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GLOBAL HEALTH: SCIENCE AND PRACTICE
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EDITORIAL

Evidence-based public health: not only whether it works, but how it can be made to work practicably at scale

James D Shelton[a]

Because public health must operate at scale in widely diverse, complex situations, randomized controlled trials (RCTs) have limited utility for public health. Other methodologies are needed. A key conceptual backbone is a detailed ''theory of change'' to apply appropriate evidence for each operational component. Synthesizing patterns of findings across multiple methodologies provides key insights. Programs operating successfully across a variety of settings can provide some of the best evidence. Challenges include judging the quality of such evidence and assisting programs to apply it. WHO and others should shift emphasis from RCTs to more relevant evidence when assessing public health issues.

WHAT MAKES PUBLIC HEALTH DIFFERENT FROM INDIVIDUAL MEDICAL CARE? SCALE, SITUATION VARIABILITY, AND INTERVENTION COMPLEXITY

Evidence-based medicine (EBM) has greatly advanced the scientific validity, and presumably the effectiveness, of medical practice.[1] The hallmark of EBM is the randomized controlled trial (RCT) with its potentially strong ''internal validity'' to answer precise questions under narrow conditions—generally whether and how well an intervention such as a drug works for individuals. Indeed, the Cochrane Review process—the mainstay of EBM—places RCTs on a pedestal above all other forms of evidence. There is a strong temptation to apply EBM methods and standards reflexively to public health. The World Health Organization (WHO), for example, relies heavily on the GRADE (grading of recommendations, assessment, development, and evaluation) system, which gives paramount importance to RCTs, to develop recommendations for public health issues.[2]

But public health must operate at large scale, addressing the needs of large populations across clinical, behavior, and structural platforms, and necessarily entails crucial operational issues, variability, and complexity as well as consideration of resource requirements and sustainability. Thus, because situations can vary so widely, ''external validity'' or generalizability of evidence to other situations is absolutely crucial for public health applications.

Yet external validity is a severe weakness of the RCT methodology for public health decision-making. We need to know not just whether something works under narrowly prescribed circumstances but also how, when, and why it can work for broad application. Actually, the distinction between these 2 arenas is already recognized to some extent in standard terminology. We use the term ''efficacy'' to mean how well an intervention works under the best circumstances, typically based on RCT evidence, and ''effectiveness'' to mean actual results, especially at scale, which are usually attenuated under real-world conditions.

But real-world complexity extends even farther. Many of the world's leading health agencies are committed to ending preventable infant and maternal death.[3] This ambitious objective will require a considerable range of interventions, such as immunization, antibiotics for pneumonia, and promotion of exclusive breastfeeding. However, since no single intervention will be sufficient, the fundamental challenge is maximizing the *collective* effectiveness of the optimal set of interventions. That gives rise to a higher level of complex questions: What is the best set of interventions for particular settings? How should the interventions be organized and delivered within existing systems? What will it take to execute them on an ongoing, sustainable basis? With what effort and cost? What strategies are needed to best reach those most in need?

The deeper real-world understanding we need in public health actually serves 2 related purposes. The first is to **assess** whether and under what circumstances to recommend a particular public health approach. The second is to help guide program managers to **apply**

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Public health decision-making requires knowledge of not just whether something works under particular circumstances but also how, when, and why for broad application.

these approaches in their particular settings. To address such questions, evidence-based public health (EBPH) must go well beyond RCTs to include other valid methodologies to arrive at optimal public health programming. More challenging, but more interesting.

LIMITATIONS OF RCTS FOR PUBLIC HEALTH

Challenges to conducting RCTs are many, only beginning with high cost and time requirements.

RCT methodology entails a host of challenges, including burdensome cost and time requirements. Sometimes randomization is not possible for ethical or logistical reasons. But crucially, RCTs are necessarily "**reductionist**," which limits their utility for complex public health issues. With laser-like precision, they typically zero in on very specific issues in constrained time and place. Because human biology is pretty consistent across time and place, that often works quite well for medical questions about individuals. But major variability can occur even for biologic questions. For example, trivalent polio virus vaccine is quite efficacious in the developed world. However, in Northern India vaccine efficacy was only 9% per dose.[4] Possible explanations offered include co-infection, malnutrition, genetic differences, size of viral inoculum, and enteropathy. Moreover, since RCTs are "controlled," they are typically carried out under optimal and rather **artificial** conditions, which are frequently difficult to transfer to practical real-world conditions.

Complex Interventions in Complex Environments

Consider the challenges of designing and implementing public health programs at scale. Contexts vary widely, especially related to culture, social structure, health systems, resources, economics, politics, and the physical environment. Furthermore, services can be delivered through a range of modalities, each with a multitude of permutations of how the services can be organized. Trying to apply the laser-like RCT approach is akin to trying to light up a football stadium with a slowly moving laser pointer—very precise, rigorous, and artificially intense but not very illuminating.

Trying to apply the laser-like RCT approach is akin to trying to light up a football field with a slowly moving laser pointer—very precise, rigorous, and artificially intense but not very illuminating.

Examples of Problematic Application of RCTs to Public Health

The deference for RCTs in EBM has spilled over to public health, for example, via "cluster" randomized trials that randomize population groups rather than individuals. But typically so many variables affect the result, and the trials are often conducted under rather artificial optimal conditions, that generalizing to the variable range of real-world situations can be tenuous at best. Moreover, research culture tends to focus on the "whether" questions, driving study designs, data collection, and what scientific journals like to report. Alas, the crucial questions of "how" and "under what circumstances" typically get short shrift. Some examples:

- **Variability and failure to assess the causal pathway fully.** It is believed concurrent infection with certain sexually transmitted infections (STIs) may facilitate HIV transmission. A large and expensive cluster randomized trial in Mwanza, Tanzania, found that when STIs were treated, HIV transmission decreased. However, several other population-level RCTs failed to show such a reduction.[5] Unfortunately, while measuring HIV incidence, the Mwanza study failed to adequately document whether the crucial intervening variable—prevalent STIs—was actually reduced. Subsequent commentators have speculated that the different study outcomes might have resulted from differences in the existing burden of STIs and from the intense, active phase of the HIV epidemic in Mwanza at the time.[5] Regrettably, the role for STI treatment in HIV prevention remains rather unresolved.
- **Overgeneralization and lack of process detail.** A cluster randomized trial involving peer mentors with HIV infection to promote wellness behavior among pregnant South African women living with HIV (WLH) drew this unqualified conclusion: "WLH benefit by support from HIV-positive peer mentors …" Actually, the study was small and localized to one area of South Africa; it found significant and mostly modest change in only 4 of 19 behaviors (mostly related to improvements in exclusive breastfeeding); and it provided little intervention detail and no qualitative evidence about the thinking and motivations of the WLH.[6] Moreover, participation in the study was partial and follow-up rates rather incomplete.

In fairness, some cluster trials do include complementary methodologies beyond simply whether the intervention worked or not. Notably, the very large Project Accept study, which is assessing whether widespread HIV testing plus community engagement reduces

risky behavior, includes a major ideational component assessing attitudes and motivation.[7]

THE CRUCIAL DETAILS: CONSTRUCTING A CAUSAL PATHWAY OR THEORY OF CHANGE

Properly implementing a public health initiative involves engaging a plethora of issues that can include constellation of interventions, staffing, deployment, job functions, competence, motivation, compensation, program policies, organization of work, standards and guidelines, job aids, quality assurance, supply chain, physical infrastructure, budget, cost recovery, demand creation, healthy behavior promotion, public support, supervision, change management, epidemiologic surveillance, and service data collection and use, to name a few—all customized to the dynamic local context.

Real-world managers typically address these challenges through intuition, trial and error, and experience. That is actually not a bad starting point. After all, it is how our species survived through millennia in a complex environment. However, this intuitive process can be improved by systematically laying out a posited causal pathway, sometimes called a ''theory of change,'' of the steps and components that need to happen to get the desired results. The task then becomes identifying the best evidence, both internal and external, on what helps each component, as well as the whole, to function better.

WHAT SHOULD WE USE FOR EBPH EVIDENCE?

EBPH approaches have much in common with management science. Both use experiment-like tests of effectiveness but must rely heavily on evidence that is observational, experiential, or essentially systematic trial and error. Validity often derives from whether things ''work'' in a particular environment. Broader applicability emerges when consistent patterns of findings or collective ''lessons learned'' materialize. Some examples:

- **Successful implementation/positive deviance.** One major way of addressing the crucial issues of scale and complexity is examining what actually works (or not) at scale, and then parsing the details. Such a ''case study'' or positive deviance approach is a backbone of business schools. This approach can also be comparative. For example, the management classic *Built to Last: Successful Habits of Visionary Companies* compares the attributes of highly successful companies matched with less successful ones.[8] When a repeated pattern of success is seen across many different situations, it provides confidence in the general approach. Accordingly, a family planning nongovernmental organization, Marie Stopes, successfully provided more than 700,000 contraceptive implants in 2012 across a wide variety of countries in sub-Saharan Africa. They describe their 3 service delivery modalities, along with operational details including provider training, client outreach, robust supply chains, and quality assurance measures. A generalizable concept or best practice that emerges is the ''dedicated'' provider for such labor-intensive contraceptive methods.[9]
- **Systematic trials and program tests.** This category includes a wide variety of methodologies, ranging from randomized trials and quasi-experimental designs to demonstration projects. Such investigations (including RCTs) should provide extensive detail on what did and did not work, as well as how. In the 1970s, studies in many settings found that community-based provision of family planning was acceptable to a substantial proportion of couples, making expanding contraceptive access a major pillar of family planning programming.[10] Likewise, a recent analysis of 12 successful community-based child survival projects found intensive outreach to caregivers and community leaders was a crucial common element.[11]
- **Performance improvement.** In this approach, with its roots in management science, managers, typically along with staff, assess critical strengths and weaknesses in programs using a variety of analytical tools. They formulate solutions, test them, and measure whether and how performance improves. Generalized knowledge can arise when patterns of solutions emerge, common across multiple program experiences. Thus for male circumcision, a variety of incremental improvements in mobile service delivery have been identified, including client preparation outside the facility, use of a forceps-guided surgical procedure, reorganized bed use, task shifting, and task sharing, that have resulted in substantial increases in efficiency with good quality.[12]
- **Simple measurement across the causal pathway.** A wide variety of data can be

Patterns of findings or collective ''lessons learned'' that are consistent across multiple settings are especially valuable for EBPH.

useful to assess and guide implementation such as: routine service provision data, qualitative data on client or provider perspectives, facility assessments, supply chain monitoring data, epidemiologic surveillance, fixed-interview surveys such as the Demographic and Health Surveys (DHS), costing data, national health account data to assess health spending, mapping data on location of facilities and transport networks, and other key data such as air quality and food, alcohol, and tobacco consumption. In addition to using such data for direct program assessment, useful general patterns can emerge. For example, a worldwide analysis based on DHS data revealed that a substantial proportion of people access the private sector for key child health services in many developing countries, arguing for more programmatic effort to engage private-sector providers.[13]

- **Additional epidemiologic methods.** These include cohort and case-control studies to help assess factors predicting health, disease, and adverse outcomes, as well as phylogenetic studies to assess patterns of disease transmission.
- **Modeling.** While modeling doesn't actually generate new data, this exploration of the *implications* of data can provide insights into whether, when, and how interventions may work. For example, antiretroviral drugs (ARVs) reduce HIV transmission, but their population-level potential to abate the HIV epidemic is unclear.[14] Credible modeling indicates that investing in treating those already infected, especially with more advanced disease, is more cost-effective than providing ARVs to those uninfected but at risk of infection.[15] But beware. The greater the situational complexity, the more variability can arise from the assumptions and model mechanics. Modeling can definitely be misleading.
- **Human functionality, culture, and biology.** This approach, which includes both experimental and observational methods, is somewhat reductionist and far-ranging. It can comprise task analysis issues, such as how many clients a provider can effectively see daily, how many tasks a community health worker can effectively provide, and what training approaches result in competence; how medical culture influences programs; how social networks influence behavior; and what neuroimaging changes correlate with approval or disapproval when individuals see an anti-smoking ad.
- **Evaluation.** Summative evaluations that assess program effectiveness can be designed in advance as well as conducted post hoc. They can make use of a variety of methods as described above. Here also, it is important not only to assess whether something worked or how well it worked but also to uncover the details of the many factors that caused it to work or not. Probably the paradigm of ideal evaluation is the ''Realist Review.''[16] This approach ''aimed at discerning what works for whom, in what circumstances, in what respects, and how'' is a deep-dive approach to evaluation,[16] beginning with a detailed theory or causal chain on how an intervention is intended to produce impact and then populating the series with available empiric evidence.

A starting point for assessing the quality of EBPH evidence is how well the studies contribute to other evidence.

QUALITY OF EBPH EVIDENCE

There are well-established criteria for assessing the quality of RCTs. However, addressing quality of evidence in the complex and variable terrain of public health, with its diverse and more complex questions (when, how, how cost-effective, and how sustainable) and with its heterogeneous forms of evidence, is far less cut-and-dried. Nevertheless, quality criteria for methodologies such as qualitative approaches do exist. Pawson lays out key principles for quality of evidence in his seminal paper, ''Assessing the quality of evidence in evidence-based policy: why, how and when?''[17] Ultimately, in addition to specific criteria for particular methodologies, he judges quality of studies based on how well they contribute to or triangulate with other evidence, in coherent and credible explanatory patterns. We need to build on such concepts to further refine and assess the quality of public health evidence.

SYNTHESIS FOR APPLICATION, THE ULTIMATE CHALLENGE FOR EBPH

A key value-added of EBPH is identifying and synthesizing patterns of findings across multiple experiences, less than perfect though they may be, in enough detail to meaningfully inform

similar efforts across a variety of situations. Simple examples I personally have observed include:

- Referrals from one place in the health system to another risk a high loss to follow up.
- Success in programs, including scaling up, often depends on finding and cultivating committed and capable ''champions.''
- Important population-level behavior change, such as reducing tobacco use, most often results not from any one single campaign or intervention but from a sustained combination of interventions, including structural interventions such as increasing taxation, individual persuasion, and changing social norms.

Another example of synthesis is a systematic review of strategies to increase health services in mountainous locations. It found benefit from: task shifting, strengthened roles of community health workers, mobile teams, and inclusive structured planning forums.[18] A major agenda for EBPH is identifying such common patterns and helping program managers adapt and apply that knowledge.

CONCLUSION

To achieve ambitious global health goals, such as ending preventable child and maternal mortality, we need evidence on the ''how and when'' of implementation at scale, in the face of vast real-world complexity and situational variability. Evidence arising within a specific program can help with better implementation in that setting. But beyond locally relevant learning, a major objective is identifying systematic patterns for wider application. Triangulating and otherwise bringing together evidence arising from different methodologies with sufficient detail to illuminate causal relationships is essential to applying such knowledge to real-world public health problems across diverse situations. When assessing public health evidence, WHO and others should move beyond predominant reliance on RCT evidence.

Some may question the rigor of these approaches. But we are not advancing mere anecdote. Rather, our mandate is an even greater and more difficult standard of rigor: of investigation, observation, accumulation, systemization, and appropriate application. Narrow internal rigor elegance is not an end in itself. The overriding virtue of EBPH is real-world relevance.

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Synthesizing common patterns across multiple methodologies and helping program managers apply that knowledge are key goals for EBPH.

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EDITORIAL

Oxytocin: taking the heat

Stephen Hodgins[a]

Oxytocin-in-Uniject satisfied the standards of its temperature-time indicator (TTI) in severe home storage conditions, although that required resupply every 30 days—a logistically onerous programmatic standard. Possible advances include: (1) incorporating TTIs with packaged batches of less expensive and more widely used conventional vials of oxytocin; (2) using TTIs calibrated more closely to the actual temperature sensitivity of oxytocin; and (3) researching whether a lower dose of oxytocin would be equally efficacious in preventing postpartum hemorrhage.

Globally, the leading cause of maternal deaths is postpartum hemorrhage (PPH). The single most important preventive intervention for PPH is active management of the third stage of labor, the most important element of which is administration of oxytocin (misoprostol, an orally administered drug, is almost as efficacious). It is encouraging that oxytocin now appears to be widely used for this purpose.[1] Nevertheless, as Smith,[2] in this issue of *Global Health: Science and Practice* (GHSP), points out, "challenges remain with … distribution, proper storage, and … maintaining a regular supply of the medicine." There are reasons, in particular, to be concerned about *temperature stability* and *storage conditions*.

As with any pharmacologic intervention, an effective dose of the active ingredient needs to be delivered to the patient. The currently available formulations of oxytocin degrade more rapidly when exposed to high temperatures.[3] In principle, in settings with high ambient temperatures, if a "cool-chain" (i.e., protection from high temperatures) cannot be maintained, we run the risk of administering an inadequate dose. Mullany and colleagues,[4] in this issue of GHSP, make a useful contribution by raising this important issue in their drug storage simulation study in rural Ghana. Their approach is creative, the analysis sound, and the argument engaging.

In the study, the product used was Oxytocin-in-Uniject (OIU), delivering 10 International Units (IU). It should be noted that OIU is not in large-scale commercial production and costs at least 3 times as much as the conventional product. The standard form for PPH prevention is glass vials of 5 or 10 IU, at unit costs as low as US$0.10. In some markets, these vials are generally sold in blister packs.

The temperature-time indicator (TTI) (manufactured by the TempTime Corporation) currently incorporated as an element of the OIU device was used to determine the reject threshold. As the authors explain, the specific TTI used for the OIU is calibrated quite conservatively, resulting in the rejection of a considerable portion of oxytocin doses while they still fell within the industry-standard 90%–110% dosage specification band. Furthermore, as the authors also acknowledge, the Cochrane review[5] of oxytocin efficacy for preventing PPH includes studies with doses ranging from 10 IU down to 3 IU, without any indication of the lower dose being any less effective in reducing blood loss (although no head-to-head comparison studies have yet been done).

Based on their findings, Mullany and colleagues conclude that even without special provisions for refrigeration at point-of-use, a stock resupply protocol that—on a *monthly* basis—recovers and disposes of any unused oxytocin would result in very few doses falling below the TTI reject threshold. But the trade-off here is achievement of high sensitivity for inefficacious product at the cost of low specificity; many doses that could still be clinically effective are likely to be rejected. More important is that full monthly replacement with new stock—with high reliability—may be quite challenging in many high-need settings, where logistics systems are often not very strong.

Much more widespread use of a temperature-time monitor for oxytocin, like the TTI currently used for OIU, would certainly be helpful in providing managers and clinicians a clear indication of which doses to reject and where there may be breaches in the "cool-chain."

[a] *Global Health: Science and Practice*, Associate Editor for Maternal and Child Health.

What might be some helpful next steps? We offer the following suggestions:

- In principle, TTIs could be incorporated in the packaging for *conventional* glass vials of oxytocin (for example, affixing them to blister-pack flats). At a cost of about 7 cents each, affixing one TTI to a blister-pack flat containing 8 or 10, 10 IU-vials would add less than 10% to the unit cost.
- To avoid unnecessary wastage, TTIs calibrated to more closely approximate the temperature sensitivity of oxytocin should be used.
- Rejecting a dose of oxytocin because it has slipped below the equivalent of 9 IU may be unnecessarily conservative; further dose-finding research could be warranted to determine whether a lower dose (say, 5 IU) would be equally efficacious for PPH prevention.

Oxytocin is an important weapon in our armamentarium for the reduction of PPH mortality. But to be effective, it needs to be protected against exposure to high temperatures. Considerable efforts have been made over the past decade to ensure that even women living in more remote areas benefit from giving birth with skilled health care providers. We need to ensure that these health care workers have all that is required to provide life-saving care, including efficacious medicines.

Competing Interests: None declared.

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COMMENTARY

Combating trafficking in persons: a call to action for global health professionals

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Health care professionals can help identify victims of human trafficking, who commonly come into contact with providers during captivity. Providers can also help restore the physical and mental health of trafficking survivors. Training should focus on recognizing trafficking signs, interviewing techniques, and recommended responses when a victim is identified.

Trafficking in persons—also known as modern slavery—is a crime that undermines the most basic rights of an individual. Despite more than a decade of international and domestic laws against it, human trafficking affects every country in the world, including the United States. As global awareness of human trafficking has grown, efforts to combat it have also increased. An Internet search using the term "human trafficking" yielded more than 32 million results in seconds. Awareness of the impact of this crime on victims and of its various manifestations has also evolved. Victims have been found in, and freed from, slave-like conditions in nearly every industry: agriculture, manufacturing, construction, hospitality, health care, janitorial services, mining, fishing, domestic service, as well as commercial sex. The scale of the problem has prompted professionals and advocates to embrace the notion that all sectors must be equipped with the knowledge and relevant skills to contribute to ending modern slavery.

Social science experts estimate there are 20.9 million[1] to 29.8 million[2] people around the world living in servitude. A report from the International Labour Organization (ILO) provided additional information about the victims of human trafficking[1]:

- Of the total number of 20.9 million victims, 18.7 million (90%) are exploited in the private economy by individuals or enterprises; the remaining 2.2 million are in state-imposed forms of forced labor. Of those exploited in the private economy, 4.5 million (22% of the total number) are victims of forced sexual exploitation, and 14.2 million (68% of the total number) are victims of forced labor exploitation.
- Women and girls comprise the majority of victims—11.4 million (55%)—representing nearly all the victims of forced sexual exploitation and approximately 40% of the victims of forced labor exploitation.
- Children represent approximately one-quarter (26%) of the victims of human trafficking.
- Victims spend, on average, approximately 18 months in forced labor.

Each victim, regardless of gender, age, sexual orientation, ethnicity, or country of origin, has his or her own personal story. For example:

> *Vannak Anan Prum was lured from Cambodia to Thailand by the promise of a lucrative job, but instead he was deceived by a labor broker. He was forced to work on a Thai fishing vessel from 2005 to 2009 in slave-like conditions, never receiving a salary. Mistreated, starved, and tortured … Mr. Prum escaped with another fisherman by jumping off the boat and swimming four kilometers to shore when the boat anchored off Malaysian Borneo. According to his account, upon attempting unsuccessfully to obtain help returning to Cambodia, he was sold by corrupt officials to a palm oil plantation. After several months of forced labor on the plantation, an altercation with another worker landed him in detention. While [there], he was able to establish contact with Malaysian and Cambodian human rights NGOs, which collaborated to have Mr. Prum repatriated to Cambodia, though not until he had spent several additional months in detention.*[3]

Since regaining his freedom, Vannak Prum—like many survivors of abuse—has become an advocate,

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An estimated 21 million to 30 million people worldwide are living in servitude.

The majority of victims of human trafficking are women and girls.

committed to preventing others from suffering a similar fate. He has worked to raise awareness of labor trafficking in the Thai fishing industry through a series of intricate drawings of his experience, and he was honored by U.S. Secretary of State Hillary Clinton as a ''2012 Trafficking in Persons Report Hero'' for his tireless efforts to end modern slavery. Mr. Prum's efforts are an example of survivor activism that, along with the advocacy of governments, nongovernmental organizations (NGOs), and multilateral organizations, has contributed to the formation of a global movement.

This article is a call to action for clinicians and public health professionals to engage in the response to human trafficking globally. It provides an overview of the prevalence of the crime, terminology, its common manifestations and health consequences, advancements in addressing it, and suggestions for how global health professionals can contribute to ending modern slavery.

WHAT IS HUMAN TRAFFICKING?

''Trafficking in persons'' and ''human trafficking'' are used as umbrella terms for all acts involved in recruiting, harboring, transporting, providing, or obtaining a person for compelled service or commercial sex acts through the use of force, fraud, or coercion.[4] Since 2000, the United States *Trafficking Victims Protection Act of 2000* (TVPA)[5] and the United Nations *Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children* (Palermo Protocol)[6] have described this compelled service using several overlapping concepts, including involuntary servitude, slavery, practices similar to slavery, debt bondage, and forced labor. Under both the TVPA and the Palermo Protocol, if commercial sex involves a minor, then force, fraud, or coercion does not need to be present. The TVPA and the Palermo Protocol also embrace a victim-centered approach to the crime of human trafficking and adopt the ''3P Paradigm'' as the international framework for responding to human trafficking:

Most countries prohibit human trafficking, but it remains a hidden crime.

- Prosecution of traffickers
- Protection and assistance for victims
- Prevention of trafficking from occurring

In recent years, a fourth ''P''—Partnerships—has been recognized by many as the critical ingredient to establishing comprehensive responses to human trafficking.

In the past decade, there has been greater understanding of the trafficking phenomenon and manifestations of the crime. For example, exploitation and compelled service and the coercive and deceptive practices used by traffickers are at the heart of the many forms of modern slavery. Individuals may be victims of trafficking regardless of whether they once consented to work for the trafficker, participated in a crime as a direct result of being trafficked, were transported into the exploitative situation, or were simply born into a state of servitude. And although the term ''trafficking'' suggests movement, the crime does not require movement. Many people are enslaved in their own communities or in cities within their country of origin.

GOVERNMENT RESPONSES TO HUMAN TRAFFICKING

The United States emerged as a world leader on this issue in 2000, when comprehensive anti-trafficking legislation, the TVPA, was passed, which authorized establishment of the Office to Monitor and Combat Trafficking in Persons in the U.S. Department of State (TIP Office). The TIP Office compiles an annual report to Congress assessing governments' efforts to implement anti-trafficking laws and policies. The 2014 *Trafficking in Persons Report* (TIP Report) contains rankings and individual country narratives for 188 countries, including the United States.[7]

Since 2000, a remarkable international consensus has developed regarding the need to address human trafficking. Most governments have taken concrete steps to create the legal framework to address this crime: 159 countries have become parties to the Palermo Protocol,[6] and 133 countries prohibit all forms of trafficking.[8] Even with this progress, human trafficking remains a hidden crime, and the identification of victims of human trafficking continues to be a fundamental challenge. As a consequence, millions of victims suffer in grossly exploitative situations every day, and only a small number of the victims held in compelled service have been given the assistance and services they need. Figures gathered for the 2014 TIP Report[7] show an enormous gap between the estimated number of victims globally (as many as 29.8 million) and the estimated number of victims actually identified globally (only approximately 44,800). In

addition, most traffickers are not apprehended and punished. Fewer than 9,500 prosecutions were reported globally, resulting in approximately 5,800 convictions.

Several factors have contributed to underidentification of victims—including those who are still in the trafficking situation and those who have been freed. Traffickers maintain control over victims through isolation, debt bondage, deception, violence, and coercion, including threats against them or their families, false promises of future pay for work already done, and threats of arrest or deportation. Unaware of their rights and of the existence of protections for trafficking victims, many victims do not come forward to identify themselves and are treated by authorities as criminals, illegal migrants, people in prostitution, or juvenile delinquents.[9,10]

After 2000, initial programmatic and enforcement efforts to combat human trafficking focused primarily on sex trafficking of women and girls across national borders. Programs to assist female survivors increased in number, and they developed comprehensive services, including shelter, health care, counseling, legal advocacy, and assistance with repatriation and community reintegration. Less attention was given to trafficking of men and boys. Research shows that male trafficking victims are often not recognized due to commonly held beliefs or assumptions that trafficking is about women who are held in sexual servitude, whereas exploited men are seen as irregular migrants who should be deported without investigating their circumstances.[11] Interviews with male victims have provided examples of how numerous professionals (doctors, border guards, police, and prison officials) have failed to identify male victims, even when the men described what had happened to them.[12,13]

HEALTH CONSEQUENCES OF HUMAN TRAFFICKING

The physical and mental health consequences of human trafficking have become clearer through systematic research and through the work of NGOs who address the care and assistance needs of trafficking survivors. One study found that more than half of female survivors of sex trafficking seeking services (59%) reported sexual or physical violence prior to the trafficking experience; nearly all (95%) reported physical or sexual violence during the trafficking situation.[14] Most of the survivors (57%) reported physical injuries, and the vast majority (76%) reported they were never able to do as they wished or go where they wanted. In the first 2 weeks of their post-trafficking care, the majority of respondents reported physical symptoms including: headaches (82%), fatigue (81%), dizzy spells (70%), back pain (69%), memory difficulty (62%), pelvic pain (59%), and gynecological infections (58%). Most (63%) reported more than 10 concurrent physical health problems. Additional research on female survivors of sex trafficking showed comorbidity for 3 mental health outcomes—anxiety, depression, and post-traumatic stress disorder (PTSD)—and the severity of symptoms was associated with the length of time spent in the trafficking situation.[15] Risk of HIV infection is also an issue. Both young age when first becoming a victim of sex trafficking and length of time in the brothel were found to heighten the risk of becoming infected with HIV.[16] A systematic review found HIV prevalence among trafficked women ranging from 22.7% to 45.8% and documented the high prevalence of physical symptoms when trafficked women come into care.[17] The presence of multiple traumas experienced by many sex trafficking victims has implications for interventions, treatment, and planning for the safe return and reintegration of survivors.

Systematic research on the health impact of trafficking on male victims is not yet available, but recent research indicates that many male victims of forced labor experience violence and need access to physical and mental health services. In a recent case series report of 35 adult victims of forced labor in the United Kingdom who received services post-trafficking (27 of whom were men), 40% experienced physical violence (for example, being kicked, hit, hurt with a gun or knife, or intentionally burned) while in the trafficking situation, and 81% reported one or more symptoms of poor physical health.[18] In other research, interviews with male survivors of forced labor show that many experience harsh and traumatizing treatment from their exploiters: physical abuse and assaults, threats of violence, loss of control over basic life functions, and loss of freedom of movement.[12,19] Survivors reported being forced to live in cramped, locked settings, with poor diet and sanitation, and some are exposed to the elements. Anecdotal reports from NGOs and law

enforcement in the United States also show that forced labor cases may include exploitation of drug or alcohol dependency, mental illness or disability, and sexual assault or threats of sexual assault as methods of control. Commercial sexual exploitation of boys and men has received less attention, but cases have been reported in Kenya, Southeast Asia, Spain, and the United States, and it is widely suspected that such cases are significantly underreported.[20]

HEALTH RESPONSES AND RESOURCES

Human trafficking is increasingly recognized as a global public health problem, and guidance for health care providers has emerged in the literature[21,22] as well as calls for the development and implementation of new education and training programs for health care professionals.[23] In addition, there is evidence that victims of human trafficking commonly come into contact with a health care provider during their captivity and exploitation, but too often these encounters represent missed opportunities for victim identification and assistance.

Through interviews with survivors, 2 studies in the United States have explored the experiences of sex trafficking and/or forced labor victims who received medical or dental care during the time they were being exploited. Of the 21 survivors interviewed in one study, 28% had come into contact with health care providers.[24] In the other study, half of the 12 survivors had received health care.[25] Victims of involuntary domestic servitude were taken for treatment for respiratory or systemic illnesses or bodily injury that prevented them from performing household duties. Sex trafficking victims saw health care professionals for sexually transmitted infections and abortions. Victims were seen in a variety of settings, from small clinics and private offices to large public medical facilities. These studies show, and experienced practitioners observe,[26] that victims are not likely to be taken for health care until the condition becomes serious. They also note several obstacles to a victim's disclosure of the trafficking situation, including fear for themselves or their families, shame, a language barrier, concern that they would be ridiculed or not believed, and the limited interaction between the victim and health care staff. This limited interaction can often be attributed to the behavior of traffickers who accompany and speak on behalf of the victim or seek to monitor or control the victim's communication during the health care visit.

To ensure that health care services are not a missed opportunity for victim identification, training must go beyond raising awareness of the plight of victims and recognizing the signs of human trafficking. It should also cover guidance on interacting with potential victims, interviewing techniques, recommended responses, and resources.[27] A literature review[28] of recommended strategies for U.S. human service agencies (such as health care, child welfare, social service, juvenile justice, domestic violence, and victim advocacy) that engaged in identifying victims of sex trafficking found consistency in the literature regarding human trafficking indicators, for example:

- Signs the person is being controlled by someone who is accompanying him or her
- Signs the person does not have freedom to exit a job or move
- Signs of physical abuse
- Signs indicating a person is fearful or depressed

There was less agreement in the literature, however, about what a human service provider should do in response to a suspected case, including how providers should interact with potential victims, how they should screen for sex trafficking safely and sensitively in the context of a single encounter, and what their immediate response should be once a sex trafficking victim is identified. Acknowledging that these are topics for further practice development and research, studies agree that human service providers should have more training on victim identification and resources for trafficking victims before undertaking screening strategies.

A publication designed for an international audience of health care providers, *Caring for Trafficked Persons: Guidance for Health Providers*,[29] provides more detailed guidance to help all types and levels of health care providers meet the challenges of diagnosing and treating trafficked persons. It discusses the health problems associated with sex trafficking and labor trafficking, the risks and safety issues when encountering a suspected trafficking situation, and safe and appropriate approaches to providing health care for trafficked persons. This guide was a collaborative effort between the International Organization on Migration (IOM) and the

Gender Violence and Health Centre of the London School for Hygiene and Tropical Medicine and was supported by the United Nations Global Initiative to Fight Trafficking in Persons (UN.GIFT). It has been translated into Arabic, Chinese, and Spanish. Building on this effort, the U.S. State Department's TIP Office supported the development of the companion training facilitator's guide, *Caring for Trafficked Persons: Guidance for Health Providers, Facilitator's Guide*,[30] to promote wider training of health care professionals globally.

Increasingly local and national governments are encouraging the involvement of health care providers in victim identification and are providing them with information and guidance on the signs of human trafficking, recommended screening procedures, and how to obtain/access resources. For instance, the Belgian government has a cooperation project with hospitals to improve detection of trafficking victims who may be seeking medical treatment; preliminary findings of the project indicate that victims are more willing to talk to medical staff than to police.[20] Examples of government dissemination of information and resources include:

- U.S. Department of Health and Human Services, Rescue and Restore campaign with online toolkits for health professionals (http://www.acf.hhs.gov/programs/orr/resource/rescue-restore-campaign-tool-kits)
- UK National Health Service publication, *Identifying and Supporting Victims of Human Trafficking: Guidance for Health Staff* (www.gov.uk/government/publications/identifying-and-supporting-victims-of-human-trafficking-guidance-for-health-staff)

CAST (Coalition to Abolish Slavery & Trafficking), a Los Angeles-based NGO that was presented the Presidential Award for Extraordinary Efforts to Combat Trafficking in Persons by U.S. Secretary of State John Kerry in 2014, is also working to expand the knowledge base of health professionals working on human trafficking and to link them with others doing similar work. CAST supports the exchange of trafficking and health-related information across an interdisciplinary network of health professionals (physicians, nurses, dentists, psychologists, counselors, public health workers, health educators, researchers, social workers, administrators, and other health professionals) through its website: www.castla.org/trafficking-and-health. The purpose is to share best practices, expand evidence-based practices, and promote improved systems of care for victims of human trafficking. Interested professionals can also join an affiliated Human Trafficking and Health Care listserv (at http://www.humantraffickingandhealthcare.com) that uses Google Groups to facilitate communication within this online community.

THE ROLE OF GLOBAL HEALTH PROFESSIONALS

Restoring the physical and mental health of trafficking survivors is a critical part of protection and assistance services, and the role of global health professionals in meeting this challenge is evolving rapidly. Researchers and clinicians have called for more specialized education and training for health care professionals, the development of new protocols for the identification of trafficking victims in health care settings, culturally sensitive and safe procedures for responding when a victim is identified, and the provision of comprehensive care post-trafficking.

While modern slavery is unique in its manifestations and impact on victims, global health professionals are encouraged to build on lessons learned from decades of experience shaping the public health response to other forms of abuse, such as domestic violence, in order to improve and expand upon current practices. In addition, global health professionals are uniquely positioned to conduct research on the epidemiology of human trafficking, as well as to evaluate the effectiveness of various treatment approaches and direct services provided to victims of trafficking. Depending upon their specialty and position, global health professionals can provide leadership and can contribute in numerous ways to improve the response to human trafficking, only a few of which are listed below:

- Become informed about the contexts in which human trafficking is found today and be able to identify a person who may be a victim of human trafficking.
- Develop and teach human trafficking courses in education and training programs for health professionals who serve in a wide range of health care settings and who may come into contact with victims of human trafficking or be called on to support services for victims. Such training is needed for the

full range of health professionals, including physicians, nurses, physician assistants, dentists, psychologists, social workers, drug abuse counselors, health administrators, and others.

- Build on the existing body of human trafficking-related research and evaluation by conducting studies that examine key health issues resulting from human trafficking and that explore effective means of health care delivery.
- Become informed about local laws and government policies and procedures related to human trafficking, and identify ways to improve health-related responses and the delivery of comprehensive, coordinated services for survivors.
- Establish linkages with interagency partners that have responsibility for policies and procedures related to human trafficking, and participate in interagency task forces and other efforts aimed at developing coordinated, interdisciplinary anti-trafficking protocols.
- Work to develop trauma-informed policies and procedures in health care delivery settings that ensure recognition of the signs of human trafficking, the establishment of protocols to follow for suspected cases of human trafficking, linkages with appropriate resources, and staff training to ensure implementation.
- Work with NGOs and faith-based communities that are providing services to survivors of human trafficking to help expand and improve services to address the physical and mental health needs of survivors.
- Join or create an online network of health professionals to share information on challenges and advances in health care responses to human trafficking.

CONCLUSION

Vannak Prum's journey to freedom described earlier is an inspiration, and his unique contributions to ending modern slavery reflect the resilience displayed by many survivors of horrendous abuses suffered at the hands of traffickers. His experience also highlights the challenges we face going forward. From the time he escaped the fishing boat on which he was enslaved, Mr. Prum encountered police, nurses, doctors, and jailers who did not recognize his circumstances to be those of human trafficking. Most of the people with whom he came in contact did not see him as a trafficking victim in need of help, but rather as an illegal alien, a migrant worker, or an arrestee. The tragedy of Mr. Prum's situation going unrecognized, untreated, and unserved is repeated countless times every day around the world. With in-depth training, improved protocols, and enhanced interagency coordination, health professionals can change previously missed opportunities into concrete steps toward our common goal—a world without slavery.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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COMMENTARY

Maximizing the benefits of improved cookstoves: moving from acquisition to correct and consistent use

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The adoption of clean cooking technologies goes beyond mere product acquisition and requires attention to issues of cooking traditions, user engagement, gender dynamics, culture, and religion to effect correct and consistent use.

INTRODUCTION

The goal of this article is to put forth the most critical considerations regarding cookstove adoption that were identified at a meeting of the Working Group to Address Increasing Adoption of Improved Cookstoves. The meeting was hosted by the environmental health project WASHplus (funded by the United States Agency for International Development [USAID]) and the research project Translating Research into Action (TRAction) in Washington, DC, in October 2013. In this article, we use the term improved cookstoves (ICS) to mean those that demonstrate more efficient fuel use and more reductions in the emissions of carbon monoxide and particulate matter than traditional biomass stoves. At a time when new ICS programs are being created and implemented, it is important to disseminate the latest knowledge about effective ICS adoption and use.

There are numerous examples in the developing world of products whose potential benefits far outweigh their costs but are not readily adopted. As there is no commonly accepted definition for adoption of a technology, we loosely define it as the acquisition and substantive use of a technology by the user. Some products known to suffer from this adoption puzzle include insecticide-treated bed nets, safe-water products, toilets, and ICS. Of these, ICS adoption faces some of the greatest challenges as less than 30% of biomass stove users globally cook with some form of an improved cookstove.[1] Furthermore, access to high-efficiency, low-emission, low-cost stoves, while expanding, is still limited. Importantly, in households with an ICS, there is often incorrect, inconsistent, and non-exclusive use, a fact that can curtail the benefits to be gained.

At the household level, the benefits of ICS may include reducing the time, money, and labor required for acquiring fuel. Environmental benefits may include reductions in anthropogenic climate change and deforestation. The stoves may also have the potential to improve health by reducing exposure to household air pollution (HAP) for cooks and accompanying children.[2] As 40% of the world's population (2.8 billion people) continue to cook on inefficient traditional cookstoves, there is considerable potential for clean-burning technologies to make a large global impact.[3] Moreover, the "Global Burden of Disease Report"[4] indicated that HAP was the fourth most significant risk factor for premature deaths worldwide, and the second in South Asia and sub-Saharan Africa. Although the evidence that ICS use leads to improved health is weak, a number of large-scale randomized trials are currently underway.

To maximize the energy-saving and potential health impacts from ICS, the stoves must first be acquired, then used correctly and consistently. Perhaps most critically, the stoves must come to displace the use of the traditional stoves. However, user demand for ICS is not yet sufficient to result in mass adoption. The challenge is thus to bring ICS adoption to scale. As this challenge is being addressed by numerous concurrent initiatives, in this article we focus on the critical

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aspects of building consumer demand and ensuring the correct and consistent use of ICS.

BUILDING DEMAND FOR ICS

Although ICS may be considered ''adopted'' once it is acquired, it will not displace traditional technology without correct and consistent use. Nonetheless, the most basic requirement for ICS adoption is acquisition, which necessitates that consumers know about and have access to ICS and are motivated to buy one. It also requires that consumers have the decision-making power and the economic resources to make the purchase.

Financing Options

Impact Carbon, a household energy implementing organization based in San Francisco, CA, successfully increased the acquisition of a rocket-style stove in villages in and around Mbarara, Uganda, from 4.6% to 57% by using a novel sales offer that included free trials, time payments, and return options.[5] In a related study, as part of an initiative funded by USAID/India, Abt Associates connected stove sales agents with a microfinance institution in Uttarakhand, India, to facilitate increased consumer access to purchasing capital, which resulted in more than 200 stove purchases.[6]

Marketing Campaigns

Marketing plays a powerful role in demand creation and in the accumulation of goods in almost every society. However, marketing campaigns to promote cookstoves have yielded mixed results over the past decades, and generally adoption rates remain low. Two types of product marketing techniques are generally used in the household energy sector:

1. Carefully crafted mass marketing campaigns
2. Focused approaches to engage households deeply and consistently through locally appropriate product demonstrations and follow-up visits

In the case of mass marketing campaigns, targeted consumer engagement can be effective. Several important lessons from marketing frameworks commonly used by global private-sector advertising may be applicable to the uptake of ICS.[7] Generally, effective marketing requires a creative strategy that is built around insights about consumers; in contrast, public health formative research is generally limited to end-user perspectives and habits. Effective advertising is rarely proscriptive. Rather, their messages engage the consumer in a simple, directional manner that piques interest and over time drives behavior change. Cookstove promoters should be confident in marketing the product based on what the consumer has identified as the most important attribute.

Successful ICS adoption goes beyond acquisition to ensure correct and consistent use.

Experience has shown that status can play an important role in ICS adoption, as when potential customers learn the adoption choices of opinion leaders in their community.[8] Established social networks and peer contacts may also influence perceived stove status as well as facilitate learning about stove attributes and performance. Perhaps in recognition of this, several stoves are being manufactured using bold signature color schemes and components that call attention to their perceived high level of technical sophistication. Empirical evidence of consumer patterns of Internet purchases in higher-income countries reveals that when given price options, people do not always choose the cheapest option. The same can be true in lower-income countries, particularly where status can be shown to be a driver of decision-making.[8]

There is substantial evidence that health-related messaging, while important in increasing health knowledge, does not actually increase ICS sales and adoption.[9–12] The Shell Foundation's Room to Breathe social marketing campaign in Southern India, which used television and radio advertising, raised awareness of the risks of household air pollution from 43% to 69% in their campaign districts according to a post-campaign survey.[13] Moreover, 83% of respondents said they would buy an ''improved'' stove, but only 2% actually did. In this case, traditional mass marketing raised awareness, but it did not drive new cookstove purchases.

Instead, studies are recognizing the importance of non-health motives, including cost and intra-household gender dynamics, in adoption decisions.[14,15] But even here, the experience can be mixed. A recent experiment in rural Uganda tested the impact of marketing messages on willingness to pay for an ICS (measured as an actual purchase, not a hypothetical question). Despite locally developed marketing messages and best-practice strategies including vivid messaging and local experience with the ICS, there was no consistent increase in the willingness to pay as a result of the message, ''the stove can improve health,'' or the message, ''the stove can

Marketing campaigns should focus on the key product attributes identified by consumers.

save time and money.'' Thus, there is a critical need to understand underlying user preferences and hidden costs beyond health in the design and delivery of ICS, specifically, how external and intra-household relations shape decisions regarding energy and technology acquisition and use.[16]

Effective User Engagement

ICS is a new product category for many households. For ICS to be adopted, retailers need to engage with users directly. In a recent study of 10 stove manufacturers in India, all 10 companies identified product demonstrations as the most effective driver of stove adoption.[17] In addition to letting customers see and use the stove, demonstrations also helped address product perception issues. For instance, in Maharashtra, India, customers routinely question whether an improved stove can cook *chapatis*, the local flatbread, as effectively as on an open fire. Manufacturers have concluded that the best way to prove the capability to cook local cuisine is to let prospective customers taste the results.

Retailers need to engage with users through demonstrations, training, and post-sales support.

However, engagement should not stop at the point-of-sale. With any new technology, there is a user learning curve. In addition to training at the point-of-sale using formal and informal input, customers should receive regular follow-up visits until they have mastered the technology. These visits are critical to fostering correct and sustained use of the new stove. Without them, customers abandon the product and go back to using an open fire—a vexing reality faced by many public health intervention implementers.[18] The worst outcome would be substantial numbers of poor households investing in a relatively expensive new appliance and not using it.

The extent of behavior change required on the part of the user affects consumer demand. In the case of cookstoves, the behavioral shift required for ICS use is significant, particularly when compared with the behavior shift required for health programs such as vaccines or vitamin distribution. ICS use requires numerous changes on a daily basis that are often associated with a financial cost and that break with long-standing family cooking tradition. Therefore, it is important that manufacturers design products that are more consistent with local practices rather than trying to substantially change cooking practices and fuels. Finally, correct and consistent use of ICS requires that consumers are engaged as full partners in the move toward clean and efficient fuel and technologies and that they clearly understand the ICS value proposition.

Addressing Intra-Household Gender Dynamics

In households that burn biomass fuel for cooking, women are nearly always responsible for the cooking, and along with their children, they disproportionately suffer most of the health-related consequences of HAP. By contrast, men of the household are often not home when meals are being prepared, yet they hold disproportionate control over household purchasing decisions. This non-price barrier to ICS adoption is an identified intra-household externality: male financial decision-makers do not internalize the health benefits of a new technology that accrues to their wives and children.[18,19] In an experiment regarding the willingness-to-pay for an ICS in rural Mbarara, Uganda, 55% of households reported that women and men share joint decision-making about purchases for durable goods. However, among married households, women are willing to pay 21% to 23% less than men for an ICS, suggesting they have less spending power and less money to offer than men. In addition, when it comes to actual decision-making, the amount of power exercised by women who perceive themselves to be joint decision-makers (or who are in couples who self-identify as having shared decision-making power) is not statistically significant compared with women or couples who do not identify themselves as having shared decision-making power. Thus, even when reported as joint decision-makers with their husbands, women's power over household spending may be limited. As a response, efforts to increase willingness to pay for ICS may be more successful by designing and disseminating cookstoves with features valued more highly by men, without sacrificing the features valued by women so that they consistently use it.[20]

The Shell Foundation's aforementioned Room to Breathe campaign concluded that ''94% of households said buying a stove was a joint decision between man and wife, which means social marketing must reach both audiences.'' This conclusion was corroborated by a study of the First Energy Oorja stove in rural Maharashtra, which concluded that the third most common explanation for not purchasing a clean stove in Maharashtra, India, after household income and family size, was ''husband not

interested.''[18] To address this lack of interest, some recent stove designs have included electricity generation to charge mobile phones.

Intra-household factors that influence decision-making can also be seen at various levels of the ICS value chain. For example, the extent to which women are involved in enterprises and programs that provide modern energy and technologies depends on their bargaining power and control over assets and resources. Growing evidence shows that uptake will be limited unless women gain more say in household purchases and access to credit. As we move toward expanding acquisition globally, it will be critical to recognize the challenges of gender-related dynamics and to find opportunities to engage women more effectively across the value chain.

Engaging Women Across the Value Chain

From a public health perspective, women are central to improving health for themselves and their families. In general, when women have greater control over the use of household income, expenditures tend to be more focused on meeting the basic needs of the family and of the children.[21] Including women in all aspects of energy programming could yield positive benefits for themselves and their families. Women are one of the fastest growing cohorts of entrepreneurs in many developing countries,[22] and leveraging their strengths offers an opportunity for the energy sector. In a study of female entrepreneurs globally, researchers found that women are more likely to start businesses with both social and economic goals, or hybrid ventures.[23] Regarding clean-cooking solutions, women's substantial informal networks can open doors for new cooking-product businesses and provide access to consumers in hard-to-reach markets. In countries where gender disparity is high, employing women as sales agents can be a way to access untapped female markets as it is often easier for women to buy directly from other women in the community than having to go to cities or marketplaces. One example is the Al Johar Initiative created by Vodafone in 2010 that engaged all-female networks to access female markets in Qatar in hopes of overcoming cultural restrictions in movement and communication with men; the women reached 100% of their sales targets.[24]

Women are uniquely positioned to promote use of ICS. As the primary energy consumers and beneficiaries of ICS, women are well-versed in understanding the challenges of ICS adoption and continued use and are therefore integral to any consumer awareness and education campaign. Several women-focused initiatives in Africa, including ENERGIA Solar Sisters and Maasai Stoves and Solar are documenting the critical role women play in promoting the use of ICS among their peers. Women can also play central roles in microenterprise and as extension workers supporting maintenance and as leaders, networkers, and promoters for ICS in their region. Considerable challenges exist, and efforts to increase both external resources and internal agency are required.[25] Key to moving forward will be to effectively engage women in ways that accommodate or help overcome existing constraints while building intrinsic and extrinsic supports for their successful involvement.

Additional Cultural Considerations

Religious and cultural beliefs can also be an important consideration in ICS uptake and usage. According to many households in rural India, the open fire is not just a cooking appliance, but the spiritual center of the home.[18] Families saw the fire in their kitchen as a domestic god, a deity, and the smoke as a link between the earth and heaven. They prayed before the stove daily, and created *rangoli*, artwork drawn around the stove to consecrate it, to make it a sacred object. The religious significance of the open fire, as an obstacle to uptake of so-called ''smokeless'' cookstoves, is relevant in India, sub-Saharan Africa, and Latin America. For instance, many Peruvians interpret cooking smoke as a manifestation of God's presence (personal communication with A. Laurent, co-founder of Microsol, the carbon accreditation organization, Peru, 2011). These examples of gender and cultural considerations demonstrate how critical it is that ICS programs engage with communities to understand how their products will be most likely used in households.

STOVE USE AND BENEFITS

The extent to which the new stoves are beneficial is influenced by how correctly and consistently they are used as well as by how much they displace traditional stoves. Correct use includes both operation and maintenance requirements, and it is influenced by a host of factors, including ease of use, consumer education received at the point-of-purchase, formal and informal input and advice offered to the user, compliance with proper use instructions, and how well cooking with the stove

Stove producers must ensure their designs can handle the cooking tasks responsible for the greatest emissions and fuel consumption.

meets consumer needs and expectations. These factors affect whether the new stove is used consistently and the extent to which the new stove displaces the traditional stove, or is used alongside other cooking technologies (is "stacked").[26]

Health Benefits

The displacement of inefficient, polluting traditional stoves is critical to achieving health benefits. For example, based on the air quality model in the "International Workshop Agreement (IWA): Guidelines for Evaluating Cookstove Performance" (ISO 2012),[27] a 3-stone-fire would have to be used for less than approximately 1 hour per week, and there must be zero emissions from any other source in order to stay below the World Health Organization (WHO) Annual Interim 1 Target for PM 2.5 (particulate matter 2.5 μm in diameter and smaller) in the kitchen. Put simply, for protection of health at WHO levels, users not only must use an extremely clean stove but also must use it almost exclusively. Integrated exposure-response models for PM 2.5 for heart disease, stroke, and respiratory illness provide quantitative support for standards of acceptable indoor air pollution exposures.[28]

Fuel Efficiency

From a fuel efficiency perspective, to achieve a 50% fuel savings, the most efficient cookstoves (Tier 4 for fuel efficiency as defined by the ISO International Workshop on Cookstoves[27]) must displace 70% of typical baseline stove use, or a mid-level stove in terms of efficiency (Tier 2) must be used exclusively.[29] While currently this may appear to be unattainable in many settings, it is important to acknowledge the value of incremental progress in areas of technology, demand creation, and consumer support that is advancing us toward this goal.

Traditional cookstoves produce high levels of ambient air pollution even outside the dwelling.

Cookstove Use Patterns

The quantification of cookstove use is possible using technologies and time-use pattern survey tools such as Stove Use Monitoring Systems (SUMS); Nexleaf Analytics Wireless Cookstove Sensors (WiCS); the SWEETSense STOVE; and direct survey tools. However, few studies have reported how consumers use cookstoves in parallel and for what tasks. Knowing which cooking tasks are responsible for the greatest emissions and fuel consumption helps stove producers ensure their designs are well-suited for those tasks, and this can inform user training efforts to strategically encourage consumers to use the ICS specifically for those tasks. Understanding the daily patterns of traditional and nontraditional cooking technologies is essential for researchers and policy makers attempting to reduce indoor air pollution and environmental degradation from inefficient cookstoves.

Berkeley Air Monitoring Group investigated fuel savings of the EcoChulha forced draft stove with respect to specific cooking tasks in their field study funded by the United States Environmental Protection Agency with Alpha Renewable Energy in Gujarat, India. Using the EcoChulha for only the energy intensive tasks of cooking bread and vegetables, for example, would result in 80% traditional stove displacement and 50% fuel savings.[30] While full displacement of traditional stoves would, of course, maximize benefits, this analysis demonstrates that it can help to focus stove design and behavior change strategies on addressing the most energy-intensive tasks.

Incremental Progress

The IWA framework recognizes the importance of incremental progress toward the larger goals of widespread adoption of cooking solutions with the highest efficiency/fuel use, emissions, and safety. As stated in the IWA,[27] these guidelines acknowledge progress while setting aspirational goals and allow organizations and countries to select indicators and tiers based on local priorities. In addition, programs should consider

whether the need for free or heavily subsidized stoves is an appropriate strategy to achieve wide-scale adoption in some settings. Ultimately, protecting health and the environment will depend on whether the household energy sector can provide cookstoves with low-pollutant emissions while also meeting consumer needs. Thus, addressing those needs will be fundamental to achieving health and environmental goals.

CONCLUSION

ICS must meet consumer needs and preferences if they are to lead to correct and consistent use and to successfully displace traditional stoves. This is also necessary for reducing household air pollution and fuel consumption, and therefore providing maximum health and environmental benefits. However, consumer needs and preferences are complex and are influenced by many contextual and social factors that require a deep understanding of culture, going beyond technology and economics. Successful ICS business models will need to be sensitive to cultural practices in both the design of the product and marketing strategies.

Key considerations that can aid in large-scale ICS adoption include:

1. Recognizing that stove adoption does not equate with stove acquisition and that long-term consistent and continuous use requires consumer buy-in and understanding of the value proposition that ICS can provide
2. Designing marketing campaigns that engage the consumer by identifying key attributes of importance to the consumer, rather than long lists of attributes that do not necessarily influence the consumer's decision
3. Ensuring effective user engagement by including demonstrations, training, and post-sales support
4. Addressing intra-household gender dynamics to enhance equity in purchasing decisions
5. Including women more effectively throughout the cookstove value chain by improving both resources and agency-based support
6. Identifying and respecting the cultural significance of cooking food
7. Understanding the actual-use scenarios of the stove (for example, boiling water for tea versus frying flat breads)

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Addressing consumer needs is fundamental to achieving health and environmental goals.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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ORIGINAL ARTICLE

Are national policies and programs for prevention and management of postpartum hemorrhage and preeclampsia adequate? A key informant survey in 37 countries

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Most surveyed countries have many supportive policies and program elements, but issues remain that impede maternal health efforts, including: inconsistent availability of essential commodities, particularly misoprostol; limitations on midwives' scope of practice; incomplete or out-of-date service delivery guidelines; and weak reporting systems.

ABSTRACT

Introduction: Although maternal mortality has declined substantially in recent years, efforts to address postpartum hemorrhage (PPH) and preeclampsia/eclampsia (PE/E) must be systematically scaled up in order for further reduction to take place. In 2012, a key informant survey was conducted to identify both national and global gaps in PPH and PE/E program priorities and to highlight focus areas for future national and global programming.

Methods: Between January and March 2012, national program teams in 37 countries completed a 44-item survey, consisting mostly of dichotomous yes/no responses and addressing 6 core programmatic areas: policy, training, medication distribution and logistics, national reporting of key indicators, programming, and challenges to and opportunities for scale up. An in-country focal person led the process to gather the necessary information from key local stakeholders. Some countries also provided national essential medicines lists and service delivery guidelines for comparison and further analysis.

Results: Most surveyed countries have many elements in place to address PPH and PE/E, but notable gaps remain in both policy and practice. Oxytocin and magnesium sulfate were reported to be regularly available in facilities in 89% and 76% of countries, respectively. Only 27% of countries, however, noted regular availability of misoprostol in health facilities. Midwife scope of practice regarding PPH and PE/E is inconsistent with global norms in a number of countries: 22% of countries do not allow midwives to administer magnesium sulfate and 30% do not allow them to perform manual removal of the placenta.

Conclusions: Most countries surveyed have many of the essential policies and program elements to prevent/manage PPH and PE/E, but absence of commodities (especially misoprostol), limitations in scope of practice for midwives, and gaps in inclusion of maternal health indicators in the national data systems have impeded efforts to scale up programs nationally.

INTRODUCTION

In 2010, approximately 287,000 women worldwide died of pregnancy-related causes—a decline of 47% since 1990.[1] Despite this considerable progress, maternal mortality remains unacceptably high in many countries, with sub-Saharan Africa and South Asia having the greatest burden of maternal death.

Efforts to reduce maternal mortality have included attention to the 2 leading causes: postpartum hemorrhage (PPH) and preeclampsia/eclampsia (PE/E). Global recommendations point national maternal health programs to a set of key components that should be addressed to successfully reduce maternal morbidity and mortality:

- The presence of oxytocin, misoprostol, and magnesium sulfate, in correct dosages, on the World

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Postpartum hemorrhage and preeclampsia/eclampsia are the 2 leading causes of maternal death.

Health Organization (WHO) and national essential medicines lists[2]

- The need to ensure that these commodities are available in sufficient quantities and stored correctly at health facilities[3]
- Policy and service delivery guidelines that support the provision of uterotonics (including use of active management of the third stage of labor [AMTSL]) for the prevention of PPH,[4] the use of misoprostol at home birth when AMTSL is not possible,[4] and the use of magnesium sulfate in the management of severe PE/E[5] by the appropriate categories of personnel
- Legal authorization, or authorization through national guidelines, for midwives to administer oxytocin and magnesium sulfate and to perform manual removal of placenta, as well as their education in these practices[6] or task shifting, as may be needed for advanced distribution of misoprostol
- Inclusion of up-to-date, evidence-based guidelines as the basis of in-service training and preservice education[7,8]
- Monitoring, evaluation, and reporting on the provision of uterotonics as a national indicator[4]

The extent to which these interventions are in place in a country indicates the likelihood that a country will be addressing their major causes of maternal mortality.

With this in mind, the Maternal and Child Health Integrated Program (MCHIP), with support from the United States Agency for International Development (USAID), undertook an augmented key informant survey in 2012 of national health programs supported by USAID in 43 countries, especially those facing the highest burden of maternal mortality. The goal of this multi-country survey was to provide a global snapshot of the extent to which these essential policies and programs were in place and to provide program managers and development partners with evidence on the key processes that facilitate scale up and expansion of maternal health interventions, especially evidence-based PPH and PE/E program interventions. This article summarizes the most relevant findings from the 2012 survey. The full report, including the questionnaires (in English, French, and Spanish), is available at: www.mchip.net/globalstatusreportdownloads.

METHODS

Between January and March 2012, we conducted a key informant survey of national programs for the prevention and management of PPH and PE/E. The survey consisted of a 44-item questionnaire that addressed 6 core programmatic areas: policy, training, medication distribution and logistics, national reporting of key maternal health indicators, programming, and challenges to and opportunities for scale up. (See the supplementary material for the survey instrument.) The majority of questions required a dichotomous yes/no response, while some required responses on a graded scale. Qualitative open-ended questions were asked in 2 areas: programming and challenges to and opportunities for scale up. All questions included the option to provide additional explanation, and some specifically requested more information, depending on the response. Professional translators translated the survey instruments from English into French and Spanish, and assisted with back-translation of responses into English.

We sent the questionnaire to 43 countries and received responses from 37 countries. The 6 countries that did not participate could not due to lack of funds, lack of permission from national authorities, or a need to attend to other priorities.

An in-country focal person from the Ministry of Health (MOH), MCHIP, or partner NGO led the national review and data collection in each country. These focal persons worked with local partners and stakeholders through a national consultative group to gather the necessary information and data and to complete the questionnaire. The consultative group was typically a maternal health working group convened by the government, with representation from relevant departments of the MOH, development partners, and implementing agencies.

Through an iterative series of participatory meetings, the partners reviewed the questions, provided responses, sought additional data for unanswered questions, and finally confirmed the responses on the completed instrument. We asked the groups to use nationally relevant documents, such as policies, the national essential medicines list (EML), service delivery guidelines (SDGs), and clinical standards, to respond objectively and with sufficient detail. Since the experts gathered in these consultative meetings are the people who would be at the forefront of policy implementation and practice in their countries, the information

provided by them represents the most reliable and valid data available for the questions posed. Clarification was provided by the MCHIP/Washington team as required. Survey responses were sent to the MCHIP/Washington office where data were reviewed and cleaned. Data were entered into a Microsoft Access database to facilitate ease of data entry and analysis.

We also asked countries to provide copies of national guidelines and SDGs, and we analyzed national SDGs from 20 countries to determine the accuracy of survey results compared with the SDGs, as well as of national guidelines compared with global guidelines as the standard of reference. (See a list of documents reviewed in the supplementary material.) Using a standardized checklist adapted from WHO's *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors*,[9] we focused on the following components in the SDG review: practice of AMTSL (including use of uterotonics); use of misoprostol for the prevention of PPH; diagnosis and management of PE/E, including the use of magnesium sulfate; and use of antihypertensives for severe hypertension in pregnancy.

Twelve SDGs were in English and were independently reviewed by the research team. The remaining 8 SDGs were in French and Spanish and were reviewed with an MCHIP country representative using a shorter checklist. Only questions asked of all countries about SDGs are included in the final sub-analysis. (See supplementary material for the checklists.)

Ethical clearance was not required because the survey reported on publically available information and respondents' responses were not recorded or individually reported.

RESULTS

Results are organized according to policy and program elements deemed necessary by global recommendations for successful PPH and PE/E programming.

Availability of Uterotonics (Oxytocin and Misoprostol)

Among the 37 countries surveyed, 33 countries (89%) reported regular availability (available "more than half the time") of oxytocin *in facilities*, while only 10 countries (27%) reported regular availability of misoprostol (Figure 1). The 4 countries that reported that oxytocin was not regularly available were Bangladesh, Liberia, South Sudan, and Yemen. The vast majority of countries (34 of 37, or 92%) reported regular availability of oxytocin *in the national medical store or warehouse*. Countries that reported infrequent availability of misoprostol noted a lack of a national policy supporting misoprostol as a principle cause.

About 70% of the countries (26 of 37) reported that oxytocin was provided for free to clients at public health facilities (Figure 1). In 9 countries, however, respondents reported that clients sometimes had to pay for oxytocin, even though national policy indicates that it should be provided at no cost. Illustrative follow-up responses explained why oxytocin is not always free to clients:

> *It is free of cost, whenever available. Most of the time it is not available and patients have to buy it or it is provided through charity/donation but not refrigerated.*

> *If the Medical Supply at the Ministry distributes it, it will be free. But most of the time, it may not be there, as the amount distributed to health facilities is not sufficient. If it is not available, the family may buy it from the private pharmacy.*

It was not specified whether this payment was for oxytocin inside the facility or for purchasing oxytocin outside the facility.

Availability of Magnesium Sulfate

Most surveyed countries (28 of 37, or 76%) reported regular availability of magnesium sulfate in facilities (Figure 2). Of the 9 countries that reported that magnesium sulfate is still not regularly available at least half the time, 6 were in Africa and 3 in Asia. More countries (32 of 37, or 86%) reported that the medicine was regularly available in the MOH central medical store. Among surveyed countries, 46% reported that stock-outs of magnesium sulfate were rare, and an additional 46% reported that stock-outs occurred sometimes or were frequent.

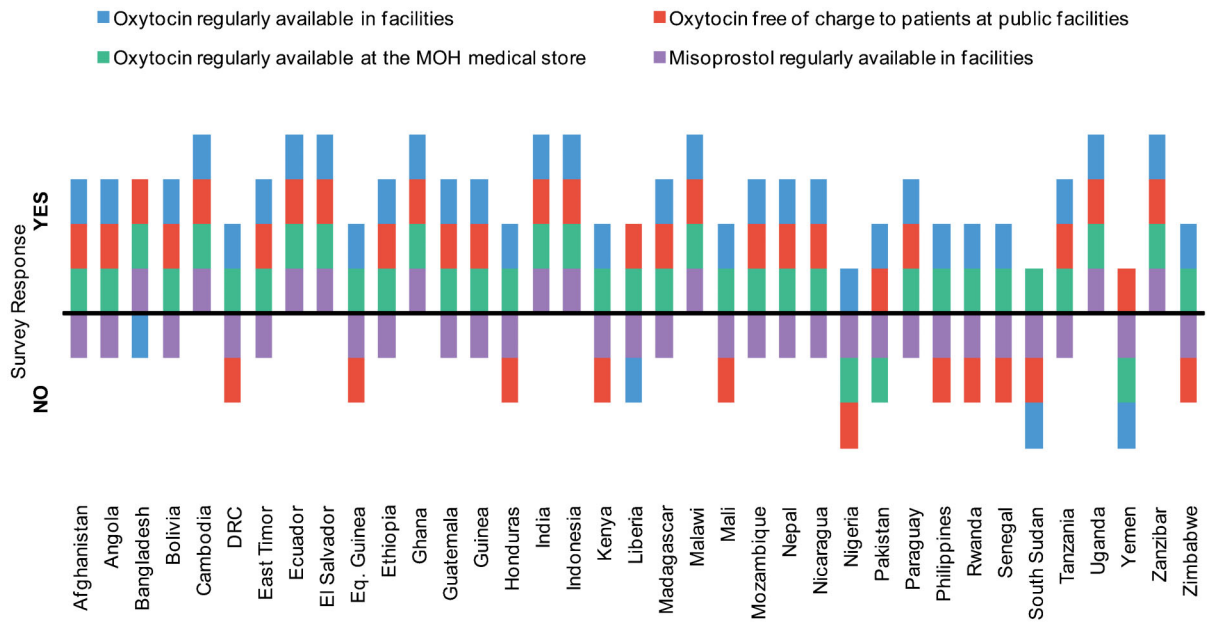
Medicines Approved at the National Level

All countries surveyed, except Equatorial Guinea, responded that oxytocin was on the EML for prevention/treatment of PPH (Figure 3). Only 21 of 37 countries (57%), however, reported that misoprostol was on the EML for prevention/treatment of PPH.

More countries included oxytocin on their essential medicines list than misoprostol.

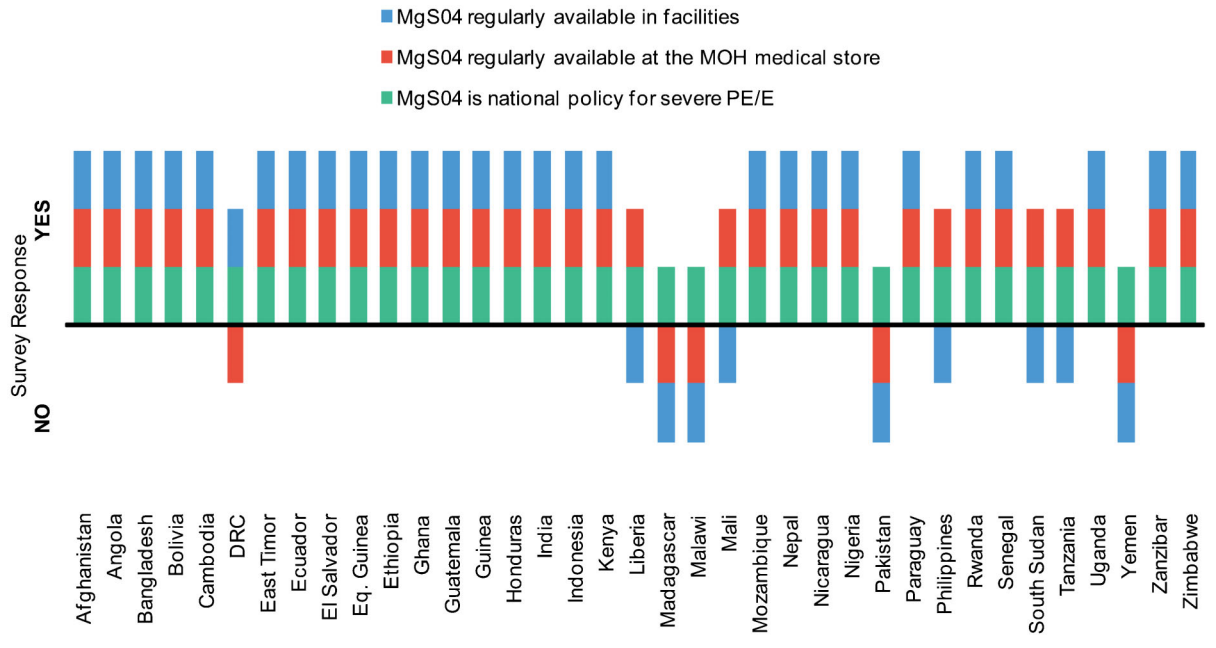
All countries surveyed reported that magnesium sulfate is approved in national policy as a first-line anticonvulsant treatment for severe PE/E.

FIGURE 1. Availability of Uterotonics, 37 Surveyed Countries, 2012



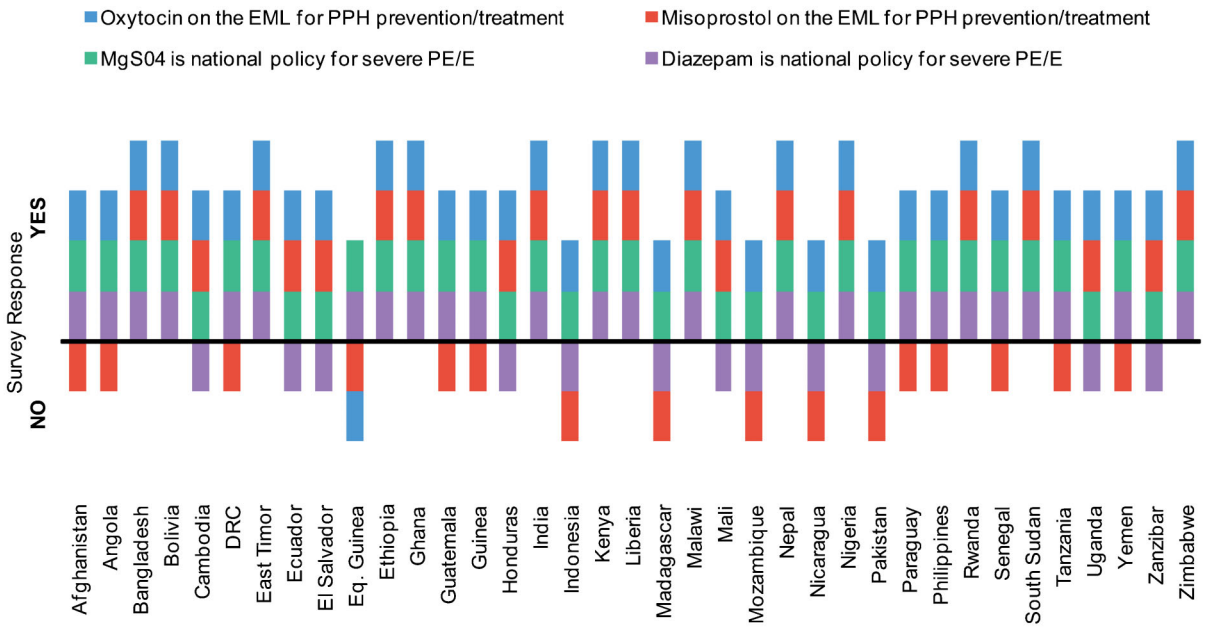
Abbreviations: DRC, Democratic Republic of Congo; MOH, Ministry of Health.

FIGURE 2. Availability of Magnesium Sulfate, 37 Surveyed Countries, 2012



Abbreviations: DRC, Democratic Republic of Congo; MOH, Ministry of Health; MgSO4, magnesium sulfate; PE/E, preeclampsia/eclampsia.

FIGURE 3. Medicines Approved at the National Level, 37 Surveyed Countries, 2012



Abbreviations: DRC, Democratic Republic of Congo; EML, essential medicines list; MgSO4, magnesium sulfate; PE/E, preeclampsia/eclampsia; PPH, postpartum hemorrhage.

A substantial number of countries (25 of 37), however, also included diazepam for the same indication. Of the 20 SDGs reviewed, 6 showed incomplete or inaccurate instructions for the use of magnesium in severe PE/E, compared with the WHO standard protocol for use of the drug.[9]

Current Practice and Tracking of AMTSL

All but 1 surveyed country (South Sudan) reported that AMTSL was approved as national policy; 35 of 37 reported that it was included in the national SDGs (Figure 4). The focused review of national SDGs showed that all 20 SDGs included oxytocin as part of AMTSL; 18 of 20 indicated the correct dose of the medicine, but only 9 of the 20 contained accurate descriptions of the 3 essential components of AMTSL. A minority of surveyed countries (16 of 37) reported tracking AMTSL in their national health management information system (HMIS).

Piloting Misoprostol for Home Birth

Sixteen of 37 countries (43%) reported that they were piloting or had piloted misoprostol for prevention of PPH at home birth; only 5 of 37, however, reported efforts to take this program to national scale (Figure 5). In follow-up qualitative responses, 7 countries reported that their governments do not support misoprostol for use at home births.

Scope of Practice for Midwives/Skilled Birth Attendants

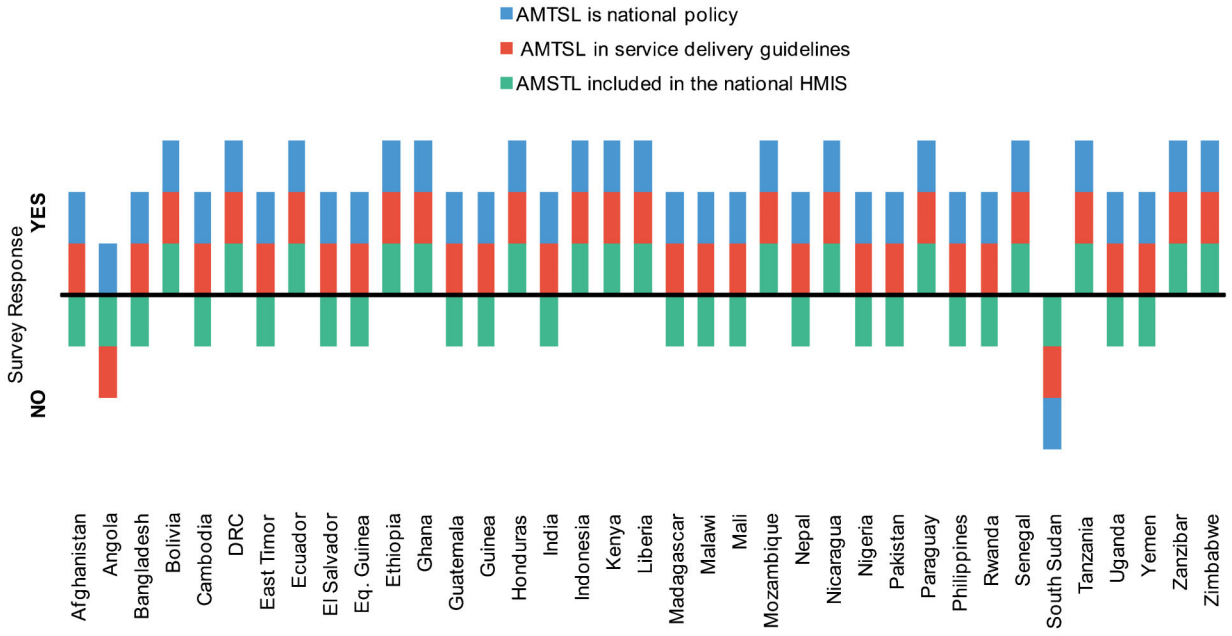
Most countries (31 of 37, or 84%) reported that midwives/skilled birth attendants (SBAs) were authorized to perform AMTSL, including administration of oxytocin (Figure 6). Fewer (29 of 37, or 78%) reported that midwives/SBAs were authorized to diagnose severe PE/E and to administer magnesium sulfate to treat the condition. Fewer still (26 of 37, or 70%) reported that midwives/SBAs were authorized to perform manual removal of the placenta.

Some countries have piloted use of misoprostol to prevent PPH at home birth, but far fewer have taken the strategy to scale.

DISCUSSION

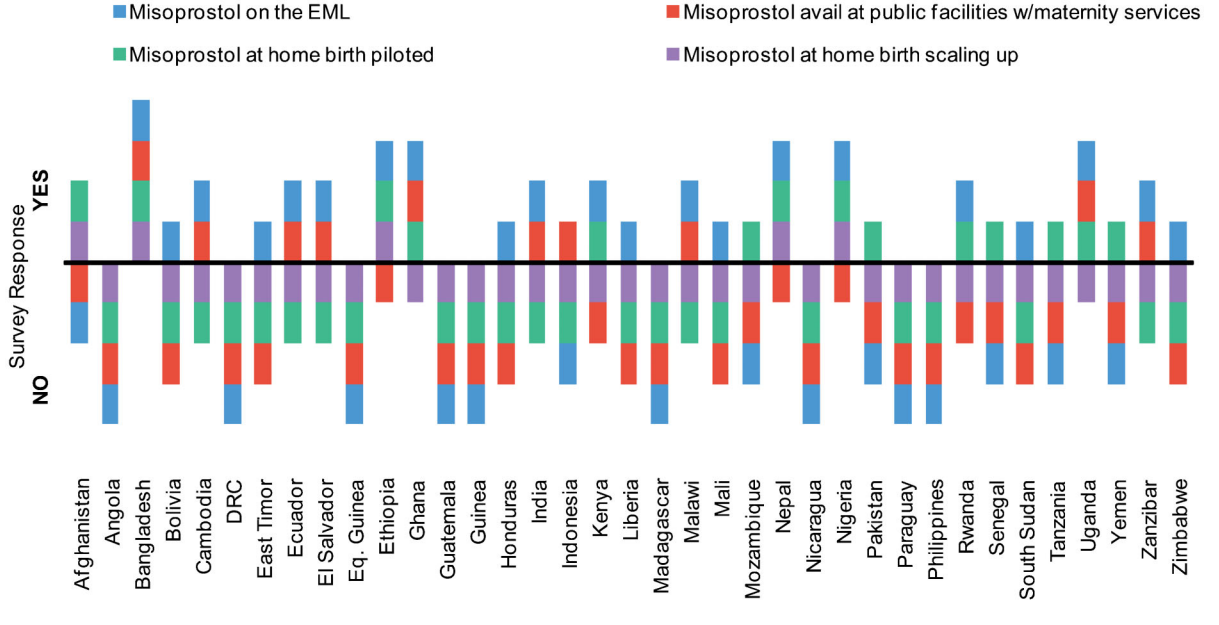
Overall, results of this key informant survey suggest that most countries are appropriately

FIGURE 4. National Policy and Guidelines on AMTSL, 37 Surveyed Countries, 2012



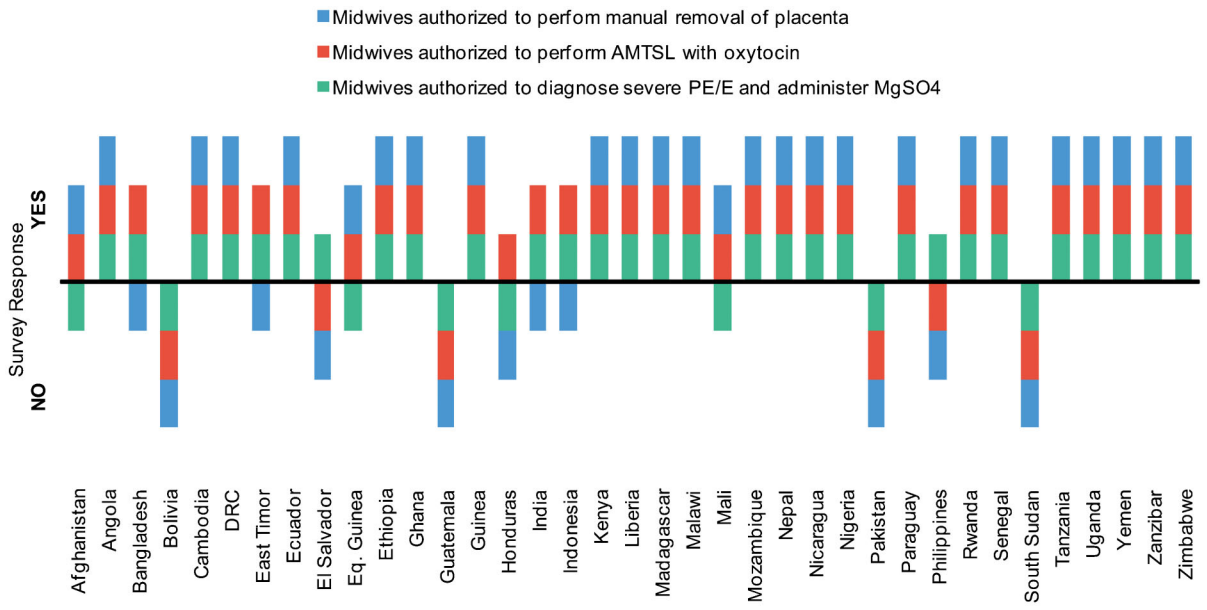
Abbreviations: AMTSL, active management of the third stage of labor; DRC, Democratic Republic of Congo; HMIS, health management information system.

FIGURE 5. Availability and Use of Misoprostol, 37 Surveyed Countries, 2012



Abbreviations: DRC, Democratic Republic of Congo; EML, essential medicines list.

FIGURE 6. Midwifery Scope of Practice, 37 Surveyed Countries, 2012



Abbreviations: AMTSL, active management of the third stage of labor; DRC, Democratic Republic of Congo; MgSO4, magnesium sulfate; PE/E, preeclampsia/eclampsia.

prioritizing policies and practices that are essential for strong PPH and PE/E programs. Issues remain, however, that need to be addressed.

Availability of Essential Medicines

Inconsistent availability of essential medicines limits implementation of national priorities and can lead to inadequate clinical management. Despite general approval of oxytocin as an essential medicine for preventing PPH, challenges with free distribution, proper storage, and maintaining a regular supply of the medicine persist. This suggests a need for better supply chain management of maternal health medicines and supplies, as well as greater coordination between clinical/service provision, the central medical stores, and supply chain management and logistics departments of health ministries. This type of key informant survey cannot address the additional issue of oxytocin potency. It must be recognized, however, that heat instability and oxytocin deterioration can be an additional and critical dimension in any consideration of uterotonic availability.

Magnesium sulfate has global approval as an essential medicine for managing PE/E and its consequences. This was similarly reflected in our multi-country survey. As with oxytocin, however, free distribution and maintenance of a regular supply of the medicines are ongoing challenges that limit success despite universal endorsement. Qualitative responses to the survey reveal that for PE/E in particular, lack of regular magnesium sulfate availability is one of the most critical barriers to scaling up the intervention. Strengthening the supply chain for magnesium sulfate, ensuring that all SBAs are permitted and competent to use it, and identifying and addressing additional barriers are necessary components of national programs.

Better supply chain management of maternal health medicines and supplies is needed.

Likewise, although misoprostol is known to be effective in preventing PPH, most of the surveyed countries reported limited availability, both in facilities and at the national store. Although the use of misoprostol to prevent PPH at home birth has been piloted in many countries,[10] in this survey only 5 of the 16 countries that have piloted the strategy have moved toward scale up—Afghanistan, Bangladesh,

A midwife in Tanzania checks in on a mother and her newborn baby.

National service delivery guidelines must be updated continually to keep pace with the evolving global evidence.

Ethiopia, Nepal, and Nigeria. This disconnect between pilot and scale up is concerning and reflects lingering skepticism about the place of this important intervention in maternal health programming. This could be due in part to conflicting global guidance, which has, until recently, limited countries' willingness to proceed. In 2012, however, WHO revised its PPH guidelines to state that "when skilled birth attendants are not present and oxytocin is unavailable, community health care and lay health workers should administer misoprostol (600 μg PO) for PPH prevention." These new recommendations may result in changes to some national program strategies in the coming years. Additionally, the inclusion of misoprostol as one of the 13 essential commodities of the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) has given global prominence to this medicine. Our survey findings suggest an opportunity for global action and advocacy, especially given the growing support for programs to prevent PPH using misoprostol and the research that continues to emerge.

Midwives should be permitted to perform all 7 basic emergency obstetric and newborn care functions.

Barriers to access and availability of key maternal health medicines where they are needed are now being addressed under the high-level UNCoLSC, which is leading advocacy and policy efforts to ensure sufficient supply, quality, and use at the country level.[11] Paying for medicines is a bottleneck to improving coverage of high-impact interventions, despite the fact that the 3 life-saving commodities addressed in the survey are considered to be inexpensive. As countries accelerate progress toward Millennium Development Goal 5 (improve maternal health), greater emphasis must be given to equity and the need to focus efforts on reaching the poorest and most vulnerable groups.[12]

Up-to-Date Service Delivery Guidelines

Acceptance of the use of uterotonics (and AMTSL) as a routine part of care during childbirth is nearly universal. New evidence has highlighted the central importance of the administration of a uterotonic in the prevention of PPH.[13] However, technical inconsistencies in national SDGs must be addressed. National guidelines were sometimes incomplete or out-of-date, a fact that sometimes conflicted with respondents' answers to the survey. This suggests that stakeholders may perceive their country guidelines to be more accurate than they in fact are. Such discrepancies may be expected as national SDGs try to keep pace with the advancing and evolving global evidence. Efforts must be made, however, to disseminate new information and to support countries as they revise existing guidelines.

Reporting Systems

Lack of national reporting in the HMIS on use of uterotonics (and AMTSL), as well as other key indicators related to maternal health, currently limits and will continue to constrain progress. Gathering sufficient data on implementation of critical interventions is important to ensure that these interventions are prioritized and that progress is measured.

Scope of Practice for Midwives

A "scope of practice" defines the responsibilities and activities that a licensed practitioner is permitted to perform in health care, per national policy. Although there has been some progress in expanding midwifery scopes of practice, not all countries include all 7 basic emergency obstetric and newborn care (BEmONC) signal functions within that scope,* despite the fact that they are included in the *Essential Competencies for Basic Midwifery Practice*[6] of the International Confederation of Midwives (ICM) and listed as essential interventions by WHO and others.[14,15] Our survey

* BEmONC includes 7 signal functions: administer parenteral antibiotics; administer uterotonic drugs; administer parenteral anticonvulsants; perform manual removal of placenta; perform removal of retained products (for example, manual vacuum aspiration); perform assisted vaginal delivery (for example, vacuum extraction); perform neonatal resuscitation.

results confirm that the role of the midwife varies by country and that midwives have a larger scope of practice in Asia and Africa than in Latin America, where in Bolivia, Guatemala, and Honduras, midwives are not allowed to perform AMTSL.

If the need for an emergency maternal health intervention exceeds the availability or capacity of service providers to provide it, women's lives are at risk. When there are complications during childbirth, a midwife or SBA needs to be both competent and authorized to perform all 7 BEmONC skills. There is strong and increasing support for a scope of practice for midwives that will allow them to provide the services needed to reduce the main causes of maternal mortality, including endorsements by WHO, the United Nations Population Fund (UNFPA), ICM, and the United Nations Children's Fund (UNICEF).[15] In the qualitative responses in this survey, task shifting and supportive policies were also reinforced as essential for program scale up.

Limitations

This survey had several limitations, despite efforts to ensure that the survey was as objective as possible. In some cases, country respondents may not have had complete information or data, or full access to such information or data, to allow for thorough, objective quantitative responses, for example, records on commodity stocks. Therefore, stock-outs may have been underestimated in this study. Additionally, there was little information on the representatives in the stakeholder group, specifically MOH involvement, although this was actively promoted. Qualitative responses provided valuable information and helped to triangulate the quantitative responses, but they are based on opinion and may or may not represent the majority opinion of health professionals in a particular country. There were often gaps in answers about approved medicines for PE/E. When possible, the research team worked with countries to fill these gaps, and this may have affected objectivity. Many countries use different terms for the same activity or process and during attempts to clarify these differences, certain nuances may have been lost.

CONCLUSION

This survey offers opportunities to review national programs for addressing PPH and PE/E. It provides a multi-country snapshot of policy, practice, supplies, and activities, and guides national and global program managers and policy makers in setting priorities.

Recommended actions, based on the available data, include:

- Increased support for using misoprostol to prevent PPH at home births to allow greater coverage of uterotonic use in the third stage of labor than allowed by facility-based oxytocin alone. This is especially important in areas with high home birth rates and low skilled birth attendance.
- Additional effort to ensure availability and use of magnesium sulfate, as part of appropriate and comprehensive management of women with PE/E
- Clear definition of and uniform application of the midwifery scope of practice, consistent with the ICM's recognized essential competencies and the international definition of a midwife[6,16]
- Updating national clinical guidelines and essential medicines lists to be consistent with WHO recommendations for PPH and PE/E
- Revision of health monitoring and reporting systems to include and track key interventions in maternal health

As countries scale up prevention and treatment programs for PPH and PE/E, national programs will need to ensure both adequate coverage and sustainability, and tracking the progress of national programs while supporting greater efforts to reduce maternal morbidity and mortality will be essential.

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ORIGINAL ARTICLE

Cumulative effects of heat exposure and storage conditions of Oxytocin-in-Uniject in rural Ghana: implications for scale up

Luke C Mullany,[a] Sam Newton,[b] Samuel Afari-Asiedu,[b] Edward Adiibokah,[b] Charlotte T Agyemang,[b] Patience Cofie,[c] Steve Brooke,[c] Seth Owusu-Agyei,[b] Cynthia K Stanton[a]

Oxytocin-in-Uniject devices could be stored 30 to 40 days without refrigeration under typical field conditions, with wastage levels below 10%, based on simulation studies.

ABSTRACT

Objective: Postpartum hemorrhage can be reduced substantially in home deliveries attended by community-based workers by using Oxytocin-in-Uniject (OIU) devices affixed with temperature-time indicators. We characterized the distribution of time to discard of these devices when stored under normal field conditions in Ghana.

Methods: Two drug storage simulation studies were conducted in rural Ghana in 2011 and 2012. Devices were transported under refrigeration from manufacture (Argentina) to storage at the study site. Twenty-three field workers each stored at home (unrefrigerated) 25 OIU devices and monitored them daily to record: (1) time to transition from usable to unusable, and (2) continuous digital ambient temperature to determine heat exposure over the simulation period. Time to discard was estimated and compared with mean kinetic temperature exposure of the devices during the shipment and storage phases and with characteristics of the storage locations using Weibull regression models. We used the time to discard distributions in a Monte Carlo simulation to estimate wastage rates in a hypothetical program setting.

Results: Time for shipment and transfer to long-term refrigerated storage and mean kinetic temperature during the shipment phase was 8.6 days/10.3°C and 13.4 days/12.1°C, for the first and second simulation studies, respectively. Median (range) time to discard when stored under field conditions (unrefrigerated) was 43 (6 to 59) days and 33 (14 to 50) days, respectively. Mean time to discard was 10.0 days shorter in the second simulation, during which mean kinetic temperature exposure was 3.9°C higher. Simulating a monthly distribution system and assuming typical usage, predicted wastage of product was less than 10%.

Conclusion: The time to discard of devices was highly sensitive to small changes in temperature exposure. Under field conditions typical in rural Ghana, OIU packages will have a half-life of approximately 30 to 40 days based on the temperature monitor used during the study. Program managers will need to carefully consider variations in both ambient temperature and rate of use to allocate the appropriate supply level that will maximize coverage and minimize stock loss.

INTRODUCTION

Oxytocin has been included on the World Health Organization (WHO) *Model List of Essential Medicines* since it was first published in 1977,[1] and it is the drug of choice to prevent and treat postpartum hemorrhage—the leading cause of maternal death globally.[2] There is considerable international commitment to expanding access to this drug, as reflected in recent recommendations from the UN Commission on Life-Saving Commodities for Women's and Children's Health. These recommendations include developing effective global mechanisms for pooled procurement and aggregated demand; supporting at least 3 manufacturers to develop and market high-quality, competitively priced oxytocin; and standardizing national regulatory processes for oxytocin registration.[3]

An important constraint to expanding access is that oxytocin is not heat stable, a key consideration in peripheral settings in low-income countries where

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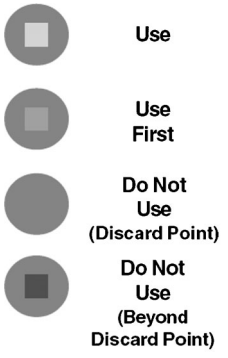
FIGURE 1. Visual Changes to the Temperature-Time Indicator Resulting From Cumulative Heat Exposure



Oxytocin is the drug of choice to prevent and treat postpartum hemorrhage, but access has been constrained because it needs to be refrigerated.

consistent and reliable cold-storage capability is often lacking.[4] This factor discourages health planners from procuring oxytocin for peripheral sites and could lead to waste and/or discarding of potentially usable oxytocin due to concerns about loss of potency. On the other hand, lack of heat stability can lead to sale and use of poor-quality oxytocin; for example, 74% of oxytocin samples purchased at private pharmacies in Ghana were outside manufacturer specification for active pharmaceutical ingredient (API).[5]

Current *International Pharmacopoeia* guidelines recommend storing oxytocin at 2℃ to 8℃ and protecting it from light exposure, but the drug can withstand moderate heat exposure.[6] A simulated temperature exposure study demonstrated that when exposed to either low (4℃ to 8℃) or high (30℃) temperature continuously for 12 months, oxytocin retained 100% and 86% of its API, respectively, and was not affected by light exposure.[4] The authors recommended that all oxytocics be refrigerated to the extent possible but that temporary storage up to 30℃ for 3 months was acceptable.

Temperature-time indicators change color in response to cumulative heat exposure, providing a way for health workers to monitor usability of oxytocin kept outside the cold chain.

One possible strategy for extending access to oxytocin to the peripheral health system would be to store the drug under cold-chain conditions at regional drug depots and health facilities with reliable refrigeration (as used for vaccines), and then for community-based providers to maintain a smaller temporary supply outside the cold chain, only accessing the refrigerated stock periodically for resupply. For this approach to be successful, the community-based providers would need to know the point at which an individual ampoule or injection device for oxytocin should be discarded. This would depend on cumulative exposure to heat, which would be expected to vary under different field conditions. Temperature-time indicators (TTIs) that change color in response to cumulative heat exposure provide a solution for this issue. The TTI is a simple label depicting a square enclosed in a circle (Figure 1); as the TTI (and therefore the drug) is cumulatively exposed to heat, the inner square begins to darken (a signal to prioritize use of this drug first), and then reaches the same color (or darker) than the outer circle, signaling that the drug should be discarded.

We recently completed a cluster-randomized trial of the effect of prophylactic use of Oxytocin-in-Uniject (OIU) on postpartum hemorrhage among home deliveries, which found that OIU reduced postpartum hemorrhage by half in home deliveries in Ghana.[7,8] OIU is a prefilled, sterile, non-reusable injection device with a single, 10 IU dose of oxytocin. In that trial, we conducted a sub-activity to systematically assess the duration that oxytocin can be stored outside the cold chain based on use of a TTI that had been applied to the foil envelopes containing the OIU devices. Specifically, we aimed to estimate the overall distribution and median time to reaching the discard point when oxytocin is removed from the cold chain and stored under realistic field conditions in rural Ghana.

The specific TTI used in this study, and that has been used previously for oxytocin, was designed to reach the discard point at the equivalent of 17.2 days at 40℃, 72.5 days at 30℃, or 154 days at 25℃. The choice of this particular TTI is conservative, as oxytocin exposed to these heat equivalents could actually remain within API specifications for longer time periods. Because the TTI was designed for monitoring vaccine vials, it does not function correctly when exposed to ultraviolet light and thus, if used to monitor oxytocin, requires storage in darkness.

METHODS

This study was a sub-activity of a larger cluster-randomized trial of the impact of OIU on postpartum hemorrhage among women delivering at home in the Brong-Ahafo region of Ghana, the design[7] and results[8] of which have been published previously. In the randomized trial,

OIU devices (with TTI) were distributed to community health officers (CHOs) on a regular basis guaranteeing that they would have a sufficient supply when called (by mothers/family members) at the time of labor and delivery. The CHOs maintained their supply of OIU without refrigeration in their assigned Community-based Health Planning and Services (CHPS) compound. During trial implementation, the CHOs used only those devices for which the TTI indicated that the drug had not yet reached the discard point.

Overview of the Simulation Study

We were interested in systematically characterizing the distribution of time to which the TTI reached the discard point. During a pre-simulation phase between 2010 and 2011, we monitored the state of the OIU devices and the temperature conditions during storage from the time between manufacture and shipping to our storage facility at the Kintampo Health Research Centre (KHRC) in Kintampo, Ghana, and during storage at that site. We then conducted a simulated storage activity between 2011 and 2012 by asking field workers to store a quantity of devices in their homes while monitoring once daily the status of the TTI. Ambient temperature was monitored using a LogTag device, a battery-operated, digital ambient temperature recorder. The simulation exercise was conducted twice using different shipments of OIU devices during 2 different calendar periods, representing seasonal variation in rural Ghana. We also collected some basic information regarding the characteristics of field workers' homes and how they stored the devices out of refrigeration.

Pre-Simulation: Temperature Monitoring From Manufacture to Arrival at KHRC

Prior to shipment from Biol, the Argentina-based manufacturer of the OIU used in this study, LogTag devices were placed in the containers used to transport the OIU in order to monitor the temperature to which the OIU devices were exposed during shipment from manufacturing site to storage at the KHRC. Two such pre-simulation studies were conducted on separate batches of OIU devices. Devices used in the first pre-simulation were shipped in August 2010, while the second set of devices was shipped in November 2011. In each shipment, there were 2 separate containers; within each was packed a separate LogTag, and these devices were synchronized to record at the same time points and with equal recording interval (every 30 and 15 minutes for the 2010 and 2011 shipments, respectively). For both batches, OIU devices were manufactured and stored at Biol, air transported under refrigeration from Buenos Aires, Argentina, to Johannesburg, South Africa, to Accra, Ghana. Upon arrival in Ghana, the containers remained at the airport (a non-climate-controlled environment) through customs processing, before being transported by road to the KHRC in Kintampo (a distance of about 450 km), and being returned to refrigeration upon arrival at the center. The LogTag collected data continuously from preparation of the shipment from Biol until placement of the OIU devices in controlled refrigeration at KHRC, where they were stored at 2℃ to 8℃ until received by field workers for the simulation exercise.

Simulated Field-Based Storage Exercise

Starting in July 2011, and again in February 2012, we exposed packages of OIU devices to continuous ambient temperatures in the community. To avoid wastage, the OIU device itself was removed from its package, because we were interested only in monitoring the time for the TTI that was adhered to the package to reach the point of discard.

We chose 23 field workers to conduct this simulation and collect the monitoring measurements. All field workers were KHRC workers actively engaged in the parent randomized trial within which this activity was nested. We provided each field worker with 25 packages stapled to a piece of cardboard for easy viewing. In order to prevent direct exposure to light, the board was folded and placed in a small backpack during storage in the field worker's house. Each OIU package was pre-labeled with a unique identifying number.

Workers used a calendar data collection form into which he/she recorded the status of the TTI on a daily basis with 1 of 3 values:

- ''1'' (inner square lighter than outer circle)
- ''2'' (inner square same color as outer circle)
- ''3'' (inner square darker than outer circle)

A value of ''2'' corresponds to the discard point of interest in this study. In addition to the 25 devices, also included in each backpack was a LogTag device, set to record the temperature within the storage container at regular intervals. The temperature was recorded in degrees Celsius

every 10 minutes and every 23 minutes in the first and second rounds, respectively. Field workers checked the status of their packages each morning and continued doing so until the TTI for all 25 packages on their board had reached the discard point.

Characterization of Storage Locations

Basic information about each field worker's storage location was collected. These data included the district (Kintampo North vs. South); GPS waypoints; the storage location within the household; exposure of the backpack (in which the OIU packages were stored) to direct sunlight; construction materials used for roof, ceiling, wall, and floor; presence of fan; and whether the field worker cooked in the same room in which the devices were stored.

Sample Size

We calculated the number of devices required to estimate with 95% confidence the median time to discard within 1 week (+/− 7 days). To do so, we assumed that the probability of discard increases with time, and thus anticipated modeling the time to discard using a Weibull distribution; without prior knowledge we assumed the mean time would be 180 days with a shape parameter of 3. For sample sizes ranging from 100 to 1,000, we simulated 10,000 datasets distributed as Weibull with these parameters, and we estimated the proportion of datasets resulting in median discard times within 7 days of the median parameter; this proportion reached 95% when the sample size was 580. Therefore, we distributed 25 OIU packages to each of 23 field workers for a total of 575 OIU packages.

Analysis

The pre-simulation data (data on storage and handling of the OIU devices from manufacture to shipping to the storage facility at KHRC) were analyzed as follows: For each time point during transport, the exposure temperature was defined as the average temperature recorded by the 2 LogTag devices at that time point. The curve of temperature exposure for the first and second shipments was plotted over the time of shipment. In order to visualize and compare across the 2 shipments, the x-axis (in units of days) was standardized such that elapsed time was relative to the moment of shipment from Biol. Mean kinetic temperature for each shipment was calculated over the period of shipment using the batch-specific interval temperature measurements.

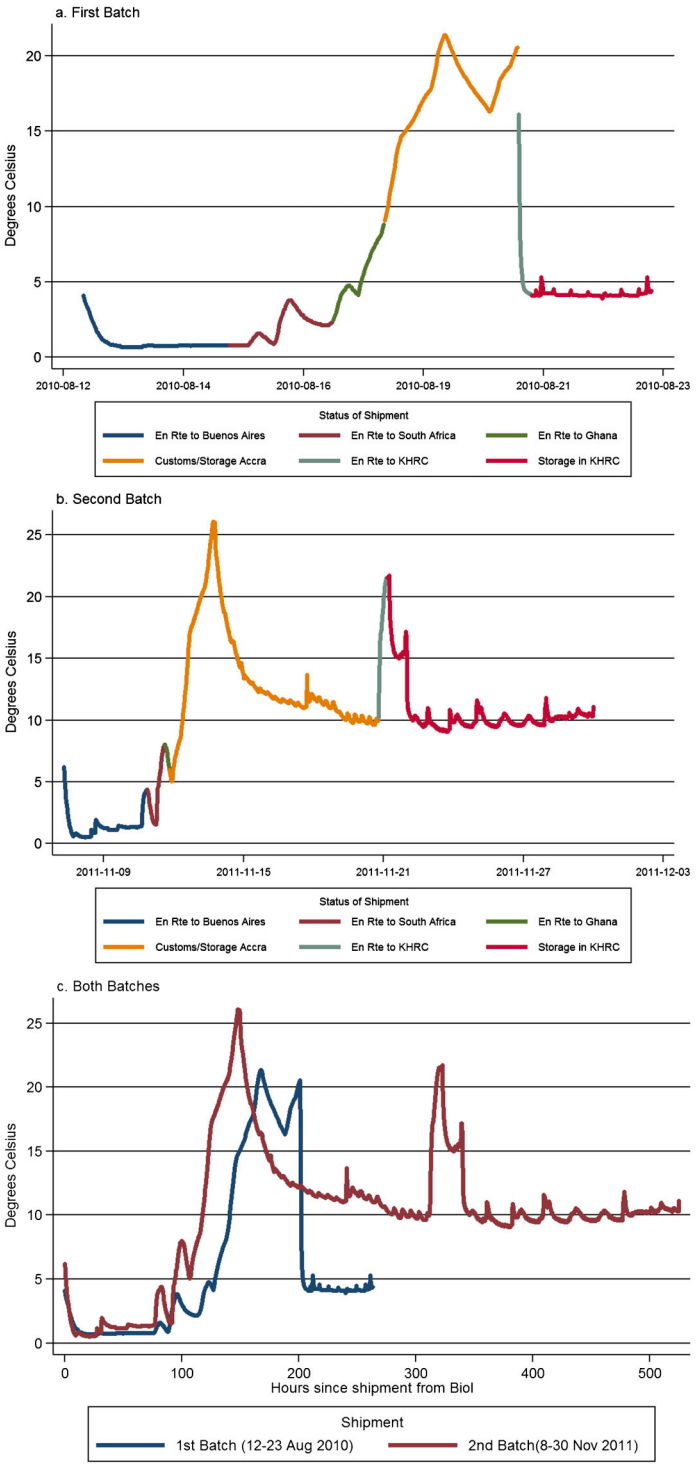
For the simulation exercise, the date at which the field worker received the test packages was defined as time 0 (T_0). For each package, the time of discard, T_f, was defined as the date that the field worker first recorded a switch from ''1'' to ''2'' (that is, when the inner square reached the same color as the outer circle), and the difference between T_0 and T_f indicated the time to discard. The Kaplan-Meier estimate of the survival (discard) function was constructed, and the median and 95% confidence interval (CI) were estimated. Individual scatter plots of ambient temperature exposure across the time period of the simulation exercise were constructed. For each package, a measure of ambient temperature exposure was estimated by calculating the mean kinetic temperature from individual daily estimates of minimum/maximum temperature. To determine the effect of ambient temperature exposure and to examine other variables such as shipment (first vs. second), district (Kintampo North vs. South), and characteristics of the storage location, we estimated hazards ratios using a Weibull survival regression model and accounted for possible correlation within storage location using the Huber-White sandwich estimator. Mann-Whitney tests were used to compare the distribution of summary measures (mean, standard deviation, maximum, minimum) of temperatures to which each of the 23 groups of 25 devices were exposed during Phase 1 and Phase 2 with selected characteristics of the storage location, including roof and wall materials, presence of ceiling or a fan in the room, and whether the storage room was also used for cooking. Those found significant were then examined for their association with time to discard in Weibull regression models. We conducted a Monte Carlo simulation study using the estimated distribution of time to discard, in order to estimate the wastage that might occur in a hypothetical scaled-up program with monthly distribution and provision of a 10% buffer (excess supply beyond predicted actual use). All analyses were done with STATA 12.1.

RESULTS

Pre-Simulation Studies

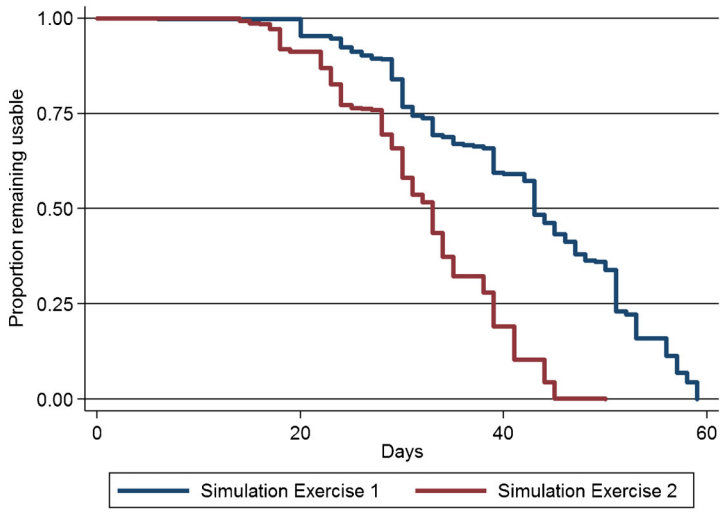
For each of the 2 batches included in the pre-simulation study, the transportation period consisted of 6 distinct stages:

FIGURE 2. Average Ambient Temperature Exposure During Shipment Period, by Batch



Abbreviation: KHRC, Kintampo Health Research Centre.

FIGURE 3. Proportion of Packages With TTI Status of Usable Over Time, by Simulation Exercise



Abbreviation: TTI, temperature-time indicator.

1. En route from manufacturer to Buenos Aires
2. En route to South Africa
3. En route to Ghana
4. Customs and storage in Accra, Ghana
5. En route to KHRC
6. Storage in KHRC

The pattern of fluctuation in temperature to which the devices were exposed during these 6 transportation stages was similar between batch 1 (Figure 2a) and batch 2 (Figure 2b), but overall exposure was higher in the second batch (Figure 2c), mainly due to higher temperature during the road transport stage. Mean kinetic temperature exposure prior to reaching long-term storage in the KHRC refrigerators was 10.3℃ and 12.1℃ in batch 1 and batch 2, respectively. Total duration from shipment to storage in KHRC for the first and second pre-simulation studies was 8.6 and 13.4 days, respectively.

Mean kinetic temperature/time exposure between shipment of the devices and storage at the central facility was 10°C–12°C / 9–13 days.

Simulation Study

The first simulation study started on July 25, 2011. Among 23 field workers initially provided with 25 OIU packages each, TTI status data were available for 550 of the 575 packages; information for all 25 packages for 1 field worker was missing for 1 month, during which all the indicators reached the discard point, thus the discard time could not be determined.

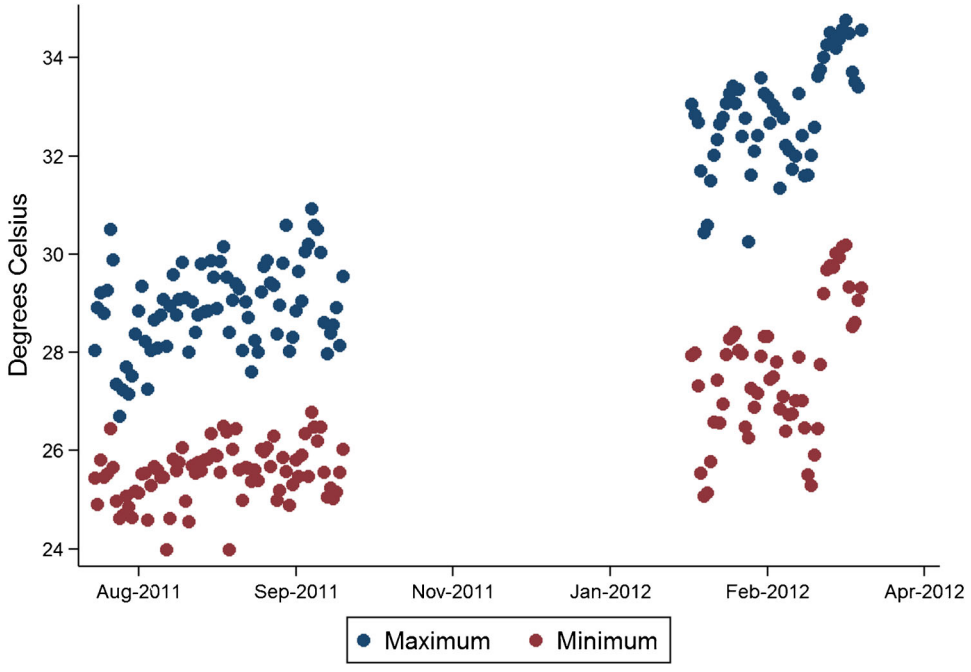
Among the 550 packages with analyzable data, the durations at which the TTI indicators reached the discard point ranged from 6 to 59 days, and the median time was 43 days (95% CI=43–45) (Figure 3). At 30 days, a common interval for community-based resupply of materials, 16% (88/550) of the packages had reached the discard point. Mean kinetic temperatures recorded across the 23 field workers' storage sites during the first simulation ranged from 25.1℃ to 28.5℃.

The second simulation study used OIU packages from the second shipment batch and was started on February 1, 2012. Among 23 field workers provided with 25 OIU packages each, information from this simulation exercise was available for all 575 packages. The durations at which the TTI reached the discard state during the second simulation study ranged from 14 to 50 days, and the median time was 33 days (95% CI=31–33). At 30 days, 34% (196/575) of packages reached the discard state. Mean kinetic temperatures recorded across the 23 field workers' storage sites during the second simulation ranged from 27.6℃ to 33.0℃.

The mean time to reaching discard was 10.0 days (95% CI=4.4–15.7) shorter in the second study than in the first, and the hazard ratio of reaching discard was approximately 3.64 times higher (95% CI=2.03–6.52). This was, however, nearly fully explained by the difference in ambient temperature exposure between the 2 simulation periods (Figure 4). The average maximum daily temperature across all OIU packages was approximately 3.9℃ (95% CI=3.6–4.3) higher during the second study period (32.8℃) compared with the first study period (28.9℃). Each degree increase in mean kinetic temperature increased the hazard of discard by 1.60 (95% CI=1.28–2.00).

Individual OIU packages were exposed to a wide range of temperatures, and, in some cases, there was substantial variation in exposure temperatures by field worker, illustrated with scatter plots of the individual LogTag measurements collected by each of the 23 workers in the first (Figure 5a) and second studies (Figure 5b). Differences in temperatures were also seen by district, with the northern part of the study area

FIGURE 4. Daily Maximum and Minimum Temperature, by Day, for First and Second Simulation Exercises



having consistently higher average exposure temperature than the southern portion.

All 23 workers reported that they were able to store their packages out of direct sunlight within their homes. None of the household characteristics examined were associated with mean, maximum, or minimum temperatures measured. However, *variation* in temperature was significantly higher among the 13 workers reporting that they had no ceiling (compared with 10 others reporting either a plywood or mat ceiling). Concurrently, many of these same 13 workers indicated that they felt their room became very hot because they did not have a ceiling. The hazard of discard was approximately 1.60 times higher (95% CI=0.98–2.64) for devices stored in homes without a ceiling than in those with a ceiling.

In our Monte Carlo estimation, frequency of supply was set at 30 days (monthly distribution), and quantity of supply was sufficient to cover expected usage plus a 10% buffer. Using the time to discard distributions of the first and second field simulation exercises, the expected wastage rate was 3.5% and 8.8%, respectively.

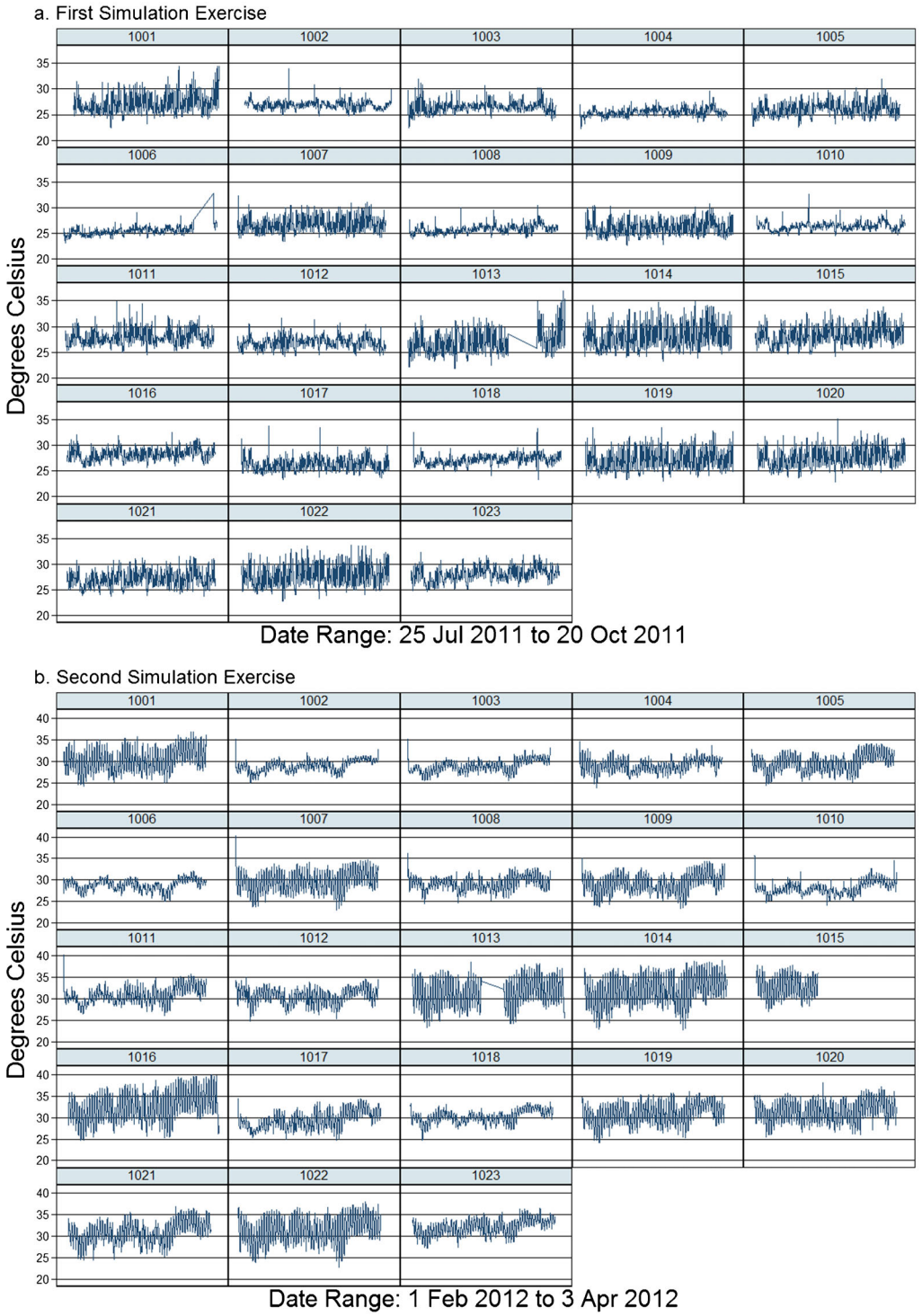
DISCUSSION

Median time to discard was 43 days and 33 days, in the first and second simulation studies, respectively.

The results of these 2 simulation activities indicate that in rural Ghana, the median time between distribution to field workers and transition to a non-usable state for Oxytocin-in-Uniject (based on the TTI in current use) is on the order of 30 to 40 days (4 to 6 weeks) and is highly dependent on ambient temperature. Using a commonly used monthly resupply schedule, the number of devices discarded would be very low if the true discard time followed a distribution similar to that observed in this study, because a substantial proportion of devices would be used (rather than simply stored) before reaching discard. It is important to note that our simulation study did not include cold-chain storage at the final stage (that is, with the field workers), as is typical of many low-resource settings. However, we acknowledge that the cold chain was maintained at our central site, prior to distribution to the field workers, which in some instances may not be achieved in program settings.

The number that would be lost to heat exposure is a complex interaction between the

FIGURE 5. Scatter Plots of Temperature Readings by LogTag Device



rate of use, the excess supply provided (the proportion provided to the worker that is beyond the expected number that will be used), and the specific distributional characteristics of the time to discard. Our data from the first and second simulation exercises indicate that 16% and 34% of packages, respectively, reached the discard point within 30 days when not being used (that is, they were stored only). It is essential to note, however, that the actual wastage would be substantially less than this, because in an actual program setting, the devices would be used, not simply stored. When this usage was taken into account in our Monte Carlo estimation, we found predicted wastage rates to be substantially lower than 10%

Limitations and Strengths

There are a number of limitations to this study. The first is that we characterized only the distribution of time to discard the packages, based on cumulative exposure to heat of the TTIs. While this is a proxy for heat degradation of oxytocin that would, under programmatic implementation, be stored within these packages, an endpoint of greater interest is the API remaining at various time points over this time range. It is unlikely that the actual API levels of oxytocin stored under similar conditions would follow both the shape and scale parameters of curves for the device packages shown in Figure 3. This is because our empiric estimates of the distribution of time to discard indicates that 100% ''failure'' occurs on the order of 50 to 60 days, while assays of oxytocin API have generally demonstrated much slower attrition of API under similar temperatures.[4] Furthermore, the quantitative relationship between deviations from 90% to 110% API, the manufacturer's range of acceptable API, and actual clinical effectiveness of oxytocin is not well understood. For example, a Cochrane Review of the effects on postpartum bleeding of prophylactic oxytocin administered during the third stage of labor included clinical trials in which the dosage of oxytocin varied from 3 to 10 IU, and the mode of delivery included intramuscular injection and intravenous administration.[9] Thus, it is possible that many of the devices that would need to be discarded as ''non-usable'' when following the TTI in current use might contain oxytocin that is still within manufacturer specification. Further research is needed to better quantify the optimal level of oxytocin required to produce a clinically sufficient response.

Another limitation is that we did not have sufficient overlap in ambient temperature exposure between phase 1 and phase 2. That is, the mean kinetic temperature to which packages in phases 1 and 2 were exposed rarely overlapped, and thus phase and ambient temperature were too highly correlated for us to determine the impact of the higher mean kinetic temperature exposure during shipment of the phase 2 containers.

This simulation study, however, did use LogTags to document daily variation in temperature exposures from manufacturer to storage in the field under realistic conditions in Ghana and to show how sensitive the time to discard point was to relatively small absolute changes in ambient temperature. Furthermore, our study included a large number of units (N=550 to 575) examined during 2 different seasons, allowing us to accurately characterize the distributional parameters of the time to discard. By distributing these devices across a set of 23 field workers and collecting characteristics of the storage location, we were also able to further understand the degree to which storage conditions (such as common building construction techniques) influence this distribution of time to discard.

At 30 days, wastage levels ranged from 16%–34% in the simulations; actual wastage would be less because field workers would use some of the devices.

CONCLUSION

With careful handling of the drug during transport from manufacture to the main storage facility, and careful planning around the appropriate levels of provision to field workers, given known information about rate of use (i.e., the number of units used per day or month), program managers could effectively resupply field workers without refrigeration access with an appropriate level (based on a known usage rate) of Oxytocin-in-Uniject devices (or ampoules of oxytocin) on a monthly basis. Such a schedule would result in high levels of coverage with low overall overage or wastage percentages and would fit with common current resupply schedules for other materials and meeting/supervision schedules.

The TTI used in this study is very conservative with time to discard temperature indicators set at 30℃ to 35℃; even lower levels of wastage or more flexible scheduling and resupply schemes could be implemented with a TTI designed to reflect oxytocin stability more closely. Manufacturers

could play a role in accelerating programmatic implementation in low-resource settings by developing such a TTI with greater specificity for oxytocin, by improving flexibility in packaging such that TTIs could be affixed to either OIU packages or oxytocin vials (which are more widely available and cost less), and by further elucidating the relationship between temperature exposure and API under various conditions. Oxytocin remains the drug of choice for prevention of postpartum hemorrhage, and OIU has been demonstrated to reduce postpartum hemorrhage by half in home deliveries in Ghana.[8] The data from this simulation study provide some guidance to program managers as to how this effective intervention might be rolled out at scale and how oxytocin could be used at peripheral health facilities without cold-chain capacity.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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ORIGINAL ARTICLE

Strategic contracting practices to improve procurement of health commodities

Leslie Arney,[a] Prashant Yadav,[b] Roger Miller,[c] Taylor Wilkerson[c]

Practices such as flexible, pre-established framework agreements can improve timeliness and cost of procurement and help improve commodity security. Addressing legislative barriers and building technical capacity in contract management may facilitate the use of such practices.

ABSTRACT

Public-sector entities responsible for procurement of essential medicines and health commodities in developing countries often lack the technical capacity to efficiently ensure supply security. Under strict public scrutiny and pressures to be transparent, many agencies continue to use archaic procurement methods and to depend on inflexible forecasts and cumbersome tendering processes. On the basis of semi-structured literature reviews and interviews, we identified framework agreements as a strategic procurement practice used by the U.S. federal government that may also be suitable for global health supply chains. Framework agreements are long-term contracts that provide the terms and conditions under which smaller repeat purchasing orders may be issued for a defined period of time. Such agreements are common in U.S. and United Nations procurement systems and in other developed countries and multilateral organizations. In contrast, framework agreements appear to be seldom used in procurement of health commodities in countries of sub-Saharan Africa. The current practice of floating tenders multiple times a year contributes to long lead times and stock-outs, and it hampers the manufacturer's or supplier's ability to plan and respond to the government's needs. To date, government's use of strategic contracting practices in public procurement of health commodities has not received much attention in most developing countries. It may present an opportunity for substantial improvements in procurement efficiency and commodity availability. Enabling legislation and strengthened technical capacity to develop and manage long-term contracts could facilitate the use of framework contracts in sub-Saharan Africa, with improved supply security and cost savings likely to result.

BACKGROUND

Procurement and contracting play a significant role in determining the availability of, and thus access to, health commodities. The mean availability of many essential medicines in the public sector is lowest in the World Health Organization (WHO) Africa Region, followed by the WHO South East Asia Region, the regions which account for the majority of least-developed countries of the world.[1,2] While different national procurement models exist across developing countries, procurement of essential medicines to serve many of these populations remains largely centralized in the Ministry of Health and/or a Central Medical Store (CMS) and relies heavily on public monies, international funding mechanisms, and donor funding.[3] These public entities often lack the technical capacity to efficiently and strategically carry out the procurement process. Inadequate planning and forecasting, use of archaic procurement methods, and tendering yearly or multiple times a year contribute to high commodity costs, long lead times, stock imbalances, and, overall, commodity insecurity.[3] Indeed, across all WHO regions, the mean availability of selected medicines is consistently lower in the public sector than in the private sector.[1]

An important outcome of the Paris Declaration on Aid Effectiveness was renewed focus on strengthening national procurement systems, as well as a commitment by donors to increase the use of country systems and procedures, such as national budgets and public financial management systems.[4] In the last decade,

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many countries have seen the historical predominance of in-kind donations gradually replaced by direct budgetary support to governments.[3] In other cases, donors have begun phasing out direct support to low-and middle-income countries (LMICs) who have graduated from low-income status.[3] As a result of these shifts, many country governments have become increasingly responsible for the procurement of essential medicines and health care supplies.[3]

Public-sector procuring entities face unique challenges and constraints.

The private sector is often held up as a benchmark for efficiency for the public sector, but perhaps unfairly. Public-sector procuring entities face unique challenges and constraints, such as greater public scrutiny and lengthy procurement procedures. Corruption also presents a significant challenge, as some actors may encourage or maintain opacity to allow them to collect greater rents from the system. While transparency and corruption prevention are needed in the use of public monies, many feel that adopting additional checks and balances limits the agility and responsiveness of procurement practices. Even within the public sector, procurement of health commodities requires more flexibility and responsiveness to change (in population health and in environmental conditions) than procurement of other products.

A variety of federal pricing arrangements help the DOD and VA control drug costs.

The U.S. federal government, under public scrutiny in the use of public monies, is responsible for the provision of a large volume of health commodities. In 2012, the Department of Veterans' Affairs (VA) provided prescription drug coverage to 8.8 million military veterans, with prescription drug spending totaling approximately US$4.2 billion.[5] In the same year, the Department of Defense (DOD) provided prescription drug coverage to 9.7 million active-duty and retired military personnel and their dependents, with spending totaling $7.6 billion.[5] Provision of pharmaceuticals to a combined 18.5 million beneficiaries necessitates the use of strategic and efficient methods to control drug costs and ensure supply security. This study offers an overview of VA and DOD procurement and contracting practices and focuses on one strategic procurement and contracting practice that developing countries may benefit from adopting—framework agreements.

METHODS

We conducted semi-structured literature reviews and interviews to identify strategic procurement and contracting practices of the U.S. DOD and VA that may be suitable for public procurement systems in developing countries. We reviewed key characteristics of these strategic practices as well as case studies of their use by other national governments and multilateral agencies. We then explored the public procurement legislation of selected countries of sub-Saharan Africa and evaluated the use and the challenges and barriers to use of these strategic practices in these settings. Much of the relevant literature on these topics is not published in peer-reviewed journals, but rather it is grey literature—presentations, websites, reports, government-issued assessments, and legislative documents. We obtained additional country-specific information through interviews and correspondence with persons involved in public procurement in selected countries of sub-Saharan Africa.

FINDINGS

U.S. Federal Government Procurement of Health Commodities

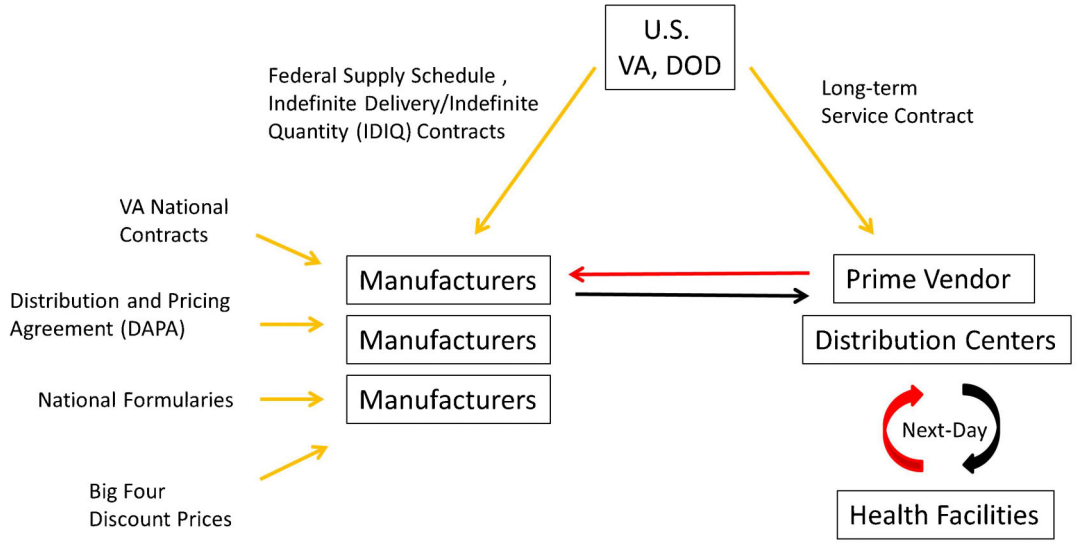
The VA and DOD procurement systems are generally characterized by centralized negotiation and contract management with decentralized purchasing/ordering authority. Key components of the 2 procurement systems include various federal pricing arrangements to control drug costs and the use of strategic contracting practices to maintain procurement flexibility. Direct purchase and distribution of commodities is then facilitated by prime vendor programs (Figure 1).

Pricing Arrangements

Under the rubric of centralized management and decentralized purchasing, a variety of federal pricing arrangements, among other mechanisms, help the DOD and VA control drug costs. First, the DOD and VA, along with the Public Health Service and U.S. Coast Guard (the so-called ''Big Four'' medical purchasers in the U.S. federal government), are eligible to receive federal ceiling prices, known as ''Big Four'' prices, on pharmaceuticals. These prices are statutorily mandated to be 24% lower than the manufacturer's average price for commercial customers.[6] The DOD and VA also maintain prescription drug formularies, which help them obtain even more competitive prices from manufacturers for drugs included on the formularies.[6]

The DOD and VA receive discounts in return for commitment to vendors through a DOD- or VA-specific national contracts program.[5] Similarly, the pricing of items procured by the Defense

FIGURE 1. Overview of the U.S. Department of Veterans' Affairs and Department of Defense Procurement Systems for Essential Medicines



Yellow arrows represent contracting or pricing arrangements, red arrows represent orders, and black arrows represent flow of supplies.

Logistics Agency (DLA) for DOD, as well as for other government military branches, takes place through direct negotiations with manufacturers through a Distribution and Pricing Agreement (DAPA).[7] For DAPA pricing structures, vendors are allowed to unilaterally lower prices, usually to generate higher volumes and therefore improve market share.

Flexible Contracting Practices

The VA has the authority to establish the VA Federal Supply Schedule (FSS) for procurement of health care and medical commodities on behalf of all federal government agencies. Under the FSS, the VA negotiates firm, fixed-ceiling prices directly with manufacturers based on their most-favored commercial customer price.[8] Through full and open competition, the VA establishes flexible multi-year contracts of indefinite delivery/indefinite quantity (IDIQ) with pre-approved suppliers under multiple-award schedules. VA Schedules are essentially catalogues of pharmaceutical products at prices available to all government agencies.[9] Any agency's facilities can place orders directly with the prime vendors holding these Schedule contracts.

The VA and DOD gain procurement efficiency and added discounts through the Pharmaceutical Prime Vendor Program and the Medical/Surgical Prime Vendor Program, respectively. Prime vendors are preferred drug and medical supply distributors that facilitate the purchase of drugs and medical supplies by government facilities, followed by just-in-time (often next-day) delivery from a distribution center directly to the purchasing facility. Prime vendor programs shift inventory, inventory management, transportation, and personnel costs from the government to commercial firms.[7] The VA and DOD also receive distribution fee discounts from their prime vendors. These are fixed percentage discounts off the lowest price available (FSS or Big Four).[7]

For prime vendor contracting, the United States is divided into regions, and regional contracts are awarded through a competitive process to the vendor, or combination of vendors, whose bid represents the best value for the government.[9] It is important to note that prime vendors are not involved in the FSS or DAPA agreements or price negotiations established between the government and manufacturers. Although they may offer additional discounts,

prime vendors are private wholesalers engaged in separate service contracts that facilitate the efficient ordering and delivery of the pharmaceutical products included under these government-wide framework contracts.

Framework Agreements

As we have described, the use of flexible long-term framework agreements is a salient strategic practice of the VA and DOD procurement systems. We use the term **"framework agreement"** to describe **any contracting mechanism in which long-term contracts provide the terms and conditions under which smaller repeat purchasing orders (or call-off orders) may be issued for a defined period of time.**[10] Different types of framework agreements may have different names depending on the context or legal system[11]—for example, long-term agreements (LTAs), task-order contracts, indefinite-quantity contracts, call-off contracts, umbrella contracts, rate or running contracts, system contracts, general service agreements, blanket purchase agreements, and standing offers.[10–15]

Two Stages

Framework agreements are typically comprised of 2 stages and can involve single or multiple suppliers. In a single-supplier framework agreement, a single contract is awarded to one supplier through a competitive process during the first stage of procurement, and then multiple call-off orders are placed directly against the contract throughout the duration of the agreement.[11] In a multi-supplier framework agreement, a contract for the same good or service is signed with multiple suppliers in the first stage of procurement. The second stage of procurement in multi-supplier frameworks can be carried out in different ways: a secondary bidding process may take place for each call-off order, suppliers may have been ranked according to preference or capacity, orders may be rotated among the different suppliers, or fixed order amounts may be assigned to each supplier in the initial contract.[11]

With framework agreements, buyers secure the benefits of centralized purchasing while retaining flexibility in purchase quantities and delivery schedules.

Advantages

Framework agreements can save significant procurement time and resources by avoiding the repetition of all steps for each purchase (Figure 2).[10,11] Entities can secure the benefits of centralized purchasing, through demand aggregation, while retaining flexibility in purchase quantities and delivery schedules. Framework agreements may also incentivize manufacturers or distributors to invest in assets (for example, equipment, personnel training, administrative, or operating procedures), which are specifically tailored to better serve government orders. The use of multiple-supplier framework agreements can help to ensure supply security, as a shortfall by one supplier can be compensated for or replaced by another supplier on the contract.[11]

Case Studies of Framework Agreements

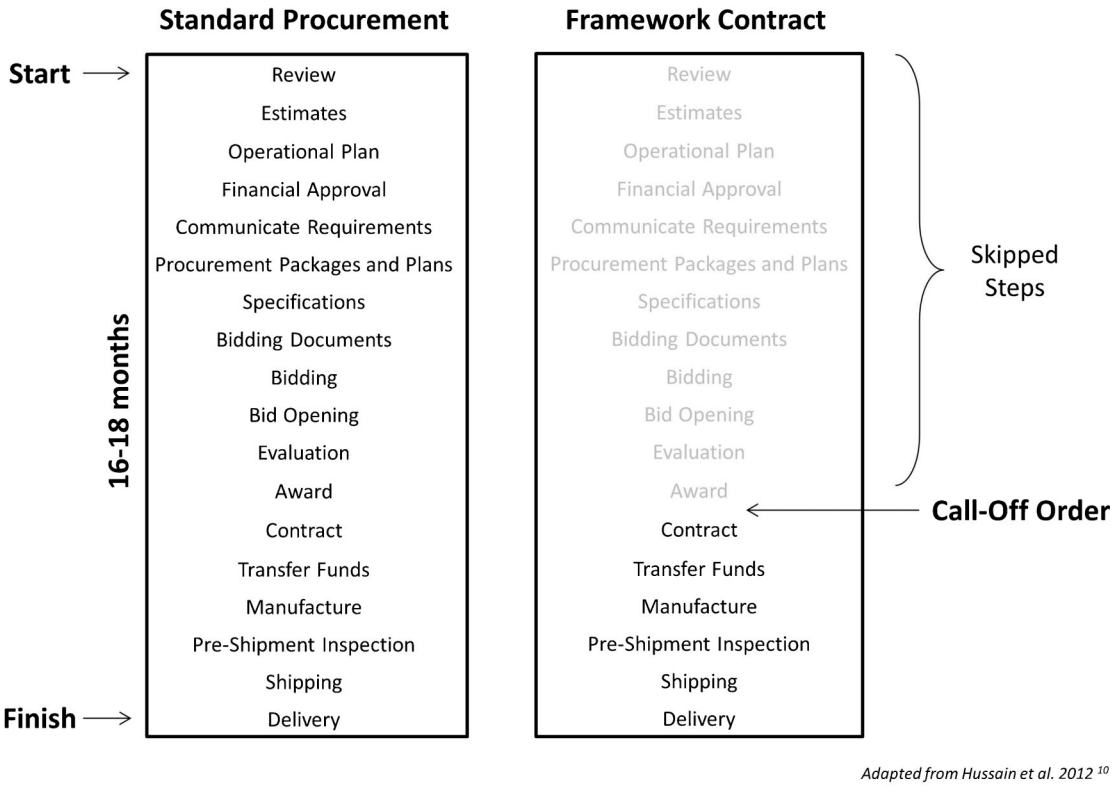
Various other national governments and multilateral organizations make use of framework agreements in diverse settings and procurement systems.

Chile created a government-wide e-procurement system, known as **ChileCompra**, in 2010 to enable government agencies to take advantage of the benefits of centralized purchasing without compromising the flexibility of decentralized ordering.[16] Much like the VA and DOD procurement systems, ChileCompra negotiates multi-year agreements with suppliers for selected products. All government agencies can then order against these agreements using an electronic catalogue, receiving the lower prices negotiated by ChileCompra and avoiding the costs and lead times associated with floating individual tenders.[16]

In **Mexico,** the **State's Employees' Social Security and Social Services Institute** (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado) (ISSSTE) is an important health service provider in Mexico's fragmented health-care system; it serves more than 12 million employees of the public sector and their families.[15] In 2010, the Ministry of Public Administration (Secretaría de la Función Pública), which oversees public procurement in Mexico, initiated the use of framework agreements.[15] As of 2012, ISSSTE had 10 framework agreements in place for the provision of various commodities including patented medicines, vaccines, vehicle maintenance, work wear, and personal protection equipment.[15]

The Joint Inspection Unit of the **United Nations** (UN) conducted an assessment in 2012 to evaluate the use, efficiency, and effectiveness of LTAs throughout the UN system. The assessment found that use of LTAs increased substantially between 2008 and 2011. The majority of UN organizations were realizing the benefits of LTAs, including the creation of administrative

FIGURE 2. Framework Contracts Can Significantly Reduce the Number of Steps Involved in the Procurement Process



Adapted from Hussain et al. 2012 [10]

efficiencies and opportunities for greater volume leverage.[14] The organizations making the most use of LTAs, as a percentage of total procurement, were the United Nations Children's Fund (UNICEF) at 93%, the United Nations Secretariat at 73%, and the United Nations Population Fund (UNFPA) at 45%.[14] Both UNICEF and UNFPA *require* the use of global LTAs for the purchase of strategic goods, such as pharmaceuticals, vaccines and reproductive health products.[14]

The inspectors observed that there was no common definition or way to calculate the benefits or costs of LTAs within the UN system; indeed, with few exceptions, there was usually no calculation of the financial savings attributable to LTAs.[14] Efficiency assumptions were often used in place of cost savings calculations.[14]

UNICEF establishes LTAs with manufacturers for the purchase of pharmaceuticals and vaccines following a competitive tendering process.[17] The objective of these LTAs is to establish forecasts of quantities to be produced by the manufacturer(s) and quantities to be purchased in order to secure supply of the product over the duration of the agreement.[17] UNICEF uses both single- and multiple-supplier LTAs to ensure greater supply security, and commonly splits arrangements to issue awards to multiple suppliers of each vaccine presentation.[14,17] UNICEF procurement policies define 2 types of LTAs. Target-value LTAs are generally used for strategic essential supplies, are often split among multiple suppliers, and expire when either the maximum target amount or the date of contract expiry is reached.[14] Time-bound LTAs are used when the unreliability of historical data and/or forecasted demand precludes creation of target-value LTAs; time-bound LTAs expire when the date of contract expiry is reached regardless of the volume procured.[14] The duration for UNICEF LTAs has ranged from 1 to 10 years,

Use of long-term agreements in the UN system increased substantially between 2008 and 2011.

with an average of 2 years plus a possible 1-year extension.[14]

There has been a trend toward harmonization of public procurement procedures to promote international trade.

Framework agreements are often seen—and feared—as anti-competitive. When a government engages in a framework contract with one manufacturer, other manufacturers may be discouraged from entering the market for the duration of the contract. UNICEF policies explicitly provide for the entrance of new manufacturers into the market in the middle of a multi-year tender.[17] If a new manufacturer is not WHO-prequalified for the vaccine/product at the time of tender, the manufacturer must show a plan for obtaining prequalification.[17] When the manufacturer obtains WHO prequalification, UNICEF considers awarding or reallocating a quantity to the manufacturer if UNICEF is facing a monopoly situation, if the current manufacturers' performance is inadequate, *or* if supply from the current manufacturer(s) is insufficient.[17]

UNFPA, as the largest procurer of reproductive health commodities, can achieve economies of scale and competitive prices on a variety of quality-assured products. UNFPA has established LTAs with more than 50 international manufacturers, with the intent to include all products under LTAs eventually.[18] National governments, nongovernmental organizations, and other public-sector purchasers can take advantage of the competitive prices negotiated by UNFPA through the AccessRH portal, a UNFPA-managed procurement and information service for reproductive health commodities.[19]

The **Global Fund to Fight AIDS, Tuberculosis and Malaria** is another key global health stakeholder using framework agreements. A key component of the Global Fund's long-lasting insecticidal net (LLIN) strategy is a shift toward use of long-term contracts to optimize production, create a more sustainable market, and assist planning for manufacturing capacity. The bulk of the forecasted volume of LLINs for 2014 will be allocated using a 2-year LTA to multiple suppliers.[20]

According to the UNCITRAL Model Law of 2011, a framework agreement procedure may be used when the procuring entity expects the need for procurement to arise on a repeated, indefinite, or urgent basis during a given period of time.

The **Organisation for Economic Co-operation and Development** (OECD) conducted a survey on public procurement in 2012. Of the 32 OECD member countries responding to the survey, 31 reported routine use of framework agreements by some or all central-level procuring entities.[21] About half of the OECD member countries were calculating the cost savings of the use of framework agreements, while a lack of data was commonly cited as the reason for not performing these calculations.[21]

Framework Agreements in Selected Countries of sub-Saharan Africa

Legislative Provision

While there is no ''single appropriate model'' of public procurement, there has been a trend toward harmonization of public procurement procedures both within and across countries in an effort to promote international trade.[11] First issued in 1994, the United Nations Commission on International Trade Law Model Law on Procurement of Goods, Construction and Services (UNCITRAL Model Law) was designed to help countries develop their public procurement systems and to provide a framework for procurement regulation.[11] The Model Law serves as a template that national governments can flexibly use to reform or implement procurement legislation in accord with local circumstances and existing legislation.[22] Generally, the Model Law promotes a procurement system based on a decentralized purchasing and decision-making mechanism but central regulatory or oversight authority.[23] As of 2010, approximately 30 countries had enacted legislation based on the Model Law, including, in sub-Saharan Africa, The Gambia, Ghana, Kenya, Malawi, Nigeria, Rwanda, Tanzania, Uganda, and Zambia.[22] Thus, the procurement laws of these countries share common guidelines and provisions but may differ on specific issues, such as value thresholds for permissible procurement methods.[23] The list of countries may underestimate the influence of the UNCITRAL Model Law, as countries are not obligated to report adoption or use of the Model Law to the UN.[22]

The UNCITRAL Model Law of 1994 made no explicit mention of framework agreements, but the UNCITRAL Model Law of 2011 clearly outlines the conditions for use of framework agreements and corresponding procedures.[11,24] According to the Model Law of 2011, a framework agreement procedure may be used when the procuring entity determines that the procurement need is expected to arise on a repeated, indefinite, or urgent basis during a given period of time.[24]

We reviewed the public procurement legislation and other official documents issued by the national procurement authorities of 7 sub-Saharan African countries for provisions concerning framework agreements (Table). The public procurement laws of Tanzania, Uganda, and Zambia explicitly provide for framework agreements.[13,25,26] Although the laws of Ghana, Kenya, and Rwanda do not explicitly mention

TABLE. Summary of the Review of Public Procurement Legislation and Official Documents for Provision to Use Framework Agreements (FAs)

Country	Procurement Authority	Legislation Governing Procurement	Legislative Provision for FA	Other Official Documents on FA	Terminology
Ghana	Public Procurement Board	Public Procurement Act of 2003	No mention	Manual – Public Procurement Act of 2003	Framework (call-off) contract
Kenya	Public Procurement Oversight Authority	Public Procurement and Disposal Act of 2005	No mention	Public Procurement Manual for Health Sector 2009; The Public Procurement Guidelines for Framework Contracting 2010	Framework contract
Mozambique	Unit for the Supervision of Acquisitions	Decree No. 15/2010: Rules and Procedures on Procurement of Public Works, Supply of Goods and Services	No mention	—	—
Rwanda	Public Procurement Authority	Law n° 12/2007 of 27/03/2007 on Public Procurement	No mention	Intermediate Level Training Module in Public Procurement	Framework agreement (Indefinite Quantity Contract)
Tanzania	Public Procurement Regulatory Authority	Public Procurement Act of 2011	Yes	—	Framework agreement
Uganda	Public Procurement and Disposal of Assets Authority	Public Procurement and Disposal of Public Assets Act of 2003	Yes	The Public Procurement and Disposal of Public Assets Guidelines on Use of Framework Contracts 2011	Framework contract
Zambia	Public Procurement Authority	Public Procurement Act of 2008	Yes	—	Rate or running contract

framework agreements, the procurement authorities of each country have issued other official documents or guidelines on the use of framework agreements.[27–29] Mozambique's laws do not explicitly mention framework agreements, and we were unable to find supplemental documents or guidelines issued by the Government of Mozambique on their use.[30]

Current Use

In **Zambia**, seeking to avoid the long lead times associated with international tenders, the Ministry of Health (MOH) in 2008 began creating flexible long-term contracts with national suppliers.[31] Currently, the MOH is engaged in single-supplier framework contracts with 5 manufacturers or wholesalers for essential medicines from the Zambia National Essential Drug List, including antimalarial drugs, intravenous fluids, and various antibiotics for infectious diseases. These framework contracts are time-bound, with fixed volumes per product; they have a minimum duration of 2 years. Orders that have been forecasted are placed once a year, corresponding to budgetary allocation, and generally 4 call-off orders and deliveries take place per year per supplier. The use of framework agreements has added flexibility in quantities ordered and delivery schedules, increased the availability of medicines, and decreased stock-outs. The Zambia MOH has

also seen an improvement in relationships with suppliers, additional transparency, and overall efficiency gains from the use of framework contracts (personal communication with Zambia Drug Supply Budget Line, September 2013).

The Zambia experience shows that a range of political, legal, and economic factors must be in place before framework contracts can be successfully used. The sequencing of activities in procurement reform is important to ensure that framework contracts are not used prematurely, which could contribute to the opacity of procurement practices. It is important, before framework contracts are used, first to establish a platform for monitoring procurement and contracts. This platform can share procurement information with responsible civil society groups and help enhance transparency and accountability in the procurement system, leading to greater trust and confidence in the procurement system.

In 2008, the **Ghana** Health Service was in the process of establishing National Framework Agreements with local private-sector suppliers in order to use the central-level contracting capacity to negotiate lower prices for the decentralized procuring entities.[31] Time-bound framework agreements are currently in place for procurement of antiretroviral medicines. Although the benefits in terms of commodity assurance far outweigh the potential disadvantages, there have been problems with suppliers' adherence to shipment schedules, which have led to overstocking, expiries, or shortages (personal communication with Ghana Ministry of Health, October 2013).

The **Kenya** Medical Supply Agency (KEMSA) is a parastatal organization mandated to manage the forecasting, procurement, warehousing, and distribution of essential medicines and health commodities to the population of Kenya. In the country's newly devolved health system, the Government of Kenya will begin allocating health budgets to county governments, which will purchase essential medicines and health commodities from KEMSA or (possibly) other sources. Aided by the creation of a contract management department within the organization, KEMSA has recently begun using framework agreements for procurement of all health commodities funded by the government. These 2-year framework contracts with domestic suppliers are of indefinite quantity at fixed prices. Each quarter, KEMSA issues forecasts and orders for the estimated quantities needed; payment is made on delivery (personal communication with KEMSA, March 2014).

The Secretariat Procurement Unit of the **Southern African Development Community (SADC)** manages a database of approved suppliers and places purchase orders under multiple framework contracts.[32] SADC engages in pooled procurement, whereby Member States purchase directly from prequalified regional suppliers holding framework contracts.[33]

Barriers to Use

Lack of explicit legislation. In **Mozambique,** the public procurement legislation, Decree 15, does not explicitly mention framework agreements, and we learned from correspondence with the Central de Medicamentos e Artigos Médicos (CMAM), the CMS of Mozambique, that Decree No. 15/2010 does not allow for use of framework agreements. The lack of explicit legislative provision for framework agreements may constitute a barrier in other countries as well.

Lack of technical capacity. Engaging successfully in framework agreements requires adequate financial and human resources, including technical capacity in contract management and the ability to continually prepare, negotiate, manage, evaluate, and conduct performance reviews. A general lack of technical capacity at both the national and sub-national procuring entity levels has often been cited as a barrier to more efficient procurement practices and supply security.[3,34,35] In Zambia, establishing a platform for procurement and contracts monitoring was a necessary first step in the adoption of framework agreements. Similarly, the creation of a new contracts management department within KEMSA was cited as essential to the adoption and implementation of framework agreements (personal communication with KEMSA, March 2014).

Other issues. Additional concerns about framework agreements, which may act as barriers to their introduction and use, include price volatility, local manufacturers' participation, and the inclusion of new technology during the course of the framework contract. Concerns regarding the timeliness of payment from procurers (that is, payment discipline) can also deter manufacturers from engaging in framework agreements.

As mentioned, multi-supplier framework agreements involve 2 stages and varying levels of competition. To deal with volatile markets, framework agreements may exclude prices from the terms and conditions agreed upon in the first stage of competition. Call-off orders may then be

allocated to suppliers through a mini-competition at revised, current prices.[11] Procuring entities in the UN system mitigate the risks of price volatility to LTAs by expressing the price as a fixed percentage discount off the supplier's catalogue price.[14]

As for local manufacturers, because call-off orders are of smaller volumes than bulk procurements and are spread over a longer period, multi-supplier framework agreements may promote participation of local manufacturers or of small and medium enterprises (SMEs) by rotating call-off orders among the suppliers.[11] Target-value (volume-based) LTAs also may be split among multiple suppliers, with an appropriate, capacity-based volume allocated to local suppliers.

As in the U.S. government's prime vendor programs, the success of a framework contract depends on the availability, accuracy, and timeliness of shared data to improve the synchronization of public, donor, and supply chain systems. Additionally, while framework contracts can enable decentralized execution (ordering), they do not guarantee it; some framework contracts are used to support CMSs or other public supply chain organizations that do not delegate ordering functions to the local level.

Flexibility and responsiveness in the procurement of health commodities are especially important to take advantage of new technology. To promote open competition and the overarching goal of improving health, framework agreements for health commodities must consider provisions for the entry of new suppliers into the market during the course of an existing framework contract. UNICEF procurement policies allow for the entrance of new manufacturers in the middle of a multi-year tender, but the set of conditions permitting this does not specifically include emergence of new technology, products, or competitors. Framework agreements do effectively lower the levels of competition *within* the contracted period. Therefore, they may not be suitable in markets where new suppliers are likely to enter within the duration of the agreement. In this regard, the use of framework agreements is better suited for products with more mature markets.

DISCUSSION

With adequate technical capacity, shared information, and appropriate legal provisions, framework agreements can allow for flexibility and responsiveness in ordering and delivery while maintaining transparency and achieving greater value-for-money in the procurement of essential medicines and health commodities. In assessing the public procurement systems of 2 U.S. federal agencies involved in buying health products, we identified the use of centralized framework agreements as a key factor in retaining flexibility in procurement while controlling drug costs. Framework agreements also are widely used in the UN system and by most OECD member nations, perhaps reflecting the level of technical capacity in procurement more commonly found in global agencies and developed countries.

Limited Use in Africa

In contrast, the use of framework agreements in the public procurement of health commodities in sub-Saharan Africa appears to be limited. While we did not explore the procurement legislation and systems of all countries of sub-Saharan Africa, the countries selected provide insight into the general use and barriers to use of framework agreements in the region. To varying degrees, Ghana, Kenya, and Zambia have adopted framework agreements for procurement of selected essential medicines. In some instances, however, the lack of enabling legislative may be a significant barrier to use, as in Mozambique. Still, the procurement laws of both Ghana and Kenya also do not explicitly mention framework agreements, but supplemental guidelines or manuals on their use have been issued by each country's procurement authority. Inadequate understanding or differing interpretation of public procurement legislation may impede the use of framework agreements and other strategic procurement and contracting practices, especially for countries that have undergone recent legislative reform. Insufficient technical and contract management capacity is commonly cited as a weakness of national procurement systems and may constitute a salient barrier to the use of strategic contracting practices by many developing countries.

Similarly, in many countries of sub-Saharan Africa, there are currently few well-developed, high-quality distributors that can be engaged as prime vendors to facilitate the direct purchase and distribution of commodities ordered from framework contracts. As the health commodity distribution market develops, it will be important for governments to explore the use of prime vendor arrangements for distribution.

The use of framework agreements does not, in and of itself, guarantee their benefits.

Framework agreements can allow for flexibility and responsiveness in ordering and delivery while maintaining transparency and achieving greater value-for-money.

Discretion in the use of framework agreements, strategic planning in the formulation of the agreement, sufficient contract management, and continual evaluation all are required to use a framework agreement in a way that preserves flexibility, achieves greatest value for money, and ensures supply security. Also, the use of framework agreements is not without risks. Given the smaller size of call-off orders, it may prove challenging to monitor the awarding of all call-off orders for legal violations, creating risks to competition and transparency.[11] Therefore, corruption mitigation actions, such as counter verification mechanisms, must accompany the use of framework agreements.

The impact of framework agreements on SME participation and performance will also depend upon how the agreement is designed and operated.[11] While some framework agreements can promote SME participation, the aggregation of smaller purchases can put SMEs at a competitive disadvantage.[11] Furthermore, framework agreements can make it more difficult for SMEs to estimate costs, given that many work on a fairly small purchasing cycle due to lower credit availability. If limited credit or working capital constrains an SME from importing or producing the required quantities in a timely manner, missed deliveries—and, thus, stock-outs—could result. Good enforcement of service level agreements, and penalties and flexibilities embedded in the long-term agreement, are critical to ensure that there are no negative impacts for procurers. Mechanisms to increase credit availability to SMEs can help improve timeliness of deliveries and supply security and mitigate negative impacts for SMEs.

Recommendations

Additional and more comprehensive research on the use of framework agreements for the public procurement of health commodities in developing countries is warranted. Highlighting successful use of framework contracts in sub-Saharan Africa may encourage additional countries to adopt more strategic contracting practices. A first step for all countries not currently using framework agreements should be to thoroughly examine national public procurement legislation. For countries without legislative provision for framework agreements, we recommend that public procurement authorities work toward legislative reform that includes such provisions in public procurement legislation. Where enabling legislation is in place, we encourage procuring entities to work to strengthen technical and contract management capacity and to consult stakeholders with experience and expertise in the use of framework agreements. A robust procurement organization in which framework contracts can be used requires 2 strong parts—procurement people and procurement procedures. Developing procurement human capital in ministries of health will help to promote greater use of framework contracts and will have broader benefits from more effective and efficient procurement in general. Organizations such as the Chartered Institute of Purchasing and Supply (CIPS) and People that Deliver can act as resource partners for such capacity-building efforts.

Technical working group. An international technical working group would be well-positioned to help developing countries adopt and manage framework agreements for procurement of health commodities. The technical working group could be constituted under the Interagency Pharmaceutical Coordination group (IPC) and composed of international agencies (for example, WHO, the United Nations Development Programme, UNICEF, the World Bank, the African Development Bank, and the Global Fund), developing-country ministries of health, and individuals with expertise and experience in framework contracting for pharmaceuticals and other health products. The aim of the technical working group could be to support procurement departments in ministries of health or medicines supply agencies in developing countries in the use of framework contracts. More specifically, the technical working group could:

- Provide technical leadership in developing framework contracts as a procurement approach
- Develop new knowledge resources to fill information gaps related to the use of framework contracts
- Develop and implement a strategic plan for promoting the use of framework contracts wherever suitable
- Design a workshop for developing-country procurers to disseminate information about the value of framework contracts.

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ORIGINAL ARTICLE

Major challenges to scale up of visual inspection-based cervical cancer prevention programs: the experience of Guatemalan NGOs

Anita Nandkumar Chary,[a] Peter J Rohloff [b]

Scale up of visual inspection with acetic acid (VIA) in Guatemala encountered major challenges, including high attrition of people trained, didactic training without hands-on skills building, lack of continued supervision, and provision of VIA alone without immediate on-site provision of cryotherapy.

ABSTRACT

Background: Like many other low- and middle-income countries, Guatemala has adopted visual inspection with acetic acid (VIA) as a low-resource alternative to the Pap smear for cervical cancer screening. Nongovernmental organizations (NGOs) introduced VIA to Guatemala in 2004, and a growing number of NGOs, working both independently and in collaboration with the Guatemalan Ministry of Health, employ VIA in cervical cancer prevention programs today. While much research describes VIA efficacy and feasibility in Latin America, little is known about NGO involvement with VIA programming or experiences with VIA outside the context of clinical trials and pilot projects in the region.

Methods: To explore challenges faced by NGOs implementing VIA programs in Guatemala, we conducted semi-structured interviews with 36 NGO staff members involved with 20 VIA programs as direct service providers, program administrators, and training course instructors. Additionally, we collected data through observation at 30 NGO-sponsored cervical cancer screening campaigns, 8 cervical cancer prevention conferences, and 1 week-long NGO-sponsored VIA training course.

Results: Frequently highlighted challenges included staff turnover, concerns over training quality, a need for opportunities for continued supervision, and problems with cryotherapy referrals when immediate treatment for VIA-positive women was unavailable.

Conclusions: Reducing staff turnover, budgeting to train replacement providers, standardizing training curricula, and offering continued supervision are key strategies to improve VIA service quality and program sustainability. Alternative training methods, such as on-the-job mentoring and course prerequisites of online learning, could help increase training time available for clinical supervision. Efforts should be made to ensure that VIA testing is coupled with immediate cryotherapy, that providers trained in VIA are also trained in cryotherapy, and that cryotherapy supplies and equipment are maintained. Where this is not possible and only VIA screening is available, referral systems must be strengthened.

INTRODUCTION

Cytology-based screening can significantly reduce cervical cancer incidence and mortality among previously unscreened populations. In high-income countries, it is very efficacious.[1] However, in many low- and middle-income countries (LMICs), the availability of cytology-based screening and follow-up is limited. These countries lack infrastructure for transporting and processing cytological samples, performing colposcopy, interpreting biopsies, and providing follow-up care to patients through multiple clinical visits from initial screening to treatment.[2,3] As a result, the great majority of the 266,000 deaths worldwide each year due to cervical cancer occur in LMICs.[4]

The World Health Organization (WHO) and the Alliance for Cervical Cancer Prevention (ACCP) have promoted visual inspection with acetic acid (VIA) as a low-cost, safe, and effective alternative to cytological screening in resource-poor settings.[5,6] When coupled with cryotherapy, VIA allows for a single-visit approach,

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The great majority of the 266,000 deaths each year due to cervical cancer occur in low- and middle-income countries.

in which women with precancerous cervical lesions detected during the exam can be immediately treated. Indeed, the ''see-and-treat'' paradigm has been advanced as the primary advantage of the technique.[7] VIA and cryotherapy can be performed inexpensively, without electricity, and by specifically trained non-physician providers.[8] Randomized controlled trials comparing VIA with no screening have demonstrated reductions in cervical cancer incidence and mortality through VIA-based screening.[9,10]

VIA is becoming a common approach to cervical cancer screening in Guatemala, a small Central American country with a large rural population.[11] Cervical cancer is the second most common cancer and the second leading cause of cancer deaths among Guatemalan women.[4] Free health care is a constitutional right for Guatemalan citizens, and the Guatemalan Ministry of Health (MOH) offers women Papanicolaou (Pap) smears in its facilities free of charge.[12] However, about half of Guatemala's population lives in rural areas[11] with limited access to health care, including cytological screening.[12] Annual screening coverage by the MOH is only 12%–18%.[13] Total screening coverage of women ages 25–64 in Guatemala is estimated at 40%,[14] in contrast to WHO recommendations of 80% coverage for successful national screening programs.[6] Furthermore, cytology services are centralized in urban areas, quality control is poor, and delayed reporting of results and loss of patients to follow-up is common.[15–17] Vaccination against human papillomavirus (HPV), which causes most cervical cancer, and HPV DNA testing are not yet available through public-sector care.[13]

In this context, nongovernmental organizations (NGOs) have played an important role in increasing cervical cancer screening coverage. As a result of health care reform in the 1990s, financed by the Inter-American Development Bank and the World Bank, many basic health services in Guatemala are now delivered through government-contracted NGOs.[18,19] Many NGOs also work independently of the MOH to deliver health care services to impoverished populations. There are an estimated 10,000–15,000 NGOs currently operating in Guatemala,[20] with an estimated 45%–60% offering some level of health care programming.[21–23]

One of the NGO sector's most significant contributions to cervical cancer prevention in Guatemala has been pioneering the use of VIA–cryotherapy.

Cervical cancer screening and treatment became priorities for many NGOs in the last decade. NGOs provide at least 15% of all cervical cancer screening nationally and a much larger percentage in rural areas.[13] One of the NGO sector's most significant contributions to cervical cancer prevention in Guatemala has been pioneering the use of VIA–cryotherapy. In 2004, in an effort to overcome problems with cytology-based screening, a small group of NGOs began pilot-testing VIA–cryotherapy in their own clinics. These NGOs also approached local MOH administrators in 3 of the 24 MOH-designated national health districts, who agreed to have staff at selected clinics participate in NGO-sponsored VIA–cryotherapy training and screening campaigns monitored and evaluated by the NGOs.[24] Success with initial demonstration projects encouraged the development of several formal NGO-sponsored VIA–cryotherapy programs in various regions throughout the country.

In part due to NGO leaders' advocacy and NGO-sponsored VIA trainings for MOH staff, MOH officials incorporated VIA into national health care services in 2008. The MOH now has its own national VIA program: Officials report training thousands of providers in VIA or VIA–cryotherapy since 2008 and estimate that approximately two-thirds of all MOH-conducted cervical cancer screening is VIA-based.[13] For several years, both before and during MOH integration of VIA into the national reproductive care program, NGOs constituted the primary trainers of VIA providers in Guatemala. Leaders of the most prominent NGOs that offer training courses have certified at least 1,000 NGO and MOH providers in VIA or VIA–cryotherapy (personal communication with Patty Baiza, Clinical Coordinator, Faith in Practice, May 2013; Ana Garcés, Director, Una Voz Contra El Cáncer, July 2012).

Today, many NGOs continue to offer training courses for their own staff, foreign volunteers, lay health promoters, lay midwives, and MOH physicians and nurses. As well, many NGOs continue to operate VIA-based cervical cancer prevention programs. Some organizations work independently of the MOH, holding VIA screening campaigns or including VIA in broader reproductive or primary health care services. Other NGOs offer a variety of VIA support services such as donating materials for VIA exams and cryotherapy equipment to MOH facilities and other NGOs; providing training courses to MOH personnel and staff of other NGOs; continually supervising MOH or NGO trainees; and offering cryotherapy treatments for women referred from MOH facilities or NGOs lacking cryotherapy equipment.

While much research has been conducted about the efficacy of VIA and VIA training courses in Latin America,[25–29] little is known about VIA implementation outside of clinical

trials or about the attitudes of providers in the region toward the technology.[30] In Guatemala, NGOs have been at the center of VIA service implementation and training of providers for over a decade. As VIA is increasingly incorporated into national health policies throughout Latin America, it is important to understand the experiences that these organizations have had with VIA-based cervical cancer screening and with providing training and capacity building to MOH facilities.

METHODOLOGY

Study Design

We identified 20 NGOs operating VIA programs in Guatemala through online NGO directories, investigator participation at cervical cancer prevention conferences, and local recommendations by MOH and NGO staff. As there is no comprehensive NGO registry in Guatemala, it is not possible to determine the proportion of NGOs with VIA programming reflected in the sample. However, the NGOs identified do represent the full spectrum of program offerings in terms of: (a) types of VIA programming (direct service provision and/or training course); (b) models of service provision (one-time community campaigns, established VIA clinics, or screening as part of a comprehensive health care program); (c) geographical scope of programming (working in one department, multiple departments, or countrywide); and (d) collaboration with the MOH (working independently from or in collaboration with the MOH). Table 1 describes NGO characteristics. Table 2 describes models of NGO collaboration with the MOH.

Data Collection

From May 2012 through August 2013, we conduced semi-structured interviews with 36 staff members of 20 NGO-based VIA programs. We interviewed direct service providers, VIA program administrators, NGO directors, and VIA training course instructors (Table 3). Interviews lasted from 40 minutes to 2 hours and were conducted at the interviewee's workplace in Spanish or English according to the interviewee's preference. We recorded all interviews, with permission, and transcribed them verbatim. In addition, we observed 30 days of screening campaigns and attended 8 cervical cancer prevention conferences and a 1-week VIA training course.

TABLE 1. Characteristics of NGO Sample

Characteristic	Number
Organizational Focus (n=20)	
Cervical cancer screening	3
Maternal–child health	1
Medical clinic	3
Medical/surgery mission trips	4
Primary health care	2
Reproductive health	7
Type of Program (n=20)	
Service provision	13
Service provision and training course	4
Training course	3
Service Provision Model (n=17)	
Community campaigns	6
Comprehensive care	7
Comprehensive care and community campaigns	1
VIA clinic	3
Collaboration With MOH (n=20)	
Yes	11
No	9
Region (n=20)	
Central Highlands	6
Central Highlands and Pacific Coast	1
Countrywide	6
Pacific Coast	1
Peten	1
Peten and Verapaces	1
Western Highlands	3
Western Highlands and Verapaces	1

Abbreviations: MOH, Ministry of Health; NGO, nongovernmental organization; VIA, visual inspection with acetic acid.

Data Analysis

We applied an inductive approach to analyze the data.[31] As common themes emerged through preliminary review of verbatim transcripts and

TABLE 2. Types of NGO Collaboration With MOH[a]

Collaboration	Number
Accept cryotherapy referrals from MOH	8
Donate material/equipment to MOH facility	5
Organize campaigns with or in MOH facility	8
Supervise MOH personnel after training course	2
Train MOH personnel	6

Abbreviations: MOH, Ministry of Health; NGO, nongovernmental organization.
[a] Some NGOs collaborate with the MOH in multiple forms; N=11 NGOs.

TABLE 3. Characteristics of Interviewees (N=36)

Characteristic	Number
Professional Role in NGO[a]	
NGO administrator or director	13
Service provider	19
Training course instructor	10
VIA program director	3
Women's health program director	3
Nationality	
European	2
Guatemalan	17
Other Latin American	1
U.S.	16
Professional Training (place of training)	
Auxiliary nurse (Guatemala)	4
Professional nurse (Guatemala)	5
Nurse practitioner (United States)	3
Physician (n=8, Guatemala; n=4, United States)	12
Bachelor's degree	6
Master's degree	6

Abbreviations: NGO, nongovernmental organization; VIA, visual inspection with acetic acid.
[a] 12 of 36 interviewees held multiple professional roles.

notes from observations, we developed a codebook. Data were coded for dominant themes using the qualitative data analysis software Saturate App. Subsequently, we compared dominant themes by NGO program type (service delivery or training course), engagement with the MOH (collaboration or independent work), and professional identification of the interviewee (service provider, administrator, or training course instructor), as we hypothesized that experiences might differ among these categories. However, in the end, common themes arose with interviewees across all professional roles, program types, and levels of collaboration with the MOH, and so results are not organized by these categories.

Ethics

The Institutional Review Board of Washington University in St. Louis, MO, approved this research. Locally, NGO administrators granted permission for staff to participate in the study. Interviewees received explanations about the study objectives and assurance of confidentiality. Interviewees then provided verbal consent for participation in the research.

RESULTS

Interviewees described 4 major challenges in VIA implementation:

- Staff turnover
- Training quality
- Continued supervision
- Cryotherapy referrals

Staff Turnover

Twenty-four interviewees working with 13 of 20 NGOs reported turnover of staff trained in VIA was a problem—either among former trainees or their own programs' practitioners. Specific concerns with staff turnover differed based on interviewee involvement with training versus service provision.

Turnover of trainees in the MOH. NGOs offering training courses encountered difficulties with turnover of trainees, and especially MOH trainees. Central American Ministries of Health rotate personnel between services every few years, particularly with electoral changes in political leadership. NGO program directors reported that MOH nurses they had trained in VIA offered the exam in their posts in reproductive health for

1–2 years but then were rotated into a new service with no VIA component (for example, child nutrition, labor and delivery). Staff turnover within the MOH also results from changes of administration, which can lead to supervisors' decisions to lay off personnel performing VIA and reduce or eliminate VIA program budgets. As one VIA training course instructor reported:

> *[The MOH] would send us women, nurses, doctors [they] wanted us to train. We trained them. We even gave some of them [cryotherapy] guns. But inevitably, more than half of them, the doctor left to go somewhere else, the nurse got fired, or whoever was in charge of the department, their interest disappeared.*

This instructor estimated that only about 50% of the nurses and physicians that his NGO trained in VIA ended up using the skill after the course. Program administrators of another NGO, which had performed a study with former trainees, noted that fewer than one-third of the MOH nurses they had trained over 4 years (2008–2011) were still practicing VIA in 2012. Indeed, the MOH reported that, in 2008, only 50–85 of 1,211 personnel previously trained in VIA (about 4%–7%) still actively provided the service.[32]

One Guatemalan training course instructor feared that lower-level providers would lose their clinical observation skills if not in constant practice:

> *During the course, many people are trained, and afterwards, they rotate through other services and forget it. If you don't use the skill and just do Pap smears, you will not be able to do [VIA] because it's hard to do. It's often hard to see.*

Staff turnover results in temporary or permanent discontinuation of VIA programs when posts remain unfilled. As a result, training course instructors felt that monetary and human resource investments were being used suboptimally.

Staff turnover among MOH administrators also disrupted long-term VIA collaborations with NGOs. A Guatemalan program administrator stated:

> *We made contacts with government officials to train people from the MOH. We began very well and all, but the lines of communication break pretty easily with them. They change personnel every 4 years, every time there is another election, and then whatever you've been doing with them goes downhill.*

Some interviewees expressed frustration over expending resources on travel and meetings with MOH representatives when VIA collaborations fell through due to MOH leadership changes. Other interviewees, however, reported building relationships successfully in 2 departments, whose health directors expressed great enthusiasm for VIA and popularized the method among other staff and their successors.

Turnover in NGOs. Changes in leadership and staff turnover frequently affected not only NGO–MOH training collaborations but also internal NGO VIA programs. NGO programs were particularly vulnerable to unexpected shifts in funding streams and strategic mission. One European VIA provider voiced frustration that the NGO she worked for tended to ''take on a lot of projects'' but not follow through with them. VIA became one such project, and shortly after sending her to training, administrators had a ''change of heart'': ''They decided not to do VIA-cryo for no apparent reason.''

Job shopping and leveraging salary differentials were also major sources of VIA staff turnover in NGOs. In Guatemala, NGOs and the private sector offer health practitioners higher salaries than the public sector,[33] and salaries vary widely between NGOs of differing sizes. As a result, ''internal brain drain'' is a common problem. One NGO administrator observed that MOH nurses trained in VIA market this skill and leave their government posts to earn higher wages elsewhere. Similar job switching from less to more lucrative NGO posts was also common. As one NGO administrator from the United States related:

> *Right now, we are not doing VIA. This was not a strategic decision, but rather bad happenstance. There used to be a community health worker who did community screenings. She got trained in [VIA], and between her and another doctor who got trained in the method, they were able to bring people in. Unfortunately, we lost both staff members [to other NGOs], and so we lost capacity to offer the programming.*

Staff turnover results in temporary or permanent discontinuation of VIA programs when posts remain unfilled.

Several interviewees remarked that funding constraints prevented them from responding to this ''brain drain,'' since they had not budgeted to send new staff to VIA training courses. In contrast, one NGO director reported accounting for staff turnover in yearly programming budgets: ''That's not a problem for us. We pay to train new providers.''

Training Quality

Twenty-two interviewees working for 11 of 20 NGOs described ensuring VIA training quality as a serious challenge. Interviewees endorsed the quality of VIA courses delivered by 2 large and well-known NGOs, as well as those offered in some health districts of Guatemala with strong leadership among local MOH administrators. These courses rigorously adhered to VIA educational materials developed by Jhpiego, the organization that designed and pioneered the global gold standard of VIA training courses.[8]

Shorter courses that offer only didactic training, with no clinical supervision, are common.

Commonly, however, interviewees described visiting or participating in shorter courses that offered only didactic training with no clinical supervision. For example, while MOH officials at the national level report offering week-long courses,[14] an interviewee with a part-time MOH affiliation alleged:

> *[The MOH] was trying to form courses, but with many deficiencies…. [They] offer a 2- or 3-day course that is purely theoretical, with no practicum.*

Similarly, an NGO physician and former MOH employee noted that the MOH scheduled its courses with so little advance notice that participants did not receive or review materials prior to training. Furthermore, she reported, the MOH did not recruit enough women to serve as screening subjects for the training courses, with the result that trainees lacked opportunities for clinical training.

Also, some NGOs and short-term medical missions use non-standard curricula. A Guatemalan nurse related that she had participated in 2 VIA training courses sponsored by U.S. physicians. The first was with an NGO that offered a one-time 3-day VIA course and another with a well-established NGO that had been offering 5-day courses following Jhpiego standards for several years. She contrasted her experiences in the 2 courses:

> *In the first one, they just told us how to do it, and then we went off on our own and attended the women, but [the instructors] were not there with us. The second time, they were there with us, and it was harder because there were exams.*

Because of variations in the length and perceived quality of VIA training courses, several interviewees feared that deficient training might result in low-quality services and negative publicity surrounding VIA. ''The problem is that even those who do not pass the course can go on to practice VIA, because there is no regulation to stop them,'' a Guatemalan training course instructor lamented. An NGO director from the United States described receiving reports from a relatively small and recently formed North American NGO in eastern Guatemala that had experienced both high false positive and false negative rates in a VIA pilot program. This group, she explained, had offered its practitioners minimal and inadequate training before beginning to offer services:

> *I'm afraid that some of these smaller groups are out there doing VIA, but there's not any quality control, and they aren't doing it well. And that worries me, because that can give a bad name to the procedure … Pretty soon people are going to say, ''Well, that procedure doesn't work.''*

Continued Supervision

Twenty-two interviewees working for 11 of 20 NGOs reported concerns about a lack of continued on-site supervision and long-term support for health care providers after VIA training. Most NGOs and MOH trainers lack resources to offer continued mentoring to former trainees. One training course instructor, a Guatemalan physician, expressed concerns about this as she described visiting a group of Guatemalan nurses and health promoters who had been certified in VIA by a one-time U.S.-sponsored medical mission. These VIA providers had difficulty distinguishing between positive and negative exams, but they did not have the means to communicate with their international trainers for ongoing guidance.

Interviewees described a lack of continued mentoring for MOH-trained providers, as well. A Guatemalan nurse and course instructor reported witnessing problems at government-run VIA clinics, such as examiners using inadequate light sources or no light source at all during exams, sniffing acetic acid to determine its concentration, manipulating the cervix with tongue depressors that obstructed their vision, and performing cryotherapy incorrectly.

Pointing out the implications of such lack of oversight, several interviewees drew attention to an incident in which a group of women were severely burned by undiluted acetic acid during VIA exams gone awry in Guatemala City.[34] As a Guatemalan VIA training course instructor remarked:

Now [the MOH is] having to remove staff that they trained in VIA from their posts, because this year complications arose. In some public clinics in Guatemala City, they burned patients because they used pure acetic acid without diluting it … So people lost faith; they don't go to that health center anymore.

A U.S. physician working for another NGO reported that, because of this incident, some of her patients resisted VIA exams, which they referred to as ''acid Paps,'' and demanded ''real Paps.''

Program directors often asserted that their own staff could benefit from continuing supervision and refresher courses, as over time some employees had strayed from protocol. For example, some administrators said that their staff performed cryotherapy on women under the age of 25, even though it is recommended that the test be performed only on women ages 25–50.[35,36] Additionally, one U.S. program director found that trained local staff treated women with ''a little touch'' (*toquecito*) of the cryotherapy probe rather than following guidelines to freeze, thaw, and refreeze lesions for 3, 5, and 3 minutes, respectively[35]:

Sometimes I wonder what we're doing. It's like, are you kidding me? Someone gave a 22-year-old a ''little touch'' of cryo? What does that mean? What does that do? What are we doing? Okay, so now we're doing ''little touches'' of cryo to all these 20-something-year-old Guatemalan women?

This program director subsequently sent local staff to a refresher course.

Cryotherapy Referrals

Seventeen interviewees working for 12 of the 20 NGOs mentioned concerns about contact with MOH facilities or other NGO programs in which VIA and cryotherapy are not performed together, within a single visit. As one program director stated:

VIA is not being done here in the way it is proposed in international medical journals. VIA is supposed to be see-and-treat.

In part, this is because some MOH facilities and NGOs in Guatemala have materials to perform VIA exams, but they lack equipment or run out of supplies to perform cryotherapy. While the MOH does not report problems with gas supply at the national level,[32] interviewees explained that local-level MOH facilities in which providers had been trained in VIA-cryotherapy often lack funds for replenishing gas supplies. Furthermore, there is no national system for maintenance of cryotherapy equipment.[32]

Training in VIA but not cryotherapy. Another reason that VIA and cryotherapy are not coupled is that some providers are trained in VIA but not cryotherapy. For instance, in 2008, the MOH reported that only 252 of 1,211 VIA-trained providers (about 21%) were also trained in cryotherapy.[32] Similarly, some NGOs reported certifying only a subset of VIA trainees in cryotherapy. Training course instructors aim to supervise trainees during 5–10 cryotherapy procedures, in line with Jhpiego recommendations.[35] This generally limits the number of cryotherapy trainees to 1 to 2 practitioners per 100 women screened. However, NGO administrators sometimes enroll more students (for example, 10–20) in their courses than can be trained in cryotherapy, feeling that they can benefit from learning VIA alone until they are eventually trained in cryotherapy in a subsequent course. As a result, about 20%–25% of trainees participating in these courses received training in both VIA and cryotherapy. Not all interviewees agreed with this strategy. One U.S. NGO director familiar with large training courses stated, ''I'm scratching my head wondering why they would train you in one and not the other.'' This NGO had limited the size of its course to 5 trainees so that all would have the opportunity to learn cryotherapy.

Because of shortages of cryotherapy equipment and trained personnel, NGO and MOH providers may refer women who test positive to other NGOs or larger MOH facilities for treatment. For example, one NGO director reported forming a relationship with the MOH:

The MOH, they're doing VIA, but they don't have the capability to do cryo, so they're referring cryotherapy patients to us.

NGO staff also made contact with other NGOs to overcome inability to offer cryotherapy. As one NGO administrator described it:

We did the screening, but what are we going to do to help them [screening-positive women]? We made an alliance with [another NGO]. They give us treatment when we refer patients directly to them … And that's how we're working, because we haven't been trained to do the VIA and the cryotherapy.

For various reasons, many women who are found to be positive on VIA do not receive cryotherapy immediately, as the see-and-treat paradigm calls for.

Loss to follow-up. Nine interviewees working in 7 of 10 NGOs participating in cryotherapy referral networks reported challenges with ensuring follow-up care for VIA-positive women. While interviewees regarded the emergence of NGO–MOH referral networks as a practical solution to resource scarcity, they highlighted 2 major problems with these systems. First, VIA-positive women often did not complete cryotherapy referrals because of economic, transportation, and childcare barriers. One Guatemalan NGO auxiliary nurse, trained in VIA but not cryotherapy, described the case of a woman she had referred for a later cryotherapy appointment at the same facility:

> *We gave her an appointment so that she would come back to the health center to get her cryotherapy. But she didn't come. So what I was doing was calling and calling … I told her that when she comes, they're going to give her the treatment free, because she'd have spent money on getting there. And she says, ''Yes, I'm going to go.'' But she doesn't come.*

Interviewees who received cryotherapy referrals reported the same problems. At one VIA–cryotherapy campaign we attended, only 2 of 16 women who had been referred for cryotherapy after prior VIA testing arrived for their appointments. The nurse charged with their treatment remarked, ''This makes us feel as if we are not really doing anything [with VIA].'' A program administrator, exasperated with the situation, stated: ''If you can't follow-up on the whole package, I'm not sure how much value there is [in doing VIA].'' Some NGOs overcame referral problems by directly organizing and financing transportation for women to complete referrals or working with local MOH facilities and municipal offices to do so.

Coordination problems. A second concern with cryotherapy referrals related to the difficulties of inter-institutional coordination. One NGO director reported that her organization had the resources to offer free treatments to women in need of follow-up but had troubles establishing reliable contacts with MOH personnel and staff of another NGO with ''broken'' cryotherapy equipment willing to coordinate referrals. Rather, many VIA-positive women learned of her clinic on their own, through word-of-mouth. This problem was not as salient in other health districts, where NGOs had established strong relationships with active MOH leaders.

The Cervical Cancer Consortium could address staff turnover and ''internal brain drain'' by establishing an ''NGO code of conduct'' and setting agreed salary levels.

DISCUSSION

This research identified 4 major challenges faced in NGO-sponsored VIA programs in Guatemala (staff turnover, non-standard training courses, lack of on-site supervision, and disruption of the VIA–cryotherapy ''see-and-treat'' paradigm), which points to strategies for improving service delivery, sustainability, and resource allocation.

Interviewees most frequently reported **staff turnover** as an important challenge. Because of MOH service rotation systems and competitive NGO hiring practices, VIA-trained providers may not continue to practice the skill. On the positive side, providers who move to other positions take with them increased understanding of VIA–cryotherapy and cervical cancer. On the negative side, however, staff turnover raises concerns about service quality, gaps in service delivery, and suboptimal use of limited training resources, as documented in other countries such as Mozambique, Peru, and Uganda.[37,38] Additionally, VIA training may become a marketable skill for MOH providers who leave their posts for higher-paying civil-sector jobs. Such drains of public-sector health care providers by the NGO sector are common in LMICs and by no means limited to VIA training.[39] This study also indicates that turnover among MOH and NGO administrators can detrimentally affect VIA program continuity. This phenomenon has also been documented in Bolivia, where frequent leadership changes among MOH staff decrease possibilities for VIA-related capacity building.[40]

Reducing turnover. While reconsideration of MOH staff rotation systems is advisable in Guatemala, staff turnover is unlikely to change because obligatory staff rotations are a long-standing human resources policy within many Central American Ministries of Health. NGOs operating their own VIA-based screening programs, however, may be able to partially mitigate the effects of staff turnover within the NGO sector and ensure continuity of services by budgeting to train new providers to replace those who leave. Also, NGOs should avoid using salary differentials to hire VIA-trained staff away from either the public sector or other NGOs.[39] In 2013, the MOH, several major NGOs, and local universities formed a Cervical Cancer Consortium to develop national cervical cancer prevention policy. The Consortium could provide a valuable forum for addressing staff turnover and ''internal brain drain'' by establishing an ''NGO code of conduct,'' as has been

proposed for the African region,[39] and setting agreed salary levels for VIA providers.

Two additional and interrelated concerns raised by interviewees were **non-standard training courses**, which lacked practice under clinical supervision, and **lack of continued on-site supervision** for former trainees. Interviewees felt that these problems lead to considerable heterogeneity of practice among VIA providers, especially regarding the age range of patients screened and standardized application of cryotherapy. These problems compromised the technique's reputation among local service users and providers, a finding also reported in India.[41] Program administrators and providers in Guatemala described a need for continued supervision and refresher courses, a perception widely reported in evaluations of VIA programs worldwide.[8,32,38,40,42]

Regulating training. Greater regulation of training programs is necessary. One of the future tasks of the Cervical Cancer Consortium in Guatemala will be standardizing a VIA training curriculum based on Jhpiego materials. A certification system should be developed that allows only those who have passed approved training courses to conduct VIA–cryotherapy. Additionally, both the MOH and NGOs should budget for trained supervisors who can rotate among former trainees to provide guided supervision, identify problems, and assess needs for refresher training.[8] The Consortium could play a valuable role in setting standards of quality care, ratios of field supervisors to providers, and frequency of on-site mentoring and evaluative visits.

Making time for clinical supervision in training. Additionally, other training options should be explored. Rather than relying on concentrated training with a minimal period of clinical supervision, VIA training could take place through continuous on-the-job mentoring. Online training modules could serve as prerequisites for training courses, which could help increase time available for clinical supervision. Similarly, refresher courses could include online components with image and protocol reviews. The Consortium is ideally positioned to develop standardized criteria for such training experiences.

Another major challenge, and the most significant finding of this study, is the endemic **disruption of the VIA–cryotherapy "see-and-treat" paradigm**. Interviews suggested that often only VIA is performed and VIA-positive women are lost to follow-up care. Often, access to functioning cryotherapy equipment is limited, especially in MOH facilities, and many providers are trained only in VIA, but not in cryotherapy. Resource shortages leading to the breakdown of the VIA–cryotherapy link also have been described in other LMICs.[32,43]

The most significant finding of this study is the endemic disruption of the VIA–cryotherapy ''see-and-treat'' paradigm.

This situation reflects problems common to all screening and referral models. It is a particularly important problem in this instance because one of the most compelling justifications for VIA–cryotherapy is that providing immediate treatment for VIA-positive patients eliminates financial, administrative, and logistical barriers that lead to loss to follow-up in resource-poor settings. These strengths of the ''see-and-treat'' paradigm are thought to overcome the shortcomings of cytology-based screening, which has failed to produce significant gains against cervical cancer in LMICs.[7,15,17,44] Indeed, large trials of VIA-only programs, where VIA is not directly coupled with cryotherapy, have shown problems with follow-up similar to those encountered in cytology-based programs.[2,45] Therefore, the VIA-only model is particularly concerning in countries with inadequate and underdeveloped referral systems such as Guatemala.

A certification system should be developed that allows only those who have passed approved training courses to conduct VIA–cryotherapy.

Re-coupling VIA and cryotherapy. The VIA–cryotherapy linkage can be improved through long-range plans for servicing and distributing cryotherapy equipment and comprehensive training programs that certify all providers in both techniques. For the time being, however, it is likely that screening-only VIA programs will proliferate in Guatemala and elsewhere, given the issues of turnover, equipment maintenance, and training capacity documented here. Therefore, VIA funders and implementers working in this context should address the empirical barriers to effective patient referral.

Improving referral systems in LMICs is a complex and ambitious task, but initial steps can be taken to decrease loss to follow-up of VIA-positive women in Guatemala. Mapping of clinical centers offering VIA-only versus VIA–cryotherapy in each health district could facilitate inter-institutional coordination of VIA referrals. Additional actions must be taken to address patients' economic and logistical barriers to obtaining treatment. This study indicates that NGO and MOH clinics may be able to help overcome referral problems by organizing and subsidizing transportation for VIA-positive women to cryotherapy appointments. Additionally, by analogy with successful care coordination systems developed in other LMICs for other conditions, Guatemala's robust national cell phone infrastructure could be

Clinics may be able to help overcome referral problems by organizing and subsidizing women's transportation to cryotherapy appointments.

harnessed to create shared mHealth platforms for tracking patients and coordinating referrals for VIA-positive women.[46,47]

Limitations

This study has 3 primary limitations. First, as we relied on a convenience sample of NGOs, results may not be generalizable to other NGOs operating VIA programs in Guatemala or in Latin America. However, because the NGOs involved varied widely in terms of size, program models, and extent of collaboration with the MOH, the study likely describes the full range of challenges in NGO-sponsored VIA programming in Guatemala. Second, since the study focused exclusively on NGOs' roles in VIA programs, MOH personnel were not interviewed. Undoubtedly, MOH personnel would describe additional challenges not discussed here. This is an area for future research. Third, given the qualitative nature of the study, we cannot specify the absolute frequency of reported phenomena such as the breakdown of the "see-and-treat" paradigm. Further quantitative research is needed to assess this issue.

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ORIGINAL ARTICLE

Can traditional birth attendants be trained to accurately identify septic infants, initiate antibiotics, and refer in a rural African setting?

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Despite having limited training, these TBAs were able to accurately identify critically ill neonates, initiate treatment in the field, and refer for further care. Given their proximity to the mother/infant pair, and their role in rural communities, training and equipping TBAs in this role could be effective in reducing neonatal mortality.

ABSTRACT

Background: Neonatal sepsis is a major cause of neonatal mortality. In populations with limited access to health care, early identification of bacterial infections and initiation of antibiotics by community health workers (CHWs) could be lifesaving. It is unknown whether this strategy would be feasible using traditional birth attendants (TBAs), a cadre of CHWs who typically have limited training and educational backgrounds.

Methods: We analyzed data from the intervention arm of a cluster-randomized trial involving TBAs in Lufwanyama District, Zambia, from June 2006 to November 2008. TBAs followed neonates for signs of potential infection through 28 days of life. If any of 16 criteria were met, TBAs administered oral amoxicillin and facilitated referral to a rural health center.

Results: Our analysis included 1,889 neonates with final vital status by day 28. TBAs conducted a median of 2 (interquartile range 2–6) home visits (51.4% in week 1 and 48.2% in weeks 2–4) and referred 208 neonates (11%) for suspected sepsis. Of referred neonates, 176/208 (84.6%) completed their referral. Among neonates given amoxicillin, 171/183 (93.4%) were referred; among referred neonates, 171/208 (82.2%) received amoxicillin. Referral and/or initiation of antibiotics were strongly associated with neonatal death (for referral, relative risk [RR]=7.93, 95% confidence interval [CI]=4.4–14.3; for amoxicillin administration, RR=4.7, 95% CI=2.4–8.7). Neonates clinically judged to be ''extremely sick'' by the referring TBA were at greatest risk of death (RR=8.61, 95% CI=4.0–18.5).

Conclusion: The strategy of administering a first dose of antibiotics and referring based solely on the clinical evaluation of a TBA is feasible and could be effective in reducing neonatal mortality in remote rural settings.

INTRODUCTION

Neonatal mortality accounts for about 40% of all childhood mortality in low- and middle-income countries. Neonatal sepsis, birth asphyxia, and neonatal hypothermia are responsible for the largest number of preventable deaths.[1–3] These conditions are particularly difficult to manage in remote rural settings where home deliveries predominate. In such settings, traditional birth attendants (TBAs) provide 20%–40% of obstetrical care.[4] Given their close access to the mother/infant pair, strengthening TBAs' capacity could be effective in reducing neonatal mortality.

The Lufwanyama Neonatal Survival Project (LUNESP) was a community-based effectiveness trial in Zambia that assessed the impact of a package of TBA-delivered interventions on all-cause mortality through postpartum day 28.[5,6] In LUNESP, TBAs were randomized either to continue their existing standard of care (controls) or to receive training and supplies

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enabling interventions targeting key preventable causes of neonatal mortality (intervention): birth asphyxia, hypothermia, and neonatal sepsis.[7] The intervention had 2 components: (1) a simplified version of the neonatal resuscitation protocol (NRP), which targeted deaths from birth asphyxia and neonatal hypothermia; and (2) administration of oral antibiotics with facilitated referral (AFR) to a rural health center, which aimed to reduce deaths from neonatal sepsis.

The LUNESP interventions reduced all-cause day-28 mortality among live-born neonates by nearly half (relative risk [RR]=0.45, 95% confidence interval [CI]=0.33–0.9), with the largest reductions during the first 48 hours of life (7.8 deaths/1,000 live births vs. 19.9 deaths/1,000 live births, RR=0.4, 95% CI=0.19–0.83).[6] However, mortality also trended lower during weeks 2 to 4 (RR=0.47, 95% CI=0.20–1.11). A late effect of NRP is unlikely to account for this but is consistent with a benefit from AFR. To explore this further, we conducted a secondary analysis focusing on the process by which the intervention TBAs identified, treated, and referred neonates to receive the AFR intervention. We addressed the following issues:

1. How often did the intervention group TBAs refer, and how often was referral coupled with the first dose of amoxicillin (or vice versa)?
2. What were the clinical indications cited for referrals, and how accurately did these predict a fatal outcome for the infant?
3. Is there evidence that TBAs were exercising reasonable clinical judgment in the implementation of the AFR intervention?

METHODS

LUNESP was a cluster-randomized controlled clinical trial conducted between June 2006 and November 2008 in Lufwanyama District, a vast, sparsely populated, rural, and poorly developed region in Zambia's Copperbelt Province. Full details of the LUNESP study have been published previously.[6,7] LUNESP was registered on Clinical Trials.Gov as NCT00518856, with ethical oversight by Boston University Medical Center and the Tropical Diseases Research Centre in Ndola, Zambia. At the time of the LUNESP study, the district included 12 health posts staffed by midwives or clinic officers; there were no physicians and no hospitals. Initially, 120 Zambian TBAs who had previously undergone basic obstetrical training (see below) were randomized 1:1 to intervention or control arms. Control TBAs were trained on reporting aspects of the study, but otherwise they continued their existing care; intervention TBAs received training in NRP and AFR. For this analysis, we used data pertaining to the 60 intervention TBAs.

Detailed information about the TBAs' baseline obstetrical training and the additional training provided for LUNESP has been published in a separate methods paper.[7] In brief, prior to LUNESP, TBAs already working in Lufwanyama were recruited and registered by the Lufwanyama District Health Management Team. These TBAs were women who had already practiced as TBAs informally for many years but had been nominated by their local village health committees to undergo standardized training on the basis of their perceived skills and value by their community. With that said, this was not synonymous with higher levels of education. Among the TBAs in this analysis, only 17% had received any secondary education, and many could not read or write. All such TBAs received basic obstetrical training, focusing primarily on clean delivery practices, the use of a clean delivery kit with every delivery, and indications for referral (for example, high-risk pregnancies and danger signs emerging during labor). In most cases, this training was provided by the Lufwanyama DHMT itself, but many TBAs were trained instead or in addition by local nongovernmental organizations working in Lufwanyama, and such trainings varied in their duration and intensity. As such, these TBAs served as auxiliary community health workers (CHWs), supported and registered by the local DHMT, and thus could be described properly as ''trained TBAs.''

Interventions reduced all-cause day-28 mortality among live-born neonates by nearly half.

The LUNESP trainings, focusing on AFR and the neonatal resuscitation interventions, were highly standardized. These began with 2 week-long workshops, followed by refresher workshops lasting 2–3 days each, every 3–4 months for the duration of the study. At each workshop, TBAs received group instruction about the interventions, which, due to low levels of literacy, was all done verbally without any supporting text materials. After these combined didactic sessions, TBAs were sorted into working groups of 5–6 for skills training. Each of the TBAs had to complete all steps of the interventions perfectly for the group to graduate. Once all groups had passed, the TBAs underwent one-on-one observed

standardized clinical examinations with the master trainer. Only after 100% of the TBAs had passed this final step was the workshop concluded. Because the TBAs' activities (deliveries and AFR interventions) occurred across the vast expanse of Lufwanyama district, there was no opportunity for a supervisor to physically attend these events. Thus, the competence of the TBAs to perform the study interventions was based on their performance during the workshops.

For the AFR intervention, TBAs were trained to identify signs/symptoms of potential severe neonatal infection and neonatal sepsis. These criteria are commonly observed in septic neonates, or those with focal infections at risk for developing sepsis, and were based predominantly on the World Health Organization's (WHO's) Young Infant Clinical Signs Study.[8] Specific categories of signs/symptoms were:

- Generalized/behavioral changes (lethargy, irritability, poor feeding, sleepy or difficult to arouse, hypotonia, dehydration)
- Temperature instability (too hot or cold)
- Respiratory distress (tachypnea, chest indrawing or retractions, cough, any ''breathing difficulty'')
- Central nervous system (CNS)-specific (seizure, bulging fontanel)
- Gastrointestinal (GI)-related (vomiting, diarrhea, abdominal distension)
- Focal infection (skin or umbilical erythema or pustules)

From these, a set of 14 specific criteria were reported by TBAs. In addition, the TBA could trigger the intervention if either the mother or the TBA felt that the baby ''appeared ill,'' even if no other criteria were met; this brought the total number of criteria to 16.

If any criteria were met, the TBAs were to prepare a slurry of 500 mg amoxicillin using chlorinated water, to administer as much as the infant would accept, and to then encourage the mother to immediately take the infant to the nearest rural health center (RHC), ideally accompanying the mother/infant pair. Amoxicillin use was always to be coupled with referral. A separate team of data collectors interviewed the mothers at the neonates' first and fourth weeks of life documenting TBA referrals and/or amoxicillin use, reasons for referrals, final infant vital status, and the timing of any deaths.

The analysis set comprised all live-born neonates delivered by intervention TBAs with valid data through at least the week-1 visit. We generated descriptive statistics identifying the frequency of TBA referrals, the reasons for AFR, the concordance between RHC referral and amoxicillin administration (and vice versa), the survival rates of referred neonates, and the frequency with which referred mother/infant pairs completed the referral. A ''completed referral'' was defined as a referred infant who was taken to an RHC for clinical evaluation.

Where appropriate, we conducted bivariate analyses to generate relative risks and 95% confidence intervals for death. Due to the relatively small number of deaths (n=43), we did not conduct multivariate analyses. In addition, we calculated sensitivities and specificities with 95% CI for a fatal outcome, along with positive and negative likelihood ratios (LR+, LR-), respectively, in the presence or absence of each criterion. In the case of neonates referred twice, we used only the final referral for this calculation (which is synonymous with the total number of children ever referred). An LR+ is defined as (sensitivity)/(1-specificity); an LR- is defined as (1-sensitivity)/(specificity).[9]

TBAs from Lufwanyama District, Zambia, attend a LUNESP training workshop to improve neonatal survival.

RESULTS

The intervention TBAs conducted a total of 2,007 deliveries, of which 38 were stillbirths (1.9%). Among live-born neonates, we had complete follow-up data on 1,889/1,969 (95.9%) (Figure). Table 1 summarizes baseline characteristics of the mothers and the 1,889 neonates who comprised the analysis set, stratified by the neonates' final vital status by day 28 of life (that is, alive vs. dead). Maternal baseline characteristics were similar between the 2 groups, except that more mothers of surviving neonates had been dewormed during pregnancy. Surviving neonates (n=1,846) were significantly more likely to be female or to have been exclusively breastfed during the study period than those who died (n=43). The gestational age of surviving neonates also trended lower, but the difference was not statistically significant.

Table 2 summarizes characteristics of the TBAs. Most TBAs were married, identified farming as their primary occupation, and had worked as TBAs for an average of 6.3 years. Their educational backgrounds were quite limited: 83.3% either had no formal schooling or had failed to advance beyond primary school.

Of the 1,889 neonates, 208 (11.0%) were referred to an RHC, and 11 (0.6%) were referred twice. Thus, a total of 219 referrals occurred, 113 during week 1 (51.6% of referrals) and 106 during weeks 2–4 (48.4% of referrals). The majority of neonates (176/208 [84.6%]) completed their referral to the RHC. TBAs administered amoxicillin 188 times, 99 times during week 1 (52.7% of total administrations) and 89 times (47.3% of total administrations) during weeks 2–4. Among referred neonates, 171/208 (82.2%) received amoxicillin; among neonates given amoxicillin, 171/183 (93.4%) were referred (referral status unknown for 5 subjects).

Referred neonates had been ill for a median of 2 days prior to the TBAs' evaluation. TBAs cited a median of 3 criteria to justify their referrals, with a range of 0 (8 times) to 8 (2 times) reasons. A single reason for referral was cited 19 times; 2 reasons, 23 times; 3 reasons, 52 times; 4 reasons, 73 times; and 5 or more reasons, 41 times. The 6 most common reasons for referral, alone or in combination, were because: (1) the TBA thought the neonate "appeared ill" (82.8%), (2) the mother thought the neonate "appeared ill" (80.8%), (3) "felt hot" (41.2%), (4) "had a cough" (40.4%), (5) "was not making urine" (31.9%), or (6) was having "difficulty breathing" (26.4%).

FIGURE. Data on Live-Born Neonates, June 2006–November 2008

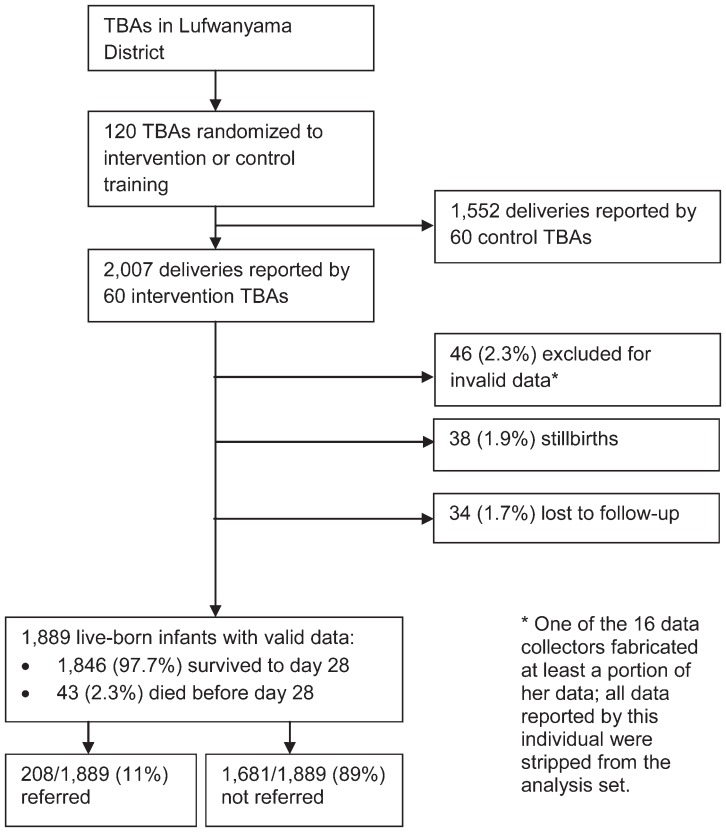

Table 3 summarizes the accuracy for the 16 referral criteria for identifying neonates who subsequently died. Individually, none displayed both high sensitivity and high specificity. Moreover, several signs were nearly ubiquitous in their presence and some were tautological. For example, 95% of referred neonates included the criterion that the TBA thought the baby "appeared ill," but logically a TBA would be unlikely to refer otherwise. Moreover, this criterion was never cited alone but was always accompanied by other, more specific criteria. Criteria that were cited frequently were "felt hot/cold," "had cough," "refused to feed," had "difficulty breathing," and "not making urine." Conversely, "rapid breathing," "bulging fontanel," and "infected umbilicus" were rarely cited, and no neonates were referred for "diarrhea" or "chest wall in-drawing."

TABLE 1. Baseline Maternal and Infant Characteristics Stratified by Infant Vital Status at Day 28 of Life

Characteristic	Infant Survivors (n=1,846)	Infant Deaths (n=43)	All Neonates (N=1,889)	*P* Value
Maternal Characteristics				
Age, y, mean (SD)	25.3 (0.15)	25.7 (1.27)	25.3 (0.15)	.77
Education (highest level attained), %				.41
None	16.7	20.9	16.8	
Some primary	69.2	58.1	68.9	
Some secondary	13.8	20.9	14.0	
Some higher	0.3	0.0	0.3	
Marital status, %				.84
Married	89.4	86.0	89.3	
Widowed	0.8	0.0	0.8	
Separated/divorced	2.5	4.7	2.5	
Never married	7.3	9.3	7.4	
No. of ANC visits attended, mean (SD)	3.3 (0.03)	3.2 (0.21)	3.3 (0.03)	.67
Receipt of treatment				
IPT of malaria with SP, %	89.8	83.7	89.6	.20
Deworming treatments, %	65.9	55.8	65.6	.01
Folic acid supplementation, %	85.5	95.3	85.8	.07
Iron supplementation, %	92.5	90.7	92.5	.65
Tetanus toxoid, %	72.8	65.1	72.6	.26
Infant Characteristics				
Female, %	50.5	32.6	50.1	.02
Gestational age at birth, weeks, mean (SD)	38.0 (0.31)	43.0 (2.19)	38.1 (0.31)	.33
Exclusively breastfed, %	96.8	86.0	96.6	<.001

Abbreviations: ANC, antenatal care; IPT, intermittent preventive therapy; SD, standard deviation; SP, sulfadoxine-pyrimethamine.

Overall, the most useful sign for both predicting and excluding a fatal outcome was the criterion ''difficulty breathing,'' with sensitivity of 65% and specificity of 78%, yielding positive and negative LRs of 3.0 and 0.4, respectively. Infrequent signs that predicted a fatal outcome were: ''baby sleepy/unarousable'' (LR+ 9.1), ''rapid breathing'' (LR+ 5.9), ''bulging fontanel'' (LR+ 5.9), ''refuses to feed'' (LR+ 5.4), ''convulsions/fits/seizures'' (LR+ 5.4), ''infected umbilicus'' (LR+ 4.5), and ''floppy/poor muscle tone'' (LR+ 3.4). Conversely, the only criterion strongly predictive of infant survival was if the TBA did not feel that the infant looked sick, where the LR- was 0.3. The opinion of the mother was neither sensitive nor specific (LR+/− both 1.0).

Among live-born neonates, 43 (2.3%) died during the first 28 days of life. Among referred neonates, 9.6% (20/208) ultimately died. By contrast, among neonates who were not referred,

only 1.2% died (22/1,658), with 1 neonate whose referral status was missing. Since a neonate who dies shortly after birth has little opportunity to be referred, we assessed referral status relative to the timing of deaths. Of the non-referred deaths, 10/22 (45%) occurred on the first day of life, while only 4/20 (20%) of the referred deaths occurred on the first day of life.

Neonates sick enough to warrant referral (regardless of whether given amoxicillin or not) were nearly 8 times more likely to die than babies who were not referred (RR=7.93, 95% CI=4.4–14.3). Similarly, neonates deemed sick enough to receive amoxicillin (regardless of referral status) were nearly 5 times likely to die as those not given amoxicillin (RR=4.7, 95% CI=2.5–8.7).

The TBAs recorded a subjective impression of illness severity for 185/208 referred neonates (88.9%), as summarized in Table 4. Neonates judged as ''extremely sick'' by the referring TBA were far more likely to die than those deemed ''not sick'' or only ''moderately sick'' (RR=8.61, 95% CI=4.0–18.5).

TABLE 2. Characteristics of the Intervention TBAs (N=60)

Characteristic	
Female, %	100
Age, y, mean (SD)	49.2 (0.79)
Years working as TBA, mean (SD)	6.3 (0.81)
Education	
Total years of education, mean (SD)	6.3 (0.48)
Never attended school, %	5.0
Primary education only, %	78.3
Main occupation, %	
TBA	1.7
Farmer	98.3
Source(s) of training prior to LUNESP,[a] %	
Trained by family	11.5
Trained by community, not family	42.6
Trained by Lufwanyama DHMT	60.3
Trained by another government organization	33.3
Trained by an NGO	32.7

Abbreviations: DHMT, district health management team; LUNESP, Lufwanyama Neonatal Survival Project; NGO, nongovernmental organization; SD, standard deviation; TBA, traditional birth attendant.
[a] TBAs often received training from more than 1 source.

DISCUSSION

In LUNESP, about 11% of neonates cared for by the intervention TBAs were targeted for AFR, a rate that is consistent with the incidence of serious bacterial infections during the first 28 days of life.[10] Notably, neonates who were referred were approximately 8 times more likely to have a fatal outcome than those who did not, and those who received amoxicillin were nearly 5 times more likely to die. It makes little sense that referral in itself causes death and implausible that a safe and well-tolerated antibiotic like amoxicillin would increase mortality. Therefore, a more logical interpretation is that referral and/or use of amoxicillin were both markers of very ill children at high risk of death. This interpretation is supported by the observation that neonates deemed ''extremely sick'' by the referring TBA were about 9 times more likely to die than neonates judged less severely ill. Taken together, we conclude that the TBAs demonstrated sound clinical judgment and reacted according to their training, which strongly supports the feasibility of using TBAs in this role.

With that said, in order for an intervention like AFR to be effective, several conditions must be met. First, the CHW must have sufficient clinical judgment to accurately identify those children who are in crisis. Second, they must be empowered, trained, and equipped to act upon that determination. Third, the actions that ensue as a consequence must be sufficient to interrupt the disease process that would ultimately lead to death.

Our analysis suggests that the first 2 conditions were met, but evidence for the third is more ambiguous. In our main effects analysis, during weeks 2–4 of life, the period during which AFR would presumably have been most effective (and the effects of NRP minimal), mortality among neonates cared for by intervention TBAs was reduced by about 50%, but this did not reach statistical significance.[6] Our study had been powered to detect an overall effect on mortality due to the combination of NRP and AFR, so the infrequency of sepsis could have left us underpowered to isolate the effect of AFR. This possibility could be evaluated in a larger clinical trial. However, another possibility is that the

Neonates sick enough to warrant referral were nearly 8 times more likely to die than babies who were not referred.

Neonates deemed ''extremely sick'' by the referring TBA were about 9 times more likely to die than neonates judged less severely ill.

TABLE 3. Sensitivity, Specificity, and Likelihood Ratios of Specified Reasons for Referral at Predicting a Fatal Outcome for the Referred Infant

Reason for Referral[a]	Times Cited	Prevalence % (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)	LR+	LR-
Fever or felt hot	82	41.2 (34.3–48.4)	15.0 (3.2–37.9)	55.9 (48.3–63.3)	0.3	1.5
Had cough	80	40.4 (33.5–47.6)	25.0 (8.7–49.1)	57.9 (50.3–65.2)	0.6	1.3
Diarrhea	15	7.6 (4.3–12.2)	0.0 (0.0–16.1)	91.6 (86.5–95.2)	0.0	1.1
Refusing to feed	24	12.1 (7.9–17.4)	45.0 (23.1–68.5)	91.6 (86.6–95.2)	**5.4**	0.6
Sleepy or difficult to arouse	8	4.0 (1.8–7.8)	20.0 (5.7–43.7)	97.8 (94.3–99.4)	**9.1**	0.8
Floppy or poor muscle tone	18	9.1 (5.5–14.0)	25.0 (8.7–49.1)	92.7 (87.8–96.1)	**3.4**	0.8
Not making urine	22	31.9 (21.2–44.2)	57.1 (18.4–90.1)	71.0 (58.1–81.8)	2.0	0.6
Convulsions, fits, or seizures	8	4.1 (1.8–7.8)	15.0 (3.2–37.9)	97.2 (93.5–99.1)	**5.4**	0.9
Difficulty breathing	52	26.4 (20.4–33.1)	65.0 (40.8–84.6)	78 (71.1–83.8)	**3.0**	**0.4**
Rapid breathing	5	2.5 (0.8–5.8)	10.0 (1.2–31.7)	98.3 (95.1–99.6)	**5.9**	0.9
Chest wall in-drawing	1	0.5 (0.0–2.8)	0.0 (0.0–16.1)	99.4 (96.9–100.0)	0.0	1.0
Skin pustules or red rash	6	3.0 (1.1–6.5)	0.0 (0.0–39.0)	96.6 (92.8–98.7)	0.0	1.0
Infected umbilicus	3	1.5 (0.3–4.4)	5.0 (0.1–24.9)	98.9 (96–99.9)	**4.5**	1.0
Bulging fontanel	5	2.5 (0.8–5.8)	10.0 (1.2–31.7)	98.3 (95.1–99.6)	**5.9**	0.9
TBA thought baby appeared ill	164	82.8 (76.8–87.8)	95.0 (75.1–99.9)	18.5 (13.1–25.0)	1.2	**0.3**
Mother thought baby appeared ill	160	80.8 (74.6–86.0)	80.0 (56.3–94.3)	19.1 (13.6–25.7)	1.0	1.0
Other[b]	62	NA	NA	NA	NA	NA
No reason cited	8	NA	NA	NA	NA	NA

Abbreviations: CI, confidence interval; LR+ and LR−, positive and negative likelihood ratios (clinically relevant LR+ and LR− values are in bold); NA, not applicable.

[a] TBAs were free to specify more than 1 reason for a given referral, so the total number of reasons for referral exceeds the number of neonates who were referred (208).

[b] Among the ''other'' reasons cited, those cited more than once included 12 citations for abdominal complaints (not making stool, swollen or tender belly, or diarrhea); 8 citations for inconsolable crying; 6 because the baby had been resuscitated at birth (all of which occurred during the first follow-up visit during week 1); 6 for skin rashes or sores; 4 for congenital defects or prematurity; 3 for respiratory complaints; and 3 for eye infections or discharge.

Rural health clinics may not be sufficiently prepared to manage neonatal sepsis.

receiving RHCs were insufficiently prepared to manage neonatal sepsis, which would be an essential pre-condition for the third condition listed above. If so, 2 potential solutions are suggested.

First, one could focus resources on strengthening the ''back end'' of the referral process, that is, the receiving RHCs. In this approach, one would continue to limit the role of TBAs to giving a first dose of antibiotics and facilitating referral, essentially using the TBAs to extend the reach of the RHCs into the community while focusing resources to strengthen the capacity of the RHCs to manage newborns with serious bacterial infections.

Alternatively, one could invest in strengthening the ''front-end'' by increasing the capacity of the TBAs themselves, following the model of Bang and Bang in India.[11–13] There, village health workers were responsible not just for identifying sepsis but also for administering the full antibiotic treatment course in the community using a

TABLE 4. Survival of Neonates Stratified by the Subjective Severity of Illness Rating Assigned by the Referring TBA (N=185)[a]

	Severity Rating, n/N (%)		
Outcome	**Not sick**	**Moderately sick**	**Extremely sick**
Died	3/49 (6.1%)	6/113 (5.3%)	11/23 (47.8%)
Survived	46/49 (93.9%)	107/113 (94.7%)	12/23 (52.2%)
Total	49/185 (26.5%)	113/185 (61.1%)	23/185 (12.4%)[b]

Abbreviation: TBA, traditional birth attendant.
[a] A total of 208 neonates were referred; TBAs provided a severity assessment for 185 of the 208 neonates (88.9%). Data for analysis relates only to the final referral if the infant was referred more than once given that an infant referred twice could not possibly have died during the first referral event.
[b] Chi square=37.3 with 2 df, $P< .001$; comparing ''extremely sick'' vs. combined (''not sick'' and ''moderately sick''), RR of fatal outcome=8.61, 95% CI=4.0–18.5.

combination of oral and injectable antibiotics. This approach is ambitious since it requires that CHWs be trained to use injectable antibiotics dosed according to infant body weight and that systems be established for managing contaminated sharps, storing antibiotics appropriately, and for reclaiming expired drugs. However, this strategy minimizes the delay between identification of a sick child and the start of definitive antibiotic therapy, and it largely eliminates the problem of non-adherence to referrals.

One distinction: the CHWs from studies in South Asia had significantly more training than the LUNESP TBAs, both in terms of their background education and in the intervention training specifically.[14–16] Even so, a hybrid of these 2 models might yet be feasible: TBAs could be responsible for identifying neonates with possible sepsis, initiating therapy, and referring, but the single-dose amoxicillin could be replaced with broader spectrum antibiotics with longer half-lives, or combinations of drugs such as the oral cotrimoxazole and injectable gentamicin used by Bang and Khanal.[12,16] Decisions about which strategy is most appropriate will depend on the capacity of the CHWs, the local epidemiology of neonatal sepsis, the capacity of RHCs, and especially the average transit times to the RHCs. Logically, the strategy of embedding more capacity in TBAs or other CHWs becomes more attractive as distances to the RHCs increase.

Several other findings in this analysis were of interest. First, one of the most common reasons cited for initiating AFR was that the TBA thought the neonate ''appeared ill.'' This criterion had been included to empower the TBA to initiate AFR based on general clinical impressions, absent more specific definable signs or symptoms.[8] Notably, among referred neonates who did not meet this criterion, mortality was about one-third lower. This lends further credibility to the clinical judgment of the TBAs and is consistent with other researchers' experience with more highly skilled CHWs in Bangladesh, India, and Nepal.[14–16] By contrast, the criterion ''mother thought infant looked sick'' was neither sensitive nor specific.

Second, the most clinically useful criterion was ''difficulty breathing.'' This criterion predicted mortality when present (LR+ 3.0), and it was protective when absent (LR- 0.4). Conversely, ''rapid breathing'' (a sign of ''severe pneumonia'') was rarely cited, and ''chest wall in-drawing'' (a criterion for ''very severe pneumonia''), was never cited. Both signs require some skill to identify, and, in the case of rapid breathing, a timer to count respiratory rates, so their absence as reasons for referral by TBAs should be interpreted cautiously. The clinical sign that most strongly predicted a fatal outcome was ''difficulty arousing the child,'' with a 10-fold increased likelihood of death. It is relevant that several of the referral criteria that performed best in the hands of TBAs were included in the young infant integrated management of childhood illness algorithm and validated in the Young Infant Clinical Signs Study.[17,18]

Solutions might combine boosting capacity of RHCs with expanding TBAs' treatment capabilities in the field.

Third, the AFR training appeared successful at coupling the actions of referring and administering amoxicillin. In more than 80% of instances, the one behavior predicted the other. While one can lament the fact that roughly

One of the most common reasons why TBAs initiated AFR was because they thought the neonate ''appeared ill.''

one-fifth of referrals were not completed, this rate is comparatively high relative to other similar community intervention strategies of this kind.[19,20] Nonetheless, it is clearly a vulnerable point in the AFR strategy. While our data do not indicate the reason for failure to complete a referral, previous research has suggested that mothers may decline referral for a variety of reasons, including distance to facility, financial barriers, and reluctance to comply in the absence of a spouse's authorization.[15,19,21–24]

A general limitation of this analysis was that despite having very complete data from the TBAs about the reasons for referral, data were not collected from the RHCs, which were outside of the LUNESP study. Future studies should assess both sides of the referral system, and also assess the average elapsed time between a TBA's first contact with a sick infant and the first dose of amoxicillin, as well as average transit times to the nearest RHC.

TBAs can be trained to identify sick neonates, initiate treatment, and refer them.

Despite these limitations, our findings provide cause for optimism. Can TBAs be trained to identify sick neonates, refer them, and initiate treatment at the community level? The answer is ''yes.'' Whether this translates into reduced mortality is a testable question. Moreover, these results should be highly generalizable. The LUNESP TBAs were relatively advanced in that they had all received formal training in obstetrical care prior to this study, but they were not highly educated (83% never advanced beyond primary school), and most were illiterate, requiring that our trainings be done without text materials. As such, our study demonstrates that lack of formal education does not mean that individuals are unintelligent or un-trainable. Quite the opposite: despite their lack of formal schooling, the Lufwanyama TBAs proved to be eager and successful students, capable of mastering complex concepts and acting upon them appropriately. Our experiences justify further investigations to assess the effectiveness of community-based identification and presumptive treatment of sepsis in the hands of a relevant cadre of CHWs who, by dint of their obstetrical work, have close access to newborns during their period of greatest vulnerability.

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ORIGINAL ARTICLE

Nationwide implementation of integrated community case management of childhood illness in Rwanda

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Between 2008 and 2011, Rwanda introduced iCCM of childhood illness nationwide. One year after iCCM rollout, community-based treatment for diarrhea and pneumonia had increased significantly, and under-5 mortality and overall health facility use had declined significantly.

ABSTRACT

Background: Between 2008 and 2011, Rwanda introduced integrated community case management (iCCM) of childhood illness nationwide. Community health workers in each of Rwanda's nearly 15,000 villages were trained in iCCM and equipped for empirical diagnosis and treatment of pneumonia, diarrhea, and malaria; for malnutrition surveillance; and for comprehensive reporting and referral services.

Methods: We used data from the Rwanda health management information system (HMIS) to calculate monthly all-cause under-5 mortality rates, health facility use rates, and community-based treatment rates for childhood illness in each district. We then compared a 3-month baseline period prior to iCCM implementation with a seasonally matched comparison period 1 year after iCCM implementation. Finally, we compared the actual changes in all-cause child mortality and health facility use over this time period with the changes that would have been expected based on baseline trends in Rwanda.

Results: The number of children receiving community-based treatment for diarrhea and pneumonia increased significantly in the 1-year period after iCCM implementation, from 0.83 cases/1,000 child-months to 3.80 cases/1,000 child-months ($P=.01$) and 0.25 cases/1,000 child-months to 5.28 cases/1,000 child-months ($P<.001$), respectively. On average, total under-5 mortality rates declined significantly by 38% ($P<.001$), and health facility use declined significantly by 15% ($P=.006$). These decreases were significantly greater than would have been expected based on baseline trends.

Conclusions: This is the first study to demonstrate decreases in both child mortality and health facility use after implementing iCCM of childhood illness at a national level. While our study design does not allow for direct attribution of these changes to implementation of iCCM, these results are in line with those of prior studies conducted at the sub-national level in other low-income countries.

INTRODUCTION

In the mid-1990s, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) launched an Integrated Management of Childhood Illness (IMCI) strategy to reduce child deaths from pneumonia, diarrhea, measles, malaria, and malnutrition.[1] The strategy focused on improving case management skills of health care providers, overall health systems, and family and community health practices.

By 2005, IMCI had been rolled out in 100 countries. An evaluation conducted in a subset of these countries highlighted both the successes and limitations of the

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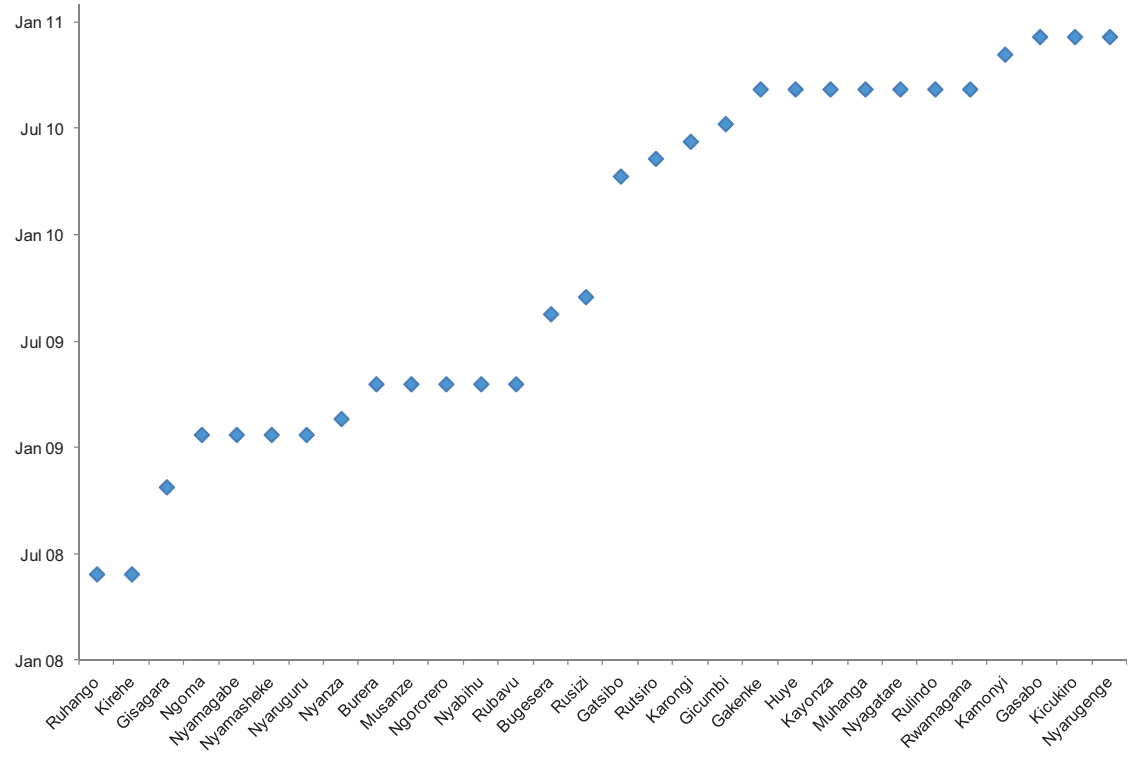
FIGURE 1. Date of Implementation of Integrated Community Case Management by District, Rwanda



IMCI strategy and stressed the importance of community-based case management to further reduce under-5 mortality.[2] A joint statement by WHO and UNICEF acknowledged that, by providing community-based case management of childhood illnesses, trained community health workers (CHWs) could improve child survival rates.[3]

Despite major reductions in under-5 mortality over the past 2 decades, pneumonia, diarrhea, and malaria still cause more than 2.7 million child deaths each year.[4] WHO and UNICEF estimate that timely diagnosis and provision of basic curative services for these diseases could reduce pneumonia deaths by 70%, diarrhea deaths by 70%–90%, and malaria deaths by 40%–60%.[5] The Lancet Diarrhoea and Pneumonia Interventions Study Group recently indicated that impact evaluation of community case management of diarrhea and pneumonia in resource-limited settings was an urgent research priority.[6] While several published studies have investigated the quality and effectiveness of care provided by local-level CHW programs, fewer studies have documented public-sector experiences in implementing integrated community case management (iCCM) for childhood illness on a national scale, and no prior studies have evaluated the impact of iCCM on both child mortality and health facility use at the national level.

By 2011, iCCM had been rolled out to all 30 districts in Rwanda. This article summarizes the iCCM implementation experience in Rwanda and then uses existing data sources to examine changes in child mortality and health facility use in the 1-year period after iCCM implementation in each district. In addition, we also report on changes in the number of children receiving community-based treatment for pneumonia, diarrhea, and malaria during this time period.

Community-based case management of childhood illnesses could improve child survival rates.

ICCM IMPLEMENTATION IN RWANDA

After the 1994 genocide in Rwanda, community-based health activities were introduced, although it took another 10 years before a national iCCM policy was developed. Between 2003 and 2004, in

By 2011, iCCM of childhood illnesses had been scaled up nationwide in Rwanda.

BOX. iCCM Community Health Worker Activities in Rwanda

Health Promotion

- Community sensitization about immunization, awareness of common diseases, hygiene and sanitation, birth spacing, family planning, and breastfeeding
- Growth monitoring and malnutrition surveillance

Diagnostic and Curative Services

- Diagnosis of malaria with rapid diagnostic tests
- Treatment of confirmed malaria with artemether-lumefantrine
- Treatment of acute respiratory infections with amoxicillin
- Treatment of diarrhea with oral rehydration solution and zinc

Referral and Reporting Services

- Equipped with cell phone to alert local health center and district hospital of emergencies and to call ambulances
- Report new births and deaths via text message to local health center and Ministry of Health
- Refer children with moderate and severe acute malnutrition, severe pneumonia, severe malaria, and severe dehydration to local health center or district hospital

response to persistently low antimalarial treatment rates for children under 5, Rwanda's Integrated National Malaria Control Program (INMCP) began drafting a strategic plan to introduce home-based management for malaria in 6 pilot districts and, in collaboration with the WHO Regional Office for Africa (AFRO), developed implementation guidelines for home-based management of malaria. The program was modeled after programs in Kenya and Uganda, using trained community volunteers to treat children with fever with prepackaged antimalarial drugs for presumed malaria.

In 2008, the Rwandan Ministry of Health (MOH) expanded this program, in partnership with a consortium of international nongovernmental organizations (NGOs) and with the support of the President's Malaria Initiative (PMI), the United States Agency for International Development (USAID), and the Global Fund to Fight AIDS, Tuberculosis & Malaria (the Global Fund). This Expanded Impact Program, or *Kabeho Mwana*, trained and equipped CHWs to provide community-based treatment for uncomplicated cases of diarrhea and pneumonia, in addition to malaria, in specific intervention areas. An early evaluation of *Kabeho Mwana* revealed that, in the 6 intervention areas, the proportion of children with diarrhea who received oral rehydration solution (ORS) increased from 19% to 33%, and that antibiotic use for pediatric pneumonia rose from 13% to 54%.[7]

Based on these data and the success of iCCM programs in other low-income countries, the MOH rolled out iCCM in all 30 Rwandan districts between June 2008 and January 2011 (Figure 1). During this implementation period, each of Rwanda's 14,837 villages elected 2 community members, 1 man and 1 woman, to provide comprehensive primary health care services—a ratio of approximately 1 CHW for every 50 children under 5 in the population. The majority of these CHWs are between the ages of 30 and 49, have completed primary school, and are employed as agricultural workers.[8]

CHW Training and Activities

Community health workers provide a variety of health promotion, diagnostic, curative, referral, and reporting services for their villages (Box). All CHWs have participated in a 5-day, 31-hour training course on iCCM at their closest health center. The course, taught by nurses in charge of community health activities for their sector, is based on *Community Case Management Essentials: Treating Common Childhood Illnesses in the Community*.[9] The Rwanda MOH, with expert advice from WHO and UNICEF, adapted this guide to create locally acceptable treatment algorithms, which CHWs use to calculate age-specific doses of ORS and zinc for diarrhea; artemether-lumefantrine for malaria; and amoxicillin for pneumonia. The adapted training module also teaches CHWs to use malaria rapid diagnostic tests and respiratory rate timers to diagnose malaria and pneumonia, respectively.[10]

Quality Assurance

The nurse in charge of community health for each sector or a cell supervisor conducts quarterly site visits to evaluate the iCCM diagnostic and curative

services provided by CHWs. The cell supervisor is a trained CHW appointed to provide iCCM program oversight in a catchment area comprising 5 or 6 villages.[11] Specifically, the cell supervisor is responsible for compiling the CHWs' iCCM registers and verifying that the reported data are both complete and correct. Data are considered complete if the CHW has recorded the symptoms, disease classification, and prescribed treatment for each child included in the iCCM registry. For registry data to be considered correct, the total number of sick child visits must equal the sum of children treated and children referred.

The nurse in charge of community health organizes quarterly 2-day refresher trainings in conjunction with site visits. These training sessions provide CHWs an opportunity to ask questions about the iCCM package, treatment protocols, and data collection tools, as well as for the nurse to introduce changes to national iCCM treatment policy. For example, the MOH recently rolled out the *m'Ubuzima* program, which collects iCCM data through an interactive voice response program; the nurses have been tasked with teaching the CHWs how to use the new software on their government-issued cell phones. The MOH aims to have the *m'Ubuzima* program, in combination with RapidSMS reports, replace paper iCCM registers. This initiative is expected to increase the number of CHWs who complete monthly reports and improve the accuracy of those reports by eliminating human error in data aggregation.

Financing

The CHWs are further held accountable for the quality of care they provide through a performance-based financing scheme. Community health workers are organized into cooperatives, which meet monthly at the health center in each sector. The MOH disburses funds to these cooperatives once per quarter on the basis of key health indicators, including number of households using insecticide-treated bed nets, appropriate management of diarrhea-related dehydration, and accurate data reporting in iCCM registers. The majority (70%) of performance-based financing grants are invested into income-generating projects chosen by cooperative vote. The remaining 30% is paid directly to CHWs as cash bonuses equivalent to approximately US$0.73 per month per CHW. The MOH has contracted with a local organization, Square Entrepreneurship Development Consult, to develop the business planning and financial management capacities of cooperatives as grants for performance-based financing from the Global Fund are phased out over time.

Supply Chain

The Medical Procurement and Distribution Division (MPDD) of the MOH purchases medical supplies for the national health care system from both national and international pharmaceutical manufacturers. Purchased drugs and medical supplies are stored in district pharmacy warehouses until distribution to district hospitals and health centers. Medicines were previously available only at the district hospital; now all drugs earmarked for community distribution are sent to the health center. Cell coordinators obtain medicines from the health center on an as-needed basis and then supply the CHWs in their catchment area. This supply chain was developed to reduce the frequency of community-level stock-outs, which originally posed challenges for the home-based management for malaria program. The MOH has made additional efforts to improve supply chain management by partnering with John Snow, Inc., to develop a tool to more accurately forecast community-level demand for medical supplies.

Policy and Partnership

In addition to monitoring iCCM indicators and managing performance-based financing grants, the MOH, through the Ministry's Community Health Desk (CHD) and Malaria and other Parasitic Diseases Division, also oversees iCCM protocol revision and develops CHW training tools. A Technical Working Group, which includes many of the same organizations that were involved in the development and implementation of the original *Kabeho Mwana* program, assists the MOH in these tasks. Overall funding for the iCCM program has come from the Government of Rwanda, the Global Fund, PMI, USAID, and the Canadian International Development Agency (CIDA).[10] In addition, several NGO partners—Partners in Health, Concern Worldwide, and the International Rescue Committee—have played significant roles in Rwandan community-based health initiatives by providing technical, financial, oversight, and quality assurance support in individual districts.

To encourage good performance, the MOH disburses funds through cooperatives to CHWs who have met key health indicators.

METHODS

Data Sources

The primary data for this study were obtained from the Rwanda health management information

system (HMIS) database, which collects data at both the community and health facility levels. The **community-based data** were derived from monthly CHW reports, which include the number of non-health facility child deaths in each village (referred to as community deaths) and the number of children treated for pneumonia, diarrhea, and malaria by CHWs (referred to as community-based treatment). These CHW reports are transferred to a cell supervisor, who regularly audits CHW data collection, as described earlier. Data officers at each health center then aggregate the data from all cell supervisors in their catchment area and enter them into the HMIS database.

The **health facility data** reported in the HMIS database include monthly counts of health center visits, district hospital admissions, and health facility deaths for every district, stratified by age group. To estimate total public-sector health facility use from these data, we summed the total number of health center visits and district hospital admissions for children under 5 for all causes. We derived health facility mortality by adding available health center mortality and district hospital mortality figures for all causes.

Finally, we combined available under-5 community mortality data with our under-5 health facility mortality data to calculate the all-cause under-5 mortality rates for each district.

Population-Based Rates

We calculated population-based rates by dividing the crude HMIS data by district population size, derived from data published by the National Institute of Statistics of Rwanda (NISR). The NISR uses national census data to estimate annual population growth rates for each district based on changes in district population between the 2000 and 2010 national censuses. We used these estimates to determine district populations for each year of our study period. Based on NISR data collected for the 2010 Demographic and Health Survey (DHS), we assumed that 16.2% of the population was under the age of 5. We divided monthly district totals for community-based treatment, under-5 mortality, and health facility use by the estimated under-5 district population and multiplied by 1,000 to generate rates per 1,000 children under 5 in the population.

Seasonal Matching

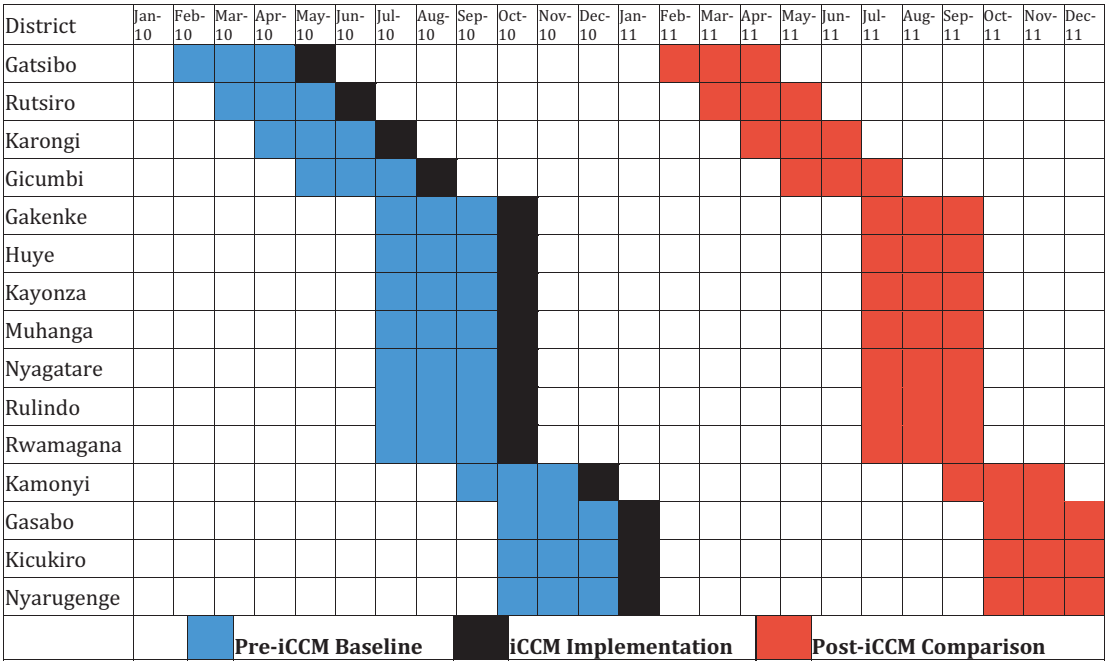
To measure the impact of iCCM on child health in Rwanda, we compared monthly averages for indicators of interest before and after iCCM implementation. Because iCCM was implemented at different times in different districts of Rwanda, and since child morbidity is seasonally variable, we compared a 3-month, pre-iCCM baseline period for each district to a seasonally matched 3-month comparison period 1 year after iCCM implementation. For each district, we calculated monthly rates for our indicators in both the baseline and comparison periods, averaging the monthly values within each period. If data were missing from all 3 months of a given period, we excluded that district from our analysis. We also performed a more conservative analysis by eliminating districts if even 1 month of data was missing from either the baseline or comparison period. For each indicator, we specified the number of districts providing complete data for analysis.

Strict quality control mechanisms for data collected by CHWs were put in place beginning in late 2009. Therefore, reliable baseline data on the number of child deaths occurring in the community and the number of children treated for pneumonia, diarrhea, and malaria in the community are not available for most districts that implemented iCCM before 2010. Figure 2 illustrates the timing of the baseline and comparison periods we applied to the 15 districts for which we have complete community mortality data. Similar baseline and comparison periods were applied to those districts for which we have complete community-based treatment data, health facility use data, and health facility mortality data to calculate pre-iCCM and post-iCCM averages for each district for these additional indicators.

Comparison of Actual Versus Expected Trends

To compare actual versus expected trends, we determined trends in total under-5 mortality and in health facility use in Rwanda prior to iCCM implementation. We then projected these trends to each individual district to determine the expected decrease in total under-5 mortality and health facility use during the 1-year period after iCCM implementation, assuming constant baseline trends. Next, we compared the actual changes to the expected changes for each district to determine whether the actual decreases in mortality and health facility use were greater than would have been expected due to baseline trends.

FIGURE 2. Seasonal Average Schematic Applied to Community Mortality Data, Rwanda



Abbreviation: iCCM, integrated community case management.

For total mortality, we used the UN Interagency Group for Childhood Mortality Estimation (CME Info) database to establish a baseline trend for under-5 mortality in Rwanda during the decade prior to iCCM implementation.[12] To determine a baseline trend for health facility use, we used available data from the HMIS database, which began aggregating national health facility data in 2008. For each district where data were available, we calculated the annual percentage change in health facility use during the 1-year period prior to iCCM implementation and used this value to approximate the baseline percentage change in health facility use.

Statistical Analysis

We used the Wilcoxon signed-rank test, which does not require data to be normally distributed, to compare community-based treatment, under-5 mortality, and health facility use rates for pre-iCCM baseline and post-iCCM comparison periods in each district. For comparison of actual and expected time trends in under-5 mortality and health facility use data, we again used the Wilcoxon signed-rank test to compare the actual change in each variable to the expected change in each variable. We considered alpha $< .05$ to be significant in all cases. All analyses were performed using SPSS version 20 (IBM, New York).

RESULTS

Treatment for Childhood Illness

Data from 21 districts revealed that the number of children who received community-based treatment for diarrhea and pneumonia increased significantly with iCCM implementation (Table 1). The average number of children with diarrhea who received treatment from a CHW rose from 0.83 cases/1,000 child-months at baseline to 3.80 cases/1,000 child-months during the comparison period, an average increase of 2.97 cases/1,000 child-months (95% confidence interval [CI]=0.97–4.97; $P=.01$). The mean number of children who were treated for pneumonia increased from 0.25 cases/1,000 child-months to 5.28 cases/1,000 child-months, an

Community-based treatment of children for diarrhea and pneumonia increased significantly with iCCM implementation, while treatment for malaria decreased.

TABLE 1. Treatment of Childhood Illnesses by Community Health Workers Before and After iCCM Implementation, Rwanda, 2010–2011, N=21 Districts

Illness	Baseline Period	Comparison Period	Difference (95% CI)	*P* Value (2-tailed)
Pneumonia	0.25	5.28	5.03 (3.06, 7.00)	< .001
Diarrhea	0.83	3.80	2.97 (0.97, 4.97)	.01
Malaria	19.14	7.27	−11.87 (−21.92, −1.83)	.03

Treatment data are reported as number per 1,000 child-months.

average increase of 5.03 cases/1,000 child-months (95% CI=3.06–7.00; $P<.001$).

In contrast, the average number of children who were treated for malaria by a CHW decreased from 19.14 cases/1,000 child-months to 7.27 cases/1,000 child-months, representing a decline of 11.87 cases/1,000 child-months (95% CI=1.83–21.92; $P=.03$). This decrease may be attributed to the introduction of rapid diagnostic tests for malaria as part of the iCCM treatment algorithm; with diagnostic testing, treatment is limited to children with positive rapid tests, as opposed to all children with fever.

Community under-5 mortality declined significantly with iCCM implementation, while health facility under-5 mortality did not change significantly.

Under-5 Mortality

Baseline and comparison data for under-5 mortality were available in 15 of 30 districts. In these 15 districts, the community under-5 mortality rate declined by 47% during the year after iCCM implementation, from 0.38 deaths/1,000 child-months to 0.20 deaths/1,000 child-months (Table 2). This represents an average decline of 0.18 deaths/1,000 child-months (95% CI=0.11–0.24; $P<.001$). By comparison, health facility under-5 mortality did not change significantly in the 28 districts for which baseline data were available ($P=.41$) (Table 2).

Despite the lack of change in health facility mortality, total mortality did decrease significantly after iCCM introduction, since nearly three-quarters of child deaths in Rwanda occur in the community; in the 15 districts with both baseline and comparison data, total all-cause, under-5 monthly mortality rates declined by 38% during the 1-year period after iCCM rollout, from 0.48 deaths/1,000 child-months to 0.30 deaths/1,000 child-months, for an average decline of 0.19 deaths/1,000 child-months (95% CI=0.10–0.27; $P<.001$). Total mortality declined in all districts except Karongi (Figure 3).

Health Facility Use

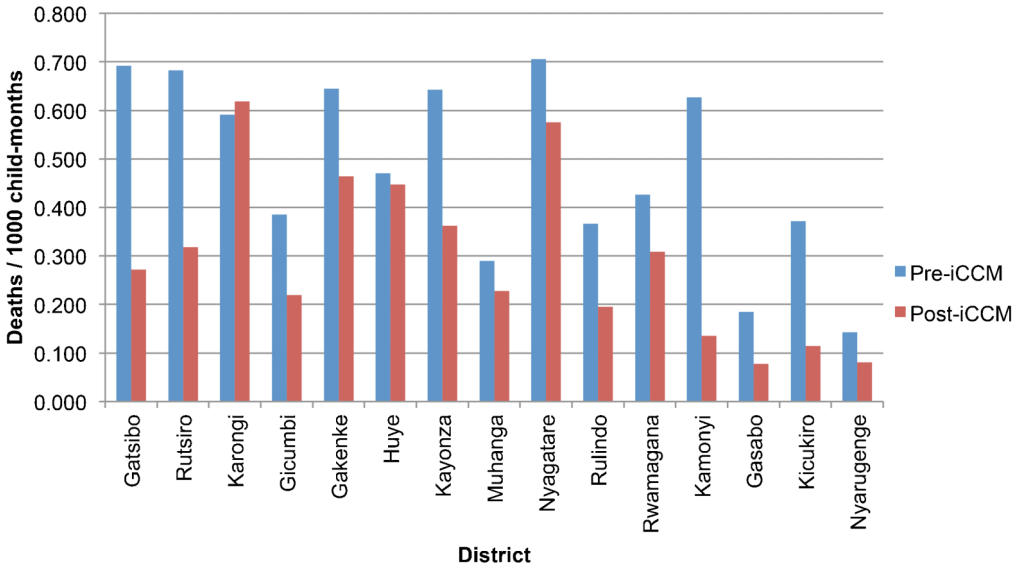
Data from all 30 districts show that health center visits decreased from an average of 2.48 visits/

TABLE 2. Under-5 Mortality and Health Facility Use Before and After iCCM Implementation, Rwanda

Indicator (No. of Districts)	Baseline Period	Comparison Period	Difference (95% CI)	*P* Value (2-tailed)
Community mortality (15)	0.38	0.20	0.18 (0.11, 0.24)	< .001
Health facility mortality (28)	0.09	0.10	−0.02 (−0.05, 0.01)	.41
Total mortality (15)	0.48	0.30	0.19 (0.10, 0.27)	<.001
Health center use (30)	2.48	2.00	0.48 (0.13, 0.82)	.009
District hospital use (28)	2.17	1.91	0.26 (−0.08, 0.59)	.10
Total health facility use (28)	4.57	3.88	0.69 (0.15, 1.23)	.006

All data are reported as number per 1,000 child-months. Because of rounding, differences may not appear exact.

FIGURE 3. Total Under-5 Mortality by District, Rwanda



Abbreviation: iCCM, integrated community case management.

1,000 child-months to 2.00 visits/1,000 child-months, representing a decline of 0.48 visits/1,000 child-months (95% CI=0.13–0.82; P=.009), or a 19% decrease in health center use. District hospital admissions also declined during the study period, from 2.17 admissions/1,000 child-months to 1.91 admissions/1000 child-months in the 28 districts for which data were available, although the change was not statistically significant (95% CI=−0.08–0.59; P=.10).

Finally, total health facility use for children under 5 for all causes declined significantly during the 1-year period after iCCM implementation in the 28 districts for which data were available, from 4.57 contacts/1,000 child-months to 3.88 contacts/1,000 child-months. This represents a decrease of 0.69 contacts/1,000 child-months (95% CI=0.15–1.23; P=.006), representing a 15% decline. Total health facility use declined in 20 of the 28 districts in which data were available (Figure 4).

Comparison of Actual Versus Expected Trends

Using data from the CME Info database, we modeled an 11% annual reduction in total under-5 mortality for Rwanda between 1998 and 2008.[8] Applying this estimated trend to our baseline pre-iCCM data in each district, we calculated an expected average decline of 0.05 deaths/1,000 child-months over the year following iCCM implementation (Table 3). We found that the actual decrease of 0.19 deaths/1,000 child-months was significantly greater than the expected decrease for the 15 districts in which complete data were available (P=.003).

To compare actual versus expected trends in health facility use, we used HMIS data to calculate a baseline annual percentage change in health facility use for the 19 districts included in our analysis. Applying this annual percentage change in health facility use to the baseline pre-iCCM average for each district, we expected an average decline of 0.05 contacts/1,000 child-months in the year following iCCM implementation (Table 3). We found that the actual decrease of 1.04 contact/1,000 child-months was significantly greater than the expected decrease (P=.03).

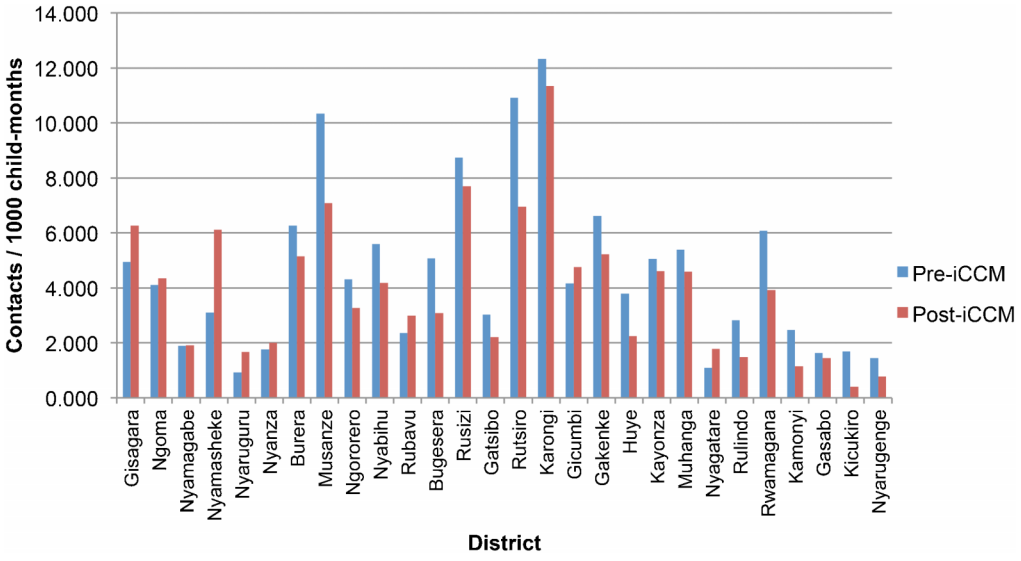
Total health facility use for children under 5 declined significantly after iCCM implementation.

DISCUSSION

Relationship to Prior Studies

While a few studies have examined the impact of iCCM on child mortality in individual districts of

FIGURE 4. Total Under-5 Health Facility Use by District, Rwanda



Abbreviation: iCCM, integrated community case management.

low-income countries, and others have looked at indirect measures of iCCM efficacy at the national level, to our knowledge, this is the first study to explore both changes in health facility use and in child mortality after iCCM implementation at the national level.[13–28] The results of our study are, however, in line with others carried out in similar settings worldwide.

In Chokwe District, Mozambique, researchers observed a 62% decline in under-5 mortality with the introduction of a community-based child survival program.[18] A 3-year study conducted in Gadchiroli District, India, demonstrated a 45.7% decrease in infant mortality in areas where home-based neonatal care was introduced compared with control areas.[29] A randomized control trial of both facility- and community-based pediatric case management in the Matlab District, Bangladesh, found a non-significant trend toward decreased mortality in intervention areas.[13]

A few studies conducted at the national level have examined the impact of different types of community-based interventions on child health. In Nepal, between 2004 and 2007 a community-based program focused on acute respiratory infection and diarrhea case management was scaled up in 48 of the country's 75 districts. Using MOH data, researchers noted a decline in cases of severe pneumonia and dehydration, although they did not report a decline in total under-5 mortality.[20] A descriptive study of the Lady Health Workers Program (LHWP) in Pakistan, a community-based program to improve maternal and child health covering an estimated 60% of the population nationally, found that infant mortality in 2007 was lower in LHWP areas compared with the national average, although the study did not directly compare intervention and non-intervention areas.[23]

Prior studies have also examined process measures of iCCM performance. Studies conducted in several developing countries have demonstrated high rates of appropriate management of pediatric pneumonia, diarrhea, and malaria by CHWs.[13,15,21,22,24,25,27,28,30–32] In Rwanda, a 2010 rapid evaluation of the iCCM program in the 17 districts where CHWs had been practicing iCCM for at least 3 months concluded that 68% of children with pneumonia, 72% of children with diarrhea, and 86% of children with malaria were prescribed the appropriate course of treatment.[8]

Additional studies have demonstrated improvements in caregiver knowledge and immunization rates with implementation of iCCM programs.[13,17,23,33] One study in Honduras documented a decrease in health facility use and significant cost savings with the implementation of a community case management program.[19]

Relationship to DHS Data

The results of our study are also in line with those of the 2010 Rwanda DHS, although there are important differences in the methods used to collect the data in the DHS and HMIS databases. The 2010 DHS was conducted prior to complete implementation of iCCM nationwide in Rwanda, which was accomplished in 2011. Even so, the 2010 DHS found that 13%–16% of children in Rwanda experiencing symptoms of acute respiratory infection, diarrhea, and fever were seen and evaluated by a CHW.[34] While this proportion might seem low, a recently published review found that Rwanda had the highest rates of CHW use in the region for both acute respiratory infections and diarrhea.[35]

It is important to note, however, that while the DHS measures the proportion of children with specific symptoms who were *evaluated* by a CHW in the 2 weeks prior to the survey, the Rwanda HMIS instead tracks the number of children who were *treated* by a CHW for specific symptoms each month. According to both international guidelines and the Rwanda trainer's guide for CHWs, only a fraction of children with cough, diarrhea, and fever require specific treatment; most simply require reassurance and clear instructions to the parent about when to return for worsening symptoms. Table 4 compares the DHS and HMIS data, providing a glimpse into the proportion of children with various symptoms evaluated by CHWs in Rwanda who received a specific treatment for those symptoms.

Comparison of the DHS and HMIS data also provides insight into the proportion of deaths being captured by the HMIS. While the DHS provides an unbiased estimate of the actual under-5 mortality rate (76 deaths per 1,000 live births in 2010), the HMIS data captures only those deaths that come to the attention of the CHW or that occur in the health center or hospital setting (0.49 deaths per 1,000 child-months); HMIS data, therefore, miss deaths occurring at home that are never reported.

In order to compare the DHS mortality data to the HMIS data, certain calculations must be conducted first since the DHS measures child mortality in terms of deaths per 1,000 live births and the HMIS measures child mortality in terms of monthly deaths per 1,000 children in the

A community health worker draws blood from a child for malaria testing.

TABLE 3. Comparison of Expected With Actual Declines in Child Mortality and Health Facility Use, Rwanda

Indicator (No. of Districts)	Expected	Actual	Difference (95% CI)	*P* Value (2-tailed)
Health facility use (19)	0.05	1.04	1.00 (0.16, 1.84)	.03
Total mortality (15)	0.05	0.19	0.13 (0.06, 0.21)	.003

All data are reported as number per 1,000 child-months. Because to rounding, differences may not appear exact.

TABLE 4. Comparison of Rwanda 2010 DHS With 2010 HMIS Data for CHW Use

	Rwanda 2010 DHS			Rwanda 2010 HMIS	Comparison
Illness	Proportion With Symptoms in Past 2 Weeks	Proportion Seeking Care or Advice From CHW	No. Children/ 1,000 Child-Months Seeking Care or Advice From CHW	No. Children/1,000 Child-Months Receiving Treatment From CHW	Proportion of Those Seeking Care Who Received Treatment From CHW
ARI	4%	13%	9.62	5.28	55%
Diarrhea	13%	13%	34.06	3.80	11%
Fever	16%	16%	49.30	7.27	15%

Abbreviations: ARI, acute respiratory infection; CHW, community health worker; DHS, Demographic and Health Survey; HMIS, health management information system.

population. For the data to be comparable, we must first multiply the DHS figure of 76/1,000 by the Rwanda live birth rate (approximately 2.6%), and then divide by the proportion of the population under 5 (16.2%), and finally divide by 12 months per year. The result is 1.02 deaths per 1,000 child-months. The HMIS number of 0.49 per 1,000 child-month is 48% of the DHS number, suggesting that the HMIS database captures about half of all child deaths in Rwanda. In fact, the proportion is likely somewhat larger, since the mortality rate in the 2010 DHS is an average for the years 2006–2010; the actual mortality rate in 2010 is likely lower than 76, making the proportion of deaths captured by the HMIS database somewhat larger than 48%.

The Rwanda HMIS database captures about 48% of all under-5 child deaths.

Relationship to Other Public Health Interventions

Although the declines in health facility use and all-cause under-5 mortality in the year after iCCM implementation are greater than would be expected due to baseline trends in Rwanda, these changes could be due in part to other major public health interventions introduced around the same time as iCCM in any given district, such as mass distribution of long-lasting insecticide-treated nets (LLINs) for malaria prevention; introduction of the pneumococcal conjugate vaccine (PCV) as part of the routine childhood vaccination schedule; and introduction of the rotavirus vaccine.

In September 2006, Rwanda instituted mass, nationwide distribution of LLINs for all children under 5, followed afterwards by routine distribution of LLINs to pregnant women at their second antenatal care visit and to children at their 9-month measles vaccination beginning in December 2006.[36] Given that routine distribution of LLINs began almost 2 years prior to the introduction of iCCM in any district in Rwanda, it is unlikely to have affected the changes in mortality and health facility use between the baseline and comparison periods in our study.

PCV was introduced in April 2009 as part of the national routine childhood vaccination schedule; in relation to our study, this occurred between the baseline and comparison period for 13 districts and prior to the baseline period for 17 districts, including all 15 districts that were in our mortality analysis. Based on the best available data in the literature, PCV has been shown to decrease rates of all-cause child mortality by 11%,[37] so it certainly may have contributed to a portion of the 38% decline in total all-cause under-5 mortality noted in our study.

Rotavirus immunization, on the other hand, was introduced into the routine childhood vaccination schedule in May 2012, which was after the comparison period for all districts in our study, and therefore could not have impacted our findings.

Limitations

As described earlier, our study uses Rwanda HMIS data to estimate changes in under-5 mortality. Prior research has shown that vital registry data underestimate under-5 mortality compared with data obtained from household surveys,[18] and in our study the HMIS data likely capture only about half of all child deaths. While national household-based birth history data are available from the 2010 Rwanda DHS,

this survey provides only a 5-year average of national under-5 mortality, not district-level, monthly totals of under-5 deaths, which are needed to examine the impact of iCCM in the first year of implementation in each district.[38] Although our community-based HMIS data likely underestimate under-5 deaths, we expect them to underestimate deaths similarly in both the baseline and implementation periods. While it is possible that the completeness of CHW data collection improved over time, this would mean that actual decreases in child mortality were even greater than our estimates suggest.

The HMIS data presented in this study provide the absolute number of children treated for pneumonia, diarrhea, and malaria by CHWs but do not describe the quality or appropriateness of that treatment. However, the proportion of children treated for acute respiratory infection (Table 4) is similar to the proportion of children with cough found to have pneumonia in prior facility-based research in Rwanda,[39] and the proportion of children with fever treated with an antimalarial is also similar to the proportion of children with fever in Rwanda found to have malaria in prior research.[40] While the rate of treatment with ORS and zinc for diarrhea seems low, this may be due to differences in the way diarrhea was assessed in the DHS (caregiver report of any diarrhea symptoms) compared with the way it was assessed by CHWs (at least 3 loose stools in a 24-hour period).

Data quality at the community level remains another limitation, partly due to limited CHW numeracy. A recent study of CHW reporting in one Rwandan district during May–June 2011 found that only 57% and 79% of monthly village CHW reports agreed perfectly with the tally of individual sick-child encounter forms for the number of children treated for pneumonia and malaria, respectively.[41] However, as pointed out in the study, the quality of CHW data collection is likely to be better for more noteworthy events, such as child deaths, where the total number for a village in a given month is almost certain to be either 0 or 1, and would not at all impact the health facility use figures, which are based on actual visits to health centers and admissions to hospitals.

Missing data in the HMIS database is another limitation. To control for the effect of missing data, we performed a more conservative analysis that eliminates districts with any missing data in either the pre-iCCM baseline or post-iCCM comparison period. The results of the conservative analyses were similar to those of our primary analyses, with the caveat that we had slightly less power to detect differences. This conservative analysis cannot control, however, for the absence of baseline community mortality data for districts that implemented iCCM prior to 2010, when regular collection of community mortality data began nationwide. As such, changes in community mortality with implementation of iCCM cannot be generalized to the entire country, but rather only to the 15 districts that implemented iCCM in 2010 and 2011.

Finally, while we have endeavored to control for baseline trends in both child mortality and health facility use using the best available data, we cannot completely disentangle the effects of iCCM from those of other major public health interventions instituted in Rwanda at about the same time as iCCM. As discussed earlier, we believe it unlikely that either the LLIN distribution in 2006 or the introduction of rotavirus vaccine in 2012 would have impacted our results, as these interventions were well outside the time frame for iCCM implementation. However, it is certainly plausible that the introduction of PCV in 2009 may have contributed to a portion of the 38% decline in total all-cause under-5 mortality noted in our study.

CONCLUSION

Between 2008 and 2011, Rwanda brought iCCM to scale in all 30 of its districts nationwide. We find significant increases in community-level treatment rates for childhood diarrhea and pneumonia during the 1-year period after iCCM implementation in each district. These increases correspond with decreases in under-5 community mortality, total mortality, health center use, and total health facility use. Moreover, the decreases in total under-5 mortality and health facility use are greater than would be expected due to baseline trends. Due to limitations in our study design, including the lack of a co-temporal control group for comparison, we cannot entirely attribute these decreases to the implementation of iCCM. In addition, each nation is unique and the experience of iCCM implementation in Rwanda cannot be directly extrapolated to other resource-limited settings, which may lack the highly organized and well-regulated government health system present in Rwanda. However, our study demonstrates that with sustained political

will, reliable financial support, and robust monitoring and evaluation, community case management can be effectively brought to scale in a low-income country and, alongside other important public health interventions, may help reduce both health facility use and child mortality.

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ORIGINAL ARTICLE

Plausible role for CHW peer support groups in increasing care-seeking in an integrated community case management project in Rwanda: a mixed methods evaluation

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During national scale up of iCCM in Rwanda, greater improvements in care-seeking were found in the districts where Kabeho Mwana implemented its model than in the rest of the country. Success was attributed to an emphasis on routine data review, intensive monitoring, collaborative supervision, community mobilization, and, in particular, CHW peer support groups.

ABSTRACT

Background: The Kabeho Mwana project (2006–2011) supported the Rwanda Ministry of Health (MOH) in scaling up integrated community case management (iCCM) of childhood illness in 6 of Rwanda's 30 districts. The project trained and equipped community health workers (CHWs) according to national guidelines. In project districts, Kabeho Mwana staff also trained CHWs to conduct household-level health promotion and established supervision and reporting mechanisms through CHW peer support groups (PSGs) and quality improvement systems.

Methods: The 2005 and 2010 Demographic and Health Surveys were re-analyzed to evaluate how project and non-project districts differed in terms of care-seeking for fever, diarrhea, and acute respiratory infection symptoms and related indicators. We developed a logit regression model, controlling for the timing of the first CHW training, with the district included as a fixed categorical effect. We also analyzed qualitative data from the final evaluation to examine factors that may have contributed to improved outcomes.

Results: While there was notable improvement in care-seeking across all districts, care-seeking from any provider for each of the 3 conditions, and for all 3 combined, increased significantly more in the project districts. CHWs contributed a larger percentage of consultations in project districts (27%) than in non-project districts (12%). Qualitative data suggested that the PSG model was a valuable sub-level of CHW organization associated with improved CHW performance, supervision, and social capital.

Conclusions: The iCCM model implemented by Kabeho Mwana resulted in greater improvements in care-seeking than those seen in the rest of the country. Intensive monitoring, collaborative supervision, community mobilization, and CHW PSGs contributed to this success. The PSGs were a unique contribution of the project, playing a critical role in improving care-seeking in project districts. Effective implementation of iCCM should therefore include CHW management and social support mechanisms. Finally, re-analysis of national survey data improved evaluation findings by providing impact estimates.

INTRODUCTION

Integrated community case management (iCCM) is an equity-focused strategy designed to increase access to effective treatment for the leading causes of under-5 mortality by training and supporting front-line community health workers (CHWs) to identify and treat children for malaria, diarrhea, and pneumonia at the household level.[1] This strategy has gained prominence on the global health agenda over

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BOX. Milestones in iCCM Scale Up in Rwanda

1995: National election of 12,000 volunteer community health workers (CHWs), with the initial task of community sensitization on preventive measures such as immunization, hygiene, and nutrition.

2004: Pilot of home-based management of malaria (HBM) in 3 districts.

2005: Second round of CHW elections, with 1 male and 1 female CHW (called *binômes*) elected from each village. HBM pilot expanded to 2 additional districts, and community case management of diarrhea with oral rehydration solution (ORS) and zinc piloted in 1 district.

2006: HBM scaled up to all 19 malaria endemic districts.

2007: MOH Community Health Desk established. Treatment of community case management for diarrhea with ORS and zinc approved.

2008: Treatment of acute respiratory infection (presumed pneumonia) with amoxicillin approved. National rollout of iCCM in initial 10 districts.

2010: iCCM scale up to all 30 districts.

the last decade. Over the past 2 decades, the Rwandan Ministry of Health (MOH) placed a strong emphasis on accessible care at the community level, holding the initial election of 12,000 volunteer CHWs in 1995. This was the start of a national community health strategy that led to the provision of iCCM to all communities. The Box highlights key benchmarks in the evolution of the Rwanda CHW and iCCM program.

Between 2005 and 2010 the Rwanda national iCCM program expanded and evolved into a robust community health network. CHWs received a 4-day training on iCCM, covering topics such as recognition and referral of danger signs, assessment and treatment, drug management, reporting, and community mobilization.[2] CHWs were supervised by the health center-based community health in-charge as well as by cell coordinators, who were also CHWs and mainly responsible for supervising monthly reporting. CHWs were not paid for their services, but they did receive modest per diem for participation in official trainings. The main strategy for motivating the CHWs was a community performance-based financing (PBF) system, funded by government and donor resources, whereby CHWs were organized into cooperatives and received small payments into group accounts based on reporting and achievement of treatment and referral targets.[3]

PROGRAM DESCRIPTION

In synergy with, and supporting, the evolution of MOH policies, 3 international nongovernmental organizations (NGOs) active in Rwanda—Concern Worldwide, the International Rescue Committee and World Relief—began implementing home-based management (HBM) in 2004. Building on the success of HBM, the 3 NGOs formed a consortium to implement the Kabeho Mwana (''Life for a Child'') Expanded Impact Child Survival Project from October 2006 to September 2011 with funding from the United States Agency for International Development Child Survival and Health Grants Program (CSHGP) and other donors. The project covered 6 districts in Rwanda—Gisagara, Kirehe, Ngoma, Nyamagabe, Nyamasheke, and Nyaruguru—representing one-fifth of all districts and about 1.9 million people, or 18% of the country's total population. These districts were predominantly rural (97% compared with the national average of 88%) with less access to health care: in 2010, 34.1% of women in the project districts reported serious problems accessing health services because of distance, compared with 24.2% in the non-project districts.[4] (See Supplementary Tables 1 and 2). According to the statistics and the project budget of the Organization for Economic Cooperation and Development, Kabeho Mwana support represented 3.8% of the total health expenditure (government and partners) in Rwanda from 2006–2010.[5,6]

The purpose of the Kabeho Mwana project was to build the capacity of the MOH to roll out iCCM in line with national guidelines. To do so, Kabeho Mwana trained more than 6,100 CHWs in the national iCCM curriculum and provided tools required for the provision of iCCM, including a lockable box for storing drugs and supplies, respiratory timers, a spoon and cup for mixing oral rehydration solution (ORS), and treatment registers. The project supported the initial procurement

The Bahomwana CHW Peer Support Group meets in Gasambu village, Rwanda, to exchange ideas and challenges in order to accomplish and improve their work.

of zinc, amoxicillin, ORS, and, later, rapid diagnostic tests for malaria and related supplies. These products then became part of the regular national supply chain, but the project continued to monitor stock levels and worked with district management to help prevent stock-outs.

Beyond training and equipping CHWs, the project provided intensive technical support

Beyond training and equipping CHWs to implement iCCM consistent with the national guidelines, Kabeho Mwana established a strong presence with field offices in each district, allowing project staff to provide regular, intensive technical support to each of the MOH district offices and regular visits to each of the 88 health centers. Project interventions designed to strengthen the community health system included training key health center staff in iCCM supervision, with financial support in the first years of the project given directly to facilities to pay for supervision visits. Project staff also initiated quarterly data reviews with health center staff and the cell coordinators. All interventions and services were carried out through structures in the national health system.

Peer support groups were identified as a way to provide critical quality control and motivation for CHWs.

The project prioritized community mobilization strategies designed to promote healthy behaviors and create demand for CHW services. Within the framework of the national health system, Kabeho Mwana introduced CHW peer support groups (PSGs), bringing together an average of 20 CHWs from 2 to 4 neighboring villages for monthly meetings. Peer support groups were designed primarily to support health promotion activities; however, they also served as fora for increased interaction between CHWs, encouraging problem-solving and mutual accountability. During group meetings, CHWs were trained in health promotion, guided through joint planning of home visits to deliver messages on healthy family practices and to monitor their adoption, and they worked together to compile monthly reports. CHWs received no material or financial incentives for attending PSG meetings and were also expected to perform their regular CHW functions.

Three project promoters per district supported the formation and training of PSGs. Meeting facilitation was primarily the responsibility of the elected cell coordinators, who, under the supervision of the community health in-charge, were already tasked with collecting information from and supervising CHWs. The additional work of leading the PSGs was fairly limited; in fact, the meetings allowed cell coordinators time to collect, review, and discuss reports from all PSG members together at a single location, thus easing the work of reporting.

The Kabeho Mwana project final evaluation compared population health outcomes and community health service statistics in project districts with published national trends, which suggested a high level of achievement by the project.[6] This sparked discussions between the MOH and partners and interest in the overall impact of the project approach, and whether achievements in the supported districts were attributable to the project or reflected improvements typical in all districts. The CHW PSG model implemented by Kabeho Mwana was identified as a unique element with the potential to provide critical motivation and quality control for CHWs. The nationwide scale of the Rwanda iCCM program created the opportunity for an innovative re-analysis of the DHS to examine the impact of the Kabeho Mwana project. If results were similar across the country then the Kabeho Mwana approach offered little benefit beyond the standard national iCCM package. However, if project districts had significantly outperformed non-project districts, then the MOH might choose to look more closely at the Kabeho Mwana approach and consider incorporating aspects of it, such as the PSG model, into its national program.

METHODS

This paper's primary method is re-analysis of the 2005 and 2010 DHS surveys to examine changes

in care-seeking behavior for Kabeho Mwana project districts compared with districts without project support. This re-analysis is supplemented by the mixed-method external project final evaluation, conducted in August 2011, which we will turn to again to analyze factors that may have contributed to our findings.

Analysis of How Project and Non-Project Districts Differed in DHS Estimates

We used data from 2 Demographic and Health Surveys (DHS) conducted in 2005[7] and 2010,[4] which approximately bracket the period of project implementation, to simulate a quasi-experimental design to evaluate the impact of the Kabeho Mwana project on care-seeking for diarrhea, symptoms of acute respiratory infection (ARI), and malaria. This analysis was possible because districts were the sampling strata used for the DHS. Both surveys used the standard DHS methodology for sampling[8] and questionnaire[9] construction, with some minor changes between the 2 surveys. In 2005, the sample size was 7,797 children 0–59 months, of whom 1,575 lived in project districts. In 2010, these figures were 8,605 and 1,780, respectively. Supplementary Table 3 presents the reported prevalence and the sample sizes by district for each year.

In both surveys, respondents were asked whether a child under 5 in the household had been ill in the past 14 days, the nature of the symptoms, and whether and what kind of health care provider was consulted. The definition for ARI symptoms changed between 2005 and 2010: In 2005, caregivers were asked about cough and rapid breathing, while in 2010 caregivers were asked about cough and rapid breathing that was chest-related and/or difficult breathing that was chest-related. From this information, we calculated rates of care-seeking for fever, diarrhea, and ARI symptoms, both from any provider (physician, nurse, or CHW) and specifically from a CHW. In addition, we included 3 non-project-specific maternal and child health indicators to determine whether there was a significant difference in the performance of project districts in health areas not related to iCCM (coverage of at least 3 antenatal visits, diphtheria, pertussis, and tetanus [DPT] immunization coverage, and vitamin A coverage). We also wanted to determine whether the focus of the project on iCCM might have inadvertently led to reduced performance in other health service areas.

We calculated the coverage rates for each of the indicators in 2005 and 2010 for all districts, for Kabeho Mwana project districts, and for non-project districts. The percentage increase in coverage in non-project districts was subtracted from the percentage increase in project districts to obtain the difference in the differences. We used logit regression to test whether the level of increase seen could be attributed to the project interventions or to other factors, controlling for the timing of the first CHW training in iCCM in each district and whether or not malaria was endemic in the district. (Supplementary Table 2 presents the basic characteristics of the districts included in the model.) The district was included as a fixed categorical effect to control for other unknown differences between the districts. The regression also included an interaction term coded ''1'' for the combination of the second survey and the project districts, and ''0'' otherwise. The coefficient of this interaction term will capture any additional use of services in the second survey and the project districts, beyond what would have been expected with an additive model.

Separately we calculated care-seeking rates by provider to compare the number of cases that consulted CHWs with the number of cases that consulted another trained provider at a government health facility, using a Pearson's chi-squared test to evaluate whether the difference between project and non-project districts was significant in each of the 2 years.

Final Project Evaluation Methods

The final evaluation used a mixed-methods approach, including pre-post comparison of knowledge, practice, and coverage (KPC) surveys; process review data from project monitoring and the national health information system; qualitative methods (group and key informant interviews); and participatory engagement of the project team, including MOH staff. Indicators analyzed included the number of treatments given by CHWs per month, the number of home visits by CHWs per village per month, and the percentage of CHWs submitting complete reports to supervisors per month.

The project conducted 15 key informant interviews and 30 focus group discussions (FGDs) and analyzed observations from designers and implementers of the CHW PSG model. Sites for field visits, interviews, and FGDs were selected to represent all 6 districts equally and to purposively introduce some diversity and representativeness in the sample. Focus group discussions were held with mothers of children under 5 found

at the health center, CHW members of the PSGs, cell coordinators, and members of CHW cooperatives. Interviews were conducted with community health in-charges, key project staff, the head of the National Community Health Desk, and hospital and district administrators. Interview and FGD transcripts were recorded, translated, and analyzed through thematic coding. Additional details on the evaluation methodology are included in the final evaluation report.[6]

Findings suggest that the peer support group model helped improve CHW performance, supervision, and collaboration.

Care-seeking for fever, diarrhea, and acute respiratory infection improved across all districts, but especially in project districts.

RESULTS

Re-analysis of Rwanda Demographic and Health Surveys

Notable improvements in care-seeking for fever, diarrhea, and ARI symptoms occurred between 2005 and 2010 across all districts in Rwanda. However, the increases were significantly greater in the districts supported by Kabeho Mwana (Table 1). Care-seeking from any provider for all 3 conditions combined increased from 16% to 46% in the project districts, vs. 26% to 40% in non-project districts. The OR for care-seeking for each of the 3 conditions and for all 3 combined increased significantly more in project districts than non-project districts (adjusted OR for additional increase in use associated with project districts: fever OR=2.54, $P \leq .001$; diarrhea OR=2.56, $P \leq .001$; ARI OR=2.35, $P \leq .01$; combined OR=2.24, $P \leq .001$) (Table 2).

We also looked specifically at care-seeking from CHWs. Care-seeking from CHWs for the 3 conditions combined was exceedingly low in both project and non-project districts in 2005 (1.2% and 0.6%, respectively). By 2010, it had risen to 12.4% in project districts and to 4.9% in non-project districts. As a result, the CHWs were contributing about one-quarter (27%) of the overall consultations in project districts compared with 12% in the non-project districts (Figure). Across all 3 iCCM conditions, CHWs in the districts supported by Kabeho Mwana were seeing a larger percentage of the cases than in other districts (Table 3).

Differences between the 2 surveys make it impossible to compare actual *treatment rates* between the 2 years for either fever or ARI symptoms. For diarrhea treatment with ORS or recommended home solution, the treatment levels increased nationally from 18.6% (95% confidence interval [CI]=15.9–21.2) to 34.5% (CI=31.4–37.6) with no significant difference between project and non-project districts. Current treatment guidelines include both ORS and zinc, but coverage for zinc, specifically, could not be measured.

The 3 health indicators not related to iCCM included in the analysis (coverage of at least 3 antenatal visits, DPT immunization coverage, and vitamin A coverage) all increased nationally with no significant difference between project and non-project districts.

Results From the Final Project Evaluation

Findings, particularly from the FGDs and interviews, suggested that the PSG model served as a manageable and valuable sub-level of CHW organization that was associated with improved CHW performance, supervision, and increased social capital.

Performance and Coordination of CHWs

CHW productivity, reporting, motivation, and coordination were elements of CHW performance addressed through the PSG model according to those interviewed.

- **Productivity:** CHW productivity, as defined by home visits for health promotion activities and the number of treatments administered by CHWs, was greater in districts with PSGs than elsewhere. CHWs in Kabeho Mwana project districts averaged 44 visits per village per month, compared with 10–30 visits per village per month in a non-project district.[10] On average, 356,387 home visits were conducted per quarter during the last 4 quarters of the project with beneficiary households receiving more than 2 visits per quarter. On the curative side, in the 12-month period prior to the project final evaluation, CHWs in project-supported districts provided one-third of all community treatments in Rwanda, while representing just 18% of the national target population for iCCM (personal communication, Cathy Mugeni and Erick Gajui; Rwanda MOH).
- **Reporting:** CHW reporting in project districts was high; 93% of CHWs submitted reports each month over the life of the project. While compensation from national PBF mechanisms likely played a role in the high levels of reporting, interviewees also suggested that regular interaction between CHWs and their supervisors during the PSG meetings eased the burden of work related to the compilation of reports, resolution of discrepancies, and timeliness. In contrast, the default structure of CHW cooperative meetings was not conducive to anything beyond data aggregation.

TABLE 1. Care-Seeking for Fever, Diarrhea, and ARI Symptoms and Other MCH Interventions for Kabeho Mwana and Non-Kabeho Mwana Project Districts in 2005 and 2010

	Non-KM Project Districts			KM Project Districts			Difference in the Differences
	2005	2010	Change	2005	2010	Change	
	N (%)	N (%)	%	N (%)	N (%)	%	%
Care-Seeking From Any Trained Provider							
Diarrhea	803 (16.2)	808 (36.3)	+20.0	292 (8.4)	308 (40.0)	+31.6	+11.6***
Fever	1,485 (31.5)	1,003 (40.8)	+9.3	546 (20.3)	332 (48.7)	+28.4	+19.1***
ARI symptoms	964 (30.5)	233 (47.4)	+16.9	357 (20.9)	85 (57.9)	+37.0	+20.0**
All 3 conditions	2,551 (26.0)	1,570 (40.0)	+14.0	877 (16.3)	541 (46.0)	+29.7	+15.7***
Non-Project Specific Indicators							
At least 3 ANC visits in the most recent pregnancy	4,269 (13.7)	5,036 (36.2)	+22.5	1,115 (12.0)	1,274 (32.2)	+20.2	−2.3
Child 12–23 months received DPT3	1,271 (87.0)	1,262 (97.3)	+10.3	343 (88.5)	330 (95.7)	+7.2	−3.1
Child 6–59 months received vitamin A in past 6 months	5,461 (83.7)	6,168 (94.7)	+11.1	1,394 (85.8)	1,589 (85.6)	−0.2	−11.3

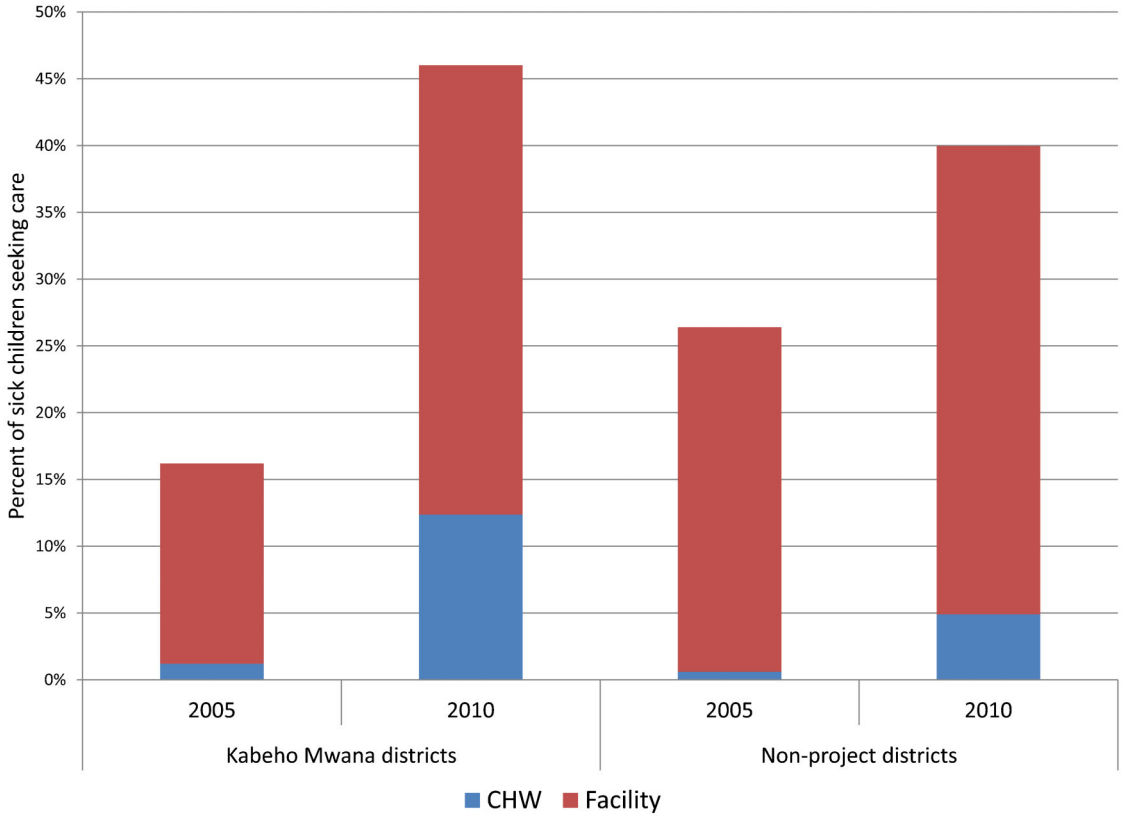
Abbreviations: ANC, antenatal care; ARI, acute respiratory infection; DPT3, diphteria, pertussis, and tetanus; KM, Kabeho Mwana; MCH, maternal and child health.
All of the tests are one-tailed. The tests in the last column of Table 1 correspond with the tests of the unadjusted odds ratios given in Table 2.
*$P \leq .05$, ** $P \leq .01$, *** $P \leq .001$.

TABLE 2. Odds Ratios for Care-Seeking for Sick Children in Kabeho Mwana Project Districts vs. Non-Project Districts After Controlling for 2005–2010 Gains in Both Types of Districts

Conditions	Unadjusted OR (95% CI)	Adjusted OR[a] (95% CI)
Diarrhea	2.47*** (1.47–4.15)	2.56*** (1.47–4.46)
Fever	2.49*** (1.66–3.73)	2.54*** (1.68–3.85)
ARI symptoms	2.53** (1.29–4.95)	2.35** (1.20–4.62)
All 3 conditions	2.31*** (1.66–3.21)	2.24*** (1.60–3.16)

Abbreviations: ARI, acute respiratory infection; CI, confidence interval; iCCM, integrated community case management; OR, odds ratio.
[a] Adjusted to control for the duration of time since implementation of iCCM, the district (as a fixed categorical effect), and whether malaria was endemic in the district. All of the tests are one-tailed.
*$P \leq .05$, ** $P \leq .01$, *** $P \leq .001$.

FIGURE. Care-Seeking From CHWs and Facilities for All iCCM Conditions in Children 0–59 Months, Kabeho Mwana Project vs. Non-Project Districts



Abbreviations: CHWs, community health workers; iCCM, integrated community case management.

TABLE 3. CHW Contribution to Care-Seeking, Kabeho Mwana Project Districts vs. Non-Project Districts, 2005 and 2010

	2005		2010	
	Non-KM Project Districts	KM Project Districts	Non-KM Project Districts	KM Project Districts
Diarrhea	**n=1,103**		**n=1,132**	
Any provider	16.2 (13.3–19.1)	8.4*** (5.6–11.3)	36.2 (32.5–39.8)	40.0 (34.0–46.0)
CHW	0.2 (−0.2–0.60)	1.1 (0.1–2.1)	9.5 (7.3–11.7)	21.8*** (16.1–27.4)
Facility	16.2 (13.3–19.1)	8.4*** (5.6–11.3)	26.7 (23.0–30.3)	18.2* (13.6–22.9)
Fever	**n=2,046**		**n=1,355**	
Any provider	31.5 (28.7–34.3)	20.3*** (15.9–24.7)	40.8 (37.2–44.4)	48.7* (43.1–54.3)
CHW	0.4 (0.0–0.8)	1.2 (0.0–2.4)	12.1 (10.1–14.2)	26.1*** (21.0–31.3)
Facility	31.1 (28.3–33.9)	19.1*** (15.0–23.3)	28.6 (25.4–31.9)	22.5* (18.3–26.8)
ARI Symptoms	**n=1,332**		**n=322**	
Any provider	30.5 (27.2–33.8)	20.9** (16.3–25.5)	47.4 (39.2–55.7)	57.9 (45.9–69.9)
CHW	0.5 (0.0–0.9)	0.4 (−0.2–1.0)	7.7 (4.4–11.0)	27.5*** (16.6–38.3)
Facility	30.0 (26.8–33.2)	20.5** (15.8–25.1)	39.8 (31.8–47.7)	30.4 (20.8–40.1)
All 3 Conditions[a]	**n=2,847**		**n=2,142**	
Any provider	26.4 (24.1–27.6)	16.2*** (15.1–22.1)	40.0 (37.1–42.9)	46.0 (37.1–42.9)
CHW	0.6 (0.3–0.9)	1.2* (0.3–2.0)	4.9 (3.7–6.1)	12.4*** (8.9–15.9)
Facility	25.8 (23.5–28.1)	15.0*** (11.6–18.4)	35.1 (32.–38.1)	33.6 (29.3–38.0)

Abbreviations: ARI, acute respiratory infection; CHW, community health worker; KM, Kabeho Mwana.
[a] Includes children presenting with multiple conditions.
All data are shown as % (95% CI).
P values given are for the difference between rates of care-seeking in KM and non-KM districts in the same year.
*$P \leq .05$, ** $P \leq .01$, *** $P \leq .001$.

- **Motivation:** The energizing effect of joint planning among PSG members, according to FGD participants, kept CHWs engaged and committed to perform. Many CHWs reported being motivated to pool their resources to buy key household items, such as soap, in order to model target behaviors for their communities. The CHWs expressed their sense of being invested in the health of the households they covered. One PSG member explained, ''It is a neighbor meeting a neighbor. They know each other. They know the local realities and education becomes easy.''
- **Collaboration:** The PSGs strengthened the role of the CHWs in linking the health facilities to the communities they served. A hospital director in Nyaruguru explained that CHWs are ''our ambassadors in the community.'' They ''provide us with information which we can use to make decisions and transmit health messages to households; they serve as our representatives and guides.'' A Maternal and Child Health Integrated Project (MCHIP) comparison assessment, which took place in the same period as the final evaluation and which evaluated iCCM activities in a non-project district, found that iCCM activities were better coordinated in project districts since there were mechanisms for peer support and the CHWs felt more accountable to the PSG.[10]

Supervision

In Rwanda, the community health in-charge was expected to visit each CHW to check drug stocks,

A community health worker and member of a Peer Support Group on a routine home visit.

ensure appropriate storage and drug management, and review the CHW register on a quarterly basis. In addition, the cell coordinator was expected to conduct peer supervision visits to all CHWs on a monthly basis. The position of cell coordinator was initially created by the project and ultimately scaled up nationally. Barriers to supervision by both the in-charges and cell coordinators were lack of sufficient time, transport, and human resources. Interviewees noted that PSGs lessened these barriers by enabling supervisor access to CHWs at an intermediate level between facility and community, during which they could address many supervision tasks within a small group setting. In addition, the PSGs provided an opportunity for informal peer supervision. Health facility personnel testified that this peer supervision helped to compensate for health facility staff limitations. The medical director of Nyamasheke District supported this assertion, ''There is a difference since the establishment [of PSGs], and members train each other, self control, and do reports … you can follow up everyone regularly at lower cost.''

Social Capital

Participants in the FGDs explained that PSGs allowed for frequent interactions between members, experience sharing, and opportunities for cross-learning, ultimately resulting in a sense of camaraderie between members. The solidarity between CHWs also led to increased accountability, as no CHW wanted to under-perform. A cell coordinator in Ngoma District summarized the sense of collective and individual accountability in PSGs versus CHW cooperatives: ''The more CHWs are present, the less they listen; but in a small group like the [PSG], their attention increases and they receive messages … things work well because there is a small group so results are more visible because everyone assesses their neighbor's performance.'' Several cell coordinators cited examples where the PSGs voted to replace CHWs who were not committed and failed to model healthy behaviors.

In addition to accountability, the PSGs fostered a sense of trust, as demonstrated through the voluntary initiation and participation in rotating savings group activities. Group members contributed personal finances at each meeting, entrusting their investment to the group and to those approved to take out micro-loans. Kabeho Mwana did not provide any inputs for these activities; it was a group-initiated activity, thus underscoring its value to participants.

DISCUSSION

Results of our analysis are twofold. First, care-seeking started from lower levels and increased significantly more in project districts than in non-project districts. Second, the contribution of CHWs to that increase was substantial. The contention that the approach used and the nature of the support provided under the

Kabeho Mwana project was instrumental in attaining the greater improvements is supported by the lack of significant difference in the rates of increase of the 3 non-project indicators. It also suggests that the focus on iCCM under the Kabeho Mwana project did not have a negative impact on other aspects of health care.

The Kabeho Mwana project was one of several actors supporting the MOH initiative to scale up iCCM from 2006 to 2011, and the core intervention of training and equipping CHWs to implement iCCM was not unique to the project. A variety of actors supported iCCM scale up in non-project districts, notably United Nations agencies, the National Malaria Control Program with support from the Global Fund, and other NGOs including World Vision, IntraHealth, and Management Sciences for Health. While specific data on the level of funding and nature of support for iCCM in the 24 non-project districts are unavailable, we assume that they varied between districts and consisted mainly of training and supplies to implement the standard national iCCM guidelines and structure. Kabeho Mwana achieved its mandate of providing technical support for iCCM scale up by going beyond simply training and equipping CHWs to implementing a series of interventions aimed at strengthening the overall health system, with a strong focus on CHW organization and supervision at the community level, all the while operating through the national health system without disproportionate financial expenditure.[5,6]

In addition to iCCM, all CHWs in Rwanda were trained in basic community mobilization and encouraged to do home visits, but the sole support structure developed by the national system was the supervision provided in principle by the health center community health in-charge (initially with financial support from the project). However, Kabeho Mwana also established PSGs to catalyze these health promotion activities, in addition to supporting the CHW curative role, and trained the cell coordinators to lead these groups. Integrating the curative function of the CHWs with frequent household visits promoted by the PSGs increased the visibility of CHW services, built the trust of the community, and may have led more mothers to recognize CHWs as an important source of care.

The qualitative evidence demonstrates that, in addition to supporting community mobilization and prevention activities, the PSGs provided a critical mechanism to stimulate social capital and motivation among CHWs. The groups also facilitated CHW coordination, supervision, and reporting functions and increased interactions among and between CHWs and health center staff, leading to more effective community-facility linkages that may have contributed to the increase in care-seeking at the facility level.

Findings suggest that focusing on iCCM did not have a negative impact on other aspects of health care.

Other aspects of the project may also have contributed to CHW performance. Quarterly data review meetings and increased supervision drew the attention of health facility staff and district management to the results reported by CHWs. This level of scrutiny may have motivated CHWs to increase their level of engagement with the community. We cannot differentiate the specific contributions of each element of support provided under the project; the PSGs should be considered as part of a comprehensive set of interventions to support community health and iCCM. However, our analysis suggests that PSGs—as the main intervention with CHWs who worked directly with the community—increased the visibility, accountability, and effective engagement of their members with the community, gaining the trust of caregivers of children under 5, and plausibly were a strong driver of increased care-seeking behaviors.

Peer groups may have driven increased care-seeking behavior by helping CHWs gain the trust of care-givers.

These findings support other evidence that has shown that peer support, specifically group meetings, may be an important contributing factor to CHW motivation.[11] While the contribution of peer motivation, peer support, and peer accountability prompted by the PSGs cannot be quantified, they do appear to be fundamental motivators leading to a high level of CHW productivity. As a result, CHWs are highly engaged in their communities, beyond simply treating children. Home visits may contribute to increased demand for curative services at both the community and facility levels. A mixed-method impact evaluation from Uganda also showed that health promotion, including home visits by CHWs, improved care-seeking practices.[12] The Kabeho Mwana model of the PSG was intended take advantage of these mechanisms to improve CHW performance.

Other studies have demonstrated the contribution of joint government–NGO partnerships implementing community-based strategies to higher coverage of key child health outcomes and reduced child mortality compared with concurrent sub-national secular trends as measured by the DHS.[13] As documented by the *Lancet* series on child survival, projects such as Kabeho Mwana, that achieve high coverage of high-impact, evidence-based interventions related to sick-child care seeking and treatment also have a direct impact

on under-5 mortality.[14] Projects with similar implementation strategies and results in Mozambique and elsewhere have documented reductions in under-5 mortality of up to 62%.[15]

Limitations

The DHS re-analysis provided an innovative complement to the pre-post mixed-method project evaluation. As an admittedly post-hoc exercise, however, it faced natural limitations.

Our assessment of integrated iCCM scale up does not capture all the variation in the implementation of iCCM across districts over time and with variable degrees of support, both internal and external. More data on CHW performance, supervision, and social capital in both project and non-project districts would have contributed significantly to this analysis, as would more information on the implementation of iCCM in other districts.

The analysis uses individuals as the unit of analysis but does not include individual-level covariates such as wealth or education. The main interest is in whether the change in care-seeking was different in the project districts than in the non-project areas—that is, in macro-level differences of differences—rather than in how the impact may have been different for different kinds of respondents.

Our analysis examines the change in care-seeking behavior. Actual treatment would have been a more proximal indicator for improvement in child health, but this was not possible because of differences between the 2 surveys. For ARI symptoms, treatment was not asked in 2005, and for fever, the addition of rapid diagnostic tests prior to data collection in 2010 makes it impossible to compare the results of the 2 surveys. The use of zinc for diarrhea was not asked in either survey. There was a change in the definition of ARI symptoms that results in a smaller number of more serious cases being included in the 2010 survey than was the case for 2005, which may account for some measure of the increase in care. The accuracy of care-giver reporting on ARI symptoms and its correlation to clinical pneumonia has been questioned by many,[16] but in this case since we are comparing the difference in results for 2 groups within the surveys, we do not feel these concerns affect our conclusions.

The PSGs were unique to Kabeho Mwana districts and, as stated above, our analysis suggests that they may have contributed to improved CHW performance and ultimately to increased care-seeking. However, Kabeho Mwana implemented a comprehensive health systems strengthening approach to scale up iCCM, of which PSGs were just one element. All aspects of the project benefited from active engaged leadership, a flexible management style, skilled and dedicated Rwandan project staff, and enthusiastic collaboration from the MOH and local leaders. We cannot distinguish the specific effect of the PSG strategy on the overall performance of Kabeho Mwana districts. It is plausible that the main driver of improved outcomes in project districts was the difference in intensity of implementation support by Kabeho Mwana compared with other actors in non-project districts.

While a thorough treatment of the issue of sustainability is beyond the scope of this paper, the final evaluation and subsequent discussions with district and national leaders highlighted interest in scaling up the PSG model nationally. Enhancing CHWs' social capital, coordination, and peer support through a PSG approach could serve to sustainably strengthen the overall health system, and specifically community-level initiatives. However, this leads to some key questions about the cost of integrating PSGs into the national model. The cost to implement PSGs was not the subject of either the final evaluation or this analysis, and the cost if implemented by the MOH would likely differ from the cost as implemented by an externally funded NGO. Because the PSG model augments the existing strategy by adding a sub-level of organization, its costs should be manageable, but further examination to quantify those costs are needed to better inform policy decisions.

CONCLUSION

Rwanda has achieved remarkable results in reducing child mortality. From a health systems strengthening perspective, while iCCM was being scaled up nationally in Rwanda, the Kabeho Mwana project placed additional emphasis on building community health systems and establishing and strengthening CHW supervision and peer support systems. These elements contributed to significantly greater improvements in care-seeking for fever, diarrhea, and ARI in districts supported by Kabeho Mwana as compared with other districts. While it is not surprising that an externally supported project resulted in improved care-seeking as compared with the existing national CHW strategy, these

differences are now quantified and suggest that the approach used under Kabeho Mwana can be useful in improving CHW performance, and possibly improve the cost-effectiveness of performance-based financing.

Effective implementation of iCCM must go beyond training and equipping CHWs and include both overall health systems strengthening as well as CHW support mechanisms at the community level.[17] The CHW PSG appears to have been an effective model for CHW peer support and motivation that enabled intensive population coverage of all households in the 6 districts while also providing a mechanism to integrate CHWs' preventive and curative functions and increased opportunities for supervision and reporting. Further testing of the PSG strategy for national scale up would require a quasi-experimental design, with attention to care-seeking and appropriate treatment. It should also focus on additional health promotion benefits and intermediary results in CHW supervision, motivation, and performance.

This article reports an innovative approach to estimating the effect of an iCCM intervention led jointly by 6 Rwandan health districts and a consortium of NGOs. From an evaluation perspective, DHS data proved useful in supplementing evaluation findings and elucidating the differential impact of iCCM under 2 implementation modalities. Countries and partners may seek to identify appropriate evaluation designs when sufficient clusters and enumeration areas can be included in the ''intervention zone,'' and timelines allow. This could enrich country evaluation models for large-scale innovations in service delivery.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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TECHNICAL NOTE

Exclusive breastfeeding: aligning the indicator with the goal

Thomas W Pullum[a]

While the global objective is exclusive breastfeeding (EBF) for a full 6 months duration, the standard indicator is a "prevalence" indicator, that is, the percentage of all children under age 6 months who are exclusively breastfed at a point in time. That yields a higher percentage than a more direct indicator of duration and can be easily misunderstood, exaggerating the amount of EBF. A measurement of actual percentage of children exclusively breastfeeding for a full 6 months can be easily calculated from standard DHS and MICS data.

Recognizing that exclusive breastfeeding (EBF) is a key to child survival, the World Health Organization (WHO) recommends that "infants should be exclusively breastfed for the first 6 months of life to achieve optimal growth, development and health."[1] To assess EBF, WHO, the United Nations Children's Fund (UNICEF),[2,3] and the United States Agency for International Development (USAID)[4] use an indicator defined as the percentage of children under 6 months of age who are being exclusively breastfed at a point in time. A recent and valuable report from WHO, *World Health Statistics 2013*, includes that indicator for most countries of the world under the label "exclusively breastfed **for** the first 6 months of life."[5]

Thus, a discrepancy exists between the recommendation and the indicator. The programmatic recommendation is stated as a duration of EBF, but the indicator is stated as the prevalence of EBF in an age group at a point in time. To be more specific, the recommendation is that every child should be exclusively breastfed until reaching the 6-month anniversary of its birth, that is, for a duration of 6 months. The indicator, however, describes whether children under 6 months of age are currently being exclusively breastfed at the time that the survey is taken; in other words, it describes the prevalence of EBF. The recommendation and the indicator are misaligned. Moreover, the labeling of the indicator in the WHO report is ambiguous, depending crucially on the preposition "for," and thus is easily misinterpreted.

The prevalence indicator yields much higher levels of EBF than a more direct indicator of duration would imply. For example, the WHO report gives an estimate of 52% for Ethiopia in the time interval 2005–2012. As explained below, Demographic and Health Survey (DHS) data can produce an indicator that measures actual duration. When applied to the Ethiopia data, this measure implies that the percentage of children who were being exclusively breastfed 6 months after their birth was 23%, less than half of the prevalence value of 52%.

It is useful to review the basic DHS data on breastfeeding. DHS surveys do not include a question such as "how long did you breastfeed [name]?" Whenever such a question has been asked, the responses are heavily heaped on multiples of 3 months, and especially multiples of 6 months, and thus are nearly useless for analysis. Instead, all DHS surveys use a current status question about the most recent child born in the past 36 months: "Are you currently breastfeeding [name]?" A "yes" response is followed by other questions on additional liquids or solid foods in the past 24 hours, making it possible to determine whether the child is being breastfed exclusively or with supplementary liquids or solids. The reference to the past 24 hours adds specificity, but it is of course possible that the child was given supplements at some earlier time and has moved in and out of the criteria for exclusive breastfeeding. The question is restricted to children who are living with the mother (the respondent) at the time of the survey, under the assumption that children not living with their mother are not being breastfed.

DHS reports the percentage of children who are being exclusively breastfed at the time of the survey for various age ranges. The Table provides some numbers that appear in the report on the Ethiopia 2011 DHS survey.[6] For the age range 0–5 months (that is, less

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The extent to which EBF is reaching 6 months should be the indicator on center stage instead of the currently used prevalence indicator.

TABLE. Percentage of Children Currently Being Exclusively Breastfed (% EBF), by Elapsed Months (*a*) Between the Child's Month of Birth and the Month of Interview

a	% EBF	n
0–1	70.3	363
2–3	55.3	479
4–5	31.8	406
6–8	16.9	608
0–5	52.0	1,248

Numbers of children (n) are weighted. Limited to children who are living with the mother at the time of interview. Source: Ethiopia 2011 Demographic and Health Survey.

than 6 months) the percentage of children currently being exclusively breastfed is 52.0%. It is clear that this is the source of the figure of 52% for Ethiopia that is given in the WHO report.

In another table in the same report, the median duration of exclusive breastfeeding is given as 2.3 months. The calculation of the median requires smoothing and interpolation, but the methods are not sophisticated.[7] The same logic that underlies the calculation of the median duration of breastfeeding, and the same smoothing and interpolation techniques, could easily produce an indicator that would correspond to the WHO recommendation for 6 months of exclusive breastfeeding. Applying this approach to the Ethiopia 2011 DHS survey (and setting aside the matter of EBF interruptions noted above), it can be estimated that 23% of children had been exclusively breastfed for 6 months at the time of that survey.

Analysis of data from Ethiopia indicates that about 23% of children had been exclusively breastfed for 6 months at the time of the survey vs. 52% of children who were currently being exclusively breastfed.

Besides the DHS, the other major program of population-based surveys is UNICEF's Multiple Indicator Cluster Surveys (MICS). These surveys gather data on EBF in a very similar fashion to that of the DHS and could also generate the same indicator of the duration of EBF.

The currently used prevalence indicator has some advantages and has a legitimate role. Because it includes the entire sample of infants less than 6 months old, it has more statistical stability. Moreover, the health benefits of EBF are greater for the earlier months of life, and the prevalence indicator tends to give more weight to early EBF than the duration-to-6 months indicator. Still, if we want to promote 6 months of EBF, the extent to which EBF is reaching 6 months should be the indicator on center stage.

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FIELD ACTION REPORT

Development and use of a master health facility list: Haiti's experience during the 2010 earthquake response

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Collaboration between the Haitian government and NGOs after the 2010 earthquake contributed to a more accurate and complete master health facility list, which helped coordinate emergency response operations as well as strengthen the routine health information system. Open data and social networks facilitated the collection and sharing of health facility information and in maintenance of the list over time.

ABSTRACT

Master health facility lists (MHFLs) are gaining attention as a standards-based means to uniquely identify health facilities and to link facility-level data. The ability to reliably communicate information about specific health facilities can support an array of health system functions, such as routine reporting and emergency response operations. MHFLs support the alignment of donor-supported health information systems with county-owned systems. Recent World Health Organization draft guidance promotes the utility of MHFLs and outlines a process for list development and governance. Although the potential benefits of MHFLs are numerous and may seem obvious, there are few documented cases of MHFL construction and use. The international response to the 2010 Haiti earthquake provides an example of how governments, nongovernmental organizations, and others can collaborate within a framework of standards to build a more complete and accurate list of health facilities. Prior to the earthquake, the Haitian Ministry of Health (Ministère de la Santé Publique et de la Population [MSPP]) maintained a list of public-sector health facilities but lacked information on privately managed facilities. Following the earthquake, the MSPP worked with a multinational group to expand the completeness and accuracy of the list of health facilities, including information on post-quake operational status. This list later proved useful in the response to the cholera epidemic and is now incorporated into the MSPP's routine health information system. Haiti's experience demonstrates the utility of MHFL formation and use in crisis as well as in the routine function of the health information system.

INTRODUCTION

Accurate and regularly updated master health facility lists (MHFLs) are essential for effective planning, coordination, and delivery of health services, particularly in low- and middle- income countries with extensive external donor presence. MHFLs are also important during disasters because the lack of accurate, usable information is a major obstacle to effective disaster response.[1,2] According to the World Health Organization (WHO), an MHFL is a complete list of health facilities in a country (both public and private) with a set of attributes to uniquely identify each facility,[3] and it includes basic information about the facility's services and capacities.

With the release in 2012 of draft WHO guidance on the creation and governance of MHFLs, countries may be considering devoting resources to develop such lists.[3] However, there are few documented experiences on the construction or use of MHFLs.

The earthquake in Haiti on January 12, 2010, underscored the need for countries to have an MHFL. At the time of the earthquake, the Haitian Ministry of

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Lack of accurate information is a major obstacle to effective disaster response.

Health (Ministère de la Santé Publique et de la Population [MSPP]) had a list of public-sector health facilities. However, the MSPP list contained little information about privately managed health facilities—a major part of the health delivery system in Haiti—and it lacked critical attributes needed to uniquely identify facilities.

During the earthquake response, the MSPP worked with the Haiti Health Facilities Work Group (Work Group), composed of a multinational group of organizations and governments, to develop a functioning MHFL, which proved useful during not only the earthquake response but also subsequent events such as the cholera outbreak.

This article reviews the development and use of the MHFL and provides a model for other countries interested in developing similar lists, which are increasingly needed to align donor-supported information systems with national health information systems.

THE NEED FOR A COMPLETE HEALTH FACILITY LIST IN HAITI

The epicenter of the 2010 Haiti earthquake was close to the most densely populated areas of Haiti, including the capital, Port-au-Prince. Approximately 250,000 buildings collapsed, including many hospitals.[4] In the confusion that followed, there was uncertainty about the extent of damage to health facilities[5] as well as a lack of information about the temporary clinics that were rapidly being set up. First responders were uncertain whether they were referring to the same health facility when communicating about the type, status, and capacity of facilities.

Master health facility lists help emergency response personnel know they are communicating about the same facility.

The MSPP is responsible for the health of the population and for the delivery of health-related services.[6] At the time of the earthquake, the public health care system included more than 500 health institutions (approximately 30% of the country's health facilities), ranging from community health clinics providing basic primary services to university hospitals. In addition, there were more than 250 nongovernmental organizations (NGOs) providing a substantial proportion of the primary health services.[4,7]

Broad representation in the Haiti Health Facilities Work Group facilitated coordination while minimizing duplication of efforts.

Prior to the earthquake, multiple, incomplete, and conflicting health facility information systems existed in Haiti; no entity served as a repository for an up-to-date, comprehensive master list. For example, the Haiti Health Information System (Système d'Information Sanitaire d'Haïti [HSIS]) functioned as a health management information system but was incomplete. Similarly, the Electronic Monitoring, Evaluation and Surveillance Interface for HIV-infected patients (MESI) collected data from public, and some private, health facilities in Haiti but primarily from sites receiving support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

DEVELOPMENT AND USE OF HAITI'S MASTER HEALTH FACILITY LIST

In the immediate aftermath of the earthquake, the U.S. Department of Health and Human Services (HHS) coordinated the formation of the Work Group in support of the MSPP. The first meeting of the Work Group took place via teleconference 5 days after the earthquake (on January 17, 2010) with representatives from U.S. federal agencies; academia; international, local, and Haitian diaspora NGOs; multilateral organizations; foundations; and businesses (Table 1). All Work Group activities were coordinated through conference calls and a shared web space.[8] Staff of the MSPP's Planning and Evaluation Unit (Unité de Planification et d'Evaluation [UPE]) were responsible for the HSIS; they participated in the Work Group and had final determination regarding edits to the MHFL.

Between January 2010 and August 2011, UPE staff collaborated with the Work Group to develop a single, comprehensive list of all public, private, and mixed (public and private) health facilities. The list was standardized, validated, and up-to-date to guide and coordinate the health response to the earthquake. Senior MSPP leadership provided input and direction during several meetings in 2010.

The MHFL's initial purpose was to address the urgent need for a common list of health facilities in Haiti to ensure all emergency response personnel knew they were communicating about the same facility. The Work Group adapted guidelines on a minimum set of data elements necessary to uniquely identify a health facility, known as a signature domain,[9] to inform the core set of information contained in the MHFL (Box). These elements included:

- A unique identifying code for each facility
- The facility name, address, and type
- The entity that manages/owns the facility
- Each facility's geographic coordinates

TABLE 1. Organizational Participation in the Haiti Health Facilities Work Group by Category (N=56)

Haitian Government	**NGOs and Private Consultants**
Ministère de la Santé Publique et de la Population	Arkemie
U.S. Government	Association of Haitian Physicians Abroad, Florida Chapter
Department of Defense (DOD)	Baertracks
Department of Education	Christian Connections for International Health
Department of Health and Human Services	Christian Medical and Dental Associations
Department of Homeland Security	Citizen Command Center Database Team, Citizen Action Team
Department of State	Communibuild Technologies
Peace Corps	CrisisCommons
United States Southern Command (DOD)	DirectRelief
U.S. Agency for International Development	Evotech, Inc.
Multilateral Organizations	FortiusOne, Inc.
Geo-Operations Unit, United Nations	Global Health Action
International Organization for Migration (IOM)[a]	Haitian Mental Health Network
Office for the Coordination of Humanitarian Affairs, United Nations	Haiti Village Health
World Health Organization/Pan American Health Organization	Humanitarian Medical Aid Direct Relief
United Nations Development Programme	ICF International
World Health Organization headquarters	IMA World Health
Academia	InSteDD
Bloomberg School of Public Health, Johns Hopkins University	InterAction
Center for Geographic Analysis, Harvard University	Logistics for Health
Emory University	MEASURE Evaluation
The George Washington University	Medical Mission Exchange
Institute for Global Leadership, Tufts University	OpenStreetMap
Lincoln Laboratory, Massachusetts Institute of Technology	Project Medishare for Haiti
Mailman School of Public Health, Columbia University	ReliefWeb
Foundations	Sahana Software Foundation
Clinton Foundation	Shoreland, Inc.
Google Foundation	Synergist Technology Group, Inc.
	Thermopylae Sciences + Technology
	Ushahidi
	World Cares Center
	World Concern

[a] Although IOM is not part of the UN system, it works very closely with the UN specialized agencies and is part of UN Country Teams around the world.

Haiti's master health facility list was posted to a public Google Site to increase the chances of it being used and updated over time.

Online dissemination of the MHFL helped integrate the unique health facility codes into other data collection efforts.

Haiti's master health facility list developed for the earthquake response was eventually incorporated into the routine health information system.

BOX. Recommended Data Elements for Master Health Facility Lists

Signature Domain (set of data elements that do not change significantly over time)

- Unique identifier
- Facility name
- Facility type
- Ownership/managing authority
- Location/address
- Administrative units
- Geographic coordinates
- Operational status
- Year data collected

Service Domain (set of data elements that provide some basic information on a facility's services and capacities)

- Core basic services offered
- Number of core medical personnel
- Number of inpatient and maternity beds available

Adapted from the World Health Organization.[3]

A codebook for the signature domain fields was created building on codes created by the Institut Haïtien de Statistique et d'Informatique (Supplementary Appendix).

The first iteration of the MHFL that contained only the signature domain fields was created on January 29, 2010, by blending the MSPP's existing HSIS health facility list with partial lists, volunteered geographic information, and local knowledge on the post-earthquake status of health facilities in order to produce a more comprehensive list (Table 2). To improve functionality, the Work Group included standardized names of each facility in English, French, and Haitian Creole. The Work Group verified information by soliciting feedback on a publicly posted version of the MHFL coupled with direct outreach to health facilities by phone or in-person when possible.

In keeping with United Nations recommendations on the coordination of information during humanitarian emergencies, the Pan American Health Organization's Emergency Operations Center (PAHO EOC) took a lead role in managing the MHFL.[10,11] The PAHO EOC published the first iteration of the MHFL and codebook to a public Google Site.[12] Posting the list to an open website increased the likelihood that the MHFL and its codes would be used and that those involved in the response would provide feedback to note missing facilities and to correct errors. Contributors through the site included NGOs, members of the Crisis Mappers Network,[13] and health facility staff. Between January 29 and March 18, 2010, WHO/PAHO released 6 updated versions of the Master List. Each version of the MHFL included new health facilities, fewer duplicates, and corrected variable values (Table 2).

The MHFL was used widely in the initial earthquake response. In addition to the Google Site, a link to the list was posted to many of the information portals that proliferated following the earthquake. The MHFL was also used as the reference data set for health facilities in the OpenStreetMap (OSM) platform.[14,15] OSM updated its health facility layer with each of the 7 versions of the list.[16]

As the initial effort transitioned from emergency response to reconstruction, stewardship of the MHFL was transferred to Shoreland, Inc., during April 2010.[17] Following the cholera outbreak in Haiti in October 2010, fields for cholera treatment centers (CTCs) and cholera treatment units (CTUs) were added. The MSPP used the MHFL to determine which communities lacked health facilities so CTCs and CTUs could be installed to provide care to the affected population.[18]

In September 2011, the MSPP incorporated data from the MHFL into its routine health information system, which collects information on key services provided and human resources present at each facility. The MHFL formed the basis of the *Liste des Institutions Sanitaires*, the MSPP's listing of health facilities in the country,[19] which is an updated and more robust version of the HSIS. It was also integrated into the *Carte Sanitaire*, the MSPP's service delivery and infrastructure status database.[20,21] MEASURE Evaluation and the MSPP's UPE continue to work collaboratively to update and validate the *Liste des Institutions Sanitaires* in coordination with the directors of statistics and epidemiology within each of the 10 departments. Health facilities and field hospitals can now be uniquely identified. However, some duplicates and data quality issues remain.

TABLE 2. Evolution of the Haiti Master Health Facility List

Version	Date	Host	Edits/Additions	Comments
Pre-earthquake	Before 2010	The HSIS list was available online through the HSIS website.	Last updated in 2009.	No entity served as a repository for an MHFL. The HSIS became the basis for the MHFL, but it was incomplete; it did not cover the non-public sector and had variable reporting from the 750 public health facilities in it.
1	January 29, 2010	PAHO	Information on health facilities from the HSIS was merged with other lists creating a total of +/- 1,260 records. The 2009 HSIS health facility list included the following fields: rank (a number assigned to the facility according to when it was created in the commune); name of the department, district, and commune where the facility is located; name of the facility; category (e.g., dispensary, hospital); and type (public, private, or mixed).	Information sources included: HSIS, MESI, USAID, PAHO, PEPFAR, UNOCHA, the Sahana Foundation, MINUSTAH, and Ushahidi.
2	February 9, 2010	PAHO	7 new health facilities were added.	
3	February 12, 2010	PAHO	New fields were added for damage and operational status information; 39 new health facilities were added (including field hospitals); and 41 duplicate records were removed.	
4	February 16, 2010	PAHO	63 new health facilities were added; 19 duplicate records were removed; and metadata was updated.	
5	February 26, 2010	PAHO	HealthC_IDs (unique identification codes) were added to facilities that previously lacked one.	All HealthC_IDs from version 4 remained unchanged, but changes were made to the algorithm used to generate new unique identifiers in the metadata (Supplementary Appendix).
6	March 11, 2010	PAHO	Region, commune, and department IDs in the MHFL were matched to the MSPP_2010 list; official facility names were added; inaccurate values for the various codes used by the MSPP were corrected; geocodes of numerous MSPP sites were corrected; and about 20 duplicate records were removed. This version included all 2010 MSPP health facilities.	New information received post-earthquake from MEASURE Evaluation on behalf of the Haitian MSPP was incorporated into the new MHFL.

TABLE 2 (continued).

Version	Date	Host	Edits/Additions	Comments
7	March 18, 2010	PAHO. Stewardship transferred to Shoreland, Inc., in April 2010, and version 7 was republished on Shoreland's Travax system.[17]	50 duplicates were removed and more than 80 new health facilities were added. CATEGORIE, TYPE, and SANTE_ID fields were updated with the latest information from the MSPP.	When the list was republished on the Travax site,[17] a field for cholera treatment centers was added.
Liste des Institutions Sanitaires	Summer 2011	MSPP	Health facilities and field hospitals can now be uniquely identified. Data are updated and validated through self-reporting from facilities and data collection efforts by the MSPP and partners. Some duplicates and data quality issues remain. The list does not include information on mobile clinics (those that are still operational).	The MSPP incorporated the MHFL for a key input to its routine health information system. The MHFL forms the basis of the Liste des Institutions Sanitaires[19] and is integrated into the MSPP's service delivery and infrastructure database.[20,21] It is used on an ongoing basis to measure health service coverage.

Abbreviations: HSIS, Haiti Health Information System (Système d'Information Sanitaire d'Haïti); MESI, Electronic Monitoring, Evaluation and Surveillance Interface for HIV-infected patients; MHFL, master health facility list; MINUSTAH, United Nations Stabilization Mission in Haiti; MSPP, Haitian Ministry of Health (Ministère de la Santé Publique et de la Population); PAHO, Pan American Health Organization; PEPFAR, U.S. President's Emergency Plan for AIDS Relief; UNOCHA, United Nations/Office for the Coordination of Humanitarian Affairs; USAID, U.S. Agency for International Development.

GOVERNANCE OF A NATIONAL MHFL: OPPORTUNITIES AND CHALLENGES

Ministries of health play an essential role in creating, managing, and verifying data for master health facility lists.

In routine health system planning, lists of health facilities, generally maintained by ministries of health, help organize information about health systems and are instrumental to answering basic questions such as how health services are distributed in a country and how resources may be allocated to address gaps in health service coverage.[22,23] These lists facilitate reporting on the condition of health infrastructure and capacity to deliver services, which are key information requirements during a response to a humanitarian crisis, such as a natural disaster.[24] Such lists are also essential for routine health information systems because they allow information about specific health facilities to flow within distributed networks in support of health decision-making.[25,26]

Challenges

Multiple Sources of Information

In many countries, information about health facilities exists within stand-alone systems designed for discrete purposes. Lack of standardized naming conventions and codes unique to each facility but common across information systems introduces ambiguity to facility identity when comparing or consolidating multiple lists, resulting in duplications.[27] It may be difficult to link multiple sources of information to support decision-making under normal circumstances, let alone during a disaster.[28,29]

Lack of Procedures

Ministries of health hold an essential ownership, management, verification, and communication function for MHFLs. Several dynamics explain why many ministries of health do not have an adequate MHFL. Procedures for regular updates may be lacking, causing information to easily become out-of-date. It is also common for facility-based health services in low- and middle-income countries to involve a complex array of multilateral, bilateral, public, and private for-profit and not-for-profit organizations.[30] These organizations typically maintain information about the health facilities they support. However, there may be little or no information sharing among these groups or with the ministry of health. This is

certainly the case in Haiti, where coordination between the government and the NGO community has historically been poor.[31]

Coordination

Haiti's MHFL provides a national-level view of Haiti's health facility infrastructure. The MHFL is updated at one central location by the UPE and consolidates information from the MSPP, WHO/PAHO, HHS/Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), and the NGO community. Yet some coordination issues remain. Although publically available, there is a gap in regular updates to the MHFL and ongoing quality control efforts are necessary to maintain and improve the quality of the data and to remove duplicate records.

Opportunities

Open Data and Social Networks

When MHFLs do not exist or are incomplete, responders during crises will need to collect data for immediate purposes. In the case of Haiti, open data, social networks, and volunteered geographic information were major factors that facilitated information flow about health facilities during the earthquake response.[15,32–37] In addition, multiple organizations collected information directly from health facilities following the earthquake. However, lack of coordination among these organizations created confusion and overwhelmed health facility personnel. A pre-existing list that was updated at a central location could have mitigated this situation.

Quality Control Processes

The process of integrating data from multiple sources can spawn a proliferation of duplication and errors. For multi-sourced data to be widely accepted as reliable information, quality control processes must be in place to rapidly screen and verify data before it becomes official data. In the case of Haiti, central-level engagement of officers within the health system provided a quality check of the information in each of the iterations of the MHFL. However, validation can best occur with the engagement of appropriate staff at more local levels of health system administration.

Free, Online Access

Web-based repositories for MHFLs, such as Haiti's or Kenya's repositories, ensure that lists are available when needed and also can provide a platform for the maintenance of facility data over time.[3,21,38] Ease of access to health facility lists increases the likelihood of data use. Data users and generators can then feed information to the system to create a cycle that should improve list completeness and quality over time.

The draft guidance from WHO on how to create an MHFL outlines a standardized process and provides WHO-endorsed standards for data format and data governance.[3] The WHO guidelines also provide information on how the content of an MHFL can be made accessible and maintained over time.

CONCLUSION

Having an accurate, regularly updated, and freely accessible national MHFL is important for effective routine planning and the delivery of health care services. During the 2010 Haiti earthquake response, the creation of a functioning MHFL proved useful for coordination and reconstruction efforts including subsequent events such as the cholera outbreak. A pre-populated data set that was comprehensive, accurate, and relatively up-to-date would have greatly facilitated initial relief efforts. Recognizing that disasters can occur anywhere and that accurate data are critical for effective response, countries without lists should develop and maintain an MHFL. Modest efforts in this area could greatly enhance the ability to mount a rapid, coordinated, and effective response.

Open data, social networks, and volunteered geographic information are playing an increasing role in crisis response.

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STORY FROM THE FIELD

Reaching out to a community to improve maternal health in Ghana: the story of one midwife

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The story below of a Ghanaian midwife from the Ashanti region illustrates how one person was able to mobilize local community members in rural Piase in the Bosomtwi district to create demand for, and improve access to and use of, emergency and routine maternal health services. Her story demonstrates how involving communities in maternal health issues can improve both access to services and maternal health outcomes.

"When I was first posted to Piase in 2005 as a midwife, attendance at antenatal care (ANC) clinics was very low. Women were also delivering their babies at home. So I became very worried. I was particularly worried because maternal and newborn care services were provided free-of-charge at the health facility. I therefore started asking a lot of questions regarding why the women were not using our services.

I discovered that the women were not coming because of certain things that were happening in the community. For example, I found out that they [the women] were using the services of TBAs [traditional birth attendants], and these TBAs were actively discouraging the women from coming to the health facility to receive skilled care. The surprising thing I also found was that some religious leaders, I mean pastors, were discouraging their congregants from using health facility services [and instead encouraging them to find relief] through prayers and spiritual healing.

I was indeed very worried, and this was so because the midwife who came to the community before I did had a very bad relationship with the TBAs, religious leaders, and some traditional or opinion leaders in the community. The stories I have heard are that the community members complained that my predecessor showed gross disrespect for the culture and traditional authority structures of the community. In addition, I was told the midwife had several confrontations with the TBAs, with most of them complaining that the midwife had come to take away their jobs and source of livelihood.

As a form of protest and discontent, TBAs, pastors, and traditional authorities, particularly the queen mother, embarked on a silent campaign that sought to discourage pregnant women from accessing and using the services that were being provided at the health facility. When I discovered all these, I didn't really know what to do to make things better … In fact, I was scared, and I wanted to seek transfer to a different community.

But after thinking through the problem, I decided that I would stay in the community and reach out to the traditional leaders, TBAs, pastors, and women themselves. So I visited the chief, queen mother, assemblymen, and each of the TBAs and pastors in the community to first introduce myself to them as the new midwife. I also visited women's groups in the community and churches to introduce myself. During these introductory meetings, I asked them about what they thought the problems of maternal health care were and how we could come together to work to make things better. You know, the TBAs were very surprised that I was asking for their opinions because I was the midwife and I was supposed to know everything. But I said that, 'Well, I might not know everything,' and given that I am new in the community, I believe they [the TBAs] could be of immense help. I did the same thing with the pastors. In fact, I organized a meeting and invited all the pastors, TBAs, community leaders, and women to discuss how best we could ensure that no woman suffers or dies as a result of pregnancy and childbirth.

During the meeting, I made it clear that they should see the problem of maternal health as belonging to all of us, and that they too could help. Because of the problems my predecessor had with the TBAs and also because the Ghana Health Service in the district does not recognize TBAs as skilled caregivers, I reassured all the TBAs that I did not come into their community to take their jobs but to work with them, so that together we could make things better. For the pastors too, I told them that their prayers too were still

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important during pregnancy or labor. I told them that I was ready to assist with the physio-biological aspects of the health of mother and newborn while they [the pastors] deal with spiritual matters.

After these individual meetings, I sought permission from the chief and queen mother to organize a *durbar*. This was a big ceremonial meeting, which was attended by several of the community members, especially husbands and wives, and was marked with celebrations, food, and traditional dances. During this meeting, we held discussions on the importance of women accessing and using skilled care services during pregnancy, delivery, and thereafter, the barriers to services use, and how they [the community members] could act as partners with us, the health care providers, to improve both access to care and birth outcomes.

Following this big meeting, we formed a community maternal health watchdog committee. The chairperson for the committee was the queen mother, and the committee was tasked to undertake house-to-house sensitization and home visits to identify pregnant women and encourage them to attend ANC clinics. The committee also monitored and reported on issues related to maternal and newborn health such as miscarriage and abortion. On my part, I worked closely with the committee, pastors, and TBAs.

At the beginning, many of the community leaders and TBAs were very reluctant to engage with me on the issue of maternal health. But I continued to consult with them as well as to express my desire for us to work together as partners. I even went to help some of the TBAs conduct deliveries at home. It was through this that the TBAs came to realize that I had some skills that they did not have. So gradually, the TBAs and pastors started to encourage pregnant women to come for ANC … Now the TBAs themselves will even bring the women to the clinic to deliver. I am really surprised. And the same thing is happening with the pastors. They are also encouraging the pregnant women in their various churches to attend ANC. When a woman goes into labor too, they usually come along to pray for a smooth delivery. So now, we are all working like a team, and I can say that it has contributed a lot to all the progress we are making in this community.

In addition to the fact that the community members and myself have become partners in promoting access to and improving maternal health, no maternal or neonatal death has occurred in the community since 2007. I believe we have achieved this success because of the increase in the proportion of women who now deliver at health facilities.

Of course I know that my approach is slightly alien to the health system in Ghana and might therefore not be accepted in some contexts. But the modest gains we have attained in this community suggests the need for the Ghana Health Service and us, the individual health care providers, to do more to build partnerships with traditional midwives or TBAs, traditional and religious leaders, as well as community members on the issues of maternal health. For me, partnerships means shared responsibility between us, the health care providers, and individual women and communities, and this can offer us opportunities to change women's as well as local communities' beliefs and attitudes toward hospital-based maternity care services. My own experience over the years as a woman who has gone through pregnancy and childbirth and who has worked at both urban and rural settings as a frontline midwife providing maternity care services has taught me that community engagement and partnership is the only way to enhance the potential for cooperation between health care workers and community members, as well as to increase opportunities for nurses and midwives to train TBAs to increase their skills to offer competent and safe maternity care services, including responsive referrals of cases at the community

A midwife engages the community chief, queen mother, and women from the community on how to improve maternal health.

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A midwife consults with a community leader on how to encourage women to seek skilled maternal health care services.

level. My personal belief is that if we want to make progress with maternal health, then we must begin to foster more collaboration between nurses, midwives, TBAs, and traditional and religious leaders at the community level.''

KEY PROGRAMMATIC LESSONS

The story of this midwife is drawn from my 6-month research journey starting in November 2011, from my English town of Oxford to the West African country of Ghana. My primary goal was to elicit and document the experiences and views of a wide range of people on why the maternal mortality rate was still very high, and accessibility to and use of skilled maternal health care services was low despite the implementation of a free maternal health care policy in Ghana since 2003.[1–3] I conducted focus group discussions, interviews, and structured field observations with 185 expectant and lactating mothers, 15 TBAs, 12 traditional and opinion leaders, and 20 health care providers (i.e., community health nurses, midwives, doctors, health facility managers, district and regional directors of health, district and regional public health nurses, and policy makers at the Ministry of Health and Ghana Health Services).

The approach adopted by the midwife highlighted in this story did not merely raise community awareness or persuade community members to participate in activities that the midwife and the local health delivery system had already designed or decided on. Rather, her approach involved a comprehensive consultative and participatory strategy that involved a series of activities including:

1. Conducting formative research to understand factors within the community that constrain women's access to and use of services
2. Entering the community and establishing credibility and trust
3. Galvanizing the support of traditional authorities in the community mobilization process
4. Working with community leaders and other stakeholders to invite childbearing women and organize their participation in strategic activities
5. Monitoring and evaluation of community maternity care activities

The processes the midwife followed showed great respect for community members and acknowledged and/or used existing local structures, resources, and networks to generate interest in, and demand for, skilled maternal health care services. Although there could be challenges such as lengthy processes and community members' unwillingness to engage in the process, this particular midwife's story suggests that the overall potential benefits of engaging with target communities outweigh the challenges.

As efforts to improve maternal health continue, it is essential that local communities are engaged to generate support and demand for skilled birthing services as well as create the needed behavioral and attitudinal changes.

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