they

The Implementation Kit was pretested in Niger and Togo with women, male partners, community and facility health workers, journalists, program implementers, and other NGO and government representatives.

**TABLE 3.** Healthy Timing and Spacing of Pregnancies I-Kit Elements Implemented by Pilot Partner Organizations and Time Period of Each Pilot

MSI-Niger July to October 2016	ATBEF September 2016 to March 2017				
Implementation manual for program managers	Implementation manual for program managers				
Client brochure for more conservative audiences	Client brochure for less conservative audiences				
Counseling and assessment guide for providers	Counseling and assessment guide for providers				
Counseling and assessment guide for community health workers	Counseling and assessment guide for community health workers				
Reminder poster for facility-based providers	Reminder poster for facility-based providers				
Journalist guide	Infographics for policy and decision makers				

Abbreviations: ATBEF, Association Togolaise pour le Bien-Être Familiale; I-Kit, Implementation Kit; MSI, Marie Stopes International.

discuss with their clients. Because of the pilot, MSI reports they now integrate advanced maternal age and high parity into their provider and outreach trainings and daily outreach activities and are able to better tailor their reproductive health counseling to their at-risk clients. MSI mobile health agents and community-based health workers now inform their communities about advanced maternal age and high parity pregnancy risks and how to avoid or address them. The organization also shared the I-Kit with public-sector maternal and child health care providers to use and distribute.

In Togo, ATBEF providers found the I-Kit provider poster summarizing key counseling steps particularly salient and the infographic highlighting the urgency of addressing advanced maternal age and high parity to be useful in their community and group education sessions. ATBEF community health workers regularly rotate their discussion topics in community conversations; because of the I-Kit, they now include advanced maternal age and high parity pregnancy risks in that rotation. They found discussing the risks led women to share with others their personal experience with pregnancy or birth complications, realizing for the first time that age or parity may have played a role. Communities have been so receptive to the information and messages that ATBEF now includes advanced maternal age and high parity pregnancy risk information in all of its community health worker trainings. Clients participating in pilot activities even suggested that advanced maternal age and high parity information be shared in all communities and health facilities.

While the pilot was successful in producing adapted materials for use by each organization within their respective country, it did not allow for each material to be revised and reproduced, nor for data collection to measure actual behavior change among priority audiences. The pilot does, however, highlight lessons learned and recommendations on how MSI, ATBEF, and other similar organizations might adapt and prepare to use the I-Kit moving forward. Among them:

- Create more image-centered materials for low-literacy clients. While literacy is often higher in urban areas, rates are lower in smaller villages where advanced maternal age and high parity might be more prevalent. Replacing text with pictures of advanced maternal age and high parity complications would help non-literate clients to better retain necessary information.
- Develop materials for delivering messages to large groups. I-Kit materials, such as the counseling guides, infographics, and client brochures, were developed with one-to-one interactions in mind. Because much of MSI's and ATBEF's work involves community outreach and education sessions, they had a difficult time converting the counseling guides into a group discussion format. Creating a flip chart from these materials could be a worthwhile effort for organizations with similar portfolios.
- Emphasize managing and planning to reduce advanced maternal age and high parity risks, rather than solely avoiding

Communities in
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Implementation
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such types of pregnancies. Participants in Niger especially questioned that 5 children was too many, and participants in both countries had difficulty accepting age 35 as an age to slow or stop childbearing. While the current I-Kit materials include information on the importance of seeking antenatal care and attended delivery for advanced maternal age and high parity pregnancy, they also encourage women to plan early to avoid having 5 or more children, or having children at age 35 or older. Any discussion of limiting childbearing is typically rejected in Niger. In such cases, adapted materials could more strongly emphasize recognizing and managing advanced maternal age and high parity pregnancy risks over outright pregnancy avoidance. Conversely, some women in urban Togo expressed desires to intentionally delay children to first pursue career and education goals. Here, tailoring materials to speak to younger womenperhaps university-aged—could help clients identify when they want to start or grow their families to avoid advanced maternal age pregnancy risks in the future.

- Allow time for practice using new materials. Both MSI and ATBEF implementers found the counseling guides replete with new or technical information, which was difficult to remember and assimilate at first. However, with practice, this information can become second nature. Both organizations appreciated the need to truly take the time to internalize the guides and practice with them to allow bettertailored counseling for clients.
- Develop materials for men and revise terminology. Especially in Niger, it was recommended that men and religious leaders be brought more into conversations about advanced maternal age and high parity pregnancy and family planning use. The I-Kit's brochures and counseling guides include men as secondary audiences and a guide for working with community-based groups highlights the importance of working with religious leaders. However, because these 2 groups are often family planning influencers or decision makers in pronatalist and conservative contexts such as Niger, developing modified counseling guides and brochures could more effectively engage them in conversation, involve them in changing harmful norms, and catalyze individual and community behavior change.

# CONCLUSION

Our qualitative research and the Niger survey revealed that advanced maternal age and high parity pregnancies are linked to strong contextual and cultural factors in both Niger and Togo, and that family planning programs often do not sufficiently address the critical risks associated with pregnancies among women 35 years and older or those with 5 or more births. As shown in the Niger and Togo pilots, HC3's Healthy Timing and Spacing of Pregnancies I-Kit is a unique resource for governments, communities, service providers, women, and couples to learn and better communicate about advanced maternal age and high parity pregnancy dangers, and can provide the foundation for constructive change in beliefs, knowledge, and attitudes that perpetuate these risky pregnancies.

Since the I-Kit's launch, 2 additional projects (one in Cameroon, the other spanning multiple Latin American countries) have expressed interest in using the I-Kit in their context. Our pilot and adaptation activities, as well as these requests to use the materials, show that while discussing advanced maternal age and high parity pregnancy risks can be sensitive due to social and cultural taboos regarding birth limiting and modern contraceptive use, there is undeniable receptiveness to addressing these pregnancies in low- and middle-income countries. These opportunities should not be ignored and must be instead fanned as sparks to a momentous fire for action and constructive change.

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#### En français

#### L'âge maternel avancé à haut risque et la grossesse à parité élevée : s'attaquer à un besoin négligé par la recherche formative et l'action

Des normes sociales néfastes et le manque de connaissances contribuent aux grossesses à risque chez les femmes âgées et à haute parité dans les pays à revenu faible et intermédiaire. Une ressource de communication pour le changement social et de comportement combinant des conseils techniques avec du matériel tangible pour les clients et les prestataires a été conçue pour traiter et prévenir de telles grossesses au Niger et au Togo.

## RÉSUMÉ

La grossesse chez les femmes d'âge maternel avancé (35 ans ou plus) ou chez les femmes de grande parité (celles ayant eu 5 naissances ou plus) est liée à la mortalité maternelle et infantile. Pourtant, on sait peu de choses sur les causes de ces grossesses, car elles sont souvent négligées dans les programmes existants de planification familiale et de santé reproductive. Pour mieux comprendre le contexte dans lequel se produisent des grossesses chez les femmes d'âge avancé et de parité élevée et l'acceptabilité de discuter des risques associés, le Health Communication Capacity Collaborative (HC3) a mené une recherche qualitative formative entre janvier et mars 2015 sur la perception et les déterminants de ces grossesses dans les zones rurales et urbaines du Niger et du Togo. Nous avons complété cette recherche par des analyses secondaires de données provenant des Enquêtes Démographiques et de Santé et d'une enquête menée au Niger en 2014. Notre recherche formative a montré que les participants togolais urbains ont démontré plus de connaissances des risques de la grossesses à l'âge maternel avancé et à parité élevée que les participants au Niger dans son ensemble. Nous avons constaté que ces grossesses étaient généralement considérées comme faisant partie des normes de reproduction dans les situations où les taux de fécondité restent exceptionnellement élevés, en particulier au Niger. Les normes sociales, religieuses et de genre, y compris la compétition entre coépouses, ont également conduit les femmes à des situations de parité élevée et d'âge maternel avancé, notamment au Niger, soulignant la nécessité d'intégrer les hommes et les leaders communautaires et religieux dans les discussions de planification familiale afin d'accroître son acceptation. L'étude a également fourni des informations importantes nécessaires pour traiter ces grossesses à haut risque à travers des interventions de communication de santé culturellement appropriées. Une idée principale était que les prestataires avaient souvent des informat

ces risques de grossesse avec les clients. HC3 a utilisé ces résultats et d'autres pour créer un kit de mise en œuvre (I-Kit) pour les responsables de programmes de planification familiale et de santé maternelle et infantile, avec des conseils et des outils concrets pour faire face à la grossesse à l'âge maternel avancé et à parité élevée grâce à la communication sur le changement social et comportemental. Le I-Kit comprend du matériel de communication sur la santé pour engager les femmes, les hommes, les décideurs, les communautés, les prestataires de soins de santé, les journalistes et autres. En 2016 et 2017, une organisation au Niger et une au Togo ont piloté le I-Kit, intégrant des outils I-Kit sélectionnés dans leurs programmes uniques, et documentant leurs expériences. Les deux organisations ont crédité le I-Kit d'élargir la portée de leurs programmes pour aborder maintenant l'âge maternel avancé et la grossesse paritaire élevée et ont fourni des suggestions concrètes pour adapter le matériel en fonction de l'activité et du public visé

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# SHORT REPORT

# Malaria Case Detection Among Mobile Populations and Migrant Workers in Myanmar: Comparison of 3 Service Delivery Approaches

Soy Ty Kheang, a May Aung Lin, b Saw Lwin, b Ye Hein Naing, b Phyo Yarzar, b Neeraj Kak, a Taylor Price

In 3 regions of Myanmar, village malaria workers (VMWs) and mobile teams tested a higher number of people than strategically placed fixed screening points at border crossings, but VMWs and screening points yielded higher malaria positive rates. We recommend using a combination of these approaches in the Greater Mekong Subregion for such populations depending on the strategic approach of the program.

# ABSTRACT

**Background:** Mobile populations and migrant workers are a key population to containing the spread of artemisinin-resistant malaria found in the border areas between Cambodia, Myanmar, and Thailand. Migrants often have limited knowledge of public health, including malaria, services in the area, and many seek care from unregulated, private vendors.

Methods: Between October 2012 and August 2016, we implemented malaria case finding and treatment in Tanintharyi Region, Kayin State, and Rakhine State of Myanmar through 3 entry points: village malaria workers (VMWs), mobile malaria clinics, and screening points. A total of 1,000 VMWs provided passive case detection and treatment services to residents in malaria-endemic villages. Active case finding through mobile malaria clinics was conducted by staff in 354 remote villages and work sites, where regular monitoring and supervision of VMWs would be difficult to maintain. Malaria screening points were a hybrid combination of active and passive case finding in which screening points were set up at fixed locations in Tanintharyi Region and Kayin State, such as bus stops, ferry docks, or informal border crossing points, and migrants entering into or departing from endemic areas could voluntarily receive malaria testing and treatment. Using routine monitoring data, we assessed and compared the malaria positive rate—the number of positive malaria cases out of those tested—across the 3 approaches as an indication of the programmatic effectiveness in identifying malaria cases in the population. Most testing was conducted with rapid diagnostic tests.

**Results:** Mobile teams (169,859) and VMWs (157,048) tested a higher number of community members than screening points (3,676) as they covered a wider geographical area. However, the malaria positive rate was higher among VMWs (7.29%) and screening points (7.10%) than mobile teams (2.64%). VMWs were located in hard-to-access areas that have higher malaria prevalence and are difficult to reach by vehicle while screening points specifically targeted mobile populations and migrant workers. Mobile teams also screened non-fever patients during their visits, which may explain their lower malaria positive rate.

Conclusions: A combination of malaria testing approaches helps achieve both maximum reach and high case finding as it allows access to a range of migrant communities and provides an opportunity for continuity of service delivery as the migrants travel to their destinations.

#### BACKGROUND

Mobile populations and migrant workers who move from their permanent residence to malaria-endemic areas for work or other purposes are a key population to containing the spread of artemisinin-resistant malaria found in the border areas between Cambodia, Myanmar, and Thailand. There are an estimated 2 million Burmese migrants and 248,000 Cambodian

migrants working in Thailand, the main recipient country in the Greater Mekong Subregion.<sup>2</sup>

There is also significant internal migration in the countries. For instance, it is known that most migrants in Cambodia are internal,<sup>3</sup> and while there is little information on migration within Myanmar, it is estimated to be very high.<sup>4</sup> A study conducted in Myanmar in 2015 by the International Labour Organization found that a greater percentage of internal labor migrants migrate for work across states or regions within the country rather than within their own states/regions (62% vs. 38%, respectively).<sup>5</sup> However, this varied across Myanmar. In addition, those migrating from a

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rural area were likely to migrate to another rural area. In Magway and Ayeyarwady regions, the majority of migrants are men (66% and 60%, respectively) and about 80% are between the ages of 11 and 30 years. New to the community, they often have limited knowledge of public health services in the area, including how to prevent malaria, and many seek care from unregulated, private vendors.

There are, however, differences between migrant communities. A study by Wangroongsarb et al. found significant differences between long-term (over 6 months) and short-term Burmese and Cambodian migrants living in Thailand's border areas. Most long-term migrants had heard of malaria, but only about half of short-term migrants had. Short-term migrants were also more likely than long-term migrants not to know any malaria symptoms or preventive methods. Yet a majority (over 86% for all groups) had slept under a bed net the previous night, in accordance with the cultural norms in the Greater Mekong Subregion. 8

The President's Malaria Initiative (PMI) and the United States Agency for International Development (USAID) Control and Prevention of Malaria (CAP-Malaria) Project, implemented between October 2012 and August 2016, worked in border areas between Cambodia, Myanmar, and Thailand to contain the spread of multidrug resistant *P. falciparum* malaria in the Greater Mekong, home to large numbers of mobile populations and migrant workers (Figure). CAP-Malaria worked in collaboration with Myanmar's National Malaria Control Program (NMCP) and ethnic health organizations in project areas.

Myanmar's National Strategic Plan: Intensifying Malaria Control and Accelerating Progress Towards Malaria Elimination 2016–2020 mentions 2 types of populations: static and migrant. Static populations are those who live and work in their villages while migrants and mobile populations include seasonal agricultural laborers, defense services, nonstate actors, and forest workers. The plan identifies 3 key entry points for malaria service delivery for migrants who are scattered in remote areas in Myanmar: community-based village malaria workers (VMWs), mobile malaria clinics, and screening points. The purpose of this article is to describe the CAP-Malaria Project's activities using these 3 approaches and compare the malaria positive rate (number of positive cases out of those tested) among the 3 approaches to assess their effectiveness in malaria case detection.

# **METHODS**

#### Intervention

CAP-Malaria's main approach was the establishment of VMW networks to fill service gaps in target areas. Mobile malaria clinics were also organized at least 3 times each year (especially during pre- and post-monsoon season, which lasts from May/June to early October) in very remote areas with a high malaria burden and/or in areas not covered by VMWs or private providers to conduct active case detection and management. Finally, the project established screening points at common entry points for migrants and mobile populations.

# Village Malaria Workers

Because malaria prevalence is often highest in the most remote locations, and as interpersonal communication was found to be the preferred source of malaria information in a CAP-Malaria survey, CAP-Malaria supported at least 1 VMW in each of the target villages that were geographically hard-to-reach and had high malaria case load/transmission, no appointed public health staff, and no other malaria service providers. The VMWs were recruited from their own communities with the help of village chiefs. From October 2012 to March 2015, 1,000 VMWs in total provided malaria prevention and control services in 23 townships in Tanintharyi Region and Kayin and Rakhine States.

VMWs have a strong network with long-term and temporary community residents, and are familiar with local health services. They were trained to provide their respective communities malaria education; help migrants recognize malaria symptoms; diagnose malaria with rapid diagnostic tests; treat simple malaria according to national malaria treatment guidelines and monitor treatment adherence; and refer severe cases (with no initial treatment) and pregnant women to health centers. Support and supervision was provided during visits by mobile malaria clinics or at monthly township-level meetings to monitor existing or potential diagnostic and treatment stock-outs for provision of continuous malaria services. During the monthly meetings, basic health staff replenished VMW supplies, collected reports, discussed challenges and solutions, and provided refresher training.

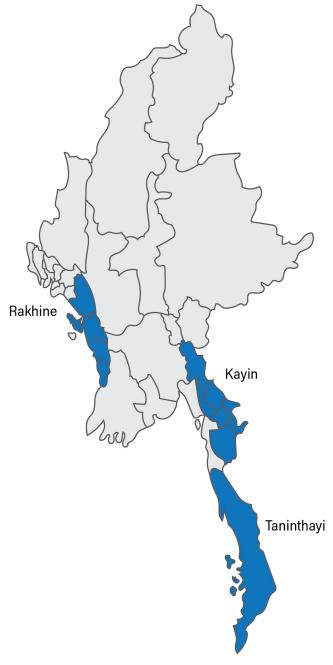
#### **Mobile Malaria Clinics**

For migrant communities in remote villages or work sites that could be accessed by motorbike or

The CAP-Malaria
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Between 2012 and 2015, 1,000 village malaria workers provided malaria prevention and control services in 23 townships in Myanmar.

FIGURE. Areas Covered by the CAP-Malaria Project, October 2012-March 2015



Abbreviation: CAP-Malaria, Control and Prevention of Malaria.

The project worked in 10 townships in Tanintharyi Region, 7 townships in southern Rakhine State, and 6 townships in Kayin State.

vehicle, CAP-Malaria introduced mobile malaria clinics to provide screening and treatment of malaria cases. Criteria for communities to be eligible for mobile malaria clinics included: no health facility or volunteer services, recruitment of VMWs impractical due to high costs and inability for them to attend monthly meetings and regularly submit reports because of access issues, or a high malaria burden. Mobile malaria clinics were staffed by a doctor, a microscopist, a health worker, and, when needed, an interpreter. Each mobile clinic served approximately 30 zones or villages in its assigned area. The timing of the mobile clinic's visit was coordinated with the VMW or other local contact who promoted the visit in the community, and village chiefs provided community mobilization. The mobile clinics provided support to the VMWs, replenishing supplies and answering questions.

From October 2012 to March 2015, mobile clinics visited 354 villages/work sites in 23 townships in Tanintharyi Region and Kayin and Rakhine States. At the village level, the mobile clinics raised communities' awareness about malaria prevention and the importance of early diagnosis and prompt and adequate treatment. They also offered testing services to anyone in the target community.

# **Screening Points**

The project set up malaria screening points at key fixed locations aimed to reach migrants while traveling between sites or during entry into or departure from endemic areas, such as bus stations or jetty terminals. For example, each month thousands pass through the Myoma Jetty and Bus Terminal in Kawthoung Township, a major departure area for Burmese migrants. Screening points were decided in discussion with Township Medical Officers. Migrants could voluntarily have their temperature checked, be tested for malaria with a rapid diagnostic test, and receive treatment if necessary. Migrants were also provided with information on malaria risks, services available, and prevention methods. Screening points were established at bus and boat terminals in Bokpvin and Kawthoung townships in Tanintharyi Region and Hpa-an, Hlaingbwe, Kawkareik, and Myawaddy townships in Kayin State. All testing activities were on a volunteer basis and provided free of charge.

# **Data Collection**

The malaria positive rate, or the number of positive cases out of those tested, provides a good indication of the programmatic effectiveness in identifying malaria cases in a population. The number of cases tested and diagnosed through each of the 3 approaches mentioned above (VMWs, mobile malaria clinics, screening points) was monitored between October 2012 and March 2015 in Tanintharyi Region and Kayin and Rakhine States. Data were collected from the



Mobile clinic staff conduct active case detection of malaria at Hte Hta village, Dawei in Taintharyi Region of Myanmar. © 2017 University Research Co., LLC.

CAP-Malaria summary database after validation against source documents (e.g., VMW and health facility registers) by CAP-Malaria staff.

Most testing was done by a rapid diagnostic test, with microscopy used only in health facilities implementing a strong quality assurance/quality control system. Privacy and confidentiality of personal information were maintained throughout data collection and analysis.

Mobile clinics visited
354 villages of

Mobile clinics visited 354 villages and work sites in remote areas.

#### RESULTS

Between October 2012 and March 2015, CAP-Malaria tested more than 330,000 people and provided appropriate treatment to more than 16,000 people who had been diagnosed with malaria (Table).

Mobile teams were able to test a higher number of community members as they covered a wider geographical area providing active case detection. The mobile teams also screened nonfever patients during their visits. This may explain the relatively low malaria positive rate of 2.64%.

VMWs were an ongoing presence in the hard-to-access areas that have higher malaria prevalence and are difficult to reach by vehicle. VMWs provided passive case detection to patients presenting with fever or symptoms. They tested nearly as many people as mobile malaria clinics (157,048 vs. 169,859, respectively) but had a higher malaria positive rate, at 7.29%.

Screening points specifically targeted mobile clinics but had a populations and migrant workers. Although higher malaria malaria screening points screened the fewest positive rate.

Village malaria workers tested nearly as many people as mobile clinics but had a higher malaria positive rate.

**TABLE.** Malaria Positive Rate by Service Delivery Approach in Tanintharyi Region and Kayin and Rakhine States, Myanmar, October 2012–March 2015

	Total Tested			Positive Cases					
Approach	FY2012	FY2013	FY2014 (Q1-Q2)	Total	FY2012	FY2013	FY2014 (Q1-Q2)	Total	MPR
Mobile malaria clinics	41,550	61,725	66,584	169,859	1,748	1,082	1,649	4,479	2.64%
VMWs	21,978	86,316	48,754	157,048	3,290	5,495	2,669	11,454	7.29%
Screening points	884	1,953	839	3,676	116	119	26	261	7.10%
Total	64,412	149,994	116,177	330,583	5,154	6,696	4,344	16,194	4.90%

Abbreviations: FY, fiscal year (October to September); MPR, malaria positive rate; Q, quarter; VMWs, village malaria workers.



A village malaria worker provides health education to community members in Htaung Phee village in Bokpyin Township, Tanintharyi Region of Myanmar. © 2015 University Research Co., LLC.

number of people (3,676 total), they yielded a similar malaria positive rate (7.10%) as VMWs, as these approaches screened suspected patients who presented with fever or symptoms.

#### DISCUSSION

Effective malaria control among migrant workers and mobile populations requires a combination of approaches for 2 reasons: (1) there are differences between migrant groups in terms of knowledge, health-seeking behavior, and access to services, and (2) the combination of approaches maximizes the opportunities for migrants to obtain information and services while they travel and at their destination community. The 3 service delivery approaches used by the CAP-Malaria project have

their advantages and disadvantages in terms of operation and cost.

The use of mobile teams can be expensive depending on frequency, distance, and remoteness of the areas covered. However, the more aggressive nature of case finding allows the program to access more people and identify cases that may normally be missed through routine passive case detection. Mobile teams should be provided as a complementary approach to health facility-based and community-based malaria testing and treatment services. Updated malaria information in the local context should be used to plan and implement mobile team activities to ensure higher malaria positive rate and for cost-control measures.

The use of VMWs requires a strong monitoring and supervision component to ensure quality of uninterrupted services by VMWs in the community. Operational costs are lower when the monitoring and supervision is integrated into local health systems and rural health staff are engaged as part of monitoring and supervision of VMWs. While this approach is effective in treating uncomplicated malaria, strong linkages and referral systems must be set up to refer complicated malaria cases. Village-based stratification of malaria information is important to effectively allocate resources.

Screening points, strategically located in areas highly frequented by migrant communities, combine active and passive case detection. The location and timing of screening points, and the criteria for screening, are important factors in the resulting malaria positive rate. Updated information and continuous evaluation of the results will help to better target resources to improve the malaria positive rate using this approach.

The most efficient approach for case finding appears to be through VMWs since they provide quality services with minimal resources required. However, VMWs have only limited reach in a population as they provide services only within their community. In comparison, mobile clinics identify fewer cases but are able to reach more people with malaria services and malaria information with wider geographical coverage. Scheduled mobile clinics contribute to sustain VMWs' activities in remote villages and work sites by replenishing supplies and providing supervision. While screening points resulted in a fewer number of people being tested, they nevertheless identified a large number of malaria cases by specifically targeting mobile populations and migrant workers when routine monitoring was not efficient. Screening points also raise awareness of malaria among travelers, preparing them to recognize malaria symptoms and seek care more quickly in their destination community.<sup>4</sup> Quality data from these approaches is important to stratify villages and high-risk areas. Village-based stratification of malaria information is important to effectively allocate resources.

# CONCLUSION

As Myanmar and other countries move toward pre-elimination/elimination, malaria will begin to cluster among certain high-risk groups, including migrants and mobile populations. A combination of program approaches helps increase testing among high-risk populations and achieve high case finding rates, which will be critical to achieve elimination.

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**Screening points** identified a large number of cases by specifically targeting mobile populations and migrant workers.

# **METHODOLOGY**

# Monitoring Progress in Equality for the Sustainable Development Goals: A Case Study of Meeting Demand for Family Planning

Yoonjoung Choi, a Madeleine Short Fabicb

As demand for family planning has increasingly been satisfied, disparities between groups within a country have also generally declined but persist. To monitor disparity across countries and over time, we recommend comparing met demand by wealth quintile because it is most comparable to interpret and highly correlated with disparity by education, residence, and region. Within country, comparing disparity in met demand across geographic region can identify populations with greater need for programmatic purposes.

# ABSTRACT

**Objectives:** Equality is a central component of the Sustainable Development Goals (SDGs). We took one SDG indicator and benchmark—percent of family planning demand met with modern contraceptives, with a benchmark of at least 75% in all countries—as a case study to illuminate recommendations for monitoring equality. Specifically, we assessed levels, patterns, and trends in disparity by key background characteristics and identified disparity measures that are programmatically relevant and easy to interpret.

**Methods:** Data were from the Demographic and Health Surveys in 55 countries that have conducted at least 2 surveys since 1990. We calculated absolute difference among subgroups, disaggregated by age, education, household wealth quintile, urban/rural residence, subnational region/administrative unit, and marital status. Our unit of analysis was survey, and we conducted largely descriptive analyses. To understand trends in disparity, we used a fixed-effect linear regression model to estimate an annual rate of change in absolute differences.

**Results:** A significant level of disparity existed across various background characteristics, ranging from a median difference of 5 percentage points by marital status to 32 percentage points by administrative unit. On average across the study countries, national level of met demand has increased over time while disparity has declined in most disaggregates including by education, wealth, residence, and age. We found statistically significant positive correlations among 4 disparity measures—education, wealth, residence, and administrative unit. Disparities by wealth quintile were easiest to interpret over time and across countries.

**Conclusions:** At the global level, we recommend monitoring disparity in met demand by wealth quintile, which is strongly correlated with disparity by education, residence, and region and comparable across countries and over time. For monitoring by individual countries and for programmatic purposes, we further recommend monitoring disparity by first-level administrative unit, which can provide direct programmatic relevance.

# BACKGROUND

The Sustainable Development Goals (SDGs) are a set of 17 goals in support of people, planet, and prosperity for every country to achieve by 2030. Each goal has specific targets and each target is monitored through at least 1 indicator, identified and defined in the United Nations Global Indicator Framework for the SDGs. With 193 participating countries, 17 goals, and 169 targets, SDG indicators are parsimonious per target; even

so, the Global Indicator Framework recommends a total of 232 indicators to monitor progress in each country and globally.

Adding to the complexity and importance of SDGs monitoring is the need to monitor inclusiveness and equality.<sup>2–4</sup> In response, the SDGs have an overarching principle of data disaggregation<sup>5</sup>:

indicators should be disaggregated, where relevant, by income, sex, age, race, ethnicity, migratory status, disability and geographic location, or other characteristics, in accordance with the Fundamental Principles of Official Statistics.

Disaggregates will vary based on country context. For example, in ethnically homogeneous countries, geographic information may be more important than ethnic

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disaggregates. Such differences in country context present challenges for monitoring disparity at the global level,<sup>6</sup> where data must be available and comparable to inform global estimates, projections, and focus. Additionally, with such a large set of indicators, disaggregation must be as prudent as possible to facilitate measurement and accountability.

SDG Goal 3 is devoted to health and one of its targets, target 3.7, is specific to reproductive health<sup>2</sup>:

By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes.

Progress in achieving the family planning component of the target is monitored with the indicator, "demand for family planning met with modern contraception" (hereinafter referred to as "met demand"), with a proposed benchmark of "at least 75 percent in all countries by 2030." The above-mentioned disparity measurement challenges apply to the met demand indicator. A critical question is what disaggregates should be used to monitor subnational disparity, both within a given country and across countries?

Our article aims to address the data disaggregation challenge using the SDG indicator of reproductive health—met demand—to explore various measures of disparity and their trends, and to make recommendations about appropriate global-level disaggregates. Specific aims are to: (1) assess levels, patterns, and trends in disparity for met demand by key background characteristics; and (2) identify disparity measures that are programmatically relevant and easy to interpret.

# METHODS

# Data

Data are from the Demographic and Health Surveys (DHS) Program, an international survey platform supported by the U.S. Agency for International Development. The DHS are nationally representative household surveys that provide comparable, high-quality data on population and health in 90 countries. <sup>10</sup> All women 15–49 years of age living in sampled households are eligible for the women's interview, which collects information on fertility, family planning, maternal and child health, and more. All DHS have a stratified two-stage cluster design that results in a sample that is generally representative

at the national level, regional level (departments, states), and residence level (rural/urban). Because data are collected using a common methodology and common questionnaire, DHS data are comparable across time and place. Further details of DHS survey design and methodology are described elsewhere. 11

DHS have collected detailed information on background characteristics since the program's inception in 1984. Around 1990, DHS began collecting information on housing conditions and household ownership of assets, which enabled computation of the household wealth index, an important dimension of disaggregation in our study. Our analysis was therefore restricted to countries with 2 or more DHS since 1990. As of September 2017, 213 surveys from 55 countries were eligible (Supplement 1). Among the 55 study countries, the average number of surveys since 1990 was 3.9 (range: 2-9) and the average interval between the earliest and latest survey was 16 years (range: 3-25 years). We used the DHS Application Programming Interface (API), available at http://api.dhsprogram.com/, to obtain estimates of met demand by background characteristics from the 213 surveys. Of note, all estimates in the DHS API were adjusted for sampling weights and calculated using standardized definitions, and, thus comparable.

# Measures Met Demand by Background Characteristics

Met demand—demand for family planning met with modern methods-is defined as the proportion of women using modern contraceptives among women with demand for family planning. The indicator's denominator—women with demand for family planning-is comprised of women using any method of contraception and women with unmet need for family planning (i.e., sexually active women who report a desire to delay, space, or limit childbearing and also report no current contraceptive use). The numerator-women whose demand for family planning is met—is comprised of women who report current use of modern contraception. The main elements of met demand are: unmet need, contraceptive prevalence, and modern contraceptive prevalence.

Met demand is typically disaggregated by various background characteristics including age (5-year groups between 15 and 49 years), education (none, primary, and secondary or higher), household wealth quintile, residence (urban,

Progress in achieving the family planning SDGs target is monitored by assessing demand for family planning met with modern contraception.

This study analyzes levels, patterns, and trends in disparity for met demand among 213 DHS surveys from 55 countries. rural), and subnational region/administrative unit. The administrative unit refers to subnational geographic regions that have planning authority and/or program implementation responsibility, such as states in Nigeria and counties in Kenya. These estimates are available through the DHS API. Disparity can present itself through other characteristics, including race, ethnicity, and religion. These data are available from DHS as well and should be monitored in countries with variation across such background characteristics, but we did not employ them in our analysis since they are highly dependent on country context.

Since some countries —typically in South Asia and the Middle East and North Africa—depart from the standard DHS methodology and interview only ever-married women, we limited our analysis to estimates among women in union (i.e., currently married or living with a partner) for the purpose of comparison across all available study countries. Because the denominator of met demand includes only women who have demand for family planning, unmarried women consist of a small fraction and excluding them from our calculations generally made no notable impact on the national-level estimate. Across the 213 study surveys, there was an average 1.4 percentagepoint difference between met demand among all women and met demand among married women. In a handful of countries in Western and Southern Africa, the differences were larger, with the largest difference being 11.6 percentage points in Sierra Leone. Since women's access to family planning information and services can vary by union status, in a large subset of countries where all women are interviewed, we examined estimates of met demand and disparity by current union status (in union, not in union).

# **Disparity Measurement**

Disparity in health has been studied extensively, <sup>12–20</sup> and disparity trends are measured in various ways depending on study objectives. For example, some studies have examined **rates of change** across subgroups to explore whether various subpopulations have experienced similar trends in improvements to health indicators. <sup>12,20</sup> Persistent disparity, however, can be observed with comparable improvement across subgroups. Further, since a baseline level for a more disadvantaged subgroup is generally lower, there is a larger margin of improvement that is mathematically and programmatically possible. <sup>21</sup> **Relative difference**, another measure of disparity, has been

also studied. 12,13 The advantage of monitoring relative difference over time is that changes in the underlying rates between subgroups are already adjusted.<sup>21</sup> Relative difference may, however, over- or under-emphasize disparity when levels across subgroups are relatively low or high, respectively. An additional challenge in using relative difference is selection of a reference group, since the measure can be sensitive to the choice.2 A more widely used approach is to assess trends of absolute differences across subgroups. 12,13,22-24 Absolute difference is an intuitive summary measure of disparity. Its trend, however, is determined by various trends among subgroups. Decreasing disparity can result from different trends in 2 subgroups—for example, improvement in both groups but more rapid improvement in a disadvantaged group, or improvement in the disadvantaged group but no improvement or even deterioration in the advantaged group.<sup>24</sup>

While all disparity measures are informative, for the purpose of monitoring national-level disparity trends in addition to national-level averages, absolute difference is generally recommended.<sup>12</sup> We therefore chose to use absolute differences to examine equality trends.

#### Reference Group Choice

For background characteristics with generally clear socioeconomic order, our reference group was the most advantaged. We calculated the percentage-point difference between the mostand least-advantaged groups—that is, between secondary or higher education and no education; highest and lowest household wealth quintile; urban and rural; and currently in union and not in union. If disparity patterns follow the usual socioeconomic pattern of health service utilization (i.e., the more advantaged, the higher the met demand), the absolute difference between the most- and least-advantaged socioeconomic subgroups would be the largest possible among all subgroups and greater than zero. Such patterns, however, do not necessarily exist in all disaggregates and subpopulations. We conducted preliminary analyses to compare absolute difference by typical socioeconomic order against the largest possible difference regardless of expected order (Supplement 2). Despite a few country-specific outliers, the two measures of socioeconomic disparity—the difference in levels between the usual least-advantaged socioeconomic category and the most-advantaged and the difference between the lowest and highest levels—correlated

closely for education, household wealth, and residence. By union status, the pattern varied greatly.

Meanwhile, for two background characteristics age and administrative unit-there was no straightforward way to order the subgroups across countries. We therefore calculated the absolute differences between the lowest and highest estimates among subgroups. The difference in these cases simply represented the magnitude of variation, which was always greater than zero.

In addition, the number of subgroups varied across the background characteristics, ranging from 2 (urban/rural and in union/not in union) to 7 (5-year age groups) or more, depending on survey design (administrative unit). We expect to see higher disparity when a population is disaggregated into more subgroups, given distribution of met demand in the population. Therefore, direct comparison of the disparity magnitude across different disaggregation dimensions is inappropriate.

# **Analysis**

Our unit of analysis was survey, and we conducted largely descriptive analyses. For any summary statistics, we used unweighted averages across countries regardless of their population size for two reasons. First, family planning policies and programs are generally developed and implemented at the national level. Second, the unit of SDG monitoring is expected to be the country, rather than an aggregated global average weighted by population size.

To understand disparity trends, we used a fixed-effect linear regression model to estimate an average annual absolute change per year, controlled for any unobserved country-level characteristics. We included 1 covariate—national-level estimate of met demand-in order to control for changes in the national-level average, which may be associated with the level of disparity. We used STATA 14.2 statistical software for all analyses (Stata Corporation, College Station, USA).

# RESULTS

# Levels and Trends of Disparity

Data from each country's latest survey showed sizeable within-country disparity (Figure 1). The median disparity in met demand by education was 15 percentage points (first box on the far left in Figure 1), by household wealth 15 percentage points (second box), and by residence (urban/ rural) 9 percentage points (third box). Met demand among women in union was about 5 percentage points lower than among women not in union (median); however, the disparity pattern was not as consistent as disparity by education, household wealth, or residence. In 38% of study countries, met demand was higher among women in union than among women not in union. In terms of age, met demand was about 21 percentage points higher in the best-performing age group (often women ages 35-39, but not universally) compared with the lowest-performing age group (often women ages 15-19, though again not universally) (Supplement 3). Meanwhile, disparity by administrative unit/region presented the largest differentials, partly due to a large number of subgroups (average number of regions: 17, standard deviation [SD]=12, range: 3–54, n= 55 latest surveys in each country). Specifically, the best-performing regions achieved, on average, 32 percentage points higher met demand than the poorest-performing regions (median: 30 percentage points) (Figure 1).

Turning to trends in magnitude of disparity, we observed that disparity by education, wealth, urban/rural residence, and age has decreased over time (bivariate model columns in the Table). For example, disparity by education has dropped by 0.55 percentage points each year. When controlling for changes in the national level of met demand, the magnitude of change in disparity by education, wealth, and urban/rural residence was reduced substantially (multivariate model columns in the Table). Nevertheless, we still observed statistically significant reductions in disparity by education, wealth, residence, and age (-0.24,-0.43, -0.19, and -0.36 percentage points per year, respectively). Meanwhile, we saw increases in disparity by region (0.36 percentage points per year) though this is likely a measurement artifact as DHS data have become more granular with larger sample sizes and more administrative units of estimation. There was no statistically significant change in disparity by union status in the multivariate model.

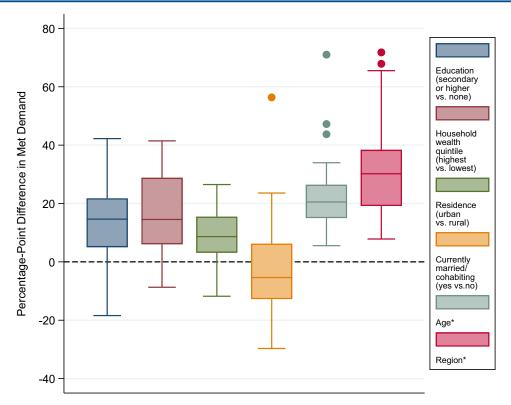
Variation in disparity trends across countries needs to be noted. Figure 2 shows how the overall levels of met demand and disparity have changed by country over time. Each dot represents a survey, and a line is connected in the order of survey year. If a line moves from top left to bottom right (as shown in the example of Madagascar), it depicts that overall met demand has increased and disparity has decreased over time—as observed in most countries. However, a handful of countries, mostly in Central and Western countries.

**Disparity by** education, wealth, urban/rural residence, and age has decreased over time.

**Data from each** country's latest survey showed sizeable withincountry disparity.

**Overall** met demand has increased and disparity has decreased over time in most

FIGURE 1. Boxplot Distribution of Within-Country Disparity in Family Planning Demand Met With Modern Methods (Percentage Point) Between the Most- and Least-Advantaged Subgroups,\* by Background Characteristic



All disparity measures are among women in union, except disparity by union status, which is among all women.

Length of the box represents the interquartile range, the horizontal line in the box is median, the vertical line is a range of lower and upper adjacent values, and dots are outside values.

Data were from the latest DHS from 55 countries.

Africa, had different patterns. For example, in Burkina Faso and Côte d'Ivoire, disparity decreased, following a period of a temporary increase, while the national-level met demand has increased continuously. Meanwhile, in Cameroon and Nigeria both disparity and the national level of met demand increased.

Even countries that meet the "at least 75% with met demand" benchmark have varying levels of disparity by wealth. In Morocco and Malawi, for example, no disparity by wealth was observed when the 75% benchmark was attained. On the other hand, large disparity still exists in Namibia and Lesotho even though both have reached the benchmark. And virtually zero disparity exists in Ghana even though it is still

quite far from achieving the benchmark. Supplement 1 presents the national level of met demand and disparity by various disaggregates and survey.

Country context is further examined in Figure 3, which presents trends in disparity among 4 countries with increasing national levels of met demand—Madagascar, Ethiopia, Cameroon, and Nigeria. While disparity by wealth reduced substantially in Madagascar, it increased in Nigeria. In Ethiopia and Cameroon, the level of disparity between the highest and lowest wealth quintiles remained constant between the last 2 surveys for 2 different reasons: Met demand across wealth quintiles increased in Ethiopia but stagnated in Cameroon.

 $<sup>^{\</sup>star}$  Disparity by age or administrative unit represents the largest possible absolute gap among all subgroups.

TABLE. Estimated Annual Changes in Disparity in Family Planning Demand Met With Modern Methods Between the Most- and Least-Advantaged Subgroups<sup>a</sup> by Background Characteristic (Percentage-Point Change per Year)

	Bivariate Model		Multivariate Model <sup>b</sup>				
Absolute Disparity by:	Coeff. on Year	P Value	Coeff. on Year	P Value	Coeff. on National Average	P Value	
Education (secondary or higher vs. none)	-0.55	<.001	-0.24	.007	-0.27	<.001	
Household wealth (highest vs. lowest quintile)	-0.61	<.001	-0.43	<.001	-0.17	.003	
Residential area (urban vs. rural area)	-0.42	<.001	-0.19	.002	-0.20	<.001	
Union status (in union vs. not in union)	0.75	<.001	0.17	.21	0.48	<.001	
Age <sup>a</sup>	-0.05	.46	-0.36	<.001	0.28	<.001	
Administrative unit <sup>a</sup>	0.47	<.001	0.36	.001	0.10	.12	

<sup>&</sup>lt;sup>a</sup> Disparity by age or administrative unit represents the largest possible absolute agp among all sub-groups. All disparity measures are among women in union, except disparity by union status which is among all women.

# Interpretation of and Correlation Among Measures by Various Disaggregates

To inform our identification of a parsimonious set of disaggregates to monitor disparity in ways that are programmatically relevant and easy to interpret, we assessed correlation among disparity measures and distribution of population by the background characteristics. We found that there were statistically significant positive correlations among 4 disparity measures—education, wealth, residence, and administrative unit (Figure 4)—as expected since education, wealth, and residence are highly correlated. Pairwise correlation coefficients among disparity by education, wealth, and residence were especially high (0.90 by wealth and residence; 0.78 by education and wealth; and 0.71 by education and residence). Disparity by union status, however, was negatively related with disparity by education, wealth, and residence. This may be due to selective data availability, which were largely from sub-Saharan Africa and Latin America. Perplexingly, disparity by age was negatively associated with disparity by education and was not significantly associated with any other disparity measures.

Among the 4 correlated disparity measures, education had the greatest interpretation challenges in terms of comparability over time and across countries. Though improving overall, educational attainment showed great variation across countries (Figure 5). To elaborate, 2 countries can have the same level of disparity between the mostand least-educated women. But if they have vastly different levels and/or trends of female educational attainment, interpretation and implications of the disparity are different. Take, for example 2 countries with similar levels of met demand and similar levels of disparity by education-Niger and Cameroon. The percentage of women who attended secondary school or higher is still minimal in Niger, while it has grown steadily in Cameroon. The education categories have different percentages of women over time, which makes the scope, breadth, and depth of the disparity difficult to ascertain. Similar challenges present when observing disparity by urban/rural status with countries having different levels and rates of urbanization and also periodic changes in urbanrural designation based on censuses. Monitoring disparity by education and residence gives only magnitude of disparity between subpopulations of undefined size. It is therefore neither comparable nor easily interpretable between countries.

#### DISCUSSION

There is substantial variation in the level of disparity in met demand for family planning across countries. As expected, the level of met demand largely follows socioeconomic order. In terms of increased, the trends, on average, disparity by socioeconomic level and characteristics has decreased over the last 2 decades, controlling for national-level increases. Nevertheless, while most countries in our analysis **specific.** 

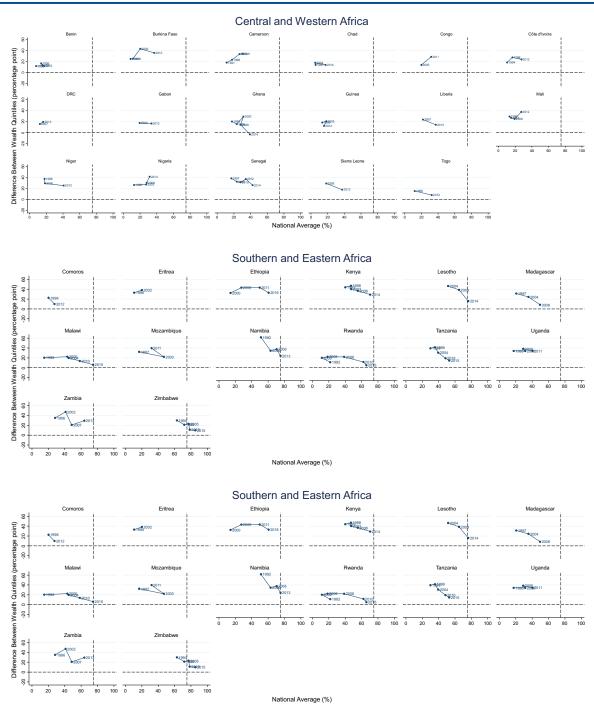
**There were** statistically significant positive correlations among 4 disparity measures: education, wealth, residence, and administrative unit.

While most countries witnessed reduced disparity in met demand as the overall level of met demand magnitude of change is context

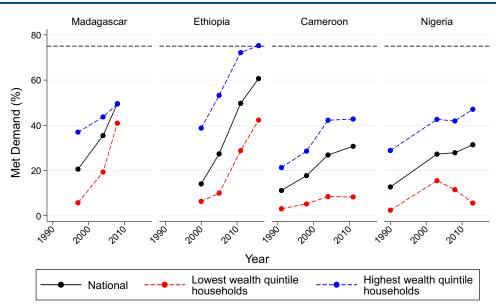
<sup>&</sup>lt;sup>b</sup> Multivariate models include 2 covariates: year and national average.

Note: Sample size for regression is 213 surveys from 55 countries, except disparity by union status where only 161 surveys from 45 countries were available for analysis.

**FIGURE 2.** Trends in National-Level Family Planning Demand With Modern Methods (%) and Disparity by Wealth<sup>a</sup> (Percentage Point), by Region and Country



 $<sup>^{\</sup>mbox{\tiny a}}$  Difference between the highest and lowest wealth quintiles.



**FIGURE 3.** Illustrative Examples of Varying Trends of Family Planning Demand Met With Modern Methods (%), Nationally and by Household Wealth Quintile

witnessed reduced disparity in met demand as the overall level of met demand increased, the level and magnitude of change is context specific. For SDG 3.7, meeting the benchmark of "at least 75%" does not necessarily imply that equality will be achieved. We also find that disparity between administrative units has increased significantly. This may be due to uneven progress among regions, but it is also due to the increasing number of administrative units for which a survey was designed to provide estimates.

We now turn our attention to our second specific aim of this study: identifying key measures of disparity necessary for effective programming and monitoring at national and global levels. In this space, it's worth discussing the inconsistent disparity pattern by union status, which is noteworthy and reflects multiple factors: differential access to family planning by union status, differential strength of fertility intentions by union status, and/or potential data issues. Specifically, one would expect lower levels of met demand among unmarried women in countries where access to family planning services is limited to unmarried women due to restrictive requirements and/or provider bias. 25,26 On the other hand, unmarried sexually active women may have more steadfast fertility intentions and therefore may be more likely to use contraception, resulting in higher met demand. Finally, there may be selection bias at 2 levels. Unmarried women who self-report to be sexually active may have certain characteristics that are associated with increased use of contraception or increased reporting of contraceptive use. Also, data are unavailable in countries where the cultural context precludes participation of never-married women in the women's interview. For these reasons, drawing conclusions, especially at the global level, about disparity by union status remains challenging.

Among the other dimensions of disaggregation included in our analysis—education, wealth, residence, age, and administrative unit—one indicator rises to the fore for monitoring withincountry disparity at the global level: disparity by wealth quintile. Since relative wealth quintile distribution is constant, its interpretation is clear over time and across countries: the difference between the wealthiest 20% and poorest 20% of the population at any time and in any country. Additionally, since disparity by wealth is highly correlated with disparity by education, residence, and region, it can serve as a tracer indicator for disparity among other subpopulations; If disparity by wealth is high, it is likely that disparity by other characteristics is also high. Importantly, the measure has been also routinely used to monitor progress toward Millennium Development Goals.<sup>27</sup>

If disparity by wealth is high, it is likely that disparity by other characteristics is also high.

Disparity by education (secondaryvs. none) (% point) 80 Disparity by wealth (highest vs. lowest 40 0 quintile) (% 0.78\*\* -40 80 Disparity by residential 40 area (urban vs. rural) (% point) 0 0.71\* 0.90\*\* 40 80 Disparity by union status -0.37\* -0.60\* -0.61\* 40 (in-union vs. not in-union) (% 0 point) Disparity by 5-year age group (% point) 40 0 -0.31\* -0.17-0.17-0.02 -40 80 40 by administrative unit (% point) 0 -0.08 0.33 0.44\* 0.24 0.06 -40 800

**FIGURE 4.** Correlation Matrix Among Various Disparities in Family Planning Demand Met With Modern Methods, With Correlation Coefficient

For education, household wealth, and residential area, disparity is between the most and least-advantaged subgroups. For age and administrative unit, disparity represents the largest possible absolute gap among all subgroups.

Data are from the latest DHS from 55 countries.

All disparity measures are among women in union, except disparity by union status, which is among all women.

We recognize that the absolute level of poverty or wealth in a same quintile may vary substantially across countries and over time within a given country. Regardless, from the perspective of ensuring inclusive development, our interest is to monitor within-country equality at any given time—even with improving economy—which wealth quintiles allow.

Moving from the global to the national level, it becomes critical for an indicator of disparity to

have programmatic relevance. Disparity by wealth can be programmatically meaningful at the country level when policies and programs are designed to target the poor, such as subsidized health care costs for low-income individuals and families. More often, however, intervention programs in a country are targeted to specific geographic areas, which often serve as proxies for reaching disadvantaged groups of individuals with certain background characteristics. For example, it can be

<sup>\*</sup> P value < .05; \*\* P value < .01.

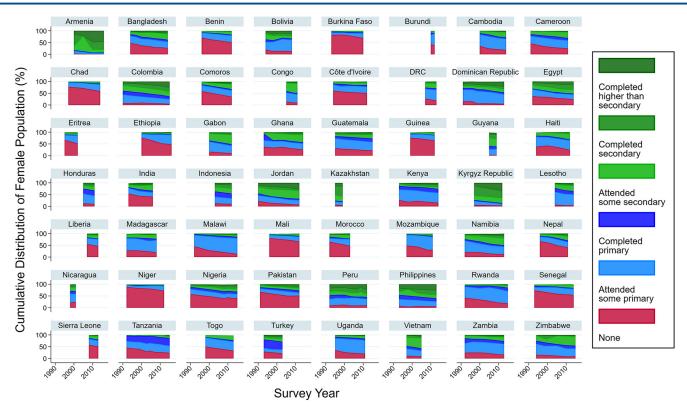


FIGURE 5. Changes in the Distribution of Educational Attainment Among Female Population 6 Years and Older

Graph area varies by the number of surveys and intervals between them.

Source: DHS Program Application Programming Interface (API), available at http://api.dhsprogram.com/.

challenging and inefficient to identify target households based on wealth quintile and implement interventions for them, so programs instead target regions with high poverty. Thus, the more programmatically relevant disparity dimension at the national level is administrative unit, where geographies in greatest need are easily identified and budgeting and planning can be determined. While monitoring disparity at the administrative level will inform policies and programming to reduce disparity, we also recognize the importance of monitoring disparity by other background characteristics, including urban/rural divides, that many country-level programs already use to direct limited resources to the most underserved.

A consideration with this approach is potential comparability issues over time if a substantial change is made in the administrative systems. Further, in countries where planning and budgeting is determined at second or lower administrative units, there may be need to disaggregate by

even lower administrative units. Because measurement of met demand requires populationlevel survey data, 28-30 data availability at subregional levels is challenging even with improved routine health information systems. Considering technical challenges and limited financial and human resources to conduct large-scale surveys, subregional data may come from statistical model-based estimation, 28-30 though it will require efforts to explain the data and limitations such as uncertainty of estimates, which may be larger than survey sampling error, to data users, or oversampling in selected regions where programmatic investment is concentrated. Another consideration with the approach we describe herein is that comparisons between highest and lowest groups mask variation among the intermediate groups, which may have very different spreads based on country context. Where possible, the spread of disparity among all subgroups should also be monitored. Relatedly, it is

At the national level, the more programmatically relevant disparity dimension is administrative unit, where geographies in greatest need are easily identified and budgeting and planning can be determined.

important to note that disparity by union status and age may also have additional programmatic relevance in countries where discrimination against unmarried and/or younger women is prevalent or perceived to be problematic. Finally, in using any measures of disparity, incorporating and communicating uncertainty in estimates by background characteristics is the next step to be explored.

#### CONCLUSION

Using DHS data among 55 countries, we report a wide range of disparity in met demand across various dimensions. While disparity has decreased, our data show persistently high disparity even among countries with high national levels of met demand. To achieve the SDG promise that "no one is left behind," within-country disparity needs to be monitored and addressed at global, national, and, where possible, subnational levels. At the global level, we recommend monitoring withincountry disparity by wealth quintile, as it provides comparable and easily interpretable information. At the national level, we recommend monitoring by administrative unit, considering its programmatic relevance. Our recommendations are applicable to other health areas. Strong correlation among socioeconomic characteristics implies that disparity by wealth mirrors disparity by other socioeconomic characteristics for health areas beyond family planning. 12,18,27 Additionally, the programmatic importance of data disaggregated by region applies to all health areas, including and beyond family planning.

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