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GLOBAL HEALTH: SCIENCE AND PRACTICE
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EDITORIAL

Reducing Sepsis Deaths in Newborns Through Home Visitation and Active Case Detection: Is it Realistic?

Stephen Hodgins,[a] Robert McPherson[b]

Severe bacterial infection remains one of the major causes of newborn deaths in low-income countries. A key challenge for reducing this burden is making definitive treatment more easily available. Active case detection through early postnatal home visits can work under trial conditions but is difficult to implement at scale under routine conditions. In many settings, making treatment available at peripheral-level primary health care facilities may be more feasible.

See related article by Hailegebriel.

THE ISSUE OF SERIOUS NEWBORN INFECTION

Serious bacterial infection remains 1 of the 3 leading causes of newborn deaths globally[1] and in some high-burden settings accounts for more than a third of such deaths. Reducing this burden requires strategies that result in more timely case identification and initiation of suitable antibiotic treatment. In many low-income, high-burden settings, achieving such improvements requires services to be pushed out more peripherally to make them more easily accessible. This is particularly challenging in places where much of the population does not currently have easy access to hospital-based care.

EARLIER LANDMARK STUDIES

Bang et al. (1999)[2]—working in a poorly served, comparatively remote area of India—piloted an approach to reduce newborn mortality that relied on community health workers (CHWs) to provide postnatal home visits, with an intensive, closely monitored, 7-visit schedule over the first month of life. These CHWs were to identify and treat cases of possible sepsis, using oral cotrimoxazole and intramuscular gentamicin. The package also included having the CHWs assist traditional birth attendants at childbirth, resuscitating any newborns not spontaneously initiating breathing at birth. This quasi-experimental study achieved greater than 60% reduction in newborn deaths. These findings challenged a fatalistic attitude then widespread in the global health community, which assumed that important progress in reducing newborn mortality would not be possible without wide access to sophisticated hospital-based services.

Almost a decade later, in 2008, Baqui and colleagues published the results of a comparably important study,[3] testing a similar approach in rural Bangladesh, using a cluster-randomized control trial (RCT) design with a much larger sample than in the Bang study. Like the earlier study, this trial recruited and trained its own CHWs to provide this package of services, and in addition to active case detection and treatment of possible sepsis, the intervention included CHW counseling for women and household members on essential newborn care and danger signs. It also included a community mobilization component. However, the package of interventions did not include resuscitation of non-breathing newborns. The schedule of home visits was less intensive than in the Bang study (2 visits during pregnancy, 3 in the first week of life), and the trial was implemented in a less isolated setting, where treatment services were more readily available than in the Bang study setting. The Baqui trial achieved 34% lower mortality in the intervention than the comparison arm. The findings of this study drew considerable attention, including its recognition as the *Lancet* "paper of the year" in 2008.

WHO/UNICEF RECOMMENDATION

On the strength of these 2 studies, along with several others that didn't include a sepsis treatment component, in 2009 the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) issued a joint statement recommending introduction of postnatal home visitation by health professionals or CHWs, with assessment for danger signs and counseling on essential newborn care practices.[4] More recently published

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WHO and UNICEF issued a joint statement in 2009 recommending introduction of postnatal home visitation, with assessment for danger signs and counseling on essential newborn care practices.

papers[5,6] report on a similar approach entailing active detection of cases of possible sepsis, through an intensive schedule of home visits with referral to the most peripheral level of the primary health care system for outpatient antibiotic treatment for cases for which hospital referral is not feasible. These studies demonstrated equivalent outcomes for simplified antibiotic regimens, in comparison with 7 days of injections of procaine penicillin and gentamicin, given on an outpatient basis.

THE CURRENT STUDY

Despite considerable support during the trial, it was difficult to achieve and sustain adequate home visitation coverage and volume of care seeking for possible newborn infection.

The study by Hailegebriel and colleagues, reported in this issue of GHSP,[7] is a useful additional piece of evidence that can inform the development of more effective strategies to reduce the population burden of preventable infection deaths among newborns. In this cluster RCT, home visitation (3 visits during pregnancy and 5 postnatally) was introduced in both intervention and control arms. One of the pregnancy visits and 2 of the postnatal visits were to be done by paid, government health auxiliaries (Health Extension Workers, or HEWs); the remainder of the visits were to be done by community volunteers, 3,500 of whom were recruited and trained for the trial. Home visits were to focus on counseling on essential newborn care practices and assessment for danger signs. Any identified cases of possible sepsis were to be referred. In the intervention arm, outpatient antibiotic treatment was made available at the health post level, provided by HEWs, if caregivers of the sick newborn were unable or unwilling to go to a higher-level facility. The intervention also included monthly review meetings with HEWs.

Difficulty Delivering Home Visitation Even in This Trial Setting

Home visitation by CHWs may seem like a simple, low-tech approach to improve maternal and newborn outcomes, but doing it successfully takes considerable program effort.

During the initial months of the trial, although most newborns received at least some postnatal home visits, the number of cases of possible sepsis identified and treated was low. Formative research was conducted to determine barriers to care seeking, and the intervention was modified to incorporate community mobilization activities in intervention communities, following which there was a marked increase in the number of cases treated. However, even with this increase, the number of cases treated came to only about half the number expected. Furthermore, over the final 2 quarters of the intervention period, home visitation and number of cases treated tapered off. So, despite a level of support considerably exceeding what would be possible under routine conditions at scale, it was difficult to achieve and sustain adequate home visitation coverage and volume of care seeking for possible severe bacterial infection.

A consequence of low numbers of cases identified for the trial was that it had inadequate statistical power to detect the effect size anticipated at the time the study was planned. Failing to show a statistically significant difference between intervention and control arms on the primary endpoint of the trial (day 2–27 neonatal mortality) means that the study does not provide compelling evidence for mortality-reduction effectiveness. However, neither does it provide evidence for lack of effectiveness. The measured effect size was compatible with chance (adjusted risk ratio [RR] 0.83, P =.33 per cluster-level analysis; RR 0.72, P =.09 per secondary, individual-level analysis) but also compatible with a mortality effect of the magnitude anticipated at the time of the study design, given that only about 50% of expected cases were reached. Lower than expected utilization resulted in inadequate statistical power. But this problem reflects the real-world challenges in attempting to implement such a strategy and cuts to the heart of our concern with postnatal home visitation as a strategy to reduce newborn mortality.

There is evidence (e.g., from the Bang[2] and Baqui[3] studies) that early postnatal home visitation can be an effective way to reach mothers and newborns with interventions that can improve outcomes, but—as results of the Hailegebriel[7] study demonstrate—this is not easy. Key challenges with such an approach include ensuring that home visits actually happen early, at sustained, high coverage, and ensuring delivery of effective content (counseling, case detection, referral/treatment). This could be summarized as ensuring high effective coverage. Doing so requires adequately intensive inputs and program quality assurance.

In response to the 2009 WHO/UNICEF Joint Statement,[4] a number of countries have made efforts to implement postnatal home visitation under routine public-sector program conditions. In almost all instances, countries have been unable to achieve high coverage of early postnatal home visitation.[8] Home visitation by CHWs may seem like a simple, low-tech approach, but achieving high coverage and making sure that what happens during these contacts contributes to better outcomes takes considerable program effort. Even in the context of these trials, this was challenging. For national programs run under routine

conditions, in most low- and middle-income settings this is too demanding to be feasible.

The Self-Referral Alternative

By initial design, the primary means of identifying and ensuring early initiation of treatment for possible severe bacterial infection in the Hailegebriel[7] trial was home visitation and active case detection. However, the study found that over time self-referral made up an increasing proportion of cases treated, and by the end of the intervention period accounted for the majority of cases. It appears that, with reliable provision of such treatment at the health post, those requiring this service were increasingly motivated to seek care, without the need for case detection during home visits. This is an encouraging sign.

The Government of Ethiopia is now moving forward to scale up provision of treatment for possible severe bacterial infection at the health post level. As such care at the health post level is being rolled out across Ethiopia, it is relying primarily on self-referral of cases rather than active case detection based on home visitation, as done under the trial. This was a sound move, given the practical difficulties with a strategy requiring active case detection.

In every setting, health sector planners and policy makers need to make a realistic determination of the circumstances in their settings, adopting and adapting strategies most likely to be feasible and effective under real-world conditions.[9]

Competing Interests: None declared.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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EDITORIAL

Not Ready for Primetime: Challenges of Antenatal Ultrasound in Low- and Middle-Income Country Settings

Even under optimized trial conditions, antenatal ultrasound was difficult to implement in Equateur Province, DRC. Moreover, the broader study across 5 countries failed to find an impact on pregnancy outcomes. Use of antenatal ultrasound screening appears not to be ready for wide application in low- and middle-income countries.

See related article by Swanson.

There are instances when simple technological fixes can have a major public health impact. For example, investments by the U.S. government and the Bill & Melinda Gates Foundation (and others) to facilitate widespread use of effective vaccines have undoubtedly made an important contribution to reducing the burden of child deaths in low-income countries. But, more commonly in global health, the deployment of an otherwise promising technology is insufficient—on its own—to produce marked improvements in outcomes in the face of real-world complexity. This is well illustrated in an article by Swanson and colleagues,[1] published in this issue of *Global Health: Science and Practice* (GHSP). The article addresses challenges experienced implementing a field trial. But it is of particular interest to the journal and to many of our readers for lessons that can be drawn on program implementation more broadly.

Swanson and colleagues report on implementation of the First Look Ultrasound study, in which the main intervention consisted of making ultrasound available for routine antenatal screening in peripheral-level health facilities (conducted in 5 countries: Democratic Republic of the Congo [DRC], Guatemala, Kenya, Pakistan, and Zambia). On the face of it, this seems like a straightforward, unequivocal, good thing; routine screening should allow for earlier detection and more timely management—at a suitable level in the health care system—for conditions such as placenta previa, abnormal lie, and twins.

The endpoints of the trial were service utilization (antenatal care, facility birth) and pregnancy outcomes (mortality, morbidity). The article in this issue of GHSP focused on implementation issues encountered, particularly in the most difficult of the study sites, Equateur Province, DRC. From this experience, the authors make the point that *threshold conditions* need to be met for feasibility; in the DRC site, such conditions were stretched to the limit. Specific challenges encountered were:

- Power supply (special arrangements needed to be made to install solar panels)
- Equipment maintenance and repair (costs, delays when repairs were needed)
- Supply chain for consumables
- Security, as the ultrasound equipment was expensive and therefore an attractive target for theft—this required complicated logistical arrangements
- Availability of clinical staff—the study hired its own nurses to do the screening, due to logistical challenges transporting equipment and concern about protocol adherence by regular nursing staff (including documentation) in the absence of close supervision
- Functional referral to a center capable of providing comprehensive emergency obstetrical care (including blood, anesthesia) and geographically and financially accessible to potential users
- Streamlining/coordination to reduce procedural barriers for patients at the receiving health facility
- Quality assurance for ultrasound diagnostics

If implementation under comparatively well-resourced trial conditions turned out to be very challenging, how much more so would it be under routine conditions?

Although not the focus of the article published in GHSP, the authors have published overall results of their trial elsewhere.[2] With pregnancy outcomes as their main endpoint, their multicountry trial failed to find an impact.

An intervention or a technology may have high face validity. That is to say, it may seem like a no-brainer that it should be deployed and that, having done so, one should expect it to produce a benefit. But generally speaking, interventions or technologies are embedded in systems with many other moving parts.

For routine obstetrical ultrasound screening, even in high-income settings it is unclear how much net benefit this yields.[3,4] Based on the results of the First Look

study,[2] conducted in low-income country settings, the investigators succeeded—with considerable effort—in delivering the screening intervention; across the whole study 78% got at least 1 ultrasound and, of those for whom screening detected a high-risk condition, 71% completed referral. However, there were no clear benefits with regard to either increased use of antenatal care or hospital births or improved birth outcomes. In their publication of the main effects of the trial, the authors rightly conclude that "introducing routine [obstetrical] ultrasound screening in low and middle income countries is unlikely to improve outcomes and would potentially pose a large burden on available resources, and detract from other more beneficial services."[2]

In the first instance, an intervention needs to be efficacious. That is to say that it should produce net benefit, at least under optimal conditions. But secondly, it must be feasible to deliver it, without detracting from other services. It is clear that this intervention, in this kind of setting, is not ready for prime time on either count. –*Global Health: Science and Practice*

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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EDITORIAL

Long-Acting HIV Treatment and Prevention: Closer to the Threshold

Matthew Barnhart[a]

Substantial progress has been made toward viable, practical long-acting approaches to deliver HIV treatment and prevention through: (1) continued improvements in long-acting antiretrovirals (ARVs); (2) better innovative delivery systems; and (3) collaboration of willing partners to advance new ARVs. More progress on those 3 fronts is still needed to arrive at the goal of optimized HIV treatment and prevention for all who would benefit—and of finally controlling the HIV epidemic.

WHY WE NEED LONG-ACTING ANTIRETROVIRALS

With 18.2 million people currently receiving HIV treatment, 2.1 million new HIV infections per year, and guidelines recommending that treatment be offered to all 36.7 million people living with HIV,[1] the need to improve HIV treatment and prevention is clear. Long-acting antiretrovirals (ARVs) are one approach that holds great promise to enable major gains in efficiency and effectiveness.

The crucial advantage of long-acting ARVs stems from their potential to improve patients' adherence, which is critical for good outcomes both for treatment and prevention. For treatment, being able to directly administer a long-acting regimen on a monthly or less frequent basis to a patient might minimize risk of treatment failure and resistance due to inconsistent adherence while also potentially reducing the need for costly laboratory tests to monitor treatment efficacy. For prevention, the benefits of long-acting agents compared with daily oral agents may be even more compelling, as oral pre-exposure prophylaxis (PrEP) has been demonstrated to be very effective when used,[2,3] but poor adherence has been reported in several studies,[4,5] limiting impact. In addition to the greater efficacy that long-acting ARVs might bring, they may also have potential to reduce drug costs, since long-acting formulations typically contain agents that are effective at a very low dosage, which, other things equal, can translate into lower manufacturing costs.

New interventions should ideally be highly effective, safe, user-friendly, of suitable duration, inexpensive, socially acceptable, and easy to implement.[6] Several long-acting candidates for HIV prevention and treatment that may meet these criteria are now advancing closer to the threshold for global health impact.

TANGIBLE PROGRESS ON A 1- OR 2-MONTH INJECTABLE

Phase III development is underway for a monthly injectable regimen containing 2 ARVs, the integrase inhibitor cabotegravir and the non-nucleoside reverse transcriptase inhibitor rilpivirine,[7] which are intended to be used as a maintenance regimen among people who have already attained undetectable viral load on a standard 3-drug oral combination. The prospects were supported by a phase II study in which monthly or every-other-monthly injections of these 2 agents as maintenance therapy resulted in similarly high rates of viral suppression compared with patients who remained on oral treatment.[8] Along with injectable cabotegravir's potential use in treatment, it is also now in late-stage clinical development as an every-other-monthly injection for HIV prevention.[9] Cabotegravir is highly effective in preventing HIV acquisition in animal models,[10] and hopes are high that it might be similarly effective in humans.

Drawbacks of Injectable Cabotegravir and Rilpivirine

Although the potential of long-acting ARVs is clear, the current formulations of cabotegravir plus rilpivirine have several suboptimal characteristics that would likely limit their ability to achieve widespread population-level health impact, especially in the low- and middle-income countries of the world where the vast majority of people living with HIV reside. Limitations of these current investigational products include:

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1. Dosing volumes are high (3 mls or more), with injections given intramuscularly in the buttocks, a relatively uncomfortable approach for patients compared with subcutaneous injection.
2. An extended tail of subtherapeutic residual levels of the drug may occur when patients stop the long-acting drugs,[11] which could increase the risk of resistance among patients who are lost to follow-up.
3. Deliverability of injections is resource-intensive, requiring staff time and frequent patient clinic visits with a dosing frequency of every 1–2 months.
4. An oral lead-in period may be required to rule out rare hypersensitivity reactions that might arise, complicating implementation.

Further downsides specific to the rilpivirine formulation component of the treatment regimen include that it requires a cold chain, is not compatible with the commonly used tuberculosis medication rifampicin,[12] and has a relatively weak barrier to resistance.

NEW ARVS MAY HELP OVERCOME THESE DOWNSIDES

The good news, however, is that the cabotegravir and rilpivirine nanoemulsion combination may only be the first-generation forerunner of a much more expansive armamentarium of long-acting antiretroviral agents and delivery systems in the pipeline. One key characteristic for ARV agents to be considered candidates for long-acting systemic use is a low daily dose—the lower the better—in order for the volume of injection or size of implant to be acceptable and the cost to be minimal. Thankfully, in addition to cabotegravir and rilpivirine, there are now several other types of agents with potential to be at least as potent, and perhaps even more so. Further, these long-acting ARV candidates have resistance profiles that are highly complementary to one another. This could allow them to be combined in various ways in regimens for both treatment-naïve and treatment-experienced patients, and also reduces concern about cross-resistance emerging to treatment if some of these agents are used for prevention.

One promising new ARV belongs to a totally new class of ARVs—the capsid inhibitor, GS-CA1, which has extremely high *in vitro* potency. A single injection of a long-acting formulation in animals produced levels for at least 10 weeks well above those necessary to inhibit viral replication.[13] Beyond GS-CA1, there are several other promising new nucleoside/tide reverse transcriptase inhibitors (NRTIs) that may have the necessary potency for long-acting formulations, including EFdA,[14] GS-9131,[15] and tenofovir alafenamide fumarate (TAF).[16] These NRTIs have the advantage that their active intracellular metabolites have very long half-lives, as they are effectively trapped within cells, thereby amplifying their levels and potency. A single oral dose of only 10 mg of EFdA in humans inhibited replication for at least 1 week,[17] and studies in rats involving an implant suggested that greater than 6 months' release of EFdA at adequate levels may be feasible.[17] Although EFdA is only in early-stage development, TAF is another NRTI that is already approved as an oral agent and is now being explored as an agent to be released from several different types of long-acting implants.[18,19] And GS-9131 is an early-stage NRTI prodrug with a structure and potency somewhat similar to TAF, but with a very robust barrier to resistance and unique resistance profile.[15] Of note, a prodrug that has the same active metabolite as GS-9131 has been described that is much more potent *in vitro* (>20 fold) and produced about fivefold greater levels of active metabolites within cells after intravenous injection in dogs compared with GS-9131.[15] Prodrugs of cabotegravir have also been developed that, when formulated as nanoparticles, attained higher levels for a substantially longer duration in target tissues in animal studies.[20] Substantial improvements in potency and pharmacokinetics offered by such prodrug approaches could enable longer duration of actions and/or smaller volumes of implants or injections (Table).

Long-acting ARVs have the potential to improve patients' adherence, which is critical for good outcomes both for treatment and prevention.

Several long-acting ARV candidates are now advancing closer to the threshold for global health impact.

A key characteristic for ARV agents to be considered candidates for long-acting systemic use is a low daily dose.

BROADLY NEUTRALIZING ANTIBODIES: A POSSIBLE ALTERNATIVE TO LONG-ACTING ARVS FOR PREVENTION

In addition to small-molecule ARVs with long-acting potential, it is important to note that broadly neutralizing antibodies (bnAbs) are another type of long-acting agent that holds promise, particularly for prevention. Many highly potent bnAbs have been identified within recent years, which can block HIV viruses from multiple different clades and have been demonstrated to prevent HIV acquisition in macaques.[21] Two large trials are now underway with a bnAb called VRC01 to attempt to demonstrate the scientific

TABLE. Antiretrovirals With Long-Acting Potential: Illustrative Examples from Different Drug Classes

Drug Class	ARV Name	Development Phase	Company
Non-Nucleoside Reverse Transcriptase Inhibitor	Rilpivirine	Phase III injectable (oral agent approved)	Janssen
Integrase Inhibitor	Cabotegravir	Phase III injectable	ViiV
Nucleoside/Nucleotide Reverse Transciptase Inhibitor (NRTI)	EFdA	Phase I	Merck
	Tenofovir alafenamide fumarate (TAF)	Preclinical implant (oral agent approved)	Gilead
	GS-9131	Preclinical/Phase I	Gilead
Capsid Inhibitor	GS-CA1	Preclinical	Gilead

proof of principle that neutralizing antibodies can prevent infections in people.[22,23] Although VRC01 needs to be given intravenously, which would not be practical for a prevention product, combinations of other bnAbs with expanded breadth can neutralize virtually all HIV strains at concentrations that are several orders of magnitude (about 100-fold) lower than VRC01.[24] Further, so-called "LS" (linker substitution) mutations have been made in antibodies, which enhance neonatal Fc receptor binding and thereby greatly extend the *in vivo* half-lives of antibodies,[25] which are already quite long. The combination of these 2 approaches, increasing potency and half-life, could potentially enable antibody-based products to be developed that could be given on a 6-monthly basis by subcutaneous injection for prevention. However, even if bnAbs do show success in human trials, for them to be a competitive alternative long-acting ARV in low-income countries would require demonstrating the feasibility of manufacturing antibodies at high scale and reasonable cost, and also of formulating them in so that they would stable in settings with weak cold-chain infrastructure.

IMPLANTS THAT ARE EASIER TO IMPLEMENT: BIODEGRADABLE AND REFILLABLE APPROACHES

It seems likely that ARVs rather than antibodies may be the first agents widely available as products in low- and middle-income countries.

Given these significant (albeit surmountable) challenges in advancing optimized antibody-based products, it seems likely that ARVs rather than antibodies may be the first agents widely available as products in low- and middle-income countries. Along with the improved low-dose ARVs themselves, the formulation or devices through which long-acting ARVs are delivered will be a critically important component influencing effectiveness, patient acceptability, deliverability, and cost of the ultimate products. Silicone matrix implants are widely used for contraceptive implants and cost less than US$10 for generic versions of an implant that is effective for 5 years.[26] But the daily doses required for long-acting hormonal contraception, which, after an initial burst phase, typically release doses of active agents of 50 micrograms or less per day,[27] is about 2 orders of magnitude less than the daily amount to be released from the current long-acting nanoemulsion of cabotegravir. Thus, even if some of the new very potent, long-acting ARV candidates prove to be substantially more potent in humans than cabotegravir, it seems only to be realistic currently to imagine a duration of up to 1 year, even with an optimal formulation. For implants, this raises an implementation issue, as annual removal and replacement may not be feasible or acceptable, particularly in resource-constrained settings.

One possible approach to address this problem is to make the implants biodegradable, so that they do not require removal. While developing such biodegradable implants has long been a goal for long-acting reversible contraception, it has proved elusive due to several potential challenges, including a prolonged tail of low levels of the active agent and the possibility of dumping large amounts of the agent when the implant terminally biodegrades. However, new designs for biodegradable implants may overcome these challenges for ARVs, such as a thin-film polymer device that contains a thin biodegradable coat and a reservoir filled with an ARV (TAF, noted above, is an ARV that is being used in one investigational device).[18] The ARV diffuses through the membrane,

allowing the reservoir to gradually empty after which the outer coat biodegrades, thereby decoupling the biodegradation from the release and hopefully avoiding dumping or a prolonged tail. In addition to improved designs of biodegradable implants, another approach that might make implants more practicable for implementation is to make them refillable, so that they do not need to be implanted or removed repeatedly. One such refillable device involving nanochannels has been recently described that showed potential to release several different types of ARVs at relatively high dosages.[28]

IMPROVED INJECTION APPROACHES: SIMPLIFYING ADMINISTRATION, REDUCING COST AND DISCOMFORT

Along with improved implants, other approaches should also be explored that may simplify delivery of injectable ARVs, such as devices that allow patients themselves and/or community health workers to more easily deliver long-acting ARVs in a manner through which pain is minimized. In this regard, easier-to-use injection devices have been developed that enable subcutaneous administration of key global health medicines such as the DMPA (depot medroxyprogesterone acetate) contraceptive injectable[29] or oxyctocin,[30] and microneedle-based patches are another promising approach for simplifying delivery of injections.[31] With several candidates in the pipeline that could conceivably have low enough dosages and volumes to enable quarterly dosing for prevention and possibly even treatment, these types of simplified delivery approaches may be important to enable such injections to be implemented in a feasible, affordable, and accessible way, particularly in low-income countries. The cost of manufacturing and supplying the delivery device, while it may seem a small part of the cost for affluent countries, can be a very significant, and sometimes prohibitive, cost for low-income countries. Considering the needs of low-income countries at an early stage of product development when design decisions are being made will be critical to increase the likelihood that long-acting products that come to market will be feasible and affordable for these settings.

COLLABORATIVE EFFORTS TO ADVANCE NEW ARVS

In recent years, public and private partners have intensified collaborative efforts to accelerate the development and introduction of optimized oral ARV regimens for low- and middle-income countries.[32] These efforts have been motivated in part by the desire to minimize the long delays that occurred in the past between when improved ARV agents were made available in affluent countries and when they were introduced in low- and middle-income countries, such as the 7-year lag between 2006 when Atripla (efavirenz, emtricitabine, tenofovir disoproxil fumarate) was adopted as the first once-daily fixed-dose combination in the United States and when a similar generic combination was recommended as the preferred first-line regimen in the 2013 World Health Organization guidelines. Requirements for products for resource-limited settings may be more stringent than for affluent countries for characteristics such as lack of cold-chain dependence, cost of manufacturing, safety in pregnancy, and compatibility with tuberculosis medications. Therefore, developing long-acting products for these parameters, particularly for treatment which would require multiple ARVs, may necessitate especially proactive collaboration and planning, both to design and prioritize the most promising ones, as well as to ensure they are tested in a timely fashion in priority populations such as pregnant women and children.

Developing long-acting products may necessitate especially proactive collaboration and planning among public and private partners.

CONTINUING DOWN THE ROAD TO ULTIMATE SUCCESS

The many people and organizations involved in the successful development of long-acting agents thus far deserve praise for their ingenuity, hard work, and collaboration. With several highly potent agents in the pipeline and a healthy proliferation of many promising technologies for long-acting delivery, the prospects for very long-acting ARVs for treatment and prevention have never been brighter. But to be ultimately successful, ideally with a choice of strong long-acting ARV systems, all the exemplary efforts will need to be vigorously sustained and focused on developing products well fit for implementation not only in in affluent countries but also in low-income ones. If the current promise is fulfilled, long-acting ARVs can be the keystone in finally controlling the HIV epidemic, and many of the technological and scientific advances made in the process will have application to combatting other global health scourges, multiplying the long-term impact of these efforts.

The prospects for very long-acting ARVs for treatment and prevention have never been brighter.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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COMMENTARY

The Importance of Mental Well-Being for Health Professionals During Complex Emergencies: It Is Time We Take It Seriously

Mary Surya,[a] Dilshad Jaff,[b] Barbara Stilwell,[c] Johanna Schubert[b]

We call on humanitarian aid organizations to integrate proven mental health strategies to protect the mental health of their workforce and improve staff capacity to provide care for vulnerable populations. Such strategies could include:

- **Pre-deployment training**
- **Team building**
- **Mindfulness or contemplative techniques**
- **Narrative Exposure Therapy**
- **Art therapy**
- **Physical exercise**
- **Mind-body exercises**
- **Eye movement desensitization and reprocessing**

BACKGROUND

The number of people displaced from their homes or villages as a result of conflict has increased in the last 20 years.[1] As a result, millions have been forced to live far from their homes and communities in refugee camps sometimes for months or years. In 2014, an estimated 60 million refugees worldwide fled war-torn and conflict areas and, of these, more than 60% were forcibly uprooted and displaced within their own countries, according to the United Nations High Commissioner for Refugees (UNHCR).[1] As a result, the demand for an emergency health care response has increased, as has the need for a qualified health care workforce, particularly nurses, physicians, and similarly trained or licensed professionals.[2] Additionally, as the number of man-made and natural disasters have increased, the demand for aid has also risen, especially in settings where complex emergencies have occurred. The World Health Organization (WHO) defines complex emergencies as "combin[ing] internal conflict with large-scale displacements of people, mass famine or food shortage, and fragile or failing economic, political, and social institutions. Often, complex emergencies can be created by natural disasters."[3] With the incidence of global complex emergencies and humanitarian crises rising, local and expatriate health professionals have become increasingly exposed to stress and trauma for protracted periods. This type of stress and psychological trauma can be further defined as primary or secondary: primary stress and psychological trauma involves direct dangers or events that happen to one's self while secondary stress and trauma results from exposure to the experiences of others.[4]

While small steps have been taken to mitigate mental health consequences, more can be done to support the psychosocial well-being of health professionals in crisis situations. This article calls on humanitarian aid organizations to address the mental health of their local and expatriate workforce by integrating proven mental health strategies, including psychosocial support, into health delivery models, thereby protecting, enhancing, and improving staff capacity to provide care for vulnerable populations. In this article, the authors review the possible effects of acute and prolonged stress on the mental health of health professionals, and propose new ways for organizations to ensure that health professionals have the support they need in order to remain effective in the field.

COMPLEX EMERGENCIES AND THEIR CONSEQUENCES ON HEALTH PROFESSIONALS

WHO defines mental health as "a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community."[5] The mental and psychological well-being of health professionals is imperative to their ability to function effectively, particularly when exposed to extreme environments. Such exposure could result in negative mental health consequences, which may in turn affect the functioning and productivity of humanitarian organizations.[6]

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Health professionals, particularly those working in complex and rapidly changing environments, experience high levels of stress due to overwhelming work demands such as long hours, extreme temperatures, unsafe and unfamiliar environments, and exposure to violence and human suffering.[7–10]

Acute episodes of stress can have the beneficial effect of enhancing our reactions and abilities; however, it can also lead to further mental and physical distress. "Stress is positive when it forces us to adapt and thus to increase the strength of our adaptation mechanisms, warns us that we are not coping well and that a lifestyle change is warranted if we are to maintain optimal health."[11] Distress occurs when a stressful or disturbing situation exceeds a person's ability to process it in a healthy way. It can be debilitating[12] and can lead to depression, fatigue, depersonalization, and burnout.[8] Posttraumatic stress disorder (PTSD) occurs when a person who has experienced a shocking or dangerous event continues to suffer clinical symptoms—such as intrusive memories and flashbacks, avoidant behavior, and hyperarousal—beyond the first 4 weeks after the traumatic event has passed.[13] Studies have also shown that health professionals working in extreme settings are vulnerable to symptoms of PTSD as a reaction to assisting traumatized and distressed individuals.[14] This form of secondary traumatic stress—also known as "compassion fatigue" or "vicarious trauma"—usually develops over time through prolonged indirect exposure to traumatic events, such as narratives of firsthand experiences.[15,16] Organizationally, both types of stress can contribute to decreased efficiency and effectiveness.[17]

Evidence shows that chronic stress and posttraumatic stress have serious health consequences.[18–20] Chronic stress can alter the immune system, resulting in immune suppression or excessive inflammatory reactions.[11,21] Stress impacts the immune system through multiple physiological pathways and contributes to chronic illness. Stress can alter sleep patterns and lead to behavioral changes that further influence health, such as using drugs or tobacco or using excessive amounts of alcohol or caffeine.[22] Physical illnesses associated with or exacerbated by stress, include asthma,[23] gastroesophageal reflux disease,[24] irritable bowel syndrome,[25] peptic ulcer disease,[26] coronary artery disease,[27] myocardial infarction,[28] and cancer.[29] Chronic stress and psychological distress may also result in physical pain or other illness such as depression and anxiety.[30,31] Health professionals continue to be at increased risk for depression and burnout after they return from deployments, and studies have found that this risk continues even up to 3 to 6 months after assignment completion.[6] On the basis of the data presented, it is plausible that such factors may affect all those impacted by complex emergencies. Therefore, in order to provide effective interventions in these settings, it is crucial for humanitarian aid organizations to prioritize mental well-being for their staff at both organizational and operational levels.

With the rising incidence of global complex emergencies and humanitarian crises, health professionals have become increasingly exposed to stress and trauma for protracted periods.

Acute episodes of stress can have the beneficial effect of enhancing our reactions and abilities, but it can also lead to further mental and physical distress.

70% to 89% of humanitarian aid workers have experienced mental health issues related to their job, according to some studies.

EPIDEMIOLOGY

Some studies suggest that 70% to 89% of humanitarian aid workers have experienced mental health issues related to their job.[6,17,32] However, researchers noted that "the majority of agencies contacted from the initial list of possible organizations declined participation or did not respond to the inquiry,"[6] suggesting that these figures may not adequately measure the scope of the problem. Research focusing on national health staff engaged in aid work in China found that 30% of national Red Cross nurses experienced PTSD symptoms compared with 10.2% of their nursing peers not involved in disaster relief.[33] Many tools have been developed to measure symptoms of psychological distress, such as anxiety, depression, burnout, emotional exhaustion, depersonalization, substance use disorder, and life or job dissatisfaction. However, just as there is no universal expression of distress, even validated tools for depression and anxiety cannot assess fully and accurately its prevalence. Furthermore, simply identifying and assessing current needs poses a challenge because most stress and distress levels among the workforce are self-reported, but not systematically so. Literature indicates that health professionals who have worked in high-risk or high-stress situations are not tracked after service, which means that self-reporting is most likely the way that ongoing mental health needs would be known or met.[10] According to a survey carried out by UNHCR among its own staff, only one-quarter of the staff who had suffered a life-threatening critical incident had any form of longer-term follow up. UNHCR recommended investment in an interactive confidential website, which would provide access to a self-assessment tool and Skype consultation with an external therapist.[17]

FAILURE TO IMPLEMENT CURRENT GUIDELINES

Introducing systems and processes to support evidence-based practices on an organizational level is a priority for recognizing and addressing the psychosocial needs of health professionals and members of the populations affected by crisis. The Inter-Agency Standing Committee (IASC) has developed guidelines for organizations to address the mental health and psychosocial support needs of their workforce. The guidelines outline many key actions, including[34]:

- Ensuring availability of a concrete plan to protect and promote staff well-being, specific to the emergency
- Ensuring national and international staff receive adequate information and training in the emergency context to prepare them for their role
- Addressing work-related stressors
- Ensuring access to health care and psychosocial support
- Providing support, such as psychological first aid, to staff for all critical incidents
- Ensuring availability of post-deployment support

Some organizations have policies in place similar to *UNHCR's Mental Health and Psychosocial Support for Staff*, which outlines the need for psychosocial support and highlights 8 principles of good practice.[17] In addition, the Anteres Foundation's *Managing Stress in Humanitarian Aid Workers, Guidelines for Good Practice* identified key principles for organizations, including policy, screening and assessment, preparation and training, monitoring, ongoing support, crisis support, end-of-assignment support, and post-assignment support.[35] However, according to surveys conducted among several humanitarian aid agencies, there was only 35% to 68% compliance with these principles organizationally.[17] While international guidelines on addressing the mental health and psychosocial support needs of humanitarian aid workers are in place, they are not being successfully implemented.

While international guidelines on addressing the mental health and psychosocial support need of humanitarian aid workers are in place, they are not being successfully implemented.

ADDRESSING THE MOST PRESSING CHALLENGES

Four of the most pressing challenges for implementation of mental health interventions for health professionals in complex settings include (1) mental health stigma around relief work, (2) limited organizational capacity to provide the necessary mental health support for their staff, (3) structural inequalities, and (4) lack of mental health services in mission countries and globally.

Mental Health Stigma and Attitudes Around Relief Work

In some cases, a culture of "heroism" surrounds relief and rescue work. Because the construct is based on a mission of helping others, it perpetuates the myth that the "heroes" offer help but do not require any support for themselves.[36] Institutionally, this stance may be reinforced as the overwhelming volume of work limits the time and resources available for self-reflection and processing of difficult situations. An attitude of self-sacrifice may also creep into the ego of many relief workers leading to a discomfort with being physically and emotionally comfortable while others are suffering. As one field-based health professional notes in her blog, "I have come to see that when I am faced with a waiting room full of patients who themselves are likely hungry, it is really OK to break for a cup of tea and an oatmeal nut bar, if that is what it takes to keep me 'buoyant'."[37] Through this experience, the writer realized that in taking time to address her own physical health she would be better able to help others. In order to develop effective mental health interventions for health professionals, the range of stigma and attitudes around relief work should be acknowledged and futher examined.

Organizational Capacity

Many NGOs lack appropriate support measures for their staff.[38] For some NGOs, support and access may be limited by financial constraints, resulting in a near absence of effective formal mental health services, especially in countries where complex emergencies occur. Access is also limited by the poor integration of psychosocial support into the structure of many humanitarian organizations. Even where staff welfare services exist, utilization is not always guaranteed due to employees' lack of time, skepticism about trustworthiness and confidentiality, or resistance to admit the need for help.[39,40] Understanding the protective factors and coping mechanisms available to health professionals is important. Many resources have been reported as possible moderators of or risk factors for the effects of chronic and traumatic stress during deployment. Social

support has been identified as a moderator of the effects of trauma exposure leading to PTSD for humanitarian workers[41] and inadequate communication with family and friends has been identified as a risk factor for depression.[42,43] Another factor related to the development of depression among health workers is lack of support from within the aid organization.[42] This lack of support is compounded by the fact that communication in complex emergencies is unreliable at best and reaching outside the country and organization may not be an option for individuals seeking support.

Structural Inequalities

Inequality between staff members. While the entire health workforce can experience stress and distress, those who have known personal injustice may be at the highest risk. Health workers who have experienced paternalism, harassment, racism, homophobia, religious persecution, or any other perceived injustice may be predisposed to feeling overwhelmed or traumatized when they witness abuse during a field assignment. As was pointed out in the IASC guidelines, "emergencies erode normally protective supports, increase the risk of diverse problems and tend to amplify preexisting problems of social injustice and inequality."[34] This is as much true for the population affected by the emergency as it is for the health care responders.

Taking gender as an example, research on demographic risk factors for PTSD in the general population suggests that women are twice as likely as men to develop this condition in their lifetime.[44] Being a woman also increases the risk of developing depression and anxiety.[45] These risks can be exacerbated when working in complex and stressful settings with no support. Contributing to these statistics is likely the experience women have in their workplaces. For example, responsibility without power is likely to be highly stressful, and this situation can happen when organizations fail to offer women equity within positions of power or adequate levels of decision making. Moreover, organizations may fail to protect the interest or safety of women who are at risk of experiencing paternalism, harassment, exploitation, violence, or abuse resulting from the cultural subordination of women. Without the opportunity for self-reflection, a systemized means to report abuse or discrimination, or the time for perceived injustices to be respectfully acknowledged, women may experience higher levels of distress due to a lack of adequate means of support within their organization. Research in this area is scarce.

Opportunities for staff feedback. Without feedback, organizations are left without the information or pressure needed to examine and adjust their policies and structure. Due to the increasing trend of short-term contracts in international organizations, physically and emotionally exhausted staff might drop out at the end of their term for reasons unnoticed by their organizations, as few organizations assess the reasons why short-term staff do not not reapply for positions. Ideally, aid workers' social networks and health systems will help with psychosocial aftercare once they leave the organization or sector. Currently, no data are available to show what percentage of international humanitarian workers leave the sector for psychosocial reasons, or how long individuals need, on average, to recover before taking on a new position or occupation. Even if organizations receive feedback, those without a formal process to respond and implement change may be hesitant to acknowledge grievances for fear of being discredited and losing contracts. For example, if concerns by any one group are not being addressed it is likely to decrease motivation and productivity, thus limiting the ability of the organization to effectively accomplish their objectives and mission. This lack of feedback may also perpetuate structural inequalities within the organization by leaving the concerns unrecognized or unaddressed. Ultimately, this may affect the organization's credibility and decrease its chances for future funding or qualified applicants. When an organization is one of the few available to offer support during a crisis, then it may seem especially challenging to dedicate time or resources to address structural inequalities.

Lack of Mental Health Services in Mission Countries and Globally

Formal mental health services in low- and middle-income countries are almost nonexistent. There are only 9 mental health providers per 100,000 people globally; an extra 1.7 million mental health workers are needed in low- and middle-income countries alone.[46] Even in wealthy countries, 40% to 60% of people with severe mental disorders do not receive adequate care.[47] Despite the lack of resources, lessons may be learned from countries where official mental health services are not yet fully functioning but informal community-level psychological support has been implemented. Well-organized

Formal mental health services in low- and middle-income countries are almost nonexistent, and even in wealthy countries, 40% to 60% of people with severe mental disorders do not receive adequate care.

psychological support at the community level can be particularly effective because it is usually adapted to meet a community's needs and resources. However, for an international health worker with a unique spectrum of personal experience, this may make care especially difficult to access or even understand, depending on the specific culture of mental health care. Additionally, when social structures break down due to a local crisis, implementation or reconstruction of informal support systems may be more difficult, and perceptions may be that such services are for local beneficiaries, rather than international aid workers.

STRATEGIES, TOOLS, AND RESOURCES

Strengthening the capacity for resilience is key to mental health for global health professionals and local populations alike. Resilience, in this context, is the ability to adapt and respond to changing circumstances while maintaining physical and emotional wellness. Several specific evidence-based practices have been successful to reduce or mitigate distress; decrease specific trauma-related symptoms, such as anxiety, depression, PTSD, or burnout; and improve resilience among health workers or others involved in complex emergencies. Some practices can be used for self-support after training, while others should be used by therapists with specialist training:

- **Pre-deployment training** is a way of offering preparation for unexpected or unsettling situations that may arise during a particular health care response to disaster and providing opportunities for pre-deployment self-reflection and awareness of potential vulnerabilities.[48] Psychological first aid manuals and a number of other well-organized guides are available, including *Psychological First Aid: Facilitator's Manual for Orienting Field Workers*.[49]
- **Team building** involves strengthening communication and relationships and enhancing a sense of belonging between coworkers, which may result in improved delivery of care and overall outcomes.[50] Building a sense of belonging in the workplace, specifically, has been shown to be protective against organizational stressors and is an important strategy in the cultivation of resilience.[50]
- **Mindfulness or contemplative techniques**, such as Mindfulness-Based Stress Reduction (MBSR) practices and Progressive Muscle Relaxation,[51] use stress reduction techniques based on mindfulness and (self) compassion and include practices such as body scan and sitting meditation.[52] Relaxation response training is another technique that has been proven to help reduce stress and improve health.[53]
- **Narrative Exposure Therapy** (NET) is based on principles of behavioral and cognitive therapy and includes a wide range of activities, such as motivational interviewing, storytelling for resilience, and reflecting on and reconceptualizing traumatic experiences.[54] NET has been used in the context of natural disasters to successfully treat symptoms including PTSD, anxiety, depression, general mental stress, and increased posttraumatic growth.[55]
- **Art therapy** involves a range of techniques that have been proven to enhance creativity, flexibility, problem solving, and coping skills, making this style of therapy a good fit for relief workers facing uncertain circumstances.[56] One study showed similar outcomes for art therapy as a cognitive behavioral intervention for stress and trauma.[57] Art therapy has also been used successfully among social workers in the context of war, suggesting that it would be feasible in complex or dangerous situations.[58]
- **Physical exercise** can be particularly problematic for people working very long exhausting hours, especially in settings with temperature extremes and limited access to safe space. Activities that involve minimal equipment such as jump roping, hula hooping, and dance, have been shown to reduce stress, burnout, and compassion fatigue.[59,60]
- **Mind-body exercises** are deliberate muscle movements combined with breathing and mental focus. Specific techniques, such as yoga[61] and Tai chi,[62] can both be effective against the ill effects of stress and build resilience.
- **Event-triggered counseling sessions** using techniques such as cognitive behavioral therapy, either in-person or using a telemedicine approach, attempt to challenge negative thoughts and promote resilience through cognitive flexibility and restructuring.
- **Eye movement densensitization and reprocessing** is a highly effective therapeutic short-term intervention to process both fresh and old traumatic experiences on the level of memory networks and the limbic system.[63,64]

IDENTIFYING INNOVATIVE SOLUTIONS

Design thinking is "a systematic innovation process that prioritizes deep empathy for end-user desires, needs and challenges to fully understand a problem in hopes of developing more comprehensive and effective solutions."[65] Any psychosocial intervention developed to address distress among health professionals could benefit from integrating design-thinking strategies by, for example, integrating open-ended questions into the structure of an intervention and ensuring the program has the flexibility to react to feedback. Feedback questions might include: What does it look like when you feel stressed? Which parts or components of your day are the most stressful? What coping or relaxation strategies are effective for you? How might this organization support your coping techniques? A design-thinking approach allows organizations the opportunity to shift from problem-based single-solution thinking to a more interactive process-based style—providing program designers with the tools to address diverse experiences, expressions, and manifestations of stress and aid with coping and healing strategies. Design-thinking techniques can also be used to facilitate individual feedback and organizational reactivity, allow for opportunities to customize psychosocial support practices, and "improve capacity for uncovering unforeseen changes and unintended consequences."[66] Innovative feedback mechanisms also have the potential to offer opportunities to explore and address structural inequalities within an organization in manageable ways. Finally, the quality of management on all organizational levels plays a crucial role in creating an enabling environment for stress prevention and recovery from high-intensity deployments, and creates a validating culture where staff feel empowered to talk about their personal challenges, including organizational shortcomings, without fear of consequences to future employment.

DISCUSSION

The significant increase in complex global emergencies has resulted in prolonged stressful conditions for many health workers as (and after) they respond to humanitarian operations. While it is clear that chronic stress and distress are unhealthy and unsustainable, this review reveals that relief workers are not routinely provided with the adequate psychosocial support, tools, and strategies they need in order to be effective and remain healthy. While coping methods emerge naturally in response to stress and distress, not all responses are healthy. The literature demonstrates that chronic high levels of stress and distress contribute to *unhealthy* coping methods, resulting in poor health and decreased overall efficiency. Even though it is clearly in the interest of humanitarian organizations to provide support to health professionals who are stressed, we have found that such care is still scarce. The basic aims of supporting the health workforce under difficult circumstances includes cultivating more responsible engagement in fieldwork and encouraging cooperation, creativity, adaptability, and teamwork. Another aim of psychosocial support is to help health care providers develop their skills to become more focused practitioners and compassionate healers. Resilience and relaxation training, as well as psychosocial support, is also beneficial for organizations, particularly with regard to increased retention and enhanced productivity.

Chronic high levels of stress and distress contribute to unhealthy coping methods, resulting in poor health and decreased efficiency.

Organizations working in this context must prioritize psychosocial support and ensure that it is built into each component of their infrastructure:

- Screening and assessing (Many psychological screening tools are currently available but not widely or systematically used.)
- Preparation and training
- Monitoring
- Ongoing support
- Crisis support
- End-of-assignment support
- Post assignment support
- Policy framework

Strong organizational support has the potential to strengthen mental health and well-being during the process of rebuilding after a crisis. Using local mental health resources in field assignments is an admirable way to provide psychosocial support during and after a crisis or disaster. Unfortunately, use of local mental health resources may not always feasible due to poor or insufficient levels of services, disabled services as a result of a crisis, the types of services or infrastructure being targeted, safety and security concerns causing inaccessibility of services, or cultural, religious, and linguistic barriers.[67] The need for more focused actions and joint opportunities tailored to psychosocial needs has never been greater. The Box summarizes strategies to

BOX. Strategies to Improve Mental Well-Being of Health Professionals During Complex Emergencies for Organizations Working in These Settings

- Train all expatriate and local staff on mental health first aid and selected peer supporters in counseling
- Standardize methods for prevention, reporting, and referral
- Recognize and address mental health issues
- Organize various activities to raise awareness about mental health issues, such as online courses, workshops, and trainings
- Explore opportunities within the existing local health or public service sector and strengthen (or build) those services
- Consider community-based training and intervention for local and international staff
- Conduct studies and systematic research to understand the size of the problem and to develop effective mechanisms
- Adapt and use available resources and techniques
- Improve and increase information sharing and communication related to mental health and well-being between organizations
- Set up comprehensive and supervised peer support systems to provide low-threshold contact points for affected staff members
- Consider the use of design-thinking techniques to integrate individual perspectives with organizational structure and to improve organizational response, flexibility, and adaptation.

address key challenges to improving the well-being of health professionals during complex emergencies.

CONCLUSION

Globally, human safety and security will continue to be affected by ongoing complex emergencies. While the information and tools needed to improve the quality of psychosocial support for health professionals, and those with whom they interact, in these complex situations are available, substantial gaps related to mental health support for these health professionals still exist. Organizations and agencies must integrate these strategies into relief efforts, in order to improve the health, resilience, responsibility, creativity, and effectiveness of the workforce, while at the same time building organizational capacity to address organizations with whom they work. The time has come to address these issues by integrating psychosocial support into health delivery models for the health workforce. Doing so will help to protect the health of the workforce and improve their capacity to provide optimal care for the world's most vulnerable people.

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COMMENTARY

Integrated Person-Centered Health Care for All Women During Pregnancy: Implementing World Health Organization Recommendations on Antenatal Care for a Positive Pregnancy Experience

Sarah de Masi,[a] Maurice Bucagu,[b] Özge Tunçalp,[a] Juan Pablo Peña-Rosas,[c] Theresa Lawrie,[a] Olufemi T Oladapo,[a] Metin Gülmezoglu[a]

The 2016 WHO guideline on routine antenatal care (ANC) recommends several health systems interventions to improve quality of care and increase use of services including:

- **Midwife-led continuity of care throughout the antenatal, intrapartum, and postnatal periods**
- **Task shifting components of ANC, including promotion of health-related behaviors and distribution of nutrition supplements**
- **Recruitment and retention of health workers in rural and remote areas**
- **Community mobilization to improve communication and support to pregnant women**
- **Women-held case notes**
- **A model with a minimum of 8 antenatal care contacts**

In 2015, United Nations member states adopted the Sustainable Development Goals (SDGs) in order to continue the momentum of the Millennium Development Goals and address a broader range of development issues. The World Health Organization (WHO) identified target 3.8, universal health coverage, as the key to achieving all other health-related SDGs.[1] To that end, the Every Woman Every Child movement developed the *Global Strategy for Women's, Children's, and Adolescents' Health (2016–2030)*[2] with the aim of ending all preventable deaths of women, children, and adolescents and ensuring their health and well-being. The strategy provides a framework for countries to achieve the highest attainable standards of health for all women, children, and adolescents to "Survive, Thrive and Transform."[2]

Building on the goal of achieving universal health coverage, WHO developed a global strategy for people-centered and integrated health services,[3] recommending that countries consciously consider the perspectives of individuals, families, and communities, and respond to their preferences and needs. Furthermore, "WHO envisions a world where every pregnant woman and newborn receives quality care throughout pregnancy, childbirth and the postnatal period,"[4] underscoring that the provision of integrated high-quality antenatal care (ANC) services is a critical part of the global agenda of achieving equitable, people-centered universal health coverage.[5,6]

In November 2016, WHO issued a new global guideline on routine ANC: *WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience*.[5] The main focus of the guideline is the prioritization of person-centered health and well-being in accordance with a human rights-based approach. The guideline defines having a positive pregnancy experience as[5]:

> *maintaining physical and sociocultural normality, maintaining a healthy pregnancy for mother and baby (including preventing or treating risks, illness and death), having an effective transition to positive labour and birth, and achieving positive motherhood (including maternal self-esteem, competence and autonomy).*

This is the first WHO guideline on routine ANC to consolidate components of the essential core package of services and care that women and adolescent girls should receive throughout the pregnancy period. It is comprehensive in the sense that alongside prevention,

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The main focus of WHO's new global guideline on routine ANC is the prioritization of integrated person-centered health and well-being.

detection, and management of pregnancy-related conditions, it also includes recommendations on health promotion, nutritional interventions, and prevention of concurrent diseases, such as malaria, HIV, and tuberculosis. This integrated approach aims to provide pregnant women with a universal package of quality care that ensures effective evidence-based practices, along with timely and relevant information and support during pregnancy.

Intended to inform health care policies and clinical protocols, the 2016 WHO ANC recommendations are based on the most current evidence available and will be updated as new evidence emerges. Because ANC is currently an underutilized platform for maternal and perinatal health in many settings, we expect that through the implementation of these recommendations within an integrated quality service delivery approach, ANC can be a driver for health systems strengthening. The ANC recommendations were deliberately designed to be adaptable and flexible so countries with different health care settings, burdens of disease, social and economic situations, and health systems structures could ensure that the needs of their populations are met. These factors will inform the adaptation of the 2016 ANC model in terms of the content of the service package and determining *who* provides the care, *where* the care is provided, and *how* the care is provided to meet pregnant women's needs.

The WHO ANC recommendations were deliberately designed to be adaptable and flexible to meet different countries' needs.

The new guideline adopts a health systems approach, recommending several interventions to improve the quality of care delivery, which should lead to increased utilization and quality of ANC services (Table). At the same time, the guideline also aims to improve communication with, and support for, pregnant women throughout the antenatal period. This commentary focuses on health systems-related recommendations that are essential to the WHO ANC guideline implementation in countries.

DELIVERY OF ANTENATAL CARE SERVICES

Recruitment and retention of staff is an important strategy to providing good-quality ANC services in rural and remote settings.

Midwifery-led continuity of care is a model of providing ANC that has been proven to improve maternal and newborn outcomes.[10] In this model, a known and trusted midwife or a small group of known midwives are the primary providers of ANC for healthy pregnant women. The midwife provides support for the woman throughout the antenatal, intrapartum, and postnatal periods, facilitating a healthy pregnancy and childbirth as well as healthy parenting practices. Because this model of care requires an adequate number of skilled practicing midwives to ensure the continuum and quality of ANC, policymakers need to ensure that a well-functioning midwifery program is in place before scaling up the implementation of this model. Group ANC, provided by qualified health care professionals, integrates the usual individual pregnancy health assessment with tailored group educational activities and peer support, and might be an effective and feasible option to complement services offering individual ANC; however, at this point, group ANC is recommended only in the context of research.

Women highly value continuity of care. In low-resource settings, where the health workforce is often disproportionate to population needs and midwifery care may not yet be sufficiently available, task shifting components of ANC delivery can be a feasible way of improving women's access to ANC services and continuity of care, while policymakers work toward midwifery-led care for all women. In such contexts, the new WHO ANC guideline recommends task shifting the promotion of health-related behaviors for maternal and newborn health to a broader range of cadres, including lay health workers, auxiliary nurses, nurses, midwives, and doctors. The health-related behaviors covered by the recommendations include birth preparedness and complication readiness, insecticide-treated bed net use, companionship in labor and childbirth, nutritional advice, nutritional supplements, HIV testing during pregnancy, exclusive breastfeeding, postnatal care and family planning, and immunization. Additionally, the distribution of recommended nutritional supplements and intermittent preventative treatment in pregnancy for malaria prevention can be delivered by auxiliary nurses, nurses, midwives, and doctors. It is important that services provided as part of community outreach, including health promotion activities by lay health workers, are recognized and integrated into the health care system and that the task shifting occurs within a team approach, where regulatory support is provided and the mandate of all health workers involved is clearly defined.

Recruitment and retention of staff poses a major challenge to providing good-quality ANC services in rural and remote settings. Therefore, policymakers are encouraged to consider educational, regulatory, financial, personal, and professional support interventions to recruit and retain qualified health workers in such areas. Providing a safe and good working environment, including

TABLE. Health Systems Interventions to Improve the Use and Quality of Antenatal Care as Recommended by the 2016 WHO Guideline on Routine Antenatal Care[5]

Recommended Interventions	Description
Midwife-led continuity of care	Midwife-led continuity-of-care models, in which a known midwife or small group of known midwives supports a woman throughout the antenatal, intrapartum, and postnatal continuum, are recommended for pregnant women in settings with well-functioning midwifery programs.
Group antenatal care	Group antenatal care provided by qualified health care professionals may be offered as an alternative to individual antenatal care for pregnant women in the context of rigorous research, depending on a woman's preferences and provided that the infrastructure and resources for delivery of group antenatal care are available.
Task shifting components of antenatal care delivery[a]	Task shifting the promotion of health-related behaviors for maternal and newborn health[b] to a broad range of cadres, including lay health workers, auxiliary nurses, nurses, midwives, and doctors, is recommended.
	Task shifting the distribution of recommended nutritional supplements and intermittent preventive treatment in pregnancy for malaria prevention to a broad range of cadres, including auxiliary nurses, nurses, midwives, and doctors, is recommended.
Recruitment and retention of staff in rural and remote areas[c]	Policymakers should consider educational, regulatory, financial, and personal and professional support interventions to recruit and retain qualified health workers in rural and remote areas.
Community-based interventions to improve communication and support	The implementation of community mobilization through facilitated participatory learning and action cycles with women's groups is recommended to improve maternal and newborn health, particularly in rural settings with low access to health services.[d] Participatory women's groups represent an opportunity for women to discuss their needs during pregnancy, including barriers to reaching care, and to increase support to pregnant women.
	Packages of interventions that include household and community mobilization and antenatal home visits are recommended to improve antenatal care utilization and perinatal health outcomes, particularly in rural settings with low access to health services.
Women-held case notes	It is recommended that each pregnant woman carries her own case notes during pregnancy to improve continuity, quality of care, and her pregnancy experience.
Antenatal care contact schedules	Antenatal care models with a minimum of 8 contacts are recommended to reduce perinatal mortality and improve women's experience of care.

[a] Recommendations adapted and integrated from WHO (2012).[7]
[b] Including promotion of the following: care-seeking behavior and antenatal care utilization, birth preparedness and complication readiness, sleeping under insecticide-treated bed nets, skilled care for childbirth, companionship in labor and childbirth, nutritional advice, nutritional supplements, other context-specific supplements and interventions, HIV testing during pregnancy, exclusive breastfeeding, postnatal care and family planning, and immunization according to national guidelines.
[c] Recommendation adapted and integrated from WHO (2010).[8]
[d] Integrated from WHO (2014).[9]

appropriate equipment and supplies, supportive supervision and mentoring, and relevant legal support, can motivate qualified health workers to both accept and remain working in rural and hard-to-reach environments.

In rural settings with low access to health services, community mobilization through facilitated participatory learning and action cycles with women's groups is also recommended, where feasible, to improve maternal and newborn health in

these settings. These groups give women the opportunity to build close relationships with other pregnant women, enhance their sense of empowerment, and discuss their pregnancy needs and strategies for accessing care. Packages of interventions that include household and community mobilization are recommended and should be implemented alongside health systems strengthening interventions. Although antenatal home visits by lay health workers might be a helpful component of these packages, they should not replace regular ANC contacts.

The WHO ANC guideline recommends that pregnant women carry their own case notes.

Women should be empowered to access their own health-related information; to that end, the ANC guideline recommends that pregnant women carry their own case notes. In many low- and middle-income countries, this is already common practice as these case notes are often the only medical records available. Qualitative evidence suggests that women are likely to favor carrying their own case notes, and that this practice improves the continuity, quality, and experience of care for pregnant women.[11] However, careful consideration needs to be taken as to what information is included in the case notes, as certain sensitive information, such as HIV status, can cause stigma and discrimination if the information is not kept confidential.

A minimum target of 8 ANC contacts is associated with fewer perinatal deaths and a more positive pregnancy experience for women.

The 2016 WHO ANC guideline recommends an increase in the number of ANC contacts between the woman and the health care provider from 4 in the previous model to a minimum of 8 contacts. This recommendation is based on evidence that a minimum target of 8 contacts is associated with fewer perinatal deaths and a more positive pregnancy experience for women.[12] The word "contact" is purposely used for this new recommendation, as it implies a more active connection between the woman and the ANC provider that allows sufficient time for provision of individualized person-centered care, including psychosocial and emotional support, for the woman. The 2016 WHO ANC model recommends the first contact occurring within the first trimester/12 weeks of gestation; 2 contacts in the second trimester, at 20 and 26 weeks; and 5 contacts in the third trimester, at 30, 34, 36, 38, and 40 weeks. The reason for increasing the number of contacts during the third trimester is that this is the period when the mother and unborn fetus are most at risk. Through increased contact many asymptomatic complications, such as hypertension, can be detected and managed, resulting in improved pregnancy outcomes. While all of the recommendations have been mapped to the 8 contacts in order to facilitate implementation of the guideline, countries still have considerable flexibility to determine how best to implement the recommendations and adapt the schedule to include practices and interventions best suited for their country context. These 8 contacts also provide enhanced opportunities for continuity of care for pregnant women and increased communication and trust within the woman–provider relationship. Quality of care is paramount, as evidence shows that if the quality of ANC is inadequate women do not attend ANC services regardless of recommended number of contacts in the model and, as a result, health benefits are reduced.

IMPLEMENTING THE NEW RECOMMENDATIONS

The integrated approach recommended in the new guideline gives countries the opportunity to use the ANC platform more effectively and efficiently, by providing comprehensive access to other relevant services, including those related to HIV, malaria, and tuberculosis. While the implementation of nationwide ANC programs in settings where health systems are already overstretched will be a challenge, investment in good-quality integrated ANC services in low- and middle-income countries will have far-reaching benefits for individual women, families, communities, and countries.

Investment in building the capacity of health care providers and increasing the number of midwives is absolutely imperative for improving the quality of ANC delivery and service utilization. Empowered health care professionals with excellent clinical and interpersonal skills are needed to provide quality ANC services. Therefore, staff pre- and in-service training programs should not only focus on evidence-based practices but also emphasize the need for positive staff behavior and attitudes. By receiving training in communication and respectful care, providers would have the necessary interpersonal skills to deliver individualized person-centered care. This will ultimately play a crucial role in the successful implementation of the ANC guideline.

In the context of a universal health coverage framework, the extent to which the new ANC guidelines will be adopted and scaled up will depend on nationally driven processes for the implementation and financing of comprehensive country ANC programs—under strong government leadership in long-term partnerships with

key stakeholders. As recommended by WHO, countries should raise sufficient funds to support scale up, reduce reliance on direct payments from users to finance services, and improve the efficiency and equity of ANC services. Equally important to the implementation process is the active involvement of national professional organizations, end-users such as health care professionals, women's organizations, and community representatives to further increase chances of program sustainability.

WHO and partners are currently developing a set of policy briefs and an implementation guide for facilitating the adoption and adaptation of the *WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience*.[5] Regional dissemination of the new ANC guideline is underway in various WHO regions in partnership with Ministries of Health, other United Nations agencies, The Global Fund to Fight AIDS, Malaria and Tuberculosis, and other partner and professional organizations. WHO will continue to work with countries and partners to support the development of tools for implementation, monitoring, and evaluation of the WHO ANC model.

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ORIGINAL ARTICLE

Effect on Neonatal Mortality of Newborn Infection Management at Health Posts When Referral Is Not Possible: A Cluster-Randomized Trial in Rural Ethiopia

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Health Extension Workers (HEWs), in general, properly provided antibiotic treatment of possible severe bacterial infections in newborns at the health post level. But only about half of newborns estimated to have infections in the intervention area received treatment by HEWs, and home visits and referrals declined in the final months of the study. Cluster-level analysis suggests a mortality reduction consistent with this level of treatment coverage, although the finding did not reach statistical significance.

ABSTRACT

Background: The World Health Organization recently provided guidelines for outpatient treatment of possible severe bacterial infections (PSBI) in young infants, when referral to hospital is not feasible. This study evaluated newborn infection treatment at the most peripheral level of the health system in rural Ethiopia.

Methods: We performed a cluster-randomized trial in 22 geographical clusters (11 allocated to intervention, 11 to control). In both arms, volunteers and government-employed Health Extension Workers (HEWs) conducted home visits to pregnant and newly delivered mothers; assessed newborns; and counseled caregivers on prevention of newborn illness, danger signs, and care seeking. Volunteers referred sick newborns to health posts for further assessment; HEWs referred newborns with PSBI signs to health centers. In the intervention arm only, between July 2011 and June 2013, HEWs treated newborns with PSBI with intramuscular gentamicin and oral amoxicillin for 7 days at health posts when referral to health centers was not possible or acceptable to caregivers. Intervention communities were informed of treatment availability at health posts to encourage care seeking. Masking was not feasible. The primary outcome was all-cause mortality of newborns 2–27 days after birth, measured by household survey data. Baseline data were collected between June 2008 and May 2009; endline data, between February 2013 and June 2013. We sought to detect a 33% mortality reduction. Analysis was by intention to treat. (ClinicalTrials.gov registry: NCT00743691).

Results: Of 1,011 sick newborns presenting at intervention health posts, 576 (57%) were identified by HEWs as having at least 1 PSBI sign; 90% refused referral and were treated at the health post, with at least 79% completing the antibiotic regimen. Estimated treatment coverage at health posts was in the region of 50%. Post–day 1 neonatal mortality declined more in the intervention arm (17.9 deaths per 1,000 live births at baseline vs. 9.4 per 1,000 at endline) than the comparison arm (14.4 per 1,000 vs. 11.2 per 1,000, respectively). After adjusting for baseline mortality and region, the estimated post–day 1 mortality risk ratio was 0.83, but the result was not statistically significant (95% confidence interval, 0.55 to 1.24; P=.33).

Interpretation: When referral to higher levels of care is not possible, HEWs can deliver outpatient antibiotic treatment of newborns with PSBI, but estimated treatment coverage in a rural Ethiopian setting was only around 50%. While our data suggest a mortality reduction consistent with that which might be expected at this level of coverage, they do not provide conclusive results.

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INTRODUCTION

Serious infections such as sepsis, meningitis, and pneumonia are estimated to cause more than 550,000 newborn deaths each year.[1] Most of these deaths could be averted by preventive measures, such as hygienic practices and cord care, as well as by timely identification of signs of infection and treatment with appropriate antibiotics.[2,3] In low-income, high-mortality settings, however, access to hospitals where treatment can be provided is often difficult or impossible for many newborns with signs of infection.[4–7]

Based on new evidence from the African Neonatal Sepsis Trial (AFRINEST) and the Simplified Antibiotic Therapy Trial (SATT),[8–10] the World Health Organization (WHO) recently provided guidelines for the treatment of possible severe bacterial infections (PSBIs) in infants where referral to hospital is not feasible.[11] These guidelines recommend that trained health care providers give outpatient treatment for newborns and young infants 0–59 days of age with PSBI using simplified regimens; for infants with clinical severe infection, the recommended regimen is injectable gentamicin plus oral amoxicillin, and for infants with isolated rapid breathing, oral amoxicillin only. These recommendations were classified as "strong" according to WHO Grading of Recommendations Assessment, Development, and Evaluation (GRADE) criteria.[12] The primary outcome in the carefully conducted AFRINEST and SATT trials was "treatment failure," including clinical outcomes in addition to death. However, there is limited experience implementing this approach in routine, primary health care settings, and the mortality impact is not known.

In Ethiopia, facility-based care, and in particular hospital-based care, is not accessible to much of the population. Only 40% of women receive antenatal care, only 15% deliver with a skilled attendant, and just 12% receive postnatal care within 2 days after birth.[13] In 2003, Ethiopia launched the national Health Extension Program to address access issues.[14] Under this program, nearly 34,000 Health Extension Workers (HEWs) have been deployed to 14,000 health posts, the most peripheral level of the health system.[15] The Health Extension Program includes 16 packages of mostly preventive health interventions delivered by HEWs at health posts and through community outreach. The program initially provided limited curative services, but in mid-2010 it introduced integrated community case management (iCCM) for treatment of pneumonia, diarrhea, malaria, and severe acute malnutrition in children 2–59 months.[16]

Between 2008 and 2013, the Community-Based Interventions for Newborns in Ethiopia (COMBINE) trial evaluated the impact of a regimen of intramuscular gentamicin and oral amoxicillin—a regimen similar to the new WHO recommendations—given by HEWs in Ethiopia to newborns and young infants with signs of PSBI when referral was not possible. The purpose of this article is to present findings on the feasibility and mortality impact of this approach. When this trial was conceived, families were required to seek care for infections in newborns and young infants at higher-level facilities. With the high neonatal mortality rate in Ethiopia (37 deaths per 1,000 live births according to the 2011 Demographic and Health Survey[17]), treating newborns closer to home could avert many preventable deaths.

The COMBINE trial evaluated the impact of a simple antibiotic regimen given by HEWs in Ethiopia to newborns and young infants with signs of possible severe bacterial infection when referral was not possible.

WHO recently provided guidelines for the treatment of possible severe bacterial infections in infants where referral to hospital is not feasible.

METHODS

Study Setting

COMBINE was conducted in a population of 640,000 in 3 zones—East Shoa and West Arsi in Oromia Region and Sidama in Southern Nations, Nationalities, and People's Region (SNNPR)—that are demographically and socioeconomically similar to Ethiopia's agrarian regions where 85% of the country's people live. Ethiopia's tiered primary health care system includes hospitals (approximately 1 per 100,000 population), health centers (about 1 per 25,000), and health posts (about 1 per 5,000). Health centers are usually staffed by several nurses. The satellite health posts are staffed by 2 HEWs, who are females with 10th-grade education recruited from the communities they serve. The Health Extension Program provides HEWs with 1 year of training.

Study Design

COMBINE was a 2-arm, cluster-randomized trial evaluating the impact of making newborn infection management available at health posts when referral to health centers was not possible.

Clusters comprised a health center with 5 or 6 health posts and their catchment population; each cluster had around 1,000 births annually.

We assumed the neonatal mortality rate was 32 deaths per 1,000 live births at the start of implementation of the intervention in 2010 (representing a 22% reduction in rural neonatal mortality from the 2005 DHS,[18] which we expected after activities to strengthen the Health Extension Program had been completed in all study areas), with 50% of deaths occurring within 24 hours after birth.[19] Few deaths within 24 hours after birth would be due to infection and those that were would be difficult to identify and treat. Assuming a coefficient of variation of 0.24 and postulating 33% mortality reduction, we sought to detect a reduction in post–day 1 neonatal deaths from 16.0 to 10.7 per 1,000 day 1 survivors. Eleven clusters were required per arm for 80% power.[20]

Randomization and Masking

Clusters were randomized 1:1 stratified on region and using restriction to ensure arms were balanced in population size, annual number of births, baseline neonatal mortality rate, and proportion of HEWs resident in their village.[21] Allocation was not masked, although survey teams were blinded to minimize interviewer bias.

Intervention Description

Before the start of the study, community meetings were held to orient religious and administrative leaders and other community representatives on the study's purpose and to obtain community consent to conduct the study in these areas. Because HEWs already have many responsibilities, we decided to introduce volunteers to help the HEWs make the desired number of home visits we wished to achieve in our study. In both arms, a community-led process was held to select female volunteers (1 per 100–150 population) from groups of women active in health promotion activities.

Both volunteers and HEWs conducted home visits to counsel families about danger signs and care seeking and to identify infants with possible severe bacterial infection.

The study used a simple clinical algorithm with 8 danger signs to identify infants with possible severe bacterial infections.

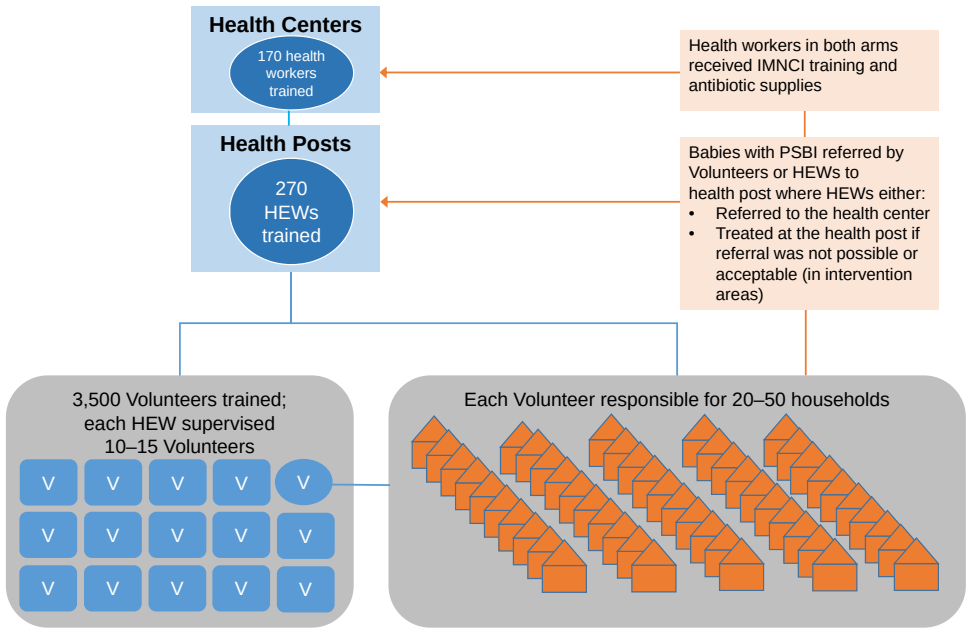
We trained a total of 3,500 female volunteers and 270 HEWs. Volunteers received 4 days of training on what to do during home visits, including counseling families about the importance of antenatal care, danger signs for women and newborns that should prompt care seeking, birth preparedness, clean delivery, and healthy newborn care practices that prevent infection and other illnesses. Training also included how to identify and refer sick newborns to health posts. Volunteers were not paid but received transportation and lunch allowances during trainings. HEWs received 4 days of training on home visits (same content as the volunteer training), 3 days on volunteer support, and 6 days on iCCM, including assessing and referring infants under 2 months with PSBI signs to health centers and case management for sick children 2 months and older. The iCCM training was included because national rollout had not yet been completed. The HEWs in the intervention areas also received 1 additional day of training on the study treatment algorithm (described below), administration of medicine to newborns, and injection safety. In accordance with Ethiopia's Health Sector Development Plan, each HEW supervised and supported 10–15 volunteers, with each volunteer responsible for visiting 20–50 households (Figure 1).[14]

For both arms, the schedule of home visits consisted of 2 visits during pregnancy from volunteers, after identifying the pregnancy through monthly surveillance or receiving notification from the community or family, plus 1 pregnancy visit by HEWs, after receiving notification from volunteers. Postnatal visits were scheduled with volunteers on the day of birth, day 3, and day 7, and with HEWs within 2 days of birth and on day 4. During counseling, volunteers and HEWs used pictorial materials adapted from the national Family Health Card.

In both arms, HEWs referred newborns with PSBI to health centers. At the health center, in line with the integrated management of neonatal and childhood illnesses (IMNCI) standard of care, health workers administered pre-referral antibiotics to the newborns with PSBI and then referred the newborns to the hospital. To ensure high-quality referral care, health centers were supplied with job aids and antibiotics, and health center staff were trained on IMNCI using the national 7-day curriculum.

In the intervention arm only, HEWs were trained to treat PSBI in newborns and young infants at health posts, if referral was not possible or acceptable. This study used a similar clinical algorithm for PSBI to the simple algorithm identified in the WHO Young Infants Clinical Signs Study (YICSS) as predicting severe illness in infants aged 0–2 months, which consisted of 7 signs: history of difficulty feeding, history of convulsions, movement only when stimulated (or no movement even when stimulated), respiratory rate of 60 breaths or more per minute, severe chest indrawing, temperature of 37.5°C or more, temperature below 35.5°C.[23] The COMBINE study added grunting as an eighth danger sign (Figure 2). HEWs treated babies diagnosed with PSBI with daily gentamicin injections for 7 days and oral amoxicillin (administered by caretakers)

FIGURE 1. Relationship Between Health Extension Workers, Volunteers, and Households in Identifying and Managing Newborn Infections, Rural Ethiopia



Abbreviations: HEW, Health Extension Worker; IMNCI, integrated management of neonatal and childhood illnesses; PSBI, possible severe bacterial infection; V, Volunteer.

3 times daily for 7 days. Intervention health posts were supplied with job aids and antibiotics for treating neonatal PSBI. Additional community meetings were held in intervention clusters to raise awareness of the availability of treatment for sick newborns at health posts to encourage care seeking. Table 1 summarizes the study inputs for each of the 2 arms.

Project Officers (POs) with nursing backgrounds were employed by the study in both arms, each supporting 2–4 health posts through twice-monthly visits for monitoring and supervision. POs, HEWs, and volunteers also met monthly to review home visit coverage, documentation, and counseling and assessment skills. In intervention areas, additional monthly meetings were held for PSBI data review and clinical mentoring.

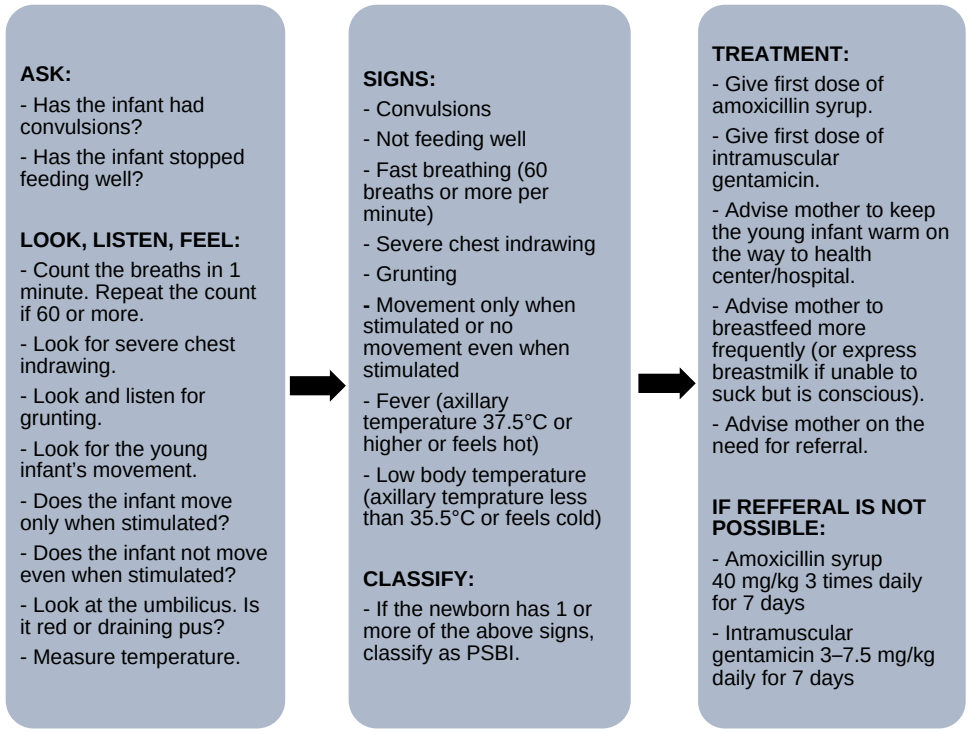
Health systems strengthening activities, including the initial trainings of HEWs, volunteers, and health center staff and provision of antibiotics and supplies to health posts and health centers, were completed in both arms by March 2010. Also in March 2010, HEWs and volunteers started conducting home visits to counsel and support caregivers on exclusive breastfeeding, keeping the baby warm, clean cord care, and handwashing, as well as to identify and promptly refer cases of PSBI. Clusters were randomized in August 2010, and treatment of PSBI by HEWs if referral was not possible or acceptable was implemented in the intervention arm from July 2011 to the end of the study (June 2013). The time lag between randomization and the start of the intervention was due to unforeseen external delays unrelated to the restriction or sampling criteria.

Primary Outcomes

The primary study outcome was post–day 1 neonatal mortality (deaths on days 2–27 after birth). In the absence of ongoing demographic surveillance, data were collected via surveys of all consenting households in the study area. Baseline data were collected from June 2008 to May 2009. A 6-year truncated pregnancy history was

In the absence of ongoing demographic surveillance data, we collected neonatal mortality data through household surveys.

FIGURE 2. Algorithm for Assessment, Classification, and Treatment of Newborn Infection by Health Extension Workers at Intervention Health Posts



Abbreviation: PSBI, possible severe bacterial infection.

collected from consenting women ages 15–49. Information on socioeconomic status, knowledge, practices, and care seeking was collected from women who had delivered during the previous 60 days. Verbal consent was obtained. The endline survey (conducted between February 2013 and June 2013) used the same methodology except it employed a 3-year pregnancy history to reduce the data collection workload. We estimated mortality based on births and deaths in the year preceding each survey to ensure endline estimates covered a period when the intervention was in place and fully functional.

Data Collection and Analysis

Baseline survey data were collected by staff hired by the project who were supervised by the POs. The POs conducted the verbal autopsies. For the endline survey, we hired an independent company to collect the data. The baseline and endline household surveys employed several levels of data quality assurance. Periodic observation of interviews, re-interviews, review meetings, questionnaire review, and hand tallies of selected indicators were done in the field. Before data entry, forms were checked for completeness, legibility, linkage, and consistency. Data were double-entered with range and consistency checks. We used 4 survey modules to collect the necessary data: (1) a household listing administered to the head of the household; (2) a pregnancy history administered to women of reproductive age identified in the household listing; (3) a questionnaire on newborn care practices administered to women who had delivered within the past 60 days; and (4) verbal autopsy administered to caregivers who reported a newborn death.

We also collected routine monitoring data. Volunteers and HEWs submitted forms for every identified pregnancy/birth and home visit. The validity of this system was assessed through a household survey in November 2011 using multistage

TABLE 1. Description of Newborn Infection Management Intervention by Arm and Health System Level, Rural Ethiopia, 2008–2013

	Control	Intervention
Community and Household		
Half-day meetings to orient religious and administrative leaders and other community representatives on the study purpose and to obtain community consent to conduct study in these areas	Yes	Yes
1-day meetings with religious and administrative leaders and other community representatives to select female volunteers for the study	Yes	Yes
4-day training for HEWs and volunteers on conducting home visits to counsel women and families on the importance of antenatal care, facility delivery, and postnatal care; birth preparedness (saving money, planning place of delivery, transport, and blood donor); healthy newborn care practices; recognition of danger signs in mothers and newborns that require prompt care seeking; postpartum family planning; and identification and referral of sick newborns	Yes	Yes
2-day refresher training for volunteers to reinforce initial 4-day training	Yes	Yes
3-day training for HEWs on how to work with and support volunteers	Yes	Yes
Identification of pregnant women by study volunteers	Yes	Yes
Pregnancy and postnatal home visits by HEWs and volunteers per training	Yes	Yes
1-day meetings to raise community awareness of the availability of treatment for sick newborns at health posts	No	Yes
Health Post		
6-day training for HEWs on assessment and referral of newborns with signs of PSBI and case management for sick children older than 2 months (using national iCCM materials)	Yes	Yes
1-day training for HEWs on treatment of newborns with signs of PSBI when referral is not possible or acceptable	No	Yes
Monthly meetings among PO, HEWs, and volunteers to reinforce counseling skills, referral of sick newborns, and reporting on home visits	Yes	Yes
Supervision of HEWs by POs	Yes	Yes
Provision of antibiotics and supplies for PSBI case management to health posts	No	Yes
Treatment of newborns with signs of PSBI by HEWs, if referral to the health center was not possible or acceptable	No	Yes
Monthly PSBI case management review meetings between POs and HEWs	No	Yes
Documentation of symptoms, diagnosis, treatment initiation, and referrals for sick young infants by HEWs on iCCM registers	Yes	Yes
Tracking of the number and timing of antibiotic doses and outcome by HEWs	No	Yes
Health Center		
7-day training for health center staff on IMNCI using national curriculum	Yes	Yes
Provision of antibiotics and supplies for PSBI case management to health centers	Yes	Yes
Documentation of symptoms, diagnosis, treatment initiation, and referrals for sick young infants by health center staff on IMNCI registers	Yes	Yes

Abbreviations: HEW, health extension worker; iCCM, integrated community case management; IMNCI, integrated management of neonatal and childhood illnesses; PSBI, possible severe bacterial infection; PO, project officer.

cluster sampling and interviewing women with a birth within the previous 3–4 months.

POs extracted data on symptoms, diagnosis, treatment initiation, referrals, and outcomes from iCCM registers at health posts and IMNCI registers at health centers. We introduced a separate form at intervention health posts to track the number and timing of antibiotic doses, which were not recorded in the iCCM register. From mid-2011 through early 2012, POs accompanied HEWs on home visits when possible and independently assessed neonates to evaluate the quality of HEWs' assessments. POs stopped parallel assessments after sufficient data were available to demonstrate HEWs were skilled in conducting assessments.

Data were analyzed using Stata version 12 (www.stata.com). Baseline descriptive demographic information was analyzed to examine the comparability of the arms. The primary analysis was by intention-to-treat using cluster-level summary data due to the small number of clusters. From the pregnancy history, babies born 1 year preceding baseline or endline survey and those surviving day 1 were identified, and cluster-level mortality risks for days 0–27, days 0–1, and days 2–27 were computed. (We grouped newborns that died less than 1 day after birth and on the day after birth to ensure we captured all deaths within 24 hours.) Analyses compared each of the 3 different mortality risks between intervention and comparison arms at endline, adjusted for baseline risks. Analyses of covariance were performed in which the dependent variable was the log of the cluster-specific mortality risk at endline. Covariates in the model were treatment arm, region, and the log of cluster-specific baseline mortality risk. Results of fitting these models provided an estimate of mortality risk ratios in the intervention arm compared with the control arm adjusted for baseline mortality, 95% confidence intervals, and a test of the null hypothesis of no difference between arms. A secondary analysis, based on individual-level data using generalized estimating equations to account for intra-cluster correlation, was also performed.

To estimate coverage of pregnancy and postnatal home visits, routine data were used to identify the number of women and newborns receiving pregnancy and postnatal home visits in 2011. Endline survey data were used to estimate denominators (number of births in 2011 for pregnancy visits, number of live births in 2011 for postnatal visits). Including all women who received a visit during pregnancy in 2011 in the numerator would overestimate coverage of pregnancy visits since some women visited in 2011 gave birth in 2012. Practically, we could not exclude women who gave birth after 2011 since we did not have the date of birth for all women. Therefore, we assumed the number of women visited in 2011 and gave birth in 2012 was roughly similar to the number of women who received a first pregnancy visit in 2010 and gave birth in 2011. Thus, we excluded women who received a first pregnancy visit in 2010 from the numerator for coverage of pregnancy visits. Since the window for scheduled postnatal visits in our study was narrow (within 7 days of birth), we assumed only a very small number of women received a postnatal visit in 2011 but gave birth in 2010, and therefore did not exclude any women from our numerator for coverage of postnatal visits. Data from the 2011 validation survey were analyzed for comparison to estimates obtained from the routine data, accounting for clustering using Taylor's linearization method.[22]

Data from the iCCM register were extracted to obtain the number of newborns presenting to health posts and health centers, the number of cases of PSBI, symptoms, referrals, and outcomes. Because a separate form was introduced at intervention health posts to track the number and timing of antibiotic doses and outcome, unique identifying information was used to link this information to data extracted from the iCCM register. Data extracted from the iCCM register were also used to calculate the case fatality rate and estimate the number needed to treat to prevent 1 death. We compared POs' and HEWs' assessment of signs of PSBI using cross-tabulations.

Ethical Approval and Role of Funding Source

The Ethiopian Science and Technology Agency and the London School of Hygiene & Tropical Medicine Ethics Committee approved the study protocol. The study was registered at ClinicalTrials.gov, number NCT00743691.

The funder had no role in study design, data collection, data analysis and interpretation, writing of the report, or decision to submit for publication. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

TABLE 2. Basic Sociodemographic Characteristics at Baseline (2008–2009), Rural Ethiopia

	Comparison	Intervention
No. of households interviewed	**58,944**	**60,408**
No. of residents per household, median	5	5
No. of women of reproductive age interviewed	**58,497**	**56,733**
General fertility rate (no. of live births per 1,000 women of reproductive age)	163	169
No. of women with a live birth in past 1 year	**9,531**	**9,600**
Age in years of women with live birth in past 1 year, mean (SD) (range)	28 (6) (14–50)	28 (6) (14–50)
No. of lifetime live births prior to interview among women with live birth in past 1 year, median	4	4
Neonatal mortality rate among women with live birth in past 1 year (deaths during days 0–27 per 1,000 live births)	33.6	35.0
No. of women with a live birth in past 60 days	**1,371**	**1,358**
Percentage of women with live birth in past 60 days who ever attended school	33%	26%
No. of years of education among women with live birth in past 60 days who ever attended school	4	4
Wealth quintiles among women with live birth in past 60 days, No. (%)		
Lowest	287 (21%)	253 (19%)
2nd	258 (19%)	280 (21%)
3rd	274 (20%)	273 (20%)
4th	261 (19%)	280 (21%)
Highest	280 (20%)	262 (19%)
Missing	11 (1%)	10 (1%)

Abbreviation: SD, standard deviation.

RESULTS

Background Characteristics

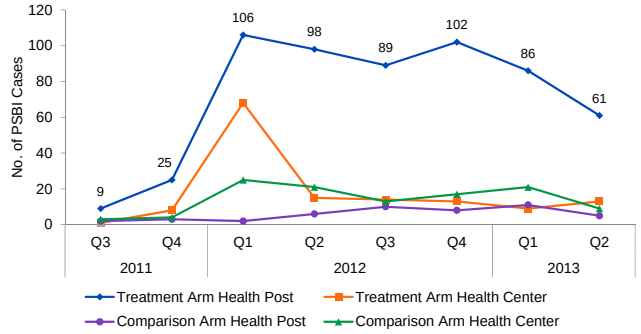
Most baseline characteristics were similar between arms (Table 2). The general fertility rate was slightly higher in the intervention arm than the control arm (169 live births per 1,000 women of reproductive age vs. 163 per 1,000, respectively), and a lower proportion of women reported having any education (26% in the intervention arm compared with 33% in the control arm).

Home Visit Coverage

Routine data collected from volunteers and HEWs suggested high home visit coverage in both arms. In 2011, the first full year of home visit implementation, an estimated 84% of women in comparison areas were reported to have received pregnancy visits and 77% postnatal visits, compared with 92% and 77% of women, respectively, in intervention areas. The volunteers conducted most of the home visits in both arms (82% of pregnancy visits and 88% of postnatal visits). The validation survey, conducted in November 2011, produced similar home visit coverage estimates as the routine monitoring data in the comparison arm (84% for pregnancy visits and 74% for postnatal visits), but somewhat lower coverage estimates in the intervention arm (76% for pregnancy visits and 71% for postnatal visits). We were not able to link survey data and routine data from the same mothers to determine which source was more valid for capturing home visits. There was a decline in home visits

Volunteers conducted most of the home visits in both arms of the study.

FIGURE 3. Number of Newborns With at Least 1 Sign of PSBI Presenting at Health Centers or Health Posts by Study Arm, Rural Ethiopia, July 2011–June 2013



Abbreviation: PSBI, possible severe bacterial infection.

The number of cases with possible severe bacterial infections presenting to health posts increased dramatically in intervention areas, but a decline was evident toward the end of the study period.

toward the study's end, evident in the routine monitoring data and also reflected in endline survey data among women with births in the preceding 60 days. In comparison areas, 38% of these women reported pregnancy visits and 27% reported postnatal visits; in intervention areas, 43% reported pregnancy visits while 36% reported postnatal visits.

PSBI Cases

The number of PSBI cases presenting to health posts increased dramatically in intervention areas, from only 9 cases in the third quarter of 2011 to a high of 106 cases in first quarter of 2012 (Figure 3). During the remainder of 2012, the number of PSBI cases presenting to health posts remained relatively steady at about 90 to 100 cases each quarter, but the numbers appeared to decline in 2013 with a low of 61 cases. In contrast, in comparison areas there was little change in the number of PSBI cases presenting to health posts with no more than 13 cases seen per quarter. In both arms, there was an initial spike in PSBI cases seen at health centers during the first quarter of 2012, but thereafter few cases were seen at health centers in either arm.

57% of sick newborns presenting at intervention health posts were identified by HEWs as having 1 or more signs of possible severe bacterial infection.

Of 1,011 sick newborns presenting at intervention health posts from July 2011 to June 2013, 576 (57%) were identified by HEWs as having 1 or more signs of PSBI. About half (53%) of the PSBI cases were referred to the health post by a volunteer, while the rest were either self-referred (33%), referred by an HEW after identification during a home visit (11%), or had missing data (4%). Of the 576 identified cases, 521 (90%) were treated by HEWs at health posts, 22 (4%) received the first treatment dose by HEWs and were then referred to health centers, 19 (3%) were referred by HEWs to health centers without treatment at the health post, and 14 (2%) had missing data.

HEW Performance

Table 3 compares identification of 7 danger signs (all but rapid breathing) by HEWs and POs. HEWs generally performed well, identifying all danger signs identified by POs except in 5 cases (2 cases of fever, 2 cases with low temperature, and 1 case with grunting). Compared with POs, HEWs may have slightly overdiagnosed PSBI, identifying 10 babies with PSBI (13 danger signs) whom POs did not identify. Ability to identify rapid breathing was assessed by comparing the number of breaths per minute recorded by HEWs and POs for 855 babies. HEWs recorded the same breathing rate plus or minus 2 breaths for 591 babies (69%) (data not shown). HEWs counted 3 or more breaths per minute over the PO's count for 112 babies (13%), and HEWs counted 3 or more breaths fewer than POs for 152 babies (18%). Few of these assessments were in babies with a sign of PSBI.

PSBI Signs

Of 521 PSBI cases treated at intervention health posts by HEWs, 163 (31%) had fast breathing as the only symptom. In this trial, children with isolated fast breathing received the same treatment as children with other signs of PSBI. Twenty-five treated cases (5%) had a history or presence of convulsions, a sign of critical illness, and 237 (45%) of treated cases had more than 1 sign of PSBI. Only 6 cases (1%) had grunting, which is not part of the YICSS algorithm, as the only danger sign.

Treatment Completion Among PSBI Cases

Of the 521 cases treated by HEWs at the health post, 414 (79%) could be linked using unique identifying information to data on administered doses, which was collected separately. Among the linked cases, 408 (99%) received 7 gentamicin doses per study protocol. If we assume no other PSBI cases completed treatment, the treatment completion rate among all PSBI cases treated at the health posts would be 79%. However, an additional 79 babies were recorded as receiving 7 gentamicin doses but could not be linked with the administrative data. Therefore, the completion rate is likely greater than 79%. Among all

521 treated cases, 10 (2%) died. All 10 babies who died had multiple signs of infection.

Mortality Impact

Mortality impact analyses were based on the pregnancy history data from the household surveys. In comparison areas, 98.6% of identified women of reproductive age were interviewed for the endline survey; 9,319 women reported a pregnancy in the preceding year, resulting in 9,003 live births. In intervention areas, 98.5% of identified women of reproductive age were interviewed; 10,157 women reported a pregnancy in the preceding year, resulting in 9,744 live births (Figure 4). The total number of births across both arms (18,747) was slightly lower than the expected number used to calculate sample size (1,000 per cluster or 22,000 total).

Deaths on days 0–1 declined in both arms, with no evidence the treatment intervention was associated with a reduction in these very early neonatal deaths (adjusted risk ratio [RR], 1.04; 95% confidence interval [CI], 0.70 to 1.55; *P*=.83) (Table 4). Post–day 1 mortality declined more in the intervention arm than in the control arm. After accounting for baseline mortality risk and region, results from the cluster-level analysis are consistent with a 17% reduction in post–day 1 mortality, but the results were not statistically significant (RR, 0.83; 95% CI, 0.55 to 1.24; *P*=.33) (Table 4). Results from the secondary individual-level analysis suggest a greater reduction (27%) in post–day 1 all-cause mortality in intervention areas, but these results were also not statistically significant (RR, 0.72; 95% CI, 0.49 to 1.06; *P*=.09).

If we assume mortality was reduced 22%, which is midway between the estimated mortality reduction from the cluster-level analysis (17%) and the individual-level analysis (27%), then we estimate the intervention averted about 20 deaths in the intervention arm in the year prior to the endline survey. In this 1-year period (January 2012 through December 2012), 359 PSBI cases were treated by HEWs at health posts, suggesting that the number needed to treat to prevent 1 death is around 18. Given 9,744 live births in the intervention arm 1 year prior to the endline survey, we estimate that about 3.7% of live births received antibiotic treatment by HEWs at health posts.

TABLE 3. Comparison of Assessments of Newborn Danger Signs by HEWs and POs, Rural Ethiopia, 2011–2012

Danger Signs	Identified by Both the HEW and PO	Identified by HEW Only	Identified by PO Only	Agree Sign Not Present
Convulsions	2	0	0	825
Not feeding well	4	1	0	811
Chest in-drawing	14	4	0	840
Grunting	8	5	1	832
Lack of movement	42	2	0	810
Fever	10	0	2	797
Low temperature	13	1	2	769

Abbreviations: HEW, Health Extension Worker; PO, Project Officer.

DISCUSSION

To our knowledge, this trial is the first to evaluate the implementation and mortality impact of outpatient newborn infection treatment using a simplified regimen at the most peripheral level of a health system in a low-resource country. Bang et al. tested a package of home visits with home-based newborn infection management by project-employed community health workers and reported a 62% mortality reduction.[4] Baqui et al. used project-employed workers to provide home visits with home-based treatment of newborn infections when referral was not possible and reported a 34% mortality reduction.[5] Both these studies were conducted in places with a much higher baseline neonatal mortality rate (62 deaths per 1,000 live births and 47 deaths per 1,000 live births, respectively) compared with the baseline rate in our study (34.3 deaths per 1,000 live births in intervention and comparison areas combined), and neither was implemented through the existing health system. A 2003 meta-analysis of trials of community-based pneumonia management estimated a 27% mortality reduction and 42% pneumonia-specific mortality reduction among neonates; only 5 studies provided data on neonatal mortality and most of the data points came from Bang et al.[24] A study in Zambia of management of common perinatal conditions by traditional birth attendants concluded that offering a first dose of antibiotics at home without strengthening referral care was insufficient to reduce mortality from infection.[25]

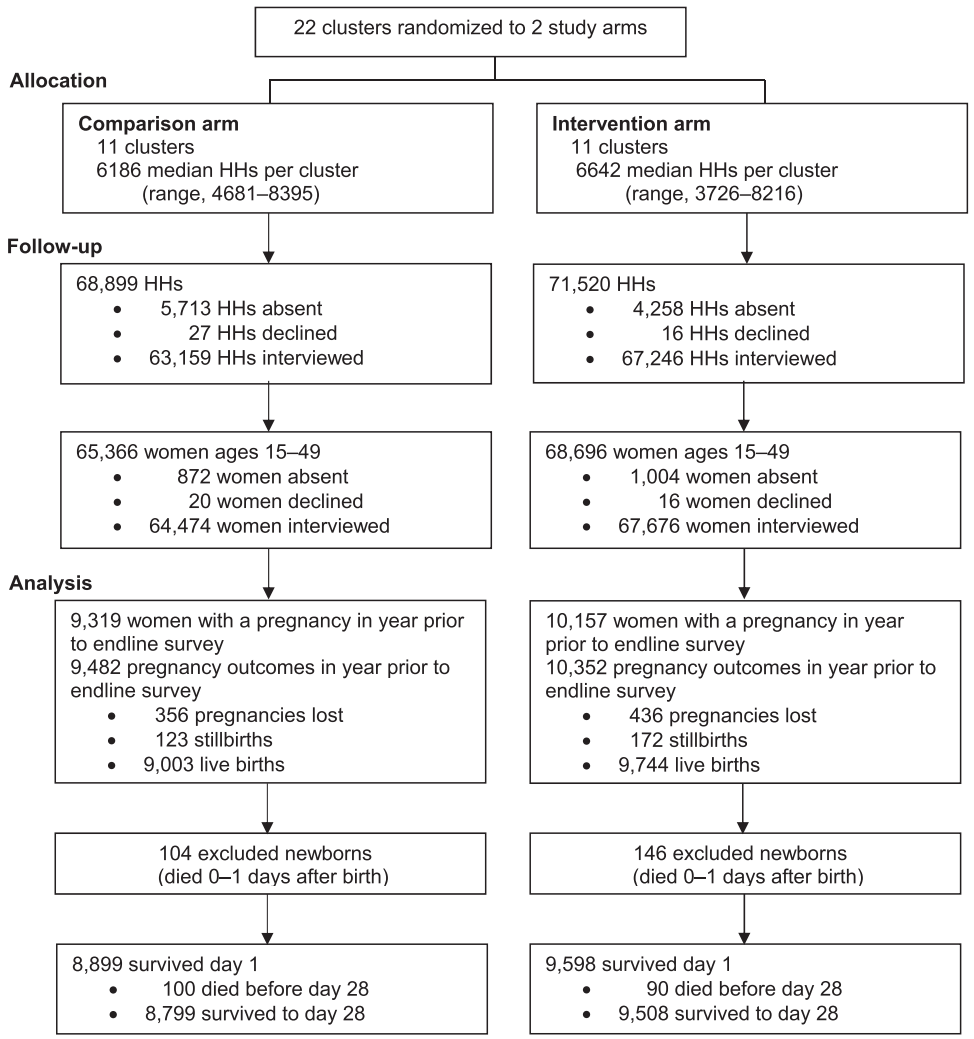
Our study suggests HEWs in Ethiopia are able to correctly identify signs of PSBI, and there is high treatment compliance among PSBI cases

90% of cases identified by HEWs as having possible severe bacterial infection were treated by HEWs at the health posts.

At least 79% of cases with possible severe bacterial infection treated by HEWs at the health post completed the treatment regimen.

Post–day 1 mortality declined more in the intervention arm than in the control arm.

FIGURE 4. Study Allocation and Participants Interviewed and Included in Main Outcome Analysis Using Endline Survey



Abbreviation: HH, household.

About half of all babies with possible severe bacterial infection were treated by HEWs at health posts, suggesting the need for additional interventions to remove barriers to accessing care.

treated by HEWs. While our data are consistent with a reduction in post–day 1 neonatal mortality following the introduction of newborn infection management by HEWs at health posts, we must acknowledge the inconclusive nature of the statistical evidence. A recent meta-analysis of 22 studies estimated a global PSBI incidence risk of 7.6%, with a slightly higher incidence (8.2%) among studies using the YICSS algorithm and a slightly lower incidence (6.2%) in studies in sub-Saharan Africa (6 study sites in Africa).[26] In our study, which used a case definition of PSBI that was very close to the YICSS algorithm, an estimated 3.7% of live births were treated by HEWs at health posts, suggesting that somewhere in the region of half of all babies with PSBI were treated at health posts. Thus, despite substantial inputs, it appears that the intervention tested in our study did not remove all barriers to accessing care. Furthermore, home visit coverage and the number of PBSI cases presenting to the health post appeared to decline in the final months of study,

TABLE 4. Neonatal Deaths at Baseline (2008–2009) and Endline (2013) by Study Arm and Timing of Deaths, Rural Ethiopia

	Comparison		Intervention		Intervention vs. Comparison	
Timing of Neonatal Deaths	Denominator N	Mortality Rate (n)	Denominator N	Mortality Rate (n)	Adjusted Risk Ratio[a] (95% CI)	*P* Value
Days 0–27						
Baseline	9,531 live births	33.6 (320)	9,600 live births	35.0 (336)	0.94 (0.72, 1.22)	.61
Endline	9,003 live births	22.7 (204)	9,744 live births	24.2 (236)		
Days 0–1						
Baseline	9,531 live births	19.4 (185)	9,600 live births	17.4 (167)	1.04 (0.70, 1.55)	.83
Endline	9,003 live births	11.6 (104)	9,744 live births	15.0 (146)		
Days 2–27						
Baseline	9,346 surviving day 1	14.4 (135)	9,433 surviving day 1	17.9 (169)	0.83 (0.55, 1.24)	.33
Endline	8,899 surviving day 1	11.2 (100)	9,598 surviving day 1	9.4 (90)		

Abbreviation: CI, confidence interval.
[a] Endline intervention vs. comparison, adjusted for baseline mortality risk and region.

indicating that the study inputs may not have been sufficient to sustain a change in care-seeking behavior as project inputs were reduced. Our point estimate suggests a 17% reduction in post–day 1 neonatal mortality in the context of around 50% treatment coverage. Extrapolating this further suggests that complete treatment coverage could have had the potential to reduce post–day 1 deaths by around one-third. This figure appears plausible given that an estimated 27% of all neonatal deaths in Ethiopia are due to severe infections[1] and that the proportion of post–day 1 deaths due to infections will be considerably higher. In the context of declining neonatal mortality and improved preventive measures, it will become increasingly difficult to detect the contribution of infection treatment to mortality reduction. To achieve a detectable mortality impact in such a scenario, sustained high treatment coverage would be necessary.

In most settings where implementation of outpatient infection management would be appropriate, systems strengthening inputs are needed, including in-service training, supervision, commodities, monitoring, and community mobilization. In our study, we engaged, trained, and supervised volunteers to support HEWs in improving care seeking among community members and in identifying and referring PSBI cases. In fact, these volunteers conducted most of the home visits and referred about half of the PSBI cases seen at intervention health posts. HEWs, who have multiple responsibilities and must spend time at health posts, did not make as many home visits, and few cases seen at health posts had been referred by HEWs during a home visit. These findings demonstrate that successful case detection is highly dependent on having a cadre with both the skills to identify and refer cases and the time to conduct multiple home visits. The importance of the volunteers in our study was evident as the number of identified cases declined toward the end of the study because the volunteers reduced their activity levels in anticipation that newborn treatment would not continue after the end of the study. In addition, introduction of the government's new volunteer strategy called the Health Development Army created confusion and sidelined many existing volunteers. Given that about a third of the PSBI cases in our study were self-referred, in the longer run, community education and mobilization efforts, aside from home visits, could change care-seeking norms and thus diminish the need for active case detection. But until norms change, effective, active case detection is required to

Successful case detection of infants with infection requires a cadre with both the skills to identify and refer cases and the time to conduct home visits.

achieve meaningful mortality reductions. In our study, we estimated around 18 PSBI cases needed to be treated at the health post level to prevent 1 death.

The case fatality rate among cases treated by HEWs in this study was 2%, which is in line with the case fatality rate for babies treated by community health workers in Baqui et al.'s community-based trial (1.4%)[27] and the case fatality rates for cases of clinical severe illness treated in all arms of the SATT (2%) and AFRINEST (1.5%) trials.[9,10] Approximately 31% of cases in our study had isolated fast breathing, which were excluded from the definition of clinical severe illness in SATT and AFRINEST, and we would expect low mortality in this group even without treatment. On the other hand, 5% of treated cases had convulsions. Such cases were classified as having critical illness and were excluded from SATT and AFRINEST. A further 45% of cases in our study had multiple signs of illness compared with 38% in SATT and 13% in AFRINEST. Despite some differences in case mix compared with these other studies, the case fatality we observed in our routine program setting seems to be broadly in line with what has been observed in carefully controlled trials.

Previous studies focused on home-based treatment because it was believed that many families would not be willing to take their newborns outside the home for treatment, especially in a country such as Ethiopia where there is a traditional practice of keeping newborns at home.[28] Initially, our study had low care seeking at health posts (Figure 3). In response, we conducted qualitative interviews to identify barriers to care seeking, which elicited such barriers as fear of the "evil eye," beliefs that exposure to the sun made newborns sick, and a tradition of keeping the baby away from strangers (including health workers) until the newborn was blessed by spiritual leaders. The project then implemented community mobilization activities, which likely drove the observed improvements in home visits and care seeking in the intervention arm.

Families may be willing to seek care for their infants outside the home over several days when services are nearby.

Distance also often presents an insurmountable barrier to accessing care in settings where service provision is sparse, transport infrastructure weak, and populations poor.[29,30] However, our study suggests families are willing to seek care outside the home over several days—specifically, for 7 days of treatment in this study—when services are close. In both arms of the study, counseling families on danger sign recognition and care seeking was strengthened with treatment for PSBI offered at the health center level (in addition to the health post level in the intervention arm if referral was not possible or acceptable), but few families sought care for their sick newborns at these higher-level facilities. While there was an initial spike in cases seen at intervention health centers, mirroring the increase in cases seen at intervention health posts, this trend was not sustained. The inability to sustain the increase at health centers could be explained by the policy of giving a first antibiotic dose at health centers and then referring to the higher-level hospitals, which requires time and resources from families. In contrast, there was a large increase in care seeking for newborn illness at health posts in intervention areas, where newborns with PSBI could receive the full course of antibiotic treatment if referral was not possible or acceptable, with high treatment completion. Therefore, these results from the COMBINE study demonstrate the importance of improving access to newborn health care by making treatment available closer to home.

Strengths and Limitations

Study strengths include the cluster-randomized design and large geographic area covered. Further, the study was designed to be pragmatic with case management delivered through the existing system, although some additional inputs were provided. Study limitations include incomplete monitoring records on treatment adherence; we had linked information on the number of doses administered for only 79% of cases at intervention health posts, and it proved impossible to collect this information at health centers. In addition, mortality impact data were dependent on survey recall data and mothers were often unable to recall the precise timing of birth and death. Therefore, we excluded deaths on day 0 (day of birth) and day 1, which allowed us to exclude all deaths within 24 hours, but we may have included some deaths that occurred after 24 hours. Furthermore, the relatively small number of clusters, 11 per arm, resulted in a very wide confidence interval around our primary outcome effect estimate. Finally, although baseline neonatal mortality rate, the criteria used for randomization, was similar between arms (4% higher in intervention areas at 35.0 per 1,000 live births compared with 33.6 per 1,000), the baseline post–day 1 mortality rate was 24% higher in intervention versus comparison areas (17.9 per 1,000 live births compared with 14.4 per 1,000, respectively).

CONCLUSIONS

The Ethiopian Ministry of Health, with partner support, has started to scale up the COMBINE model of community-based newborn care with newborn infection management by HEWs at health posts.[31] However, the new cadre of volunteers called the Health Development Army may not do as much active case detection as the volunteers did in the COMBINE study. Based on the experience of COMBINE, we expect low coverage of treatment until care-seeking norms change. In other settings where most families do not seek care for sick newborns, the introduction of treatment needs to be accompanied by a comprehensive plan to change care-seeking behavior. Adaptation of the COMBINE model in other countries must also consider the available health delivery platforms. Ethiopia already had an established cadre of community-based health professionals with 1 year of basic training—HEWs. These HEWs cover a sufficiently large catchment population to see enough cases to justify resources for training, supervision, and monitoring on neonatal infection management and to maintain their skills through continued practice. In other contexts, a similar community-based cadre may not be available and thus it may be more appropriate to introduce outpatient treatment of neonatal infections at primary health facilities.

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Competing Interests: None declared.

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ORIGINAL ARTICLE

Improving Adherence to Essential Birth Practices Using the WHO Safe Childbirth Checklist With Peer Coaching: Experience From 60 Public Health Facilities in Uttar Pradesh, India

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Implementation of the WHO Safe Childbirth Checklist with peer coaching resulted in >90% adherence to 35 of 39 essential birth practices among birth attendants after 8 months, but adherence to some practices was lower when the coach was absent.

See related article by Kara.

ABSTRACT

Background: Adherence to evidence-based essential birth practices is critical for improving health outcomes for mothers and newborns. The WHO Safe Childbirth Checklist (SCC) incorporates these practices, which occur during 4 critical pause points: on admission, before pushing (or cesarean delivery), soon after birth, and before discharge. A peer-coaching strategy to support consistent use of the SCC may be an effective approach to increase birth attendants' adherence to these practices.

Methods: We assessed data from 60 public health facilities in Uttar Pradesh, India, that received an 8-month staggered coaching intervention from December 2014 to September 2016 as part of the BetterBirth Trial, which is studying effectiveness of an SCC-centered intervention on maternal and neonatal harm. Nurse coaches recorded birth attendants' adherence to 39 essential birth practices. Practice adherence was calculated for each intervention month. After 2 months of coaching, a subsample of 15 facilities was selected for independent observation when the coach was not present. We compared adherence to the 18 practices recorded by both coaches and independent observers.

Results: Coaches observed birth attendants' behavior during 5,971 deliveries. By the final month of the intervention, 35 of 39 essential birth practices had achieved >90% adherence in the presence of a coach, compared with only 7 of 39 practices during the first month. Key behaviors with the greatest improvement included explanation of danger signs, temperature measurement, assessment of fetal heart sounds, initiation of skin-to-skin contact, and breastfeeding. Without a coach present, birth attendants' average adherence to practices and checklist use was 24 percentage points lower than when a coach was present (range: −1% to 62%).

Conclusion: Implementation of the WHO Safe Childbirth Checklist with coaching improved uptake of and adherence to essential birth practices. Coordination and communication among facility staff, as well as behaviors with an immediate, tangible benefit, showed the greatest improvement. Difficult-to-perform behaviors and those with delayed or theoretical benefits were less likely to be sustained without a coach present. Coaching may be an important component in implementing the Safe Childbirth Checklist at scale.

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Note: At the time of publication of this article, the results of evaluation of the impact of the BetterBirth intervention were pending publication in another journal. After the impact findings have been published, we will update this article on the effect of the intervention on birth practices with a reference to the impact findings.

BACKGROUND

We aimed to assess whether implementation of the WHO Safe Childbirth Checklist with peer coaching was associated with improved performance of essential birth practices.

Childbirth and the first 24 hours postpartum remains a precarious time for both mother and newborn despite improvements in maternal and neonatal mortality over the past 2 decades.[1–3] Previously, poor outcomes were thought to result primarily from childbirth occurring outside of health care facilities and from lack of access to skilled care. However, strategies such as the Janani Suraksha Yojana (JSY) program in India have increased rates of facility-based childbirth without significantly decreasing maternal and neonatal mortality.[4–7] Thus, improving the quality of care provided during facility-based childbirth is a key strategy to decrease maternal and neonatal mortality globally.[8] The World Health Organization (WHO) *Quality of Care Framework for Maternal and Neonatal Health* describes quality care as being safe, effective, timely, efficient, equitable, and people-centered.[9] Use of evidenced-based practices for routine care and management of complications is key to achievement of high quality of care.[10]

Essential birth practices that reduce harm and save lives during childbirth are well documented but often not performed.

Essential birth practices that reduce harm and save lives during childbirth are well documented, but all too often, they are not performed. Other areas of health care have used a checklist-based approach to address this "know-do" gap.[11,12] WHO's Safe Childbirth Checklist (SCC), developed in 2009, is a low-cost tool that codifies these essential birth practices in a format designed to be accessible to birth attendants to ensure that timely, lifesaving practices are performed for every facility-based birth, thus improving the quality of care.[13,14]

The BetterBirth Program used a 3-pronged approach to support adoption and use of the WHO Safe Childbirth Checklist: engagement with key stakeholders, a motivational launch event, and peer-coaching support to birth attendants.

Checklists are job aids designed to support routine adherence to evidence-based practices, and as such are intended to change health care workers' behaviors.[15] Job aids alone have not been found to improve health care workers' performance,[16] and experience with implementing checklists has demonstrated that additional strategies are needed to promote behavior change.[17] Previous studies of the SCC have suggested that peer coaching based on feedback about SCC use,[18] ensuring buy-in from the larger health care system, and integrating the SCC into existing workflows[19] increased the likelihood of making real, sustained improvements in the quality of facility-based childbirth care. The BetterBirth Program—an intervention aiming for sustained SCC adoption through coaching-based implementation—was developed based on lessons learned from early implementations of the SCC and from other quality-improvement projects.[20,21]

We aimed to assess whether the behavior change intervention of this SCC-based peer-coaching program was associated with improved performance of essential birth practices during facility-based childbirth care. First, we examined birth attendants' adherence to a set of essential birth practices in 60 intervention facilities, as observed by a coach. Then, in a subset of these facilities, we employed independent observers to verify adherence to these practices in the absence of the coach.

METHODS

Study Design

The BetterBirth Trial was a matched-pair, cluster-randomized controlled trial conducted in Uttar Pradesh, India, to test whether the introduction of the SCC paired with peer coaching—the BetterBirth Program—could reduce maternal morbidity and mortality and perinatal mortality in 120 health care facilities (60 intervention facilities and 60 control facilities receiving standard of care) (ClinicalTrials.gov: NCT2148952; Universal Trial Number: U1111-1131-5647). The methodology of the trial is available elsewhere,[20] and a detailed description of the intervention is published as a companion article in this issue of *Global Health: Science and Practice*[21]; reporting on the impact of the intervention on perinatal mortality, maternal mortality, and severe maternal morbidity is forthcoming.

Intervention: The BetterBirth Program

The BetterBirth Program supported adoption and use of the SCC using a 3-pronged implementation pathway (Box)[21]:

1. Engagement with facility leaders and government officials at the district and state level
2. A 2-day motivational launch event of the SCC for facility staff
3. Support to birth attendants, facility leaders, and government officials through visitation of peer coaches to give regular feedback

The intervention used a coaching strategy as the primary mechanism to encourage behavior change among health care workers. Coaches were trained

nurses who worked directly with birth attendants. Coach team leaders were trained physicians or public health leaders who worked directly with facility leaders and government officials and who supervised the nurse coaches. Coaches visited the facility twice weekly during the early stages of the intervention, with the frequency of visits decreasing to once monthly by the end of the intervention, for a total of 43 visits over an 8-month period. Coaches did not provide patient care. Although coaches did not clinically intervene in emergencies, if needed they could escalate emergency situations to be addressed by a medical officer at the facility. Additionally, coaches had the discretion to encourage appropriate referral of a mother or a baby before, during, or after patient observation, as this is directly related to the SCC.

Birth attendants were coached to use the SCC at 4 critical "pause points" during childbirth:

1. On admission
2. Before pushing or before cesarean delivery
3. Soon after birth (within 1 hour)
4. Before discharge

The paper-based checklist itself was commonly attached to a mother's chart or bedhead ticket for ease of reference and so completed tasks could be checked off for each patient at each pause point. Posters of the SCC were also posted on the wall in the delivery area.

The BetterBirth intervention used a behavior change framework to facilitate the adherence to checklist-based essential practices.[22,23] The core of this framework is characterized by coaching birth attendants and leaders to recognize gaps in essential birth practices, barriers to delivering them, and solutions for overcoming those barriers. To support ongoing facility-level adherence to essential practices, a facility staff member was identified and trained to support SCC use after the intervention was completed. The program is described in more detail elsewhere.[18,20,21] Technical training and supplies were not provided. Instead, coaches and team leaders worked with facility staff to resolve these barriers through existing channels. Control sites in the BetterBirth Trial received the standard of care. Although Indian national guidelines recommend use of the SCC,[24] we did not observe its use at any control facilities throughout the trial.

Setting and Site Selection

Uttar Pradesh, India's most populous state, has some of the highest maternal mortality ratios and

BOX. The BetterBirth Intervention

TOOLS

The World Health Organization Safe Childbirth Checklist (SCC) comprises 28 essential birth practices to improve the quality of labor and delivery care.

Pulse is an electronic data management system for quality improvement. Coaches entered their observations of birth attendants' behavior into Pulse via mobile-phone apps; Pulse then generated real-time "heat maps" to guide facility staff to identify gaps in care and find effective solutions.

STRATEGY: COACHING FOR EMPOWERMENT

Goals of coaching:

- Motivating birth attendants to change their practices.
- Observing, recording, and feeding back information about birth attendants' behavior.
- Supporting birth attendants to problem solve and resolve barriers to essential practices.

Principles of coaching:

- Multilevel: Coaches worked with birth attendants, and coach team leaders worked with facility and district leadership to problem solve and facilitate change across the health system.
- Collaborative: Coaches and birth attendants had supportive, constructive, respectful, peer-to-peer relationships.
- Provider-centered: Coaches responded to the needs of the birth attendants and facility and district leaders with whom they worked rather than following a predetermined agenda.

IMPLEMENTATION: ENGAGE-LAUNCH-SUPPORT

- **Engage:** Program goals and strategies were introduced to leadership at the national, state, and district level.
- **Launch:** A motivational event at each facility introduced the significance of the tools, explained the coaching strategy, and enlisted the participation of staff in a needs assessment.
- **Support:** Nurse coaches supported SCC adoption and quality improvement by making 43 visits to each facility over 8 months (twice weekly for months 1–4; once weekly for months 5–6; fortnightly for month 7; and monthly for month 8). Coach team leaders, who were physicians or public health professionals, accompanied coaches on half of the visits in order to address system-level and supply issues at the facility.

SUSTAINABILITY PLAN

A motivated and respected staff member was selected by facility leadership to be a childbirth quality coordinator (CQC) at each facility. The CQC worked closely with team leaders to improve quality of care and champion the SCC beyond the BetterBirth Program.

For a detailed description of the intervention, see Kara, Firestone, Kalita, et al. (2017).[21]

neonatal mortality rates.[25] Across the state, 773 community health centers (CHCs) and 3,497 primary health centers (PHCs) serve as public-sector facilities to provide health services, including obstetric care, for nearly 200 million inhabitants of the state.[25] Patients with major complications needing a cesarean delivery or blood transfusion are referred to a district hospital or a CHC first referral unit (CHC-FRU).

The BetterBirth Program was implemented in 60 public-sector facilities, including PHCs, CHCs, and CHC-FRUs, across 24 districts of Uttar Pradesh from December 2014 to September 2016. Site selection for the overall trial and batch-wise implementation is described elsewhere.[20] Of the 60 intervention facilities, a pragmatic sample of 15 facilities was selected based on geographic location, in which independent observers recorded birth attendant behavior when coaches were absent.

Outcomes of Interest

For the primary analysis, we operationalized the 28 items on the SCC into 43 discrete measures (39 essential practices related to patient care and supply preparation plus 4 measures of checklist use) (Table 1), as some of the items on the checklist require multiple steps. For example, the first checklist item—"Does mother need referral?"—requires a birth attendant to separately measure temperature to assess for fever, to measure blood pressure to assess for preeclampsia, and to assess the fetal heart sounds to detect fetal distress. We selected measures that could be clearly observed by a coach who was standing nearby.

For the subanalysis of 15 facilities conducted after the first 2 months of coaching were completed, the outcome of interest was the difference between birth attendants' adherence to essential birth practices in the presence of a coach and birth attendants' behavior documented by independent observers in the absence of the coach. Since not all observed behaviors were recorded in the same way by the coaches and independent observers due to differences in data collection procedures, we included only the

TABLE 1. Essential Birth Practices Observed by Peer Coaches, by SCC Pause Point[a]

Pause Point 1: On Admission	Pause Point 2: Before Pushing	Pause Point 3: Within 1 Hour of Delivery	Pause Point 4: Before Discharge
• **Mother's temperature on admission**	• Mother's temperature before delivery	• **Glove use at birth**	• Check bleeding before discharge
• **Mother's blood pressure on admission**	• Mother's blood pressure before delivery	• Was baby breathing assessed at birth?	• Mother's temperature before discharge
• Measurement of fetal heart sounds	• **Clean towel available at bedside**	• **Skin-to-skin immediately after birth**	• Baby's temperature before discharge
• Vaginal exam done	• Gloves available at bedside	• **Oxytocin given 1 minute after birth**	• Check baby breathing before discharge
◦ If yes, hand hygiene before exam (soap and water or alcohol rub)	• **Pads available at bedside**	• Check bleeding after delivery	• Check baby feeding before discharge
◦ If yes, gloves worn for exam	• Oxytocin available at bedside	• Mother's temperature after delivery	• BCG vaccine given
• Danger signs explained to mother or birth companion at admission	• **Blade available at bedside**	• Mother's blood pressure after delivery	• OPV given
• **Checklist use at admission**	• **Cord ligature available at bedside**	• **Baby's temperature after delivery**	• Family planning discussed
	• **Mucus extractor available at bedside**	• **Baby's weight**	• Danger signs explained to mother or birth companion before discharge
	• **Neonatal bag and mask available at bedside**	• **Breastfeeding initiation**	• Checklist use before discharge
	• **Hand hygiene before delivery (soap and water or alcohol rub)**	• Danger signs explained to mother or birth companion after delivery	
	• **Checklist use before delivery**	• Skin-to-skin at 1 hour	
		• **Checklist use after delivery**	

Abbreviations: BCG, bacille Calmette-Guérin; OPV, oral polio vaccine; SCC, Safe Childbirth Checklist.

[a] Bolded practices (n=18) were observed by both coaches and independent observers.

18 overlapping checklist-related behaviors in the analysis (Table 1).

Data Collection

Coach Observation

Coaches used standardized tools to document SCC use and adherence to essential birth practices at the 4 pause points listed on the SCC. Deliveries were selected for observation based on if a patient was present and a birth attendant was available to be observed for at least 1 complete pause point. Birth attendants could be observed for 1 or more pause points at each delivery. During the 8-month intervention, coaches attempted to observe each birth attendant at a facility multiple times. Data were first collected on paper forms while observing childbirth and subsequently entered into a mobile phone-based CommCare app (Dimagi, Cambridge, MA) on the same day but after the coach left the patient care area. Practices were coded as either "completed" (green), "completed after prompt" (yellow), or "not completed" (red) and transformed into a standardized heat map report, displayable on a mobile device for coaches and team leaders to report back to birth attendants and facility leadership on adherence to the SCC and to essential birth practices.[21]

Independent Observation

For the subanalysis, independent observers assessed SCC use and birth attendants' adherence to essential birth practices. Starting during the eighth week of coaching, independent observers visited facilities on non-coaching days to record adherence to essential practices. Independent observers collected data for a period of 6 to 12 weeks, depending on the delivery load of the facility, with a goal to reach 240 pause point observations per facility. Independent observers selected any case for which a pause point could be observed from start to finish. A mother was observed for as many pause points as possible. Data collected by independent observers were considered a proxy for birth attendant behavior under everyday conditions at the facility.

Independent observers were nurses trained in childbirth who used a standardized tool to record behavioral data. Intensive training to ensure data quality was provided.[26] Similar to coaches, independent observers recorded data on all behaviors within a specific pause point; birth attendants could be observed for 1 or more pause points. Due to differences in how facilities handled the process of patient discharge, independent observers did not observe the fourth pause point of the SCC ("before discharge"). Independent observers also first recorded data on paper forms and subsequently entered the data into an app on the same day after leaving the patient care area. Data collected by independent observers were not shared with facility staff. Moreover, in emergency situations, independent observers did not provide care nor did they intervene to facilitate a response.

Data Analysis

We analyzed adherence to each of the 43 coach-observed practices by month over the 8-month intervention. First, we calculated an adherence proportion for each behavior based on the number of times a behavior was completed divided by the number of times that a behavior was expected to be completed at a given pause point. We then plotted this proportion across the 8 months of the intervention to understand how adherence to essential practices changed over time.

Since coaches visited facilities only fortnightly or monthly by the seventh and eighth months of the intervention, data from these 2 months were combined (represented as Month 7). We used percentage-point differences to compare adherence during Month 7 versus Month 1 and allocated behaviors into 3 categories:

1. Minimal improvement (<15 percentage-point absolute difference)
2. Moderate improvement (15 to 24 percentage-point absolute difference)
3. Major improvement (≥25 percentage-point absolute difference)

We developed a logistic regression model for each behavior to assess the probability of birth attendants' adherence to a given behavior across the 8 months of the intervention, controlling for facility clustering using dummy variables for facility. We calculated odds ratios and 95% confidence intervals to test how adherence changed over time. Results were considered statistically significant at $P<.05$.

For the subanalysis, we calculated adherence to each of the 18 measured practices recorded by both nurse coaches and independent observers. We used percentage-point differences to compare adherence when a coach was present versus absent. Each behavior was categorized as having a:

1. Minimal difference (<15 percentage-point absolute difference)
2. Moderate difference (15 to 24 percentage-point absolute difference)

3. Major difference (≥25 percentage-point absolute difference)

A Rao-Scott chi-square test was used to adjust for clustering within facility when comparing the overall proportion of practices completed between coaches and independent observers. We also compared adherence rates reported by coaches at the 15 sites of the subanalysis with the 45 sites not included in the subanalysis to assess differences between the 2 groups. All data analyses were conducted using Stata SE 13.1 for Mac and Microsoft Excel 2011.

35 of 39 essential birth practices had achieved >90% adherence in the presence of a coach by the final month of the intervention.

Qualitative Study to Explore Explanatory Factors

As a strategy to improve the quality and effectiveness of the BetterBirth Program, we used an explanatory qualitative study. We presented adherence rates documented by coaches and independent observers to members of the field implementation staff during a week-long workshop in September 2016. Successes and challenges related to birth attendants' adherence to individual behaviors were discussed and documented.

Ethics Approval and Consent Process

The BetterBirth Trial, including data for this analysis, was approved by the Harvard T.H. Chan School of Public Health Institutional Review Board, the World Health Organization Ethics Review Board, the Population Services International Research Ethics Board, the Community Empowerment Labs Ethics Review Committee, and the Jawaharlal Nehru Medical College-Belgaum Ethics Review Board. All activities were conducted in partnership with the Government of Uttar Pradesh.

Behaviors that did not reach >90% adherence consisted of measurement of a mother's temperature and blood pressure before delivery and administration of BCG and oral polio vaccines to an infant before discharge.

For coaching, each facility and birth attendant formally agreed to participate in the BetterBirth Program as a quality improvement initiative at the beginning of the intervention. Coaches accompanied birth attendants during their work shift and documented practices during patient-care activities at the facility. Coaches did not collect any patient identifiers.

For independent observation, each facility and birth attendant formally agreed to participate in the study. Since these data were collected solely for the purpose of research as part of the larger BetterBirth Trial, and identifying information of the mother was collected, a more rigorous consent process was used. Prior to each observation, independent observers verbally confirmed that the birth attendant agreed to be observed. Patients signed written consent to have independent observers present during their care.

RESULTS

Coach Observers

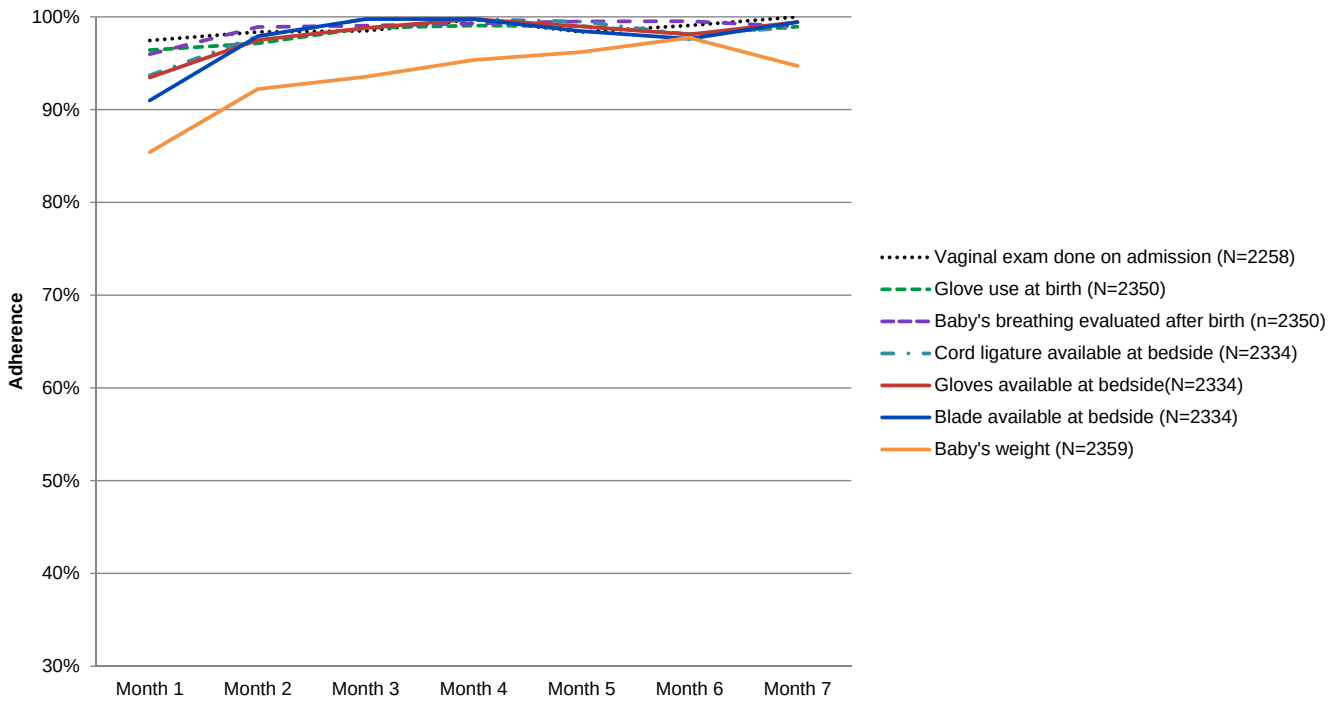
In 60 public health facilities during 8 months of intervention, coaches observed care provided by birth attendants during 5,971 deliveries at 1 or more pause points during childbirth. Additional facility characteristics and intervention process measures are available in Supplement 1. By the final month of the intervention, 35 of 39 essential practices had achieved >90% adherence in the presence of a coach (Supplement 2), compared with only 7 of 39 practices that had achieved this level of adherence during the first month (Figure 1). Throughout the intervention, coaches observed consistently high adherence to the preparation of birth supplies at the bedside, with nearly 100% adherence noted by the second month of coaching.

Essential birth practices with the greatest absolute increase in adherence over time included explaining danger signs to the mother or to her birth companion on admission (45% to 96%; $P<.001$) and after delivery (54% to 92%; $P<.001$), measurement of baby's temperature (57% to 93%; $P<.001$), measurement of mother's temperature before (46% to 81%; $P<.001$) and after delivery (65% to 95%; $P<.001$), and measurement of fetal heart sounds on admission (62% to 97%; $P<.001$) (Figure 2 and Supplement 2). More moderate increases were seen across other practices, including oxytocin administration within 1 minute of delivery (81% to 99%; $P<.001$), skin-to-skin infant care (71% to 94%; $P<.001$), and hand hygiene before delivery (76% to 94%; $P<.001$). Across all 39 behaviors, improvements ranged from an absolute increase of 2 percentage points to 51 percentage points from the first to the final month.

Behaviors that did not attain an adherence rate of 90% or above for any month of the intervention included measurement of a mother's temperature (46% to 81%; $P<.001$) and blood pressure (53% to 80%; $P<.001$) before delivery, as well as administration of bacille Calmette-Guérin (BCG) vaccine (75% to 87%; $P<.001$) and the oral polio vaccine (OPV) (86% to 89%; $P<.001$) to an infant before discharge.

Checklist use at each pause point increased between the first and final month of coaching, including checklist use on admission (84% to

FIGURE 1. Essential Birth Practices Consistently Performed by Birth Attendants in 60 Facilities Across the 8-Month BetterBirth Intervention, Uttar Pradesh, India



98%; P=.002), before delivery (66% to 94%; P<.001), after delivery (75% to 95%; P<.001), and before discharge (90% to 99%; P<.001).

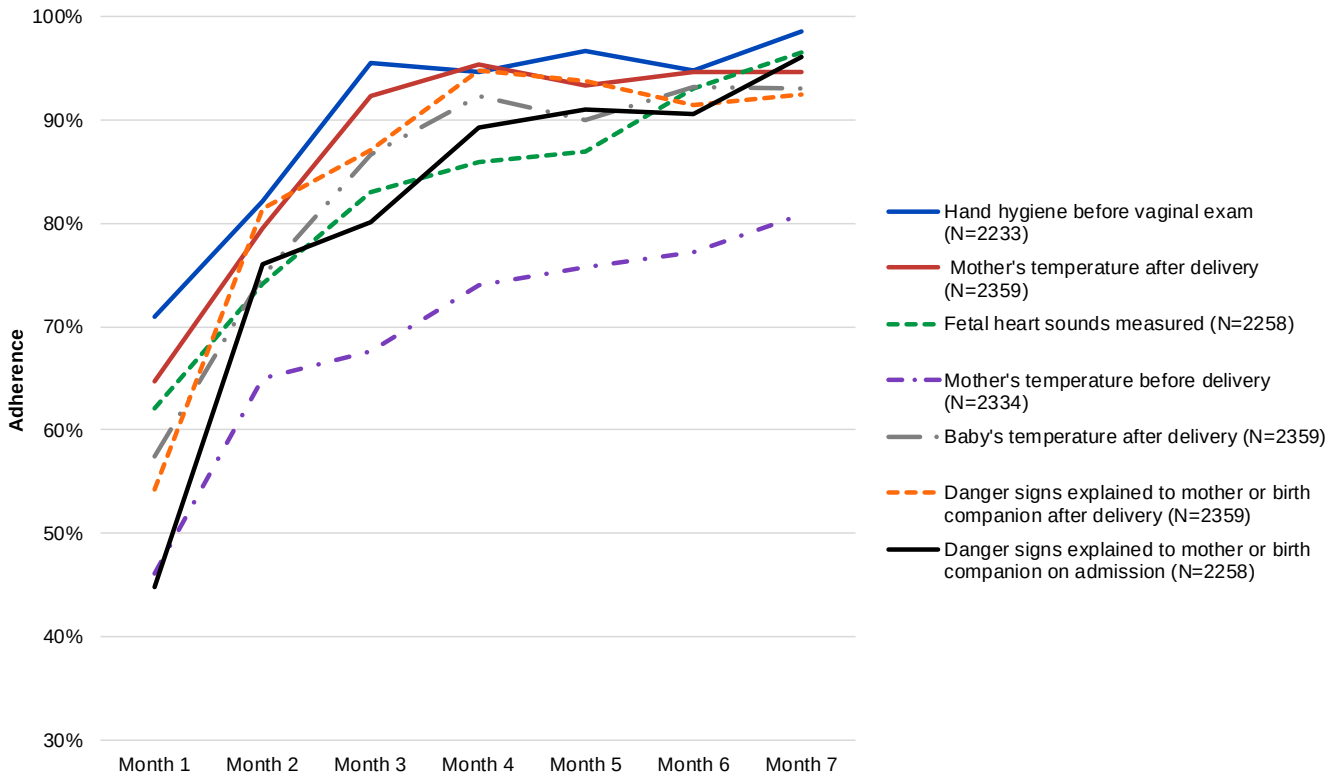
Independent Observers

In the subset of 15 facilities, independent observers documented essential practices after 2 months of coaching on 1,277 deliveries at 1 or more pause points, while coaches observed 736 deliveries over the same 12-week period in the same facility. There was an absolute difference of 24 percentage points (range: −1 to 62 percentage points) in the proportion of the 18 practices completed when the coach was present versus absent (Figure 3 and Supplement 3). Of the essential birth practices recorded by both coaches and independent observers, a minimal absolute difference (<15 percentage points) in levels of adherence was observed for preparation of supplies including cord ligature, neonatal bag and mask, mucus extractor, pads and clean towel, weighing of the baby, glove use during delivery, and immediate skin-to-skin care. A moderate absolute difference (15 to 24 percentage points) was observed across 3 behaviors, including practices such as oxytocin administration within 1 minute of birth and breastfeeding within 1 hour of birth. A major absolute difference (>25 percentage points) was seen with hand hygiene, measuring the baby's temperature, and measuring the mother's blood pressure and temperature. We found no major differences between the coach-recorded adherence rate in the 15 facilities of the subanalysis versus the 45 facilities not in the subanalysis.

Through the explanatory exercise conducted with the BetterBirth Program implementation team, we documented experiences from the field related to coaching on various behaviors (Table 2). In particular, many of the practices with the greatest improvements in adherence were those in which the birth attendants saw tangible benefits to implementing them, such as checking the mother for bleeding after delivery to recognize hemorrhage early, when it is easier to treat, and initiating immediate skin-to-skin contact between baby and mother to better regulate temperature

There was an absolute difference of 24 percentage points in the proportion of the 18 practices completed when a coach was present versus absent.

FIGURE 2. Essential Birth Practices With the Greatest Increase in Adherence by Birth Attendants in 60 Facilities Across the 8-Month BetterBirth Intervention, Uttar Pradesh, India



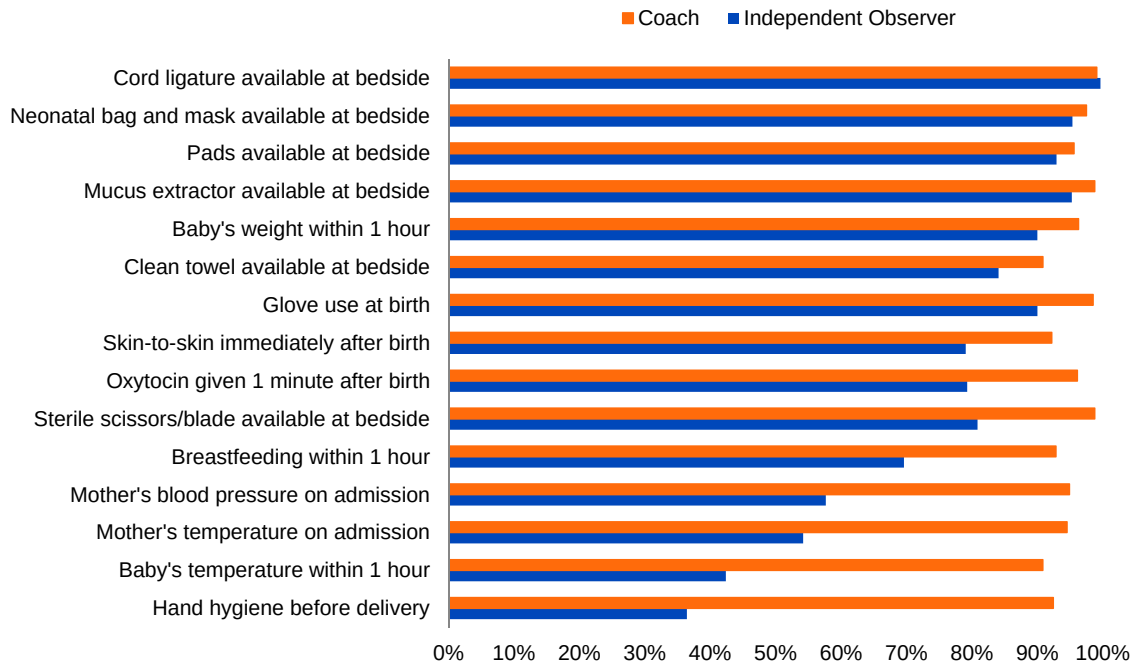
and more easily initiate breastfeeding. Those practices with minimal improvement, namely, BCG vaccine and OPV administration, may have been due to incentives to minimize waste; for example, each BCG vial contained 10 doses, so coaches observed birth attendants avoiding administration unless a certain number of babies was present to avoid wasting vaccines.

DISCUSSION

Implementation of the WHO Safe Childbirth Checklist with peer coaching and data feedback was associated with improved uptake of essential birth practices among birth attendants in the presence of a coach. We found greater than 90% adherence by the final month of the intervention for 35 of 39 essential birth practices when a coach was present, compared with only 7 of 39 practices during the first intervention month. However, when coaches were not present, independent observers noted an average absolute difference of 24 percentage points in adherence in a subset of behaviors after 2 months of coaching.

Pilot testing of SCC implementation using a multilevel coaching approach in Karnataka, India, which served as a model for the larger BetterBirth Program in Uttar Pradesh, found similar improvements in the overall number of essential birth practices completed.[27] Other coaching or nurse mentoring programs designed to improve facility-based childbirth care have additionally included program-provided birth-related supplies[28] or technical training[29] while requiring relatively fewer coaching visits; these programs have found similar increases in the number of essential practices performed by birth attendants, although strategies to measure practice adherence varied across studies. Other attempts to improve the quality of childbirth using the SCC without peer coaching, such as in a tertiary hospital in Sri Lanka, found poor levels of adoption.[30]

FIGURE 3. Adherence to Essential Birth Practices by Birth Attendants in 15 Facilities, as Observed by Coaches Versus Independent Observers (With Coaches Absent) After 2 Months of the BetterBirth Intervention, Uttar Pradesh, India



Using a coaching-based implementation of the SCC in Uttar Pradesh, we have identified a number of themes that may account for the patterns of improvement observed, including degree of change and level of adoption, which may have broader implications for implementing the SCC in other settings.

Behaviors With Highly Visible Benefits

Health care workers do not want to cause harm and are often reluctant to try new ways of doing things.[31] Available evidence suggests that experiencing immediate, visible benefits from a new practice increases the likelihood that an individual will repeat the new practice; this visibility can support behavior change and habit formation.[32,33] For birth attendants in intervention facilities, essential birth practices with tangible benefits were more easily incorporated into routine practice. These early wins helped to increase birth attendants' interest and commitment to incorporating essential practices on the SCC into their daily routines. For example, soon after initiation of coaching, birth attendants in many facilities reported switching their use of oxytocin from intravenous administration to augment labor to intramuscular administration immediately postpartum, which they felt reduced the incidence of hemorrhage and fetal distress. This represents a lifesaving improvement in care and complies with WHO guidelines for the Active Management of the Third Stage of Labor (AMTSL) that every woman should receive a uterotonic soon after delivery to prevent hemorrhage.[34,35] Likewise, although immediate skin-to-skin contact was not common practice, with coaching support birth attendants recognized tangible improvements in babies' status, including better temperature regulation and easier initiation of breastfeeding. A third behavior with visible benefits was for the birth attendant to check the mother for bleeding after delivery and before discharge. Although postpartum hemorrhage is a well-known cause of maternal mortality, routinely checking for bleeding in the mother was frequently skipped. With coaching reminders, birth attendants saw the value of routinely assessing bleeding in order to recognize hemorrhage early.

Experiencing immediate, visible benefits from a new practice increases the likelihood that an individual will repeat the new practice.

TABLE 2. Implementation Experience of Coaches and Independent Observers on Implementing the WHO Safe Childbirth Checklist in Uttar Pradesh, India

Summary of Coach-Observed Adherence Over Intervention Period	Essential Birth Practice Example	Average Adherence Level Observed by Coach	Absolute Difference Over Time (Observed by Coach)	Qualitative Summary of Coaches' Implementation Experience	Summary of Independent Observers' Findings
Minimal improvement (<15 percentage points) due to high initial adherence	Supply preparation before delivery (gloves, cord ligature, blade)	98%, 98%, 97%	6%, 5%, 8%	Coaches used the SCC to encourage birth attendants and labor room staff to prepare and organize materials prior to deliveries or early in the day so that supplies were ready to use.	Supply preparation remained consistent even when the coach was absent
	Measuring baby's weight after birth	93%	9%	Measuring a baby's weight is a standard requirement in birth registries and used to calculate Vitamin K dosage, thus weight was frequently taken. Additional pressure from families to know a baby's birth weight contributed to high adherence.	Measuring a baby's weight remained consistent even when the coach was absent.
Minimal improvement (<15 percentage points) achieved	BCG vaccine administration	77%	13%	Incentives at the facility and district level to minimize waste may have contributed to less consistent administration of BCG and other vaccines. Each BCG vial contained 10 doses; birth attendants were observed to avoid administration unless a certain number babies were present to avoid wasting vaccines.	N/A (not measured).
	Oral polio vaccine administration	87%	3%		
Moderate improvement (15 to 24 percentage-point absolute difference)	Hand hygiene before delivery	90%	18%	Coaches found that hand hygiene was more consistently done before delivery, compared with before a vaginal exam during admission.	This behavior saw the greatest difference between coach and independent observer (92% vs. 36%).
	Oxytocin administration within 1 minute of delivery	92%	19%	Birth attendants noticed the effects of changing the timing and route of oxytocin administration—from IV administration to augment labor to IM administration immediately postpartum—which they felt contributed to decreased hemorrhage and decreased fetal distress.	Moderate absolute difference (17 percentage points) when the coach was not present.
	Skin-to-skin immediately after birth	87%	23%	Coaches observed that birth attendants appreciated tangible improvements in babies' status from initiating skin-to-skin immediately, including better temperature regulation and easier initiation of breastfeeding.	Minimal absolute difference (13 percentage points) when the coach was not present.

Continued

TABLE 2. Continued

Summary of Coach-Observed Adherence Over Intervention Period	Essential Birth Practice Example	Average Adherence Level Observed by Coach	Absolute Difference Over Time (Observed by Coach)	Qualitative Summary of Coaches' Implementation Experience	Summary of Independent Observers' Findings
Greatest improvement (≥25 percentage-point absolute difference)	Check mother for bleeding after delivery	89%	26%	Coaches noted that birth attendants saw the value of routinely assessing bleeding in order to recognize hemorrhage early, when it is easier to treat.	N/A (not measured).
	Initiation of breastfeeding	87%	27%	Coaches felt that they were able to reinforce the importance of this practice due to the clear governmental guidelines that promote breastfeeding.	Moderate absolute difference (23 percentage points) when the coach was not present.
	Skin-to-skin at 1 hour	83%	29%	If skin-to-skin was not initiated immediately, coaches found it difficult to gain commitment to this practice, as birth attendants faced competing priorities of needing to complete birth-related paperwork and families' pressure to show the newborn to relatives waiting outside of the labor room.	N/A (not measured).
	Temperature measurement after delivery (mother, baby)	86%, 81%	30%, 36%	Birth attendants commonly used their hand to subjectively feel if a patient had a fever and were satisfied with this method. Thermometers may have been broken or misplaced. Many facilities experienced unreliable electricity, and thermometers were difficult to read in dark rooms. Coaches found that it was challenging to gain commitment to this behavior.	Major absolute difference in measurement of baby's temperature (48 percentage points) when the coach was not present. Independent observers did not document mothers' temperature after delivery.
Variable improvement in checklist use	Checklist use On admission Before delivery After delivery Before discharge	 94% 87% 92% 97%	 14% 28% 21% 9%	More structured patient assessments that occurred on admission and within 1 hour after birth were conducive to SCC use. Just before delivery was an extremely busy time for birth attendants; birth attendants frequently regarded referring to a checklist as more of a burden or barrier to providing timely care at pause point 2. Because the SCC was a standalone document and not integrated into the existing patient record (bedhead ticket), it was easy to overlook. Coaches saw the importance of advocating to the heads of facilities to integrate the SCC into the bedhead ticket.	Moderate to major absolute difference when the coach was not present (38 percentage-point difference in checklist use on admission, 62 percentage-point difference before delivery, 21 percentage-point difference after delivery). Independent observers were not present at discharge.

Abbreviations: BCG, bacille Calmette-Guérin; IM, intramuscular; IV, intravenous; SCC, Safe Childbirth Checklist; WHO, World Health Organization.

Behaviors that required extra effort with little visible benefit were more challenging for coaches to gain birth attendants' buy-in.

Slow or Resistant Change

Checklist-related behaviors that required extra effort with little visible benefit were more challenging for coaches to gain birth attendants' buy-in, even if there was a well-researched reason or mandate to comply. For example, lack of compliance with hand hygiene practices is a well-known issue for health care workers.[36] We found that birth attendants would wash hands if a coach was physically present, but when a coach was not present birth attendants performed hand hygiene on only 36% of occasions before delivery. Although hand hygiene is critical for infection prevention,[37] symptoms generally do not occur until after a mother and baby have been discharged from the facility and no longer are receiving care from the birth attendants. Thus, lack of a clear, immediate benefit from handwashing as well as the additional time and effort needed to perform the behavior likely limited the sustainability of improvements in handwashing.

Some birth practices were practiced in most facilities from the beginning due to governmental oversight and required documentation, such as measuring baby's weight after delivery.

Likewise, using a thermometer to measure a mother's or baby's temperature was not current practice at many facilities at the beginning of the intervention. Although adherence with this practice with the coach present was 95% for mother's temperature and 91% for baby's temperature after just 2 months of the intervention, when coaches were not present, temperature was measured for mothers in only 54% of occasions and in babies in only 42% of occasions. Field staff reported that birth attendants commonly used their hand to subjectively feel if a patient had a fever and were satisfied with this method, especially if a thermometer was missing. Additionally, many facilities experienced unreliable electricity, and thermometers are difficult to read in dark rooms. The increased complexity of using a thermometer instead of tactile approximation in addition to the difficulty of seeing the thermometer in a dark room represent 2 unfortunate barriers that have reduced adoption of new behaviors.[33]

Importance of Leadership Support

The SCC is included as part of the Government of India Maternal and Newborn Health Toolkit[24]; however, it has not been widely used in Uttar Pradesh and was not in use at any participating facility at the start of the trial. Formally ensuring state- and district-level administrative support for the program and the subsequent 2-day training for facility staff to launch the BetterBirth Program at each facility may have contributed to the high initial adherence to many essential birth practices during the first month of the intervention (mean: 77%; range: 45% to 98%). This is especially relevant given the low level of birth attendants' adherence to essential practices found in similar studies in the region.[38]

Systems-Level Incentives

Certain essential birth practices were practiced in most facilities from the beginning of the intervention due to governmental oversight and required documentation. For example, measuring a baby's weight following delivery is a standard requirement in birth registries and thus was frequently performed. Breastfeeding, although also part of a governmental promotion strategy, did not require specific documentation and thus did not have the same high level of adherence. However, behaviors such as breastfeeding practices were responsive to coaching and increased during the intervention, with coaches reporting that this occurred because they were able to reinforce the importance of the practice due to the clear governmental guidelines.

Conversely, incentives at the facility and district level to minimize waste may have contributed to less consistent administration of BCG and other vaccines. Each vial contained 10 doses, and birth attendants were observed to be avoiding administration unless a number of babies were present at once in order to not waste vaccine. Due to limitations in data collection, we did not know how many babies returned to the facility at a later date to receive the vaccines.

Integrating the SCC Into Existing Workflows

Encouraging the habit of SCC use had mixed success. The more structured patient assessments that occurred on admission and within 1 hour after birth were conducive to SCC use. However, just before delivery (pause point 2) is an extremely busy time for birth attendants; birth attendants frequently regarded referring to a checklist as more of a burden or barrier to providing timely care at this point. Because the SCC was not always well integrated into the existing patient record ("bedhead ticket"), it was easily overlooked. Practices that improved at pause point 2, namely ensuring the necessary supplies were ready at the bedside, likely improved through advance preparation of birth trays with all necessary supplies at the start of the shift.

Limitations

This analysis had a number of limitations. Given the high level of adherence reported by coaches, it

is possible that coaches may have overstated birth attendants' adherence due to social desirability or fear of bad reviews if improvement was not seen. Additionally, although we assume that adherence to essential practices recorded by an independent observer reflects normal day-to-day care, it is possible that we experienced a Hawthorne-like effect in our measurements. However, Leonard and Masatu found that while having an observer present will cause clinicians to positively change their behavior when first observed, clinicians return to their typical practices after 10 to 15 observations.[39] Since BetterBirth staff spent substantial time at each facility, this may limit the influence of any Hawthorne-like effect. To minimize bias, we could have installed video cameras or another passive observation tool,[40] but this approach was not cost-effective for the scale of the intervention and likely would not have been accepted by facility staff, patients, or the Institutional Review Boards reviewing the trial's ethical procedures.

Observations were structured to record only whether clinical practices occurred, such as taking blood pressure and listening for fetal heart sounds. We did not determine the accuracy of measures taken by birth attendants or whether clinical practices, such as neonatal resuscitation, were conducted correctly. A forthcoming analysis will look at whether the intervention was associated with reductions in maternal and neonatal mortality and maternal morbidity.[20] Additionally, for this analysis we did not focus on the ultimate receivers of care—the patients themselves—who may perceive the performance of essential practices and their overall quality of care differently.

Coaches and independent observers were not able to document adherence to essential practices at all pause points for all deliveries. For example, neither coaches nor independent observers made observations at night due to safety concerns for study staff; practices at night may be different than those during the day. Coaches worked with birth attendants and facility staff in all intervention facilities to standardize discharge procedures, to improve the quality of recovery room offerings, and to encourage women and their families to stay for the minimally recommended 24 hours postbirth. Nevertheless, many women left facilities within 6 hours after birth due to family pressures and lack of food availability, and these departures were generally against medical advice. Because women often leave without informing facility staff, it was not possible for independent observers to observe discharge procedures in a standard manner across all study facilities.

Due to the small number of facilities included in the subanalysis, we were unable to confidently assess if particular facility characteristics or programmatic factors were associated with these differences. In comparing the coach-recorded adherence rate in the 15 facilities of the subanalysis versus the 45 facilities not in the subanalysis, we found no major differences between the 2 groups.

Future Research

While we advanced the understanding of how and when checklists are used in the presence or absence of a peer-coach, there are many areas to explore further. As part of the randomized controlled trial, the BetterBirth Program used a standard number of coaching visits with a prescribed frequency across all facilities. Further inquiry is needed on how the frequency and length of coaching can be structured to maximize sustained behavior change. Additional research is also needed to assess if there is a threshold level of adherence to essential practices that would be associated with improvement in health outcomes since consistent and complete adherence to the SCC and essential birth practices may not be likely in standard clinical practice. More research is needed to understand if there are specific programmatic, facility, or maternal characteristics that account for differences in adherence and how the SCC with coaching could operate as a team-based vs. individual-level intervention for health care workers. Sustainability will be assessed in a forthcoming analysis that explores adherence to essential practices 12 months after the start of the coaching program. Finally, a cost analysis of delivering this intervention in the context of Uttar Pradesh is currently underway.

Further research is needed to discover how the frequency and length of coaching can be structured to maximize sustained behavior change.

CONCLUSION

We conclude that coaching was effective in increasing the uptake of birth attendants' essential birth practices when a coach was present, but adherence to some behaviors was reduced when the coach was absent. These findings will help to optimize the use of peer coaches and improve overall implementation of the SCC at future facilities, to improve the quality of care available during childbirth, and to understand how to improve behavior change interventions with health care workers.

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Competing Interests: Atul A Gawande receives royalties for books and essays, including on improving quality and delivery of health care using checklists. The other authors declare no competing interests.

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ORIGINAL ARTICLE

The BetterBirth Program: Pursuing Effective Adoption and Sustained Use of the WHO Safe Childbirth Checklist Through Coaching-Based Implementation in Uttar Pradesh, India

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The BetterBirth Program relied on carefully structured coaching that was multilevel, collaborative, and provider-centered to motivate birth attendants to use the WHO Safe Childbirth Checklist and improve adherence to essential birth practices. It was scaled to 60 sites as part of a randomized controlled trial in Uttar Pradesh, India.

See related article by Marx Delaney.

ABSTRACT

Shifting childbirth into facilities has not improved health outcomes for mothers and newborns as significantly as hoped. Improving the quality and safety of care provided during facility-based childbirth requires helping providers to adhere to essential birth practices—evidence-based behaviors that reduce harm to and save lives of mothers and newborns. To achieve this goal, we developed the BetterBirth Program, which we tested in a matched-pair, cluster-randomized controlled trial in Uttar Pradesh, India. The goal of this intervention was to improve adoption and sustained use of the World Health Organization Safe Childbirth Checklist (SCC), an organized collection of 28 essential birth practices that are known to improve the quality of facility-based childbirth care. Here, we describe the BetterBirth Program in detail, including its 4 main features: implementation tools, an implementation strategy of coaching, an implementation pathway (Engage-Launch-Support), and a sustainability plan. This coaching-based implementation of the SCC motivates and empowers care providers to identify, understand, and resolve the barriers they face in using the SCC with the resources already available. We describe important lessons learned from our experience with the BetterBirth Program as it was tested in the BetterBirth Trial. For example, the emphasis on relationship building and respect led to trust between coaches and birth attendants and helped influence change. In addition, the cloud-based data collection and feedback system proved a valuable asset in the coaching process. More research on coaching-based interventions is required to refine our understanding of what works best to improve quality and safety of care in various settings.

Note: At the time of publication of this article, the results of evaluation of the impact of the BetterBirth Program were pending publication in another journal. After the impact findings have been published, we will update this article with a reference to the impact findings.

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INTRODUCTION

The reduction of preventable maternal and neonatal morbidity and mortality associated with childbirth remains a critical challenge in global health.[1,2]

Previously, countries—especially low- and middle-income countries—have embraced interventions focused on encouraging childbirth to take place in health care facilities; however, despite the success of many of these interventions, the shift to facility-based childbirth has not succeeded in improving all childbirth-related outcomes at the levels expected.[3] Improving the quality of care received by mothers and newborns during facility-based childbirth is the next step in improving these health outcomes.

One important component of high-quality health care is the provision of care according to evidence-based guidelines. In facility-based childbirth care, one of the main causes of preventable harm is the failure to deliver essential birth practices to all mothers and newborns at the appropriate time during childbirth. Essential birth practices are provider behaviors for which evidence exists to prove that they increase the quality and safety of care during childbirth; these practices, when performed consistently and correctly, can save the lives of mothers and newborns. The failure to perform these practices is often called a "know-do" gap and has been identified in many areas of health care.[4]

In specific health care settings, well-implemented checklists have successfully bridged the know-do gap, changing provider behavior by increasing adherence to evidence-based guidelines.[5] Studies have demonstrated that this approach to improving quality of care has significantly improved outcomes in intensive care medicine and in surgery, including in resource-limited settings.[6,7] Based on these successes, the World Health Organization (WHO) and collaborators developed the WHO Safe Childbirth Checklist (SCC), a collection of 28 evidence-based essential birth practices associated with improved maternal and neonatal outcomes.[8,9]

Experience with the WHO Surgical Safety Checklist and with similar quality-improvement and patient-safety interventions has established that simply introducing a checklist to a facility or provider without a plan for engagement and sustained reinforcement does not lead to improvement in health care practices.[10–13] Ensuring consistent adherence to these practices requires both their codification into guidelines, as well as deliberate behavior change interventions to support adoption of these evidence-based practices.[14]

With the BetterBirth Program, we aimed to develop a systematic approach that would enable health care workers to adopt and use the WHO Safe Childbirth Checklist during their provision of childbirth care. As such, we sought to empower birth attendants and other facility and district personnel to identify, understand, and ultimately resolve barriers they might face in using the SCC to deliver quality maternal and newborn care, with coaching as the main strategy to engage with health care workers. The BetterBirth Trial, a matched-pair, cluster-randomized controlled trial, was implemented in 120 facilities (60 intervention, 60 control) across 24 districts in the state of Uttar Pradesh, India.[15] Evidence of the impact of the BetterBirth Program on birth attendants' performance of essential birth practices and on health outcomes for mothers and newborns is forthcoming.

One of the main causes of preventable harm in facility-based childbirth care is the failure to deliver essential birth practices.

Behavior change interventions and adoption of evidence-based practices are enhanced by application of a theoretical framework to organize strategies of behavior change.[14] To develop the BetterBirth Program, we modified the Opportunity-Ability-Motivation (OAM) framework of behavior change to ground our strategy design, particularly in how we aimed to structure coaching and supervision of health care workers.[14,16–18] Originally, the OAM framework was used to describe consumer behavior; to make it more applicable to our work—given the prevalence of supply-related challenges in resource-limited settings—we separated "Supply" from the more general category of "Opportunity." Thus, our modified OAMS framework contained 4 categories into which barriers to behavior change can be classified:

- **Opportunity:** "external" and systems-level barriers concerning the circumstances under which the provider must practice the new behavior (e.g., the amount of staff available, the time available for performing the practice, the size of the facility/number of beds available, the characteristics of the patient population)
- **Ability:** barriers concerning the provider's knowledge, skills, and competence related to the new behavior (e.g., clinical skills, communication skills)
- **Motivation:** "internal" barriers concerning the provider's willingness to change his or her behavior (e.g., understanding and believing in the significance of the new behavior)
- **Supplies:** a subset of Opportunity, specifically referring to the availability of necessary medications, equipment, and other consumable materials

While checklists have successfully bridged the know-do gap, experience has shown that a plan for engagement and sustained reinforcement is also needed to improve health care practices.

Here, we describe the design of the BetterBirth Program in detail. We include specific, concrete

examples to illustrate the various aspects of our intervention: quotes that the implementation team gathered in focus group discussions with coaches and other examples drawn from the Coach Support Tools (qualitative data collection tools used by coaches during their work in facilities). We have described the methodology of the BetterBirth Trial,[15] including pilot testing of the intervention,[19] elsewhere. A companion article published in this issue of *Global Health: Science and Practice* presents results on the effect of the intervention on birth practices.

INTERVENTION: THE BETTERBIRTH PROGRAM

The BetterBirth Program incorporated 4 key components: implementation tools, an implementation strategy, an implementation pathway, and a sustainability plan.

BetterBirth Implementation Tools: SCC and Pulse

The WHO Safe Childbirth Checklist is organized into 4 pause points when birth attendants should check that they have completed essential birth practices: on admission, just before pushing, soon after birth, and at discharge.

By reminding birth attendants to perform essential birth practices at the appropriate time, the SCC is intended to improve the safety and quality of care received by mothers and newborns. The SCC is organized into 4 pause points, or critical moments, in facility-based childbirth care, when birth attendants should "check" that they have completed essential birth practices: (1) on admission, (2) just before pushing (or before cesarean delivery), (3) soon after birth (within 1 hour), and (4) at discharge (Supplement). These pause points allow birth attendants to make their "checks" both at critical times when they can protect the mother and newborn against dangerous complications and when it is convenient for them to take the time to perform the checks.[9]

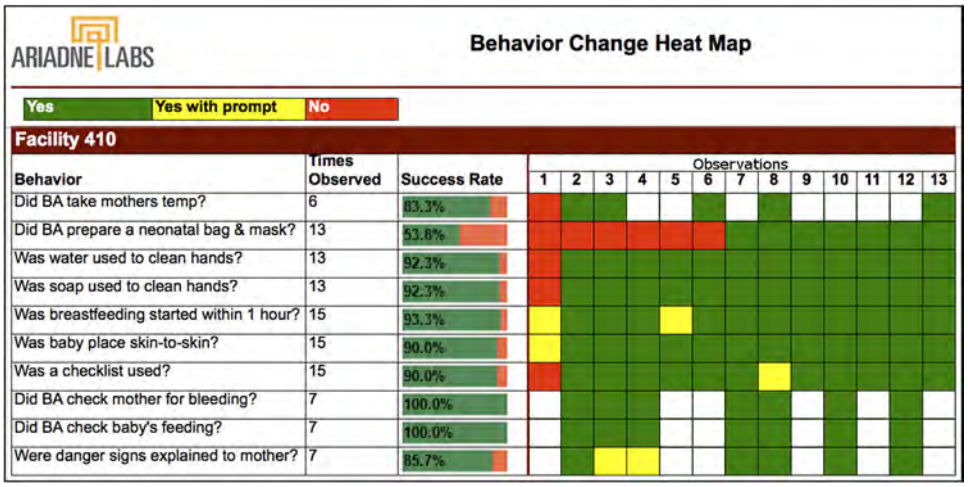
In the BetterBirth Trial, birth attendants completed a new paper version of the SCC—which was initially adapted to fit the relevant national guidelines of India—for each mother and attached it to the mother's chart or bedhead ticket to allow them to more easily track practices for each mother-and-baby pair.[15] Most commonly, the birth attendants applied the "Read-Do" method: they first read the item on the SCC, then completed the task. Alternatively, they used the "Do-Confirm" method, in which they completed the task then immediately read the item on the paper or poster SCC to confirm that it was performed appropriately. As they completed each essential birth practice, birth attendants put a check in the box located to the left of the item to indicate completion. Relevant notes, such as temperature and blood pressure readings, were written to the right of each item, where additional information is provided to guide the birth attendant in clinical decision making. For example, prompts to check temperature and other clinical signs are noted to the right of the SCC item related to the administration of antibiotics. While the SCC was primarily completed by an individual birth attendant for each patient, it was sometimes used as a team, particularly in the case of organizing supplies for mother and baby as indicated in Pause Point 2.

In a pilot study, with successful adoption and sustained use of the SCC, birth attendants demonstrated improved adherence to essential birth practices.[19,20] Moreover, the SCC further facilitated implementation of the BetterBirth Program by serving as a tool for coaches. The organized list of essential birth practices on the SCC served as the foundation of coaches' observations of birth attendants' behavior.

Built to facilitate the implementation of the BetterBirth Program and the management of the BetterBirth Trial, Pulse is a management information system designed to provide rapid feedback on implementation status. Operable on mobile phones and tablets, Pulse provided near-real-time access to information about the use of the SCC, adherence to specific essential birth practices, and supply availability. A data entry app developed by Dimagi (http://www.dimagi.com/products/), called CommCare, allowed coaches to record their observations and put those observations to use in further coaching. For example, a coach would record whether a birth attendant performed specific practices (such as skin-to-skin warming and breastfeeding), and if not, diagnose and record the underlying barrier according to the OAMS framework. Coaches and coach team leaders were able to access a summary report of that birth attendant's practices or an aggregate report of the facility's practices. These summary data were generally displayed in a visual heat map (Figure 1), allowing coaches, birth attendants, and other facility and district personnel to more easily recognize trends in the performance of essential birth practices and underlying barriers preventing behavior change. Finally, Pulse facilitated the overall implementation of the BetterBirth Program by aggregating coaches' observations at the facility and district levels to help various stakeholders analyze systemic trends and barriers to SCC use.

Visual heat maps allowed coaches and birth attendants to more easily recognize trends in the performance of essential birth practices.

FIGURE 1. Partial Facility-Level Heat Map of Adherence to Essential Birth Practices, Illustrative Example (Not Real Data)



Success rates calculated as follows: green=1, yellow=0.5, red=0, white=N/A.

Abbreviation: BA, birth attendant.

BOX. Lessons Learned About Behavior Change From the U.S. Agricultural Extension Service

The success of the U.S. agricultural extension service resulted from how it pursued its goals: extension agents went out "into the field" to work with local farmers on integrating new developments in technology and farming techniques into the farmers' work. Moreover, each extension agent was guided by certain principles, which led to more successful relationships with the farmers:

- **Farmer-centered:** the agents paid close attention to and responded directly to the farmers' needs, and the agents' work was guided directly by a council comprised of local farm-community leaders.
- **Collaborative:** the agents invited the farmers to participate extensively in the processes of identifying what the local community needed, planning solutions, and evaluating the success of those programs.
- **Multilevel:** the agents also worked closely with other levels of the agricultural research establishment (such as the agronomy research departments at the then-young land-grant universities).

BetterBirth Implementation Strategy: Coaching

We understood from previous work with checklists and other quality-improvement and patient-safety programs that changing behavior is a challenging process requiring ongoing support.[21–23] Thus, we looked to other fields' successes for inspiration. In sports,[24] business,[25] and education,[26] coaching has been a popular and successful strategy for changing individuals' performance. One such example of a successful behavior-change intervention is the U.S. agricultural extension service, which was established in 1911 to help make American farmers' practices more modern and efficient by incorporating then-new scientific techniques (Box). Client-centered,

TABLE. Selection Criteria and Responsibilities of BetterBirth Program Team Members

Team Member	Qualifications/Selection Criteria	Responsibilities
Coach	• Nurse qualification • Trained in childbirth practices • Recruited from same hub as facility assignments	• Coach facility birth attendants (increase motivation, observe, and facilitate problem solving) • Manage 2–4 facilities at any one time; conduct 43 visits per facility
Coach Team Leader	• Physician or trained public health practitioner • At least 4 years of experience • Recruited from same hub as facility assignments	• Provide supportive supervision to the coach • Coach facility and district leaders to strengthen the health care system • Manage 4–5 facilities at one time; conduct 23 visits per facility
Childbirth Quality Coordinator	• Facility-based staff • Motivated and interested in the BetterBirth Program • Ability to influence and coach others • Well respected among other facility- and district-level personnel	• Orient new staff to the Safe Childbirth Checklist • Coach facility birth attendants • Coach facility and district leaders to strengthen the health care system • Collect data on facility progress and areas for improvement

collaborative, multilevel, in-person support—or coaching—allowed the Green Revolution to flourish.[27] These crucial lessons, as well as lessons from other models such as the Improvement Collaborative Approach, provided a foundation in designing the BetterBirth coaching strategy.[28] BetterBirth coaching emphasized the individual barriers to adopting essential birth practices and also employed a team-level approach to address systemic barriers to adoption.

In the program, nurse coaches worked closely with birth attendants, who were also typically nurses, to provide the support that the birth attendants needed in order to use the SCC to improve care. Simultaneously, coach team leaders, who were either physicians or public health professionals, supported facility and district leaders as they strengthened the health care systems' facilitation of the use of the SCC. To ensure a local facility-level champion, coaches and facility leaders collaboratively chose and provided support to a childbirth quality coordinator (CQC) (an individual or a small team), who conducted many of the coaching tasks in the absence of the BetterBirth coach. The CQC was identified during the first 2 months of the program. Please see the Table for details on qualifications and selection criteria for each of these roles. Within the BetterBirth Trial, coaching entailed 3 main tasks and was characterized by 3 main principles, enumerated below.

Coaches pursued 3 main types of activities: motivated birth attendants to use the checklist; observed, recorded, and fed back information about use of the checklist; and guided birth attendants to solve problems.

To prepare coaches, each coach attended a 5-day interactive training that focused on core coaching skills, such as effective communication, respectful relationship building, and barrier and solution identification, as well as on the OAMS behavior-change framework. Throughout the trial, coaches and coach team leaders also received 2–3 day refresher trainings, which offered similar skills training and opportunities for peer learning and troubleshooting. Coach team leaders also provided supportive supervision to coaches during facility visits, in which both coaches and coach team leaders were present.

Three Coaching Tasks

Coaches pursued 3 main types of activities during their facility visits. First, based on local circumstances and dynamics, coaches worked to *increase birth attendants' motivation* to use the SCC. If a birth attendant did not perform a specific essential birth practice, a coach might explain the significance of that practice by using the SCC as a visual aid or by telling a story about a childbirth in which the practice was performed. Coaches had to identify what motivated each birth attendant—competition among peers or other facilities, facts and data, or emotional stories—and tailor their approach accordingly. Coaches would keenly observe the birth attendant and the contextual environment, as well as probe with open-ended questions, to understand the root cause of the barrier. When

describing how coaches overcame resistance to using the SCC, one coach noted:

> *We have to empathize with the birth attendant and explain the importance of conducting each item on the SCC. As humans, it's not always possible for us to remember each item—especially when we are busy.*

Similarly, coaches celebrated success, both with the birth attendant and among the birth attendant's peers within the facility.

Second, using the Pulse app, coaches *observed, recorded, and fed back information* about SCC use, the status of the facility's systems (such as supply availability), and any barriers the birth attendant, facility, and/or district faced in using the SCC. By making birth attendants and facility leaders aware of the performance (and nonperformance) of essential birth practices within the facility, the coaches helped to identify areas for improvement. The importance of this task draws from the lessons learned with the Standards-Based Management and Recognition (SBM-R) model.[29] Ongoing measurement of performance was recorded to guide the improvement process and motivate the providers to improve care over time. Coaches and coach team leaders recorded their observations in Pulse using a quantitative tool, which also captured the specific barrier to performing the practice using the OAMS framework. The reports generated from Pulse showcased activities performed without prompting in green, while practices that were prompted were marked yellow, and practices not performed at all were marked red (Figure 1). For each observation marked red (not performed), a barrier was also indicated to describe why: O for opportunity, A for ability, M for motivation, and S for supplies. Coaches remarked that birth attendants were motivated by the heat maps and worked to turn "reds" (unperformed practices) into "greens" (practices performed unprompted).

Similarly, Coach team leaders collected information on and offered feedback about the state of a facility's systems and practices to facility leaders. When coaches were not able to directly observe any of the pause points during the facility visit, they still found opportunities to discuss past cases, current supply gaps, and skilled birth attendant national guidelines. Coaches and coach team leaders also completed structured diaries for each facility visit and district engagement that captured qualitative information about each of their interactions, drawing not only from direct observations but also from discussions related to practices and processes even in the absence of direct observations. The coach team leader qualitative tool specifically captured information on team-based coaching discussions and data feedback meetings, particularly around supply availability as well as facility-level practice and processes changes.

In the third task, *problem solving*, coaches guided birth attendants through a problem-solving process based on the results of the second task (observe, record, and provide feedback). When the coach identified an essential birth practice that the birth attendant did not perform even after prompting from the coach, the coach collaborated with the birth attendant to identify what barrier blocked her from performing the practice and to categorize that barrier according to the OAMS framework. Finally, the coach and the birth attendant agreed upon a strategy for resolving the identified barrier and worked together as a team toward realizing that strategy. The coach team leader helped by facilitating the escalation of the problem to higher levels of facility and district leadership if needed, where the coach team leader also facilitated the problem-solving process. When there was turnover of staff and shift changes, coaches and coach team leaders would make every effort to arrange their visits such that they could work individually with as many birth attendants at the facility.

Coaches did not typically have problems finding time with birth attendants to discuss cases and review feedback and thus were generally able to build a strong relationship and rapport with each birth attendant. When coaches observed that birth attendants were routinely not performing the tasks associated with the fourth pause point (at discharge), they engaged the birth attendants in discussions to determine what barriers were preventing the adherence to these essential birth practices. The birth attendants pointed out that, for cultural and logistical reasons (e.g., wanting to introduce the new baby to family members, needing to return home to care for other children, not having access to food in the facility), mothers often left the facility—against medical advice—much earlier than the expected 24 hours postpartum recommended by the SCC. Their early departures left no time for the birth attendants to perform the fourth pause point. Together, birth attendants and coaches agreed to administer the discharge practices (pause point 4) regardless of how soon the mother left the facility. They also decided together to approach the female community health workers (Accredited Social Health Activists or ASHAs) who accompanied women to

the facility for childbirth in order to educate them on the need for women to remain in the facility for 24 hours after giving birth. The birth attendants shared with the ASHAs the potential dangers of leaving the facility early and warning signs to watch for once a mother had returned home. As a result, the ASHAs began to encourage mothers to remain at the facility longer post-delivery.

Three Coaching Principles

Coaching was multilevel, collaborative, and provider-centered.

What coaches focused on was only one part of the intervention. Equally, if not more, important was *how* the coaches pursued their tasks. First, coaching in the BetterBirth Program was *multilevel*. While coaches worked with birth attendants, coach team leaders similarly worked with facility and district leaders to strengthen the systems necessary to facilitate sustained use of the SCC. For example, coaches noticed birth attendants refusing to administer the bacille Calmette-Guérin (BCG) vaccine to only 1 or 2 babies at a time, instead asking the mothers to return to the facility at a later time for the vaccine. Discussions with birth attendants revealed that they believed they were required to use all 10 doses of vaccine in each vial immediately upon opening it; thus, to avoid waste, they would only vaccinate if many babies were present in the facility at once. To resolve the misunderstanding, coaches and coach team leaders worked with facility- and district-level health care leaders to clarify the policy around the supply of BCG vaccine. In addition, at a district-level meeting, leaders explained to the birth attendants the ready availability of plenty of vaccine as well as the procedures for acquiring more for their facility, in order to motivate them to vaccinate each baby—to open a vial even when only 1 baby was present. To be successful, this effort required collaboration not only between the peer-to-peer pairings of coaches and birth attendants, coach team leaders, and health care leadership but also between the 2 pairs as well.

Second, coaching in the BetterBirth Program was *collaborative*. Coaches worked with birth attendants, and coach team leaders worked with facility and district leaders, in a supportive, constructive, respectful peer-to-peer manner. The coaches were also nurses (and, due to cultural norms, female) with similar backgrounds and training as the birth attendants they coached; the coach team leaders who worked with facility and district leaders—both clinical and administrative—were physicians or experienced public health professionals. Coaches and coach team leaders used strong communication skills and a nonjudgmental attitude to build a relationship of trust and understanding with the individual(s) they coached. One birth attendant remarked:

> *At first I didn't think that this young BetterBirth Coach could help me very much. But she was very polite and pleasant to work with. The coach helps me to remember and learn to do each practice in a systematic and consistent way for every patient. I bring the skills, she brings the process.*

Another noted:

> *It wasn't like talking to someone who was trying to find mistakes. It was like talking to a friend.*

Birth attendants and facility and district leaders thus were invited to be active, equal participants in the process of improvement.

Third, coaching was *provider-centered*. Similar to the Client-Oriented, Provider-Efficient services model (COPE), coaching focused on enabling providers to identify problems and develop their own solutions using local resources.[30] At all levels of the health care system, coaches set local priorities for the implementation of the BetterBirth Program based not upon the expectations and needs of the coaches and the coach team leaders but upon the expectations and needs of the birth attendants and facility and district leaders they coached. The initial priorities that coaches and coach team leaders addressed in each facility, for example, were determined by the facility personnel at the launch events; these ranged from clarifying referral protocols to handling biological waste to improving communications. As a result of this provider-centered attitude, coaches needed to be nimble and adaptive to differing circumstances and contexts as the priorities of birth attendants and facility and district leaders shifted. Overall, coaching in the BetterBirth Program was customized to the specific individual being coached and the situation in which the individuals were working.

BetterBirth Implementation Pathway: Engage, Launch, Support

The BetterBirth implementation pathway incorporated 3 stages: Engage, Launch, and Support (Figure 2). Each stage involved discrete, sequential goals that built upon one another. Together, the 3 stages linked together in a pathway leading from the first collaboration between implementers and

FIGURE 2. BetterBirth Implementation Pathway, Uttar Pradesh, India

key stakeholders to a process aimed at improved safety and quality of care for mothers and newborns during facility-based childbirth care.

The core of the *Engage* stage of the BetterBirth implementation pathway was collaborating with key leaders at multiple levels of the health care system to introduce them to the SCC and gather support for the BetterBirth Program, identify local needs, and engage in problem solving to begin addressing those needs.

During the Engage stage of the BetterBirth Trial in Uttar Pradesh, India, implementers worked closely with state health care officials to adapt the SCC to fit the Government of India maternal and child health guidelines. Coach team leaders from the BetterBirth Program also met with facility and district leaders in order to secure their commitment to the BetterBirth Program and to identify their priority areas for improvement.

The *Launch* stage aimed for collaboration between BetterBirth Coaches and those individuals who would be adopting and using the SCC (and those who would be directly supporting them). This stage involved introducing the key stakeholders to the SCC and gathering support for the BetterBirth Program's goals and methods, beginning to identify local barriers to adopting essential birth practices, and engaging in problem solving to begin resolving those barriers. BetterBirth Coaches led a "launch event" with facility personnel, seeking both to strengthen the sense of responsibility and motivation for ensuring high-quality care in childbirth services and to create an atmosphere of excitement and inspiration that would build confidence in the idea of behavior and system change.

During the Launch stage in the BetterBirth Trial, coaches used a flipbook illustrated with diagrams of SCC essential birth practices and motivational multimedia presentations to engage participants in a discussion about why each practice on the SCC is critical for a safe childbirth.[31–33] Coaches also facilitated a gap analysis, in which each facility's personnel—including those not directly involved in providing care during childbirth (e.g., pharmacists)—began the process of identifying the barriers to using the SCC in their facility and brainstorming resolutions for those barriers. These participatory gap-analysis discussions also served to guide coaches and coach team leaders in choosing initial areas of focus.

The central goal of the *Support* stage was to bolster the adoption and ongoing use of the SCC within facilities and to reinforce birth attendants' adherence to essential birth practices. To this end, coaches and coach team leaders visited facilities and worked directly with birth attendants and facility leaders (as well as with other facility personnel) to increase motivation, collect data, provide feedback, and problem solve around barriers to behavior change.

The Support stage of the BetterBirth Trial in Uttar Pradesh involved coaches visiting each intervention facility 43 times over 8 months. During the first 4 months, coaches visited each facility twice per week, then the frequency of their visits tapered until they visited each facility only once in the eighth month. Coach team leaders followed a similar but less intensive schedule, visiting each facility 23 times. Each coach was responsible for 2–4 facilities at a time; each coach team leader managed 4–5 facilities at a time.

Coaches visited each intervention facility 43 times over an 8-month period.

BetterBirth Sustainability Plan: Coaching for Empowerment and the Childbirth Quality Coordinator

BetterBirth Coaches and Coach Team Leaders provided neither monetary nor other material

benefits to the individuals or facilities they coached, nor did they offer those individuals direct skills training. Instead, a coach's central goal was to *empower* health facility leadership and staff. Coaching helped birth attendants and facility and district leaders to recognize the barriers they faced in using the SCC, and helped them develop the strategies to resolve those barriers by using the resources already available within the facility and the district—and, when possible, by strengthening the facility and district systems to support the use of the SCC. By empowering the birth attendants and facility and district leaders through coaching, the BetterBirth Program sought to create culture and capacity change that would last beyond the coaches' visits. As one birth attendant commented:

> *My coach helps to show me the path to where the solution exists. Now I feel confident to bring up issues to the MOIC [Medical Officer In Charge] or LMO [Lady Medical Officer].*

During the Support stage, coaches also collaborated with the personnel in each facility in order to produce a local sustainability plan for continuing to pursue the goals, methods, and effects of the program after the coaches moved on to other facilities. The local sustainability plan offered facility personnel another tool with which they could continue to practice and advocate better safety and quality of facility-based childbirth care.

Checklists alone do not resolve all barriers to behavior change.

As a second part of the sustainability plan, a CQC was collaboratively chosen early in the BetterBirth Program by coaches and facility leaders to be the "local champion" of the SCC. The choice of facility CQC was based on a staff member's motivation and interest in the BetterBirth Program, his or her ability to influence and coach others, and the level of respect she or he held among other facility- and district-level personnel, rather than on his or her title or role in the facility. With support from coaches and facility leaders, the CQC was responsible for the use of the SCC within the facility during and after the implementation of the BetterBirth Program, making certain that the facility practiced the principles embodied by the BetterBirth Coaches, even when those coaches were not present. According to one CQC:

> *We gained energy to continue quality and infection control measures and keep on improving [the] BetterBirth Program.*

Once the CQC was identified during the first 2 months of coaching, coaches oriented and supported CQCs in basic coaching skills for approximately 6 months before the intervention period ended. Within the intervention period, a formal training session was also organized at the district level to train the facility and district CQCs in observation and data collection techniques, delivering feedback, and other coaching methods. Practically, the CQC oriented new staff to the SCC, and continually motivated all staff in its adoption and use, and monitored and aided staff members in collaboratively addressing facility- and district-level barriers to SCC adherence. Another CQC reported:

> *. . . a very high motivation and self-confidence that safe birth practices can be very well implemented and continued even in the absence of BetterBirth. I can manage and check things and supplies very easily.*

The CQC received no extra incentives for playing this role within the facility or district.

LESSONS LEARNED

Although the BetterBirth Program revolved around using the WHO Safe Childbirth Checklist to improve essential birth practices, coaching was at the core of the program. Recognizing that checklists alone do not resolve all the barriers to behavior change, we adapted lessons from other behavior-change strategies, including the Improvement Collaborative Approach, COPE, and SBM-R,[28–30] into a public health intervention responsive to local needs. Further research is still required to understand what components of coaching, both individual and team-based, are most effective in influencing behavior uptake and other systemic change, and in which contexts. The BetterBirth Program required performing the coaching tasks (increasing motivation, measuring and offering feedback, problem solving) and operationalizing the coaching principles (multilevel, collaborative, provider-centered) in order to achieve adoption and sustained use of the SCC. BetterBirth Coaches' emphasis on relationship building and respectful communication during measurement-and-feedback and problem-solving tasks helped in creating trust and influencing change, even in situations where coaches were less senior or less experienced than the birth attendants they coached. However, in some facilities, this age gap remained a challenge. Initial results from pilot studies and data from the larger trial have indicated that the program was able to

increase essential birth practices in facilities, even when a coach was not present.[19,34]

At the same time, the implementation of the intervention across 60 study facilities and 24 districts (representing a population of approximately 60 million) in the state of Uttar Pradesh as part of the BetterBirth Trial suggests that with the same level of resources, the BetterBirth Program is replicable in a variety of facilities in Uttar Pradesh and in other similar contexts globally. We partially attribute the scale-up to 60 sites to the robust cloud-based data collection and feedback system, Pulse, which proved to be a unique and valuable asset in the process of coaching. However, lower-cost, lower-tech models may also prove to be equally effective in ensuring a robust monitoring and data-feedback loop to facilitate bringing the coaching-based intervention to scale.

Because we implemented the BetterBirth Program in the context of a matched-pair, cluster-randomized controlled trial, we followed a strict trial protocol for the intensity and frequency of coaching. For each of the 60 facilities, the intervention closely adhered to the protocol and the outlined implementation pathway (Engage, Launch, and 43 Support visits). However, outside of a trial context, a truly provider-centered (and therefore adaptive) coaching approach would involve adjusting the timing of coaching visits to match the needs of the facilities and the hours of birth attendants who had less exposure to coaching during daylight hours. Still, several organizations across India are currently testing coaching-centered interventions of various intensities, suggesting that a coaching-based model could be realistic for this context, albeit with fewer facility visits. Jhpiego's SCC implementation across the state of Rajasthan, India, includes facility-based coaching visits every 2 weeks for the first 2 months, followed by 4 once-per-month coaching visits,[35,36] and the Technical Support Unit in Uttar Pradesh has implemented monthly coaching visits for a period of 6 months for a childbirth case-sheet.[37,38] Given contextual limitations (such as high transfer rates of facility staff across Uttar Pradesh, including CQCs, and the safety concerns and significant distances that prevented the all-female nurse coaches from coaching in facilities after dark), we need more research on how to best structure and customize coaching-centered interventions like the BetterBirth Program in order to achieve and sustain the most effective adoption of essential birth practices.

CONCLUSION

The BetterBirth Program was centered around coaching in an effort to encourage the consistent, effective delivery of essential birth practices through adoption and use of the SCC, and to sustain this change through individual and facility- or team-level empowerment. The trial showed an improvement in performance of these practices after only 2 months of the intervention.[34] These results suggest that the BetterBirth strategy of implementing the WHO SCC with coaching can be a method for achieving change in facility-based childbirth care.[34] However, further research is needed to clarify which aspects of coaching-centered interventions contribute most to increasing use and sustainability of the SCC and to consistent adoption of essential birth practices. Other coaching-based interventions using the SCC have incorporated technical skills training in addition to coaching.[35,37,39] For example, Jhpiego incorporated a 1.5-day clinical training,[35] and the Technical Support Unit created a 3-day technical training.[37,38] Additional research is needed to understand which components of these coaching-based interventions influence sustainable behavior change and consistent application of essential birth practices using the SCC. Should health systems choose to integrate such a strategy to improve quality of care, understanding how it should be integrated into existing supervision models will be important. The goal of the BetterBirth Trial was to test effectiveness of a coaching-based approach to improve quality of care. Therefore, a highly structured, intensive intervention protocol was developed, based on the best available evidence on intensity and duration of coaching. Some elements to enhance sustainability were incorporated, such as the CQC, but overall, BetterBirth was designed to test effectiveness rather than sustainability. Therefore, there is ample scope for additional programmatic innovation to develop more sustainable models. As this becomes a public model for improving facility-based quality of care, sustaining funding for coaching visits and understanding how to prioritize among facilities appropriately will be important factors for sustainability and feasibility.

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ORIGINAL ARTICLE

Limited Service Availability, Readiness, and Use of Facility-Based Delivery Care in Haiti: A Study Linking Health Facility Data and Population Data

Wenjuan Wang,[a] Michelle Winner,[a] Clara R Burgert-Brucker[a]

Proximity to a health facility offering delivery services and readiness of the facilities to provide such services were poor in both rural and urban areas outside of Port-au-Prince. Availability of a proximate facility was significantly associated with women in rural and urban areas delivering at a facility, as was the quality of delivery care available at the facilities but only in urban areas.

ABSTRACT

Background: Understanding the barriers that women in Haiti face to giving birth at a health facility is important for improving coverage of facility delivery and reducing persistently high maternal mortality. We linked health facility survey data and population survey data to assess the role of the obstetric service environment in affecting women's use of facility delivery care.

Methods: Data came from the 2012 Haiti Demographic and Health Survey (DHS) and the 2013 Haiti Service Provision Assessment (SPA) survey. DHS clusters and SPA facilities were linked with their geographic coordinate information. The final analysis sample from the DHS comprised 4,921 women who had a live birth in the 5 years preceding the survey. Service availability was measured with the number of facilities providing delivery services within a specified distance from the cluster (within 5 kilometers for urban areas and 10 kilometers for rural areas). We measured facility readiness to provide obstetric care using 37 indicators defined by the World Health Organization. Random-intercept logistic regressions were used to model the variation in individual use of facility-based delivery care and cluster-level service availability and readiness, adjusting for other factors.

Results: Overall, 39% of women delivered their most recent birth at a health facility and 61% delivered at home, with disparities by residence (about 60% delivered at a health facility in urban areas vs. 24% in rural areas). About one-fifth (18%) of women in rural areas and one-tenth (12%) of women in nonmetropolitan urban areas lived in clusters where no facility offered delivery care within the specified distances, while nearly all women (99%) in the metropolitan area lived in clusters that had at least 2 such facilities. Urban clusters had better service readiness compared with rural clusters, with a wide range of variation in both areas. Regression models indicated that in both rural and nonmetropolitan urban areas availability of delivery services was significantly associated with women's greater likelihood of using facility-based delivery care after controlling for other covariates, while facilities' readiness to provide delivery services was also important in nonmetropolitan urban areas.

Conclusion: Increasing physical access to delivery care should become a high priority in rural Haiti. In urban areas, where delivery services are more available than in rural areas, improving quality of care at facilities could potentially lead to increased coverage of facility delivery.

INTRODUCTION

Haiti has the highest maternal mortality ratio in Latin America and the Caribbean, at an estimated 359 deaths per 100,000 live births.[1] Every year, thousands of women in Haiti die from causes that could be prevented by access to comprehensive and skilled obstetric care during pregnancy, childbirth, and the postpartum period.[2,3] Use of maternal health services, especially facility delivery, remains low in Haiti. Only 36% of births take place in health facilities, according to the 2012 Haiti Demographic and Health Survey (DHS).[4] Unless a woman delivers at a health facility, she is

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unlikely to have access to emergency obstetric care, which is considered the most important strategy for reducing maternal deaths.[5,6] Increasing use of facility delivery is critical for reducing maternal mortality in Haiti.

An extensive body of literature exists on factors that influence facility delivery.[7–11] The majority of studies have focused on the demand side—for example, the characteristics of women and their families. A few studies have looked at social contextual factors such as community norms, media access, and the level of local development.[12–15] In Haiti, a few studies have found that facility delivery was associated with maternal and birth characteristics, household poverty, use of antenatal care services, and community exposure to mass media.[16,17]

The effect of the supply side—delivery care offered in health facilities—on facility delivery has received only limited attention.[8,11] One of the main reasons that research on the effects of service provision is limited is lack of suitable data. Supply-side data typically come from health facilities and need to be linked to data from population-based surveys in order to explore the relationship between the provision of services and women's use of facility-based delivery care.

With the availability of geographic data from both household surveys and health facility surveys, it has become possible to link population data and health facility data within a geographic information system (GIS). A few studies have linked DHS data and facility census data to assess how distance to the closest facility affects women's use of reproductive health services.[18–20] For example, a study in Malawi and Zambia linking DHS clusters and health facilities (from a facility census) found that in both countries a longer straight-line distance from the DHS cluster to the closest facility offering emergency obstetric care significantly reduced the likelihood of facility delivery.[19] Another study in Zambia with the same methodology but focusing on antenatal care found that distance to the closest facility had a significant effect on the content of care women received but had no effect on number of antenatal care visits or timing of the first visit.[18] In a rural setting in Ghana, Nesbitt and colleagues linked health facility census data and health and demographic surveillance data from about 600 villages and found a significant association between distance to the closest delivery facility and women's likelihood of delivering in a health facility.[20]

While these studies have contributed to establishing a geospatial methodology to assess the relationship between service provision and use, linking DHS clusters and closest facilities is subject to misclassification errors. Because DHS cluster coordinates are displaced before release of the data (to ensure respondent confidentiality is maintained), the closest facility identified based on the released geographic data may not be the nearest facility in reality. Skiles and colleagues indicated that, due to displacement of cluster coordinates, the distance to the closest facility can be misclassified for 34% to 43% of clusters.[21] The displacement is an important limitation of the data, so instead of only looking at the closest facility our study measured the service environment (all available facilities) within a reasonable distance of the displaced cluster, thus representing the likely service environment of the real cluster location.

Increasing use of facility delivery is critical for reducing maternal mortality in Haiti.

Because of Haiti's mountainous terrain, physical accessibility remains one of the biggest barriers to using health care.[22,23] Gage and Guirlène Calixte linked women's reports on use of facility delivery care and community key informants' reports on health services and found that in rural Haiti the physical accessibility of health facilities was strongly associated with women's use of delivery care.[23] Women's odds of being attended by a skilled birth attendant were positively associated with the presence of a health worker providing antenatal care in the neighborhood but negatively associated with living in a mountainous terrain and with distance from the nearest hospital. Ruktanonchai and colleagues found that in the 5 East Africa countries studied, geographic inaccessibility was an important predictor of use of maternal health care services, including skilled birth attendance.[24] This furthers the argument that straight-line distance linkage between a facility and a DHS displaced cluster may cause misclassification in the Haiti context. Thus, the service environment approach is a better approximation of the likely access to health facilities for a woman.

Physical accessibility remains one of the biggest barriers to using health care in Haiti due to the mountainous terrain.

While physical access is important, another key determinant of service utilization is the quality of care. Families may bypass the nearest health facility when quality is an issue.[25–27] In examining the effect of the quality of care on use of services, some studies have looked at the quality of care from the user's perspective.[15,28] While this perspective is indicative, it is subject to the respondents' level of knowledge about the services provided at health facilities, which may be biased or misinformed. Among the limited number of

Another key determinant of service utilization, beyond physical proximity, is the quality of care of services.

studies based on linked population data and facility data, a few have looked at the quality of service provision in health facilities. The study in Zambia by Kyei and colleagues measured the level of care using an index that combined several process and structural aspects of antenatal care provided at facilities.[18] The level of service provision at the closest health facility was found to be significantly associated with the content of antenatal care received. In Nepal, when quality of care was measured solely in structural terms (e.g., infrastructure, availability of medicine, number of staff) a significant effect was also seen on the use of antenatal care and immunization services.[29]

Haiti has a hierarchical system of health care provision in which small facilities are located in villages or small communities and larger, better-equipped facilities are located in cities. Small or low-level facilities may not provide delivery services, however, and among those that provide these services there is little information on how prepared they are to provide good-quality delivery care and how their service preparedness affects utilization. The Haiti 2013 Service Provision Assessment (SPA) and 2012 DHS provide an opportunity to link data for health facilities and DHS clusters in order to explore the influence of service availability and readiness on use of delivery care in facilities.

We limited our analysis to women who had a live birth in the 5 years preceding the survey, with the final analysis sample comprising 4,921 women.

DATA AND METHODS

Data

The Haiti DHS provides data on women's socio-demographic characteristics and their use of maternal health care services, including facility-based delivery care. The Haiti SPA provides information on the availability of delivery care at health facilities and the readiness of facilities to provide good-quality services. This study used geographic data collected in both surveys to link DHS clusters and SPA facilities.

This study used geographic data collected in the Haiti Demographic and Health Survey (DHS) and the Service Provision Assessment (SPA) to link DHS clusters and SPA facilities.

Population Data

The 2012 Haiti DHS is a population-based household survey that provides representative estimates for both urban and rural areas and for the 10 administrative departments of Haiti. The survey used a 2-stage cluster sampling design. At the first stage, 445 clusters were selected with probability proportional to their population size from a master national sample frame. At the second stage, a systematic sample of households was drawn in each of the selected clusters. All women ages 15–49 in the sampled households were eligible for individual interview, which collected data on their socio-demographic characteristics and use of health care services. A total number of 14,287 women were interviewed.

The Haiti DHS georeferenced the locations of the sampled clusters by using Global Positioning System (GPS) receivers to collect the coordinates of the center of the populated areas of the clusters. Prior to release of the geographic dataset, the cluster coordinates were verified and geographically displaced.[30] Coordinates of urban clusters were displaced up to a maximum distance of 2 kilometers (km); average urban displacement was 0.8 km. In rural areas, the displacement distance was up to 5 km with a further, randomly selected 1% of rural clusters displaced up to 10 km; average rural displacement was 2.1 km. These displaced GPS locations were used in our analysis.

Given that the outcome of interest was facility delivery, we limited the analysis to women who had a live birth in the 5 years preceding the survey (N=5,218) with a focus on their most recent birth. We excluded 234 women interviewed in 45 camp clusters that housed the population displaced by the 2010 earthquake because they were likely to have lived in a different area when they had their most recent birth. Thus, the health care environment where they had the birth was likely different from where they had been surveyed. Another 63 women were excluded from the analysis because they were from 8 clusters with missing georeferenced data. The final analysis sample consisted of 4,921 women from 392 clusters with GPS data available.

Health Facility Data

The 2013 Haiti SPA is a health facility census of 907 public and private facilities, from hospitals at the highest level to dispensaries at the lowest level. The SPA provides data on availability of key health services and readiness to provide these services. Data were collected using 4 types of survey instruments: the inventory questionnaire, health provider interviews, observation of consultations, and client exit interviews. For our analysis, facility data primarily came from the inventory questionnaire, which was administered to the facility manager or the most knowledgeable person for specific service areas. The inventory questionnaire collects data on the facility's infrastructure, supplies, medicines, staffing, trainings, and routine practices in providing general and specific services.

The SPA georeferenced the locations of the health facilities by using GPS receivers. Unlike the

DHS GPS data for each cluster, facilities' GPS coordinates were not displaced. Data on 195 hospitals and health centers with a bed that offer delivery services were analyzed in this study. We excluded health centers without a bed and dispensaries from the analysis because they are not mandated to provide delivery care and are rarely used for delivery care.[4,31] Figure 1 shows the location of the SPA facilities as well as the DHS (displaced) clusters that were included in the analysis.

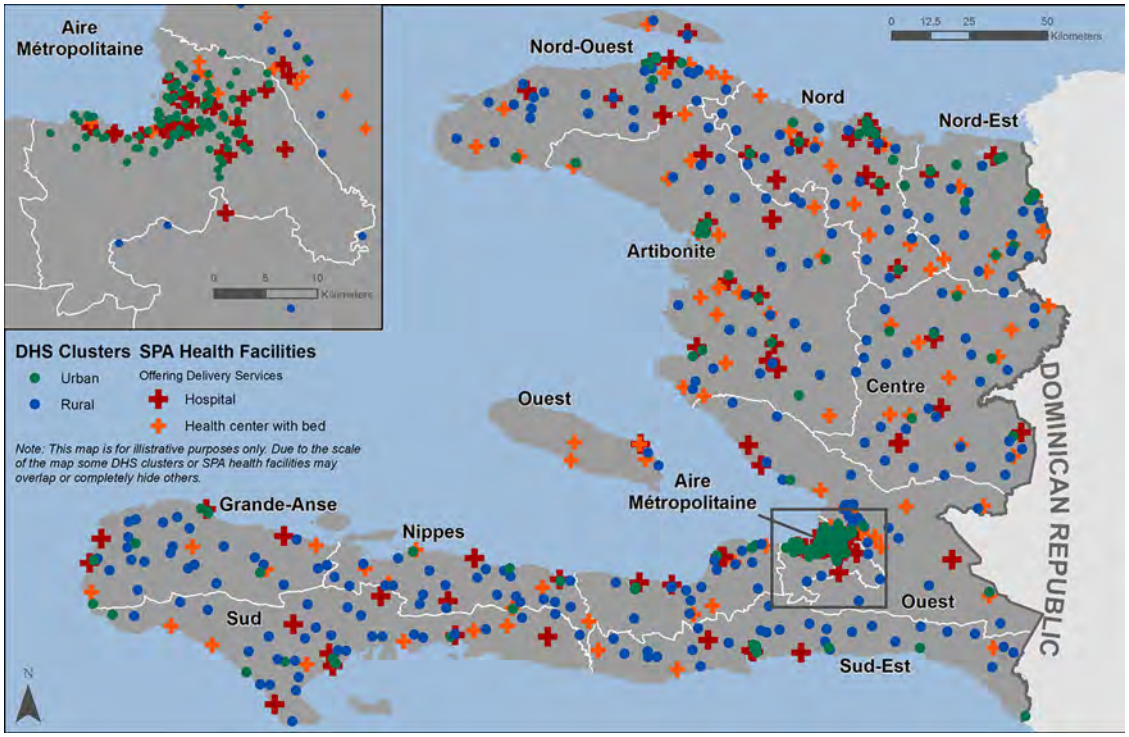
Linked Data Between DHS Clusters and SPA Facilities

Using publicly available GPS data for DHS (displaced) clusters and SPA facilities, we linked facilities to clusters to measure the health service environment of the clusters. We first created a distance matrix with the direct distance measurement from every DHS (displaced) cluster location to every health facility. The distances were then used to identify facilities within a 5-km buffer distance from an urban cluster and a 10-km buffer distance from a rural cluster. These buffer sizes around the displaced location were chosen to ensure that facilities within the same distance around the real (non-displaced) location of the cluster were included within the buffer, given the displacement radius used for urban (maximum 2 km) and rural locations (maximum 10 km). We also believe that facilities within the chosen buffer distance reasonably represent the service environment where individuals seek health services, if not the exact facilities they visit. Lastly, data from all the facilities within the buffer distance were summarized for each cluster to measure the cluster's service environment.

Data on 195 hospitals and health centers with a bed that offered delivery services were analyzed.

Definitions of Key Measurements. The outcome variable was dichotomous, indicating whether a woman delivered her most recent birth at a health facility. We measured the service environment with 2 indicators: availability of facilities

FIGURE 1. Geographic Distribution of 2012 DHS (Displaced) Clusters and 2013 SPA Facilities Included in the Analysis



Abbreviations: DHS, Demographic and Health Survey; SPA, Service Provision Assessment.

offering delivery care and facilities' readiness to provide good-quality delivery care. Both were measured at the DHS cluster level and derived from the facility-level data after linking facilities to DHS clusters.

At the facility level, we measured availability using the SPA definition of facilities offering delivery care, which the SPA obtained by asking the facility manager if the facility provides delivery services. We measured facility's readiness to provide good-quality delivery care by a readiness score created with principal component analysis based on a set of service readiness indicators defined by the World Health Organization.[32] For each indicator—according to whether the facility met the criteria for availability—facilities were assigned a binary variable: 1=available, 0=unavailable. A total of 37 readiness indicators were constructed; their definitions are presented in Supplementary Table 1. The readiness score was computed based on the first component resulting from the principal component analysis, which explained the largest proportion of the total variance. The readiness score is a relative summary indicator of how ready a health facility is to provide good-quality delivery services. A higher score represents better readiness and a lower score represents poorer readiness compared with other facilities. Availability of delivery service and readiness indicators were then summarized to the DHS cluster level, as described below.

We measured a facility's readiness to provide good-quality delivery care by a readiness score based on 37 indicators defined by WHO.

To measure availability of delivery services, we counted the number of facilities offering delivery services within the specified buffer of each DHS cluster. We categorized clusters into groups with 3 levels of availability:

We categorized clusters into groups with 3 levels of availability of delivery services: low, medium, or high.

1. Low availability: no facility with delivery services within the buffer distance
2. Medium availability: 1 facility with delivery services within the buffer distance
3. High availability: 2 or more facilities with delivery services within the buffer distance

We measured facilities' readiness to provide delivery services by the median readiness score of all the facilities within the buffer and divided clusters into low-, medium-, or high-level readiness groups based on the score terciles.

Facilities' readiness to provide delivery care was measured by the median readiness score of all the facilities within the buffer. Given that the readiness score is a relative measurement, we divided the clusters into low-, medium-, and high-level readiness groups based on the score terciles at the cluster level. Clusters with a median score (median score of all facilities within the buffer) falling in the top 33% were considered in the high-level readiness group; those with a median score in the bottom 33% were categorized into the low-level readiness group; and the rest were put in the medium-level readiness group.

Statistical Analysis

The analysis was stratified by urban and rural residence because of differences between urban and rural areas in the health service environment and women's health care-seeking behaviors. We further separated the Port-au-Prince metropolitan area (comprising the capital city Port-au-Prince and the urban zones of the Ouest region) from other urban areas because of the substantial differences in the density and types of health facilities.

Random-intercept logistic regressions were used for the multivariable analysis. DHS data follow a hierarchical structure—that is, individuals are nested within households and households are nested within clusters. Respondents who live in the same household or cluster may not be independent of one another. Moreover, the outcome variable is at the individual level but the key exploratory variables—level of service availability and readiness of facilities to provide delivery services—are at the cluster level. A multilevel analysis approach is more appropriate to allow for simultaneous investigation of the effect of the group-level and individual-level predictors on individual-level outcomes.[33] Therefore, we applied multilevel (individual- and cluster-level) random intercept logistic models to investigate how the service environment measures affect women's use of facility-based delivery care. The household level was omitted since there were few women who had a child in the 5 years preceding the survey living in the same household.

Other variables adjusted for included women's age at birth, birth order, mother's education, household wealth quintile, number of antenatal care visits, and region (department), all of which have been found to be associated with facility delivery.[12,34]

RESULTS

Sample Characteristics

For health facilities, we analyzed data on hospitals and health centers with a bed that provide delivery services. The distribution of these facilities in each residence location by facility background characteristics is presented in Supplementary Table 2. Overall, hospitals and health centers each accounted for half the facilities; but in the metropolitan area most facilities offering delivery services were hospitals, while in rural areas most were health centers. With regard to the managing

Most facilities offering delivery services were hospitals in the metropolitan area and health centers in rural areas.

authority, more than half of the facilities in the metropolitan area were private for-profit, while government health facilities were more common in other urban areas and rural areas. Facility distribution also varied across regions in rural and other urban areas. In rural areas, some regions, such as the Ouest region, had many health facilities, while some, such as Sud-Est and Grand-Anse, had only a few.

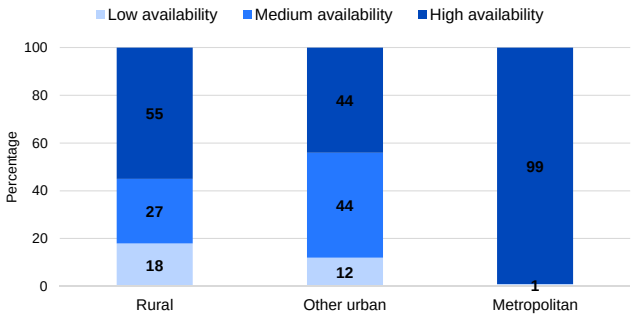
For use of facility-based delivery services, data were based on 4,921 women who had a live birth in the 5 years preceding the DHS survey (including 2,878 women in rural areas, 1,214 in the metropolitan area, and 829 in other urban areas). Supplementary Table 3 provides the distribution of these women by background characteristics and receipt of antenatal care for the most recent birth. In all 3 location categories, a majority of the women reported having their most recent birth between ages 20–34, while 14% to 15% were under age 20 when they had their most recent birth. Most women in the metropolitan and other urban areas had 3 children or fewer, with about 40% having the most recent birth as their first birth. In contrast, in rural areas a higher percentage of women (38%) had 4 children or more. In the metropolitan and other urban areas, most women reported having a primary education and close to 60% had secondary or higher education. In contrast, in rural areas only 25% of women had secondary or higher education, while 27% had no education. In the metropolitan and other urban areas, women in the study were primarily in the upper 3 wealth quintiles, while in rural areas 71% of women were in the poorest 2 quintiles. As for women's receipt of antenatal care during pregnancy for their most recent birth, more than three-quarters of women in the metropolitan and other urban areas had 4 or more antenatal care visits compared with less than two-thirds (60%) of rural women.

Availability of Delivery Services

Availability of facilities offering delivery services varied by location; there was a greater number of facilities within the buffer of clusters in the metropolitan area than in other urban areas and rural areas. The number of facilities with delivery services within the buffer distances from the DHS clusters (i.e., within 5 km for the metropolitan and other urban areas and within 10 km for rural areas) ranged from 0–28 in the metropolitan area, from 0–6 in other urban areas, and from 0–7 in rural areas. Figure 2 presents the percentage distribution of women by levels of availability to delivery services. Proximity to a facility with delivery services was nearly universal in the metropolitan area; 99% of women lived in an area with a high level of availability of delivery services (2 or more facilities within 5 km from their clusters). In contrast, 12% of women in other urban areas and 18% of rural women lived in areas with low availability—that is, no facility offering delivery services within 5 km for women in other urban areas and 10 km for women in rural areas.

Proximity to a facility with delivery services was nearly universal in the metropolitan area, whereas 12% of women in other urban areas and 18% of rural women lived in areas with no such facility.

FIGURE 2. Percent Distribution of Women by Level of Availability of Facilities With Delivery Services Within the Buffer Distance,[a] Haiti, 2012–2013



[a] Low availability=no facility with delivery services within the buffer distance; medium availability=1 facility with delivery services within the buffer; high availability=2 or more facilities with delivery services within the buffer. The buffer distance was 5 km for urban clusters and 10 km for rural clusters.

Facilities' Readiness to Provide Delivery Services

Readiness to provide delivery services among facilities that offered delivery services was measured by the availability of a number of basic and comprehensive obstetric care services and items available at the facility on the day of the survey. Table 1, which presents the availability of these 37 services and supplies, shows wide variation by the facility's location. Facilities in the metropolitan and other urban areas had many of the items while those in rural areas had few. Some items were commonly available across locations, such as a delivery bed, gloves, injectable antibiotics, and parenteral administration of oxytocic drug, while other items were rare, such as manual vacuum extractor and guidelines for integrated management of pregnancy and childbirth. Overall, the availability of comprehensive obstetric care items was low, especially at facilities in rural areas.

Availability of comprehensive obstetric care items was low across the board, but especially in facilities in rural areas.

As discussed earlier, to assess the level of service readiness at facilities that the DHS cluster was linked to, an overall readiness score was generated for each cluster based on the median score of all facilities within the buffer. The clusters were divided into low-, medium-, and high-readiness groups based on the readiness score terciles at the cluster level. Figure 3 shows that the distribution of readiness scores differed by residence area. In the metropolitan area, the cluster readiness scores were more homogenous, while the interquartile range was wider in other urban and rural clusters. The readiness score distribution in other urban areas was highly skewed to high readiness scores, indicating that some facilities had much better readiness than others. A few outlier facilities with markedly different (better or worse) readiness compared with the rest of facilities were also observed in each residence area.

Use of Facility Delivery Services by Level of Availability and Readiness of Delivery Services

Overall, 39% of women delivered their most recent birth at a health facility and 61% delivered at home. Delivery at a health facility was far more common in the metropolitan and other urban areas (60% and 59%, respectively) compared with rural areas (24%).

In both urban and rural areas, availability of delivery services was significantly associated with women's use of facility delivery care.

Figure 4 highlights the bivariate association between availability of delivery services and the percentage of women who delivered their most recent birth at a health facility. Since nearly all women in the metropolitan area lived in clusters with 2 or more facilities within 5 km, the effect of availability of delivery services was assessed only for other urban and rural areas. In both types of area, use of facility delivery was significantly associated with levels of availability of facilities offering delivery services. In rural areas, facility delivery coverage increased incrementally with the level of availability. In rural clusters without a facility with delivery services within 10 km, only 8% of women delivered the most recent birth in a facility compared with 19% of women in clusters with access to 1 such facility, and 32% of those with 2 or more such facilities. Service availability was also associated with use in other urban areas but the difference was less remarkable between medium and high availability.

Figure 5 indicates that use of facility delivery services was also positively associated with the level of readiness at the facilities within the buffer distance in the metropolitan and other urban areas. In other urban clusters, 45% of women delivered in a facility with low level of readiness compared with 63% of women for facilities with a medium level of readiness and 71% of women for facilities with a high level of readiness. In rural areas, however, there was little association between facilities' level of readiness and women's use of facility delivery services.

Results of Multivariable Analysis

Using random-intercept logistic models, we assessed how women's use of facility delivery was associated with availability of delivery services within the buffer and service readiness of the facilities. We first ran models for nonmetropolitan urban areas and rural areas to examine the effect of availability. This model was not run for the metropolitan area since almost all metropolitan women had a high level of availability to delivery services. We then ran models to examine the effect of service readiness for all 3 locations after controlling for availability and other covariates. Since readiness is only available for clusters with at least 1 facility within the buffer distance, women in clusters with no facility were dropped from this model.

Table 2 presents odds ratios (ORs) and 95% confidence intervals (CIs) from the regression models of facility delivery on the availability indicator, as well as for the covariates adjusted for in the models. In both urban and rural areas, availability of delivery services was significantly associated with women's use of facility delivery care after controlling for other covariates. In rural

TABLE 1. Percentage of Facilities Offering Delivery Services With Availability of Basic and Comprehensive Obstetric Care Services and Items, by Residence, Haiti, 2013

	Rural %	Other Urban %	Metropolitan %	Total %
Basic obstetric care indicators				
Parenteral administration of antibiotics	68.9	78.0	94.9	77.9
Parenteral administration of oxytocic drug	86.5	95.1	94.9	91.8
Parenteral administration of anticonvulsants	40.5	67.1	48.7	53.3
Assisted vaginal delivery[a]	90.5	92.7	89.7	91.3
Manual removal of placenta	58.1	79.3	59.0	67.2
Manual removal of retained products	48.6	75.6	64.1	63.1
Neonatal resuscitation	51.4	72.0	53.8	60.5
Guidelines for IMPAC	21.6	31.7	12.8	24.1
Staff trained in IMPAC	48.6	53.7	46.2	50.3
Emergency transportaion	32.4	36.6	35.9	34.9
Sterilization equipment	75.7	84.1	87.2	81.5
Examination light	43.2	43.9	59.0	46.7
Delivery pack	87.8	92.7	87.2	89.7
Suction apparatus	93.2	98.8	79.5	92.8
Manual vacuum extractor	16.2	19.5	20.5	18.5
Vacuum aspirator or D&C kit	20.3	35.4	30.8	28.7
Newborn bag and mask	51.4	62.2	59.0	57.4
Delivery bed	97.3	100.0	94.9	97.9
Partograph	32.4	41.5	33.3	36.4
Gloves	93.2	93.9	89.7	92.8
Antibiotic eye ointment for newborns	66.2	84.1	66.7	73.8
Injectable uterotonic	62.2	74.4	64.1	67.7
Injectable antibiotics	89.2	92.7	94.9	91.8
Injectable magnesium sulphate	60.8	78.0	74.4	70.8
Skin disinfectant	60.8	81.7	61.5	69.7
Intravenous solution with infusion set	74.3	84.1	82.1	80.0
Regular reviews of maternal or newborn deaths	25.7	32.9	48.7	33.3
Comprehensive obstetric care indicators				
Cesarean delivery services	23.0	52.4	71.8	45.1
Blood transfusion	23.0	50.0	61.5	42.1

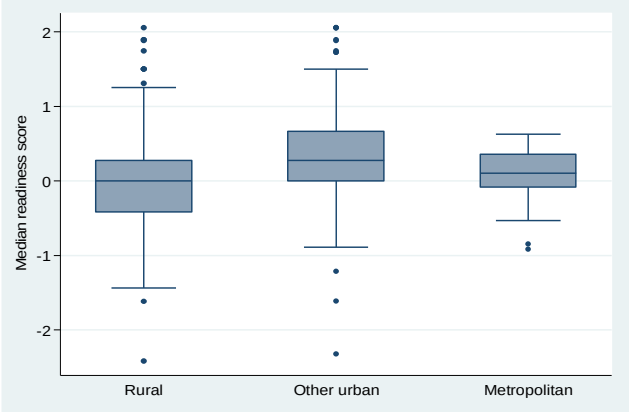
Continued

TABLE 1. Continued

	Rural %	Other Urban %	Metropolitan %	Total %
Guidelines for CEmOC adapted for Haiti	6.8	15.9	7.7	10.8
Staff member providing delivery trained in CEmOC	44.6	45.1	38.5	43.6
Anesthesia equipment	10.8	15.9	25.6	15.9
Incubator	10.8	23.2	23.1	18.5
Blood typing	17.6	42.7	56.4	35.9
Cross matching test	4.1	3.7	10.3	5.1
Blood supply sufficiency	12.2	19.5	20.5	16.9
Blood supply safety	16.2	37.8	53.8	32.8
Total number of facilities	**74**	**82**	**39**	**195**

Abbreviations: CEmOC, comprehensive emergency obstetric care; D&C, dilation and curettage; IMPAC, integrated management of pregnancy and childbirth.
[a] Assisted vaginal delivery was actually interpreted as "attended vaginal delivery" in the Haiti Service Provision Assessment.

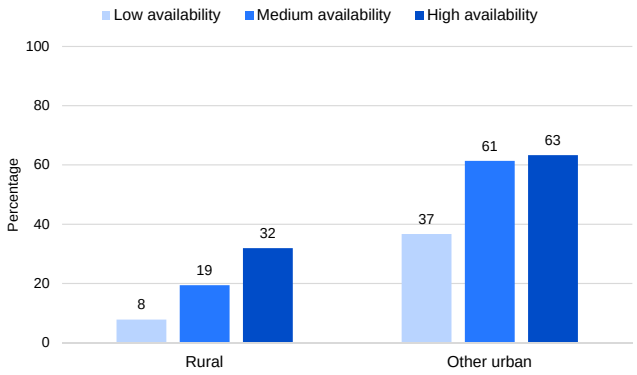
FIGURE 3. Distribution of Cluster-Level Median Readiness Scores Among Facilities Offering Delivery Services, by Residence, Haiti, 2012–2013



areas, women in clusters with medium-level availability to delivery services had 1.9 times higher odds of going to a facility for delivery (CI, 1.14 to 3.13; $P<.05$) and women in clusters with high availability had 3.6 times higher odds (CI, 2.23 to 5.66; $P<.001$) compared with women with low availability. Similarly, in other urban areas higher availability of delivery services was also significantly associated with a greater likelihood to deliver in a facility. Although the odds ratio appears lower for high availability (OR, 2.64; 95% CI, 1.13 to 6.19; $P<.05$) than medium availability (OR, 3.83; 95% CI, 1.57 to 9.31; $P<.01$), the difference was not statistically significant (results not shown).

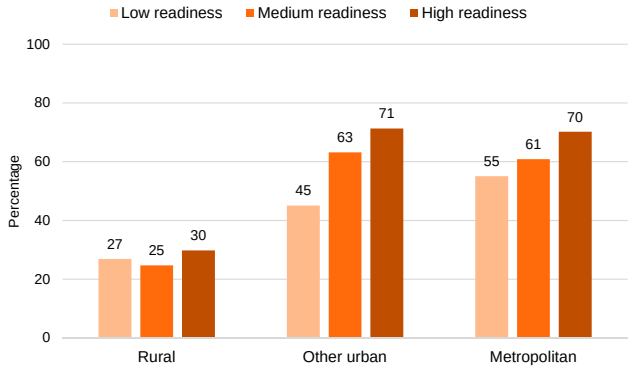
As expected, maternal age at birth, the number of antenatal care visits, and household wealth were positively and significantly associated with

FIGURE 4. Percentage of Women Who Delivered at a Facility by Availability of Facilities With Delivery Services Within the Buffer Distance,[a] Haiti, 2012–2013



[a] Low availability=no facility with delivery services within the buffer distance; medium availability=1 facility with delivery services within the buffer; high availability=2 or more facilities with delivery services within the buffer. The buffer distance was 5 km for urban clusters and 10 km for rural clusters.

FIGURE 5. Percentage of Women Who Delivered at a Facility by Level of Readiness[a] at Facilities With Delivery Services Within the Buffer Distance,[b] Haiti, 2012–2013



[a] Low-, medium-, and high-level readiness=median readiness score of the facilities within the buffer falling in the bottom 33.3%, middle 33.3%, and top 33.3%, respectively. The buffer distance was 5 km for urban clusters and 10 km for rural clusters.

[b] Women living in clusters with no health facility offering delivery services within the buffer distance were excluded from this figure since the readiness score was applied only to clusters with 1 or more health facilities.

women's use of delivery care in a health facility, while the child's birth order was negatively associated.

Table 3 shows the results of the regression models of facility delivery on service readiness and availability after controlling for women's characteristics and antenatal care variables. Service readiness was significantly associated with facility delivery only in urban areas (other than the metropolitan area). Women in clusters with a high level of service readiness had 2.7 times higher odds of delivery in a health facility

Service readiness was significantly associated with facility delivery only in urban areas.

TABLE 2. Multivariable Model Results for the Regressions of Facility Delivery on Availability of Facilities With Delivery Services Within the Buffer, Controlling for Other Variables, Haiti, 2012–2013

	Rural		Other Urban	
Variables	**Odds Ratio**	**95% CI**	**Odds Ratio**	**95% CI**
Availability of facilities with delivery services				
Low availability	1.00		1.00	
Medium availability	1.89*	1.14, 3.13	3.83**	1.57, 9.31
High availability	3.56***	2.23, 5.66	2.64*	1.13, 6.19
Mother's age at birth	1.06***	1.03, 1.08	1.08***	1.04, 1.13
Birth order				
1	1.00		1.00	
2–3	0.30***	0.23, 0.39	0.30***	0.19, 0.48
4–5	0.15***	0.10, 0.22	0.23***	0.12, 0.46
6+	0.10***	0.06, 0.17	0.14***	0.05, 0.37
Education				
None	1.00		1.00	
Primary	1.37	0.99, 1.89	0.95	0.48, 1.89
Secondary or higher	1.85**	1.27, 2.68	1.64	0.80, 3.35
Wealth quintile				
Lowest	1.00		NA[a]	NA[a]
Second	1.86***	1.38, 2.50	NA[a]	NA[a]
Middle	2.99***	2.12, 4.20	1.00	
Fourth	5.72***	3.61, 9.07	1.43	0.91, 2.25
Highest	10.73***	4.83, 23.80	3.39***	1.91, 6.04
Antenatal care visits				
None	1.00		1.00	
1	4.46***	2.05, 9.69	1.38	0.36, 5.29
2–3	3.90***	2.09, 7.28	1.40	0.51, 3.82
4+	6.75***	3.71, 12.27	2.85*	1.13, 7.17
Departement				
Ouest	1.00		1.00	
Sud-est	1.17	0.61, 2.23	2.96	0.73, 12.08
Nord	0.92	0.53, 1.60	1.83	0.64, 5.28
Nord-est	1.62	0.79, 3.32	1.74	0.53, 5.78

Continued

TABLE 2. Continued

	Rural		Other Urban	
Variables	**Odds Ratio**	**95% CI**	**Odds Ratio**	**95% CI**
Artibonite	1.17	0.76, 1.78	1.37	0.49, 3.86
Centre	1.64	0.97, 2.78	1.42	0.39, 5.20
Sud	1.56	0.94, 2.59	1.90	0.52, 6.88
Grand'anse	1.21	0.57, 2.57	0.68	0.17, 2.73
Nord-ouest	1.04	0.56, 1.93	0.67	0.19, 2.39
Nippes	1.35	0.67, 2.70	1.71	0.26, 11.14
Number of clusters	**241**		**85**	
Observations	**2,878**		**829**	

[a] In other urban areas, no women were in the first wealth quintile and very few women were in the second wealth quintile; they were combined into the third quintile.
***$P<.001$; **$P<.01$; *$P<.05$.

compared with women in clusters with low readiness (95% CI, 1.34 to 5.60; $P<.01$). The difference in facility delivery between women in clusters with low readiness and those with medium readiness was not significant after controlling for other covariates. Similar to the findings from the models on availability, in other urban areas there was no significant difference in coverage of facility delivery between clusters with medium availability and clusters with high availability of delivery services. In rural areas, after controlling for service readiness and other variables, having high availability of delivery services—that is, having 2 or more facilities within the buffer distance—was associated with significantly greater odds of delivery in a health facility compared with medium availability—that is, having only 1 facility with delivery services within the buffer distance (OR, 1.94; 95% CI, 1.38 to 2.72; $P<.001$).

DISCUSSION

The availability of the recent DHS and SPA surveys in Haiti, both with GPS data, enabled analysis linking women's use of facility delivery care with their physical access to delivery care and facilities' readiness to provide the care. This analysis showed that women in rural areas of Haiti have very limited physical access to obstetric care. Almost 1 in 5 women in rural areas lives in a place where there is no facility that provides delivery services within a 10 km distance. It should be noted that the 10 km distance is a straight-line measurement. The actual travel distance could be longer because of travel paths, road networks, and the mountainous terrain. In rural areas, physical access to health care can be further constrained by poor road conditions and lack of transportation.

The regression results highlight the importance of service availability to the use of facility delivery in rural areas. Living reasonably near a facility that provides delivery services is significantly associated with greater probability of women delivering at a health facility. Physical access as an important barrier to service use in rural Haiti was also demonstrated in previous research that measured access with the distance to the nearest facility reported by key community informants.[23] Our finding also agrees with previous research that having physical access to services is a strong determinant of use of delivery care.[28,34–36]

Living reasonably near a facility that provides delivery services is significantly associated with greater probability of women delivering at a health facility.

Quality of care—measured in our study by analyzing how prepared the facility is to provide the needed services—is important to the use of health services. Our results show that hospitals and health centers with a bed are not well prepared to provide delivery services. A large number

Women in rural areas of Haiti have very limited physical access to obstetric care.

TABLE 3. Multivariable Model Results for the Regressions of Facility Delivery on Service Readiness of Facilities With Delivery Services, Controlling for Availability of Services and Other Variables, Haiti, 2012–2013

	Rural		Other Urban		Metropolitan	
Variables	**Odds Ratio**	**95% CI**	**Odds Ratio**	**95% CI**	**Odds Ratio**	**95% CI**
Facilities' readiness to provide delivery services[a]						
Low readiness	1.00		1.00		1.00	
Medium readiness	1.43	0.93, 2.18	1.74	0.71, 4.26	1.02	0.74, 1.41
High readiness	1.33	0.95, 1.85	2.74**	1.34, 5.60	1.41	0.96, 2.05
Availability of facilities with delivery services[b]						
Medium availability	1.00		1.00		NA	
High availability	1.94***	1.38, 2.72	0.72	0.37, 1.41	NA	
Mother's age at birth	1.05***	1.03, 1.08	1.09***	1.05, 1.14	1.023	0.99, 1.05
Birth order						
1	1.00		1.00		1.00	
2–3	0.31***	0.23, 0.42	0.28***	0.17, 0.47	0.61**	0.43, 0.88
4–5	0.15***	0.10, 0.24	0.22***	0.10, 0.48	0.50*	0.29, 0.86
6+	0.12***	0.07, 0.20	0.17**	0.06, 0.49	0.42*	0.20, 0.91
Education						
None	1.00		1.00		1.00	
Primary	1.47*	1.04, 2.08	0.91	0.42, 1.96	3.23***	1.71, 6.12
Secondary or higher	2.06***	1.39, 3.06	1.91	0.86, 4.24	5.01***	2.63, 9.55
Wealth quintile[c]						
Lowest	1.00		NA[c]	NA[c]	NA[c]	NA[c]
Second	1.89***	1.37, 2.61	NA[c]	NA[c]	NA[c]	NA[c]
Middle	3.04***	2.11, 4.38	1.00		1.00	
Fourth	5.72***	3.56, 9.21	1.47	0.87, 2.46	1.05	0.68, 1.63
Highest	11.14***	4.95, 25.07	2.82**	1.49, 5.35	2.56***	1.55, 4.20
Antenatal care visits						
None	1.00		1.00		1.00	
1	4.75***	2.05, 10.99	2.02	0.47, 8.73	3.60*	1.25, 10.32
2–3	4.17***	2.13, 8.17	2.16	0.69, 6.76	2.20*	1.12, 4.32
4+	7.24***	3.81, 13.79	3.88*	1.36, 11.05	3.95***	2.17, 7.18

Continued

TABLE 3. Continued

	Rural		Other Urban		Metropolitan	
Variables	**Odds Ratio**	**95% CI**	**Odds Ratio**	**95% CI**	**Odds Ratio**	**95% CI**
Departement						
Ouest	1.00		1.00			
Sud-est	0.98	0.47, 2.03	1.00	0.11, 9.03		
Nord	0.89	0.50, 1.57	2.00	0.57, 6.98		
Nord-est	1.63	0.79, 3.39	2.37	0.55, 10.15		
Artibonite	1.19	0.75, 1.88	1.60	0.46, 5.62		
Centre	1.64	0.92, 2.92	1.92	0.46, 7.94		
Sud	1.62	0.95, 2.76	2.46	0.48, 12.64		
Grand'anse	0.97	0.40, 2.34	0.58	0.12, 2.79		
Nord-ouest	1.02	0.54, 1.92	0.65	0.16, 2.68		
Nippes	1.36	0.66, 2.81	2.67	0.31, 22.83		
Number of clusters	**201**		**69**		**59**	
Observations	**2,571**		**802**		**650**	

[a] Regressions excluded women living in clusters with no health facility offering delivery services within the buffer since the readiness score is applied only to clusters with 1 or more health facilities.
[b] Since the analysis excluded women living in clusters with no health facility offering delivery services within the buffer (i.e., the low availability group), the medium availability group was set as the reference.
[c] In the metropolitan and other urban areas, no women were in the first wealth quintile and very few women were in the second wealth quintile; they were combined into the third quintile.
***$P<.001$; **$P<.01$; *$P<.05$.

of facilities lack essential equipment and supplies for routine delivery care, and most have limited capacity to provide emergency obstetric care. Only about one-third of facilities have functional emergency transportation, and the availability of Cesarean delivery services is limited, especially in rural areas. Delivery in a health facility itself cannot reduce maternal mortality unless women are assisted by a skilled birth attendant capable of managing common life-threatening obstetric complications.[38] In Haiti, however, less than half of the facilities have staff who received training in comprehensive emergency obstetric care (CEmOC) during the last 2 years. Guidelines for CEmOC were not available in service areas at most facilities. All of these limitations increase the risk of death for mother and newborn when an obstetrical emergency occurs.

Despite the poor readiness of health facilities to provide delivery services, service quality appears to play an important role predicting facility delivery in urban areas, where delivery services are more available, compared with rural areas. Urban areas have more facilities, more accessible transportation, and more financial resources, and thus women may be able to choose to deliver at facilities offering a better quality of care. In rural areas, however, especially in mountainous areas, there is less availability of facilities and thus having access to at least 1 health facility seems more important to the use of delivery care than the facility's level of readiness to provide the services.

Hospitals and health centers with a bed in Haiti are not well prepared to provide delivery services.

We did not find an association between service readiness and use of facility delivery in the metropolitan area. This could be because a 5 km buffer may not be appropriate for defining the service environment for clusters in the metropolitan area. Because of a high density of health facilities and DHS clusters in the metropolitan area, using a 5 km buffer may result in adjacent clusters

linking to more or less the same group of facilities; therefore, there is limited variation across metropolitan clusters in terms of the service environment. This is indicated by less variation in readiness among clusters in the metropolitan area compared with clusters in rural and other urban areas. Moreover, people in metropolitan areas are likely to have more transportation options available and better accessibility to health services that are geographically further from their home.

Strengths and Limitations

Linking women's use of health services to the service environment within a reasonable distance from DHS clusters is less prone to misclassification errors (resulting from the displacement of DHS clusters) than linking to the closet facility.

As discussed, because of methodological constraints in linking population data and health service data, most previous studies have been limited to measuring service provision from the client's perspective. Several recent studies have taken advantage of geographic data to associate health facilities and DHS clusters. These studies focused primarily on distance to the closest facility or the service available in the closest facility; however, this approach can be problematic because DHS cluster locations have been displaced. Our study improved on this methodology; instead of looking at a single facility (the closest facility)—where estimates may be subject to misclassification errors—we measured the effect of the service environment within a reasonable distance. In addition to the methodological improvement of measuring the service environment, some of the other strengths of our study lie in the use of facility census data and nationally representative household data, measuring service readiness with a wide range of items that the World Health Organization has identified as essential for providing high-quality delivery services. Together, these improvements in methodology have led to more generalizable results. Additionally, the use of observed availability of equipment and items instead of self-reported data during facility data collection increases the robustness of the readiness indicators and thus the accuracy of the relationship between the provision of delivery services and their use.

This study also has some limitations. One limitation is the temporal gap between the outcome variables and the service variables. Facility data reflect the "current" service environment at the time of the Haiti 2013 SPA, while use of facility delivery was measured over a 5-year time period preceding the 2012 Haiti DHS. Associating service provision and facility delivery use data could be problematic if the service environment changed substantially over this time period. Given the nature of delivery services, however, we do not expect that there was a substantial change in the availability of services and facilities' readiness to provide the service over the period.

While linking women to all of the facilities that they likely used reduces misclassification errors from the DHS GPS displacement procedure, the straight-line buffer approach does not take into account the mountainous terrain or the impassibility of roads during the rainy season, which may limit access to a linked facility. However, Nesbitt and colleagues compared 6 different measures of spatial access and found that the straight-line linkage yields results similar to other geospatial algorithms in a developing-country setting.[20] Finally, the buffer linkage between DHS clusters and SPA facilities may not be appropriate in areas where there is a high density of both health facilities and population, such as Haiti's metropolitan area. More precise measurements of the service environment are needed for such areas, as well as a better understanding of other drivers of use in areas where service availability may be less of an issue.

CONCLUSION

This study indicates the importance of improving physical access to delivery services in rural Haiti. Overall, health facilities in Haiti are poorly equipped and do not appear ready to provide high-quality delivery services. Improving the quality of care at health facilities could contribute to increased use of facility delivery particularly in nonmetropolitan urban areas, where 40% of women still deliver at home. Over the years, the global community has recognized the importance of providing women with quality maternal health services to reduce maternal mortality.[38] After all, reducing maternal mortality by having women deliver in health facilities will only work if these facilities are ready to provide comprehensive obstetric care.

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ORIGINAL ARTICLE

Benefits and Limitations of Text Messages to Stimulate Higher Learning Among Community Providers: Participants' Views of an mHealth Intervention to Support Continuing Medical Education in Vietnam

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The original intention was to deliver technical content through brief text messages to stimulate participants to undertake deeper learning. While participants appreciated the convenience and relevance of the text messages, their scores of higher-order knowledge did not improve. The intervention may not have been successful because the messages lacked depth and interactivity, and participants were not explicitly encouraged to seek deeper learning.

ABSTRACT

Background: A randomized controlled trial was conducted in 2015 to evaluate a mobile continuing medical education (mCME) intervention that provided daily text messages to community-based physicians' assistants (CBPAs) in Thai Nguyen Province, Vietnam. Although the intervention failed to improve medical knowledge over a 6-month period, a companion qualitative study provided insights on the views and experiences of intervention participants.

Methods: We conducted focus group discussions (FGDs) and in-depth interviews (IDIs) among participants randomized to receive text messages containing either simple medical facts or quiz questions. Trained interviewers collected data immediately following the conclusion of the trial in December 2015. Using semi-structured question guides, respondents were queried on their views of the intervention, positive and negative, and perceived impacts of the intervention. During analysis, after learning that the intervention had failed to increase knowledge among participants, we also examined reasons for lack of improvement in medical knowledge. All analyses were performed in NVivo using a thematic approach.

Results: A total of 70 CBPAs engaged in one of 8 FGDs or an IDI. One-half were men; average age among all respondents was 40 years. Most (81%) practiced in rural settings and most (51%) focused on general medicine. The mean length of work experience was 3 years. All respondents made positive comments about the intervention; convenience, relevance, and quick feedback (quiz format) were praised. Downsides encompassed lack of depth of information, weak interaction, technology challenges, and challenging/irrelevant messages. Respondents described perceived impacts encompassing increased motivation, knowledge, collegial discussions, Internet use to search for more information, and clinical skills. Overall, they expressed a desire for the intervention to continue and recommended expansion to other medical professionals. Overreliance on the text messages, lack of effective self-study, and technical/language-based barriers may be potential explanations for intervention failure.

Conclusion: As a form of mCME, daily text messages were well-received by community-level health care providers in Vietnam. This mCME approach appears very promising in low-resource environments or where traditional forms of CME are impractical. Future models might consider enhancements to foster linkages to relevant medical materials, improve interaction with medical experts, and tailor medical content to the daily activities of medical staff.

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INTRODUCTION

Vietnam, like many countries, is establishing a national continuing medical education (CME) program for health care practitioners.[1,2] This effort is embodied in Vietnam's new "Law on Medical Examination and Treatment," which requires licensure of all clinicians, along with documented CME activities to retain licensure.[3,4] It has been supported by large investments such as the Asian Development Bank's "Health Human Resources Sector Development Program" (2011–2015)[5] and a recent US$106 million World Bank loan to Vietnam's Ministry of Health to help create and manage new CME courses, databases, and monitoring systems.[6] The success of these activities is critical to help ensure that doctors, nurses, community health workers, and other providers are equipped to provide quality services.

CME can improve knowledge and skills of providers, but data are lacking on the effectiveness of different delivery methods.

The available evidence indicates that CME can improve knowledge and skills of providers, although data are lacking on the validity, reliability, efficacy, and cost-effectiveness of different CME delivery methods.[7] While use of new technologies, including electronic, digital, and mobile approaches, appear promising, little research has been conducted comparing traditional CME with these newer delivery strategies.[8–10] Three studies that assessed use of short message service (SMS)-based messaging, or text messaging, for CME purposes suggest that such approaches are feasible and may be useful for distance learning, but the studies provide little insight into how to use text messages to maximum advantage.[11–13] While not focused on CME, a recent systematic review of eLearning approaches for undergraduate medical education in low-resource settings published by the World Health Organization highlights potential advantages—cost-savings, scalability of educational materials, freed-up instructor time, ease of developing and updating content, and portability—that might extend to CME provision.[14] It also summarized benefits described by learners that may offer insights into features affecting learning: ease of access, flexibility, improved student-teacher contact and discussions, and more exchange with peers.[14]

To provide evidence on a potentially scalable and cost-effective CME approach in Vietnam, our Boston University (BU)-Pathfinder, Inc. team collaborated with Vietnam's Ministry of Health to assess a text message-based CME intervention, the results of which have been previously reported.[15] Because most clinicians in Vietnam practice at the community level, we focused on providers working at community health stations (CHSs), known as community-based physicians' assistants (CBPAs). The trial was implemented in Thái Nguyên, a rural province north of Hanoi, with the Thái Nguyên Provincial Department of Public Health. A total of 638 CBPAs were randomized to 1 of 3 arms: group 1 (control arm) received a weekly non-medical SMS message; group 2 (passive intervention arm) received a daily medical SMS message related to primary care, with a reply requested using any combination of letters and numbers; and group 3 (interactive intervention arm) received a 4-option multiple-choice SMS question (covering the same themes as the messages sent to group 2), with an answer requested and an immediate reply provided indicating whether the answer was correct. Message content was based on the content of CBPAs' original training curriculum covering 6 topic areas: surgery, internal medicine, pediatrics, infectious diseases, sexually transmitted infections, and family planning. Messages were delivered in random order rather than being organized by topic.

Our hypothesis was that the intervention, by delivering daily messages over a 6-month period on previously learned topics, would provide 2 pathways to improved knowledge: (1) learning from the SMS messages themselves (weak pathway), and (2) motivation to increase "lateral learning," or self-study (strong pathway). Given evidence that interactive approaches are better liked and more effective in improving knowledge,[16–19] we also anticipated that group 3 (whose members answered quiz questions and received subsequent responses) would be more motivated than group 2. We assessed impact by comparing post-intervention exam scores (percentage of questions answered correctly) between groups and within-group pre-and post-intervention scores, using typical multiple-choice questions designed around the 6 topic areas, in line with CBPAs' original clinical training. The exam questions were similar to the daily quiz questions provided to group 3, although they were more complex than the quiz questions. That is, the quiz questions required a simple answer to a direct question, such as '*What is the optimal antibiotic for streptococcal pharyngitis?*' (answer: amoxicillin). The exam questions required knowing 2 or more medical facts to answer. For example, a typical exam question was worded as such: "*A child with a sore throat developed a macular rash after taking an antibiotic. What was the most likely cause of the sore throat?*" (answer: mononucleosis.) To answer this exam question correctly, the participant

required knowing the differential diagnosis of sore throats, the most likely treatment (amoxicillin) for streptococcal pharyngitis, and the fact that macular rash is a common result of using amoxicillin in the setting of mononucleosis. The exam questions were not designed to be answerable from knowing the correct answers to the quiz questions alone; rather, they assumed further knowledge above and beyond the content of the quiz questions. A detailed description of the trial's methods and results is available in the main effects paper, published in November 2016.[15]

One component of the project, the focus of the present study, was a qualitative exploration focused on the experiences of trial participants. Data were collected immediately following the trial while the intervention experience was fresh in the minds of CBPA participants. The main study questions were: (1) What were trial participants' views of the intervention, both positive and negative?, and (2) What were the perceived impacts of the intervention?

After completing data collection, we learned from the trial results that the intervention did not achieve the primary goal of increasing medical knowledge. As reported in the main effects paper, we found that mean test scores varied from 36.1% to 39.0% at baseline and from 40.1% to 40.9% at post-intervention, with no significant differences between arms at either point or within arms over time, meaning that the intervention did not succeed in its primary objective of improving medical knowledge.[15] However, the results also showed that the intervention was well-received by CBPAs in terms of participation rates, technical feasibility, and potential cost-savings, provided it could be effective. Given support for a second mobile continuing medical education (mCME) trial, we wanted to understand how we might modify our approach to improve the likelihood of a positive effect. We thus added a third study question in the analysis stage: Were there features of participants' experiences that could help us understand why the intervention failed?

METHODS

Study Site and Participants

Study respondents were CBPAs who participated in the mCME trial, and thus had met enrollment criteria at baseline. They were 18 years or older and provided primary care services in Thái Nguyên. Each had completed high school, had graduated from an accredited 2-year medical training program, and owned an SMS-enabled cell phone. Given our focus on intervention experiences, respondents were limited to group 2 (passive intervention) or group 3 (interactive intervention) trial participants. Respondents engaged in a focus group discussion (FGD) or an in-depth interview (IDI).

Design and Sampling

In light of time and budget constraints, we elected to conduct a total of 8 FGDs, with 1 FGD for trial participants within each of 8 categories, stratified by study arm (group 2 vs. 3), gender (male vs. female), and SMS response rate during the trial (high, which we defined as >90% among women and >75% among men, vs. low, defined as <10% among women and <25% among men; these proportions differed due to the distribution of high vs. low response rate by gender[15]). These groupings were designed to ensure collection of a range of perspectives, particularly because response rate could be interpreted as a proxy for intervention enthusiasm. A total of 8 participants in each group were selected randomly and invited to participate in an FGD by written invitation from collaborators from the Thái Nguyên Provincial Department of Public Health. In each group, there were an additional 6–10 participants whom we identified as backups for FGDs and for IDIs. One participant within each group was identified randomly for IDI participation. We also purposefully identified 7 participants who had displayed various challenges responding to texts during the trial for offer of participation, thereby providing a total maximum sample of 15 participants for IDIs.

Data Collection

Data were collected in December 2015. Before data collection commenced, members of the study team held a training workshop in Hanoi for 8 local interviewers. The workshop focused on the protocol, qualitative research methods, and protection of human subjects in research. We reviewed the question guides to ensure their clarity and appropriateness of questions and probes and engaged in role play to sensitize local interviewers to issues that might arise during data collection.

During the FGDs and IDIs, interviewers worked in teams of 2, with one asking questions and the second one taking notes (to clarify potentially confusing responses, document non-verbal reactions, etc.). Discussions were conducted in Vietnamese, at the Thái Nguyên Provincial Department of Public Health in Thái Nguyên City.

We conducted a qualitative study to learn how to modify a text message-based CME program to improve the likelihood of having a positive effect on providers' knowledge.

Interviewers used semi-structured question guides that queried specific topics yet allowed for open-ended responses and follow-up probing. Each FGD and IDI was audio-recorded and took 60–90 minutes to complete. Respondents were not compensated but received snacks.

Questions focused on views of and experiences related to receiving CME via text messages, and, for respondents assigned to group 3, the daily quiz questions. We queried whether and how the intervention might have impacted attitudes and behaviors; we also asked about the SMS intervention compared with traditional forms of CME, and what respondents thought were the benefits and drawbacks to using text messages for CME.

Data Analysis

The FGD and IDI recordings were transcribed verbatim and then translated into English. Boston-based team members analyzed transcripts in QSR NVivo 11. Transcripts were read, with themes and subthemes identified and cross-checked by multiple readers. We created a theme codebook, which was used to code each transcript. The analysis included comparing FGD and IDI responses; we also examined responses by group assignment and gender. We prioritized responses by their frequency and also explored divergent views. Responses were included whether mentioned spontaneously or in reply to a follow-up probe.

Nearly all respondents highlighted the convenience of the mobile CME approach.

Ethical Review

The study was reviewed and approved by the institutional review boards at Boston Medical Center and The Hanoi School of Public Health. All respondents provided written informed consent.

RESULTS

Background Characteristics of CBPA Participants

We conducted 8 FGDs and 15 IDIs, with a total of 70 respondents. Between 5 and 8 CBPAs participated in each FGD. One-half of the respondents were men, and the average age of all respondents was 40 years (Table). About half (49.3%) were former group 2 participants. Of FGD respondents, about one-half (52.7%) had high response rates during the trial; among IDI respondents, 7 had "medium" response rates, while 4 each were in high and low response strata. The majority (81%) of all respondents practiced in rural settings; only 3 were city-based. Most (51.4%) focused on general medicine; fewer worked in obstetrics and pediatrics (20%), traditional medicine (21.4%), or preventive medicine (7.2%). The mean length of service was 3 years.

Views of the Intervention

All respondents, regardless of group assignment or gender, communicated positive attitudes and experiences with the intervention. The most common adjective used to portray the mCME text messages was "useful," with expanded descriptions including "incredibly helpful," "very good," "very effective," and "very useful for us CBPAs." Detailed reactions coalesced around the text messages' convenience and relevance. Some respondents noted drawbacks to the messages. The vast majority wanted the intervention to continue. These themes are explored in more detail below and summarized in the Figure. We note differences by gender, group, and data source (IDI vs. FGD), with illustrative statements provided.

Convenience. Virtually all respondents highlighted the convenience of the mCME approach, noting that the text messages could be accessed anytime, anywhere, with responses submitted later. They liked receiving messages at work, where content could be discussed with colleagues. Many highlighted the succinct nature of messages (which had length restrictions), their comprehensibility, daily arrival, and ease of phone-based access and storage. One typical statement was:

> *This new method makes use of our free time, and doesn't force us to go any place to study . . . we can study one day after another steadily.* (Male FGD participant, group 3)

Most respondents contrasted the texts' convenience favorably with traditional CME approaches. They highlighted the time and expense of workshop-related travel and attendance, which often were insurmountable barriers. As one male FGD participant (group 2) stated:

> *Through this method, many people can learn and access information at the same time, while [with] traditional training, it's hard to organize for us because we are experienced CBPAs and [work long hours] so we cannot participate in 3–6 month training courses just to update our information. Who will take over our tasks . . .?*

Many compared the ease of phone-based information with the bulky books and materials common to workshops. Others emphasized that text messages did not interfere with their work, lauding their focused, daily information:

TABLE. Background Characteristics of mCME Participants, Thái Nguyên, Vietnam, December 2015

	IDIs (N=15)	FGDs (N=55)	Total (N=70)
Gender, No. (%)			
Female	8 (53.3)	27 (49.1)	35 (50.0)
Male	7 (46.7)	28 (50.9)	35 (50.0)
Age, mean (SD), years	38.6 (10.5)	40.8 (11.2)	40.3 (11.0)
Study arm, No. (%)			
Group 2: medical facts	4 (26.7)	30 (54.6)	34 (49.3)
Group 3: medical questions	11 (73.3)	25 (45.4)	36 (50.7)
Response rate during study,[a] No. (%)			
High	4 (26.7)	29 (52.7)	33 (47.1)
Medium	7 (46.6)	0 (0.0)	7 (10.0)
Low	4 (26.7)	26 (47.3)	30 (42.9)
Practice setting, No. (%)			
Rural	12 (80.0)	45 (81.8)	57 (81.4)
Town	2 (13.3)	8 (14.6)	10 (14.3)
City	1 (6.7)	2 (3.6)	3 (4.3)
Medical specialty, No. (%)			
General medicine	8 (53.3)	28 (50.9)	36 (51.4)
Obstetrics and pediatrics	3 (20.0)	11 (20.0)	14 (20.0)
Traditional medicine	3 (20.0)	12 (21.8)	15 (21.4)
Preventative medicine	1 (6.7)	4 (7.3)	5 (7.2)
Years in health sector, mean (SD)	2.7 (0.4)	2.9 (0.5)	2.9 (0.5)

Abbreviations: FGD, focus group discussion; IDI, in-depth interview; mCME, mobile continuing medical education; SD, standard deviation.
[a] High response rate refers to those in the 90th and 75th percentiles for women and men, respectively; medium refers to those between the 10th and 90th percentile for women and between the 25th and 75th percentile for men; low refers to those in the 10th and 25th percentiles for women and men, respectively.

> *I can remember if I learn just a bit every day, but it's impossible if I have to stay in a class all day long from morning 'til night! I'm very satisfied with this approach.* (Female FGD participant, group 2)

One mentioned that traditional CME was stressful due to the intensive studying and testing involved, whereas texts were "… *nearly stress-free*."

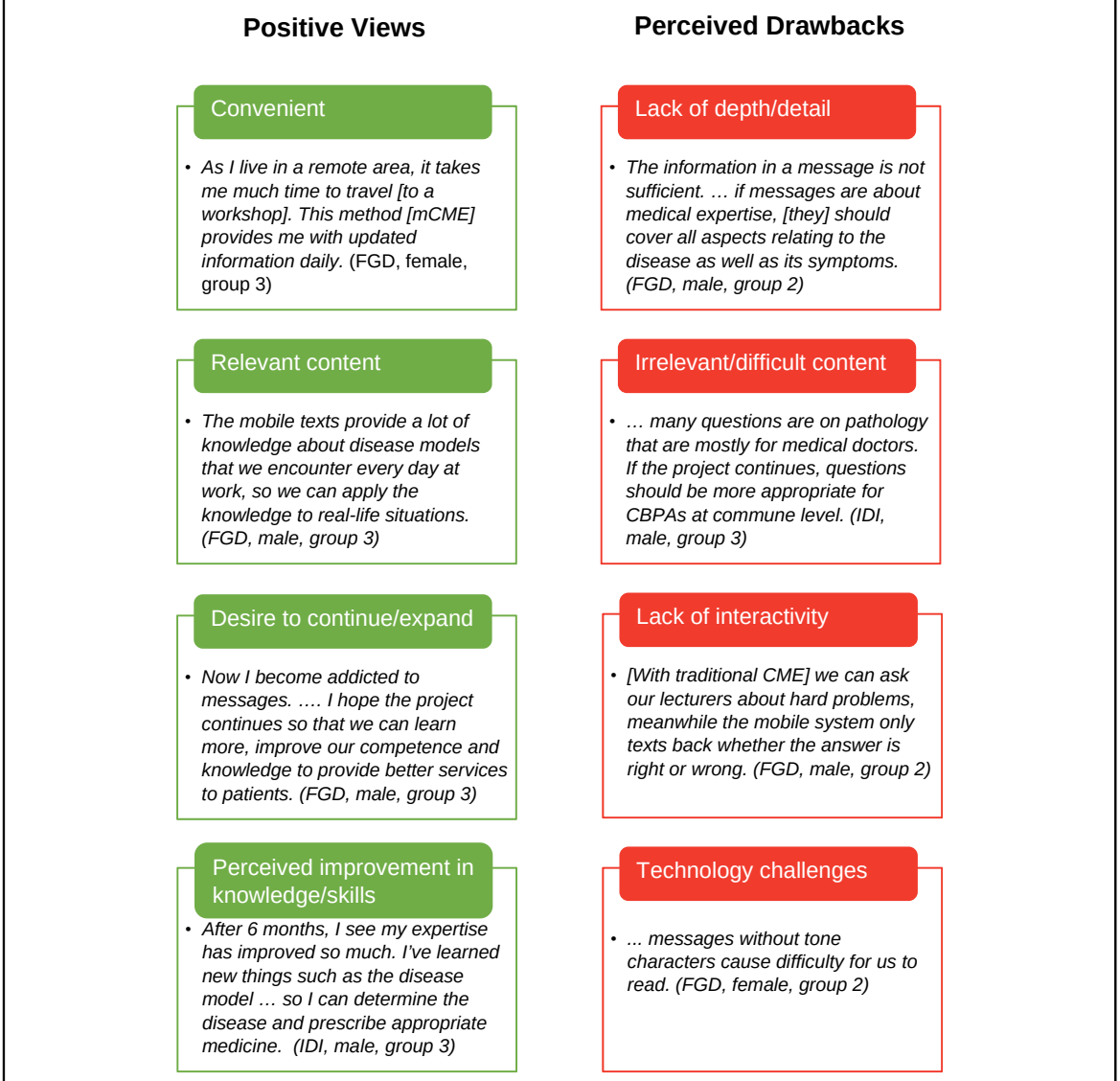
Several respondents were circumspect about the text messages' relative advantages:

> *For mCME, firstly it's fast; secondly it saves time; thirdly, it doesn't interfere with work. But the traditional training method has its advantages as well; the written materials have detailed tables of content so I can easily find what I want to review if I forget.* (Female FGD participant, group 3)

A handful noted that, although convenient, phone-based information entailed risks:

> *We think that the questions are very useful, but it's easy to lose them. One day I went to a shop to repair my*

FIGURE. Participant Views of the mCME Intervention With Illustrative Quotes, Thái Nguyên, Vietnam, December 2015



Abbreviations: FGD, focus group discussion; IDI, in-depth interview; mCME, mobile continuing medical education.

phone, and the technicians deleted all my texts in my inbox. I couldn't find the medical texts anymore, not even one left. All gone. (Female FGD participant, group 3)

Relevance. Most respondents found both forms of messaging, simple medical facts and quiz questions, appropriate for CBPAs. The text messages were described as "very suitable" and "relevant." One male FGD participant (group 2) summarized:

Many questions provide knowledge relevant to the diseases at my work—it's so useful.

Others stressed the texts' practicality and application "*. . . to real-life situations*." Several mentioned that message content received on one day

had been helpful when treating a patient on the very same or next day.

Relevance was linked frequently to the wide range of topics covered in the text messages. Respondents claimed that, as community-level primary providers, they required understanding of numerous topics, unlike higher-level providers, who usually specialized in one field. Many noted the value of information on specific conditions—mentioning specifically tuberculosis, HIV, Parkinson's disease, gynecological diseases, low weight and malnutrition in children, diarrhea, obstetric complications, bleeding problems, and children's choking—and in different medical areas, including symptoms, diagnosis, prevention, and treatment. Several contrasted the text messages' breadth with conventional CME:

> *I think this approach [mCME] provides wide and diverse medical knowledge that could not be fully covered in traditional training sessions.* (Female FGD participant, group 3)

While respondents liked both text formats (daily medical facts and daily quiz questions), they revealed a clear preference for the latter. Quiz questions were seen as intriguing and motivating, and respondents liked receiving quick "right or wrong" responses. As one FGD female participant (group 3) explained:

> *Since feedback to our answers is immediate, we know which questions are correct or wrong, so we would know if we make mistakes or not.*

While most group 2 FGD participants said that they benefited from medical facts alone, others desired feedback:

> *But it'd be better to have interaction with the system like reading questions and then answering and waiting for the system's feedback, rather than only replying.* (Female FGD participant, group 2)

In one FGD, a group of men agreed that they liked the quiz format best:

> *As Group 2, we receive the statement about the symptoms . . . but the other group can answer the question. It's more interesting if you can join quizzes.*

Drawbacks. The most frequently mentioned disadvantage of the text messages was lack of depth. Although most respondents liked the texts' brevity, one-half (slightly more in FGDs than in IDIs) noted that the texts lacked detail. As one male FGD participant (group 2) stated:

> *. . . the SMS's content is insufficient; [it's] so short and limited.*

The most frequently mentioned drawback of the text messages was lack of depth.

Several suggested that text messages should provide not just more information but information delivered in a logical order:

> *Today you send the symptoms of one disease, diagnosis tomorrow, and treatment after that.* (Female FGD participant, group 2)

Just over one-third of respondents indicated that some texts were either irrelevant or difficult. Most typically, they referred to messages about diseases or procedures that CBPAs do not normally encounter or perform, such as lab tests. A smaller group found some text messages very difficult to understand. This is recounted from a FGD with men, all from group 3:

> Participant A: *The education level of this project is for doctors or for whom? Because there are many questions even doctors at my CHS aren't able to answer.*
>
> Participant B: *A lot of questions are beyond my knowledge; CBPAs at communes like me can't answer.*
>
> Participant A: *That's why I want to ask, what is the purpose of producing those hard questions? Who are they for? I know this project is for education, but who is it trying to educate?*

In addition, about one-third of respondents indicated that lack of interaction—particularly the inability to ask questions—was a limitation. They admitted readily that, while convenient, the simplicity of text-based communication could be frustrating. One male FGD participant (group 3) explained:

Respondents liked to receive both medical facts and quiz questions via text message, but had a clear preference for the interactive quiz questions.

> *There's no one to answer my questions if I don't understand.*

Many respondents noted the lack of interaction as a limitation to the text messages.

Several offered suggestions for incorporating feedback; as a female FGD participant (group 2) recommended:

> *It would be better if the system may send us the questions/SMS and then ask if we understand it/how we feel about it, [do you have] any questions about this issue, etc.*

Finally, about a third of FGD participants and half of IDI respondents described challenges with technology. This included challenges with cell phone use generally and/or poor reception; more found it difficult to read texts without the phonetic symbols common to written Vietnamese,

or to respond to texts. As one male FGD respondent (group 3) stated:

> *. . . messages should be written more precisely with tone marks, so that we do not have to think hard.*

In response, his FGD companions explained that they shared confusing texts with other CBPAs, who helped them decipher messages, so opinions differed on this point. Another subset of respondents struggled to respond correctly to the text messages. A female IDI respondent (group 3) described her experience:

> *At the beginning . . . I wrote 'Answer A, B . . . .' I also sent responses like 'Answer A is correct . . .,' and the system [responded that this '] was incorrect. It's true that I was very disappointed . . . . Later on, I was provided with an explanation on how to send responses. I became more used to it and found it very interesting.*

Continuing and Expanding mCME. Virtually all respondents expressed a desire for the intervention to continue. Several said they had felt nervous initially but had become accustomed to daily messages and would miss not receiving them. As one male FGD participant (group 3) claimed:

> *Once we get used to it, we will like it. Now I no longer receive messages. I feel like I'm losing knowledge.*

Some recommended a year-long timeframe; others stated more generally that they would prefer the training to last longer or to be implemented continuously. One male FGD participant (group 3) claimed that he was "addicted" to the texts. Some stated that the texts were so valuable they would pay themselves for continued delivery.

Similarly, most respondents believed that mCME should be expanded to other health care providers. The most common view was that nurses, doctors, and midwives could also benefit from text-based information. Several also reiterated the importance of tailored content:

> *I'd like this approach to expand to doctors and nurses as well, with levels of questions suitable for each of the profession.* (Female FGD participant, group 3)

Perceived Impacts of the Intervention

Respondents described numerous impacts they believed stemmed from the intervention. Many emphasized that just being the focus of an educational intervention had improved their outlook regarding their work. As one male FGD participant (group 3) noted:

> *We need to receive more knowledge . . . this type of education is very good. It helps change our attitude.*

More substantively, respondents described impacts that encompassed improved knowledge, confidence, and skills; increased Internet use; and more discussion of medical issues at the CHSs. Some felt that the intervention had made them better CBPAs. We explore these themes in more detail below.

Improved Knowledge. Virtually all respondents indicated that the intervention had improved their knowledge—or that it had such potential. Increased knowledge was linked to accessibility, understandability, and frequency of the text messages:

> *Each day, we can gain more knowledge. Messages are sent daily so we can remember them more effectively . . . .* (Male FGD participant, group 2)

Many believed that the texts rekindled a desire to learn. Several stressed their ability to motivate lateral learning:

> *The best thing we get is that the project promotes us to think and learn new knowledge or improve old knowledge. (Male FGD participant, group 3)*

A major theme was the role of the text messages in helping respondents relearn material. As an IDI male respondent (group 2) stated:

> *The most useful thing is that I'm reminded of past knowledge that I've learned at medical school.*

Many referred to their lengthy service as providers, lamenting their lack of CME opportunities. Some admitted to long-forgotten knowledge. This statement was typical of older participants:

> *Younger people have high qualifications, but I graduated 30 years ago so my knowledge and skills are faded.* (Male FGD participant, group 2)

A sense that daily messages provided important support and prompted a desire to learn was conveyed by a number of respondents, as in this statement:

> *It has been 20 years since I [have been] work[ing] as a CBPA. At the local level, there's not much training and refresher training. Since I joined this type of education, I feel like I have received much help. When I received*

messages, I had to study hard and then tried to give correct answers. . . . From this project, I gained more knowledge. (Male FGD participant, group 3)

Respondents also stressed the new knowledge they believed they had gained. Although some felt that certain messages were irrelevant to their work, the majority expressed appreciation for the chance to learn new things, an important opportunity for some given the passage of time since their training:

After 20 years, books are also out of date, partly because of new knowledge. This type of training helps us revise what we have learned. It can replace a teacher. In addition, there are things we haven't learned or we just know a little about. This training provides us with more knowledge. (Male FGD participant, group 3)

When queried about quiz question feedback (telling them whether their answer was correct), most group 3 FGD participants claimed they were sad or disappointed at receiving "incorrect" feedback, yet learned more from such responses. As one female IDI respondent elaborated:

I think the wrong answers are very useful, especially when I discover that, 'Ah, I answered this question wrong. This one is the correct answer.' Through each wrong answer, I can learn a new lesson . . .. (Female IDI respondent, group 3)

Others highlighted the way that such feedback motivated them:

But when I answer incorrectly, I study more, use my brain more, such as looking up books, asking colleagues or using other methods to find out where I was wrong, and then I note it down or else I would forget. (Male FGD participant, group 3)

Increased Self-Study and Discussion. Additional major themes were perceived changes in lateral learning (self-study) and in discussion with colleagues about medical issues. Many respondents communicated that the text messages prompted them to look things up, to study, and, especially, to use the Internet to search for more information. For some, because the information provided in the text messages was necessarily limited, the text messages provoked a craving for more information, as explained by a male FGD participant (group 2):

The SMS is short, but it encourages us to find more information online. It's helpful to motivate us to learn more.

As noted earlier, some respondents linked such motivation to the feedback received from the mCME program on an incorrect quiz answer. This statement by a female IDI respondent (group 3) illustrates this point:

Before, I rarely went on the Internet, I just read medical books. But since participating in the project, I often go online to search for information when I get the answers wrong.

Respondents thought they had gained new knowledge from the text messages.

Many respondents recounted how the text messages had spurred discussions at their CHSs. They described asking their colleagues, including doctors, specific questions about the information included in a text message. Several expressed delight that the texts seemed to stump their senior colleagues. Others described animated debates that took place among colleagues; some claimed camaraderie among the CBPAs was enhanced from the intervention. As one male FGD participant (group 2) noted:

Many respondents recounted how the text messages had spurred discussions with their colleagues.

Staff in healthcare station receive messages at 9 or 10; they will discuss [the texts] with each other, so the atmosphere in the CHS is very good.

Enhanced Confidence. The vast majority of respondents claimed that the intervention had improved their self-confidence. As one female FGD participant (group 3) explained:

I feel that I have more knowledge, I'm more confident in my expertise.

This reaction was common among group 2 participants as well:

During 6-months of receiving SMS, I feel more confident because of [improved] professional knowledge. I have studied those [points] but forgot them . . .. I can improve my knowledge and feel more confident in handling daily tasks. (Female FGD participant, group 2)

Improved Competence. A number of respondents perceived improved clinical skills. Most frequently, they described an enhanced ability to diagnose conditions. Several spoke generally of improved technical competence. In the words of a female FGD participant (group 3):

With this project, I know more symptoms. There are cases that I am not sure [about], but now I am confident. With the knowledge I receive, I see my technical competence is improved.

Others relayed that their job performance was better than before:

From this project, I get more knowledge. It's very good and useful . . . . That greatly improves my job." (Male FGD participant, group 3)

Why Did the Intervention Fail?

Several themes are suggestive of why the 6-month intervention failed to show improved medical knowledge. These encompass overreliance on text messages for medical information, lack of effective self-study, and specific issues with technology and messages. Each is explored below.

Many respondents viewed the text messages as the main, if not sole, source of medical information.

Exclusive Focus on Text Messages as "Professional Handbook." Many respondents seemed to view the text messages as the main, if not sole, source of medical information, rather than as a stimulus to further learning. As discussed earlier, they liked the texts largely because of their simplicity and brevity; this convenience may have encouraged them to focus on the texts exclusively in lieu of exploring more detailed materials, whether book- or Internet-based, which might have helped them to score better on the endline exam. As one male FGD participant (group 2) relayed:

In the traditional training, it's different. We need a certain period of time to sit down and study, while this new method is much more convenient; we only need to open our phone and read text messages.

In addition, the random sequence of the texts may have hindered learning. Thus, while respondents said that the text messages prompted self-study, the predominant behavior appears to have been text message-focused, with the content of the text messages raised to an exalted status, as conveyed in this statement:

I consider the texts as a professional handbook. (Female FGD participant, group 2)

It is also possible that traditional modes of learning in Vietnam, which stress memorization rather than thoughtful inquiry, reinforced a tendency to simply memorize the text messages rather than to use them as a springboard to meaningful learning. Many respondents described reviewing the text messages, repeating their ease of access. Said one respondent:

In the evening at home I'll read the messages for an information update. It would be much harder to review books or professional materials. (Female FGD participant, group 3)

Memorization, rather than a probing approach, may also have limited deeper learning from other medical sources.

Lack of Meaningful Self-Study. As discussed earlier, many respondents described changes in behavior, particularly increased Internet use and collegial discussions, that could be expected to lead to increased knowledge. Since we know knowledge did not improve measurably, we can suppose that any actual behavioral changes were ineffective pathways to learning. Thus, when a respondent said, "I often go online to search for information when I get the answers wrong," that alone does not mean that accurate information was obtained or that something was learned. Similarly, increased CHS-based discussions prompted by the text messages cannot ensure meaningful education. Indeed, many respondents noted that they took unclear content to their physician colleagues, but often without a helpful result. As one male FGD participant described:

I've discussed the questions with specialized doctors and MAs [Masters degree holders]; sometimes even they answer incorrectly. (Male FGD participant, group 3)

Technology and Content Challenges. As indicated above, some respondents experienced technology challenges and/or found the content in the text messages challenging to understand. While this does not seem to have stifled generally positive views of mCME, it may have impacted behavior during the trial to a greater degree than respondents themselves realized. Several suggested that if CBPAs encountered difficult text messages, the text messages might be ignored. A female IDI respondent (group 3) elaborated, as follows:

Sometimes, using difficult words made them unable to understand and answer, which would reduce their motivation . . . they might think that the questions were not relevant with their daily work, so they might give up.

DISCUSSION

This qualitative study sheds light on participants' experiences during a 6-month trial that assessed a novel approach to CME in a low-resource setting—using mobile technology to deliver daily text messages to community-level health providers in Vietnam. We found mainly positive views of two forms of mobile messaging

(passive and interactive); respondents highlighted convenience, relevance, and feedback, as well as perceived benefits including increased motivation, knowledge, collegial discussions, Internet use to search for more information, and clinical skills. They also described downsides to the text messages: lack of depth, inability to interact, technical difficulties, and challenging content. Overall, they reacted positively, and expressed a clear desire for the mCME intervention to continue and to be expanded to other medical professionals. Given the potential of mHealth approaches to reshape the CME landscape and the lack of evidence on effective strategies to provide mCME,[1,7] these findings provide important evidence that can inform future mCME research and implementation efforts.

The hypothesis for the trial was that daily text messages would motivate lateral learning and lead to improved knowledge, as measured by post-intervention exam scores. This did not occur, and the present qualitative study's findings help illuminate why it did not. First, respondents expressed an extraordinary focus on the text messages themselves. Yet the messages were, by design, limited in content and not organized with intensive studying in mind. To the contrary, they were meant to motivate CBPAs to seek out and use more detailed sources of medical information. With the benefit of hindsight, we postulate that our lack of clarity with trial participants about the goal of self-study and the exam content not being solely based on the text messages, along with the possible lack of easily accessible, reliable medical materials, may have played a role in extensive focus on and use of the text messages. Because the exam questions were more complex than the quiz questions, a strategy of focusing on the text messages alone was unlikely to be successful in terms of performing better on the endline exam compared with the baseline exam. It is also possible that daily practicalities drove CBPAs' behaviors. Previous research on eLearning has shown that users value ease of access and flexibility.[14] Respondents in this study prized convenience; it may be precisely their easy access and flexibility that made the text messages so irresistible, perhaps fostering an illusion of and satisfaction with "studying" by reviewing the text messages, but not deeper learning. Participants were also receiving text messages in a busy environment (their clinics); multitasking may have hindered full absorption and later follow-up.

While respondents' accounts of changes in knowledge, confidence, and study habits are encouraging, our trial results confirmed that such changes, where they occurred, did not result in increased medical knowledge. As discussed above, Internet searches and collegial discussions do not translate automatically into effective learning. Indeed, given that respondents revealed a strong disinclination toward traditional and intensive forms of CME, Internet searches and discussions may have supported a tendency to avoid serious study and engage instead in lighter activities that, again, provided impressions of learning without meaningful gains in knowledge. Additionally, given that some time had passed since formal training for many CBPAs, and that some may have lacked direct, convenient access to reliable material, it is possible that focused and effective self-study was simply very hard to achieve.

To address some of these issues, our next mCME project will be more transparent about behavior-change aims and will incorporate links to existing Internet-based CME courses in the text messages. With a focus on HIV providers in Vietnam, our goal will be to provide participants with accessible, reliable medical sources to supplement the information received in the text messages. In this way, we hope to discourage the temptation to focus only on the text messages and to support the use of existing relevant continuing education. Because the Vietnamese government has made an enormous investment in online courses, this also serves to support the country's long-term CME goals.[1,2,5]

It is also critical to consider creative approaches to overcoming the downsides of text-based CME while retaining its strengths. Again our qualitative data are informative. Respondents' affirmative attitudes toward mCME centered on its convenience; their perspectives also underscored the role of relevant content, feedback, and interaction in motivating professionals—qualities previously identified as important in CME.[7,20] Respondents themselves suggested that relevance could be enhanced by tailoring content more precisely for professionals in different medical fields. They also recommended that messages be organized in a sequence that mirrors clinical encounters (symptoms, diagnosis, treatment), although clearly there is room for experimentation, in both the substance and sequencing of content. Another approach might be to add a component on searching and finding quality information on the Internet. These endeavors are time-demanding but certainly possible technically.

Addressing the text messages' lack of depth and inability to interact is more complicated, since

this should be done without compromising simplicity. Several approaches come to mind; further research would help examine their potential promise. One is to add optional additions for those who desire more, with opt-out choices for those who do not. First, for more depth, links to further online information and courses by topic and to in-person courses, could be incorporated into the text messages (as we are now doing); these might be complemented with other resources (fact sheets, infographics, Internet-based eLearning sessions, etc.). Second, for more interaction, daily text messages could be supplemented by optional weekly group chats, call-in numbers to a hotline staffed by a professional, and web-based, interactive workshops. Third, a champion or expert on-site might be identified to lead discussion groups. Fourth, text- or computer-based quizzes could be added to the end of specific modules (say, after 1 or 2 weeks) so that participants can assess their own learning immediately after finishing a sequence of texts. The ability to ask questions, obtain immediate feedback, and observe progress over time might well substantially enhance the appeal of the basic text-based mCME package assessed in this first trial. While any of these could be stand-alone options, a combination of options could also be incorporated into a fixed package. The goal is the same: keep the simplicity and convenience but create room for depth and interaction.

To improve interactivity, text messages could be supplemented by group chats, hotlines, and web-based workshops.

Limitations

We acknowledge limitations to this study. First, some respondents may have provided biased information—whether from a desire to please facilitators (moderator-acceptance bias); to avoid expressing conflicting views in the company of respondents who held strong opinions (dominant-respondent bias); or because of poor recall. Since many respondents provided a range of views, we do not believe such potential bias is concerning. Second, we collected data from a limited number of participants in a specific experiment; the views reported here are not generalizable beyond CBPAs practicing in Vietnam. That said, our goal was precisely to learn about the reactions to such participation to improve on this initial mCME experiment. Given the potential scalability and cost-effectiveness of mCME approaches, we believe these findings are important in contributing to understanding about the strengths and weaknesses of text-based learning and suggest possible paths forward for work in this important field.

CONCLUSION

This qualitative study found predominantly positive reactions from participants in an mCME trial in Vietnam, where efforts are underway to expand CME to health professionals. Participants provided positive feedback on the text message-based intervention and were enthusiastic about its perceived convenience, relevance, and motivating effects. However, the results confirmed that text messages alone cannot stand on their own; they require a framework to translate motivation into meaningful behavior change. They also underscore the higher appeal and superiority of interactive approaches in engaging learners. If adapted appropriately for different settings and medical professionals, mCME could be a promising tool for distance learning.

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ORIGINAL ARTICLE

Availability and Quality of Family Planning Services in the Democratic Republic of the Congo: High Potential for Improvement

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A few facilities provided good access to and quality of family planning services, particularly urban, private, and higher-level facilities. Yet only one-third offered family planning services at all, and only 20% of these facilities met a basic measure of quality. Condoms, oral contraceptives, and injectables were most available, whereas long-acting, permanent methods, and emergency contraception were least available. Responding to the DRC's high unmet need for family planning calls for substantial expansion of services.

ABSTRACT

Objective: To determine the availability and quality of family planning services within health facilities throughout the Democratic Republic of the Congo (DRC).

Methods: Data were collected for the cross-sectional study from April 2014 to June 2014 by the Ministry of Public Health. A total of 1,568 health facilities that reported data to the National Health Information System were selected by multistage random sampling in the 11 provinces of the DRC existing at that time. Data were collected through interviews, document review, and direct observation. Two dependent variables were measured: availability of family planning services (consisting of a room for services, staff assigned to family planning, and evidence of client use of family planning) and quality of family planning services (assessed as "high" if the facility had at least 1 trained staff member, family planning service delivery guidelines, at least 3 types of methods, and a sphygmomanometer, or "low" if the facility did not meet any of these 4 criteria). Pearson's chi-square test and odds ratios (ORs) were used to test for significant associations, using the alpha significance level of .05.

Results: We successfully surveyed 1,555 facilities (99.2%) of those included in the sample. One in every 3 facilities (33%) offered family planning services as assessed by the index of availability, of which 20% met all 4 criteria for providing high-quality services. Availability was greatest at the highest level of the health system (hospitals) and decreased incrementally with each health system level, with disparities between provinces and urban and rural areas. Facilities in urban areas were more likely than in rural areas to meet the standard for high-quality services ($P<.001$). Public facilities were less likely than private facilities to have high-quality services ($P=.02$). Among all 1,555 facilities surveyed, 14% had at least 3 types of methods available at the time of the survey; the most widely available methods were male condoms, combined oral contraceptive pills, and progestin-only injectable contraceptives.

Conclusion: Availability and quality of family planning services in health facilities in the DRC remain low, with inequitable distribution of services throughout the country. To improve access to and use of family planning, efforts should focus on improving availability and quality at lower health system levels and in rural areas where the majority of the population lives.

INTRODUCTION

Maternal and infant mortality remain high worldwide, especially in low-income countries.[1–3] In the Democratic Republic of the Congo (DRC) specifically, in 2014 the estimated maternal mortality was 846 deaths per 100,000 live births and the estimated

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neonatal mortality was 28 per 1,000 live births.[4] About 18% of women's deaths worldwide are due to preventable causes related to pregnancy and delivery, especially postpartum hemorrhage, hypertensive disorders, abortion, and sepsis.[1,5–10] Three-quarters of these deaths could be prevented if health centers and hospitals provided a package of high-quality maternal care services.[11,12] The risk factors of maternal and perinatal mortality are strongly entwined, with the first 24 hours of a newborn's life being those in which the risk of neonatal death is highest.[13,14]

Family planning is one of the most cost-effective interventions to improve maternal and child health outcomes[15–17]; it contributes to a reduction in the number of unwanted pregnancies, thus reducing the number of unsafe abortions and deaths from this cause. Family planning also reduces the *proportion* of pregnancies that are considered to be high risk—that is, pregnancies that occur too early or too late in relation to the mother's age, those that are spaced too closely together, or those that are considered high parity. By helping women time and space their pregnancies, family planning also helps ensure healthy nutritional outcomes for both mother and child.[18] Raising women's awareness about family planning during antenatal care and childbirth and providing postpartum contraception during childhood vaccination visits are among the strategies that improve the use of family planning.[19,20]

The modern contraceptive prevalence rate in the DRC remains low at 8%, with significant disparities among provinces. The total fertility rate is high, estimated at 6.6 children per woman.[4] Early childbearing among adolescents 15 to 19 years old also remains high, at 13 pregnancies per 1,000 girls. Approximately 27% of adolescent girls already have been pregnant or have given birth.[4,21]

The use of family planning is strongly related to both its availability and quality.[22] In previous research conducted in Africa and Asia, the quality of family planning services tends to be higher in private than public facilities, and beneficiaries tend to be more satisfied with the quality of service provided by private health facilities compared with public providers.[22–24] The quality of family planning is strongly influenced by the availability of trained human resources, materials, and equipment.[25]

According to the 2013–2014 Demographic and Health Survey (DHS) conducted in the DRC, unmet need for family planning was estimated at 27.7% among women in union and 43.0% among those not in union but sexually active. These high unmet need figures are due in part to limited access to quality family planning services in the country.[4] The DRC faces several major challenges in meeting the family planning needs of its population, including the large land mass, which is the size of Western Europe, and poor supply chain management, which greatly hinders service delivery of any type of health service. The National Multisectoral Strategic Plan for Family Planning 2014–2020 set the objective of establishing family planning services in all 516 health zones of the country by 2020, but to date family planning services are available in less than half of those zones.[26] In addition, provision of family planning services, including a range of contraceptive methods, are part of the minimum package of activities for all types of health facilities in the DRC.[27,28]

Family planning is one of the most cost-effective interventions to improve maternal and child health outcomes.

To date, no study has been conducted at the national level on the availability and quality of family planning services in the DRC—a major logistical feat given the physical expanse and poor transportation infrastructure of the country. The objective of this study was to determine the availability of family planning services within health facilities throughout the country and to assess their quality.

The objective of this study was to determine the availability and assess the quality of family planning services in health facilities throughout the DRC.

METHODS

Data collection for this cross-sectional study was conducted from April 2014 to June 2014 by the Ministry of Public Health with technical and financial support from WHO and in collaboration with the Kinshasa School of Public Health.[29]

The health system in the DRC includes 4 types of facilities:

- Hospitals (including national and provincial hospitals, district hospitals, and secondary hos-pitals)
- Referral health centers
- Health centers
- Health posts

To be eligible for inclusion in this study, the facility had to be listed on the Ministry of Public Health roster of facilities and to have provided data to the National Health Information System (NHIS, known locally as SNIS) during the 6 months prior to the study as an indication that it was active.

Before selecting health facilities, the research team reviewed the list of facilities with health officials from each province and used the information

The index of quality was based on 4 elements: presence of 1+ trained staff, existence of family planning service delivery guidelines, availability of 3+ methods, and availability of a sphygmomanometer.

to update the roster of facilities that were reporting to the NHIS. Only functional health facilities were included in the sampling frame. Each province was considered as a stratum, with 4 substrata corresponding to the 4 types of facilities. Because the proportion of health facilities providing family planning services in the DRC is not known, the sample size for the study was calculated considering a proportion (p) of 0.5 of health facilities having this characteristic of interest. The sample size was calculated for each of the 4 substrata and the selection of health facilities within the substratum was conducted by systematic random sampling using a sampling interval after arranging the health facilities in ascending order according to their national identification number. This procedure yielded a sample of 1,568 facilities. Additional details about the sampling procedures are provided in the full survey report.[29]

In view of the vast geographical expanse of the DRC and logistical challenges to collecting data, the research team divided the country into 38 "pools" corresponding to the major urban centers. The team contacted provincial health officials to determine the means of access to each selected facility and the resources needed to reach it.

Dependent and Independent Variables

From the data collected, 2 dependent variables were created: an index of availability of family planning services and an index of quality of family planning services. These indices were calculated by modifying WHO-proposed tools to measure the preparation and availability of services.[30]

The index of family planning availability was based on 3 criteria: infrastructure, staff, and service use.

The **index of availability** was based on 3 criteria. A facility had to meet all 3 of these criteria to be considered as a facility that offered family planning services:

1. **Infrastructure:** existence of a room in which to provide family planning (and other) services that ensured the confidentiality and privacy of clients to be respected
2. **Staff:** existence of a health staff assigned to family planning services
3. **Service use:** evidence of client use of family planning services, based on service statistics (at least 1 client listed as obtaining family planning services in the 6 months preceding the survey)

The index of quality was informed by Donabedian's model of quality medical care.[31] According to this model, there are 3 dimensions to judging quality: the structure of care in terms of inputs, material, staff, funds, and organizational structure; the processes used to deliver care (i.e., standards of care); and outcomes. The **index of quality** used in this study was based on 4 elements:

1. Presence of at least 1 staff member trained in family planning during the 2 years preceding the survey
2. Existence of family planning service delivery guidelines (printed manual of instructions or standards)
3. Availability of at least 3 types of contraceptive methods on the day of the survey (specifically, the 3 most widely used by clients, according to data from the 2013–14 DHS,[4] which were male condoms, combined oral contraceptive pills, and injectable contraceptives)
4. Availability of a sphygmomanometer to measure blood pressure, which is desirable when prescribing certain contraceptive methods

These elements focused mostly on Donabedian's first dimension of quality care, which is focused on structure of care. Donabedian's second dimension, standards of care, was captured in our index by observing whether family planning service delivery guidelines existed. Since the elements included in our index comprised a modest measure of quality, only facilities that met all 4 of the criteria were classified as having "high" quality; if 1 or more of the criteria were not met, the facility was assessed as having "low" quality.

Independent variables included the health facility sector (public versus private), location of the facility (urban versus rural), type of facility (hospital, referral health center, health center, or health post), and province. Before carrying out statistical analyses, all non-state health facilities were grouped under the category "private," which included private for-profit facilities, not-for-profit facilities, and church-managed facilities. Prior to 2015, the DRC had 11 provinces. In 2015, the provinces were further subdivided for a total of 26 provinces. This analysis is based on the 11 provinces in existence at the time of data collection.

Data Collection and Analysis

Within each of the 38 pools, 2 staff from health facilities not selected for the study were recruited and trained by supervisors from Kinshasa as interviewers for the study. They visited all facilities selected for inclusion in that pool and collected

data through structured interviews with managers and the person responsible for family planning services of health facilities. The first interviewer asked the questions and recorded the answers on a paper form while the second interviewer simultaneously recorded the information on an electronic form on a laptop computer. After the interview was completed, the 2 interviewers resolved any discrepancies between the paper and electronic forms. The interviewers also performed document review and directly observed conditions in the facilities (i.e., counting contraceptive products in stock, analyzing contraceptive use registers, availability of service delivery guidelines, and appearance of the consultation room). Supervisors revisited 10% of the facilities to validate the data.

Data were entered using CSPro 5.0, using double entry for quality control. All data were weighted by stratum before analysis. The data were then exported to Microsoft Excel 2010 to produce graphs and charts. SPSS Statistics version 21.0 and WINPEPI version 11.54 were used for analysis and testing of associations. The indices of availability of family planning and quality of services were calculated as a proportion of all facilities. Pearson's chi-square test or the Fisher exact test were used to test the association of different variables. The odds ratios (ORs) helped to measure the effect size of specific associations. All hypotheses were tested using the alpha significance level of .05.

Ethical Review

The study was reviewed and approved by the Ethics (Human Subjects) National Committee. The research team obtained authorizations from national and provincial health authorities prior to the survey. Data were collected anonymously, after obtaining informed consent from participants.

RESULTS

In total, 1,555 facilities of the 1,568 included in the sample (99.2%) were successfully surveyed across the 11 former provinces of the DRC. The 13 health facilities for which data were not collected were extremely difficult to access, with some requiring use of a motorized canoe.

Availability of Family Planning Services Among the Total Sample of 1,555 Facilities

Of the 1,555 facilities surveyed, 33.0% offered family planning services, as assessed by the index of availability (i.e., availability of a room for family planning service provision, existence of staff assigned to family planning services, and evidence of client use of family planning services from service statistics) (Table 1). Hospitals were more likely to offer family planning (53.1%) than referral health centers (38.5%), health centers (31.1%), or health posts (8.9%). This relationship was statistically significant ($P<.001$). Availability of family planning was also significantly higher in urban areas than in rural areas ($P=.02$). By contrast, there was no relationship between the availability of family planning and whether the facility was in the public or private sector ($P=.37$).

Family planning service availability was unevenly distributed across the country.

As shown in Figure 1, family planning service availability was unevenly distributed across the country. The provinces with the highest percentages were Sud-Kivu (81%) and Nord-Kivu (60%), in contrast to the lowest percentages in province Orientale (15%), Bandundu (18%), Equateur (21%), and Kongo Central (28%). The bars in Figure 1 also indicate the percentage of facilities at the national level and in each province with 3 or more methods available (indicating greater choice) versus fewer than 3 methods. At the national level, of the 33% of facilities with family planning services, more had fewer than 3 methods (19%) while a few number of facilities had 3+ methods (14%). Sud Kivu and Nord Kivu had the highest percentage of facilities with 3+ methods, in stark contrast to Bandundu, Equateur, and Province Orientale (with 5% of health facilities or less having 3+ methods).

The 3 most commonly available methods available were condoms, combined oral contraceptives, and injectables.

The relative availability of different contraceptive methods is evident from Figure 2. Based on the total of 1,555 facilities surveyed, the 3 most commonly available methods were condoms (28%), combined oral contraceptives (23%), and injectables (19%). Methods available in less than 10% of facilities were the intrauterine device (IUD), emergency contraception, and female and male sterilization. The availability of specific methods was higher in private than public facilities for implants, IUDs, emergency contraception, and female sterilization, but not significantly different for other methods (data not shown).

Quality of Family Planning Services Among the 513 Facilities With Family Planning Available

Only 33% of surveyed facilities offered family planning services, as assessed by the index of availability.

In this analysis, we developed a quality index based on 4 items for the 513 health facilities with family planning services available. As shown in Figure 3, just over half of these health facilities

TABLE 1. Percentage of Health Facilities With Family Planning Services, as Defined by the Availability Index,[a] DRC, 2014 (N=1,555 Facilities)

	No. of Health Facilities	Family Planning Services Available[a] No. (%)	*P* Value
Total	1,555	513 (33.0)	
Type			<.001
Hospitals	433	230 (53.1)	
Referral health centers	244	94 (38.5)	
Health centers	498	155 (31.1)	
Health posts	380	34 (8.9)	
Sector			.37
Public	872	296 (33.9)	
Private	683	217 (31.8)	
Location			.02
Urban	367	140 (38.1)	
Rural	1,188	373 (31.4)	

Abbreviation: DRC, Democratic Republic of the Congo.
[a] Index of availability: (1) availability of a room for family planning service provision; (2) existence of staff assigned to family planning services; and (3) evidence of client use of family planning services from service statistics.

Only 20% of facilities were assessed as having high-quality family planning services.

The 513 facilities with family planning services available had a mean number of 3 methods available.

This study demonstrates the acute lack of access to quality family planning services in the DRC.

had service delivery guidelines (53%) and staff trained in family planning (51%). The large majority (85%) had a sphygmomanometer in good condition, and about 65% had at minimum male condoms, combined oral contraceptive pills, and injectable contraceptives available. However, only 1 of every 5 health facilities (20%) met all 4 quality criteria and thus met the standard of having a "high" quality of family planning services.

The quality findings show marked differences by province (Figure 4). The facilities with the highest percentages offering high-quality family planning services were in Kinshasa (44%), Sud-Kivu (40%), Nord-Kivu (29%) and Kasai-Occidental (28%). By contrast, in the remaining provinces, 17% of facilities or less were judged to be of high quality.

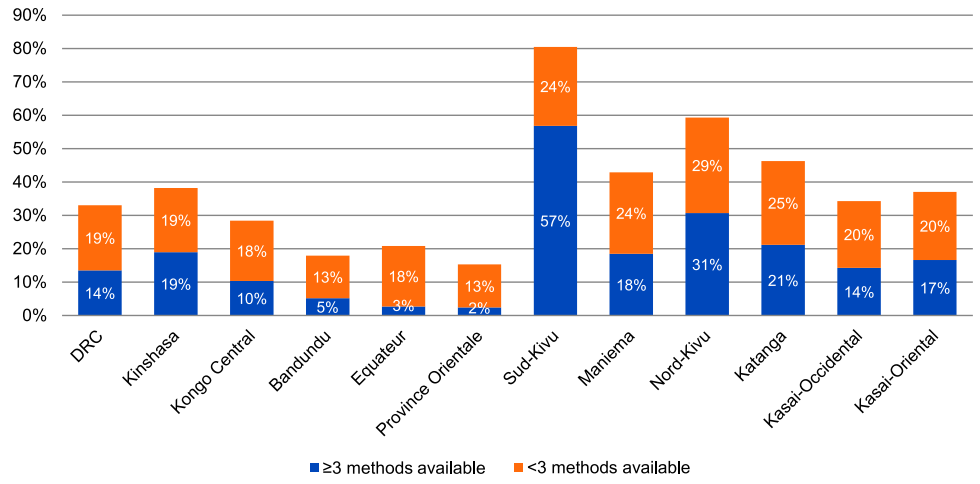
According to the results in Table 2, the percentage of health facilities assessed to have high quality of family planning services was significantly higher for urban (35.1%) than rural areas (14.8%). It was also significantly higher among private health facilities (25.0%) than public (16.4%). Finally, quality was highest among hospitals (27.5%) and lowest among health centers (14.8%) and health posts (0.0%).

The number of methods available is important in family planning services because it serves as a proxy for the choice that clients have (more being better). The 513 facilities with family planning services available had a mean number of 3.0 methods available (Table 3). The number was higher for referral health centers (4.9) and national or provincial hospitals (4.7) than for health centers or posts (1.6).

DISCUSSION

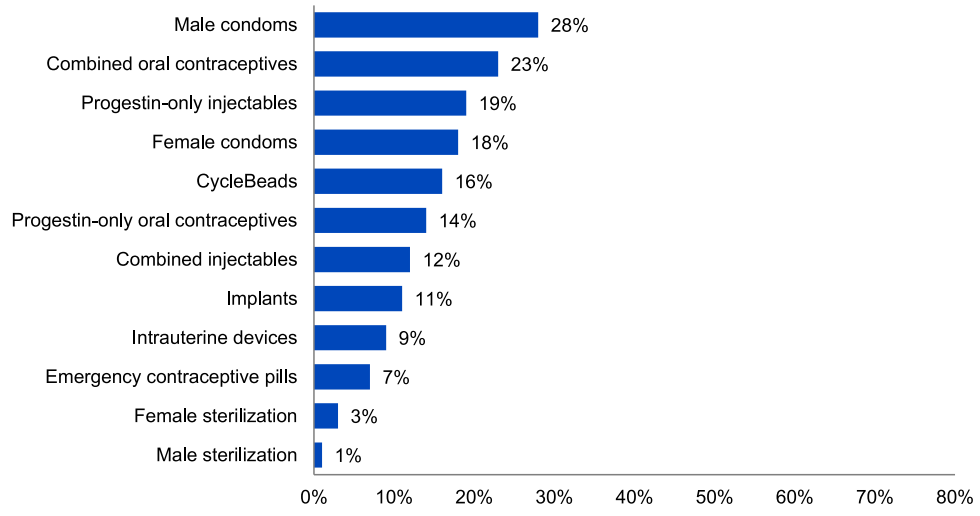
This study demonstrates the acute lack of access to quality family planning services in the DRC. Only 1 in 3 health facilities had family planning services available (defined as having a room in which family planning services could be provided, staff assigned to family planning services, and evidence of client use of family planning services). And of these facilities, only 1 in 5 were assessed to have "high" quality services (defined as having family

FIGURE 1. Percentage of Health Facilities With Family Planning Services Available by Province, Broken Down by Those With 3+ Methods Available, DRC, 2014 (N=1,555 Health Facilities Nationally)



Abbreviation: DRC, Democratic Republic of the Congo.

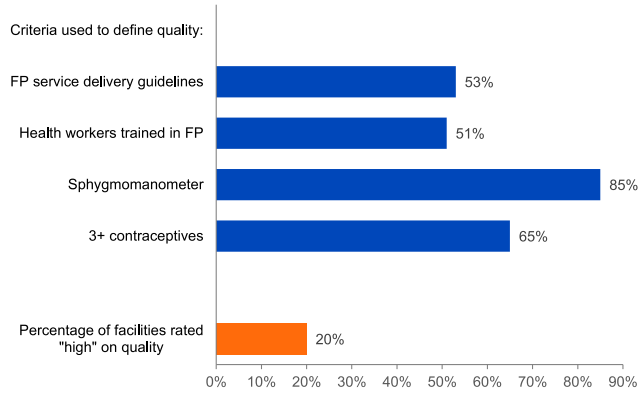
FIGURE 2. Percentage of Health Facilities With Specific Contraceptive Methods in Stock at the Time of the Survey, DRC, 2014 (N=1,555 Facilities[a])



Abbreviation: DRC, Democratic Republic of the Congo.

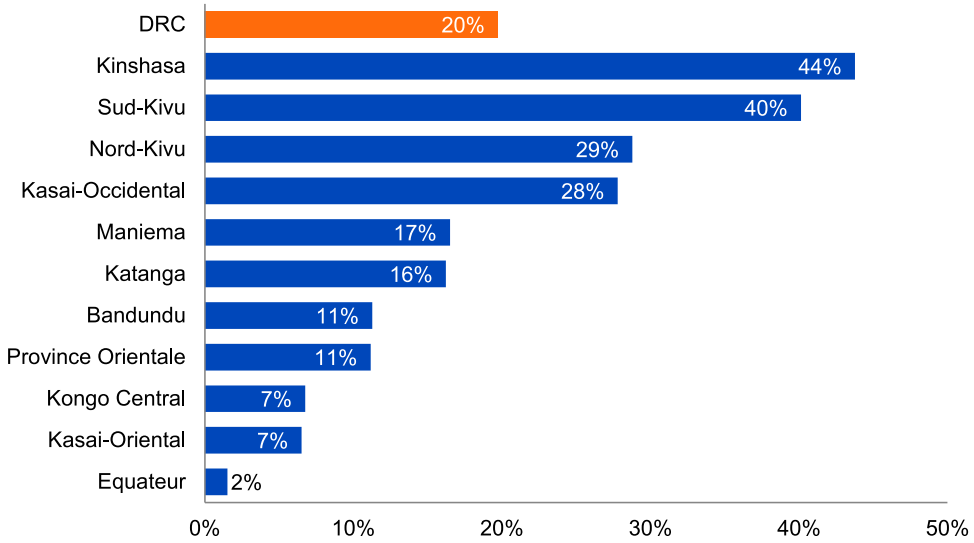
[a] Data are based on the full sample of 1,555 health facilities surveyed, not the subset that had family planning services available as defined by the index of availability.

FIGURE 3. Percentage of Health Facilities With Family Planning Services Available That Met the Criteria for High Quality, by Element and in Total, DRC, 2014 (N=513 Health Facilities)



Abbreviation: DRC, Democratic Republic of the Congo.

FIGURE 4. Percentage of Health Facilities With Family Planning Services Available That Were Rated "High" on Service Quality,[a] Nationally and by Province, DRC, 2014 (N=513 Health Facilities)



Abbreviation: DRC, Democratic Republic of the Congo.

[a] Facilities were assessed as providing high-quality family planning services if they met all 4 criteria of the quality index: (1) availability of at least 1 staff trained in family planning in the prior 2 years; (2) existence of service delivery guidelines in family planning; (3) availability of, at minimum, male condoms, combined oral contraceptive pills, and injectables; and (4) availability of a sphygmomanometer.

TABLE 2. Quality of Family Planning Services by Health Facility Characteristic, DRC, 2014 (N=513 Health Facilities)

	High Quality No. (%)	Low Quality No. (%)	*P* Value
Total	103 (20.1)	410 (79.9)	
Type			<.001
Hospitals	63 (27.5)	166 (72.5)	
Referral health centers	17 (18.1)	77 (81.9)	
Health centers	23 (14.8)	132 (85.2)	
Health posts	0 (0.0)	35 (100.0)	
Sector			.02
Public	48 (16.4)	245 (83.6)	
Private	55 (25.0)	165 (75.0)	
Location			<.001
Urban	47 (35.1)	87 (64.9)	
Rural	56 (14.8)	323 (85.2)	

Abbreviation: DRC, Democratic Republic of the Congo.

TABLE 3. Number of Contraceptive Methods Offered by Type of Health Facility, DRC, 2014 (N=513 Facilities With Family Planning Service Availability)

	Type of Health Facility (%)			
No. of Contraceptive Methods	National and Provincial Hospitals[a] (n=10)	District Hospitals and Referral Health Centers[a] (n=217)	Health Centers and Posts (n=286)	All Health Facilities (N=513)
0	30.0	34.8	67.9	53.4
1–2	20.0	4.6	6.3	5.7
3–4	0.0	5.4	8.8	7.3
≥5	50.0	55.2	17.1	33.6
Mean number	4.7	4.9	1.6	3.0

Abbreviation: DRC, Democratic Republic of the Congo.
[a] In the DRC, hospitals are classified into 3 categories: national, provincial, and district.

planning service delivery guidelines, health workers trained in family planning in the past 2 years, a sphygmomanometer, and at least 3 types of contraceptive methods). These results confirm those found in 2012 through a stake-holders' mapping in maternal, newborn, and child health that also found family planning services were available in only approximately one-third of health facilities.[32]

Unmet need for family planning in the DRC is high among both women in union and sexually active women not in union.[4,33] The low availability and quality of family planning services found in this study highlights the need for the country to improve access to and availability of services to better meet the demand for family planning.

Family planning services are more available in hospitals than in health centers and in urban than rural areas in the DRC.

In addition, we found that family planning services are more available in hospitals than in health centers and in urban than rural areas in the DRC. These differences could explain the persistence of low modern contraceptive prevalence of 8% in the country, with significant disparities between urban (15%) and rural areas (5%) and between provinces.[4,32] In the DRC, the majority of the population lives in rural areas where health care is mainly provided through health centers. In this study, the majority of the provinces which had a higher percentage of facilities with family planning service (Sud-Kivu, Nord-Kivu, Katanga, Maniema, Kinshasa, and Kasai-Oriental) are among those that have a large number of urban cities.

The National Multisectorial Strategic Plan for Family Planning 2014–2020 in the DRC defines the quality of family planning service as "high" when a health facility has at least 1 staff trained in family planning and provides a varied range of contraceptive methods, specifically at least 3 types of contraceptive methods comprising 1 long-acting method, 1 short-acting method, and 1 natural method.[26] When looking specifically at the number of methods available, we found that 14% of all health facilities surveyed in our study had at least 3 types of contraceptive methods; although the 3 minimum methods defined in our study were all short-acting methods (condoms, pills, and injectables), this definition is consistent with the standards proposed by the National Program of Reproductive Health.[34] Although this figure is low, it seems that progress has nevertheless been made over the past 2 years, with the percentage of health facilities offering at least 3 types of contraceptive methods increasing from 6% in the 2012 mapping study[32] to 14% in our study.

Facilities in urban areas are more likely than those in rural areas to meet the quality standard, as are private facilities compared with public facilities.

Male condoms, combined oral contraceptive pills, and progestin-only injectable contraceptives were the most available methods in health facilities in our study; these results are similar to those found in the 2012 stakeholders' mapping study as well as by Utoo and colleagues in Nigeria.[32,35] We think the predominance of condoms highlighted in these studies may be due to their use in other programs such as HIV and sexually transmitted infection control programs. In contrast, other recent studies have found high popularity of long-acting reversible contraceptives (LARCs) in several countries of Africa and Asia. For example, Jesse Rattan et al., reporting on an initiative to increase the availability, quality, and use of contraceptives in crisis-affected settings in Chad and the DRC, found a dramatic and sustained increase in use of implants and IUDs; these methods became among the most used methods in both country settings.[36] Similarly, Munroe et al., using data from social franchising programs in 17 African and Asian countries (not including the DRC), showed the majority of the clients chose LARCs.[37] Rattan and colleagues reported on an intervention project focused mainly in eastern DRC during the last humanitarian crisis, which likely explains the difference in high availability of LARCs in that study and low availability in our study. A greater percentage of private than public health facilities in our study offered LARCs. Private facilities thus provide a significant portion of family planning services in the DRC, especially as LARCs may be increasingly preferred by sexually active women of childbearing age compared with short-acting methods. To reach the goal of 19% of modern contraceptive prevalence outlined in the National Multisectoral Strategic Plan for Family Planning 2014–2020,[26] the Government should strengthen partnerships with private providers, despite the fact that private health facilities are inequitably distributed between urban and rural areas.[27]

We also showed that facilities in urban areas are more likely than those in rural areas to meet the quality standard, as are private facilities compared with public facilities. The quality of family planning deteriorated when moving down the health system chain, from hospitals to health posts. These results are consistent with those found in the multicenter study by Hutchinson et al. in Ghana, Kenya, and Tanzania, which showed that the quality of the family planning offered by private providers was better than that offered by public providers,[23] particularly when comparing primary-level health facilities. Private health facility users liked the short waiting times and infrequent shortages of inputs.[22,23] These results corroborate the finding that health services that are under the direct responsibility of public administrations often raise problems of poor resource management.

Kayembe et al. reported in 2015 that the capability of health facilities in Kinshasa, the capital city of the DRC, to provide quality family planning services had improved between 2012 and 2013,

with clinics offering higher-quality family planning services than hospitals and health centers.[38] The number of years in operation and the number of available methods were linked to these improvements. In our study, there were overall few clinics integrated into the NHIS, resulting in a small sample size. Based on our numbers, we found that only 44% of health facilities in Kinshasa met the quality standard, compared with 68% of clinics in the Kayembe report. The difference is likely due to differences in the way quality was measured between the 2 studies and in different sampling approaches.

Low availability and quality of family planning are among the main reasons for the low contraceptive prevalence in the DRC, but not the only reasons. Demand for family planning among the population also needs to be taken into account. For example, the majority of the population in the DRC is influenced by religious leaders who often are opposed to family planning. Moreover, in developing countries overall and in the DRC specifically, many people hold "pronatalist" views and are therefore hesitant to use family planning. To improve access to and use of family planning, health officials need to address both supply and demand considerations.

Strengths and Limitations

This study is the first to assess progress toward increasing access to and quality of family planning services on a national scale in the DRC. Also, it was methodologically stronger than the previous 2012 stakeholder mapping because of the sampling technique used, which involved stratification by province and type of health facility leading to greater representativeness of all types of health facilities. In addition, one of the strengths of this study is that it used a systematic sampling strategy and collected data representing the whole country despite important challenges in this context.

Data collection for this study covered approximately 10% of health facilities integrated into the NHIS of the DRC. The main limitation is that the sampling excluded health facilities not integrated into the NHIS, which could have led to selection bias, leading to an overestimation of family planning service availability and quality. However, we believe facilities not reporting to the NHIS receive less support and thus the availability and quality of family planning services is likely to be poor. On the other hand, we did not consider certain practices, such as the use of hangars for family planning service provision (an outside location with only a roof overhead), in our index of availability of family planning services because confidentiality and privacy of the clients would be difficult, if not impossible, under these circumstances. In addition, pharmacies—the major source of contraception in the 2007 and 2013–14 DHS studies—were excluded from this study. These facts may have resulted in an underestimation of family planning service availability. Finally, the measurement of quality was based on the availability of pills, condoms, and injectables, because they were the most widely reported methods; in contrast, other studies of this type base the measure of "at least 3 methods" on the availability of *any* type of modern method.

CONCLUSION

Availability and quality of family planning services in the DRC remain low. Family planning services are inequitably distributed throughout the country, with better availability in urban than rural areas and with significant differences in availability between provinces. Although efforts have been made to improve the availability of family planning services in selected rural areas, given the vast number of rural health zones that are still lacking family planning interventions, services are more available in urban areas than in rural areas where the majority of the population lives. Private health facilities are likely to provide better quality family planning services than public health facilities. Health authorities should work toward strengthening public-private partnerships to achieve improved access to and quality of care in family planning services.

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ORIGINAL ARTICLE

Increasing Access to Family Planning Choices Through Public-Sector Social Franchising: The Experience of Marie Stopes International in Mali

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While social franchising has been highly successful with private-sector providers, in Mali the approach was expanded to public-sector community health clinics. From 2012 to 2015, these clinics served >120,000 family planning clients, 78% of whom chose long-acting reversible methods. Many clients were young, poor, and had not been using a method during the 3 months prior to their visit.

ABSTRACT

Background: Mali has one of the world's lowest contraceptive use rates and a high rate of unmet need for family planning. In order to increase access to and choice of quality family planning services, Marie Stopes International (MSI) Mali introduced social franchising in public-sector community health centers (referred to as CSCOMs in Mali) in 3 regions under the MSI brand BlueStar.

Program Description: Potential franchisees are generally identified from CSCOMs who have worked with MSI outreach teams; once accredited as franchisees, CSCOMs receive training, supervision, family planning consumables and commodities, and support for awareness raising and demand creation. To ensure availability and affordability of services, franchisees are committed to providing a wide range of contraceptive methods at low fixed prices.

Methods and Results: The performance of the BlueStar network from inception in March 2012 until December 2015 was examined using information from routine monitoring data, clinical quality audits, and client exit interviews. During this period, the network grew from 70 to 135 franchisees; an estimated 123,428 clients received voluntary family planning services, most commonly long-acting reversible methods of contraception. Franchisee efficiency and clinical quality of services increased over time, and client satisfaction with services remained high. One-quarter of clients in 2015 were under 20 years old, and three-quarters were adopters of family planning (that is, they had not been using a modern method during the 3 months prior to their visit).

Conclusion: Applying a social franchising support package, originally developed for for-profit private-sector providers, to public-sector facilities in Mali has increased access, choice, and use of family planning in 3 regions of Mali. The experience of BlueStar Mali suggests that interventions that support quality supply of services, while simultaneously addressing demand-side barriers such as service pricing, can successfully create demand for a broad range of family planning services, even in settings with low contraceptive prevalence.

INTRODUCTION

Mali has one of the world's lowest contraceptive prevalence rates (CPRs), with just 10% of married women reporting use of a modern method of family planning in the most recent Demographic and Health Survey (DHS) in 2012/13, below the West and Central Africa average of 17%.[1,2] Use of contraceptives in Mali is much higher in urban than rural areas, with 23% of married women in the capital region of Bamako using a modern method compared with 3%–11% in other areas. A quarter of married women and 55% of sexually active unmarried women report an unmet need for family planning.[2] The fertility rate in Mali remains high at 6.1 children per woman, along with high maternal mortality at 368 deaths per 100,000 live births.[1]

Along with low CPR, the contraceptive method mix in Mali remains heavily skewed toward short-acting

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BOX. Mali Health System

Mali has a 4-tiered public health system, from community health centers to national referral hospitals. At the "entry-level" tier are the Centres de Santé Communautaires (CSCOMs), community health centers that are contracted by the government to provide a minimum package of basic health services. CSCOMs are the most common facilities for clients' first visits when seeking a health consultation.[5]

CSCOMs may be staffed by a single health care provider or a number of providers, including *matrones* (traditional birth attendants), nurses, pharmacy manager, midwives, and/or doctors. The majority of CSCOMs, particularly those in rural areas, are led by nurses rather than doctors.[5,6] The government is responsible for training and supervision of all CSCOM staff although some training may be supported by external organizations with particular areas of expertise. Staffing levels and technical capacity vary considerably from one CSCOM to another.

Each CSCOM is established through an agreement with a commune mayor (the elected leader). The agreement specifies the shared responsibilities and financial commitments of each party and the devolving authority of the facility to the community. Management of the facility becomes the responsibility of an Associations de Santé Communautaire (ASACO), community health associations made up of individuals elected from the community.

The government provides most of the funding for initial CSCOM construction and equipment and for most health worker salaries. The remainder of CSCOM operating costs (e.g., some staff salaries, medication purchases, travel expenses, demand generation) are covered through patient fees for consultations and prescriptions, as well as contributions from the community.

Although CSCOMs themselves are private nonprofit entities, they exist to provide health services on behalf of the government and are thus commonly considered part of the public sector. In addition to public-sector health services, there are multiple private medical practices and hospitals in Mali, predominantly located in the urban areas of Bamako.

contraceptives, with injectables and oral contraceptive pills the most commonly used methods.[1] The majority of married women (72%) report obtaining their method from the public sector, most commonly community health centers, while 23% obtain their method from the private sector.[1] Although family planning is included within the minimum package of health care services in the public sector, this does not always translate into availability of all methods. For example, many facilities do not have the commodities and equipment to provide long-acting or permanent methods. Even when these methods are available, the low rate of provision is a risk to provider competency and the safety of some family planning services.

Clinical social franchising—defined as the organization of small independent health care businesses into quality-assured networks[3]—can increase access to family planning services as well as choice and quality of services.[4] Typically clinical social franchising involves intensive capacity building and training of private providers, which generally includes clinical training, branding, monitoring of quality, and commodity support, as well as support for marketing and consumer behavior change.[4]

Mali operates a "semi-public" approach at the lowest tier of its public health system (Box), thus presenting an opportunity to trial the introduction of the Marie Stopes International (MSI) BlueStar social franchising model into the public sector. This article describes the operation and results of the MSI Mali BlueStar network for its first 4 years of operation, using routine monitoring data, clinical quality audits, and client exit interviews. The MSI experience in Mali provides a useful case example of whether and how clinical social franchising approaches can be introduced in the public sector to improve family planning access, choice, and quality.

PROGRAM DESCRIPTION: PUBLIC-SECTOR FRANCHISING MODEL IN MALI

Clinical social franchising can increase access to family planning services and to choice and quality of services.

Mali provided an opportunity to trial the introduction of the social franchising model into the public sector.

Marie Stopes International Mali (MSIM) is the largest nongovernment provider of family planning services in Mali, providing family planning services in 7 of the country's 9 regions. In 2012, MSIM began supporting the provision of family planning services at 70 community health centers (known in Mali as *Centres de Santé Communitaires*, or CSCOMs), deploying a social franchise approach using the MSI global franchising brand BlueStar. CSCOMs were identified as the facility type with the most potential to build a franchise network focused on expanding access and choice, due to their wide geographical and

population reach, compared with the limited presence and affordability of private facilities.

Initially the MSIM BlueStar network was launched in Koulikoro and Mopti, 2 regions with high levels of poverty and low CPR. In 2015, the network was expanded to the region of Sikasso, bordering Burkina Faso. Mopti is located in the north of Mali and has been affected since 2012 by the ongoing armed conflict between the government and Islamist insurgents.

Once demand for family planning has been primed through mobile outreach services, MSIM shifts to a social franchising approach in the area.

The introduction of social franchising approaches to CSCOMs was part of the wider MSIM strategy to address differing capacity and needs across the Mali health system to deliver family planning services. In areas where family planning knowledge, use, and public capacity for provision of family planning service is low, MSIM provides mobile outreach services at CSCOM and other sites to increase awareness of, access to, and choice of family planning services. Once community awareness and demand for family planning has been primed, and CSCOMs with an interest and potential capacity to provide these services have been identified, MSIM shifts to a social franchising approach in the area, building CSCOM capacity to ensure sustained family planning choice and access. The role of mobile outreach teams in these areas is then reduced, such that these teams then focus nearly exclusively on the provision of permanent methods of family planning (described in more detail below). The complementary nature of services provided by franchisees and mobile outreach teams maximizes the range of family planning choices available while ensuring the quality of more clinically demanding services such as bilateral tubal ligation.

Franchisees pay an annual membership fee, for which they receive in turn competency-based training, clinical supervision and quality assurance, consumables and commodities, marketing support, and branding of health centers.

Social franchising in Mali moves beyond capacity building of providers as it importantly includes the development of a long-term relationship with the *Association de Santé Communautaire* (ASACO) (Community Health Association) and the CSCOM. This involves quality improvement interventions and supply chain for contraceptives, as well as branding, local awareness creation, and contractual agreement on standards for service pricing (which includes price subsidies).

Selection and Accreditation of Franchisees

Potential BlueStar franchisees may be identified from CSCOMs who are already working alongside MSIM mobile outreach teams. Other CSCOMs may be selected in consultation with the regional and district health authorities. Privately owned practices are also eligible to join as franchisees, but the limited scale and reach of the private sector in Mali has meant a limited focus on for-profit private providers.

Once identified, potential franchisees undergo an accreditation process to ensure their capacity to deliver quality family planning services. The accreditation process is conducted by MSIM and the district and regional health authorities and involves assessment of human resource capacity, current provision of family planning services, availability of materials and equipment, the building condition, and for CSCOMs, the functionality of the managing ASACO. A contract outlining the roles and responsibilities is signed between MSIM and the responsible ASACO (on behalf of the CSCOMs) or the clinic owner (for privately owned practices).

Once accredited, franchisees pay an annual membership fee of CFA 10,000 (US$17), which is always paid in practice. In return, franchisees receive:

- **Competency-based training, including refresher training,** in family planning counseling and services including provision of long-acting reversible contraception, infection prevention, HIV counseling and testing, emergency preparedness, stock management, and reporting
- Ongoing routine **clinical supervision and quality assurance,** including establishment of clinical minimum standards, quarterly supportive supervision visits (often joint missions with regional health authorities), and annual clinical audits
- **Consumables and commodities** to provide a wide range of quality family planning services
- **Marketing support** to raise community awareness of family planning services (see details in section below)
- **Branding** of health centers

Franchisee Services

All social franchisees provide the following services under the BlueStar brand:

- Family planning counseling
- Provision of short-acting methods of family planning—pills, condoms, injectables, emergency contraception
- Provision and removal of long-acting reversible methods of family planning—the 10-year copper intrauterine device (IUD) and the 5-year implant

- HIV counseling and testing
- Referrals and appointments for voluntary female sterilization (MSIM does not currently offer vasectomy services)

Depending on the location of the client, clients choosing a permanent method are either referred to the MSIM clinics in Bamako or Mopti (if the CSCOMs are close enough, e.g., those in peri-urban areas in Bamako) or to the MSIM mobile outreach teams. CSCOMs have the monthly schedule of the mobile outreach teams and inform the client to return on the specific dates of the next outreach team visit to the CSCOM. The monthly schedule of the mobile outreach teams is also available to clients via posters in CSCOMs, the MSIM social marketing agents (described below), and the MSIM call center.

Pricing Strategy

As one of the intentions of the BlueStar network in Mali is to provide quality **family planning services at affordable costs**, MSIM purchases the family planning commodities through the public health system at a subsidized cost and provides them for free to BlueStar franchisees, who are only allowed to charge for these up to a maximum, subsidized price. This strategy enables franchisees to charge the same price as non-franchised CSCOMs for short-acting methods, and lower prices for long-acting reversible methods. For example, franchisees can provide IUDs for CFA 300 (US$0.49) compared with CFA 4,000–7,500 (US$6.60–12.30) at non-franchised CSCOMs. In line with the contract signed with the ASACOs, all BlueStar CSCOMs provide services free of charge to those unable to pay, and they may also run periodic promotional days with free services.

Awareness Raising

A range of strategies are used to increase community awareness and demand for a broad mix of family planning services. To directly support franchisees, MSIM employs social marketing agents to provide franchisee marketing and communication support; each agent supports 6 to 9 franchisees. Social marketing agents work closely with community health workers, providers, community and religious leaders, women's groups, and schools to conduct awareness raising and community mobilization activities. These involve group and one-to-one communication in a variety of locations such as schools, markets, hairdressers, and in private houses. ASACOs have also received training on community mobilization and marketing techniques, and some ASACOs support the social marketing agents with their sensitization activities.

Network-wide awareness raising activities have also been undertaken, such as a publicity campaigns on 22 community radio stations to increase awareness of the broad range of services provided by BlueStar franchisees.

METHODS

We examined the performance of the MSIM BlueStar network from its inception in March 2012 until December 2015 by combining information from routine monitoring data, clinical quality audits, and client exit interviews. Routine monitoring data are collected during each visit to a social franchise and include information about the types of service and number of commodities provided. Clinical quality audits are based on observations using a standardized MSI global tool and are conducted annually; internal audits are conducted by MSIM staff on all franchisees that have trained providers in place and have been operational for at least 6 months, while external clinical audits are conducted by international MSI staff on a smaller random sample of franchises. Client exit interviews are conducted annually using an MSI global standardized interviewer-administered questionnaire to a random sample of clients following their visit; the questionnaire covers client demographics and socioeconomic status, services obtained, choice of contraceptive methods, and client experience. All data collection and analysis were conducted according to international principles of maintaining privacy and confidentiality of personal information.

MSIM purchases family planning commodities through the public health system at a subsidized cost and provides them for free to franchisees.

In line with previous analyses of the MSI BlueStar network,[4] results are presented under the 4 intended outputs of the MSI results framework: **access, efficiency, quality, and equity:**

- **Access:** the extent to which potential clients can reach or obtain services regardless of geographic or cultural barriers to access
- **Efficiency:** how inputs (financial, human, technical) are used to maximize output
- **Quality:** the degree to which a provider or facility meets certain objectives and perceived levels of expectations of health care delivery standards
- **Equity:** the extent to which a program ensures all clients have an equal or fair opportunity to access services

To assess **access**, consistent with previous analyses,[4] the number of clients receiving short-acting contraceptive methods was estimated by dividing the number of commodities provided by the number of commodities needed for a full year of contraceptive protection. The estimated number of clients receiving long-acting methods (implants and IUDs) was based on the number of insertion services provided (i.e., 1 insertion was taken to be equivalent to 1 client). The number of services and commodities provided was then converted into couple-years of protection (CYPs), a standard measure of the estimated time a couple will be protected against unintended pregnancy per unit of the contraceptive method used, using standard conversion factors that account for method effectiveness and wastage.[7] Services for condom provision and removals of implants and IUDs were excluded from estimates of client numbers and are reported separately.

Efficiency was measured by dividing the total number of CYPs for the MSIM BlueStar network in each year by the number of franchisees in operation at the end of each calendar year.

Quality was assessed using clinical audit scores and exit interview results. For clinical audit scores, the average score of audited franchisees was calculated, along with the proportion of audited franchisees scoring at or over 80%. Data on the information received by clients and client satisfaction with services received were extracted from client exit interviews; interviewed clients are asked about the information provided to them during their visit and also asked to rate their experience on a scale of 1 (very poor) to 5 (very good) on a range of questions including friendliness and respect demonstrated by providers, waiting time, and facility cleanliness.

Equity was assessed based on the 2015 client exit interviews, and included the proportion of clients who newly adopted a modern method of family planning ("adopters," defined as those who had not been using any modern method of family planning during the 3 months prior to their visit), the proportion aged under 20 and 25 years of age, and the proportion living below US$1.25 and $2.50 a day as assessed via the Progress out of Poverty Index.[8]

From March 2012 to December 2015, the MSIM BlueStar network provided more than 120,000 estimated clients with voluntary family planning services.

78% of the clients chose long-acting reversible methods.

The MSI Impact 2 model[9] was used to estimate maternal disability-adjusted life years (DALYs) lost and the number of additional users of contraception contributed by the social franchise network from 2013 to 2015. Contraceptive services provided from 2012 to 2015 were entered into the model, along with the client profile data (proportion of clients who are adopters, continuing users of modern contraception sourced from BlueStar ["continuers"], and women who were previously served by other providers ["provider-changers"]) for 2013 to 2015. The number of additional users is the estimated number of women reached by BlueStar who contribute to growth in overall levels of contraceptive use in the country compared with 2012; the calculation accounts for some women discontinuing contraception each year and excludes the estimated number of "provider-changers" as these do not represent additional users of contraception at a national level.

Where possible, results from the MSIM BlueStar network are compared with national figures on family planning use from the 2012/13 Mali Demographic and Health Survey.[1]

RESULTS

The MSIM BlueStar network commenced providing services in March 2012. By the end of 2015, there were 137 franchisees, up from the 70 franchisees in 2012. From March 2012 until December 2015, the MSIM BlueStar network provided 497,096 family planning and HIV-related services including 127,181 HIV counseling and 27,355 HIV testing services, along with distribution of 98,610 condoms.

The remainder of the results presented in this article focus on provision of short- and long-acting methods of contraception; condoms are excluded from measures of access as the majority of condoms provided related to HIV prevention rather than prevention of pregnancy.

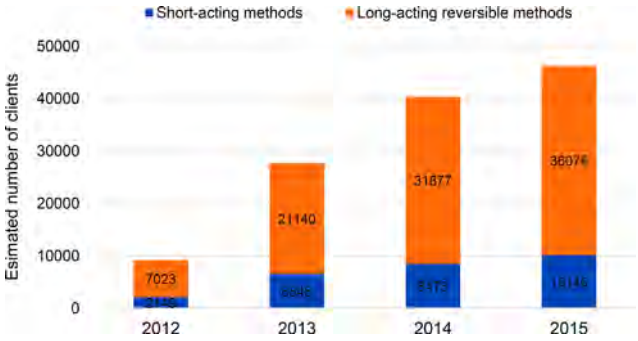
Access

Number of Family Planning Clients

The number of clients receiving voluntary family planning services at MSIM BlueStar franchisees has grown rapidly, from an estimated 9,172 clients provided with contraception in 2012 to an estimated 46,222 clients provided with contraception in 2015. Over the period March 2012 to December 2015, the MSIM BlueStar network is estimated to have provided a cumulative total of 123,429 clients with voluntary family planning services (Figure 1).

Clients receiving long-acting reversible methods accounted for an estimated 78% of clients overall (76%–79% in each individual year; Figure 1). Implants accounted for 72% of the methods provided to clients (Figure 2) and 92% of all long-acting reversible methods

FIGURE 1. Estimated Number of Family Planning Clients Served by MSIM BlueStar Franchisees, by Year and Method Type[a]



Abbreviation: MSIM, Marie Stopes International Mali.

[a] This figure presents estimated number of clients rather than number of services provided; if number of services were considered, services for short-acting methods would make up the majority of services provided.

provided; these proportions remained steady throughout the 4 years of franchise operation.

Compared with women surveyed in the 2012/13 Mali Demographic and Health Survey who reported use of modern contraception sourced from public clinics (33%), a substantially higher proportion of clients at BlueStar franchisees were using implants (72%), and a lower proportion were using pills and injectables (Table 1). The proportion using IUDs appeared higher among clients of MSIM BlueStar franchisees, although the difference was not as substantial as for the other methods compared.

During the period 2012–2015, there were 8,213 services for removal of implants and IUDs at MSIM BlueStar franchisees. Removal services as a proportion of all implants and IUDs provided were 8.5% overall, increasing from 7.2% in 2012 to 9.1% in 2015 (Figure 3 and Figure 4).

Number of CYPs

The total number of CYPs delivered by the MSIM BlueStar network increased from 29,127 in the first 10 months of operation in 2012 to 149,282 during 2015, a more than 500% increase. Overall, the network has provided 397,952 CYPs through the end of December 2015.

Efficiency

The number of MSIM BlueStar franchisees increased from 70 franchisees in 2012 to 137 franchisees in 2015. While the network almost doubled in size, the increase in franchisee outlet numbers does not account solely for the increase in estimated client numbers or CYPs. Efficiency, as measured by the number of CYPs generated by each franchisee each year, increased from an average of 416 CYPs per franchisee in 2012 to 1,090 CYPs per franchisee in 2015 (Figure 5). This compares favorably with the annual average CYPs per franchisee globally (941 in 2013)[4] and regionally in Africa (744 in 2015; data not shown).

The average number of CYPs generated by each franchisee each year increased from 416 in 2012 to 1,090 in 2015.

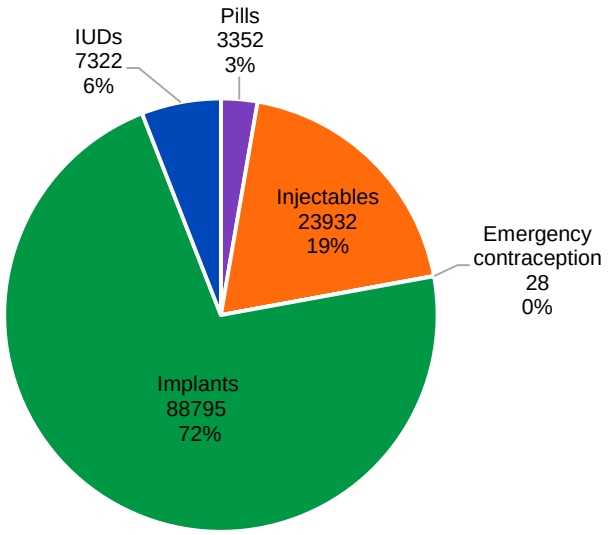
Quality

Clinical Quality

The quality of clinical services provided by franchisees, as measured by internal and external audits, increased over time from 2013 to 2015 (Table 2). All franchisees included in the external audits each year scored higher than the minimum standard score of 80%, and higher than the global average of 77% of MSI franchisees reaching this minimum in 2013 and 84% reaching this minimum in 2014.[4]

Client exit interviews confirmed these trends of high and increasing quality, with increasing proportions of surveyed BlueStar clients receiving counseling on method side effects during their visits in 2015 compared with 2013 (Table 3). The majority (80%) of clients surveyed in 2015 reported they received counseling on side effects, felt

FIGURE 2. Contraceptive Method Mix[a] Among All MSIM BlueStar Social Franchisee Family Planning Clients, 2012–2015



Abbreviations: IUDs, intrauterine devices; MSIM, Marie Stopes International Mali.

[a] Data shown consist of number of users of each method and the percentage of method users among all family planning users.

comfortable to ask questions, received about the right level of information during their visit, and learned, on average, about 4 family planning methods during their visit. Clients at social franchisees generally reported a higher level of satisfaction with clinical quality of care than clients attending other MSIM service delivery channels (data not shown).

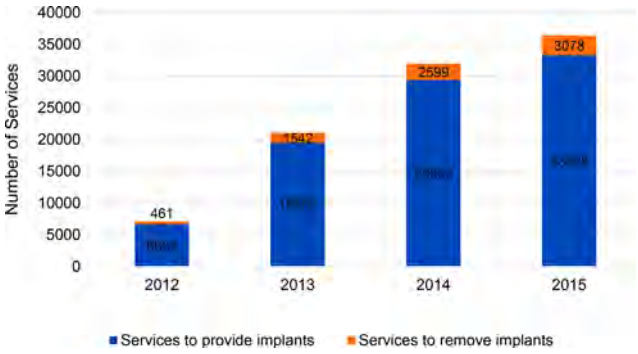
TABLE 1. Method Choice Among Modern Method Users, Mali DHS 2012/13 Respondents Using Modern Contraception From a Public Clinic[a] Compared With MSIM BlueStar Franchisee Clients 2012–2015

		MSIM BlueStar Franchisee Clients				
Proportion Reporting Use of:	**DHS Respondents**	**2012**	**2013**	**2014**	**2015**	**Overall**
Pills	16.3	1.7	2.7	2.9	2.8	2.7
Injectables	44.2	21.7	20.9	18.1	19.1	19.4
Implants	33.4	72.3	70.4	72.8	72.0	71.9
IUDs	3.8	4.3	5.9	6.2	6.0	5.9

Abbreviations: DHS, Demographic and Health Survey; IUDs, intrauterine devices; MSIM, Marie Stopes International Mali.

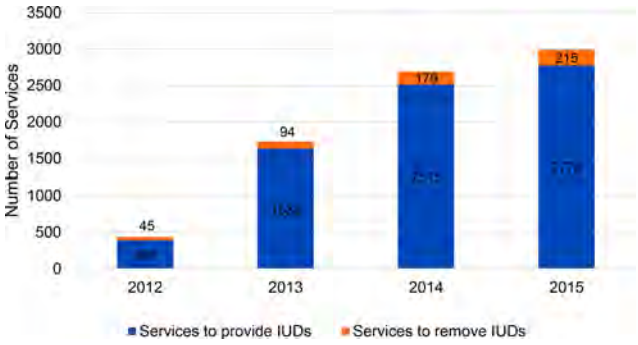
[a] The users of modern contraception in the DHS are derived from the women surveyed who were married or unmarried but sexually active at the time of the survey and who reported using a modern method of contraception sourced from a public clinic. The proportions included in the table do not total 100% for these users, as the table includes only those selected methods of contraception that were available at MSIM BlueStar franchisees.

FIGURE 3. Number of Implant Provision and Removal Services at MSIM BlueStar Franchisees, by Year



Abbreviation: MSIM, Marie Stopes International Mali.

FIGURE 4. Number of IUD Provision and Removal Services at MSIM BlueStar Franchisees, by Year



Abbreviations: IUD, intrauterine device; MSIM, Marie Stopes International Mali.

Client Satisfaction

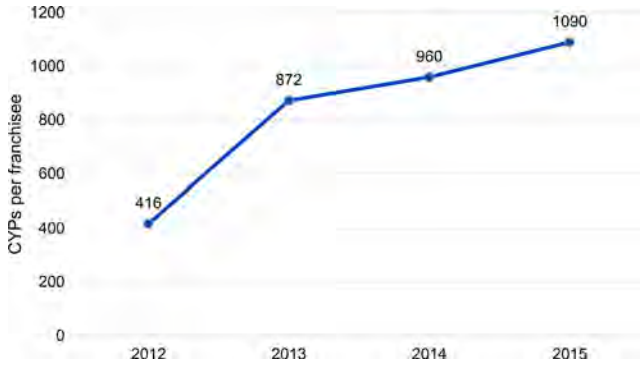
Overall clients appeared satisfied with the services received at BlueStar franchisees, with 90% of those surveyed in 2015 reporting they were likely or very likely to recommend the facility to a friend, and 97% reporting they were likely or very likely to return to the facility in the future for a service.

Looking at specific aspects of visits, generally, almost all clients were satisfied with aspects such as levels of friendliness, respect on arrival, degree of privacy, and opening hours (Table 3). Although most clients surveyed in 2015 were satisfied with facility cleanliness (82%) and length of waiting time after registration (85%), this was lower than the levels of satisfaction reported previously for these aspects (98% and 96%, respectively, in 2014), which may be due to the increased number of clients in 2015. The levels of satisfaction of franchisee clients in 2015 generally was similar to, or exceeded, the level of satisfaction of clients from the other MSIM service delivery channels (data not shown).

77% of BlueStar clients surveyed in 2015 reported paying a fee for services and most were satisfied with the fee charged.

Regarding fees, 77% of BlueStar clients surveyed in 2015 reported paying a fee, paying, on

FIGURE 5. Average CYPs Provided per MSIM BlueStar Social Franchisee, per Year



Abbreviations: CYPs, couple-years of protection; MSIM, Marie Stopes International Mali.

TABLE 2. MSIM BlueStar Franchisees Clinical Quality Audit Scores, 2013 to 2015

	2013	2014	2015
No. of active franchisees	101	137	137
Internal clinical audit			
No. of franchisees audited	50	93	122
Average quality score of audited franchisees	77%	80%	88%
Proportion of audited franchisees scoring 80% or higher	40%	58%	93%
External clinical audit			
No. of franchisees audited	11	10	12
Average quality score of audited franchisees	89%	90%	94%
Proportion of audited franchisees scoring 80% or higher	100%	100%	100%

Abbreviation: MSIM, Marie Stopes International Mali.

average, 680 CFA (US$1.12). Almost all those who paid a fee in 2015 (94%) were satisfied with the fee charged, an increase from 2014 when 79% reported being satisfied with the fee charged.

Half of all BlueStar franchisee clients in 2015 were under 25 years old and about a quarter were under 20 years.

Equity

Half of all BlueStar franchisee clients in 2015 were under 25 years old, including just over a quarter (26%) who were under 20 years (Table 4). Two-thirds of surveyed clients were found to be living below US$2.50 a day. Over half of clients had not completed primary education and over three-quarters of clients had 1 or more living children.

Compared with the 2012/13 Mali DHS, a higher proportion of BlueStar franchisee clients were aged 15–19 years (26%) compared with the proportion of modern contraceptive users in this age group in Mali as a whole (10%). Compared with the global MSI BlueStar results for 2013, a greater proportion of BlueStar clients in Mali in 2015 were aged 15–19 years (26% compared with 5% globally) and lived below US$1.25 a day (27% compared with 12% globally).

TABLE 3. MSIM BlueStar Franchisee Client Exit Interview Results for Quality of Services and Client Satisfaction, 2013 to 2015

	2013 (N=220)	2014 (N=208)	2015 (N=265)
Quality-related variables			
Average number of family planning methods learned about during visit	4	3	4
Received about the right level of information during visit *(not too much or too little)*	NA	74%	82%
Were counseled on a method other than the one they received	NA	NA	92%
Received counseling on side effects	50%	86%	91%
Received instructions on what to do if had problems/side effects	93%	97%	91%
Felt comfortable to ask questions	NA	96%	80%
Satisfaction-related variables			
Satisfied or very satisfied with:			
Overall experience	100%	100%	99%
Operating hours	95%	94%	89%
Facility cleanliness	93%	98%	82%
Length of waiting time after registration	93%	96%	85%
Respectfulness of staff	98%	100%	99%
Level of privacy during time with provider	97%	99%	98%

Abbreviations: MSIM, Marie Stopes International Mali; NA, not asked.

Regarding use of family planning, three-quarters of BlueStar franchisee clients in 2015 reported they had not been using a modern method in the 3 months prior to their visit—that is, they are considered adopters of family planning (Table 4). One-quarter of those surveyed were continuing users of family planning; of these, 15% were users who continued to source their method from MSI-affiliated services and 10% had previously sourced their method from another provider (Table 4). Compared with the global MSI BlueStar results for 2013, a greater proportion of BlueStar clients in Mali in 2015 were adopters of family planning (75% compared with 37% globally).

Health Outcomes

We estimate that the services provided under BlueStar in Mali in 2015 will avert an estimated 12,473 maternal DALYs lost (Figure 6).

In terms of additionality, we estimate that BlueStar contributed 61,056 additional users of family planning in Mali over the period 2013–2015 (assuming all other providers at least maintained their baseline contributions), as well as maintaining the estimated 8,718 baseline users of modern contraception in BlueStar in 2012.

DISCUSSION

The introduction of social franchising into the public sector in Mali has successfully increased the number of clients provided with voluntary family planning services and has reached a high proportion of young women and adopters of family planning. The intervention has proven scalable while maintaining service quality and client satisfaction. Taken together, our findings suggest that interventions that support quality supply of services while simultaneously addressing demand-side barriers, such as service pricing, can successfully create demand for a range of family planning services even in low CPR settings.

TABLE 4. MSIM BlueStar Franchisee Client Profile From 2015 Client Exit Interview Results (N=265)

Client Characteristic	Proportion
Age	
Under 20 years	26
Under 25 years	51
Poverty	
Living below US$1.25 a day	27
Living below US$2.50 a day	65
Living below national poverty line	36
Other demographics	
Not currently married or living with partner	23
Have not completed primary education	61
Traveled 1 hour or more to reach facility	15
Use of family planning methods	
Newly adopted a method[a]	75
Continued using a method, existing MSIM client	15
Continued using a method, previously sourced from another provider	10
Changed from a short- to long-acting method	8

Abbreviation: MSIM, Marie Stopes International Mali.
[a] Defined as not using a modern method in the 3 months prior to their visit.

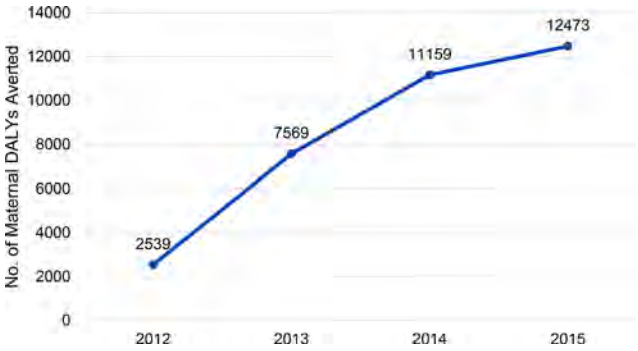
Clinical social franchising can complement mobile outreach service delivery models to ensure access to a broad range of voluntary family planning methods.

MSI's experience in Mali suggests that clinical social franchising can complement contraceptive mobile outreach service delivery models to ensure access to a broad range of voluntary family planning methods across a range of community profiles, and supports a transition from dedicated provider models to approaches more integrated with the national health system. Although not fully self-sustainable financially, we would argue that our model of training local staff and improving infrastructure and management of existing facilities is no less sustainable then many common programming approaches in the region, such as free distribution of family planning commodities. Furthermore, the fees charged to clients are retained by facilities and thus contribute to covering their ongoing operational costs.

From the Mali experience, it appears that some level of independence at subnational facilities is required to successfully franchise public-sector facilities. This includes facilities being able to self-select to join a franchise network, as well as officials who are responsible for facilities being able to enter into franchise agreements on their own, use revenue toward operating costs, and have some level of scope to reward facilities for increased quality and efficiency of services (as in Mali, where facilities retain the fees paid by clients). It is also important to ensure a functioning commodity supply chain and adequate staffing and capacity to provide a range of services.

One the challenges experienced in the implementation of the clinical social franchising model in Mali related to commodities, particularly CSCOM capacity to forecast the number of contraceptive commodities and report on stock levels. MSIM is currently in the process of building CSCOM capacity in these areas, as well as participating in processes to develop a strategic plan to improve management of reproductive health commodities nationally.

FIGURE 6. Estimated Maternal DALYs Averted Due to MSIM BlueStar Services, 2012–2015



Abbreviations: DALYs, disability-adjusted life years; MSIM, Marie Stopes International Mali.

Building upon the success of the MSI social franchise model to date, Marie Stopes International Mali is currently increasing the number of franchisees in Mali and extending an adapted franchise model to rural maternity centers. The objective is to increase the range of services offered by franchisees while at the same time training traditional birth attendants ("*matrones*") to provide implants, and to make effective referrals for contraceptive methods that they are not authorized to provide (insertion and removal of IUDs, removal of implants, provision of permanent methods). We also want to better understand the role of our pricing strategies in the success we have seen, as well as the factors underpinning our success in reaching a high proportion of young women through this service model. Not only will this learning inform future expansion of the MSI Mali BlueStar network, it will also contribute to a wider MSI strategy across all our country programs in the Sahel for social franchising, to increase access to and choice of family planning services in this high-need region.

MSIM is currently increasing the number of franchisees in Mali and extending the model to rural maternity centers.

Limitations

Limitations of the analyses presented in this article include the estimation of client numbers from number of services and commodities provided, which may lead to over- or underestimates of true client numbers. Client numbers may also be underestimated as we did not include clients who had received family planning services such as counseling or the removal of IUDs or implants but who did not also choose to receive a modern contraceptive method at the same time. The exclusion of condom services from client and CYP estimates will have resulted in underestimates of the impact of the MSIM BlueStar franchisee network. For clinical quality audits, there were slight changes made each year to the sampling and checklists; these changes were intended to strengthen the audits based on lessons from previous years but could reduce comparability between years. Measures of client satisfaction from the exit interviews may be affected by courtesy bias. The number of additional users are a modeled estimate only and assume other providers of contraceptive services at least maintain their contribution from the baseline year of 2012. Reported results include results from the small number of privately owned practices that are part of the MSIM BlueStar franchise network (n=8 in 2015) that could not easily be excluded for analysis purposes. Finally, the model of social franchising presented in this article may not be generalizable to all public health care systems, particularly to systems where facilities are not able to generate, retain, or control their own income streams.

CONCLUSION

Our experience in Mali suggests that our private-sector franchise model is adaptable to other types of health care facilities and can successfully increase demand for a broad range of family planning services even in low-CPR settings. Through addressing supply and demand for services, along with reducing out-of-pocket expenditure, we were able

to greatly increase population access to a range of voluntary family planning services, including long-acting contraceptives. The existing network of CSCOMs provided a platform to provide high-quality family planning services at scale to rural populations, including populations most in need nof services. Similar approaches could be used in other public health systems with decentralized models, particularly where facilities have some level of independence and control over how funds are spent. MSI also operates a public franchising model in other contexts including Madagascar and Vietnam and is planning to expand the model elsewhere in the Sahel; learning regarding the relative effectiveness of our model in varied public-sector environments will inform future strengthening and scale up of the approach.

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REVIEW

Inequitable Access to Health Care by the Poor in Community-Based Health Insurance Programs: A Review of Studies From Low- and Middle-Income Countries

Chukwuemeka A Umeh,[a] Frank G Feeley[a]

The poor lack equitable access to health care in community-based health insurance schemes. Flexible installment payment plans, subsidized premiums, and elimination of co-pays can increase enrollment and use of health services by the poor.

ABSTRACT

Background: Out-of-pocket payments for health care services lead to decreased use of health services and catastrophic health expenditures. To reduce out-of-pocket payments and improve access to health care services, some countries have introduced community-based health insurance (CBHI) schemes, especially for those in rural communities or who work in the informal sector. However, there has been little focus on equity in access to health care services in CBHI schemes.

Methods: We searched PubMed, Web of Science, African Journals OnLine, and Africa-Wide Information for studies published in English between 2000 and August 2014 that examined the effect of socioeconomic status on willingness to join and pay for CBHI, actual enrollment, use of health care services, and drop-out from CBHI. Our search yielded 755 articles. After excluding duplicates and articles that did not meet our inclusion criteria (conducted in low- and middle-income countries and involved analysis based on socioeconomic status), 49 articles remained that were included in this review. Data were extracted by one author, and the second author reviewed the extracted data. Disagreements were mutually resolved between the 2 authors. The findings of the studies were analyzed to identify their similarities and differences and to identify any methodological differences that could account for contradictory findings.

Results: Generally, the rich were more willing to pay for CBHI than the poor and actual enrollment in CBHI was directly associated with socioeconomic status. Enrollment in CBHI was price-elastic—as premiums decreased, enrollment increased. There were mixed results on the effect of socioeconomic status on use of health care services among those enrolled in CBHI. We found a high drop-out rate from CBHI schemes that was not related to socioeconomic status, although the most common reason for dropping out of CBHI was lack of money to pay the premium.

Conclusion: The effectiveness of CBHI schemes in achieving universal health coverage in low- and middle-income countries is questionable. A flexible payment plan where the poor can pay in installments, subsidized premiums for the poor, and removal of co-pays are measures that can increase enrollment and use of CBHI by the poor.

INTRODUCTION

The World Bank defines the poor as individuals or families who do not have the resources or abilities to meet their daily needs.[1] Poverty is usually associated with poor health outcomes, with the poorest of the poor having the worst health outcomes.[2,3] Furthermore, the poor are most disadvantaged by out-of-pocket expenditures, and they are the ones who are most likely to be ill and less able to afford to pay for health care.[4,5] To ensure that the poor have access to health care when they need it and that they are protected from catastrophic health expenses, health systems need to be financed by either tax or prepayment schemes.[1,3] The prepayment scheme should lead to a large risk pool and enough money in the health system to cross-subsidize the sick and the poor. While health insurance schemes are the norm in high-income countries, the story is different in low-income countries.[1,3]

In light of this, there is a push to encourage countries to provide access to basic health care for all their citizens through prepayment or tax schemes. A general taxation

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Some poor countries have chosen community health insurance schemes as a way of providing access to basic health care for those in rural communities and the informal sector.

scheme would be most desirable, but this is not feasible in several low- and middle-income countries because people are poor and many work in the informal sector, making revenue collection difficult.[6] This has led some poor countries to choose community health insurance schemes as an alternative way of providing access to basic health care for those in rural communities and the informal sector.[7,8]

Community-based health insurance (CBHI) schemes refer to voluntary, nonprofit health insurance schemes organized and managed at the community level. While CBHI schemes vary in design and implementation, all are based on the principle of risk pooling and involve regular payments of a small premium in exchange for reducing direct payments at the point of service.[9] This is important because direct payment at the point of service has been shown to delay or deter the use of health services.[10,11]

Community-based health insurance schemes include not-for-profit prepayment plans, community control, and voluntary membership.

CBHI schemes share 3 common characteristics: they include (1) not-for-profit prepayment plans, (2) community control, and (3) voluntary membership.[12] CBHI schemes have been shown to improve use of health services among children and pregnant women[13,14] and to reduce catastrophic health expenditure.[15,16] Catastrophic health expenditure results in families cutting down on other necessities such as food, clothing, and children's education, and its impact is greatest for the poorest families.[4] In a cross-country analysis, Xu and colleagues noted that catastrophic payments would be reduced if health systems relied less on out-of-pocket payments.[17]

This review focuses on the effect of socioeconomic status on willingness to enroll, actual enrollment, and use of community-based health insurance in low- and middle-income countries.

The focus of this article is on demand for CBHI by the poor. Demand for health insurance is influenced by the benefit consumers expect to derive from health insurance, by the amount they are expected to pay as premium, and by their income. Additionally, demand for health insurance is influenced by consumers' probability of getting sick (with the elderly and chronically ill more likely to sign up for insurance) and their aversion to risk. Risk-averse consumers are willing to pay higher premiums to avoid the risk of a greater loss.[18] Thus, consumers will purchase CBHI if the expected benefits exceed the benefits of out-of-pocket payment.[18,19]

Demand for health insurance is negatively influenced by other factors such as inadequate knowledge or awareness of the existence of a health insurance scheme and how to enroll in the scheme,[20,21] actual or perceived poor quality of health services,[22,23] inconvenient enrollment process,[22] inadequate benefit package,[22,24,25] long distances to health facilities,[22] negative provider attitude,[22] lack of trust in CBHI officials,[21,22,26] lack of provider choice,[24] low education status,[27] positive perception of the adequacy of traditional care,[27] and a low proportion of children living within a household.[27]

Objectives of the Present Study

Although CBHI has been shown to be helpful in increasing the use of health services and reducing catastrophic health expenditure,[13–16] there is need to better understand how CBHI affects the poor who ordinarily should benefit more from the health insurance scheme. This review seeks to explore the:

- Effect of socioeconomic status on willingness to join and pay for CBHI
- Effect of socioeconomic status on actual enrollment in CBHI
- Effect of socioeconomic status on use of CBHI by enrollees
- Effect of socioeconomic status on drop-out rate from CBHI schemes

Although there have been previous reviews of health insurance schemes in low- and middle-income countries, to the best of our knowledge this is the first review that is focused on the effect of socioeconomic status on willingness to enroll, actual enrollment, and use of CBHI in low- and middle-income countries.

METHODS

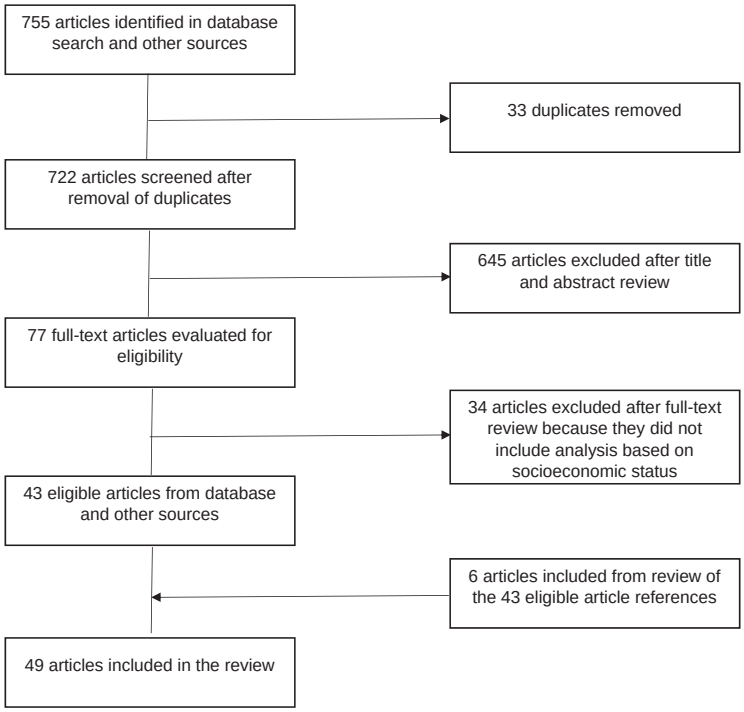
The authors searched PubMed, Web of Science, African Journals OnLine, and Africa-Wide Information (the latter incorporating South African Studies, African Studies, and African HealthLine) for studies on willingness to enroll in CBHI, enrollment in CBHI, use of services by CBHI enrollees, and drop-out from CBHI. We also searched a collection of articles on health financing for the poor published by the World Bank, *Health Financing for Poor People: Resource Mobilization and Risk Sharing*,[28] for relevant articles/chapters. The search terms we used included: (1) willingness to pay AND community health insurance; (2) community health insurance AND low and middle income countries; (3) community health insurance AND utilization of health services; (4) community health insurance AND drop out; (5) community health insurance AND premium AND subsidy; and (6) community health insurance AND enrollment.

We conducted the literature search in August 2014 and restricted our search to studies published between 2000 and August 2014 to obtain current information on CBHI. In addition, we restricted our search to articles written in English. Furthermore, we searched the reference list of identified articles for additional resources.

After we completed the literature search, we reviewed all the articles based on our predetermined inclusion criteria. The inclusion criteria were that the study must have been conducted in low- and middle-income countries and involved analysis based on socioeconomic status. Varied measurement of socioeconomic status was accepted, including self-reported income, assessment of assets, self-reported expenditures, and community wealth ranking (whereby community members categorize families into different wealth categories). There was also no restriction on the type of study that was included in the review. The titles and abstracts of articles were first reviewed based on our inclusion criteria. The full text of selected articles that met the inclusion criteria were then reviewed in full.

We developed a data extraction sheet, and one author extracted the data from the included studies while the second author reviewed the extracted data. Disagreements were mutually resolved between the 2 authors. Data were extracted from the included studies on: (1) characteristics of the study (including country where study was conducted, date of data collection, sample size, setting of study [urban or rural], and study design); and (2) the findings of the study. The findings of the studies in the different subsections were analyzed to identify their similarities and differences and to identify any methodological differences that could have accounted for contradictory findings.

FIGURE. Summary of Search Results



RESULTS

Study Selection

A total of 49 articles were included in the review. Our initial search of the relevant databases and other sources yielded 755 articles. After removing duplicates, 722 articles remained. Of these, 645 articles were excluded after screening the titles and abstracts because they did not meet our inclusion criteria. The full text of the remaining 77 articles were evaluated in more detail, of which 34 were excluded because they did not include analysis based on socioeconomic status. The remaining 43 articles were included in the review, as were an additional 6 articles that were identified in the reference lists of the 43 included articles (Figure).

The studies that were finally selected for review used a range of study designs, including pre- and post-test with control, pre- and post-test without control, post-test with control, post-test without control, and cross-sectional community-based pre-intervention surveys. The selected studies were conducted in Africa (in countries such as Burkina Faso, Nigeria, and Senegal); Asia (in countries such as China, India, and the Philippines); and South America (Ecuador).

49 articles were included in this review.

Socioeconomic Status and Willingness to Join or Pay for CBHI

There were mixed results on the effect of socioeconomic status on willingness to join a CBHI program (Table 1). Several studies, including those conducted in Ethiopia,[29–31] China,[32] India,[33] and Cameroon,[34] found that socioeconomic status was positively associated with willingness to pay, with the rich more willing to pay for CBHI than the poor. Study participants consisted of those who did not presently have health insurance. A

Several studies found that socioeconomic status was positively associated with willingness to pay for community-based health insurance.

TABLE 1. Summary of Studies on Willingness to Join or Pay for Community-Based Health Insurance

Study	Country	Date of Data Collection	Sample Size[a]	Urban/ Rural	Study Design	WTJ/P
Positive Association Between Socioeconomic Status and WTJ/P						
Haile M et al. (2014)[29]	Ethiopia	2013	845	Rural	Cross-sectional community based survey	WTJ was 4.2 times higher in richest vs. 2nd poorest quintile (95% CI: 1.6, 10.9)
Asfaw A et al. (2004)[30]	Ethiopia	2000, 2001	550	Rural	Cross-sectional community based survey	1% increase in income increased the WTP by 8.4%
Ololo S et al. (2009)[31]	Ethiopia	2007	803	Urban	Cross-sectional community based survey	WTJ was 2.7 times higher in richest vs. poorest quintile. (95% CI: 2.1, 6.7)
Zhang L et al. (2006)[32]	China	2002	2,830	Rural	Cross-sectional household survey	WTJ was 1.37–1.66 times higher among farmers who owned luxury assets vs. those who did not
Ghosh S et al. (2011)[33]	India	NS	1,502	Urban	Cross-sectional household survey	WTP was 2.1 times (P=.07) higher in richest vs. poorest quintile
Dong H et al. (2005)[40]	Burkina Faso	2001	2,414	NS	Cross-sectional household survey	WTP was 1.7 times higher in richest vs. poorest (P<.01)
Onwujekwe O et al.[42]	Nigeria	NS	450	Both	Cross-sectional household survey	WTP was 1.8 times higher in richest vs. poorest (P=.001)
Onwujekwe O et al. (2010)[43]	Nigeria	NS	3,070	Both	Cross-sectional household survey	WTP was 1.7 times higher in richest vs. poorest quartile
Babatunde OA et al. (2012)[45]	Nigeria	NS	360	Rural	Cross-sectional household survey	WTP was 2 times higher in richest vs. poorest quartile
Gustafsson-Wright et al. (2009)[46]	Namibia	2008	1,750	NS	Cross-sectional household survey	WTP was 2.6 times higher in richest vs. poorest quintile; richest willing to pay 1.2% of income while poorest willing to pay 11.4% of income
Dror DM et al. (2007)[47]	India	NS	3,024	Both	Cross-sectional household survey	WTP was 2 times higher in richest vs. poorest
Binnendijk B et al. (2013)[48]	India	2008–2010	7,874	Rural	Cross-sectional household survey	Richest willing to pay more than poorest but poorest willing to pay higher proportion of total income
Shafie AA et al. (2013)[49]	Malaysia	2009	472	NS	Cross-sectional household survey	WTP was 2 times higher in richest vs. poorest quintile
Parmar D et al. (2014)[51]	Burkina Faso	2004–2008	6,827	Both	Cross-sectional household survey	WTJ was 0.27 lower in poor vs. rich (P=.001)

Continued

TABLE 1. Continued

Study	Country	Date of Data Collection	Sample Size[a]	Urban/ Rural	Study Design	WTJ/P
Negative Association Between Socioeconomic Status and WTJ/P						
Oriakhi HO et al. (2012)[36]	Nigeria	NS	360	Rural	Cross-sectional household survey	WTJ was 0.66 times lower in high- vs. low-income groups
Mixed Results or No Association						
Bukola A (2013)[35]	Nigeria	NS	900	Both	Cross-sectional household survey	53% decrease in WTP with 1 unit increase in income quintile in rural areas; conversely, 77% increase in WTP with 1 unit increase in income quintile in urban areas
Eckhardt M et al. (2011)[36]	Ecuador	2006	153	Rural	Cross-sectional household survey	No difference in WTJ by income groups (P=.23)

Abbreviations: CI, confidence interval; NS, not stated in article; WTJ, willingness to join; WTP, willingness to pay.
[a] Sample size is the number of households.

2007 cross-sectional survey in southwest Ethiopia found that households in the highest quintile were 2.7 times more willing to join a CBHI program than families in the lowest quintile.[31] A more recent survey in southwest Ethiopia in 2013 showed that households in the highest wealth quintile were more than 4 times more willing to join the CBHI compared with households in the second wealth quintile.[29] Similarly, Asfaw et al. found that a 1% increase in income in rural Ethiopia led to an 8.4% increase in the probability of willingness to pay for health insurance.[30] In India, households in the highest wealth quintile were 2.1 times more willing to pay for CBHI compared with those in the lowest quintile.[33] Similarly, in China, Zhanga et al. found that willingness to join a CBHI program increased by 0.83% to 1.54% when income increased by 100 Yuan in a year. The farmers who owned luxury assets were 1.37 to 1.66 times more likely to join a CBHI program than those who did not own such assets.[32] That wealthier households are more willing to join or pay for CBHI is expected and not surprising.

However, studies in Nigeria[35,36] showed that the rich in rural areas were significantly less willing to pay for CBHI than the poor. A cross-sectional survey in the south-south region of Nigeria showed that respondents with lower income were 1.4 times more willing to join a CBHI program than those with higher income.[36] Another study in southwest Nigeria showed that income was negatively associated with willingness to pay for CBHI in rural areas while it was positively associated in urban areas where more services were available and costs were higher. A unit increase in income quintile decreased willingness to pay by 53% in rural areas while it increased it by 77% in urban areas. A possible explanation for the results in these 2 Nigerian studies is that there might be low-quality services in rural health centers and so the rich prefer to travel to urban areas where they will get better services. Another possible explanation is that health services in rural areas are usually less expensive and of lower quality than in urban areas, and so the rural rich might feel they are able to pay their health bills out of pocket anytime the need arises.[35]

A study in rural Ecuador did not find any association between wealth and willingness to join a CBHI program, although those who were less educated were more willing to join.[37] However, in Ecuador at the time of the study, one health insurance scheme covered most workers in the formal sector while another insurance scheme covered the rural population. The scheme for the rural population was noted for low-quality services, although neither of the schemes was operational in the rural village where the study was carried out. The low-quality services associated with the

insurance scheme in rural areas might have explained the reason why the more educated in the rural areas were less willing to join the CBHI scheme.

The premium amount that individuals and families were willing to pay appears to be directly related to their socioeconomic status.

The amount that individuals and families are willing to pay as premium appears to be directly related to the socioeconomic status of the individuals/families. Studies from Burkina Faso,[38–41] Nigeria,[42–45] and Namibia[46] showed that the rich were willing to pay a higher premium than the poor. However, the poor were willing to pay a higher percentage of their income as premium.[46–48]

Some studies have shown that the rich are willing to pay a higher premium to cross-subsidize the poor.

In Nigeria,[42,43,45] Burkina Faso,[38–41] and Malaysia[49] families/individuals in the highest wealth quintile were willing to pay a premium 1.6 to 2 times higher than those in the lowest quintile, while in Namibia those in the richest quintile were willing to pay a premium 2.6 times as much as those in the poorest quintile.[46] The higher disparity between what the rich and poor in Namibia are willing to pay is consistent with the wealth disparity in Namibia, which has about the highest Gini coefficient in the world.[50]

Conversely, the poor are willing to pay a higher proportion of their income as premium. In India, those in the lowest income quintile were willing to pay 1.8% of their income as premium compared with 0.84% for those in the highest income quintile.[47] However, in Namibia those in the richest quintile were only willing to pay 1.2% of their income as premium, while those in the poorest quintile were willing to pay about 11% of their income on premium.[46] In general, willingness to pay is higher among the rich, but the poor are willing to pay a higher percentage of their income.

Willingness to Enroll in CBHI and Preferred Method of Premium Payment

In-depth interviews conducted in India[69] and Burkina Faso[70] showed that the poor prefer monthly premium payments to yearly payments because they do not have the money to pay the yearly premium at one time. Another study in Ethiopia showed that, in general, 95% of those who were willing to join the CBHI preferred to pay a monthly premium instead of yearly premium.[31]

In most studies, actual enrollment in community-based health insurance was directly associated with socioeconomic status.

Furthermore, studies in Nigeria showed that the rural poor would be more willing to enroll in a CBHI scheme if they were given the option of paying their premiums using commodities. In a study in southwest Nigeria, respondents in rural areas were willing to pay 2.6 times more if they were to pay in-kind, rather than with cash. Conversely, respondents in urban areas were willing to pay 0.8 times less if they were to pay in-kind instead of cash. It is important to note that 61% of the rural respondents were in the lowest 2 wealth quintiles.[71] A similar study in southeast Nigeria showed that rural households were willing to pay a premium that was 2 times as high if they were to pay with commodities instead of cash.[44,72,73] The preference to pay monthly premiums instead of yearly premiums or to pay premiums using commodities might be due to the inability of poor rural families to save enough money to pay the yearly premium at once.

Willingness to Enroll in CBHI and to Cross-Subsidize the Poor

Studies in Nigeria and Tanzania showed that the rich are willing to pay a higher premium to cross-subsidize the poor. In a study in southeast Nigeria, 53% of the respondents were willing to contribute money to cross-subsidize the poor, with 75% of those in the richest quartile willing to cross-subsidize the poor.[42] A similar survey in Tanzania showed that 46% of rural dwellers and 41% of urban dwellers were willing to cross-subsidize the poor. However, urban households were willing to pay a higher amount to cross-subsidize the poor compared with rural households, presumably because the urban wealthy have more income than the rural wealthy.[68]

In summary, studies on socioeconomic status and willingness to join a CBHI scheme suggest that in the absence of factors that might negatively affect demand for insurance (such as actual or perceived poor quality of health services),[22,23] willingness to join a CBHI scheme is directly related to family income. Higher family income is also associated with greater willingness to pay a higher premium to cross-subsidize the poor. Additionally, willingness to join a CBHI scheme increases when families are offered flexible premium payment options such as monthly premium payments and payment using commodities.

Socioeconomic Status and Actual Enrollment Into CBHI

In most studies, actual enrollment in CBHI was directly associated with socioeconomic status (Table 2), meaning that although a lot of the poor are willing to join CBHI, most of them do not because they cannot afford to pay the premium. Studies conducted in Burkina Faso,[27,51] Senegal,[8,52] the Philippines,[53] Uganda,[54,55] and

TABLE 2. Summary of Studies on Enrollment in Community-Based Health Insurance

Study	Country	Date of Data Collection	Sample Size	Urban/ Rural	Study Design	Enrollment
Poor Less Likely Than the Rich to Enroll						
Parmar D et al. (2014)[51]	Burkina Faso	2004–2008	990 households	Both	Pre and post without control (repeated measures)	The poor were less likely to either enroll or use CBHI
Jutting JP (2004)[52]	Senegal	2000	346 households	Rural	Post without control	Higher-income group significantly more likely to enroll in health insurance
Dror DM et al. (2005)[53]	Philippines	2002	1,953 households		Post with control	The poor were more uninsured than the rich
Basaza R et al. (2007)[54]	Uganda	2004–2005	63 individuals	Rural	Case study with key informant interviews	Inability to pay premium most common reason (80%) for non-enrollment
Basaza R et al. (2008)[55]	Uganda	2005–2006	185 individuals	Rural	Qualitative—focus group discussions and in-depth interviews	Inability to pay premium most common reason for non-enrollment
Franco LM et al. (2008)[56]	Mali	2004	2,280 households	Both	Post with control	Enrollment was significantly higher in the rich wealth quintile than other quintiles; insured were more likely to use health services
Saksena P et al. (2011)[58]	Rwanda	2005–2006	6,800 households	Both	Post with control	Poorer households were less likely to be insured
De Allegri M et al. (2013)[28]	Burkina Faso	2004	547 households	Both	Post with control	Enrollees in insurance scheme were more likely to be wealthier than non-enrollees
Jütting JP (2004)[9]	Senegal	2000	346 households	Rural	Post with control	The poor were less likely to enroll in CBHI
No Association Between Socioeconomic Status and Enrollment						
Schneider P et al. (2004)[57]	Rwanda	2000	2,518 households	Rural	Post with control	No relationship between socioeconomic status and enrollment in health insurance or use of it by enrollees
Premium Subsidy Increased Enrollment						
Oberländer L et al. (2014)[59]	Burkina Faso	2008–2009	25,494 individuals	Both	Regression discontinuity	Probability of enrollment increased by 30 percentage points with eligibility for premium subsidy
Parmar D et al. (2012)[60]	Burkina Faso	2004–2007	990 households	Both	Pre and post without control (repeated measures)	With onset of subsidy, percentage of the insured who were poor increased from 3.4% in 2006 to 26.0% in 2007
Souares A et al. (2010)[61]	Burkina Faso	2006–2007	7,122 households	Both	Pre and post without control	With the onset of subsidy in 2007, the proportion of the poor enrolled in CBHI increased from 1.1% in 2006 to 11.1% in 2007

Continued

TABLE 2. Continued

Study	Country	Date of Data Collection	Sample Size	Urban/ Rural	Study Design	Enrollment
Zhang L et al. (2008)[74]	China	2004–2006	1,169 households	Rural	Post without control (repeated measures)	Low-income group was less likely to enroll in the subsidized CBHI than the middle- and high-income groups
Wagstaff A et al. (2007)[75]	China	2003, 2005	8,476 households	Rural	Pre and post with control (propensity score matching)	Subsidized insurance improved use of services in the poorest 10% of the population

Abbreviation: CBHI, community-based health insurance.

As premium decreased, the number of poor people who enrolled in community-based health insurance increased.

Mali[56] support this finding. In Burkina Faso, the poor were 73% less likely to enroll in CBHI than the rich.[51] Another study in Burkina Faso showed that the rich were more likely to be insured than the poor, with the median household expenditure (a proxy for household wealth) 2.6 times higher among those who were insured than among the uninsured.[27] These findings are not surprising because the rich have more money at their disposal to pay the premium than the poor.

However, a study in Rwanda in 2000 did not show any relationship between socioeconomic status and enrollment into the CBHI scheme.[57] The explanation given for this was that the CBHI scheme in Rwanda allowed households to pay the premium in installments and households were enrolled as full members once they completed paying the premium. This encouraged the poor to enroll. In addition, churches and community members helped to pay enrollment fees for the poor, widows, and orphans. There was also participatory and democratic management of the CBHI scheme, which increased trust and a sense of ownership by the entire community.[57] However, a more recent analysis from a 2005–2006 nationally representative survey in Rwanda showed a positive relationship between socioeconomic status and enrollment in health insurance. While 50% of those in the richest quintile were insured, only 29% of those in the poorest quintile had insurance ($P < .001$).[58] It is important to state that confounding factors that could have influenced the demand for health insurance, such as educational status, were not controlled for in the studies.

Co-pays may be a disincentive for poor households to join community-based health insurance schemes.

Our review also showed that as premium decreased the number of poor people who enrolled in a CBHI scheme increased. This shows that enrollment is price-elastic for the poor. Some households that could not afford the CBHI's initial high premium were able to enroll when the premium was lowered. Studies in Burkina Faso showed that providing subsidies increased enrollment for the poor[59–61] while another study in China showed that at a lower premium, more households were willing to enroll in health insurance.[32] Additionally, a study in Burkina Faso showed that with the onset of subsidies for the poor in the Naouna district in 2007, the proportion of the poor who were enrolled in the CBHI scheme increased from 1.1% in 2006 to 11.1% in 2007.[61] Furthermore, in 2006 only 3.4% to 4.9% of all the insured were from poor households, but this increased to 26.0% to 28.8% in 2007.[60,61] Another study in Burkina Faso showed that the price elasticity of the demand for CBHI was close to 1.[59] Similarly, in China a study in 2002 showed that with a premium of 10 Yuan per year 76% of people were willing to join the CBHI. However, with a premium of 20 Yuan only 43% were willing to join the scheme.[32]

Enrollment in CBHI and Co-Pays

Studies in China showed that co-pays may be a disincentive for poor households to join CBHI schemes. An analysis of 4-year panel data on a voluntary CBHI scheme in rural China (Rural Mutual Health Care) showed that the low-income group was less likely to join the subsidized CBHI scheme than the middle- and high-income groups. One of the reasons that was given for this was that the co-pays might be too high for some poor people who then choose not to join.[74] Another study that looked at the impact of China's cooperative medical scheme in rural communities showed that although premiums are

highly subsidized for the poor, the scheme did not lead to improved use of services among the poorest 10% of the population. This was attributed to the co-pays at the point of accessing the services.[75]

To summarize, in the absence of factors that might negatively influence enrollment into CBHI, the rich are more likely to enroll into CBHI than the poor. In addition, CBHI enrollment is price-elastic, and the higher the premium, the smaller the number of people that will enroll in the scheme. Furthermore, we also saw that in Rwanda, supporting the poor to pay premiums removes the relationship between socioeconomic status and actual enrollment in CBHI. Finally, co-pays could negatively affect enrolment in CBHI and use of services even after enrollment.

Socioeconomic Status and Use of Health Care for Enrollees

There were mixed results on the effect of socioeconomic status on use of health care among those enrolled in CBHI (Table 3). Studies in Burkina Faso showed that rich enrollees used health care more than poor enrollees.[51,62] In Burkina Faso, the poor who were enrolled in the CBHI scheme had a 50% lower odds of using health services compared with the rich who were enrolled in the scheme.[51] In another study in Burkina Faso, outpatient visits were 40 percentage points higher among the insured than the uninsured. However, this difference was only significant among the richest wealth quartile. This showed that the insurance scheme generally benefitted the rich more. Although there were no co-pays in the CBHI scheme in Burkina Faso and the insurance scheme covered essential drugs and referrals to the district hospital, the non-significant utilization by the poor might be due to other non-financial barriers to utilization such as distance from health facilities.[62]

A study in Rwanda did not find any difference in health service utilization between rich and poor enrollees.[57] In addition, household wealth quintiles in Mali did not show any consistent pattern of association with use of health services

TABLE 3. Summary of Studies on Community-Based Health Insurance Utilization or Drop-Out

Study	Country	Date of Data Collection	Sample Size[a]	Urban/ Rural	Study Design	Utilization or Drop-Out
Franco LM et al. (2008)[56]	Mali	2004	2,280	Both	Post with control	Insured were more likely to utilize health services
Schneider P et al. (2004)[57]	Rwanda	2000	2,518	Rural	Post with control	Utilization of health services by enrollees not associated with socioeconomic status
Gnawali DP et al. (2009)[62]	Burkina Faso	2006	990	Both	Post with control	Outpatient visits in insured 40% higher than in uninsured
Chankova S et al. (2008)[63]	Ghana, Mali, Senegal	Not stated	5,545	Both	Post with control	No difference in utilization based on socioeconomic status in the insured
Kent Ranson M et al. (2006)[64]	India	2003	3,844	Both	Post with control	Submission of claims for reimbursement was inequitable in rural areas; the rich were significantly more likely to submit claims than the poorest
Kent Ranson M (2004)[65]	India	2000	700	Both	Post with control	No significant difference in hospitalization among the different wealth quintiles
Dong H et al. (2009)[66]	Burkina Faso	2006	1,309	Both	Post with control	No statistically significant difference in the drop-out rate between income groups
Mladovsky P (2014)[67]	Senegal	2009	382	Both	Post with control	Those who dropped out were poorer than those who did not although this was not statistically significant

[a] Sample size is the number of households.

among those enrolled in the mutual health organization.[56] Furthermore, studies in Burkina Faso and Rwanda showed that for the most part enrollment in CBHI schemes led to increased utilization of health services among the enrolled compared with the unenrolled.[51,57,62] However, a study in Senegal did not find any difference in utilization between the insured and uninsured.[63] This was attributed to the 25% to 50% co-payment for outpatient care in the Senegal CBHI scheme.

Utilization of Health Care and Reimbursement After Paying Out of Pocket

CBHI schemes that reimburse enrollees after paying for services out of pocket seem not to favor the poor. A study of the Self-Employed Women's Association (SEWA) insurance scheme in India, a CBHI scheme whereby members settle their hospital bills out of pocket and are reimbursed by the insurance scheme, suggested that there was an inequitable submission of claims among rural members. The mean socioeconomic status of rural claimants was significantly higher than the mean socioeconomic status of all rural members of the scheme. The poorest 30% of the members accounted for only 20% of the claims. Qualitative data revealed that the poorest in the rural communities might lack the money to pay bills at the time of hospitalization and so will use less of the services. Furthermore, the poor may also not be literate enough to fill the insurance claim form and so do not apply for reimbursement even after being hospitalized.[64]

There is a high drop-out rate from community-based health insurance schemes mainly due to inability or unwillingness to continue paying premiums.

However, in another SEWA survey there was no significant difference in hospitalization among the different wealth quintiles. This could be due to the small sample; there were only 28 admissions among the SEWA respondents in the 1-year recall period.[65] In addition, there was no difference in hospitalization between the insured and uninsured.[65] This could also be explained by the fact that the insured still need to pay out of pocket and be reimbursed later.

In summary, being insured was found to increase use of services compared with being uninsured. Although there were inconsistent findings on the relationship between socioeconomic status and use of health services among those enrolled in CBHI schemes, some studies showed lower use of services among the poor than the rich, which could be due to co-payments, travel costs, or non-financial barriers to use of services. Additionally, schemes that reimburse enrollees after they pay for services out of pocket seem to decrease use of services by the poor.

Some studies showed lower use of services among poor enrollees than rich enrollees, which could be due to co-payments, travel costs, or non-financial barriers to use of services.

Socioeconomic Status and Drop-Out From CBHI

We noticed a high drop-out rate from CBHI schemes in the studies included in our study (Table 3). Although in the Nouna (Burkina Faso) CBHI scheme there was no statistically significant difference in the drop-out rate between income groups, the main reason people gave for dropping out was lack of money to pay the premium (28%) followed by dislike of medical staff behavior (19%).[66] The drop-out rate from the Nouna district CBHI scheme in Burkina Faso was 31% in 2005 and 46% in 2006 for all the enrollees.[66]

Similarly, in a survey of 382 households in Senegal, the overall drop-out rate from the CBHI scheme was 72%. Those who dropped out were poorer than those who did not, although the difference was not statistically significant. The lack of statistical significance could be due to the small sample size.[67]

In summary, there is a high drop-out rate from CBHI schemes mainly due to inability or unwillingness to continue paying premiums. This affects all income groups and calls into question the effectiveness of CBHI programs as a means of achieving universal health coverage in low- and middle-income countries.

POLICY IMPLICATIONS

As we stated earlier, a general taxation scheme is more desirable for providing comprehensive health insurance coverage for families, but this is not feasible in several low- and middle-income countries because people are poor and many work in the informal sector, which makes revenue collection difficult.[6] This has led some poor countries to choose community health insurance schemes as an alternative way of providing access to basic health care for those in rural communities and the informal sector.[7,8]

The idea of CBHI schemes in most low- and middle-income countries is to provide improved health care access by the poor who might not be able to purchase private insurance or pay out of pocket for services. That explains why many of the CBHI schemes are located in areas where people are poor or work in the informal sector of the economy. However, for the scheme to be effective in achieving its goal of reaching the poor, several program features must be carefully designed. From our review, the measures in designing a CBHI scheme that would be beneficial to the poor include:

1. Offering flexible payment plans
2. Providing premium subsidies for the poor
3. Eliminating co-pays for the poor
4. Removing or reducing the waiting period after premium payment
5. Avoiding making patients pay out of pocket for services and getting reimbursed later

Flexible Payment Plans

A flexible payment plan or schedule in which the poor can pay in installments would be beneficial to the poor, although this might be administratively more expensive for programs to implement. Giving people the option to pay monthly, quarterly, or semiannually has been shown to help the poor pay their premium.[57,76] This is because some of the poor who might be interested in enrolling into the scheme do not have the money to pay the yearly premium at one time. Under this flexible payment plan, families would be allowed to pay in installments and would be covered by the scheme once they complete their payment. This has been used in Rwanda and has been partly associated with the success of the scheme in covering the poor in the country.[57] Families who are covered by the scheme can also start paying in installments for the next year. This would help reduce the high drop-out rate currently seen in CBHI schemes, which occurs because families do not have money to pay their yearly premiums when due. This might also be useful in rural communities where peasant farmers can start paying in installments for the next year once they sell their crops during the harvest season.

Premium Subsidy for the Poor

Enrollment into a CBHI scheme is highly price-elastic for the poor, meaning that with highly subsidized premiums, more poor people will enroll in CBHI. The big questions are how to fund the subsidy and how to identify the poor. For nationally supported community health insurance schemes, government might subsidize the poor using money raised from taxes and external donors. A challenge is that not all countries might mobilize the financial resources to subsidize premiums for the poor in the face of other competing priorities. However, countries should prioritize premium subsidies if they want to increase scheme participation by the poor.

For small local CBHI schemes where funds are pooled at the community level, it becomes more difficult to raise money to subsidize the poor. Since studies have shown that the rich are willing to cross-subsidize the poor, one way is to have a progressive premium where the rich pay a little extra to cover the premium for very poor families. This is unlike many current CBHI schemes in which everyone pays a flat premium rate irrespective of income. Organizations such as churches, clubs, wealthy individuals in the community, and international donors can also be approached to make donations to subsidize the poor or to take up the premiums of specific very poor families who are willing to be so supported. This proved to be effective in the early stages of the CBHI scheme in Rwanda.[57]

The bigger question, however, is how to identify the poor who will receive the subsidy. Four common ways of identifying the poor include (1) means testing (identifying the poor using self-reported income or expenditure), (2) proxy means testing (classifying socioeconomic status based on ownership of assets and access to services), (3) geographical targeting (classifying people based on where they live, e.g., urban slums as poor), and (4) community wealth ranking (community members identify poor households based on their own definitions and perceptions)[77–81] (Table 4).

Giving people the option to pay monthly, quarterly, or semiannually has been shown to help the poor pay their health insurance premium.

In means testing, a questionnaire, such as the Living Standards Measurement Survey (LSMS) developed by the World Bank, is used to collect detailed information on household expenditure and consumption. Means testing is expensive because it involves collecting very detailed data through a household survey. This is in addition to other challenges such as the difficulty of assigning monetary value to food that local farmers harvest from their farms and recall bias for expenditures.[78–80]

Proximal means testing is being increasingly used to measure household socioeconomic status. Data on ownership of assets and access to services are collected from households, which are then used as proxies to determine household socioeconomic status. Some drawbacks of proximal means testing include cost of survey, inconclusive evidence that assets are good proxies of socioeconomic status, and the possibility of wrongly classifying the poor as not poor.[78–80]

In geographical targeting, families are classified as rich or poor based on the neighborhood in which they live. For example, families living in urban slums would be classified as poor. It could also involve the use of national survey data such as Demographic and Health Survey data to identify poor communities. However, geographical targeting could lead to the poor who are living in non-poor neighborhoods being excluded from

TABLE 4. Methods of Identifying the Poor

Method	Ideal Condition to Use	Drawbacks
Means testing	When cost is not a consideration	Very expensive
Proximal means testing	Low-poverty incidence in urban areas	Expensive, measures relative poverty
Geographic targeting	High-poverty incidence in both urban and rural areas	Could lead to the non-poor who live in poor neighborhoods being exempted from premium
Community wealth ranking	Low-poverty incidence in rural communities	Measures relative poverty, cannot be used where community ties are weak

Adapted from Umeh CA (2017).[81]

the subsidy while the non-poor living in poor neighborhoods receive the subsidy that they do not need.[78–80]

In community wealth ranking, the community decides on the criteria that will be used to categorize the poor in the community. Then the community chooses key informants who have lived in the community for a long time and know all the households. The key informants individually categorize the families into different wealth groups. Then all the key informants meet to reach a consensus on the wealth categories of all the families. The advantage of this is that it is a fast and cost-effective way of assessing poverty level in the community. In addition, it is done by the community and because of the community participation, it will be easy for community members to agree to cross-subsidize the poor.[59–61] The challenge with the community wealth ranking approach is that it might be difficult to use in urban areas where community ties are weak and people might not know each other very well.[61] Another challenge with community wealth ranking is that it measures relative poverty. So someone who might be seen as poor in one community might not be identified as poor in another community depending on the average level of wealth in the different communities.

To improve the ability to correctly identify the poor cost-effectively, countries can combine more than one means of identifying the poor.

One particular method of assessing the poor might not work in all settings. To improve the ability to correctly identify the poor in a cost-effective manner, countries can combine more than one means of identifying the poor, such as first identifying the poor using community wealth ranking or geographical targeting and then using means testing or proximal means testing to screen those identified. It is left to the CBHI schemes to discover the method(s) that will best work for them in the specific locations and circumstances where they operate.

Removal of Co-Pays for the Poor

Although co-pays are put in place to prevent excessive use of health care services by those who do not need them (moral hazard), it is detrimental to the poor who really need the health care services but cannot afford the co-pay.[74,75] Some might argue that removal of co-pay for the poor will lead to moral hazard for the poor, but that argument pales in light of the fact that there are other non-financial barriers that stop the poor from overusing health care services. Such things as transportation cost and opportunity cost of the time spent in the hospital are already barriers to excessive use of health care services by the poor.[82]

Removal or Reduction of Waiting Period After Premium Payment

In a bid to reduce adverse selection, some CBHI schemes introduce a waiting period (usually 3 months) between the payment of premium and coverage by the insurance scheme.[62] However, the waiting period seems to adversely affect the poor more than the rich. This is because after paying for the premium, the poor might not have money to pay out of pocket during the waiting period. Although waiting periods are being used by many health insurance schemes to prevent adverse selection, we could not find studies that evaluated their effectiveness in preventing adverse selection. However, it was shown not to be effective in Burkina Faso[83] as there was still adverse selection even with the waiting period in place.

CBHI schemes should consider the use of other methods that have been shown to be effective and are less harmful to the poor in preventing adverse selection. The use of enrollment at the household level where everyone in the household must be enrolled has been shown to be effective in reducing adverse selection.[84] However, this did not eliminate adverse selection in some studies, because some households did not truly enroll all their household members.[83,85] Another way to deal with adverse selection is to make signing up for insurance compulsory for everyone, with premium subsidies for the poor.[86]

Reimbursement of Expenses After Use of Services

The SEWA insurance scheme in India that reimbursed expenses after payment seemed not to favor the poor as there was an inequitable submission of claims, with the poorest 30% submitting fewer claims than the richer members.[64] Although direct payment may potentially give consumers some leverage over provider quality, CBHI schemes that are structured in that way might be detrimental to the poor. One way to deal with this is for the insurance schemes to have an agreement with a network of health facilities and have their members receive treatment from those health facilities. Instead of the members paying out of pocket and being reimbursed later, the health facilities bill the insurance scheme directly and receive payment for the service from the insurance scheme. Insurers might also use the capitation payment method, which has been used in some CBHI schemes.[76]

CONCLUSION

Achieving universal health coverage in low- and middle-income countries through CBHI schemes will be a difficult feat. For CBHI schemes to succeed in providing access to health care by the poor, and especially the poorest of the poor, such programs need to provide a subsidized premium for the poor and not to charge a premium at all for the poorest of the poor. In addition, providing flexible premium payment plans will help improve enrollment into CBHI schemes. Furthermore, removal of co-pays (especially) for the poor and removal of the waiting period between payment of premium and coverage by the health insurance scheme are steps that will be very beneficial to the poor. It is important to state that our recommendations are subject to the context of different countries in which the CBHI schemes operate.

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FIELD ACTION REPORT

Challenges of Implementing Antenatal Ultrasound Screening in a Rural Study Site: A Case Study From the Democratic Republic of the Congo

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In the context of a well-resourced research project on obstetric ultrasound, we encountered major challenges, including security and maintenance of the equipment, electricity requirements, health systems integration, and a variety of other systems issues. We propose future ultrasound interventions have at minimum a functioning health system with skilled and motivated staff, access to a referral hospital capable of providing affordable and higher levels of care, and feasible transportation means.

ABSTRACT

Persistent global disparities in maternal and neonatal outcomes and the emergence of compact ultrasound technology as an increasingly viable technology for low-resource settings provided the genesis of the First Look Ultrasound study. Initiated in 2014 in 5 low- and middle-income countries and completed in June 2016, the study's intervention included the training of health personnel to perform antenatal ultrasound screening and to refer women identified with high-risk pregnancies to hospitals for appropriate care. This article examines the challenges that arose in implementing the study, with a particular focus on the site in Equateur Province of the Democratic Republic of the Congo (DRC) where the challenges were greatest and the efforts to meet these challenges most illuminating. During the study period, we determined that with resources and dedicated staff, it was possible to leverage the infrastructure and implement ultrasound at antenatal care across a variety of remote sites, including rural DRC. However, numerous technical and logistical challenges had to be addressed including security of the equipment, electricity requirements, and integration of the intervention into the health system. To address security concerns, in most of the countries field sonographers were hired and dispatched each day with the equipment to the health centers. At the end of each day, the equipment was locked in a secure, central location. To obtain the required power source, the DRC health centers installed solar panels bolted on adjacent poles since the thatch roofs of the centers prohibited secure roof-top installation. To realize the full value of the ultrasound intervention, women screened with high-risk pregnancies had to seek a higher level of care at the referral hospital for a definitive diagnosis and appropriate care. While the study did provide guidance on referral and systems management to health center and hospital administration, the extent to which this resulted in the necessary structural changes varied depending on the motivation of the stakeholders. In order for such an intervention to be scaled up and sustained as part of a health system's general services, it would require considerable effort, political will, and financial and human resources. Preliminary results from the study indicate that taking routine antenatal ultrasound screening to scale is not warranted. Lessons learned in implementing the study, however, can help inform future studies or programs that are considering use of ultrasound or other imaging technology for other applications in low-resource settings.

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BACKGROUND

First Look Ultrasound Study

The Global Network First Look Ultrasound study was a cluster-randomized trial whose primary aim was to assess the impact of antenatal ultrasound screening performed by health care personnel on a composite

outcome consisting of maternal mortality and maternal near-miss, stillbirth, and neonatal mortality in low-resource, rural community settings. The study addressed the lack of maternal and neonatal outcome data based on actual deployment of compact ultrasound in rural, low-income country settings brought to light in a seminal article by Harris and Marks.[1] Details of the First Look study, including ethical reviews and approvals, are discussed in depth elsewhere.[2]

Briefly, the study used the existing research infrastructure of the Global Network for Women's and Children's Health Research sites in the Democratic Republic of Congo (DRC), Guatemala, Kenya, Pakistan, and Zambia. Central to each site was the development and maintenance of the Global Network Maternal Newborn Health Registry in defined geographic areas or clusters. Within these clusters, the Registry documented all pregnancies and their outcomes to 6 weeks post-delivery, providing population-based rates of stillbirth, maternal and neonatal mortality and morbidity, and health care utilization.[3] In the 5 countries, the First Look study was conducted in 58 clusters (29 clusters were randomized to the intervention and 29 to the control). Clusters were defined geographical areas with at least 1 health center and approximately 500 births per year. The study began in 2014 and was implemented for at least 18 months in each country site; it was completed in all sites in June 2016.

The intervention included 4 components:

1. Training of ultrasound-naïve health workers (e.g., nurses, midwives, clinical officers) to perform 2 ultrasound screening examinations during antenatal care, targeted at 18–22 weeks gestation and at 32–36 weeks gestation
2. Training of referral hospital staff in emergency obstetric and neonatal care as necessary
3. Guidance to Ministry of Health officials and hospital administrators on possible referral system enhancements
4. Community sensitization activities to inform women and their families of the availability of ultrasound at their antenatal care clinics

The main focus of the First Look Ultrasound study was training health workers to perform antenatal ultrasound and to refer high-risk pregnancies to a higher level of care.

The main focus of the intervention was on the first component—training health workers to perform ultrasound examinations and to refer high-risk pregnancies to a higher level of care. Trainees were taught to assess gestational age, to identify high-risk pregnancies (including multiple gestations, fetal anomalies, mal-presentation, placenta previa, and risk of preterm delivery), and when and how to refer to the hospital for appropriate care. A 10-day course was administered under the supervision of the University of Washington, Department of Radiology (UW), in the 5 Global Network country sites. In concert with local sonographer trainers, UW then oversaw a quality assurance process including review of stored images of all ultrasound scans collected during a 3-month pilot period and 10%–20% of images collected throughout the study. Both the initial training and the quality assurance process are discussed in detail elsewhere.[4] In the DRC, Pakistan, and Zambia, the sonographers were based in the field and traveled to the health centers in their assigned clusters each day with the necessary equipment to perform ultrasound examinations. In Guatemala and Kenya, the sonographers and equipment remained stationed at the health centers. Control clusters had the Registry, but none of the 4 interventions described above.

The purpose of this article is to examine the challenges arising during implementation of the study's ultrasound intervention, with a particular focus on the study site in the DRC where the challenges were the greatest.

PERFORMANCE SITE IN THE DRC

While the study was being conceived, the Global Network was reestablishing the Maternal Newborn Health Registry in Equateur Province in the DRC. Equateur Province was also emerging from a period of political conflict and peace negotiations, lasting from 2009–2013. The study team conducted an initial assessment of the DRC site to determine whether the infrastructure in Equateur Province was sufficient for the study's ultrasound intervention. The Global Network's decision to conduct the study in Equateur Province was made with the understanding that its inclusion would examine the effectiveness of the ultrasound intervention across a broader range of resource-limited settings, with Equateur Province representing the lower boundary.

Equateur Province is located in northern DRC bordering the Republic of the Congo to the west and the Central African Republic to the north. Karawa, the town around which the study is centered, is situated 68 kilometers east of Gemena along National Highway 24—a red clay roadway maintained by hand and shovel—which can take 3 hours or more to travel by vehicle depending

on the season. The Gemena airport had weekly 4-hour flights to Kinshasa via Mbandaka, a journey that might otherwise take 1–2 months by river and land. Houses in the area are made of wooden poles, earth, and thatch, as are most health centers, with the addition of plaster and paint. Farming is central to livelihood and networks of cropland and streams surround the villages, linked by paths sometimes wide enough for a vehicle to pass.

The Karawa Mission, where the hospital is located, has endured extended periods of evacuation during stretches of political conflict and war since 1960. The impact of periods of substantial support that brought running water, hydroelectricity, an airstrip, and significant infrastructure to the mission is apparent, as is the toll of decades of isolation. The hospital, consisting of buildings several decades old separated by manicured hedges, houses a maternity ward with 20 beds and an active operating room. During the trial period, electricity was generally available on demand from a generator, and water carried and stored in barrels. Five Congolese physicians led the hospital's staff.

FEASIBILITY ASSESSMENT

Before exploring the challenges faced during implementation of the study in the DRC, we first review the inclusion of Karawa Hospital and its satellite health centers in the study to shed light on the criteria essential to making ultrasound feasible for research and implications for broader sustainability. To determine whether Karawa Hospital and its health centers would be suitable for the study, we first determined whether the intervention was appropriate for the health care environment. We then determined the extent to which providers and health care administrators were willing to participate in the study.

Appropriateness of the Ultrasound Intervention in the DRC

We anticipated several critical features of the environment that would be necessary to realize any potential improvements in perinatal outcomes as a result of antenatal ultrasound screening. First, each health center in which ultrasound was performed had to have a power supply and adequate security for the ultrasound units. In addition, the surrounding health system needed to have basic functions, including health centers staffed with trained personnel providing antenatal care, guidance for referrals, and assistance in deliveries. The value of obstetric ultrasound screening is minimized when patients with high-risk pregnancies are unable to attain the level of care that screening indicates. Therefore, a referral hospital that provided continuous Comprehensive Emergency Obstetric and Neonatal Care (CEmONC) had to be available.[1] Karawa Hospital partially met this requirement. Although some of the signal functions of CEmONC were not always readily available, including blood and anesthesia, the hospital did have a functioning operating room and physicians who perform cesarean deliveries.[5] Blood was often supplied by relatives with matching blood types and anesthetics purchased in shops outside the hospital when necessary. However, provision of these resources requires additional time and planning and therefore may have limited the impact of the ultrasound intervention. Intermittent power precluded the hospital's ability to maintain a blood bank, but the generator could provide power to the operating room as needed.

The value of obstetric ultrasound screening is minimized when patients with high-risk pregnancies are unable to attain the higher level of care that screening indicates.

Another essential feature was the ability of patients to reach the referral facility. The availability of a vehicle for transport is ideal but not essential for the effectiveness of the intervention.[1] Ultrasound screening can provide a woman with knowledge of a high-risk pregnancy, the time to plan, and encouragement to travel to the referral hospital prior to delivery. In Equateur Province, most likely a woman would need to walk to the hospital. Bicycles are sometimes available, but motorcycles are rare. Canopied bicycle trailers for transporting semi-recumbent patients are available at some health centers. There is a limit, however, to the distance a pregnant woman in late pregnancy or with an emergent problem can reasonably travel without advanced modes of transportation.

The cost of hospital care was also an important consideration. An alternative hospital with its surrounding health centers was considered as a study site; however, the cost of a cesarean delivery at this hospital was the equivalent of US$50 and the cost of a vaginal delivery, approximately US$10. These prices represent an enormous barrier to care for a population living largely beneath the poverty line, with limited access to money. The catchment area for Karawa Hospital, on the other hand, was supported by a 5-year grant from the United Kingdom's Department for International Development (DFID), which lowered these costs by 80% throughout the study period.[6] While this certainly limits the scalability of the intervention in Equateur

Province beyond the limits of the DFID grant, it was more closely aligned with other Global Network sites, such as Kenya and Zambia, where maternal health care is ostensibly free. The DFID grant also supported the hospital and health centers with medicines and supplies, increasing the value of attending antenatal visits.[7]

Willingness of Health System Management and Staff

Two recent studies have emphasized the importance of having willing providers to implement ultrasound interventions in low-resource settings.[8,9] Of similar importance is the enthusiasm and participation of those managing health systems, because improvements must be made to take advantage of the new information made available by ultrasound screenings. As such, the commitment of potential referral hospitals and zonal health systems to employ the intervention was factored into selection of the clusters. The health system in the Karawa area demonstrated such commitment, further differentiating it from other health systems assessed. Karawa Hospital had a physician with ultrasound experience and a keen interest in the study's intervention. This contrasted with the indifference and inquiries about compensation expressed at the other potential hospitals. Similarly, the zonal health coordinator in Karawa was eager to undertake the study.

At the DRC site, field sonographers transported the ultrasound equipment to the health centers daily by motorcycle and locked the equipment each night at a staff member's house.

CHALLENGES TO IMPLEMENTING THE ULTRASOUND STUDY

Many of the challenges faced in the study and the actions taken to meet them reflect the temporary nature of the study and the innovative nature of the intervention. Addressing these challenges required balancing the desire to simulate an intervention that could be studied and potentially taken to scale with constraints of time and limits of influence intrinsic to the study's design. In some cases, the choices were straightforward. For example, at the outset, requests came from each health system hosting the study for transportation to assist women requiring a higher level of care. We did not provide or subsidize transportation because we believed that to do so would confound the study results and impact inferences about scalability.

Ultimately, the specifics of the study implementation at each site were the result of negotiated agreements of a broad partnership of donors, academic institutions, and research organizations. Each Global Network country site is co-managed by investigators from a local and a U.S.-based university, each has a large degree of autonomy, and each has developed longstanding relationships with the health systems that encompassed their clusters. The choices made to meet the challenges of implementing the study reflect a process that incorporates all these points of view. Below is a discussion of the challenges faced and how they were addressed, with an eye toward guiding similar interventions going forward.

Security

The security of the ultrasound equipment was a substantial concern from the conception of the study. The GE Healthcare Logiq-e ultrasound unit, including console, transducer, printer, and accessories, sold for more than US$22,000 at the beginning of the study. The stark contrast of this to the value of existing equipment in targeted health centers necessitated that extraordinary measures be taken.

In the case of the DRC site, the ultrasound machines were locked up each night at a staff member's house within the Karawa Mission premises, and the trained field sonographers transported them to the health centers daily by motorcycle. At some other sites, the distance of the health centers from a secure, central storage location made this approach impractical. In Kenya, for example, the equipment was locked each evening in custom-built metal cabinets that were securely bolted to the walls of rooms with lockable doors, within health centers guarded by security personnel.

That these measures are not likely to be replicable on a large scale may be balanced by the understanding that the GE Healthcare Logiq-e is substantially more technologically robust than its use in the study warranted. This, coupled with the continuing reduction in the price of ultrasound technology,[1] may obviate the need for these measures over time. However, similar programs will need to consider the security of equipment.

Electricity

In initial assessments of the health facilities in Equateur Province, none of the health centers had electricity. In some health centers, solar power had once been available, but the solar panels, inverters, and/or batteries were missing at the time of our visit. We were informed that the equipment had either been stolen or removed for

the purpose of security. The initial assumption was that the source of power for the ultrasound devices would need to be a portable generator brought daily to the health center along with the ultrasound machine. DRC site staff, however, opted to install solar panels bolted on 10-foot poles next to the health centers. The thatch roofs of the health centers prohibited secure roof-top installation. Batteries and inverters were secured in locked boxes within the health centers. Each health center has security personnel to protect medical supplies and equipment, and the combination proved sufficient during the trial.

In Pakistan, large batteries, or uninterruptible power supplies (UPSs), were charged throughout the night at the site office and transported along with the ultrasound machines to health centers daily. In Kenya and Zambia, the health centers are connected to the electrical grid, although power has become increasingly intermittent. The GE Healthcare Logiq-e ultrasound came equipped with 2 additional batteries, each with an initial working time of 45 minutes. These often sufficed during power outages, though Kenya also employed UPSs.

Electrical power demands of the Logic-e ultrasound are greater than the newer tablet-size versions that are now available. The corresponding reduction of the size and cost of solar equipment should simplify what is required to power ultrasound technology, but electricity requirements remain an important consideration in the implementation of this type of intervention.

Ultrasound Machine Servicing

The challenge of servicing the ultrasound machines in Equateur Province was anticipated, and 2 spare ultrasounds were supplied by GE Healthcare. When a machine malfunctioned, the unit had to be shipped back to Kinshasa, where a service provider contracted by GE Healthcare managed repairs. This process took 3 months or more, in large part due to the complexities of importing replacement parts. The Office of the United States Trade Representative describes the DRC as having "complex regulations, a multiplicity of overlapping administrative agencies and a frequent lack of professionalism and control by officials responsible for the regulatory environment."[10] Attaining exemptions for charitable donations in this environment in a reasonable amount of time was not possible. As a result, the costs of importing the replacement parts could equal the cost of the parts themselves. At the other country sites, GE Healthcare had established relationships with local service providers prior to the study, and the repair process was less time consuming and expensive. For more permanent ultrasound interventions, greater emphasis on developing and costing the management of maintenance at the outset appears warranted.[11]

Electricity needs of the ultrasound equipment were met in the DRC by installing solar panels bolted on poles adjacent to the health centers.

Supply Chain

An appealing aspect of the ultrasound intervention was the limited amount of supplies required, which consisted only of gel and paper towels for cleaning the gel off of patients. The study also supplied printers, with the thought that providing an ultrasound image to patients may encourage family members to support attendance at antenatal visits and compliance with recommendations for referral. The printers required thermal paper. Both the gel and the paper had to be shipped from Kinshasa to Equateur Province. This required planning and bulk purchasing, neither of which was a problem during the study.

Field Sonographers

In Equateur Province, nurses other than those stationed at health centers were trained to perform ultrasound screening for the study in part due to logistical considerations. Hiring nurses both to transport the ultrasounds by motorcycle and to screen patients addressed the practical matter of transporting 5 ultrasound units from Karawa Mission out to remote health centers and back each day. Similar considerations led to the hiring of external medical personnel as field sonographers in Pakistan and Zambia.

Another factor that influenced the decision to hire nurses outside of health centers to perform ultrasounds for the study relates to the limit of influence the study could have on health systems. While the study aimed to simulate an environment in which health center personnel integrated ultrasound screening into antenatal care provision, the extent to which nurses and midwives stationed at health centers would engage in screening without active supervision was a concern highlighted in another study.[8] A health system's willingness to participate in the study was not a guarantee that it could, for 18 months, muster the managerial capacity and will to ensure compliance to screening at the health center. The additional time and effort required of nurses to collect data for each screened patient was also a concern specific to the study. These considerations led to an approach at the Kenya site—where the

ultrasound equipment was stored at health centers—of hiring, training, and stationing clinical officers at those health centers. In Guatemala, nurses and medical officers employed by the Ministry of Health and permanently stationed at health centers were trained and engaged for the study, though some needed assistance by site-employed field sonographers to ensure that sufficient screenings occurred. Engaging existing health center personnel for this intervention required structural change within the health system, which was beyond what could be orchestrated for a limited period by external researchers, but important for future endeavors.

Engaging health center staff for the intervention required structural change within the health system that was beyond the scope of the research project, so we hired field sonographers instead.

Training

The preference of the study was for training to take place in the hospitals where study patients would be referred during the trial. This created the potential for hospital sonographers to be engaged as co-trainers or participants, depending on their level of skill. By doing so, the hospital could be made aware of the intervention, and the hospital sonographers and trainees could develop relationships, which may have enhanced communication about referrals. This was possible in Karawa Hospital with the inclusion of a doctor and nurse from the hospital. Because the hospital was substantially smaller than those where trainings took place in other country sites, there was a concern about having a sufficient number of patients to screen during the training. The goal was to have each trainee complete at least 2 scans each day during the 10-day course. Each woman, for the sake of comfort, could only be scanned once. This amounted to having at least 16 women with second- and third-trimester pregnancies at the hospital each day. The DRC site accommodated this by notifying women in advance about which days to present at hospital. There were, as a result, ample patients each day of the training. In fact, the DRC site staff was remarkably capable in overcoming this concern and the many issues of intermittent power and management of time that the training presented.

The language of instruction in the DRC is French, requiring all training materials and slide presentations to be translated prior to the training. However, because Lingala is the language most commonly understood, and because much of the training was interactive, hands-on training and communication with the patient was an essential component of the training, an obstetrician from Kinshasa with strong ultrasound training skills and fluency in both languages was hired to conduct the training.

Quality Assurance

A system of quality assurance was developed that entailed reviewing specific images from each ultrasound scan for a period of 3 months after the initial training and then 10%–20% of the ultrasound exams thereafter. These were reviewed on a website by UW radiologists and, in the case of the DRC, by the obstetrician from Kinshasa who conducted the training. In the DRC, this entailed saving the images on flash drives at the time of the scan and transporting the flash drives at least every 2 weeks to Gemena where Internet connectivity is sufficient for uploading. Remedial training that was indicated by the quality assurance review was conducted by a physician from Gemena with ultrasound imaging skills who had also served as a co-trainer during the initial 10-day course. Through email correspondence, he received instructions on which trainees needed help with which aspects of the training, a system that matched the recommendations of another study.[9] This quality assurance system is discussed in detail elsewhere.[12] During the course of the study, however, this local physician took a position that kept him from playing this role. The solution was to assign the role of relaying these instructions to the most skilled of the trainees as a means of remedial training, which proved to be successful.

Health Systems Integration

The concept of screening with ultrasound requires confirmation of the findings of the screening. The training of the sonographers was comprehensive, including, as mentioned previously, an initial 2-week course in basic obstetric ultrasound screening with 3 months of quality assurance review, periodic observation, and targeted remedial training for ultrasound-naïve health personnel. However, it was never considered sufficient for the trainees to make definitive diagnoses. Patients screened by trainees require confirmatory scans by a fully trained sonographer and physician before the diagnosis of any condition is made and acted upon. The intervention, by design, engaged referral hospital personnel in this confirmatory role. At best, health centers in the Global Network clusters provided Basic EmONC. Much of the value of introducing ultrasound into the health clusters was in providing visual and metrical information to encourage women with high-risk pregnancies to seek a higher level of care.[13]

With the engagement of referral hospital personnel, the new possibility of using this information to help streamline the care patients received at referral hospitals existed.

The barriers that keep referred patients from presenting at hospitals appear to be many and are not fully understood. While studies have begun to explore these barriers in similar settings,[14–16] the First Look study is being complemented by a qualitative survey for further understanding. From the rural patients' perspective, traveling to a city-based referral hospital without guidance can entail having to find where to receive care and to wait separately for mandatory antenatal care provision, ultrasound scanning, and care from an obstetrician. In some hospitals linked to Global Network clusters, this process can consume several days before a confirmatory ultrasound is made and an appointment with a clinician who has the results of the ultrasound exam occurs. This may be sufficiently discouraging. On the other hand, with the information from the ultrasound screening and the engagement of a sonographer and physician at the referral hospital, this process may be streamlined. Determining with the patient a date to present at the referral hospital, communicating this to the hospital, indicating where and to whom the patient should present on arrival, providing a pass that confirms this, and outlining to the patient what the visit will entail may encourage patients to overcome some of the obstacles to referral.

Providing guidance on referral and systems management was part of the study's protocol; however, the extent to which this guidance has effected change in the health systems at the 5 country sites varied in relation to the willingness of health systems to attempt the proposed changes. The Karawa health system, as mentioned previously, was included in the study in part because of its expressed willingness to participate. Moreover, the hospitals where the initial trainings took place and to which participating health centers referred high-risk pregnancies appear to have been more inclined to develop streamlining processes. These processes were built around the hospital sonographers who served as co-trainers of the field-based/health center sonographers. This was true in Guatemala and Zambia. Streamlining in Kenya and Pakistan, where the trainings occurred at hospitals not directly linked to the health centers, was more problematic.

In the DRC, training engaged a doctor and a nurse employed by Karawa Hospital who had some ultrasound imaging skills. The doctor was enthusiastic about the ultrasound intervention and played the important role of performing confirmatory scans at the hospital. Time constraints limited his ability to play an active role in tracking and receiving patients, meaning these roles were assumed by the hospital nurse who had participated in the trainings. She was significantly less interested in the training and the study, and her ultrasound skills were minimal and improved less during the training than those of the other participants. This was reflected in her lack of willingness to participate in developing and maintaining the streamlining process. Several months into the study, the doctor was transferred to another hospital and both the confirmatory process and the streamlining process were put into peril.

A solution sprang from an earlier decision to train 6 nurses for the 5 health centers. The sixth sonographer was positioned at the hospital and performed confirmatory scans in collaboration with physicians. In addition, he developed the streamlining processes and communicated with the screening nurses at the health centers about anticipated and non-compliant referrals. Moreover, because blood and anesthesia were not always readily available, this nurse helped the hospital and patients coordinate the timing and blood donors necessary for cesarean deliveries. This temporary solution aimed to simulate the structural change a health system would need to undergo were the intervention to be more permanent and integral to it.

LOOKING FORWARD

We have discussed the challenges of implementing antenatal ultrasound screening in a low-resource setting and how these challenges were addressed during the study period. We believe our methods of addressing these challenges may help those considering research on similar interventions. The article also describes the complexities of implementing the intervention within the context of the study. In addition to the primary study, examining impact of ultrasound on mortality and morbidity, we have undertaken an economic analysis of the intervention and a qualitative survey to evaluate patient and health care personnel's perceptions of ultrasound in obstetric care and opportunities to improve that care. Both were undertaken with the aim of understanding the implications and limits of the impact of this intervention as it was designed. Combined, they aim to aid in the consideration of how ultrasound

technology should be employed in low-resource settings.

Implications for Scale-Up

While we have described the necessary prerequisites for establishing a research project focusing on providing routine ultrasound evaluations during prenatal care, we recognize additional resources were made available to the study communities through the First Look study—resources that will likely not be available to a clinical program. We demonstrated that it was feasible to conduct a technically challenging intervention even in remote and rural areas with minimal infrastructure, exemplified by our experience in Equateur Province, DRC.

However, we also recognize that multiple challenges would be faced by health systems implementing this intervention in the absence of research support. Specifically, political will, substantial resources, and continuous training and retraining would be required to initiate and maintain the ultrasound program over time. As described elsewhere, because of failure to maintain equipment and resultant breakdowns, absence of service providers, and high costs, developing-country hospitals are famous for abandoned equipment from well-intentioned donors. In order for an ultrasound program to be successful in a resource-limited setting, it would need to include continuous staff training and a system to provide quality assurance, the ultrasound equipment and its ongoing maintenance, and a continuous source of disposable supplies. These conditions do not happen by chance; they require an enabling environment as well as dedicated health care workers. Even short lapses in provider training and oversight and in the provision of supplies and equipment maintenance are sufficient to cause a program to fail.

The First Look study surfaced the importance of structural change within health systems to accommodate ultrasound interventions.

In this light, the preliminary results from the First Look study indicate that taking routine antenatal ultrasound screening to scale is not warranted.[17] The clinical applications of compact ultrasound equipment, on the other hand, continue to expand. Applications now include trauma imaging, focused echocardiography, obstetric emergencies, lung diseases, surgical emergencies, deep venous thrombosis, dehydration evaluation, and diagnostic breast ultrasound.[18–20] As such, the lessons learned in implementing the First Look study should be of benefit for those considering employing the expanding uses of ultrasound or other imaging technology into low-resource settings.

Preliminary results from the First Look study indicate that taking routine antenatal ultrasound screening to scale is not warranted.

Extrapolating From the Lessons Learned in the DRC

The process of implementing the study in Equateur Province in the DRC provides insight into where and how similar interventions might be deployed. Certain perceived thresholds below which the impact of the ultrasound intervention may be prohibitively limited become apparent. These thresholds include: (1) a functioning health system with staffed facilities providing antenatal care and assisted deliveries; (2) a referral hospital providing continuous CEmONC; (3) a distance and cost of existing means of transportation from health center communities to referral hospitals that most patients and their families can cover; (4) costs of maternal health care services that most patients can be expected to pay given the advance notice of a high-risk pregnancy that ultrasound provides.

In places that exceed such thresholds, determining the efficacy of an intervention using ultrasound or future imaging modalities and analyzing its cost relative to other interventions remain as pertinent to evaluating the need for its inclusion in low-resource settings as they were at the initiation of the First Look study. What has surfaced throughout this review is the need for structural change within health systems to accommodate the ultrasound intervention. Its importance may warrant a new way of viewing this and similar interventions. One might consider ultrasound screening as a means of strengthening referral systems. By targeting systems with an expressed willingness to take advantage of the information that ultrasound screening provides, a country could consider the provision of ultrasound as an incentive for making the necessary structural changes. For example, those systems with physicians and sonographers at referral hospitals who are willing and able to train and support health center personnel and provide a blueprint for the development of streamlining processes for referral might be awarded the opportunity to integrate ultrasound screening.

Another criterion might be a plan for managing the compliance of health center personnel to integrating ultrasound screening into the provision of care. This compliance might also involve an incentive system. Using obstetrics as an example, the early detection of high-risk pregnancies coupled with the storing of a patient's images

during health center screenings and confirmatory scans by referral hospital sonographers might provide the means of recording those patients that were referred and successfully delivered at referral hospitals. These records could provide the basis for incentivizing successful preventative maternal care.

Consideration of the potential structural changes to health systems made possible by the new information that ultrasound brings to low-resource settings might best serve as a starting point for conceiving future interventions. Improving the efficiency of health systems with the flow of this information may further benefit patients encouraged by this same information to seek higher levels of care.

Future Considerations

The implementation of this ultrasound intervention in the DRC and the 4 other country sites has shown insights into which similar interventions might be targeted and how they might be structured to be most effective. Moreover, the consideration of introducing ultrasound screening as a means to strengthen referral systems has surfaced as a promising approach to improving health outcomes in rural, low-resource settings. Future initiatives for expanding the use of ultrasound in these settings may benefit from this broader consideration.

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INNOVATION

Design Improvements for Personal Protective Equipment Used in Ebola and Other Epidemic Outbreaks

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We redesigned the personal protective equipment ensemble widely used during the 2014 Ebola outbreak into a relatively simpler and more versatile coverall and hood, to improve protection and usability for frontline workers treating patients in infectious disease outbreaks around the world.

BACKGROUND

In 2014, the world witnessed the worst Ebola outbreak on record, with widespread disease in the West African countries of Guinea, Liberia, and Sierra Leone—infecting more than 28,000 people and killing more than 11,300 in the span of 2 years.[1] It was the first Ebola outbreak to reach large city centers, where it spread rapidly. The disease particularly impacted health care workers because it is so highly infectious and difficult to defend against, placing additional pressure on already fragile health care systems. By August 2015, 880 health care workers had become infected, and 512—nearly 60%—of those workers had died.[2]

One of the greatest times of risk for health care workers occurs when they remove their personal protective equipment (PPE) and are exposed to the virus on the outer surfaces, especially during glove and gown removal (doffing). Compounding the danger is the complexity of the doffing protocols and of the multipiece PPE ensembles themselves.[3] Every additional element and step in a multicomponent PPE ensemble, either in donning or doffing, adds an opportunity for error and increase in risk.

In October 2014, in response to these issues and to the United States Agency for International Development's (USAID's) Grand Challenge for Development to help health care workers respond to the epidemic, Johns Hopkins University's Center for Bioengineering Innovation and Design (CBID) and Jhpiego, an NGO affiliate of Johns Hopkins University, organized the "Johns Hopkins Emergency Ebola Design Challenge," a hackathon-type event in which participants worked in teams to address specific issues with existing PPE ensembles. The event was also supported by the State of Maryland and Clinvue, a Maryland-based medical device innovation and design company. Experts from many disciplines, including experts in the care of Ebola patients and use of PPE, were brought together for the event, which was aimed at understanding and designing mitigations to a wide range of issues pertaining to use of PPE in infectious disease outbreaks like Ebola. More than 80 people participated throughout the 3-day event, and teams were formed for continued development for many weeks after. They addressed such issues as doffing, donning, comfort, visibility, fogging, patient/family fear of caregivers, and overall complexity of protection from the virus. More than 100 concepts to address these issues were generated. After additional development and refinement, the leading concepts were combined into a set of new PPE designs. Further development was supported by a grant from USAID, a partnership with DuPont Corporation, and additional support from CBID and Jhpiego. Here, we discuss the new improved features of the PPE (hood and coverall) and current commercialization prospects.

THE DESIGN

Traditional PPE used by Médecins Sans Frontières (MSF) consists of a coverall or gown to protect the body, a separate hood to cover the head, a mask to cover the mouth and nose while allowing for breathing (typically a duckbill N95 respirator and surgical mask), laboratory-type goggles to cover the eyes, 2 layers of gloves for the hands and forearms, rubber boots, and often a heavy plastic apron in front. Ideally, this ensemble is worn in a way that completely covers the skin of the health care worker: the goggles overlap

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Health care workers face many challenges with personal protective equipment that must be worn during epidemic outbreaks, especially during doffing when the risk of contamination is highest.

We assembled a design team to improve the personal protective equipment worn by health care workers during outbreaks.

with the face mask, the hood has to overlap the coveralls, etc. Any gap could expose the health care worker to infectious agents.

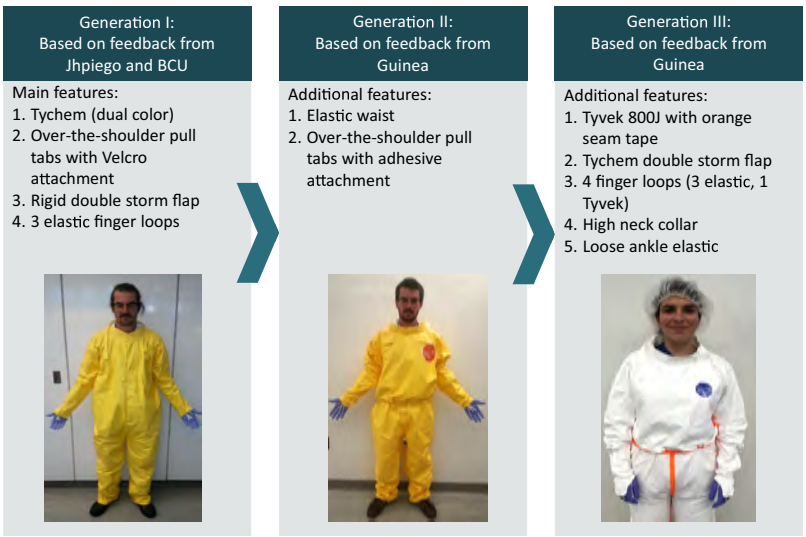
Multiple studies have described the challenges associated with PPE, especially during doffing, when the risk of contamination is highest. These challenges include contamination of hands and wrists during glove removal, exposure and contamination of the neck during doffing, overheating and discomfort, gowns opening while in use, and a restricted field of vision, made worse by fogging inside the goggles.[4,5] Additional elements of complexity include the many steps in the protocol to don and doff this ensemble, as well as the multiplicity of sources for the products in the ensemble.

In the later stages of the response to an outbreak, the risks associated with these issues are minimized, as training and experience reach high levels. In the earliest stages of an outbreak, however, when health care workers are just learning how to use PPE, such complexity and design weaknesses may add significantly to the magnitude of the risk, and subsequently, to the magnitude and trajectory of the crisis.

CBID teams obtained feedback throughout the design process from more than 200 health care workers (hygienists, medics, health experts, midwives, maternal and obstetrics and gynecology experts, PPE trainers) at the Johns Hopkins Bio Containment Unit, Jhpiego, and health facilities in West Africa, including clinicians who had worked in Ebola Treatment Units. Additional insights were gathered through visits to MSF headquarters in Brussels and to the World Health Organization (WHO) in Geneva.

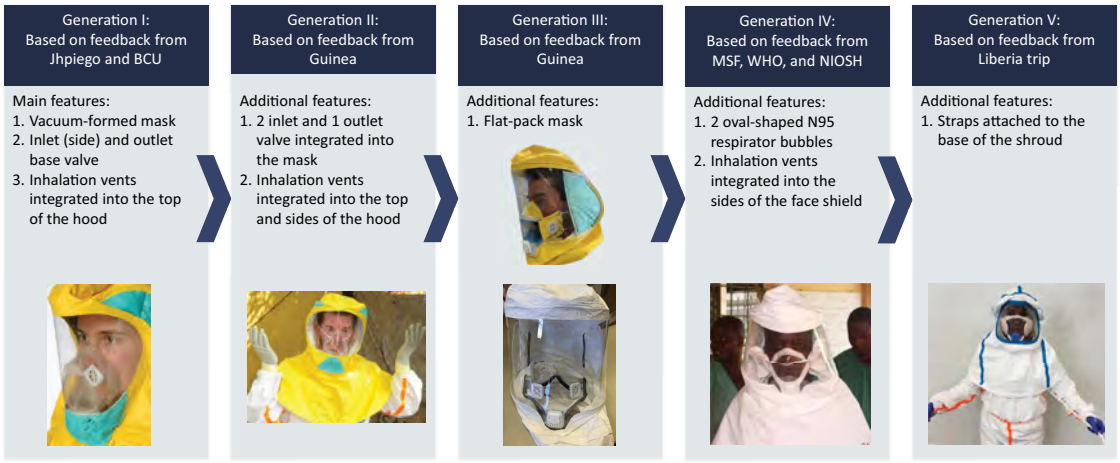
With an understanding and deeper assessment and ranking of the various problems facing health care workers, our team focused further development efforts on concepts that simplify the doffing procedure, reduce the risk of contamination during use, improve comfort, improve visibility of the patient to the caregiver's face, improve the vision of the wearer, and reduce the number of steps and parts. Multiple iterations of the improved coverall and hood were produced based on this feedback, and design refinements were regularly shared with DuPont, the product commercialization partner (PCP). DuPont partners further refined the PPE design, incorporating factors such as cost and manufacturability, and then built the next set of prototypes (Figure 1 and Figure 2).

FIGURE 1. Design Iterations to Personal Protective Equipment Coveralls



Abbreviation: BCU, Johns Hopkins Bio Containment Unit.

FIGURE 2. Design Iterations to Personal Protective Equipment Hood and Respirator



Abbreviations: BCU, Johns Hopkins Bio Containment Unit; MSF, Médecins Sans Frontières; NIOSH, National Institute for Occupational Safety and Health; WHO, World Health Organization.

Final Design

The final ensemble was reduced to 3 product concepts:

1. An improved coverall, covering the user from the neck down
2. An improved hood, which would replace several parts and functions of the existing hood/goggle/mask ensemble covering the head and face
3. A combined single product incorporating the coverall and hood

The new coverall aimed to improve ease of doffing and reduce the risk of contamination during the process. Elements of the coverall design included enabling a cocoon-type doffing technique, a rear zipper, doffing tabs, protective flaps for the zipper, simplified labeling with instructions, finger loops to reduce risk of wrist exposure, and others. In the new hood design, elements included a clear, large face shield to improve visibility and comfort of use, reengineered air flow pattern that allowed fresh air to flow in over the inside of the face shield to reduce fogging, straps attached to the base of the shroud to secure it to the waist and aid during doffing, and a simpler combination that is more intuitive to use and has fewer separate parts, to simplify protection especially in the earliest stages of an outbreak. A training video demonstrates the features and donning and doffing of the new PPE: https://www.youtube.com/watch?v=App79IR0Y-c.

Doffing safety and time was improved by reducing the number of steps and simplifying the process dramatically. A rear-entry dual zipper protected by a double storm flap to prevent contamination and accidental unzipping was added to the back of the suit. The double storm flaps were reinforced with a rigid material to maintain configuration during use. Other features include doffing pull-tabs at the crown of the head, elastic seams at the waist, and fingerless gloves that keep inner gloves in place during removal of the coverall and outer gloves. Preliminary unpublished results from a small usability study showed that more than 75% of participants at field sites in Liberia and the United States found the doffing process for the new coverall and hood easier and more intuitive than a current standard PPE suit and doffing protocol.

MARKETING AND COMMERCIALIZATION

A key objective of the project was identifying a PCP early on in the project. Typically, for academic-based innovation and design efforts, considerable amount of work is done prior to engaging an outside PCP. Part of the CBID

Doffing safety and time was improved with the redesigned personal protective equipment by reducing the number of steps and simplifying the process.

The redesigned coverall, with a rear zipper, doffing tabs, finger loops to reduce risk of wrist exposure, and several other improved elements, aimed to improve ease of doffing and reduce the risk of contamination during the process.

Innovation Model is to engage the PCP and other key stakeholders from the very beginning of the project to ensure that what is designed is something the PCP is eager to commercialize. Given the considerable investment and employee time required to bring a new product to market, such early and sustained interaction significantly increases the likelihood of commercialization. In this project, after considered requests from several PPE manufacturers, DuPont was engaged as a partner under an agreement that the company would introduce products based on these designs into its normal product development and commercialization process, contribute design elements to reduce costs and improve performance, and prepare prototypes for use during the design-feedback iterations.

An important design target during the development process was to produce a design that could be manufactured and sold in large volumes at a price comparable to that of current PPE ensembles. The coverall and hood will use similar materials and manufacturing as is currently in use, and best estimates are that such price is not to be more than 20% higher than the price of existing designs. Manufacturing of the third product concept, the full body suit, will follow the final design and manufacturing of the coverall and hood.

CHALLENGES AND NEXT STEPS

At the conclusion of the USAID-funded part of the project, CBID design teams transferred designs, data, and future plans to DuPont and USAID. DuPont remains committed to manufacture and make available to their customers products based on concepts developed by this project. Prototypes of the coverall and hood products have undergone Department of Defense (DoD) testing and preliminary Centers for Disease Control and Prevention (CDC) testing (results have not been published yet). Preliminary results showed some improved performance as well as areas that could benefit from continued refinement.

Several challenges have arisen during the project. One involves changes pertaining to the regulatory clearance process for PPE, for both the designs and materials, in the view of the US Food and Drug Administration (FDA). Note that new material development was not the focus of this project. Additionally, other organizations that provide standards and guidance for PPE, primarily WHO, have been working to modify and refine those standards (including material selection, donning, doffing, and future product needs) over the years since the first outbreak. The identification and publication of these standards, and build-up of demand for better PPE products, will help accelerate company investment in production. It is anticipated that the coverall will enter large-scale manufacturing by the end of 2017. The new hood will continue to undergo technical development by DuPont based on results of usability studies.

In conclusion, using the tools and methodology of biomedical engineering and product design, including short-time Design Challenges as well as sustained work by Design Teams, and engaging all key stakeholders early on in an iterative design process, this team was able to design a new safer, simpler, and versatile PPE coverall and hood that has the potential to improve protection of frontline health care workers treating patients in infectious disease outbreaks around the world.

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LETTER TO THE EDITOR

Cost of Contraceptive Implant Removal Services Must Be Considered When Responding to the Growing Demand for Removals

Jill E Sergison,[a] Randy M Stalter,[a] Rebecca L Callahan,[a] Kate H Rademacher,[a] Markus J Steiner[a]

See related article by Christofield and Lacoste.

In a recently published article in *Global Health: Science and Practice*, "Accessible contraceptive implant removal services: an essential element of quality service delivery and scale-up," Christofield and Lacoste emphasized the growing unmet need for quality implant removal services.[1] The authors projected the numbers of implant removals in 69 Family Planning 2020 (FP2020) focus countries to more than double between 2015 and 2018 (from 2.2 million to between 4.9 and 5.8 million). The Implant Removal Task Force of the Implants Access Program Operations Group is developing best practices and solutions to meet this increasing demand.

In addition to the sheer numbers of implants that will require removal in coming years, the cost of removal services must also be considered. To begin to understand this impending resource need, we conducted a modeling exercise to forecast potential demand for contraceptive implant removals between 2016 and 2020 in the 5 countries with the highest levels of implant procurement in 2015 (Tanzania, Nigeria, Ethiopia, Kenya, and Zambia).[2] We then applied a direct cost (supplies and labor) of US$2.41 per removal derived from projections based on previously developed cost estimates for Kenya.[3]

Our analysis differed from Christofield and Lacoste in 2 ways:

1. Instead of assuming all implants are removed at the end of the implants' couple-years of protection (2.5 years to 3.2 years depending on the type of implant), we calculated the number of expected removals per year using cumulative discontinuation rates reported in the most recent Cochrane review assessing the contraceptive effectiveness and acceptability of implants compared with other reversible methods.[4]
2. We estimated the number of implants needed to be removed by 2020 from available Reproductive Health Interchange historical shipment data and from Reproductive Health Supplies Coalition Coordinated Supply Planning procurement projections from 2016–2019.[2,5] As with the Christofield and Lacoste model, we assumed a 12-month pipeline delay from in-country receipt of implants to insertion in a client.

According to our modeling, which includes procurement projections beyond 2015, annual implant removal demand rises to approximately 4.5 million by 2020 in just the top 5 implant-procuring countries (Figure). In 2018, our projection for removal demand in these 5 countries is 2.5 million compared with Christofield and Lacoste's projection of 4.9–5.8 million for all 69 FP2020 countries.[1]

We estimate the direct cost of providing 4.5 million removals (at $2.41 per removal) will be approximately $10.9 million (about $6.1 million in supply costs and $4.8 million in labor costs). Costs of supplies were taken from both the United Nations Population Fund's (UNFPA's) Access RH Product Catalog (commodity and consumable supplies)[6] and the IDA Foundation's Electronic Price Indicator (consumable supplies only).[7] Consumable supplies included sterile gloves, sharps boxes, syringes, scalpel blades, sterile drapes, and anesthetics. Instruments included items such as forceps, bowls, scalpel handles, scissors, and specula.[8]

To calculate a unit cost for reusable supplies, the total cost of the item was divided by an estimated number of procedures. We assumed that nurse-midwives would provide implant insertions and removals,[9] and labor costs were calculated using labor times from Avenir Heath's OneHealth Tool[10] and public-sector staff's average salary information in Kenya.[3] Based on our estimates, more than 22,747 staff hours/week, or 569 full-time equivalents (FTEs), will be required to provide these 4.5 million removals, with nearly 14,500 hours/week

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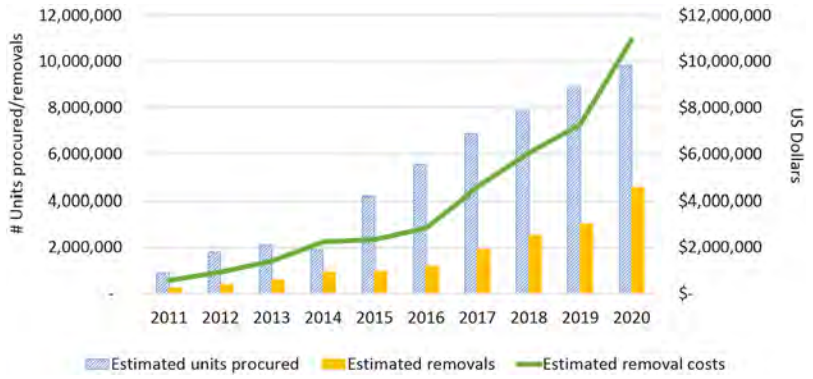
FIGURE. Estimated and Projected Number of Procurements and Removals of Implants, Including Estimated Removal Costs, Among the Top 5 Implant-Procuring Countries[a]



[a] Tanzania, Ethiopia, Kenya, Nigeria, and Zambia.

(363 FTEs) required in Ethiopia and Tanzania alone (for the more detailed analysis, see the Supplement). Of note, the annual cost estimates are substantially lower when modeling is based on self-reported implant use from Demographic and Health Surveys and Performance Monitoring and Accountability 2020 surveys rather than procurement projections from the Reproductive Health Supplies Coalition.[5] However, assuming all implants that are procured are eventually used, the total resource demand and removal cost would be the same but would be distributed over additional years.[11]

The best current source of information about expected demand for removals comes from well-controlled prospective studies. A randomized study of Implanon and Jadelle in 7 countries reported Year 1 and Year 2 continuation rates of 88.2% and 76.3%, respectively.[12] Similarly, in 2 recent prospective studies of implant use in Kenya, Year 1 continuation rates for implants were 91.8% in one study and 79% in the other.[13,14] In other words, one would expect up to 20% of implant users to ask for removals during the first year of use in settings where removal services are readily available.

Some evidence from service delivery data suggests current capacity to provide implant removals may be insufficient even before the expected large increase in demand for removals. A recent synthesis of service statistics in 3 sub-Saharan African countries (the Democratic Republic of the Congo, Tanzania, and Uganda) by EngenderHealth reported 136,737 insertions and only 4,092 removals between January 2014 and June 2016.[15] Admittedly, these service statistics data have limitations including: (1) timing of the insertions and removals during this 29-month period was not presented, so annual rates cannot be calculated; (2) it is possible that other service delivery groups in these geographic areas where EngenderHealth was providing implant insertions were providing removal services, and thus some removals may not have been captured in the EngenderHealth statistics; and (3) insertion data collection is more complete than removal data collection. Despite these data limitations, the overall 3% removal rate over the 29-month period is sufficiently low to raise questions about adequate access to removal.

The need for implant removals will increase dramatically in the coming years, and donors and service delivery programs must be poised to mobilize appropriate resources for quality and timely implant removal services. Dramatic increases in demand for resources for implant removal services will coincide with continued or increasing demand for resources to provide implant insertions. Rigorous collection, synthesis, and analysis of routine service statistics of implant insertions and removals are needed to ensure resources are appropriately balanced in countries such

Annual implant removal is projected to rise to about 4.5 million by 2020 in just the top 5 implant-procuring countries.

It will cost approximately $10.9 million to provide the 4.5 million implant removals.

More than 22,000 staff hours/week will be required to provide these 4.5 million implant removals.

A recent synthesis of service statistics data from 3 sub-Saharan African countries reported more than 136,000 implant insertions but only about 4,000 removals between 2014 and 2016.

Donors and service delivery programs must be poised to mobilize appropriate resources for quality and timely implant removal services.

that women have access to high-quality services that guarantee implant removal upon demand.

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