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Cover caption: The Kisoro District Hospital follow-up team use motorcycles to locate patients lost to follow-up in their communities. © 2019 Charles Moon/Doctors for Global Health.

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EDITORIAL

Retaining Patients in Care: An Important but Neglected Challenge

Stephen Hodgins[a]

A hospital-based follow-up program in Uganda helped improve retention of patients in care across a range of health problems. Although the specific approach may not be replicable in other settings, hospitals in Uganda and beyond should consider how they can improve retention of patients requiring long-term care, including for HIV, TB, malnutrition, and noncommunicable diseases.

See related article by Alizadeh.

A challenge all health care systems struggle with is ensuring needed continuity of care. The less robust the system, the more difficult that is. The article by Alizadeh et al., in this issue of GHSP, gives an account of efforts made by a rural district hospital in Kisoro, Uganda, to improve retention of patients across several different services in the hospital including those with HIV, receiving antiretrovirals (ARVs); tuberculosis (TB); severe malnutrition; and other chronic, noncommunicable diseases (NCDs).[1]

The hospital developed a defaulter-tracking program, under which outreach staff would periodically visit clusters of villages once a threshold number of patients lost to follow-up was reached for that cluster, and encourage patients to return for follow-up treatment. The hospital made available a motorcycle for this purpose and offered field staff an incentive for patients successfully found and referred back for care.

DEFAULTER-TRACKING FOR HIV AND TB

Similar programs have been introduced elsewhere in sub-Saharan Africa. However, as Alizadeh et al. point out, most of these programs have been developed for disease-specific programs, mainly for ARV or TB treatment follow-up.

With funding from sources including the Global Fund to Fight AIDS, Tuberculosis and Malaria and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program, HIV treatment has generally had more substantial financial support than other services. Certainly, a strong argument can be made for household and community-level adherence support and other community outreach activities to try to retain ARV patients in treatment. Treatment interruptions lead to shorter life expectancy and increase the need for more expensive second- and third-line treatment regimens.

Similarly, TB programs in Africa have benefited from more external funding than many other programs. There is a compelling public health case for special follow-up measures to maximize TB treatment completion and minimize risk of further transmission and of development of drug resistance. But other conditions—notably NCDs—call for long-term, often lifelong, continued care.

WHAT DID KISORO DISTRICT HOSPITAL DO?

In the case described in the article by Alizadeh and colleagues, the hospital had access to funds allowing it to develop a more integrated follow-up program, to help improve retention across a range of health problems, including conditions not prioritized by donors. With one full-time coordinator and several part-time outreach workers, in the year for which they provided documentation in their article, they attempted to contact 1,285 patients lost to follow-up, of whom just under two-thirds were located.[1] Of those found, one-third either had died or were mistakenly included on the list. The outreach service was less effective in tracking down ARV defaulters, finding only half of them.

Of patients found and referred back, over 90% of TB patients returned for follow-up, close to three-quarters of those with NCDs returned, and just over half of the referred ARV patients returned. The authors report this level of performance was considerably better than several years earlier; they attributed this particularly to introduction of the performance-based incentive for the outreach workers.

The annual recurrent cost for this outreach was US$6,600.

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WHAT ABOUT JUST PHONING PATIENTS AND REMINDING THEM OF THEIR APPOINTMENT?

As the authors report, although mobile phone use has increased over the last several years, at the time the follow-up service was introduced phone use was uncommon; therefore, relying on phone contact for follow-up would not have been effective. With mobile phone use now more widespread, in the future a mobile device platform could be used to supplement the face-to-face follow-up model that has been used to date.

Giving program attention to achieving improved retention in care for issues like ARV treatment, TB, severe malnutrition, and NCDs is not a luxury.

Unlike some other programs developed to improve retention and adherence, the service described by Alizadeh and colleagues focused only on face-to-face contact in the community to encourage defaulting patients to return for follow-up; it did not include peer support or other community-based forms of support to address barriers to treatment continuity. Although adding such components could further improve retention in care, clearly this would also cost more money, posing new challenges with regard to sustainability and scalability.

WHAT IS THE RELEVANCE OF THIS EXPERIENCE ELSEWHERE IN UGANDA, AND BEYOND?

Unlike typical government hospitals in Uganda, Kisoro District Hospital benefited from external financial support, which allowed it to develop this defaulter-tracking program. Generally speaking, government district hospitals have less discretionary money available for such innovations. But one can certainly argue that providing modest additional funds to achieve higher retention in treatment for such cases would be a sound investment, one that could even be cost-saving. As the authors point out, addressing the problem of loss to follow-up using an integrated, multiservice approach is considerably more efficient than implementing separate, disease-specific follow-up programs.

Across different parts of Uganda, conditions vary. So the specific details of an optimal follow-up program will also vary. But giving program attention to improved retention for health issues like ARV treatment, TB, severe malnutrition, and NCDs is not a luxury. Starting patients on treatment and losing them to follow-up is wasteful of resources, results in avoidable bad outcomes for the patients concerned, and—for some conditions (like active TB)—represents a threat to the health of the community.

The specific details of the follow-up scheme used by Kisoro District Hospital may or may not be well-fitted to hospitals in other parts of Uganda and it may or may not be feasible for government to closely replicate such a model. All the same, government, donor partners, and hospital leadership across Uganda and beyond should be asking themselves how they can improve retention of those of their patients requiring long-term follow-up care, not only for the traditionally better-funded HIV and TB programs but also for other conditions needing similar continuity of care.

Competing Interests: None declared.

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EDITORIAL

Scale and Ambition in the Engagement of Private Providers for Tuberculosis Care and Prevention

William A. Wells[a]

The tuberculosis (TB) community knows the importance of engaging private providers to reach critical TB targets, and knows how to engage successfully. The next challenge is to transition such efforts to government stewardship and financing in order to reach scale.

See related article by Ananthakrishnan.

PUBLIC PROGRAMS FOR PRIVATE PROVISION

Tuberculosis (TB) programs find themselves in an unusual position. They are the quintessential public health program, focused on an airborne public health threat with many externalities beyond an individual's health, thus justifying a substantial public investment. Yet globally, one of the largest pieces of unfinished business for these public programs is to engage with private health care providers.

The reason is simple: TB is now largely concentrated in countries with large numbers of private health care providers. A recent landscape analysis of private provider engagement (PPE) in TB[1] found that 7 of the highest TB burden countries (India, Indonesia, Philippines, Pakistan, Nigeria, Bangladesh, and Myanmar), which account for 57% of the global TB incidence and 63% of unreported ("missing") TB cases,[2] have dominant private sectors. In these countries, 75% (67%–84%) of initial care seeking is to private providers, and 61%–74% of total expenditure on health is private. Yet only 19% (5%–28%) of total TB notifications and 12% (1%–18%) of estimated TB incidence are notified by private for-profit TB providers.[1]

When national TB programs are not fully engaging private providers, what happens to TB patients? Indonesia and Nigeria provide contrasting experiences. In Indonesia, only an estimated one-third of the non-notified TB patients are not diagnosed; the remaining two-thirds are diagnosed but not notified.[3] They are thus inaccessible to public interventions that would improve the quality of the 6-month treatment, reduce the likelihood of developing multidrug-resistant TB, and ensure treatment completion and success. In Nigeria, by contrast, qualitative evidence suggests that many clients of private providers do not get correctly diagnosed with TB, likely leading to extensive mortality or at a minimum delayed diagnosis, which results in ongoing transmission.

ENGAGING COLLABORATIVELY

In this issue, Ananthakrishnan et al. report on a TB PPE project implemented in a population of 5.3 million people in Chennai, India.[4] During 21 months of implementation, the project team engaged 227 private providers (half of those initially contacted), with an average yield of 11 symptomatics and 5 TB patients per provider, for a total of 1,232 TB diagnoses (including 26 with confirmed multidrug-resistant TB) and an overall 10% increase in TB notification in Chennai. Their approach drew from many of the lessons learned previously,[1,5–7] such as designing the intervention in collaboration with private providers, using an "intermediary agency" to bridge between public and private, and bringing modern TB diagnostics into the private sector rather than demanding immediate referral to the public sector. The project also confirmed some previous findings, such as the occurrence of a few "super-referrers"; in their case, 9% of engaged providers supplied almost half of all referrals.

Ananthakrishnan et al. have contributed to the process of iterative learning in TB PPE, which, as the authors noted, also assisted their own work through lessons from previous donor-funded TB PPE projects in India. Their PPE effort will be expanded almost threefold by the city Corporation of Chennai. Such a process of getting past the learning stage is critical: in the past, TB PPE has been plagued by numerous small projects coming and going.[8] Ultimately, such efforts need to go to scale—a challenge that India in particular is in the middle of confronting.

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TB is now largely concentrated in countries with large numbers of private health care providers.

Engagement of private providers in TB has been plagued by numerous small projects coming and going.

PAY NOW, WORRY LATER

There are two developmental strategies to this challenge of scale-up. One is to use donor financing for the implementation work now and worry about sustainability later—when the TB burden, and therefore financial need, will be lower based on the earlier, intensive effort. This is largely the approach in two substantial efforts in Pakistan and India financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (see below), though the Global Fund inputs are also subsidized by a social business model (in Pakistan[9]) and by leveraging diagnostic and drug procurements by government (in India).

Results thus far are impressive. In Pakistan, the Global Fund-financed PPE project has screened more than 3 million people for TB symptoms and detected more than 61,000 TB patients in just over 2 years.[10] In India, the Joint Effort for Elimination of Tuberculosis (JEET) project aims to reach 49 large cities and 406 smaller cities and to engage 15,000 private doctors, resulting in an expected 1.6 million notifications over 3 years (this would include a 39% contribution to the national target of 2 million private notifications in 2020). Early progress has resulted in more than 150,000 TB notifications in the first 8 months of implementation alone (personal communication, Shibu Vijayan, PATH, 2019).

Deliberate financing is needed for certain public health functions of TB care that private providers are unlikely to supply.

AMBITIOUS PLANS IN INDIA

The ambition of JEET is part of an ongoing sea change in the TB response in India. The targets under India's current *National Strategic Plan for Tuberculosis Elimination, 2017–2025*[11] start from a baseline of 11% of notifications coming from the private sector (0.19 million out of 1.74 million total notifications in 2015) and increase to a projected 56% contribution from private providers in 2020 and 2023, with 97% of the 1.86 million additional notifications in 2020 vs. 2015 projected to come from the private sector. Already, TB notifications from private providers have been steadily increasing, from 3,547 in 2012 up to 540,365 (33% of total national notifications) in 2018.[12]

It is worth quoting extensively from this *National Strategic Plan* on this change in focus[11]:

> *The proposed strategy amounts to a total transformation of the way in which the programme has engaged private providers heretofore. It will be systematic and large-scale, rather than ad hoc and insignificant. It will capitalize on advances in information and communications technology and on India's drive towards digital financial inclusion. Mistrust will be replaced by constructive partnership. Rather than compete with private providers, the programme will work with them to deliver quality … services to the entire population. Rather than additionally burdening existing under-trained and over-stretched staff, the programme will contract professional agencies with the skills and capacity to engage with thousands of providers. For the first time, budgetary resources commensurate with both the problem and the opportunity of private sector care will be allocated to address the challenge.*

TRUE SUSTAINABILITY

With the large-scale achievements of these predominantly donor-funded projects in mind, the second important strategy is to push for the sustainability of these efforts, meaning ultimately stewardship and financing by domestic governments.[13] This includes government financing of curative TB care by private providers, often via social health insurance,[14] with the opportunities for improved government stewardship of quality that this brings. But there also needs to be deliberate financing of the public health function as it applies to private providers. For TB, the public health function includes all of the activities—such as recording and reporting, adherence monitoring during 6 months of treatment, and contact investigation—that providers are unlikely to supply if paid primarily for curative tasks.[14] Such functions are a particularly important input for achieving good TB outcomes. Governments can finance such a function either by hiring an expanded, dedicated PPE cadre within government itself,[15] or by contracting out this function to the intermediaries currently supported by donor funding.[1]

In the longer term, successful PPE requires the methodical development of health system steering abilities, so that governments faced with a mixed health system[16] can govern both public and private providers equally effectively. As these competencies are being developed, a continued push for ambitious financing and achievement in the area of TB PPE remains a high priority,[17] and is essential if the world is going to have any chance of reaching the ambitious targets[18] arising from the United Nations High-Level Meeting on TB.

Disclaimer: The views and opinions expressed in this article are those of the authors and not necessarily the views and opinions of USAID.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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VIEWPOINT

Where Do We Go From Here? Defining an Agenda for Home-Based Records Research and Action Considering the 2018 WHO Guidelines

David W. Brown,[a] Xavier Bosch-Capblanch,[b] Lora Shimp[c]

Recent WHO guidelines point to knowledge gaps about home-based records despite their widespread use. Future research should explore their impact on health outcomes, challenges including production costs and confidentiality breaches, the role of design in their use, and the business case for investing in them.

Home-based, personal health records—such as vaccination cards or child health passports—are an important public health tool and serve many critical roles, especially in the delivery of immunization services (Box 1). Home-based records (HBRs) provide frontline health care workers with a standardized patient history that is convenient, comprehensive, and vital to making informed decisions about the need for immunization services and, in some instances, other primary health care services. HBRs extend the relationship between the health care worker and client or caregiver beyond an individual health encounter by improving caregiver understanding and expectations about health services. Of course, to fulfill these functional roles, certain conditions must be satisfied. For example, HBRs must be available in the right place, at the right time, and in the right quantity to avoid stock-outs.[1] They must be valued and retained by caregivers, and health care workers must request them, reference them, and ensure they are legibly completed and up-to-date. Importantly, HBRs are a document rightly due of all newborns and their caregivers as part of national promises made by signatories to the Convention on the Rights of the Child (Articles 3 and 24)[2] to protect children's health through primary health care and engagement of caregivers in making decisions about the health care (and protection from vaccine-preventable disease) of their children.

In September 2018, the World Health Organization (WHO) published the *WHO Recommendations on Home-Based Records for Maternal, Newborn and Child Health*.[3] The guidelines were the result of a 2-year process that identified, reviewed, graded, and discussed available evidence on the potential benefits of HBRs for maternal, newborn, and child health (MNCH) outcomes. While the 2018 HBR guidelines are not the first issued by WHO to countries,[4] these guidelines have been produced following widely accepted, transparent, and systematic methods,[5] which combines, in a collaborative process, research evidence from systematic reviews and other types of evidence to produce qualified recommendations. Having studied HBRs from the perspective of immunization service delivery since 2010 (DWB) and engaged with targeted learning on HBR design, availability, and use from 2016 to 2018 (LS),[6] we are encouraged by these efforts and the opportunity the guidelines present to reflect on current patterns of HBR use. We are equally excited to see how the community responds in defining an agenda for future research and action.

The findings and recommendations set forth in the 2018 HBR guidelines underscore several themes. First, despite a relative lack of robust evidence, the HBR Guideline Development Group concluded that HBRs are generally a feasible tool within MNCH programs; HBRs are particularly valued and used as a critical component of immunization service delivery.[7] Second, much of the HBR research was conducted prior to the year 2000 or in high-income countries. As such, populations in low- and middle-income countries, which may benefit most from HBRs as a primary form of documented evidence for basic health care, are disproportionately underrepresented. Finally, HBRs have evolved over time[8] in form and function—from simple cards issued in the 1800s to document proof of vaccination against smallpox[9,10] to the comprehensive MNCH handbooks (rich with public health messaging as well as clinical and public health recording areas) used by some countries today. The variety of HBR designs and formats[11] mark this evolution and reflect expanded MNCH knowledge. For example, growth monitoring charts first appeared in HBRs during the 1960s and

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BOX 1. Functional Roles and Requisite Conditions of Home-Based Records

Functional Roles

- Home-based records (HBRs) serve as a tool for documenting vaccinations and other primary care services, particularly during childhood but increasingly across the life course, in a standardized manner.
- When appropriately completed and referenced, HBRs provide necessary information for frontline clinical decision making that may ultimately improve continuity of care and reduce inefficiencies (for example, missed opportunities for vaccination and instances of unnecessary extra vaccination).
- HBRs complement facility-based record systems and serve as a verified surrogate in the absence of functioning facility-based record systems.
- HBRs help stimulate demand for vaccination services by raising caregivers' awareness of the benefits of vaccines, the recommended vaccination schedule, and the date of the child's next vaccination visit.
- HBRs serve as a prompt to initiate a discussion between health care workers and caregivers about the importance of immunization during a health encounter at a facility or during an outreach session.
- HBRs serve as a source of documented evidence of vaccination history that is important for public health monitoring through small-scale community-based rapid coverage assessments and larger population-based cluster coverage surveys.

Requisite Conditions

- HBRs are designed alongside end-users to meet their needs and to facilitate appropriate understanding and use.
- HBRs are printed on durable material and/or made available with protective covers to help them withstand exposure to harsh environments.
- HBRs are printed in sufficient quantities and appropriately distributed to avoid stock-outs.
- HBRs are made available to caregivers (ideally, free of charge) with appropriate counseling about the importance of the document and to keep the document safe from harm.
- HBRs are brought by caregivers to each health encounter, regardless of reason for the visit.
- HBRs are requested, referenced, and updated in legible handwriting by health care workers at each health encounter.

1970s—supporting the importance of infant and young child feeding with periodic growth monitoring.[12] More recently, HBRs have been used to deliver information about bed nets, handwashing, management of diarrhea, and other health topics to caregivers. In some instances, HBR content has reflected multilateral and bilateral donor development aid and assistance investments and influence with agencies lobbying by including HIV status, testing, and treatment content in HBRs and encouraging the use of MNCH handbooks over other HBR formats.

Rarely have the evolutionary changes in HBR content and form been accompanied by evaluations aimed at understanding the impact of changes on HBR function and MNCH outcomes. Do HBR design and use patterns satisfy the desired operational functions and end-user values, comprehension, and needs? In most instances, we don't know. The 2018 HBR guidelines noted numerous, persistent knowledge gaps. Identifying these evidence gaps is important to focus future primary research, systematic reviews, and the guideline development process. It is also noteworthy because recognizing the voids helps us to consider context and chart a course forward.

For example, the utility of growth monitoring and its relevance to the promotion of child health during the first years of life are unquestioned and the technical growth standards that underlie growth monitoring charts have been rigorously developed,[13] despite the paucity of robust evidence on its effects.[14] Unfortunately, growth monitoring charts found on HBRs around the world are complicated in their design—the format does not support health care worker use or caregiver understanding nor are they reinforced in practice. As a result, suboptimal use of growth monitoring charts by health care workers was recognized in the mid-1980s[15,16] and areas for recording growth on HBRs still often remain blank.[17] Evidence shows that health care workers do weigh and measure children; however, the measurements are often not recorded in the growth monitoring chart. Some workers adopt alternative approaches to record these measurements for monitoring purposes (such as writing the measurements in a notes section), but oftentimes this information is lost. Consequently, the valuable HBR tool is incomplete with unused colored charts, adding pages to the HBR and driving up the cost of the document.

Home-based records have evolved from simple cards to document proof of vaccination to comprehensive handbooks.

Despite the potentially massive investment, it remains unclear whether holistic health handbooks, as an alternative to simple cards, are useful or appropriate.

Another concern is a shift toward comprehensive MNCH handbooks, which have become just that—hefty volumes filled with text and graphic health messages across numerous intervention areas. Despite this potentially massive investment, it remains unclear whether holistic health handbooks are useful or appropriate. In some HBRs, readability is often misaligned with the literacy levels of caregivers and, in some cases, health care workers. Additionally, graphics may not be understood if images are not vetted with a generalizable audience of end-users to ensure messages are clear. In countries challenged by scarce health resources or where community literacy levels are improving yet remain low, comprehensive MNCH handbooks may not be prudent. Moreover, the higher costs of these records[18] may contribute to challenges with HBR stock availability.[1,6] Research is needed to test whether MNCH handbooks are superior to alternatives, and if so, under what conditions.

With the introduction of health handbooks, the breadth of HBR content has also expanded to include clinical gynecologic and obstetric histories for women and detailed examination recording tables and sometimes even lab results for newborns—information that is clinically important but potentially better maintained in a clinical, facility record. Although HBRs may be well suited to complement suboptimal use of facility-based record systems, this does not ensure that information is better kept or more accessible in HBRs based on our observations. Similarly, documentation of childhood oral health assessments and treatments is important; however, we question whether such content belongs in an HBR, particularly in countries where access to dental services remains suboptimal or where dental problems in childhood are not so prevalent. And instruction on the use of insecticide-treated bed nets is undoubtedly important in preventing malaria; however, it remains unclear whether individuals who maintain an HBR with these instructions are any more, or less, likely to appropriately use a bed net than those without the HBR instruction. In the end, many HBR content areas are unreferenced (despite lengthening the document and adding to production and printing costs of the HBR) and often unused—indirectly sending an adverse message to caregivers that the content is not important.

Many content areas in the home-based record are unreferenced and often unused.

Given that HBRs have evolved without appropriate evaluation of content and design, it is no surprise that the WHO HBR Guideline Development Group was unable to recommend any one HBR format over another. In fact, the quality of the available evidence led the group to assign very low or low certainty evidence scores to most of the few identified HBR research studies. This is certainly a disappointment to those who believe, quite strongly, that MNCH handbooks are superior to vaccination-only cards or vaccination-plus-growth monitoring cards because they may reduce the need for multiple records[19] or support improved continuity of care.[20] While this may be true, or true for some populations under certain circumstances, at this point, we simply do not know. No appropriate research studies have examined this very important question.

The systematic review supporting the HBR Guideline Development Group thinking did not identify any studies that explored whether HBR use was associated with more equitable MNCH outcomes, nor did it find any reports of undesirable effects of HBRs, although care must be taken with such a result since the *absence* of evidence about undesirable effects is not the same as evidence of the *lack* of undesirable effects. Undesirable effects may include disproportionate production costs, misleading caregivers, diverting attention from some health care areas in favor of others, and misuse and confidentiality breaches, among others. Studying the potential undesirable effects of HBRs or their design features is crucial, particularly given recording of HIV testing, status, and treatment within some HBRs—a practice that is questionable from an ethical perspective and that should be reconsidered given the sensitive and potentially stigmatizing and discriminatory nature of the information.[3]

Consistent with prior reports,[21] the 2018 HBR guidelines identified no economic evaluations of HBRs. A recent case study[22] suggests cost savings with use of integrated HBRs but falls short of the rigorous economic evaluation needed to formulate well-informed guidelines or recommendations. While an informal, theoretical business case for investment in HBRs has been discussed,[21] opportunities remain to demonstrate with greater rigor whether such a business case exists as well as the cost-effectiveness of different HBR designs (for example, MNCH handbook versus vaccination-plus-growth monitoring card).

We would like to see the modest momentum of the past 10 years continue. Since 2010, the revitalization of HBRs within immunization service delivery has taken several incremental steps forward and, based on observations at regional immunization program manager meetings and

recent work within several countries, there is a feeling that modest improvements have been made in awareness of HBR availability and use among immunization programs. In 2011, the Bill & Melinda Gates Foundation supported the *Records for Life* contest,[23] which reinforced the importance of user-centered HBR design. Workshops in South Asia[24] and Africa[25] alongside a JSI Inc. learning project[6] further explored the user-centered approach and led to redesigned HBRs in Afghanistan, Cameroon, the Democratic Republic of the Congo, Ethiopia, India, Nepal, and Zimbabwe. Now, after the release of the 2018 HBR guidelines, we ask, what lies ahead for the HBR agenda?

An expansive program of work is necessary to fill the gaps that have been identified in our understanding of HBR design, function, and implementation (Box 2): a combination of public health research, rapid prototyping, usability testing, and other mixed-method approaches is required. As part of the process for updating guidelines, we must promote the uptake of the identified knowledge gaps, particularly in relation to questions for which no evidence was found and questions supported by only low certainty evidence. This is particularly the case with regards to questions of impact of the HBR on outcomes, the role of HBR design in the document's uptake and use, and the business case for investing in HBRs in the first place. This program of work extends far beyond any individual donor, country, or institution; it must not be taken on as a siloed program but as a part of a broader, ongoing effort to support the delivery of high-quality, universal primary health care to all people regardless of who they are or where they live. Robust research is required and possible, as some examples brilliantly show.

A mix of public health research, rapid prototyping, usability testing, and other approaches is required to fill the identified gaps in knowledge about home-based records.

BOX 2. Research Questions Addressing Knowledge Gaps About Home-Based Records

Impact of home-based records on MNCH outcomes

- Do HBRs impact MNCH outcomes, particularly in low- and middle-income countries?
- Which HBR components impact MNCH outcomes?

Home-based record design

- Are certain HBR formats (health handbooks, vaccination-only cards, vaccination-plus-growth cards) superior to others, and, if so, under what circumstances?
- Does using an HBR designed with durable paper or protective sleeves improve the likelihood that the HBR will be retained by a caregiver through the first 5 years of a child's life?
- Do certain public health messaging topics or presentations in an HBR influence health care-seeking behavior?

Improving home-based record uptake and use

- Can HBR design features improve the uptake and value of the document by caregivers and health workers?
- Are incentives an effective and sustainable strategy for improving HBR uptake and use?

Economic evaluation of home-based records

- Are comprehensive MNCH handbooks cost-effective as compared to vaccination-plus-growth monitoring records or vaccination-only HBRs?
- Is using HBRs for delivering public health messages cost-effective?
- Should countries consider using paid advertising within HBRs to help finance HBR costs?

Understanding potential ethical concerns of home-based records

- Is it ethical to include HIV testing, status, and treatment recording fields within HBRs?
- How can we determine the potential harm of HBR content or design from the perspective of end-users?

Home-based record systems challenges

- Does bundling HBRs with other vaccine delivery supplies, both in terms of forecasting and procurement, reduce HBR stock-outs?
- Is using an HBR coordinating committee an effective strategy for overcoming the challenges of fragmented oversight in countries where multiple ministry departments maintain content ownership of the HBR?
- What opportunities exist for regional market shaping to reduce the costs of durable paper products and printing services for HBRs in low- and middle-income settings?

Knowledge gaps noted above are informed, in part, by Chapter 4 and Chapter 5 of the 2018 *WHO Recommendations on Home-Based Records for Maternal, Newborn and Child Health*.[3]

We remain hopeful that the HBR knowledge base will continue to expand. New thinking and creative, collaborative solutions are needed to address existing challenges confronting HBRs and to expand and improve the availability of documented evidence of vaccination history and other child survival interventions. We appreciate the leadership of WHO and other institutions in the work completed as of today. We also believe opportunities exist for inserting HBRs and the importance of documented evidence of vaccination (and potentially other services) within the Health Data Collaborative agenda to strengthen health information systems.[26] With commitment, coordination, and resources, these organizations and their country partners can collectively do more to propel our knowledge of the direct and indirect roles HBRs might play in global initiatives to expand birth registration, extend the lifesaving benefits of immunization to all persons, and improve infant and young child nutrition among many other areas of maternal and child health.

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COMMENTARY

Leveraging a Partnership to Disseminate and Implement What Works in Family Planning and Reproductive Health: The Implementing Best Practices (IBP) Initiative

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The IBP initiative, a WHO-based partnership of NGOs, civil society organizations, governments, academic institutions, and other implementing partners, promotes evidence-based global guidelines, tools, and other interventions for local application, and incorporates implementation experience and learning back into the global discourse.

BACKGROUND

The global health community has mobilized around various initiatives to advance the 2030 Sustainable Development Goals (SDGs) to improve the lives of women and children. The United Nations (UN) *Every Woman Every Child* strategy,[1] Family Planning 2020 (FP2020),[2] and most recently the World Health Organization's (WHO's) *Thirteenth General Programme of Work 2019–2023* (GPW13)[3] have all emphasized the need for regional- and country-level investments, collaboration, partnership, and accountability to move the agenda forward.

But what does strong collaboration and partnership really look like? The Implementing Best Practices (IBP) initiative is an example of a longtime partnership dedicated to supporting the dissemination and use of evidence-based family planning and reproductive health guidelines, tools, and practices.[4] IBP was created in 1999 with support from WHO, the United States Agency for International Development (USAID), and the United Nations Population Fund (UNFPA) to "effectively exchange and transfer knowledge, information, expertise and experience in order to improve practice."[5] Through its WHO-based Secretariat and growing network of more than 60 member organizations, spanning global, regional, and local NGOs and civil society organizations (CSOs), IBP has made significant efforts to bridge the gap between knowledge generated by the family planning community and the use of that knowledge to improve family planning and reproductive health outcomes. In addition, IBP has helped create a platform for field-based implementers to feedback local implementation experience and learning into the global discourse.

Over the past 15 years, IBP and its network of partners have made notable contributions to global family planning events and initiatives, such as the biennial International Conference on Family Planning[6] and the Family Planning High Impact Practices (HIPs) collaboration,[7] and have helped expand the global knowledge base on implementation and scale-up. At regional levels, IBP has used its leadership role to mobilize partners to support the East, Central and Southern Africa (ECSA)[8] Best Practices Forums and the West African Health Organization (WAHO) Forums on Best Practices in Health.[9] Recently IBP partnered with FP2020 and their regional focal points in Asia to host an IBP Asia Regional Workshop in Delhi, sparking new membership and revitalizing efforts for family planning knowledge exchange in the region. At the country level, IBP partners have convened workshops and conducted various activities such as documentation exercises and share fairs to support the dissemination and use of evidence-based interventions.

As family planning and reproductive health continues to gain momentum, we present IBP's strategic plan, explore some achievements of the initiative, and offer insights into how partners can leverage IBP to help achieve global development goals. More analytical information on how the collaboration has worked and areas for improvement is forthcoming, based on results of a midterm evaluation.

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IBP'S ROLE WITHIN GLOBAL REPRODUCTIVE HEALTH PARTNERSHIPS

Since the time IBP was started, the family planning and reproductive health landscape has evolved with new partners, donors, and alliances working to increase the visibility of family planning and international and national commitments to scale up family planning services. In 2004, the Reproductive Health Supplies Coalition was started, bringing together a diversity of partners to increase access to a full range of affordable, quality reproductive health supplies in low- and middle-income countries.[10] Several years later, in 2011, the Ouagadougou Partnership committed to focusing efforts to increase access to voluntary family planning in 8 francophone countries in West Africa.[11] In 2012 FP2020 was launched and has since mobilized countries and governments to provide 120 million more women and girls access to voluntary family planning by 2020.[12] Most recently, a new financing mechanism, the Global Financing Facility (GFF), has also included family planning and reproductive health as part of its mandate to better finance the global strategy for *Every Woman Every Child*.[13] All the while, existing stakeholders like UN agencies, country governments, donor agencies, academic institutions, NGOs, and CSOs continue to invest in efforts to strengthen and improve family planning and reproductive health outcomes. Each of these partnerships plays a unique role in advancing family planning advocacy, policy, financing, and programming globally.

The Figure illustrates some of the many stakeholders needed to ensure that global family planning goals are met. These stakeholders range from those focused on developing evidence-based guidelines and tools, to those galvanizing commitment and advocacy for an enabling environment, to those working on the ground to support quality implementation and scale up. The latter is where IBP has an important role to play as it is a platform dedicated to support the implementation and scale-up of evidence-based guidelines, tools, and practices.

IBP STRATEGIC PLAN 2016–2020

Previous assessments of IBP have documented its achievements and provided guidance to the current 2016–2020 IBP strategy.[14,15] The Table outlines IBP's 2016–2020 strategic objectives along with some cross-cutting mechanisms used to achieve them.

Objective 1: Increase Access to Evidence-Based Guidelines, Tools, and Resources

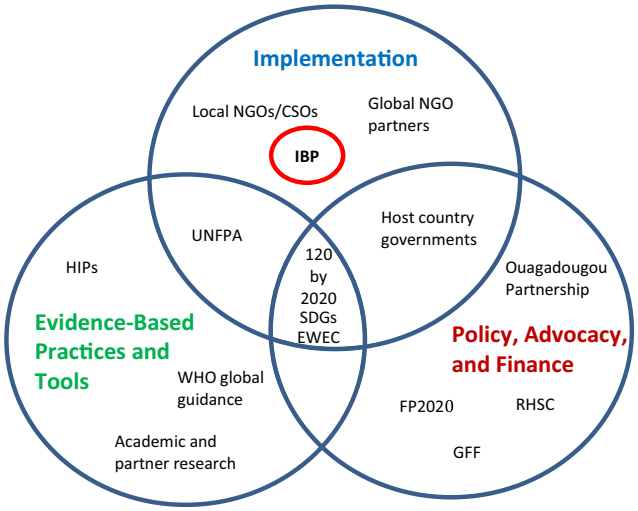
IBP has made significant efforts to bridge the gap between knowledge generation and knowledge use in family planning and reproductive health.

The family planning and reproductive health community has invested in a plethora of tools and approaches to further strengthen the provision of family planning services. The IBP strategy has focused on a selected set of tools for its core work, including WHO's *Medical Eligibility Criteria for Contraceptive Use* (MEC),[16] *Selected Practice Recommendations for Contraceptive Use* (SPR),[17] *Family Planning: A Global Handbook for Providers*,[18] the *Training Resource Package for Family Planning*,[19] and *Programming Strategies for Postpartum Family Planning*.[20] In addition, IBP has increased its support of the HIPs, a set of evidence-based programmatic interventions in family planning. IBP has introduced each of these guidelines, resources, and practices to broader audiences through its webinars, its regional and country-based meetings, and its participation in periodic global and regional family planning meetings, forums, and events. In addition, IBP uses an online platform to communicate with members and facilitate learning about implementation and scale-up. This online platform enables IBP members to interact with each other on a low-bandwidth platform through an email-based interface. The platform hosts listservs and online communities of practice and facilitates knowledge exchange through discussion forums, shared libraries, and community calendars. IBPs webinar series also help to disseminate resources in a way that showcase technical content but also highlight programmatic field-based application. With IBPs wide network webinars regularly register over 150 participants from countries all over the world.

Objective 2: Support Implementation and Scale-Up

In addition to dissemination, IBP has invested efforts to support the implementation, use, and scale-up of evidence-based interventions. IBP has facilitated the development of online communities of practice that allow participants to share their experiences about implementing and scaling up various interventions. In some instances, IBP has served as a launch pad for these communities to grow into larger separately funded networks. For example, the Health Information and Publications Network (HIPNet) and the Inter-Agency Working Group for Reproductive Health in Crises (IAWG) started on the IBP Knowledge Gateway but have since been able to secure resources to create separate online

FIGURE. IBP in the Context of Other Development Actors in Family Planning



Abbreviations: CSOs, civil society organizations; EWEC, *Every Woman Every Child*; FP2020, Family Planning 2020; GFF, Global Financing Facility; HIPs, Family Planning High Impact Practices; IBP, Implementing Best Practices; RHSC, Reproductive Health Supplies Coalition; SDGs, Sustainable Development Goals; UN, United Nations; UNFPA, United Nations Population Fund; WHO, World Health Organization.

Note: "120 by 2020" refers to the FP2020 global mandate to reach 120 million more women and girls with voluntary contraception by 2020.

presences. In addition, IBP has provided the ability to archive and maintain institutional knowledge around technical topics beyond the life of any one project. For example, the Family Planning and Immunization Integration Working Group started under the Maternal and Child Health Integrated Program (MCHIP) and has continued to be active beyond the life of the project.

IBP has also contributed to the development of tools to support implementation and scale-up. In 2013, the WHO *Guide to Fostering Change to Scale Up Effective Health Services*[21] was developed by IBP partners to illustrate a comprehensive way to institute change to support scale-up of health interventions. In 2018, this guide, along with other documented approaches to scale-up such as WHO and

TABLE. WHO/IBP Strategic Objectives 2016–2020

Objective	Mechanisms to Achieve the Objective
Objective 1: Increase access to evidence-based guidelines, tools and resources	Online knowledge management platform Technical webinars Partner dissemination
Objective 2: Support implementation and scale up	Communities of practice Development of tools Documentation
Objective 3: Enhance collaboration through increased partnership and coordination	Global and regional IBP meetings Engagement of new partners Linkages with other global networks
Cross-cutting themes: Institutionalization; Documentation; Monitoring and evaluation	

Abbreviations: IBP, Implementing Best Practices; WHO, World Health Organization.

ExpandNet's *Nine Steps for Developing a Scaling-Up Strategy*,[22] was revisited and consolidated into the *WHO Concise Guide to Implementing and Scaling Up Family Planning Service Improvements*.[23] Efforts to create tools to better link clinical guidelines and programmatic interventions are also underway to further support use.

Objective 3: Enhance Collaboration Through Increased Partnership and Coordination

IBP has benefited from a diverse network of members both through member organizations formally joining the initiative and individuals subscribing to IBP's online communities of practice. This diverse membership has allowed for collaborations and partnerships among partners based globally and in the region. Through IBP, organizations have collaborated on sessions for the International Conference on Family Planning (ICFP). Starting with the first meeting in Uganda in 2009 to the most recent meeting in Rwanda, IBP partners have worked together to develop technical panels, posters, and interactive knowledge exchange sessions as part of this global conference. Often the most interactive sessions during the conference, the IBP track has become known to foster dialogue and sharing around implementation experiences in FP. IBP has fostered collaboration among partners through participation in IBP webinars, partner meetings, and in documenting implementation experiences.

Cross-Cutting Themes

In addition to the 3 primary strategic objectives, IBP has prioritized 3 cross-cutting themes to better support its work: institutionalization, documentation, and monitoring and evaluation.

Institutionalization refers to IBP partners' joint ownership of IBP and commitment to support their own individual work by engaging with IBP and its activities. Often times with global networks, "ownership" is restricted to those directly supporting the network at the global or headquarters level. This may occur through identified working groups, focal points, or, in the case of IBP, organizational points of contact. In order to ensure IBP is a known resource at all levels of member organizations and not just at headquarters level, efforts are being made to engage more staff beyond the main points of contact and among staff in regional and country offices. Institutionalizing IBP also means recognizing the importance of country and regional buy-in. To this end, IBP works deliberately at regional and country levels to ensure that key evidence-based guidelines, tools, and practices are introduced, adopted, and adapted as needed in line with the epidemiological, social, and cultural context. IBP support to the WAHO Forums on Best Practices in Health highlights the impact of these efforts. From the first forum in 2015, the WAHO Forums have now evolved to one of the premier conferences in the region mobilizing ministers of health, partners, and policy makers.

Documentation is an overlooked but important investment to help understand what works and doesn't work when implementing public health interventions. IBP, in collaboration with partners, has developed a tool to better document such efforts. In 2013, in partnership with WAHO and the WHO Regional Office for Africa, IBP supported the development of a documentation guide template. The template was further adapted by WAHO and the WHO Regional Office for Africa, and in 2017 was published as *A Guide to Identifying and Documenting Best Practices in Family Planning Programmes*.[24] IBP partners have used this documentation guide to help document adolescent-friendly contraceptive services in Latin America and India and the provision of family planning in drug shops in Ghana. In addition, the guide was identified as a key resource as part of the 2018 WAHO Forum on Best Practices in Health and reached 1,600 downloads in the 6 months leading up to the forum. Documentation of implementation experiences can help us not only understand how and why evidence-based resources are being used but also ensure this 'experiential evidence' is fed back into the formal evidence base.

Monitoring and evaluation are critical to measure success and better document both successful and less successful experiences around implementation and scale-up. IBP has invested in monitoring and evaluation by conducting a baseline survey of the IBP 2016–2020 strategy assessing the use of IBP-supported resources. Preliminary results indicate that the tools used most by members were WHO's MEC, through use of the MEC wheel,[25] and the HIP briefs.[7] Use varied based on the type of resource. For example, the MEC wheel and the Training Resource Package were used for in-service provider training, whereas the HIP briefs and the WHO Postpartum Family Planning Compendium[26] were used for advocacy and to inform policies. Over 50% of IBP member organizations reported limited time and resources as a major barrier to expanded use. Challenges linking clinical guidelines to programmatic needs were commonly reported barriers for use of WHO

IBP works deliberately at regional and country levels to ensure key evidence-based guidelines, tools, and practices are adopted and adapted as needed.

guidelines, whereas difficulty measuring impact and limited country contextualization were reported as barriers for using the HIP briefs. Despite some challenges in use of IBP-supported resources, a majority (95%) of IBP member organizations participated in at least some IBP activities, whether they were partner meetings or communities of practice, and over 85% reported their membership in IBP added value to their work. Efforts to conduct a midterm survey are underway that will incorporate more field-based insights.

THE ADDED VALUE OF IBP

A Neutral Platform That Reduces "Collabetition" and Promotes Collaboration

The IBP Secretariat is housed at WHO, which provides a neutral space for IBP members to exchange learning experiences, resources, tools, and lessons learned. IBP member organizations contribute their own funds to support joint IBP activities, which also prevents any competition for funds among IBP members. The term "collabetition" was coined by IBP partners to capture the challenge faced when trying to balance the pressure by donors and governments to collaborate in a time when there is competition for limited donor and government resources.[14] Through its neutral convening platform, IBP has moved away from *collabetition* toward more *collaboration* between its partners. Collaboration among IBP member organizations is evident through the IBP tracks at the biennial International Conference on Family Planning, pre-conference workshops, and joint technical webinars and partner meetings. For example, IBP webinars regularly include more than 150 registrants from over 50 countries around the world. IBP's neutral platform also allows tools to be featured in, for example, Uganda's first family planning conference, held in 2014. At the time, political reasons prohibited U.S. government and U.S.-funded partners from attending. However, the neutrality of IBP and the important connection between IBP and WHO enabled IBP to attend, ensuring that evidence-based resources were shared as part of this important conference.

IBP has more than 60 member organizations and close to 80,000 individual subscribers to its online communities of practice.

Bringing Implementer Perspectives to Global Guidelines and Research

IBP can serve as a broker bringing implementation perspectives to create user-friendly derivative tools for global guidelines and to inform implementation research agendas. For example, in 2016 as WHO was developing an implementation guide to facilitate the incorporation of the MEC and SPR guidelines into national policies and programs,[27] IBP convened a day-long workshop among its partners to provide feedback on the draft and solicit input on their use of the MEC wheel and SPR. Feedback revealed that while the MEC wheel and SPR guidelines were useful, the cost of the MEC wheel was prohibitive and the SPR guidelines document was bulky in nature and structured in a way that made it difficult to find relevant information. Feedback from IBP partners guided the preparation of a new decision support tool targeted for frontline providers of contraception in humanitarian settings. The tool presents key information from both the MEC and SPR in one place in a practical, simplified format and is available as an app for iOS and Android devices.[28] More recently, IBP and the WHO Alliance for Health Policy and Systems Research (the Alliance) collaborated to develop a joint call for implementation research on service provision in drug shops. Prior to developing the research call, IBP helped leverage a technical working group meeting on drug shops and pharmacies to gather field-based experience from IBP implementers. Preliminary results highlighted both expected issues such as accreditation and supply chains and unexpected ones such as motivation of drug shop owners as barriers to service delivery. These topics added a different dimension to the research themes and were used to help inform the final research call.

A Network Approach with Global, Regional, and Local Partners

Over the years, IBP has expanded its membership to more than 60 member organizations. In addition to member organizations, individual subscribers to IBP's online communities of practice have reached close to 80,000 in more than 150 countries. IBP member organizations include global NGOs, academic institutions, regional bodies, and CSOs. Individual members are equally diverse and represent governments, students, policy makers, researchers, and community activists among other groups. The breadth of the IBP network also enables IBP to reach local NGOs and CSO partners who may not be part of larger global initiatives or global projects. This network approach also helps to foster unique collaboration that may otherwise rarely occur. For example, in 2018, IBP partner organizations Equipop and the

YP Foundation were introduced to each other at an IBP regional meeting in India. The YP Foundation was implementing youth audits for sexual and reproductive health services in local clinics to improve youth engagement and quality services. Equipop was hoping to implement a similar strategy in Burkina Faso. Rather than start from scratch, the YP Foundation made a video for Equipop showcasing their approach to youth-led audits. Equipop then translated the video into French and used it in their training on youth audits among the Burkina Faso team (personal communication, Manak Matiyani, YP Foundation and Elise Petitpas, Equipop). This example of a collaboration between a youth-led Indian NGO and a French-based NGO working in West Africa showcases the unique advantage IBP has in bringing a range of global-, regional-, and country-level organizations together. Fostering interactive knowledge sharing and encouraging collaboration through hands-on facilitation, IBP creates opportunities for such collaboration to occur.

A WAY FORWARD AND GETTING INVOLVED

IBP has come a long way since its inception in 1999. A focus on disseminating key guidelines, tools, and resources, efforts to strengthen implementation, and a concerted effort to expand the partnership have yielded some exciting activities and unique collaboration opportunities. In order to further elevate the profile of IBP, additional efforts are underway to strengthen the initiative and engage more partners in its vision.

Measuring Progress and Telling the IBP Story

IBP will continue to communicate its value to the family planning and reproductive health community at large through rigorous measurement and documentation of its work. Monitoring, evaluation, and documentation have been prioritized in the new 2016–2020 strategy, and surveys and in-depth interviews with key stakeholders are underway.

In addition to quantitatively assessing the use of tools and guidelines, IBP will also work to better capture the experiential and field-based stories from IBP partners who are using IBP-supported tools and resources in the field. IBP will also explore further the mechanisms of collaboration, partnership, and successful communities of practice. We encourage current IBP member organizations to help document the added-value of the IBP network through blog posts, articles, or social media posts illustrating collaborative efforts, knowledge exchanges, or connections made as a result of IBP activities.

Expanding Membership to More Local and Regional Partners

IBP will continue to expand its membership, with a focus on engaging more regional and local partners from Africa, Asia, Europe, and Latin America and strengthening efforts to support more regional- and country-level workshops and activities. Since 2017, IBP has welcomed more than 16 new member organizations ranging from global partners such as International Medical Corps to organizations in the European Region like Share-Net International, to local partners such as the Love Matters in India. IBP is well-placed to support better engagement with CSOs through these local and regional opportunities. Leveraging local and regional partners also helps align IBP with the WHO GPW13 that encourages new partnerships with local and regional organizations in order to show impact at country level. We encourage organizations to consider joining the IBP network or, at minimum, participating in IBP activities. Membership is simple and provides a unique opportunity to stay connected not only with the range of partners in the network but also with global partners such as UNFPA, WHO, and USAID.

Strengthening Coordination with Other Family Planning and Reproductive Health Efforts

As referenced earlier, there are many more partnerships, donors, and organizations dedicated to family planning and reproductive health today than ever before. In order to fully maximize these resources, we should recognize and use the comparative advantages of each to its fullest potential. IBP has already made strong linkages with the HIPs initiative and has been supporting dissemination of HIPs through global webinars and regional activities and has developed tools to better facilitate the use of HIPs. IBP will continue to strengthen coordination with FP2020, particularly with the FP2020 civil society focal points. IBP has long been a clear link between implementing partners and WHO, and IBP will continue to leverage this relationship with WHO Headquarters as well as WHO regional and country offices. As IBP grows, opportunities to further explore linkages with partnerships such as the Partnership for Maternal, Newborn and Child Health and the GFF will be

prioritized to complement efforts around family planning and reproductive health.

CONCLUSION

The diversity of IBP member organizations has enabled wide-ranging collaboration between other global and regional networks and organizations from around the world. As more organizations, donors, and partners invest in family planning and reproductive health efforts, it is important for IBP to maintain its comparative advantage as a consistent and committed partnership dedicated to promoting knowledge exchange around implementation and scale-up of evidence-based guidelines, tools, and practices in family planning and reproductive health. Investments to better understand and measure successful collaboration through IBP will help shape the way new partnerships and other collaborative efforts are developed. As the global health community rallies around FP2020, *Every Woman Every Child*, and the SDGs, capitalizing on the strengths of partnerships like IBP will be an important step to help us achieve the ambitious goals to improve the lives of women, children, and families worldwide.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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SYNTHESIS

Saving Mothers, Giving Life: It Takes a System to Save a Mother (Republication)

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A multi-partner effort in Uganda and Zambia employed a districtwide health systems strengthening approach, with supply- and demand-side interventions, to address timely use of appropriate, quality maternity care. Between 2012 and 2016, maternal mortality declined by approximately 40% in both partnership-supported facilities and districts in each country. This experience has useful lessons for other low-resource settings.

Note: This is a republication of an article first published in GHSP, Volume 7, Supplement 1, "Saving Mothers, Giving Life: A Systems Approach to Reducing Maternal and Perinatal Deaths in Uganda and Zambia."

ABSTRACT

Background: Ending preventable maternal and newborn deaths remains a global health imperative under United Nations Sustainable Development Goal targets 3.1 and 3.2. Saving Mothers, Giving Life (SMGL) was designed in 2011 within the Global Health Initiative as a public–private partnership between the U.S. government, Merck for Mothers, Every Mother Counts, the American College of Obstetricians and Gynecologists, the government of Norway, and Project C.U.R.E. SMGL's initial aim was to dramatically reduce maternal mortality in low-resource, high-burden sub-Saharan African countries. SMGL used a district health systems strengthening approach combining both supply- and demand-side interventions to address the 3 key delays to accessing effective maternity care in a timely manner: delays in seeking, reaching, and receiving quality obstetric services.

Implementation: The SMGL approach was piloted from June 2012 to December 2013 in 8 rural districts (4 each) in Uganda and Zambia with high levels of maternal deaths. Over the next 4 years, SMGL expanded to a total of 13 districts in Uganda and 18 in Zambia. SMGL built on existing host government and private maternal and child health platforms, and was aligned with and guided by Ugandan and Zambian maternal and newborn health policies and programs. A 35% reduction in the maternal mortality ratio (MMR) was achieved in SMGL-designated facilities in both countries during the first 12 months of implementation.

Results: Maternal health outcomes achieved after 5 years of implementation in the SMGL-designated pilot districts were substantial: a 44% reduction in both facility and districtwide MMR in Uganda, and a 38% decrease in facility and a 41% decline in districtwide MMR in Zambia. Facility deliveries increased by 47% (from 46% to 67%) in Uganda and by 44% (from 62% to 90%) in Zambia. Cesarean delivery rates also increased: by 71% in Uganda (from 5.3% to 9.0%) and by 79% in Zambia (from 2.7% to 4.8%). The average annual rate of reduction for maternal deaths in the SMGL-supported districts exceeded that found countrywide: 11.5% versus 3.5% in Uganda and 10.5% versus 2.8% in Zambia. The changes in stillbirth rates were significant (−13% in Uganda and −36% in Zambia) but those for pre-discharge neonatal mortality rates were not significant in either Uganda or Zambia.

Conclusion: A district health systems strengthening approach to addressing the 3 delays to accessing timely, appropriate, high-quality care for pregnant women can save women's lives from preventable causes and reduce stillbirths. The approach appears not to significantly impact pre-discharge neonatal mortality.

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INTRODUCTION

Despite a 45% drop in global maternal deaths between 1990 and 2015,[1] maternal mortality

remains an intractable public health problem in many low-resource settings. Only 1 sub-Saharan African country, Rwanda, achieved the target for Millennium Development Goal 5 (reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio).[1,2] Attempts have been made to bring high-level visibility to the cause, but many countries have not directed sustained political attention or sufficient resources to eliminate preventable maternal mortality[3]—despite solid evidence of the profound effects a mother's death has on her family, her community, and on development in general.[4,5] The situation is particularly dire in sub-Saharan African countries where 60% of global maternal deaths occur.[1,5,6] In these countries, obstetrical risk is compounded by high fertility rates, raising the lifetime risk of death due to childbirth to 1 in 36, compared with 1 in 8,400 in the European Union.[7–9]

Newborns fare no better. Globally, the reduction in newborn deaths has not kept pace with the reduction of deaths in children under age 5, with newborn deaths now contributing to nearly half of child mortality.[1] The average neonatal mortality rate is 27 deaths per 1,000 live births in low-income countries compared with 3 deaths per 1,000 live births in high-income countries. Eight of the 10 most dangerous places to be born are in sub-Saharan Africa.[10]

In 2011 the Office of the Global Health Initiative (GHI) within the U.S. Department of State was tasked with designing an endeavor that would bring public and private investment together with committed Ministry of Health (MOH), national, and district leaders to address maternal mortality in sub-Saharan Africa.[11,12] It was felt that a highly visible, well-financed, bold initiative similar to the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative, and Feed the Future was needed to inspire and recruit new public and private actors to the cause, while energizing and mobilizing the global health and development communities. The resulting initiative was Saving Mothers, Giving Life (SMGL), a public–private partnership. SMGL was composed of 6 U.S. agencies: GHI; the United States Agency for International Development (USAID) (which took over oversight of the partnership from GHI in July 2012 and responsibility as Secretariat from Merck for Mothers in 2014); the U.S. Centers for Disease Control and Prevention (CDC); the Office of the Global AIDS Coordinator (OGAC); Peace Corps; and the Department of Defense. It also included the Governments of Norway (became inactive in 2014), Uganda, Zambia, and Nigeria (joining in 2015 as the third SMGL country and slated to end in October 2019); Merck for Mothers; Every Mother Counts; the American College of Obstetricians and Gynecologists; and Project C.U.R.E (joined the partnership in 2013). SMGL's initial goal was to decrease maternal mortality by 50% in 1 year in SMGL-designated districts in Uganda and Zambia, building on existing national public health platforms and systems, and aligning with country maternal health strategies and aspirations.[13,14] At the end of the first phase of the partnership, the time frame for the goal was extended to the close of the initiative in 2017. An additional goal of reducing the neonatal mortality rate by 30% was added in 2013.

SMGL's initial goal was to decrease maternal mortality by 50% in 1 year in selected districts in Uganda and Zambia.

The Saving Mothers, Giving Life journal supplement consists of 11 articles on the SMGL initiative. The articles describe the formation and function of the partnership, the SMGL theory of change, programming approach and costs, and the results achieved in Uganda and Zambia where implementation ended in October 2017 (Table 1). It aims to answer key questions about the initiative and identify outstanding implementation issues. Results from Nigeria will be reported in 2019 after implementation in that country has ended.

THEORY OF CHANGE

The SMGL theory of change model was built on a district health systems strengthening approach. It was designed to surmount the critical demand- and supply-side delays that prevent women and newborns from receiving lifesaving care in a timely manner, while strengthening the capacity and resilience of the health care system (Figure 1).[15]

The SMGL theory of change was built on a district health systems strengthening approach.

The governments of Uganda and Zambia, their public health systems, the PEPFAR- and USAID-supported maternal and child health platforms, and private for-profit and nonprofit providers were critical inputs and served as the foundation for SMGL's contributions to the district maternity care system. Evidence-based interventions were designed to address all key delays, be context-specific, and strengthen the capacity of the district health system. Four outcomes were anticipated: (1) increased use of services and improved self-care, (2) timelier access to appropriate care, (3) improved quality and experience of care, and (4) a more robust and resilient district health system. It

TABLE 1. Saving Mothers, Giving Life Supplement Articles

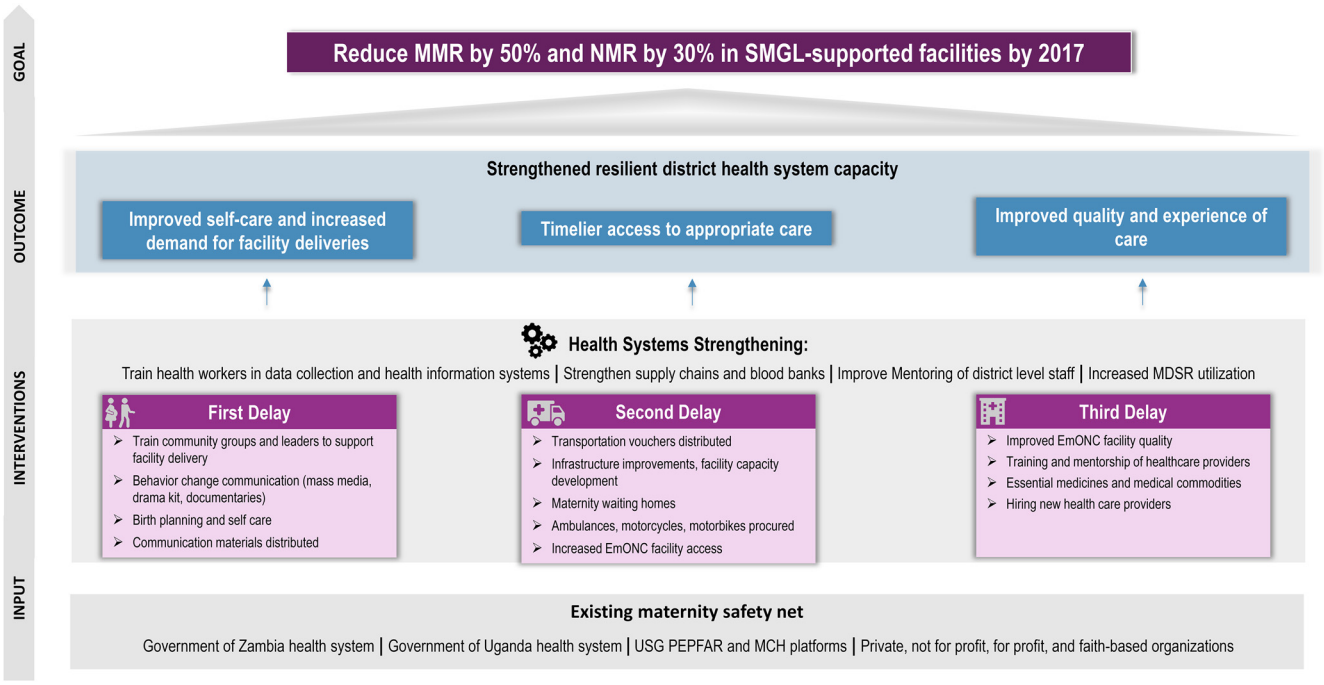
Article No.	Article Title
1	Saving Mothers, Giving Life: it takes a system to save a mother
2	Impact of the Saving Mothers, Giving Life approach on decreasing maternal and perinatal deaths in Uganda and Zambia
3	Addressing the first delay in Saving Mothers, Giving Life districts in Uganda and Zambia: approaches and results for increasing demand for facility delivery services
4	Addressing the second delay in Saving Mothers, Giving Life districts in Uganda and Zambia: reaching appropriate maternal care in a timely manner
5	Addressing the third delay in Saving Mothers, Giving Life districts in Uganda and Zambia: ensuring adequate and appropriate facility-based maternal and perinatal health care
6	The costs and cost-effectiveness of a district-strengthening strategy to mitigate the 3 delays to quality maternal health care: results from Uganda and Zambia
7	Saving lives together: a qualitative evaluation of the Saving Mothers, Giving Life public-private partnership
8	Community perceptions of a 3-delays model intervention: a qualitative evaluation of Saving Mothers, Giving Life in Zambia
9	Did the Saving Mothers, Giving Life initiative expand timely access to lifesaving care in Uganda? A spatial district-level analysis of travel time to emergency obstetric and newborn care
10	Saving Mothers, Giving Life approach for strengthening health systems to reduce maternal and newborn deaths in 7 scale-up districts in northern Uganda
11	Sustainability and scale of the Saving Mothers, Giving Life approach in Uganda and Zambia

was hypothesized that if these 4 outcomes were achieved together, SMGL-designated populations would see a substantial decrease in maternal and perinatal mortality.

Implementation of the SMGL theory of change followed 7 organizing principles:

1. Reap system-level synergies by addressing all 3 delays to obtaining lifesaving maternal and newborn care concurrently: delays in seeking appropriate care, delays in reaching services in a timely manner, and delays in receiving quality care at a health facility with the capacity to perform 9 signal emergency obstetric and newborn care (EmONC) functions.[16–22]
2. Recognize the district health system, which extends from community health workers to district hospitals (and to higher levels of care through referrals), as the primary unit for strengthening capacity.[23–25] Potential interventions should be assessed in terms of their contributions to improving the functioning of the entire district-level system.
3. Apply a "whole market approach," which requires identifying and including both public and private inputs (e.g., providers, delivery systems, stakeholders) in planning, execution, and evaluation in a designated district. Together they form the district maternity safety net.
4. Focus on improving services during the most vulnerable period for mothers and newborns—labor, delivery, and early postpartum. Interventions at this time have the possibility of saving the lives of mothers and newborns and preventing fresh stillbirths. The level of fresh stillbirths is often seen as an indicator of the quality of care during labor and delivery.
5. Strengthen the capacity of the health care system to provide comprehensive emergency obstetric and newborn care (CEmONC) within 2 hours of travel time from home or a delivery site for all pregnant women, approximately 15% of whom will experience a life-threatening complication, many without clear predictors.[26,27]
6. Integrate maternal and newborn health (MNH) services with other reproductive health services, including (1) HIV counseling and testing services to maximize identification and treatment of seropositive pregnant

FIGURE 1. Saving Mothers, Giving Life Theory of Change Model



Abbreviations: EmONC, emergency obstetric and newborn care; MCH, maternal and child health; MPDSR, maternal and perinatal death surveillance and response; MMR, maternal mortality ratio; NMR, neonatal mortality rate; PEPFAR, U.S. President's Emergency Plan for AIDS Relief; SMGL, Saving Mothers, Giving Life; USG, U.S. Government.

Source: Adapted from Saving Mothers, Giving Life.[57]

women and prevent mother-to-child transmission, and (2) postpartum family planning for women wishing to delay their next pregnancy.

7. Count, analyze, and report all maternal and perinatal deaths along with the cause of death; improve completion of facility records and registries; institutionalize maternal and perinatal death surveillance and response (MPDSR) in each district and foster high-level awareness of these reviews among traditional, religious, and political leadership to learn from each preventable death and promote necessary health system and cultural changes.

COUNTRY CONTEXT

In 2011, Uganda and Zambia were chosen as the first SMGL-supported countries based on (1) their interest to the Global Health Initiative; (2) high levels of maternal mortality—MMR of 420 in Uganda and 262 in Zambia in 2010[1]; (3) solid MOH commitment to decreasing maternal and newborn mortality, as evidenced by their Roadmap to Accelerate Reduction of Maternal and Neonatal Mortality and Morbidity and Campaign to Accelerate the Reduction of Maternal, Newborn, and Child Mortality in Africa plans; and (4) the existence of robust PEPFAR- and USAID-supported maternal and child health platforms.[28–30] Direct causes of maternal deaths were similar in both countries, with postpartum hemorrhage being the leading cause followed by preeclampsia/eclampsia, sepsis, obstructed labor/ruptured uterus, and complications of unsafe abortions.[1] The most deadly indirect causes were malaria and HIV.[29,31]

Inadequate skilled human resources for health were a major constraint to providing effective coverage in both countries.[29,31] When SMGL began, the human resources vacancy rate at

health facilities in SMGL-supported districts was 40% in both Uganda and Zambia.[11,12,32–34] Uganda and Zambia also shared high HIV rates (7% and 12% among adults ages 15 to 49, respectively) and their total fertility rates were among the highest in the world (6.2 for both countries) (Table 2). Less than half of births in Zambia, and 57% in Uganda, were attended by skilled birth attendants and the cesarean delivery rates were low at 5% in Uganda and 3% in Zambia. Neonatal mortality rates were 27 and 34 per 1,000 live births in Uganda and Zambia, respectively (Table 2).

PROJECT DESIGN, IMPLEMENTATION, AND ASSESSMENT

SMGL Learning Districts

Four districts each in Uganda and Zambia were selected for SMGL support by their MOH based on the large numbers of deliveries and maternal deaths, the availability of existing implementing partners working in the district, and national priorities. The 8 districts in total, designated as the SMGL learning districts, were mostly rural and poor.[8,11,12,30,31] Figure 2 shows the learning districts and the scale-up districts. Over the life of the initiative, the 4 learning districts in each country were administratively split further to total 6 learning districts in each country.

In Zambia, the 4 initial learning districts were spread across the country with 2 in Eastern Province (Nyimba and Lundazi), 1 in Southern Province (Kalomo), and 1 in Luapula Province (Mansa). The 4-district population was 880,000 with 46,157 deliveries in 2011. Throughout the initiative, 110 health facilities were engaged, 94% public and 6% private, including 16 health posts, 88 health centers, and 6 hospitals.[11,35] Uganda's SMGL-supported districts (Kyenjojo, Kamwenge, Kabarole, and Kibaale, aka "the 4Ks") were contiguous and located in Western Uganda. The population in the 4Ks was 1.75 million with 78,400 deliveries in 2011. Throughout the initiative, 105 delivering facilities, 61% public and 39% private (18 health centers II, 70 health centers III, 11 health centers IV, and 6 hospitals), were supported by SMGL.[12,36]

SMGL Phases

The SMGL initiative was divided into 3 phases: Phase 0—design and startup (June 2011 to May 2012), Phase 1—proof of concept (June 2012 to

TABLE 2. Uganda and Zambia National-Level Indicators at the Start of the SMGL Initiative

Indicator	Uganda	Zambia
Maternal mortality ratio (per 100,000 live births)	420[a]	262[a]
Deliveries in facilities	57%[b]	48%[c]
Births by cesarean delivery	5%[b]	3%[c]
Birth attended by skilled birth attendant	57%[b]	47%[c]
Antenatal care coverage: at least 4 visits	48%[b]	60%[c]
HIV prevalence among adults 15–49	7%[d]	12%[d]
Pregnant women with HIV receiving antiretroviral therapy	61%[d]	93%[d]
Total fertility rate	6.2[b]	6.2[c]
Modern contraceptive prevalence rate among all women 15–49	21%[b]	25%[c]
Neonatal mortality rate (per 1,000 live births)	27[b]	34[c]

Abbreviation: SMGL, Saving Mothers, Giving Life.
[a] 2010 data from *Trends in Maternal Mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division* (https://www.who.int/reproductivehealth/publications/monitoring/maternal-mortality-2015/en/).
[b] 2011 data from *Uganda Demographic and Health Survey 2011* (https://dhsprogram.com/pubs/pdf/FR264/FR264.pdf).
[c] 2007 data from *Zambia Demographic and Health Survey 2007* (https://www.dhsprogram.com/pubs/pdf/FR211/FR211[revised-05-12-2009].pdf).
[d] 2011 data from UNAIDS AIDSinfo (http://aidsinfo.unaids.org/).

December 2013), and Phase 2—scale-up and scale-out (January 2014 to October 2017).

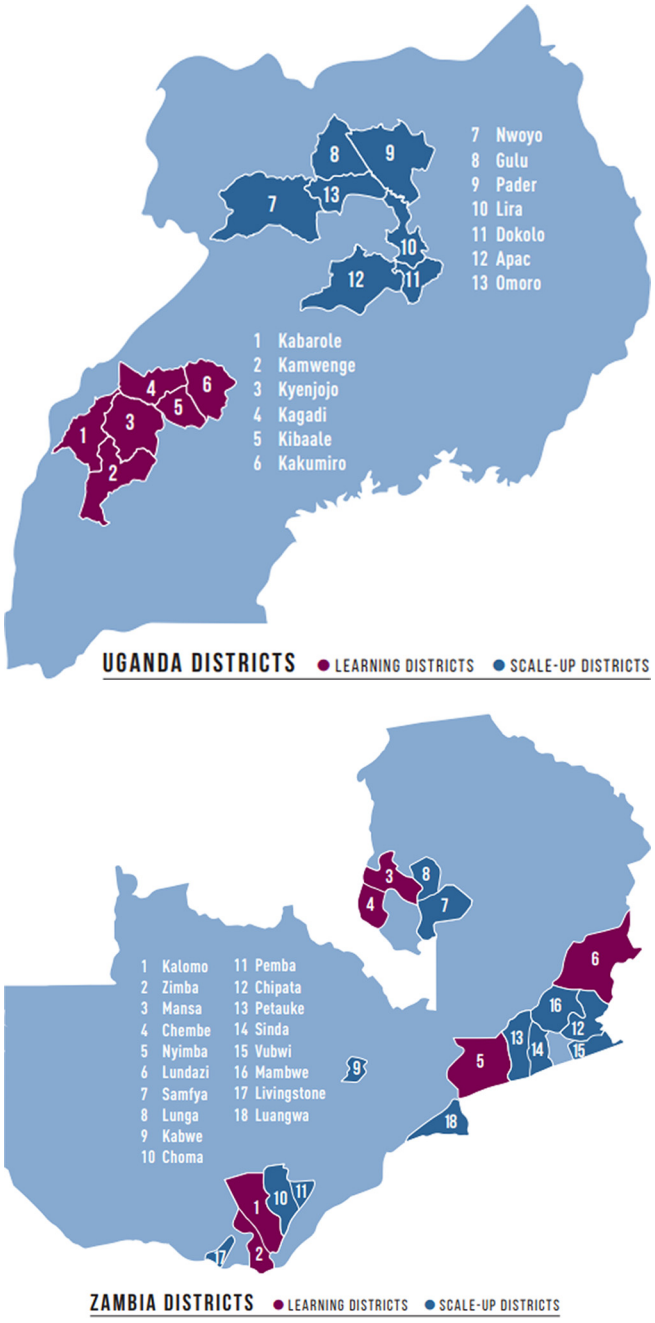
Phase 0: Design and Startup

Initiative design. Design of the SMGL district health systems strengthening approach began in mid-2011 under the aegis of the Global Health Initiative. The Global Health Initiative convened a design team of MNH and HIV technical experts in project development, implementation, costing, policy formulation, and monitoring and evaluation. The aim was to create a highly visible, bold initiative that would galvanize global action and financial support. A draft SMGL model was developed, guided by GHI principles and informed by extensive examination of the evidence base and modeling from the Lives Saved Tool (LiST). (Supplement 1) A goal was established to reduce maternal mortality in SMGL-supported facilities in Uganda and Zambia by 50% in 1 year and an implementation plan was formulated. A notable feature of the plan was that partner funding for SMGL implementation was only guaranteed for an initial 12-month period; if performance was deemed subpar, funding for SMGL could end.

After country and district selection, the U.S. ambassadors for Uganda and Zambia assigned coordination roles to U.S. agency heads (USAID mission director, CDC director, PEPFAR coordinator, Peace Corps lead, and Department of Defense liaison), and interagency working groups were formed. The working groups collaborated with national, provincial, and district MOH-designated SMGL leads (usually district health officers) and implementing partners, forming SMGL country teams. The country teams initially met weekly and then monthly to develop plans and leverage existing partner programs and capabilities. Country teams then created intensive 1-year workplans for the pilot districts in Uganda and Zambia based on addressing the 3 delays and strengthening the system.

The rapid design and execution of the initial SMGL 1-year plan required the participation of existing implementing partners working in SMGL-selected districts. Between Uganda and Zambia, 39 implementing partners were identified, most with set workplans and deliverables (Supplement 2). Under the leadership and supervision of MOH district health management teams and district health and medical officers, extant implementing partner workplans were adapted to support SMGL country and district plans.

FIGURE 2. Saving Mothers, Giving Life-Designated Learning and Scale-Up Districts in Uganda and Zambia



Source: Adapted from Saving Mothers, Giving Life.[57]

SMGL developed a robust evaluation plan that included ongoing enumeration of all maternal deaths with verbal autopsies to ascertain cause of death.

Evaluation design. The ability to assess and report health outcomes resulting from SMGL efforts required robust evaluation. The headquarters monitoring and evaluation (M&E) committee, composed of specialists from CDC and USAID, developed an ambitious evaluation plan for Phase 1 that was endorsed by the ministries of health and implementing partner representatives in both countries.[37] The plan included ongoing enumeration of all maternal deaths with verbal autopsies to ascertain cause of death. (See the article by Serbanescu and colleagues from the SMGL supplement.[38])

Thirty-one indicators were selected for monitoring care at all delivering facilities through quarterly record and registry reviews in SMGL-supported districts in Uganda and Zambia (Supplement 3). In Uganda, these data were collected through Pregnancy Outcomes Monitoring Studies; data were also gathered and displayed monthly at selected SMGL facilities in Uganda using a simple matrix referred to as "BABIES" (Birthweight by Age-at-Death Boxes for Intervention and Evaluation System), which provided short-loop feedback to improve newborn care. Formative special studies[37] included a qualitative study of women's and communities' perceptions of childbirth in Zambia and a 2-hour travel-time mapping study in Uganda.[39] (See the article by Schmitz and colleagues from the SMGL supplement.[40])

Baseline assessment. During Phase 0, baseline studies were undertaken in the 8 learning districts. MMRs were measured through a census with verbal autopsies of deaths among women of reproductive age in Zambia and a Reproductive Age Mortality Survey (RAMOS) in Uganda. (RAMOS uses a variety of sources to identify all deaths of women of reproductive age and decide which of these are maternal- or pregnancy-related.) Health facility assessments (HFAs) of capacity and readiness of the system to provide 9 lifesaving signal functions were undertaken in all public and private delivering facilities in the SMGL-supported districts (Table 3). This enabled planners and implementers to take stock of the existing availability of basic and comprehensive emergency obstetric and newborn care. HFAs were carried out at 3 time points during SMGL: (1) at baseline, to inform SMGL planning and design and to identify needed investments; (2) at the end of the pilot year in 2013 to gauge progress and inform funding and operational decisions during subsequent years; and (3) at endline in 2017 to assess outcomes.

Common gaps identified from the baseline HFA included the following:

- **Delay 1: Demand.** The number of Government-established community health workers, village health teams (VHTs) in Uganda and Safe Motherhood Action Groups (SMAGs) in Zambia, was inadequate. Women booked late for antenatal care visits and attendance of 4 or more antenatal care visits was low (46% in Uganda).[41]
- **Delay 2: Access.** Women had limited access to comprehensive CEmONC facilities within 2 hours (only 51% to 55% of women were able to reach CEmONC within 2 hours using motorized vehicles) due to few operating theaters and blood banks, and lack of transport vehicles and referral protocols. Maternity waiting homes were often dilapidated and deserted.
- **Delay 3: Quality.** Many maternity blocks in hospitals and health centers were run-down and overcrowded, and they lacked water,

TABLE 3. Emergency Obstetric and Newborn Care 9 Signal Functions

Basic Services	Comprehensive Services
1. Administer parenteral antibiotics	Perform signal functions 1 through 7 plus:
2. Administer uterotonic drugs (i.e., parenteral oxytocin, misoprostol)	8. Surgery (cesarean delivery)
3. Administer parenteral anticonvulsants for preeclampsia (i.e., magnesium sulfate)	9. Blood transfusion
4. Manually remove the placenta	
5. Remove retained products of conception (e.g., manual vacuum extraction, misoprostol, dilation and curettage)	
6. Perform assisted vaginal delivery (e.g., vacuum extraction, forceps delivery)	
7. Perform basic neonatal resuscitation (e.g., bag and mask)	

Source: WHO, UNFPA, UNICEF, and Mailman School of Public Health.[27]

electricity, and functioning toilets. Equipment was missing, inoperative, or insufficient for the client load. Facilities lacked 24-hour staffing of skilled birth attendants, anesthetists, and surgeons.

- **Health Systems Strengthening.** In the face of limited quality improvement activities, facilities experienced frequent drug and supply stock-outs and weak capture, analysis, and reporting of health outcome data.

These gaps and other district-specific challenges were addressed in SMGL district workplans.

Startup. Startup activities began early in 2012. At the national level in Uganda and Zambia, routine meetings were held with the interagency working groups, MOH representatives, and implementing partners. Preparations for work with private providers through the Programme for Accessible Health Communication and Education (PACE) project and Marie Stopes International were initiated in Uganda. In Zambia, where the SMGL learning districts were spread out across the country, SMGL district coordinators—often retired midwives—were hired to harmonize all SMGL activities in their district with district health officers and district health management teams, and to serve as a link with implementing partners. During this phase, training commenced for providers and existing government-sponsored community health workers—SMAGs and VHTs. These health workers were recruited from the local community. Groups were a mix of men and women and often included former traditional birth attendants. SMGL provided these volunteers with resources such as gumboots, flashlights, T-shirts, and bicycles. In Zambia, Peace Corps volunteers were recruited and trained as community mobilizers to work with SMAGs to increase demand and organize community transport systems. By the end of the initiative, SMGL-dedicated Peace Corps volunteers were in all 18 SMGL-supported districts.

Phase 1: Proof of Concept

Results for Phase 1 are based on data for the 12-month period from June 2012 through May 2013. Analysis and write-up of lessons, however, continued through December 2013.

Interventions. District-level MOH staff led the implementation process working with implementing partners funded by PEPFAR, CDC, USAID, and Merck. In the learning districts, the following interventions were carried out to address the health system gaps identified in the Phase 0 HFAs, by delay, in accord with the SMGL theory of change.

- **Delay 1: Demand.** Tackling this delay required not only effecting change in individual behaviors but also influencing community norms. SMAGs and VHTs identified pregnant women and initiated antenatal home visits covering all villages across the 8 learning districts. They provided childbirth education and anticipatory guidance. Specific topics included: self-care and a healthy diet, attending antenatal and postnatal care visits and delivering in a facility, family planning, recognition of maternal and newborn danger signs, being tested for HIV, and undertaking birth planning and saving to cover the costs of transport and medical care. Messages given during these family visits were reinforced by including husbands and household members, holding community sensitization meetings, and training traditional leaders to be "change champions." Multimedia campaigns, which included community sensitization skits, radio announcements, community documentary screenings, and billboards, were also fielded in both countries. In Zambia, Peace Corps volunteers trained SMAGs on a home-visit protocol using the national SMAG curriculum. (See the article by Serbanescu and colleagues from the SMGL supplement.[41])
- **Delay 2: Access.** A travel-time study in Uganda and HFA results from both countries confirmed that timely access to care was a major problem in all 8 SMGL-supported districts. SMGL programming addressed this problem in 3 ways: bringing lifesaving care closer to women, decreasing travel time to appropriate care, and bringing women closer to emergency services. Select maternity wards and surgical theaters were refurbished to upgrade facility capacity and optimize 2-hour access to CEmONC care. In Uganda, subsidized motorcycle transport vouchers and private-care vouchers, distributed by VHTs, were rapidly scaled up during Phase 1. In Zambia, where long distances to care are the norm, maternity waiting homes were refurbished or built next to EmONC facilities by the Department of Defense and the Merck-led Maternity Waiting Home Alliance. In both countries, SMGL ensured appropriate communication tools, such as cell phones and radios, and district-specific protocols to facilitate transfers. (See the article by Ngoma et al. from the SMGL supplement.[42])

To address barriers to timely access to care, SMGL brought lifesaving care closer to women, decreased travel time to appropriate care, and brought women closer to emergency services.

- **Delay 3: Quality.** Baseline HFA results had revealed the need for significant improvements in the quality of services provided if women were to receive lifesaving care for complications; many aspects of the health system would need to be strengthened. Efforts to improve the quality of services engaged frontline health care providers and facility managers. SMGL hired strategically placed midwives, nurses, anesthetists, and doctors (147 providers in Uganda and 19 in Zambia). In both countries, many of the midwives hired were retired, seasoned health professionals. In Uganda, staff was hired with the understanding that their positions would be picked up by the MOH when SMGL funding ended. SMGL doctors received increases in their salaries to work in rural health center IVs rather than hospitals, an incentive that was subsequently adopted nationally by the MOH. Quality improvement committees were formed and the BABIES matrix was introduced into all EmONC facilities. Quality improvement committees were trained to sensitize providers on the importance of respectful care. Merck for Mothers worked through the PACE project to provide technical assistance to private providers in order to upgrade their skills.

  Health care providers in both countries were trained by MOH trainers and routinely mentored on EmONC, Helping Babies Breathe, essential newborn care, uterine balloon tamponade (Zambia), maternal and perinatal death reviews, syphilis screening, prevention of mother-to-child transmission of HIV, infection prevention, and operative skills. Obstetricians and gynecologists associations in both countries provided clinical mentoring to district medical officers and district health officers in SMGL-designated districts and the professional societies were in turn strengthened with technical assistance from the American College of Obstetrics and Gynecology. Project C.U.R.E. supplied donated facility-specific, essential equipment and commodities (including hospital and delivery beds, surgical tables and lights, resuscitation supplies, sterilization equipment, sutures, and gloves), shipping 16 containers to Uganda and 20 to Zambia over the life of the initiative. (See the article by Morof et al. from the SMGL supplement.[43])

- **Health systems strengthening.** Activities to strengthen the health system included providing HIV-related diagnostics and treatment and family planning services at the same location and times as MNH services to create "one-stop" shops. Both countries followed the Option B+ HIV treatment guidance, which supports HIV testing and counseling during antenatal care and offering women found to have HIV infection lifelong antiretroviral therapy. This facilitated the SMGL HIV testing and treatment approach: pregnant women were tested for HIV during antenatal care visits, and if seropositive, midwives were empowered to place them on antiretroviral therapy to protect the life of the mother and prevent mother-to-child transmission. In select SMGL-supported districts, providers were trained to provide postpartum family planning. District medical and health officers and in-charges received instruction on drug logistics and forecasting to prevent chronic stock-outs of essential medicines. Facilities were equipped with rainwater catchment systems, solar panels, and functioning toilets. Maternal and perinatal deaths were reviewed through routine maternal and perinatal death surveillance and response efforts in facilities. The CDC provided capacity strengthening of district-level teams on monitoring and evaluation. SMGL staff supported monthly district-led data reviews of MNH indicators, quarterly provincial-level reviews, and strengthening of the District Health Information Management System (DHIS2), a free and open-source health management data platform. (See the article by Serbanescu and colleagues from the SMGL supplement.[38])

Health systems strengthening activities included providing HIV-related diagnostics and treatment and integrated family planning services.

- **Data collection activities.** After 12 months of Phase 1 implementation (June 2012 to May 2013), endline Phase 1 studies were conducted in the 8 learning districts to assess the status of the SMGL indicators and thus gauge progress at the end of year 1.[17] In addition, a mixed-methods external implementation evaluation of Phase 1 was undertaken by Columbia University.[29] This evaluation examined the reach, extent, fidelity, and dynamic effects of the initiative in order to identify best practices and remaining barriers to reducing maternal mortality. Data from these evaluations were analyzed and results were reported at an SMGL global dissemination meeting in January 2014.[44,45] (See Supplement 4.)

Phase 2: Scale-Up and Scale-Out

Early in 2014, the partners met to examine SMGL performance and to modify SMGL's approach, governance, assessment, and implementation for

Phase 2. These adjustments are described in the following sections.

Initiative. The partners decided to maximize the return on initial investments in Uganda and Zambia by committing to operate in both countries until October 2017. SMGL would aim to achieve near-national coverage of the SMGL approach in Uganda and Zambia, defined by the partners as ≥70% population coverage, and would select 1 additional country for SMGL implementation. In 2015, Nigeria became the third and final SMGL country.[46] There, the SMGL systems approach was rolled out across Cross River State (population 3.7 million) and will be supported until October 2019. The governing partners for SMGL Nigeria are USAID Washington, USAID Nigeria, Merck for Mothers, and Project C.U.R.E.

Governance. MOH representatives were invited to join the Leadership Council, SMGL's global governing body, and partners agreed to re-examine their resource pledges and submit quarterly contribution reports.

Scale-up district assessment. The SMGL partners agreed that due to the high cost and management burden of undertaking detailed information gathering, a limited number of M&E activities would take place in the scale-up districts of both countries. The focus of these efforts would be to guide program adjustments for quality improvement: HFAs at baseline to inform initial programming, quarterly record and registry data gathering at CEmONC facilities only, and Health Management Information System reporting on indicators of interest for all facilities on a quarterly basis. (See the article by Isabirye et al. from the SMGL supplement.[47])

Implementation. Interventions introduced in Phase 1 were largely maintained with a few exceptions: Mama Pack distribution in Zambia ended based on concerns about sustainability; repair or replacement of 2-way radios became unnecessary as the availability of cell phones increased; and ongoing enumeration of maternal deaths by Zambia SMAGs was discontinued after problems with data gathering during the proof-of-concept phase. VHTs in Uganda continued ongoing enumeration. The partners endorsed several context-specific programmatic changes for the learning districts and the scale-up districts. The SMGL time frame of interest was lengthened from intrapartum through 24 hours postpartum to 48 hours postpartum in Uganda and 72 hours postpartum in Zambia to conform to host country guidelines and enable greater focus on postpartum family planning and postnatal care. In the face of nonsignificant reductions in pre-discharge neonatal mortality in Uganda during Phase 1, SMGL increased programming for newborns. Additional interventions included: ensuring availability of newborn corners (flat surfaces for newborn resuscitation) in each delivery room; opening neonatal special care units, and Kangaroo Mother Care units in 8 health center IVs and 3 hospitals where stable low birth weight and premature newborns could be cared for; upgrading the existing neonatal intensive care unit at Fort Portal Regional Referral Hospital; increasing training and drilling on newborn resuscitation and essential newborn care; and implementing the BABIES matrix in additional facilities. (See the article by Morof and colleagues from the SMGL supplement.[43])

In Zambia, where postpartum hemorrhage was the leading cause of maternal death and in the context of long distances to delivery care, 3 interventions were prioritized for Phase 2: (1) constructing and refurbishing maternity waiting homes, (2) introducing and institutionalizing uterine balloon tamponade, and (3) strengthening the national blood transfusion system. Maternity homes, located next to SMGL-supported EmONC facilities, were built or refurbished by the U.S. Department of Defense or under the Maternity Waiting Home Alliance. (See the article by Ngoma and colleagues from the SMGL supplement.[42]) SMGL helped drive policy changes that allowed uterine balloons to be placed by nurses and midwives and for uterine balloon tamponade to be included in the national EmONC curriculum. Across the 18 Zambian SMGL districts, providers were trained in the assembly and use of uterine balloon tamponade. With funds from SMGL and the government of Zambia, several district blood bank hubs were established to provide 24-hour blood testing and availability of fresh-frozen blood and plasma.

Contextual changes. Important contextual changes occurred during Phase 2 at the district level. The 4 original learning districts in Uganda were divided into 6 districts—Kabarole, Kibaale, Kamwenge, Kyenjojo, Kakumiro, and Kagadi—and 7 new scale-up districts were added in the north—Nwoya, Gulu, Omolo, Pader, Lira, Apac, and Dokolo. All were selected by the MOH. Due to a change in the implementing partner for the new SMGL Uganda northern districts, full execution of the SMGL approach did not begin until 2015 and ended 2 years later. (Project description and results can be found in the article by Isabirye and colleagues from the SMGL supplement.[47]) In Zambia,

SMGL increased programming for newborns during the second phase, including opening neonatal special care units and increasing training on newborn resuscitation.

the 4 learning districts were divided into 6 districts through an administrative re-districting process—Nyimba, Lundazi, Kalomo, Zimba, Mansa, and Chembe—and 12 additional districts were added across the country—Samfya, Lunga, Kabwe, Choma, Pemba, Chipata, Petauke, Sinda, Vubwi, Mumbwa, Livingstone, and Luangwa (Figure 2).

Endline evaluation studies. After the Phase 1 endline studies showed a 35% reduction in facility maternal mortality and positive results for process and quality indicators in the SMGL-supported learning districts in both countries, a summative evaluation plan was developed by the M&E committee and the SMGL Secretariat. The plan was endorsed by the SMGL Leadership Council members who also pledged funding for executing the plan. Using 2016 as the index year for SMGL final results, end-of-initiative studies were undertaken in 2017 to establish outcomes in the learning districts: (1) a census in Zambia and a RAMOS in Uganda,[38,48] (2) repeat HFAs in all delivering facilities in the learning districts,[38] (3) a cost-effectiveness study addressing the 3 delays,[7] (4) a secondary analysis comparing SMGL district outcomes with findings from the Uganda Demographic and Health Survey (DHS) in comparison districts and nationally,[31] (5) a follow-on qualitative study of community perspectives on childbearing in Zambia,[49] and (6) a repeat travel-time mapping study in Uganda to gauge if the SMGL initiative resulted in greater access to care.[50]

Cesarean delivery rates increased by 71% in SMGL-supported districts in Uganda and by 79% in Zambia.

RESULTS

Key Health Facility and Population-Based Assessment Results

Select results from Phase 1 have previously been reported.[7,17,29,39,51–53] What follows is an overview of key results at baseline and 2016 endline for the SMGL-supported learning districts. Table 4 compares selected baseline and endline indicators by type. A description of data collection methods, indicators, and baseline and endline results are included in the article by Serbanescu and colleagues from the SMGL supplement.[38] A comparison of SMGL outcomes with those from DHS and UN maternal mortality estimates is presented in Supplement 5.

The institutional delivery rate increased by 47% in SMGL-supported facilities in Uganda and by 44% in Zambia.

Demand

The chances of surviving childbirth are improved when a woman gives birth in a facility, attended by a skilled birth attendant.[54–56] Over the life of SMGL, the institutional delivery rate, or the proportion of births occurring in delivery facilities, increased from 46% to 67% in Uganda (a 47% increase) and from 63% to 90% (a 44% increase) in Zambia SMGL-supported facilities.

Timely Access

SMGL prioritized bolstering the system's capacity to provide timely lifesaving emergency care. The number of facilities that performed all 7 signal functions that constitute basic emergency obstetric and newborn care (BEmONC) increased from 3 to 9 in Uganda (200%) and from 3 to 8 in Zambia (167%). Similarly, the number of CEmONC facilities increased from 7 to 17 (143%) in Uganda and from 4 to 5 (25%) in Zambia.

In 3 SMGL-supported districts in Uganda, transportation vouchers enhanced women's access to essential and emergency health ser-vices by covering the cost of motorcycle rides to facilities for delivery, 4 antenatal care visits, and 1 postnatal care visit. In 2016, almost 1 out of 4 women who delivered in SMGL facilities used transportation vouchers to reach care. In Zambia where motorcycle transport is not generally available, maternity waiting homes were built or upgraded to provide mothers a safe place to stay near an EmONC facility during the last weeks of pregnancy. The proportion of SMGL facilities that reported having an associated maternity waiting home increased significantly from 29% at baseline to 49% at endline (a 69% increase).

Quality

The range of interventions that SMGL implemented to enhance quality of care largely proved effective:

- Population-based cesarean delivery rates increased by 71% (from 5.3% to 9.0%) in Uganda and 79% (from 2.7% to 4.8%) in Zambia in SMGL-supported districts. The rates achieved are still below the World Health Organization (WHO) recommended rates of 10% to 15%. (Regardless of the rate, cesarean deliveries should be performed only when medically indicated).
- The percentage of facilities reporting having performed newborn resuscitation in the last 3 months increased by 155% (from 34% to 88%) in Uganda and by 173% (from 27% to 75%) in Zambia.
- The percentage of all SMGL-supported facilities in Uganda that reported active management of the third stage of labor increased by 28% (from 75% to 96%). In Zambia, the change from baseline was 33% (72% to 96%).

TABLE 4. Key Results at Baseline and Phase 2 Endline in the SMGL Learning Districts

	Uganda				Zambia			
SMGL Indicator	2012 Baseline	2016 Phase 2 Endline	% Change Baseline to Phase 2	Significance[a]	2012 Baseline	2016 Phase 2 Endline	% Change Baseline to Phase 2	Significance[a]
GOAL								
Institutional MMR (per 100,000 live births)	534	300	−44	***	370	231	−37.6	***
Community MMR (per 100,000 live births)	452	255	−44	***	480	284	−40.8	***
Pre-discharge neonatal mortality rate (per 1,000 live births)	8.4	7.6	−10	NS	7.7	8.7	+14	NS
Institutional perinatal mortality rate (per 1,000 births)	39.3	34.4	−13	***	37.9	28.2	−26	***
Institutional total stillbirth rate (per 1,000 births)	31.2	27.0	−13	***	30.5	19.6	−36	***
DEMAND								
Health facilities that report having a VHT (Uganda) or SMAG (Zambia) (%)	18	92	+400	***	64	93	+46	***
Institutional delivery rate (%)	46	67	+47	***	63	90	+44	***
Deliveries in EmONC facilities (%)	28	41	+45	***	26	29	+12	***
Deliveries in lower-level facilities (health center II, III) (%)	17	26	+48	***	37	61	+67	***
ACCESS								
Facilities that report having an associated mother's shelter (%)	0	4	NA	NA	29	49	+69	***
Institutional deliveries supported by transport vouchers (%)	6	24	+277	***	Vouchers not provided in Zambia			
Number of BEmONC facilities where the 7 signal functions were performed in last 3 months	3	9	+200	NA	3	8	+167	NA
Number of CEmONC facilities where the 9 signal functions were performed in last 3 months	7	17	+143	NA	4	5	+25	NA
24/7 services at health centers (%)	75	89	+18	NS	65	96	+41	***
QUALITY OF CARE								
Facilities reporting having performed newborn resuscitation in the previous 3 months (%)	34	88	+155	***	27	75	+173	***
Facilities providing active management of the third stage of labor (%)	75	96	+28	***	72	96	+33	***
Population-based cesarean delivery rate (%)	5.3	9.0	+71	***	2.7	4.8	+79	***
Hospitals that currently have at least 1 long-acting family planning method (%)	63	94	+51	**	50	75	+50	NS
Number of women receiving PMTCT treatment	1262	2155	+71	NA	930	1036	+11	NA
HEALTH SYSTEMS STRENGTHENING								
Hospitals conducting maternal death audits or reviews (%)	31	94	+201	***	50	100	+100	NA
Health facilities that did not experience stock-outs of oxytocin in the last 12 months (%)	56	82	+46	***	75	75	−0.4	NS
Health facilities that did not experience stock-outs of magnesium sulfate in the last 12 months (%)	48	64	+34	***	20	43	+115	***

Abbreviations: EmONC, emergency obstetric and newborn care; BEmONC, basic emergency obstetric and newborn care; CEmONC, comprehensive emergency obstetric and newborn care; MMR, maternal mortality ratio; NA, not applicable; NS, nonsignificant; SMAG, Safe Motherhood Action Group; VHT, Village Health Team; PMTCT, prevention of mother-to-child transmission of HIV.

[a] *** $P<.01$; ** $P<.05$; * $P<.10$. NA in cases where significance testing was not warranted.

Source: Serbanescu et al.[38]

- Having at least 1 long-acting reversible family planning method in SMGL-supported facilities increased in both counties. In Uganda, availability increased by 51% (from 63% to 94%) of facilities. In Zambia, it improved by 50% (from 50% to 75%) of facilities.
- The percentage of hospitals conducting maternal death audits tripled in Uganda (from 31% to 94%) and doubled in Zambia (from 50% to 100%).
- The number of HIV-seropositive women who received prophylaxis or treatment for the prevention of mother-to-child transmission increased by 71% in Uganda, from 1,262 to 2,155 women, and by 11% in Zambia, from 930 to 1,036 women (denominators not available).

Health Systems Strengthening

Access to medications was positive but uneven. While SMGL funds were not used to procure medicines in Phase 2, providers were trained in supply chain management. The proportion of all health facilities that did *not* experience stock-outs of oxytocin in the last 12 months increased by 46% (from 56% to 82%) in Uganda but did not change in Zambia (from 75% to 75%). The proportion of all health facilities that did *not* experience stock-outs of magnesium sulfate in the last 12 months increased significantly in both countries, by 34% (from 48% to 64%) in Uganda and by 115% in Zambia (from 20% to 43%).

The MMR declined significantly in both SMGL-supported facilities and districts in Uganda and Zambia.

Impact

From baseline to endline (2012–2016), the MMR declined by 44% in both facilities and districtwide in Uganda (from 534 to 300 per 100,000 live births in facilities and from 452 to 255 in the community). MMR declined by 38% in SMGL-supported facilities in Zambia (from 370 to 231) and by 41% districtwide (from 480 to 284). All declines were statistically significant.

In Uganda, the perinatal mortality rate declined by 13% in SMGL-supported facilities (from 39.3 to 34.4 perinatal deaths per 1,000 births). The total institutional stillbirth rate also declined by 13% (from 31.2 to 27.0 per 1,000 births). Both values are statistically significant. The pre-discharge neonatal mortality rate fell by 10% (from 8.4 to 7.6 per 1,000 live births); however, this was a nonsignificant change. In Zambia, the institutional perinatal mortality rate declined by 26% in SMGL-supported facilities (from 37.9 to 28.2) and the institutional stillbirth rate declined by 36% (from 30.5 to 19.6). Both declines were significant. The change in the pre-discharge neonatal mortality rate was not significant at +14% (from 7.7 to 8.7).

Public and Private Health Care Facilities

In Uganda, where 40% of facilities receiving SMGL support were private, the endline evaluation explored in a separate analysis whether any differences existed in the impact indicators by the type of sector providing delivery care (Table 5). The majority of SMGL facility deliveries occurred in public facilities (83.4% public vs. 16.6% private). The proportion of women who delivered by cesarean delivery was slightly lower in public-sector facilities compared with the private sector (13.0% vs. 15.7%, respectively) (data not shown). Generally, no significant differences existed in the occurrence of

TABLE 5. Select Indicators by Delivery Care Service Sector in Uganda, 2016

Indicator	Public-Sector Facilities	Private-Sector Facilities	Significance[a]
Maternal mortality ratio (per 100,000 live births)	301	295	NS
Direct case fatality rate	1.8	1.5	NS
Perinatal mortality rate (per 1,000 births)	34.0	36.4	NS
Intrapartum stillbirth rate (per 1,000 births)	13.8	17.0	**
Total stillbirth rate (per 1,000 births)	26.6	28.7	NS
Pre-discharge neonatal mortality rate (per 1,000 live births)	7.6	7.9	NS

Abbreviation: NS, nonsignificant.
[a] ** $P<.05$.
Source: Serbanescu et al.[38]

adverse pregnancy outcomes among women delivering in the private and public sectors in 2016 in Uganda, with the exception of the intrapartum stillbirth rate, which was higher in private facilities than in public facilities (17.0 vs. 13.8 per 1,000 births, respectively). See Supplement 6 for more information about private-sector activities in Uganda.

DISCUSSION

The positive results from the SMGL Phase 2 endline evaluation studies (2016 data) in the learning districts in Uganda and Zambia are substantial. However, SMGL's non-randomized, before-and-after design makes it challenging to attribute the outcomes documented after nearly 5 years of implementation solely to the SMGL health systems strengthening approach. The Columbia University implementation evaluation of SMGL's proof-of-concept year did include comparison districts, but there was no randomization. Still, the MMR declined significantly faster in the SMGL-supported learning districts compared with national-level declines. Over a 5-year span the average annual rate of reduction in Uganda learning districts was 11.5% compared with the national rate of 3.5% using DHS values. The difference-in-differences between the drop in MMR in SMGL areas compared with the drop in the MMR nationally is statistically significant ($P = .02$) (Supplement 5).

The findings for Zambia are similar although the timing of the DHS did not allow use of DHS data for comparison. Instead, the UN maternal mortality estimates for Zambia for the period 2011–2015 were used. The average annual rate of reduction in SMGL districts in Zambia was 10.5% vs. a national rate of 2.8%.[1] These more rapid declines in MMR in SMGL program areas compared with national levels in both countries over a 5-year period suggest that SMGL outcomes are not solely due to secular trends (Supplement 5).

The results of the SMGL evaluation provide answers to some questions that are critical to ending preventable maternal and newborn deaths, while leaving other questions unresolved.

Why Does the SMGL Theory of Change Focus on All Pregnant Women Rather Than Only Those Experiencing a Complication?

The 3-delays model, introduced by Thaddeus and Maine in 1994 in their seminal article,[16] provided a conceptual framework for programming to surmount the key barriers faced by women with obstetric complications. In the SMGL theory of change, we focused on all pregnant women within the SMGL-supported districts because many maternal complications are difficult to predict and prevent, can arise quickly, and can result in a maternal death in a short period of time. The SMGL systems approach aimed to provide access to emergency care within 2 hours from home or a lower-level health facility for all pregnant women in SMGL-supported districts.

Can a District Health Systems Strengthening Approach Addressing the 3 Delays Contribute to Maternal Mortality Reductions in High-Burden, Low-Resource Countries?

The MMR declined significantly faster in the SMGL-supported districts than nationally.

The data show significant reductions in the MMR in the learning districts in both Uganda and Zambia after nearly 5 years of SMGL implementation. The contribution of SMGL to these changes is plausible given the greater rate of reduction in program areas compared with national rates in both countries (Supplement 5). In Uganda, 70% of the total MMR reduction, from baseline to endline Phase 2, occurred during Phase 1, suggesting that once inputs were in place, the systems approach was successful in sustaining the reduced MMR. This is particularly instructive as after Phase 1, in the context of erratic funding flows, implementation was uneven. In spite of these lapses, reductions were sustained over the life of SMGL, based on robust analysis of the SMGL routine quarterly indicators and Pregnancy Outcomes Monitoring Studies values.[57]

What About Newborn Deaths and Stillbirths?

Decreases in institutional perinatal deaths were statistically significant in Uganda and Zambia at 13% (31.2 to 27.0) and 26% (37.9 to 28.2), respectively. The declines in the total stillbirth rate (fresh and macerated stillbirths) were also significant in both countries (13% in Uganda and 36% in Zambia).[38] However, changes in pre-discharge neonatal mortality rates were nonsignificant. Further analysis is needed to understand why the SMGL approach was able to decrease stillbirths but not newborn deaths. We hypothesize that, in the past, newborns who were not breathing at birth were laid aside and categorized as stillbirths but that after HBB training some were successfully resuscitated. A portion of these now breathing newborns potentially succumbed to fatal complications. It is also unclear if the public-private differences seen in intrapartum stillbirth rates in Uganda reflect differences in health care provision or in

clinical risk factors. (See the article by Serbanescu and colleagues from the SMGL supplement.[38])

What Is the Minimum Package of Interventions Needed to Reduce Maternal and Neonatal Mortality?

The SMGL theory of change posits that an integrated systems approach addressing both demand- and supply-side barriers is more impactful than individual and/or uncoordinated interventions, especially for a complex and multifaceted problem such as maternal mortality. The results of the Qualitative Comparative Analysis (QCA) modeling from Uganda support this hypothesis.[58] The QCA examined the relative power of varied *bundles of interventions* to replicate the Phase 1, first-year achievement of reducing *community* maternal mortality in SMGL-supported districts in Uganda by 30% (*facility* deaths were reduced by 35%) The results suggest that the most powerful bundle of interventions (most effective at lowest cost) was comprised of 4 interventions: VHTs (*demand*); transportation vouchers (*access*); availability of staff (*quality*); and availability of medicines (*health systems strengthening*). If run individually, none of these interventions achieved the 30% MMR reduction, and if the results from these individual interventions were then added together, the sum did not achieve the reduction of the optimal bundle. It appears that it is not only these critical interventions but the synergy created by addressing both supply- and demand-side barriers that accelerates change.[60] It would be instructive to undertake a QCA study in Zambia to see if similar results are found.

What About Cost?

Results from a modeling exercise support the SMGL theory of change that an integrated systems approach addressing both demand- and supply-side barriers is more impactful than individual interventions.

SMGL's achievements are often tempered by concerns that the SMGL approach was too expensive for replication. In order to rigorously examine this critical consideration and establish the relative value for money, it is necessary to compare the cost of SMGL implementation with other initiatives that have achieved equivalent health outcomes. Unfortunately, few MNH projects are comparable to SMGL in terms of complexity, robust capture of both facility and districtwide health outcomes (MMR, perinatal mortality rate, neonatal mortality rates, cause of death), and commitment to tallying expenditures.[29,60] Even when examining the cost-effectiveness of individual MNH interventions, there is a paucity of high-quality cost-effectiveness studies.[61–64] These features have left evaluators without ideal counterfactuals.[65–67]

To better understand relevant SMGL cost outlays over the life of the initiative, 3 costing studies were undertaken (Supplement 4). All 3 studies projected that after investing in essential capital improvements and streamlining operations, running costs would decrease substantially. Those predictions proved accurate. By design, external funding tranches for SMGL implementation in Uganda and Zambia were decreased yearly while the number of SMGL districts increased, resulting in substantial reductions in funding per learning district over Phase 2. During that same period, maternal health outcomes in the learning districts continued to show improvement.

The endline 3-delays costing study looked at the cost in 2016 of addressing all 3 delays: demand generation, accelerating access to appropriate care including referral, and improving the quality of care at the facility. The expenditure per maternal and perinatal life-year gained was found to be US$177 in Uganda and US$206 in Zambia. These values are inclusive of startup and capital costs—both expressed as annual equivalents. The authors conclude that the SMGL approach is cost-effective, with the cost per life-year gained in Uganda at 25.6% of gross domestic product (GDP) per capita and at 16.4% of GDP per capita in Zambia. Both values are less than 50% of GDP per capita, a benchmark for cost-effectiveness. In terms of affordability, the additional (incremental) costs associated with the SMGL approach would add less than 0.5% to the health spending from GDP in both countries (from 7.3% to 7.5% in Uganda and from 5.4% to 5.8% in Zambia). Recent models suggest that, at a minimum, an additional US$11 per capita per year is necessary to meet the full needs of MNH care in sub-Saharan Africa.[68] The incremental costs of the SMGL initiative of US$1.36 per person per year in Uganda and US$4.85 per person per year in Zambia are far less than these modeled estimates, and much less than that spent on antiretrovirals per person treated per year, which stood at an average of US$136.80 in 2015.[69] (See the article by Johns and colleagues from the SMGL supplement.[70])

What About Sustainability?

In Uganda and Zambia there is both increased MOH commitment to the health systems strengthening approach and heightened societal awareness that most maternal and newborn deaths can and should be prevented.[29] Yet, it is likely that

ongoing donor funding and technical assistance will be required in the short term to maintain the positive results achieved during SMGL implementation. Below, we look at country capacity and ownership as 2 important domains to gauge the likelihood that key elements of the SMGL health systems strengthening approach will be sustained.

Country capacity. Capacity building of district-level medical and public health staff included clinical training, monthly on-site mentoring, and management; data gathering, analysis, reporting, and response; quality improvement; drug logistics; and budget development. Physicians in both Uganda and Zambia were trained (for the first time) on International Classification of Diseases (ICD) 10 Maternal Mortality coding of deaths, a prerequisite skill for a functioning maternal death surveillance and response system and a civil registration and vital statistics system. In both countries, the initiative led to improvements in tracking routine service delivery indicators as part of the national health management and information systems. In 2011, the governments of Uganda and Zambia began using DHIS2 as an electronic platform for aggregated health service data. In both countries, the SMGL-supported districts piloted DHIS2 implementation to collect, store, and analyze data on maternal and reproductive health. The improvements were scaled up to the national level by the end of 2012. Another important activity in Zambia was training SMGL district doctors and nurses in blood transfusion safety. Hospital Transfusion Committees were established to improve monitoring of blood supplies through the use of short message services (SMS or texts) for forecasting and planning to avert shortages. When donor funding recently decreased for blood-safety programs, the government of Zambia increased its health budget to ensure an adequate supply of blood for its citizens. (See the article by Healey et al. from the SMGL supplement.[71])

Beyond training, SMGL country technical leads were supported to assume leadership positions within SMGL and to provide technical assistance to other SMGL countries. A team of Uganda SMGL leads traveled to Nigeria to provide technical assistance to the Nigeria SMGL team to carry out HFAs in Cross River State health care facilities, public and private, and also to Zambia to support HFAs in Phase 2 scale-up districts. A Zambia SMGL lead traveled to Afghanistan and assisted the USAID Mission to incorporate lessons learned from the SMGL approach into their MNH strategic plan. SMGL country staff prepared posters and presented at the yearly SMGL team-building meetings, and staff members were encouraged to submit abstracts and present at global MNH meetings.

Country ownership. District health leaders in Uganda reported high levels of ownership of SMGL and cited the addition of key inputs as strategic: filling human resource gaps; strengthening referral systems; expanding the number of CEmONC facilities; improving the supply of blood for transfusion; mentoring health personnel; and increasing demand and access through VHTs, transportation vouchers, and community champions. SMGL also influenced national planning and budgeting for maternal health: the Wage Bill included allowances to support doctors working at health center IVs located in rural areas based on SMGL's remuneration approach; nearly 75% of the midwives hired by SMGL were picked up by the MOH; additional midwifery training was provided for enrolled nurses; and the voucher program laid the groundwork for a national program.[29] Lessons learned from the SMGL approach were incorporated into the Global Financing Facility Investment Case,[72] the WHO Quality, Equity, Dignity initiative country plan, and USAID requests for assistance and contracts. Between these initiatives, over half of the Ugandan population will be covered by a district health systems strengthening approach by 2020. (See the articles by Healey et al.[71] and Palaia et al.[73] from the SMGL supplement.)

In both Uganda and Zambia, SMGL led to improvements in tracking routine service delivery indicators as part of the national health management and information systems.

In Zambia, preexisting CDC cooperative agreements with provinces and district-support from CDC and USAID implementing partners enabled early leveraging of funds and increased district ownership of SMGL. SMGL worked with other donors, the Swedish International Development Cooperation Agency (SIDA) and the UK Department for International Development, to carry out direct government-to-government funding to provincial and district public health systems through the Reproductive, Maternal, Newborn, Adolescent Health and Nutrition Continuum of Care Program, blanketing 6 of 10 provinces. With this partnership alone, over 50% of the Zambian population is covered by projects informed by the SMGL systems approach.[17] (See the article by Healey et al. from the SMGL supplement.[71])

What Were the Main Challenges?

The initial 1-year time frame. Frustration was generated when SMGL funding was guaranteed

Future systems approaches focused on maternal and newborn mortality reduction should commit to a minimum of 5 years of support.

for only 1 year with subsequent support based on achievement of unprecedented reductions in maternal mortality within a highly compressed time frame. At the end of Phase 1 implementation (June 2013) and before results from the Phase 1 endline studies were available (December 2013), host countries and implementing partners were without SMGL funds. Yet they were expected to continue with interventions while a decision on continuation was made. This 6-month period from July to December 2013 was chaotic. Any future systems approach focused on maternal and newborn mortality reduction should commit to a minimum of 5 years of support from the outset.[29] (See the article by Palaia et al. from the SMGL supplement.[73])

The heavy management burden. SMGL was a partnership (all U.S. government) within a partnership (countries, a global corporation, nongovernmental organizations, and a professional society). Each partner had a different bottom line, constituency, funding timeline, requirements, and restrictions that all needed to be forged into a dynamic force for change. The positive driver was the ongoing commitment of all partners and stakeholders to dramatically reduce maternal deaths. When the SMGL Leadership Council was recruiting additional countries for SMGL at the end of Phase 1, "management burden" was cited by USAID Mission directors and CDC country office directors as their main concern and rationale for not engaging. A simpler management structure where partnerships provide direct-to-government support with appropriate oversight and ample technical assistance might produce similar results; it might also accelerate country self-sufficiency and increase value for money by decreasing implementing partner overhead charges. At the same time, the diversity of SMGL partners encouraged innovation and enabled access to a wide array of expertise and experience.

Erratic funding. Because of the complexity of the partnership and its myriad resource streams, funding to the implementing partners in both countries was profoundly delayed for several periods during Phase 2. These lapses in funding were the result of prolonged U.S. government procurement processes, changes in funding mechanisms, and delays in disbursements from agency headquarters to country offices. If public–private partnerships are increasingly used to advance the goals of U.S. government agencies, streamlining funding for these endeavors will be needed to increase flexibility and responsiveness and to preserve momentum. Smaller amounts of reliable funding are easier to manage than larger tranches of unpredictable financial support.

What Were Some of the Unexpected Effects?

Having a range of stakeholders participating in SMGL created a think-tank atmosphere that brought together people with varied talents: obstetricians, midwives, nurses, communications specialists, epidemiologists, and district medical and health officers. It also led to collective yearly planning and country budget creation. In many of the routine implementing partner meetings, organizations would share tasks as well as ideas that crossed bureaucratic and competitive barriers. The bold goal of a rapid 50% reduction in maternal mortality fostered a collaborative "all hands on deck" spirit that inspired district leadership and partners alike.

SMGL's insistence on capturing, analyzing, and reporting all maternal deaths resulted in strengthened data gathering and interpretation by district teams. District-level data were presented and critically reviewed by district M&E staff at routine provincial and regional epidemiological meetings. Results were compared within the provinces and among the different project sites, and served as a motivating factor for good performers and as a call for improvement among less successful districts. The heightened appreciation of the need for quality mortality data accelerated the rollout and practice of maternal and perinatal death surveillance and response in both countries. In Zambia, the district commissioner, as the chair of the audit committee, was made responsible for reporting surveillance and response results locally and at the provincial level. This high-level ownership of data was immediately replicated on a national basis and had the effect of positioning maternal mortality not just as a health concern but also as a broader social issue, bringing in other sectors of government and traditional leaders to grapple with and be accountable for preventing maternal mortality.

Better birth planning, involvement of men, and increased community demand for facility deliveries required leaders to raise awareness and address community concerns in order to change cultural norms. Involvement of chiefs and traditional leaders in Zambia and local councils and religious leaders in Uganda created "change champions" who took on these challenges. However, qualitative research by Greeson et al.[74] identified punitive actions by Zambian village chiefs and headmen,

such as fining a husband a goat if he did not provide a sufficient reason for why his wife delivered at home. Researchers suggested that negative unintended consequences are possible by-products of a "big push" endeavor where pressure to succeed is high.[74] These "disciplinary" actions were not endorsed by SMGL or the MOH, but they do represent a traditional approach by cultural leaders to induce social change in their communities.

What Are the Main Recommendations Coming Out of the SMGL Experience?

Given the complexity of the SMGL initiative, extracting lessons learned and turning them into a few salient recommendations is challenging. The following points are put forward in support of SMGL's theory of change and organizing principles:

1. Create a culture of zero tolerance for preventable maternal and newborn deaths at all strata of society including parliamentarians and their constituents.
2. Follow key organizing principles by addressing all 3 delays with interventions that are context-specific and time-bound (e.g., setting a 2-hour 'time-to-service' limit for complications and focusing on labor, delivery, and 72 hours postpartum).
3. Assess the gaps in the existing maternity care safety net, created by both public and private providers, in the public health catchment area of interest (e.g., district, woreda, county, local government area).
4. Ensure district-level capacity building around planning, execution, and evaluation; consider working in contiguous areas to achieve economies of scale, reduce management burden, and facilitate greater coordination.
5. Support the local health system; work across the district or relevant administrative units to reinforce the system from communities to health centers to hospitals in order to provide equitable lifesaving care and support for mothers and newborns, and by extension, other community members.
6. Sensitize and mobilize community change agents to accelerate normative change but be aware of potential unintended consequences of a "big push" effort.
7. Count, analyze, and report all maternal and perinatal deaths and cause of death.

CONCLUSIONS

While a 50% reduction in maternal deaths was not achieved during the initiative, the 44% decrease in MMR in Ugandan SMGL-supported facilities and districts, the 38% decrease in Zambian SMGL-supported facilities, and the 41% decrease in Zambian SMGL districts were substantial. There was a marked increase in facility deliveries in both countries and also in population cesarean delivery rates: a 71% increase (5.3% to 9.0%) in Uganda and a 79% increase (2.7% to 4.8%) in Zambia. Perinatal health outcomes were small but significant: the perinatal mortality rate was reduced by 13% in SMGL-supported facilities in Uganda and by 26% in Zambia. The SMGL goal for reduction of newborn deaths (30%) was not achieved in Zambia or Uganda.

Still at question is whether the SMGL health systems strengthening approach to addressing the 3 delays will be adopted or adapted to other country contexts and implemented by MOHs, donors, and multilaterals. Clearly, the level of management burden is high, and partners, especially bilateral donors, are traditionally not structured to be nimble, proactive, or inventive. Yet several global endeavors could benefit from endorsing the SMGL approach. For example, with expansion of the number of Global Financing Facility countries and GFF emphasis on results-based financing, having a ready approach to improving effective coverage (range plus quality) could accelerate GFF impact. Similarly, the district health systems strengthening approach dovetails closely with the objectives and goals of the WHO Quality, Equity, and Dignity initiative.

Several global endeavors, such as the Global Financing Facility and the WHO Quality, Equity, and Dignity initiative, could benefit from endorsing the SMGL district health systems strengthening approach.

SMGL was a bold attempt to show that maternal mortality could be reduced significantly in developing countries over a few years of strategic, synergistic programming. It was inspired by the progress achieved by other U.S. government global initiatives that showed how high-level political leadership, focused public attention, evidence-based demand- and supply-side interventions, a broad coalition of stakeholders, and strong M&E could achieve impressive results in a short time. For many, it was an opportunity to change the narrative around the serious problems pregnant women face in the developing world.

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ORIGINAL ARTICLE

Successfully Engaging Private Providers to Improve Diagnosis, Notification, and Treatment of TB and Drug-Resistant TB: The EQUIP Public-Private Model in Chennai, India

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Based on a participatory program design that addressed the self-described needs of private providers, a local NGO offered the providers access to rapid diagnostics and support for notification and patient treatment including free anti-TB drugs. The model resulted in high provider participation, contributing more than 10% of the overall TB case notifications, and an 89% treatment success rate for drug-sensitive TB.

ABSTRACT

Background: Private physicians in India see and treat more than half of all people with tuberculosis (TB) each year and thus have potential to make significant contributions to TB control. The EQUIP project was designed as a prospective cohort study to assess the potential of private providers to diagnose and appropriately treat drug-resistant TB (DR-TB) in the Central and South districts of Chennai, India.

Methods: The private-sector engagement model consisted of free access to rapid diagnostics; choice of free daily or thrice-weekly treatment regimens; support for notification of patients; and patient support including directly observed therapy through EQUIP centers staffed by a community-based interface agency. Data were collected on provider participation; referral results; treatment regimens prescribed; and treatment outcomes.

Results: From October 2015 through June 2017, 227 of the 466 (48.7%) private providers approached referred at least 1 patient to an EQUIP center for evaluation. A total of 2,621 patients received testing and 1,232 (47.0%) were diagnosed with TB. Of those, 727 (59.0%) were bacteriologically confirmed, including 694 (56.3%) using GeneXpert and 33 (2.7%) using smear microscopy. A total of 26 (3.7% of GeneXpert diagnosed) patients were confirmed as rifampicin-resistant cases. EQUIP-related notifications comprised approximately 10% of TB and DR-TB notifications in Chennai during the project period. The project initiated 1,167 (96.8%) drug-sensitive TB patients on treatment. Of those, 691 (59.2%) received standard daily regimens with EQUIP support and 288 (24.7%) received standard intermittent regimens. At the time of writing, 89.4% of 868 drug-susceptible TB patients receiving EQUIP support had treatment success. Of the 26 rifampicin-resistant TB cases notified, 20 (77%) started and continued on second-line treatment; 2 died and 4 were lost to follow-up prior to treatment initiation.

Conclusion: Private providers can make a substantial contribution to detection and appropriate treatment of patients with TB and DR-TB in India when provided with access to rapid diagnostics, support for notification and patient treatment through interface agencies, and free, quality anti-TB drugs.

INTRODUCTION

India has the largest burden of tuberculosis (TB) and drug-resistant tuberculosis (DR-TB) in the world, with an estimated 2.8 million new cases of TB occurring annually, of which 5% are DR-TB requiring second-line treatment.[1]

In Chennai, the capital of Tamil Nadu state, an estimated 15,185 TB cases occur each year but only about 8,600 are notified, leaving more than half of the incident TB cases unaccounted for.[2,3] One important factor is the large, diverse, and poorly coordinated private health sector, where more than 60% of people with TB first seek care.[4] Based on available evidence,[5–11] there is continuing concern about lack of notification of privately diagnosed TB cases, inappropriate diagnostic confirmation of these cases, inappropriate treatment regimens, use of

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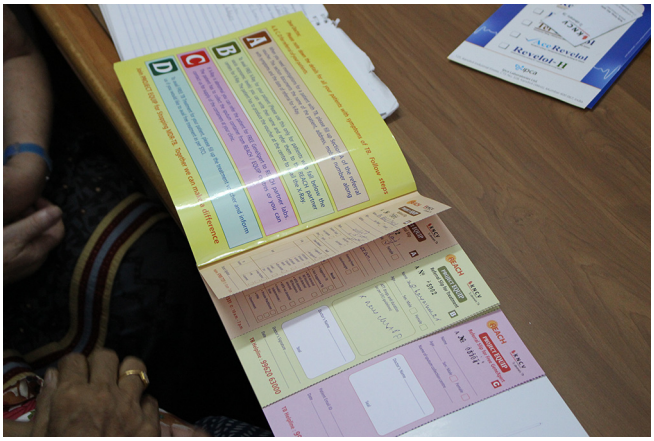
low-quality drugs, and lack of support for treatment completion among private-sector patients.

Many efforts have been launched to engage the private sector effectively in TB control, with varying degrees of success.

Many efforts have been launched to engage the private sector effectively in TB control, with varying degrees of success.[12–15] Since 1998, the Resource Group for Education and Advocacy for Community Health (REACH) has worked to increase patient access to the public health services of India's Revised National TB Control Program (RNTCP). REACH encourages private health care providers to refer their patients to one of REACH's 4 public-private mix centers in Chennai, where REACH ensures continuity of care between the private and public sectors through project-implemented counseling, education, food support, and directly observed treatment (DOT).[16] Using lessons learned from this work and from focus group discussions with private providers and patients, REACH and KNCV Tuberculosis Foundation developed and tested a model under Project EQUIP (Enhanced Use of Quality Drugs and Utilization of Innovative Diagnostics for TB Management in the Private Sector) to evaluate the potential for private providers to contribute to appropriate diagnosis and treatment of DR-TB.

At the point of project launch, no other effort had focused specifically on the issue of private providers' engagement in prevention, diagnosis, and treatment of DR-TB. EQUIP set out to demonstrate a sustainable model for private-sector engagement in DR-TB; encourage private providers to use state-of-the-art diagnostics for their patients with TB symptoms; promote the use of standardized TB and DR-TB treatment regimens with quality-assured drugs; and provide coordinated support for private-sector patients to improve treatment success. While data were collected, analyzed, and are presented here for both TB and DR-TB, the primary question of interest was what effect private-sector engagement would have on notification and treatment of DR-TB in Chennai.



Simple guidance steps and vouchers provided by the project allowed private providers to easily refer patients for TB diagnostic testing. © Jasper Hamann

The project operated between April 2015 and June 2017, with patient follow-up until December 2017, in 2 of the 3 districts of Chennai (Central and South), comprising a population of approximately 5.3 million people.

METHODS

Study Design

The study used a prospective cohort design. The primary cohort of interest was the group of private providers in the Central and South districts of Chennai who were oriented to the project and who agreed to participate. The secondary cohort of interest was the group of private-sector patients who were diagnosed by participating private providers between October 1, 2015 and June 30, 2017.

Setting

Chennai is a metropolitan city in Tamil Nadu with a total estimated population of 7,196,515. The public-sector TB control program in Chennai has been implemented by the Greater Chennai Corporation. Greater Chennai Corporation covers 15 zones across 36 TB units and is subdivided into 3 districts—North, Central, and South Chennai. South Chennai has a historically lower case detection rate than North and Central Chennai. This project was implemented in Central and South Chennai with the population of 5,387,132 covering 27 TB units.

Formative Research

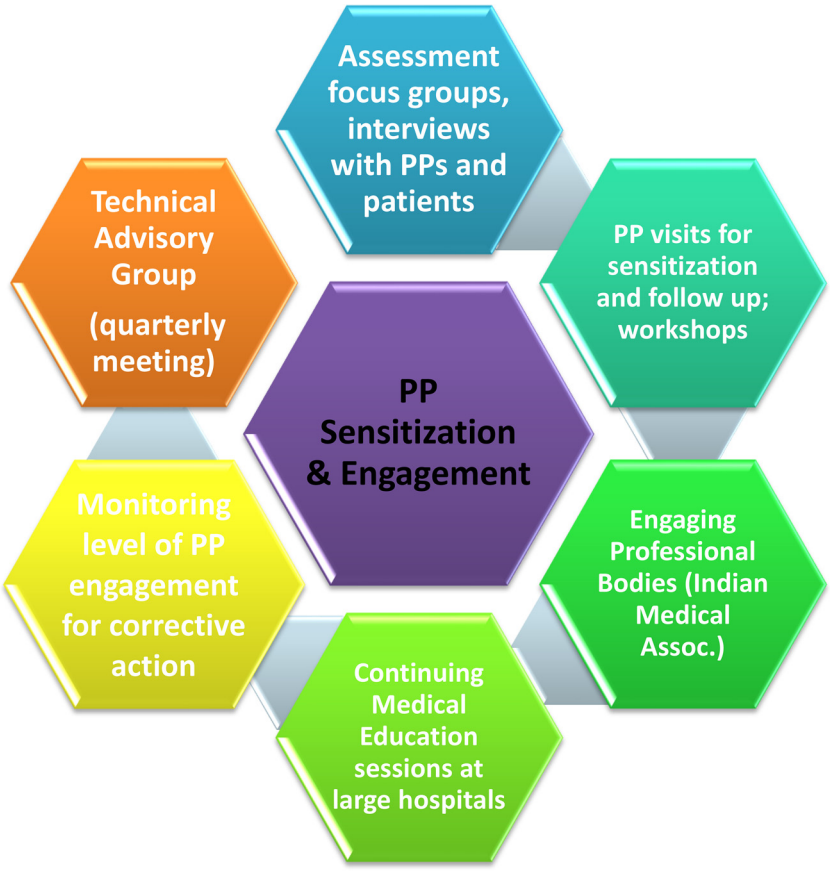
REACH and KNCV designed the EQUIP model with the hypothesis that involving the target audience (private providers and their patients) at the beginning of the process would lead to a high participation rate by directly addressing their self-identified needs. To do so, we mapped the private provider landscape and selected a subgroup of providers—chest physicians, general practitioners, and selected specialists—who likely saw high numbers of people with symptoms of TB. We then convened focus group discussions and individual interviews with private provider and patient representatives to understand barriers to engagement in public TB control efforts. In addition, we formed an advisory group of well-

respected senior private practitioners—chest physicians, microbiologists, pediatricians, and TB experts from the National Institute for Research in Tuberculosis; representatives from the Indian Medical Association; and the District TB Officer and Superintendent of the Tambaram Sanatorium (the tertiary referral hospital)—to provide advice on the model. The advisory group continued to meet after the initial phase during quarterly meetings organized by REACH to update members on progress and seek technical expertise and guidance. Suggestions from the group were debated and incorporated into the model over the course of the project. The engagement process is depicted in Figure 1.

Data Collection and Analysis

A Microsoft Excel database already in use at REACH to document care for TB patients diagnosed and treated with support from REACH was expanded to record information on individual provider characteristics and behaviors, including type of provider (general practitioner, chest physician, or specialist), number of referrals for TB testing over time, and number of patients diagnosed with TB. Data regarding the basic sociodemographic, diagnostic, and source of referral details were collected and recorded for all patients referred who reached the diagnostic step of the pathway. For all diagnosed TB patients, basic clinical, sociodemographic, and treatment regimen and outcome details from the standard treatment card were entered into the database. The data were compared for consistency and all inconsistencies were resolved by referring to the treatment card. Data were analyzed using IBM SPSS Statistics 20 for Windows 8. Univariate analysis was conducted and the results were expressed in

FIGURE 1. The Private Provider Engagement Process Under Project EQUIP



Abbreviations: EQUIP, Enhanced Use of Quality Drugs and Utilization of Innovative Diagnostics for TB Management in the Private Sector; PP, private provider.

proportions. We used standard World Health Organization definitions related to TB diagnosis and treatment outcomes for purpose of the study.[17] Only the key project personnel and data manager had access to the project data, which were stored in a password-protected non-networked computer.

Ethical Approval

The study design was reviewed and approved by the Independent Ethics Committee of REACH.

RESULTS

Formative Research Findings From Consultations With Private Providers

Focus group discussions and individual interviews with our target groups of providers yielded the following key information used in developing our engagement model.

Many private physicians preferred a daily TB treatment regimen over the thrice-weekly regimen.

Many private physicians preferred daily treatment over the thrice-weekly treatment regimen that was free and supported by the RNTCP and national guidance documents. Reasons for this were twofold: (1) they did not believe the thrice-weekly treatment regimen was adequate treatment and therefore thought it may result in more relapses, and (2) they believed the higher doses required in the thrice-weekly regimen led to increased side effects and higher discontinuation of treatment for patients. Since the thrice-weekly regimen was the only one available through RNTCP at the time of project implementation, many providers preferred not to cooperate with the RNTCP but to prescribe and treat independently using a daily regimen that patients had to purchase. The RNTCP supported the daily regimen and planned to start it in the country in pilot districts at the time the project started.

Most private providers were unaware of the new diagnostic technology available for TB (GeneXpert) or were unsure of its reliability. After learning more about it during the orientation sessions, most expressed interest in accessing the technology to improve the accuracy and turnaround time between testing and result. They saw this as a way to improve customer service and satisfaction.

Of the 466 providers sensitized to the private-sector engagement model, nearly 50% actively participated in it.

Private providers perceived the TB case notification process as too time-consuming. Many were unfamiliar with the national online notification platform (Nikshay) available since 2013 and did not have direct access to report cases themselves. In addition, providers were concerned about patient confidentiality, especially for their more affluent patients who might lose social standing in their communities if discovered to have TB.

The vast majority of private providers preferred not to treat DR-TB patients, for several reasons: (1) the higher likelihood of a poor outcome and therefore damage to the provider's reputation; (2) perceived increased risk of infection to themselves and their staff; (3) lack of second-line drugs in pharmacies; and (4) lack of skills and experience in treating complex DR-TB cases. Almost all providers preferred to refer these patients to RNTCP facilities for second-line treatment. However, DR-TB was usually only diagnosed after the initial treatment prescribed by the private provider had failed to cure the patient.

Focus group discussions and individual interviews with patients revealed that TB had important financial implications for them, due to costs for diagnosis and treatment as well as reduced income. In addition, TB continues to be surrounded by stigma, leading patients to be unwilling to disclose their status to others or allow home visits by DOT supporters.

The EQUIP model was designed to address these concerns. The key components of the model are the provider engagement modality through one-to-one visits; the continuous regular involvement of a technical group of public and private technical experts; the access to free GeneXpert testing and preferred daily TB drugs; the choice for the provider and patient to decide whether the patient will receive treatment at the EQUIP centers at private facilities, another private practice, or referral to the RNTCP public centers; and the EQUIP field staff support to both patient and provider during the entire cascade of TB care. Box 1 summarizes these key features, and Figure 2 presents the benefits for each group of participants in the project. Figure 3 depicts the private-sector patient pathway from presentation to diagnosis and treatment completion. Of note, unlike a number of other private-sector engagement models, private providers received no direct or indirect financial compensation for participating in the EQUIP network.

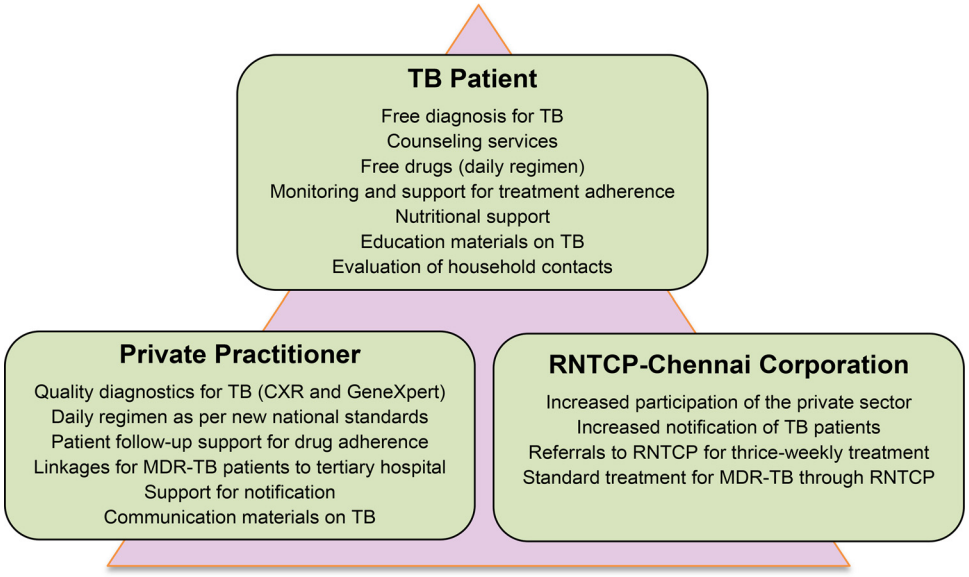
Engagement of Providers

A total of 466 private practitioners were approached and oriented during 7 quarters of project activity. Of those, 12% were chest physicians, 65% general practitioners, and 23% specialists (pediatricians, gynecologists, and orthopedic specialists). Of the 466 providers

BOX 1. Key Features of the EQUIP Model

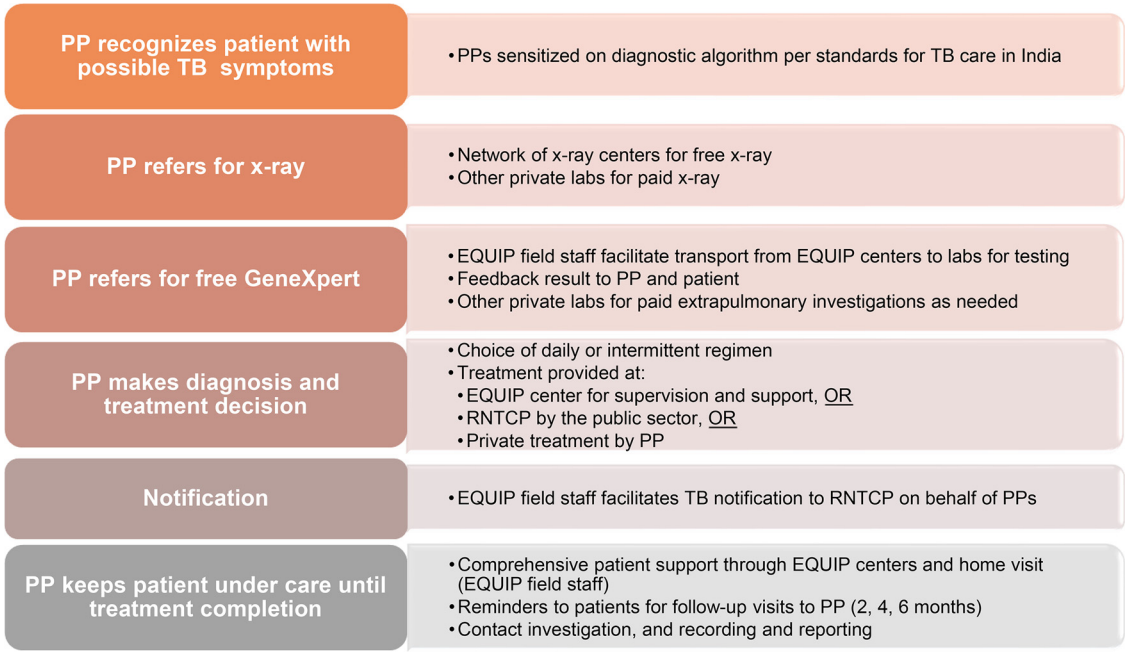
- Providers were recruited to participate through an initial sensitization visit and orientation to standards of TB care in India, including diagnosis and treatment per the national guidelines.
- EQUIP staff conducted monthly one-on-one follow-up visits with providers to actively involve and maintain their interest in diagnosing and treating TB patients while reducing their effort and time investment to come to meetings.
- All participating providers received access to free diagnostics with chest x-ray and GeneXpert through a voucher system.
- EQUIP centers, located at private health facilities and staffed by the EQUIP project, provided a free interface between private providers and patients.
- Choice of the treatment regimen (thrice-weekly or daily) and whether to receive DOT at the EQUIP centers, with support of community volunteers, or by the private doctor was decided by the private provider and patient.
- EQUIP field staff:
  - Instructed referred patients how to produce a sputum specimen and where to go for testing
  - Transported specimen to GeneXpert sites as needed
  - Provided rapid reporting of results from chest x-ray and GeneXpert facilities to referring doctor by email and/or SMS
  - Assisted private providers with the TB case notification process
  - Provided access to free quality-assured drugs for TB treatment using either a thrice-weekly or a daily treatment regimen (supplied by RNTCP or through EQUIP-funded pharmacy vouchers, respectively)
  - Facilitated quick referral for diagnosed DR-TB patients for treatment initiation at the public referral hospital
  - Offered patient and private provider-friendly communication materials
  - Provided counseling services for treatment adherence and mitigation of the social impact of TB
  - Offered conditional nutritional enablers for TB patients through a coupon system
  - Gave ongoing feedback to private providers on patient status

FIGURE 2. Benefits of the EQUIP Model for Participating Groups



Abbreviations: CXR, chest x-ray; EQUIP, Enhanced Use of Quality Drugs and Utilization of Innovative Diagnostics for TB Management in the Private Sector; MDR-TB, multidrug-resistant tuberculosis; RNTCP, Revised National TB Control Program; TB, tuberculosis.

FIGURE 3. Private-Sector TB Patient Pathway to Cure in the EQUIP Model



Abbreviations: EQUIP, Enhanced Use of Quality Drugs and Utilization of Innovative Diagnostics for TB Management in the Private Sector; PP, private provider; RNTCP, Revised National TB Control Program; TB, tuberculosis.

sensitized, 227 (48.7%) actively participated during the project period by referring 1 or more patients with TB symptoms for diagnosis and/or treatment support through EQUIP. After initial orientation visits, providers were encouraged to refer their patients through monthly one-on-one visits. Most of the active private providers referred a patient within 1 to 3 months of agreeing to participate in the EQUIP network. While participation in the project was high, a much smaller subset of providers (the "super-referrers"—those referring 30 or more patients during the project) accounted for a high proportion of the patients referred. Twenty-one providers (9.3% of all active providers) accounted for approximately 48% of total referrals, while more than half of the engaged providers referred only 1 to 5 patients over the life of the project.

As is often the case, there were a few "super-referrers" among the practitioners who participated, who accounted for the majority of the referrals. Specificially, 21 providers (9.3% of all active providers) accounted for approximately 48% of total referrals, while 142 (62.6%) providers referred only 1 to 5 cases over the life of the project (Table 1). In discussions with the providers, they offered 2 explanations for the super-referrer phenomenon: (1) chest physicians receive a number of referrals from general practitioners for suspected cases of TB and therefore have a concentrated high-risk patient load, and (2) certain providers are situated close to high-burden areas such as slums or low-income population centers.

TABLE 1. Number of TB Referrals by Individual Providers

No. of Referrals	No. (%) of Providers	Cumulative Percentage
1–5	142 (62.6)	62.6
6–10	33 (14.5)	77.1
11–30	31 (13.7)	90.7
31–50	14 (6.2)	96.9
51–70	2 (0.9)	97.8
71–100	2 (0.9)	98.7
>100	3 (1.3)	100.0
Total	**227 (100.0)**	

TABLE 2. Number and Yield of TB Referrals by Type of Provider and Quarter

	Chest Physician			General Practitioner			Specialty Physician			Total		
Quarter and Year	No. of Referrals	No. of TB Cases	Yield (%)	No. of Referrals	No. of TB Cases	Yield (%)	No. of Referrals	No. of TB Cases	Yield (%)	No. of Referrals	No. of TB Cases	Yield (%)
Q4 2015	40	28	70.0	46	39	84.8	8	6	75.0	94	73	77.7
Q1 2016	81	43	53.1	154	101	65.6	32	19	59.4	267	163	61.0
Q2 2016	101	60	59.4	128	69	53.9	30	15	50.0	259	144	55.6
Q3 2016	110	61	55.5	207	108	52.2	25	9	36.0	342	178	52.0
Q4 2016	109	47	43.1	233	104	44.6	48	18	37.5	390	169	43.3
Q1 2017	153	82	53.6	380	139	36.6	65	17	26.2	598	238	39.8
Q2 2017	151	78	51.7	443	155	35.0	77	34	44.2	671	267	39.8
Total	**745**	**399**	**53.6**	**1591**	**715**	**44.9**	**285**	**118**	**41.4**	**2621**	**1232**	**47.0**

Abbreviations: Q, quarter; TB, tuberculosis.

It appears that all types of providers contribute substantially to identifying TB cases, particularly general practitioners because of their sheer numbers (Table 2). Chest physicians had the highest yield, at 53.6% of their referred cases, while general practitioners and specialty physicians yielded 44.9% and 41.4% of cases, respectively. There are clearly a small number of highly active participants in TB case identification. Table 3 details the TB referrals among super-referrers only. For chest physicians and general practitioners, the yields of TB cases from their referrals (53.3% and 41.5%, respectively) are similar to the overall respective population of providers (53.6% and 44.9%, respectively), but they also account for a very large proportion of the cases notified. The 8 high-referring chest physicians represented only 20% of the participating chest physicians, but accounted for 61% of the patients referred by chest physicians and 61% of the TB cases diagnosed. High-referring general practitioners accounted for 7.7% of the participating general practitioners but contributed 45% of the referrals and 41.5% of the TB cases identified by general practitioners. In contrast, 2 high-referral specialists (4.5% of participating specialists) had a much lower yield than the overall population of their colleagues, at 22.2% versus 41.4% for all specialists. However, these 2 specialists accounted for 31.6% of referrals and 17% of TB cases diagnosed through specialists. These data are more difficult to interpret due to the inherent difficulties in diagnosing extra-pulmonary TB; recommendations on engaging specialists would depend on additional investigation and analysis.

Referral, Diagnosis, and Notification

The 227 active providers referred a total of 2,621 patients for diagnostic tests, by chest x-ray, and/or GeneXpert (Figure 4). Of the 2621 patients referred by private providers for TB diagnosis, 1,232 (47.0%) were diagnosed with TB, of which 727 (59.0%) were bacteriologically confirmed (Table 4), including 694 (56.3%) using GeneXpert and 33 (2.7%) with positive sputum smear microscopy but negative GeneXpert. In addition, 265 (21.5%) patients were diagnosed by abnormal chest x-ray (a common diagnostic of choice in the private sector) and the remaining 240 (19%) were diagnosed based on other laboratory testing (e.g., magnetic resonance imaging [MRI], fine needle aspiration cytology [FNAC], biopsy, or histopathology) or clinical suspicion only. This compares favorably with overall diagnostic practices reported by the RNTCP for these 2 districts in Chennai: in 2016, 55% of all notified cases in Central Chennai and 54% in South Chennai were bacteriologically confirmed.

Of the 2,621 patients referred by private providers for TB diagnostic tests, 47% were diagnosed with TB.

TABLE 3. Number and Yield of TB Referrals Among Super-Referrers Only (>30 Referrals), by Type of Provider

Type of Provider	No. of Referrals	No. of TB Cases	Yield (%)
Chest physician (n=8)	458	244	53.3
General practitioner (n=11)	716	297	41.5
Specialty physician (n=2)	90	20	22.2
Total (N=21)	**1264**	**561**	**44.4**

Abbreviation: TB, tuberculosis.

TABLE 4. Number of Patients Referred to EQUIP by Type of Private Provider

	Provider Type			
	Chest Physicians (n=40)	General Practitioners (n=143)	Specialists (n=44)	Total (n=227)
No. of referred patients	742	1,592	287	2,621
No. of patients referred for GeneXpert testing	620	1,158	167	1,945
No. of patients diagnosed with TB	396	716	120	1,232
No. (%) of patients diagnosed with TB with bacteriological confirmation (GeneXpert/SSM)	243 (61.3%)	436 (60.8%)	48 (40.0%)	727 (59.0%)
No. (%) of patients confirmed with RR-TB	NA	NA	NA	26 (3.7%)

Abbreviations: EQUIP, Enhanced Use of Quality Drugs and Utilization of Innovative Diagnostics for TB Management in the Private Sector; RR-TB, rifampicin-resistant tuberculosis; SSM, sputum smear microscopy; TB, tuberculosis.

Among the 694 specimens positive for TB with GeneXpert, 31 tested positive for rifampicin resistance. Five of those were later determined to be drug-sensitive using conventional drug susceptibility testing (Line Probe Assay or Mycobacteria Growth Indicator Tube) or repeat GeneXpert, for a total of 26 (3.7%) confirmed rifampicin-resistant cases found through GeneXpert testing and notified to RNTCP during the project period.

All 1,232 patients diagnosed through EQUIP were notified to the RNTCP. In addition, private providers also requested EQUIP to notify 36 patients they had diagnosed and managed themselves outside of the project. By comparison, in previous years the private sector accounted for substantially fewer notifications: 301 in 2013, 487 in 2014, and 524 in 2015 in all 3 districts of Chennai.

Treatment Regimens and Outcomes for TB and DR-TB

Of the 1,206 patients diagnosed without rifampicin resistance, 1,167 (96.8%) initiated treatment, 11 (0.9%) died, 13 (1.1%) were lost to follow-up, and another 13 (1.1%) transferred out prior to treatment start. Among those who started treatment, 691 (59.2%) received standardized daily regimens with treatment support provided by EQUIP. In addition, 288 (24.7%) received standardized intermittent regimens, either delivered by EQUIP (n=177) or through public RNTCP facilities (n=111), while 185 (15.9%) bought private prescriptions on their own. Only 3 patients refused to be treated with standard allopathic anti-TB regimens and instead chose to visit

FIGURE 4. Private Provider Engagement, Referrals for TB Diagnosis, and TB Cases, October 2015–June 2017

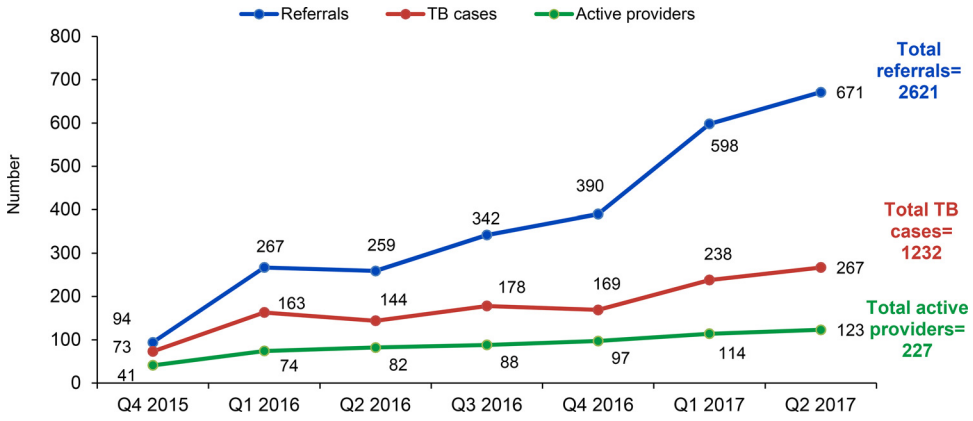


TABLE 5. Treatment Outcomes for Patients Without Confirmed RR-TB and Who Received Treatment Support Through EQUIP

Treatment Outcomes	Patients Referred by:			Total (n=868)
	Chest Physicians (n=226)	General Practitioners (n=513)	Specialist Physicians (n=129)	
Completed, No.	182	350	108	640
Cured, No.	21	103	12	136
Treatment success, No. (%)	203 (89.8%)	453 (88.3%)	120 (93.0%)	776 (89.4%)
Died, No.	9	20	5	34
Lost to follow-up, No.	13	29	4	46
Transferred to private facility treatment, No.	0	2	0	2
Transferred to RNTCP facility treatment, No.	1	5	0	6
Treatment failure, No.	0	3	0	3
Still on treatment, No.	0	1	0	1

Abbreviations: EQUIP, Enhanced Use of Quality Drugs and Utilization of Innovative Diagnostics for TB Management in the Private Sector; RNTCP, Revised National TB Control Program; RR-TB, rifampicin-resistant tuberculosis.

traditional practitioners who prescribed traditional (herbal or ayurvedic) medicines.

At the time of writing, 89.4% of the 868 patients with drug-susceptible TB who received treatment through EQUIP and were eligible to have completed their treatment by this date had done so successfully (Table 5). Of the 26 rifampicin-resistant TB cases notified, 20 (77%) were started on second-line treatment. Nineteen of those started treatment through the RNTCP system and one started treatment through a private provider. Two patients treated through RNTCP died shortly after treatment initation. Of the 6 patients who did not start treatment, 2 died and 4 were lost to follow-up prior to treatment initiation.

DISCUSSION

Many efforts have been launched to engage the private sector effectively in TB control in India. A number of those models have been successful in increasing case notifications but have been difficult to expand because priority has been given to strengthening the public sector with less emphasis on creating lasting partnerships with private-sector providers. The EQUIP model shares a number of characteristics with other models, including the Strengthening Health Outcomes through the Private Sector (SHOPS) project, supported by the United States Agency for International Development (USAID) and implemented by Abt Associates from 2012 through 2015, on which the successful Mumbai Public-Private Interface Agency (PPIA) project was later modeled. All of these models mapped, recruited, and trained local private providers; provided support for notification; increased access to diagnostic technologies; and provided standardized treatment as well as treatment support to patients through an interface agency. There are several differences in EQUIP to note. First, the EQUIP model is the only effort to have focused specifically on DR-TB detection in the private sector. Second, EQUIP actively engaged the target population of providers in formative research and project design and continued to consult with them on an ongoing basis.

89% of patients with drug-susceptible TB who received treatment by the project had treatment success.

A staff member at an EQUIP center supports a patient to improve TB treatment literacy and adherence. © Jasper Hamann

Third, EQUIP's centers were established within existing private-sector facilities and relied more heavily on in-person support to help patients navigate the complex health care system, as opposed to electronic communication. Fourth, EQUIP sought to establish diagnostic sites within their own network of private facilities to increase the convenience for providers and patients. Fifth, the EQUIP model was the only one to offer a daily treatment option to providers and patients. Finally, in an effort to increase chances for sustainability, the model offered no direct or indirect compensation to private providers for participating in the network, unlike the other models that have included cash transfers, phone minutes, or other rewards.

Effective participation of the private sector in TB control efforts in India is possible.

The project demonstrated that effective participation of the private sector in TB control efforts in India is possible and can yield significant benefits to private providers and their patients as well as the public sector by encouraging appropriate TB diagnostic and treatment behaviors. Through EQUIP, DR-TB cases were identified quickly using state-of-the-art diagnostics, and they promptly received appropriate treatment with ongoing support for treatment adherence. Coordination through EQUIP as the interface agency between diverse private and public stakeholders and patients was critical to success. Key recommendations going forward are summarized in Box 2.

High Level of Engagement of Private Providers

The level of participation by private providers (almost 50%) was much higher than anticipated (an estimated 10% to 15% based on previous REACH private-sector engagement work) and can be attributed to the benefits providers received from the project's services. First, we involved providers in the design of the model and individualized the approach to sensitization and follow-up. Second, we offered providers a comprehensive range of services: sputum collection and transport; free-of-charge GeneXpert testing with rapid turnaround times; and free-of-charge, quality daily treatment regimens for drug-sensitive TB while retaining their patients. Third, we provided reliable referral of DR-TB patients to public RNTCP clinics for second-line treatment.

While participation in the project was high, a much smaller subset of providers (the "super-referrers" who provided more than 30 referrals

BOX 2. Recommendations to Effectively Engage the Private Sector in TB Care

- Ongoing outreach to private providers on a one-to-one basis and through other channels is necessary to maintain their interest in TB activities, given their many competing priorities. To maintain their motivation, providers' efforts to diagnose and notify TB cases to RNTCP and to prescribe appropriate, low-cost regimens to their patients should be recognized. The updated guidance from RNTCP allowing for daily regimens should be widely publicized, and providers should be encouraged to access RNTCP daily regimen drugs to treat their patients. These are labor-intensive activities that must be considered when planning private-sector initiatives.
- Private-sector engagement continues to require some sort of "interface" agency to play the coordination role between RNTCP, individual providers, and patients. This will likely continue to be the case until processes are streamlined, notification becomes mandatory, and quality services are widely available and affordable. The role and scope of the interface agency should be recognized and integrated within government reimbursement schemes.
- Continue to provide free or low-cost access to cartridge-based nucleic acid amplification tests (CB-NAAT), such as GeneXpert, as the initial diagnostic for private patients with TB symptoms. Make CB-NAAT available in private facilities, as Project EQUIP did. Encourage private providers to refer more of their symptomatic patients for CB-NAAT testing. Report back to them on the overall yield of their referrals and discuss why referring additional patients is warranted.
- Support for notification of TB cases through Nikshay is necessary to increase the proportion of notifications of private-sector patients. Although the online system allows access by private providers, most do not take the time to complete the forms, particularly the smaller clinics with few support staff. A more simplified process will be required to engage the private sector in the notification process.
- Providing patient- and provider-centered services is an essential component of any private-sector engagement model. Advocacy for expansion of the EQUIP treatment model can help maintain excellent treatment success rates.
- All private provider types can contribute substantially to increasing TB case notification and early DR-TB case detection and should be engaged in TB control efforts. Using a database capable of tracking referrals and TB cases diagnosed by individual provider can help target further efforts to engage the private sector by identifying high performers as well as areas for improvement.
- Reasons for the unexpectedly high yield of cases from referrals should be explored further to inform revisions to the approach that could increase the number of patients referred.
- A direct comparison of all successful private engagement models to combine the best practices of each could result in an optimized approach for private-sector engagement in India.

each) accounted for a high proportion of the patients referred. These super-referrers could be the focus of future efforts to continue private-sector engagement in the case that resources are limited. However, in order to identify this subgroup of providers, referrals and yields must be tracked by individual provider, requiring a substantial data collection and analysis effort.

High Yield of Cases Among Patients Referred for GeneXpert

The yield of TB cases among people referred for GeneXpert testing was extremely high, with 47% of all referrals resulting in a confirmed TB diagnosis. In general, one would expect that about 10% of people with symptoms would have a positive TB diagnosis in a high-burden setting. True interpretation of these data is not possible without gathering further information about provider referral habits, which will continue in the ongoing phase of the work. Several possible explanations for the high yield exist. Providers may have concentrated on referring only those for whom they had a very high index of suspicion for TB based on chest x-ray or clinical presentation rather than referring all those with symptoms that could have been related to TB. In addition, they may have prescribed a course of general antibiotics first to rule out other causes of illness before referring for TB evaluation. They may also have preferentially referred patients with clinically diagnosed TB in whom they wanted to rule out drug resistance. Because this was the first year of engagement for many of the providers, it also may simply take more time to establish a trusting relationship that will encourage them to refer more of their clients for diagnosis. Although still high, the yield (proportion of cases diagnosed over the number referred) did decrease markedly over time among all provider groups, as shown in Table 3. This may be related to an increase in trust and therefore an increase in willingness to refer patients, as well as a gain in knowledge about who, how, and where to refer patients for testing.

Private Providers' Contribution to Increasing Both TB and DR-TB Case Notifications

Prior to the project, most private-sector TB patients were not notified to the RNTCP and did not have a treatment outcome recorded. Mandatory notification of TB was instituted in 2012, but few private providers complied with the requirement because they were unaware; did not have appropriate forms and contacts to perform the task; refused due to concerns about patient confidentiality; or did not allocate time to do so. These barriers accounted for low notifications in previous years—for instance, total private-sector notifications for all of Chennai accounted for only 524 TB cases in 2015.

During the period October 2015 through June 2017, in total 12,171 TB patients were notified from Central and South Chennai to the RNTCP. In addition to the 1,232 patients diagnosed through EQUIP, private providers also requested EQUIP to notify 36 patients they had diagnosed and managed themselves. These 1,268 patients accounted for approximately 10% of all TB notifications to the RNTCP from these districts in the same period.

Twenty-six DR-TB cases were notified through EQUIP during the project period. In comparison, a total of 160 DR-TB cases were notified with the RNTCP in all of Chennai in 2016. While a direct comparison with overall DR-TB notification is not possible because of the differing time frames and geographies of RNTCP and EQUIP data, the contribution of EQUIP to DR-TB diagnosis and notification is nevertheless considerable, estimated to be similar to the contribution to drug-sensitive notifications at approximately 10% of DR-TB cases notified.

Treatment at EQUIP Centers Preferred

Most (74%) of the 1,167 drug-sensitive TB patients who started treatment were treated through the private EQUIP treatment centers, which expanded from 4 centers at the beginning of the project to 13 centers at project conclusion. Of the patients treated at the EQUIP centers, 80% received daily treatment. Only 9% of drug-sensitive TB patients diagnosed through the EQUIP center were treated at an RNTCP center, usually when this center was more conveniently located for the patients. Approximately 16% were treated with anti-TB regimens under private prescription without treatment support from EQUIP, and only 0.25% were treated using non-standard traditional medicine.

Improved Diagnostic and Treatment Practices and Good Treatment Outcomes

During 7 quarters of active project operations, the private sector referred 2,621 patients and diagnosed 1,232 TB cases in the Central and South districts of Chennai, approximately 10% of the total cases notified in these districts during the period. Without the project, it is likely that few of these

The private-sector model contributed about 10% of the total TB cases notified in the project districts.

cases would have been notified to the RNTCP and would have remained among the "missing" cases instead. Of the cases diagnosed in the private sector, 694 (56%) were bacteriologically confirmed using GeneXpert, a technology that was rarely used in the private sector in Chennai prior to the project. While this is a great improvement in bacteriological confirmation of TB in the private sector, there is room for further improvement. Private providers continue to rely heavily on chest x-ray for diagnosis and have few means of confirming extrapulmonary TB, which continues to be diagnosed primarily by clinical judgment.

The project demonstrated high levels of private provider adherence to standardized, quality-assured treatment regimens, with more than 82% of patients prescribed a standard daily or intermittent regimen with quality-assured drugs. Perhaps even more important, their willingness to access treatment adherence support through EQUIP or RNTCP to ensure better outcomes for their patients produced excellent results. At the time of writing, 89% of patients who were eligible to complete treatment had done so successfully, approaching global and national targets for treatment success. Prior to the project, most private-sector patients did not have a treatment outcome recorded at all. Our result compares favorably with the 84% treatment success (42% cure and 43% treatment completed) for the full RNTCP cohort (2016 Q1–Q3 patient cohort; data obtained from RNTCP).

Although the private-sector engagement model has been adopted for scale-up, sustainability remains a concern.

Limitations

Notwithstanding the success of our approach in facilitating quality diagnosis, treatment, care, and notification for patients seeking care in the private sector in Chennai, some limitations are to be mentioned. The main limitation is the absence of key baseline data to compare against the data collected during the project because these data did not exist. The value of this project also lies in beginning the process of actually collecting data to quantify the potential contribution of the private sector in detecting TB and DR-TB. Without having had the opportunity to collect such baseline data ourselves through the private providers, we have no comparator related to the number of private providers engaged and the number of referrals per provider. Also, we do not know the proportion of all patients and eligible patients referred for diagnosis, as providers were unwilling to provide such data. The high proportion of patients diagnosed with TB indicates selective referral of patients, as discussed earlier. Whether it implies we missed a substantial proportion of TB diagnoses among the client population of the providers engaged will require follow-up research. The proportion of bacteriological confirmations did go down during the project period (78% in the fourth quarter of 2015 to 40% in the second quarter of 2017; data not shown), which indicates that with time private providers may be referring an increasing proportion of presumptive TB patients for bacteriological testing.

CONCLUSION

The 13 EQUIP centers, now renamed Nakshatra ("Star") centers, are a key element of the TB Free Chennai Initiative, led by the Corporation of Chennai, which plans to expand the REACH-led Nakshatra centers to a total number of 36 in Chennai. The TB Free Chennai Initiative will receive funding from USAID (to local government) and the Stop TB Partnership (to REACH). Within the TB Free Chennai Initiative, GeneXpert testing will continue to be available through the previous EQUIP-networked private hospital using the voucher system. As under EQUIP, this work will still be financed through external funding (USAID). Other mechanisms and new diagnostic tools are needed to make diagnostic testing more affordable for the private sector.[18] In addition, domestic funding support will be required to ensure sustainability of the model, like all public-private models in India.

REACH as the interface NGO takes care of sputum collection and transport, quick results delivery, and treatment adherence support to make the services as patient-friendly as possible. The Nikshay online case reporting platform has improved accessibility to reporting for private providers but remains time-consuming and will require the support of an interface NGO unless the amount of data required is reduced. The coming years should be used to develop mechanisms for government funding to support this type of qualified interface NGO. Given that demand is much greater than existing public health services can cover, these public-private interface models are important to extend quality diagnostic and treatment services to the majority of people with TB in India, many of whom prefer to seek care in the private sector.

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ORIGINAL ARTICLE

Factors Affecting Continued Use of Subcutaneous Depot Medroxyprogesterone Acetate (DMPA-SC): A Secondary Analysis of a 1-Year Randomized Trial in Malawi

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Community health workers can adequately provide DMPA-SC directly or train women on self-injection.

ABSTRACT

Objective: To assess the supply- and demand-side factors influencing continued use of the injectable contraceptive subcutaneous depot medroxyprogesterone acetate (DMPA-SC).

Methods: We conducted a 12-month randomized controlled trial in Malawi to measure DMPA-SC continuation rates. A total of 731 women presenting to clinic-based providers (CBPs) at 6 Ministry of Health clinics or to community health workers (CHWs) in rural communities were randomized to receive DMPA-SC administered by a provider or be trained to self-inject DMPA-SC. Data collectors contacted women after the reinjection window at 3, 6, and 9 months to collect data on discontinuation and women's experiences. Twelve months after enrollment or at early discontinuation, women had their final interview, including pregnancy testing. We compared continuation, pregnancy, and safety by whether DMPA-SC or self-injection training was provided by CHWs versus CBPs. We also conducted an exploratory analysis assessing the association between women's sociodemographic factors and the risk for discontinuation using stratified Cox proportional hazards models.

Findings: The type of provider did not seem to influence continuation, pregnancy, or safety. As reported previously, women in the self-injection group were significantly less likely to discontinue the method compared with women in the provider-administered group (hazard ratio, 0.43; $P<.001$). The risk for discontinuation was also different among health facility catchment sites ($P<.001$). No other assessed sociodemographic factors were found to significantly influence the risk for discontinuation.

Conclusions: Public-sector CHWs can safely and effectively provide DMPA-SC and train women to self-inject DMPA-SC in low-resource settings. DMPA-SC continuation did not seem to be influenced by the type of provider, whether CBP or CHW, or women's sociodemographic characteristics.

BACKGROUND

Injectable contraceptives are increasingly popular in low-and middle-income countries and are the predominant modern method used by women in sub-Saharan Africa.[1] In Malawi, the use of modern contraceptive methods by married women has increased from 7% in 1992 to 58% in 2015–2016; however, unmet need for family planning is considerable at 19%.[2] Injectables are the most commonly used method—of married women in Malawi who use a modern method of contraception, 30% use injectables. Despite their high use, discontinuation rates for injectables are high; 41% of women of reproductive age have reported discontinuing the method in the first year.[2] In addition to method-related concerns, travel distance to a nearby health center—over 80% of the approximately 17 million people in Malawi live in rural areas[3]—and frequent contraceptive stock-outs are common barriers to use and continuation.[4]

The World Health Organization (WHO) has endorsed task sharing as a strategy to bridge the human resource gap in the provision of reproductive health services in low-income countries, noting that "task sharing is envisioned to create a more rational distribution of tasks and responsibilities among cadres of health workers to improve access and cost-effectiveness."[5] When clinic-based providers (CBPs) share tasks with CHWs, the workload of CBPs is reduced, which allows more time for them to provide higher-level care and curative services while increasing access to contraception for women living in hard-to-reach places—thereby helping to address their unmet family planning needs.[6]

Malawi's program for community-based access to injectable contraception started with a pilot in 2008.[7] CHWs in Malawi (also called health surveillance

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assistants) provide health services to catchment areas of approximately 1,000 people each; they are the lowest level of paid government workers.[8] They have completed secondary school and received 12 weeks of training—the first 8 weeks are in a classroom, followed by 4 weeks of practical training. As is the case in many other low- and middle-income countries, CHWs in Malawi administer intramuscular depot medroxyprogesterone acetate (DMPA-IM) to clients in community settings as part of the family planning method mix they offer.

A subcutaneous (SC) version of DMPA is delivered in a prefilled, auto-disabled Uniject injection system (Sayana Press with 104 mg of medroxyprogesterone acetate in 0.65 mL suspension for injection). DMPA-SC is steadily gaining popularity among family planning users and providers in sub-Saharan Africa as an easy-to-use and accessible contraceptive option. Studies in Senegal and Uganda found that family planning providers preferred the subcutaneous version over the intramuscular formation—providers indicated that DMPA-SC was easier and faster to administer, would decrease stock-outs (due to its all-in-one presentation compared with DMPA-IM, which requires a vial and syringe that may become separated), and would be less painful and therefore preferable for women.[9] Research has also demonstrated that CHWs can safely provide DMPA-SC in community settings.[10,11] Moreover, given the simplified delivery system and subcutaneous administration route, a growing body of evidence underscores the feasibility, acceptability, and efficacy of self-injection of DMPA-SC. Self-injection was found to be acceptable and feasible in Senegal and Uganda.[12,13] In the current study, a randomized trial recently conducted in Malawi, self-injection improved 12-month continuation rates significantly compared with provider-administered DMPA-SC, by more than 50% (the primary results are reported elsewhere).[11] In the Malawi study, both CHWs and CBPs were trained to administer injections and to teach women to self-inject.

The recent trial in Malawi demonstrated that public-sector family planning providers, including CHWs, can safely provide DMPA-SC and train women to self-inject. However, little is known about whether and how outcomes—including continuation, adverse events, side effects, and pregnancy—vary by supply-side factors such as the type of family planning provider (CHW or CBP) who provides DMPA-SC or self-injection training to women. CBPs in the trial were government nurses and midwives with more health care training than the CHWs, which may influence the quality of services provided. Furthermore, the knowledge base is nascent regarding demand-side factors such as the sociodemographic characteristics of women that may influence 12-month DMPA-SC continuation, especially for self-administered DMPA-SC. The numerous studies that have been conducted to assess determinants of continuation of DMPA-IM indicate that women who receive complete and accurate information on possible side effects are more likely to continue using DMPA[14–18] and that side effects, especially menstrual disturbances, are an important factor influencing discontinuation.[16,19–23] In contrast, age, marital status, educational level, and parity have not been shown to significantly impact DMPA-IM continuation.[1,17,24,25]

It is unclear how factors influencing continuation of IM and SC formulations will differ, especially when DMPA-SC is self-administered. Two nonrandomized cohort studies in Burkina Faso and Uganda found no difference in continuation rates between DMAP-SC and DMPA-IM when both were administered by CBPs, but findings showed that increased age and partners' acceptance of family planning increased DMPA continuation in Burkina Faso (no other variables tested with the Uganda data were statistically different).[26] In acceptability trials conducted with DMPA-IM clients in Senegal and Uganda, most clients preferred DMPA-SC after trying it; the most common reason for this preference was that clients perceived fewer side effects from DMPA-SC compared with DMPA-IM,[10] though previous safety and effectiveness trials have not demonstrated this difference.[27,28] A recent nonrandomized cohort study in Senegal also observed fewer side effects among clients who self-injected DMPA-SC compared with those who received DMPA-IM from a CBP.[29]

A growing body of evidence shows that self-injection of DMPA-SC is feasible and acceptable and that CHWs can safely provide it.

Given the limited research on factors affecting continued use of DMPA-SC, especially for self-injected DMPA-SC, the aim of this article is to assess the influence of selected supply- and demand-side factors on continued use of DMPA-SC among Malawian women enrolled in a year-long randomized controlled trial. These data can be used to inform task-sharing decisions and optimize service delivery in Malawi and other low-resource settings.

METHODS

We used data collected as part of a randomized controlled trial we conducted to compare

continuation rates between women who self-inject DMPA-SC and women who receive the same product from a provider. The trial was conducted from September 2015 to February 2017 in 6 Ministry of Health clinics and surrounding communities in rural Mangochi District, Malawi. During the trial, CBPs and CHWs randomized 731 women seeking family planning services to either receive DMPA-SC administered by the provider or be trained to self-inject DMPA-SC. Eligible participants were ages 18 to 40 years, in self-reported good general health, able to understand and willing to sign an informed consent document, willing to give contact information for follow-up, willing to have follow-up visits or interviews, willing to be randomized to the self-injection arm or provider-administered injection group, not pregnant according to WHO guidelines, and able to meet eligibility criteria for receiving DMPA per WHO medical eligibility criteria.[30–32] Women in the self-injection group who successfully self-injected at enrollment (assessed by the provider) received 3 doses of DMPA-SC to take home for subsequent self-injections, whereas women in the provider-administered injection group were asked to return to the provider for injections at 3, 6, and 9 months post-enrollment. Data collectors (not providers) contacted women after the reinjection window at 3, 6, and 9 months to collect data on discontinuation and women's experiences. Twelve months after enrollment or at early discontinuation, women had their final interview, including pregnancy testing. Neither participants nor study staff were blinded after randomization; however, the statistical team remained blinded until key decisions for the primary analysis were made. A detailed description of the methods of the randomized controlled trial has been published elsewhere.[11]

Our primary outcome was DMPA-SC discontinuation. Women were considered discontinuers if they did not report receiving an injection within the allowable window of time (12 to 14 weeks after the last injection, according to Sayana Press guidelines). Given that reinjection provides 3 months of protection, participants without a DMPA-SC injection within the window or who were lost to follow-up were considered to have discontinued 3 months after the previous injection. Those who had not discontinued by 12 months were censored at 12 months, when the study ended.

We collected data on adverse events, side effects, and pregnancies occurring throughout the 12-month follow-up. In this article, we report outcomes comparing women assisted by CBPs or CHWs. The analysis of safety data included only participants who successfully received or administered a DMPA-SC injection after randomization.

We estimated Kaplan-Meier cumulative probabilities of contraceptive continuation coverage (with 95% confidence interval [CI] at 3, 6, and 9 months) by provider type and compared the distribution of continuation between these groups using a log-rank test stratified by site using a .05 significance level for a 2-sided comparison. We present these results separately by the original randomization group (i.e., self-injection and provider-administered DMPA-SC) since the primary results demonstrated a large treatment effect on continuation.[11] We also provide discontinuation incidence estimates and incidence rate ratio with 95% CI comparing the 2 provider types.

We also assessed factors that could potentially influence DMPA-SC discontinuation using Cox proportional hazards models with each of the following covariates: treatment group (i.e., self-injection or provider-administered DMPA-SC), site (i.e., the health facility catchment area where the participant was enrolled), woman's age, marital status, whether she works outside the home, parity, education, religion, previous experience with contraceptives and injectable contraceptives, and whether a CBP or CHW provided DMPA-SC or self-injection training at enrollment.

We assessed each covariate separately and planned to include all covariates found significant at the .05 level in the univariate models in a multivariable model. Except for when we analyzed the effect of site specifically, site was used as a stratification variable in the models as consistent with the randomization scheme. Hazard ratios for discontinuation and 95% CI were provided for each covariate modeled.

The study protocol was reviewed and approved by the Protection of Human Subjects Committee at FHI 360, Durham, NC, USA, as well as the College of Medicine Research and Ethics Committee, University of Malawi. All study staff completed training on research ethics, the protocol, and informed consent administration. All trial participants provided their informed consent to participate. The trial was registered with ClinicalTrials.gov (NCT02293694).

RESULTS

Participants' sociodemographic characteristics are shown in Table 1. Over 70% were enrolled in the study by a CHW. The mean age was 27 years, and

TABLE 1. Baseline Sociodemographic Characteristics of Participants, September 2015 to February 2017, Mangochi District, Malawi (N=731)

Characteristic	Value
Provider type at enrollment, No. (%)	
Clinic-based	205 (28.0)
Community health worker	526 (72.0)
Age group, years, No. (%)	
18–24	264 (36.1)
25–29	238 (32.6)
30–35	184 (25.2)
>35	45 (6.2)
Age, years, mean (SD)	26.9 (5.2)
Education, No. (%)	
No school/less than primary school	545 (74.6)
Completed primary school or higher	185 (25.3)
No response	1 (0.1)
Religion, No. (%)	
Christian	310 (42.4)
Muslim	418 (57.2)
None	1 (0.1)
No response	2 (0.3)
Married or has regular sexual partner, No. (%)	
Not married and no regular sexual partner	25 (3.4)
Married or regular sexual partner	705 (96.4)
No response	1 (0.1)
Husband/partner knows respondent receiving family planning today, among those with partner,[a] No. (%)	
No	137 (20.1)
Yes	522 (76.8)
Don't know	13 (1.9)
No response	8 (1.2)
Ever given birth, No. (%)	
No	5 (0.7)
Yes	725 (99.2)
No response	1 (0.1)
Number of living children, among those who gave birth, No. (%)	
Less than 3 living children	321 (44.3)
3 or more living children	404 (55.7)
Number of living children, among those who gave birth, mean (SD)	3.0 (1.64)

Continued

TABLE 1. Continued

Characteristic	Value
Would like to have a/another child, No. (%)	
No	182 (24.9)
Yes	529 (72.4)
Don't know	17 (2.3)
No response	3 (0.4)
Ever used contraception, No. (%)	
No	47 (6.4)
Yes	679 (92.9)
No response	5 (0.7)
Ever used injectables, among those who ever used contraception, No. (%)	
No	21 (3.1)
Yes	657 (96.8)
No response	1 (0.1)

Abbreviations: No., number; SD, standard deviation.
[a] This question purposefully excludes 25 women who were married but were not living with their husband and had no other regular sexual partner.

75% had no schooling or did not complete primary school. Over half were Muslim. Almost all were married or had a sexual partner, and 20% said that their husband or partner did not know about their appointment to receive family planning. Almost all had previously given birth and had 3 living children, on average. The large majority (93%) had previously used contraception, primarily injectables. One-quarter did not want additional children.

Reasons for discontinuation did not differ significantly by provider type, whether CBP or CHW.

There was no significant difference in continuation rates between women who received DMPA-SC self-injection training from clinic-based providers versus CHWs.

Cumulative probabilities of continuation and 95% CI for each quarter by type of provider at enrollment and treatment group are presented in Table 2. Among women in the self-injection group, the continuation rate through 12 months of contraceptive use was not significantly different for women who received DMPA-SC self-injection training from a CBP [0.79 (95% CI, 0.70 to 0.86)] than those who received the training from a CHW [0.70 (95% CI, 0.64 to 0.75)] (P=.77). Though the continuation rates were much lower in the provider-administered group (the self-administered and provider-administered groups had 99 and 199 discontinuations, respectively), we did not find a significant difference between women who received DMPA-SC from a CBP [0.48 (95% CI, 0.39 to 0.57) and those who received the method from a CHW [0.44 (95% CI, 0.38 to 0.50)] (P=.78). The incidence rate of discontinuation for those who received self-injection training from a CHW was 9 per 100 injection cycles (95% CI, 7 to 11) compared with 6 per 100 injection cycles (95% CI, 4 to 9) among those who were trained by a CBP. For the provider-administered group, the incidence rate for those who received DMPA-SC from a CHW was 21 per 100 injection cycles (95% CI, 18 to 25) compared with 19 per 100 injection cycles (95% CI, 14 to 25) among those who received the method from a CBP.

The distribution of reasons for discontinuation did not differ significantly by provider type for self-injectors (P=.49) or for those in the provider-administered group (P=.26). The most common reason for discontinuing was due to missing the reinjection window (data are reported elsewhere[11]). Other reasons for discontinuing (in order of decreasing frequency) included loss to follow-up; by the woman's request, mostly related to side effects of DMPA-SC; and less commonly, by the provider's request for medical reasons. The reasons for discontinuation may underestimate the role of side effects during the trial. This is because after women discontinued, they were no longer counted in the estimates of side effect occurrence as the trial moved forward.

Data from pregnancy tests were incomplete due to refusals, loss to follow-up, and data

TABLE 2. Cumulative Probability of Continuation Among Self-Administered and Provider-Administered Clients, Stratified by Type of Provider at Enrollment

	Clinic-Based Provider		Community Health Worker	
Month	**Number at Risk**	**Probability (95% CI)**	**Number at Risk**	**Probability (95% CI)**
Self-administered				
First quarter	97	0.99	267	1.00
Second quarter	96	0.88 (0.79, 0.93)	267	0.86 (0.81, 0.90)
Third quarter	83	0.81 (0.72, 0.88)	226	0.77 (0.71, 0.82)
Fourth quarter	76	0.79 (0.70, 0.86)	202	0.70 (0.64, 0.75)
Provider-administered				
First quarter	108	1.00	259	1.00
Second quarter	108	0.69 (0.60, 0.77)	258	0.67 (0.61, 0.73)
Third quarter	74	0.58 (0.48, 0.67)	171	0.53 (0.47, 0.59)
Fourth quarter	59	0.48 (0.39, 0.57)	135	0.44 (0.38, 0.50)

Abbreviation: CI, confidence interval.

collectors neglecting to administer a pregnancy test as planned (pregnancy status was unknown for 12% in the self-administered group and 21% in the provider-administered group). Among 612 women tested, 8 pregnancies were identified; 1 with a conception date prior to enrollment and 7 during follow-up. Of the 7 pregnancies, 3 occurred in the self-injection group (1 among CBP clients and 2 among CHW clients) and 4 in the provider-administered group (1 among CBP clients and 3 among CHW clients). Differences observed by type of provider within the self-injection group ($P>.99$) and the provider-administered group ($P>.99$) were not statistically significant.

The percentage of continuing women who experienced side effects decreased over time across all groups (Table 3 and Table 4). The differences in percentages of women experiencing side effects among those trained to self-inject by CBPs compared with those trained by CHWs were not statistically significant: 3 months—20% vs. 28% ($P=.21$), 6 months—15% vs. 18% ($P=.74$), and 9 months—12% vs. 14% ($P=.70$). Similarly, there were no statistically significant differences between those who received DMPA-SC from a CBP compared with a CHW: 3 months—34% vs. 31% ($P=.61$), 6 months—23% vs. 22% ($P>.99$), and 9 months—15% vs. 19% ($P=.69$). Among women who reported side effects, the majority across all groups reported little to no effect on daily life.

Twenty related or possibly related adverse events were reported by 10 women in the self-administration group (data not shown). Nine of these events were reported by 3 women who received self-injection training by CBPs and 11 of these events were reported by 7 women who received training by CHWs. These differences by type of provider were not statistically significant ($P=.73$ for the differences in proportion of women experiencing adverse events). Twenty-eight related or possibly related adverse events were reported by 17 women in the provider-administered group (data not shown). Nine of these events were reported by 7 women who received DMPA-SC from CBPs and 19 of these events were reported by 10 women who received DMPA-SC from CHWs; these differences were not statistically significant ($P=.28$ for the differences in proportion of women experiencing adverse events). Furthermore, there were no significant differences between the groups in the types of adverse events reported. There were 5 serious adverse events reported during the trial by 4 different women. Two events related to DMPA-SC (menorrhagia and anemia requiring hospitalization) were reported by the same woman in the provider-administered group who was enrolled by a CHW and resolved without sequalae. The other serious adverse events, including 1 death (suspected liver cirrhosis), were unrelated to DMPA-SC.

The percentage of women experiencing side effects were not significantly different by provider type.

TABLE 3. Experience With Side Effects in Last 3 Months Among Self-Administered Participants, Stratified by Type of Provider at Enrollment, No. (%)

	3-Month Follow-Up			6-Month Follow-Up			9-Month Follow-Up		
	CBP	CHW	Overall	CBP	CHW	Overall	CBP	CHW	Overall
Experienced any side effects or problems over last 3 months?									
No	74 (79.6)	190 (72.5)	264 (74.4)	72 (84.7)	197 (82.4)	269 (83.0)	68 (88.3)	197 (86.0)	265 (86.6)
Yes	19 (20.4)	72 (27.5)	91 (25.6)	13 (15.3)	42 (17.6)	55 (17.0)	9 (11.7)	32 (14.0)	41 (13.4)
Type of side effects (among women reporting side effects)									
Irregular bleeding/spotting	5 (26.3)	14 (19.4)	19 (20.9)	1 (7.7)	4 (9.5)	5 (9.1)	2 (22.2)	5 (15.6)	7 (17.1)
Amenorrhea	10 (52.6)	22 (30.6)	32 (35.2)	7 (53.8)	21 (50.0)	28 (50.9)	5 (55.6)	19 (59.4)	24 (58.5)
Heavy bleeding	3 (15.8)	17 (23.6)	20 (22.0)	1 (7.7)	3 (7.1)	4 (7.3)	0 (0.0)	0 (0.0)	0 (0.0)
Weight gain	1 (5.3)	1 (1.4)	2 (2.2)	0 (0.0)	4 (9.5)	4 (7.3)	0 (0.0)	1 (3.1)	1 (2.4)
Weight loss	1 (5.3)	2 (2.8)	3 (3.3)	1 (7.7)	2 (4.8)	3 (5.5)	0 (0.0)	0 (0.0)	0 (0.0)
Backaches	8 (42.1)	19 (26.4)	27 (29.7)	3 (23.1)	17 (40.5)	20 (36.4)	1 (11.1)	15 (46.9)	16 (39.0)
Headaches	8 (42.1)	21 (29.2)	29 (31.9)	3 (23.1)	14 (33.3)	17 (30.9)	3 (33.3)	10 (31.3)	13 (31.7)
Abdominal pain	7 (36.8)	27 (37.5)	34 (37.4)	4 (30.8)	20 (47.6)	24 (43.6)	3 (33.3)	14 (43.8)	17 (41.5)
Nausea/vomiting	6 (31.6)	12 (16.7)	18 (19.8)	2 (15.4)	4 (9.5)	6 (10.9)	2 (22.2)	5 (15.6)	7 (17.1)
Decreased libido	6 (31.6)	9 (12.5)	15 (16.5)	3 (23.1)	6 (14.3)	9 (16.4)	2 (22.2)	3 (9.4)	5 (12.2)
Soreness at injection site	3 (15.8)	12 (16.7)	15 (16.5)	2 (15.4)	7 (16.7)	9 (16.4)	1 (11.1)	4 (12.5)	5 (12.2)
Skin irritation at injection site	4 (21.1)	3 (4.2)	7 (7.7)	1 (7.7)	7 (16.7)	8 (14.5)	2 (22.2)	9 (28.1)	11 (26.8)
Pain at injection site	7 (36.8)	21 (29.2)	28 (30.8)	1 (7.7)	7 (16.7)	8 (14.5)	1 (11.1)	5 (15.6)	6 (14.6)
Other	4 (21.1)	15 (20.8)	19 (20.9)	3 (23.1)	4 (9.5)	7 (12.7)	3 (33.3)	5 (15.6)	8 (19.5)
How much did these side effects interfere with daily activities?									
Not at all	11 (57.9)	46 (63.9)	57 (62.6)	9 (69.2)	37 (88.1)	46 (83.6)	8 (88.9)	30 (93.8)	38 (92.7)
Very little	0 (0.0)	5 (6.9)	5 (5.5)	0 (0.0)	2 (4.8)	2 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Little	2 (10.5)	7 (9.7)	9 (9.9)	0 (0.0)	1 (2.4)	1 (1.8)	0 (0.0)	2 (6.3)	2 (4.9)
Moderate	1 (5.3)	4 (5.6)	5 (5.5)	1 (7.7)	1 (2.4)	2 (3.6)	0 (0.0)	0 (0.0)	0 (0.0)
Very much	5 (26.3)	9 (12.5)	14 (15.4)	3 (23.1)	1 (2.4)	4 (7.3)	1 (11.1)	0 (0.0)	1 (2.4)
Don't know	0 (0.0)	1 (1.4)	1 (1.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Abbreviations: CBP, clinic-based provider; CHW, community health worker; No., number.

Self-injectors were significantly less likely to discontinue DMPA-SC than those who received it from providers.

The results of the Cox model are presented in Table 5. Only treatment group and health facility catchment site were statistically significant predictors of continuation; therefore, no additional multivariable analyses were conducted. Consistent with the primary analysis reported elsewhere, we found that women in the self-injection group were significantly less likely to discontinue compared with women in the provider-administered group (hazard ratio, 0.43; $P<.001$). Risk for discontinuation was also different among clinics ($P<.001$).

DISCUSSION

Contraceptive continuation is important for reducing unintended pregnancies. This is one of the first studies to explore factors that affect continued use of DMPA-SC through 12 months,

TABLE 4. Experience With Side Effects in Last 3 Months Among Provider-Administered Participants, Stratified by Type of Provider at Enrollment, No.(%)

	3-Month Follow-Up			6-Month Follow-Up			9-Month Follow-Up		
	CBP	CHW	Overall	CBP	CHW	Overall	CBP	CHW	Overall
Experienced any side effects or problems over last 3 months?									
No	63 (65.6)	169 (68.7)	232 (67.8)	55 (77.5)	143 (78.1)	198 (78.0)	50 (84.7)	125 (81.2)	175 (82.2)
Yes	33 (34.4)	77 (31.3)	110 (32.2)	16 (22.5)	40 (21.9)	56 (22.0)	9 (15.3)	29 (18.8)	38 (17.8)
Type of side effects (among women reporting side effects)									
Irregular bleeding/spotting	7 (21.2)	20 (26.0)	27 (24.5)	1 (6.3)	4 (10.0)	5 (8.9)	1 (11.1)	6 (20.7)	7 (18.4)
Amenorrhea	12 (36.4)	20 (26.0)	32 (29.1)	8 (50.0)	14 (35.0)	22 (39.3)	4 (44.4)	10 (34.5)	14 (36.8)
Heavy bleeding	11 (33.3)	13 (16.9)	24 (21.8)	2 (12.5)	8 (20.0)	10 (17.9)	1 (11.1)	4 (13.8)	5 (13.2)
Weight gain	1 (3.0)	4 (5.2)	5 (4.5)	2 (12.5)	4 (10.0)	6 (10.7)	5 (55.6)	3 (10.3)	8 (21.1)
Weight loss	1 (3.0)	3 (3.9)	4 (3.6)	0 (0.0)	2 (5.0)	2 (3.6)	0 (0.0)	3 (10.3)	3 (7.9)
Backaches	11 (33.3)	22 (28.6)	33 (30.0)	5 (31.3)	16 (40.0)	21 (37.5)	3 (33.3)	14 (48.3)	17 (44.7)
Headaches	18 (54.5)	30 (39.0)	48 (43.6)	4 (25.0)	15 (37.5)	19 (33.9)	3 (33.3)	11 (37.9)	14 (36.8)
Abdominal pain	17 (51.5)	34 (44.2)	51 (46.4)	7 (43.8)	13 (32.5)	20 (35.7)	2 (22.2)	9 (31.0)	11 (28.9)
Nausea/vomiting	6 (18.2)	9 (11.7)	15 (13.6)	2 (12.5)	7 (17.5)	9 (16.1)	2 (22.2)	4 (13.8)	6 (15.8)
Decreased libido	5 (15.2)	10 (13.0)	15 (13.6)	5 (31.3)	4 (10.0)	9 (16.1)	4 (44.4)	7 (24.1)	11 (28.9)
Soreness at injection site	2 (6.1)	7 (9.1)	9 (8.2)	0 (0.0)	2 (5.0)	2 (3.6)	1 (11.1)	2 (6.9)	3 (7.9)
Skin irritation at injection site	2 (6.1)	6 (7.8)	8 (7.3)	0 (0.0)	4 (10.0)	4 (7.1)	0 (0.0)	1 (3.4)	1 (2.6)
Pain at injection site	6 (18.2)	16 (20.8)	22 (20.0)	3 (18.8)	8 (20.0)	11 (19.6)	0 (0.0)	3 (10.3)	3 (7.9)
Other	6 (18.2)	8 (10.4)	14 (12.7)	6 (37.5)	7 (17.5)	13 (23.2)	2 (22.2)	6 (20.7)	8 (21.1)
How much did these side effects interfere with daily activities?									
Not at all	19 (57.6)	52 (67.5)	71 (64.5)	11 (68.8)	31 (77.5)	42 (75.0)	8 (88.9)	22 (75.9)	30 (78.9)
Very little	4 (12.1)	9 (11.7)	13 (11.8)	1 (6.3)	4 (10.0)	5 (8.9)	0 (0.0)	2 (6.9)	2 (5.3)
Little	3 (9.1)	5 (6.5)	8 (7.3)	1 (6.3)	1 (2.5)	2 (3.6)	0 (0.0)	1 (3.4)	1 (2.6)
Moderate	3 (9.1)	4 (5.2)	7 (6.4)	0 (0.0)	4 (10.0)	4 (7.1)	0 (0.0)	2 (6.9)	2 (5.3)
Very much	4 (12.1)	7 (9.1)	11 (10.0)	3 (18.8)	0 (0.0)	3 (5.4)	1 (11.1)	2 (6.9)	3 (7.9)
Don't know	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Abbreviations: CBP, clinic-based provider; CHW, community health worker; No., number.

including self-administered DMPA-SC. A retrospective study of 2015–2016 Demographic and Health Survey data in Malawi found a 12-month discontinuation rate of 41% for injectable contraceptive users.[2] In this prospective trial, the discontinuation rates of DMPA-SC through 12 months were 52% and 56%, for clients who received the injections from CBPs and CHWs, respectively. The discontinuation rates for self-injecting clients trained by CBPs and CHWs were substantially lower, 21% and 30%, respectively. The differences in the continuation rates by provider type (CBPs and CHWs) were not statistically different for either self-administered or provider-administered DMPA-SC.

We did not find evidence that the type of provider influenced the risk of discontinuing, pregnancy, or safety, which suggests that CHWs—not only CBPs—can provide DMPA-SC or training on self-injection in low-resource settings without

TABLE 5. Baseline Factors That May Influence DMPA-SC Discontinuation (N=731)

Factor	Sample Size[a]	*P* Value	Hazard Ratio (95% CI)
Self-administered vs. provider-administered	364 vs. 367	<.001	0.43 (0.33, 0.54)
Age at enrollment	731	.18	0.98 (0.96, 1.01)
Health facility catchment site[a]	731	<.001	—
Site 1 vs. Site 6	293 vs. 146	—	2.01 (1.39, 2.89)
Site 2 vs. Site 6	67 vs. 146	—	1.78 (1.09, 2.91)
Site 3 vs. Site 6	90 vs. 146	—	1.75 (1.11, 2.74)
Site 4 vs. Site 6	75 vs. 146	—	2.90 (1.88, 4.47)
Site 5 vs. Site 6	60 vs. 146	—	1.18 (0.66, 2.09)
Married/regular sexual partner vs. none	705 vs. 25	.48	0.81 (0.45, 1.45)
Worked outside home for pay in last 12 months vs. not	96 vs. 634	.18	1.25 (0.90, 1.72)
Given birth vs. never given birth	725 vs. 5	.08	0.42 (0.15, 1.12)
Completed primary school or higher vs. less or no school	185 vs. 545	.27	0.86 (0.65, 1.13)
Christian, none, or other vs. Muslim	418 vs. 311	.10	1.24 (0.96, 1.61)
Previous use of contraceptives vs. none or no response	679 vs. 52	.11	0.72 (0.48, 1.08)
Previous use of injectables vs. none	657 vs. 68	.29	0.82 (0.56, 1.19)
Community health worker vs. clinic-based provider	526 vs. 205	.45	0.90 (0.68, 1.19)

Abbreviations: CI, confidence interval; DMPA-SC, subcutaneous depot medroxyprogesterone acetate; vs., versus.
[a] Sample size for each factor varied due to missing values.
[b] Except for site, the univariable models for all other factors were stratified by site.

Permitting CHWs to train women on DMPA-SC self-injection could increase access to contraception and alleviate the work load of other providers.

Education levels did not affect women's ability to self-inject.

hampering continuation. Wait times at health facilities are often long and health facilities are often overcrowded and understaffed. Permitting CHWs to train women on DMPA-SC self-injection in community settings would enable women to circumvent the long lines and alleviate some of the work load at these health facilities. CHWs are based in rural and low-income areas where there is often high unmet family planning need, and they are more likely to remain in their communities once trained.[33] In 2009, WHO concluded that CHWs can safely and effectively administer injectable contraceptives in non-clinical settings.[34] CHW provision of injectable contraception was once innovative but is now a standard of practice. Our results add to the body of evidence supporting task sharing and CHWs' potential to increase access to contraception and reduce unmet family planning needs, despite lower levels of training.[6] Based on the evidence, self-administered and provider-administrated DMPA-SC should be scaled up in community settings using CHWs.

Of the factors explored, treatment group and health facility catchment site were the only factors that significantly influenced the risk of discontinuation, with self-injection leading to a reduced risk of discontinuation compared with provider administration. Consistent with previous studies of DMPA-IM,[1,17,24,25] we did not find evidence that sociodemographic factors influenced DMPA-SC continuation. Importantly, we found that education levels did not affect women's ability to self-inject. Most women enrolled in the study had very little education and could inject on time and continue using DMPA-SC during the year-long trial.

Our findings are consistent with findings from nonrandomized prospective cohort studies in Senegal and Uganda, which observed that clients who self-injected DMPA-SC had a lower risk of discontinuing relative to clients who received DMPA-IM from CBPs.[29,35] However, our findings differed from these studies in that they observed several other variables—some that we included in our model and some we did not—that influenced DMPA continuation. In Uganda, rural location and being younger increased discontinuation risk, whereas having a primary or greater education (versus no education), more children, and

partner support for family planning increased continuation. In Senegal, paying for travel to the clinic and experiencing side effects increased discontinuation risk, whereas having more education, children, and household assets increased continuation. It may be that our site variable encompasses other underlying factors, such as rurality, which are not otherwise included in our model.

Our results are also similar to a study of provider-administered DMPA-SC in urban Nigeria that found no differences in continuation at 3 months according to the place women received DMPA-SC.[36] In that study, data were collected from a convenience sample of users who obtained DMPA-SC from selected private-sector providers working in hospital, clinics, and retail drug outlets, as well as licensed Community Health Extension Workers. Unlike our study, the Nigeria study found differences in sociodemographic characteristics: women with some college education or more and those with 4 or more children were more likely to obtain another dose at 3 months. They also found that quality of counseling and side effects influenced continuation.

One limitation of our study is that women's reported outcomes may have been influenced by social desirability bias. Another challenge we faced was missing data for the pregnancy outcome. Given this, our pregnancy data should not be used for estimating the DMPA-SC failure rate. The study was also not designed to assess whether women with different characteristics or being assisted by various types of providers had different risks of discontinuation; therefore, the sample size for some of the comparisons may be too small to be conclusive. Furthermore, these are non-randomized comparisons and may be affected by selection biases. Lastly, there are numerous other variables and combinations of variables that we did not explore but which may influence continuation.

Although we did not find any of the sociodemographic factors associated with DMPA-SC discontinuation to help us target future efforts, the differences observed across sites may indicate the presence of other underlying factors that would be interesting to explore in future studies. For example, providers' management of clients who would like to continue using injectables but arrived late for their scheduled reinjections (although still within the grace period) has been documented to vary and to directly affect clients' continued use of contraception.[37] Understanding the context and other characteristics of the populations served by these sites is important, but further exploration is not possible in our study due to our sample size and data contents. Despite the site differences, the positive effects of self-injection were present in all sites, which speaks of the robustness of this finding across contexts and further supports our recommendations for scaling up DMPA-SC. Implementation challenges will need to be addressed to make this recommendation possible, including resources and planning for training and advanced provision of commodities for self-administration; however, the introduction and scale-up of this new evidence-based approach addresses the severe shortage of family planning providers and the persistent problem of DMPA discontinuation. We urge WHO and the global health community to expand their endorsements of CHW provision of injectables to include CHW provision of DMPA-SC for self-injection.

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ORIGINAL ARTICLE

Scaling Up Misoprostol to Prevent Postpartum Hemorrhage at Home Births in Mozambique: A Case Study Applying the ExpandNet/WHO Framework

Karen Hobday,[a] Jennifer Hulme,[b] Ndola Prata,[c] Páscoa Zualo Wate,[d] Suzanne Belton,[a] Caroline Homer[e]

Facilitating factors for this community-level scale up in 35 districts included strong government support, local champions, and a national policy on preventing postpartum hemorrhage (PPH). Challenges included a lack of a systematic scale-up strategy, limited communication of the PPH policy, a shift from a universal distribution policy to application of eligibility criteria, difficulties engaging remote traditional birth attendants, and implementation of a parallel M&E system.

ABSTRACT

Background: Mozambique has a high maternal mortality ratio, and postpartum hemorrhage (PPH) is a leading cause of maternal deaths. In 2015, the Mozambican Ministry of Health (MOH) commenced a program to distribute misoprostol at the community level in selected districts as a strategy to reduce PPH. This case study uses the ExpandNet/World Health Organization (WHO) scale-up framework to examine the planning, management, and outcomes of the early expansion phase of the scale-up of misoprostol for the prevention of PPH in 2 provinces in Mozambique.

Methods: Qualitative semistructured interviews were conducted between February and October 2017 in 5 participating districts in 2 provinces. Participants included program stakeholders, health staff, community health workers (CHWs), and traditional birth attendants (TBAs). Interviews were analyzed using the ExpandNet/WHO framework alongside national policy and planning documents and notes from a 2017 national Ministry of Health maternal, newborn, and child health workshop. Outcomes were estimated using misoprostol coverage and access in 2017 for both provinces.

Results: The study revealed a number of barriers and facilitators to scale-up. Facilitators included a supportive political and legal environment; a clear, credible, and relevant innovation; early expansion into some Ministry of Health systems and a strong network of CHWs and TBAs. Barriers included a reduction in reach due to a shift from universal distribution to application of eligibility criteria; fear of misdirecting misoprostol for abortion or labor induction; limited communication and understanding of the national PPH prevention strategy; inadequate monitoring and evaluation; challenges with logistics systems; and the inability to engage remote TBAs. Lower coverage was found in Inhambane province than Nampula province, possibly due to NGO support and political champions.

Conclusion: This study identified the need for a formal review of the misoprostol program to identify adaptations and to develop a systematic scale-up strategy to guide national scale-up.

INTRODUCTION

Each day around the world, approximately 830 women die giving birth or due to complications during pregnancy, childbirth, and the following weeks.[1] Urgent investment in maternal, newborn, and child health (MNCH) programming is needed in order for countries to achieve Sustainable Development Goal (SDG) 3.1—reduce global maternal mortality to less than 70 per 100,000 live births by 2030.[2] Scale up of high-impact MNCH interventions that reduce maternal mortality and benefit entire populations is a growing public health and political priority.[3–6]

Postpartum hemorrhage (PPH) remains one of the leading causes of maternal mortality globally and the number one cause in sub-Saharan Africa.[7] Mozambique, located in Southern Africa, has a high maternal mortality ratio (MMR) of 489 per 100,000 live births.[8] PPH is one of the main causes of maternal deaths in Mozambique; estimates range from 30.7%[9] to 38.0% of maternal deaths.[10]

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The Ministry of Health (MOH) has prioritized the prevention of maternal mortality in its *Health Sector Strategic Plan 2014–2019*.[11]

Access to rural health services in Mozambique is limited by distance, lack of transportation, health facility coverage, and quality.[12,13] In 2013 there were 0.05 physicians and 0.40 nurses and midwives per 1,000 population.[14] This is significantly below the WHO standard for health worker density of 2.5 doctors, midwives, and nurses per 1,000 population.[15] With inadequate resources to train and retain health staff,[16] Mozambique experiences both brain drain and internal migration.[17]

Nationally, an estimated 30% of Mozambican women give birth at home without assistance from a skilled birth attendant.[18] Women who give birth at home often have support from a traditional birth attendant (TBA) or family member/friend. In Inhambane province, a reported 89.1% of women gave birth with a skilled birth attendant, 3.9% with a TBA, 6.6% with family/friends, and 0.4% alone in the 2 years preceding the 2015 Demographic and Health Survey. In Nampula province, 74.4% of women gave birth with a skilled birth attendant, 11.7% with a TBA, 13.2% with family/friends, and 0.7% alone.[18]

Oxytocin, an injectable uterotonic, is the first-line therapy to prevent and treat PPH and is available in the majority of health facilities across Mozambique.[19] However, oxytocin must be administered by a trained health worker as an injection and ideally stored in a refrigerator.[20] In many low-income contexts, misoprostol, a heat-stable tablet that can be used as an alternative uterotonic, can be administered orally by a community health worker (CHW) or the woman herself.[21] However, opponents of misoprostol for the prevention of PPH often fear that it will be used incorrectly or for abortion.

In 2014, the abortion laws in Mozambique were changed to permit women to have a safe abortion up to 12 weeks, up to 16 weeks in cases of rape or incest, and up to 24 weeks if there are fetal abnormalities.[22] As of 2018, women can access abortion in primary, secondary, and tertiary health facilities that have received training and resources to carry out the procedure.[23]

In 2009–2010, Bique et al. studied the use of misoprostol for the prevention of PPH in home births in Mozambique.[24] The pilot study was conducted in response to the MOH request for local research to establish the safety of using misoprostol in the community. Misoprostol was distributed in advance to pregnant women via MNCH staff during antenatal care visits and through direct administration to women from TBAs. Results revealed that TBAs and women themselves could safely and effectively administer misoprostol at home births. In 2011, the results of the pilot were presented to the Mozambique MOH, which subsequently approved the scale-up of the use of misoprostol for the prevention of PPH. For more information about the role of TBAs and CHWs in Mozambique, see Box 1.

Postpartum hemorrhage is one of the main causes of maternal deaths in Mozambique.

In 2015, the MOH launched the national *Strategy for the Prevention of Postpartum Hemorrhage at the Community Level* (referred to as the National PPH Strategy). The first objective of the strategy was the implementation of the misoprostol program, which included advance distribution of misoprostol to women during pregnancy and direct administration by TBAs to women who give birth in the community to reduce maternal mortality associated with PPH.[29] The National PPH Strategy included a 2-year general plan of activities with the intention that each province would develop a specific action plan for program implementation. The target was to roll out the misoprostol program in 35 districts in 10 provinces. The MOH opted for a stepwise approach, initially limiting implementation to 6 districts in 2 provinces—3 in Inhambane and 3 in Sofala. The intent was to learn from the experience of the first 6 districts before further expansion. The second phase of expansion took place in 2016–2017 in 29 districts across 8 provinces. By June 2017, the misoprostol program was being implemented in 35 districts. See Figure 1 for a timeline of events.

There is an urgent need for information about the process of scale-up of MNCH interventions that highlights the operational realities countries experience.[30,31] ExpandNet, in collaboration with the World Health Organization (WHO), defines scale-up, as the ". . . deliberate efforts to increase the impact of health service innovations successfully tested in pilot or experimental projects so as to benefit more people and to foster policy and programme development on a lasting basis."[32] We recognize that moving from pilot to early expansion and ultimately to population-level scale-up is a challenging and lengthy process.[3] The ExpandNet/WHO framework is a conceptual tool to guide the analysis of issues to consider in the development of a scale-up strategy or management of a scale-up process.[33] It serves as the basis for the tool entitled *Nine Steps for Developing a Scaling-Up Strategy*,[34] which assists stakeholders in developing a scale-up strategy and to manage the process. The ExpandNet/WHO framework has been used to analyze the complex processes of

BOX 1. The Role of TBAs and CHWs in Mozambique

TBAs play a supportive role for pregnant women, providing assistance during birth and the postpartum period. In Mozambique, TBAs are female and generally illiterate. They do not receive a salary, and they work with very few resources. For example, they do not receive clean birthing kits. The majority of Mozambican TBAs do not have formal training or certification in child birth practices or obstetric emergencies.[25,26]

The TBAs involved in the misoprostol program are affiliated with the participating health facilities. They receive a 3-day training on how to safely administer misoprostol to women after they give birth, distribute chlorhexidine, and recognize danger signs for referral and safe birth practices. The training emphasizes the role of TBAs in referring or accompanying women to the health facility to give birth. When a TBA is aware of an impending birth in the community, she requests a dose of misoprostol from the CHW in her catchment area. The TBA is responsible for safeguarding that dose until she attends the birth and administers it directly to the woman after she gives birth. TBAs and CHWs do not distribute misoprostol to pregnant women.

CHWs in Mozambique are referred to as *Agentes Polivelantes Elementares* (APEs) in Portuguese. The vast majority (85%) of APEs are men, mainly due to the prerequisite of primary school education and the need to undertake a 4- to 5-month training, often outside their community. The APE program is now actively working to improve gender equality by recruiting more women.[27] APEs receive a monthly salary of 1,200 meticals (approximately US$18 in 2018) and are expected to cover a catchment area of 8 to 25 km from the health facility with which they are affiliated.

Integrated community case management of malaria, pneumonia, and diarrhea is a key component of the work that CHWs undertake. The CHWs receive a small medical kit and have the authority to provide medicines, including antimalarials, amoxicillin, and zinc.[28] In 2016, 4 new products were added to their role: family planning including administration of injectable contraceptives, vitamin A, chlorhexidine, and distribution of misoprostol to TBAs.

scale-up in a variety of programs and contexts.[35–37] It addresses 5 main elements of scaling up: the innovation, environment, user organization, resource team, and 5 strategic choice areas for managing scale-up (Figure 2).[34]

This article uses the ExpandNet/WHO framework to retrospectively analyze the early phases of scale-up of the community distribution of misoprostol to prevent postpartum hemorrhage in Mozambique. The aim of this article is to present a case study that will inform MNCH stakeholders about the barriers and facilitators in the early expansion of the misoprostol program and offer recommendations to stakeholders, both within Mozambique and internationally, of the key components to bring programs to scale.

METHODS

We used a mixed-methods approach to assess the implementation of the early expansion phase of scaling up misoprostol in 2 provinces in Mozambique. The objectives of this study were to: (1) identify facilitators and barriers to the

FIGURE 1. The Evolution of the Distribution of Misoprostol for Prevention of Postpartum Hemorrhage in Mozambique

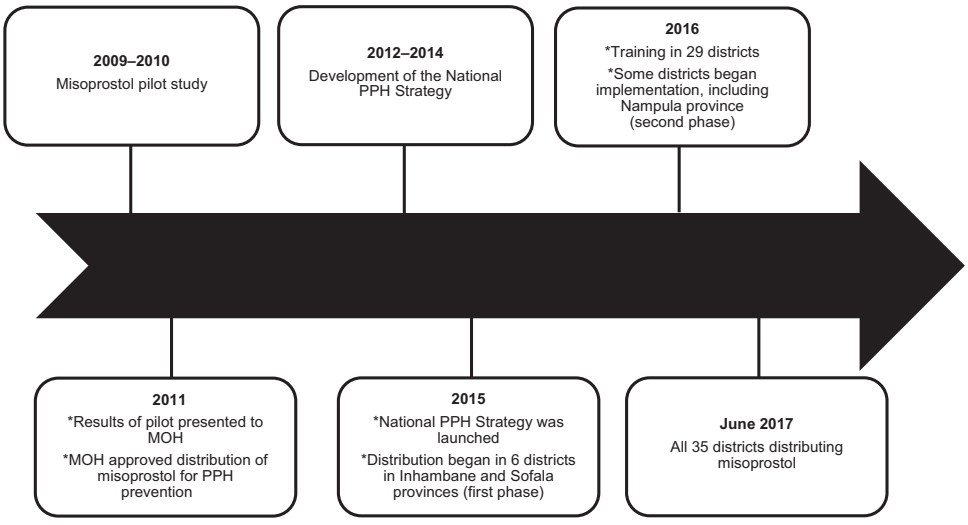
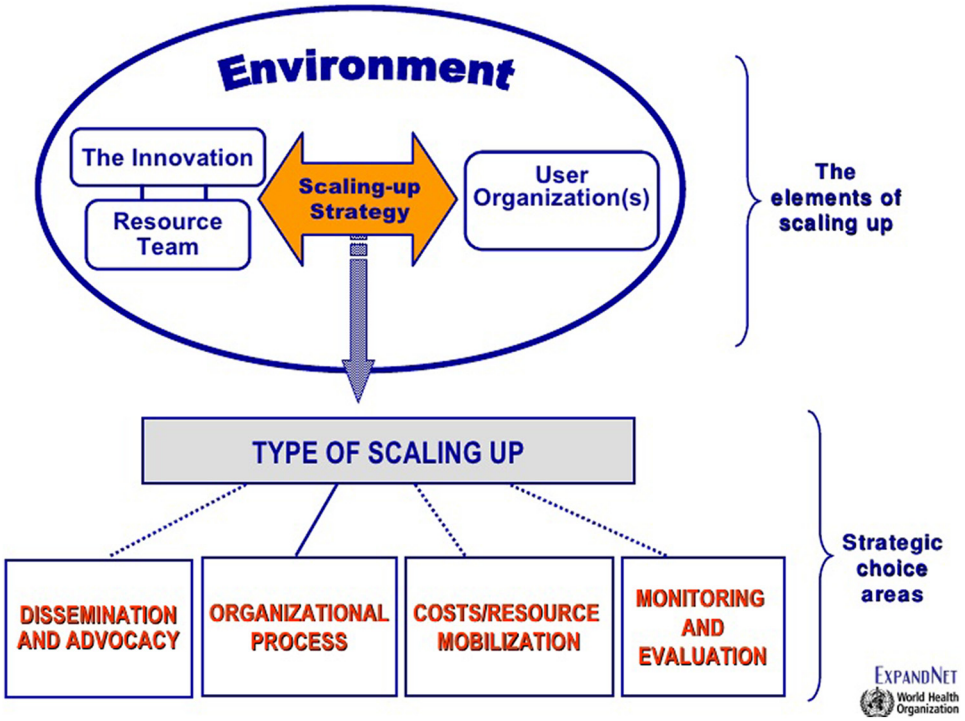


FIGURE 2. ExpandNet/World Health Organization Scale-Up Framework



early expansion of the misoprostol program for the prevention of PPH at the community level, and (2) examine coverage and use of misoprostol in the 2 provinces.

The qualitative component of the study applied a phenomenological approach to understand the experiences of those involved in Mozambique's misoprostol program. Phenomenology is an interpretive approach based on the lived experiences of people who participated in the phenomenon.[38] Data were collected between February and October 2017 in Maputo City and in 2 districts in Inhambane province and 3 districts in Nampula province. These provinces were chosen due to geographic region—Inhambane is located in the southern region, and Nampula in the northern region of the country. Inhambane province initiated implementation in 2015, whereas Nampula, one of the provinces selected during the second phase of expansion, commenced implementation in 2016. Districts were chosen based on inclusion in the misoprostol program, geographic accessibility, and discussions with provincial and district health authorities.

One-to-one, semistructured qualitative interviews were conducted with (1) MNCH national, provincial, and district stakeholders with experience working on the misoprostol program; (2) health staff (MNCH nurses and midwives, medical chiefs, hospital directors, pharmacists, and health technicians); and (3) CHWs (referred to as *Agentes Polivalentes Elementares* in Mozambique) and TBAs. In addition, focus group discussions were conducted separately with CHWs and TBAs. The ExpandNet/WHO framework and the document entitled *20 Questions for Developing a Scale-up Case Study*[30] were used to assist in the design of the interview guides for stakeholder and health staff interviews. Focus group discussion questions for CHWs and TBAs focused on the use and understanding of the medication and barriers and facilitators to the misoprostol program. The interview and focus group discussion guides were revised with input from the MOH and local research assistants to ensure questions could be understood in the local language and were relevant to the context.

Participants were recruited via purposive sampling based on advice from key stakeholders in the program and assistance from district health staff and CHWs. We applied the phenomenological approach and interviewed a relatively varied

sample of participants engaged in various aspects of the program. We sought to gain a range of experiences rather than selecting an established number of participants. We contacted 18 MNCH stakeholders via email or phone to arrange interviews. Interviews with 19 health staff were organized with assistance from district health authorities who called the health facility in advance. Fifteen of the stakeholders and all of the health staff contacted agreed to be interviewed.

CHWs and TBAs were selected with assistance from the district MNCH coordinator who contacted the CHWs and asked them to come to the health facility for the interview. Where possible, the research team would drive to meet the CHW or TBA at their home or in the community to conduct the interview. In total, we interviewed 15 CHWs and coordinators and 15 TBAs. Three CHWs and 4 TBAs who were contacted were not available to attend an interview due to prior commitments. Additionally, we conducted 4 FGDs with TBAs in Nampula province and 1 FGD with CHWs in each province. Interviews were conducted in English, Portuguese, and local languages where appropriate. The first and second authors conducted the stakeholder interviews. One international and 3 local research assistants trained in qualitative data collection methods and ethical protocols conducted interviews and focus group discussions at the health facility and in the field. Interviews were recorded with permission, transcribed and translated verbatim into Portuguese, and then translated to English. Participant numbers were determined based on obtaining thematic saturation.

National policy and planning documents were analyzed alongside notes and observations from a 2017 national MOH MNCH workshop, which included a review of the misoprostol program. Notes, policy documents, and qualitative interviews were coded and analyzed using NVivo 11 software.

Quantitative data were provided by the provincial health directors at a national MNCH workshop. These data were analyzed to estimate coverage of and access to misoprostol in Inhambane and Nampula provinces from January through September 2017. We present descriptive statistics in the results. The resulting indicators are not based on directly reported data, but primarily based on calculated, indirect data estimates leading to some imprecision.

Women received misoprostol either directly during an antenatal care visit or through TBAs who administered it to women after they gave birth at home.

We organized the data according to the ExpandNet/WHO framework's planning and management categories. Categories of the planning phase included: the environment, the innovation, the user organization, and the resource team. Management of scale-up was coded into the 5 strategic choice areas of the ExpandNet/WHO framework in the following categories: type of scale-up; dissemination and advocacy; organizational process; costs/mobilization of resources; and monitoring and evaluation. We also referenced the *20 Questions for Developing a Scale-Up Case Study*[30] in coding the transcripts into the planning and management categories. Results were further categorized as facilitators and barriers to scale up, or both. Finally, we included an additional category to report outcomes, including coverage and uptake, to assess progress of the expansion phase. Outcomes were coded into access, utilization, and logistics systems. We defined access as the number of women who delivered with a TBA and received the drug or who received it in advance during an antenatal care visit, as a proportion of the estimated number of expected home births in the catchment area. Utilization was defined as the number of women who used misoprostol (i.e., unreturned doses of misoprostol) as a proportion of the estimated number of expected home births in the catchment area.

Ethical clearance was obtained from the Human Research Ethics Committee at Charles Darwin University, Australia (HREC 2015–2445), the Mozambican National Bioethics Committee, and the MOH. All participants provided informed consent and none requested to be withdrawn from the study.

RESULTS

In total, we included in the analysis qualitative interviews with 15 stakeholders, 19 health staff, 15 CHWs and coordinators, and 15 TBAs; 6 focus group discussions; and a review of national policy and planning documents.

Planning the Scale-Up Strategy 2011–2014

The Innovation

In the ExpandNet/WHO framework, the innovation refers to "the health service interventions or other new practices that are being scaled up."[33] Here, the innovation was the distribution of 600 micrograms of oral misoprostol to pregnant women through 2 channels: (1) during antenatal care visits at 28 weeks or greater to women who meet the criteria for self-administration (Box 2), or (2) via TBAs who administer it to women

directly after they give birth at home. The aim of the innovation was to increase access to misoprostol for women who give birth in the community to reduce maternal mortality associated with PPH.

A woman who meets the eligibility criteria at her antenatal care visit receives information from the nurse regarding how and when to take misoprostol and a dose (3 pills in a blister pack) to safeguard until her labor. Distribution at the community level occurs between the TBA and the pregnant woman directly after the birth of the baby and before the placenta has been delivered. A CHW provides the TBA with the misoprostol. CHWs, who are salaried employees and have access to a bicycle, are the link between the health facility and TBAs. Upon request, the CHWs usually receive 3 doses (9 pills) of misoprostol, which they then distribute to the TBA(s) in their coverage area monthly (Figure 3).

Some challenges arose with the flow of distribution. In many cases, CHWs lived further from the facility than the selected TBAs. CHWs provided TBAs with the supply of misoprostol, but the CHWs themselves were not trained or permitted to distribute it to pregnant women. In some cases, CHWs lived too far from the TBAs, and they both suggested that the TBAs collect the misoprostol directly from the health facility during monthly TBA meetings. A health staff member from Inhambane province identified this as a major challenge, saying:

> *. . . the only constraint that we have had with the TBAs . . . is the fact that we do not give misol to them directly.*

This may have limited distribution of misoprostol and reach to remote areas.

During the initial pilot phase, the MOH shifted from a universal distribution strategy, as outlined in the National PPH Strategy, to application of eligibility criteria (Box 2). This shift was proposed by the MOH in response to the number of returned misoprostol doses by women who gave birth at a health facility and to increase controls on the amount of misoprostol in the community. The MNCH Sector Wide Approach (SWAp) Technical Working Group agreed to the implementation of the eligibility criteria in May 2015. The criteria were adopted to target distribution to women deemed most likely to have home births, limit unnecessary distribution, and improve controls on the availability of misoprostol in the community.

BOX 2. Eligibility Criteria for Misoprostol Distribution to Pregnant Women for the Prevention of Postpartum Hemorrhage

A pregnant woman must:

1. Be registered for antenatal care (i.e., have a prenatal health record on file where misoprostol will be registered)
2. Have reached 28 weeks gestation

She must additionally meet at least 1 of these criteria:

1. Have a history of giving birth at home/outside of the health facility
2. Live more than 8 km from a health facility
3. Be a grand multipara (more than 5 previous births)
4. Have a current or past history of multiple pregnancies
5. Have a history of postpartum hemorrhage

This shift impacted the amount of misoprostol required for the program; only 8% of the forecasted stock for universal distribution was needed. The criterion of distance from a facility was explicit (live >8 km from a health facility); however, interpretations of "far from the facility" varied widely among health staff. Some nurses and midwives felt that if a woman lived 10 or 15 km away they would not need misoprostol, as they "should be able to reach the facility" prior to or while in labor. Others defined "far" as 20–30 km from the health facility and thought that only then should women receive the medication. Some MNCH stakeholders and health staff based in the field applauded the additional controls, stating that misoprostol was 'flooding' the communities, which increased the risk for potentially using misoprostol for abortion. They also believed that too many doses were returned to the health facility, which produced issues for recordkeeping and disposal. Others criticized the criteria for limiting the number of women who received uterotonic coverage:

> *So if we want to prevent PPH it has to be covered universally, it cannot be how it is being done. . . . this strategy has to be reviewed as soon as possible, it must be universal distribution of misoprostol.* (Stakeholder, Maputo)

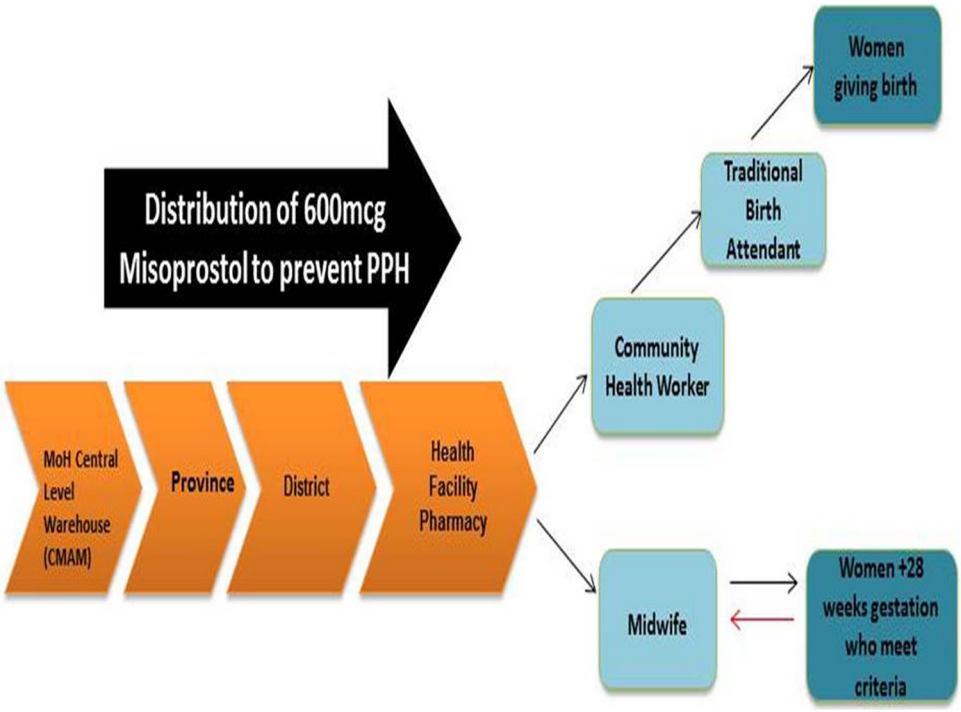
A number of stakeholders and health staff in the MOH national MNCH workshop in October 2017 proposed removing the restrictions to improve coverage.

CHWs provided TBAs with the supply of misoprostol, but the CHWs themselves were not trained or permitted to distribute it to pregnant women.

Environment

The environment consists of political, sociocultural, and economic factors that impact scale-up and can present opportunities or challenges to

FIGURE 3. The Innovation: Misoprostol Distribution Chain



expansion.[33] Several key environmental factors affected the planning and management phases of the misoprostol program, namely the country's financial situation, government support for the initiative, changes to the abortion law, limited capacity of the health system, and wavering support for TBAs.

The MOH branded misoprostol for postpartum hemorrhage prevention as 'misol' to differentiate it from misoprostol used for induction of labor or abortion.

The country's financial situation was an important environmental factor. In 2016, the Mozambican economy experienced a significant disruption with the revelation of US$1.4 billion in undisclosed debt. The International Monetary Fund halted credit to the country and many international donors, including bilateral governments, withdrew funding. Economic instability was cited as a key issue that could impact scalability of the misoprostol program. Fiscal spending became limited across all government institutions. Many health staff described low motivation with the lack of essential consumables, including gloves for births and vaginal examinations.

Financial constraints were tempered by strong government support for the program. The MOH prioritized the prevention of maternal mortality in the *National Health Sector Strategy 2014–2019*.[11] The distribution of misoprostol for the prevention of PPH at the health facility is the second objective listed in the strategy to help reduce the MMR. International evidence and advocacy efforts from the Association of Mozambican Obstetricians and Gynaecologists (AMOG) helped garner the support needed for the MOH to approve the expansion of the use of misoprostol across selected districts in Mozambique.

Changes to the abortion law in Mozambique may have positively influenced the political and legal settings in which misoprostol for PPH was introduced. The MOH branded misoprostol for the prevention of PPH as 'misol' to differentiate it between misoprostol used for induction of labor or abortion.

Some central and provincial stakeholders were very supportive of the changes to the legislation and the impact that they would have on improving maternal health. For example, a stakeholder from Maputo explained:

> *I think that PPH and safe abortion are very distinct matters. . . . And when we think that as a country we are limiting the access to misol because we don't want to give access to providers, to women, in case they can misuse this misol . . . I think we are just limiting access to life.*

However, other stakeholders feared that misoprostol could be misdirected for abortion or labor induction and wanted stricter controls:

> *We need to control the misoprostol because other people can use it for other purposes like abortions, and they also know about this use for misoprostol and so we think the district should distribute it to ensure the best control.* (Health Staff, Inhambane)

The environment also includes the capacity of the health system to deliver care and services that impact the success of the planned scale-up.[33] The limited number of qualified health staff in rural Mozambique resulted in health staff citing they had inadequate time to include distribution of misoprostol to their workload. Few additional resources were provided.

Varying support for working alongside TBAs also impacted planning for the scale-up of misoprostol. Historically, involvement of TBAs within the formal health sector has been limited in Mozambique.[39] An evaluation of TBA training in one province in 1999 found no impact on MNCH outcomes.[40] By the year 2000, the MOH shifted the focus on increasing skilled birth attendants to achieve Millennium Development Goal (MDG) 5.[39] This affected some stakeholders' acceptance of the role of TBAs in the misoprostol program, fearing it would detract from facility-based births:

> *Some TBAs charge people and promote these births to be held on her account so she can gain something.* (Stakeholder, Maputo)

Others in favor of TBA participation argued that the health system did not have the capacity to provide a skilled birth attendant for every woman due to a lack of sufficient transport and human resources:

> *That woman who lives 25–30 km from the health unit, she will go to prenatal consultation until the sixth, seventh month of pregnancy and then she will not go, and where will she have the baby? She'll go to the [traditional] midwife. In my opinion, it is not to say that the traditional midwife should not help women to give birth, my opinion is to enable the traditional midwife to make a clean birth.* (Stakeholder, Nampula)

These political, sociocultural, and economic factors were all essential components that influenced the planning and management of the misoprostol program.

The User Organization

The user organization in the ExpandNet/WHO framework is defined as the institution(s) and/or organization(s) that are expected to adopt and implement the innovation at scale.[33] The user organization in this case study is the Mozambican MOH, specifically the MOH Department of Women's and Child Health, which leads the implementation of the National PPH Strategy and coordinates monitoring and evaluation (M&E) of the program. Initially, AMOG was selected as the intended user organization to support the MOH to implement the misoprostol program due to their experience in the pilot phase. Later, the MOH deemed they were better suited as the sole user organization given their established infrastructure and staff. The national MOH's leadership role greatly facilitated the expansion of the scale-up as they added to the innovation's credibility and acceptability. However, a number of key national MOH staff members changed positions, and advisors seconded to the ministry moved on. This turnover resulted in delays in finalizing the national PPH strategy and program initiation.

Misoprostol is distributed using the routine supply chain for MNCH commodities, with the addition of CHWs as the distributors between the health facility and the TBAs. In Inhambane province, the supply chain experienced weaknesses in distribution between provincial to district warehouses. Misoprostol stock was procured 1 year prior to the official launch of the program and, as a result, the remaining shelf life of the initial supply was shortened by 1 year. (Misoprostol is a somewhat unstable compound that can degrade quickly when exposed to humidity; it is therefore labeled with a shorter shelf life than most other drugs.)

Provincial MNCH coordinators were requested to lead the misoprostol program with support from the provincial CHW coordinator. Program execution varied widely depending on the leadership of the MNCH coordinators at the district level in each of the 35 implementing districts. Some MNCH coordinators stated that they felt strongly that misoprostol was a lifesaving medication and were committed to the misoprostol program. For example:

> *I think it will help a lot as we are in the district, yes deliveries outside the maternity are reducing, for sure, but they continue to occur. This [misoprostol program] is a great asset for us to avoid maternal deaths in the community due to postpartum hemorrhage.* (Health Staff, Inhambane)

Other MNCH coordinators were not very supportive and believed it was not "their program" and instead allocated responsibility to the implementing health facilities.

MNCH nurses were directly responsible for the distribution of misoprostol in advance to pregnant women during antenatal care visits. Some were discouraged by the additional workload associated with the program (e.g., having to ensure the woman met the eligibility criteria, explaining how to use misoprostol and about possible side effects, and recording the information in the register). Several MNCH nurses believed the program was a pilot, especially in Inhambane province where they had experienced multiple hiccups in the supply chain. This negatively impacted their motivation to distribute misoprostol during antenatal care visits or monitor the program. Yet quantitative results revealed that over 80% of all misoprostol distributed was distributed to women in advance during antenatal care visits.

CHWs and TBAs were recruited in coordination with the CHW program and the MNCH department. TBAs were recommended either by the health facility or the CHWs. As a result, recruited TBAs often lived close to the health facility. This was also identified as a key factor in the low coverage experienced in some districts:

> *To map all TBAs was very difficult for the health facility and even at the district level. So we said to the MNCH nurses, "Please select first the ones that are reporting to you and then identify some that the CHWs recognize . . ." Those were the 2 inclusion criteria that we used. We didn't use distance because it was very difficult. . . . I don't know if we are reaching the TBAs that are really far away.* (Stakeholder, Maputo)

The Resource Team

In the planning phase, key members of the resource team included the MOH, AMOG, the United States Agency for International Development (USAID), WHO, Jhpiego's Maternal and Child Health Integrated Program (MCHIP), and the United Nations Population Fund (UNFPA). The latter 2 organizations also provided technical support to the program but were not direct implementers. Jhpiego's Maternal and Child Survival Project (MCSP), which followed from MCHIP, provided essential technical support to the program in Nampula and Sofala provinces. AMOG was involved in the development and implementation of the pilot, along with the NGO Venture Strategies Innovation. Using the evidence from the pilot study, AMOG played a critical role in advocating the need to scale up misoprostol.[41] UNFPA was responsible for the procurement of stock. The resource team worked together to develop the national PPH strategy.

Mozambique's national PPH strategy outlines a horizontal scale-up strategy, focusing first on 35 districts in 10 provinces.

The resource team members also participate in the MNCH SWAp Technical Working Group. This group has made some critical decisions surrounding the misoprostol program, including the adoption of eligibility criteria for distribution of misoprostol during antenatal care visits. The group reportedly met regularly in 2015 and 2016; however, one informant revealed that the SWAp had not met during the first 10 months of 2017 due to changes in central government staff. The resource team's input and updates regarding progress on the misoprostol program was limited during this period.

Management of the Scale-Up

Management of the scale-up was categorized as: type of scale-up; dissemination and advocacy; organizational process; costs/resource mobilization; and monitoring and evaluation.

Type of Scale-Up

The scaling-up strategy refers to the plans and actions taken to establish the innovation in policies and programs.[33] The ExpandNet/WHO framework describes 4 types of scale-up: spontaneous, diversification, horizontal (expansion or replication), and vertical (or institutional).[33] The resource team approached the scale-up of misoprostol through horizontal scale-up via stepwise expansion and also to some extent vertical scale-up through national policy and steps toward institutionalization.

Horizontal scale-up or expansion occurs when innovations are replicated in different geographic locations or are extended to serve larger or new populations. The innovation should be adapted to the new context in the additional location(s). Vertical scale-up occurs when governments reach a formal agreement to adopt the innovation nationally or sub-nationally, the adoption is institutionalized through national planning, policy, or legal processes, and it is implemented nationally or sub-nationally, including maintaining provisions to ensure ongoing effective delivery. Dimensions from both horizontal and vertical scale-up need to be incorporated for an innovation to be sustainable.[33]

The National PPH Strategy outlines a horizontal scale-up strategy, or the expansion of the innovation across different geographical locations to reach a larger population[33]; the expansion of misoprostol focused on 35 districts in the 10 provinces of Mozambique. Districts were chosen based on the following criteria: high incidence of home

births; reasonable access to health facilities for women who have obstetric complications; existence of maternal waiting homes; population density; and the existence of CHWs and TBAs who work with the health facility.[29] In April 2015, the program was initiated in 6 districts in Sofala and Inhambane provinces. The rationale was to allow adequate time for feedback and evaluation before expanding to the remaining 29 districts. District-level stakeholders and health staff identified a number of drawbacks to this strategy, namely, that implementing in 5 districts per province contributed to confusion about whether this was a pilot project and to a lack of trained health staff, as staff are mobile and regularly rotate between implementing and non-implementing districts.

In June 2016, results from Sofala and Inhambane were presented at the MNCH SWAp Technical Working Group meeting in Maputo. Progress in Sofala was limited to 1 district due to conflict that impacted both implementation and M&E. In September 2016, the MOH prioritized trainings to take place in the remaining 29 districts. By June 2017, all 35 districts had commenced distribution of misoprostol (Figure 2).

Vertical scale-up began simultaneously to horizontal expansion via the development of the National PPH Strategy and the beginning of institutionalization into MOH systems, albeit in selected districts. The National PPH Strategy outlined the commitment to incorporating the program into routine MOH systems[29] (p. 19):

> *As PPH is a major cause of maternal death, prevention interventions are part of the larger Ministry of Health plan to reduce maternal mortality involving several National Directorates, Departments and Partners. Thus, during the implementation of the first phase of this strategy, every effort will be made to ensure that interventions and their resource needs are integrated into existing management, funding, coordination and service delivery mechanisms.*

The misoprostol program has yet to be institutionalized. In the early expansion phase, training was delivered to selected MOH staff in the selected districts; UNFPA procured medication and distributed it through the routine MOH supply chain; and M&E was developed parallel to the national health information system.

Dissemination and Advocacy

Dissemination involves methods to promote, communicate, and encourage uptake of the innovation by the user organization.[33] In Mozambique, this included the dissemination of the National PPH Strategy, communication to provincial health staff, and cascade training of health staff and CHWs.

The National PPH Strategy was disseminated from the central to provincial level. The provincial health authorities were responsible for distributing the National PPH Strategy and informing the districts about the program. Memos about the program, particularly around stock, were sent from the central MOH to the provincial health authorities. Communication about the national PPH strategy was a challenge from the beginning, particularly between provincial and district levels but also from the district health offices to the health facilities. Weak flow of information was attributed to insufficient time to disseminate the strategy and induct health staff.

In April 2015, the MOH began training MNCH nurses, CHWs, and TBAs on the distribution of misoprostol for PPH prevention and safe delivery methods. The initial trainings took place in 3 districts in Inhambane and 3 districts in Sofala provinces in 2015. Cadres in Nampula province underwent training for 3 days in August 2016, and distribution of misoprostol commenced in 5 districts in September 2016. In total, the resource team trained 36 master trainers, 548 provincial trainers, and 1,050 CHW supervisors at the health facility level.[42] Four of the MNCH nurses interviewed were not formally trained in the program as they were not working in the district during the training phase.

In Inhambane significantly more CHWs than TBAs were trained (337 CHWs vs. 47 TBAs), whereas in Nampula a significant number of TBAs were trained (189 CHWs and 980 TBAs). Staff mobility meant that some MNCH staff were not aware of the program or their role. For example:

> *We trained the traditional midwives and a nurse from each health unit. We know that there is always movement of the nurses, some nurses do not even know what happened to the misol . . . if we want to have good results we need to involve all members of the maternal health team, regardless of being in the maternity or prenatal consultation.* (Health Staff, Nampula)

While nurses and midwives were generally supportive of the program some hesitated to distribute misoprostol without formal training.

National-level advocacy played an important role in the decision to scale-up the innovation due to divisions among stakeholders about initiating the misoprostol program. The main hesitations were fears that misoprostol would potentially

detract from facility-based births and/or would be used for abortion. The MNCH SWAp group reviewed global studies and the MOH requested that a pilot be conducted in Mozambique to assess whether misoprostol could be distributed safely during antenatal care visits and by TBAs.[24] This review, alongside the results of the Mozambican pilot and meetings with AMOG and other MNCH stakeholders about the benefits of misoprostol, eased fears about controlling the medication in the community. After discussions, the MOH agreed to allow the distribution of misoprostol for the prevention of PPH at the community level.

Organizational Process

Organizing the process of scale-up involves those responsible for decision making and implementation.[33] In the case of Mozambique, the central MOH was the critical decision maker and communication about the misoprostol program came from the central to the provincial health authorities. The provincial health authorities were then expected to implement the program in partnership with the district health authorities and health staff. Central-level government involvement was a key facilitator for the initial phase of introducing misoprostol into some parts of the health system. However, coordination and communication between the levels was a barrier. In speaking about the barriers of managing the system, a stakeholder from Maputo revealed:

The misoprostol M&E system was developed in parallel to the national health information system.

> *When you had misol at the provincial warehouse then it was difficult sometimes to get the misol to the district warehouse. So we had this challenge at the time - people, values, managing the system; all this was challenging to improve the system for misol to flow.*

The organizational process was also marked by gradual scale-up starting with only 6 districts in 1 year. Given the delays initiating the program, rapid rollout in the remaining 29 districts occurred over just 6 months in response to pressure from the national MOH to implement in all of the selected 35 districts. This limited time for monitoring and lessons learned to be considered.

Costs/Resource Mobilization

A budget of US$2.6 million was outlined in the National PPH Strategy for the first 2 years of the program.[29] The MOH budget covered the fixed operational and human resources costs for ongoing delivery of services. Short external donor grants were the main source of upfront program funding. Partners within the resource team provided some financial resources to initiate the rollout. Originally, USAID planned to provide both technical support and funding to procure misoprostol. However, they raised concerns surrounding the supervision and controls of the medication at the community level and requested further measures to ensure that it would not be misdirected and used for abortion in the community. This led to several months of delays. UNFPA then agreed to procure misoprostol and became the major donor, funding both the procurement and training components. Other partners, including Jhpiego, provided funding for training in 2 provinces where they supported MNCH projects.

In 2015, Jhpiego's MSCP project also provided a 1-year grant to AMOG to provide technical support including supervision. In early 2017, the initial grant from UNFPA expired and the program continued on a limited budget. UNFPA received funding from the UK Department for International Development (DFID) for 2018–2020 to continue support for the program. However, limited funds were allocated to the program outside of those for procurement, training, and the production of communication materials. The lack of available funding was cited as a major barrier to ensuring the program's sustainability, ongoing supervision, and evaluation.

Monitoring and Evaluation

The misoprostol M&E system was developed in parallel to both the national MNCH and CHW databases and separate to the national health information system. Data collection on misoprostol indicators represented additional tasks for the district MNCH nurses, who, without a clear system, were documenting returned doses of misoprostol by writing data on a separate paper or creating new columns in the prenatal registers. As a result, health staff at every level were concerned about the validity of monthly data collation:

> *Sometimes we send a message, 'Colleague tell me there, when and how many pills you distributed and to the CHW too,' she [MNCH nurse] will give you that information. Then you add it and you feel that there is some number missing but you cannot confirm why because you do not have a concrete instrument for evaluating the information.* (Stakeholder, Provincial Level)

Furthermore, no additional funding was provided at the provincial or district level to undertake supervision visits. Between 2015 and 2017, the MNCH staff alongside partners, including UNFPA, Jhpiego, and AMOG, conducted several

isolated supervision visits, the findings of which were not widely disseminated. Some provincial MNCH coordinators were able to monitor alongside supervisory visits to other programs, but overall they felt that time spent was insufficient. Similarly, some district MNCH coordinators felt that they did not have the budget, time, or mandate to supervise the program. In other cases, district MNCH nurses were very involved in the program. Many stakeholders in Maputo and at the provincial level felt that the lack of M&E was a major barrier for the sustainability of the program.

Outcomes

Access and Utilization

Program data, collated by the provincial MNCH coordinators for the MOH MNCH workshop held in Maputo in October 2017, were used to estimate access to and utilization of misoprostol for the first 9 months of 2017 (Table 1). Weaknesses in the M&E system may have resulted in discrepancies in both numerators and denominators.

There was large variation in overall access and utilization between districts and the 2 provinces. Access to misoprostol in Nampula exceeded Inhambane province by 17%, and utilization was much greater in Nampula (91%) than in Inhambane (23%). Two districts in Nampula reported over 100% coverage of misoprostol of women who gave birth at home. Coverage is a combined measure of both access and utilization of misoprostol (Table 1).

In Inhambane, we found a number of possible reasons for low coverage. Health staff restricted access to misoprostol justified by using the eligibility criteria. There were also frequent stock-outs. TBAs and health staff reported that their priority was to ensure women gave birth at the health facility. Therefore, TBAs said they administered misoprostol only to women who had "surprise" births at home or who had "birthed along the way" to the health facility, as they indicated they always encouraged women to give birth at a health facility.

In Nampula, higher coverage than Inhambane may be in part attributable to the institutional memory of the 2009–2010 pilot study: health staff and CHWs had previous training and were familiar with and supportive of the program. Distribution in Nampula started almost 1 year after Inhambane, such that we may have captured a period of initial high motivation. Political champions for misoprostol in Nampula province may also have positively impacted MNCH health staff attitudes and willingness to implement the program. There were significantly more TBAs trained and involved in the program than Inhambane (980 vs. 47, respectively). Further, the program in Nampula benefited from technical support from Jhpiego's MSCP program. See Table 2 for a comparison of inputs.

Table 3 reveals that from January through October 2017, MNCH nurses in Nampula distributed significantly more misoprostol during antenatal care visits than in Inhambane (13,602 doses vs. 989, respectively). In both provinces, the majority of misoprostol was distributed during antenatal care visits rather than by TBAs. In Inhambane, 194 doses provided to the CHWs were not accounted for (not provided to the TBA nor returned to the antenatal care clinic). No data were available provincially for misoprostol returns from CHWs or TBAs in Nampula, although we found individual health centers recording returns.

The majority of misoprostol was distributed during antenatal care visits rather than by TBAs.

Logistics System

The initial quantity of misoprostol distributed from the central to the provincial level was based on the projection for 100% coverage of home deliveries in the chosen districts. The introduction of eligibility criteria in 2015 reduced the number of eligible women. This led to an excess of misoprostol available at all levels. Much of this stock was never distributed, resulting in the expiry and subsequent incineration of the first wave of commodities.

Access to and utilization of misoprostol varied widely between districts and between the 2 provinces.

As of October 2017, in Inhambane 87% of misoprostol stock was available at the provincial warehouse, but only 13% had been distributed to the district or health facility level. In contrast, in Nampula, almost all of the stock (99%) was distributed to the district health facilities. Informants in Inhambane stated that this was due in part to lack of leadership from some district medical chiefs to request adequate misoprostol stock, as well as hesitation by pharmacists to fill requisitions. Further inquiry suggested that pharmacists and some medical chiefs were hesitant to distribute what was previously a medication with the highest restrictions into the community and feared it would be used for abortion. One health staff said the medication was kept "locked under 7 doors" due to concerns about the controls in the community and the maternity units. Some informants felt that this was one of the largest barriers to reaching high coverage. Notably, pharmacists were not included in the dissemination of the National PPH Strategy.

TABLE 1. Estimated Access to and Utilization of Misoprostol to Prevent Postpartum Hemorrhage in Inhambane and Nampula Provinces, Mozambique, January–September 2017

	A	B	C	D	E	F	G	H	I	J	K
Location	Misoprostol Distributed Through ANC and TBAs	Misoprostol Distributed Minus Returned	District Population (2017)	Annual Births in District (2017)[a]	Proportion of Health Facilities Enrolled in Misoprostol Program	Annual Births in Misoprostol Areas[b]	Births in Misoprostol Areas (First 9 Months of 2017)[c]	Home Births in Misoprostol Areas (First 9 Months of 2017)[d]	Access to Misoprostol at Home Births[e]	Utilization of Misoprostol at Home Births[f]	Interpretation
Inhambane Province											
Zavala	616	243	163,620	7,363	38%	2,798	2,098	630	98%	39%	Excellent access, poor utilization
Homoine	417	45	131,680	5,926	46%	2,726	2,044	613	68%	7%	Fair access, very poor utilization
Total both districts	1,033	288	295,300	13,289	42%	5,581	4,143	1243	83%	23%	Good access, poor utilization
Nampula Province											
Mecuburi	1,464	840	189,880	8,545	43%	3,674	2,756	827	100%[g]	100%[g]	Excellent access and utilization
Erati	2,568	2,034	322,737	14,523	54%	7,842	5,882	1,765	100%[g]	100%[g]	Excellent access and utilization
Monapo	1,357	1,039	389,902	17,546	43%	7,545	5,659	1,698	80%	61%	Good access, fair utilization
Total 3 districts	5,389	3,913	902,519	40,613	47%	19,088	14,296	4,289	100%[g]	91%	Excellent access and utilization

[a] Column C * 4.5%.
[b] Column E * Column D. The calculation uses a fixed number of residents and assumes population figures are similar across the country, leading to imprecision in the calculation of access and utilization indicators.
[c] Column D * 0.75.
[d] Column G * 0.30.
[e] Column A/Column H.
[f] Column B/Column H.
[g] In Mecuburi, access was 100% with 637 remaining doses and 13 additional doses utilized; Erati had 100% access with 803 remaining doses and 269 additional doses utilized. In total, there were 1,440 remaining doses in all 3 districts of Nampula.

Lack of availability of the commodity at district level was a key reason for low coverage in Inhambane. From September 2016 through June 2017, misoprostol stock was rationed in Inhambane with only 5–10 doses distributed per participating health facility. One district pharmacist reported requesting 1,000 doses and received only 30 doses. Records revealed that other districts requested very small amounts—30 or 60 pills at a time (sufficient for 10–20 women).

At the time of publication, the MOH had not yet set a timeline to achieve national scale-up. Between 2018 and 2020, the MOH will continue to focus on strengthening the program in the existing 35 districts and improving M&E mechanisms before further expansion.

DISCUSSION

Our analysis of factors that facilitated scale up of use of misoprostol to prevent postpartum hemorrhage (Table 4) suggest that the political environment was critical in allowing adoption of the innovation, benefiting from a high level of national political support, particularly as reduction of maternal mortality is the first indicator in the *Mozambique Health Sector Strategic Plan 2014–2019*. The misoprostol program was central to the National PPH Strategy and facilitated by national leadership, allowing for inclusion into some of the MOH infrastructure, systems, and human resources.

While the MOH led the program planning and implementation process, misoprostol is being used

TABLE 2. Program Inputs Provided in Inhamabane vs. Nampula Provinces, Mozambique

Inputs	Inhambane	Nampula
Supervision	• Ad hoc supervision from health staff when time/resources permitted	• Routine supervision from Jhpiego MCSP staff • Some initial supervision visits from AMOG (funded by MCSP)
Personnel	• Health staff strongly believed the misoprostol program was a pilot project as it was only in selected districts in the province • Strictly implemented eligibility criteria • Significantly less misoprostol distributed at ANC (989 doses) than Nampula • Fear of misuse limited distribution	• Greater sense of support from health staff as many were aware of the 2009–2010 pilot and appreciated the potential misoprostol has to reduce PPH and MMR • Less sense of a need to limit women due to criteria • Significantly more distributed at ANC (13,602 doses) than Inhambane
Champions	• Lack of clear champion; MNCH leaders supportive yet constrained by lack of resources	• Provincial and district MNCH leaders showed very strong support for the program and encouraged implementation
Training	• Funded by UNFPA; led by trained MOH master trainers, with UNFPA technical support • Training imbalanced; targeted more CHWs (337) than TBAs (47)	• Funded by Jhpiego's MCSP program; led by AMOG and MOH with MCSP technical support • Provided significantly more TBAs with training (980), providing greater community coverage
Logistics	• Challenges distributing stock from province to districts; as of October 2017, 87% of misoprostol stock remained in provincial warehouse	• Fewer challenges distributing stock from province to districts; only 1% of stock remained in provincial warehouse as of October 2017
Monitoring and evaluation	• Parallel system; not integrated in the national health information system	• Parallel system; not integrated in the national health information system • MCSP provided technical support to develop M&E tools but they were not adopted at the national level • No data available provincially on misoprostol returns from CHWs/TBAs

Abbreviations: AMOG, Association of Mozambican Obstetricians and Gynaecologists; ANC, antenatal care; CHW, community health worker; MCSP, Maternal and Child Survival Project; M&E, monitoring and evaluation; MMR, maternal mortality ratio; MNCH, maternal, newborn, and child health; MOH, Ministry of Health; PPH, postpartum haemorrhage; TBA, traditional birth attendant; UNFPA, United Nations Population Fund.

for the prevention of postpartum hemorrhage only within selected districts and has yet to be incorporated into routine MOH systems. The inputs outlined in Table 2 suggest that Jhpiego's MCSP program may have been a factor in Nampula's success at achieving greater coverage, particularly surrounding supervision and dissemination of information via communication materials. Institutionalization into the existing government priorities and health system is a critical factor to ensure the program is supported nationally.[43] Until misoprostol is fully integrated into the national health system and long-term funding is secured, it may continue to be viewed as a vertical project.

AMOG and partners employed a successful advocacy strategy to encourage the MOH and MNCH SWAp members of the potential high impact misoprostol had on improving incidence of PPH. The innovation was equally supported by international evidence and positive results from the local pilot study.

The program benefited from the strong existing network of CHWs and TBAs who provided the local capacity for implementation and credibility. However, very few TBAs received misoprostol for direct distribution (Table 3) compared with the supply that was provided to the CHWs. This reveals that there was a weakness in distribution between CHWs and TBAs in both provinces, which coincides with qualitative interviews that found some TBAs were having challenges receiving misoprostol from CHWs. Furthermore, in Inhambane significantly more CHWs were trained versus TBAs, whereas the opposite occurred in Nampula. This may have been due to the number of TBAs available and willing to participate in the misoprostol program.

Weaknesses in distribution of misoprostol between CHWs and TBAs existed in both provinces.

We provide a number of recommendations for the MOH and resource team based on the lessons

TABLE 3. Distributed and Returned Misoprostol by Cadre, January–October 2017

Province	Total Distributed at ANC	Total Distributed by CHWs	Total Distributed by TBAs	% of Total Distributed to CHWs Reaching TBAs[a]	% of Total Distributed at ANC via TBAs[b]	Returned to ANC	Returned to ANC by CHW or TBA
Inhambane (Homoine, Zavala districts)	989	325	44	14%	4.4%	201	87
Nampula (Mecurburi, Erati, Monapo districts)	13,602	5,578	900	16%	6.6%	1662	Unknown

Abbreviations: ANC, antenatal care; CHW, community health worker; TBA, traditional birth attendant.
[a] Total distributed by TBAs divided by total distributed by CHWs * 100.
[b] Total distributed by TBAs divided by total distributed at ANC * 100.

learned in the expansion phase (Box 3). There is clearly a need to allow flexibility in who can distribute misoprostol. In areas that do not have TBAs, CHWs could potentially distribute misoprostol in advance to women in addition to advance distribution at antenatal care visits. A number of studies in Ethiopia, Ghana, Nepal, Nigeria, and Rwanda have shown that CHWs can correctly and effectively distribute misoprostol to women.[44–46] TBAs emphasized their role in supporting women to give birth at the health facility. While positive, this may also have implications for detracting from safe delivery for women who are encouraged by TBAs to walk for kilometers in labor to attempt to reach the health facility and instead give birth on the side of the road, in transit. This finding was reported and discussed in more detail in a related article.[47]

Overall, the innovation was well-defined, credible, and adapted to the context. However, the introduction of restrictive eligibility criteria further complicated the distribution, limiting which women were targeted. The distance criteria was particularly contested by stakeholders and corroborated by health staff who made arbitrary decisions about who could or could not feasibly walk to the health facility while in labor. Applying eligibility criteria placed emphasis on facility-based birth instead of increasing uterotonic coverage. Due to the difficulty in assessing who is likely to experience PPH, misoprostol is often implemented as a population-based universal prevention method.[46,48–50] We recommend revising the eligibility criteria to increase the number of women targeted to receive misoprostol in advance at antenatal care visits.

Four of the nurses and midwives interviewed had not received training in the misoprostol program, limiting their involvement and impact. Fewer than half of all TBAs have been trained on the use of misoprostol and distance was not considered in recruitment. As a result, many women who give birth at home are not receiving misoprostol via their TBA. Both of these factors may have contributed to reduced coverage. We recommend future expansion plans consider implementation of the misoprostol program within all health facilities in the selected districts and/or province and training all health staff including pharmacists, CHWs, and TBAs to avoid these gaps in program implementation.

The budget for the misoprostol program was not fully funded by the government and depended on external funding. Funding is an essential component of catalyzing and sustaining scale-up, and the nature of short-term donor grants can impede a government's capacity to achieve national scale-up.[31] While some organizations assisted with the costs of training and provided technical support, the government and partners did not commit sufficient resources for adequate M&E. We recommend the resource team provide funding for supervision as well as technical support to introduce the misoprostol indicators within the national health information system to improve efficiency and remove the existing parallel data collection system. M&E is an element for successful scale-up as outlined in the ExpandNet/WHO framework and other scale-up literature.[31,51]

The study revealed disparity between the coverage and access of misoprostol for PPH prevention in Inhambane and Nampula provinces. A number of factors may have resulted in inflated numerators. Some CHWs may have maintained their supplies that had yet to be distributed to TBAs or returned to the health facilities. One

supervisor found duplication, where both a TBA and her client had received misoprostol. Given our finding that there was no space in the MNCH registers for returned misoprostol (Table 1, Column B), returned pills may not have been recorded. We found no evidence of diversion in this study. Denominators using the estimate of 4.5% of women of reproductive age also likely underestimate the population, given the high fertility rate in misoprostol target areas.

In 2017, Inhambane reported good access (83% of expected users received misoprostol) yet limited utilization (23% of women who received misoprostol used it). Limited utilization may have been due to the emphasis on facility births in the province resulting in women coming to the health facility to give birth, or perhaps due to limited communication to the community surrounding the purpose of misoprostol. The barriers presented in Table 4 may have impacted the outcomes, specifically the strict application of the criteria; retention of trained staff; limited availability of stock at district level; limited participation of TBAs who live in more distant rural areas; and minimal support and resources provided.

On the other hand, high coverage and utilization was found in Nampula province, resulting in high uterotonic coverage at home births. This was perhaps due to the program being in the first year of implementation, provincial MNCH champions who encouraged implementation, a greater number of participating TBAs, and the additional benefits of technical support from an NGO, particularly relating to supervision. The original pilot took place in Nampula, which may have also positively contributed to increased buy-in from local MNCH leaders, health staff, CHWs, and TBAs.

The lack of a data collection tool to record returned misoprostol was a barrier. In Inhambane, approximately 200 doses provided to CHWs were unaccounted and there was no data provided regarding misoprostol returns from CHWs or TBAs in Nampula. This may be attributed to the following: (1) most CHWs kept the medication in their drug kit for months until the TBA requested the misoprostol; (2) recording returns was not a formal process in the antenatal care clinics and not always recorded; (3) some CHWs directly distributed the medication to women where there was no TBA available; or (4) potentially misdirected for abortion or induction; however, there was no evidence to support this.

The program experienced significant difficulties with the logistics system to distribute the misoprostol, which should be anticipated and addressed as part of program planning and M&E. The majority of misoprostol was distributed in advance at antenatal care clinics with less than 20% distributed to CHWs to provide to TBAs (Table 3). The introduction of CHWs as the middle distributor from the health facility to the TBAs added an additional step and increased the complexity of the logistics system. Challenges managing the commodity are common in scale-up programs.[43,52] In Mozambique, this phenomenon is not unique to misoprostol. A study in Sofala province found that between 2011 and 2013,

BOX 3. Key Recommendations to the Mozambique Ministry of Health and Resource Team

The Innovation

- Distribute misoprostol directly to TBAs in situations where there are no CHWs
- In areas without TBAs, allow CHWs to distribute misoprostol in advance to pregnant women in their catchment area
- Adjust one or more criteria:
  - Reduce the timeline to receive misoprostol at ANC from 28 weeks gestation to 24 weeks
  - Reduce the distance to 5 km or measure it in time (e.g., 30 minutes or 1 hour walking)

Dissemination and Advocacy

- Widely disseminate the National PPH Strategy to all health staff including pharmacists and provincial and district authorities
- Implement a human rights-based approach that advocates to health staff and communities that women have a right to access misoprostol
- Increase demand in the community by disseminating information about the benefits of misoprostol, how to safely use it, and where to access it via CHWs, TBAs, and mobile health units

Organizational Process

- Undertake a formal review of the misoprostol program to identify needed adaptations and develop a systematic scale-up strategy for the next phases
- Medical chiefs and pharmacists should ensure a consistent supply of misoprostol, which meets the demand; review the push/pull system to allow for timely requisitions of misoprostol
- Train more TBAs and health staff to increase the number of qualified people who can distribute misoprostol

Costs/Resource Mobilization

- Develop a long-term plan for resource mobilization or redistribution of resources to fund the misoprostol program and next phase of scale-up

Monitoring and Evaluation

- Provide technical support to introduce the misoprostol indicators within the national health information system
- Appoint provincial focal persons to support timely reporting and data analysis
- Provide a formal record/system to accurately record misoprostol provided to CHWS and returns of misoprostol

TABLE 4. Facilitators and Barriers to Scaling Up Misoprostol for the Prevention of Postpartum Hemorrhage in Mozambique, by ExpandNet/WHO Framework

Factors	Facilitator	Barrier
Planning Phase		
Environment		
1. Financial situation		✓
2. Government support including champions	✓	
3. Changes in abortion law	✓	
4. Limited capacity of health system		✓
5. Wavering support for TBAs		✓
Innovation		
1. Clear, concise, well-defined	✓	
2. Adaptation of criteria		✓
3. Flow of distribution		✓
User Organization		
1. MOH Central	✓	
2. MOH MNCH health staff	✓	✓
3. MOH pharmacists		✓
4. APE (dependent on TBA relationship and distance)	✓	✓
5. TBA recruitment (close to health facility)		✓
Resource Team		
1. Members	✓	✓
2. Existence of SWAp MNCH Technical Working Group	✓	
3. SWAp MNCH Technical Working Group irregularity of meetings		✓
Management Phase		
Type of Scale-Up		
1. Horizontal (phased expansion)	✓	
2. Limited sites in each district (5 health facilities in selected districts)		✓
3. Untrained health staff due to mobility		✓
4. Vertical (institutionalization)	✓	
Dissemination and Advocacy		✓
1. Development of National PPH Strategy	✓	
2. Communication of PPH Strategy		✓
3. Training of health staff, APEs, and TBAs	✓	✓
Organizational Process		
1. MOH Central	✓	
2. MOH Provincial	✓	✓
3. MOH District		✓

Continued

TABLE 4. Continued

Factors	Facilitator	Barrier
Costs/Resource Mobilization		
1. Available Budget		✓
Outcomes		
1. Utilization and access in Nampula province	✓	
2. Utilization and access in Inhambane province		✓
3. Logistics system		✓

Abbreviations: APE, Agentes Polivalentes Elementares (community health worker); MNCH, maternal, newborn, and child health; MOH, Ministry of Health; PPH, postpartum hemorrhage; SWAp, Sector Wide Approach; TBA, traditional birth attendant; WHO, World Health Organization.

85% of district warehouses (n=13) experienced a stock-out of an essential drug at least once in the 3 annual stock assessments.[53] Medicine stock-outs were strongly associated with distance from the district warehouse to the health facility. However, in 2015 a UNFPA assessment found that 84% of health facilities across Mozambique had at least 7 essential maternal and reproductive health medicines, marking an improvement from the previous assessment of 59% in 2014.[54]

Concerns that misoprostol for the prevention of PPH would be used by CHWs, TBAs, or women for abortion impacted implementation. First, the program faced initial delays at the central level due to stakeholder concerns about the potential of incorrect use at the community level, and the need for further supervision delayed initial donor support for the misoprostol program in Mozambique.[41] Second, the MNCH SWAp Technical Working Group introduced eligibility criteria to impose further restrictions and limit distribution at the community level. Third, there was hesitation by some provincial and district medical chiefs and pharmacists to distribute misoprostol to CHWs and TBAs. In Mozambique, opponents of misoprostol for the prevention of PPH often fear that it will be used incorrectly or for abortion.[41] However, our study found no evidence of confusion about the objective of misoprostol for the prevention of PPH or diversion of the drug for induction of labor or abortion.

Communication, advocacy, and a human rights-based approach that reinforces that women have a right to access this lifesaving medication is needed from health leaders and champions to shift this culture of fear and ensure all staff understand the aims and protocol of the misoprostol program. The delivery gap—when public health professionals know what is effective and yet a gap remains on how the intervention is executed—remains a critical issue to implementation of health innovations.[55] Due to delays initiating the program in the first 6 districts, roll-out in the remaining 29 districts took place relatively quickly, arguably without adequate time for reflection and lessons learned. We recommend that the resource team and relevant stakeholders identify needed adaptations and develop a systematic strategy to guide future scale-up. We further recommend that the MOH and resource team improve communication and understanding of the National PPH Strategy and commit to incorporating the misoprostol program into the MOH institutional systems, including the national health information system.

Limitations

We interviewed national-level stakeholders and analyzed national documents and meeting notes. However, fieldwork was based in only 2 of the 10 provinces undertaking the misoprostol program. Inhambane province and Nampula province experienced differences in program inputs, resources, and outcomes. This limits the generalizability of the study to Mozambique and to other countries. This case study cannot project the impact of the program and analysis is limited to the early expansion phase. It is also important to note that this was a retrospective analysis of the planning and management of the misoprostol program using the ExpandNet/WHO framework; the framework was not explicitly utilized by the user group or resource team in Mozambique as a guide in their scale-up efforts. Lack of availability of quantitative data limited analysis and therefore we were only able to provide estimates of the coverage of misoprostol in the first 9 months of 2017. Furthermore, data on access to and utilization of

misoprostol were based primarily on calculated, indirect estimates, not directly reported data, leading to imprecision.

CONCLUSION

This study provided a retrospective analysis of the planning and the management of the early expansion of the scale-up of misoprostol for PPH prevention. The ExpandNet/WHO framework is a useful tool to plan, track progress, and allow for continuous learning. While the framework was not used in the planning or management of the misoprostol program in Mozambique, the scale-up effort would have benefited from the development of a more systematic scale-up strategy during the initial planning phase.

This case study identified barriers and facilitators to scale-up, as well as recommendations for the misoprostol program rooted in the ExpandNet/WHO framework. The Mozambican misoprostol program benefits from political support, inclusion within the National PPH Strategy, and integration into some of the MOH infrastructure, systems, and human resources. Between 2018 and 2020, the MOH and resource team will focus on implementation in the existing 35 districts. This study identifies the need to have a formal review of the misoprostol program with the MOH, resource team, and other stakeholders to identify lessons learned and needed adaptations, and to develop a systematic scale-up strategy to guide the continued national scale-up process.

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ORIGINAL ARTICLE

Association Between the Quality of Contraceptive Counseling and Method Continuation: Findings From a Prospective Cohort Study in Social Franchise Clinics in Pakistan and Uganda

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Higher scores on the 3-question Method Information Index (MII)—measuring client-reported receipt of contraceptive information—was associated with continued use of family planning over 12 months. We recommend incorporating use of the MII in routine assessments of family planning service quality.

ABSTRACT

Quality of family planning counseling is likely associated with whether or not women continue to use the same contraceptive method over time. The Method Information Index (MII) is a widely available measure of contraceptive counseling quality but little is known about its association with rates of method continuation. The index ranges from 0 to 3 based on a client's answer to whether she was told about other methods, potential side effects with her chosen method, and what to do if she experienced side effects. Using data from a prospective cohort study of 1,998 social franchise clients in Pakistan and Uganda, we investigated the relationship between reported baseline MII and the risk of method continuation over 12 months using survival analysis and Cox proportional hazard models. At baseline, about 65% of women in Pakistan and 73% of women in Uganda reported receiving information about all 3 MII aspects. In Pakistan, 59.4% of the 165 women who stopped using their modern method did so while still in need of contraception. In Uganda, of the 77 women who stopped modern method use, 64.9% discontinued while in need. Despite important differences in the demographics and method mix between the 2 countries, we found similar associations between baseline MII and discontinuation: in both countries as the MII score increased, the risk of discontinuation while in need decreased. In Pakistan, the risk of contraceptive discontinuation was 64% lower (crude hazard ratio [HR_{crude}]=0.36; P=.03), and 72% lower (HR_{crude}=0.28; P=.007), among women who were told about any 2, or any 3 aspects of MII, respectively. After adjusting for additional covariates, only the difference in the risk of contraceptive discontinuation between MII=3 and MII=0 remained statistically significant (HR_{adj}=0.35; P=0.04). In Uganda, women who reported being informed about all aspects of MII were 80% less likely to discontinue while in need (HR_{adj}=0.20; P<.001), women informed about any 2 aspects of MII were 90% less likely (HR_{adj}=0.10; P<.001), and women who were informed about any 1 aspect of MII were 68% less likely (HR_{adj}=0.32; P<.02) to discontinue contraceptive use while in need as compared to women who reported not being informed about any aspect of MII. Baseline MII scores were positively associated with method continuation rates in our sample of clients from social franchises in both Pakistan and Uganda and could potentially be used as an indicator of contraceptive counseling quality.

BACKGROUND

Quality of care is increasingly recognized as a critical driver of health care seeking, use, and outcomes.[1] Family planning quality has been integral to the vision of the Family Planning 2020 (FP2020) global partnership from its inception in 2012. The partnership's goal is to reach 120 million additional women and girls with modern contraceptives by 2020 by expanding access to contraception, assuring method choice, overcoming barriers to use, and improving quality of care.[2] This goal recognizes that some new modern method users will come from traditional method users switching to modern methods; therefore, some substitution of method type may result with regard to total use.[2]

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The Method Information Index is a self-reported proxy measure for whether the client received complete contraceptive counseling.

In pursuit of this goal, FP2020 has increased its attention on contraceptive discontinuation.[3] Method discontinuation, for reasons other than a reduced need for contraception, returns women to the pool of those with an unmet need for family planning.[4,5] The Demographic and Health Surveys (DHS) defines discontinuation while in need as women who stop contraceptive use without the intent to become pregnant and are at risk of unwanted pregnancy.[6] In a 2013 analysis of DHS from 34 low- and middle-income countries, Jain et al. found that women who discontinued a modern method while in need accounted for 38% of all women with current unmet need.[4]

While quality has been emphasized in family planning programs for decades based on a widely adopted framework,[7] and there is some evidence that multidimensional clinical quality is associated with method continuation,[8] measurement of quality has remained a work-in-progress with many tools but no agreed-on measures, scales, or indicators.[9]

It is not yet clear whether the provision of high-quality family planning counseling is associated with improved outcomes such as continued contraceptive use.

Discontinuation while still in need of contraception, as Jain and others have argued, may be considered an outcome of the quality of family planning services.[4,5] Providing women with a choice of contraceptive methods and high-quality counseling are essential components of rights-based family planning.[10] However, while increased choice has been linked to the increased adoption of family planning,[11] limited evidence exists on, and it is not yet clear, whether the provision of high-quality counseling is associated with improved outcomes such as continued contraceptive use. A quasi-experimental study by Jain et al. found that provider training to improve information exchange resulted in better counseling received as reported by the client, but there was no significant difference in modern contraceptive continuation.[12] Léon et al. reported similar results from training with the *Balanced Counseling Strategy*—a toolkit that provides health care providers with information and materials to offer high-quality family planning counseling.[13,14] Work on method switching and discontinuation found that clients reporting they had all questions answered by a provider were more likely to switch to another method rather than abandon contraception altogether.[15] Thus far, limited work has been done to investigate correlations between aspects of quality of counseling (distinct from service readiness) that are associated with sustained contraceptive use.

This study was designed to assess whether the Method Information Index, as a measure of counseling quality, is associated with discontinuation rates at the service provision level.

One important measure of counseling quality is the Method Information Index (MII), which is currently part of the 18 'Core Indicators' tracked by FP2020. The MII is a proxy measure for whether the client received complete counseling, including whether her choice of method was informed. It is a self-reported measure that is used when direct observation of the client-provider interaction is not possible; it captures a woman's recall and understanding of the information exchanged at the time of adoption, in addition to whether the exchange occurred.[16] While studies have shown that client recall is flawed, and counseling descriptions collected simultaneously from exit interviews and by direct observation may vary significantly,[17] both collection methods have advantages.[18] Some argue for the use of client recall because it is less costly to collect and because information that is remembered or 'received' may be a better measure of likely impact on behavior and decisions than information 'provided.'[19]

The DHS has incorporated the 3 questions that comprise the MII in its nationally representative surveys of reproductive-aged women since DHS round IV (1997–2003).[20] The MII is calculated from responses to 3 questions about the information that contraceptive users received from providers during their family planning visit, consisting of whether they were told about (1) other methods aside from their current method, (2) possible side effects from their current method, and (3) what to do if they experienced side effects.[21] Users' responses are coded 1 if they answered "yes" or 0 otherwise for each of these questions, and the reported MII score is the percentage of users who responded "yes" to all 3 questions.

The flexibility and versatility of the MII is appealing; in the absence of direct observation of the client-provider interaction, its questions can be asked through exit interviews with family planning clients and mystery clients in addition to being asked of household respondents in the DHS. Given its ubiquity as a measure of system quality at the national level, the MII could be attractive as an indicator of facility-level quality if it could be shown to correlate with family planning outcomes. As yet, limited research has been conducted to test this relationship and to better understand whether MII is related to family planning continuation. There are, moreover, few measures of family planning quality at the facility level that have been shown to be associated with outcomes of any kind.

This study was designed to address this lacuna and to assess the following: Is the MII, as a measure of counseling quality, associated with discontinuation rates at the level of service provision?

We conducted a prospective cohort study in a sample of social franchised family planning facilities in Pakistan and Uganda to understand the relationship between client-reported MII at baseline, a proxy for the quality of counseling received, and 12-month modern method discontinuation while in need. The findings of this study will contribute to the literature on the role of quality of family planning programs in promoting method continuation in low-income country settings.

METHODS

All data from this study were collected over 12 months in Pakistan and Uganda using similar methodologies. Pakistan and Uganda were selected due to the presence of strong partners and due to the fact that both countries have high rates of unmet need for family planning. In both countries, the partners delivered services through social franchises—networks of private health care providers, linked through a common brand. Typically, in such arrangements, the franchisor provides training, commodities, and quality assurance while the franchisees agree to provide franchised services, be audited, and adhere to price ceilings.[22] Working with franchises allowed the study to leverage existing administrative and quality assurance systems and to work with a large number of service delivery sites.

This study was conducted in collaboration with Population Services International's (PSI's) Ugandan partner Program for Accessible Health Communication Education (PACE)-Uganda, which operates the ProFam franchise of health clinics throughout the country, and Marie Stopes Society in Pakistan, which operates the Suraj franchise. The ProFam franchise is a network of privately owned health clinics that are located across the country and offer a range of health services, including family planning, HIV, malaria, cervical cancer screening, and maternal health. Clinics are mostly owned by practicing or retired midwives, nurses, nursing assistants, and, in a few cases, medical doctors. The Suraj fractional franchise is focused on family planning services, and the health care providers are primarily midwives.

Context

Uganda has one of the highest fertility rates in the world (total fertility rate=5.4), and 41% of all births in Uganda are mistimed or unwanted.[23] Ugandan women have a high need for limiting or spacing pregnancies (67% of married women of reproductive age), but only 35% of married Ugandan women use a modern method of contraception.[23] According to the 2016 Uganda DHS, Uganda's method mix predominantly consists of short-acting methods, with injectables accounting for more than half of the method mix. The next most frequently used method is implants (18% of modern method mix) while intrauterine devices (IUDs) account for only 4%. However, the situation in Uganda is changing rapidly; data from Performance Monitoring and Accountability 2020 (PMA2020) suggest that the rates of use of implants almost doubled from 15.5% in 2016 to 26.7% in 2018.[24]

In Pakistan, 16% of births in the 5 years preceding the 2012–2013 DHS survey were mistimed or unwanted, and the total fertility rate is 3.8.[25] Over one-quarter (26.1%) of married women use a modern contraceptive method while 20.1% of married women have an unmet need for family planning. Recent data (2012) from Pakistan indicates that Pakistani women using modern methods are predominantly using female sterilization or condoms (each comprising 35% of modern contraceptive use), with 7% to 11% of contraceptive users using the IUD, pill, or injectable.[25] Implant availability is increasing, but the method has been available in Pakistan only since 2010; recent data on implant prevalence is not available.[26]

The study was conducted in social franchise clinics in Pakistan and Uganda.

Method discontinuation is an issue both Uganda and Pakistan. In Uganda, 45% of contraceptive users will discontinue within 12 months. Discontinuation rates are highest for pills (67%) and injectables (52%). The most common reason for discontinuation is side effects or health concerns, with more than 1 in 3 users discontinuing for this reason. Of those who discontinued any method and stated wanting another method, just 5% switched to another method within 2 months.[23] In Pakistan, 37% of women discontinue within 12 months, and the majority of those women discontinue while still in need of contraception (26%). Similar to Uganda, the most common reason for discontinuation in the first year of use is side effects or health concerns, and the rate of switching is relatively low, with 7.6% of contraceptors switching within the first 12 months.[25] In both countries, more than one-third of current family planning users obtained their method from the private medical sector (35% in Pakistan, 39% in Uganda).[23,25] This study was conducted in the private-sector facilities that are affiliated with our study partners.

Facility Selection, Eligibility, Recruitment, and Follow-Up

In Uganda, we recruited women for this study from high-volume ProFam franchise clinics that provided a full range of modern contraceptive methods. As of July 2016, there were 193 active ProFam clinics operating in Uganda. Of these, we deemed for inclusion 163 clinics (84%) that provided at least 1 of 3 reversible forms of contraceptives (IUDs, implants, or injectables) in the first 6 months of 2016. We restricted the sample to clinics that had at least 28 new family planning clients per month (which was approximately the 50th percentile in the full sample of ProFam clinics) in order to be able to recruit at least 1 new patient per day per clinic. We also limited our sample to clinics in the Central, Southwest, and East regions to minimize data collection costs. However, the excluded regions tended to also have lower patient flows, so this geographic restriction did not reduce the number of high-volume clinics in our sample by very much. We randomly selected 32 clinics from the remaining list of 69 facilities in our sample. Among those selected, 2 clinics were in the process of leaving the ProFam network, so we excluded them from our study, leaving us with 30 clinics in our final sample.

In Pakistan, we used multi-stage sampling to first select 12 districts in 3 provinces of Pakistan (Sindh, Punjab, and Khyber Pakhtoon Khwa). We chose these districts in consideration of project budget and ease of monitoring. Second, all providers who belonged to another project that was closing were dropped from the sampling frame. Finally, 75 Suraj social franchise centers were randomly selected from a total of 81 centers in those provinces in late 2016. The total number of study facilities was chosen based upon a desire to have sufficient heterogeneity in quality while being mindful of feasibility. All Suraj franchises provide condoms, pills, injectables, and IUDs.

In Uganda and Pakistan, PACE-Uganda and Marie Stopes Society, respectively, notified selected facilities about the study and sought their consent to participate in the study. All selected facilities agreed to participate in the study.

First-time users, method switchers, and lapsed users of reversible contraception were eligible for inclusion in the study.

Women were eligible to participate in this study if they had received a modern contraceptive method (male or female condom, pill, injectable, implant, IUD, or emergency contraceptive) during the visit in which they were recruited and were either first-time users (reported using contraception for the first time in their life), switching to a different modern method, or lapsed users returning to use (reported not using any contraceptive method in the 3 months prior to the baseline interview). Additionally, to be eligible in Uganda, women must also have provided at least 1 phone number at baseline where they could be reached for follow-up interviews. Women who obtained a resupply of an existing method, received sterilization, or were using non-modern methods, such as withdrawal, were not eligible. All eligible women were asked to provide written informed consent to participate in the study. Exit interviews were conducted in a private setting to ask about their visit and demographics immediately after adopting a modern method during a visit to a social franchise site.

Study recruitment took place in Pakistan from December 2016 to February 2017, and in Uganda, between February and April 2017. To recruit women, in both countries women exiting a study clinic were screened for eligibility, and if eligible, asked to take an exit survey and also to consent to follow-up at 3, 6, and 12 months after the visit. In Uganda, the women consented for follow-up at 9 months, too. Eligible women who consented to participate were given a short exit survey at the time of recruitment that covered demographics, patient experience, method use, subjective measures of quality and satisfaction, including the 3 items from the MII index, and provider trust (Uganda only). The baseline questionnaire was administered by trained enumerators either inside the clinic or immediately outside of the clinic, depending on the clinic's setup. In both cases, special areas were set aside to conduct the interviews to provide privacy to the women.

In Pakistan, baseline and follow-up data were collected on paper surveys via in-person interviews. Data were double-entered into an EpiData database, and exported to Stata 13 for analysis.[27,28] Surveys were conducted in Urdu. Women were requested to provide specific contact details including a phone number, where available, in order to schedule in-person follow-up interviews. At the baseline interview, enumerators discussed how participants wanted to be contacted for follow-up, including if they wished to meet in their homes or at a neutral location if they preferred other household members not be present during interviews, and how the enumerator should identify themselves if they tried to contact the participant by phone. All participants elected to be interviewed at follow-up visits in their homes. Data collectors introduced themselves as field workers who were raising awareness about

maternal and child health, in order to further protect study participants. In both countries, follow-up interviews were conducted with a 2-week delay (e.g., 3.5 months, 6.5 months) in order to allow a buffer for women who needed subsequent doses of injectables.

In Uganda, all baseline survey data were collected using tablets, and questionnaires were available in English and locally spoken languages (Luganda, Lumasaba, Runyankole, Runyoro, Lusoga, and Lugwere). Enumerators were typically fluent in English and at least 1 other language and were assigned to health facilities where the second language was more likely to be used by survey respondents. Follow-up interviews were conducted by mobile phone. Women who did not own a phone at baseline were asked to provide alternate contact phone numbers (e.g., a friend's phone number or the number of a village phone vendor). All women were asked to provide primary, secondary, and alternative phone contacts to be used in case they could not be reached at the primary phone number as well as preferred days and times to be reached. All women who completed the survey were given a small gift of mobile phone airtime, worth 5,000 Ugandan shillings (approximately US$1.40), transferred to the first phone number provided, to compensate her for her participation with the survey. Women received a similar gift upon completion of the follow-up interviews. To follow-up, enumerators attempted to contact the women at the preferred times. If the phone line was busy, women were re-contacted. Excluding busy responses, at least 3 attempts were made to reach each woman via phone. After 3 non-busy attempts, women were considered lost to follow-up.

Following baseline data collection, the government of Uganda implemented a new policy requiring all SIM cards be registered using an individual's national identification card. Non-registered phones were to shut off during the summer of 2017, greatly affecting our ability to follow-up with a potentially large number of women at 3 months. In the 3-month follow-up, all women whose phone line had been switched off or was continuously busy at the first follow-up were sought in person by ProFam agents to see if they were willing to continue to be engaged in the study. If women were identified, agents did not conduct the survey immediately but provided a mobile phone to allow the trained enumerator to collect the 3-month follow-up survey. At the end of the survey, women were asked to provide new phone numbers to be reached for subsequent follow-up surveys.

In both countries, sample size calculations were based upon a hypothesized rate of discontinuation in each setting, with a 95% confidence interval, precision of 0.07, and 80% power. Loss to follow-up, given the 12-month duration of follow-up in this cohort study, and potentially low mobile phone ownership at baseline were important potential factors that we accounted for in the sample size calculations. We planned to assess correlations between measures of observed structural and process quality, as well as the self-reported MII and discontinuation of family planning over the 12-month period. Given the large number of correlations, the analyses needed to account for the increased probability of a false positive. As an approximation of the sample size required to reach a higher type 1 error threshold, the chosen sample size was based upon α=0.01. Given the 2 different contexts, the design effect and assumed loss to follow-up differed for each sample size calculation. In Uganda, we determined that we needed to have at least 530 women complete our endline survey. We also assumed a design effect of 1.5, which generated a minimum number of 796 women completing the survey at 12 months. After inflating this up to account for loss to follow-up (30%), we needed to enroll at least 1,140 eligible women to complete the baseline interview. In Pakistan, a sample of 514 women needed was adjusted by a design effect of 1.3, and 20% potential loss to follow-up, for an effective sample of 800.

Treatment of Missing Data

All women who were enrolled in the study had complete baseline information. In Pakistan, none of the dates of discontinuation were missing. In Uganda, 12% of women who discontinued while in need had a date of discontinuation which was missing or set to missing due to the fact that the reported date did not fall between 2 adjacent rounds of data collection. These dates were imputed by taking a random date in between the 2 adjacent rounds of data collection for the woman. Women who reported method discontinuation but did not report a reason for discontinuation were assumed to have discontinued while in need. Women were considered lost to follow-up if they could not be located at the address or phone number(s) given, or if they were not available after 3 attempts to contact them.

The Method Information Index sums a client's binary responses to 3 questions on whether the client was told about other methods, side effects, and what to do if she experienced side effects.

Definition of Variables

The MII was calculated by summing the binary responses to the following 3 questions:

1. "During your visit today, were you told about other methods of family planning that you could use?"
2. "Were you told about side effects or problems that you might have with (your chosen) method?"
3. "Were you told what to do if you experienced side effects or problems?"

The index, ranging from 0 to 3, was used as an ordinal variable as well as a binary variable (3 or less than 3) in the analyses. Age was categorized into 3 groups (15–24, 25–34, 35+), and a woman's primary baseline method was categorized as short- or long-acting (implant or IUD). The household's relative wealth was assessed using an asset index, benchmarked to the most recent DHS survey from each country (2012–2013 in Pakistan, 2016 in Uganda). The asset index was generated from the EquityTool, a shortened list of country-specific assets that are highly correlated with the full list of assets used to generate the wealth index employed by DHS.[29]

Time to discontinuation was treated as a continuous variable, measured in days, with a maximum allowable time of 360 days in Pakistan and 300 days in Uganda. Time in Uganda was truncated due to violation of model assumptions at the end of the reporting period. No events took place in the final 60 days of the reporting period. The event of interest was defined as discontinuation of a modern method while in need. The event occurred if the self-reported reason for discontinuation of any modern method (not necessarily the method obtained at baseline) was method-related (side effects, health concerns, method failure); related to access to resupply (cost, travel time); or social (disapproval of a family member). Women who discontinued for other reasons without switching to another modern method were censored.

Analytic Methods

This study used survival analysis and Cox proportional hazard models with robust standard errors to account for clustering by facility to assess the degree of correlation between MII and discontinuation. Log-rank tests and Kaplan-Meier survival curves assessed the unadjusted effect of MII. Discontinuation rates were estimated from survival curves. Explanatory variables tested in each country were age, wealth group, parity, education, method type at baseline (short- or long-acting), and user type at baseline (first-time user, returning to contraception after a lapse in use, method switcher). Assumptions of proportionality for each covariate were tested numerically and graphically. We tested correlation between the potential covariates and dropped parity due to a high correlation with age. Variables were considered for the final adjusted model if they were significant at $P \leq .10$ when included with MII in a Cox proportional hazard model. We tested each significant variable to see if it was time-dependent and assessed model fit using parameters available in Stata 13.[30(pp164-194)] In Uganda, a model curtailed at 300 days was compared to one for the full available time, and the curtailed model had better fit without changing model parameters. Finally, we tested the significance of the joint effect of method selected at baseline and MII on discontinuation. The parsimonious Cox proportional hazard model is thus presented for both contexts, adjusted for covariates that met significance criteria ($P \leq .10$) in at least 1 country. The results are presented in the form of crude and adjusted hazard ratios; the adjustment accounts for women's age category, prior contraceptive use (new user, switcher, lapsed user), and whether a short- or long-acting method was adopted at baseline.

Ethical Approval

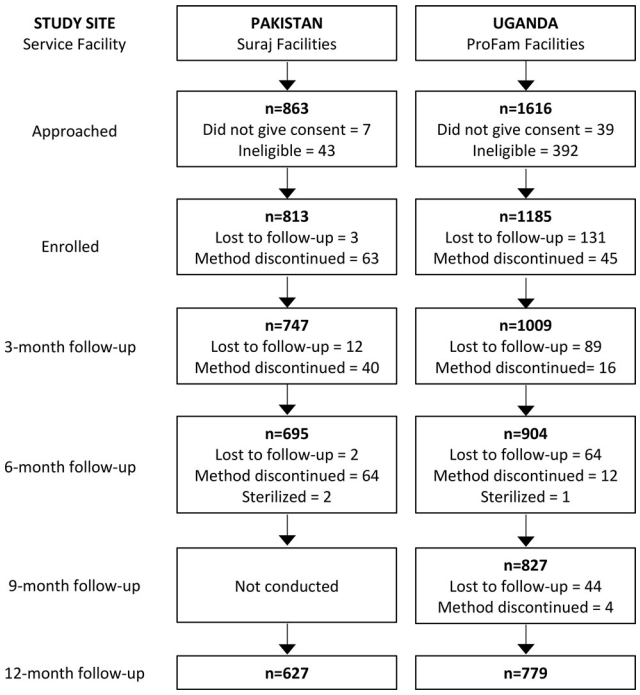
Approval for the study arm in Pakistan was obtained from Ethical Review Committee (ERC) Marie Stopes International (MSI), UK (022-16), and the National Bioethics Committee (NBC) at Pakistan Medical Research Council (PMRC), Islamabad (4-87/17/NBC-227/RDC/2308). Approval for the study arm in Uganda was obtained from the Makerere University School of Public Health Higher Degrees Research and Ethics Committee (451) and the Uganda National Council of Science and Technology (UNCST), Kampala (SS4215).

RESULTS

A total of 1,998 women were enrolled across the 2 countries: 813 women from 75 Suraj facilities in Pakistan and 1,185 women from 30 ProFam facilities in Uganda (Figure 1). Of those enrolled, 2.1% (n=17) in Pakistan and 27.7% (n=328) in Uganda were lost to follow-up.

Table 1 summarizes the demographic and reproductive characteristics of study participants, according to country. The sample comprised

FIGURE 1. Flow Diagram of Participant Enrollment and Follow-Up



Note: Women who were lost to follow-up are indicated in the flow chart at the time they were last contacted, while those who discontinued between 2 rounds are shown in the former round.

relatively younger women in Uganda (40% under 24 years of age) compared with Pakistan (15% under 24 years of age). As a result, women in the sample from Uganda reported lower parity (70% reported 3 or fewer live births) compared with Pakistan (52% reported 3 or fewer live births). Women in the sample from Uganda were also more likely to have received education (only 2.4% never having gone to school) compared with Pakistan (57.6% reported never having gone to school). Three-fourths of the sample in Uganda belonged to the highest (wealthiest) quintile. In contrast, 47.9% of the women in the sample from Pakistan belonged to middle or lower wealth quintiles.

Of those enrolled, approximately 3 in 5 women across both countries who left with a modern method were using a different contraceptive method when they came to the clinic (switcher). In contrast, 36.2% in Pakistan and 26.5% of women in Uganda were first-time adopters of a contraceptive method. More women in Pakistan (56.9%) chose a short-acting method at baseline, notably driven by use of condoms, as opposed to Uganda where 59.7% chose an implant or IUD.

Figure 2 presents the distribution of MII scores according to country. At baseline, 64.6% of women in Pakistan and 72.7% in Uganda reported receiving information about all 3 MII aspects from their service provider when they began using their method.

At baseline, 65% and 73% of women in Pakistan and Uganda, respectively, reported receiving information about all 3 aspects of the Method Information Index.

In Pakistan, among the 165 women who stopped using modern methods, 98 (59.4%) discontinued while in need. In Uganda, of the 77 women who stopped modern method use, 50 (64.9%) discontinued while need. In Figure 3 and Figure 4, Kaplan-Meier survival curves are used to compare the probabilities of continuation of a modern method over the 12-month study period. Women who discontinued a modern method because they no longer had need were censored, and time is reported in days. Figure 3 compares the cumulative probability of women continuing to use their modern method between those who received information about all 3 MII aspects (MII=3) and those who received less information (MII<3). In Pakistan, the continuation rates differed significantly between the 2 groups; by 360 days, the probability of continuation was 0.91 for women with an MII score of 3 versus

TABLE 1. Baseline Characteristics of Study Participants, by Country

	Pakistan (n=813) No. (%)	Uganda (n=1185) No. (%)
Age group, years		
15–24	125 (15.4)	475 (40.1)
25–34	443 (54.5)	531 (44.8)
35–49	245 (30.1)	179 (15.1)
No. of prior live births		
None	1 (0.1)	112 (9.5)
1	97 (11.9)	255 (21.5)
2–3	317 (39.0)	448 (37.8)
4–5	235 (28.9)	239 (20.2)
6 or more	163 (20.0)	131 (11.1)
Highest completed education		
None (never went to school)	468 (57.6)	29 (2.4)
Primary	145 (17.8)	401 (33.8)
Secondary	151 (18.6)	595 (50.2)
Beyond secondary	49 (6.0)	160 (13.5)
Wealth quintile		
1 (lowest)	54 (6.6)	21 (1.8)
2	126 (15.5)	46 (3.9)
3	210 (25.8)	43 (3.6)
4	228 (28.0)	180 (15.2)
5 (highest)	195 (24.0)	895 (75.5)
User type		
First-time adopter	294 (36.2)	314 (26.5)
Lapsed user	42 (5.2)	177 (14.9)
Switcher	477 (58.7)	694 (58.6)
Type of method adopted at baseline		
Intrauterine device	350 (43.1)	276 (23.3)
Implant	0 (0.0)	431 (36.4)
Injectable	199 (24.5)	335 (28.3)
Pill	149 (18.3)	122 (10.3)
Male condom[a]	115 (14.2)	21 (1.8)

[a] Also includes 1 female condom user and 1 emergency contraceptive user in Uganda.

0.81 for those with a score of less than 3 ($P<.001$). A similar trend was observed in Uganda; however, this difference was not statistically significant (log-rank test P value=.10). The cumulative probability of method continuation when MII is stratified by score (ranging from 0 to 3) is presented in Figure 4. In Pakistan, we observed an incremental improvement in continuation rates with a unit increase in MII scores. The 12-month probability of method continuation among women who had a MII of 0, 1, 2, and 3 were 0.72, 0.77, 0.89, and 0.91, respectively, and the log-rank test of equality indicated that the curves were significantly different ($P<.001$). In Uganda, the 4 curves were also significantly different from each other ($P<.001$) and the lowest rate of continuation (0.78) was found among women who received no information about any aspect of MII. The 12-month probability of continuation did not differ substantially between other MII groups (MII=1, 0.93; MII=2, 0.98; and MII=3, 0.96).

Table 2 and Table 3 show the risks of contraceptive discontinuation while in need, associated with binary and ordinal measures of MII, respectively. In Pakistan, the risk of method discontinuation among women who were informed about all aspects of MII (MII=3) decreased by 48% (adjusted hazard ratio [HR_{adj}]=0.52; 95% confidence interval [CI]=0.32 to 0.85; P=.009) compared with women who were not told about all aspects of MII (MII<3). Although the direction of the relationship was similar, neither the crude nor the adjusted model demonstrated a statistically significant effect of the binary measure of MII on method discontinuation for the sample from Uganda (HR_{adj}=0.64; 95% CI=0.35 to 1.18; P=.16). In both countries, women who obtained a short-acting method at the baseline visit were significantly more likely to discontinue while in need. In neither country did adjustment for this, and other variables, affect the magnitude or significance of the MII to discontinuation relationship, seen by comparing the crude and adjusted hazard ratios.

Figure 5 depicts the combined effect of MII score and method type used at baseline on method continuation. The blue line, representing women who reported receiving less than 3 pieces of information and who obtained a long-acting method at baseline, is the same as the baseline hazard for the overall Cox proportional hazards model. In Uganda, there was no significant difference in method continuation between users who received full counseling information and those who received incomplete information (regardless of the type of method used at baseline). A comparison of the blue line (MII<3, LARC user) and green line (MII=3, LARC user) for Pakistan shows an approximately 6% significant difference in the proportion of women who used a LARC at baseline continuing method use at 12 months. In other words, women starting a LARC method

FIGURE 2. Distribution of Method Information Index Scores, by Country

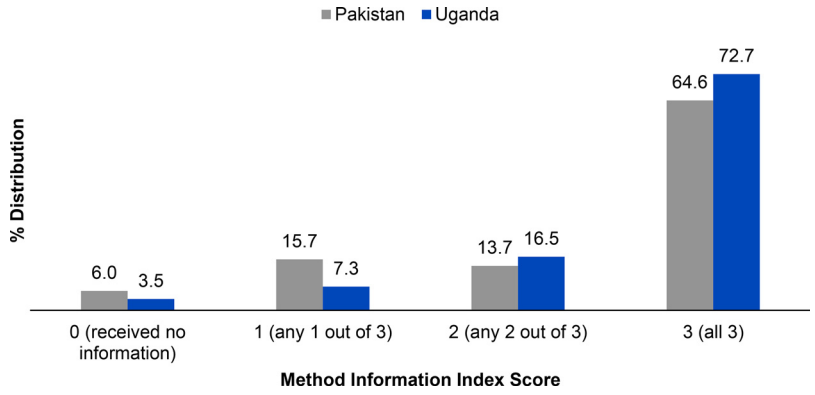
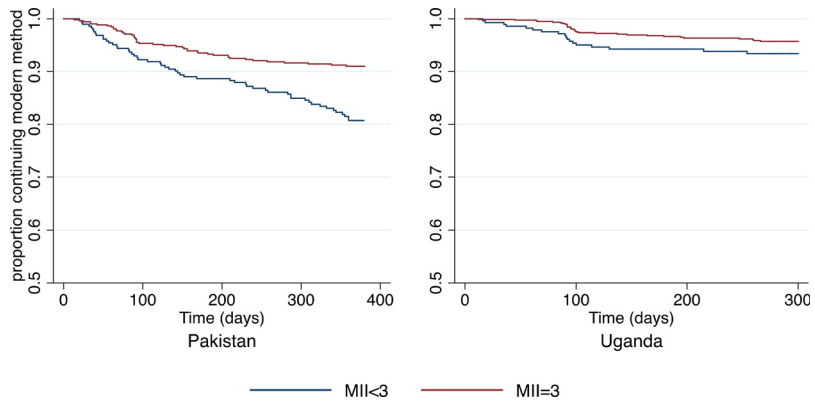


FIGURE 3. Cumulative Probability of Modern Method Continuation Among Women in Need, by MII Score (Binary) and Country



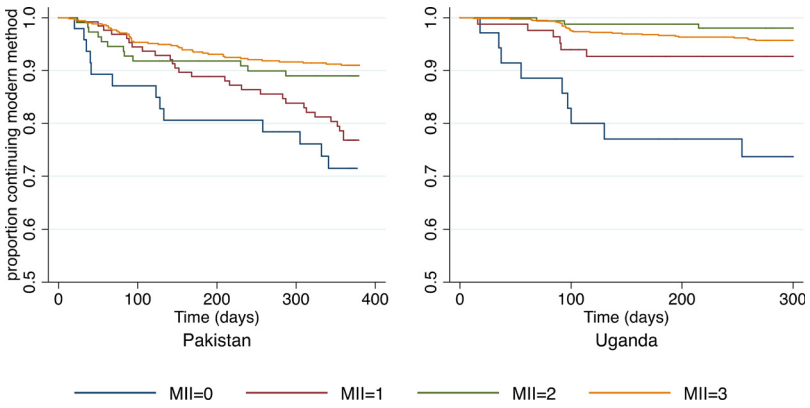
Abbreviation: MII, Method Information Index.

who did not receive full counseling information were more likely to discontinue at 12 months than women receiving a LARC method and full counseling information. Visually, this difference appears more pronounced in Pakistan when comparing short-acting method users (orange vs. red lines). To investigate if the method type received at baseline differentially affected the relationship between MII score and discontinuation, we tested the joint effect of these 2 variables. The joint effect, i.e. the difference in the 2 differences (blue vs. green lines versus orange vs. red lines), was not significant in either country, and likelihood ratio tests indicated that the adjusted models presented in Table 2 were not significantly different than a model with the joint effect (results not shown). Therefore, the effect of MII score on discontinuation did not differ among short- versus long-acting method users.

In both countries, we found that as the ordinal MII score increased, the risk of discontinuation while in need decreased (Table 3). In Pakistan, the risk of contraceptive discontinuation was 65% lower (HR_{crude}=0.35; 95% CI=0.14 to 0.90; *P*=.03), and 72% lower (HR_{crude}=0.28; 95% CI=0.11 to 0.70; *P*=.007), among women who were told about any 2, or any 3 aspects of MII, respectively, than among women not told about any aspects of MII. In the adjusted model, however, only the difference in the risk of contraceptive discontinuation between MII=3 and MII=0 remained statistically significant (HR_{adj}=0.35; 95% CI=0.13 to

In both countries, as the ordinal Method Information Index score increased, the risk of discontinuation while in need decreased.

FIGURE 4. Cumulative Probability of Modern Method Continuation Among Women in Need, by MII Score (Ordinal) and Country



Abbreviation: MII, Method Information Index.

TABLE 2. Risk of Modern Method Discontinuation While in Need, by Country, With MII as a Binary Variable

	Pakistan (N=810)				Uganda (N=1,054)			
	Unadjusted HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value	Unadjusted HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value
MII Score								
MII<3 (ref.)	–		–		–		–	
MII=3	0.45 (0.28, 0.74)	.001	0.52 (0.32, 0.85)	.009	0.62 (0.35, 1.09)	.097	0.64 (0.35, 1.19)	.16
Type of Method Used at Baseline								
LARC (ref.)								
Short-acting method			1.75 (1.10, 2.80)	.02			7.67 (3.76, 15.63)	<.001
Age Group, years								
35–49 (ref.)								
15–24			1.43 (0.74, 2.75)	.28			2.06 (0.69, 6.13)	.19
25–34			1.56 (0.91, 2.68)	.11			2.52 (1.04, 6.13)	.04
Prior Contraceptive Use								
First-time adopter (ref.)								
Return user			0.73 (0.25, 2.12)	.56			1.86 (0.73, 4.74)	.19
Method switcher			0.63 (0.43, 0.91)	.02			1.09 (0.50, 2.39)	.83

Abbreviations: CI, confidence interval; HR, hazard ratio; LARC, long-acting reversible contraceptive; MII, Method Information Index.

0.95; *P*=.04). Significant differences in risk of method discontinuation were also seen between women who reported MII=1 and MII=3 (*P*=.006); there were no significant differences in risks of discontinuation between MII=1 versus MII=2, and between MII=2 versus MII=3 (results not shown).

In Uganda, the ordinal measure of MII exhibited strong association with contraceptive discontinuation: women who reported being informed about all aspects of MII were 80% less likely to discontinue while in need (HR_{adj}=0.19; 95% CI=0.08 to 0.44; *P*<.001), women informed about any

TABLE 3. Risk of Modern Method Discontinuation While in Need, by Country, With MII as an Ordinal Variable

	Pakistan (N=810)				Uganda (N=1,054)			
	Unadjusted HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value	Unadjusted HR (95% CI)	*P* Value	Adjusted HR (95% CI)	*P* Value
MII Score								
0 (ref.)								
1	0.73 (0.29, 1.82)	.50	0.73 (0.29, 1.84)	.51	0.25 (0.09, 0.74)	.01	0.32 (0.12, 0.83)	.02
2	0.35 (0.14, 0.90)	.03	0.48 (0.16, 1.42)	.18	0.06 (0.02, 0.22)	<.001	0.10 (0.03, 0.34)	<.001
3	0.28 (0.11, 0.70)	.007	0.35 (0.13, 0.95)	.04	0.14 (0.07, 0.29)	<.001	0.19 (0.08, 0.44)	<.001
Type of Method Used at Baseline								
LARC (ref.)								
Short-acting method			1.53 (0.86, 2.71)	.15			6.79 (3.41, 13.52)	<.001
Age Group, years								
35–49 (ref.)								
15–24			1.40 (0.73, 2.70)	.32			2.36 (0.78, 7.19)	.13
25–34			1.54 (0.90, 2.64)	.12			2.71 (1.05, 6.96)	.04
Prior Contraceptive Use								
First-time adopter (ref.)								
Return user			0.75 (0.26, 2.21)	.61			1.73 (0.64, 4.69)	.28
Method switcher			0.65 (0.44, 0.96)	.03			1.03 (0.47, 2.21)	.95

Abbreviations: CI, confidence interval; HR, hazard ratio; LARC, long-acting reversible contraceptive; MII, Method Information Index.

2 aspects of MII were 90% less likely (HR_{adj}=0.10; 95% CI=0.03 to 0.34; *P*<.001), and women who were informed about any 1 aspect of MII were 68% less likely (HR_{adj}=0.32; 95% CI=0.12 to 0.83; *P*=.02) to discontinue contraceptive use while in need as compared to women who reported not being informed about any aspect of MII. Moreover, in Uganda, risk of method discontinuation was significantly lower for women with an MII score of 2 versus 1 (*P*=.03). There was no significant difference in hazard of method discontinuation between MII=1 versus MII=3, and between MII=2 versus MII=3 (results not shown).

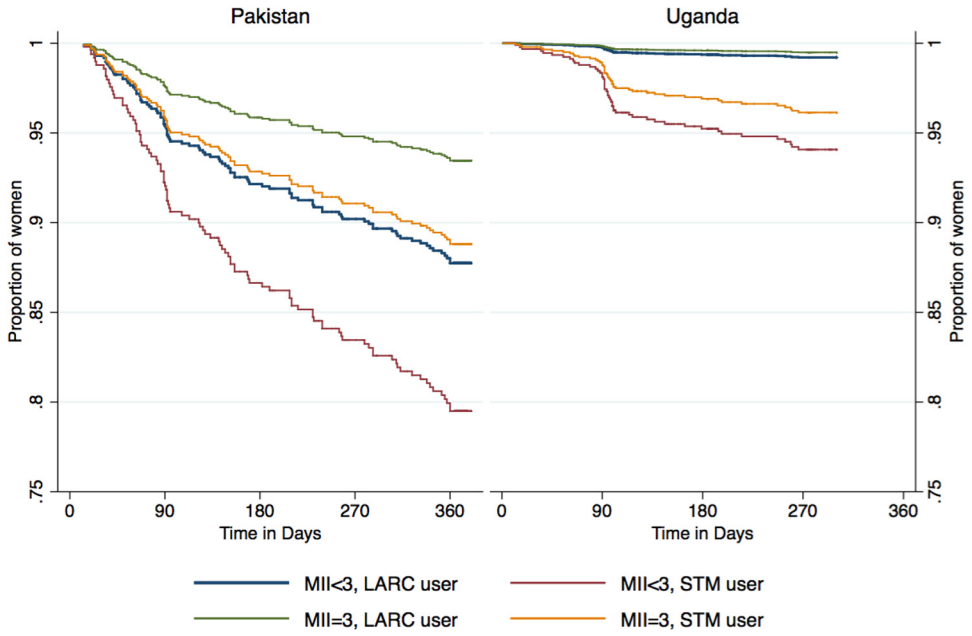
Table 4 shows the effect of each MII aspect (question) on discontinuation of modern contraception while in need, according to the country. In the unadjusted model, each MII question is considered separately, while in the adjusted model, all 3 questions are included, in addition to women's age category, prior contraceptive use category, and choosing a short-acting method at baseline. In Pakistan, the crude estimates show that provision of information to women about potential side effects (HR_{crude}=0.36; 95% CI=0.24 to 0.54; *P*<.001), and what to do if they occur (HR_{crude}=0.36; 95% CI=0.24 to 0.54; *P*<.001), at the time of method adoption decreased the likelihood of method discontinuation. However, the relationship became insignificant when adjusted for the other MII questions and the covariates. In Uganda, the chances of method discontinuation significantly dropped (73% lower risk of discontinuation) when women were informed about other methods (HR_{adj}=0.27; 95% CI=0.13 to 0.56; *P*<.001), and when they reported being informed about how to manage side effects if they occur (55% lower risk of discontinuation; HR_{adj}=0.45; 95% CI=0.24 to 0.85; *P*=.01).

DISCUSSION

High-quality family planning counseling, as measured by the MII score at clinic exit, was associated with subsequently higher 12-month continuation rates in this clinic-based prospective cohort study. The main findings are consistent with the literature, which posits that a client's receipt of

High-quality family planning counseling, as measured by the client-reported Method Information Index at clinic exit, was associated with subsequently higher 12-month continuation rates.

FIGURE 5. Cumulative Probability of Modern Method Continuation Among Women in Need, by MII Score (Binary) and Method Type Used at Baseline, by Country



Abbreviations: LARC, long-acting reversible contraceptive; MII, Method Information Index; STM, short-term.

Note: Model presented for new users aged 35–49 years.

contraceptive information is a critical component in realizing full method choice and high-quality care.[8] Although other studies have found that a facility's quality of care is associated with subsequent continuation of contraceptive use,[12,31,32] to the best of our knowledge, this is the first study to find a persistent pattern of high MII scores at facility exit and lower rates of discontinuation over a 12-month follow-up period. Looking at the MII as an ordinal variable, the largest difference is between receiving no information and receiving any 1 of the 3 pieces of the MII, suggesting that at the very core, any counseling (versus nothing) matters. While the MII has traditionally been presented as binary (receiving all 3 pieces, or not receiving all 3 pieces of information), our findings suggest value in looking at the MII as a more conventional index.

Our findings suggest that the Method Information Index can be measured at the clinic level and be comparable across clinics and networks of clinics.

Although other studies have looked at aspects of counseling, counseling interventions, or other correlates of discontinuation, this is the first to our knowledge to look specifically at the MII. As a key indicator of FP2020, the MII is increasingly a standard indicator for family planning programs. The association between the MII and method continuation found in this study is promising as it demonstrates that the MII can be measured at the clinic level and be comparable across clinics and networks of clinics.

Our study also finds that the type of method obtained at baseline (short- vs. long-acting) is significantly associated with discontinuation while in need, unsurprising given that method-related dissatisfaction is the most common reason for method discontinuation globally.[3,6,33] However, comprehensive counseling, as measured by higher MII scores, is associated with improved continuation, irrespective of method type chosen. Which, if any, single aspect of counseling, may influence this relationship is not clear from our analyses. In Pakistan, where women experienced higher rates of discontinuation, no single MII question was more strongly protective of discontinuation, while in Uganda, being informed of other methods or how to deal with side effects mattered more than being told about the side effects. Abdel-Tawab and RamaRao describe the relationship between client-provider interaction and contraceptive continuation as a puzzle, to which our study contributes a piece. The MII is a way to assess the

TABLE 4. Risk of Modern Method Discontinuation While in Need, by MII Aspect (Question), by Country

MII Questions	Pakistan				Uganda			
	Unadjusted HR (95% CI)	*P* Value	Adjusted HR[a] (95% CI)	*P* Value	Unadjusted HR (95% CI)	*P* Value	Adjusted HR[a] (95% CI)	*P* Value
Informed about other methods (ref.=no)	0.74 (0.45, 1.21)	.23	0.89 (0.44, 1.82)	.75	0.27 (0.14, 0.50)	<.001	0.27 (0.13, 0.56)	<.001
Informed about side effects (ref.=no)	0.36 (0.24, 0.54)	<.001	0.58 (0.32, 1.07)	.08	0.61 (0.33, 1.14)	.12	1.74 (0.72, 4.22)	.22
Informed of what to do if experienced side effects (ref.=no)	0.36 (0.24, 0.54)	<.001	0.73 (0.41, 1.31)	.29	0.3 (0.16, 0.55)	<.001	0.45 (0.24, 0.85)	.01

Abbreviations: CI, confidence interval; HR, hazard ratio; MII, Method Information Index.
[a] Adjusted for participants' age, prior contraceptive use, and short-acting baseline method use. All 3 MII questions are included in the adjusted model.

information-giving component of the client-provider interaction, but as the authors note, it does not capture non-verbal communication, empathy, or partnership building.[34] The index also does not capture the content of information exchanged. In related research with this same population, we used follow-up questions to "adjust" the MII score, reducing the score if the side effects reported by the client, for example, were not medically associated with the method she received. Depending on the strictness of the definition, adjusted and unadjusted MII scores were significantly different.[16] Nevertheless, to the extent that the information offered by the provider is a necessary factor in plugging the "leaky bucket,"[35] MII is a simple and straightforward assessment.

Strengths and Limitations

Despite the significance of the study, there are several limitations to note. Given that the sample of facilities in both Pakistan and Uganda is drawn from social franchise networks, which tend to be more urban, serve middle-income clients, and often receive both family planning training and supplies directly from the organizations/franchisors who sponsor them, care should be taken in generalizing findings beyond those networks.[36] Further research is needed to understand if similar associations are present in national (public-sector) programs, where counseling may not be as strongly emphasized.

The reliance on mobile phones for follow-up and the introduction of the policy to switch off non-registered phones in Uganda may have also affected our ability to follow-up with women and may have affected the comparability of the 2 countries. Researchers designed follow-up interviews in Uganda to be conducted by mobile phone, a decision made in deference to the operational practicality, low unit costs, and high mobile phone ownership in Uganda. The researchers anticipated a high loss to follow-up in their sample size calculations. However, there may have been unbalanced loss to follow-up by country. The factors associated with the participant being unable or unwilling to continue participating in the study (e.g., lack the means to maintain her phone) may be similar to the factors associated with contraceptive discontinuation (e.g., lack the means to return to facility for pill refills or injections). Since the analysis truncated data from participants lost to follow-up, any discontinuation they experienced later would be unobserved. Compared to the Pakistan cohort, differences in discontinuation rates between low and high MII participants in the Uganda cohort was less pronounced; however, method discontinuation rates may have been confounded by access to phones in Uganda and the analysis may have underestimated the relationship between the MII and method discontinuation.

Another potential limitation of this study is the response bias inherent to MII. Clients are self-reporting what they recall being told about key components of the contraceptive counseling process. In the absence of observation of the actual counseling session, this analysis relies on self-reported data. Prior work comparing exit interview data to observation in facility surveys demonstrated that clients tended to overreport when asked if they received counseling about side effects of their method.[37,38] However, the impact of this limitation is unclear as there is no evidence to

suggest that what women perceive they were told during their counseling session is any less salient or significant in terms of subsequent contraceptive use.[39]

Finally, the analyses presented here limit the assessment of quality to the MII. In reality, quality is a multidimensional construct,[7] and the facilities and providers who do a better job at counseling may also perform better on other aspects of quality, such as their technical competence, availability of methods, or general patient-provider interaction. Testing the relationship of facility quality and MII simultaneously on discontinuation would have required a far larger sample of facilities; this may be an area of further research.

The study design also has several unique strengths. First, in both settings, the study collected a robust amount of data over 12 months, including contraceptive continuation over time. The study likely captured the majority of contraceptive discontinuation as the highest rates of discontinuation tend to occur within the first 12 months.[3,40] Second, the MII questions are asked of clients as part of an exit survey, minimizing recall bias for this measure, which often has been asked retrospectively of clients in population-based surveys, sometimes months or years after the service. Finally, this study was implemented in 2 different settings, where the sample in Pakistan included fewer youth, more participants with no schooling, and more who belonged to the middle or lower wealth quintiles compared with Uganda. We obtained similar findings in both of these settings, however.

Additional research is needed to better understand whether the association between the Method Information Index and contraceptive continuation holds in public-sector facilities.

Importantly for programs, the MII provides a measure of quality that is highly implementable and relevant to important outcomes such as contraceptive continuation. The short, streamlined nature of the index is desirable for programs and makes the measure appealing and scalable as opposed to other indices composed of a long list of questions that require more time for clients to respond to and are easier to implement incorrectly. Social franchises can undertake this simplified measure much as they have adopted the EquityTool. Additionally, given the 3-question simplicity of the MII, routine monitoring of family planning quality may be possible using mobile technology that engages consumers in post-service accountability.

Studies on the impact of MII provide evidence that further justify the use of MII in establishing and monitoring policy objectives. For FP2020, the MII is included among the 18 core indicators as a key quality metric to track progress in meeting the goal of 120 million additional contraceptive users by 2020. Greater adoption of MII across governments' reporting systems brings with it the potential to manage quality improvement initiatives, set standards for minimum quality, and identify reasonable targets in the next generation of strategic purchasing initiatives.[41,42] For example, the MII is being explored as a quality metric to link to incentives in results-based financing initiatives funded by the Global Financing Facility (GFF) and partner governments. The MII is an important opportunity to link family planning quality to purchasing mechanisms that will increasingly draw from domestic resources over the near future.[43–45]

CONCLUSION

Our study found a positive association between higher MII, collected from exit interviews with family planning adopters, and method continuation over 12 months in a sample of clients of social franchises from 2 diverse settings. While future work is needed to better understand whether this relationship holds in public-sector facilities, our findings are important because while MII has been adopted widely as an indicator for systems quality, this study provides the first strong evidence of the value of MII as a validated measure of facility quality. Management of the use of MII is facilitated by regular collection of data that correlate to better performance. The short, easy-to-collect nature of the MII and the validation of a link between index performance and improved outcomes therefore has important programmatic implications. Use of MII at the program and point-of-service level may facilitate more feasible, routine measurement of quality and more impactful actions to assure and improve quality in resource-strained facilities. Our findings require replication in other settings but, if confirmed, will have important programmatic and policy implications for service delivery and regulatory frameworks. A validated tool to assess information exchange in a family planning counseling session, a key component of family planning service quality, offers an important opportunity to monitor, benchmark, compare, and improve programs that provide family planning services, and through this to positively impact reproductive outcomes.

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FIELD ACTION REPORT

Identifying and Reengaging Patients Lost to Follow-Up in Rural Africa: The "Horizontal" Hospital-Based Approach in Uganda

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Between 30% and 60% of hospital outpatient clinic patients were lost to follow-up. A defaulter-tracking service using performance-based remuneration for outreach workers, cutting across different clinical services, improved patient retention overall but varied by disease, with the poorest outcomes among patients with HIV.

ABSTRACT

Among the many challenges facing health systems grappling with the explosive growth of chronic disease in Africa are continuity of care, particularly in poor, rural areas. We report the strategy, field experience, and results of an ongoing 6-year follow-up program operating in a rural district hospital in Kisoro, Uganda, that attempts to locate and reengage patients lost to follow-up (LTFU) from communities that are largely without phones, addresses, or paved roads. The program works with diverse hospital clinics, including chronic diseases, HIV, tuberculosis (TB), nutrition, and women's health, to identify patients who have not returned to care, employing a modest staff who spend about 20 days monthly making outreach visits by motorcycle in search of approximately 130 patients. We describe the organization of this unique "horizontal" program and report on follow-up outcomes between November 2015 to October 2016. Between 30% and 60% of patients were found to have lapses in care. The follow-up program was able to locate 64% of patients, with a reengagement rate of 54% to 92% (average, 69%) depending on the clinic. The program costs approximately US$5 per patient LTFU but about US$40 per patient maintained in care. The hospital-based follow-up program that cuts across diverse clinics and wards was novel and feasible in this rural sub-Saharan African setting.

INTRODUCTION

While adherence to medication is a challenge for patients with chronic disease everywhere, it's particularly problematic in low- and middle-income countries (LMICs) where the disease burden is great and growing and access to care is most limited. Treatment of tuberculosis (TB), HIV, noncommunicable diseases (NCDs), and malnutrition are fraught with attrition, undermining disease control.

In 2015, there were 10.4 million new cases of TB worldwide. Although the World Health Organization (WHO) reported a 4% lost to follow-up (LTFU) rate globally (with only 9% of countries reporting >15% LTFU), these data are at odds with experience in the field and there is growing concern over the accuracy of population-level estimates.[1] A recent report from Uganda provides a more sober picture: only 66% of patients with TB and HIV coinfection living in rural areas completed TB therapy compared with 81% of urban dwellers.[2,3] HIV affects an estimated 37 million people globally, of whom 70% live in sub-Saharan Africa. Two meta-analyses of tracing programs for patients with HIV in LMICs revealed LTFU rates of 17% to 29% at 24 months.[4–6] In terms of NCDs, they are already a leading cause of morbidity and mortality in LMICs, with 74% of the 38 million annual NCD deaths occurring in LMICs and over 80% of deaths considered "premature."[7] Reports from various LMICs reveal a 22% to 42% LTFU rate at 6 years for patients with hypertension, a 35% LTFU rate for patients with diabetes, and 27% to 34% LTFU rate at 1 year for patients with epilepsy.[8–12] The literature on malnourished children LTFU from nutrition programs[3,13] and women LTFU after screening positive for cervical cancer paint a similar picture.[14–17]

Although there are some reports of disease-specific programs for HIV or TB that address the LTFU issue,[3,13,18–22] there have been no descriptions of

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hospital-wide initiatives that routinely follow patients in rural communities in low-income countries. In this article, we describe a strategy to maintain in care patients from various outpatient clinics of a remote, rural district hospital in Kisoro, Uganda. The experience of this follow-up program is germane to both clinicians and researchers trying to improve outcomes for long-term care in rural Africa.

The southwest Ugandan district of Kisoro is poor and rural with 86% of the population earning US$1–2 each day as subsistence farmers.[23] There are only two hospitals in the district of nearly 300,000 population, one public—Kisoro District Hospital (KDH)—and the other private, and there was 1 doctor per 40,000 people in the Kisoro district at the time of this study. Due to a paucity of trained medical personnel, in 2005 KDH partnered with a U.S.-based NGO (Doctors for Global Health) and a U.S. academic medical center (Montefiore Hospital/Albert Einstein College of Medicine) to help staff the inpatient adult medicine wards. Through this collaboration, the Chronic Care Clinic (CCC) was started in 2006. The mission of the CCC is to provide continuity of care to patients with chronic disease. The CCC was the first chronic disease clinic in Southwestern Uganda and the only institutional source of free continuous care in the district. The need for ongoing monitoring and daily medications for chronic disease was largely unrecognized among the rural population at the time the clinic was founded, a situation compounded by lack of experience in chronic disease management among KDH's novice and ever-changing providers. Local surveys indicated that less than 10% of the clinic population could afford or would be willing to buy medications for chronic disease management in local pharmacies or the private hospital, with almost all such "affluent" clients living within Kisoro town proper. Patients with NCDs were identified on the inpatient wards and given CCC appointments on discharge. However, many of these "ward discharges" failed to return.

The Kisoro District Hospital follow-up program was started in 2012 and is currently an integral component of multiple clinical services.

Discontinuing therapy was also a major problem among patients newly diagnosed with TB, and the local TB program did not have the funding or personnel to contact patients at home. Adherence to TB medications is not supported by directly observed therapy (DOT) in Kisoro, but rather by patient self-recording of drug ingestion, possibly with family assistance. DOT had never been established due to funding shortages, but for some years prior to 2010 the Global Fund to Fight AIDS, Tuberculosis and Malaria provided money for "family treatment supporters" who would identify and coach a family member to deliver and document treatment. When the funding ended in 2010, so did the program, replaced only by a monitored schedule of drug pickup at KDH or a local health center at specified intervals. If the patient did not pick up the medication from the hospital or health center, it was recorded—but tracing the patient in the community was not possible until KDH established the follow-up program.

Access to phones in the community was low (and still is low but improving), making it difficult to locate the patients. In 2018, for example, only about half of KDH patients had phone access, either personal or family, and most of the time the phones were off or not charged.

In 2012, the KDH follow-up program was initiated, run by 1 staff member on a motorcycle, to locate ward discharges and patients with TB who were lost to follow-up, attempt to reengage them in care, and document outcomes. As the program matured, it started to also follow patients with HIV and long-term CCC enrollees who were LTFU. In October 2015, a coordinator and additional field assistants were hired and patients who screened positive for cervical cancer in the women's clinic and malnourished children who were LTFU incorporated. Thus, the KDH follow-up program, which began as a side project, became embedded in the larger hospital system as an integral component of multiple clinical services.

Since a major determinant of successful follow-up with health services is the cost borne by the patient, it should be emphasized that all health services and medication costs are free at KDH and in the public health sector of Uganda generally. However, drugs are often not in stock at these facilities. With the support of WHO, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), and other international funding initiatives, HIV and TB medications are usually in stock, but drugs for NCDs such as hypertension and diabetes are available only 50% to 80% of the time depending on drug and month. When the drugs are unavailable, KDH outpatients are asked to purchase the medications in local pharmacies with vouchers, supported by Doctors for Global Health, that cover 60% of the cost.

PROGRAM DESCRIPTION AND METHODS

Feeder Clinics and Geographical Sets

The KDH follow-up program traces patients LTFU from 6 hospital units or "feeders": ward

discharges, the inpatient TB registry, and 4 hospital clinics (comprising the HIV, CCC, nutrition, and women's clinics). Although follow-up results from the women's clinic have been within the range of the other feeder clinics, data were lost due to computer mishaps, and so its results are not included in this article.

Lists of patients LTFU from each feeder are submitted and patient locations entered into 1 of 9 geographically organized "sets" of 8–15 villages, each served by a common district road. Once a set has at least 8 patients LTFU, the follow-up coordinator first reconfirms with the feeders that the identified patients have not returned to the clinic recently, and a staffer sets off to locate and follow-up with the patients. The follow-up team meets with the various feeder clinics 1 to 2 times monthly to report on outcomes of the follow-up efforts and resolve any problems. Approximately 90% of patients seen at KDH live within Kisoro District and qualify to be enrolled in the follow-up outreach should they become LTFU.

Follow-Up Procedures

The follow-up staff members consult the village chairman, the community health worker, or others in the community to help locate the patient. To maintain confidentiality, if asked (a rare occurrence), the staff members say that they are carrying a message from a hospitalized friend. If the patient is not home, a message to phone is left with the family. If no return call is or can be made, the follow-up staff member makes a second visit. If family members want details, none are provided, and the staff member explains that the message to contact was relayed by hospital personnel.

If the patient is located, the staff member first administers a brief disease-specific survey inquiring about reasons for not returning to the clinic and then discusses important aspects of the disease emphasizing the role of continuous care. Patients are encouraged to return and given an appointment and a note to provide to the clinic staff. For patients who do not return to KDH after being contacted and referred, a second outreach is made only for patients with TB due to the disease's public health consequences.

Staff and Stipend System

The KDH follow-up program employs 1 full-time coordinator and 3 part-time assistants. All are university graduates though not in the health care field. All of the assistants have other roles in the hospital or district (as a CCC coordinator, environmental officer, and social worker). The program averages 20 follow-up days monthly, or 1–2 outreach days in the field weekly per staff member. At current capacity, the system has the potential

The Kisoro District Hospital follow-up team (including authors Gideon Muhoza and Christopher Habimana) use motorcycles to locate patients lost to follow-up in their communities. © 2019 Charles Moon/Doctors for Global Health

The hospital uses a performance-based system to motivate field workers to locate patients lost to follow-up.

to make approximately 150 patient visits per month and averages 130 follow-up visits.

After a year of generally lackluster (but individually variable) success locating patents, a point-based stipend system was instituted to motivate the field workers to find and interview patients, or if that proved impossible, to determine what happened to them. The field workers earn 2 points for each patient they find and interview, 1 point for contacting the family, or 0.5 point if they cannot locate the patient. They earn 100% of their daily salary when they accumulate 10 points. Thus, with 8 patients in a set, each field worker can potentially make 160% of his usual salary if they find and interview each patient. If a field worker scores less than 10 points on a particular day (which is rare), he would get a lower salary for that day.

Definition of Terms

Loss to follow-up was defined differently by each of the program's 6 feeders, depending on treatment goal (curative or chronic-indefinite), the clinical or public health implications of foregoing treatment, and the feasibility of tracking patients for the clinic (Table 1). For example, ward discharge patients were considered LTFU if it had been 1 month or more since their last clinic appointment; 1 month was deemed the approximate time when patients' medications would be depleted or their clinical condition would start to deteriorate. In contrast, the LTFU time period for TB clinic patients was 2 or more weeks because patients are scheduled to pick up their medications every 2 weeks, with significant public health implications when there are breaks in treatment. Given the large numbers potentially requiring follow-up and the program's limited capacity, disease-specific severity criteria (not shown) were incorporated to define CCC patients LTFU. For example, for patients with "severe" NCDs, the LTFU period was 3 months, whereas for those with "moderate" severity, the LTFU period was 6 months. It should be noted that some patients identified as LTFU by the KDH follow-up program may actually have been receiving suitable follow-up from another service provider, but this was probably rare given the lack of providers and the poverty of the population.

In addition to assessing LTFU rates, we also assessed lapses in care from the CCC and HIV clinics, using an interval of 3 months (without severity criteria) to define lapse from the CCC clinic and 2 months to define lapse from the HIV clinic. These proportions reflect the general level of appointment adherence we could expect in our rural district hospital among *all* patients. Thus, lapse proportions are based on an inception cohort of "all-comers" to the CCC and HIV clinics over a

TABLE 1. Lost to Follow-Up Defined at Kisoro District Hospital, Uganda, by Hospital Unit

Hospital Unit	LTFU Definition	Rationale	Frequency of Chart Review
Ward discharge	Missed first CCC appointment by 1 month	Approximate time before clinical deterioration and/or depletion of medications.	Weekly
Inpatient TB registry	Missed drug refill appointment by 2 or more weeks	Patients pick up medication every 2 weeks; public health implications for breaks in treatment are significant.	Monthly[a]
HIV clinic	Missed 2 monthly appointments (either pre- or post-ART initiation)	Although patients are scheduled to pick up medications monthly, many come 1 or 2 weeks post-appointment, so a 2-month interval captures the late-comers.	Every 2 weeks
Chronic Care Clinic	Patient with at least 2 prior visits (i.e., regular CCC patient) who has not returned for 3–6 months, depending on disease severity (3 months for most severe 25% of patients, 6 months for less severe)	Risk severity stratification applied due to large number of CCC patients and limited outreach capacity.	Every 2 months
Nutrition clinic	Missed 1 appointment	Low threshold applied due to population of vulnerable children.	Monthly

Abbreviations: ART, antiretroviral therapy; CCC, Chronic Care Clinic; LTFU, lost to follow-up; TB, tuberculosis.
[a] TB patients identified as LTFU could be off their medications for more than 1 month since staff identify TB patients LTFU once a month.

defined period of time, whereas LTFU rates are based on selected groups of patients meeting various clinically pragmatic inclusion criteria. We measured rates of 3-month lapse from CCC care or 2-month lapse from HIV care for both new enrollees (incidence cohort) and existing clinic patients (prevalence cohort) between May 2015 and April 2016. For the incidence group, a lapse counted as any such period in their first post-enrollment year, thus extending well into 2017 for those who enrolled in 2016. Inclusion criteria for *active* "prevalence" patients were at least 3 CCC or HIV clinic visits before May 2015 with at least 1 visit between January and April 2015, or, if they first enrolled in early 2015, returning at least once within 3 months after May 1, 2015. A lapse for these prevalence patients was any period 3 months or more between May 1, 2015, and April 30, 2016. To further understand lapse behavior for CCC patients, we also recorded whether the patient returned to the clinic after lapsing, but corresponding data for HIV clinic patients were unavailable.

Data Analysis

Analysis of patients lapsing from the CCC and HIV clinics focused on clinic data collected between May 2015 and April 2016, yielding the following outcomes: the total number of patients in care; the number of new enrollees over 1 year; proportions of patients lapsed from care for 3 months from the CCC clinic and 2 months from the HIV clinic; the proportion of CCC patients that eventually returned to the CCC clinic.

Analysis of patients LTFU focused on the outcomes of community follow-up over a 1-year period, either from January through December 2016 or from November 2015 through October 2016. These outcomes included the proportion of patients located by the follow-up team and referred back to care; the proportion who refused to return back to care or who were unable to return; the proportion of confirmed deaths; the proportion of located patients erroneously designated as LTFU; the proportion of patients LTFU who reengaged in care; and the proportion of patients remaining in care 6 months after returning (for CCC patients, defined as 1 visit within 6 months after the initial return visit and 1 visit any time after 6 months).

Due to the different definitions of lapsed from care and LTFU and variable time intervals of data collection, the total number of patients for similar categories may differ between tables.

For statistical comparison of outcomes between feeder clinics and between new versus established patients, since *all* patients seen in the clinic during the designated time intervals were incorporated into the analysis and group selection was not biased in a systematic manner, we used a 2-sample proportion test (alpha=.05) and report *P* values of interest. However, since patient selection was not random, outcome differences must be interpreted carefully.

We also present approximate costs of the follow-up program over 1 year.

Ethical Approval

The study was approved by Kisoro District Hospital and the institutional review board of the Albert Einstein College of Medicine.

RESULTS

Lapses From Care for CCC and HIV Patients

In 2015, the CCC had 5,046 patient visits. Of the total visits, 38% were for treatment of hypertension, 28% for diabetes, 9% for both hypertension and diabetes, 8% for congestive heart failure, 5% for asthma, 3% for epilepsy, and 8% for other conditions including renal, hepatic, and other chronic diseases.

Between May 2015 and April 2016, 223 patients enrolled as new CCC patients (incidence cohort). Of these, 95 (43%) lapsed from the clinic for 3 months within 1 year post-enrollment (Table 2). Of the 441 CCC patients active as of May 2015 (prevalence cohort), 252 (57%) lapsed for 3 months over the subsequent year. The difference between the incidence and prevalence cohort was significant at $P<.001$.

Since its inception in 2005, a total of 3,921 patients attended the HIV clinic and 2,565 were prescribed monthly antiretroviral (ARV) medications. Of the incidence cohort of 361 patients newly enrolled between May 2015 and April 2016 and on ARVs, 216 (60%) lapsed for 2 months, interrupting therapy within their first year. Of the prevalence cohort of 1,321 patients active as of May 2015, 401 (30%) lapsed for 2 months within the year (Table 2). The difference between the incidence and prevalence cohort was significant at $P<.001$.

Lost to Follow-Up for TB, Malnutrition, and Ward Discharge Patients

In 2016, 3,766 patients in total were admitted to KDH (including medical, surgical, pediatric, and

TABLE 2. Lapses From Care for Chronic Care Clinic and HIV Clinic Patients,[a] Kisoro District Hospital, Uganda, May 2015–April 2016

	New Patients[b]	Existing Patients[c]
CCC patients, N	**223**	**441**
No. (%) of CCC patients who lapsed from care[d]	95 (43)	252 (57)
No. (%) of lapsed CCC patients who later returned	29 (31)	141 (56)
HIV clinic patients, N	**361**	**1321**
No. (%) of HIV patients who lapsed from care	216 (60)	401 (30)

Abbreviation: CCC, Chronic Care Clinic.
[a] Lapse from care defined as 3 or more months since the last appointment for CCC patients and 2 or more months for HIV clinic patients.
[b] New patients (inception cohort) are those who first enrolled in the clinic between May 2015 and April 2016.
[c] Existing patients (prevalence cohort) are those who made at least 3 clinic visits before May 2015 with at least 1 visit between January and April 2015, or, if they first enrolled in early 2015, returning at least once within 3 months after May 1, 2015.
[d] Median lapse=6 months; longest lapse=19 months.

maternity wards), 2,545 of whom were admitted to the medicine ward. Of those admitted to the medicine ward, 185 (7%) adults were diagnosed with TB (56% were documented by acid-fast bacilli testing and 44% were diagnosed clinically and treated empirically). In total, 79 (43%) missed a drug refill appointment by 2 or more weeks, thus interrupting therapy and triggering follow-up (Table 3).

From 2008 to 2016, the nutrition clinic enrolled 3,067 severely malnourished patients. Of the 245 children enrolled in 2016, 75 (31%) missed at least 1 monthly appointment for food and monitoring.

In 2016, 2,545 patients were admitted to the internal medicine wards at KDH, with 448 given follow-up appointments to the CCC after discharge. Of these, 182 (41%) did not return within 1 month of their follow-up appointment.

Over a 1-year period in 2015–2016, 1,285 patients were reported as lost to follow-up, and the hospital's follow-up program located 64% of them.

Follow-Up Outreach Outcomes

Over a 1-year period from November 2015 through October 2016, contact was attempted with 1,285 patients reported as LTFU. Table 4 details the outcomes of these attempts, per feeder. Of the total reported as LTFU, 816 (64%) were located in the community, whereas 469 (36%) could not be located. Of those located, 65% were referred to care (53% to a KDH-based clinic and 12% to another closer clinic), 19% had died, and 14% were not actually LTFU (listed erroneously). Only about 3% refused or were unable to return because they were imprisoned or bed-bound. Of those who could not be located, the follow-up team found that 36% had actually moved away from Kisoro.

Of note, the proportion of patients with HIV who were located (52%) was less than all other 4 feeder groups (range 74% to 81%, mean 77%; $P<.001$).

Reengagement in Care

Table 5 presents data on patient reengagement in care from the chronic disease feeders (lifelong therapy), comprising established CCC attendees,

TABLE 3. TB, Nutrition, and Ward Discharges LTFU, 2016[a]

	TB	Nutrition	Ward Discharges
Total number of new enrollees in 2016	185	245	448[b]
No. (%) of new enrollees LTFU	79 (43)	75 (31)	182 (41)

Abbreviations: LTFU, lost to follow-up; TB, tuberculosis.
[a] LTFU defined differently by hospital unit: TB=missed drug refill by 2 or more weeks; nutrition=missed 1 appointment; ward discharges=missed first CCC appointment by 1 month.
[b] 2,545 were admitted to the internal medicine ward in 2016 but only 448 were given follow-up appointments to the CCC upon discharge.

TABLE 4. Follow-Up Outcomes Among Patients Lost to Follow-Up, by Hospital Unit, November 2015–October 2016 (N=1,285)

	CCC (n=310)	Ward Discharge (n=149)	HIV (n=691)	TB (n=73)	Nutrition (n=62)	Total (N= 1,285)
Patients found, No. (%)	**234 (75)**	**121(81)**	**360 (52)**	**54 (74)**	**47 (76)**	**816 (64)**
Recording error (*not* LTFU), No. (%)	39 (17)	11 (9)	57 (16)	4 (7)	4 (9)	115 (14)
Referred back to KDH clinic, No. (%)	142 (61)	81 (67)	138 (38)	36 (67)	32 (68)	429 (53)
Referred to another clinic, No. (%)	10 (4)	2 (1)	84 (23)	1 (2)	1 (2)	98 (12)
Refused to return, No. (%)	2 (1)	1 (1)	8 (2)	1 (2)	1 (2)	13 (2)
Unable to return (imprisoned, bed-bound), No. (%)	2 (1)	2 (1)	4 (1)	0 (0)	0 (0)	8 (1)
Confirmed dead	39 (17)	24 (20)	69 (19)	12 (22)	9 (19)	153 (19)
Patients not found, No. (%)	**76 (25)**	**28 (19)**	**331 (48)**	**19 (26)**	**15 (24)**	**469 (36)**
Not at home, No. (%)	9 (12)	3 (11)	9 (2)	0 (0)	1 (7)	22 (5)
Could not find home, No. (%)	32 (42)	15 (54)	214 (65)	10 (53)	8 (53)	279 (59)
Moved from Kisoro, No. (%)	35 (46)	10 (36)	108 (33)	9 (47)	6 (40)	168 (36)

Abbreviations: CCC, Chronic Care Clinic; KDH, Kisoro District Hospital; TB, tuberculosis.

TABLE 5. Patient Reengagement Outcomes Among Patients With Chronic (Lifelong) Conditions Who Were Located and Referred Back to KDH, November 2015–October 2016 (N=361)

	CCC (n=142)	Ward Discharge (n=81)	HIV (n=138)
Did not return to care, No. (%)	**36 (25)**	**22 (27)**	**64 (46)**
Returned to care, No. (%)	**106 (75)**	**59 (73)**	**74 (54)**
6-month analysis not possible,[a] No. (%)	18 (17)[b]	19 (32)[b]	11 (15)[b]
Alive and eligible for 6-month follow-up, No. (%)	**88 (83)**	**40 (68)**	**63 (85)**
Still in clinic at 6 months, No. (%)	62 (70)	21 (52)	43 (68)

Abbreviations: CCC, Chronic Care Condition; KDH, Kisoro District Hospital; LTFU, lost to follow-up.
[a] Analysis not possible because either the patient file was lost or the patient died before the 6-month mark, was discharged from the clinic, or was transferred to another clinic after returning.
[b] No. of patients who died before the 6-month analysis period: CCC (4), ward discharge (1), HIV (0), total (5).

recent ward discharges with CCC appointments, and HIV clinic patients. As mentioned previously, active engagement in care at 6 months was defined as 1 visit within 6 months after the initial return visit and 1 visit any time after 6 months.

Of the 459 CCC-related follow-up patients (CCC=310, ward discharges with CCC appointments=149), 223 (49%) were located and referred back to the CCC. Of those referred, 165 (74%) actually returned. This proportion was identical for both established CCC patients and ward discharges. However, the long-term result differed between these 2 CCC feeders. Of the 106 *established* CCC patients who returned, 88 (83%) were alive and in the district 6 months later and of these, 62 (70%) were still engaged with the CCC. A smaller proportion of ward discharge patients were alive or eligible for follow-up at 6 months (68%), and of these a smaller proportion again (52%) remained engaged with the CCC (P=.03 for proportion of eligible established CCC patients vs. ward discharges who remained engaged in care at 6 months).

Patients with HIV, who were harder to locate in the community, also returned to care less frequently than CCC-related patients after referral.

Of the 138 patients with HIV who were located and referred back to the HIV clinic, only 74 (54%) returned ($P<.001$ when compared with CCC-related patients). However, if the patient returned once, the proportion who stayed in care for 6 months or more was similar regardless of whether the patient was a CCC-related patient (70%) or a patient with HIV (68%).

Table 6 presents data on patient reengagement in care from the TB and nutrition feeders (curative treatments). For the TB patients, 33 of the 36 (92%) patients located and referred to KDH returned after referral. For the malnourished patients, 23 of the 32 (72%) patients returned after referral.

Only 3 of the 36 TB patients located in the community and referred back to care failed to return. Of the 33 TB patients who initially returned, 2 charts were later lost, 3 patients refused further treatment, 10 became LTFU a second time before ultimately returning and reengaging in care after a second outreach, 2 were LTFU a third time and never completed treatment, and 5 died. However, 21 (64%) were alive and successfully reengaged in care: 14 completed treatment and 3 were still on treatment at KDH at the time of writing, and 4 had been transferred to closer health centers to complete therapy.

Similar to the TB patients, about half the malnourished children LTFU could be located in the community by the follow-up team and referred back to care. Of the 32 that were found and referred back to the nutrition clinic at KDH, 23 (72%) returned. Of the 23 who returned, 1 died, 3 were LTFU a third time, and 19 were successfully reengaged in the nutrition program. Of those reengaging in the nutrition program, 16 completed and 3 were completing treatment at the time of writing.

Cost of the Program

In 2016, the total cost of the KDH follow-up program was approximately 23.8 million Ugandan shillings (US$6,600). Most of this cost—17.7 million Ugandan shillings (about US$4,900)—went either to salaries of full-time staff or program-related "top offs" of part-time staff primarily employed by KDH or the district. These costs do not include the services of U.S.-based consultant staff.

The performance-based point system increased staff income costs but more than tripled program productivity. With performance measured by points and facilitated by searching within geographical sets for a minimum of 8 patients, each staff could potentially earn 160% of his usual salary. In practice, the average outreach garnered 115% of the staff's per diem salary.

The next highest annual cost was for the motorcycles (including fuel, repair, and replacement but not amortized purchase cost of the motorcycles) used for transportation, averaging 4.9 million Ugandan shillings annually (US$1400), followed by miscellaneous costs (e.g., phone, Internet, office supplies) at $400.

DISCUSSION

The myriad challenges of ensuring continuity of care in rural Africa involve patients, providers,

TABLE 6. Patient Reengagement Outcomes Among Patients Receiving Curative Treatment Who Were Located and Referred Back to KDH, November 2015–October 2016 (N=68)

	TB (n=36)	Nutrition (n=32)
Did not return to care, No. (%)	3 (8)	9 (28)
Returned to care, No. (%)	33 (92)	23 (72)
Completed therapy, No. (%)	14 (42)	16 (70)
Still on therapy at time of analysis, No. (%)	3 (9)	3 (13)
Referred for treatment at a closer health center after returning, No. (%)	4 (12)	–
Refused treatment after returning, No. (%)	3 (9)	–
Died after returning, No. (%)	5 (15)	1 (4)
LTFU again, No. (%)	2 (6)	3 (13)
Charts lost and long-term outcome analysis not possible, No. (%)	2 (6)	0 (0)

Abbreviations: KDH, Kisoro District Hospital; LTFU, lost to follow-up; TB, tuberculosis.

A field worker (author Gideon Muhoza) locates and meets with a patient who was lost to follow-up. © 2019 Julius Maniriho/Kisoro District Hospital

and systems. Patient barriers include poverty, difficulties with understanding disease states and the importance of treatment and follow-up, and lack of access to health services. Provider barriers include inadequate training, inexperience, and turnover while systems-level barriers consist of understaffing, underfunding, drug stock-outs, donor mandates that may conflict with local hospital priorities, and lack of feasible strategies to support patients in continuous care. The Kisoro District Hospital implemented a follow-up program in an attempt to effectively and efficiently improve the continuity of care of a diverse range of patients.

Almost all prior reports of follow-up activities have been "vertical" or disease-specific in nature, such as national TB or HIV programs, involving communicable diseases with significant public health impact.[3,13,18–22] Employing telephone calls and home visits through outreach teams or community health workers, they showed moderate impact. For example, a 2013 systematic review of HIV clinics concluded that those that employed physical outreach had a lower LTFU rate (8%) than those using phone contact only (15%).[22] There are few models employing follow-up approaches across multiple clinical domains. One example is South Africa's chronic disease management model, which integrates patients with NCDs, HIV, and TB in a common clinic and trained volunteers look for them if they lapse from care. Outcomes of the follow-up effort of this integrated program have yet to be published.[24]

In this article, we describe a "horizontal" strategy to maintain in care patients from various outpatient clinics of a remote, rural district hospital in Kisoro, Uganda. In a given geographical region, the number of patients LTFU from a full array of hospital-based clinical services will far outnumber patients from any one clinic, resulting in far greater yield of finding patients LTFU and potentially of cost-effectiveness of the program.

Interruption of therapy that is required over the long term or for life is a clinical challenge worldwide and is particularly evident in our rural African district. At KDH, across all clinics over a year, 30% to 60% of patients lapse or interrupt therapy for a clinically significant period, peaking at 60% for patients newly diagnosed with HIV. The magnitude of the issue is significant and similar for each disease or clinical source of patients–including TB (43% LTFU), malnutrition (31% LTFU), ward discharges (41% LTFU), NCD (43% and 57% of new and existing CCC patients, respectively, LTFU), and HIV (30% to 60% of existing and new HIV clinic patients, respectively, LTFU). Broad themes likely underpin the tendency of patients to drop out, such as poverty, distance, education, denial, unfriendly health systems, and "human nature"—themes that must be addressed systemically and socially.

At Kisoro District Hospital, across all clinics over 1 year, 30% to 60% of patients lapse or interrupt therapy for a clinically significant period.

The lapse from care data from the CCC documents the reality of patient adherence with

monthly clinic appointments in rural Uganda, both for an "inception cohort" of new patients and a "prevalence cohort" of long-term patients. That about half of the long-term clinic patients with chronic disease lapse from the clinic for more than 3 months (median 5–6 months), with about half of these patients returning on their own, shows that long lapses from care are common and often temporary, at least where stock-outs are frequent and monthly visits are required to refill medications. To be cost-effective, follow-up programs should take this into account and establish appropriate lapse intervals and severity (or other clinically relevant) criteria before tracking patients.

Of interest, new enrollees lapse with frequencies quite different from long-term patients, and HIV and NCD (CCC) patients manifest opposite patterns. New enrollees with chronic diseases treated in the CCC are less likely than long-term patients to lapse for 3 months within the year (43% vs. 57%, respectively; $P<.001$), but if and when they do lapse, they are also less likely to return to clinic on their own (31% vs. 56%, respectively). The pattern for HIV patients was *opposite* that of CCC patients: 60% of new enrollees lapsed for 2 months versus 30% of long-term patients ($P<.001$).

We speculate that the differences in lapse rates between new and existing patients, and between feeder clinics, reflect diverse factors influencing patient behavior, such as diagnosis following clinical symptoms versus asymptomatic screening, social stigma, denial vs. acceptance, age, mobility, and sense of autonomy. For example, the above differences between the incidence and prevalence cohorts from the CCC may reflect a common experience of patients with chronic diseases: long-term patients lapse more frequently than new enrollees because they have seen that catastrophe is not immediate if they are non-adherent for a period, but they spontaneously return with greater frequency after a lapse because they generally believe in the merits of taking medication. Their long-term CCC enrollment selects for and reflects this response. The differences in follow-up behavior between new and long-term CCC patients highlight the risk inherent in drawing comparisons between different follow-up initiatives in different populations. At the systems level, distinct criteria and definitions of eligibility between feeder clinics and organizational shortcomings of hospital-based clinics are other potential explanations for observed differences.

Moving from hospital to community, the overall outcomes of the KDH follow-up program's find-and-engage strategy were relatively similar across "feeders" for patients with NCDs, TB, and malnutrition. Roughly 75% to 80% of patients LTFU could be located in the community. Of those located, about 20% had died and 65% were given a referral back to KDH. Of those referred, 70% to 75% actually returned (with the exception of TB patients, 92% of whom returned), and of those who returned, about two-thirds were still engaged in care 6 months later or completed therapy. These are gratifying results.

However, proportions are significantly different for patients with HIV. Patients with HIV proved harder to locate in the field, 52% HIV vs. about 77% other ($P<.001$), and when referred back to KDH were less likely to return, 54% HIV vs. 74% CCC and ward discharges ($P<.001$). The difficulty finding patients living with HIV in the community is undoubtedly multifactorial: such patients are young and "on the move," often working outside Kisoro; are less likely to be known in the community than an elder with an NCD; may go by locally familiar nicknames unknown to the follow-up team; and, if from Rwanda or Congo, each 7 km from Kisoro, or if afraid of stigma, may even have registered with a false address. Once successfully contacted, their lower likelihood of returning to the clinic could well involve denial of their HIV diagnosis, especially if the diagnosis was recent and health temporarily restored by treatment. Stigma/denial as an explanation for those who did not return is consistent with the observation that those who did return were just as likely to stay in care (68%) as those from other clinics.

Of note, patients undergoing treatment for TB could be located as frequently in the community as those with NCDs (about 75%) but once found and referred, TB patients were much more likely to return for medication (92% TB vs. 74% CCC and ward discharges; $P=.03$). This is not surprising given the policy mandate to treat TB, backed by the threat of forced confinement if necessary, and the very short lapse (2 weeks) triggering an active search. On the other hand, that 43% of patients with TB became LTFU (by our stricter definition) and 26% of these could not be located or had moved from the district highlights the importance of sound systems of interdistrict communication and tracing patients until treatment completion. The observation that of the 33 patients with TB who returned initially, 10 were LTFU a second time before reengaging in care after a second outreach highlights the importance (and expense) of maintaining adherence with TB treatment.

Although the numbers are small, the "granular" TB data from our follow-up program call into question the accuracy of national reports from low-income countries of TB treatment success of approximately 80% of higher. (In 2017, WHO reported Uganda's treatment success rate to be 77%.[25])

The percentage (19%) of patients confirmed dead by the follow-up team and the recording errors that identified active patients as LTFU (14%) total 33% and add considerably to the cost of follow-up efforts without improving health. The high mortality of rural African patients implies that deaths be accurately tallied when assessing long-term adherence with care. Although there is epidemiologic value in documenting mortality, the errors in accurately linking charts with patients focuses attention on the basic infrastructure required before longitudinal care can become maximally cost-effective in low-income countries.

Only 1% of patients LTFU and contacted refused to return, but 25% of CCC and 45% of HIV patients seen in the community and referred to KDH never returned. This begs the question of whether the patients appreciated being contacted by hospital personnel and whether the program's approach of presumptive consent on the part of patients to be contacted was in fact the most appropriate approach. Preliminary data from surveys of both ward and clinic patients reveal that about 95% of surveyed patients are comfortable with and welcome the follow-up initiative. In the future, we will be soliciting informed consent from patients enrolled in our feeder clinics ahead of time to allow future community-based follow-up in case of lapses in care or loss to follow-up.

What will this follow-up model look like in the future? Although KDH will not use electronic medical records anytime soon, in 2019 we anticipate identifying eligible LTFU patients via an electronic appointment registry for all CCC, ward discharge, HIV, and women's clinic patients, and thereafter, TB patients. We are preparing systems that will identify patients automatically incorporating disease severity (and thus follow-up priority), phone numbers when available, and the village/"set" of the patient's home. Important additional features such as applying patient identifiers to help trace HIV and TB patients when they transfer sites will have to await government initiatives in these arenas for consistency and cohesion.

Steps are also being taken in the CCC to improve service and thereby limit lapses from care, including streamlining the appointment system; providing drug refills more readily for suitable patients; and, as more families gain phone access, implementing a call service to save patients the time and expense of making appointments in person.

Although a formal cost-effectiveness analysis was not performed, the tallied costs of the program for 1 year was approximately US$6,600, amounting to US$5 per patient designated as LTFU and US$40 per patient found, reengaged, and completed or continued on therapy. With more efficient and accurate electronic identification of patients eligible for follow-up, these per person costs could decrease substantially. It is likely that for communicable and/or treatable diseases, including TB, HIV, and malnutrition, these costs, though considerable in the context of the miniscule health budgets of many African countries, are worth it to contain disease spread and improve workforce productivity. (The Ugandan per capita overall health expenditure annually was about US$40 to $50 between 2013 and 2016, with the government supporting less than 20% and out-of-pocket expenses totaling about 40%.[26]) For NCDs, the picture is not as clear, and a long-term lens that focuses on the financial implications for both the individual and caregiving families of the prevention of complications like stroke, heart disease, and renal failure, would have to be adopted.

The cost of the hospital's follow-up program amounts to US$5/patient designated as lost to follow-up and $40/patient found and reengaged.

Limitations

Several limitations must be acknowledged. First, the article is a retrospective description of an ongoing program, started more than 6 years ago, whose objectives were not research, but service. Second, the definitions of LTFU vary between clinics, and despite maximizing clinical relevance and feasibility for the clinic for the most part they do not conform to similar definitions in the literature. Likewise, the data were recorded by myriad providers of care and were input by clinic staff with less consistency than in a prospective study. This last issue also led to the use of slightly different annual time frames to describe different data sets, skirting months with lost data or unrepresentative personnel changes.

Kisoro District Hospital is currently undergoing preparations to identify eligible patients lost to follow-up through an electronic system.

Even if the approach described herein is adopted, results may vary in other settings. Attitudes and practices related to chronic diseases are influenced by education level and local myths and beliefs. They vary between countries, regions

within a country, and cultures. Adherence with appointments and therefore frequency of LTFU are affected by medication stock-outs, appointment frequency, distance from and access to the clinic, provider skill and familiarity, clinic function, and options for care elsewhere. Seemingly small details can affect follow up, e.g., the CCC enrolled patients only after they returned to the clinic at least once, thereby selecting for a more adherent patient population rather than an "inception cohort" of "all-comers." In addition, many of the CCC's providers have been Western volunteers.

CONCLUSION

Despite the local realities of care, the "horizontal," hospital-wide follow-up program approach of following up with patients from diverse hospital clinics and wards is novel, feasible under circumstances such as those found at Kisoro District Hospital, and maximally efficient in rural settings. The program has been operational for more than 6 years and is well integrated into the function of the hospital. Its organization contrasts with follow-up programs that are disease-specific or "vertical," with each clinical service following only patients with one defined (and separately funded) disease or health issue.

Four key features of an effective multi-service follow-up program in this setting include:

- Application of clinically relevant criteria for triggering follow-up of LTFU patients, devised in partnership with feeder clinics
- Employing a distinct and dedicated team of follow-up staff who is familiar with the communities, has experience with inquiring about patient whereabouts while maintaining confidentiality, and is committed to meeting regularly with clinic personnel
- Organization of villages according to "geographical sets" served by common roads, with outreach triggered by a minimum number of patients to locate per set from multiple feeders
- Stipends for staff based on productivity

The outcomes of the KDH follow-up program have been quite positive, although for reasons discussed, reengaging patients with HIV who were LTFU has proven most challenging. In general, of patients without HIV infection, about 75% to 80% LTFU could be located in the community, 70% to 75% of those referred back to KDH actually returned, and of those who returned about two-thirds were either still engaged in care 6 months later or completed therapy.

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FIELD ACTION REPORT

Rapid Integration of Zika Virus Prevention Within Sexual and Reproductive Health Services and Beyond: Programmatic Lessons From Latin America and the Caribbean

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During the 2015–16 Zika virus outbreak, IPPF member association providers reached clients and affected populations faster by integrating critical information and services within existing sexual and reproductive health platforms. Challenges included: (1) communicating rapidly evolving evidence to providers; (2) overcoming restrictive social norms on gender and sexuality and a related lack of public messaging on preventing sexual transmission; and (3) addressing disability stigma and breaching service gaps to support children and caregivers affected by congenital Zika syndrome.

Resumen en español al final del artículo.

ABSTRACT

The emergence of the Zika virus (ZIKV) in Latin America and the Caribbean during the 2015–2016 outbreak has required local health systems to adapt, suddenly and continuously. This field action report explores the outbreak's sexual and reproductive health (SRH) complexities and the experience of the International Planned Parenthood Federation (IPPF) and 4 of its member associations as part of the United States Agency for International Development's rapid response in the region. It outlines approaches and actions that IPPF and its member associations undertook over 3 broad programmatic phases—developing ZIKV protocols and training personnel; delivering ZIKV-integrated services and information; and providing screening, care, and support for children and families affected by congenital Zika syndrome (CZS)—as the project worked to integrate ZIKV prevention, screening, and response within SRH service delivery models. It also describes the challenges and lessons learned in implementing a ZIKV response program in the region and recommendations from a service delivery perspective that can be useful in informing the responses to future rapid onset epidemics with SRH relevance. Challenges identified include adapting to a rapidly evolving evidence base during the early stages of the epidemic; traditional and restrictive regional social norms around gender, sex, and sexuality; the lack of focus on sexual transmission in national ZIKV public health messaging; and a lack of services, government support, and referral pathways for supporting children and families affected by CZS. Some of the key recommendations include finding ways to share rapidly evolving clinical updates conveniently and frequently, such as through digital technologies and platforms; partnering with multidisciplinary organizations, such as disability rights and services organizations, that can fill gaps in needed services; and leveraging the need for urgent action as a catalyst of change around more inclusive and gender-transformative social norms and services.

BACKGROUND

The Zika virus (ZIKV) was first identified in Uganda in 1947 by scientists researching yellow fever in rhesus monkeys and subsequently isolated from humans in Uganda and Tanzania in 1952.[1] Relatively small outbreaks occurred in Micronesia in 2007 and French Polynesia in 2014, but much remained unknown about the virus and its effects until more recently. It is primarily transmitted via *Aedes species* mosquitoes, including *Aedes aegypti* and *Aedes albopictus*, but can also be transmitted vertically from mother to embryo or fetus during pregnancy or at some point around the time of birth; sexually from partner to partner; and perhaps, though it seems rare and more evidence is needed, by blood transfusion and via health care setting or laboratory exposure.[2] The virus has been detected in breast milk, vaginal fluids, urine, blood, and saliva and has been shown to remain the longest in semen, impacting the period of time it might be transferred to a sex partner.[3]

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The Box provides more detail about the known transmission methods.

Largely asymptomatic, the most devastating effects of ZIKV are now known to originate during pregnancy with the potential to severely affect embryonic and fetal development. These effects can include the development of congenital microcephaly and a range of neurological, motor, auditory, visual, and other delays and abnormalities now referred to collectively as congenital Zika syndrome (CZS),[5] with far-reaching consequences for sufferers and caregivers alike. Guillain-Barré syndrome has also been strongly associated with Zika.[6]

A major ZIKV outbreak in Latin America and the Caribbean between 2015 and 2016, the first of its scale, prompted the World Health Organization (WHO) to formally declare a temporary "Public Health Emergency of International Concern" in the region. Now considered endemic to the region, as of January 2018 authorities had recorded 806,701 cumulative confirmed and suspected autochthonous ZIKV cases across 48 countries in the region, with 3,720 confirmed instances of CZS.[7]

In Latin America and the Caribbean, sexual and reproductive rights are severely curtailed, more than half of all pregnancies are unintended,[8] and many lack even basic access to quality sexual and reproductive health (SRH) care. Given that ZIKV can be sexually transmitted and has the ability to negatively affect pregnancy outcomes, it is evident that the burden of the virus in this region rests primarily on women and girls of reproductive age. This required a coordinated response that included a specific focus on sexual and reproductive health and rights, with tailored interventions. The United States Agency for International Development (USAID) was one of several actors, including the Pan American Health Organization (PAHO), WHO, and the United Nations Population Fund (UNFPA), that acted quickly to mitigate the spread and impact of ZIKV, especially among women and girls of reproductive age.

In June 2016, through the Support for International Family Planning Organizations 2 – Sustainable Networks Project (SIFPO2), International Planned Parenthood Federation (IPPF) member associations in 4 priority countries (the Dominican Republic, El Salvador, Guatemala, and Honduras) became implementing partners in USAID's ZIKV rapid response efforts. These organizations worked together in close coordination with several USAID cooperating agencies and partners supporting complementary efforts, including the Applying Science to Strengthen and Improve Systems (ASSIST) Project, the Maternal and Child Survival Program, the Knowledge for Health (K4Health) Project, the Health Communication Capacity Collaborative (HC3), and Population Services International (PSI). While the overall USAID response was broader, incorporating vector control and policy development among other initiatives, IPPF's involvement focused especially on improving access to and delivery of quality ZIKV-integrated SRH services, including voluntary family planning for women and girls of reproductive age.

BOX. Zika Virus Transmission Methods

Mosquitoes
Zika virus is principally transmitted to humans via the bite of an infected Aedes species mosquito, including *Aedes aegypti* and *Aedes albopictus*.

Sexual Transmission and Bodily Fluids
Zika virus has been detected in vaginal fluid, blood, semen, urine, saliva, and breast milk. No known cases of transmission via urine, saliva, or breast milk have been recorded. A person that has been infected with Zika can transmit the virus to a partner sexually. The virus remains in semen longer than in other bodily fluids.

Vertical Transmission
Mothers can pass Zika virus to the embryo or fetus during pregnancy or around the time of birth, though the exact mechanisms by which these types of transmission occur are still unknown.

Blood, Blood Products, and Laboratory Exposure
A limited number of cases of Zika virus transmission via blood transfusion and laboratory exposure have been identified. No known cases of transmission via organ transplantation have been recorded.

Sources: CDC (2019),[2] Gregory (2017).[4]

The burden of Zika in Latin America and the Caribbean rests primarily on women and girls of reproductive age.

In 2016, IPPF and its local member associations led a Zika prevention project in 4 priority Latin America and Caribbean countries.

The principal goal of the SIFPO2 Zika Prevention Project was to integrate ZIKV prevention information within existing SRH services and outreach as quickly as possible (a rapid integration approach) to support and strengthen health systems in the 4 priority countries in order to minimize negative pregnancy outcomes. It aimed to do so by improving access to ZIKV-integrated SRH and child health services, including voluntary family planning services and counseling, and by improving providers' capacity to deliver ZIKV-integrated services and information.

IPPF and its regional entity, the International Planned Parenthood Federation/Western Hemisphere Region (IPPF/WHR), played key organizational, facilitating, and convening roles in the implementation of the project, providing continual technical and project management assistance to the member associations.

IPPF's member associations in each of the 4 countries have well-established networks of trained service providers operating from a range

TABLE. Snapshot of IPPF Member Associations' Institutional Size and Scope in Each Country, 2017

Country	Member Association Name	Service Delivery Points	Estimated No. of Clients, 2017	No. of FP Services, 2017	No. of SRH Services, 2017	No. of FP Commodity Units Provided, 2017
Dominican Republic	Asociación Dominicana Pro-Bienestar de la Familia (Profamilia)	2 associated clinics 28 CBD outlets 92 commercial marketing outlets 5 government outlets 2 mobile clinics 6 other agencies 657 private physicians 7 static clinics	163,940	73,568	637,023	2,218,855
El Salvador	Asociación Demográfica Salvadoreña (ADS)/Pro-Familia	999 CBD outlets 506 commercial marketing outlets 8 mobile clinics 17 other agencies 71 private physicians 13 static clinics	251,660	666,807	1,599,958	2,017,038
Guatemala	Asociación Pro-Bienestar de la Familia de Guatemala (APROFAM)	2,000 CBD outlets 5 mobile clinics 26 static clinics	327,250	513,400	1,398,973	724,418
Honduras	Asociación Hondureña de Planificación de Familia (ASHONPLAFA)	95 associated clinics 1,701 CBD outlets 1,014 commercial marketing outlets 1 government outlet 19 mobile clinics 32 static clinics	775,880	211,129	2,224,952	2,175,489

Abbreviations: CBD, community-based distribution; FP, family planning; IPPF, International Planned Parenthood Federation; SRH, sexual and reproductive health.

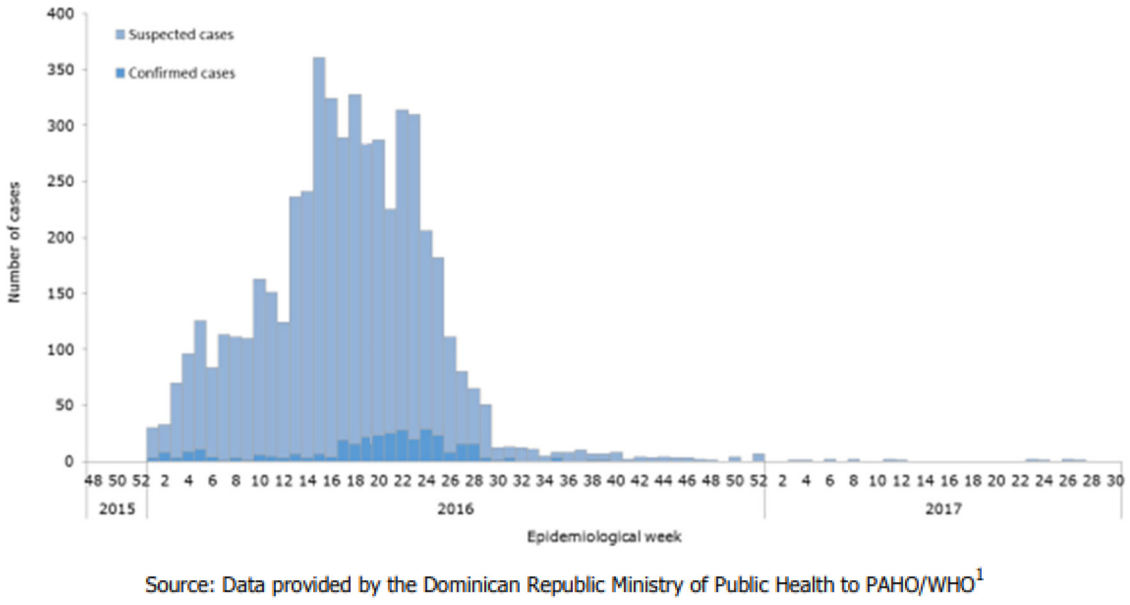
of service delivery points, from static clinics to mobile outreach services, and in some cases in partnership with government outlets. Member associations routinely work collaboratively with private- and public-sector health care providers and counterparts to refer clients to specialized services, depending on local needs and capacities. By effectively deploying and expanding these networks, the member associations—trusted local providers of a wide range of health services—were able to reach large numbers of at-risk women and men. Efforts focused particularly on (1) pregnant women who wished to avoid sexual transmission from a partner and (2) women who wished to delay or limit pregnancies, including women with an unmet need for family planning.

A summary of the 4 member associations' general reach and services is provided in the Table, and a visual representation of the ZIKV epidemic curve between 2015/2016 and 2017 from PAHO/WHO epidemiological reports is available in Figure 1 for the Dominican Republic, Figure 2 for El Salvador, Figure 3 for Guatemala, and Figure 4 for Honduras.

PROJECT DESIGN AND IMPLEMENTATION

The project consisted of 3 broad programmatic phases as indicated in Figure 5, beginning with the initial and adaptive development of ZIKV protocols and training of personnel and continuing with the direct implementation and delivery of ZIKV-integrated SRH services. Initially, the project focused on integrating the newly adapted ZIKV protocols during family planning visits, antenatal and postnatal care consultations, and community education efforts. Later, as the true scope of ZIKV implications became better understood, information was also integrated into all SRH and gynecological services in order to reach as many women and girls as possible across the continuum of care. Each member association tailored its response and specific services to its respective country context, institutional capacity, and organizational strengths. Finally, the project incorporated an expanded focus on the development of screening, care, and support services for children and families

FIGURE 1. Suspected and Confirmed Zika Virus Cases, Dominican Republic, Epidemiological Week 48 of 2015 to Epidemiological Week 30 of 2017



Source: PAHO and WHO (2017).[9]

affected by CZS during postnatal screenings and early well-child visits, where available. The approaches, challenges, and lessons learned during each of the 3 programmatic phases are discussed below in more detail.

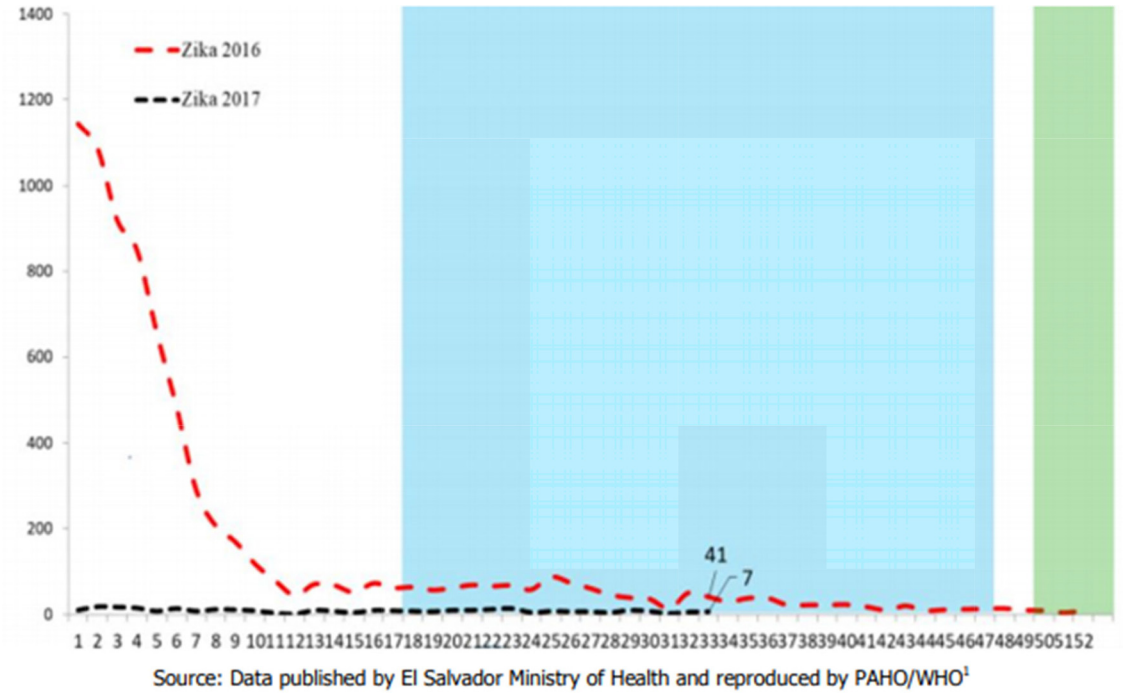
Capacity Building: Developing ZIKV Protocols and Training Personnel

A critical training phase at the outset of the project ensured that IPPF member association clinical staff and community health worker (CHWs) had sufficient skills and knowledge to deliver accurate, high-quality ZIKV-related services and information to at-risk clients. This required developing a standardized set of ZIKV integration and response protocols and training curricula to guide clinical teams and CHWs. These were then updated on a rolling basis as scientific understanding of the virus' pathology improved. Under the leadership of ASSIST, IPPF member associations worked closely with Ministry of Health officials and other implementing partners to support development and subsequent adaptations of these essential tools. ASSIST developed a package of materials including job aids, protocols, and service algorithms to guide preconception, antenatal, and family planning counseling in the context of ZIKV. PSI developed a regional communication campaign to promote the most effective ways of preventing ZIKV, and IPPF member associations also developed context-specific information, education, and communication (IEC) materials tailored to reach local communities.

Member associations launched trainings based on the new protocols and guidelines, customized for each cadre of health worker involved in the response, including direct service providers (obstetricians/gynecologists, general practitioners, counselors, psychologists), educators, and community family planning distributors and other CHWs. The content of the training included virus pathology, symptoms and prevention, voluntary and locally available family planning methods, and the newly developed protocols. Several subsequent rounds of training were provided as protocols were revised and understanding about the epidemic and its consequences evolved. By the end of the project's total 23-month period of performance, 5,298 providers of all types had been trained at least once, with 1,786 reporting having

Because the evidence base on Zika was rapidly evolving, IPPF and its partners had to quickly adapt messaging, revise protocols, and train service providers multiple times.

FIGURE 2. Suspected and Confirmed Zika Cases, El Salvador, Epidemiological Week 1 of 2016 to Epidemiological Week 33 of 2017



Source: PAHO and WHO (2017).[10]

received at least one round of updated or refresher training beyond the initial session.

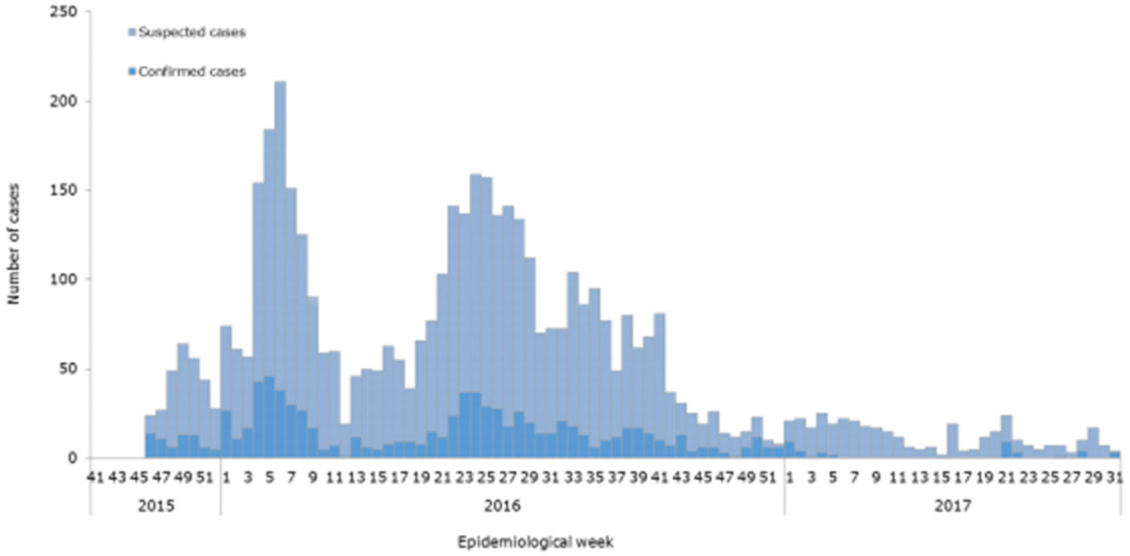
Challenges

A rapidly evolving evidence base and the need for ongoing training. The rapidly expanding ZIKV evidence base, and particularly the emerging consensus regarding the importance of early detection of CZS, required IPPF member associations and other partners to remain flexible and responsive, quickly adapting information and messaging for IEC materials, revising protocols, and conducting multiple rounds of training for service providers. This was a significant challenge for clinical directors who had to balance a range of competing demands on providers' time in scheduling trainings. To keep providers informed of the evolving evidence and best practice while reducing the burden of participating in multiple in-person trainings, the IPPF member association in the Dominican Republic, Profamilia, developed a community of practice website that providers could access individually and on their own time, helping to ease the burden.

Lessons and Recommendations

Balancing competing priorities. Organizations responding to public health emergencies like the ZIKV outbreak must remain agile and able to respond quickly yet accurately as new evidence emerges. Conducting research, performing assessments, coordinating partners, and developing standardized care protocols and guidelines as part of a comprehensive approach require time, and yet the need to reach communities with critical information and services is urgent. Achieving this balance of speed and accuracy can be difficult, so attempts to anticipate and mitigate bottlenecks in advance are helpful. Thinking creatively of ways to alleviate the impact of the additional continuous training demands on providers wherever resources and local context allow also helps to mitigate competing demands. Utilizing digital trainings and platforms to share clinical updates and reinforce in-person trainings also allows for

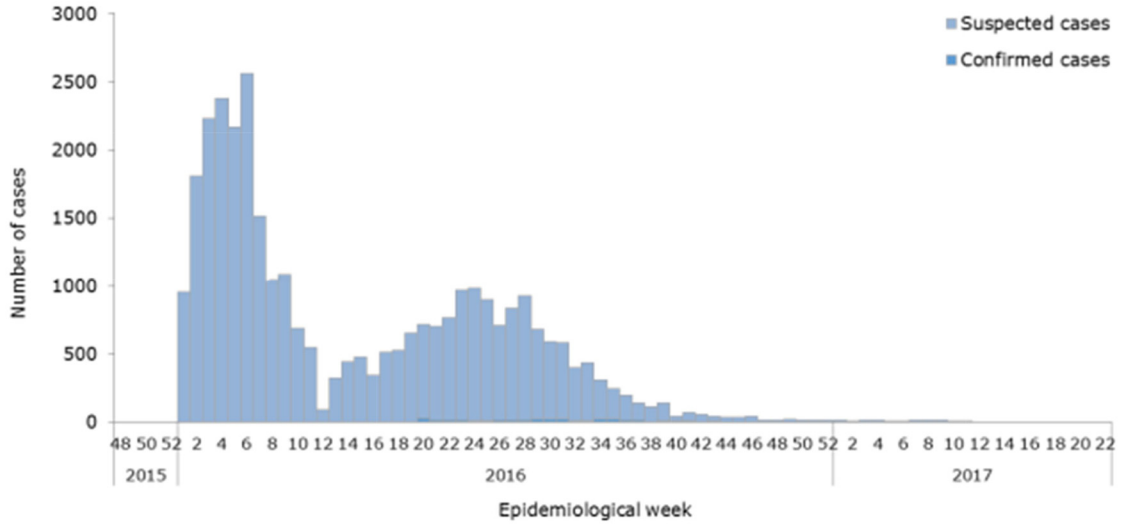
FIGURE 3. Suspected and Confirmed Zika Cases, Guatemala, Epidemiological Week 41 of 2015 to Epidemiological Week 31 of 2017



Source: Data reported by the Guatemala Ministry of Public Health and Social Assistance[1]

Source: PAHO and WHO (2017).[11]

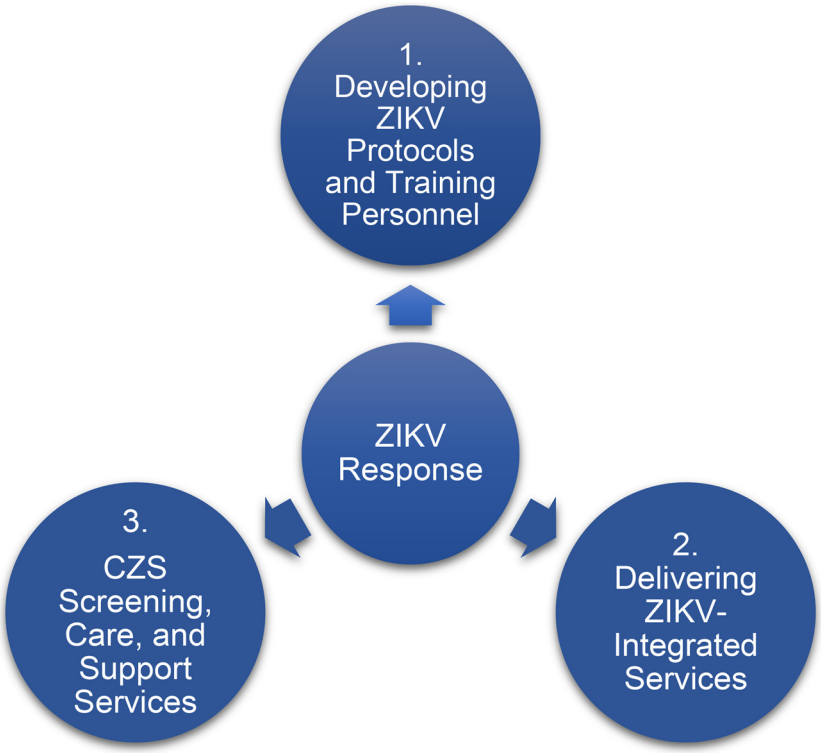
FIGURE 4. Suspected and Confirmed Zika Virus Cases, Honduras, Epidemiological Week 48 of 2015 to Epidemiological Week 22 of 2017



Source: Data provided by Honduras Ministry of Health to PAHO/WHO[1]

Source: PAHO and WHO (2017).[12]

FIGURE 5. Programmatic Components of the IPPF SIFPO2 Zika Prevention Project in Latin America and the Caribbean



Abbreviations: CZS, congential Zika syndrome; IPPF, International Planned Parenthood Federation; SIFPO2, Support for International Family Planning Organizations 2 – Sustainable Networks Project; ZIKV, Zika virus.

repeated exposure to key themes and bolsters learning. Similar programs should anticipate the need for ongoing facilitation of updates to protocols and training programs from the outset, which will improve service quality and strengthen the long-term impact of the initial response.

Prevention: Delivering ZIKV-Integrated Services and Information

The second phase of implementation involved the delivery of ZIKV-integrated services and comprehensive information to the most vulnerable, including women and girls in areas highly affected by ZIKV, those most economically disadvantaged, and pregnant women and their partners. The focus of this phase of work centered on the prevention of unintended pregnancies by improving access to voluntary family planning information and services and on the prevention of sexual transmission of ZIKV for both pregnant and nonpregnant individuals. To address financial barriers to access, relevant services were subsidized in part or in full, depending on client need in target areas and individual member association approaches. A total of 216,091 clients at project sites accepted a voluntary family planning method, resulting in the provision of an estimated 185,444 couple-years of protection (CYP) and the aversion of an estimated 88,195 unintended pregnancies, as estimated using the Marie Stopes International Impact 2 calculator.[13]

Outside of clinical settings, educators and community family planning distributors focused on increasing awareness about ZIKV prevention and voluntary family planning among vulnerable and remote communities. Trained CHWs provided short-acting methods of contraception including oral contraceptives and condoms and referred clients to clinics to receive long-acting and permanent methods as requested per clients. Community distributers and educators also provided up-to-date information about ZIKV, how to

prevent sexual transmission of the virus, and locally available voluntary family planning methods. In total, an estimated 674,287 individuals in project sites received ZIKV-integrated SRH information. IEC sessions were adapted according to target groups and settings:

- In Honduras, the Asociación Hondureña de Planificación de Familia (ASHONPLAFA) worked in partnership with bus companies, palm oil processing plants, and fast food outlets to educate workers on the job. Community educators delivered health information sessions in the workplace, sometimes *while* people worked or during extended lunch breaks, ensuring that essential information on ZIKV and locally available family planning options was shared as widely as possible.
- In El Salvador, the Asociación Demografica Salvadoreña (ADS)/Pro-Familia leveraged its regular contributions to a local radio show about relationships and SRH called *Confiésame Love* (translated roughly as "Love Confessions") to deliver ZIKV messaging to listeners. They also distributed small cosmetic bags filled with IEC materials and condoms to pregnant women, a discreet effort tailored to the local context that worked to promote the use of barrier methods during pregnancy.
- In Guatemala, the Asociación Pro-Bienestar de la Familia (APROFAM) made ZIKV a central topic at discussion clubs for pregnant mothers (*Club de la Amiga de la Embarazada*) to assist women in understanding the risks of ZIKV during pregnancy and how to prevent transmission or access support as necessary.
- In the Dominican Republic, mobile health units brought ZIKV-integrated services and language appropriate information sessions to remote, rural *bateye* communities of vulnerable Haitian immigrants that otherwise traditionally experience geographic access barriers to care and information.
- Because men and boys are affected by, involved in, and to varying degrees may control decision making and behaviors that affect SRH and contraceptive use,[14,15] their inclusion was also a critical component of the ZIKV response. In Honduras, ASHONPLAFA brought facts and judgment-free information on ZIKV-integrated SRH to an estimated 81,000 men in total, 58,000 of whom were reached via traditionally male-dominated spaces like military outposts, sports clubs, Scouts meetings, and tobacco-processing plants.

An APROFAM community health worker in Guatemala teaches members of a community-based discussion club for pregnant women about the risks of Zika and corresponding prevention strategies. © 2017 Skye Beare/IPPFWHR

Challenges

Overcoming restrictive social norms. Traditional religious, gender, and cultural norms and stigma in Latin America and the Caribbean often reinforce negative attitudes toward sex and sexuality, discourage contraceptive use, and place significant value on the role of women—including even young women—as mothers. In this context, the delivery of culturally sensitive but also gender transformative, sex positive, and medically accurate information about SRH is particularly challenging. The ZIKV epidemic created new opportunities to initiate dialogue about the value of family planning; however, in other ways it created new communication challenges. For example, messaging about the need to use condoms *during pregnancy* to prevent sexual transmission was met with some confusion and resistance from both men and women.

Lack of comprehensive public health messaging on sexual transmission. Because of the restrictive SRH and rights landscapes in project countries and in the region, public-sector responses focused primarily on vector control in their effort to halt the virus' spread, to the near total exclusion of investment in prevention of

Because of the restrictive sexual and reproductive health landscape in the region, public-sector responses to Zika focused primarily on vector control with little attention on preventing sexual transmission of the virus.

sexual transmission. National responses to the crisis like the one in El Salvador,[16] for example, have been underfunded and incomplete in merely instructing women to avoid or delay pregnancy without addressing the existing unmet need for family planning. Lack of public awareness surrounding the risks and ongoing transmission of ZIKV and the importance of using barrier methods to prevent sexual transmission persists.

Between July and August 2017, ASHONPLAFA conducted an integrated ZIKV virus and family planning Knowledge, Attitudes and Practices (KAP) study among a sample of individuals accessing health services across a range of its static clinics to better understand this persistent lack of awareness. With a sample of 620 people, the KAP survey reported that while 94% had prior knowledge and awareness of ZIKV transmission via mosquito bite, only 43% had knowledge of sexual transmission, with a mere 14% reporting having taken any form of precaution to prevent transmission. Further, only 48% reported awareness of the link between ZIKV and microcephaly. In part, this can be attributed to a lack of comprehensive messaging about sexual transmission of ZIKV and the lack of prioritization of family planning in the public sector as part of a comprehensive response. Public awareness campaigns commonly excluded information about sexual transmission and its prevention, and cultural and political sensitivities appear to have prevented a strong public focus on this aspect of the epidemic. Consequentially, community providers and clinicians who rely on the public sector to inform key populations of health threats struggled to change perceptions.

Lessons and Recommendations

Transformative gender approach. Every public health or development challenge, whether local, regional, or global in scope, in the context of an emergency or otherwise, also contains within it an inherent opportunity to challenge gendered societal inequalities. Adopting a gender transformative approach that actively promotes gender equality can help interventions to counter restrictive social norms and attitudes that inform and ultimately compromise the scientific integrity, accuracy, reach, and effectiveness of public health responses.

Improving access by removing barriers. Reducing financial barriers to access for clients in target communities was essential to increasing uptake of voluntary family planning services. While information on ZIKV has been integrated within target services, the completion of the project means each member association's ability to sustain and expand continuing provider trainings, ongoing community education activities, and—critically—subsidies for poor, young, vulnerable, and otherwise at-risk populations is negatively affected. Funding subsidized family planning services where they are not already available should be a priority for governments and donors in the region.

IPPF and its member associations champion a client-centered approach to delivering SRH services and recognize that negative client experiences can also create barriers to access. After surveying a total of 812 individual clients in the Dominican Republic, Guatemala, and Honduras using an adapted client satisfaction survey tool called the Net Promoter Score, member associations were able to use the results to directly improve service provision. For example, in the Dominican Republic, clients identified long wait times as an area of concern and potential barrier to access, so Profamilia revised its patient flow procedures and reduced the wait times. In Guatemala and Honduras, clinic directors identified services in which fewer clients reported receiving ZIKV-related information and then facilitated additional provider trainings and support to ensure more clients received this critical information. Insisting that clients are always at the center of the intervention and their feedback is not just heard but acted upon improves experiences, encouraging increased health-seeking behaviors.

Response: CZS Screening, Care, and Support Services

A third phase of work focused on addressing the needs of children and families affected by ZIKV and CZS. Significant gaps exist in public health systems across Latin America and the Caribbean for services for people living with disabilities, CZS included. Research has shown that response to treatment in infants affected by CZS is dependent on not only the severity of their complications but also how early they access treatment and essential therapies.[17] It was therefore critical that each member association also integrate ZIKV and CZS to the extent possible within its available postnatal and child wellness services.

Working closely with ASSIST, project teams in El Salvador and Honduras incorporated CZS-specific information into service provider guidelines for postnatal and early well-child health check-ups, with the aim of detecting delays and

deficits that are not always apparent at birth and might only appear later, as children fail to meet standard developmental markers. These screenings provided an opportunity to detect possible cases and to encourage positive health-seeking behavior during and after the outbreak. In Guatemala, the team hired 2 psychologists to work with infants and address the psychosocial needs of mothers and families affected by CZS, conducting routine home visits to help reach remote, rural households who otherwise struggled to access care. These personnel provided essential assessment and referral capacity to existing though limited therapeutic services through regular monitoring and early well-child health follow-ups.

Challenges

Service gaps and disability stigma. With critical gaps in public health systems across the region and limited existing referral pathways, the IPPF member associations struggled to link families to a full range of essential resources and services such as therapy and rehabilitation centers. Disability stigma also had an impact on parents and families bringing their infants for treatment and support services, particularly those with microcephaly and other visible CZS outcomes. Some member associations reported cases of parents who would obscure their baby's heads with hats during checkups in an effort to avoid detection and diagnosis, underscoring the need to bring psychosocial support to caregivers and destigmatizing IEC efforts to wider communities.

Lessons and Recommendations

Adopting broad, multidisciplinary approaches to reach at-risk populations. One way to simultaneously fill such gaps, tackle stigma, and reach especially vulnerable populations is to expand this work in a multidisciplinary manner across mixed health systems by partnering with organizations that can provide necessary but missing expertise, access, or coverage. For example, in Guatemala, APROFAM forged partnerships early in the project with local disability rights and services organizations to ensure incorporation of their specialist expertise and input throughout the design and delivery of the response. By partnering with these organizations and taking a holistic approach to the entire life cycle of SRH care that included early child wellness, the member association was able to reach more women and families with infants affected by CZS and other disabilities. Acknowledging systemic gaps in capacity early and engaging in partnerships with disability-focused organizations and other specialists will over time and with continued advocacy help to foster the growth of necessary support mechanisms. This will also help to center the voices and experiences of groups that traditionally experience high levels of stigma or discrimination as stakeholders and active participants within a given intervention, and not just as external beneficiaries.

Similarly, in Honduras, ASHONPLAFA worked to establish ties to local Afro-Caribbean Garifuna populations, bringing culturally sensitive mobile outreach to distant communities, and translated ZIKV-integrated SRH IEC messages to radio stations in the local language. In a humanitarian context, working collaboratively in multidisciplinary partnerships can help leverage limited resources and ensure the broadest, fastest, most inclusive possible reach of programmatic interventions.

More generally, incorporating a broad health systems strengthening approach to ensure all populations affected by a given public health challenge are reached with appropriate interventions may also be required. While the early stages of the project (Phases 1 and 2) focused primarily on integrating ZIKV prevention and support within existing SRH services, Phase 3 of the project saw IPPF member associations expand support within the primary health care setting to reach families and children at various points across the health system. The specific nature of the ZIKV and its consequences and relevance to SRH care as well as child health care necessarily required adaptations across health systems. NGOs and donors alike have a responsibility to consider and promote these cross-cutting adaptations wherever possible.

Stigma around disability prevented some parents of infants with microcephaly or other visible effects of Zika from bringing their infants for treatment and support services.

CONCLUSION

The ZIKV outbreak in Latin America and the Caribbean posed a new public health threat to the region and globally. The scale of the epidemic, limited disease knowledge at the outset, and the constantly evolving context presented challenges that had to be overcome with adaptive and innovative approaches. It also exposed existing gaps and weaknesses in local and national health systems.

The international community, governments, and public health actors at all levels must recognize the ongoing threat that ZIKV continues to pose globally. Globalized travel, environmental factors including climate change that increases

the range of disease vectors, increasingly variable rainy seasons and flooding that create exponential increases in levels of standing water and mosquito hatches, and the vast quantity of information that is still unknown about the virus' pathology mean future outbreaks are highly possible. It is worth noting that the same climate change-caused flooding that is projected to result in 250,000 additional deaths per year between 2030 and 2050 from malaria and other causes[18] could also result in both more frequent and more widespread ZIKV outbreaks. Reponses to such emergencies should be designed in a manner that affirms the sexual and reproductive health and rights of women and girls, acknowledging the specific contexts in which such outbreaks occur including existing barriers to health, who is most at risk, and who bears the burden of preventing negative outcomes. Working in partnership across multidisciplinary public, private, and nonprofit sector divisions will facilitate expanded intervention coverage and ensure expanded inclusivity, particularly of vulnerable populations.

Finally, all humanitarian emergencies that affect people's ability to enjoy the full range of sexual and reproductive health and rights should be addressed as such, whether through an independent effort or as part of a more comprehensive approach. A successful response to another, future ZIKV outbreak or similar public health threat—or any humanitarian or emergency situation—will recognize this and leverage the need for urgent action as a catalyst of change around more inclusive social norms and services.

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En español

Integración rápida de la prevención del virus del Zika en los servicios de salud sexual y reproductiva y más allá de estos: lecciones programáticas desde América Latina y El Caribe

Durante el brote del virus del Zika, en 2015-2016, los proveedores de las Asociaciones Miembro llegaron a clientes y a poblaciones afectadas con mayor rapidez al integrar información y servicios fundamentales dentro de las plataformas existentes de salud sexual y reproductiva. Algunos de los desafíos fueron: (1) comunicar rápidamente la evidencia cambiante a los proveedores; (2) superar las normas sociales restrictivas sobre el género y la sexualidad, y la relativa falta de mensajes públicos para prevenir la transmisión sexual; y (3) abordar el estigma por discapacidad y cerrar las brechas de servicios para apoyar a los niños y niñas y a personas a cargo de su cuidado, afectadas por el síndrome congénito del Zika.

RESUMEN

La emergencia del virus del Zika (VZIK) en América Latina y el Caribe durante el brote de 2015-2016 requirió que los sistemas locales de salud se adaptaran, de manera abrupta y continua. Este informe de acción de campo explora las complejidades del brote en materia de salud sexual y reproductiva (SSR) y la experiencia de la Federación Internacional de Planificación Familiar (IPPF) y 4 de sus Asociaciones Miembro, que formaron parte de respuesta rápida de la Agencia de los Estados Unidos para el Desarrollo Internacional en la región. Describe los enfoques y las acciones que siguieron la IPPF y sus Asociaciones Miembro durante tres fases programáticas amplias –elaborar protocolos sobre el VZIK y capacitar al personal; prestar servicios e información integrados al VZIK; y proveer servicios de detección, atención y apoyo a los niños y las familias afectadas por el síndrome congénito del Zika (SCZ) –puesto que el proyecto trabajó para integrar la prevención, la detección y la respuesta al VZIK dentro de los modelos de prestación de servicios de SSR. También describe los desafíos y las lecciones aprendidas en la implementación de un programa de respuesta al VZIK en la región y recomendaciones, desde una perspectiva de prestación de servicios, que pueden ser útiles para nutrir las respuestas ante epidemias de inicio rápido con relevancia para la SSR en la región. Los retos identificados abarcan una base de evidencias rápidamente cambiante durante las primeras etapas de la epidemia; las normas sociales tradicionales y restrictivas sobre género, sexo y sexualidad en la región; la falta de énfasis en la transmisión sexual del VZIK en los mensajes de salud pública; y la falta de servicios, apoyo gubernamental y rutas de derivaciones (referencias) para apoyar a los niños y a las familias afectadas por SCZ. Algunas de las recomendaciones esenciales incluyen encontrar alternativas para compartir de manera rápida y frecuente actualizaciones clínicas que están en constante cambio –por ejemplo, a través de tecnologías y plataformas digitales-; generar alianzas con organizaciones multidisciplinarias que puedan llenar los vacíos de servicios requeridos, como por ejemplo, las organizaciones de derechos y servicios para las personas con discapacidad; y aprovechar la necesidad de acciones urgentes que catalicen el cambio en materia de normas sociales y servicios más incluyentes y transformadores de género.

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FIELD ACTION REPORT

VECTOS: An Integrated System for Monitoring Risk Factors Associated With Urban Arbovirus Transmission

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To strengthen local surveillance of mosquito-borne viral diseases such as dengue and Zika, a multidisciplinary team developed an integrated web-based information system called VECTOS that captures geo-referenced entomological, epidemiological, and social data. The system has revealed previously unidentified features, such as specific neighborhoods, at persistently high risk.

Resumen en español al final del artículo.

ABSTRACT

In Colombia, as in many Latin American countries, decision making and development of effective strategies for vector control of urban diseases such as dengue, Zika, and chikungunya is challenging for local health authorities. The heterogeneity of transmission in urban areas requires an efficient risk-based allocation of resources to control measures. With the objective of strengthening the capacity of local surveillance systems to identify variables that favor urban arboviral transmission, a multidisciplinary research team collaborated with the local Secretary of Health officials of 3 municipalities in Colombia (Giron, Yopal, and Buga), in the design of an integrated information system called VECTOS from 2015 to 2018. Information and communication technologies were used to develop 2 mobile applications to capture entomological and social information, as well as a web-based system for the collection, geo-referencing, and integrated information analysis using free geospatial software. This system facilitates the capture and analysis of epidemiological information from the Colombian national surveillance system (SIVIGILA), periodic entomological surveys—mosquito larvae and pupae in premises and peridomestic breeding sites—and surveys of knowledge, attitudes, and practices (KAP) in a spatial and temporal context at the neighborhood level. The data collected in VECTOS are mapped and visualized in graphical reports. The system enables real-time monitoring of weekly epidemiological indicators, entomological indices, and social surveys. Additionally, the system enables risk stratification of neighborhoods, using selected epidemiological, entomological, demographic, and environmental variables. This article describes the VECTOS system and the lessons learned during its development and use. The joint analysis of epidemiological and entomological data within a geographic information system in VECTOS gives better insight to the routinely collected data and identifies the heterogeneity of risk factors between neighborhoods. We expect the system to continue to strengthen vector control programs in evidence-based decision making and in the design and enhanced follow-up of vector control strategies.

INTRODUCTION

Aedes (Stegomyia) aegypti and *Ae. albopictus* mosquitoes transmit viruses including dengue, chikungunya, and Zika, principally in urban environments where there is a concentration of larval habitats, especially artificial water containers, and an abundance of human hosts within the relatively short flight range of the *Aedes* vectors.[1] Dengue is considered to be the most important arbovirus, with an estimated 390 million infections per year, of which 96 million are symptomatic[2] and around 24,000 are fatal.[3] Chikungunya and Zika were introduced to the Americas in 2014 and 2015, respectively, resulting in outbreaks that affected most countries in the region.[4,5] Other arboviruses, such as yellow fever, Mayaro, and Oropouche are emergent or re-emergent health threats.[4,6]

Prevention and control of these diseases focus largely on the vector. However, vector control is often reactive

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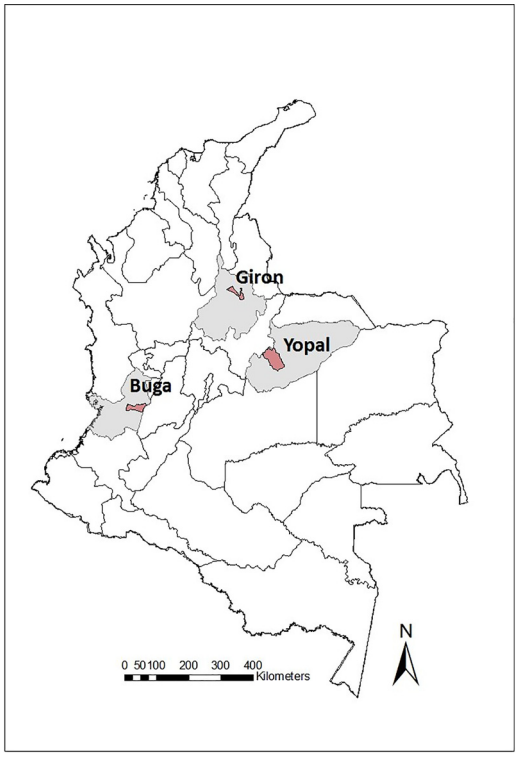
and largely relies on insecticides, which are expensive and decreasingly effective due to resistance.[7] Additionally, the complexity and granularity of urban areas requires a better understanding of local risk factors to focus vector control actions.[8–12] Factors associated with transmission include sociodemographic characteristics, household conditions, proximity among houses, water supply, solid waste, drainage systems, and lack of knowledge of the disease.[12–14] The adult mosquitoes tend to bite during the day, their flight is often facilitated by open unscreened doors and windows, and they frequently find ample wet containers to lay their eggs. The use of new tools to capture detailed information on risk factors and to analyze data in real time could strengthen surveillance and monitoring systems by informing local vector control and educational programs, including early outbreak actions.[15–18]

The development of tools based on geographic information systems (GIS) and information and communication technologies lowers barriers to multivariable analysis and identification of spatial and environmental patterns of transmission risk. These analyses have been shown to contribute to the design of targeted strategies with public health impact.[19–21] Some countries—including Brazil,[22] Argentina,[23] Mexico,[24] and Sri Lanka[25,26]—have developed technological strategies for the evaluation of indicators of transmission risk. Most of these systems are designed mainly to collect information at the municipality level and not at a granular scale, such as the neighborhood, which is important for dengue due to the short flight range of the *Aedes* vectors.[27]

In Colombia and most other Latin American countries (exceptions being Brazil and Mexico), local evidence-based decision making is limited and delayed by paper-based data collection and non-automated data analysis at a coarse level (municipality). In Colombia, no technological tools are officially in use yet, although some initiatives are beginning to be developed to collect the information to carry out real-time analysis over space and time in order to produce integrated analyses of available surveillance information.

Here we describe the lessons learned from the development of the integrated web-based (online) information system called VECTOS, which we developed following Colombia's national surveillance guidelines. The main goal is to empower local health officials to monitor risk factors for the transmission of urban arboviruses, and hence facilitate design and evaluation of focused evidence-based strategies for their prevention and control.

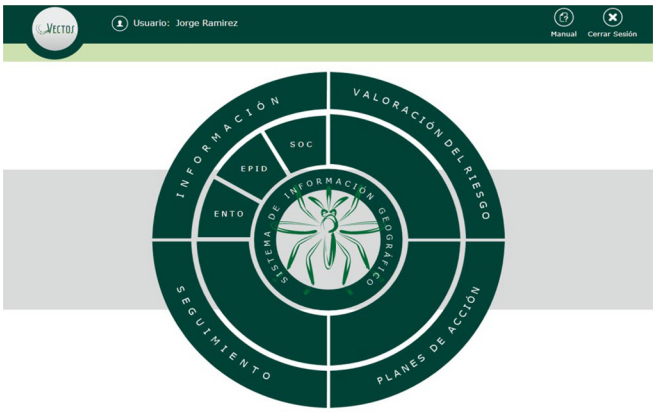
FIGURE 1. Departments (gray) and Municipalities (red) in Colombia participating in the Study, 2015–2018



PROGRAM DESCRIPTION

The VECTOS information system was developed, from 2015 to 2018, by a team of researchers (epidemiologists, entomologists, anthropologists, and systems engineers) working together with the officials of the Municipal Health Secretariat (health professionals and technicians) of Casanare, Santander, and Valle del Cauca. One municipality in each of 3 departments (states) of Colombia that participated in the project was selected: Yopal in Casanare, Giron in Santander, and Buga in Valle del Cauca (Figure 1). These municipalities are of medium size (100,000 to 150,000 inhabitants) and similar in terms of dengue incidence (336–587 cases per 100,000 habitants per year),[28] health care, and access systems. Each has an epidemiologist or statistician, and a vector-borne disease program (in Spanish *Enfermedades Transmitidas por Vectores* or ETV), with a coordinator and a relatively stable team of 5 to 10 technicians.

FIGURE 2. The Initial VECTOS Menu ("Splash Screen") Options



From top left: *Información* (Information) leads to data visualization and analysis of entomological (*Ento*), epidemiological (*Epid*), or sociological (*Soc*) data. *Valoración del riesgo* (Risk assessment) allows the user to create and visualize risk maps. *Planes de acción* (Action plans) allows the user to organize and schedule field activities. *Seguimiento* (Follow-up) allows the user to monitor progress on the action plans. In the center: *Sistema de información geográfica* (Geographic information system) shows the geo-referenced raw data.

The design of the VECTOS web system was based on the characterization of routine data collection and analysis by the Municipal Health Secretariat and the Colombian national guidance on epidemiology and entomology. These data were analyzed based on city maps and demographic information. Different stakeholders were contacted for information on patient data collection, analysis, and procedures and to share these data with other governmental entities. Based on group analysis and literature, a set of variables from patient and entomological information was used to create the preliminary web system and the reports to facilitate analysis. Improvements to the algorithms for geo-referencing the data, to the analysis report pages, and to the web interface were made throughout the study. The final purpose of the web system was to have a user-friendly spatial tool to gather and analyze data that would meet user needs in real time. This allowed the use of historic epidemiological data already computerized and the creation of mobile applications to gather entomological and social data.

VECTOS was developed to use this routinely collected information, hence avoiding a redundant parallel system and creating additional burden on local staff. Although VECTOS is scalable to other municipalities, the following information describes its products to date.

The VECTOS Integrated Model Structure

VECTOS captures epidemiological, entomological, and social data at the neighborhood level, which can be aggregated by commune (*comuna*) administrative division or sector. It is a web-based information system with a service-oriented architecture that offers robustness in terms of stability and security access and flexibility when interacting with other systems. It was developed in Microsoft Silverlight 5.0 in the C programming language. It has 3 interacting layers. First, the graphical interface or presentation layer is the front-facing system with which the user interacts (Figure 2). The second layer contains the business logic that establishes the rules to be fulfilled. Finally, the data access layer interacts with the database and delivers the data to the business logic layer.

Global Architecture

The system is made up of the following 3 components, listed in increasing level of user interaction.

- **Database management system:** This component contains the main database, configurations, and administrative tools, and ensures traceability.
- **Web application:** This is an application program that is stored on a remote server and delivered over the Internet through a browser interface. This fulfills clients' requests via visualization on browsers (e.g., Internet Explorer, Mozilla Firefox), and communicates with the database to obtain data for items such as analysis, models, and reports.
- **Clients:** These consisted of the terminals, computers, or devices with web browsers that support Hypertext Markup Language (HTML) and active content from the web application.

Administration Module

Specified users can perform actions in the administration module, such as configuring the system, creating users, and assigning roles and access privileges (for example, ability to run analyses and export data vs. to only visualize reports). These configurations define a security scheme based on the use of roles for navigation within the system.

Geographical Display

VECTOS presents geographical data in layers of: (1) political-administrative division; (2) epidemiological, entomological, and social data; and (3) risk

stratification. Maps of neighborhoods were created by digitizing physical maps using QGIS 2.18.3, an open-source geographic information software, and validating the maps with a municipal planning secretariat official. These maps, as well as their aggregates at the *Comuna* (sector) level, were plotted using Google Street Map as a base.

Field Data Collection

We developed 2 mobile applications ("apps") to capture entomological and social data in the field, called Mosquitos and VECTOS Social, respectively.

- **Mosquitos app:** This app was developed for Android 4.4.2 Gingerbread for compatibility with low-cost devices and hence increased accessibility. It was developed and tested in collaboration with field technicians to ensure its acceptability.
- **VECTOS Social app:** This captures sociodemographic data including surveys of knowledge, attitudes, and practices (KAP) regarding dengue and its control, using a questionnaire developed by an anthropologist. The app was developed for Android 4.4 Xapp.

The 2 mobile applications capture entomological and social data in the field to transmit in real time to VECTOS server, including automatic geo-location, via hypertext transfer protocol (http). In case of network failure, the data are stored and synchronized when mobile phone or Wi-Fi connectivity is restored. Both apps are available in Google Play Store, but they currently require authorization to connect to data in the web system.

Data Acquisition and Reports

Demography

Neighborhood population size was obtained from the Secretary of Municipal Planning where possible. Otherwise, it was estimated as the number of premises with a water distribution point registered with the water supply company in that neighborhood, multiplied by a factor of 5 people per premise, based on data from the entomological surveys. Other sources, such as community organizations, were also consulted. In the case of recent unplanned developments without registered water supply, we consulted the Colombian Identification System for Potential Beneficiaries of Social Programs.

Epidemiology

Epidemiological data are collected weekly by local health institutions (known as the Primary Data Generating Unit) and reported to the Colombia National System of Public Health Surveillance (Sistema Nacional de Vigilancia en Salud Pública – SIVIGILA). From the multiple variables collected by SIVIGILA, and with previous agreement with the local Secretary of Health officials, we selected key variables to be incorporated in VECTOS for epidemiological analysis such as identification of epidemiological patterns of arboviral cases, early detection of outbreaks, stratification of transmission risk at the neighborhood level, as well as for monitoring adherence to protocols and surveillance processes in health care institutions.

SIVIGILA variables captured by VECTOS can be grouped into 3 categories:

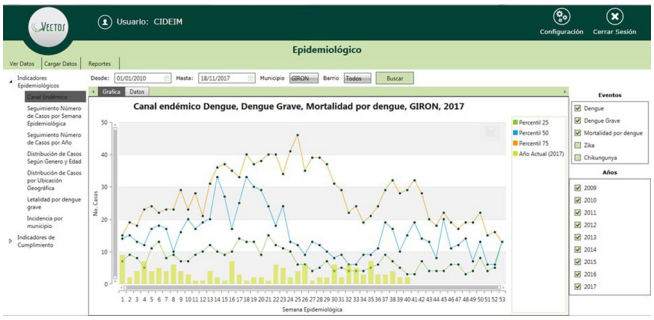
1. Basic event (disease) characterization, for example, illness event code, occurrence and reporting date, epidemiological week, name of the Primary Data Generating Unit and municipality reporting the case, and neighborhood, area, sector, municipality, and department of origin of the event
2. Patient demographics, such as age, gender, pregnancy status, residential address, neighborhood, area, sector, and municipality of residence
3. Clinical case features, management, and outcomes, such as date of consultation, date of onset of symptoms, initial and final classification of the case, hospital management of the patient, lab tests and results, and patient's final condition and case report updates

VECTOS captures information from health institutions about disease characterization, patient demographics, and clinical case features, management, and outcomes.

Two mobile applications capture entomological and social data in the field to transmit to VECTOS.

The VECTOS algorithm follows the routine clerical process of the local health secretariats. Weekly reports of 5 notifiable events (dengue, severe dengue, dengue mortality, Zika, and chikungunya) since 2008 have been uploaded to VECTOS. Reported cases represent symptomatic patients who consult at health care centers. Dengue cases are usually classified initially as probable, pending laboratory results. For Zika and chikungunya, cases are usually classified as suspected or confirmed based on clinical diagnosis. The VECTOS system can receive uploads containing the cumulative cases reported to SIVIGILA during the year, in order to reflect possible updates to case status based on lab results. These uploads are currently done manually in the form of Microsoft Excel reports generated by SIVIGILA. This could potentially be automated in the future

FIGURE 3. VECTOS Graphical Report of Epidemiological Indicators



This example shows actual data from the municipality of Giron in 2017. More specifically, the dengue endemic channel is indicated by the lines, which are percentiles of case numbers, from January 1, 2010, to November 18, 2016. Bars show the contemporaneous data for 2017.

VECTOS includes an algorithm that cross-references reported cases with their residential address, which was achieved for 84% of cases.

should national-level approval be obtained to link the systems.

Additionally, to locate each reported case at the neighborhood and sector level for spatial and temporal analysis, another algorithm was developed to geo-reference the cases' residential addresses (although this is not necessarily the locus of transmission). This algorithm was designed to cope with misspellings and abbreviations in the address and neighborhood fields. It was designed to learn from accumulating data and so improve over time. The system attempts to locate each address within the GIS polygon of the corresponding neighborhood, and this was achieved for approximately 84% of the cases.

Standard epidemiological indicators are included, such as endemic channel (i.e., the expected normal seasonal range)[29]; number of cases per week and year; distribution of cases by gender, age, and geographic location; fatality rate; and incidence by municipality and neighborhood. Graphical epidemiological reports of spatial and temporal analyses can be carried out automatically for a specified time period, municipality, neighborhood, or event (Figure 3). These reports were designed to effectively convey the local epidemiological situation and facilitate decision making. At the request of the local Secretary of Health, in order to monitor the processes of surveillance and patient care, additional indicators have been included, such as hospitalization rates and the classification of cases as suspected, probable, or confirmed.

Entomology

A household survey of potential *Aedes* larval habitats, using the Mosquitos app, was developed based on Colombian surveillance guidelines.[30] This survey, carried out by the field ETV technicians, collects the following information: (1) type of larval habitat (i.e., type of container, such as high rooftop water storage tanks, low [ground-level] water storage tanks in wash or laundry basins, water storage containers, tires, flower pots and vases, bottles or cans, natural breeding sites, small miscellaneous [<500 ml] and large miscellaneous [>500 ml] containers); (2) presence of immature stages of *Aedes spp*; (3) number of *Aedes* pupae; (4) presence of *Culex* larvae; (5) some household demographic information; and (6) the state of sewage and trash collection services. The app also collects information on potential breeding sites in public areas—such as catch basins (roadside storm drains), stormwater runoff channels, and waste disposal—to identify potential peridomestic larval habitats. In order for the pupae count to be operationally feasible, it was agreed with the technicians to count up to 30 pupae and thereafter give an approximate calculation.

All the *Stegomyia* indices (house index, Breteau index, container index) and the pupae per person index can be calculated from these data.[31] Additionally, a classification of potential breeding sites, positivity for larvae/pupae, and pupae productivity is calculated. This information can be presented graphically by time period, neighborhood, and sector.

Social

A KAP survey was developed and carried out within the context of the project. The instrument consisted of 76 questions, divided into the following blocks: (1) identification and sociodemographic characteristics; (2) characteristics of the home, access to services, and water use; (3) knowledge, attitudes, and practices about dengue; and (4) forms of community organization and access to information. The survey was carried out by the ETV technicians from each of the municipalities. Approximately 400 interviews were carried out per municipality trying to cover most of the neighborhoods of each city. A descriptive analysis, in the form of the proportions of participants who responded for each category for each question, was carried out and compared between the participating municipalities. The survey was approved by the Ethical Review Board of the

International Center for Medical Research and Training (*Centro Internacional de Entrenamiento e Investigaciones Medicas*, or CIDEIM).

Risk Stratification

Dengue indicators are constructed based on variables that are first standardized to mean zero and standard deviation 1 (z scores), then summed to give the following 4 components: (1) epidemiology, which includes cumulative incidence, percentage of cases that were severe, and number of months with 5 or more cases; (2) entomology, which includes the Breteau and pupae/person indices; (3) environment, which includes the number of containers per thousand population; and (4) demography, which includes population density and the number of sites of high concentration of people (e.g., schools, malls, churches). The sites are chosen to reflect mostly daytime activity, which is when the *Aedes* vectors prefer to feed.

For each component, all the values of the standardized variables by neighborhood were summed (with equal weights) and then this sum was divided by the number of variables of each component. Finally, the 4 values, 1 for each component, are summed to obtain a final value for each neighborhood. The results are visualized as quintiles for a given time period, municipality, and event.

Action Plans and Follow-Up

This module supports planning activities and suggests priority neighborhoods for 2 scenarios—endemic and outbreak. The scenarios are defined according to whether the number of cases reported during the previous 3 weeks in the municipality was over the 50th percentile of the endemic channel. The software alerts secretariat officials when neighborhoods have a higher rate of disease transmission, in order to facilitate action plans, without excluding actions for other neighborhoods. The software allows for planning activities by neighborhood and following their development. No automatic alerts have yet been created for the system.

Ethical Statement

The study protocol and surveys was approved by the CIDEIM Ethical Review Board for studies involving human subjects and conducted in accordance with national and international regulations and standards for research involving human participants.

OBSERVATIONS, EXPERIENCES, AND LESSONS LEARNED

VECTOS identified differences by neighborhood in the main mosquito breeding sites and their pupal productivity (data not shown). In particular, findings showed that many neighborhoods in the 3 municipalities are at low risk of mosquito-borne disease transmission, in terms of the Breteau index (number of positive containers per 100 houses) of less than 4 positive containers per 100 houses, or even free of larval breeding sites (Breteau index=0), suggesting responsiveness of their populations to public health messages (Figure 4).

During the risk stratification analysis, when we did the epidemiological analyses in the 3 municipalities, for 2008–2016, we observed that some neighborhoods were consistently at high risk during this period, particularly in Giron (Figure 5). When we compare the epidemiological and entomological stratification from Giron, some neighborhoods with consistently higher risk showed a lack of obvious association between the epidemiological component and the entomological component (in premises) (Figure 6A and Figure 6B). These results from Giron prompted a search for other larval breeding sites outside the domestic area, which detected, for the first time in this municipality, high levels of *Aedes spp* larvae in catch basins (storm drains) hidden under sidewalks. These catch basins were part of the town's old drainage system, and were only present in the neighborhoods with persistently high epidemiological risk (Figure 6C). On the basis of these results, Giron's vector control personnel applied larvicides twice per month, from May 2016 to date. Our stratification analyses showed that larval control of these catch basins notably changed the epidemiological risk patterns of this municipality (Figure 5, year 2017).

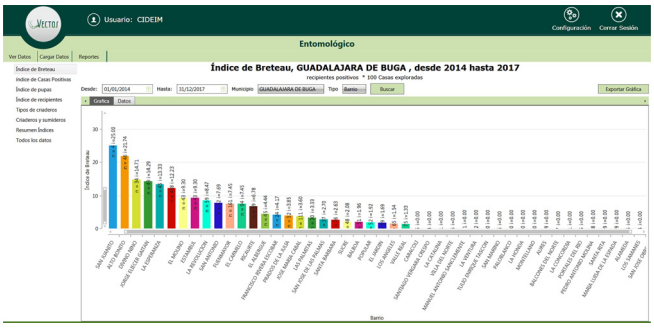
VECTOS identified, for the first time, high levels of larval breeding sites in catch basins below sidewalks in Giron.

A different situation was observed in Buga, where high variation by year in neighborhood-level risk was observed (Figure 5). In Buga, few neighborhoods had entomological risk (Breteau index of more than 4) (Figure 4). However, as we previously reported, almost the entire city can be affected by the presence of positive catch basins (Figure 7, red stars), although control measures are available.[13]

The software alerts secretariat officials when neighborhoods have a higher rate of disease transmission in order to facilitate action plans.

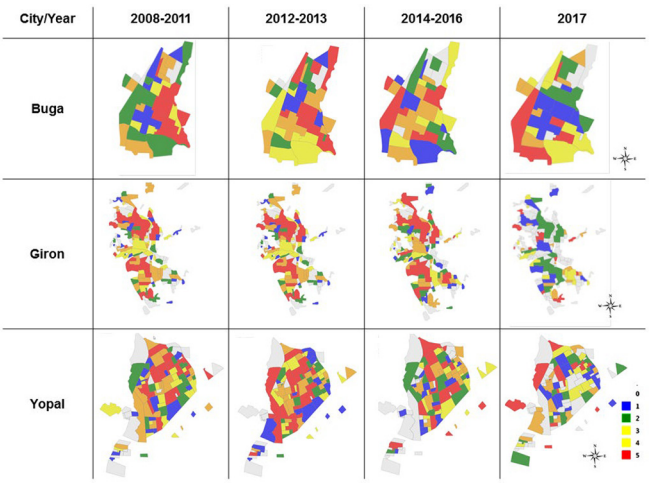
In the social component, surveys were conducted in Buga (372 homes), Giron (437 homes), and Yopal (431 homes) municipalities. The detailed findings will be reported separately. Residents of the 3 municipalities tended to agree that dengue is transmitted by mosquitoes (ranging from 81% to 87%), which bite throughout the day

FIGURE 4. VECTOS Graphical Output of Entomological Breteau Index[a] for Each Neighborhood in Buga, Colombia, January 1, 2014–December 31, 2017



[a]Number of positive containers per 100 houses.

FIGURE 5. Trends in the Quintiles of the Dengue Epidemiological Risk Component in Buga, Giron, and Yopal, Colombia, 2008–2017



Maps of quintiles of risk stratification, with 1 (blue) being the lowest and 5 (red) being the highest. 0 indicates missing data.

(41% to 54%), and whose reproduction is associated with water (85% to 93%). In terms of disease, the most frequently mentioned symptoms were fever, malaise, and joint pain, usually in that order. However, a proportion of people associated dengue with the common cold and with direct interpersonal transmission (1% to 6%). Interestingly, 12% of residents of Buga and Giron and 4% of residents in Yopal associated the presence of mosquitoes with poor hygiene. Buga was the municipality with the lowest Breteau index per neighborhood (Figure 4). Across the municipalities, few people identified the elimination of larval habitats as a control option (14% to 15%). Insecticide application was the most frequently identified option (58% to 70%), followed by the use of fans to avoid mosquito bites (23% to 43%). The numbers per neighborhood were not sufficient for robust analysis at this level.

These results confirm that risk stratification at the neighborhood level varies between and within cities. Analysis at this scale enabled us to identify neighborhoods with higher epidemiological risk that were persistent in time, as in Giron, and compare this risk with the entomological risk using standard larval indices in houses. This confirmed that cryptic larval habitats were influencing transmission. This is consistent with the paradigm proposed by the DENTARGET network, that such heterogeneity should be recognized in the design of focal dengue control campaigns.[10] The observed risk stratification demonstrated the importance of a better joint understanding of entomological risk factors and epidemiological patterns.

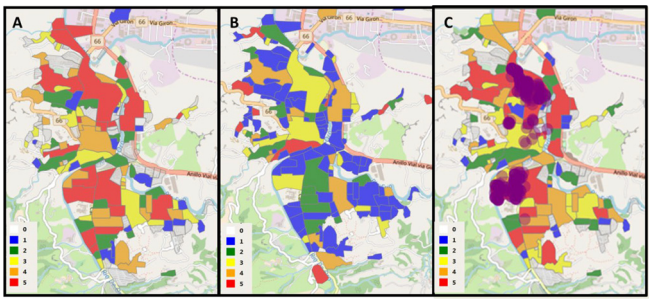
The integration of information led stakeholders to recognize the importance of improving primary data for decision making. For the epidemiological component, some health care institutions realized the importance of the primary case data for decision making, and an improvement was observed in the completeness and quality of these data, in terms of more complete case reporting, for example, in recording of residential addresses. For the entomological component, the Mosquitos app was developed in consultation with the technicians, which enabled it to facilitate field data collection and analysis, rather than being a technological hurdle. Moreover, analysis of the entomological data confirmed the technicians' personal assessments and enhanced their managers' appreciation of their work. More active participation among stakeholders resulted in a larger sample size and more comprehensive and accurate information. In particular, it enabled us to increase the sample size—from approximately 100 to 1,500 houses per survey per municipality—and hence achieve more comprehensive and accurate information. Unfortunately, other important entomological surveys, such as adult index (mosquitoes per house or area), are not among the activities carried out by the ETV technicians, which would improve entomological analysis and identification of cryptic breeding sites.

The social app (VECTOS Social) was implemented by the technicians who were already familiar with Mosquitos app. The major limitation was the length of each interview (approximately 20 minutes), but we are working to prioritize the most relevant questions for future surveys. We expect that the design of vector control strategies will also benefit from analyses of the social component since this will facilitate the design of more educationally oriented campaigns with better communication strategies. There were few technical limitations in terms of telecommunications, due to generally good wireless data service in the cities. Only a few peripheral locations had sporadic connections, but the apps were designed to cope with this.

However, there are still limitations to be addressed in terms of routine application of the system. These limitations include infrequent updating of municipal planning information in terms of neighborhood definitions and numbers of inhabitants; an unclear legal process required for the national heath entities (Colombian Ministry of Health and Social Protection and National Institute of Health) to authorize technological tools to capture official information; lack of knowledge and use of the software components among officials; and inadequate primary data collection in terms of frequency, sample size, and design of vector control strategies based on the analyses.

The development of VECTOS and the inclusion of epidemiological data from 2008 to 2017 and entomological and social information collected via apps revealed risk patterns not previously identified by the municipalities. In particular, we were able to identify neighborhoods at persistently high epidemiological risk, especially for the municipality of Giron (Figure 6). Such patterns were not readily discernible from previous routine activities.

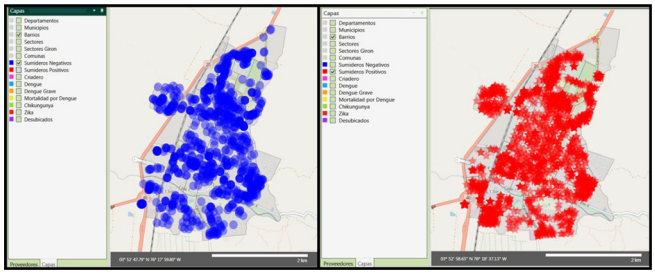
FIGURE 6. Epidemiological (A) and Entomological (B) Dengue Risk Maps and (C) Location of Positive Catch Basins[a] in Giron Neighborhoods, Colombia, January 1, 2014–December 31, 2016



[a]Indicated by purple dots over the epidemiological risk map.

Risk stratification in the maps is classified in quintiles, with 1 (blue) being the lowest risk and 5 (red) being the highest, during the observed period. 0 (white) indicates missing data.

FIGURE 7. Location of Catch Basins Surveyed in Buga, Colombia, September 2017



Negative catch basins (*Sumideros Negativos*) indicated by blue dots and positive catch basins (*Sumideros Positivos*) indicated by red stars.

CONCLUSION

Despite the limitations of the routinely collected data, their integration into the VECTOS system, including improvements to the data collection procedures, resulted in improved decision-making. Further improvements to data collection and analysis, and presenting the findings in a timely and interpretable fashion, will yield additional benefits to decision makers. Identification of risks in the 3 municipalities enabled us to identify neighborhoods with higher transmission risk that require focal intervention. The current version of VECTOS yields basic indicators over time and space, but future versions could collect additional variables and be linked to mathematical modeling to derive, for example, early warnings of increased transmission, alerts of increased risk of severe illness due to changing serotype profile, and mosquito abundance thresholds for transmission. VECTOS was developed in participation with municipalities from different regions of Colombia with different cultural features, and we expect that this breadth of experience will further strengthen the vector control programs' ability to make evidence-based decisions, and that the lessons learned will be more easily shared across regions.

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En español

VECTOS: Un Sistema Integrado para el Monitoreo de los Factores De Riesgo Asociados a la Transmisión de Arbovirosis Urbanas

Con el propósito de fortalecer la vigilancia local de las enfermedades virales transmitidas por mosquitos como el dengue y Zika, un equipo multidisciplinario desarrolló un sistema web de información llamado VECTOS que captura datos entomológicos, epidemiológicos y sociales georeferenciados. El sistema ha revelado características no identificadas previamente, como vecindarios específicos con un riesgo persistentemente alto.

RESUMEN

En Colombia, como en muchos países latinoamericanos, la toma de decisiones y el desarrollo de estrategias efectivas para el control de vectores de enfermedades urbanas como el dengue, el Zika y el chikungunya son un desafío para las autoridades locales de salud. La heterogeneidad de la transmisión en las zonas urbanas requiere una asignación eficiente de recursos para implementar las medidas de control basadas en el riesgo. Con el objetivo de fortalecer la capacidad de los sistemas locales de vigilancia para identificar variables que favorecen la transmisión arboviral urbana, un equipo de investigación multidisciplinario colaboró con los funcionarios locales de la Secretaría de Salud de 3 municipios de Colombia (Girón, Yopal y Buga) en el diseño de un sistema de información integrado llamado VECTOS del 2015 al 2018. Tecnologías de información y comunicación se utilizaron para desarrollar 2 aplicaciones móviles para capturar información entomológica y social, así como un sistema basado en la web para la recopilación, la referenciación geográfica y el análisis integrado de la información utilizando softwares geoespacial gratuitos. Este sistema facilita la captura y el análisis de la información epidemiológica del sistema de vigilancia nacional colombiano (SIVIGILA), las encuestas entomológicas periódicas (larvas y pupas de mosquitos en los predios y los sitios de reproducción peridomésticos), y las encuestas de conocimientos, actitudes y prácticas (CAP) en un espacio y contexto temporal a nivel de vecindario. Los datos recopilados en VECTOS se mapean y visualizan en informes gráficos. El sistema permite el monitoreo en tiempo real de indicadores epidemiológicos semanales, índices entomológicos y encuestas sociales. Además, el sistema permite la estratificación de riesgo de los vecindarios, utilizando variables epidemiológicas, entomológicas, demográficas y ambientales seleccionadas. Este artículo describe el sistema VECTOS y las lecciones aprendidas durante su desarrollo y uso. El análisis conjunto de los datos epidemiológicos y entomológicos dentro de un sistema de información geográfica en VECTOS ofrece una mejor comprensión de los datos recopilados de forma rutinaria e identifica la heterogeneidad de los factores de riesgo entre vecindarios. Esperamos que el sistema continúe fortaleciendo los programas de control de vectores en la toma de decisiones basadas en la evidencia y en el diseño y el seguimiento mejorado de las estrategias de control de vectores.

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FIELD ACTION REPORT

Incorporating Voluntary Medical Male Circumcision Into Traditional Circumcision Contexts: Experiences of a Local Consortium in Zimbabwe Collaborating With an Ethnic Group

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The successful collaboration resulted in a male circumcision camp where 98% of the 672 boys and men ages 10 and up chose voluntary medical male circumcision (VMMC) while traditional practices were respected. Such collaborations may improve patient safety and increase VMMC uptake in sub-Saharan Africa.

ABSTRACT

Employing voluntary medical male circumcision (VMMC) within traditional settings may increase patient safety and help scale up male circumcision efforts in sub-Saharan Africa. In Zimbabwe, the VaRemba are among the few ethnic groups that practice traditional male circumcision, often in suboptimal hygienic environments. ZAZIC, a local consortium, and the Zimbabwe Ministry of Health and Child Care (MoHCC) established a successful, culturally sensitive partnership with the VaRemba to provide safe, standardized male circumcision procedures and reduce adverse events (AEs) during traditional male circumcision initiation camps. The foundation for the VaRemba Camp Collaborative (VCC) was established over a 4-year period, between 2013 and 2017, with support from a wide group of stakeholders. Initially, ZAZIC supported VaRemba traditional male circumcisions by providing key commodities and transport to help ensure patient safety. Subsequently, 2 male VaRemba nurses were trained in VMMC according to national MoHCC guidelines to enable medical male circumcision within the camp. To increase awareness and uptake of VMMC at the upcoming August–September 2017 camp, ZAZIC then worked closely with a trained team of circumcised VaRemba men to create demand for VMMC. Non-VaRemba ZAZIC doctors were granted permission by VaRemba leaders to provide oversight of VMMC procedures and postoperative treatment for all moderate and severe AEs within the camp setting. Of 672 male camp residents ages 10 and older, 657 (98%) chose VMMC. Only 3 (0.5%) moderate infections occurred among VMMC clients; all were promptly treated and healed well. Although the successful collaboration required many years of investment to build trust with community leaders and members, it ultimately resulted in a successful model that paired traditional circumcision practices with modern VMMC, suggesting potential for replicability in other similar sub-Saharan African communities.

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BACKGROUND

Evidence suggests that offering voluntary medical male circumcision (VMMC) within traditional settings could facilitate safer outcomes for traditional circumcision practices and increase male circumcision coverage.[1–7] In Zimbabwe, the majority of people do not belong to ethnic groups that traditionally circumcise.[8] The few ethnic groups that do practice traditional male circumcision consist of the VaRemba tribe, a group of about 80,000[9] with ties to Judaism who are concentrated in the Mberengwa region of Midlands Province,[10] along with the Xhosa and Tshangani.[11]

Among the VaRemba, initiation camps are held every 1 to 2 years to complete the rites of passage from boyhood to manhood. In these camps, experienced traditional circumcisers typically perform male circumcision with the help of the community elders.[12] The initiation camp is traditionally held in the winter after the harvest season when the community can ensure enough food for the gathering. Winter season camps also coincide with school holidays, making the timing convenient for the many new school-age initiates. Although joining the camp is voluntary, adherence to tradition compels most boys and men to join. Some older VaRemba men in the villages join the camp because they have not yet been circumcised or, conversely, had been circumcised medically but wish to participate in other camp rituals. VaRemba work hard to preserve their cultural traditions and protect communal secrecy surrounding VaRemba initiation rites. Therefore, few additional details are known about the camp activities.

Although traditional male circumcision procedures are poorly documented in Zimbabwe and elsewhere, previous research has found that over one-third of males may experience adverse events (AEs) in traditional settings.[7] Lack of proper hygiene for both the procedure and the camp environment may contribute to increased AEs in these settings. Restriction of VaRemba camp attendance to only male members of the VaRemba tribe reduces documentation of these male circumcision procedures as well as identification, treatment, and verification of associated AEs.

ZAZIC is a consortium led by the University of Washington's International Training and Education Center for Health (I-TECH) and local implementing partners Zimbabwe Association of Church-Related Hospitals (ZACH) and Zimbabwe Community Health Intervention Research (ZiCHIRe) Project. The consortium receives support from the U.S President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Centers for Disease Control and Prevention (CDC) to implement a male circumcision program together with the Zimbabwe Ministry of Health and Child Care (MoHCC). ZAZIC completed nearly 200,000 male circumcision procedures from 2013 to 2017,[13] with a reported AE rate of 0.3%. Reported AEs may be moderate (requiring intervention or medication) or severe (requiring surgical intervention or hospitalization) in nature. Most of the AEs were infections among younger boys who are more likely to experience AEs than their older peers.[14]

ZAZIC aimed to facilitate and foster a win-win relationship between VaRemba and the MoHCC. The consortium aimed to maintain VaRemba traditional male circumcision ceremonies but with MoHCC-trained, VaRemba health care workers performing the actual male circumcision procedure, according to national male circumcision guidelines. Culturally appropriate education and mobilization efforts would facilitate success,[12,15] taking care to ensure active VaRemba participation and leadership at all stages of planning, implementation, and dissemination.[16–19] At the core, rather than demanding modern VMMC, this collaborative approach would promote cultural competency and sensitivity among MoHCC and ZAZIC partners[12] with the aim of forming a long-term, mutually beneficial partnership focused on future VMMC scale-up in the area. The resulting VaRemba Camp Collaborative (VCC) culminated from years of sensitization, communication, and relationship building. This article aims to provide details on the pathway to the VCC's ultimate success, along with data on uptake of VMMC, to encourage and inform similar partnerships in the future.

PROGRAM DESCRIPTION

Laying the Foundation

Working closely with the Provincial Medical Director, the District Administrator, and the Principal Cultural Heritage Officer, ZAZIC sought to establish a partnership with the VaRemba community to provide safe, standardized male circumcision and reduce AEs during traditional initiation rites. Initial VCC discussions began in 2013 with a 3-day meeting between ZAZIC, the MoHCC, the District Health Executive, and the VaRemba chief and elders, resulting in a formal declaration of collaboration. Subsequently, ZAZIC took steps to increase its presence in the local area and provide additional support for VaRemba traditional male circumcision. VaRemba cultural practice mandates that only VaRemba males be allowed in initiation camps and that VaRemba elders select the camp location. However, ZAZIC team members were aware of several hygiene concerns: no shoes are allowed in the camps; most participants did not have underwear; there were no toilet facilities; and male circumcision recovery took place in self-constructed shelters made predominantly from plastic sheeting and branches.

There were several hygiene concerns with the traditional male circumcision camps, including the self-constructed recovery shelters made predominantly from plastic sheeting and branches.

With this knowledge, between 2013 and 2016, the VCC supported the VaRemba initiation camps in several ways. First, the district supplied

Partial view of male circumcision camp shelters in Zimbabwe. © 2018 Joseph Hove/Zimbabwe Association of Church-Related Hospitals (ZACH)

Because only VaRemba could attend the male circumcision camps, 2 VaRemba nurses were trained in VMMC.

the VaRemba with medical male circumcision kits (i.e., surgical supplies) to augment the safety of traditional male circumcision procedures conducted by VaRemba circumcisers. ZAZIC also provided commodities for wound care, supplemental nutritional support, a generator, and tents to help ensure safer procedures. Lastly, ZAZIC provided male circumcision teams a vehicle to transport clients for the procedure and medical care, if needed. Between 2013 and 2016, camp enrollment reduced by more than half: 533 in 2013; 301 in 2014; and 227 in 2016. These enrollment declines were likely due to lack of guaranteed food in camp; simultaneous camps by other VaRemba groups; and some VaRemba opting into VMMC at the hospital rather than at the camp.

During the 2013–2016 period, several key steps helped solidify the VCC partnership. First, strategic ZAZIC staff, including demand creation and clinical teams, paired with MoHCC VMMC officers (Provincial VMMC Officer, District AIDS Council Officer, District Administrator's Arts and Cultural Officer) maintained close contact with VaRemba leaders, meeting several times per year for both formal and informal conversations. These meetings often overlapped with scheduled ZAZIC support visits to area hospitals in the districts and helped build trust within the partnership. Between meetings, VaRemba leaders and clinicians continued to communicate frequently by phone with ZAZIC clinicians, and ZAZIC doctors provided medical support and emergency care for traditional male circumcision clients when requested.

In late 2016, 2 male VaRemba nurses were trained in VMMC according to MoHCC guidelines in response to the requirement that only VaRemba members attend the initiation camps. These nurses were also trained in MoHCC documentation tools for VMMC. ZAZIC also began working closely with a trained demand creation team comprised of circumcised VaRemba men to encourage uptake for VMMC. Although the VaRemba community has its own communication channels through which they mobilize for the initiation camps, ZAZIC took advantage of VaRemba advocacy efforts to further advertise the camps and, simultaneously, promote other VMMC services for VaRemba and non-VaRemba men and boys in health facilities across the district. These additional activities strengthened the VCC, building confidence in the good intentions and follow-through of partners on all sides.

Planning the VaRemba Camp Collaborative

In June 2017, a meeting was held with 14 VaRemba community leaders, the District Administrator, the National AIDS Council, ZAZIC, and the MoHCC, represented by the Provincial Medical Director, the National Male Circumcision Coordinator, and Mberengwa district health officials. Following this meeting, the VaRemba formally adopted national VMMC guidelines for their upcoming initiation camp, including informed consent, counseling, and HIV testing. VaRemba leaders also granted permission for non-VaRemba, ZAZIC medical doctors to reside in the camp to attend to any potential

male circumcision complication or emergency—a critical concession for increased safety. ZAZIC supported mobilization of males over age 10 in the area, promoting the option of modern VMMC at the camp (for VaRemba males only) or routine VMMC at the local hospital (for VaRemba or non-VaRemba males). Mobilizers also emphasized screening of other health conditions that accompanied male circumcision, as per routine practice. ZAZIC, in coordination with the district, also provided male circumcision kits, commodities, salt, and underwear. The National AIDS Council provided supplemental food for the duration of camp.

Camp Implementation

The camp was conducted from August 1 to September 6, 2017, in a dusty, mountainous location. The camp was located 26 km from a hospital and 4 km from a clinic. VMMC was offered to males above 10 years of age according to MoHCC policy. Informed consent followed MoHCC policy for adults and youth. For youth, specifically, informed consent also included additional steps. First, most clients were mobilized before coming into the camp, and their consent forms were witnessed by the mobilizer and signed by parents at home weeks before camp. Second, the program-associated drivers (demand creation specialists and program managers) collected many camp attendees from their homes and further verified consent with the parents/guardians at that time. Clients brought to camp by their parents/guardians signed informed consent at reception. For all clients, VaRemba nurses completing the male circumcision procedure verified and signed every informed consent form.

All routine MoHCC data for each VMMC procedure completed was recorded in the MoHCC VMMC register and client intake forms by VaRemba nurses. Routine data included documentation of demographic data, eligibility, informed consent, the procedure, and postoperative clinical review, including intraoperative and postoperative AEs. VMMC counseling, HIV testing, and the male circumcision procedure were done on day of arrival. Clients joined and were circumcised throughout the camp period, ensuring a constant flow of clients.

Transportation was provided for hospital staff and clients; dedicated vehicles also ensured a consistent supply of available commodities to match client flow. Tents and couches supplied by ZAZIC served as an outreach-based medical facility. The MoHCC-trained VaRemba nurses performed and documented VMMCs within the camp setting and managed mild AEs among traditional male circumcision clients. The 2 non-VaRemba ZAZIC medical doctors, under strict confidentiality agreements, provided oversight as well as treatment for all moderate and severe AEs. Additional medical supplies, transportation, and inpatient care, if needed, were available from local health facilities. Cost reimbursements were given according to the structure provided by MoHCC performance-based financing (PBF) scheme for VMMC,[20] including specific allocations for medical circumcisers, local male circumcision demand creation mobilizers, and temporary demand creation mobilizers (VaRembas recruited from the community specifically for the camp). VaRemba leaders, as a group, were also all paid as part of male circumcision routine service delivery for providing the outreach location (mobile camp).

METHODS

As per routine MoHCC VMMC data collection procedures, VaRemba nurses collected data on all VMMC clients on 2 forms: the client intake form and the VMMC register. Details on these data collection procedures are provided elsewhere.[21,22] In brief, the client intake form is the primary tool used by VMMC service providers to document detailed client information and includes data on demographics, vital signs, HIV testing, preprocedure indicators, eligibility, consent verification, procedure details, AEs, and post-procedure follow-up. Each client has a unique client intake form. Information contained in the VMMC register also includes demographic information, male circumcision type (surgical, either dorsal slit or forceps-guided, or by device), AEs, and follow-up visit adherence. Each VMMC client is documented in one row of the program register. Each register page includes a summary line of aggregate client procedures, AEs, and follow-up visits. Register data are used to complete the monthly return form with aggregate reporting indicators including number of VMMCs by age, HIV status, VMMC type, AE by severity, and at least 1 follow-up visit within 14 days of procedure. VMMC data from camp attendees were included as part of Mberengwa District Hospital outreach statistics and reported to both ZAZIC and the MoHCC as part of the routine monthly return form. Descriptive statistics were compiled from the client intake forms and VMMC register used during camp.

RESULTS

98% of the males ages 10 and older who attended the 2017 camp chose VMMC.

Of 672 males ages 10 and older who attended the initiation camp, provided informed consent, and were screened for male circumcision, all were found eligible and without contraindications. In total, 657 (98%) chose VMMC. In accordance with MoHCC policy, dorsal slit VMMC method was used for all 225 boys ages 10–14 (34%) while forceps-guided VMMC was used for the 432 (66%) boys ages 15 and older (Table). All men were tested for HIV as part of routine VMMC; 4 clients tested HIV-positive and underwent VMMC. Of the 4 testing positive for HIV, 1 of the clients was already on antiretroviral therapy and the other 3 were linked with care. Having the support of VaRemba leaders was critical for VMMC acceptance. Due to their support for, and approval of, the medical circumcision performed by the VaRemba nurses, almost all eligible boys and men opted for modern VMMC, suggesting little reticence to accept modern circumcision within the camp context.

In total, 68 traditional male circumcision procedures were performed in the camp. Although underage boys were offered deferment of VMMC for a future camp, 53 boys under age 10 (who were ineligible for VMMC) were circumcised using traditional methods and 15 adult men also chose traditional male circumcision. Due to the presence of VaRemba nurses in the camp, traditional male circumcision procedures also benefited from improved hygiene. Traditional VaRemba circumcisers tried to follow the clinical way of thoroughly cleaning the penis, washing hands, and putting on new gloves for each male circumcision. They also used a new razor blade for each client and an antiseptic (methylated spirits) for pre-procedure cleaning.

Hygienic conditions of the outdoor camp setting and follow-up recovery were suboptimal. Therefore, several infection prevention steps were implemented before, during, and after the procedure. First, temporary toilet facilities were erected, and campers were encouraged to bathe in a nearby river with soap provided by ZAZIC before the circumcision procedure. Second, VaRemba nurses adhered to all intraoperative hygienic practices as recommended by the MoHCC. Third, as most initiates were young boys ages 10–14, ages that are at greater risk of infection than older clients,[14] all younger clients, including those circumcised traditionally, were given a stat dose (within 1 hour of the procedure) of amoxicillin (250 mg or 500 mg, depending on weight) for infection prophylaxis. Adults who showed signs of poor hygiene, identified at the discretion of the VMMC nurses, were also administered the same broad spectrum antibiotic. Amoxicillin was chosen because it is the most readily available and affordable broad-spectrum antibiotic. Before administration, all were asked about allergies per MoHCC preoperative assessment. Fourth, VaRemba nurses were residents in the camp and conducted daily wound inspection for all male circumcision patients from Day 2 bandage removal

TABLE. Key Voluntary Medical Male Circumcision Characteristics and Outcomes From Varemba Camp, Zimbabwe, August 1, 2017–September 6, 2017 (N=657)

	Age Group						
	10–14	15–19	20–24	25–29	30–49	50+	Total
HIV status, No. (%)							
HIV-negative	224 (34.1)	148 (22.5)	118 (18.0)	73 (11.1)	89 (13.5)	1 (0.2)	653 (99.4)
HIV-positive	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.5)	0 (0.0)	4 (0.6)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Male circumcision method, No. (%)							
Dorsal slit	225 (34.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	225 (34.2)
Forceps-guided	0 (0.0)	148 (22.5)	118 (18.0)	73 (11.1)	92 (14.2)	1 (0.2)	432 (65.7)
Moderate or severe adverse events, No. (%)	1 (0.2)	0 (0.0)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	3 (0.5)
Clients with ≥1 postoperative visit within 14 days of procedure, No. (%)	225 (34.2)	148 (22.5)	118 (18.0)	73 (11.1)	92 (14.2)	1 (0.2)	657 (100.0)
Total, No. (%)	225 (34.2)	148 (22.5)	118 (18.0)	73 (11.1)	92 (14.2)	1 (0.2)	657 (100.0)

Adult VaRemba clients receiving routine postoperative review by VaRemba nurses in Zimbabwe. © 2018 Joseph Hove/Zimbabwe Association of Church-Related Hospitals (ZACH)

and onward. This vigilance helped identify AEs, such as infections, early and likely reduced moderate or severe complications. Lastly, all camp attendees under 15 years of age were provided with clean underwear.

Only 3 moderate infections (0.5%) occurred among the VMMC cases; all were promptly treated with antibiotics (Cloxacillin) and healed well while still in camp. There were 7 mild infections, 4 of them among those traditionally circumcised. With daily reviews and timely appropriate management, these mild AEs did not progress into moderate or severe infections. Mild AEs are not reported per MoHCC guidelines. Traditional circumcision clients received the same follow-up care as those circumcised medically; however, the 53 traditional procedures were not recorded on MoHCC forms.

Additional details about the camp context are not shared to protect the privacy of VaRemba collaborators, respect cultural sensitivity, and maintain trust within the VCC.

DISCUSSION

The VCC is one of the few of its kind in Zimbabwe or elsewhere to successfully pair traditional circumcision practices with modern VMMC. In 2017, 725 men attended the VaRemba initiation camp, reversing the progressive annual drop in attendance since 2013, and 98% of eligible men chose VMMC over traditional circumcision. Multiple factors might explain the VaRemba's willingness to collaborate with the ZAZIC consortium and the MoHCC. First, ZAZIC demand creation teams are from the communities in which they serve. Therefore, they were likely more successful in correctly addressing myths and misconceptions about medical circumcision through various community engagement strategies, including school visits, soccer and music galas, and community dialogue. Also, HIV prevalence in Midlands province, where Mberengwa is located, is 14%.[23] ZAZIC teams made formal presentations to VaRemba elders on basic HIV/AIDS facts and the preventive role of VMMC to raise awareness about the national HIV prevention program and its goals. These activities were consistently complemented with a clear ZAZIC emphasis promoting respect for both traditional circumcisers and cultural practice.[24] The VCC goal was a partnership where traditional and medical practice could come together with the medical practitioners offering the medical procedure and follow-up only while all other camp activities would remain the same. The availability of food provided by ZAZIC and the National AIDS Council also likely increased participation. Lastly, parents may have been more confident in sending their children to the camp with the knowledge that modern VMMC would be provided, similar to the type of procedure routinely delivered in local health centers.

Only 3 moderate infections occurred among the VMMC cases.

The goal of the collaborative partnership was to marry traditional and medical male circumcision practices to improve safety while respecting tradition.

To maintain the low AE rates observed in this collaborative effort, more research on use of prophylactics within the VMMC context is warranted. ZAZIC's program prioritizes VMMC quality in both outreach and static sites. ZAZIC also

emphasizes messages, policies, and practices that promote hygiene, cleanliness, and proper wound care before, during, and after VMMC. Although use of surgical antibiotic prophylaxis is recommended by the World Health Organization's (WHO's) Surgical Safety Checklist,[25] WHO does not recommended antibiotic prophylaxis for VMMC.[26] In Zimbabwe, use of prophylactic antibiotics is not part of either ZAZIC or MoHCC standard VMMC program practice. However, it is possible that the antibiotic protocol used within the traditional setting may have contributed to the low postoperative infection rates at the camp.[27–29] Use of a different prophylactic antibiotic (Flucloxacillin) did not show a positive effect to prevent postoperative infections after male circumcision in a large VMMC program in South Africa.[30] A smaller study comparing male circumcision methods in Mozambique employed prophylactic antibiotics in response to perceived higher risk for wound infection.[31] Although the study was not aimed at assessing the influence of antibiotic prophylaxis, it did find a reduction, albeit non-significant, in postoperative infection from 6.9% to 1.4% after mid-study initiation of Cloxacillin prophylaxis.[31] Additional study of the use of antibiotic prophylaxis in specific contexts may be helpful to inform future VMMC policy.

Lastly, although this collaboration was positive, there are several lessons learned from the formation and implementation of the VCC that inform subsequent camp implementations. First, to avoid complications applying the MoHCC PBF model in the current Zimbabwean VMMC program, clear protocols are needed to guide acquisition and disbursement of funds, food, and transportation. Elders were not considered in MoHCC PBF guidelines; therefore, the VCC negotiated to pay these VaRemba leaders as mobilizers, providing the same amount per client as other mobilizers. Second, the VCC took time and effort above that needed for routine VMMC; however, consideration of more remote communities and settings merits attention. For example, in response to the VaRemba preference for only trained VaRemba clinicians in the camp, the VCC was less effective in early years while VaRemba nurses underwent formal MoHCC VMMC training. Although this caused delays, this training was ultimately critical for success by increasing both sustainability of the collaboration and VaRemba ownership of the VMMC process. Moreover, communication challenges must be addressed with care. In Zimbabwe, the VaRemba are fragmented into smaller groups with separate leadership, complicating efforts to establish clear, appropriate, and consistent lines of communication and joint leadership. Difficulties created by community relationships, remote locations, and poor mobile phone networks reinforce the VCC emphasis on close communication between all partners and stakeholders to help ensure proper planning, preparation, and implementation in the future. Lastly, additional preparation is needed in the more complex camp setting, especially for younger males, to ensure proper informed consent, counseling, and follow-up. The resident MoHCC-trained VaRemba nurses, in close cooperation with the ZAZIC medical doctors, worked throughout the camp implementation period to ensure verification of documentation at all points of client entry, implementation of comprehensive male circumcision counseling in the local language (including HIV counseling), and maintenance of hygienic standards throughout the postoperative period in accordance with MoHCC guidelines.

CONCLUSIONS

The VCC resulted from 4 years of persistent consultation and collaboration between ZAZIC, the MoHCC, and VaRemba traditional leaders. Multiple stakeholders were involved and informed at all stages of the collaboration, from inception to planning for replication. The approach undertaken to provide VMMC in traditional male circumcision camps appears to be both safe and acceptable for the initiates, as demonstrated in the 2017 camp effort. After the success of this effort, the VCC will continue implementation of the partnership model for future initiation camps and other VaRemba groups are now requesting similar collaborations. In fact, in 2018 ZAZIC began working with 6 VaRemba communities in other geographic areas in Zimbabwe, culminating in 1 additional successful camp collaboration in Gokwe South District: 206 medical VMMC procedures were performed without complication. Capitalizing on the momentum of the VCC, ZAZIC is also actively working to identify other VaRemba health care workers across Zimbabwe for MoHCC VMMC training. This partnership model may be replicable in other contexts in Zimbabwe and the region, expanding efforts to provide VMMC within traditional settings.

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CORRECTION

Erratum for: Odwe et al., Introduction of Subcutaneous Depot Medroxyprogesterone Acetate (DMPA-SC) Injectable Contraception at Facility and Community Levels: Pilot Results From 4 Districts of Uganda

See *updated article*.

In the article "Introduction of Subcutaneous Depot Medroxyprogesterone Acetate (DMPA-SC) Injectable Contraception at Facility and Community Levels" by George Odwe and colleagues, which appeared in the December 2018 issue (Volume 6, Number 4), in Table 4, the content for footnotes 'b' and 'c' were reversed. This has now been corrected.

Cite this article as: Erratum for: Odwe et al., Introduction of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) injectable contraception at facility and community levels: pilot results from 4 districts of Uganda. *Glob Health Sci Pract.* 2019;7(1):147. https://doi.org/10.9745/GHSP-D-19-00036

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