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Front cover: A family planning provider in Tanzania counsels a client of mobile outreach services on IUDs. © 2015 Sala Lewis/EngenderHealth.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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EDITORIAL

Helping Babies Breathe—Beyond Training

Steve Hodgins[a]

The revised Helping Babies Breathe training package now emphasizes the need for regular practice and quality improvement—an important improvement since more is needed than one-off training to have substantial impact on asphyxia-related newborn mortality.

See related articles by Kamath-Rayne.

HELPING BABIES BREATHE, FIRST EDITION

The article by Kamath-Rayne et al.,[1] in this issue of GHSP, reports on the review and revision of a widely deployed effort to reduce preventable asphyxia-related mortality and morbidity in newborns—Helping Babies Breathe (HBB). The American Academy of Pediatrics (AAP) developed this 1- to 2-day simulation-based training package on newborn resuscitation, finalizing it in 2010. Together with partners, including the World Health Organization, the United States Agency for International Development, Save the Children's Saving Newborn Lives program, the National Institute of Child Health and Human Development, and Laerdal Global Health, AAP subsequently introduced the program widely. The implementation effort, to date, has consisted primarily of large-scale campaigns to roll out the training (mainly on an in-service basis) and—in many cases—providing newborn resuscitation practice manikins in the health facilities where those trained are based. Impressively, close to half a million health workers across more than 80 countries have been reached with this training since HBB was first introduced.[2]

PRACTICE, NOT ONLY TRAINING, IS NEEDED

As acknowledged by Kamath-Rayne et al., it is evident that even delivery of a well-designed training package is insufficient to reliably change clinical practice and improve outcomes. The article cites the 3 key elements of the "Utstein Formula for Survival" as *medical science*, *educational efficiency*, and *local implementation*. Under the first version of HBB, attention was directed primarily at the first 2 elements. Under the second edition of HBB,[3] it has been better recognized that serious attention must also be directed to 2 aspects of the third element (local implementation): ongoing practice and quality improvement (Figure). This is an important step forward. As any musician or athlete is well aware, real skill mastery is not accomplished through just good training; it requires regular, serious practice. The same applies for skills essential for lifesaving clinical procedures like bag-and-mask resuscitation. And, with regular practice, comes not only skills but also the confidence to apply those skills when they're needed.

CLINICAL LEADERSHIP

It cannot be expected, however, that health workers will all, reliably and on their own initiative, regularly practice such skills. Clinical managers, notably those in charge of maternity services, must clearly communicate that, since asphyxia in the newborn is by far the most common life-threatening situation health workers will encounter at birth, it is the job of *every* health worker who could be present at birth to quickly and competently jump into action to resuscitate non-breathing newborns. And—to be reliably ready to do so—those who regularly attend births must regularly *practice* bag-and-mask resuscitation.

Clinical managers also have a responsibility to ensure that:

- there are functional *staffing arrangements* in place, such that all births are reliably attended by health workers with the necessary skills (including newborn resuscitation), and
- the needed *material conditions* for timely and effective resuscitation are met, notably, availability of a suitable space in the immediate area where the birth takes place and immediate availability of all needed resuscitation equipment, in functional and clean condition.

ANTICIPATING AND PREVENTING ASPHYXIA

As important as resuscitation is, our response to asphyxia-related morbidity and mortality in the

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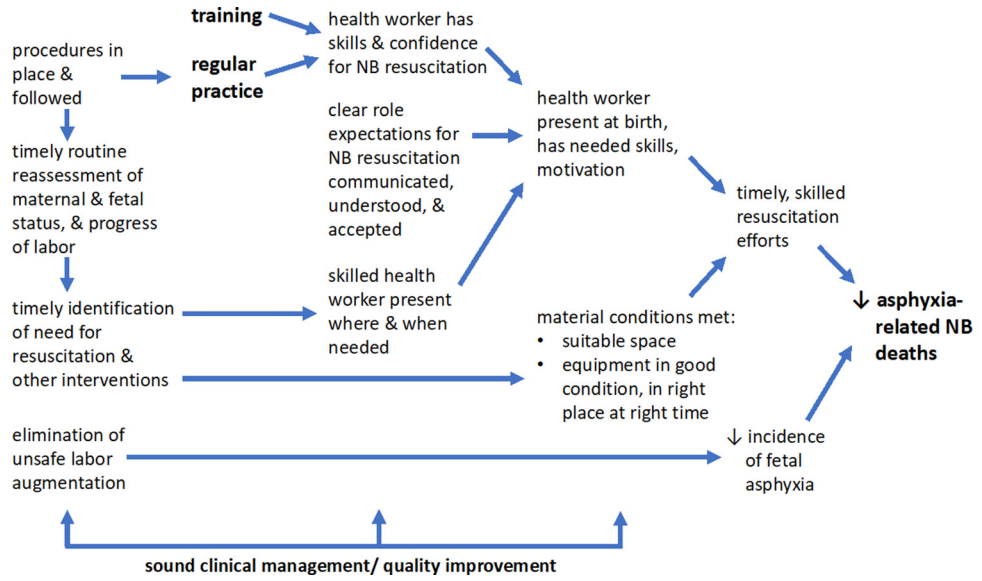
FIGURE. What Will It Take to Drive Down Asphyxia-Related Newborn Deaths?



newborn should not be confined to tertiary prevention, i.e., managing cases already potentially at death's door. There are important opportunities to intervene earlier in the causal process, with primary and secondary prevention strategies.

Cases of babies born asphyxiated and failing to spontaneously initiate breathing can usually be anticipated with regular, competent assessment of the laboring mother and her fetus. Abnormal fetal heart rate and meconium can signal fetal distress. With good labor management, problems can be picked up earlier and the health care team can mobilize to take timely action, ensuring that needed procedures are initiated on a timely basis.

In many clinical settings, labor is augmented using oxytocin, without adequate support to the mother, close monitoring of labor, and capacity to provide prompt emergency care. A predictable result is avoidable uterine hyperstimulation and fetal hypoxia, often with fatal consequences. Clinical managers responsible for childbirth care facilities have a responsibility to eliminate such unsafe practices.

WHAT WILL IT TAKE TO MAKE A REAL DIFFERENCE?

HBB provides good hands-on training in newborn resuscitation. But rollout of a training package alone—even if it includes content emphasizing the importance of practice and quality improvement—cannot notably reduce asphyxia-related newborn morbidity and mortality. As recognized by Kamath-Rayne et al., and as reflected in the new HBB second edition materials, serious attention must also be directed at an array of implementation issues associated with timely, competent resuscitation of the non-breathing newborn. Furthermore, if it is our ambition to significantly reduce the burden of asphyxia-related newborn mortality, we must also give serious attention at earlier stages in the pathological process. Those working in the global newborn space who have resources and leadership responsibilities—take note.

Since newborn asphyxia is by far the most common life-threatening situation health workers will encounter at birth, it is the job of *every* health worker who could be present at birth to quickly and competently jump into action to resuscitate non-breathing newborns.

Competing Interests: None declared.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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EDITORIAL

New Evidence on Carbetocin: Another Arrow in Our Quiver

Steve Hodgins[a]

Carbetocin is more heat stable than oxytocin with at least equivalent efficacy for preventing postpartum hemorrhage. It will certainly be helpful if the supplier can make it available in low-income country settings at a price comparable to oxytocin. But even so, programs will still need oxytocin and other uterotonic medications.

On August 23, 2018, the *New England Journal of Medicine* published the results of the large, multi-country, World Health Organization (WHO) CHAMPION trial,[1] a non-inferiority study testing carbetocin against synthetic oxytocin for prevention of postpartum hemorrhage. Publication of this trial created some buzz in the international media, with reports in BBC and the *New York Times*, including quotes from WHO officials claiming that wider use of carbetocin could "revolutionize our ability to keep mothers ... alive."[2] That may be claiming too much.

Uterotonics have a critically important role in obstetrics, notably for labor induction and augmentation and for prevention and treatment of postpartum hemorrhage. Whatever the indication, in using these drugs clinicians seek to optimize for *efficacy* and *safety*, taking into account—among other considerations—characteristics of the specific drugs, dosage, route of administration, clinical indications, and patient characteristics.

Synthetic oxytocin has been widely used in obstetrical practice since the 1960s. Carbetocin—more recently introduced—is an oxytocin analog, acting on oxytocin receptors in the myometrium, but in some important respects it differs from synthetic oxytocin: its half-life in circulation is considerably longer and it is more heat stable.[3]

CLINICAL EFFICACY

Heat-related degradation of oxytocin is well-documented,[4] and studies in both Africa[5] and South Asia[6] have found a significant proportion of oxytocin sold at retail level falling outside of manufacturer specifications. The greater heat stability of carbetocin means there is more certainty about the actual delivered dose than there is for oxytocin. But this doesn't necessarily translate into any significant difference in *clinical efficacy*. In the new study, the authors claim oxytocin has "unsatisfactory real-world efficacy as a result of sensitivity to heat."[1] However, the evidence they cite consists only of assays of the amount of active pharmaceutical ingredient in the vials sampled,[7] *not* effects on patient outcomes.

A recently published trial[8] provides good evidence that route of administration matters; in a double-blinded, head-to-head comparison of oxytocin 10 IU administered intravenously versus intramuscularly, the investigators found significant differences in clinically important endpoints, with better results for intravenous administration than for intramuscular for blood loss ≥1000 cc (adjusted odds ratio [aOR], 0.54; 95% confidence interval [CI], 0.32 to 0.91) and need for transfusion (aoR, 0.31; 95% CI, 0.13 to 0.70). So route of administration matters. But no similarly unequivocal evidence is available for a difference in clinical efficacy between 5 IU and 10 IU. A Cochrane review by Westhoff[9] found 5 trials comparing either 5 IU or 10 IU to placebo. In a pooled comparison, with blood loss ≥500 cc as the endpoint (Analysis 2.4), pooled effect sizes were similar for 5 IU (relative risk [RR], 0.42; 95% CI, 0.17 to 1.01) and 10 IU (RR, 0.47; 95% CI, 0.38 to 0.59). The Table looks a little more closely at these trials.

From these trial results, it is certainly fair to say that evidence for clinical efficacy is better for 10 IU than for 5 IU (and that evidence for effectiveness of intramuscular administration of oxytocin 5 IU is particularly weak)[*]; it would not be fair to say the evidence is definitive.

SAFETY

In addition to efficacy, an important consideration for uterotonics is *safety*, particular when used for labor augmentation. In many parts of the world, oxytocin (and sometimes other uterotonics) is commonly used for

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[*] The Abdel-Aleem trial,[13] with a total sample of 1,950, provides robust evidence of clinical benefit of 10 IU administered intramuscularly. The only 2 studies using 5 IU administered intramuscularly were De Groot[10] and Poueschmann,[11] both of which were very small and therefore lacking in adequate statistical power for our clinical endpoints of interest. As a result, they provide little evidence one way or the other about clinical efficacy of 5 IU administered intramuscularly.

TABLE. Summary of Current Evidence on 5 IU or 10 IU Oxytocin Compared With Placebo

Study	N	Route of Administration	Dose (IU)	RR for Blood Loss ≥500 cc (95% CI)	Other Clinically Important Endpoints: RR (95% CI)	Methodologic Issues
De Groot (1996)[10]	221	IM	5	0.83 (0.57, 1.22)	Blood loss ≥1000 cc: 0.80 (0.34, 1.87) Therapeutic uterotonic needed: 0.99 (0.55, 1.78)	Provisions for blinding not specified
Poeschmann (1991)[11]	52	IM	5	0.60 (0.27, 1.33)	Blood loss ≥1000 cc: 0.57 (0.10, 3.14) Therapeutic uterotonic needed: 0.17 (0.001, 3.42)	Trial ended early due to "organizational issues"
Pierre (1992)[12]	970	IV	5	0.29 (0.21, 0.41)	Blood loss ≥1000 cc: 0.33 (0.14, 0.77)	Allocation to treatment vs. control done even-odd, by order of registration Those measuring blood loss were not blinded to treatment status
Abdel-Aleem (2010)[13]	1,950	IM	10	0.53 (0.39, 0.74)	Blood loss ≥1000 cc: 0.52 (0.13, 2.08) Therapeutic uterotonic needed: 0.39 (0.26, 0.58)	
Nordstrom (1997)[14]	1,000	IV	10	0.56 (0.46, 0.70)	Blood loss ≥1000 cc: 0.71 (0.45, 1.10) Therapeutic uterotonic needed: 0.57 (0.39, 0.82)	

augmentation under unsafe conditions (not reliably ruling out mechanical obstruction, administering the drug intramuscularly or by intravenous bolus, failing to closely monitor the laboring woman, and not having timely access to emergency cesarean delivery). Because of dangers associated with uterotonic use during labor, oxytocin is designated as a high-alert medication.[15] Wide use under unsafe conditions makes an important contribution to poor birth outcomes in South Asia[16–20] and elsewhere.[21]

Carbetocin would certainly be no safer in this respect. Given its considerably longer half-life, arguably, deploying it widely in place of oxytocin could increase risk of adverse outcomes related to such inappropriate use—notably fetal asphyxia and uterine rupture.

ACCESS

Oxytocin is an inexpensive medication; the median bulk price documented in the International Medical Products Price Guide from Management Sciences for Health is US$0.17 for a 10 IU amp[22]; the price for oxytocin that the United Nations Population Fund currently has posted on its website is US$0.28 per amp.[23] And oxytocin is widely available and produced by many generic pharmaceutical manufacturers, although there are relatively few selling to low-and middle-income country markets that meet current global good manufacturing practices quality standards for oxytocin. For carbetocin to be a viable alternative to oxytocin, it would need to be similarly inexpensive and ubiquitous. It is reassuring to read that Ferring Pharmaceuticals, the sole supplier of carbetocin, hopes to make it "available in public-sector facilities of high-burden countries at an affordable and sustainable price,"[1] but we're not there yet.

For carbetocin to be a viable alternative to oxytocin, it would need to be as inexpensive and ubiquitous as oxytocin.

A QUIVER OF UTEROTONICS

Carbetocin is one of a suite of medicines that act on the myometrium and that, together, constitute an important set of tools for achieving better birth outcomes. It may be that carbetocin will eventually partially replace the use of some of the others for certain indications, in certain circumstances. But there will continue to be a need for oxytocin, misoprostol, tranexamic acid, and ergot alkyloids. Optimal strategies for how best to use this complement of drugs will vary by setting and need to take into account characteristics of the drugs, available evidence on effectiveness and safety, and the situation on the ground.

Competing Interests: None declared.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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COMMENTARY

Beyond the Safe Motherhood Initiative: Accelerated Action Urgently Needed to End Preventable Maternal Mortality

Mary Ellen Stanton,[a] Barbara E. Kwast,[b] Theresa Shaver,[a] Betsy McCallon,[c] Marge Koblinsky[d]

Many countries will need to double, or more than double, their current annual rate of reduction of maternal mortality to ensure sufficient progress toward national targets and the global Sustainable Development Goals. Dedication to the principles and actions of quality, equity, dignity, social justice, and human rights are key.

Following the 30th anniversary of the launch of the global Safe Motherhood Initiative, the world now looks ahead to renewing its visionary goal of ending preventable maternal mortality. Progress toward that aspiration is often equated with the 44% reduction in global maternal mortality between 1990 and 2015.[1] Yet this reduction was still far from achieving Millennium Development Goal (MDG) 5 of reducing the maternal mortality ratio (MMR) by three-quarters between 1990 and 2015, and it is even farther from achieving Sustainable Development Goal (SDG) 3, which aims to attain a global MMR of less than 70 deaths per 100,000 live births by 2030.

Today there are more than 300,000 maternal deaths each year worldwide.[1] More than 200 million women wish to avoid, delay, or end childbearing but are not using contraception.[2] The face of these numbers is increasingly an adolescent girl—complications during pregnancy and childbirth are the leading cause of death of 15 to 19-year-old girls globally.[3]

While facility delivery is rapidly increasing, even now more than 30 million women deliver yearly without the care of a skilled birth attendant.[4] Many, including those who do deliver in hospitals, receive substandard care in inadequate facilities and face disrespect and abuse from exhausted health care workers who are often disrespected themselves. Most significant of all is the unconscionable disparity between rich and poor nations—the lifetime risk of maternal death is more than 100 times greater in sub-Saharan Africa than in Europe. Furthermore, within nations there are inequities between subpopulations. Among the multitude of determinants, conflict, poverty, inequity, and unrealized political promises are significant factors. And, while this article focuses on maternal mortality, we would be remiss not to mention the significant burden of maternal morbidity and disability, as well as the 2.6 million newborns who die every year and an equal number who are stillborn.[5]

The overall MMR annual rate of reduction needed to reach the SDG target for maternal mortality reduction is −7.5%, significantly higher than the −5.5% needed to meet MDG 5.[6] It is sobering to note that the annual rate of reduction attained globally was only −3.0% between 2000 and 2015. Across the globe, progress in maternal mortality reduction within and between countries is highly variable. In some countries progress is stalling, with annual rates of reduction between 2005 and 2015 slowing in relation to earlier rates.[1] Even maintaining the current positive momentum in other countries will not be sufficient to meet the global SDG for maternal mortality reduction. Although there are limitations to drawing conclusions from point estimates of maternal mortality, apparent slowing or stalling in some countries should be treated as an alert—analyzed and urgently addressed.

At this point, substantially accelerated and continuous progress requiring additional investment is urgently needed across most countries. Yet after 2013, there has been a leveling out of development assistance for health funds for maternal health.[7]

THE CHANGING SCENE AFFECTING MATERNAL HEALTH

Global understanding of the determinants of maternal mortality and a global vision of ending preventable maternal mortality have resulted in a shift in global efforts from the "Safe Motherhood Initiative" launched in 1987 in Nairobi to "Ending Preventable Maternal Mortality" in 2014 in Bangkok.

Over the decades, technical and programmatic achievements included attention to the major direct

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causes of maternal mortality, the competencies of the skilled birth attendant, the place of birth, and the enabling environment. The focus widened as morbidity became more visible, initially to include obstetric fistula, and then to other morbidities and disabilities.

Programming approaches integrated infectious disease control, especially HIV and malaria, and family planning. Furthermore, the strengthening of health systems to ensure communication and the means of referral within and between levels of care and to ensure quality of care was identified as indispensable. Indeed, maternal survival has been identified as a bellwether for strengthened health systems and inter-sectoral collaboration.

There was growing recognition that maternal and perinatal health are inextricably linked. Gradually programmatic approaches became oriented to both maternal and newborn care. Actions taken to achieve Ending Preventable Maternal Mortality and Every Newborn Action Plan goals are being conducted in close coordination.

The global Ending Preventable Maternal Mortality strategy[8] moves beyond emphasis on clinical care to address the social, political, and economic determinants of maternal survival and health that have contributed to countries' failures and successes.

Significantly, maternal biomedical interventions, community approaches, and financial incentives, to name just a few, have been subjected to scientific inquiry, from qualitative studies to randomized control trials to implementation research. The lack of evidence that characterized obstetrics and midwifery since the beginning of these disciplines is no longer the norm. In recent years, expert groups led by the World Health Organization (WHO) representing all regions of the world have scrutinized increasingly available studies and formulated evidence-based recommendations and guidelines for normal care and complications, community mobilization, and health promotion.

The *Maternal Health Lancet Series 2016*,[9] following the first series from 2006, included analyses of drivers and external shocks that influence progress. "Too little, too late" and "too much, too soon" characterize the poor quality of care and the rapidly increasing, inappropriate medicalization of care.

Until recently, maternal health commodities were almost entirely neglected. The UN Commission on Life-Saving Commodities for Women and Children brought international attention at the highest levels and galvanized attention to production, supply, and use of affordable, high-quality products. Increasingly at national levels, there is testing of drugs for potency and attention to stock-outs and proper use, with initial attention to uterotonics, anticonvulsives, and antibiotics.

During the past decade, attention has gone beyond statistics and biomedical interventions, to focus on women themselves and their experience of maternity care. Qualitative and quantitative research and media reports have exposed disrespect and abuse of women in childbirth in health facilities that includes physical abuse; lack of privacy, confidentiality, and consent; non-dignified care including verbal abuse; neglect and even abandonment or detention in facilities; and lack of resources in the facilities including bed space, light, water, and sanitation.[10,11] Such mistreatment is increasingly recognized as poor quality of care and one of the biggest barriers to women seeking care.

The issue of respect has gained traction with listening to women now recognized as necessary. Human rights and social justice issues were highlighted in the White Ribbon Alliance's 2011 charter, *Respectful Maternity Care: The Universal Rights of Childbearing Women*,[12] and in WHO's 2014 statement, *The Prevention and Elimination of Disrespect and Abuse During Facility-Based Childbirth*.[13] The right of women to determine where and with whom they will give birth and to have a companion of choice is critical. Recently, WHO guidelines for antenatal and intrapartum care have specified guidance for a positive pregnancy and birth experience. Also, WHO standards for improving quality of maternal and newborn care in health facilities delineates both the experience and the provision of care as part of a forward-thinking framework for quality of care.

There is growing understanding that working conditions for midwives and other health workers—including low pay, excruciatingly long hours, inadequate supplies, and being mistreated themselves—can contribute to poor treatment of women.[14] Nations are increasingly funding their own health programs as external support diminishes and becomes a smaller proportion of overall costs. Yet still of concern are the considerable out-of-pocket costs that can impoverish families and lead to death of mothers or their newborns.

A −7.5% annual rate of reduction is needed to reach the SDG target for maternal mortality reduction, significantly higher than the −5.5% needed to meet the MDGs.

"Too little, too late" and "too much, too soon" characterize the poor quality of care and the rapidly increasing, inappropriate medicalization of care.

CONTEXT MATTERS

Since the 1990s, national successes in maternal mortality reduction have ridden the waves of economic growth, translating such growth into better

infrastructure, referral systems, and care. Conversely, conflict, natural disasters, and infectious disease outbreaks have created additional vulnerabilities for childbearing women. Population migrations and the recent Zika and Ebola outbreaks have highlighted the reality of these concerns.

Societal, technologic, and political shifts, as well as well-intentioned interventions, may result in variable outcomes for maternal health and survival in the coming decade:

- Growing international attention to noncommunicable diseases brings important linkages with hypertension, obesity, and diabetes to maternal health programs to avert many direct and indirect causes of maternal ill health. Likewise, attention to water, sanitation, and hygiene (WASH) is critical. Nevertheless, we must recognize that this growing agenda in public health may redirect attention from the unfinished agenda of maternal and child survival.
- The use of financial incentives for women and health care providers has provided the impetus to rapidly increase coverage of care in health facilities for birth. This has led, in some places, to women crowding into inadequate facilities with under-resourced services, supplies, and personnel, where even the basics of quality, respectful care are not available. In many countries, improved use of facility care for birth has not been linked with improved outcomes—signaling greater need for investment in quality improvement.
- Decentralization brings opportunity to local leaders and structures to determine their own priorities and ensure accountability. It also demands capacities to plan, budget, implement, and monitor programs sub-nationally. Building these competencies is not uniformly rapid, even as it provides great opportunities when excellent leadership is in place.
- Urbanization brings many closer to health care services, but slums and the complexity of urban environments may subject childbearing women and their babies to infectious diseases, poor sanitation, and stress of a different kind than experienced in a home village.
- The expansion of private-sector services has improved access for many, but without consistent and enforced regulations and standards, quality varies dramatically and accountability is too often lacking. Companies that are developing new markets for high-cost equipment can create demand and draw on budget allocations in places where there is insufficient basic equipment to detect and treat common life-threatening complications.
- As training in global standards and vital skills that save the lives of women and newborns is a growing priority for nurses, doctors, and midwives, newly trained staff face constant rotation within facilities and countries, denying them the ability to retain these skills effectively. Furthermore, once trained, health workers may become more attractive to private facilities or foreign countries who can pay more, contributing to the challenge of retaining a skilled health workforce.
- Innovations provide great promise as we tackle the problems of finding better, cheaper diagnostics and treatments, and using communication technologies to their full advantage. At the same time, known effective approaches or systems improvements may be overlooked as we look for "silver bullets."
- Mobile technologies and social media have expanded messaging to and communication with consumers of care and diminished the isolation of rural centers of care. However, the improved messages to families may drive increased expectations and use of services before services are ready and may incur considerable cost without evidence of improvement in outcomes or health impact.
- Economic motivation can be galvanizing to create services but may also be detrimental to women's care and health. Expectation of informal payments—even in environments where there is a "free" maternity care policy—can result in poor quality or delay or abandonment of women in urgent need.
- While there has been increased attention to the issue of adolescent pregnancy, a multi-sectoral approach is also required to tackle restrictive laws and policies, health worker bias, social and cultural support for child marriage, and limited knowledge and support for decision making by adolescents themselves.
- The increasing medicalization of pregnancy and birth has expanded access for some women to lifesaving care while also subjecting other women to unnecessary medication and surgery, including induction and augmentation of labor and cesarean delivery, resulting in such complications as uterine rupture, infections, iatrogenic fistula, hemorrhage in subsequent

pregnancies, and even death. In addition, the medicalized environment can result in an alienating environment for women during labor and birth and unnecessary costs to the health system.

RENEWING THE COMMITMENT

The SDGs for 2030 include an ambitious target for maternal mortality reduction in just 12 years. In the face of stalled progress in some countries and an inadequate rate of progress in all but a few countries, many countries will need to double, or more than double, their current annual rate of reduction of maternal mortality to ensure sufficient progress toward national targets and contribution to the global SDG and universal health care.

Each nation will need to set its own course with a rededication to the "unfinished agenda" of ending preventable maternal mortality with context-specific actions. These include effective policies, adequate budgets, and state-of-the-art monitoring and quality improvement systems.

The Global Financing Facility, is an important "country-powered" effort to reduce the massive funding gap for reproductive, maternal, newborn, child, and adolescent health and nutrition programs. [15] The promise of new economic resources, partnerships and innovation is welcome. We must put these assets to good use.

There must be a dramatic paradigm shift so that women are valued as drivers of their own health, not mere passive recipients of care. Dedication to the principles and actions of quality, equity, dignity, social justice, and human rights are key to catalyzing additional and vital action toward our vision: **No woman, no matter in what country she resides, should die of complications during pregnancy, childbirth or the postpartum period, nor lose her newborn in the process.**

Success will require that ending preventable mortality remains a political priority. [16] This will necessitate strengthening of networks, individuals, and organizations to keep up the pressure, push for investment in what works, be bold in tackling new challenges, and ultimately support nations to have resilient health systems to meet the needs of all people.

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In the face of stalled progress, many countries will need to double, or more than double, their current annual rate of reduction of maternal mortality to ensure sufficient progress toward national and global targets.

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ORIGINAL ARTICLE

The Net Promoter Score (NPS) for Insight Into Client Experiences in Sexual and Reproductive Health Clinics

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The NPS measures a customer's likeliness to recommend a company to a friend or colleague on a 0-to-10 scale. Pilot testing in 4 countries suggests the NPS can also be successfully used in nonprofit clinics and among low-literacy populations. Combining the NPS with client demographic and service-use data can provide a powerful tool for identifying populations for whom the client experience can be improved.

Resumen en español al final del artículo.

ABSTRACT

The Net Promoter Score (NPS) metric, commonly used by Fortune 500 companies to measure the customer experience, is calculated using a 0-to-10 scale to answer 1 question: "How likely is it that you would recommend [company X] to a friend or colleague?" Despite the value of this methodology as a predictor of growth and indicator of customer satisfaction in for-profit industries, uptake of the NPS has been slower in the social sector due to concerns about its applicability and acceptability in noncommercial settings, particularly among low-literacy populations. To address these concerns, we conducted a series of small-scale pilots in El Salvador, India, Kenya, and Nigeria to test different implementation approaches of the NPS in sexual and reproductive health clinics—including face-to-face interviews, a guided drop box, integration of the NPS question into an existing client exit interview, and self-administered and volunteer-assisted online surveys using tablets in clinics—and compared the traditional 0-to-10 number scale with an emoji-face scale. Findings showed that the NPS can be effectively adapted for use in low-resource health clinics among low-literacy clients using the number scale. There was no statistically significant difference in mean likeliness to recommend services when using the emoji versus numerical scales in India; however, there was a statistically significant difference when using the guided drop box approach versus face-to-face interviews. When combined with demographic and service-use questions, the NPS generated useful insights on client groups that were more or less likely to recommend the services. While providing an online survey on tablets can be an efficient methodology for implementing the NPS, self-administered approaches may be limited by a client's level of literacy or comfort with technology. For those client populations with a lower NPS, we advise using a qualitative feedback process that can elicit critical feedback to identify actions to improve their experience. Our experience with testing and implementing the NPS in SRH clinics in diverse settings suggests it is a promising approach to gaining insight into the client experience in nonprofit health care settings.

BACKGROUND

In the business world, customer feedback is widely recognized as critical for providing information to improve products and services that, in turn, enable a company to increase sales and market share. Similarly, the not-for-profit sector has increasingly recognized the importance of listening to beneficiaries as a mechanism for improving the effectiveness of social programs.[1]

Within the field of reproductive health, improving the quality of services—encompassing both clinical standards and the patient experience—is a key component to increasing the use of voluntary family planning and generating demand for services.[2] While a positive patient experience is a priority in itself, it is also important because it improves correct family planning method use, contraceptive continuation rates, and consistent use of health services.[2] The importance of a positive experience is amplified when considering the role of word-of-mouth referrals in marketing strategies[3] and the potential for generating demand for family planning services in countries with low modern contraceptive prevalence rates (mCPRs).

Family planning service delivery organizations, including International Planned Parenthood Federation (IPPF), have a long history of obtaining client—also known as patient or beneficiary—feedback on their experience with seeking and receiving services. Like most health care providers, we have traditionally relied on

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lengthy client satisfaction surveys to gather that feedback. While such client satisfaction surveys can provide useful information, our field-based partners report that these surveys are cumbersome, expensive, and often result in an overabundance of data that are difficult to analyze, interpret, and prioritize. Conversely, asking whether clients would recommend the services to others using a binary yes/no scale frequently results in more than 95% of clients reporting that they would recommend the services. In both cases, clinic staff have difficulty using such data to improve the patient experience.

Furthermore, IPPF operates across a myriad of country contexts, client populations, and service delivery settings, delivering hundreds of millions of sexual and reproductive health (SRH) services in 46,000 service delivery points located in more than 140 countries. Such a wide range of contexts makes the identification of a simple, standardized client satisfaction survey challenging.

To strengthen, streamline, and systematize feedback mechanisms on the patient experience, we began testing the use of the Net Promoter Score (NPS) in SRH clinics with low-literacy populations as an alternative approach to monitoring and improving the client experience.

The traditional Net Promoter Score question uses a 0-to-10 scale and asks customers "How likely is it that you would recommend [company X] to a friend or colleague?"

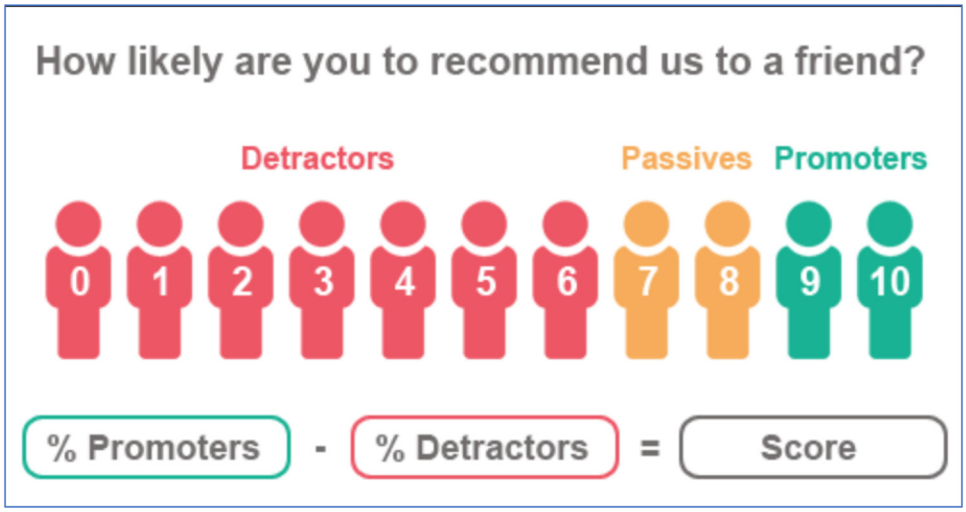
THE NET PROMOTER SCORE

In 2003, Frederick F. Reichheld argued that asking a single survey question about a customer's willingness to recommend a product or service served as a strong predictor of growth in sales and revenue.[4] In response to the question, "How likely is it that you would recommend [company X] to a friend or colleague?", customers would rate their willingness to recommend a product or service using a 0-to-10 scale. Often, this question was followed by an open-ended question, "What is the reason for your score?"

The NPS is calculated by first segmenting customers into 'promoters' (those rating their willingness to recommend as a 9 or 10), 'passives' (those rating their willingness as a 7 or 8), and 'detractors' (a willingness to recommend of 6 or below) and then subtracting the proportion of customers that are detractors from the proportion that are promoters, resulting in an NPS ranging from −100 to 100 (the final score is shown as an integer, not a percentage) (Figure 1).

Research showing that this simple metric is a stronger predictor of growth than more complicated and expensive customer satisfaction measures has led to widespread use of the NPS by global companies.[5] Although not without its critics,[6] the NPS is widely used due to its simplicity, ease of implementation, and potential for benchmarking within an industry, against competitors, and internally across products, sites, and time. As shown by the emerging body of evidence, social sector organizations have begun to incorporate the NPS into their research—testing how to adapt and use it in nonprofit settings.[7–13]

FIGURE 1. Calculating the Net Promoter Score



Source: How Likely: https://www.howlikely.com/resources/nps-what-exactly-is-it

However, within the social sector, questions remain regarding the degree to which a measure developed for the profit sector is applicable in nonprofit settings. Within the context of international SRH health care and family planning services, IPPF questioned whether the NPS could be adapted for use in low-resource and low-literacy health care settings across different cultural contexts; whether it would generate meaningful data to inform service improvements; whether generating the data would streamline the data collection burden or require significant additional resources; and whether the methodology would be acceptable to clients and staff.

METHODOLOGY

In order to make the NPS applicable for use in a health care setting, the NPS question was revised to "How likely are you to recommend this clinic to someone who needs similar services to those you received today?" The underlined section was added to address the potential that someone might hesitate to recommend the services—not because of a bad experience but rather because they would not want a friend or colleague to know they accessed SRH services, in general, or specific services such as postabortion care or HIV care and treatment.

To address the challenges of traditional client satisfaction surveys, and with the aim of finding a standardized metric that could be implemented using approaches that could be adapted for a variety of contexts, we identified opportunities within existing programmatic initiatives to iteratively test aspects of using the NPS in SRH health care clinics. Over the span of a year, we field tested the NPS as a mechanism to gather feedback about the client experience in 4 countries, using convenience samples of high-volume clinics and randomly sampling family planning or SRH clients as they exited services (Table 1):

- First, to assess the feasibility and acceptability of implementation approaches in low-resource clinical settings among clients with low-literacy levels, the NPS was implemented among 188 SRH clients in 2 clinics in Mumbai, India.
- Second, to assess whether the methodology could be used to generate meaningful comparative information about the experience of different client groups, the NPS question was integrated into an existing client profile exit survey among 590 family planning clients in 9 clinics in Kenya and Nigeria.
- Third, the feasibility of a self-administered NPS survey using tablets with the questionnaire in DHIS 2 was assessed among 226 SRH health clients in 3 clinics in El Salvador.

Testing the Feasibility of Using NPS Approaches Among Low-Literacy Clients

The experience in India was designed to assess:

- whether different implementation approaches elicited different responses among low-literacy clients,
- which scale types (numerical and pictorial) were appropriate for low-literacy clients and whether these scales elicited different responses,
- whether actionable feedback could be obtained from the open-ended 'why' question among low-literacy clients, and
- the general acceptability of the NPS methodology by staff.

Recognizing that low-literacy clients often struggle or might be reluctant to complete a written feedback form, 2 alternative implementation approaches were tested in 2 clinics in India (Figure 2):

1. Face-to-face client exit interviews: a trained interviewer used a short, structured survey to collect the client's likelihood of recommending the clinic to someone needing similar services
2. A guided drop box approach: the interviewer explained the purpose, handed the client a strip of paper with the rating scale, and directed her to a drop box to mark in private the likeliness of recommending the clinic

Trained female interviewers systematically alternated between conducting face-to-face interviews (n=92) in Hindi or Marathi, based on client preference, and guiding clients to complete a simple form in private by circling their response on the likelihood that they would recommend the services and placing the response in a drop box on their way out of the clinic (n=96). Using the Analysis ToolPak in Microsoft Excel 2016 for all statistical analysis in our NPS study, we calculated the mean value for likeliness to recommend for the interview and for the guided drop box groups

TABLE 1. Overview of Net Promoter Score Iterative Testing

	India	Kenya and Nigeria	El Salvador
Sample size	N=188	N=590	N=226
What was tested	Feasibility and acceptability of implementation approaches in low-resource clinical settings among clients with low-literacy levels	Whether the methodology could be used to generate meaningful comparative information about the experience of different client groups	Feasibility of a self-administered NPS survey using tablets with an online survey in DHIS 2
Description	A convenience sample of 2 peri-urban clinics was selected based on client population (low literacy), client volume, proximity to reach both clinics in a single day, and willingness to participate. Female clients exiting the clinic were asked how likely they are to recommend the service. Interviewers alternated between face-to-face interviews and guiding the respondent to a drop box to circle her response in private as she exited the clinic. The survey alternated between an 11-point numerical scale and an 11-point emoji-face scale. Face-to-face interviews included an open-ended 'why' question. Twenty clients were contacted for follow-up via telephone.	A convenience sample of 9 service delivery sites (6 in Kenya and 3 in Nigeria) was selected based on client volume for family planning services, representation of both static and outreach clinics, and willingness to participate. The NPS question on likeliness to recommend services was inserted into an existing client profile survey. Clients were surveyed via face-to-face interviews as they exited family planning services.	A convenience sample of 3 clinics was selected based on proximity to the capital, client volume, and willingness to participate. Volunteer youth peer promoters directed clients exiting the clinic to kiosks set up with tablets that were connected to an online survey in DHIS 2. Clients chose to complete the survey by themselves on the tablet, with assistance from a youth promoter using the tablet, or by themselves using a paper-based survey.
Variables included in NPS survey	• Consent to participate • Clinic name • Interviewer name • Approach: ◦ Interview: 49% ◦ Drop box: 51% • Scale: ◦ Emoji faces: 49% ◦ Numerical: 51% • Consent to follow-up: 96% • Likeliness to recommend services: mean 9.096 • Why (interviews only)	• Consent to participate • Country: ◦ Nigeria: 44% ◦ Kenya: 56% • Service delivery channel: ◦ Static: 48% ◦ Outreach: 52% • Service delivery site name • Interviewer name • Gender: 96% female • Age: mean 30.9 years • Family planning method received • Source of last method used • Method category: ◦ Long-acting or permanent method: 35% ◦ Short-acting reversible method: 65% • Family planning use profile: ◦ Adopter (first time or lapsed): 27% ◦ Provider continuer: 34% ◦ Provider changer: 39% • Reason for changing provider and/or method • Likeliness to recommend services: mean 8.45	• Consent to participate • Clinic name • Administration method: ◦ Paper-based: 9% ◦ Self-administered on tablet: 42% ◦ Youth promoter-assisted on tablet: 49% • Age: mean 34.5 years • Gender: 89% female • Type of service • Likeliness to recommend services: mean 9.39 • What could be improved

Abbreviations: DHIS 2, District Health Information System 2; NPS, Net Promoter Score.

FIGURE 2. Two Net Promoter Score Implementation Approaches Tested in India

and conducted a 2-sample *t* test to determine whether the implementation approaches resulted in statistically significant differences in clients' likeliness to recommend.

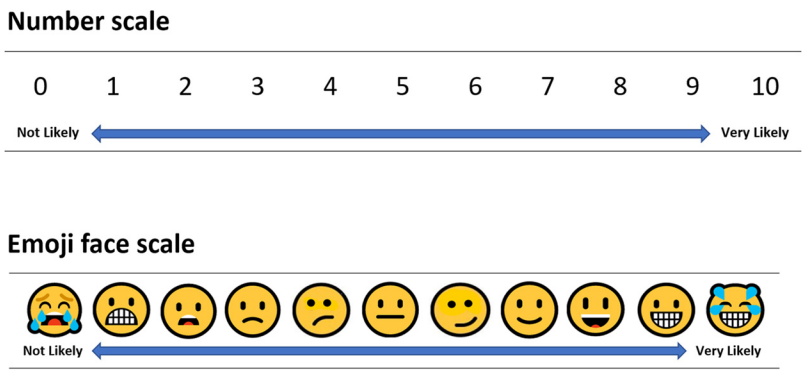
Based on concerns raised by staff in India that low-literacy clients might not understand the NPS numerical scale of 0 to 10, 2 types of rating scales were also tested:

1. The standard numerical NPS scale of 0 to 10 with anchored ends (0=not at all likely and 10=very likely to recommend)
2. A face scale modeled after the Wong-Baker FACES Pain Rating Scale[14] using an 11-point, anchored scale crafted from Microsoft emoji faces

To address the potential for different cultural interpretations of emojis,[15] we developed the emoji face scale in conjunction with staff from our Indian partner organization. They provided changes to the initial design proposal and approved the final selection of 11 Microsoft facial emojis (Figure 3).

In addition to alternating between face-to-face interviews and the drop box approach, interviewers systematically alternated between using the numerical (n=95) or emoji scale (n=93) for clients to assess their likeliness to recommend the services. Likewise, to assess whether these 2 scales elicited different responses from clients, we calculated mean values on likeliness to recommend for all clients responding using the numerical scale and all clients using the emoji scale and conducted a 2-sample *t* test to determine whether the scales resulted in statistically significant differences in likeliness to recommend.

FIGURE 3. Two Types of Net Promoter Score Rating Scales Tested in India



Finally, the pilot assessed whether actionable feedback could be obtained from the open-ended 'why' question typically used with the NPS using 2 approaches: asking clients the reason for their likeliness to recommend in the face-to-face interviews and asking all clients if they were willing to be contacted for follow-up and, if yes, collecting telephone details for later follow-up. Due to literacy limitations, clients using the drop box approach were not asked to respond to this question in writing.

Assessing the Potential of the NPS to Generate Comparative Client Group Insights Through Integration of the NPS Question Into an Existing Exit Interview

To enable disaggregation and analysis by client group, the adapted NPS question on the likeliness of recommending the clinic was added at the end of an existing short exit interview designed to collect client profile data on prior family planning use among clients receiving a contraceptive method in 9 clinics in Kenya and Nigeria.

In addition to the NPS question, clients were asked a series of questions about their age, today's family planning method, and previous experience using family planning methods. This resulted in an NPS dataset that could be disaggregated by a variety of client population subgroups (Table 1).

Where relevant, client cohort binary groups were created from the sample—for example, youth clients under age 25 and adult clients age 25 and older, long-acting and short-acting method users, and family planning method insertion and removal clients. For each of the binary client cohort groups, we calculated the mean likeliness to recommend the services and conducted a 2-sample *t* test to determine whether there were significant differences in likeliness to recommend the services between the binary client cohorts.

In El Salvador, a clinic supervisor and youth peer promoter tend a kiosk where the Net Promoter Score survey is set up for clients to provide feedback. © 2017 Moira Mendoza/International Planned Parenthood Federation/Western Hemisphere Region

Assessing the Use of Tablets for Self-Administered NPS Surveys

In El Salvador, a self-administered NPS survey was tested in 3 clinics using Internet-connected tablets that were set up in small kiosks. In addition to the NPS question on the likeliness to recommend the clinic, the survey included questions about the client's age and gender and the service that brought them to the clinic. The survey also included an open-ended question asking how the client's experience could be improved in the future.

To facilitate data collection, analysis, and warehousing, we developed an NPS survey in District Health Information System 2 (DHIS 2) software (a free and open-source health management information system used by both public and private sectors in more than 60 countries for collection, validation, analysis, and presentation of aggregate and client-based statistical data). Using an online survey eliminated the need for additional data entry, thereby reducing costs and producing real-time results.

Volunteer youth peer promoters directed SRH clients to the survey as they exited services; varying levels of literacy and comfort with technology were addressed by offering the client 3 options for the survey:

- Completing the survey themselves on the tablet
- Completing the survey on the tablet with assistance from youth promoters

- Using a paper-based survey completed by the client themselves

FINDINGS

NPS Implementation Approaches for Low-Literacy Clients

In India, interviewers reported that clients understood the NPS question without requiring additional explanation. As no issues were encountered with clients responding to the NPS question when they were guided by an interviewer to the drop box, the interviewers also concluded that the drop box approach was effective with low-literacy clients. However, the mean value for likeliness to recommend using the guided drop box approach was lower ($P<.01$) compared with the interview approach (Table 2). We interpreted the difference in the NPS as an indication that the drop box approach reduces courtesy bias—clients are more likely to feel comfortable giving a lower assessment when marking the response in private compared with providing the information to an interviewer.

Using a drop box where low-literacy clients can respond to the NPS question in private may reduce courtesy bias.

The experience in India also demonstrated that clients with low literacy were comfortable with the traditional NPS numerical scale of 0 to 10, as there was no statistically significant difference in mean likeliness to recommend the services when using the emoji versus numerical scales

Despite initial hesitation of staff, low-literacy clients understood the NPS numerical scale of 0 to 10.

TABLE 2. Two-Sample *t* Test Results Comparing Likeliness to Recommend Services of Client Groups

Client Group	No.	Mean	Standard Deviation	T-Value Calculator	T Critical Values	Degrees of Freedom	*P* Value
India (N=188)							
Implementation Approach							
Interview	92	9.52	1.09	3.11	2.61	131	.002
Drop box	96	8.69	5.75				
Scale Type							
Numerical scale	95	8.94	4.00	1.16	2.60	185	.25
Emoji scale	93	9.26	3.24				
Kenya and Nigeria (N=590)							
Age Cohort							
Adult clients	472	8.54	1.56	4.20	1.97	202	<.001
Youth clients	118	8.06	1.18				
Clinic Type							
Outreach clinics	306	8.47	1.06	0.53	1.96	513	.60
Static clinics	284	8.42	2.03				
Method Type							
Short-acting method	383	8.53	1.42	2.24	1.96	587	.03
Long-acting method	206	8.29	1.70				
Insertion vs. Removal							
IUD/implant insertion	205	8.29	1.71	2.43	1.97	178	.02
IUD/implant removal	69	7.96	0.75				
El Salvador (N=226)							
Age Cohort							
Adult clients	177	9.38	1.27	0.86	2.00	62	.40
Youth clients	48	9.58	2.25				

Abbreviation: IUD, intrauterine device.
Notes: Adult clients were ages 25 and older; youth were under age 25.

(Table 2). In addition, interviewers reported that clients intuitively understood the 0-to-10 number scale while the emoji face scale required explanation; this led us to recommend using the numerical scale in future testing, even with low-literacy clients, despite the initial hesitation of staff.

Contacting Clients for Follow-Up and Eliciting Meaningful Feedback

In India, almost all of the participating clients (96%) were willing to be contacted and provided their telephone contact details. To assess whether follow-up calls are a feasible approach for eliciting qualitative feedback, we contacted 20 clients via telephone to ask the reason for their rating; of those, we reached 19 clients (95%), indicating that contacting clients via telephone for follow-up is feasible, at least for clients in a peri-urban setting. This approach, however, may be less feasible in rural locations, where the ability to reach clients may be lower because fewer clients have mobile phones, or if the phone belongs to the client's husband rather than the client herself—an important consideration when conducting follow-up with SRH clients.

Attempts to elicit critical, actionable feedback from clients using the open-ended 'why' question typical of Net Promoter Score surveys did not yield substantive information in India.

While this demonstrated that following up with clients was possible, eliciting critical feedback—that could be used for action planning to improve the service provision—using an open-ended 'why' question both in the face-to-face interviews and in the follow-up phone calls was challenging, even with the addition of probing questions in the phone calls. Clients offered consistent and compelling reasons why they would recommend the services—for example, the staff put them at ease and their concerns and problems were addressed at the clinic—but offered few specific suggestions on how to improve the services. Further work is needed to investigate how to elicit actionable feedback, particularly in hierarchical and deferential cultures.

The Power of Disaggregating NPS Data

Comparing relative NPS data by client groups, such as age or service type, can be valuable for identifying which client groups are least likely to recommend the clinic, with follow-up actions to improve their experience.

The analysis from integrating the NPS question into client profile exit interviews in Kenya and Nigeria illustrated how combining the NPS question with a few targeted client demographic questions—such as age, service delivery channel, and method choice—can provide a powerful framework for identifying specific client populations who need an improved client experience.

By comparing the relative NPS of the client groups, clinic staff can quickly see which clients are less likely to recommend the services. Those client groups can then be targeted to obtain qualitative feedback about how to improve specific aspects of quality from their perspective. For example, data collected in Kenya and Nigeria showed that NPS varied across client subgroups. As explained above, to determine whether the differences among client groups was statistically significant, we calculated the mean value on likeliness to recommend the services and conducted a 2-sample t test. This analysis demonstrated that adult clients (ages 25 and older) were significantly more likely ($P<.01$) to recommend the services than youth clients (under age 25), and that clients coming to the clinic for an intrauterine device (IUD) or implant insertion were significantly more likely ($P<.05$) to recommend the clinic than were clients who had an IUD or implant removed (Table 2).

Comparing relative NPS data across these client subgroups demonstrated that a targeted feedback process among specific client groups is needed to identify actions these clinics can take to improve the experience for younger clients and those undergoing family planning method removal procedures. Likewise, feedback from the client groups more likely to recommend the services—in this case, older clients and those undergoing family planning method insertions—could be obtained to identify positive aspects of their experience to be scaled up to improve the experience across client populations and sites. It is worth noting that while the lower likeliness to recommend among clients having their method removed may reflect dissatisfaction of the method more than dissatisfaction with the service itself, a targeted feedback process among removal clients may nonetheless provide insights into how to improve the experiences of IUD and implant clients.

Using the disaggregated NPS data to structure the qualitative feedback component may also address the challenge encountered in India with eliciting critical feedback. Rather than asking all clients an open-ended 'why' question, which may make them feel uncomfortable, particularly in deferential cultures where a client may fear saying anything critical about a valued service, drawing on the NPS data, clients can be asked specific questions that pertain to aspects of the experience for that client group as a whole. For example, feedback may be solicited from clients who have had an IUD removed by saying, "In this clinic, we've seen that some clients coming for an IUD removal are less likely to recommend the services than other clients. What could be done to improve

the service for those clients?" Allowing participants the opportunity to provide feedback about their experience in a less personal way can deflect attention from the individual client and may increase their comfort in providing crucial information.

Using Tablets for Self-Administered NPS Surveys

Among the 226 clients who completed the NPS survey in El Salvador, 49% elected to have a volunteer youth promoter help them complete the survey on the tablet, 42% opted to self-administer the survey on the tablet, and 9% chose to complete a paper-based survey. This indicates that a client's level of literacy or comfort with technology may limit the approaches used to self-administered surveys in these SRH clinics.

Nonetheless, offering clients the choice of completing an online survey on a tablet, either by self-administration or volunteer assistance, resulted in 91% of the responses being instantly available. The benefits of using this approach includes reducing costs of interviewing and data entry and having data available in real time—or when the tablets are able to access the Internet to automatically upload responses. Providing an online survey on tablets in the clinic can be an efficient methodology for implementing the NPS. An intriguing possibility with this approach that we did not test, but could further reduce costs while supporting low-literacy clients, is the use of an online survey with an audio feature that reads the questions aloud to respondents.

Staff Acceptance of the NPS

Feedback indicated that the NPS approach was well received by both headquarters and clinic staff. Clinic staff appreciated that the NPS methodology was faster and easier for clients to complete than traditional client satisfaction surveys and noted that the open-ended question provided similar information as that gathered previously through client satisfaction surveys. Furthermore, implementing the NPS did not require additional resources, and, in fact, the use of tablets could reduce the amount of resources needed to collect and process data.

Headquarters staff noted that when asking whether clients would recommend the services, using the NPS 0-to-10-point scale provided more nuanced and, therefore, more valuable information compared with surveys using a binary yes/no scale. In addition, the staff were enthusiastic about the possibility of benchmarking the NPS and having a single standard metric that could be used over time and across different sites, and they valued the simplicity of the NPS approach compared with traditional client satisfaction surveys. Encouragingly, subsequent testing not presented in this article indicated that clinic staff were particularly engaged as they watched the live results of NPS interviews conducted in a clinic in Latin America. In this case, simple dashboards were created in DHIS 2 that automatically presented the results of interviews carried out on tablets using an online version of the NPS survey in DHIS 2.

Limitations

While using an opportunistic approach to test the NPS within existing programmatic initiatives was useful for providing evidence that the NPS could be used in low-resource clinic settings among low-literacy clients and demonstrating that implementation approaches could be adapted to address the specific contexts of each country, this iterative approach to testing did have some limitations. For example, because we were testing different aspects of the NPS at different times, we do not have a standard set of variables by which to analyze the likeliness to recommend services across all of the implementation sites. While all participating clinics provide a range of SRH services, such as family planning, maternal health, gynecology, HIV/sexually transmitted infection testing and care, and abortion-related care to the extent of legal limitations within each country, we do not have data from these pilot tests to report on variances in the NPS across standardized service types. To simplify the testing of implementation approaches for low-literacy clients in India, no data were collected related to the service for which clients had come to the clinic. In Kenya and Nigeria, due to the nature of the existing client profile survey within which the NPS question was added, only family planning clients were surveyed. In contrast, while data on service type were collected in El Salvador, 40% (n=90) of clients selected the 'other' category, leaving relatively small sample sizes—ranging from 2 to 47 clients—across the identified service types. Future implementation of the NPS by our organization will include a standardized set of variables to facilitate analysis, cross-site comparisons, and benchmarking.

Using tablets with an NPS survey can reduce the costs and burden of data collection.

The Net Promoter Score approach was well received by headquarters and clinic staff.

In India, although we used an open-ended 'why' question in the pilot test, it did not generate specific suggestions on how to improve the services and we did not test alternative mechanisms

for obtaining feedback. To quickly obtain actionable feedback without having to implement separate feedback processes for client groups more or less likely to recommend the services, additional existing approaches for gathering qualitative feedback within the NPS survey should be tested.

Ultimately, the power of using the NPS will be in determining whether it can be used as a mechanism to identify and implement actions in the clinic that lead to an improved client experience, and whether it is indeed an indicator of increased client volume. Do clinics with a higher NPS have greater volume? Do clinics with an increasing NPS see an increase in clients, indicating that word-of-mouth referrals are indeed occurring—or vice versa? While we plan to address these limitations through future implementation of the NPS, our initial pilot testing of the methodology does not provide sufficient information to address these and other crucial questions.

The NPS is a sensitive measure for identifying specific client populations in health care clinics for whom the client experience can be improved.

LESSONS LEARNED

Throughout this process of testing approaches to implementing the NPS in SRH clinics, several lessons have been learned:

- The NPS question can be used effectively in low-resource clinic settings with low-literacy clients.
- Testing demonstrates that multiple approaches to implementing the NPS methodology are effective: face-to-face interviews, a guided drop box, self-administered or guided use of tablets, and integrating the NPS question into existing surveys. Clinic administrators can identify the best approach to use for their specific context while still providing a standardized metric for the client experience, even when implementation approaches vary across clinics.
- The NPS methodology may be most powerful in generating insights when combined with a few select client demographic questions, making it possible to compare relative NPS scores by client subgroup and identify client groups for whom the experience could be improved.
- The ability to benchmark is a desired use of the NPS methodology to support performance management between clinics, across services and client groups, and over time.
- The main value of the NPS for SRH clinics is not its standalone score, but rather its ability to identify client subgroups from which in-depth qualitative feedback should be gathered to learn how to improve the client experience for that population.
- Targeted approaches for gathering qualitative feedback will likely be more effective than using an open-ended 'why' question for identifying concrete actions to improve the client experience. Programs should test alternative ways of asking for information that enable clients to provide positive feedback while also drawing out areas for improvement, such as by asking 2 specific questions: "What did this clinic do well?" and "What could this clinic do better?" Additional approaches to obtaining effective client feedback, such as focus groups or targeted follow-up interviews with specific client groups, may be the best mechanism for identifying specific feedback that can be used to improve the client experience.

CONCLUSION

Adapting the NPS for use with low-literacy clients is a promising approach to gaining insight into the client experience in SRH settings. With limited investment, the NPS can be adapted for use in low-resource and low-literacy health care clinics in different country settings. The NPS is attractive to headquarters and clinic staff because it is a simple, standardized metric that can be implemented using approaches adapted to the specific clinic context.

The NPS generated useful data to identify client groups that were less likely to recommend the services and for whom a qualitative feedback process could be used to identify actions to improve the client experience. However, for us, the open-ended 'why' question typically used in NPS surveys was insufficient for generating specific actionable insights in our international SRH clinics. Further research is needed to identify whether the NPS can be used for benchmarking, including for cross-country use where cultural contexts may lead to different expectations or norms around the likeliness to recommend a service or product.

Our experience indicates that the NPS should be used as part of a feedback process rather than as an absolute score. While focusing on a single absolute score may be tempting, without a robust dataset to generate meaningful benchmarks, the score itself is not particularly meaningful, as evidenced by the NPSs we saw that ranged from −4 to 100. Rather, we found that the immediate power of the NPS lies in helping clinic staff to unlock opportunities for analysis and greater understanding of the experience of specific client groups.

Based on testing the NPS in various field settings, we identified the following areas for additional exploration:

- What are the most effective and efficient approaches to gathering actionable qualitative feedback among the client subpopulations that have the lowest NPS?
- Does the NPS increase after actions are taken based on the feedback obtained from different client groups?
- With the aim of increasing access to key services among underserved populations, does the NPS correlate to service growth in SRH clinics? Is it apredictor of word-of-mouth referrals that lead to increased uptake of SRH services, and can it be used to identify service delivery models that should be scaled up? Are the NPS categorization thresholds for 'promoters' (likeliness to recommend services is 9 or 10), 'passives' (7 or 8), and 'detractors' (0 to 6) meaningful in relation to service growth?
- Can benchmarks be established and meaningfully used to spot trends and compare client experience across sites and countries within a global SRH organization?
- Can the NPS be effectively incorporated into broader quality assurance approaches and improvements?
- Is the NPS meaningful in contexts where access to other providers is limited or nonexistent?
- Does using the NPS impact the behavior of staff due to an awareness that clients are rating their services or because they use the NPS data to reflect on their practice and identify areas where changing behavior could lead to improved client experience?

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En español

El Índice de Promotor Neto (IPN) para generar conocimiento sobre las experiencias de clientes en clínicas de salud sexual y reproductiva

El IPN mide la probabilidad de que un cliente recomiende una organización a un amigo o colega en una escala del 0 al 10. Pruebas piloto en 4 países sugieren que el IPN puede ser utilizado exitosamente en clínicas sin fines de lucro y con poblaciones con bajo nivel de alfabetización. La combinación del IPN acompañado de algunos datos demográficos e información del servicio recibido puede servir como una herramienta poderosa para identificar poblaciones para las cuales su experiencia puede ser mejorada.

RESUMEN

La medida del Índice de Promotor Neto (IPN), comúnmente utilizada por las empresas de Fortune 500 para medir la experiencia del cliente, se calcula usando una escala del 0 al 10 para responder a siguiente pregunta: "¿Cuán probable es que usted recomiende [compañía X] a un amigo o colega?" A pesar del valor de esta metodología como predictor de crecimiento e indicador de la satisfacción del cliente para industrias con fines de lucro, la adopción del IPN ha sido más lenta en el sector social debido a preocupaciones sobre su aplicabilidad y aceptabilidad en entornos no comerciales, particularmente para poblaciones con bajo nivel de alfabetización. Para abordar estas inquietudes, llevamos a cabo una serie de estudios piloto a pequeña escala en El Salvador, India, Kenia y Nigeria con la finalidad de probar diferentes estrategias de implementación del IPN en clínicas de salud sexual y reproductiva—incluyendo entrevistas presenciales, buzón de respuestas con una guía para responder, integración de la pregunta del IPN en entrevistas existentes a la salida del cliente, y encuestas autoadministradas o asistidas por voluntarios en clínicas usando tabletas electrónicas—y comparar la escala tradicional numérica del 0 al 10 con una escala de caras emoji. Los resultados demostraron que el IPN puede ser adaptado efectivamente para clínicas de salud de bajos recursos y para clientes con bajo nivel de alfabetización mediante el uso de la escala numérica. No se encontraron diferencias estadísticamente significativas en la probabilidad de recomendar servicios entre el uso de la escala emoji versus la escala numérica en India; sin embargo, se encontró una diferencia estadísticamente significativa entre el buzón de respuestas y las entrevistas presenciales. Cuando se combinaron las preguntas demográficas y del uso de servicios, el IPN generó conocimiento acerca de los grupos de clientes que presentaban mayor o menor probabilidad de recomendar los servicios. Aunque la provisión de una encuesta en línea usando tabletas electrónicas puede ser una metodología eficiente para implementar el IPN, los métodos autoadministrados pueden ser limitados por el nivel de alfabetización del cliente o su comodidad con la tecnología. Para aquellas poblaciones de clientes con un IPN más bajo, recomendamos usar un proceso de retroalimentación cualitativa para promover retroalimentación crítica que permita identificar acciones que mejoren su experiencia. Nuestra experiencia con la prueba e implementación del IPN en clínicas de SSR en diversos ambientes sugiere que es una estrategia prometedora para generar conocimiento acerca de la experiencia del cliente en entornos de atención de salud sin fines de lucro.

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ORIGINAL ARTICLE

Human Papillomavirus Vaccine Introduction in South Africa: Implementation Lessons From an Evaluation of the National School-Based Vaccination Campaign

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Evaluation of the campaign confirmed its feasibility in this setting: it achieved high coverage, few adverse events, and mostly positive media coverage. However, challenges occurred in data and cold chain management. Future implementation requires improved partnerships between government ministries, simplified informed consent, and closer monitoring of social media messaging.

ABSTRACT

Background: In April 2014, a national school-based human papillomavirus (HPV) vaccination program was rolled out in South Africa, targeting Grade 4 girls aged ≥9 years. A bivalent HPV vaccine with a 2-dose (6 months apart) schedule was used. At the request of the National Department of Health (NDoH), we conducted an external assessment of the first-dose phase of the vaccination program to evaluate program coverage and vaccine safety and identify factors that influenced implementation.

Methods: We based our cross-sectional and mixed-methods approach on a process evaluation framework, which included a review of key planning and implementation documents and monitoring data; observation at vaccination sites; key informant interviews (N=34); and an assessment of media coverage and content related to the campaign.

Findings: There was overall success in key measures of coverage and safety. Over 350,000 Grade 4 girls were vaccinated in more than 16,000 public schools across South Africa, which translated to 94.6% of schools reached and 86.6% of age-eligible learners vaccinated. No major adverse events following immunization were detected. We attributed the campaign's successes to careful planning and coordination and strong leadership from the NDoH. The primary challenges we identified were related to obtaining informed consent, vulnerabilities in cold chain capacity, and onsite management of minor adverse events. While campaign planners anticipated and prepared for some negative media coverage, they did not expect the use of social media for spreading misinformation about HPV vaccination.

Conclusions: The first phase of the national school-based HPV vaccination campaign was successfully implemented at scale in this setting. Future implementation will require improvement in the storage and monitoring of vaccine doses, better communication of role expectations to all stakeholders, and streamlined consent processes to ensure program sustainability.

INTRODUCTION

Incidence of cervical cancer in southern, central, and east Africa is among the highest in the world, and, despite being a preventable disease, it remains a leading cause of cancer mortality for women in these regions.[1] In South Africa, 1 in 26 women develop cervical cancer during their lifetime,[2] with most cases of invasive carcinoma present late, resulting in high fatality rates.[3] Endemic levels of HIV infection among young women in the country are a strong contributing factor to this picture. HIV-infected women have a high prevalence of co-infection with human papillomavirus (HPV)[4,5]—the sexually transmitted virus responsible for almost all cases (99%) of cervical cancer—and tend to experience a poorer prognosis than women without HIV.[6,7] Despite policy changes to improve coverage, screening uptake in South Africa is generally low,[8] and there is high loss to follow-up of women identified with abnormal cytology.[7]

Traditional cytology-based screening procedures are likely to be replaced soon by more sensitive HPV testing,[9] but a national HPV vaccination program is a critical component of effective *primary* prevention. Vaccinating girls prior to sexual debut (9 to 13 years), as recommended by the World Health Organization (WHO),[10] is the most cost-effective public health measure against cervical cancer in high-prevalence settings.[11]

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National HPV vaccination programs are a critical component of effective primary prevention of cervical cancer.

Evidence to inform public-sector introduction of HPV vaccination has emerged from recent evaluations of pilot projects and national programs in low- and middle-income countries.[12–16] These evaluations show that coverage tends to be highest when vaccination is delivered through school-based programs, as found in settings as diverse as Australia,[17] Bhutan,[18] Peru,[19] and the United States.[20] However, with the introduction of any new vaccine, and despite good preparation, challenges often occur during the first year.[11] These challenges may include service delivery weaknesses as well as concerns among communities and health workers about the relative newness of the vaccine, vaccine safety and side effects, and even the specific targeting of young girls.

In South Africa, early feasibility and acceptability studies[21–25] and demonstration projects[15] identified several potential areas of concern for implementing school-based HPV vaccination programs. The first set of concerns focused on human resource shortages, limited expertise with the delivery of a large-scale vaccination program, and the vaccination of pre-adolescents in general. In practical terms, capacity limitations can negatively impact every aspect of a national program, from gaining informed consent to the management of cold chain integrity.[21]

A second set of concerns arose in relation to potential opposition to an HPV vaccination program. In the context of a broader discourse about "sexual risk," the HPV vaccine has acquired particular scientific and sexual meanings in every phase of its development, from discovery to distribution, marketing, and absorption into public health care systems around the world.[26] As a result, the vaccine has become vulnerable to lobbying by diverse anti-vaccination and "vaccine-hesitant"[27] advocacy groups. Feasibility and acceptability research to discover how receptive the public would be to vaccine messaging, undertaken prior to 2014, found strong support for HPV vaccination of young people among policy and health service representatives,[25] parents, youth, and educators.[15,21,23]

South Africa initiated a national public school-based initative to provide free HPV vaccination to all Grade 4 girls aged 9 years and over.

In general, vaccines as a technology are widely accepted in South Africa, owing to familiarity with childhood vaccinations,[25] which may partly account for these early indicators of support for HPV vaccination. While active opposition to the vaccine was not anticipated, policy makers did expect that some sectors of society might reject the HPV vaccine if the link to a sexually transmitted infection (STI) was too explicit.[25] Similar concerns have arisen in other countries,[28] and in South Africa fears about risk compensation and sexual permissiveness have surfaced as a popular response to condom provision and other sexual and reproductive health services in schools.[29] To preempt possible opposition to HPV vaccination, policy experts advised a strategy of marketing the vaccine as preventing cervical cancer rather than an STI.[25] But in South Africa, visibility of cervical cancer is low, and—as in much of sub-Saharan Africa in general[30]—there is little knowledge about the impact of cervical cancer on female morbidity and mortality.[21,23,31] The danger, then, was that parents would regard HPV vaccination as "non-essential," leading to poor uptake.

Few national HPV vaccination programs have yet been initiated in southern Africa, largely because of the high cost of the vaccine. This is a particular concern for countries in the region that are ineligible for funding from Gavi, The Vaccine Alliance. South Africa has partially overcome these cost concerns thanks to political commitment to vaccination and the registration of a 2-dose—rather than a 3-dose—schedule. In early 2014, South Africa introduced a national program of HPV vaccination, with ambitious hopes of meeting high coverage targets.[7]

We undertook a process evaluation in April 2014 to assess the success of the first-dose campaign and identify practical challenges that could be addressed prior to implementation of the second-dose campaign. Key components of the vaccination campaign were evaluated and conclusions fed back to the implementing body—the National Department of Health (NDoH). While the aim of the evaluation was to identify and resolve problem areas in time for administration of the second dose, its findings also have broader relevance for strengthening the HPV vaccination program overall. In this article, our aim is to illustrate what implementation challenges were experienced introducing a new vaccine to a new target population, outside of the traditional clinic environment, and offer useful lessons for HPV vaccine programming not only in South Africa but also in similar settings elsewhere.

METHODS

Program Description

Initiated in 2014, South Africa's national HPV vaccination campaign is a public school-based initiative to provide free vaccination to all Grade 4 girls aged ≥9 years. In the 2014 vaccination campaign, a bivalent HPV vaccine was used, with a 2-dose schedule—the second dose is provided 6 months

after the first. The campaign was housed within the relaunched Integrated School Health Program (ISHP)—a program jointly implemented by the NDoH and the Departments of Basic Education (DBE) and Social Development (DSD). Grade 4 was used to identify those most likely to be 9 years old, the youngest age cohort eligible for the vaccine. School attendance at primary school level is compulsory in South Africa and virtually universal.[32]

Prior to campaign initiation, a national task team headed by a dedicated national coordinator was formed to provide support to provincial, district, subdistrict, and school teams. All provinces prepared HPV implementation and vaccine distribution plans. The national Ministers of Health and Basic Education jointly convened meetings with school governing bodies, school principal organizations, and teacher unions at national level to explain the HPV vaccination campaign and secure agreement from them to proceed.

Social mobilization efforts involved the development of school-specific informed consent packages that included consent information, education, and communication (IEC) materials, such as posters, fact sheets, frequently asked questions, and a guide for educators (Figure). These packages were distributed by provincial DoH and DBE staff to the appropriate audiences (schools, parents, and government employees). In addition, informed consent forms were distributed in all 11 official languages of South Africa to some 18,000 public schools. Information about the campaign was placed on government websites and social media networks and relayed through broadcasts on national radio. The Health Minister's official launch of the campaign received wide television exposure on the national broadcaster's "Morning Live" breakfast show.

Training materials—developed by the NDoH with the support of partners—included a field guide and a set of training slides. A 2-day training session was held at national level and an additional 1-day training session was conducted for provincial, district, subdistrict, and facility-level teams.

On vaccination days, DoH vaccination teams visited assigned schools and implemented set procedures involving education, eligibility control, vaccination, data recording, and observation of vaccinated girls (physically separated from girls who were still awaiting vaccination). "Mop-up" visits were made where necessary to reach eligible girls who had been absent on the day of vaccination.

In terms of monitoring and evaluation, the NDoH developed a new school-based data subset linked to the District Health Information System (DHIS). Vaccination teams kept registers of vaccinated girls, completed weekly summary reports of all activities, and recorded adverse events in the DoH's routine adverse events (AE) reporting system. A target-driven strategy was adopted overall to encourage a strong focus on monitoring and reporting throughout the campaign.

Study Design and Data Collection

We used a cross-sectional and mixed-methods approach, combining qualitative and quantitative data, to evaluate the first-dose HPV vaccination campaign. The 4 principal sources of information used in the evaluation are detailed below.

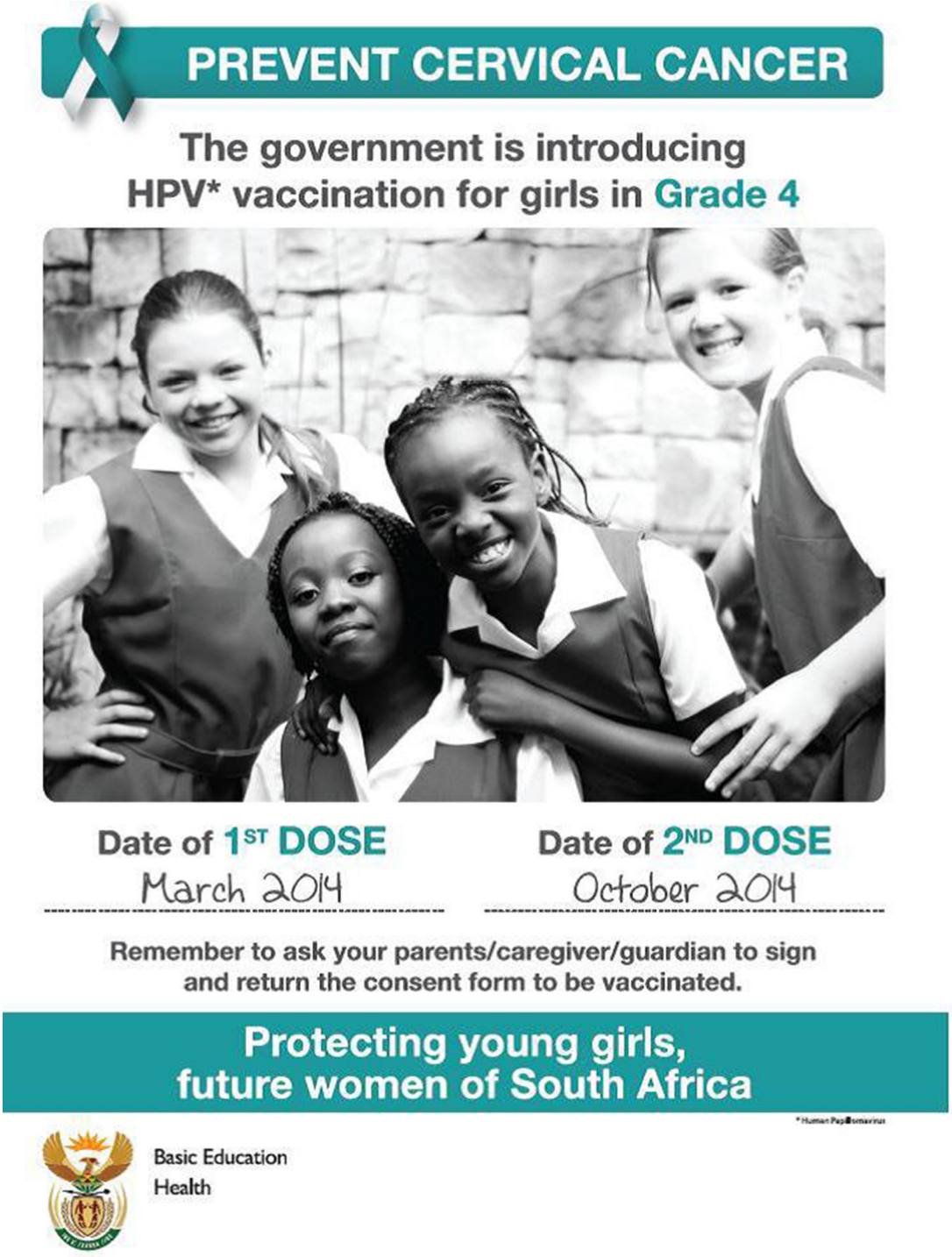
Review of Records and Materials

We reviewed all records and materials used in the planning and preparation of the campaign, as provided by the NDoH, at a 2-day post-campaign review and planning meeting. This group of primary sources included planning tools, training and social mobilization materials, core program materials (field guide, consent forms, invitation letters, data collection tools, and vaccination cards), summary reporting data (including adverse event reports), and presentations. Data were extracted from all reviewed sources in accordance with a standardized guide that had been developed beforehand.

Direct Observation of Vaccination Sessions

Three researchers observed a total of 7 vaccination events in 4 provinces—Gauteng, KwaZulu-Natal, Mpumalanga, and North West—in the final week of the first-dose campaign. Purposive sampling was used to ensure observation of vaccination activities in both rural and urban settings. To guide the observations, the researchers used a standardized NDoH tool designed to assess fidelity of implementation to the HPV Vaccination Campaign Field Guide. Observations specifically included assessments of microplans, social mobilization, vaccine session preparation and preparedness (including cold chain, safety considerations, and administrative procedures), vaccine administration (including eligibility determination and consent process, patient management, monitoring and flow, stock control, and vaccination team roles), and data and recordkeeping (Supplement 1).

FIGURE. Social Mobilization Poster Distributed by the South African Department of Health During the 2014 HPV Vaccination Campaign



Abbreviation: HPV, human papillomavirus

Key Informant Interviews

Primary data were collected through key informant interviews with a total of 29 DoH officials involved in the campaign at provincial, district, and subdistrict levels. In each of the 9 provinces, 1 district was randomly selected by number, and within each district, the 2 subdistricts with the highest and lowest coverage were selected based on preliminary data. At provincial level, all 9 HPV vaccine campaign coordinators were interviewed, while at district level, only 8 coordinators were interviewed, as 1 district lacked an appointed coordinator. Owing to the lack of appointed coordinators in some subdistricts, only 12 coordinators at this level were interviewed. In addition, a total of 5 NDoH officials were purposively selected and interviewed.

Interviews (either telephonic or in person) were conducted by 1 researcher on the team. A semistructured interview guide was used, with open-ended questions focusing on factors influencing coverage, safety, adverse events following immunization (AEFI), data capture, and social mobilization (Supplement 2). All participants provided written informed consent for both the interview and the recording of interviews. The interviews lasted an average of 60 minutes, and were conducted in English and transcribed in full for analysis.

Assessment of Media Coverage

Media coverage of the HPV campaign was reviewed retrospectively for the period March 1 to April 30, 2014. This period began several days before the start of the campaign and ended several days after the campaign's conclusion. The review, conducted by an external company specializing in media analysis, included over 900 print, broadcast, and online media sources from 80 newspapers, 291 community publications, 95 magazines, 37 radio stations, and 13 television stations. The following search terms were used to identify relevant material: HPV vaccination, HPV schools vaccination, cervical cancer vaccine, HPV vaccine, and schools HPV.

Evaluation Outcomes and Data Analysis

The main outcomes of interest in the evaluation were program coverage, vaccine safety, and factors that influence implementation of the program. The data used for the analysis were collected between March 10 and April 23, 2014, using NDoH HPV vaccination campaign data as of September 27, 2014. Program coverage was defined as: school coverage, age eligibility among Grade 4 girls (9 years or older on the date of the first-dose administration) at schools reached by vaccination teams, and age-eligible learner coverage—the term "learner" is used by the DBE and all other government departments to describe a student. The campaign had a target of 100% for school coverage, defined as the number of public schools—both ordinary primary, intermediary, and combined schools and "special schools," which were equipped to educate learners who have special needs—with Grade 4 that were reached by the campaign as a percentage of the total number of public schools with Grade 4 in the country. The target for learner coverage was 80%, which program planners considered to be the threshold required for "herd immunity"[33] although, increasingly, evidence supports even lower coverage as an adequate threshold.[34] Learner coverage was defined as the number of Grade 4 girl learners 9 years and older who were vaccinated as a percentage of the total number of age-eligible learners (Grade 4 girl learners 9 years and older).

To assess safety, we reviewed all official AEFI reports from the campaign, alongside onsite vaccination observations (described earlier) of staff preparedness for AEFIs. In South Africa, the management of AEFIs for HPV is the same as for other vaccines, and includes 5 key steps: detection and reporting, investigation, collation and analysis of data, implementation of corrective measures, and evaluation of the surveillance and handling of the cases.[35]

We analyzed the factors influencing implementation of the program using a process evaluation framework with broad parameters,[36] including planning and coordination; dose delivered by providers and dose received by target audience; recruitment through social mobilization, defined as a process of disseminating information and of gaining and sustaining involvement from all stakeholders; and media response. This allowed us to assess potential risks to sustained implementation of HPV vaccination programs of this scale in the future.

All program documentation provided by the NDoH was reviewed by 1 researcher who identified program strengths, weaknesses, and gaps, and assessed checklists—developed beforehand and completed during observation visits—for common themes. The same researcher reviewed and manually coded interview transcripts to identify common themes relating to challenges, risks, and successes in the implementation of the campaign. These themes were then sorted into a

matrix in Microsoft Word and key findings summarized to capture the content of each theme.

The media analysis company hired to assess media coverage of the campaign objectively reviewed all identified media items for content, and categorized them according to the most likely overall perception of the reader. This categorization used a 3-point rating scale based on standardized measures of positive (favorable descriptions of the campaign), neutral (unbiased, mostly factual information about the campaign), or negative (negative language and examples used to describe the campaign). In the absence of data collected directly from parents and community members, the media analysis offered vital information on the shaping of public perceptions of the vaccine.

The campaign reached about 408,000 age-eligible girls for vaccination, of whom about 87% were vaccinated.

Ethical Considerations

The study was reviewed and approved by the University of the Witwatersrand Human Research Ethics Committee. All participants provided written informed consent prior to participation.

RESULTS

Since our evaluation of the first-dose phase of the 2014 campaign was designed mainly to extract lessons to improve implementation of the second-dose phase, the analysis of our findings focused on 2 main categories: (1) areas of success and (2) aspects in need of further strengthening. In presenting our findings below, we retain this conceptual division and consider in each category how the study outcomes were impacted.

Campaign Successes

Planning and Coordination

Only 10 cases of adverse events were reported, all categorized as minor.

The campaign was introduced in the context of a high-level political mandate, and interview data showed that the strong political commitment to the campaign was an important factor driving results. Campaign planning and coordination was managed centrally by a team of highly experienced, committed NDoH staff who established strong communication mechanisms at provincial and district levels to monitor progress and address challenges. All provinces and districts appointed coordinators who oversaw microplanning at the site level to project vaccine and resource needs. Coordination mechanisms were used to mobilize support from a range of partners, including nursing schools, the South African National Defence Force and developmental partners. Collectively, this commitment helped to counter some of the challenges posed by tight timeframes and limited budget resources for a campaign of this magnitude.

Coverage

Interviews, record reviews, and observations of vaccination events showed that subdistricts had developed a clear schedule to cover 100% of schools. Contrary to concerns that low knowledge and visibility of HPV and cervical cancer might affect uptake, overall coverage was high: 91% of schools (15,620 out of 17,175) were reached with vaccination sessions in total. This suggested that vaccination teams and planners had successfully overcome the logistical challenges that arose in reaching some schools, such as flooding and lack of transportation.

With regard to learner coverage, a total of 408,273 Grade 4 girls age-eligible for vaccination were reached—received informed consent packages—during the campaign, of whom 353,564 (86.6%) were vaccinated. The eligible girls who were not vaccinated (13.4%) included girls who had not received parental consent or were absent on the vaccination day or not medically eligible for the vaccine due to ill health on the day. In terms of the proportion of Grade 4 girls who were too young to meet the eligibility criteria, based on NDoH data available through August 25, 2014, about 12% of Grade 4 girls were age-ineligible to receive the vaccine during the March 2014 campaign (range by province: 5% to 17%).

Safety

Of the over 353,000 girls vaccinated in the campaign, only 10 case reports of AEFIs (0.003%) were received by the NDoH. All 10 of the cases were categorized as minor, time-limited events, such as a rash, abdominal pain, raised temperature, dizziness, nausea, and fainting. Five of the 10 cases began experiencing symptoms shortly after receiving vaccination while still under observation by vaccination staff. All 5 were accompanied to a health facility by a member of the vaccination team. Of the remaining 5 cases whose reactions began later in the day at home, 1 child was treated at home and the other 4 were taken to a health facility, where they were treated symptomatically for faintness, rash, or nausea and then observed and later discharged. Based on our analysis of the provincial post-campaign summary reports, we identified 2 additional, unreported cases of AEFIs. These learners experienced minor reactions—fainting and vomiting—and both were

treated at the vaccination session by the same vaccinator.

Dose Delivered and Received

Observations found that the management of individual vaccination sessions was generally well organized. Program organizers were able to tap into the knowledge of retired nurses, who had vast experience of participating in Expanded Programme on Immunisation (EPI) campaigns over the years, by including them in vaccination teams wherever possible. The sequence of required procedures flowed effectively—from education, to eligibility control, vaccination, data recording, and observation—and vaccination teams paid great attention to learner comfort and preparedness. Adequate supplies in the form of bundled single-dose vaccines were delivered to provinces in good time. Overall, vaccine supply was well managed, with cooler boxes provided for each vaccination team along with adequate non-gel ice packs to prevent freezing of the vaccines.

Media Response

In any vaccination endeavor, social mobilization has the potential to be supported by positive reporting or undermined by negative reporting in the mass media. Analysis of media coverage found that a total of 373 items on HPV vaccination were published or broadcast in the period March 1 to April 30, 2014, the majority (68%) online, with just under a third (28%) in print media and only 4% in broadcast media (radio and television). Over half (55%) of all media items were categorized as neutral, with 38% considered positive and only 7% designated as negative. Of the positive media items, most (70%) were released in March (the first month of the campaign), while 59% of negative coverage was released the following month, suggesting that after the initial time period, a shift in public discourse about the campaign may have occurred. We explore possible reasons for this shift below.

Campaign Challenges

Planning and Coordination

Notwithstanding key successes, our assessment of the first-dose phase revealed some vulnerabilities in campaign planning. This planning process required the development of tools and materials at national level, and the coordination and training of hundreds of teams down to the subdistrict level, all of which was completed in an impressive 6-month period. Key informants identified training gaps in some districts and suboptimal use of NDoH microplanning tools (mainly due to lack of capacity in using Microsoft Excel worksheets). Fortunately, these vulnerabilities were offset by creative cross-program teamwork, which was evident from planning, to training, to vaccination implementation. Examples included teamwork in budget sharing and staff training, and the involvement of vaccine teams from a range of programs. For instance, in the Eastern Cape province, staff from EPI, ISHP, ward-based outreach teams, primary health care, and nongovernmental partners collaborated to form localized HPV vaccination teams.

Due largely to the ambitious planning and implementation time frame, the coordination of the range of key stakeholders was challenging. Delays in stakeholder engagement impacted social mobilization in some provinces. In particular, key informant interviews revealed that the DBE's participation in campaign planning was delayed; this limited the social mobilization that could be carried out in schools prior to the campaign. Observers noted that school readiness for the vaccination teams was also delayed in some cases. Despite a slow start, collaboration between NDoH and DBE improved at all levels over the course of the campaign, establishing a strong platform for future campaigns.

Delays in stakeholder engagement impacted social mobilization in some provinces.

Officially, the campaign was located within the ISHP, which has expertise in providing services in schools and coordinating with the DBE but lacks capacity in the crucial areas of cold chain management and campaign microplanning. Because it had only recently been relaunched in South Africa, staffing patterns in the ISHP still varied widely across the country, particularly at the provincial, district, and subdistrict levels. In districts where no ISHP staff were available for coordination roles, the role was filled by a mix of EPI program, primary health care, health promotion, and other specialist NDoH teams.

Coverage

Despite high levels of school coverage overall, we found a wide variation by subdistrict and isolated pockets of low coverage that key informants attributed to challenges experienced with informed consent and anti-vaccine activities (see below). In 2 subdistricts in KwaZulu-Natal and Mpumalanga, lows of 40% and 43% school coverage were reported, respectively. Unexpected changes made to the campaign start date also resulted in overlap

Despite high levels of school vaccination coverage overall, we found wide variation by subdistrict and isolated pockets of low coverage.

with school holidays and examinations and impacted learner coverage in several districts.

The greatest challenge in assessing coverage was in the management and reporting of data that underpinned the program at the subdistrict and district levels. Despite efforts to assign schools to health district boundaries, rather than traditional educational districts, discrepancies emerged between school lists provided by the DBE and those formed by vaccination teams on the ground.

Data quality also emerged as a challenge, with data not properly cleaned and verified prior to reporting, largely owing to inadequate capacity and tight reporting timelines. However, in the Eastern Cape, the HPV coordinator maintained a parallel reporting system and was able to identify inconsistencies in the DHIS data compared with data maintained in the parallel system. The data registers and reporting forms used in the campaign may also have contributed to data inconsistencies. Although the vaccination register used to report each vaccination session included a more detailed age breakdown than required for a grade-targeted campaign (age <9 years and ≥9 is sufficient), it lacked a place to record totals that would account for all Grade 4 girls as either vaccinated or ineligible.

Safety

While the total number of AEFIs was encouragingly low, there were minor issues with how these were handled by campaign staff. Of the 10 reported AEFI cases, the majority of cases were taken by the vaccination team to a health facility for treatment rather than being treated at the vaccination site. While the reasons for this decision are not described in the documents reviewed, it raises the possibility that the vaccinators were not comfortable or confident enough to treat AEFIs onsite. Although health care providers are trained to manage AEFIs, they are seldom required to conduct emergency procedures.

The additional risk created by administering vaccines outside of a health facility was intended to be mediated by the training of vaccination teams, the provision of emergency trays, and back-up support from local emergency services. Our assessment found that the training materials designed to prepare providers for managing AEFIs were clear and comprehensive; however, in some areas, the period of training was too short, leaving providers ill-equipped to cope with an emergency situation. In addition, observers noted that in some schools the emergency trays were not uniformly complete—for example, they lacked syringes, sterile water, and other supplies and, in most cases, emergency services had not been informed of the location of vaccine campaigns, as recommended by the field guide.

Dose Delivered and Received

Data from NDoH records, observations, and interviews confirmed that substantial pre-campaign preparation went into reducing the risk of breaks in the cold chain, particularly of vaccines freezing. Despite these preparations, important deviations from optimal cold chain were noted on observation visits and in discussions with key informants. For example, observation visits found that cold chain technologies (freeze tags, fridge loggers) were not uniformly used as intended, and ice packs were not "conditioned" in all cases, resulting in the risk of vaccines freezing. In addition, power failures occurred in some settings, while in others, domestic refrigerators—which have a higher risk of freezing vaccines—were used to store vaccines instead of specialized vaccine refrigerators. Additionally, abbreviated training at the subdistrict level, particularly for pharmacists, may have impacted training on cold chain maintenance.

Monitoring data showed that, in most provinces, reported vaccine use exceeded the number of learners vaccinated. Countrywide, 369,542 single-dose vials were reported as used, whereas only 353,564 learners were reported as vaccinated—a difference of almost 16,000, suggesting high vaccine wastage. More than 4,500 vials were reported as damaged or missing, costing just under 3 million Rand (based on an estimate of 650 Rand per vial).

Recruitment and Media Response

Implementing a new vaccine among a new target population, especially when operating outside of the traditional EPI or pediatric environment, creates a number of unique challenges. The involvement of multiple stakeholders and the unpredictability of the wider social context complicate social mobilization. At the heart of the study recruitment process is the need to obtain informed consent for a child's vaccination from their parents or guardians, a logistical challenge in its own right. More than 17,000 school-specific informed consent packages were delivered by the NDoH to the provinces, and while these packages were successfully distributed overall, late delivery of packages in some provinces delayed vaccination start dates. Large numbers of children were involved in obtaining

TABLE. Breakdown of Media Coverage of the 2014 HPV Vaccination Campaign in South Africa by Media Type and Rating (N=373)

Media Type	Rating		
	Positive No. (%)	Neutral No. (%)	Negative No. (%)
Print (n=105)	34 (32.4)	57 (54.3)	14 (13.3)
Broadcast (n=16)	10 (62.5)	1 (6.2)	5 (31.3)
Online (n=252)	96 (38.1)	148 (58.7)	8 (3.2)
Total	**140 (37.5)**	**206 (55.2)**	**27 (7.3)**

informed consent, which was sought by proxy. In this system, the child was tasked with acting as a "go-between" relaying information about the vaccination program to the parent, securing their signature on the informed consent form, and returning the form to school authorities in time for the scheduled vaccination day.

Because a measles vaccination campaign had been implemented in schools across the country just before the HPV campaign, parents were largely familiar with the consent process and, importantly, with the concept of vaccinating pre-adolescents. Nevertheless, according to key informants, this familiarity did not prevent misunderstandings and inconsistencies from arising. Additionally, the wording of the HPV campaign informed consent forms—"I hereby grant/do not grant permission for my child to receive 2 doses of the HPV vaccination"—confused many parents who believed the form referred to a social grant from the government. Parents were also reported to have been confused by the rollout of the *National Contraception and Fertility Planning Policy and Service Delivery Guidelines*[37] and, in particular, the launch of contraceptive implants, which took place around the same time as the start of the HPV vaccination campaign. According to key informants, this confusion was responsible for some parents declining consent for vaccination. While potential confusion may have been countered by the social mobilization materials developed by the NDoH and by the television appearance of the Minister of Health at the launch of the HPV vaccine campaign, the extent and impact of the confusion is not known.

In terms of media coverage, only 27 items (7% of all media coverage) about the 2014 HPV campaign were found to be negative. A rough breakdown of coverage by media type enabled us to identify the sources of negative messaging about the campaign (Table)—just over half (51.9%) of the negative media appeared in print, compared with only 18.5% in broadcast media and 29.6% online (figures not shown).

In terms of content, of the 27 negative items, a majority (63%) related to parental concerns over vaccine safety, while the remainder either highlighted the high cost of HPV vaccine in the private sector (22%) or were critical of the campaign's exclusion of boys (15%). Although social media—Facebook, email, and short messaging service [SMS] used on cell phones, among others—was not covered in the media assessment, anecdotal information suggests that anti-vaccine messaging disseminated through social media may have posed an important threat to the success of the campaign. One SMS communication circulating in Mpumalanga province during the campaign read:

> *It's a matter of life and death. If you have a daughter or granddaughter of 9 years old please listen very carefully. The schools are giving out permission forms to have these 9 year old girls vaccinated against a virus called HPV. You should under NO circumstances do this! The vaccine is unstable. 32 women died in the U.S. from the vaccine. It's still in the experimental phase and not reliable. Please moms! If you love your daughters. Refuse! You may. The government cannot force you. Please warn everyone. PLEASE! Go have a look at the link and the other links on this Page* http://www.infowars.com/japan-withdraws-support-for-hpv-vaccines-due-to-infertility-side-effects. (translation from Afrikaans)

The web address in this message directs the reader to a U.S.-based website notorious for its publication of conspiracy theories, "fake news,"[38] and anti-vaccination articles. While our evaluation of the 2014 HPV vaccination campaign was not designed to assess how public perceptions of

Only 7% of all media coverage about the HPV vaccination campaign was found to be negative.

the vaccine in South Africa were actually affected by media coverage, whether in mainstream or social media, it is noteworthy that in at least 1 province, key informants believed the negative coverage about vaccine safety had made some DoH staff nervous about vaccinating girls in this campaign. Additionally, in areas where misinformation and rumors were found to have been shared on social media, campaign staff reported a negative impact on parental consent.

DISCUSSION

The first round of the South African national HPV campaign implemented in 2014 achieved high overall coverage, a good safety profile, and mostly positive implementation experience. Implementing a vaccine campaign of this size and complexity requires careful planning, adequate resources, a receptive target population, and effective coordination throughout. Our evaluation showed that campaign success depended on a wide range of expertise, particularly in the domains of school health services, cold chain management, vaccine microplanning, health promotion, social mobilization, and health informatics. Implementation was clearly facilitated by strong political leadership and intersectoral coordination. Where gaps did emerge, many had been anticipated prior to the campaign—such as human resource shortages and cold chain weaknesses. Assuming continued political commitment to HPV vaccination in South African schools, these logistical shortcomings could conceivably be addressed with relative ease in future campaigns.

Successful school-based HPV vaccination campaigns require effective partnership building between government ministries.

Some concerns anticipated in early feasibility and acceptability research proved to be unfounded, while other concerns emerged during the campaign. While our evaluation did not assess the extent of community-level resistance to HPV vaccination based on fears of possible sexual disinhibition among vaccinated girls, even if some parents and community members had, in fact, given credit to this theory, it did not appear to gain any traction in this campaign. Similarly, virtually none of the negative media coverage identified in our evaluation focused on the sexual dimensions of HPV. Instead, the mainstream media attention was directed at vaccine safety, which dominated messaging on social media. Importantly, this messaging had a strong global imprint, as much of its content was sourced from anti-vaccination lobby groups and influential "victim" support groups based outside of South Africa.[39,40] With an extensive online presence, these groups style themselves as global outposts of resistance to HPV vaccines.[41] Their efforts to influence public discourse ignores or misinterprets extensive clinical safety data on the 2 commercially available HPV vaccines, Gardasil and Cervarix.[42]

In a study of a public-sector HPV vaccine introduction in Australia, social media was found to have had a substantial influence on acceptance of the vaccine program among parents and, subsequently, on uptake.[43] As in many parts of the world, South African parents deciding about HPV vaccination are increasingly likely to search the Internet for information about the vaccine where they will encounter an overwhelming mix of fact, opinion, and misinformation offered by online web-based groups and social media.[44] The challenge is that it is often difficult to assess the credibility of these sources. Furthermore, the user-generated content—a key feature of social media—encourages lay persons to engage with medical knowledge, selecting or rejecting information based on their personal "truths" or those of other online users.[45] This type of content can effectively mobilize those who already have low levels of trust in conventional biomedicine. As the HPV vaccination program in South Africa matures, it will be important to monitor the influence of Internet-based anti-vaccination groups and social media conversations on local attitudes toward the vaccine.

Several implementation lessons emerged from the findings of this evaluation. First, a successful HPV vaccination campaign of this scale requires effective partnership building between government ministries, primarily those responsible for health, education, and social development. This is especially important in school settings receiving multiple health interventions. From a health service delivery perspective, the prospect of delivering HPV vaccination in South African schools as part of an integrated package of care for adolescents has been proposed. Such a package could include services as wide-ranging as screening for vision and hearing impairment, information on gender-based violence, and provision of condoms and tampons.[22] This idea meshes well with the newly revitalized ISHP and with the new *DBE National Policy on HIV, STIs and TB*,[46] which was released in June 2017. The latter proposes that a wide range of services be offered to learners at schools via mobile health units or alternative channels, including dual protection and other contraception, HIV counseling and testing, adolescent-friendly health services, and screening for STIs.[46] In this context, vaccination teams would then need to manage

competing programs and ensure that the roles of all stakeholders and partners are clarified and communicated from the outset. Particularly important is the need to formalize the crucial role of the DBE in providing strategic information to target schools and learners throughout the country; in communicating effectively with parents and the wider community, including school governing boards and teachers, about the campaign; and in supporting social mobilization efforts at all levels.

Second, notwithstanding the high coverage attained in the first-dose phase of this campaign, reach and efficiency could have been further maximized with some simple adjustments to scheduling. For example, isolated, hard-to-reach schools could have been scheduled for vaccination in a different season when transport routes were not affected by rain. Furthermore, implementers could explore widening the interval between the first and second vaccine dose to 12 months, thereby necessitating only 1 campaign visit to schools each year. In the context of limited resources, consideration could also be given to eliminating or reducing mop-up visits. In the 2014 campaign, first-dose coverage exceeded the threshold needed for "herd immunity," defined as vaccinating at least 80% of learners. Therefore, mop-up visits had little strategic value. In general, they should be undertaken only if a significant proportion of age-eligible girls are unvaccinated on the initial vaccination day. To save costs, unvaccinated girls could also be followed up through health centers instead of return visits to schools.[47]

Third, the large discrepancy between reports of the number of vaccines used and the records of girls vaccinated signals a possible underestimate of vaccine coverage. However, this is difficult to confirm if a campaign has weaknesses in data quality, data reporting, and overall monitoring and evaluation planning and structure. Recommendations for addressing these weaknesses include taking steps to simplify vaccination registers and weekly summary sheets and considering electronic registers and a web-based platform for data reporting. Clear standard operating procedures for data verification should be developed to help clarify procedures at each step of data recording and define the roles for all staff involved in this process, from coordinators and team leaders to data capturers and information officers. If resources permit, experienced monitoring and evaluation staff could be hired for the 2-month duration of the campaign.

Fourth, gaps in training coverage should be closed and better training outcomes ensured to avoid the problems in data management and cold chain integrity that we observed. Since the 2014 first-dose campaign was implemented by highly skilled health care workers at all levels, formal training could be reduced to key, well-identified, critical issues for inclusion in any campaign-related training. In developing training modules and tools, particularly in the areas of cold chain management and vaccine handling, consideration should be given to replacing conventional, didactic approaches with more participatory, practical approaches. This change could help improve retention of information and build health provider confidence to manage cold chain requirements and deal with AEFIs, should they arise. Strategies like training health workers to train others—using a cascading training-of-trainers approach—could also help to improve training coverage overall and build in-country capacity using fewer resources, as found in a HPV vaccination demonstration project in Peru.[47]

Implementers could explore widening the interval between the first and second vaccine dose to 12 months so that schools will only need 1 campaign visit each year.

Fifth, the existing informed consent process used in South African schools urgently requires rethinking. On several levels, reliance on an opt-in approach that depends on children giving the form to their parents and the parents returning the signed form to the school is problematic: misunderstandings are highly likely and unconsented vaccinations can occur in error. HPV vaccination programs in more than 30 low- and middle-income countries using opt-out consent models have reported achieving higher coverage.[48] This approach is not always feasible, however, particularly in countries such as South Africa, where a historical legacy of unconsented medical interventions[49] may generate suspicion of an opt-out model. However, wherever the legal framework allows, alternative strategies for seeking consent from parents should be explored. One possibility is the use of mHealth applications to distribute vaccination information to parents and check comprehension prior to securing consent.

Opt-out vaccine consent models have reported higher coverage than opt-in models.

The final lesson relates to the management of adverse events and the role of social mobilization more broadly. Overall, our evaluation findings on the 2 unreported AEFIs that occurred suggest that the 10 reported cases may have underestimated the total number of minor AEFIs from this campaign. Importantly, no severe AEFIs were reported, leading us to conclude that AEFIs appear to be a low probability occurrence in this setting. However, even a minor AEFI that is not adequately managed has the potential to deter concerned parents from consenting to vaccination, reduce second-dose uptake, or be influenced by anti-vaccination groups. The latter, particularly, can lead

to the development of larger, more organized efforts to disseminate misinformation and undermine public trust in the HPV vaccine. Uptake of the HPV vaccine could be significantly impacted by such a risk, unless it is countered by a sustained, proactive approach to tackle misinformation in a variety of online spaces, including social media. Indeed, a media rapid response plan, prepared prior to implementation, should ideally form an integral part of the management of AEFIs. This plan should include public health messaging that conveys complex vaccination information in simple, accessible language, and be flexible enough to be activated at any level to respond in real-time to negative media coverage.[11]

Beyond such targeted responses to an emergency, effective social mobilization should be approached as a long-term investment for building community support. Managing community perceptions of safety is a crucial issue for all vaccine programs, particularly with the introduction of new vaccines that are not well known among the target population and broader community. In a survey of HPV program managers in 19 low- and middle-income countries, the most frequently reported obstacles to HPV vaccination were "erroneous perceptions of population related to the vaccine's safety and efficacy."[12] Given the profound changes in the media landscape in the past decade alone, it is time for program designers to explore innovative methods not normally used in public health communication. Possibilities include using the personal narrative format that anti-vaccination groups have appropriated so successfully, and greater use of digital applications that encourage users to interact directly with material, by sharing, commenting on, or uploading content.[50]

Limitations

Our evaluation had some limitations. The generalizability of our conclusions may be somewhat restricted by the limited sampling of key informants and the purposeful sampling used to select sites for the direct observation of vaccination sessions. In addition, only 1 researcher was responsible for conducting the document review; ideally a second researcher would have reviewed the same set of documents, thereby allowing for comparison and confirmation of results and strengthening the reliability of conclusions.

CONCLUSION

Evaluation of the 2014 campaign showed that implementation of a national school-based HPV vaccination campaign at scale was successful in this setting. Additional improvements to the storage and monitoring of vaccine doses and the informed consent processes, along with clearer stakeholder roles, will support optimization of school-based vaccination campaigns. While the impact of a national HPV vaccine campaign on cervical cancer will only be seen in the decades to come, as these early cohorts of vaccinated girls reach adulthood, the benefits of reducing HPV infections at a population level will be evident much sooner, for example, in declines in the prevalence of genital warts.[51] The eventual integration of school-based HPV vaccination into routine EPI programming is a long-term project, and implementers need to be able to deliver a logistically complex intervention across multiple settings to reach high coverage every year. Evaluations contribute valuable lessons that help programs build capacity, decrease the burden on staff, reduce costs, and improve overall efficiency, so that the broader preventative potential of the HPV vaccine may be fully realized.

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ORIGINAL ARTICLE

Client Perceptions of Quality and Choice at Static, Mobile Outreach, and Special Family Planning Day Services in 3 African Countries

Leah Jarvis,[a] Jane Wickstrom,[b] Caitlin Shannon[c]

In all 3 countries, nearly all women obtained their method of choice, with more mobile outreach and special family planning day clients having a preexisting preference for implants than static service clients. Clients of all service modalities in all countries reported experiencing most elements of full, free, and informed choice, but there is room for improvement with some aspects, such as counseling about potential side effects and giving clients the opportunity to ask questions.

Résumé en français à la fin de l'article.

ABSTRACT

Background: Use of long-acting reversible contraceptives (LARCs) has grown rapidly in the Democratic Republic of the Congo (DRC), Tanzania, and Uganda. Uptake of LARCs is particularly high during mobile outreach and special family planning day events. It is therefore important to examine client perceptions of and experiences with full, free, and informed choice (FFIC) in different service delivery modalities.

Methods: Between April and July 2015, we conducted a cross-sectional family planning client survey to assess FFIC and client satisfaction at static, mobile outreach, and special family planning day services in the DRC (n=9 sites), Tanzania (n=13), and Uganda (n=8). The study investigated clients' perceptions across 13 elements of FFIC, including measures of the quality of counseling and respondent satisfaction with services across the service delivery approaches. Composite FFIC scores were constructed and analyzed as the proportion of women who reported affirmatively to all elements and the mean score of positive responses. Satisfaction was assessed using a 4-point Likert scale. We used logistic regression to assess the association between the primary outcomes and mode of service delivery.

Results: In total, we interviewed 585 women (n=150 in Uganda, n=200 in Tanzania, and n=235 in the DRC). The large majority of clients in all countries and modalities received their method of choice. Clients of mobile outreach and special family planning days preferred LARCs and permanent methods, particularly implants, compared with clients at static services. Composite measures of FFIC were lower for mobile outreach than for static services in Tanzania among all family planning clients (odds ratio [OR]=0.5; $P \leq .001$) and among LARC clients specifically (OR=0.5; $P \leq .01$); no significant differences were found in the DRC or Uganda. A mean FFIC score among all family planning clients showed that clients in all modalities in all countries reported experiencing most elements of FFIC, with averages ranging from 4.8 to 6.1 of 7 elements. Among LARC clients specifically, mean scores ranged from 8.3 to 9.8 of 11 elements. Where greater proportions of clients experienced higher FFIC, greater proportions of clients also tended to report being "very satisfied" with aspects of services and counseling.

Conclusions: The results underscore that special family planning days and mobile outreach services are important and viable ways to increase women's access to family planning services, notably to LARCs, but further attention to respecting and fulfilling clients' full, free, and informed choice across all service delivery modalities is required.

BACKGROUND

In many sub-Saharan African countries, service delivery modalities such as mobile outreach services and special family planning days play an important role in increasing the use of modern contraception, especially underutilized, long-acting reversible contraceptives (LARCs) and permanent methods.[1–7]

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Mobile outreach services are crucial for increasing equitable access. By design, they serve poorer, marginalized, and geographically hard-to-reach communities and populations.[4,7–9] Such services are characterized by the deployment of trained providers to lower-level health facilities or temporary set-ups—such as tents or community spaces—that are equipped with the required contraceptives and supplies.[6,7,9,10]

Special family planning days are distinct events that are well-advertised in the community and organized at higher-level facilities during which a full range of contraceptive methods—including LARCs and, often, permanent methods—are available. Trained providers and counselors assemble in sufficient numbers to dedicate themselves to family planning for the day and plan to have sufficient stock on hand, thereby creating confidence in the community and among clients that family planning methods will be available.

Non-static service delivery modalities, such as mobile outreach and special family planning days, increase access to family planning, especially to LARCs.

Both of these non-static service delivery modalities increase access to family planning, especially to LARCs, for women who may not have routine access to a wide contraceptive method mix or to family planning at all. Although short-acting methods, such as hormonal injections and pills, are highly popular with family planning adopters in sub-Saharan Africa, studies show that when women are able to choose among a wide range of contraceptive options, significant proportions choose LARCs.[1,5,9,11,12] Due in part to global investments since the 2012 London Summit for Family Planning, hormonal implants have become more available and, as a result, women are especially likely to select implants, as compared with other contraceptive methods, including intrauterine devices (IUDs), when they are available.[5,8,13–16] Although implants continue to represent a smaller proportion of the method mix in sub-Saharan Africa, they are one of the most rapidly growing contraceptive methods globally.[12]

Following the 2012 London Summit, DRC, Tanzania, and Uganda set ambitious goals to increase the CPR and reduce unmet

EngenderHealth's Expand Family Planning (ExpandFP) Project (2013–2018), funded by the Bill & Melinda Gates Foundation, aimed to increase contraceptive options, with a focus on LARCs, for women and girls in the Democratic Republic of the Congo (DRC), Tanzania, and Uganda. The project began shortly after the 3 countries set aggressive goals at the London Summit: the government of DRC committed to achieving a national contraceptive prevalence rate (CPR) of 19% by 2020; Uganda's government committed to reducing unmet need to 10% by 2022; and Tanzania committed to doubling the number of family planning users to reach a national CPR of 60% by 2015.[17] Although Tanzania did not achieve 60% CPR within their stated time frame, the government recommitted to its family planning program, adding financial resources and a pledge to increase the availability of youth-friendly health services.[18] All 3 countries recommitted to their family planning goals at the London Summit meeting in July 2017, adding pledges to protect, respect, and fulfill client rights to full, free, and informed contraceptive choice.[19]

As a result of public- and private-sector family planning initiatives supported by governments, donors, and technical assistance partners, significant progress has been made in family planning use overall, and in use of LARCs more specifically. For example, in Kinshasa, DRC, rates of LARC/permanent method adoption increased quickly—from 2.5% prevalence in 2013 to 5.3% in 2015—as these methods became more available.[20] In Uganda, the 2016 Demographic and Health Survey (DHS) showed that the overall CPR was increasing, with the prevalence of implant use among married women more than doubling in 5 years—from 2.7% in 2011 to 6.3% in 2016—and with IUDs remaining a much smaller proportion of the method mix, but still tripling from 0.5% to 1.5%.[21,22] In Tanzania, the prevalence of implants nearly tripled among married women between the 2010 and 2015 DHS—from 2.3% to 6.7%—though IUDs remained below 1.0%.[23,24]

In all 3 countries, EngenderHealth's program introduced a voluntary, human rights-based approach and framework at national and project implementation levels. The goal was to build provider awareness and capacity in voluntary family planning programming, including counseling, to ensure that clients were able to make full, free, and informed choices (FFIC) and that programs assured equity and quality in the provision of care.[25,26]

Full choice is defined as access to the widest range of methods possible. To what degree that is possible may depend on what methods are approved for use at the national level and any constraints on the type of facility or cadre of provider. Free choice is a voluntary decision, without barriers or coercion, about whether to use family planning and, if so, which method to use. Informed choice is a decision based on complete, accurate, and unbiased information about family planning method options, including benefits, side effects, risks, and information about the correct use of the method chosen and the risks of family planning nonuse.[27] The concepts of quality counseling and FFIC are interrelated and fall within a larger framework of client rights. The FFIC framework includes many elements of

counseling quality, such as information on the array of contraceptive options available to the client and the benefits and side effects of each option, and how to discontinue use, when the client wants or needs to have an IUD or implant removed. However, FFIC goes beyond counseling quality and other measurement frameworks by assessing a client's ability to obtain her method of choice and by asking her who is primarily responsible for deciding whether to use family planning and which method. These specific elements of FFIC are influenced by factors that are external to provider counseling, such as method availability, cost of methods, and spousal influence.

To enhance FFIC, the ExpandFP Project invested resources into focusing on family planning clinical and counseling training for providers, facilitative supervision, infrastructure and contraceptive security improvements, community engagement, and advocacy. The project supported national trainers to train family planning providers on clinical contraceptive methods and rights-based counseling techniques. Trainings were followed by onsite provider follow up and coaching. Facilitative supervision was conducted at least twice a year in higher-level supported facilities where special family planning days occurred. The interventions supported service delivery for both short-acting (pills, injectables, and condoms) and long-acting methods (implants and IUDs). Permanent methods—male and female sterilization—were not offered at study facilities in the DRC but were available at most facilities in Tanzania and Uganda.

Project-supported public-sector special family planning days used community health workers, mass media, and dedicated family planning providers. In addition, the project-supported public-sector mobile outreach teams of dedicated family planning providers to serve lower-level facilities in remote areas with short-acting, long-acting, and sometimes permanent family planning methods. For both special family planning days and mobile outreach, community mobilizers were engaged to inform the community about upcoming events. Although special family planning days were conducted at facilities that generally had the most methods available, they frequently struggled with stock-outs and provider unavailability, while mobile outreach events typically occurred in smaller facilities that usually only had short-acting methods. In Tanzania and Uganda, all family planning methods were provided free to clients at public facilities at all times. In the DRC, family planning methods were only free to clients

Clients of mobile outreach services in Tanzania listen to a group family planning counseling session. © 2015 Sala Lewis/EngenderHealth

during special family planning days and at mobile outreach events. Special family planning days and mobile outreach events served higher client loads than routine services in all 3 countries and were particularly high in the DRC and Tanzania. On average, for special family planning days, 97 clients were served per day in the DRC, 112 in Tanzania, and 33 in Uganda. On average, during mobile outreach events, an average of 60 clients were served per day in the DRC, 133 in Tanzania, and 23 in Uganda. During these events, clients obtained information both from group education/counseling sessions and from individual counseling with the provider.

Special family planning days and mobile outreach events served higher client loads than routine services in all 3 countries.

With heightened awareness of FFIC and data showing significant increases in the number of hormonal implant adopters, especially in the DRC, government officials and program managers moved to increase their monitoring of FFIC, especially during high-volume mobile service delivery and special family planning day events. Steps to assess FFIC included improving supervision of counseling and conducting this study of client perceptions of quality and choice.[28]

This study investigated and compared aspects of FFIC and quality service delivery from the client perspective for routine static services, mobile outreach, and special family planning days. Our primary interest was to understand clients' experiences of FFIC and whether elements of FFIC varied by service delivery mode in project catchment areas. We also analyzed characteristics of the family planning clients to understand the populations reached by the 3 service delivery modalities in each country. This article adds to the literature

because previous studies have focused their research on FFIC and client satisfaction in private versus public clinics,[29] the quality of mobile outreach services,[3] and how client-centered counseling can improve client satisfaction.[30,31] While many tools exist to aid programs in human-rights based programming and monitoring, they have seldom been brought to scale in national programs or measured systematically.[32] This study goes beyond the current literature by comparing FFIC and client satisfaction among 3 service delivery modalities and underscoring the value of using existing tools to provide valuable monitoring data to inform program needs.

METHODS

We conducted a cross-sectional, facility-based survey between April and July 2015 at 30 EngenderHealth supported-facilities: 9 in the DRC, 13 in Tanzania, and 8 in Uganda. In Tanzania and Uganda, the facilities selected were in peri-urban and rural areas, whereas in the DRC, the facilities were in peri-urban and urban areas of Kinshasa. The study purposefully selected facilities geographically spread across districts receiving support from EngenderHealth. Each data collection site had mobile, static, or in the DRC only, special family planning day services during the project period. Facilities were chosen for data collection by service delivery mode, based on the timing of family planning service activities, type of support from EngenderHealth (static and special family planning days vs mobile outreach), and expected client load. Some facilities had routine client loads too low to make reaching the desired sample feasible and, thus, were excluded. Facilities for mobile outreach collection were selected based on the scheduled mobile outreach activities during the data collection period.

Answers from 13 indicators were used to arrive at a final composite FFIC score to measure clients' positive perceptions of and satisfaction with their service delivery experience.

Trained data collectors conducted exit interviews with clients immediately following their family planning visits. Clients were systematically sampled using an interval based on expected client load and were interviewed privately using a structured questionnaire. Signed informed consent was obtained in local languages prior to the interview. Eligible respondents were women aged 15 to 49 years seeking family planning services during static family planning service delivery or mobile outreach services (or in the case of the DRC only, during special family planning days), and who were not pregnant. Clients aged 15 to 17 years were eligible if they were legally emancipated. All data collectors were women to reduce respondent discomfort with questions related to reproductive behaviors and intentions.

Outcomes

The main outcomes assessed were measures of FFIC and client satisfaction.

Outcome indicators are defined in detail in Table 1. Indicators 1 through 13 directly correspond to responses to questions from client exit interviews that asked clients to report on the elements of counseling they received and their personal choice in method adoption. The majority of questions required a yes/no response: 1 recorded for a "yes" answer and 0 for "no." Indicators 1 and 2 were assessed among all respondents, indicators 3 through 9 among all respondents receiving a method, and indicators 3 through 13 among women who received a LARC. The proportion of positive responses were tabulated within the denominator category specified in Table 1.

To examine counseling and choice elements as a whole, not just individually, composite FFIC scores were constructed by summing the positive responses for indicators 3 through 9 for women receiving any method and summing positive responses from indicators 3 through 13 for women receiving a LARC method. FFIC scores were examined in 2 ways: (1) as a proportion of women who reported affirmatively to all elements in that category of user and (2) as a mean score of positive responses. The highest score possible for women receiving any method was 7 and the highest score for a woman receiving a LARC was 11 (Table 1).

We assessed satisfaction using a 4-point Likert scale: respondent was very dissatisfied, somewhat dissatisfied, somewhat satisfied, or very satisfied. Recognizing that courtesy bias contributes to high levels of satisfaction and that reporting "somewhat satisfied" versus "very satisfied" may indicate a small amount of dissatisfaction, we analyzed elements of satisfaction using a dichotomous variable categorized as "very satisfied" versus the rest.

Client characteristics assessed were reproductive intentions (i.e., desire to space or limit pregnancies), parity, marital status, age, education attained, and literacy as well as 2 proxy measures of socioeconomic status (SES): mobile phone ownership and home electricity. We also examined previous contraceptive use, method preference, and reproductive intentions as well as method received on the day of service.

TABLE 1. Indicators of Full, Free, and Informed Choice and Rationale for Inclusion

Indicator	Rationale	Denominator
1. Received an FP method	Clients receiving FP is key to FFIC; however, a client not receiving a method does not necessarily demonstrate a lack of choice. A client may come for removal, other services, or choose not to adopt a method.	All women
2. Reported being asked about reproductive intentions (when or whether a client wants more children)	Provider's knowledge of a client's desire to delay, space, or limit childbearing is important for recommending appropriate methods.	
3. Reported discussing 3 or more methods with provider	Clients should be aware that they have options to select the method best suited for them.	
4. Client given a chance to ask questions	Clients in any clinical setting should be given an opportunity to ask questions.	
5. Obtained FP method of choice	Full choice and free choice are contingent on the client receiving her desired method. The reasons for not receiving the desired method include unavailability of the method, lack of a trained provider, cost, medical contraindication, or other.	Women who adopted an FP method
6. Participated in FP decision making (client chose method by herself, jointly with the provider, or jointly with a partner)	Clients should have agency in choosing their method, either by themselves or together with the provider, with a partner, or with someone else. If the client reported that someone else made the decision for her, a lack of FFIC is indicated.	
7. Counseled on method received	The client being given general information on the method received is key to being informed.	
8. Counseled on benefits of method received	The client being told the benefits (e.g., effectiveness, health benefits) of the method received is key to being informed.	
9. Counseled on side effects of method received	The client being told and understanding the side effects of the method received is key to being informed and can also prevent early discontinuation.	
10. Told where to get implant/IUD removed	A client should know the effort required to have the LARC removed before she adopts it (e.g., long distance travel).	Women who adopted a LARC
11. Told when to get implant/IUD removed	A client should know when to have the LARC removed. This is key to correct use and fulfilling reproductive intentions.	
12. Told could have implant/IUD removed whenever she wanted	A client should know that she is free to discontinue use when desired. This is key to free choice.	
13. Could correctly state the maximum duration of implant/IUD use	This indicator verified that clients understood the maximum duration of use.	
FFIC composite: Percentage of FP adopters who responded positively to indicators 3 through 9	These 7 indicators represent the minimum threshold for a client to fully exercise FFIC. All 7 indicators had to have a positive response for this indicator to be satisfied.	Women who adopted an FP method
FFIC score: Average number of indicators 3 through 9 for which the response was positive (maximum score of 7)	The average provides a more nuanced view of the differences among service-delivery approaches.	
FFIC LARC composite: Percentage of LARC adopters who responded positively to indicators 3 through 13	These 11 indicators represent the minimum threshold for a client to fully exercise FFIC when obtaining a LARC: all regular indicators of FFIC plus 4 specific to LARC. All 11 indicators had to have a positive response for this indicator to be satisfied.	Women who adopted a LARC
FFIC LARC score: Average number of indicators 3 through 13 for which the response was positive (maximum score of 11)	The average score provides a more nuanced view of the differences among service delivery approaches.	

Abbreviations: FFIC, full, free, and informed choice; FP, family planning; IUD, intrauterine device; LARC, long-acting reversible contraception.

Sample Size

The sample size was estimated using client satisfaction as the key outcome of interest. Although satisfaction is not an ideal measure because of the potential for courtesy bias and subjectivity as an indicator of perceived quality of service delivery,[14,16,17] it was one of the only measures we could estimate in advance with relative confidence to calculate sample size. Assuming that approximately 95% of clients would be somewhat or very satisfied, a sample of 73 was adequate at the 95% confidence level to assess client satisfaction at the service modality level. Historical service statistics helped determine an appropriate sampling interval by facility and service delivery modality in order to reach desired sample size using systematic sampling, with a minimum of 73 per service delivery modality. The desired sample was then divided across facilities participating in project-supported mobile outreach or special family planning days during the data collection period.

Data Analysis

Trained data clerks entered data using the Census and Survey Processing System (U.S. Census Bureau and ICF International, Washington DC, USA) data processing software package and cleaned and analyzed the data using Stata version 13 (StataCorp, College Station, TX, USA). We summarized client characteristics using means or medians for continuous variables and proportions for dichotomous variables. We also compared the characteristics of mobile outreach service attendees (and in the case of the DRC, special family planning days) against static service clients through 1-way measures of association: *t* tests for continuous variables, such as age, and chi-square tests for categorical outcomes. To assess the association between each of the primary outcomes—1 through 13 in Table 1, the FFIC composite statistics, and client satisfaction—with mode of service delivery (static or non-static) we used logistic regression. Mode of service delivery was the only predictive variable included in the models. We did not adjust for client characteristics, because client characteristics, such as age, marital status, education, and socioeconomic status, should not affect counseling practices or FFIC. Mean FFIC scores were compared using ANOVA instead of logistic regression. In the DRC, special family planning days and mobile outreach were combined into a single group because they are both non-static, high-volume modes of service delivery supported with many of the same program inputs and have similar client profiles for those attending events. Standard errors for each estimate presented were adjusted for by clustering by facility, the primary sampling unit. Only adjusted estimates are reported; all *P* values reported are 2-sided; and differences in statistical significance at the $P \leq .05$, $P \leq .01$, and $P \leq .001$ were noted.

For both mobile outreach and special family planning days, clients preferred LARCs/permanent methods, especially implants, compared with clients at static clinics.

Ethical Approvals

The research protocol and materials were reviewed and approved by the Western International Review Board in the United States, the National Institute for Medical Research in Tanzania, the Research Ethics Committee of Makerere University in Uganda, and the Ethical Committee of the Public Health School of Kinshasa in the DRC.

RESULTS

A total of 614 women were screened for inclusion, of whom 596 were eligible; 587 consented to be interviewed; and 585 women completed the interview. Data were collected from 150 respondents in Uganda (90 static; 60 mobile outreach); 200 respondents in Tanzania (100 static; 100 mobile outreach); and 235 respondents in the DRC (55 static; 120 mobile outreach; 60 special family planning days). A smaller than anticipated client flow at static services in the DRC posed challenges for data collection, and timing and budgetary constraints resulted in a smaller than planned sample in family planning days in the DRC and mobile outreach in Uganda.

Client Characteristics

Client characteristics varied by mode of service delivery in the DRC. Overall, women seeking family planning at mobile outreach and special family planning days were similar to each other; however, compared with clients attending static services, they had less education, money, and history of family planning use and were more likely to have a preexisting preference for implants. Women at mobile outreach and special family planning days were less literate compared with women at static services (60.8%, $P \leq .01$, and 63.3%, $P \leq .05$, respectively, compared with 83.3%), and less likely to own a mobile phone (46.7%, $P \leq .001$, and 56.7%, $P \leq .05$, respectively, compared with 74.6%) (Table 2). In terms of contraceptive history, women attending mobile outreach services and special family planning days had similar levels of modern method use, which were significantly lower than women attending

TABLE 2. Profile of Family Planning Users by Country and Service Delivery Modality

	DRC (N=235)[a]			Tanzania (N=200)		Uganda (N=150)	
	Static n=55	Outreach n=120	FP Day n=60	Static n=100	Outreach n=100	Static n=90	Outreach n= 60
Age							
Age, years, mean	29.2	26.9*[b]	28.9*[c]	27.6	28.8	26.9	27.9
Age, years, range	19–49	17–45	18–44	18–49	17–46	17–47	17–41
Age groups, years, %							
15–19	1.8	11.%	5.0	5.0	11.0	11.1	5.0
20–24	25.5	30.0	18.3	41.0	26.0	28.9	23.2
25–29	29.1	22.5	35.0	17.0	19.0	26.7	33.3
30–34	16.4	24.2	23.3	19.0	13.0	16.7	23.3
35–39	23.6	9.2	10.0	8.0	20.0	14.4	11.7
≥40	3.6	2.5	8.3	10.0	11.0	2.2	3.3
Marital Status							
Married or in union, %	81.8	68.3	81.7	84.0	82.0	80.0	93.3*
No. of Children							
No. of children, mean	3.8	4.1	4.1	2.8	3.4	3.3	4.1*
No. of children, range	1–10	0–10	1–9	0–11	0–11	0–9	0–11
No. of children, distribution, %							
0–3	49.1	44.2	38.3	76.0	62.0*	54.3	43.3
>3	50.9	55.8	61.7	24.0	38.0*	45.6	56.7
Education							
Received at least some secondary education, %	83.6	75.0	75.0	25.0%	15.0	31.1	25.0
Read some/all sample sentence,[e] %	83.3	60.8**[b]	63.3*[d]	85.0	83.0	80.0	75.0
Socioeconomic Status							
Owns a mobile phone, %	74.6	46.7***[b]	56.7*[d]	59.0	38.0**	63.3	58.3
Has electricity, %	87.3	82.5	63.3**[c,d]	26.0	24.0	30.0	25.0
Occupation[f]							
Housewife/not working, %	27.3	40.8	41.7	16.0	12.0	18.9	13.3
Farmer, %	1.8	2.5	3.3	59.0	82.0***	55.6	65.0
Trader/business owner, %	47.3	43.3	43.3	15.0	2.0***	20.0	15.0
Contraceptive History							
Ever used modern FP, %	81.8	66.7*[b]	65.0*[d]	91.0	90.0	98.9	100.0
Ever used non-condom modern FP, %	74.6	46.7***[b]	51.7*[d]	83.0	84.0	88.9	96.7
Ever used LA/PM, %	5.5	2.5	3.3	33.0	36.0	25.6	15.0
Method Preferences							
Had a preference for implant, %	58.2	86.7***[b]	85.0***[d]	41.0	55.0	25.6	51.7***
Had a preference for LA/PM, %	58.2	86.7***[b]	88.3***[d]	47.0	62.0*	28.9	53.3**
Had a preference for short-acting method, %	29.1	2.5***[b]	6.7**[d]	37.0	20.0**	63.3	33.3***

Continued

TABLE 2. Continued

	DRC (N=235)[a]			Tanzania (N=200)		Uganda (N=150)	
	Static n=55	Outreach n=120	FP Day n=60	Static n=100	Outreach n=100	Static n=90	Outreach n= 60
Fertility Desires							
Wants no more children, %	34.6	41.7	30.0	14.0	32.0**	25.6	41.7*
Wants child 2 or more years, %	49.1	40.0	50.0	67.0	55.0	44.4	38.3
Doesn't know when or if want more, %	9.1	10.0	16.7	14.0	3.0	5.6	6.7

Abbreviations: DRC, Democratic Republic of the Congo; FP, family planning; LA/PM, long-acting or permanent method.
[a] One-way analyses of statistical significance were conducted between mobile outreach and static services; special family planning days and static services; and special family planning days and mobile outreach.
[b] Difference between mobile outreach and static services was statistically significant.
[c] Difference between special family planning days and mobile outreach was statistically significant.
[d] Difference between special family planning days and static services was statistically significant.
[e] Women who were visually impaired or who did not read the language on the card (n=5) were excluded.
[f] Only the 3 most common occupations overall are listed, so categories do not add up to 100%.
* $P \leq .05$; ** $P \leq .01$; *** $P \leq .001$

static services (66.7% and 65.0%, respectively, compared with 81.8%, $P \leq .05$). For both mobile outreach and special family planning days, clients preferred LARCs/permanent methods, and implants in particular, with 86.7% at mobile outreach services ($P \leq .001$) and 85.0% at special family planning days ($P \leq .001$) favoring the implant, compared with 58.2% of clients at static services. The only significant differences between clients attending mobile outreach services and clients at special family planning days were that the women attending special family planning days were older (28.9 years compared with 26.9 years, $P \leq .05$) and less likely to have electricity than mobile outreach clients (63.3% compared with 82.5%, $P \leq .01$).

A family planning provider in Tanzania counsels a client of mobile outreach services on IUDs. © 2015 Sala Lewis/EngenderHealth

In Tanzania, women attending mobile outreach were more likely to have 3 or more children (38.0% compared with 24.0%, $P \leq .05$), were less likely to own a mobile phone (38.0% compared with 59.0%, $P \leq .01$), and were more likely to be farmers (82.0% compared with 59.0%, $P \leq .001$) than women at static services (Table 2). Although preference for an implant was not as pronounced as in the DRC, there was a clear preference for LARCs/permanent methods among mobile outreach clients compared with static service clients (62.0% compared with 47.0%, $P \leq .05$). The women's reproductive intentions also varied, with 32.0% attending mobile outreach indicating that they wanted no more children compared with 14.0% at static services ($P \leq .01$).

There were fewer differences between users of static and mobile outreach services in Uganda than in Tanzania and the DRC; however, differences did emerge. Women attending mobile outreach were more likely to be married or in union (93.3% compared with 80.0%, $P \leq .05$), had a higher mean number of children (4.1 compared with 3.3, $P \leq .05$), had a stronger preference for implants (51.7% compared with 25.6%, $P \leq .001$), and had a greater desire to have no more children (41.7% compared with 25.6%, $P \leq .05$) compared with women attending static services (Table 2).

TABLE 3. Primary Family Planning Method Received, by Country and Service Delivery Approach

Method	DRC (N=235)[a]			Tanzania (N=200)		Uganda (N=150)	
	Static (%) n=55	Outreach (%) n=120	FP Day (%) n=60	Static (%) n=100	Outreach (%) n=100	Static (%) n=90	Outreach (%) n= 60
No method	5.5	2.5	0.0	6.0	9.0	8.9	18.3
Condom	0.0	0.0	0.0	3.0	1.0	2.2	0.0
Pill	1.8	0.0	0.0	13.0	9.0	11.1	11.7
Injectable	29.1	3.3***[b]	1.7***[c]	24.0	8.0**	51.1	23.3**
Implant	63.4	94.2***[b]	96.7***[c]	46.0	64.0**	24.4	43.3*
IUD	0.0	0.0	1.7	8.0	4.0	2.2	3.3
Tubal ligation	0.0	0.0	0.0	0.0	5.0*	0.0	0.0

Abbreviations: DRC, Democratic Republic of the Congo; FP, family planning; IUD, intrauterine device.
* $P \leq .05$; ** $P \leq .01$; *** $P \leq .001$.
[a] One-way analyses of statistical significance were conducted between mobile outreach and static services, special family planning days and static services, and family planning days and mobile outreach.
[b] Difference between mobile outreach and static services was statistically significant.
[c] Difference between special family planning days and static services was statistically significant.

Method Adoption

In all countries, women's preference for LARC/permanent methods, and especially for implants, was reflected in the method adopted (Table 3). Significantly higher percentages of women attending non-static services in the 3 countries adopted an implant and significantly lower percentages adopted an injectable compared with women at static services. Few clients in any modality adopted IUDs, condoms, or pills, although all of these methods were available at all service modalities. In the DRC, 63.4% of women attending static services adopted implants and 29.1% adopted injectables. In contrast, 94.2% of women attending mobile outreach and 96.7% at family planning day events adopted implants (both $P \leq .001$), whereas only 3.3% and 1.7% adopted injectables, respectively (both $P \leq .001$). In Tanzania, 64.0% of women attending mobile outreach adopted an implant compared with 46.0% at static services ($P \leq .01$), and only 8.0% attending mobile outreach adopted an injectable compared with 24.0% at static services ($P \leq .01$). Finally, in Uganda, 43.3% of women attending mobile outreach adopted an implant and 23.3% adopted an injectable compared with 24.4% adopting an implant ($P \leq .05$) and 51.1% adopting an injectable ($P \leq .01$) at static sites. The implant was the method most often adopted in each country and at each service delivery modality, with the exception of Uganda, where slightly more than half (51.1%) of the clients attending static services chose an injectable.

Composite and Individual Measures of FFIC

Several significant differences were found in elements of FFIC between service delivery modalities in each country. The FFIC composite indicator for all clients adopting family planning showed that fewer than half the clients in any country or for any service delivery modality reported experiencing all aspects of FFIC (range, 19.2% to 48.1%) (Table 4). Differences between service delivery modalities were significant only in Tanzania, where 31.9% of clients attending mobile outreach services reported experiencing all elements of FFIC compared with 48.9% of clients of static services (odds ratio [OR]=0.5; 95% confidence interval [CI], 0.4 to 0.7; $P \leq .001$). The trend was the same in the DRC, although the results were not significant. In all 3 countries, the average number of FFIC elements for which the response was positive (FFIC mean score) was between 4.8 and 6.1 (of 7). In Tanzania, women in static services reported experiencing on average 6.1 elements of FFIC compared with 5.6 in mobile outreach (P=.02); no other significant differences were found. When looking exclusively at LARC adopters, differences between service modalities were significant only in Tanzania: 26.4% of clients of mobile outreach services reported experienc-

TABLE 4. Measures of the Association of Service Delivery Approach With Elements of FFIC, by Country

Outcome	DRC (N=235)			Tanzania (N=200)			Uganda (N=150)		
	Static (n=55) %	Outreach/ Special FP Day (n=180) %	OR (95% CI)[a] or *P* Value[b]	Static (n=100) %	Outreach (n=100) %	OR (95% CI)[a]	Static (n=90) %	Outreach (n=60) %	OR (95% CI)[a] or *P* Value[b]
All women									
1. Obtained a method	94.6	98.3	3.4 (0.4,27.9)	94.0	91.0	0.6 (0.1,5.9)	91.1	81.7	0.4 (0.1,2.3)
2. Reported being asked about reproductive intentions	80.0	59.4	0.4 (0.1,2.7)	94.0	75.0	0.2 (0.1,0.7)**	64.4	55.0	0.7 (0.4,1.3)
3. Reported discussing three or more methods with provider	65.5	78.3	1.9 (0.4,10.1)	90.0	81.0	0.5 (0.2,1.1)	26.7	41.7	2.0 (0.3,12.5)
4. Given a chance to ask questions	61.8	48.3	0.6 (0.1,2.4)	72.0	70.0	0.9 (0.7,1.2)	75.6	96.7	9.4 (0.8,115.2)
Women who adopted an FP method	**n=52**	**n=177**		**n=94**	**n=91**		**n=82**	**n=49**	
5. Obtained FP method of choice	100.0	98.3	NA	92.6	96.7	2.4 (0.2,24.7)	97.6	95.9	0.6 (0.1,2.6)
6. Participated in FP decision making	96.2	74.0	0.1 (0.0,0.4)***	97.9	87.9	0.2 (0.0,2.3)	92.7	89.8	0.7 (0.4,1.4)
7. Counseled on method received	80.8	83.6	1.2 (0.2,8.7)	93.6	87.9	0.5 (0.4,0.6)***	39.0	42.9	1.2 (0.2,6.1)
8. Counseled on benefits of method received	69.2	75.1	1.4 (0.3,6.6)	84.0	78.0	0.7 (0.4,1.1)	76.8	85.7	1.8 (0.6,5.4)
9. Counseled on side effects of method received	69.2	62.7	0.7 (0.2,3.2)	75.5	58.2	0.5 (0.2,1.1)	63.4	65.3	1.1 (0.6,1.9)
FFIC composite: Percentage of women who adopted an FP method responding positively to ALL indicators 3 through 9	48.1	19.2	0.3 (0.1,1.3)	48.9	31.9	0.5 (0.4,0.7)***	22.0	20.4	0.9 (0.1,5.6)
Women who adopted a LARC	**n=35**	**n=172**		**n=54**	**n=68**		**n=24**	**n=28**	
10. Told where to get implant/IUD removed	74.3	70.4	0.8 (0.2,3.8)	96.2	79.1	0.1 (0.1,0.2)***	79.2	92.9	3.4 (1.4,10.2)*
11. Told when to get implant/IUD removed	85.7	81.4	0.7 (0.1,4.3)	98.1	89.4	0.2 (0.0,2.6)	91.7	96.4	2.5 (1.4,4.2)***
12. Told could have implant/IUD removed whenever wanted	77.1	76.7	1.0 (0.1,6.7)	84.9	68.7	0.4 (0.1,1.3)	83.3	96.4	5.4 (0.6,51.6)
13. Could correctly state when implant or IUD would expire	85.7	80.8	0.7 (0.1,4.1)	88.9	86.8	0.8 (0.5,1.4)	91.7	92.9	1.2 (0.6,2.2)
FFIC LARC composite: Percentage of women who adopted a LARC responding positively to ALL indicators 3 through 13	37.1	15.7	0.3 (0.1,1.8)	40.7	26.4	0.5 (0.3,0.8)**	20.8	17.9	0.8 (0.1,5.1)

Continued

TABLE 4. Continued

Outcome	DRC (N=235)			Tanzania (N=200)			Uganda (N=150)		
	Static (n=55) %	Outreach/ Special FP Day (n=180) %	OR (95% CI)[a] or *P* Value[b]	Static (n=100) %	Outreach (n=100) %	OR (95% CI)[a]	Static (n=90) %	Outreach (n=60) %	OR (95% CI)[a] or *P* Value[b]
FFIC mean score									
FFIC mean score: Average number of indicators 3 through 9 for which response was positive (highest possible score = 7) among women who adopted an FP method	5.5	5.2	.23	6.1	5.6	.02*	4.8	5.1	.15
FFIC mean LARC score: Average number of indicators 3 through 13 for which response was positive (highest possible score = 11) among women who adopted a LARC	8.5	8.3	.70	9.8	8.7	.002**	8.3	8.6	.33

Abbreviations: CI, confidence interval; DRC, Democratic Republic of the Congo; FFIC, full, free, and informed choice; FP, family planning; IUD, intrauterine device; LARC, long-acting reversible contraception; OR, odds ratio.
* $P \leq .05$; ** $P \leq .01$; *** $P \leq .001$.
[a] Error estimates are adjusted for clustering by facility.
[b] *P* values are reported for the FFIC mean scores at the end of the table.

ing all aspects of FFIC, including additional questions related to LARC, compared with 40.7% of clients of static services (OR=0.5; 95% CI, 0.3 to 0.8; $P \leq .01$). The directionality of differences in the DRC and Uganda was the same, but again, was not significant. The average number of FFIC elements, including LARC elements, for which the response was positive was between 8.3 and 9.8 (of 11) for all countries. The difference was again only significant in Tanzania (9.8 in static services, 8.7 in mobile outreach, $P \leq .01$). Importantly, between 92.7% and 100% of clients who received a family planning method obtained their method of choice in all countries and modalities, and the large majority of clients (74.0% to 97.9%) also reported that they made the decision to use family planning either by themselves or jointly with their partner or provider.

In the DRC, only 1 individual measure of FFIC—the client participating in family planning decision making—showed a significant difference between the service delivery approaches: 74.0% of clients of mobile outreach and special family planning days reported such joint decision making compared with 96.2% of clients of static services (OR=0.1; 95% CI, 0.0 to 0.4; $P \leq .001$) (Table 4). No other individual measures of FFIC were significant, and there was no clear trend in directionality among the indicators. However, there was a notable difference in the percentage of women who said that they were given a chance to ask questions: less than half (48.3%) attending mobile outreach/special family planning days compared with 61.8% at static services. It should also be noted that although differences in the FFIC composite indicator were not significant, only 1 in 5 clients attending mobile outreach or special family planning days reported experiencing all measures of FFIC, compared with 1 in 2 clients at static services.

Similar to the DRC, most of the indicators of FFIC did not differ significantly by service delivery modality in Tanzania. The overall trend suggested that FFIC was better at static services compared with mobile outreach, with 3 individual indicators significantly so: reporting that the provider asked about their reproductive intentions (OR=0.2; 95% CI, 0.1 to 0.7; $P \leq .01$), reporting that they were counseled on the method received (OR=0.5; 95% CI, 0.4 to 0.6; $P \leq .001$), and reporting that they were told where to have their implant or IUD (OR=0.1; 95% CI, 0.1 to 0.2; $P \leq .001$). Other elements of counseling, such as "counseled on side effects of method received" and "told could have implant/IUD removed whenever wanted" differed

Most family planning clients obtained their method of choice in all countries and service modalities.

TABLE 5. Proportion of Clients Reporting Being "Very Satisfied" With Aspects of Services, by Country and Service Delivery Modality

	DRC (N=235)			Tanzania (N=200)			Uganda (N=150)		
	Static (n=55) %	Outreach/ Special FP Day (n=180) %	OR (95% CI)[a]	Static (n=100) %	Outreach (n=100) %	OR (95% CI)[a]	Static (n=90) %	Outreach (n=60) %	OR (95% CI)[a]
Amount of time waited to see a provider	69.1	32.2	0.2 (0.1, 0.8)*	94.0	84.0	0.3 (0.1 ,0.8)*	27.8	66.7	5.2 (2.3, 12.0)***
Privacy of your consultation with the provider	78.2	42.2	0.2 (0.0, 1.1)	94.0	91.0	0.6 (0.0, 0.8)***	72.2	95.0	7.3 (1.6, 33.3)*
The cleanliness of the facility	65.5	25.0	0.2 (0.0, 1.2)	85.0	81.0	0.8 (0.2, 2.4)	41.1	61.7	2.3 (0.7, 8.0)
The amount of FP information you were given	65.5	27.8	0.2 (0.0, 0.8)*	88.0	85.0	0.8 (0.2, 2.6)	56.7	73.3	2.1 (1.2, 3.7)**
The opportunity to ask questions	45.5	16.9	0.2 (0.1, 0.7)**	87.0	80.0	0.6 (0.2, 1.7)	71.1	95.0	7.7 (1.9, 31.0)**
The quality of the FP counseling you received	61.1	33.9	0.3 (0.1, 1.3)	91.0	85.0	0.6 (0.3, 1.1)	46.7	68.3	2.5 (1.4, 4.3)**
The way you were treated by staff	87.3	43.3	0.1 (0.0, 0.4)***	95.0	88.0	0.4 (0.2, 0.7)**	67.8	86.7	3.1 (1.2, 8.3)*
The way you were treated by the provider	89.1	43.3	0.1 (0.0, 0.7)*	95.0	88.0	0.4 (0.1, 1.5)	87.8	98.3	8.2 (0.7, 88.9)
Overall satisfaction with services	79.6	40.6	0.2 (0.0, 2.0)	96.0	89.0	0.3 (0.2, 0.6)	78.9	91.7	2.9 (0.7, 11.8)

Abbreviations: CI, confidence interval; DRC, Democratic Republic of the Congo; FP, family planning; OR, odds ratio.
* $P \leq .05$; ** $P \leq .01$; *** $P \leq .001$.
[a] Error estimates are adjusted for clustering by facility.

between the 2 service delivery modalities but did not reach the level of statistical significance.

In Uganda, only 2 indicators—told where, and when, to get an IUD/implant removed—showed significant differences, both among LARC adopters. Both suggested superior counseling at mobile outreach compared with static services, in contrast to Tanzania (Table 4). Overall, where there were sizable differences between the 2 service delivery modalities on indicators that did not rise to the level of statistical significance, most measures of FFIC were better for mobile outreach services.

We did not make any statistical comparisons among the countries because their family planning programs are in different stages of development, and there were likely differences between populations served. However, we observed that in Tanzania, the absolute value of most indicators of FFIC was over 80% (Table 4). In contrast, many values in Uganda and the DRC were much lower, while variability among different measures was high. In the DRC, measures ranged from 48.3% for being given a chance to ask questions at outreach services/special family planning day events to 100% for obtained method of choice at static services. In Uganda, the measures ranged from 26.7% for provider discussed 3 or more methods at static services to 97.6% for obtained method of choice at static services.

Satisfaction

Although overall satisfaction did not differ statistically by mode of service delivery in the DRC, significantly lower percentages of respondents attending outreach services/special family planning days than those at static services reported being "very satisfied" for 5 of the 8 individual measures of satisfaction: amount of time waited, amount of family planning information given, the opportunity to ask questions, the way the client was treated by staff, and the way she was treated by the provider (Table 5). For the remaining measures, the trend was the same, although not statistically significant.

In Tanzania, lower percentages of mobile outreach clients than static service clients also reported satisfaction with aspects of services, with 3 measures significantly so: amount of time waited, privacy of consultation, and the way the client was treated by staff (Table 5).

Although overall satisfaction did not differ statistically by mode of service delivery in Uganda, significantly higher percentages of respondents attending outreach services/special family planning days than those at static services reported being "very satisfied" on 6 of the 8 individual measures of satisfaction: amount of time waited, privacy of consultation, amount of family planning information given, opportunity to ask questions, and quality of family planning counseling received, and the way the client was treated by staff (Table 5).

As stated earlier, statistical comparisons were not made among the countries. Nevertheless, it is notable that the proportion of clients reporting being very satisfied in the DRC varied widely, from just 16.9% of women attending mobile outreach services/special family planning days for the opportunity to ask questions and 25.0% for facility cleanliness to 89.1% at static services for treatment by the provider (Table 5). In Uganda, there was also pronounced variation, with just over a quarter (27.8%) of clients at static services being very satisfied with the amount of time they waited to nearly all (98.3%) clients at mobile outreach services being very satisfied with the way they were treated by the provider. In contrast, at least 80% of clients reported being very satisfied on every measure in Tanzania.

DISCUSSION

The analysis of the composite FFIC indicator suggests that, overall, clients experienced greater FFIC at static services compared with mobile outreach in Tanzania, while significant differences were not found in the DRC or Uganda. Although fewer than half of clients reported experiencing all aspects of FFIC in all countries and for all modalities, the FFIC mean score indicates that clients—all family planning adopters and LARC-only adopters—experienced the majority of elements of FFIC. The fact that few of the individual indicators of FFIC were significant in any country but showed greater differences when examined as a composite indicator may be an issue of power. It is, therefore, important to look at trends in the domains of FFIC as well as the composite measure and mean score.

The results indicate that women were equally likely to obtain a family planning method and, specifically, the method they wanted at all service delivery modalities in each country. It is important to note that a higher percentage of women who came to non-static service sites had a preexisting preference for a LARC than those attending static services in all 3 countries. Women coming to non-static services may have sought those services specifically because they knew these methods would be available, thereby potentially masking a difference in method availability between service delivery modalities. The women's preference for LARCs at mobile outreach and special family planning days suggests that the high levels of implant uptake at these services were likely related primarily to preexisting preferences, rather than the unavailability of other methods or provider bias. In particular, in the DRC, the fact that methods were free during special family planning days and mobile outreach may have attracted clients who were waiting specifically for free events in order to obtain LARCs, which are normally costly.

Findings for the other individual indicators of FFIC were mixed. One indicator showed better performance at static services in the DRC; 3 indicators showed better performance at static services in Tanzania; and 2 indicators showed better performance at mobile outreach in Uganda. In Tanzania, the better performance of static services may be a product of the lower volume of clients compared with mobile outreach, resulting in longer counseling sessions. However, we did not measure the length of counseling sessions for each client and, therefore, cannot be certain of this interpretation. In Uganda, the indicators with better results for mobile outreach services were all related to LARCs, possibly reflecting that providers who routinely participate in mobile outreach events are more skilled in the provision of and counseling for LARCs. However, the mobile outreach model in Tanzania and Uganda was similar; therefore, one would expect similar outcomes. It is also plausible that when a client arrives having already decided on a method—which was more likely for non-static services in all countries—providers are less likely to give full counseling, assuming—perhaps incorrectly—that the client has all the information she needs. In the DRC, there was no clear trend, indicating that clients at all modalities were equally likely to experience aspects of FFIC. Facilities that provided static services received more routine support and supervision than facilities that held mobile outreach,

which may have affected outcomes as well, though the pattern of impact is not clear.

Questions on counseling specifically asked whether "the provider" counseled the client about a particular element. Group counseling is common at mobile outreach services and special family planning day events. It is possible that some clients responded "no" to some elements of counseling because they received information from a different staff member, not the provider who gave her the method. This may have contributed to the low number of clients at both service delivery modalities in Uganda who stated that the provider discussed 3 or more methods with them and that the provider counseled them on the method they received. It is common for a provider to review the array of methods available during group counseling, whereas the accepted method may be given by a different provider. A more nuanced questionnaire could inform this understanding of the data.

Clients attending mobile outreach and special days tended to be of lower SES and education level. It is possible that women of lower SES might not understand all of the information during counseling, which, in turn, may have affected their reporting of FFIC. In practice, it is not possible to separate the service delivery modality from the profile of client reached. It is therefore important to consider how the client profile may affect FFIC in addition to the service delivery modality.

Across all modalities, clients were often not counseled on potential side effects or given the opportunity to ask the provider questions.

It is essential to note that even when differences between service delivery modalities were not found, some of the indicators of FFIC should be improved in all countries and for all modalities. For example, at least one-quarter of clients in each country and for each service delivery modality reported that they were not counseled on potential method side effects. In some cases, this result may have been because a client was a continuing user of a method; however, it is important to ensure that all clients are given accurate information about their method options and the benefits and risks of family planning. This is particularly true when examining whether clients were given a chance to ask questions. Although there were no significant differences between modalities in any country, Uganda was the only country where more than three-quarters of clients at any modality reported being able to ask questions. All clients should have the opportunity to ask questions. Despite this, nearly all clients received their method of choice, the large majority of clients reported independent or joint decision making, and there was no indication that any client rights were violated. More research is needed to understand why clients may not be experiencing all aspects of FFIC and how to better support providers to deliver quality counseling in various service delivery modalities.

Indicators of satisfaction appeared to align with indicators of FFIC; that is, in the modality where clients reported superior indicators of FFIC, they were also more likely to be very satisfied with various aspects of services and counseling. Overall, this indicates that ensuring that clients experience FFIC may increase client satisfaction with services, though specific analysis of any such correlation would be needed to investigate this concept. Further, some elements of services that may affect satisfaction, such as wait time, are beyond FFIC and not likely to be correlated. The proportion of women reporting being very satisfied with a variety of individual indices was notably low in both service delivery modalities in the DRC and Uganda, suggesting that improvements could be made to all services.

Although no statistical comparisons were made among countries, the relatively lower experiences of elements of FFIC and of satisfaction in the DRC and Uganda compared with Tanzania is notable. It is not possible to extrapolate from these data why this difference occurred; however, the prevalence of family planning services, the maturity of the family planning programs, the funding and political environment, and other external factors may have affected providers' abilities to deliver quality services. The implementation of the ExpandFP program also differed from country to country, with varying numbers of providers trained in family planning counseling, a different reach of the program, and slightly different models for mobile outreach and special family planning days. These environmental factors may also affect clients' expectations and experiences with family planning services.

The differences seen in client characteristics between women attending mobile outreach or special family planning days compared with those at static services are also important to consider in terms of the populations reached in the 3 countries. Findings indicate that, overall, mobile outreach and special family planning day services reached women of lower SES than static services, thus underscoring the importance of non-static service delivery options in reaching more disadvantaged and vulnerable populations. The lower proportion of women with a history of modern family planning use also indicates that mobile outreach and special family planning days may reach clients with a long-standing

unmet need, particularly an unmet need for limiting childbearing. These differences in characteristics indicate that mobile outreach and special family planning days are important strategies for increasing access to family planning. Moreover, the higher comparative uptake of LARC by women attending mobile outreach and special family planning days, and the possibility that many women came to these services with these methods already in mind, indicate that non-static services are important ways to increase access to these underutilized methods for underserved populations. The women's SES may have also affected how providers counseled them and/or how the clients experienced, understood, and recalled that counseling.

Further research is needed to explore the reasons for differences in FFIC and to determine what approaches may effectively ensure that providers enable all clients, especially women of lower SES, to make FFIC. It is equally important to ensure that the various service delivery modes, including those crucial to reaching underserved populations with underutilized methods, expand access to family planning while offering quality counseling and FFIC for all clients. Existing tools that can be used to monitor and improve clients' experiences of FFIC can and should be brought to scale at national levels—across the private, public, and non-profit spheres—and used to continually improve services. Additionally, client–provider interactions can and should be tailored to meet individual client needs: some clients may want more information than others, returning clients may be happy with their method and not need or want counseling on other methods, while others may want to hear about an array of options. Qualitative research on both the client and provider experiences with counseling can help program planners and implementers to better understand these dynamics and how to measure them. Observations of client–provider interactions are also important to understand the reasons why some clients had better experiences with some elements of FFIC than others.

Limitations

This research is not generalizable at the country level because the facilities, which were purposively selected in each country, received different levels of project support and, therefore, are not representative of facilities in general. Similarly, public-sector mobile outreach may differ from private-sector or NGO-led outreach, which was not captured here, and the client profile at study facilities may not be representative of clients, in general. Additionally, the study's findings are dependent on client recall of experiences. Recall bias was minimized by interviewing clients immediately following their receipt of services and prior to their exit from the facility. This was a strength of our study design, compared to household surveys, which interview clients about counseling practices long after the event has occurred. Courtesy bias may also have affected the reliability of study results, especially related to measures of satisfaction. This bias was minimized by interviewing clients privately and by non-facility staff conducting the interviews. In addition, measures of the elements of FFIC were limited in our study to the client's perspective. Finally, the relatively small sample size may have limited the power to detect significant differences, in particular, because the desired sample size was not reached in all modalities.

CONCLUSIONS

The study findings suggest that client experiences of FFIC elements varied among the service delivery modalities, with certain elements scoring lower, and other elements scoring higher, at some non-static service delivery modalities compared with static services. The reasons for this variance may be related to client volume during non-static service delivery events, the profile of clients who attended non-static service delivery, differences in how providers approached women of higher or lower SES, or other unknown factors. In cases where the FFIC scores were lower, provider monitoring, supervision, and follow up on appropriate counseling methods as well as ensuring sufficient staff time for comprehensive counseling may have enhanced clients' satisfaction and experiences of FFIC. Implementers may need to increase staffing, establish a maximum number of clients during special family planning events, or use other approaches to ensure enough time for counseling. Further research is needed to understand the conditions or circumstances that may make FFIC more difficult in mobile outreach settings or during special family planning days. Special family planning days and mobile outreach days play a key part in expanding access to family planning, and the large majority of clients were able to obtain the method of their choice in these events, the majority of whom chose a LARC. Each service delivery modality poses different challenges to providers to provide quality services and counseling, and these must be accounted for in program planning.

Using various service delivery modes is crucial to reaching underserved populations with underutilized methods and expanding access to family planning.

Despite some high scores, most elements of FFIC for all service delivery modalities and in all countries still showed room for improvement. Women who adopt family planning should receive high-quality care, including FFIC. This study shows the importance of monitoring FFIC as programs expand access to family planning services and methods. It is not enough to reach clients with methods and services, clients should be empowered to make decisions fully, freely, and with correct and complete information.

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En français

Perceptions des clients concernant la qualité et le choix au sein des services statiques, mobiles et lors des journées planification familiale dans 3 pays africains

Dans les 3 pays, quasiment toutes les femmes ont obtenu la méthode de leur choix, sachant que davantage de clientes des services de sensibilisation mobile et des journées spéciales planification familiale avaient auparavant une préférence pour les implants, par rapport aux clientes des services statiques. Les clientes des différents types de service ont déclaré avoir bénéficié de la plupart des éléments du choix total, libre et éclairé, certains aspects peuvent néanmoins être améliorés, comme par exemple les conseils relatifs aux éventuels effets secondaires et le fait de permettre aux clientes de poser des questions.

RÉSUMÉ

Contexte : L'utilisation de méthodes réversibles de longue durée d'action a considérablement augmenté en République démocratique du Congo (RDC), en Tanzanie et en Ouganda. L'adoption des méthodes réversibles de longue durée d'action est particulièrement élevée pendant les campagnes de sensibilisation mobile et les journées spéciales planification familiale. Il conviendrait donc d'examiner les perceptions des clientes et leur expérience en matière de choix total, libre et éclairé dans différentes modalités de prestation de services.

Méthodes : Entre avril et juillet 2015, nous avons conduit une enquête transversale auprès des clientes de planification familiale pour évaluer le choix total, libre et éclairé et la satisfaction des clientes par rapport aux services statiques, mobiles et lors des journées spéciales planification familiale en RDC (n=9 sites), Tanzanie (n=13), et Ouganda (n=8). Cette étude a permis de mener des recherches sur les perceptions des clientes eu égard aux 13 éléments du choix total, libre et éclairé notamment la mesure de la qualité des conseils et de la satisfaction des personnes interviewées à propos des différentes approches en matière de prestation de service. Les résultats composites du choix total, libre et éclairé ont été interprétés et analysés comme correspondant au pourcentage de femmes qui ont répondu par l'affirmative à l'ensemble des éléments et au score moyen de réponses positives. La satisfaction a été évaluée en utilisant une échelle de Likert de 4 points. Nous avons eu recours à la régression logistique pour évaluer le lien entre les résultats primaires et le mode de prestation de service.

Résultats : Au total, nous avons interviewé 585 femmes (n=150 en Ouganda, n=200 en Tanzanie, et n=235 en RDC). La grande majorité des clientes de tous les pays et de l'ensemble des modalités ont obtenu la méthode de leur choix. Comparées aux clientes de services statiques les clientes des services mobiles et des journées spéciales planification familiale ont préféré des méthodes réversibles de longue durée d'action et des méthodes permanentes, en particulier les implants. Les mesures composites du choix total, libre et éclairé étaient plus faibles pour la sensibilisation mobile que pour les services statiques en Tanzanie parmi l'ensemble des clientes de planification familiale (coefficient de probabilité [CP]=0,5; $P \leq ,001$) et parmi celles qui utilisent des méthodes réversibles de longue durée d'action en particulier (CP=0,5; $P \leq ,01$); aucune différence majeure n'a été constatée en RDC ou en Ouganda. Un score moyen du choix total, libre et éclairé parmi toutes les clientes de services de planification familiale a montré que les clientes de l'ensemble des modalités de tous les pays avaient signalé avoir bénéficié de la plupart des éléments du choix total, libre et éclairé avec des moyennes variant entre 4,8 et 6,1 des 7 éléments. Pour ce qui est des clientes de méthodes réversibles de longue durée d'action en particulier, les scores moyens allaient de 8,3 à 9,8 des 11 éléments. Lorsqu'un pourcentage plus élevé de clientes ont bénéficié d'un degré important de choix total, libre et éclairé, une proportion plus importante de clientes ont également eu tendance à signaler être « très satisfaites » des différents aspects de services et conseils.

Conclusions : Les résultats indiquent que les journées spéciales de planification familiale et les services de sensibilisation constituent des moyens importants et viables pour accroître l'accès aux services de planification familiale, notamment aux méthodes réversibles de longue durée d'action, mais il faut accorder une plus grande attention au respect et à la réalisation du choix total, libre et éclairé des clientes dans l'ensemble des modalités de prestation de service.

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ORIGINAL ARTICLE

Quality and Cost Interventions During the Extended Perinatal Period to Increase Family Planning Use in Kinshasa, DRC: Results From an Initial Study

Leah Jarvis,[a] Jane Wickstrom,[b] Gwyneth Vance,[c] Jewel Gausman[d]

The combined intervention of free contraceptives plus a set of quality inputs for family planning during the extended perinatal period, including provision of long-acting methods immediately postpartum, had the strongest effect on use of modern contraceptives, especially long-acting methods.

Résumé en français à la fin de l'article.

ABSTRACT

Background: Most women worldwide do not desire another pregnancy within a year after giving birth, but uptake of modern contraception during this time period is low. We independently tested 2 approaches to increasing contraceptive uptake and the 2 approaches combined using a quasi-experimental study design in Kinshasa, the Democratic Republic of the Congo.

Methods: The primary analytic data came from client exit interviews conducted post-intervention (N=563) from 4 study groups. The first arm (n=150) received free family planning, and the second arm (n=113) a quality inputs intervention involving systematic screening, referral, and immediate provision of long-acting reversible contraceptives (LARCs) after labor and delivery. The third arm (n=150) received a combination of the 2 interventions, and the fourth (n=150) no intervention. Family planning service statistics were also collected throughout the intervention period.

Results: Women in the quality arm (odds ratio [OR]=4.5; 95% confidence interval [CI], 1.8 to 10.9) and free/quality arm (OR=6.7; 95% CI, 2.8 to 16.1) were more likely to be properly screened for family planning than women in the control group, but paper referral was seldom implemented in any group. Women in the free arm (OR=3.8; 95% CI, 1.6 to 9.0) and in the free/quality arm (OR=11.0; 95% CI, 4.3 to 27.9) were more likely than the control group to report being properly counseled on family planning. Clients were more likely to be modern contraceptive users (excluding condoms) in the free arm (OR=3.2; 95% CI, 1.4 to 7.2) and in the free/quality arm (OR=8.6; 95% CI, 3.9 to 19.0) than in the control group. Clients in all study arms were more likely to use a LARC compared with the control group (Quality arm: OR=2.9; 95% CI, 1.1 to 7.9. Free arm: OR=5.6; 95% CI, 2.3 to 13.7. Free/quality arm: OR=8.4; 95% CI, 3.4 to 20.6). Service statistics from the combined intervention arm showed that a significantly greater proportion of family planning adoption occurred within the immediate postpartum period (0 to 2 days) in the quality arm ($P<.001$) and free/quality arm ($P<.001$) than in the control arm. Quality inputs, free contraceptives, and the combined intervention had positive impacts on aspects of screening and contraceptive uptake. The combined intervention performed best by all measures.

Conclusion: Providing family planning, including LARCs, in the immediate postpartum period, implementing a systematic screening and referral system, and providing free methods may improve family planning access and uptake in the extended perinatal period in this environment.

INTRODUCTION

An estimated 95% of postpartum women worldwide do not desire another pregnancy within 12 months of giving birth; however, due to low uptake of modern family planning methods, the risk of unplanned pregnancies in this group remains high.[1–4] In a 12-country analysis, nearly three-quarters of postpartum women in sub-Saharan Africa were estimated to have an unmet need for family planning,[4] an estimate that has remained fairly consistent over the past decade.[2]

Barriers to reducing unmet need for postpartum family planning (PPFP) range from sociocultural and informational[5–11] to structural and economic. Data show that family planning cost alone, particularly for long-acting reversible contraceptives (LARCs)—i.e., intrauterine devices (IUDs) and hormonal implants—and permanent methods—i.e., male and female sterilization—can be a substantial barrier to uptake.[11–14] These methods often entail higher up-front costs than do short-acting methods

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(i.e., condoms, oral contraceptives, and injectables).[15] Although LARCs and permanent methods may be well suited to the reproductive intentions of postpartum women, previous research indicates that when postpartum women do use a method, they overwhelmingly use short-acting methods.[2,16]

Strategies such as voucher systems have been used to address economic barriers to family planning; however, specific data are limited on how providing free contraceptives may impact PPFP use[17–19] and on how cost and integration interventions may work together to increase PPFP use. Integration generally refers to approaches to remediation of PPFP barriers within the health system. These efforts tend to focus on the extended perinatal period (EPP)—defined as pregnancy through the first year postpartum—visit structure, whereby exposure to antenatal care (ANC), labor and delivery (L&D), postnatal care (PNC), and infant/child health and immunization services ensure that women have frequent, scheduled contact with the health system. World Health Organization (WHO) and other international guidelines recommend using these health system contact points to provide family planning information and services and expand the availability of the range of family planning methods available. Provider training on LARCs and permanent methods delivery is an important component of the expansion.[20,21]

Much research on PPFP use to date, however, has been focused on integrating family planning messages and referrals into a single delivery point, such as immunization or ANC services, as opposed to providing services through many delivery points in a health facility. The results have been mixed.[6,7,22–25] Research in Rwanda and Liberia demonstrated increased family planning uptake by providing referrals for co-located family planning services to mothers bringing their children to immunization services.[7,24] In contrast, research on integration of family planning messages into immunization services in Ghana and Zambia found no effect on family planning uptake.[25] In other contexts, research has demonstrated that the provision of family planning counseling and services during labor and delivery and postpartum care can increase uptake of family planning immediately postpartum; this is now considered a "proven" high impact practice.[10,21]

The Democratic Republic of the Congo Context

In the Democratic Republic of the Congo (DRC), the national modern contraceptive prevalence rate among married women of reproductive age is extremely low (7.8%), while unmet need is high (27.7%) and only one-third of facilities offer any family planning services.[26,27] The Ministry of Health (MOH) is working to address these issues by making a national commitment as part of the Family Planning 2020 (FP2020) global movement and establishing a country action plan to increase PPFP access.[28–31] EngenderHealth's Expand Family Planning Project (ExpandFP) (2013–2020) is one of many efforts funded by the Bill & Melinda Gates Foundation and other donors to support the DRC MOH to move toward their FP2020 and PPFP goals.

In the DRC, ExpandFP focused efforts in Kinshasa, where unmet need is relatively high (22.6%) among married women of reproductive age and facility-based delivery is nearly universal.[26,32] This environment presented opportunities to reach women at health facilities who wanted and needed family planning during the EPP. However, throughout the DRC, family planning is not routinely provided for free in either the public or the private sector. The median cost to the client for short- and long-acting methods ranges from less than US$1 for oral contraceptives to more than US$10 for an implant, with variation among facilities.[15] In a country where the per capita gross national income is about US$460 per year, contraceptive costs may pose an important barrier to family planning use.[33] Therefore, we wanted to understand how eliminating cost as a barrier could affect PPFP uptake.

The cost of contraception in the DRC can be a barrier to family planning use.

To assist the DRC MOH National Reproductive Health Program, ExpandFP conducted an operational study to determine how to best increase family planning uptake in the EPP. Two interventions were evaluated separately and in combination with each another. The first intervention provided free contraceptives. The second, referred to as "quality inputs," focused on the perinatal contacts within the health system at all service delivery points in the EPP; these include systematic screening and referral in child health/immunization, ANC, and PNC services, along with additional training on family planning counseling and immediate provision of LARCs in L&D wards. We hypothesized that both the free contraceptives and quality inputs interventions would increase uptake in the EPP, but that the combined intervention would have the greatest effect.

Provision of family planning counseling and services during labor and delivery can increase contraceptive uptake immediately postpartum.

METHODS

The research used a 4-group, nonrandomized, posttest study design. Data evaluating the primary outcomes were collected from client exit interviews

and were bolstered by family planning service statistics. To be eligible for inclusion in the study, facilities in Kinshasa were required to meet the following minimum criteria: (1) have no other implementing partners; (2) have a relatively high monthly caseload of L&D patients, with an average of at least 30 per month; and (3) serve a peri-urban population. The 4 facilities (2 hospitals and 2 maternity referral centers) that met these criteria and were willing to participate were purposively chosen under advisement from the MOH and assigned to 1 of 4 study arms (Figure 1). The Arm 1 ("quality") facility was assigned to the quality inputs intervention, the Arm 2 ("free") facility was assigned to the free contraceptives intervention, the Arm 3 ("free/quality") facility was assigned to the free contraceptive and quality inputs intervention, and the Arm 4 facility served as the control.

Study activities were initiated in February 2016 and concluded in June 2017. Initiation of the interventions was staggered over 3 months across the 3 treatment sites and lasted a total of 12 months at each facility.

A whole-site training approach was used to deliver the training and education components of the quality inputs intervention.

Interventions

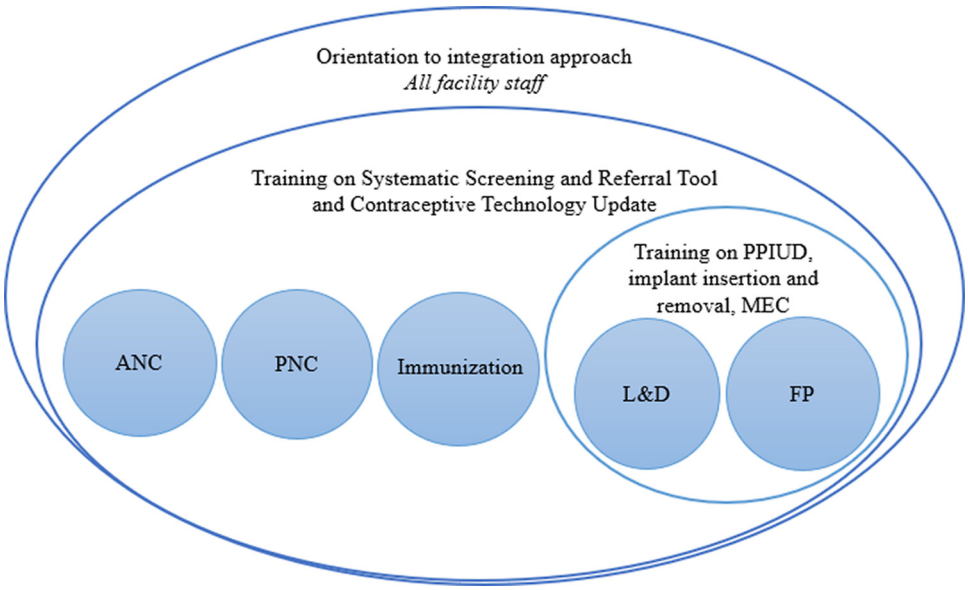
Quality Inputs (Arms 1 and 3)

The quality inputs intervention consisted of 3 components: (1) clinical training and provision of equipment for postpartum insertion of the IUD (PPIUD), (2) training on WHO's *Medical Eligibility Criteria (MEC) for Contraceptive Use*,[34] and (3) introduction of a systematic screening and referral tool for family planning.

These components were launched through whole-site training: a facility-wide approach intended to meet the learning needs of all staff in various departments and to encourage teamwork among them.[35–38] The whole-site training consisted of a 7-day, facility-based training for providers and non-clinicians alike. Providers and facility staff participated in relevant parts of the training according to their role in the intervention (Figure 1). ANC, PNC, and immunization providers were expected to screen clients for family planning need, current or future, and refer the clients as needed. L&D providers were expected to do the same, but also had the ability to counsel on and deliver some methods within their department. Family planning providers were not expected to screen and refer, but rather to counsel and deliver family planning methods.

The trainers and facility supervisors first oriented staff from the entire facility over a 2-day period to the integration approach and the goals of the intervention, at the same time assessing training and equipment needs. Then, providers were

FIGURE 1. Whole-Site Training Model



Abbreviations: ANC, antenatal care; FP, family planning; L&D, labor and delivery; MEC, medical eligibility criteria; PNC, postnatal care; PPIUD, postpartum insertion of an intrauterine device.

divided into subgroups for specialized training according to their primary function in the facility. Over 5 days, providers from the family planning and L&D departments were trained on postpartum insertion of an IUD, provided with needed PPIUD equipment, and refreshed on implant insertion and removal. The clinical training also included an update on MEC for postpartum women and a review of rights-based family planning counseling.[39] Trainees were assessed for competency using anatomical models, and supervised PPIUD insertions were conducted with available clients for on-the-job coaching on the last day of the training. As a result of the training, providers were able to provide PPIUDs, implants, and other methods within the L&D department immediately postpartum.

Providers from departments within the facility that women frequent throughout the EPP—specifically, ANC, L&D, PNC, and child health/immunization—were given a contraceptive technology update and trained on the use of the screening and referral tool.

The adapted paper-based systematic screening and referral tool, developed by the Population Council and IntraHealth International and tested in several resource-challenged settings,[40–43] was designed to help providers screen women for family planning need and provide written referrals. The first page of the tool is an abbreviated assessment of the client's reproductive intentions, pregnancy and delivery history, family planning practices and satisfaction, and desire for additional family planning information or services. When a client indicates interest in additional information or services, the provider is prompted to continue to a written referral form, which is then sent with the client to the family planning unit, where family planning counseling is continued and a method is provided if desired. Both screening forms and referral forms were filed and used as a study monitoring mechanism throughout the implementation period.

Free Contraceptives (Arms 2 and 3)

To address economic barriers to family planning access, all contraceptives were provided free of charge in Arms 2 and 3 in both the L&D and family planning units. Prior to the study, the 4 study sites offered a range of family planning methods for a fee, with the exception of male condoms, which were free at all 4 facilities. Costs to clients at these facilities varied from US$0.30 to $10 for short-acting methods and from US$5 to $10 for LARCs. Female sterilization cost US$100 to $250 at 3 of the facilities, but was only available as part of a cesarean delivery. ExpandFP provided a monthly stipend to the facilities providing free contraception that was approximately equal to lost revenue from charging for family planning; the amount of this stipend was negotiated prior to study launch. No targeted demand generation activities were conducted in any study site, as the intervention was intended to be facility-based only.

Monthly stipends were provided to facilities to compensate them for providing free contraception to clients during the study period.

Method Availability (Arms 1, 2, 3, and 4)

In all 4 facilities, clients could access IUDs, implants, injectables, oral contraceptives, and male condoms in the family planning department throughout the duration of the intervention, and facilities were supported to ensure no stock-outs occurred. Clients could not access family planning methods in ANC, PNC, or immunization departments in any of the 4 facilities.

In the quality intervention sites only (Arms 1 and 3), clients could obtain IUDs, implants, or oral contraceptives in L&D in the immediate postpartum period. They could also be referred for family planning if they chose not to adopt family planning at that time but were interested in future use.

Female sterilization was unavailable in the quality arm facility. Vasectomy was not available at any of the facilities. The project did not aim to increase the availability of permanent methods.

The study adapted a paper-based systematic screening and referral tool designed to help providers screen women for family planning need and provide written referrals.

Outcomes of Interest

The main study outcomes of interest related to family planning service provision quality and family planning uptake. Outcomes were assessed in the service delivery departments or study populations to which they were applicable (Table 1). Secondarily, we assessed how well the approaches tested targeted women in the EPP, and how the approaches affected method mix among family planning clients.

Family planning service provision quality and family planning uptake were the primary study outcomes of interest.

To evaluate the quality domain, binary outcomes for family planning screening, family planning referral, family planning counseling, and LARC counseling were assessed; criteria for each outcome are described in Table 1. From client exit interview data, affirmative answers to all criteria were necessary to justify a "Yes" classification for each outcome. The analysis set (i.e., denominator data) used for each of the outcomes varied based on the type of service delivery point. For example, family planning providers were not expected to screen for family planning need or refer for family planning, since a client presenting had already

TABLE 1. Primary Study Outcomes, Criteria, and Analysis Set

Outcome (Yes/No) by Source of Data	Criteria	Analysis Set
Client Exit Interview		
Quality FP Service Delivery		
Properly screened for FP	Client reported that (1) her provider either asked if she wanted more children or when she wanted more children and (2) provider asked client if she was interested in FP.	Women interviewed at ANC, PNC, immunization, and L&D services
Properly referred for FP	Client reported that (1) her provider asked if she was interested in FP, (2) she told the provider she was interested, and (3) the interviewer was able to observe the paper referral slip in client's hand.	Women interviewed at ANC, PNC, and immunization services
Properly counseled on FP	Client reported that her provider (1) gave her a chance to ask questions; (2) if so, the answers to questions were satisfactory; (3) the provider discussed advantages of methods; (4) the provider discussed side effects; and (5) the provider told client what to do if she experienced side effects.	Women interviewed at L&D and FP services
Properly counseled on LARC	Client reported that her provider told her (1) where her LARC could be removed; (2) when her LARC should be removed, based on maximum duration of use; and (3) that she could have her LARC removed at any time.	LARC adopters
FP Method Use		
Modern FP user	Client reported that she was using one of the following FP methods or that she had received one of the following methods on the day of interview: *male/female sterilization, IUD, implant, oral contraceptives, male/female condoms, emergency contraception, standard days method, or lactational amenorrhea method.*	All nonpregnant women
Modern non-condom FP user	Same as previous, except male/female condoms were excluded from the list of methods.	All nonpregnant women
LARC user	Same as previous, except only includes users of IUDs or implants.	All nonpregnant women
Service Statistics		
Postpartum Distribution of FP Clients		
FP client in the EPP	Client received a modern FP method and was within 12 months of last delivery.	All FP clients
FP client in immediate postpartum period	Client received a modern FP method and was within 2 days of last delivery.	All FP clients

Abbreviations: ANC, antenatal care; EPP, extended perinatal period; FP, family planning; IUD, intrauterine device; L&D, labor and delivery; LARC, long-acting reversible contraceptive; PNC, postnatal care.

expressed interest in family planning by coming to that department, so screening and referral were not evaluated among clients exiting family planning service departments.

Evaluation of the family planning uptake domain was structured around clients' use of modern methods among all nonpregnant women enrolled in the study, either including or excluding condoms (Table 1). Condoms were excluded from some analyses to look specifically at female-controlled methods used exclusively for pregnancy prevention and to better isolate the impact of free contraception, since condoms were free in all facilities.

A subanalysis compared aspects of counseling and method provision in L&D to family planning wards to help isolate how the intervention affected these service delivery points specifically and identify areas for improvement.

To evaluate the extent to which the intervention reached women in the EPP, service statistics were examined to determine the proportion of all family planning clients who were within 0 to 2 days, 3 days to 6 weeks, and more than 6 weeks to 12 months postpartum. They were also used to compare the method mix by study arm.

Data Collection

The primary sources of data for the study were (1) structured client exit interviews from L&D, family planning, ANC, PNC, and child immunization/

health departments and (2) routine family planning service statistics collected throughout the intervention.

For client exit interviews, women were eligible for participation if they were between 18 and 49 years of age. Clients provided written consent and were interviewed in their preferred language (French or Lingala). Client interviews were used to collect data on client sociodemographic characteristics and reproductive history and intentions as well as experiences with family planning screening and referral, the content of family planning counseling, and family planning use/adoption from the delivery point they had attended on the day of the interview. Questions also gauged client perspectives on the cost of methods and how cost affected method selection. Although clients who received more than 1 service in a day were not interviewed multiple times, it is possible that a client who returned to the facility during the weeks of data collection could have been interviewed more than once.

The interview forms were field-tested in both French and Lingala and were administered over a 5-week period in participants' preferred language by trained data collectors. Interviews were conducted from March to April 2017, after the intervention had been implemented for 9 to 12 months in each facility, depending on the date of initiation.

Family planning service statistics were extracted from the family planning and L&D registers for 12 months following the introduction of the intervention in each facility. A column for "date of last delivery" was added to the registers, and the registers were reviewed routinely by project staff to ensure completeness and accuracy. Data obtained from service statistics included family planning method received, date of service, and date of last delivery, allowing for calculation of the postpartum period.

Sampling

Sample size was calculated to be able to detect a 15 percentage point difference in the percentage of clients screened for family planning in intervention groups compared with the control. Assuming a 25% level of screening in the control group, and using a 2-sided test with an alpha of 0.05 and 80% power, we estimated that 100 clients per facility were needed, split evenly across ANC, PNC, immunization, and L&D services, where screening was expected to occur.

Because we also sought to assess outcomes related to family planning counseling and service provision and overcome a low family planning client load in the control arm, we interviewed an independent sample of 50 women in the family planning unit in each facility. In total, 25 clients were sampled for a quantitative interview in each of the PNC, ANC, L&D, and immunization units, and 50 clients in family planning, resulting in about 150 participants per facility. All clients meeting the study criteria were asked to participate in an interview; recruiting continued until the sample size targets were reached (Figure 2).

Data Analysis and Statistical Tests

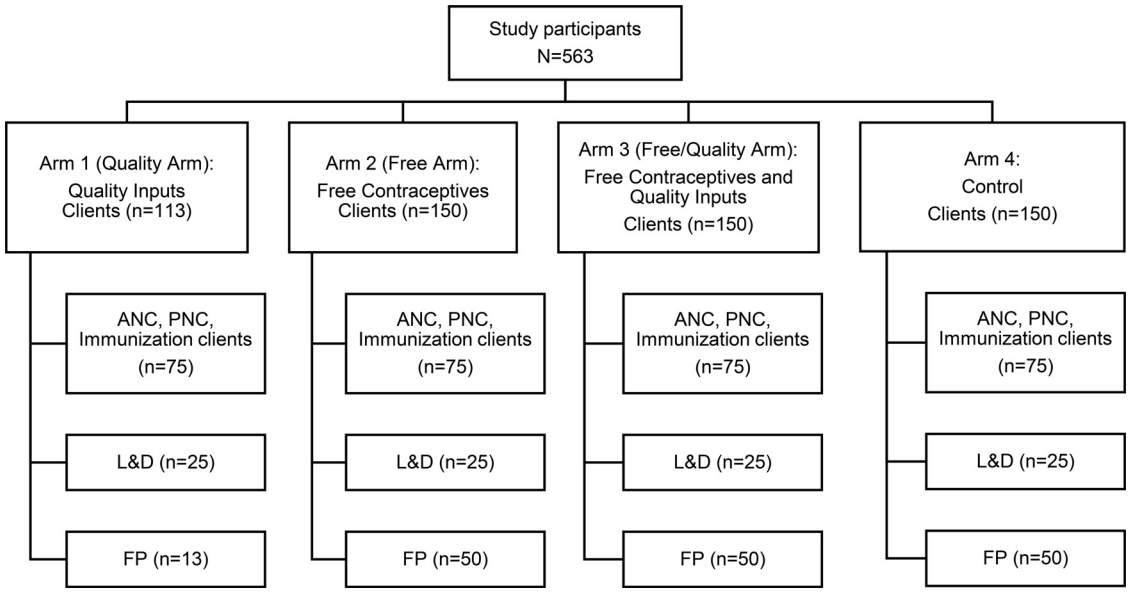
Client interview data were double-entered into Epi Info (U.S. Centers for Disease Control and Prevention, Atlanta, GA, USA) and analyzed in Stata version 14 (StataCorp, College Station, TX, USA). The main outcomes were evaluated through the development of logistic regression models (Table 1). Dummy variables representing study groups were included as covariates in the crude models; odds ratios (ORs) and 95% confidence intervals (CIs) were reported. The final models used for comparison, however, were adjusted for potentially confounding factors. To determine the factors to include as covariates in adjusted models, client background characteristics that might also relate to family planning uptake were assessed. This included client age, parity, marital status, education level, occupation, religion, ever-use of family planning methods, ever-use of LARCs, pregnancy status, postpartum period, fertility intentions, and socioeconomic status (SES). An indicator of SES was derived from several questions on assets, income, and savings through principal component analysis (PCA).[44] Briefly, PCA was used to reduce the set of SES indicators to an index score with a mean of 0 and a standard deviation (SD) of 1. SES-related variables used to construct the score were based on yes/no responses to questions about possessions, cash savings, land ownership, assets that could be used to generate income, and income earned outside the home. A PCA value of 0.32, for example, meant that the women in this group were above the mean SES of all women in the study.

Client background characteristics were used to determine what factors might contribute to family planning uptake.

Differences between each study group and the control on these factors were tested using chi-square tests for proportions and *t* tests for means. If $P \leq .05$ at the 95% CI for any client characteristics, they were treated as potential confounders and included in the adjusted logistic models.

Family planning service statistics were analyzed by calculating the proportions of family

FIGURE 2. Study Participants, by Study Arm and Facility Department



Abbreviations: ANC, antenatal care; FP, family planning; L&D, labor and delivery; PNC, postnatal care.

planning clients who chose each method and the proportions who fell within the EPP. The postpartum period was further disaggregated to the immediate postpartum (0 to 2 days), the standard postpartum (0 to 6 weeks), and the extended postpartum (0 to 12 months) periods. Nulliparous women and women for whom the date of last delivery was unknown were excluded. The proportions of women in each category were compared between study arms and the control arm, using chi-square tests. Receiving a method within 2 days of delivery indicated that the method had been provided within the L&D department. Analyzing change over time in proportion of family planning clients in the EPP was not possible due to the unavailability of baseline data.

Ethical Approval

The protocol and tools were approved by the Western International Review Board in the United States and by the University of Kinshasa School of Public Health Ethical Review Committee.

RESULTS

Client Characteristics

Data were collected from a total of 563 clients (Figure 2); low client flow in Arm 1 resulted in a lower than desired sample size. Women in all 3 intervention groups were similar to the control group in age, marital and pregnancy status, desire for children in the next 2 years, and ever-use of a LARC (Table 2). Women in all 3 intervention groups had significantly higher mean pregnancies compared with the control group. Women in the free contraceptives groups (Arms 2 and 3) had significantly lower mean SES PCA scores, educational attainment, and a higher mean number of children than the control group. The free contraceptives-only group (Arm 2) also had fewer respondents within 12 months postpartum and a lower proportion of participants who ever used modern family planning. Other covariates found to be significantly different in at least 1 arm compared with the control arm were religious affiliation and working outside the home.

Screening and Referral

The first outcome of interest was the proportion of women attending ANC, PNC, immunization, or L&D departments who were properly screened for family planning need. Women in the quality arm (Arm 1) (OR=4.5; 95% CI, 1.8 to 10.9) and free/quality arm (Arm 3) (OR=6.7; 95% CI, 2.8 to 16.1) were significantly more likely to have been

TABLE 2. Sociodemographic Characteristics of Clients, by Study Arm

	Quality Arm 1 (n=113)	Free Arm 2 (n=150)	Free/Quality Arm 3 (n=150)	Control Arm 4 (n=150)
Age, years, mean (SD)	29.2 (5.7)	29.2 (6.2)	28.1 (6.2)	27.9 (5.9)
No. of pregnancies/woman, mean (SD)	3.6 (1.9)**	4.0 (2.2)**	3.5 (1.8)**	2.8 (1.7)
No. of children/woman, mean (SD)	2.6 (1.6)	3.3 (2.1)**	3.0 (1.8)**	2.3 (1.5)
SES score, mean (SD)	0.58 (0.9)*	–0.26 (0.9)**	–0.49 (1.0)**	0.32 (0.9)
Married or living as married, %	88.5	87.3	87.3	86.7
Education: completed secondary, %	66.4	33.3**	32.0**	68.0
Religion: Christian,[a] %	72.6*	80.0	76.7*	86.0
Works outside the home, %	41.6*	68.0*	52.0	55.3
Pregnant, %	21.1	18.0	16.7	16.7
Within 12 months postpartum, %	77.7	63.8*	68.7	74.8
Does not want child in next 2 years, %	93.8	94.0	96.7	94.7
Ever used modern family planning, %	69.0	51.3*	60.0	64.7
Ever used LARC, %	9.7	9.3	8.0	6.7

Abbreviations: LARC, long-acting reversible contraceptive; SD, standard deviation; SES, socioeconomic status.
* $P<.05$; ** $P<.001$.
[a] Christian includes Lutheran, Pentecostal, Protestant, and nondenominational.

properly screened for family planning than were women in the control group. In the free/quality arm, approximately one-third (n=36, 36.0%) of women reported having been properly screened, compared with one-quarter (n=26, 26%) of women in the quality arm and approximately one-tenth in the free arm (n=11, 11.0%) and the control group (n=8, 8.0%) (Table 3).

The receipt of proper referral was assessed among women obtaining services from the ANC, PNC, and immunization service delivery points. The results indicate that no women in the control, free, or free/quality arms were properly referred; only a few women in the quality arm received a written referral (n=3, 4.0%) (Table 3).

Family Planning Counseling

Proper family planning counseling, as reported by clients, was assessed only among women attending L&D and family planning services, as providers in other services were expected to screen and refer only, not offer comprehensive family planning counseling. Women in the free arm (Arm 2) (OR=3.8; 95% CI, 1.6 to 9.0) and free/quality arm (Arm 3) (OR=11.0; 95% CI, 4.3 to 27.9) were significantly more likely to report receipt of proper family planning counseling compared with those in the control group. No difference was detected in counseling between the quality-only group and control group (Table 3).

Family Planning Use

The likelihood of being a family planning user was examined among all nonpregnant participants in all departments, including women not in the EPP (Table 4). Women in the free/quality arm were more likely to be a modern family planning user than those in the control group (OR=2.3; 95% CI, 1.2 to 4.3), while those in the quality arm were less likely than those in the control group (OR=0.4; 95% CI, 0.2 to 0.9). When analyses were restricted to modern method use excluding condoms, women in the free arm (OR= 3.2; 95% CI, 1.4 to 7.2) and free/quality arm (OR=8.6; 95% CI, 3.9 to 19.0) were significantly more likely to use modern methods compared with women in the control group. Reported use of LARCs was significantly higher across all intervention groups compared with the control (Quality arm: OR=2.9; 95% CI, 1.1 to 7.9. Free arm: OR=5.6; 95% CI, 2.3 to 13.7. Free/quality arm: OR=8.5; 95% CI, 3.4 to 20.6). The number of IUD users was too small

Despite providers receiving training to give appropriate family planning referrals, women were not properly referred, if at all, from ANC, PNC, or immunization delivery points.

Women in the free arm were more likely to use modern methods, and the use of LARCs was higher across all intervention groups compared with the control group.

TABLE 3. Crude and Adjusted Odds Ratios for Proper Family Planning Screening, Referral, and Counseling

Study Arm	Proper Family Planning Screening[a] (n=400)				Proper Family Planning Referral[b] (n=300)				Proper Family Planning Counseling[c] (n=263)			
	No.	Positive Response No. (%)	Crude OR (95% CI)	Adjusted[d] OR (95% CI)	No.	Positive Response No. (%)	Crude OR (95% CI)	Adjusted[d] OR (95% CI)	No.	Positive Response No. (%)	Crude OR (95% CI)	Adjustedd OR (95% CI)
1: Quality	100	26 (26.0)	4.0 (1.7, 9.5)*	4.5 (1.8, 10.9)*	75	3 (4.0)	NA	NA	38	8 (21.1)	1.6 (0.6, 4.3)	1.7 (0.6, 4.8)
2: Free	100	11 (11.0)	1.4 (0.5, 3.7)	1.5 (0.6, 4.0)	75	0 (0.0)	NA	NA	75	32 (42.7)	4.3 (2.0, 9.5)**	3.8 (1.6, 9.0)*
3: Free/ quality	100	36 (36.0)	6.5 (2.8, 14.8)**	6.7 (2.8, 16.1)**	75	0 (0.0)	NA	NA	75	46 (61.3)	9.2 (4.2, 20.3)**	11.0 (4.3, 27.9)**
4: Control	100	8 (8.0)	ref	ref	75	0 (0.0)	NA	NA	75	11 (14.7)	ref	ref

Abbreviations: ANC, antenatal care; CI, confidence interval; L&D, labor and delivery; OR, odds ratio; PNC, postnatal care; SES, socioeconomic status.
* $P<.005$; ** $P<.001$.
[a] ANC, PNC, Immunization, L&D.
[b] ANC, PNC, Immunization.
[c] L&D, Family Planning.
[d] Adjusted for SES, education level, religion, marital status, parity, postpartum status, and ever-use of modern contraception.

to make statistical comparisons. Clients in both arms with free contraceptives were significantly more likely to be implant users compared to the control (Free arm: OR= 5.7; 95% CI, 2.2 to 14.4. Free/quality arm: OR=5.6; 95% CI, 2.2 to 14.4) (Table 4).

Subanalysis of Labor and Delivery and Family Planning Uptake and Counseling

Subsets of L&D (n=25) and family planning (n=50) client interview data were analyzed separately (Table 5). In the free/quality arm, 60.0% (n=15) of women in L&D received a

TABLE 4. Crude and Adjusted Odds Ratios for Family Planning Use Among All Nonpregnant Women

Study Arm	Modern FP Use[a] (n=461)			Modern FP Use, Excluding Condoms[a] (n=461)			LARC Use[a] (n=461)			IUD Use (n=461)			Implant Use (n=461)		
	Positive Response No. (%)	Crude OR (95% CI)	Adj[b] OR (95% CI)	Positive Response No. (%)	Crude OR (95% CI)	Adj[b] OR (95% CI)	Positive Response No. (%)	Crude OR (95% CI)	Adj[b] OR (95% CI)	Positive Response No. (%)	Crude OR (95% CI)	Adj[b] OR (95% CI)	Positive Response No. (%)	Crude OR (95% CI)	Adj[b] OR (95% CI)
1: Quality (n=88)	18 (20.5)	0.4 (0.2, 0.8)*	0.4 (0.2, 0.9)*	14 (15.9)	0.8 (0.4, 1.7)	1.4 (0.6, 3.2)	11 (12.5)	2.1 (0.8, 5.4)	2.9 (1.1, 7.9)*	3 (3.4)	–[c]	–[c]	8 (9.1)	1.7 (0.6, 4.8)	2.3 (0.8, 6.9)
2: Free (n=123)	53 (43.1)	1.2 (0.7, 2.0)	0.9 (0.5, 1.8)	52 (42.3)	3.2 (1.8, 5.8)***	3.2 (1.4, 7.2)**	37 (30.1)	6.3 (2.8, 14.2)***	5.6 (2.3, 13.7)***	1 (0.8)	–[c]	–[c]	36 (29.3)	7.0 (3.0, 16.4)***	5.7 (2.2, 14.4)***
3: Free/ quality (n=125)	74 (59.2)	2.3 (1.4, 3.9)**	2.3 (1.2, 4.3)*	72 (57.6)	6.0 (3.4, 10.7)***	8.6 (3.9, 19.0)***	45 (36.0)	8.2 (3.7, 18.4)***	8.4 (3.4, 20.6)***	9 (7.2)	–[c]	–[c]	36 (28.8)	6.8 (2.9, 16.0)***	5.6 (2.2, 14.4)***
4: Control (n=125)	48 (38.4)	ref	ref	23 (18.4)	ref	ref	8 (6.4)	ref	ref	1 (0.8)	ref	ref	7 (5.6)	ref	ref

Abbreviations: Adj, adjusted; CI, confidence interval; FP, family planning; IUD, intrauterine device; LARC, long-acting reversible contraceptive; OR, odds ratio; SES, socioeconomic status.
* $P<.05$; ** $P<.005$; *** $P<.001$.
[a] Nonpregnant women.
[b] Adjusted for SES, education level, religion, marital status, parity, postpartum status, and ever-use of modern contraception.
[c] Odds ratios not presented due to small cell size.

TABLE 5. Quality Aspects of Family Planning Method Provision and Counseling, by Department

Outcomes	Arm 1: Quality No. (%)	Arm 2: Free No. (%)	Arm 3: Free/quality No. (%)	Arm 4: Control No. (%)
Labor and Delivery	**n=25**	**n=25**	**n=25**	**n=25**
Satisfied with FP information received	22 (88.0)	13 (52.0)	19 (76.0)	6 (24.0)
Modern method provided on day of service	0 (0.0)	0 (0.0)	15 (60.0)	0 (0.0)
Properly counseled on method on day of service	1 (4.0)	0 (0.0)	11 (44.0)	1 (4.0)
LARC provided on day of service	0 (0.0)	0 (0.0)	10 (40.0)	0 (0.0)
IUD provided	0 (0.0)	0 (0.0)	4 (16.0)	0 (0.0)
Implant provided	0 (0.0)	0 (0.0)	6 (24.0)	0 (0.0)
If LARC provided, properly counseled on LARC[a]	NA	NA	10 (100.0)	NA
Family Planning	**n=13**	**n=50**	**n=50**	**n=50**
Satisfied with FP information received	13 (100.0)	45 (90.0)	50 (100.0)	45 (90.0)
Modern method provided on day of service	8 (61.5)	41 (82.0)	48 (96.0)	26 (52.0)
Properly counseled on method on day of service	7 (53.9)	32 (64.0)	35 (70.0)	10 (20.0)
LARC provided on day of service	4 (30.8)	30 (60.0)	28 (56.0)	0 (0.0)
IUD provided	3 (23.1)	1 (2.0)	2 (4.0)	0 (0.0)
Implant provided	1 (7.7)	29 (58.0)	26 (52.0)	0 (0.0)
If LARC provided, properly counseled on LARC[a]	4 (100.0)	16 (53.3)	26 (92.9)	0 (0.0)

Abbreviations: FP, family planning; IUD, intrauterine device; LARC, long-acting reversible contraceptives; NA, not applicable.
[a] Subset of women who received a LARC on the day of service; proper counseling requires that clients were told where the LARC could be removed, when it should be removed due to maximum duration of use, and that it may be removed at any time.

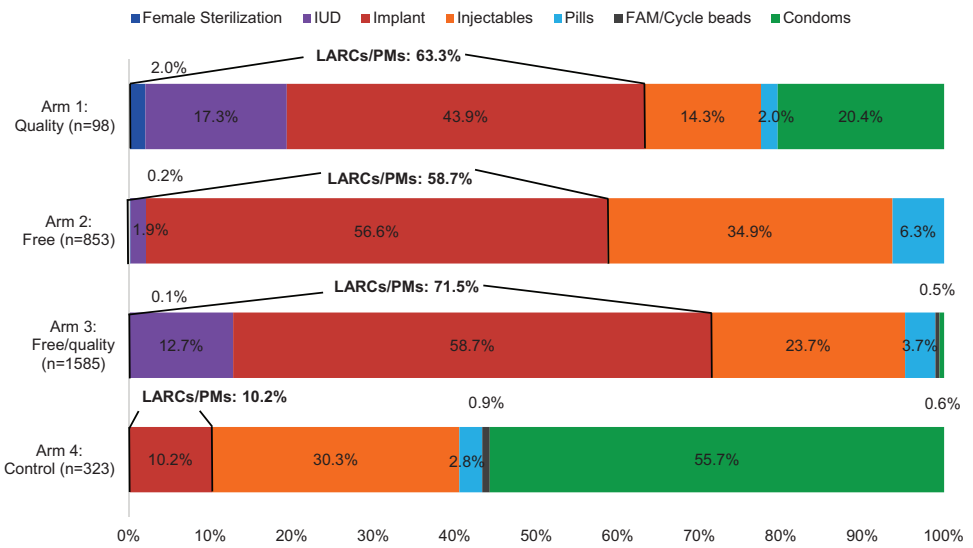
method; no women in L&D received a method in any other study arm. In L&D at the free/quality arm, 44.0% (n=11) were properly counseled, and all LARC adopters (n=10) received proper counseling on where and when to have their method removed. Satisfaction with family planning information received ranged from 24.0% (n=6) of L&D clients in the control group to 88.0% (n=22) in the quality arm.

The majority of clients in the family planning unit in each arm reported receiving a modern method on the day of service, ranging from over half (n=26, 52.0%) in the control arm to nearly all (n=48, 96.0%) in the free/quality arm. In the quality arm, the overall sample of family planning clients was very small (n=13) due to low client load; 61.5% (n=8) received a method. In both facilities with free methods, the majority of clients adopted LARCs, while only one-third in the quality arm and no clients in the control arm adopted a LARC. Between 90% and 100% of clients across all study arms reported being satisfied with the family planning information they received (Table 5).

Method Mix Among Family Planning Services

Analysis of family planning service statistic data indicates that the total number of family planning clients varied dramatically by study arm, with the highest client volume in the free/quality arm (n=1,585), followed by the free arm (n=853), the control group (n=323), and the quality arm (n=97). All intervention arms had significantly higher proportions of clients adopting LARC and permanent methods compared with the control (Quality arm: 63.3%; $P<.001$. Free/quality arm: 58.7%; $P<.001$. Free arm: 71.5%; $P<.001$. Control arm: 10.2%.), and all had lower proportions of clients adopting condoms (Figure 3). The 2 arms with the quality intervention (Arms 1 and 3) had substantial proportions of clients adopting IUDs (17.3% and 12.7%, respectively), while only 1.9% in the free arm and 0 clients in the control arm adopted IUDs. Implants were the most commonly chosen method in all 3 intervention arms (ranging from 43.9% to 58.7%), while condoms were the most common method in the control (55.7%).

FIGURE 3. Method Mix Among Family Planning Services Provided During the Study Period, by Study Arm[a,b]



Abbreviations: FAM, fertility awareness method; IUD, intrauterine device; LARCs/PMs, long-acting reversible contraceptives/permanent methods.

[a]Data represent service statistics; therefore, a client who came multiple times for refills of a short-acting method may have been counted more than once.

[b]Data represent 12 months in each study arm.

Postpartum Family Planning Reach

The study also analyzed the family planning service statistics to compare the proportions of family planning clients who obtained methods at 0 to 2 days, 3 days to 6 weeks, over 6 weeks to 12 months, and over 12 months postpartum, excluding clients for whom date of last delivery was unknown.

The quality intervention arms had higher proportions of client adopting methods 0 to 2 days and 3 days to 6 weeks postpartum than the control group.

Both quality intervention arms had significantly greater proportions of clients adopting methods 0 to 2 days postpartum (Quality arm: 15.5%; $P<.001$. Free/quality arm:17.4%; $P<.001$.) and 3 days to 6 weeks postpartum (Quality arm: 13.4%; $P<.001$. Free/quality arm: 14.0%; $P<.001$.) compared with the controls (0.0% and 2.5%, respectively) (Figure 4). Only the free arm had a significantly different proportion of all family planning clients in the EPP compared with the control group (46.6%; $P<.001$).

Cost of Methods

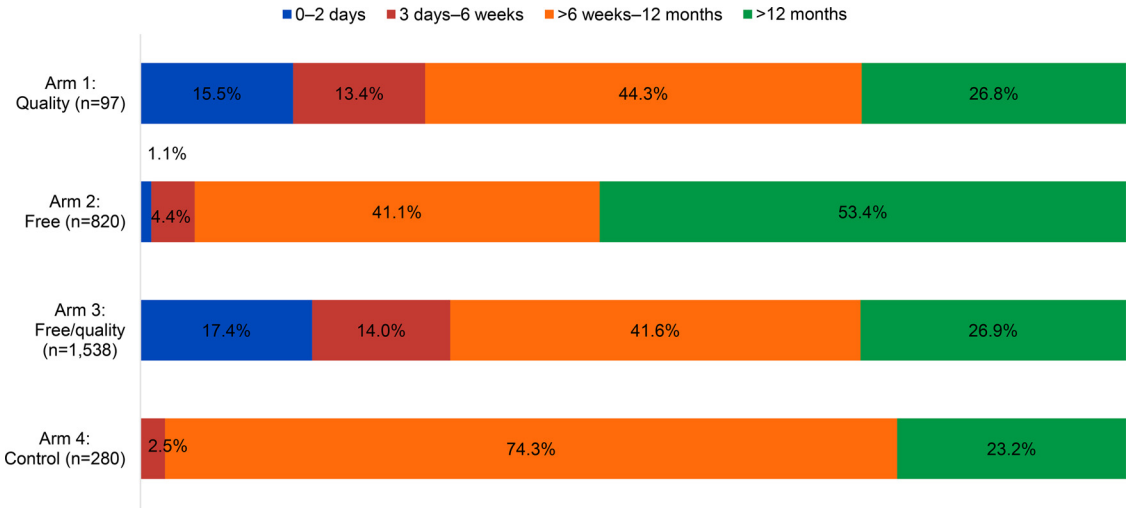
In the client interview, women were asked about the influence of cost on their decision to use family planning and on their choice of method. Of the clients who received a method on the day of the interview, more than 65% in 3 of the study arms indicated that the cost of the method choice was somewhat or very important to them (free arm 68.3%, free/quality arm 88.9%, and control 68.0%); in contrast, very few (12.5%) clients in the quality arm said that cost was important (Table 6). Additionally, in the 2 arms with free contraceptives, the majority of clients who received a method were aware that methods were free before coming to the facility (free arm 78.1%, free/quality arm 87.3%). Among women who did not receive a family planning method or who selected an alternate method to her primary method of choice, the method's expense was identified as one of several drivers of method selection in the 2 study arms where methods were not free, although it was not the most common reason cited (Table 6).

DISCUSSION

Client Characteristics

While women across study groups had many similarities, women at the 2 facilities where methods were not offered for free tended to be wealthier than women in the arms offering free contraception. This could be due to underlying differences in SES in facility catchment areas, or it may

FIGURE 4. Postpartum Distribution Among Family Planning Clients During the Study Period, by Study Arm[a,b]



[a]Clients for whom postpartum period was not known were excluded.

[b]Data represent 12 months in each study arm.

indicate self-selection, as poorer women may have purposefully come to the facilities where methods were free. Though no community mobilization was conducted to advertise free services, the majority of family planning clients at these 2 facilities reported that they knew in advance that methods were free, possibly through word of mouth, suggesting they may have come for that reason.

Screening and Referral

In the study arms that did not include quality inputs (the free and control arms), screening for

TABLE 6. Issues Relating to Method Cost Among Women and Reasons for Not Receiving a Method

Outcomes	Arm 1: Quality No. (%)	Arm 2: Free No. (%)	Arm 3: Free/quality No. (%)	Arm 4: Control No. (%)
Labor and Delivery and Family Planning	**n=38**	**n=75**	**n=75**	**n=75**
Received a method	8 (21.1)	42 (56.0)	64 (84.0)	25 (33.3)
If received a method, cost was somewhat/very important in method choice	1 (12.5)	28 (68.3)	56 (88.9)	17 (68.0)
If received a method, client was aware method would be free	n/a	32 (78.1)	55 (87.3)	n/a
Did not receive a method/method of choice	30 (79.0)	36 (48.0)	13 (17.3)	60 (80.0)
Top reasons why client did not receive method/method of choice[a]	**n=30**	**n=36**	**n=13**	**n=60**
Wanted to wait 6 weeks/45 days/until period returns or other amount of time	19 (63.3)	18 (50.0)	4 (30.8)	9 (15.0)
Came for a different service	1 (3.3)	5 (13.9)	2 (15.4)	11 (18.3)
No one informed her it was available	1 (3.3)	5 (13.9)	0 (0.0)	9 (15.0)
Due to expense	**2 (6.7)**	**0 (0.0)**	**0 (0.0)**	**12 (20.0)**
Decided on a different method	1 (3.3)	1 (2.8)	1 (7.7)	11 (18.3)
Decided not to use	1 (3.3)	3 (8.3)	2 (15.4)	4 (6.7)

[a] The list of reasons is not exhaustive; clients could give more than 1 answer; the 6 most common responses are listed here.

family planning rarely occurred. This was expected since the screening and referral tool was not introduced to these facilities. We assume any screening that did occur reflects providers asking clients questions unprompted by a tool. Comparatively, the higher incidence of proper screening of clients in the quality arms can be attributed to the introduction of the quality inputs intervention and screening tool. Nevertheless, in both quality facilities, screening overall was still lower than desired (one-third in the free/quality intervention and one-quarter in the quality arm). The goal was universal screening.

While we would not have expected universal referrals, the scarcity of proper referrals being given—only 3 in all of the ANC, PNC, and immunization clients across study arms—indicates this part of the quality intervention was not implemented as designed. While it is true that not all women screened for family planning would have accepted a referral to family planning, the fact that one-third of clients in the free/quality arm were screened but no clients were referred is unlikely to reflect lack of need. Although it is possible that providers gave women paper referrals, they did not keep them; likewise, if oral, not paper, referrals were provided, the women may not have perceived them as such. However, it is more likely that providers simply did not implement this part of the intervention as intended.

Insofar as screening was properly implemented, the greater likelihood of clients being screened at the free/quality arm suggests that the combined cost and quality interventions may have had the greatest effect on provider behavior. However, since neither screening nor referral became universally practiced at any facility, despite frequent follow up with providers throughout the implementation period, this raises questions about the acceptability and feasibility and possibly the method of introduction and supervision of the intervention itself. It is possible that providers at both quality input facilities saw the referral form as an additional burden or they did not have the time to screen and refer each client. If this were determined to be the case, further simplifying the screening and referral forms, or using verbal referrals only, may improve fidelity to this intervention. Further investigation is needed to understand why providers did not fully adopt this practice.

Clients offered free contraceptives were significantly more likely to be properly counseled than those in the quality-only and control groups.

Family Planning Counseling

Clients in the 2 study groups that offered free contraceptives were significantly more likely to be properly counseled than those in the control group. In contrast, the quality-only study group did not differ from the control. This finding was surprising; we expected both quality input facilities to have improved counseling, with no effect in the free contraceptives-only group. One explanation for this may be the low number of family planning clients in the quality arm. Indeed, when counseling was examined in family planning and L&D settings separately, proper counseling was higher among family planning clients in all 3 study groups and lower among L&D clients, except for in the free/quality study group. We were unable to determine definitively how the quality-only intervention affected counseling, except that providing free contraceptives appeared to positively impact counseling.

Family Planning Use

In both study arms with free contraceptives, clients were more likely to be modern family planning (excluding condoms), LARC, and implant users, compared with the control group, suggesting that providing free methods may impact family planning use, especially LARC use. More than half of nonpregnant clients in the free/quality arm were using a modern family planning method (excluding condoms), compared with one-fifth in the control arm. Further, one-third of nonpregnant clients in the free/quality arm were using LARCs, compared with only 6% in the control arm. The free/quality arm had the best outcomes in each category of family planning use, supporting our hypothesis that the combined intervention would have the greatest effect. In the quality arm, only the likelihood of being a LARC user was elevated compared with the controls, suggesting that the quality intervention had no impact on family planning use overall. However, interpretation of these results was impeded, as precision and accuracy of the estimates were likely impacted by the small sample size in this group.

Method Mix

Despite limitations in drawing conclusions for the quality-only study group in particular, examining family planning service data collected over the 12-month intervention period was useful. These data suggest that the intervention had a positive impact on LARC use in all 3 arms, and that the quality intervention, which included the provision of postpartum IUDs, may have increased IUD uptake, even though we could not observe this from the client interviews. However, since

the service data represent a full year, and we did not track individual women, users of short-acting methods may have been counted more than once if they returned to get more supplies. This would overrepresent short-acting method users, indicating that the proportion of individual women choosing LARCs may even be higher than calculated here. It is also notable that in the 2 study arms where all methods were free, very few clients chose condoms. The considerable difference in total number of clients in each arm may also indicate preexisting differences between facilities or external factors that affected family planning uptake.

Postpartum Family Planning Reach

Both study arms with quality inputs had significantly higher proportions of clients served in the immediate postpartum period (0 to 2 days) and within 6 weeks of delivery, compared with the control arm. These results are consistent with the expected results of the quality intervention, which aimed to introduce access to family planning in the L&D ward (0 to 2 days) and to update providers on the increasing array of methods available to women within 6 weeks of delivery. Specifically, the MEC update and postpartum IUD training made implants and IUDs available to women immediately postpartum in the 2 quality intervention arms (Arms 1 and 3). In contrast, in the facilities without quality inputs (the free arm and control arm), no methods were available in the L&D ward and only condoms and progestin-only oral contraceptives were available within 6 weeks postpartum in the family planning unit. Accordingly, we observed very few clients obtaining methods within 6 weeks postpartum in the free or control arms. This suggests that the quality intervention may have influenced when women adopt family planning and increased postpartum family planning use. It is likely that the availability of free family planning services in Arms 1 and 2 affected the number of family planning clients attending these facilities; however pre-existing and external factors likely also affected client load.

Cost of Methods

Most family planning clients in the free, free/quality, and control arms indicated that cost was somewhat or very important in their method choice. Conversely, only a few women who did not receive a method or did not receive their method of choice stated that expense was the main reason. This could be interpreted to mean that cost is only an important barrier for a small portion of the population, or it could reflect a self-selecting sample (i.e., women for whom cost is a barrier would not have come to facilities where they had to pay for a method, and thus would not have been interviewed). The cost of methods normally varies among facilities, outside the context of the study; as a result, we were unable to measure to what extent this affected if and where women sought contraceptive services. Interpreted in light of other study findings, specifically, that free facilities had higher modern family planning (excluding condoms) and LARC use, cost as a barrier seems likely and suggests that being able to obtain methods for free may be a key factor to increase family planning use in Kinshasa. However, given external factors may also affect client flow, and that baseline data are not available, we cannot conclude whether this relationship is causal.

Limitations

The study design used to evaluate the interventions was selected primarily for its feasibility in the given context and circumstances, with some expense to rigor. The lack of pretest data and randomization, coupled with having only 1 facility per study group, limited the validity and generalizability of our findings. Facility-level characteristics varied in terms of the number of providers trained to provide family planning, client load, and client demographics, among other known and unknown factors. These differences may well have affected implementation of the study by providers as well as client-level outcomes. While we controlled for client characteristics that varied between intervention and control facilities, this was insufficient to conclude that the study facilities were equivalent to each other analytically and to attribute differences in intervention performance entirely to the interventions themselves. Two of the sites, the free arm and the free/quality arm, received support from ExpandFP for 2 years prior to the study launch, which included the clinical training of providers and monthly special family planning days with free contraception. Any impact of the earlier support on the study is believed to be minimal, given that the support activities did not have screening, referral, integration, or PPFP elements, and that services were only free during distinct events. However, it is possible that these facilities were more well-known in the community for providing family planning, specifically LARCs, and this may have contributed to high client load in these facilities. A dispute over

the land on which 1 of the facilities is built (the quality arm) arose during implementation, which we believe affected overall client flow, resulting in a lower-than-desired sample in this group, as well as provider morale or performance. This situation has implications for the interpretation of data in this particular group.

It is possible that some women were interviewed more than once, on different dates. We mentioned earlier that women using short-acting methods may have been counted more than once; this may also have been the case if a woman was interviewed in L&D after giving birth and then again in PNC 2 weeks later. However, being interviewed more than once should not have altered a woman's reporting of her experience in a particular service, and any risk to measures of family planning use was likely small and distributed equivalently across study groups.

Service statistics were compared across groups as an average measure; as a result, this analysis does not fully account for changes over time that may have occurred at different rates in each study group. Finally, client exit interviews were conducted when facilities had been implementing the intervention for between 9 and 12 months. It is possible that the different time periods affected levels of intervention uptake, though monitoring of referrals throughout the intervention period did not indicate substantial changes over time. Finally, the relatively short period of implementation limited conclusions on the sustainability of such an intervention.

CONCLUSIONS

While the results of this study are limited, they do have important implications for programs operating in this and other low-resource settings where use of family planning, especially family planning within the EPP, is limited. The results provide some preliminary evidence of how integrating a PPFP intervention across service delivery units within a facility may improve family planning uptake in the EPP, and how different types of interventions (cost and quality improvements) can work together to compound improvements in PPFP uptake in highly difficult programmatic contexts.

Combining free contraceptives with quality services appears to be more effective than implementing each type of intervention alone.

In light of this, we conclude that combining the free contraceptives and quality interventions had the strongest effect on family planning screening, quality of counseling, modern family planning use, and LARCs use, specifically. Further, family planning clients in the 2 quality intervention arms were more likely to adopt a method within 6 weeks of delivery, indicating that this intervention better targets postpartum women than offering free contraceptives alone. The quality-only intervention performed well on improving screening practices but not on most other indicators, suggesting that quality interventions may be necessary but insufficient to effect change. Still, this is not conclusive, considering problems with sample size already discussed. As expected, the cost-only intervention did not improve screening or referral but was associated with improved counseling practices and modern family planning use overall.

Providing clients with access to free contraceptives is key to improving family planning use in this setting and warrants further investigation into how to make free services available and financially sustainable for the health system. Training providers to properly counsel, screen, and refer clients and to provide LARCs and other methods in the postpartum period is also crucial to improving family planning access and use. Future scale up of this or similar interventions should investigate how to adjust screening and referral practices so that they can be implemented more fully and consistently. Combining these interventions appears to be more effective than implementing either intervention alone, and addressing multiple barriers to family planning use simultaneously is necessary to effect meaningful change in access to PPFP.

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En français

Interventions sur la qualité et le coût pendant la période périnatale prolongée pour accroître l'utilisation de la planification familiale à Kinshasa, RDC : Résultats d'une étude initiale

L'intervention combinée reposant sur les contraceptifs gratuits et un ensemble d'apports de qualité pour la planification familiale lors de la période périnatale prolongée, notamment la mise à disposition de méthodes de longue durée d'action immédiatement après l'accouchement, ont eu un impact considérable sur l'utilisation de contraceptifs modernes, en particulier les méthodes de longue durée d'action.

RÉSUMÉ

Contexte : À travers le monde, la plupart des femmes n'envisagent pas une autre grossesse dans l'année qui suit un accouchement, mais l'adoption d'une contraception moderne pendant cette période reste faible. Nous avons testé de manière indépendante, 2 approches de l'augmentation de l'adoption de la contraception et les 2 approches combinées en s'appuyant sur une étude quasi-expérimentale à Kinshasa, en République démocratique du Congo.

Méthodes : Les données analytiques primaires proviennent des entretiens menés auprès des clientes après l'intervention (N=563) issues de 4 groupes d'étude. Le premier groupe (n=150) a bénéficié d'une planification familiale gratuite, et le second groupe (n=113) a bénéficié d'une intervention fondée sur les apports de qualité impliquant le dépistage systématique, l'orientation vers d'autres structures et la mise à disposition immédiate de contraceptifs réversibles de longue durée d'action après le travail et l'accouchement. Le troisième groupe (n=150) a bénéficié de 2 interventions et aucune intervention n'a été consacrée au quatrième groupe (n=150). Des statistiques issues des services de planification familiale ont également été collectées pendant la période d'intervention.

Résultats : Les femmes du groupe de qualité (coefficients de probabilité [CP]=4,5; 95% d'intervalle de confiance [IC], 1,8 à 10,9) et du groupe gratuit/qualité (CP=6,7; 95% d'IC, de 2,8 à 16,1) avaient plus de chances de subir un test dépistage correct que les femmes du groupe de contrôle, mais l'orientation vers d'autres structures par le biais de supports papier a rarement été mise en œuvre dans un des groupes. Les femmes du groupe libre (CP=3,8; 95% d'IC, 1,6 à 9,0) et dans le groupe gratuit/qualité (CP=11,0; 95% d'IC, 4,3 à 27,9) étaient plus susceptibles que le groupe de contrôle, de déclarer qu'elles avaient été conseillées correctement sur la planification familiale. Les clientes étaient plus susceptibles d'être des utilisatrices de contraception moderne (à l'exclusion des préservatifs) dans le groupe gratuit (CP=3,2; 95% d'IC, de 1,4 à 7,2) et dans le groupe gratuit/qualité (CP=8,6; 95 IC, de 3,9 à 19,0) que dans le groupe de contrôle. Les clientes de l'ensemble des groupes d'étude étaient plus susceptibles d'utiliser une méthode réversible de longue durée d'action en comparaison avec le groupe de contrôle (Groupe qualité : CP=2,9; 95% d'IC, de 1,1 à 7,9. Groupe gratuit : CP=5,6; 95% d'IC, 2,3 à 13,7. Groupe gratuit/qualité : CP=8,4; 95% d'IC, 3,4 à 20,6). Les statistiques de service issues du groupe d'intervention combinée ont indiqué qu'une proportion plus élevée de l'adoption de la planification familiale a eu lieu pendant la période du postpartum immédiat (0 à 2 jours) dans le groupe qualité ($P<,001$) et le groupe gratuit/qualité ($P<,001$) par rapport au groupe de contrôle. Les apports de qualité, les contraceptifs gratuits, et l'intervention combinée ont eu des impacts positifs sur certains aspects du dépistage et de l'adoption de contraceptifs. L'intervention combinée a obtenu les meilleurs résultats, à tout point de vue.

Conclusion : Dans ce contexte, la mise à disposition de la planification familiale y compris des méthodes réversibles de longue durée d'action pendant la période du postpartum immédiat, un système de dépistage et d'orientation vers d'autres structures, ainsi que l'offre de méthodes gratuites peuvent améliorer l'accès et l'adoption de la planification familiale durant la période périnatale prolongée.

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ORIGINAL ARTICLE

Assessment of Family Planning Service Availability and Readiness in 10 African Countries

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In the 10 countries surveyed, the availability of oral contraceptives, injectables, and condoms varied greatly, and the availability of basic items indicating service readiness, such as guidelines, trained staff, equipment, and certain commodities, was low.

Résumé en français à la fin de l'article.

ABSTRACT

Background: Access to family planning services and appropriate contraceptive methods is crucial for ensuring good health outcomes for women and adolescent girls. The World Health Organization worked with the U.S. Agency for International Development to develop the Service Availability and Readiness Assessment (SARA) survey to measure health facility capacity to provide end users with appropriate, high-quality health care. In this study, we looked at the service availability and readiness of health facilities to provide contraception in 10 African countries: Benin, Burkina Faso, the Democratic Republic of the Congo, Djibouti, Mauritania, Niger, Sierra Leone, Tanzania, Togo, and Uganda.

Methods: This study compared SARA survey data on family planning services from each of the 10 countries. We conducted a descriptive analysis of variations in facility readiness and the availability of services, contraceptive methods, trained staff, family planning guidelines, and basic health care equipment.

Results: Overall, many of the countries surveyed had a relatively high availability of at least 1 contraceptive method. Rural facilities tended to have more availability of contraception than urban facilities, and government facilities tended to have higher availability of family planning than other providers. The countries differed in their particular dominant contraceptive method, and stock-outs of contraceptive methods were observed. Countries had overall low levels of all 6 tracer items (availability of family planning guidelines, staff trained in family planning, blood pressure apparatuses, combined oral contraceptive, injectable contraceptives, and male condoms on the day of the assessment), indicating low health system readiness. There were discrepancies between reported and observed availability of blood pressure apparatuses and family planning guides and having at least 1 staff member trained to use these tools. In all countries, unmarried adolescents appeared to have less access to family planning than the general population.

Conclusion: Stock-outs and logistics management problems were common among the countries surveyed. Critical gaps between reported and actual availability of products and services often makes it difficult for end users to access appropriate family planning methods. To address many of the issues, additional health worker training is needed and more effort to target and support adolescents should be undertaken. To achieve universal health coverage targets for family planning, gaps in the availability and readiness of health systems to provide contraceptive products and services must be reduced.

INTRODUCTION

In working to achieve the Sustainable Development Goals,[1] it is important to be able to objectively monitor and evaluate the progress countries make as they implement new strategies. When working specifically toward health outcome-related goals, it is essential to measure the quality of health systems; however, this can be difficult. For this reason, the World Health Organization (WHO) has been working in coordination with the U.S. Agency for International Development (USAID) and other partners to develop a tool, called the Service Availability and Readiness Assessment (SARA) tool, that breaks down health systems into measurable, trackable components that can provide data about the progress of health systems strengthening efforts.[2] The tool builds on previous and current approaches designed to assess health facility service delivery including the Service Availability Mapping (SAM) tool and the Service

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The SARA tool measures service readiness, i.e., physical access to and capacity of health facilities to provide health services.

The data provided by the SARA tool can be used to generate detailed health system assessments and monitor and evaluate progress toward universal health coverage.

Provision Assessment (SPA) tool developed by ICF International under the USAID-funded Demographic and Health Surveys (DHS) Program.[3] The SARA tool measures access to health systems. Access has 2 components: "availability," which refers to and focuses on the physical presence or reach of the facilities and "readiness," which examines the potential of health facilities to provide basic health care interventions relating to family planning, child health services, basic and comprehensive obstetric care, HIV/AIDS, tuberculosis, malaria, and noncommunicable diseases.[2] The tool also assesses the availability of physical infrastructure and trained manpower within the a health system.[2] While these components contribute to the quality of a health facility, they, of course, do not guarantee the delivery of quality services. However, the information gained from this tool can be used to fill critical data gaps about country service delivery mechanisms and health systems strengthening and to identify places where countries should invest resources to meet their health goals.

The SARA tool is a questionnaire that was designed to measure country-specific health-related goals, including family planning. Before the tool is implemented, a country must first compile a master facility list to direct the use of the surveys. The survey can then be used to either randomly sample health facilities within a country or assess all facilities within selected local districts.[4] Data collection is performed by specially trained survey teams, or by national ministries of health or national institutes. To complete the survey, the data collection team spends an average of 2 to 4 hours at a facility. The visit involves interviewing key informants and verifying the availability of supplies, equipment, medicines, and other commodities at the time of the visit.[4] The survey information is then compiled and analyzed using standard SARA core indicators and any additional country-specific indicators that were specified in the evaluation plan. The results are then disseminated to national stakeholders and researchers.[2]

SARA is not intended to provide comprehensive data on all aspects of functioning of health services, rather, the tool focuses on key "tracer" items that are indicative of the essential health system underpinnings and crucial to programs that are scaling up or ready to do so. Family planning data from the SPA tool is more comprehensive—as it not only covers service availability and readiness but also examines client–provider interaction components of consultation, counseling and discussions, client knowledge levels, and feedback from family planning clients on service accessibility problems. In total, 10 sub-Saharan African countries have implemented the SARA tool since 2010, whereas only 3 countries have used the SPA tool during the same time frame.

The SARA tool has been successfully used to generate a detailed assessment of the status of full health systems in such countries as Uganda[5]; monitor and evaluate progress toward universal health coverage in South Africa[6]; and assess availability and readiness of health facilities to provide general and specific services, such as chronic disease management in Uganda,[7] maternal and child health in Madagascar,[8] or family planning and child immunization in Burkina Faso, Cambodia, Haiti, Sierra Leone, and Tanzania.[4] The tool has also been valuable for making multi-country assessments and comparisons of reproductive, maternal, newborn, and child health to determine successful efforts toward meeting the Millennium Development Goals;[9] assessing surgical availability and readiness in Benin, Burkina Faso, the Democratic Republic of the Congo (the DRC), Mauritania, Sierra Leone, Togo, and Uganda[10]; and achieving other research objectives.

METHODS

In this study, we used data generated from SARA surveys conducted between 2010 and 2016 to assess and compare the availability and readiness of health facilities to provide patients with family planning services in 10 African countries, with the aim of generating further evidence for the planning and management of health systems.[1] The 10 countries had volunteered to implement the SARA tool, with technical assistance from WHO and partners, in health facilities within their respective countries: Benin (2013, N=788 facilities), Burkina Faso (2014, N=766 facilities), Djibouti (2015, N=82 facilities), the DRC (2014, N=1,555 facilities), Mauritania (2016, N=288 facilities), Niger (2015, N=372 facilities), Sierra Leone (2013, N=455 facilities), Tanzania (2012, N=1,297 facilities), Togo (2012, N=100 facilities), and Uganda (2013, N=209 facilities).

Countries tend to do SARA every 2 years.[10] The sampling frame for assessment of service readiness is the master facility list.[4] This master list comprises all health care facilities, including public and private facilities as well as health centers and dispensaries, and includes information on such things as beds, staffing, and services

available.[4] If a master facility list does not exist or is incomplete, a preliminary list should be created.[4]

Countries implementing SARA used 1 of 2 different sampling methods: (1) a nationally representative simple/systematic random sample of health facilities—with stratification by type of health facility and managing authority[2]—to obtain national estimates or (2) a census of all facilities in selected districts, which can be used for subnational estimates if desired.[4] Led by national ministries of health or national institutes, 2 surveyors on each survey team collected data using paper forms and the Census and Survey Processing System (CSPro) (U.S. Census Bureau and ICF International, Washington DC, USA) electronic data processing software package.[4] On average, facility visits take approximately 2 to 4 hours. The visit involves interviewing key informants and verifying reported and observed availability of essential equipment, supplies, medicines, and other commodities.[4] A database of the survey information is then generated through double entry of the same questionnaire and comparison of responses. The range and consistency checks performed before production of standard SARA tables using Microsoft Excel program and then disseminated to national stakeholders.[4]

The SARA indicators measure service availability, general service readiness, and service-specific readiness.[2] Service availability encompasses the physical presence of the delivery of services, including health infrastructure, core health personnel, and service utilization, but does not include more complex data such as geographic barriers, travel time, and user behavior.[2] Service availability is described with an index using the 3 areas of tracer indicators, with the indicators expressed as a percentage compared with target or benchmark, then taking the mean of the area scores.[2] General service readiness is expressed with an index using the 5 general service readiness domains and then a score is associated with each domain based on the number of domain elements present, with an overall readiness score calculated with the mean of the 5 domains.[2] Service-specific readiness looks at a health facility's ability to offer a specific service and capacity to provide that service to a user. This is measured with selected tracer items such as trained staff, guidelines, equipment, diagnostic capacity, medicine, and commodities.[2]

SARA can be used to explore reported and actual percentages of facilities offering certain services in national health system. Here, the reported percentage refers to health facilities where SARA survey respondents reported that their respective health facility is providing oral contraceptives in service, which has implications for available stock. The actual percentage refers to health facilities where, on the day of the assessment, a SARA surveyor observed at least 1 valid stock of oral/injectable contraceptives in the service area or where supplies were routinely stored in the health facility. We defined the stock-out rate of a contraceptive method as the proportion of facilities providing family planning services where the SARA surveyor did not observe at least 1 valid stock of oral or injectable contraceptives in the service area or where supplies were routinely stored in the health facility on the day of the assessment.

The SARA survey-based indicators measure contraceptive method choice and stock-out of oral contraceptives, injectable contraceptives, and male condoms. Other family planning provider readiness indicators—in terms of number of trained staff, availability and use of guidelines on delivering family planning services, and availability of a blood pressure apparatus for use of family planning staff—are used for cross comparison. The data are disaggregated by type (government or nongovernment) and location (rural or urban) of the family planning provider, and analysis is performed. Under the family planning section, there is a set of questions inquiring whether the facility provides or prescribes any of the following modern methods of family planning for unmarried adolescents: combined estrogen-progesterone oral contraceptive pills (COCs), male condoms, emergency contraceptive pills, and intrauterine devices (IUDs). We compared information on proportion of facilities providing these methods for unmarried adolescents across the countries.

SARA indicators measure service availability, general service readiness, and service-specific readiness, using an index of specific tracer items.

RESULTS

Facilities Providing Contraceptives by Type of Contraceptive Offered

Niger (96%), closely followed by Sierra Leone (94%), had the highest proportion of health facilities offering family planning services (Table 1), while the DRC (33%), Djibouti (57%), and Mauritania (67%) had the lowest proportion. Very few countries had high availability of more than 1 contraceptive type. In general, COCs, male condoms, and progestin-only injectable contraception were offered at higher rates (Table 1). Burkina Faso, Niger, and Sierra Leone had the most contraceptive options available at their facilities, suggesting that more options are available

In most countries, COCs, male condoms, and progestin-only injectables were offered at higher rates than other methods.

across facilities in those countries. When looking at national-level data, Djibouti and the DRC had the fewest options available at their facilities. Implants had relatively high availability in some countries (Benin, Burkina Faso, and Niger) and low availability elsewhere (Djibouti, the DRC, Mauritania, Sierra Leone, Tanzania, Togo, and Uganda).

Location and Type of Provider

In 8 of the countries, rural facilities had a higher availability of family planning services than urban facilities.

Breakdowns of country-level urban and rural family planning availability showed that in 8 of the 10 countries—Benin, Burkina Faso, Mauritania, Niger, Sierra Leone, Tanzania, Togo, and Uganda—rural facilities had a higher availability of family planning services than urban facilities (Figure 1). Likewise, a comparison of government facilities versus other facilities—those managed by private sector, faith-based organizations, NGOs, and any others—was consistent across countries, with all 10 countries having higher percentages of family planning availability in government facilities compared with other facilities (Figure 2).

Stock-Outs on the Day of the Assessment

Among the 10 countries, stock levels varied depending on the type of method and the location or type of facility providing family planning methods (Figure 3, Figure 4, and Supplement Table for more details). Burkina Faso, Niger, and Sierra Leone seemed to have consistently high levels of stock available, with a good mix of 3 options available at similarly high rates. In contrast, Togo had a large disparity between injectables with high amounts in stock compared with oral contraceptives and male condoms, and the DRC had a disparity between higher levels of male condoms being in stock compared with oral contraceptives or injectables. Among the 10 countries, government-run facilities tended to have a higher percentage of contraceptive methods in stock—condoms being the highest percentage stocked—compared with other facilities. Both types of facilities seemed to have similar percentages of oral contraceptives, injectables, and male condoms in stock. Whether a facility was urban or rural did not seem to affect availability of stock; however, facility-type data showed "government facilities" generally had more stock for each type of contraceptive compared with "other facilities," with some exceptions. Stock-out rates also tended to be higher in countries with lower proportions of facilities providing family planning services.

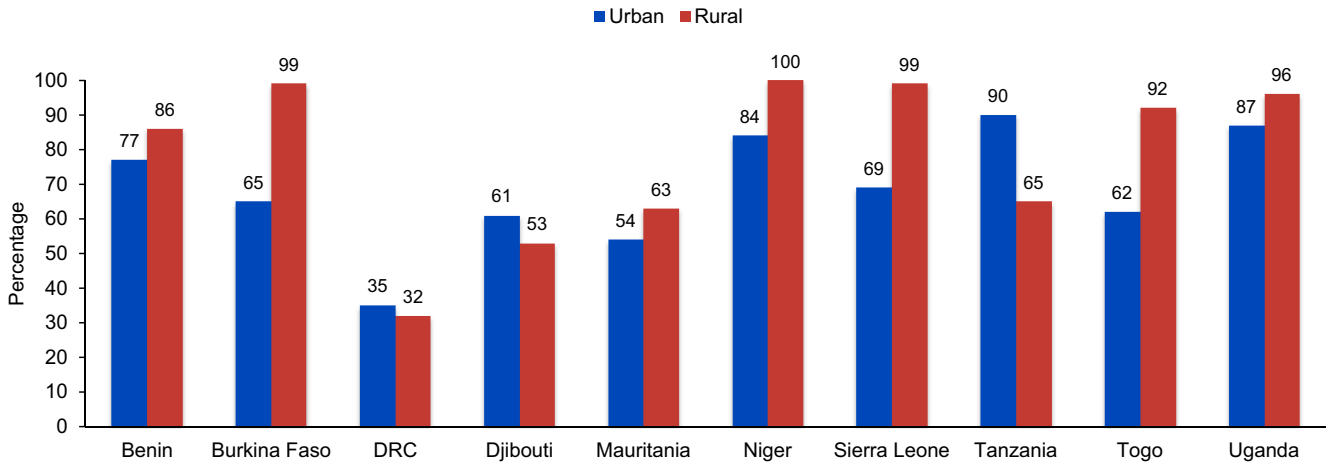
Another feature of SARA is the ability to explore reported and actual percentages of facilities offering certain services, which has implications for available stock. As mentioned earlier,

TABLE 1. Percentage of Facilities Providing Contraceptives, by Type of Contraceptive Offered

Country	Year of SARA Survey	Provides FP Services (%)	COCs (%)	POPs (%)	CICs (%)	POIs (%)	Male Condoms (%)	Female Condoms (%)	IUDs (%)	Implants (%)	CycleBeads for SDM (%)	ECPs (%)	Male Sterilization (%)	Female Sterilization (%)	Total No. of Facilities
Benin	2015	83	72	46	68	53	64	18	64	71	44	21	1	2	788
Burkina Faso	2014	91	89	80	NA	89	87	83	49	81	80	78	3	4	766
Djibouti	2015	57	50	49	32	30	45	23	29	12	1	37	1	2	82
DRC	2014	33	23	14	12	19	28	18	9	11	16	7	1	3	1,555
Mauritania	2016	67	64	55	44	59	55	28	20	29	3	9	NA	NA	288
Niger	2015	96	95	91	51	93	85	61	48	86	9	15	1	2	372
Sierra Leone	2013	94	89	85	33	79	92	79	25	33	7	43	1	1	455
Tanzania	2012	83	68	63	37	54	68	9	18	23	26	43	6	8	1,297
Togo	2012	84	65	44	38	66	65	16	40	46	31	17	NA	4	100
Uganda	2013	92	85	59	5	89	84	14	28	30	10	68	13	15	209

Abbreviations: CICs, combined injectable contraceptives; COCs, combined oral contraceptives; DRC, Democratic Republic of the Congo; ECPs, emergency contraceptive pills; FP, family planning; IUD, intrauterine device; NA, not available; POIs, progestin-only injectables; POPs, progestin-only pills; SARA, Service Availability and Readiness Assessment; SDM, Standard Days Method.

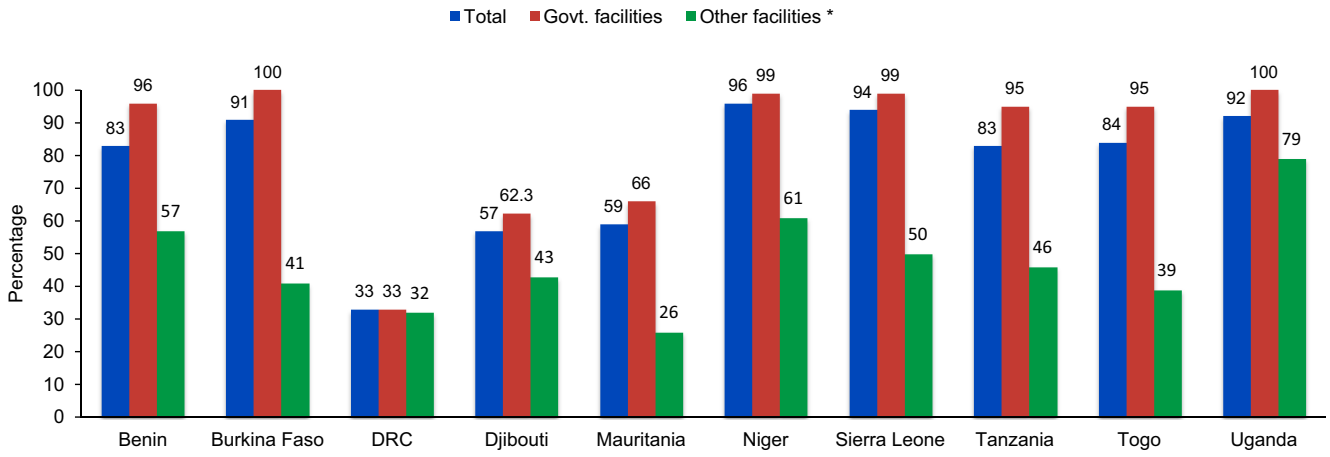
FIGURE 1. Percentage of Health Facilities Providing Family Planning, by Urban and Rural Location



Abbreviation: DRC, Democratic Republic of the Congo.

actual availability refers to whether a family planning method was observed in the service area or in the place they are routinely stored on the date of SARA survey. Data for the reported versus actual percentage of facilities providing oral contraceptives in 9 of the countries—Benin, Burkina Faso, Djibouti, the DRC, Mauritania, Niger, Sierra Leone, Togo, and Uganda—show the proportion of health facilities experiencing stock-out of oral contraceptives ranged from 2% in Niger to 35% in Togo (Figure 5). The stock-out rate in health facilities for relatively less popular injectable contraceptives ranged from 2% in Niger and Togo to 42% in the DRC. The DRC, Mauritania, and Togo also had high stock-out rates for oral contraceptives among their facilities. Data from these same 9 countries

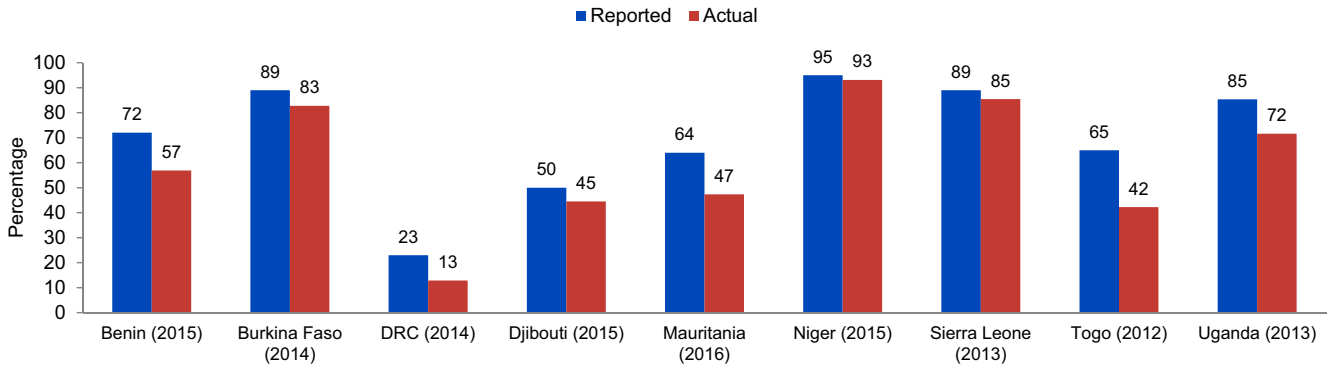
FIGURE 2. Percentage of Health Facilities Providing Family Planning Services, by Type of Facility



Abbreviation: DRC, Democratic Republic of the Congo.

* "Other facilities" includes all health care providers not managed by the government, including private sector, faith-based organizations, NGOs, and other similar organizations.

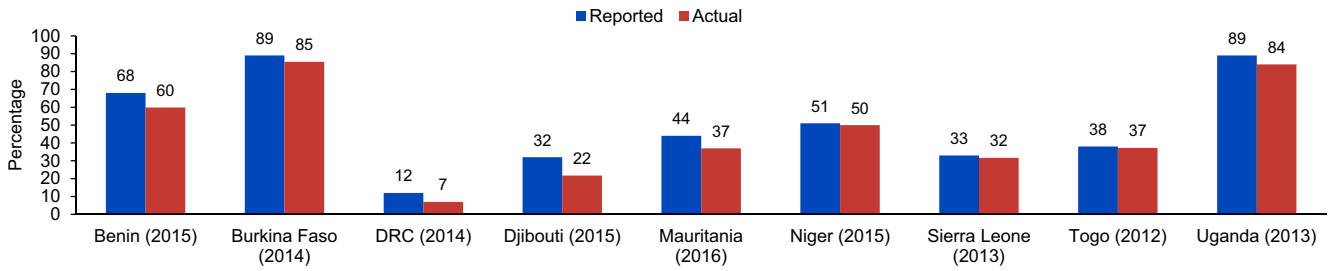
FIGURE 3. Percentage of Facilities Providing Oral Contraceptives, Reported Compared With Observed[a]



Abbreviation: DRC, Democratic Republic of the Congo.

[a] Reported percentage refers to percentage of facilities where a SARA survey respondent reported that a health facility is providing oral contraceptive services. Actual percentage refers to the percentage of facilities where a SARA surveyor observed at least 1 valid stock of oral contraceptives in the service area or in a place where they are routinely stored in the health facility, on the day of the assessment

FIGURE 4. Percentage of Facilities Providing Injectable Contraceptives, Reported Compared With Observed[a]



Abbreviation: DRC, Democratic Republic of the Congo.

[a] Reported percentage refers to percentage of facilities where a SARA survey respondent reported that a health facility is providing oral contraceptive services. Actual percentage refers to the percentage of facilities where a SARA surveyor observed at least 1 valid stock of oral contraceptives in the service area or in a place where they are routinely stored in the health facility, on the day of the assessment.

show disparities between actual and reported percentages of facilities providing injectable contraceptives and oral contraceptives (Figure 5).

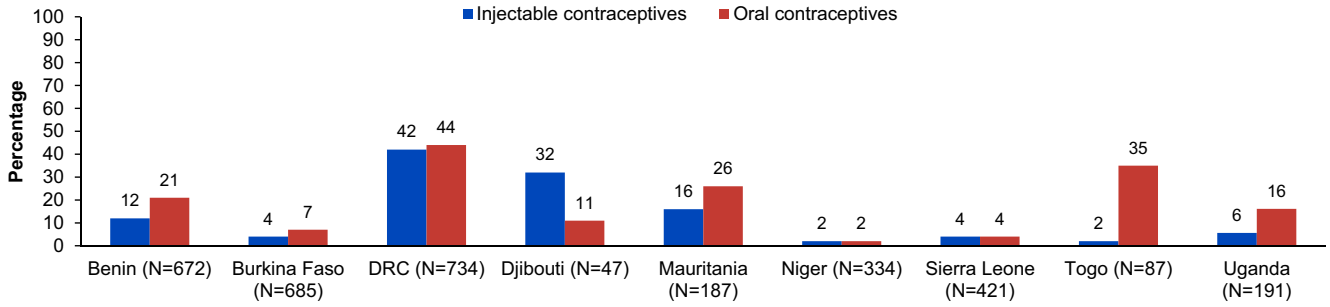
The percentage of facilities providing family planning services with all 6 tracer items ranged from 17% in Benin and Mauritania to 72% in Tanzania.

A key feature of SARA is its ability to pool data on tracer items. The 6 tracer items identified for family planning include the availability of and access to guidelines/job aids for family planning, staff trained in family planning services, blood pressure apparatuses, COCs, injectable contraceptives, and male condoms on the day of facility assessment. The percentage of facilities providing family planning services with all 6 tracer items ranged from 17% in Benin and Mauritania to 72% in Tanzania (Figure 6). The mean percentage of facilities providing family planning services with all 6 tracer items among the 10 countries was 35.3%.

Guidelines, Equipment, and Training

Access to equipment and training shows not only the availability but also the readiness of a health service. At the health facilities surveyed, Mauritania and Uganda had the lowest percentage of family planning guidelines available, while Burkina Faso had the highest (Table 2). Facilities in all countries surveyed, except Sierra Leone and Uganda, had family planning guidelines (including checklists and/or job aids) available to inform

FIGURE 5. Percentage of Health Facilities With Stock-Outs of Injectable and Oral Contraceptives



Abbreviation: DRC, Democratic Republic of the Congo.

Percentage stock-out refers to the proportion of facilities providing family planning services, where a SARA surveyor did not observe at least 1 valid stock of injectable or oral contraceptives in the service area or in the place where they are routinely stored in the health facility, on the day of the assessment.

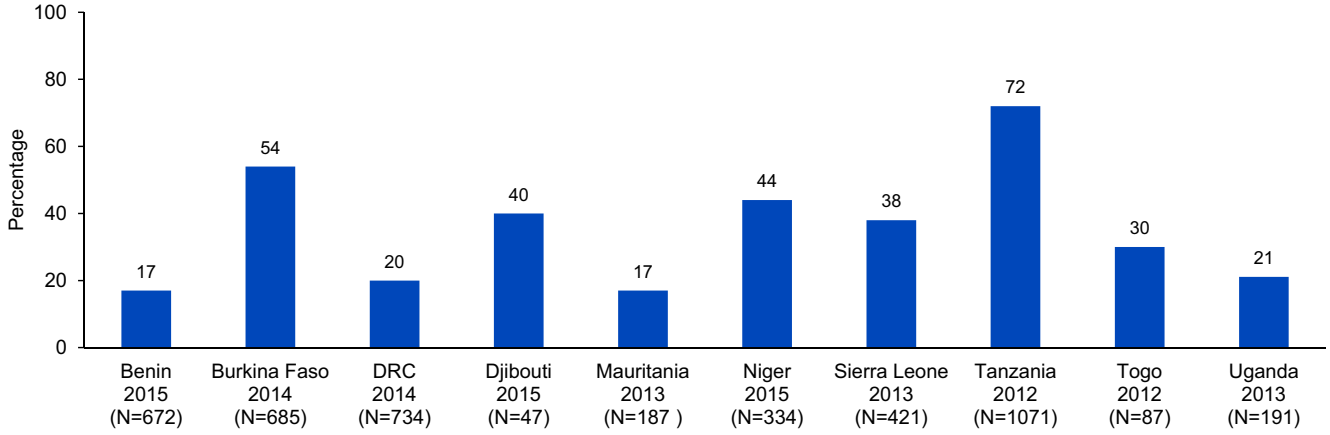
family planning service provision at health facilities and had 1 or more staff members trained in family planning. Niger and Burkina Faso had relatively high levels of family planning guidelines available and staff members trained.

All 10 countries had a relatively high availability of blood pressure apparatuses in health facilities. Overall, the percentage availability of blood pressure apparatuses was highest in facilities, while the percentage of available family planning guidelines was much lower (Table 2). In 6 of 10 countries, 50% or more of facilities had more than 1 staff member trained in family planning, and in only 3 of 8 countries with data did 50% or more of facilities have all 3 family planning-related tracer items.

Family Planning Services for Unmarried Adolescents

Adolescents are of particular interest when it comes to family planning services. The SARA tool includes separate questions about the provision of condoms and at least 1 other method of family planning to unmarried adolescents. Information provided in this section is used for comparison on availability of family planning services in general

FIGURE 6. Percentage of Facilities Providing Family Planning Services With All Tracer Items[a]



Abbreviation: DRC, the Democratic Republic of the Congo.

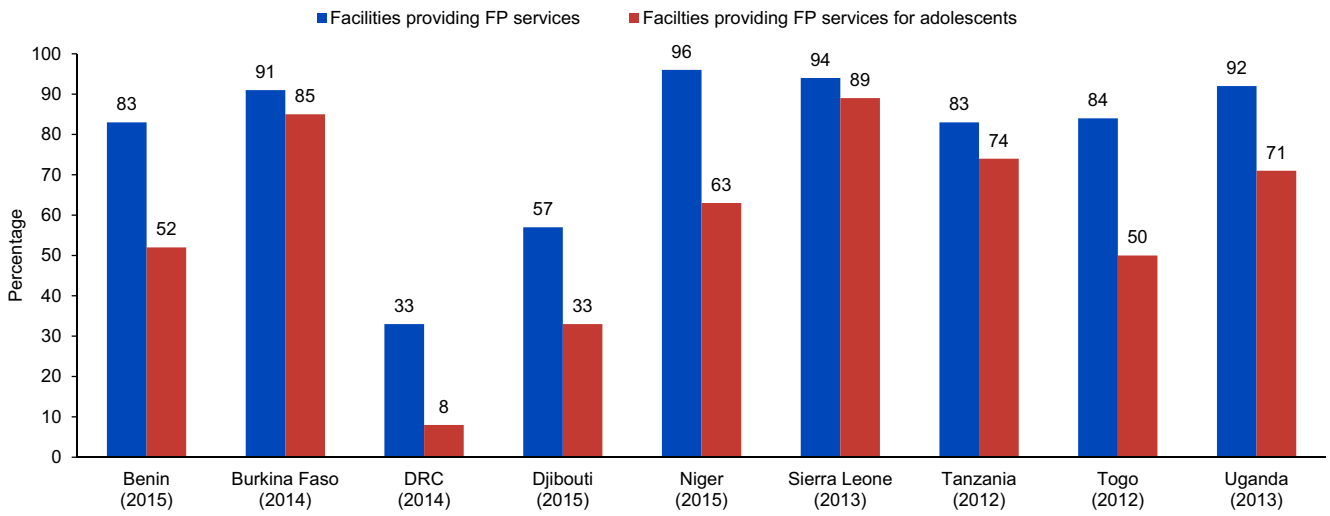
[a] Tracer items include availability of guidelines for family planning, staff trained in family planning services, blood pressure apparatus, combined oral contraceptive pills, injectable contraceptives, and male condoms on the day of facility assessment.

TABLE 2. Percentage of Facilities Providing Family Planning Services With Guidelines, Trained Staff, and Equipment

Country	Year	FP Guidelines (%)	At Least 1 Trained FP Staff (%)	BP Apparatus (%)	All 3 Items (%)
Benin	2015	64	47	96	35
Burkina Faso	2014	87	78	98	68
Djibouti	2015	74	66	87	55
DRC	2014	53	51	85	33
Mauritania	2016	44	54	91	NA
Niger	2015	82	78	83	52
Sierra Leone	2013	59	75	83	42
Tanzania	2012	57	45	89	NA
Togo	2012	67	42	88	36
Uganda	2013	44	49	86	28

Abbreviations: BP, blood pressure; DRC, Democratic Republic of the Congo; FP, family planning; NA, not available.

FIGURE 7. Percentage of Health Facilities Providing Family Planning Services to Unmarried Adolescents



Abbreviations: DRC, Democratic Republic of the Congo; FP, family planning.

While the percentage of facilities providing family planning services to unmarried adolescents varied greatly, adolescents remained underserved.

in the facility and specific availability of services for unmarried adolescents. For this metric, 9 countries were examined (data for Mauritania were not available). In 7 countries, the percentage of facilities providing family planning services was considerably higher than the percentage of facilities offering family planning services for unmarried adolescents, with Benin (31% difference), Niger (33% difference), and Togo (34% difference) having the biggest disparities (Figure 7). Burkina Faso and Sierra Leone had nearly the same level of services available to unmarried adolescents as the general public.

DISCUSSION

The SARA tool provided insightful information on the availability of family planning products and services as well as the readiness of the facilities surveyed to provide services in the 10 countries surveyed. While the results indicated overall high

levels of family planning availability of at least 1 method in 7 countries (Djibouti, the DRC, and Mauritania did not have high levels of family planning availability), they also showed that contraceptive options were limited in the countries assessed, which could limit usage of family planning if appropriate methods are not available.

Results also showed that government health facilities typically had more family planning availability, highlighting potential gaps where public facilities do not exist. The difference between rural and urban family planning availability noted here could be due to a concentration of private facilities in urban areas, which is to be explored separately. The delivery of family planning services may not be a priority area for the profit-oriented private sector, which could have indirectly contributed to the observed differences between rural and urban service availability.

The typically higher stock levels in government facilities may be due to the government having better logistics management and/or supply chains than religious, private, or traditional health facilities. As a result, modern contraception may not be offered or considered as high of a priority in nongovernment facilities.

Stock-outs are a common problem. The 10 countries had varying stock levels and inconsistent method availability of the 3 methods surveyed: oral contraceptives, injectables, and male condoms. Some countries, particularly the DRC, had very high stock-out rates for certain commodities. In contrast, Burkina Faso, Niger, and Sierra Leone had the best stock mix of the countries surveyed. Poor levels of stock may be indicative of larger supply chain problems, such as poor logistics management information systems, incorrect ordering of stock, poor budget allocation and/or use, external supply chain issues, commercial market factors, or other transportation-related issues. Other factors, such as demand or intention, may have also influenced the different stock levels of these 3 methods in each of the surveyed countries. For example, a facility may stock male condoms for sexually transmitted infection prevention rather than family planning. Male condoms also do not offer women the same control or efficacy as other methods for family planning purposes. More worrisome are the countries such as the DRC, Mauritania, and Togo, which had lower levels of stock in general compared with the other countries surveyed. Stock-out rates were higher in countries with lower proportions of facilities—the DRC and Mauritania—providing family planning services, which may indicate that family planning is less of a priority for the government and/or public.

The differences between reported and actual percentages of facilities offering family planning services indicate that each country had a disparity in their oral and injectable contraceptive supplies. This may be due to either weak logistics management information systems and inadequate information about inventory and procurement or incorrect ordering of inventory by staff members who may have not received proper training for procurement or documenting inventory, or both. Ministries of health should prioritize improving logistics management information systems to have more accurate inventories to improve family planning and other health services.

Readiness is an area where many of the countries surveyed could use improvement. Overall low levels of tracer items—guidelines for family planning, staff trained in family planning services, blood pressure apparatus, COCs, injectable contraceptives, and male condoms on the day of facility assessment—indicated that the readiness of many health facilities in these countries needs to be improved. The percentage of facilities with guidelines for family planning and at least 1 staff member trained in family planning was low in the countries surveyed. In each country, except for Sierra Leone and Uganda, family planning guidelines were more likely to be in a health facility than staff members trained in family planning. This is a cause of concern because even if guidelines are available in a facility, they may not be used if staff members are not trained to use them. Even greater disparities were seen between the high availability of blood pressure apparatuses and the share of family planning service delivery units equipped with blood pressure apparatuses. We only have information on mere availability of the apparatus, and not on whether the providers are effectively using them. However, as noted in WHO's latest *Selected Practice Recommendations for Contraceptive Use*,[11] while it is desirable to have blood pressure measurements taken, women should not be denied use of contraceptive methods simply because their blood pressure cannot be measured.

Overall low levels of tracer items indicated that the readiness of many health facilities in these countries should be improved.

According to SARA data, unmarried adolescents, in particular, are underserved. The data from Benin, Djibouti, the DRC, Niger, Togo, and Uganda showed especially low percentages of facilities with family planning services available for unmarried adolescents, which is a missed opportunity for country programs. By meeting the unmet need for modern contraception of women

By meeting adolescents' unmet need for modern contraception, countries could avert 2.1 million unplanned births, 3.2 million abortions, and 5,600 maternal deaths.

The SARA tool should be revised to include LARCs and permanent methods to more accurately reflect the method mix available in sub-Saharan African countries.

aged 15 to 19 years, countries could reduce unintended pregnancies by 6 million annually, thereby averting 2.1 million unplanned births, 3.2 million abortions, and 5,600 maternal deaths.[12] Beyond that, reducing unintended pregnancies in adolescents can decrease the negative consequences of early childbearing—such as high-risk pregnancies that can cause complications and poor health outcomes for both mother and newborn child—and increase savings in maternal and child health care and improve young women's education and economic prospects.[11]

At present, the core SARA tool focuses on measuring the availability of national guidelines, training of service providers, and availability of selected contraceptive methods, such as COCs, condoms, IUDs, and emergency contraception. The nature of information on adolescents in facility-level surveys is dependent on national policies and/or guidelines for providing family planning services for adolescents, which may vary from country to country. It is important to note that if a national policy does not support providing specific services to adolescents, then health facilities are not legally eligible to deliver them. In the absence of a national policy recommending provision of family planning method for adolescents, adolescent-specific service information is difficult to obtain. This is an inherent limitation in performing a cross-national comparison of adolescent access to various family planning methods using data from health facility surveys, including SARA.

Limitations

While SARA data can produce many useful findings, it is important to acknowledge its limitations. The data only provide information about facility availability and readiness; they do not measure actual use of contraceptives. Moreover, assessing the supply side of family planning does consider potential low demand for family planning in general or for certain methods specifically, and how facility availability or readiness to provide family planning services may be affected in a place where demand may not exist. The information obtained on the availability of family planning services for unmarried adolescents was collected by interviewing 1 or more staff members at the facility. The interviews were not in-depth or robust and may have resulted in the actual availability being less than the stated results, possibly due to courtesy bias. It is crucial to review and revise data collection methods, as suggested above, to obtain good quality and credible information for strengthening services.

This analysis is limited, as it only looks at SARA data from 10 countries in sub-Saharan Africa and cannot necessarily be generalized to other countries or regions, and because long-acting reversible contraceptives (LARCs) and permanent methods were not included in the survey focus. The analysis was focused on short-acting reversible methods—oral contraceptives, injectables, and condoms—as the tracer for medicine and commodity availability for family planning services in SARA tool. Considering the increasing popularity of LARCs in sub-Saharan Africa, core SARA instruments may also consider adding them to the existing tracer items list.

CONCLUSION

By improving the availability of an appropriate contraceptive method mix through supply-chain and logistics solutions and increasing facility readiness through training and improved health systems, more women could gain access to contraception thereby reducing an already identified unmet need.

Reducing gaps in availability and readiness of health systems to provide contraceptive products and services is needed to achieve universal health coverage targets for family planning. As discussed in this article, addressing time- and resource constraints-related limitations by expanding the scope of the core SARA tool can make it more programmatically useful for family planning planners and managers.

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En français

Évaluation de la disponibilité et de la capacité opérationnelle des services de planification familiale dans 10 pays africains

Dans les 10 pays étudiés, la disponibilité des contraceptifs oraux, des contraceptifs injectables et des préservatifs est apparue très variable, tandis que la disponibilité d'indicateurs de base de la capacité opérationnelle (par exemple, lignes directrices, personnel qualifié, le matériel et produits spécifiques) était faible.

RÉSUMÉ

Contexte général : L'accès aux services de planification familiale et à des méthodes de contraception appropriées est indispensable pour obtenir des bons résultats sanitaires pour les femmes et les adolescentes. L'Organisation mondiale de la Santé (OMS) et l'Agence des États-Unis pour le développement international (USAID) ont mis au point conjointement l'outil de mesure de la disponibilité et de la capacité opérationnelle des services (SARA), qui sert à mesurer la capacité des établissements de santé à fournir aux utilisateurs finaux des soins appropriés et de qualité. Dans cette étude, nous nous sommes intéressés à la disponibilité des services et à la capacité opérationnelle des établissements de santé à fournir des services de contraception dans 10 pays africains : le Bénin, le Burkina Faso, Djibouti, la Mauritanie, le Niger, l'Ouganda, la République démocratique du Congo, la Sierra Leone, la Tanzanie et le Togo.

Méthodes : Cette étude a comparé les données des enquêtes SARA sur les services de planification familiale qui ont été menées dans chacun des 10 pays. Nous avons mené une analyse descriptive des variations observées pour la capacité opérationnelle des établissements et du point de vue de la disponibilité des services, des méthodes de contraception, du personnel qualifié, des lignes directrices sur la planification familiale, et du matériel de soins de base.

Résultats : Globalement, dans une grande partie des pays étudiés, au moins une méthode de contraception est très largement disponible. Les contraceptifs sont généralement plus disponibles dans les établissements ruraux que dans les établissements urbains, et les services de planification familiale plus accessibles dans les établissements publics que chez d'autres prestataires. La méthode de contraception principale diffère d'un pays à l'autre, et des ruptures de stock de moyens de contraception ont été observées. Globalement, les niveaux étaient bas pour 6 indicateurs (disponibilité de lignes directrices sur la planification familiale, personnel qualifié de planification familiale, appareils de mesure de la tension artérielle, contraceptifs oraux combinés, contraceptifs injectables, et préservatifs masculins le jour de l'évaluation), indiquant un faible niveau de préparation opérationnelle. Des écarts ont été notés entre la disponibilité signalée et observée des appareils de mesure de la tension artérielle, des guides de planification familiale et d'au moins un membre de l'équipe formé à l'usage de ces outils. Dans tous les pays, les adolescents non mariés ont moins accès à la planification familiale que la population générale.

Conclusion : Les ruptures de stock et les problèmes de gestion logistique sont courants dans les pays étudiés. Les écarts entre la disponibilité notifiée et effective des produits et des services complique souvent l'accès des utilisateurs finaux à des méthodes appropriées de planification familiale. Face à une grande partie de ces problèmes, des efforts supplémentaires de formation des agents de santé sont nécessaires et il faut mieux cibler et soutenir les adolescents. Pour atteindre les cibles de la couverture sanitaire universelle en matière de planification familiale, il faut réduire les lacunes observées en matière de disponibilité des produits et des services de contraception et du point de vue de la préparation opérationnelle des établissements.

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ORIGINAL ARTICLE

Safety of Tubal Occlusion by Minilaparotomy Provided by Trained Clinical Officers Versus Assistant Medical Officers in Tanzania: A Randomized, Controlled, Noninferiority Trial

Mark A. Barone,[a] Zuhura Mbuguni,[b] Japhet Ominde Achola,[c] Annette Almeida,[d] Carmela Cordero,[e] Joseph Kanama,[f] Adriana Marquina,[e] Projestine Muganyizi,[g] Jamilla Mwanga,[f] Daniel Ouma,[h] Caitlin Shannon,[e] Leopold Tibyehabwa[f]

Trained clinical officers—nonphysicians with 3 years of specialized training—conducted the procedure safely and effectively compared with procedures performed by more advanced assistant medical officers. This evidence supports policy change allowing properly trained and supported clinical officers to perform minilaparotomy.

ABSTRACT

Background: Tubal occlusion by minilaparotomy is a safe, highly effective, and permanent way to limit childbearing. We aimed to establish whether the safety of the procedure provided by trained clinical officers (COs) was not inferior to the safety when provided by trained assistant medical officers (AMOs), as measured by major adverse event (AE) rates.

Methods: In this randomized, controlled, open-label noninferiority trial, we enrolled participants at 7 health facilities in Arusha region, Tanzania, as well as during outreach activities conducted in Arusha and neighboring regions. Consenting, eligible participants were randomly allocated by a research assistant at each site to minilaparotomy performed by a trained CO or by a trained AMO, in a 1:1 ratio. We asked participants to return at 3, 7, and 42 days postsurgery. The primary outcome was the rate of major AEs following minilaparotomy performed by COs versus AMOs, during the procedure and through 42 days follow-up. The noninferiority margin was 2%. The trial is registered with ClinicalTrials.gov, Identifier NCT02944149.

Results: We randomly allocated 1,970 participants between December 2016 and June 2017, 984 to the CO group and 986 to the AMO group. Most (87%) minilaparotomies were conducted during outreach services. In the intent-to-treat analysis, 0 of 978 participants had a major AE in the CO group compared with 1 (0.1%) of 984 in the AMO group (risk difference: –0.1% [95% confidence interval: –0.3% to 0.1%]), meeting the criteria for noninferiority. We saw no evidence of differences in measures of procedure performance, participant satisfaction, or provider self-efficacy between the groups.

Conclusions: Tubal occlusion by minilaparotomy performed by trained COs is safe, effective, and acceptable to women, and the procedure can be safely and effectively provided in outreach settings. Our results provide evidence to support policy change in resource-limited settings to allow task shifting of minilaparotomy to properly trained and supported COs, increasing access to female sterilization and helping to meet the rising demand for the procedure among women wanting to avoid pregnancy. They also suggest high demand for these services in Tanzania, given the large number of women recruited in a relatively short time period.

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INTRODUCTION

Globally, modern contraceptive use has risen substantially over the last 45 years from 36% in 1970 to 64% in 2015,[1] yet unmet need for family planning remains high. In 2017, an estimated 214 million women of reproductive age living in developing regions of the world wanted to avoid pregnancy but were not using a modern contraceptive method, accounting for 84% of unintended pregnancies in these regions.[2] In many cases, this leads to a high burden of maternal and child morbidity and mortality and to unsafe abortions.[2] Unmet need is highest in sub-Saharan Africa, and

although the number of women wanting to limit future childbearing in this region has been rising, many of these women use less effective short-acting methods of contraception instead of more effective methods such as female sterilization.[3,4]

Tubal occlusion via minilaparotomy, using local anesthesia and analgesia, with or without systemic sedation, is the simplest way to provide female sterilization. The surgery is minor and can be performed in resource-limited settings on an outpatient basis, with low risk of complications.[5,6] This procedure can be performed anytime that pregnancy can be ruled out (commonly referred to as "interval" sterilization), or within the first 7 days following vaginal delivery or first-trimester abortion; it is not recommended between 8 and 42 days postpartum but could be performed anytime thereafter.[7]

One reason women may not use female sterilization is limited access to services. In Tanzania, for example, the Ministry of Health, Community Development, Gender, Elderly, and Children (MOHCDGEC) recognizes that most health facilities are understaffed, more so in rural areas, and that a shortage of trained providers affects the availability of health care services, including female sterilization.[8] Family planning providers themselves report that service provision is hampered by a mismatch between what clients want and what facility staff are able to provide or what certain cadres are *allowed* to provide under current government regulations.[9] Access to health services can be expanded with task shifting, the delegation of some tasks to less-specialized health workers. We use the term "task shifting" to mean situations where a less-specialized health worker conducts the entire procedure (e.g., a surgical procedure) on his or her own (some may refer to this as task sharing).[10] Task shifting of surgical procedures to mid-level providers has improved access to lifesaving interventions, with clinical officers (COs) and nurses demonstrating outcomes similar to those of their higher-level counterparts in Malawi,[11] Mozambique,[12–14] and Tanzania.[15]

Task shifting could increase access to tubal occlusion, especially in rural areas where demand for family planning is high and where most health services are provided by nonphysicians.[16,17] In fact, World Health Organization (WHO) guidelines include COs among those considered competent to provide tubal occlusion. Although the guidance panel accepted that the procedure was within the COs' competency, the panel members did not review the available evidence to support their recommendation.[18] Two systematic reviews, which included older studies conducted primarily in the 1970s and 1980s, were published after the WHO guidelines were released.[19,20] Results of both reviews suggest that task shifting of tubal occlusion to nonphysicians may be a safe and effective approach to increasing contraceptive access.

Three, more recent nonrandomized studies offer additional support on the safety of task shifting tubal occlusion by minilaparotomy.[21–23] No major adverse events (AEs), defined by the authors as complications serious enough to require referral to a hospital, were reported among 164 women in Malawi through 14 days of follow-up after minilaparotomy performed by COs.[21] In Uganda, a major AE rate of 1.5% was reported among 518 women following minilaparotomy performed by a CO through 45 days after surgery.[22] The authors defined major AEs as events causing long-term incapacity or disability *and* requiring hospitalization, as well as failed minilaparotomy procedures. Finally, in Ethiopia, the rate of major AEs, defined by the authors as AEs requiring significant follow-up care or hospitalization, as well as failed procedures, among 276 women who had a minilaparotomy performed by a CO was 3%, with 6 of the 8 AEs being failure to complete the procedure.[23]

Overall, the available evidence is limited, and well-designed clinical trials are needed to definitively demonstrate the safety, efficacy, and acceptability of task shifting tubal occlusion to mid-level providers.[19–23] We aimed to establish whether the safety of tubal occlusion by minilaparotomy provided by trained COs was not inferior to the safety of the procedure when provided by trained assistant medical officers (AMOs), as measured by major AE rates.

One reason women may not use female sterilization is limited access to services.

We aimed to establish whether the safety of tubal occlusion by minilaparotomy provided by trained clinical officers was not inferior to the safety of the procedure when provided by trained assistant medical officers.

Task shifting provision of tubal ligation to mid-level providers could increase access to the procedure, especially in rural areas.

METHODS

Study Design and Participants

We conducted a randomized, controlled, open-label noninferiority trial comparing the safety of tubal occlusion by minilaparotomy when performed by trained COs and by trained AMOs at 7 study sites (2 district hospitals and 5 health centers) in Arusha region in northern Tanzania. We also recruited participants during outreach activities in Arusha, Dodoma, Kilimanjaro, Manyara, and Singida regions, since this approach is part of the MOHCDGEC's strategy to increase access to family planning. During outreach events, the trained COs and AMOs from the study sites traveled to and performed minilaparotomy

Health facility staff discuss family planning options with women waiting for outreach services in northern Tanzania. © 2016 EngenderHealth

procedures at other facilities where it was not routinely available.

We included women if they met the following inclusion criteria:

- were aged 18 years and older;
- requested and consented to tubal occlusion and provided informed consent for study participation;
- were of sound mind, in good general health, and deemed suitable to undergo tubal occlusion by minilaparotomy in accordance with the MOHCDGEC guidelines;
- understood study procedures and requirements;
- agreed to return for follow-up visits; and
- provided contact information.

We excluded women if they:

- were pregnant, based on the results of a rapid pregnancy test;
- were between 8 and 42 days postpartum or postabortion;
- had a known allergy or sensitivity to lidocaine or other local anesthetic;
- took medication contraindicating elective surgery;
- had previous abdominal or pelvic surgery;
- had a local skin infection near the area of the intended incision;
- had severe anemia, a coagulation disorder, hypertension, acute deep venous thrombosis, pulmonary embolism, or current ischemic heart disease;
- had unexplained vaginal bleeding, malignant gestational trophoblastic disease, cervical, endometrial, and/or ovarian cancer, pelvic inflammatory disease (within the last 3 months), or current purulent cervicitis, chlamydial infection, and/or gonorrhea;
- had current symptomatic gall bladder disease, active viral hepatitis, tuberculosis of pelvic organs, acute bronchitis or pneumonia, or systematic infection or gastroenteritis; or
- were currently participating in another biomedical research study.

In Tanzania, clinical officers are nonphysician providers who have undergone a standard 3-year training program; assistant medical officers have an additional 3 years of clinical work experience and 2 more years of training.

The protocol was reviewed and approved by the National Institute for Medical Research, Tanzania, Dar es Salaam, and the Western Institutional Review Board, Puyallup, WA, USA.

Randomization and Masking

Randomization was done using permuted blocks with randomly varying block sizes of 4 to 8 within each site. We randomized participants in a 1:1 ratio (i.e., minilaparotomy conducted by a CO or by an AMO). We concealed allocation through use of a text-message service (Sealed Envelope Ltd, London, UK, www.sealedenvelope.com). A researcher unaffiliated with the study computer-generated the random allocation sequence, which we then uploaded to Sealed Envelope before the start of recruitment. We randomized participants after screening had been conducted, a woman's eligibility for study participation had been confirmed, and just prior to start of the minilaparotomy procedure. Research assistants sent a text message requesting that a participant be randomized and received the random allocation in a text message reply. All study sites recruited participants until the total sample size had been reached. Because of the nature of the health facilities and services and the low availability of clinical staff at study sites, we were unable to mask participants, coinvestigators, those assessing outcomes, or other study staff to treatment allocation.

Service Providers and Clinical Training

Minilaparotomies were conducted by 7 COs and 7 AMOs employed by the MOHCDGEC, with 1 CO and 1 AMO stationed at each study site. In Tanzania, COs are nonphysician health care

providers who have undergone a standard 3-year training program. AMOs are COs who have at least 3 years of clinical work experience and who have completed an additional 2-year training program (Table 1).

The AMOs were older than the COs and more established in their careers, with only 2 of 7 AMOs having worked 7 years or less as an AMO compared with 6 of 7 COs having worked 7 years or less as a CO (with an outlier who had been a CO for 31 years). At the time of the study, 5 CO/AMO pairs were working at health centers and 2 at district hospitals. Several of the COs and AMOs had previously worked at other-level health facilities. Both the COs and AMOs provided a wide range of preventive, diagnostic, and treatment services as part of their clinical duties.

To ensure that all providers had adequate skills and used standardized procedures, prior to the start of the study we trained them to perform tubal

TABLE 1. Background Characteristics of Service Providers Conducting Tubal Ligations in the Study

	Clinical Officers (n=7)	Assistant Medical Officers (n=7)
	3-year CO training course	≥3 years of CO clinical work, plus 2-year AMO training course
Sex		
Female	1	2
Male	6	5
Age, years, median (range)	29 (27, 57)	44 (36, 59)
No. of years in career, median (range)	3 (2, 31)	7 (2, 12)
Type of facility[a]		
District hospital	2	3
Health center	5	6
Dispensary	1	1
Private hospital	1	0
No. with surgical experience before the minilaparotomy training	4	6
Frequency performing surgery[b]		
Daily	0	1
Weekly (1–5/week)	2	4
Irregularly	2	1
No. reporting experience with types of surgery[b]		
Abscess incision and drainage	1	3
Appendectomy	0	3
Cesarean delivery	0	6
Circumcision	3	0
Cyst excision	1	0
Hernia repair	0	1
Laparotomy for ruptured ectopic pregnancy	0	2
Lipoma removal	1	0
Wound repair	1	0

Abbreviations: AMO, assistant medical officer; CO, clinical officer.
[a] At current and previous postings; some worked at more than 1 type of facility during their career.
[b] Among those reporting surgical experience before the minilaparotomy training.

A clinical officer screens a woman for tubal ligation in a health facility in northern Tanzania. © 2014 EngenderHealth/S. Lewis

ligation by minilaparotomy. None of the COs or AMOs had prior experience performing the procedure, although 4 of 7 COs and 6 of 7 AMOs had experience conducting other surgical procedures. The surgical experience of the COs was limited to minor surgeries such as drainage of abscesses or male circumcision, while the AMOs had experience conducting more complex surgery such as cesarean deliveries and appendectomies (Table 1). The 11-day competency-based training followed MOHCDGEC guidelines and standards.[24] In keeping with national and international standards, we also included in the training surgical assistants who would assist the COs and AMOs while they performed the minilaparotomies.

The training included classroom sessions, practice with models, observation of minilaparotomy procedures, and conduct of procedures by the participants under supervision during the training workshop and post-training follow-up. Training covered applied anatomy, counseling, preoperative client assessment and preparation, pain management, emergency preparedness, minilaparotomy surgical skills, postsurgical assessment, follow-up, and complications prevention and management, as well as infection prevention practices relevant to minilaparotomy. We used pretests and posttests to assess individual trainees' change in knowledge. Providers used learning guides throughout the training, and trainers assessed the trainees' skills performance using an observation checklist in the training workshop and post-training follow-up. During the workshop, each provider conducted 5 procedures with assistance and coaching from a trainer. During post-training follow-up, the providers conducted minilaparotomy procedures at their work stations under a trainer's supervision. Although we do not have details on the number of procedures conducted under the trainer's supervision during post-training follow-up, all providers were deemed competent before the start of the study.

Other than during post-training follow-up, the providers were asked not to conduct any minilaparotomy procedures outside the context of the study, both before study recruitment began and once the study was underway.

Procedures

After a research assistant obtained legally effective (signed or witnessed) informed consent, we evaluated each potential participant for clinical eligibility according to the study inclusion and exclusion criteria noted above. A research assistant then randomized eligible participants as described above, and in most cases minilaparotomy was performed on the same visit (or if not, within 7 days of screening). We asked women to void before the procedure and gave them injectable atropine and diclofenac preoperatively. Sedation is not included as part of pain management in the MOHCDGEC guidelines for minilaparotomy and was not used in the study.[24] We performed all minilaparotomy procedures using 1% injectable lidocaine for local anesthesia and a uterine elevator, tubal hook and the modified Pomeroy technique for tubal occlusion, as per MOHCDGEC guidelines.[24]

COs are not allowed by Tanzania government regulations to perform minilaparotomy; however, we received permission from the MOHCDGEC for the trained COs to perform minilaparotomies during the study as long as all procedures were under the supervision of a physician experienced with and qualified to perform minilaparotomy. Supervisors were present during all procedures conducted by both COs and AMOs, to ensure comparability between the 2 treatment groups. Supervisors were able to take over the procedure if necessary for the health and well-being of the participants or if the CO or AMO was unable to complete the procedure. They also were able to provide verbal instructions or assist a provider having difficulty with a procedure. Data were gathered on any assistance provided by supervisors.

After the minilaparotomy procedures, participants remained at the site for several hours, were

monitored for any problems, and were given postoperative instructions before being discharged. We asked participants to return for 3 scheduled follow-up visits, at 3, 7, and 42 days postsurgery. We provided participants 5000 Tanzanian shillings (approximately US$2.25) to cover time and transport costs for each of the 3 scheduled follow-up visits. Providers scheduled additional visits as clinically necessary and informed participants that they should return to the site at any time if they had problems or concerns related to the procedure. During both scheduled and unscheduled follow-up visits, we gathered data on physical exam findings, AEs, and participants' experience and satisfaction postsurgery. Follow-up visits were conducted by available qualified providers; it was not practical to ensure that outcomes were assessed by someone other than the provider who had conducted the minilaparotomy. All medical procedures in the trial were conducted under the oversight of the MOHCDGEC.

Outcomes

The primary outcome was safety, defined by the overall rate of major AEs (Box) following minilaparotomy performed by COs versus AMOs, during the procedure and through 42 days follow-up. All AEs were graded according to criteria defined before the start of the study. We defined minor AEs as any deviation from the normal postoperative course where treatment was limited to observation, conservative therapy (e.g., pressure to relieve bleeding or local wound care), or medication (e.g., antiemetics, antibiotics, or pain relievers).

Prespecified secondary outcomes included:

- Rates of major and minor AEs following minilaparotomy procedures performed by COs vs. AMOs at different time points (i.e., intraoperatively, immediately postoperative, and at each follow-up visit)
- Differences in performance of minilaparotomy procedures between COs and AMOs (e.g., procedure times, requests for verbal instruction from the supervisor due to difficulty performing the procedure, requests for the supervisor to assist with the procedure, inability to complete the procedure, and maximum reported pain experienced by the participant during the procedure on a scale of 0=no pain to 10=worst possible pain)
- Participant satisfaction with the procedure performed by COs versus AMOs based on reported level of satisfaction (4-category ordinal scale: very satisfied to very dissatisfied)
- Provider self-efficacy, defined by providers' self-reported level of confidence, comfort, and perception of their ability to perform minilaparotomy

Statistical Analysis

We assessed noninferiority of the safety of minilaparotomy provided by COs compared with AMOs in terms of the proportion of participants experiencing a major AE by Day 42 postsurgery, with a 2% predefined noninferiority margin chosen on the basis of a combination of experts' clinical judgment and statistical reasoning based on the results of previously reported AE rates following tubal occlusion by minilaparotomy.[25] Assuming a 3% major AE rate in the control group (based on data from the previously reported studies), noninferiority would be shown within the margin of 2% at a 1-sided significance level of α=0.05 and a power of 80% (calculated when AE rates in both arms are the same) with a sample size of 895 per arm (1,790 women in total). After adjustment by 10% for loss to follow-up, protocol violations, and withdrawals, our planned total sample size of was 1,969 women, which we rounded to 1,970.

The primary outcome was safety, defined by the overall rate of major adverse events.

We planned to do an intention-to-treat analysis of all women randomly assigned who had a minilaparotomy procedure. All participants received the treatment to which they were allocated (e.g., participants randomized to have their minilaparotomy conducted by a CO actually had their procedure done by a CO, and vice versa). We included available data for all outcomes for

BOX. Major Adverse Events

1. Injuries to abdominal viscera, pelvic abscess, or severe peritonitis leading to unintended major surgery
2. Severe intra- or immediate postoperative hemorrhage requiring blood transfusion
3. Febrile morbidity (oral temperature greater than 38° C on at least 2 postoperative days, excluding the first 24 hours after surgery)
4. Life-threatening event (including cardiopulmonary crisis or anaphylaxis)
5. Readmission to the hospital any time after her discharge after the minilaparotomy through the end of follow-up due to a complication related to the minilaparotomy
6. Death or complication resulting in death occurring within 42 days of the surgery related to the minilaparotomy procedure

participants who withdrew or were discontinued through the time their study participation ended. Observations with missing outcome data were not considered in the analyses. No missing data were imputed.

We assessed the primary outcome using the 95% confidence interval (CI) for the difference and the ratio between the proportion of participants with a major AE in the CO versus the AMO group. We used ordinal logistic regression, including adjustment for covariates (i.e., age, minilaparotomy type, education level, etc.) for the primary outcome analysis. We used a chi-squared test to assess the difference between the major AE rates for COs versus AMOs.

We assessed secondary outcomes as follows. To compare the safety of minilaparotomy provided by COs versus AMOs at different time points (intraoperatively, immediately postoperative, and at each follow-up visit), we compared the proportion of participants with major and minor AEs using a chi-squared test. We assessed variables related to performance of minilaparotomy between COs and AMOs as follows: procedure time and maximum reported pain experienced by the participant during the procedure between the 2 groups were compared using independent samples *t* tests; and requests for verbal instruction from the supervisor due to difficulty performing the minilaparotomy, requests for the supervisor to assist with the minilaparotomy, and inability to complete the minilaparotomy between the 2 groups were compared using chi-squared tests. We analyzed data on participant satisfaction using ordinal logistic regression and reported qualitative data on what participants liked about the minilaparotomy procedure, what they did not like, and if they would recommend it to a friend or family member, including reasons why.

We assessed self-efficacy of minilaparotomy providers based on 3 measures:

- A 10-item self-efficacy scale, with a range from 10 to 40, with higher values indicating greater self-efficacy, adapted from the General Self-Efficacy Scale[26]
- A measure of confidence, with a range between 3 and 12, with higher numbers indicating greater levels of confidence with the procedure
- A measure of comfort, using a scale from 3 to 12, with higher numbers indicating greater comfort with performing minilaparotomy

We used independent samples *t* tests to compare the outcomes between the 2 groups for each of the 3 measures. We used Stata version 13.1 for all analyses.

The 3-member Data and Safety Monitoring Board (DSMB) met twice during the trial. The DSMB reviewed 1 planned interim analysis after approximately one-third of the sample had their minilaparotomies and had completed their 7-day follow-up visit. They reviewed the proportion of participants with events and the number of participants recruited unmasked by treatment group and advised that the trial should continue until its planned completion.

The trial protocol was previously published[25] and the trial is registered with ClinicalTrials.gov, Identifier NCT02944149, registered October 14, 2016.

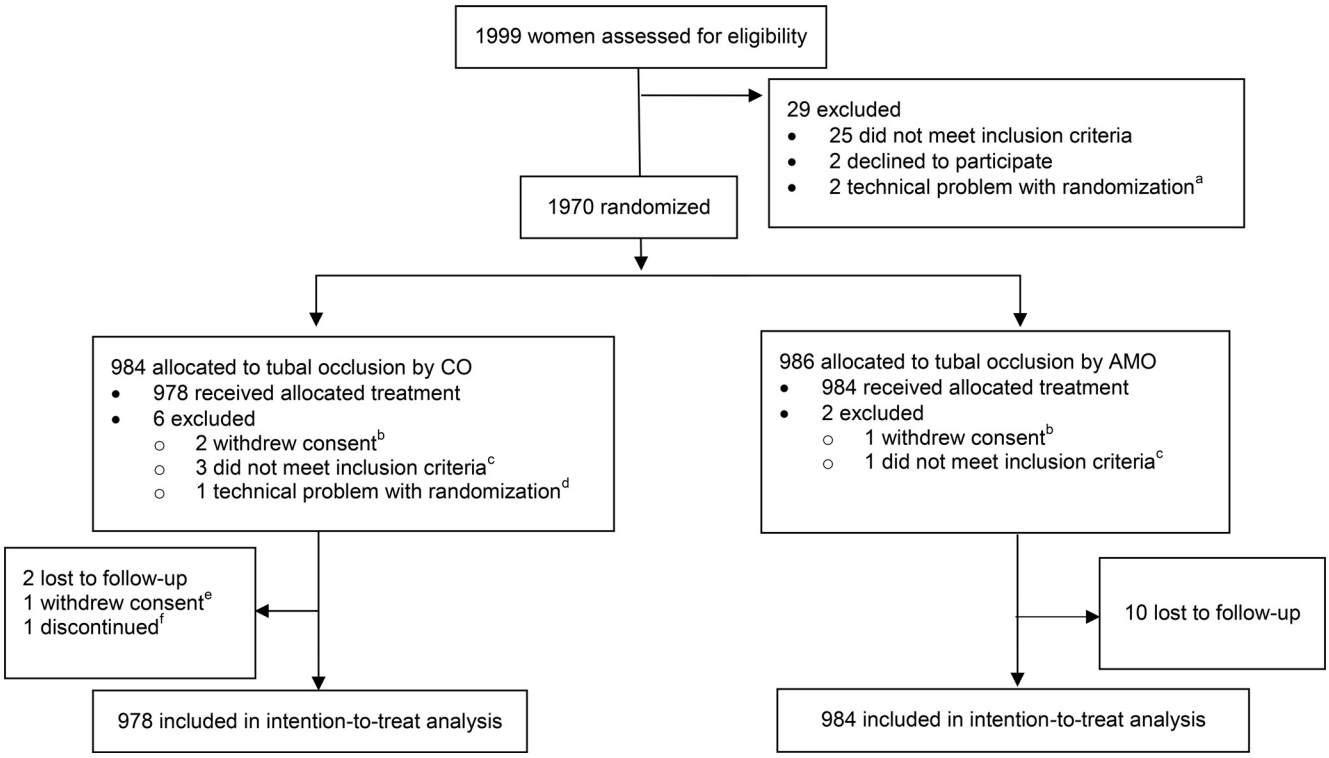
Over a 6-month period, we recruited 1,970 women and randomly allocated them to minilaparotomy by a clinical officer or by an assistant medical officer.

RESULTS

Between December 6, 2016, and June 16, 2017, we assessed 1,999 women for eligibility, randomly allocating 1,970 (98.6%) women to minilaparotomy by a CO (n=984; 49.9%) or by an AMO (n=986, 50.1%) (Figure 1). A total of 8 participants—6 (0.6%) in the CO group and 2 (0.2%) in the AMO group—were excluded from the analysis because they did not have a minilaparotomy procedure: 4 were determined not to have met the inclusion and exclusion criteria after randomization but before the procedure, 3 withdrew consent after randomization but before the procedure, and in 1 instance there was a technical problem with the text-based randomization.

We analyzed data from 1,962 participants—978 (49.8%) in the CO group and 984 (50.2%) in the AMO group. The minilaparotomy procedure was started but not completed among 2 (0.2%) participants in the CO group. One participant withdrew her consent during the procedure, as it was taking a long time and she became unsettled. In the other case, it was not possible to deliver the right fallopian tube due to adhesions, even with the assistance of the supervisor. The procedure was not completed and the participant was discontinued. A total of 12 (0.6%) participants were lost to follow-up, 2 (16.7%) in the CO group and 10 (83.3%) in the AMO group. One of these participants attended her 3-day follow-up visit but did not return for any additional visits, while the other 11 participants were lost after making their 7-day visit. Available data from participants who withdrew, were discontinued, or were lost to follow-up were included in the analyses.

FIGURE 1. Trial Profile



Abbreviations: AMO, assistant medical officers; CO, clinical officers.

[a] Randomization was done via a text message service. In these 2 cases, a cellular network outage prevented the study site from randomizing the participants.

[b] Just before the start of the procedure, 3 participants became nervous and withdrew consent.

[c] These participants were deemed to have met the study eligibility criteria and were randomized. However, before the procedure commenced, it was decided that they did not meet the criteria for the following reasons: anemia, high blood pressure, pelvic inflammatory disease, or unexplained vaginal bleeding.

[d] In this case, the participant was randomized, but a cellular network outage prevented the study site from determining the assigned random allocation group before the minilaparotomy procedure needed to be conducted for logistical reasons. The participant was discontinued.

[e] The procedure was not completed because the participant was unsettled, as the procedure was taking a long time. She asked that they stop the procedure.

[f] Adhesions made delivering the right tube a problem, and the procedure could not be completed, even with the supervisor's assistance.

The 1,962 participants were distributed among the study sites as follows: 117 at Daraja Mbili Health Centre, 324 at Kaloleni Health Centre, 277 at Karatu Designated District Hospital, 447 at Levolosi Urban Health Centre, 83 at Longido Health Centre, 396 at Monduli District Hospital, and 318 at Mto wa Mbu Health Centre. The majority of participants were recruited during outreach services (1,715; 87.4%), as opposed to at the main study sites (247; 12.6%). The median number of minilaparotomy procedures conducted by an individual provider was 162, with a range of 20 to 256. The median (range) number of procedures conducted by COs and AMOs were similar, 161 (20, 238) and 162 (37, 256), respectively.

The majority of participants were recruited during outreach services.

Baseline sociodemographic data, obstetric histories, family planning use, and reproductive intentions were similar between participants randomized to the 2 groups (Table 2 and Table 3). We noted no significant difference in the proportion of participants having a major AE following tubal occlusion by minilaparotomy between the 2 groups (CO group 0 [0.0%] of 978; AMO group 1 [0.1%] of 984) (Table 4). The risk difference for the percentage of women experiencing a major AE was –0.1% (95% CI: –0.3% to 0.1%).

TABLE 2. Baseline Sociodemographic Characteristics of Minilaparotomy Participants, by Type of Service Provider Performing the Procedure

Characteristic	Clinical Officer (N=978)	Assistant Medical Officer (N=984)	Total (N=1962)
Age groups, years, No. (%)			
18–24	2 (0.2)	2 (0.2)	4 (0.2)
25–30	38 (3.9)	34 (3.5)	72 (3.7)
31–35	149 (15.2)	140 (14.2)	289 (14.7)
36–40	526 (53.8)	514 (52.2)	1040 (53.0)
41–45	249 (25.5)	276 (28.1)	525 (26.8)
46–50	14 (1.4)	18 (1.8)	32 (1.6)
Age, years, mean (SD [range])	37.8 (3.9 [21–50])	37.9 (3.7 [22–50])	37.9 (3.8 [21–50])
Marital status, No. (%)			
Married/cohabitating	922 (94.3)	933 (94.8)	1855 (94.6)
Divorced/separated	32 (3.3)	32 (3.3)	64 (3.3)
Widowed	18 (1.8)	15 (1.5)	33 (1.7)
Single	6 (0.6)	4 (0.4)	10 (0.5)
Education level, No. (%)			
None	73 (7.5)	64 (6.5)	137 (7.0)
Some primary	113 (11.6)	117 (11.9)	230 (11.7)
Completed primary	713 (72.9)	721 (73.3)	1,434 (73.1)
Some secondary	37 (3.8)	34 (3.5)	71 (3.6)
Completed secondary	39 (4.0)	43 (4.4)	82 (4.2)
Post-secondary	3 (0.3)	5 (0.5)	8 (0.4)
Religion, No. (%)			
Lutheran	350 (35.8)	365 (37.2)	715 (36.5)
Catholic	274 (28.0)	282 (28.7)	556 (28.3)
Muslim	198 (20.3)	179 (18.2)	377 (19.2)
Protestant	96 (9.8)	109 (11.1)	205 (10.4)
Other	60 (6.1)	49 (5.0)	109 (5.6)
Occupation, No. (%)			
Farmer	711 (72.7)	674 (68.5)	1385 (70.6)
Small-scale business	183 (18.7)	209 (21.2)	392 (20.0)
Housewife	30 (3.1)	56 (5.7)	86 (4.4)
Teacher	17 (1.7)	18 (1.8)	35 (1.8)
Other	29 (3.0)	18 (1.8)	47 (2.4)
Missing	8 (0.8)	9 (0.9)	17 (0.9)

TABLE 3. Baseline Measures of Obstetric History, Family Planning Use, and Reproductive Intentions of Minilaparotomy Participants, by Type of Service Provider Performing the Procedure

Characteristic	Clinical Officer (N=978)	Assistant Medical Officer (N=984)	Total (N=1962)
Ever pregnant, No. (%)	978 (100.0)	984 (100.0)	1962 (100.0)
Outcome of pregnancies, No. (SD)			
Live birth	5.8 (1.6)	5.9 (1.6)	5.8 (1.6)
Stillbirth	0.02 (0.2)	0.02 (0.2)	0.02 (0.2)
Miscarriage/abortion	0.3 (0.6)	0.2 (0.6)	0.3 (0.6)
No. of living children, No. (SD)			
Boys	3.0 (1.3)	3.0 (1.3)	3.0 (1.3)
Girls	2.8 (1.3)	2.9 (1.3)	2.8 (1.3)
Total	5.7 (1.5)	5.9 (1.6)	5.8 (1.6)
Last family planning method used, No. (%)			
Injectables	371 (37.9)	402 (40.9)	773 (39.4)
Implant	221 (22.6)	211 (21.4)	432 (22.0)
Oral contraceptives	215 (22.0)	210 (21.3)	425 (21.7)
Intrauterine device	43 (4.4)	46 (4.7)	89 (4.5)
Male condom	27 (2.8)	22 (2.2)	49 (2.5)
Periodic abstinence	4 (0.4)	10 (1.0)	14 (0.7)
Withdrawal	8 (0.8)	6 (0.6)	14 (0.7)
Lactational Amenorrhea Method	2 (0.2)	0 (0.0)	2 (0.1)
None	87 (8.9)	77 (7.8)	164 (8.4)
First heard about female sterilization from, No. (%)			
Health care provider	840 (85.9)	860 (87.4)	1,700 (86.7)
Other sterilized person	53 (5.4)	38 (3.9)	91 (4.6)
Friend or relative	50 (5.1)	40 (4.1)	90 (4.6)
Spouse	19 (1.9)	22 (2.2)	41 (2.1)
Community leader	4 (0.4)	11 (1.1)	15 (0.8)
Public outreach worker	3 (0.3)	7 (0.7)	10 (0.5)
Brochure	3 (0.3)	3 (0.3)	6 (0.3)
Poster	3 (0.3)	2 (0.2)	5 (0.3)
Radio	2 (0.2)	0 (0.0)	2 (0.1)
TV	1 (0.1)	1 (0.1)	2 (0.1)
Main reason for wanting female sterilization, No. (%)			
Desired family size completed	850 (86.9)	877 (89.1)	1,727 (88.0)
Financial/economic reasons	72 (7.4)	51 (5.2)	123 (6.3)
Health reasons	29 (3.0)	36 (3.7)	65 (3.3)
Complications from a previous birth	18 (1.8)	15 (1.5)	33 (1.7)
Encouraged by family, friend, or spouse	8 (0.8)	5 (0.5)	13 (0.6)
Single mother with a disabled child	1 (0.1)	0 (0)	1 (0.1)
Time since deciding not to have any more children, years, mean (SD [range])	1.9 (2.1 [0.003,[a] 26])	1.9 (2.0 [0.003,[a] 20])	1.9 (2.1 [0.003,[a] 26])

[a] 0.003 years=1 day.

TABLE 4. Primary and Secondary Outcomes, by Type of Service Provider Performing the Procedure

Outcome	Clinical Officer	Assistant Medical Officer	OR (95% CI)	*P* Value
Primary outcome				
Major AEs, n/N (%)	0/978 (0.0)	1/984 (0.1)	0.0005 (0.00007, 0.0036)	.32
Secondary outcomes				
Major and minor AEs at different time points during the study, n/N (%)				
Intraoperatively	0/978 (0.0)	0/984 (0.0)	NA	NA
Immediately postoperative	0/978 (0.0)	0/984 (0.0)	NA	NA
3 days postoperative	1/969 (0.1)	0/976 (0.0)	0.0005 (0.000072, 0.0036)	.32
7 days postoperative	2/976 (0.2)	3/975 (0.3)	1.5 (0.3, 8.9)	.66
Unscheduled postoperative visits[a]	1/4 (25.0)	3/13 (23.1)	0.80 (0.2, 3.0)	.94
Performance of tubal occlusion by minilaparotomy				
Time to complete procedure, minutes, mean (SD [range])	26.0 (1.0 [14, 65])	26.0 (1.0 [15, 90)	NA	.42
Requested verbal instruction from the supervisor due to difficulty performing the procedure,[b] n/N (%)	15/978 (1.5)	20/984 (2.0)	0.75 (0.36, 1.56)	.40
Requested the supervisor assist with the procedure,[c] n/N (%)	14/978 (1.4)	13/984 (1.3)	1.08 (0.47, 2.52)	.80
Inability to complete procedure,[d] n/N (%)	2/978 (0.2)	0/984 (0.0)	NA	.25
Maximum pain during procedure,[e] mean (SD)	4.12 (2.4)	4.11 (2.4)	NA	.98
Participant very satisfied with minilaparotomy, n/N (%)	834/969 (86.1)	831/976 (85.1)	1.01 (0.88, 1.15)	.34
Self-efficacy of providers in performing minilaparotomy,[f] mean (SD)				
General self-efficacy	32.3 (6.1)	31.3 (7.5)	NA	.79
Confidence	10.9 (0.9)	11.5 (0.8)	NA	.21
Comfort	11.4 (0.5)	10.9 (1.7)	NA	.41

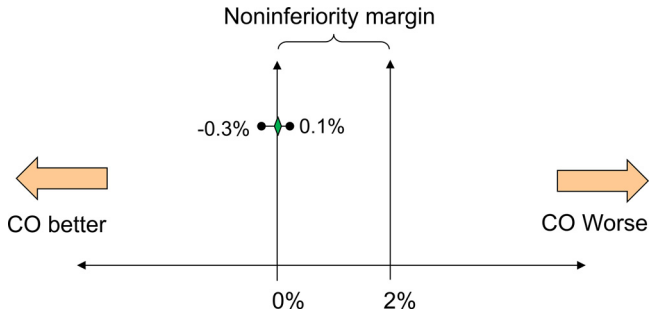
Abbreviations: AE, adverse event; CI, confidence interval; NA, not applicable; OR, odds ratio; SD, standard deviation.
[a] All AEs observed during unscheduled visits occurred between Days 2 and 6 postoperatively.
[b] Most of these cases (n=21; 60.0%) involved difficulty locating or delivering the fallopian tube(s) due to obesity, adhesions, or unspecified reasons. Other reasons included unsettled/restless participant, abnormal uterus, difficulty placing the uterine elevator, and difficulty finding the uterus after the incision was made.
[c] These cases are a subset of those where verbal instruction was requested by the provider.
[d] In 1 case, the participant was unsettled because the procedure was taking a long time. She asked that they stop. In the other case, adhesions made delivering the right fallopian tube a problem. It was not possible to complete the procedure.
[e] 0=no pain, 10=worst pain possible.
[f] General self-efficacy scale: 10=lower self-efficacy, 40=higher; confidence and comfort scales: 3=lower confidence or comfort, 12=higher.

Because the upper limit of the 95% CI for the incidence rate difference fell below the predefined noninferiority margin (2%), the results show that tubal occlusion by minilaparotomy conducted by a CO is noninferior to tubal occlusion by minilaparotomy conducted by an AMO (Figure 2).

We noted no significant differences between the 2 treatment groups in any of the secondary outcomes (Table 4). There were no differences in rates of AEs (major and minor combined) at any time during the procedure or follow-up period. Measures of performance did not differ between groups, including mean procedure time, requests for verbal instruction from the supervisor or for the supervisor to assist with procedures due to difficulty performing procedures, inability to complete procedures, reported pain during procedures, and participant satisfaction. Measures of provider self-efficacy did not differ between the 2 groups and all 14 providers said they were interested in continuing to perform minilaparotomy after the study.

Ten (0.5%) AEs occurred among 9 participants (1 participant had 2 concurrent AEs). Similar numbers of AEs (COs 4 [0.4%]; AMOs, 6 [0.6%]) were seen in both treatment groups (risk difference: –0.2% [95% CI: –0.8% to 0.4%]). All AEs occurred during follow-up. One AE was classified as major, a serious wound infection that occurred 4 days after a procedure done by an AMO. The wound was opened and drained, and the participant was hospitalized for close monitoring and to receive injectable antibiotics. She healed as expected, with no sequelae. The minor AEs included 4 (0.2%) wound infections, 3 (0.2%) cases of abdominal pain 6–7 days post-procedure requiring oral pain relievers, 1 (0.1%) case of wound dehiscence, and 1 (0.1%) case of nausea and vomiting. All the minor AEs were resolved with conservative management and without any sequelae.

FIGURE 2. Interpretation of Risk Difference Between AMOs and COs for the Percentage of Women Experiencing a Major Adverse Event



Abbreviations: AMO, assistant medical officer; CI, confidence interval; CO, clinical officer.

The green diamond represents the point estimate of the risk difference (–0.1%) and the horizontal line to the left and right of the diamond represents the associated 2-sided 95% CI (–0.3%, 0.1%). Noninferiority of minilaparotomy performed by a CO is accepted because the upper limit of the 95% CI falls below the predefined noninferiority margin of 2%.

The majority of the minilaparotomy procedures performed were interval (n=1,901; 96.9%), with few postpartum (n=58; 3.0%) and postabortion (n=3; 0.2%) procedures. We noted no significant differences between the treatment groups in variables related to performance of the minilaparotomy procedures (Table 4 and Table 5). There were few cases overall where the provider reported requesting verbal instruction from the supervisor due to difficulty with the procedure (35; 1.8%). The provider requested the supervisor assist during the procedure in 27 of those cases (1.4% of all procedures). Most of the difficult cases (n=21; 60.0%) involved difficulty in locating or delivering the fallopian tube(s) due to obesity, adhesions, or unspecified reasons. This was also

There was no significant difference in the proportion of participants with a major adverse event following tubal occlusion by minilaparotomy between the 2 group.

TABLE 5. Additional Performance Measures, by Type of Service Provider Performing the Minilaparotomy Procedure

	Clinical Officer (N=978)	Assistant Medical Officer (N=984)	Total (N=1962)	*P* Value
Additional local anesthesia injected during procedure, No. (%)	5 (0.5)	4 (0.4)	9 (0.5)	.75
Change of anesthesia to general or spinal, No. (%)	0 (0.0)	0 (0.0)	0 (0.0)	NA
Estimated incision length 2–3 cm, No. (%)	978 (100.0)	984 (100.0)	1962 (100.0)	NA
Extension of abdominal incision needed, No. (%)	0 (0.0)	1 (0.1)	1 (0.1)	1.0
Switch to laparotomy, No. (%)	0 (0.0)	0 (0.0)	0 (0.0)	NA
Discharged well from facility on day of procedure, No. (%)	978 (100.0)	984 (100.0)	1962 (100.0)	NA

A woman undergoes tubal ligation by minilaparotomy in a health facility in northern Tanzania. © 2015 EngenderHealth/S. Lewis

the most common reason why a provider requested that a supervisor assist with the procedure (n=18; 66.7%).

At the Day 3 follow-up visit, 1,665 (85.6%) participants said that they were very satisfied and 253 (13.0%) said they were somewhat satisfied with the provider who had performed their procedure. There were no significant differences between the treatment groups (very satisfied P=.34; somewhat satisfied P=.90). At the Day 42 visit, 1,938 (99.5%) said they would recommend minilaparotomy to a friend or family member, with no significant difference between treatment groups (P=.75). When participants were asked what they liked about the minilaparotomy at the 42-day visit, top responses included (multiple responses were possible): that healing went well (n=1,301; 66.8%), everyone at the facility was nice (n=840; 43.1%), the procedure was quick (n=815; 41.8%), and they experienced less pain than expected during and after the procedure (n=658; 33.8%). Twenty participants (n=10; 1.0% in each group) said that there was nothing they liked about the procedure. When we asked participants what they disliked, 1,829 (93.9%) participants reported that there was nothing they disliked, with a few participants (1.5% or less) reporting that they experienced more pain than expected or that the procedure took a long time, among other reasons.

Tubal occlusion by minilaparotomy can be conducted safely and effectively by trained clinical officers.

DISCUSSION

Our results show that tubal occlusion by minilaparotomy can be conducted safely and effectively by trained COs, with no evidence of increased risk of major or minor AEs associated with the procedure, problems with performance of the procedure, or negative effects on satisfaction among women undergoing the procedure, compared with procedures performed by an AMO. Although systematic reviews of older studies[19,20] and results from more recent nonrandomized studies[21–23] provide some evidence to support provision of minilaparotomy by nonphysicians, the results of our large, multicenter randomized trial provide solid empirical evidence to support changing international guidelines and country-level regulations to allow task shifting of minilaparotomy to trained COs and similar nonphysician cadres.

The terminology describing nonphysician clinicians varies from country to country, which may make it difficult to interpret task shifting studies. WHO uses "associate clinician" to refer to nonphysicians who generally have 3–4 years of postsecondary training in diagnosis and management of common medical and surgical conditions.[18] This is the case with COs in Tanzania, who have undergone 3 years of specialized training, and some other African countries (e.g., Kenya, Uganda, and Zambia), although in others (e.g., Malawi), similar named cadres have more postsecondary training. In our study, most of the providers had some prior surgical experience, although the COs' experience was restricted to minor surgical procedures such as wound repair, draining of abscesses, and male circumcision, whereas the AMOs had experience with more complex surgeries such as cesarean deliveries and appendectomy. Nonetheless, all the COs successfully completed the minilaparotomy training, safely conducted procedures during the study, and expressed comfort and confidence in terms of the self-efficacy measure, irrespective of prior surgical experience.

Quality of the training for task shifting minilaparotomy may be more important than the trainees' prior surgical experience. It is critical that minilaparotomy training focus on careful presurgical screening and good surgical technique in order to reduce the risk of intra- and postoperative complications, as well as detecting and dealing with possible complications such as injuries to the viscera, bleeding from the procedure site, and adverse drug reactions. This includes emergency preparedness and ensuring that trainees understand when to seek assistance or refer a client.

Inadequate numbers of trained health care workers due to shortages, inequitable geographic distribution, and difficulties recruiting and

retaining trained health workers was identified as a key reason the health-related Millennium Develop-ment Goals were not achieved in many countries.[27,28] Physicians tend to be concentrated in urban areas, even though the majority of the population in many resource-limited settings resides in rural areas. They also end up having to prioritize curative services or higher-level tasks, leaving less time for preventive services such as family planning. These human resource constraints are likely to have a more significant impact on access to clinic-based family planning methods such as minilaparotomy.[18]

In addition to reducing unintended pregnancies, satisfying unmet need for contraception reduces the numbers of induced abortions, provides substantial health benefits (including reducing maternal, newborn, and child morbidity and mortality), and contributes to a host of other development objectives necessary to achieving the Sustainable Development Goals (SDGs).[29] Expanding the health workforce will be critical to improving health, strengthening health systems, and making progress toward the SDGs. The WHO High-Level Commission on Health Employment and Economic Growth's recommendations state that task shifting, among other approaches that make optimal use of the available workforce, should be urgently pursued,[30] a recommendation seconded by the *Lancet* Commission on the future of health in sub-Saharan Africa.[31]

The only other randomized study to explore task shifting tubal occlusion by minilaparotomy to nonphysicians was conducted among 292 women undergoing postpartum minilaparotomy in a large urban hospital in Thailand, with the procedure conducted by nurse-midwives or doctors.[32] No differences in AE rates were seen, although (unlike our results) they reported that nurse-midwives took significantly longer to conduct the procedure; the time difference was relatively short (approximately 7 minutes) and may be outweighed by the advantages of having nurse-midwives provide the procedure. Unlike the study in Thailand, for logistical reasons and to ensure adequate recruitment of study participants in the time we had to carry out our study, we conducted most of the minilaparotomy procedures during outreach services. The overall rate of major AEs we observed was low and comparable to rates reported by others when minilaparotomy was provided by COs in both clinic and outreach settings, although it can be difficult to compare AE rates across studies, given different definitions (there is no universally accepted system for defining AEs/complications) and approaches to recording their occurrence.[21–23]

Our data show that minilaparotomy can be safely and effectively provided in outreach settings, whether by COs or AMOs, and supports the use of this approach to expand access to minilaparotomy. Outreach services are commonly used to increase access to a range of family planning and other health services in remote, rural, and underserved areas in Tanzania and many other developing regions. National guidelines for family planning outreach activities typically include details on how such services should be planned (including arrangements for referral and transport of clients in case of emergency), implemented (including having necessary drugs and equipment on hand), and monitored (including a supervisory team to provide quality assurance and back-up support when needed), to ensure that services are safe. Additionally, outreach teams usually include highly qualified providers, with extensive experience and expertise necessary to both reduce the risk of emergencies and handle them should they arise.

Our study also supports the use of outreach services to expand access to minilaparotomy.

We saw no evidence of differences in other outcomes between the 2 groups that would raise concern about COs conducting minilaparotomy and no evidence that provision of minilaparotomy by COs was any less acceptable to women than when provided by AMOs. The high acceptability of minilaparotomy provided by COs has also been reported by others.[21–23] We found high and equal levels of general self-efficacy, as well as confidence and comfort in performing minilaparotomy, among both COs and AMOs. All of the providers said they would be interested in continuing to conduct minilaparotomy, although the COs are unable to do so without a change in the Tanzanian government guidelines. Our data also demonstrate what appears to be high demand for female sterilization services in Tanzania, given the large number of women we were able to recruit for the study in a relatively short period of time.

There appears to be high demand for female sterilization in Tanzania, given the large number of women recruited for the study in a relatively short amount of time.

Limitations

One limitation of our study is that it was not masked. In view of the nature of the intervention and the way in which services are provided in Tanzania, it was not practical to mask study or facility staff (or the women themselves) to the treatment group (i.e., we could not hide which type of provider was doing the procedure) or to have the outcome assessments done by a provider unaware of the treatment allocation. Another limitation is

that the duration of follow-up that was practical for our study was insufficient to determine whether efficacy in preventing pregnancy was similar between the 2 provider groups. We were unable to include other nonphysician cadres conducting minilaparotomy in the study. There is some evidence—primarily from Asia—suggesting that trained nurses and nurse-midwives can safely and effectively provide minilaparotomy, although the available evidence is limited and weak.[19,20] This issue deserves further exploration as an additional way to increase access.

CONCLUSION

The results from this trial provide the evidence needed to support policy change at the national level in Tanzania and beyond.

Our results demonstrate that task shifting of tubal occlusion by minilaparotomy to COs is safe, effective, and acceptable to women. These results provide the evidence needed to support policy change at the national level in Tanzania and beyond, helping to meet the rising demand for female sterilization among women who wish to limit their childbearing and improving family planning method mix.[4] Increasing the voluntary use of modern family planning methods, including permanent methods such as female sterilization, will play a critical role in meeting women's reproductive intentions and improving maternal, neonatal, and child morbidity and mortality, and will be vital to increasing the contraceptive prevalence rates in developing regions critical to achieving the SDGs.[29]

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ORIGINAL ARTICLE

Role of Religious Leaders in Promoting Contraceptive Use in Nigeria: Evidence From the Nigerian Urban Reproductive Health Initiative

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Exposure to family planning messages from religious leaders was significantly associated with higher modern contraceptive use, after accounting for background characteristics and other variables such as myths and misconceptions. Engaging religious leaders to support positive social norms is an important strategy to improving voluntary contraceptive use in Nigeria.

ABSTRACT

Background: Despite the many supply- and demand-side interventions aimed at increasing contraceptive uptake, the modern contraceptive prevalence rate in Nigeria has remained very low (9.8%). Religion is an important part of the sociocultural fabric of many communities. As such, religious leaders have the power to inhibit or facilitate effective adoption of contraceptive methods to support family health. We assess the association of exposure to religious leaders' tailored scriptural family planning messages with contraceptive use in Nigeria.

Methods: This cross-sectional study used data from a Measurement, Learning and Evaluation Project survey conducted in 2015 in 4 Nigerian states—Federal Capital Territory, Kaduna, Kwara, and Oyo. The final study sample was restricted to 9,725 non-pregnant women aged 15 to 49 years. Data analysis included descriptive statistics and binary logistic regression analysis to explore significant relationships between current use of a modern contraceptive method, exposure to family planning messages from religious leaders, and selected background characteristics.

Results: About 2 in 5 women reported being exposed to family planning messages from religious leaders in the past year. Bivariate results revealed a higher uptake of modern contraceptives among women with high exposure to different NURHI interventions (35.5%) compared with respondents in the low or medium exposure categories (14.5% and 24.5%, respectively). The multivariable analysis revealed significantly higher contraceptive uptake among women who had exposure to family planning messages from religious leaders relative to those with no exposure (odds ratio=1.70; 95% confidence interval, 1.54 to 1.87; $P<.001$). This association remained significant after adjustment for background characteristics and other selected variables.

Conclusion: Interventions that engage clerics of different faiths as change agents for shaping norms and informing behaviors about family planning and contraceptive use are crucial for increasing contraceptive uptake in Nigeria.

INTRODUCTION

Despite the many supply- and demand-side interventions aimed at increasing contraceptive uptake, modern contraceptive prevalence rate (mCPR) has remained very low in Nigeria. Nigeria's mCPR is one of the lowest globally, currently estimated at 9.8%.[1] In comparison, the mCPRs of other sub-Saharan African countries, such as Rwanda and Malawi, are much higher (45% and 62%, respectively).[2,3]

The health and socioeconomic benefits of contraceptive use have been well-documented. These benefits include improved quality of life, increased well-being of families and communities, improved maternal and newborn health outcomes,[4–7] reduced poverty, increased female education,[8] and additional noncontraceptive health benefits of hormonal methods.[9]

In contrast, unplanned families face enormous health and developmental challenges. The micro- and macro-level socioeconomic and health consequences of high fertility—defined as a total fertility rate of 5 or more children born per woman—are diverse. At the micro or household level, children and women in high-fertility

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families are predisposed to tremendous health risks, particularly high childhood and maternal morbidity and mortality.[10–13] At the macro or national level, high fertility has been shown to slow down socioeconomic growth, diminish human capital investment, and aggravate environmental threats and degradations.[14]

While Nigeria's socioeconomic situation clearly shows that the country trails other countries in many indicators of development, an expanded family planning program could help reduce barriers to development. For example, researchers have suggested that several supply- and demand-side factors may explain the low level of contraceptive prevalence in Nigeria. These studies have implicated such factors as age at sexual debut, educational attainment, fertility intentions, and household wealth as important predictors of contraceptive use.[15,16] Other commonly cited factors inhibiting the success of family planning program in Nigeria include cultural beliefs,[17] fear of adverse effects, religious prohibition,[18] partner disapproval, poverty,[19] and common myths and misconceptions.[20–22]

Of these factors, the role of religious leaders in facilitating or inhibiting contraceptive uptake has been less well explored. Religion is often an important part of the cultural fabric of communities and, as such, can influence decision making, ideologies, and moral and ethical behaviors.[23] Religious beliefs on issues of fertility, contraceptive adoption, and abortion can differ greatly among Protestant Christians, Catholics, Muslims, and traditionalists. For instance, abortion is generally considered forbidden in Islam, although most schools of thought allow for early abortion (defined as the first 40, 90, or 120 days of pregnancy, depending on the school of thought) and for abortion in certain circumstances such as when the mother's life is in danger.[24] The Catholic Church allows only natural methods of contraception.[23] Many religious leaders hold beliefs that lead them to speak against modern contraceptive methods. As a result, they can greatly influence the demand side of family planning and, more generally, the reproductive health and well-being of their communities.

Although studies have assessed the role of religious beliefs in shaping contraceptive adoption and family formation,[25–30] there are gaps in evidence regarding the roles of religious leaders in influencing contraceptive uptake. To that end, given the implication of religious beliefs for contraceptive adoption, this article documents the Nigerian Urban Reproductive Health Initiative's (NURHI's) activities partnering with religious leaders to promote contraceptive use in Nigeria and attempts to explore the association between exposure to family planning messages from religious leaders and contraceptive uptake in selected locations in the country.

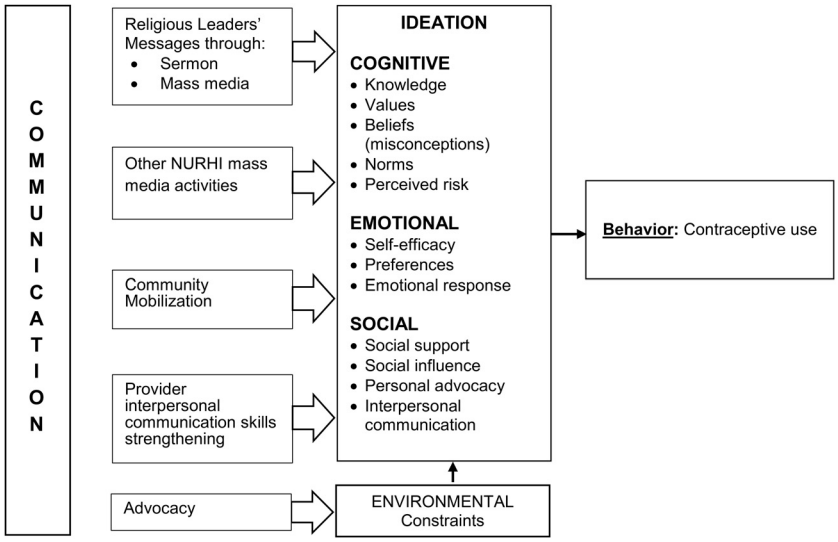
Religious Beliefs and Contraceptive Adoption: Theoretical Perspectives

The conceptualization of religious influence on demographic outcomes dates back to the early work of Goldsheider in 1971.[29,31] Goldscheider[32] posited 3 hypotheses—the characteristics hypothesis, the minority ground hypothesis, and the particularized theology hypothesis—to explain the influence of religion. As demonstrated in the works of Hirsch[31] and Agadjanian and Yabiku,[29] the characteristics hypothesis states that the influence of religion is only attributable to underlying factors, such as socioeconomic characteristics. The minority hypothesis suggests that family formation is essentially influenced by an individual's fertility desires to ensure the preservation of status by minority religious groups within the society. Lastly, the particularized theology hypothesizes that religious influence on demographic outcomes are attributable to doctrines or theological differences of various religions.

Our study builds on the particularized theology hypothesis, which suggests that religious belief itself is subject to underlying contextual influences and teachings, therefore giving importance to religious leaders and their doctrinal teachings as essential elements in contraceptive uptake and family formation processes. A study by Agadjanian[25] lends credence to this proposition by arguing that the relationship between religious beliefs and contraceptive uptake is influenced by context-specific doctrines and concerns. Similarly, a study on the religion–fertility nexus partly implicated religious doctrinal differences for variations in fertility levels across denominational affiliations.[29] These studies suggest that religious beliefs and doctrinal practices can greatly influence fertility decisions and behaviors.

This study is also supported by the ideation model advanced by Kincaid in 2000 (Figure).[33] The ideation model posits that individuals hold different ideas and views about a behavior or outcome. Kincaid argues that ideation is composed of 3 domains: emotional (knowledge, values, norms, and perceived risk), cognitive (self-efficacy, preferences, and emotional response), and social interactions (social support, social influence, and

FIGURE. Conceptual Framework Showing Relationship Between NURHI Interventions and Contraceptive Use



Abbreviation: NURHI, Nigerian Urban Reproductive Health Initiative.

Adapted from Kincaid (2000) and Babalola et al. (2015).[8]

interpersonal communication).[34] Evidence has shown that the various domains of ideation have influence on contraceptive uptake.[8,35] For example, social interactions contribute largely to shaping people's ideas and views,[33,34] which, in turn, influence demographic behaviors such as contraceptive use and fertility.

Based on the above theoretical models, individuals' beliefs, ideas, and views related to contraceptive adoption can be shaped, to a large extent, by the religious and doctrinal teachings to which they are exposed. Situating our study within this framework, we hypothesize that family planning messages that are passed through religious leaders to adherents of different faiths could help shape their ideation related to family planning and thereby contribute to increased contraceptive uptake.

INTERVENTION

The first phase of the NURHI project started in 2009 and ran through September 2015. The second phase of the project began in October 2015 and will continue through 2020. Funded by the Bill & Melinda Gates Foundation, the primary aim of the first phase of NURHI project was to increase modern contraceptive method use, with the main focus on the urban poor in selected Nigerian cities. Currently, about 48.6% of Nigeria's population lives in urban areas; and, estimates suggest that by 2050, this will exceed 50%.[36] Evidence shows that the urban poor tend to have more children than the urban nonpoor,[37] particularly because they have limited or no access to family planning services.

The NURHI model aimed at increasing contraceptive uptake through 3 major components—advocacy, demand creation, and service delivery. A fourth component, monitoring and evaluation, was included as a crosscutting issue. The first year of the project was devoted to formative and baseline research to identify local nuances and to understand what approaches would likely work in the different settings.

The overall goal of the project was to achieve a 20% increase in mCPR over the first 5 years of the project. To achieve this result, the project implementers identified key audience groups and influential people, such as religious and community/traditional leaders, exploring the knowledge, views, ideas, and attitudes that these audiences hold about family planning. These leaders hold crucial positions in Nigeria's contemporary society. They are important gatekeepers who, by their own statements, can affect the outcome of NURHI activities. Religious leaders, in particular, can substantially influence and shape people's ideas and

views about issues such as contraceptive adoption and family formation.[29] Their influence is particularly great in northern Nigeria because they serve as both religious and traditional leaders. For instance, the sultan of Sokoto is both a traditional ruler and the head of Islamic movement in Nigeria.

In order to achieve successful results from advocacy visits with eminent leaders, the project team identified and prepared important advocacy documents to guide the dialoging activities. The documents included a booklet entitled *Reproductive Health Issues in Nigeria: The Islamic Perspectives*,[38] Nigeria's *National Reproductive Health Strategic Framework and Plan, 2002–2006*,[39] and the NURHI Toolkit advocacy tools.[40] Copies of these key documents were distributed to support dialogues with religious leaders and, later, community members. Similarly, NURHI used perspectives from Islamic and Christian scriptures to engage religious leaders and discuss family planning issues. These included a biblical injunction that reads:

> *But if anyone does not provide for his own, and especially for those of his household, he has denied the faith and is worse than an unbeliever.* (1 Timothy Chapter 5 Verse 8)

A relevant message from the Quran included in the handbook reads:

> *. . . The duty of feeding and clothing nursing mothers in a seemly manner is upon the father of the child . . .* (Quran, Chapter 2, Verse 233)

Both scriptures are interpreted as injunctions that stipulate the need for child spacing/family planning.

The project set up an advocacy core group (ACG) in each state. The members of the ACG were identified through stakeholder mapping exercises. The ACG included representatives of the media, market women, professional women, technocrats, and notable community members. In all of the project cities, ACG members were trained in advocacy skills and were involved in developing advocacy strategies. They were also given specific instructions/trainings on how to dialogue with religious leaders of the main faith groups in Nigeria—Christianity and Islam. Selected from within the community, ACG members were regarded as the community voice. The project worked through them to reach the community/religious leaders first and then the community at large. Advocacy visits were used as the entry point to reach religious and community/traditional leaders and gain access to and trust within communities. During the various advocacy visits, the project implementers advocated for the health benefits of family planning, such as a reduction in maternal and newborn morbidity and mortality as well as improved health and quality of life for families.

The ACGs also met with other groups, including community members, policy makers, local government chairmen, and technocrats. Together, they successfully worked with religious leaders to give statements in support of family planning in public gatherings and on the media. Through these advocacy activities, eminent leaders, such as the emirs of Ilorin, Kano, and Zaria, made statements in support of family planning, which were repeatedly aired on radio and television.

In some parts of northern Nigeria, contraception is viewed negatively as an instrument or a ploy to depopulate the Muslim population. Anticipating a strong negative reaction, the interventions were carefully planned and implemented in a religiously and culturally sensitive manner. The religious and community-based messaging emphasized the health benefits of childbirth spacing, including the reduction of maternal and child mortality and an improved quality of life for families and the nation at large. Moreover, while working with religious leaders using the book *Reproductive Health Issues in Nigeria: The Islamic Perspectives*, the Christian community requested their own handbook. This led to the production of a Christian advocacy handbook entitled *Christian Perspectives on Reproductive Health and Family Planning in Nigeria*,[41] which was launched by Nigeria's Minister of Health at the 4th National Family Planning Conference in 2016. The document has since been adopted by the Christian community and is being used extensively to promote family planning. NURHI also provided technical support toward updating the Islamic perspectives handbook.

Other small advocacy handbooks developed by NURHI included those with Christian and Islamic sermon notes for family planning. The handbooks guide Christian and Islamic clerics/leaders as they advocate for the health and social benefits of family planning during their services, using scriptural perspectives for their messaging.

In addition to receiving messages through the religious leaders' interventions, community members were exposed to community-based media activities that focused on behavior change, improved availability and access to family planning, and improved quality of family planning services. Evidence from a NURHI

intervention to improve service provision is available elsewhere.[42]

METHODS

Study Design and Participants

First, to document NURHI activities using religious leaders to promote contraceptive uptake in Nigeria, the project's advocacy and research staff provided relevant information on the design and implementation of intervention activities. Additional information was obtained from a review of NURHI program documents.

Second, to assess association between exposure to family planning messages from religious leaders and contraceptive use, the study used cross-sectional data from a survey conducted by the Measurement, Learning and Evaluation (MLE) project in 2015 among a randomly selected sample of women of reproductive age (15 to 49) in 4 selected Nigerian states—Federal Capital Territory, Kaduna, Kwara, and Oyo (N=10,713). The survey was conducted as part of an endline evaluation of the effects of the first phase of the NURHI project in selected states in Nigeria. Evidence from the 2013 Nigeria Demographic and Health Survey[1] and recent analysis by Adeyanju and colleagues[43] showed an increase in the mCPR in these targeted locations.

A 2-stage sampling selection process was employed to select respondents for the survey. In the first stage, clusters were randomly selected in each of the selected study locations, with the number of selected clusters proportional to the size of each location. In the second stage, all the dwelling units and households within the dwelling units in selected clusters were listed, and random selection resulted in a representative sample of 41 households per cluster. Eligible respondents—women aged 15 to 49 who gave consent to participate—within the selected households were interviewed face to face using a semistructured questionnaire. The present study excluded women who reported not using contraceptives because they were pregnant. The analytic sample for the study was 9,725.

Variables Measurement

The outcome variable analyzed in this study is current use of a modern contraceptive method, defined as currently using a modern method, coded as '1,' or not currently using a modern method, coded as '0.' The key explanatory variable for the study is exposure to family planning messages from religious leaders. The operational definitions for this and other selected covariates are presented in Table 1. The selection of these variables was guided by the reviewed literature and the theoretical models.

Statistical Analysis

Bivariate and multivariable analytical approaches were employed to explore significant relationships. Given the dichotomous nature of the outcome variable, we undertook binary logistic regression analysis in the multivariable analysis. Four models were fitted in the analysis. Model 1 presents the results of unadjusted analysis that examined the association of exposure to family planning messages from religious leaders with contraceptive use. Model 2 adjusted for selected background characteristics, including religiosity, age, marital status, education, ethnicity, wealth status, children ever born, state of residence, and fertility desire. Evidence from the reviewed literature established these variables as important predictors of contraceptive use. In addition to the variables included in Model 2, we also adjusted for women's exposure to other NURHI interventions in Model 3. Finally, Model 4 is the full model into which we incorporated all of the explanatory variables, including contraceptive ideational variables of perceived self-efficacy about family planning uptake and myths and misconceptions about family planning.

Results from the analysis were presented as odds ratios (ORs) and 95% confidence intervals (CIs). All analysis was done using Stata version 13.0 (StataCorp LLC, College Station, TX, USA).

RESULTS

Outcomes of NURHI Advocacy Visits

Information provided by NURHI staff and evidence from the review of program documents indicated that the project's advocacy visits to religious and traditional leaders recorded many successes. For instance, after the advocacy visit to the Emir of Kano, he fully supported maternal and child health, including family planning, reduction or elimination of gender-based violence, improvement in girl-child education, and small family formation, particularly among the poor. The Emir has continued to give inspiring statements in support of family planning in public gatherings and through the media. Although other activities or interventions may have influenced contraceptive uptake in the study locations, the open discussions about family planning at various public events by influential traditional/religious leaders immediately after

TABLE 1. Independent Variables for Modeling Women's Uptake of Modern Contraceptive Methods in Selected Nigerian States

Variables	Operational Definitions
Exposure to family planning message	Self-reported exposure to family planning message from religious leaders, categorized as "0" had no exposure or "1" had exposure. This variable was derived from the question: "In the past year, have you heard or seen a religious leader speaking publicly in favour of family planning/child birth spacing?"
Age of respondent	Self-reported age of respondent at time of survey, categorized as: 15–24, 25–34, 35+
Religion	Respondents' religions: Catholic, Other Christian, Muslim
Parity	Number of children ever born: 0, 1–2, 3–4, 5+
Education	Highest level of education attained: none, primary, secondary, post-secondary
State of residence	Current state of residence: Federal Capital Territory, Kwara, Kaduna, Oyo
Ethnic affiliation	Respondents' ethnic affiliation: Hausa/Fulani, Igbo, Yoruba, other
Current marital status	Marital status at time of survey: married/cohabiting, never married, previously married
Wealth index	Composite index of household items/amenities, electrical appliances, toilet facility, drinking water, and floor/wall materials grouped into a quintile: (1) poorest, (2) poorer, (3) middle, (4) richer, (5) richest
Fertility desire	Respondents' desire to have another child: (1) want another child, (2) does not want another child
Need anyone's permission to use family planning	Respondent's need for someone's permission before use of family planning, categorized as: (1) Yes, permission of someone needed, (2) No, permission not needed. This variable captures a situation where a woman requires the permission of her husband/partner, mother-in-law, or someone else, before she can use a family planning method
Perceived self-efficacy	Perceived self-efficacy about family planning, generated as a composite score variable from responses to Likert-scale questions on women's level of agreement with the ideation statements. These were categorized into a tertile as: (1) low, (2) medium, (3) high; Cronbach's alpha was 0.89
Acceptance of myths and misconceptions about contraceptives	Acceptance of myths and misconceptions about contraceptives, generated as a composite score variable from responses to Likert-scale questions on women's level of agreement with the ideation statements. These were categorized into a tertile as: (1) low, (2) medium, (3) high. Cronbach's alpha was 0.89
Other NURHI interventions	Other NURHI interventions numbering 27. An overall index, i.e., composite scores, was generated to reflect the extent of exposures that respondents had to the various activities. The composite variable was categorized into a tertile as: (1) low exposure, (2) medium exposure, (3) high exposure. Cronbach's alpha for the 27-item additive index was 0.90

Abbreviation: NURHI, Nigerian Urban Reproductive Health Initiative.

advocacy visits suggests the usefulness and significance of this program.

Although the advocacy work is ongoing, previously implemented activities in the project locations in the north and south had supported a growing culture of open discussion about family planning in public spaces. Following the NURHI interventions, the level of knowledge that the primary aim of family planning is not to control population but to save lives increased among many religious leaders. Evidence suggests that in addition to family planning being discussed freely and openly in the public places, which was not the case many years ago, many religious women are beginning to see that child spacing and using contraception are not sinful.

NURHI's advocacy work to increase family planning uptake has been largely viewed as successful. Adeyanju et al's[43] findings support this claim by documenting that the NURHI project contributed to the increase in modern contraceptive use in Nigeria during the post-project period.

Descriptive Results

The highest percentages of respondents were currently married or cohabiting (65.4%), Muslim (54.3%), from households in the richest wealth quintile (38.7%), aged 15 to 24 years (37%), residents of Kaduna state (52.1%), of Hausa/Fulani ethnic origin (31.4%), and had a secondary education (45.2%) (Table 2). More than 99% of the

TABLE 2. Background Characteristics of Study Participants and Other Selected Variables, Selected Nigerian States, 2015 (N=9,725)

Characteristics	Value
Religion, %	
Catholic	6.0
Other Christian	39.7
Muslim	54.3
Extent of religiosity, %	
Strongly religious	72.9
Somewhat religious	27.1
Current age, years, %	
15–24	37.0
25–34	32.7
35+	30.3
Current age, years, mean	28.9
Education, %	
None	9.5
Primary	24.6
Secondary	45.2
Post-secondary	20.7
Parity, mean	2.8
City of residence, %	
FCT	14.5
Kaduna	52.1
Kwara	10.6
Oyo	22.9
Ethnic affiliation, %	
Hausa/Fulani	31.4
Igbo	6.2
Yoruba	32.5
Others	29.9
Current marital status, %	
Married/cohabiting	65.4
Never married	30.1
Previously married	4.5
Wealth index, %	
Poorest	9.8
Poorer	10.3
Middle	15.7
Richer	25.6
Richest	38.7
Fertility desire, %	
Want another child	78.9
Want no more	21.1
Need anyone's permission to use FP, %	
Yes	86.4
No	13.6
Degree to which religion influences FP decision, %	
Never	33.6
Somewhat	30.8
Frequent/always	35.6
Had exposure to religious leaders' message in favor of FP, %	
No	60.2
Yes	39.8

Abbreviations: FCT, Federal Capitol Territory; FP, family planning.

respondents were religious, with 72.9% reporting that they were strongly religious. The analysis also indicates an average parity of 2.8, with the majority of women reporting their desire to have another child (78.9%) and the need to gain someone's permission to use family planning (86.4%). Results also showed that the decision of majority (66.4%) of the women to use family planning was influenced by religion, whereas only one-third (33.6%) reported that their decision to use contraceptives was never influenced by religion. About 2 in 5 women reported having exposure to family planning messages from religious leaders in the past year.

Bivariate Analysis

Table 3 presents the results of bivariate relationship between modern contraceptive uptake and selected characteristics. The results show that contraceptive uptake varied significantly by all of the selected characteristics ($P<.001$). Compared with their counterparts, contraceptive use was higher among Christians (31.3%), somewhat religious respondents (25.8%), those who had exposure to religious leaders' message in favor of family planning (30.0%), respondents aged 25 to 34 (32.6%), women who had tertiary education

TABLE 3. Percentage Distribution of Respondents According to Contraceptive Use and Selected Characteristics, Selected Nigerian States, 2015

Characteristics	Currently Using Modern Method (%)	Not Using Modern Method (%)	Chi-Square
Religion			208.0
Catholic	24.5	75.5	
Other Christian	31.3	68.7	
Muslim	18.2	81.8	
Religiosity			8.42
Strongly religious	22.9	77.1	
Somewhat religious	25.8	74.2	
Had exposure to religious leaders' message in favor of FP			120.0
No	20.0	80.0	
Yes	30.0	70.0	
Current age, years			542.0
15–24	10.6	89.4	
25–34	32.6	67.4	
35+	30.0	70.0	
Education			129.0
None	15.4	84.6	
Primary	20.1	79.9	
Secondary	23.8	76.2	
Post-secondary	31.9	68.1	
Parity			586.0
0	9.1	90.9	
1–2	26.5	73.5	
3–4	36.8	63.2	
5+	28.4	71.6	
State of residence			135.0
FCT	28.4	71.6	
Kaduna	18.9	81.1	
Kwara	27.3	72.7	
Oyo	29.8	70.2	
Ethnic affiliation			353.0
Hausa/Fulani	12.4	87.6	
Igbo	24.5	75.5	
Yoruba	31.7	68.3	
Others	27.6	72.4	

Continued

TABLE 3 Continued

Characteristics	Currently Using Modern Method (%)	Not Using Modern Method (%)	Chi-Square
Current marital status			400.0
Married/cohabiting	29.8	70.2	
Never married	11.2	88.8	
Previously married	13.8	86.2	
Wealth index			235.0
Poorest	9.9	90.1	
Poorer	13.4	86.6	
Middle	23.6	76.4	
Richer	28.3	71.7	
Richest	27.7	72.3	
Fertility desire			382.0
Want another child	19.0	81.0	
Does not want another child	40.1	59.9	
Need anyone's permission to use FP			6.2
Yes	23.7	76.3	
No	26.9	73.1	
Self-efficacy and FP			926.0
Low	7.5	92.5	
Medium	26.8	73.2	
High	38.6	61.4	
Acceptance of myths and misconception index on FP			126.0
Low	27.9	72.1	
Medium	25.7	74.3	
High	16.9	83.3	
Exposure to other NURHI interventions			391.0
Low exposure	14.5	85.5	
Medium exposure	24.5	75.5	
High exposure	35.5	64.5	

Abbreviations: FCT, Federal Capitol Territory; FP, family planning; NURHI, Nigerian Urban Reproductive Health Initiative.

(31.9%), married women (29.8%), women from households in richer and richest wealth categories (28%), and women who desired no more children (40.1%). The results further reveal a higher uptake of contraceptives among women with a high self-efficacy score (38.6%) and those with high exposure to different NURHI interventions (35.5%), compared with respondents in the low or medium categories (self-efficacy: 7.5% and 26.8%, respectively; exposure to other NURHI interventions: 14.5% and 24.5%, respectively). Conversely, contraceptive use was lowest among respondents with a high score for acceptance of myths and misconceptions about family planning (16.9%) compared with those with a medium or low score.

Multivariable Analysis

Results from logistic regression analysis examining the influence of key independent variable and

other selected characteristics are presented in Table 4. In the unadjusted model, contraceptive uptake among women who had exposure to family planning messages from religious leaders was significantly higher than among those who had no exposure (OR=1.70; 95% CI, 1.54 to 1.87; $P<.001$) (Table 4). After adjusting for the effects of selected background characteristics in Model 2, similar findings were obtained (OR=1.33; 95% CI, 1.17 to 1.51; $P<.001$).

The significant association of exposure to family planning messages from religious leaders with contraceptive uptake was reported again in Model 3, which adjusted for additional variables. The influence of exposure to family planning messages from religious leaders became statistically insignificant with the introduction of ideational variables in Model 4 (OR=1.13; 95% CI, 0.99 to1.29). Summarizing the results from all model specifications, we found a statistically significant influence of exposure to family planning messages from religious leaders in promoting contraceptive uptake, with or without exposure to other NURHI interventions and irrespective of respondents' background characteristics and ideation variables—with the exception of perceived self-efficacy about family planning.

Some control variables included in the full model were also found to be significantly associated with contraceptive use. For instance, desire for no more children (OR=1.69; 95% CI, 1.41 to 2.00; $P<.01$), being aged 25 to 34 (OR=1.62; 95% CI, 1.31 to 2.00; $P<.001$), being a Yoruba woman (OR=1.90; 95% CI, 1.51 to 2.51; $P<.001$), and being from a rich household ($P<.001$) were significantly associated with contraceptive uptake, relative to those in the corresponding reference categories. Similarly, composite variables on other NURHI interventions, religiosity, number of children ever born, permission to use family planning, contraceptive ideations about myths/misconceptions, and perceived self-efficacy were significantly associated with contraceptive use ($P<.05$).

DISCUSSION

In a religiously pluralistic Nigerian setting, decision-making processes in different areas of and groups within the country are largely influenced by religious beliefs and practices.[13,44] Consequently, religion is firmly intertwined with the day-to-day life of an average Nigerian. Considering the importance of religion to a majority of the population as well as the influential positions occupied by religious leaders in Nigeria, the NURHI project adopted strategies to increase contraceptive uptake by engaging religious leaders in advocacy work. Having successfully implemented this project in selected locations in the country, the present analysis explored the association between exposure to religious leaders' family planning messages and modern contraceptive uptake in Nigeria. Despite the key position occupied by religious leaders in the country, their potential role in promoting contraceptive use had not been adequately explored until now.

Our findings established that the majority of respondents considered themselves strongly religious. The concept of religiosity connotes a strong adherence to religious beliefs and doctrinal teachings. Thus, this result indicates that the lives and behaviors of a high proportion of respondents across different societal strata are strongly influenced by religious beliefs. A previous study had also found religion to be a well-entrenched factor that influenced decision-making processes across different settings in Nigeria.[23]

This study also revealed that the family planning decisions made by the majority of women were influenced by religion. This demonstrates the importance of addressing religion in order to increase contraceptive use in Nigeria. Existing literature confirms the key role religion plays in shaping the decision to use contraceptive methods.[26,27,30] Our findings show that the NURHI intervention that engaged religious leaders in promoting family planning had substantial coverage, as a large proportion of women were exposed to religious leaders' messages on family planning in the past year. Of the women who had this exposure, about one-third were currently using modern contraceptive methods. Moreover, results from our multivariable analysis established a significant association between exposure to family planning messages from religious leaders and modern contraceptive uptake. The importance of exposure to religious leaders' family planning messages was further supported in the adjusted model that included background characteristics and exposure to other NURHI interventions. The fact that exposure to religious leaders' messages became insignificant in the model that included the ideational variables is not surprising and suggests that the effect of exposure to communication operates through its effect on ideation. These results have important policy implications.

First, given the importance of religion in Nigeria's sociocultural fabric[23,44] and the position of influence, authority, and respect occupied by various religious leaders (i.e., bishops, pastors,

TABLE 4. Relationship Between Current Use of Modern Contraception and Exposure to Family Planning Messages From Religious Leaders, Selected Nigerian States, 2015

Characteristics	Model 1[a] OR (95% CI)	Model 2[b] OR (95% CI)	Model 3[c] OR (95% CI)	Model 4[d] OR (95% CI)
Had exposure to religious leader's message in favor of FP				
No	1.00	1.00	1.00	1.00
Yes	1.70 (1.54, 1.87)***	1.33 (1.17, 1.51)***	1.27 (1.12, 1.45)***	1.13 (0.99, 1.29)
Religiosity				
Strongly religious		1.00	1.00	1.00
Somewhat religious		1.30 (1.12, 1.50)***	1.31 (1.13, 1.52)***	1.27 (1.09, 1.48)**
Age, years				
15–24		1.00	1.00	1.00
25–34		1.73 (1.40, 2.14)***	1.67 (1.36, 2.06)***	1.62 (1.31, 2.00)***
35+		0.90 (0.70, 1.17)	0.86 (0.67, 1.12)	0.87 (0.67, 1.14)
Current marital status				
Married/cohabiting		1.00	1.00	1.00
Never married		1.61 (0.26, 0.39)**	1.54 (1.10, 2.18)*	1.42 (0.99, 2.03)
Previously married		0.27 (0.18, 0.39)***	0.25 (0.17, 0.37)***	0.24 (0.16, 0.35)***
Education				
None		1.00	1.00	1.00
Less than secondary		1.15 (0.87, 1.53)	1.07 (0.81, 1.42)	0.99 (0.74, 1.32)
Secondary		1.49 (1.12, 1.98)**	1.36 (1.02, 1.81)*	1.15 (0.86, 1.55)
Post-secondary		1.98 (1.43, 2.74)***	1.76 (1.27, 2.43)**	1.38 (0.99, 1.93)
Ethnic affiliation				
Hausa/Fulani		1.00	1.00	1.00
Igbo		1.57 (1.14, 2.17)**	1.62 (1.17, 2.24)**	1.38 (1.00, 1.92)
Yoruba		2.42 (1.90, 3.08)***	2.33 (1.82, 2.98)***	1.95 (1.51, 2.51)***
Others		2.52 (2.09, 3.04)***	2.53 (2.09, 3.05)***	2.10 (1.73, 2.56)***
State of residence				
Kaduna		1.00	1.00	1.00
FCT		0.94 (0.77, 1.15)	0.96 (0.78, 1.19)	1.03 (0.84, 1.28)
Kwara		0.74 (0.57, 0.97)*	0.62 (0.47, 0.83)**	0.84 (0.63, 1.13)
Oyo		1.12 (0.91, 1.39)	1.01 (0.81, 1.25)	1.04 (0.83, 1.32)
Wealth index				
Poorest		1.00	1.00	1.00
Poorer		1.39 (0.98, 1.95)	1.32 (0.94, 1.85)	1.24 (0.86, 1.77)
Middle		2.62 (1.91, 3.59)***	2.35 (1.71, 3.23)***	2.09 (1.52, 2.89)***
Richer		3.41 (2.50, 4.66)***	2.83 (2.06, 3.87)***	2.57 (1.86, 3.55)***
Richest		2.78 (2.00, 3.86)***	2.27 (1.63, 3.16)***	2.04 (1.46, 2.87)***

Continued

TABLE 4. Continued

Characteristics	Model 1[a] OR (95% CI)	Model 2[b] OR (95% CI)	Model 3[c] OR (95% CI)	Model 4[d] OR (95% CI)
Parity				
0		1.00	1.00	1.00
1–2		5.50 (3.90, 7.69)***	5.01 (3.56, 7.05)***	4.86 (3.41, 6.92)***
3–4		7.93 (5.46, 11.53)***	7.34 (5.04, 10.68)***	7.00 (4.73, 10.35)***
5+		8.51 (5.72, 12.65)***	7.98 (5.35, 11.86)***	7.34 (4.84, 11.12)***
Fertility desire				
Want another child		1.00	1.00	1.00
Want no more		1.99 (1.67, 2.37)***	1.93 (1.62, 2.30)***	1.69 (1.41, 2.03)***
Needs anyone's permission to use FP				
Yes			1.00	1.00
No			1.16 (0.97, 1.40)	1.40 (1.16, 1.70)**
Exposure to other NURHI interventions				
Low exposure			1.00	1.00
Medium exposure			1.41 (1.19, 1.67)***	1.18 (0.99, 1.40)
High exposure			1.72 (1.42, 2.08)***	1.28 (1.05, 1.57)*
Perceived self-efficacy about FP use				
Low				1.00
Medium				3.48 (2.85, 4.24)***
High				4.78 (3.93, 5.82)***
Acceptance of myths and misconceptions about FP index				
Low				1.00
Medium				0.98 (0.84, 1.13)
High				0.58 (0.49, 0.69)***

Abbreviations: CI, confidence interval; FCT, Federal Capitol Territory; FP, family planning; NURHI, Nigerian Urban Reproductive Health Initiative; OR, odds ratio.
* $P<0.05$; ** $P<0.01$; *** $P<0.001$.
[a] Model 1=unadjusted analysis.
[b] Model 2=adjusted for selected background characteristics, including religiosity, age, marital status, education, ethnicity, wealth status, parity, state of residence, and fertility desire.
[c] Model 3=adjusted for selected background characteristics, including religiosity, age, marital status, education, ethnicity, wealth status, parity, state of residence, and fertility desire, and for women's exposure to other NURHI interventions.
[d] Model 4=adjusted for all variables included in Model 3, plus perceived self-efficacy about family planning uptake and myths and misconceptions about family planning index.

evangelists, imams, and sheiks as well as eminent trado-religious leaders, like emirs and sultans), one way of achieving a rapid increase in Nigeria's mCPR may be to continuously engage religious leaders at all levels in advocacy efforts. Generally, Nigerians are very religious and seem to accord their religious leaders greater honor and veneration than what they confer on political leaders. As a result, religious leaders wield great influence over their large congregations. Their body language and messages can inhibit or facilitate effective health care-seeking behaviors. For example, religious belief, a key determinant of child immunization completeness,[45] has previously been cited as an underlying factor for calling for a boycott of childhood immunization by trado-religious leaders in some parts of northern Nigeria. By engaging religious leaders in using appropriate

family planning messaging, the mCPR in Nigeria will likely increase.

Second, given the established relationship between effective contraception and maternal and child health,[10] religious leaders have the power to promote family health and well-being and contribute to the discourse and strategies on maternal and newborn morbidity and mortality reduction through congregational advocacy messages on the health benefits of family planning. Religious prohibition of contraceptive adoption still persists in Nigeria,[18] partly because of the spread of myths and misconceptions about family planning.[21,22] Because of this, the strategy of working with religious leaders to increase their knowledge of family planning and its benefits and, ultimately, engage them as change agents, may be crucial to increasing family planning adoption and promoting family health in Nigeria.

Moreover, our analysis indicates higher contraceptive uptake among somewhat religious women than their strongly religious counterparts. This suggests that strong adherence to religious doctrines and practices, combined with religious leaders who do not incorporate appropriate family planning messages into their communications, likely contributes to low contraceptive uptake. Religion has been established as one of the most important determinants of behaviors, including health seeking.[46,47] As religious beliefs continue to hinder contraceptive uptake in Nigeria, engaging religious leaders as potential change agents is crucial for creating positive change. The findings from this study, therefore, underscore the importance of enlisting religious leaders in efforts to increase contraceptive uptake in Nigeria.

After including the ideational variable of self-efficacy in our analytical model, the relationship between family planning messages from religious leaders and contraceptive uptake became insignificant. As established in a previous study,[8] this finding suggests the importance of incorporating contraceptive ideation and communication interventions aimed at ideational variables related to contraceptive use in efforts to increase contraceptive uptake.

In addition, and as established by prior studies,[10,27,35,48] this study documented other important predictors of contraceptive use, including fertility desire, parity, respondent's age, ethnic affiliation, wealth index, religiosity, permission to use family planning, and contraceptive ideations. Our results also underscored that other NURHI intervention activities were important for increasing contraceptive uptake in Nigeria. This finding suggests that this family planning intervention, if as well executed as other NURHI activities, may yield impactful results in Nigeria and other sub-Saharan African countries with similar contexts.

Limitations

This study is not without some limitations. Because of the nature of cross-sectional studies, we could not establish a direct cause–effect relationship. As the study was based on self-reported data, respondents may have answered questions with the aim of pleasing the interviewer, thus adding social desirability bias to the results. However, steps were taken during fieldwork to minimize bias through appropriate interviewing practices that would ensure the anonymity and confidentiality of solicited responses. It would be interesting to explore the dose–response between increased exposure to family planning messages from religious leaders and contraceptive use; however, the data do not support this type of analysis. Notwithstanding the study limitations, this article has helped to address an important gap in public health literature on the role of religious leaders in promoting contraceptive use.

CONCLUSION

Given the high level of influence held by religious leaders in Nigeria's sociopolitical landscape, interventions that engage clerics of different faiths as change agents for shaping norms and influencing behaviors related to family planning and contraceptive use are crucial for increasing contraceptive uptake in the country. By sharing tailored scriptural messages that address important health and behavior change information to support positive family health behaviors, religious leaders create a supportive environment for women and their partners to make healthy family planning decisions for themselves and their families.

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ORIGINAL ARTICLE

Helping Postpartum Women in Mali Achieve Their Fertility Intentions: Perspectives From Introduction of the Dedicated Postpartum IUD Inserter

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In this pilot introduction setting, trained providers reported higher acceptance and preference for the dedicated inserter compared with the conventional postpartum insertion with forceps, suggesting potential for the dedicated inserter to expand access to postpartum IUDs.

Résumé en français à la fin de l'article.

ABSTRACT

Background: Mali has one of the highest maternal mortality ratios in the world coupled with one of the lowest modern contraceptive use rates. Nearly a quarter of the country's 750,000 annual births occur within 24 months of a previous birth, increasing the risks for mothers and babies. Nearly 70% of postpartum women have an unmet need for family planning. In 2016, Population Services International Mali (PSI-Mali) introduced a dedicated postpartum intrauterine device (PPIUD) inserter to replace the technique of using forceps for PPIUD insertion, with the aim of helping to address this substantial family planning gap.

Methods: A mixed-methods approach was used to assess program results and the experiences of PSI-trained providers using the dedicated PPIUD inserter in 5 health facilities in Bamako. We conducted 10 key informant interviews with providers and 4 key informant interviews with operational and clinical staff involved in training and supporting providers. Further data were collected from district health surveys and facility registers. Secondary data encompassed documentation from 2011 through 2017, with the service delivery figures of PPIUD using the dedicated inserter focused on the pilot period of March 2016 through December 2017. Primary data were collected in Mali in July 2017.

Results: Between March 2016 and December 2017, PSI-Mali trained 134 providers on the dedicated PPIUD inserter and provided more than 3,500 voluntary PPIUDs. Of the 1,840 voluntary PPIUDs provided in 2017 alone, 67% were provided by facilities trained to use the dedicated PPIUD inserter. Providers stated a preference for the inserter (compared with the use of forceps) due to its ease, speed, and perceived lower associated risks of infection. Service data from the 5 facilities visited showed an overall average PPIUD uptake of 7.3% of deliveries in 2017. Although private facilities had considerably fewer deliveries than public facilities (600–900 compared with 20–30, respectively), a much higher proportion of women delivering in the private facilities chose a PPIUD.

Conclusion: The acceptance of the dedicated PPIUD inserter by providers may help reduce some of the supply-side barriers that inhibit women's access to postpartum family planning methods. With continued support to providers, coupled with ongoing efforts to address differences in service trends between sectors and demand-side barriers to the PPIUD and family planning more broadly, the dedicated PPIUD inserter could play an important role in responding to the high unmet need among postpartum women in Mali.

INTRODUCTION

Birth intervals of less than 24 months are associated with increased risk of maternal, infant, and child mortality.[1,2] Conservative estimates suggest that 9% of the 11 million annual deaths among children under 5 years of age could be averted if birth intervals were 24 or more months apart.[3] An estimated 214 million women worldwide have an unmet need for family planning,[4] with women in the extended postpartum period—defined by the World Health Organization (WHO) as the first 12 months following childbirth[5]—among those with the greatest need. Family Planning 2020 (FP2020) estimates that over 90% of postpartum women in developing countries want to space or limit a

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subsequent pregnancy, but 61% do not use a family planning method.[6]

Mali has among the highest maternal mortality ratios and infant mortality rates in the world: 587 per 100,000 live births[7] and 75 per 1,000 live births,[8] respectively. The fertility rate remains high at 6.1 children per woman and the modern contraceptive prevalence rate is one of the world's lowest at 14%.[9] More than 1 in 4 women have an unmet need for family planning: 19% for spacing and 7% for limiting births.[10] Analysis of Demographic and Health Survey (DHS) data from 2006 revealed that nearly 70% of postpartum women in Mali have an unmet need for family planning.[11] Because postpartum abstinence is practiced for a relatively short period of time (median 2.2 months), half of women are at risk of becoming pregnant again 11.7 months after giving birth.[10] Nearly a quarter of the annual 750,000 births in Mali occur within less than 24 months after the last birth,[10] representing a missed opportunity to significantly reduce maternal and child mortality by lengthening birth intervals.[3] About 48% of pregnant women attend antenatal care (ANC) visits at least once, with 38% attending at least 4 times.[12] Although, nearly 60% of births are attended by a skilled birth attendant,[13] only 40% of women and neonates receive postnatal care in the 2 days following delivery.[10] These patterns of contact between women and their ANC providers suggest strong potential for the increased role of voluntary postpartum family planning (PPFP) in helping women meet their fertility intentions within the context of access to a range of methods that are medically appropriate for immediate postpartum women.

Access to information and counseling during ANC visits could increase the likelihood of PPFP uptake immediately following childbirth.[5] According to WHO *Medical Eligibility Criteria for Contraceptive Use*,[14] the copper intrauterine device (IUD) is one of the immediate PPFP options for breastfeeding women. The postpartum IUD (PPIUD) is a highly effective, low-cost contraceptive option—lasting up to 12 years but reversible at any time—for women in the immediate and extended postpartum period. The PPIUD can be inserted within 10 minutes of delivery of the placenta before a woman leaves the delivery room (postplacental), during a cesarean delivery (intracesarean), or up to 48 hours (immediate) postpartum.[15] Immediate insertion of the IUD postpartum may be beneficial for women as it allows them to access the method prior to leaving the health facility, making some of the side effects typically associated with the IUD less noticeable.[15]

The new PPIUD inserter eliminates the need for forceps by elongating the insertion tube and having a longer string that is visible after insertion.

In 2011, Population Services International Mali (PSI-Mali) launched voluntary PPIUD services using conventional IUDs (the Copper T380A) packaged for interval insertions in health facilities with a high volume of deliveries. Between 2011 and 2015, 141 health providers and stakeholders—21 from the private sector and 121 from the public sector—from Bamako, Kayes, and Sikasso participated in PSI-Mali's PPIUD training program. During this initial phase of the program, more than 2,300 women volunteered to be provided with PPIUDs; however, the use of conventional IUDs for immediate postpartum women came with certain challenges. In low-income countries, access to commonly recommended forceps for PPIUD insertions can be limited, as they are not usually found in the maternity ward. Additionally, sterilizing the forceps can contribute to an increased workload and cost for providers in busy obstetrical units and reduce the likelihood of provision of PPIUDs to women. The insertion of conventional PPIUDs with forceps involves extra manipulation of the IUD, which can increase risk of contamination, possible subsequent infection, and/or the potential for damage to the IUD.[16]

Previous studies reveal that although PPIUDs are highly effective, their expulsion rates are typically higher than with interval IUDs.[17] One reason for this is that, due to the shape of the postpartum uterus, the strings from the conventional IUDs are too short to be visible once the PPIUD is inserted, thereby inhibiting the provider's ability to know whether the PPIUD is correctly placed. To address this challenge, PSI collaborated with the Stanford Program for International Reproductive Education and Services (SPIRES) and Pregna International Ltd to develop a new dedicated PPIUD inserter. The new product eliminates the need for forceps by elongating the insertion tube, which is firm but bends to accommodate the shape of the postpartum uterus and has a longer string that is visible after PPIUD insertion.[18] The IUD product itself remains the same (the Copper T380A), with only the insertion packaging differing. Initial trials in India found that the dedicated PPIUD inserter was effective and safe and had high acceptability among women and providers.[16] However, the trials did not allow for a comparative analysis of provider or client experiences or an exploration of their preferences between the different insertion techniques, which might

have influenced the provision and uptake of the PPIUD. Results of a recent randomized controlled trial in India comparing experiences with the dedicated PPIUD inserter and forceps indicated high provider and patient acceptability and comparable complete expulsion rates.[19]

PSI-Mali's pilot program was the first in sub-Saharan Africa to introduce the dedicated PPIUD inserter, with the aim of improving delivery of voluntary PPIUD services. The pilot set out to generate lessons learned to improve programming, inform a national strategy for increasing availability of voluntary PPIUDs in Mali, and provide a valuable road map for the introduction and scale up of PPIUD access in other country contexts. A year after the launch of the dedicated PPIUD inserter in Mali, PSI commissioned this case study to analyze internal program results and their wider implications for increasing access to voluntary PPIUD service delivery in other PSI programs. The Mali pilot project provides a unique opportunity for a comparison of a voluntary PPIUD service delivery program using the conventional IUD inserted with forceps with a service delivery program using the dedicated PPIUD inserter. This case study shares lessons from the pilot that can be applied broadly to PPIUD acceptability and uptake, with a view to increasing the method mix for postpartum women wishing to space or limit future pregnancies.

METHODS

We used a mixed-methods approach to assess program results to date as well as the experiences of PSI-trained providers using the dedicated PPIUD inserter. The data collected included a review of PSI documentation and secondary data from the PSI management information system, District Health Information System 2 (DHIS 2), and facility-level registers in PSI-trained facilities as well as primary data collected through key informant interviews. The secondary data review examined documentation produced between 2011 and 2017, which allowed a review of trends before and after the introduction of the dedicated PPIUD inserter.

Key informant interviews were conducted to collect provider perspectives on the dedicated PPIUD inserter and to explore the perceived drivers behind PPIUD uptake. Purposive sampling was used to identify public and private facilities and providers based on a range of criteria, specifically that providers have been trained in PPIUD insertion with forceps and with the dedicated inserter by PSI-Mali; facilities have a relatively high volume of deliveries; and providers work in a facility where PPIUD service provision is high, medium, or low to assess differences and outliers. The total sample was 10 providers—6 midwives, 2 gynecologists, and 2 doctors—trained on the dedicated PPIUD inserter who were based in 5 different health facilities in Bamako: 3 public referral health centers, known as *Centres de Santé de Reference*, and 2 private sector Protection de la Famille (PROFAM)-branded clinics from PSI-Mali's social franchise network. The names of facilities and providers have been omitted from this article to respect the confidentiality and anonymity of the interview informants. Instead, the facility names have been replaced with code names: Public A, B, and C for the 3 public health facilities and Private A and B for the 2 PROFAM clinics. To complement provider perspectives of the dedicated PPIUD inserter, 4 PSI-Mali operational and clinical staff who worked directly on the PPIUD program were also interviewed. The primary data that inform this case study were collected in Mali in July 2017, and the secondary data were later updated with the most recent PSI data from DHIS 2. After the interviews were transcribed, manual thematic analysis of the transcripts was conducted and codes entered into a data analysis framework to highlight key themes.

Ethical Considerations

Because the purpose of this case study was determined to be for internal programmatic improvement, it did not meet the definition of human subjects research needing the review of the Institutional Review Board. However, key steps were taken prior to meeting with the providers PSI-Mali had trained on the dedicated PPIUD inserter to ensure data collection was conducted in an ethical manner. Health authorities in the Ministry of Health (MOH) and the participating facilities were informed of the objectives of the case study and their approval was sought prior to conducting interviews with providers. The research team explained to all potential interview participants the objectives of the interview, any potential risks and benefits, that any information provided would be confidential and anonymous, and that their participation was voluntary. All providers provided written informed consent prior to participating in an interview. The MOH provided written support to publish the study results.

District- and facility-level data and provider interviews were analyzed to better understand PPIUD trends and experiences.

INTRODUCTION OF THE DEDICATED PPIUD INSERTER

In March 2016, with 5 years of experience supporting the introduction of voluntary PPIUD (using a forceps insertion technique) into the package of maternal health services, PSI-Mali gained support from the MOH to introduce the dedicated PPIUD inserter in a pilot study. The study allocated 2 midwives to support the pilot phase, including rolling out the training program and providing follow-on supportive supervision. With the assistance of MOH stakeholders, sites were chosen to pilot the dedicated PPIUD inserter. A select group of 18 providers from 10 public health facilities were initially trained. The facilities were chosen based on meeting the following key criteria:

- A sufficiently high volume of deliveries to increase the likelihood of higher volume of voluntary PPIUD services, enabling providers to build and maintain their skills
- Experience in PPIUD insertions with forceps, or interval IUD insertions as a minimum
- Demonstrated commitment from providers to counsel and provide voluntary PPIUD

While the trainings largely focused on clinical aspects of the new insertion technique, as providers were already experienced in the provision of PPIUD (with forceps), refresher trainings were also provided within the context of high-quality family planning counseling on the range of methods suitable for postpartum women.

PSI used provider training and staff orientation sessions to raise awareness and ensure that female patients would receive the correct information about PPIUDs.

Prior to the provider trainings, an orientation was conducted at each pilot site to allow a range of members of staff—from center managers to midwives and nurses—to learn about the dedicated PPIUD inserter. These sessions helped to ensure the staff had the necessary information to inform women during visits to a health facility—for vaccinations, family planning counseling, or ANC—to raise general awareness. Site orientation was done in collaboration with the MOH's 2 allocated public-sector midwives. As part of the initial introduction, and to generate evidence of the efficacy of the PPIUD with the dedicated inserter over a 4-month period, PSI-Mali monitored clinical data related to insertions, including the timing of the insertions and any postinsertion complications or side effects. Between March and June 2016, PSI-Mali identified 10 cases of PPIUD expulsions out of 343 insertions (2.9%), lower than the proportion found in the original pilot study in India (7.5%)[18] and in previous studies of PPIUD insertions with forceps, which ranged from 6.9% to 8%.[20–22] Possible explanations for the difference in expulsion rates observed in this and the Indian studies include: (1) in the Indian studies, resident physicians had less experience in PPIUD insertion than participating providers in Mali, and (2) as a result of the early Indian experience, adjustments were made to the insertion technique in Mali, particularly trimming the strings as close as possible to, or just inside, the cervical os.[19] Training sessions conducted during this initial introductory phase also allowed PSI-Mali to identify experienced and motivated providers to be trained as trainers, thus growing the pool of trainers for the successive rollout and supervision of the dedicated PPIUD inserter program. Between March 2016 and December 2017, PSI-Mali trained 134 providers on the dedicated PPIUD inserter across 4 regions (Table).

TABLE. Public and Private Providers Trained in the Dedicated PPIUD Inserter in Mali, by Region

Region	No. of Public Providers	No. of Private Providers
Bamako	42	49
Kayes	6	14
Sikasso	12	3
Mopti	8	0
Total	**68**	**66**

Together, PSI-Mali and the MOH conducted follow-on supportive supervision visits in the weeks after training as well as at the midpoint and in the final weeks of the pilot period. Public and private facilities received the same supportive supervision schedule and content. This included:

- **Community sensitization:** support conducting community sensitization events; information, education, and communication materials; training MOH community health workers
- **Supportive supervision:** all trained providers receive post-training supervision and ongoing supportive supervision in clinical and counseling skills from PSI-Mali supervisors and/or the pool of trained providers
- **Supplies:** the dedicated PPIUD inserter and all the necessary commodities for insertion were provided free of charge to facilities by PSI-Mali
- **Record keeping and data collections support:** support on data reporting and monthly collection of PPIUD service data

RESULTS

Results presented are from March 2016 through December 2017, unless otherwise stated, and are based on PSI service data in DHIS 2 and/or facility-level registers.

Provider Preferences for the Dedicated PPIUD Inserter

All providers interviewed stated a preference for the dedicated PPIUD inserter compared with inserting PPIUD with forceps for the following reasons:

- PPIUDs were easier and faster to insert
- The inserter was more convenient
- The procedure required fewer materials and no sterilization
- Patients were at less risk of infection or perforation
- Providers were confident that the PPIUD was placed correctly due to the visibility of the strings
- The procedure was perceived as less painful for women

While no provider relayed any major difficulties with inserting the PPIUD using forceps, providers expressed a much more favorable opinion of the dedicated inserter. Respondents commonly cited ease of use and reduced perceived associated risks with the new product, giving them more confidence to provide the voluntary PPIUD service:

> *[Providers] accept this method because of its ease of use. We know this influences service delivery. First, people must accept it . . . when staff are skeptical of a method, it is very hard to make it work. [The staff] have much more confidence with the new inserter.* (Gynecologist, public-sector facility, Bamako)

The rarity of complications or adverse reactions related to the dedicated PPIUD inserter also contributed to greater provider confidence. While some cases of discontinuation were reported, these were largely due to husbands wanting the IUD removed.

Several providers explained that, in their experience, if women see or hear the forceps, they often get nervous. Providers relayed instances of women changing their mind about wanting the PPIUD once they saw the forceps or nervously moving while the forceps insertion was taking place, raising provider fears of causing a perforation:

> *[The new inserter] is easier. It is less stressful for the woman, and for you . . . if the woman sees the forceps, she is scared. She doesn't stay still . . . we are scared to perforate her when she doesn't sit still.* (Midwife, public-sector facility, Bamako)

Providers preferred the dedicated PPIUD inserter because it was more convenient, faster, and required fewer materials.

Uptake of Voluntary PPIUD Services

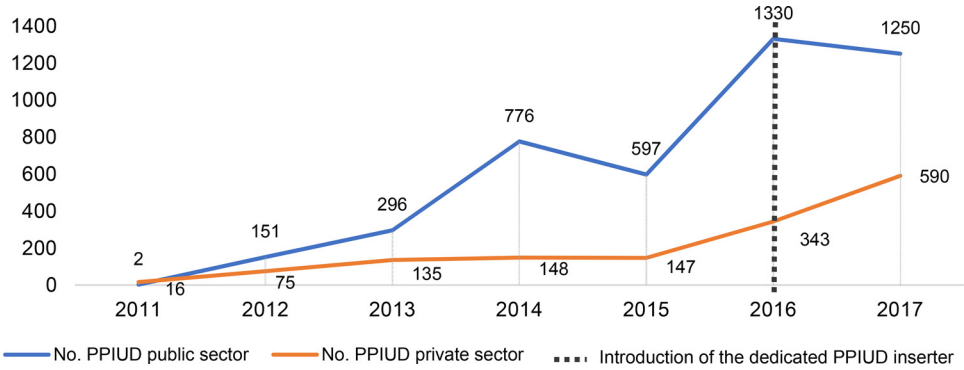
Voluntary provision of PPIUD services in the public and private sectors has steadily increased since PSI-Mali launched the first PPIUD program in late 2011. Uptake of PPIUD services saw a substantial increase in 2016 when PSI-Mali introduced the dedicated inserter, with providers delivering 1,673 voluntary PPIUD services compared with 744 in 2015. In 2017, 1,840 voluntary PPIUD services were provided, surpassing the 2016 results. In total, 3,513 voluntary PPIUD services were provided between 2016 and 2017 over the course of the pilot period. Figure 1 illustrates the trends in voluntary PPIUD uptake from the start of the voluntary PPIUD program launch in 2011 through December 2017.

While services provided in the public sector have increased over time, uptake trends have been variable, rising and falling throughout over the last 4 years. In 2017, however, the public sector nearly sustained levels of uptake compared with 2016, and substantially surpassed the uptake recorded in 2015, the year before the dedicated inserter was introduced. Prior to that, peak results for the public sector were in 2014 and 2016, which coincide with a substantial number of trainings conducted for public-sector staff (41 providers trained in 2014 and 48 in 2016). In the trainings, each provider was required to counsel and provide 3 to 5 voluntary PPIUD insertions under supervision to qualify as a certified provider. For the private sector, in 2017, uptake exceeded the number provided in 2016 and was substantially higher than in 2015. This can be attributed, in part, to the increased number of private-sector social-franchise facilities trained in the dedicated PPIUD inserter compared with the number of franchised facilities trained in the forceps insertion technique.

Of the 1,840 voluntary PPIUDs provided in 2017, 67% were provided in facilities trained to use the dedicated inserter.

While Figure 1 provides program-wide results for voluntary PPIUD services provided with either forceps or the dedicated inserter, a snapshot of the data in 2017 reveals that out of the 1,840 voluntary PPIUDs provided, the majority (67%) were

FIGURE 1. Program-Wide Voluntary PPIUD Services Provided November 2011 Through December 2017



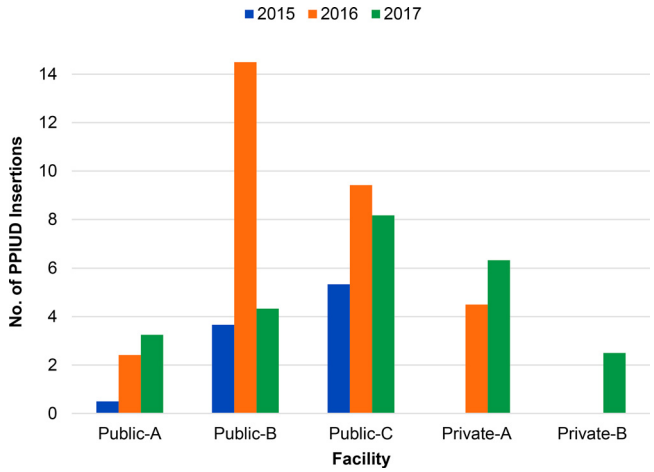
Abbreviation: PPIUD, postpartum intrauterine device; PSI, Population Services International.

provided by facilities trained in voluntary PPIUDs with the dedicated inserter.

Service data from the 5 facilities visited for the case study were analyzed, and results among the 3 public-sector facilities showed a peak in voluntary PPIUD service uptake in 2016, compared with 2015 and 2017, for 2 of the public facilities; the other showing an increase in services in 2017. In the 2 private facilities, no data were available for 2015, as either the provider had not been trained to provide voluntary PPIUD services or PPIUD data were not disaggregated from interval IUDs in client registers. However, since late 2016, the private facilities have showed promising trends in voluntary uptake. We calculated the average number of PPIUD insertions per month per facility to provide a comparative view of voluntary PPIUD uptake among the 5 case study facilities (Figure 2).

On average, the 5 facilities delivered 4.9 voluntary PPIUD services per month in 2017, compared with an average of 7.7 per month in 2016. Public facilities B and C provided the highest number of voluntary PPIUD services per month, especially in 2016. This was largely due to the practical training sessions taking place in their facilities, where numerous visiting providers had to each do 3

FIGURE 2. Average Number of Voluntary PPIUD Insertions per Month per Facility Among 5 Case Study Facilities, January 2015 Through December 2017



Abbreviation: PPIUD, postpartum intrauterine device.

insertions to qualify as a trained provider in the dedicated inserter. The average number of PPIUD insertions per month in private facility A increased substantially in 2017 compared to 2016. Because private facility B was trained in late 2016, only 2017 service data were available.

Uptake of Voluntary PPIUD Services as Proportion of Total Deliveries

Each of the 5 facilities included in the case study was asked to provide an estimated monthly average of deliveries at their facility based on tallies from their institutional log books. The public facilities estimated significantly more deliveries per month, between 600 and 900 deliveries, than did the private-sector facilities, which estimated 20 to 30 deliveries. Service data from the 5 health facilities showed an overall average voluntary PPIUD uptake of 7.3% for all deliveries in 2017 compared with 4.9% for 2016. This, however, masks variations between sectors. Voluntary PPIUD uptake as a proportion of total deliveries was considerably higher in the 2 private-sector facilities than the 3 public-sector facilities. Although private facilities have significantly fewer deliveries, they also have a much higher rate of uptake of voluntary PPIUD, defined as the number of services as a percentage of total women delivering at their facility (Figure 3).

PSI-Mali staff posit that, in the private sector, repeat interactions with the same provider for ANC visits and for delivery contributed to increased opportunity and/or increased trust between clients and providers that positively impacts discussion of PPFP. In the public sector, a woman may see several providers from different teams in the maternity unit throughout her pregnancy, delivery, and postpartum period.

Volume of Services Provided by Number of Active Providers

To understand whether the introduction of the dedicated PPIUD inserter had an impact on the number of voluntary PPIUD services, it is also necessary to understand whether the number of providers offering the service was the same or different over time. This will shed light on whether observed increases in service uptake were due to having more providers trained to offer the service or higher PPIUD service volumes per provider.

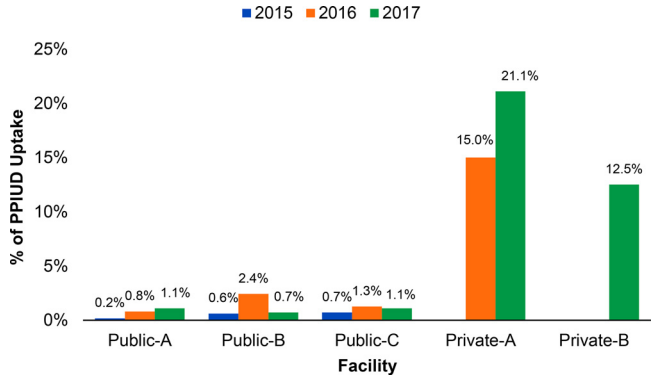
However, in order to gain a snapshot of the pilot program as a whole, data on the total number of "active" providers—defined as providers delivering at least 1 voluntary PPIUD insertion in a given month—were compared with the total number of voluntary PPIUD insertions provided (Figure 4). This provided an estimate of the average number of PPIUD insertions per active provider by month for 2016 and 2017 (Figure 5).

Figure 4 shows that the number of active providers per month fluctuates between 17 and 36. The total number of voluntary PPIUD services provided varies more dramatically, ranging from 73 to 238. Broadly, most months with high uptake of PPIUD services coincided with a greater number (>30) of active providers. There were, however, some months—for example, April and August 2016 and March and August 2017—in which a lower number of active providers provided a higher number of voluntary PPIUD services,

Compared to the public sector, the private sector had a higher average number of PPIUD services delivered per active provider and a much wider range of providers inserting voluntary PPIUDs.

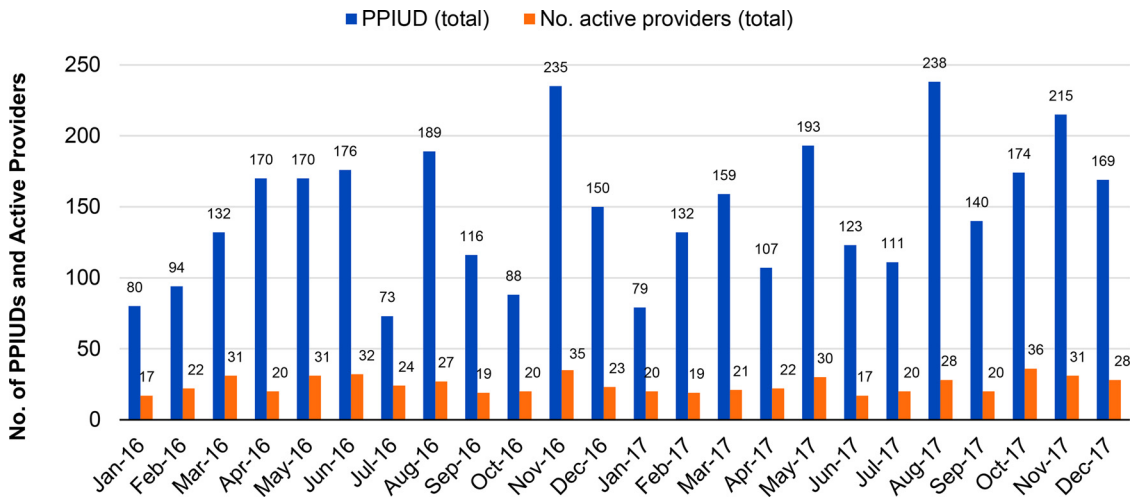
Service data from the pilot facilities showed an overall average voluntary PPIUD uptake of 7.3% for all deliveries in 2017 compared to 4.9% for 2016.

FIGURE 3. Voluntary PPIUD Uptake vs. Estimated Total Number of Deliveries Among 5 Case Study Facilities



Abbreviation: PPIUD, postpartum intrauterine device.

FIGURE 4. Number of Voluntary PPIUDs Provided and Number of Active Providers



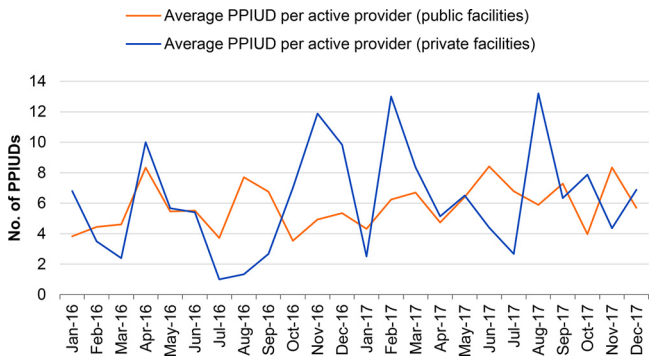
Abbreviation: PPIUD, postpartum intrauterine device.

indicating higher PPIUD client volumes per provider.The data, therefore, do not provide a clear link between an increased number of providers trained in PPIUD and an increased number of voluntary PPIUD services provided.

The data did illustrate monthly fluctuations in the average number of voluntary PPIUD services provided per active provider by sector (Figure 5). More specifically, they showed a slightly higher average number of PPIUD services delivered per active provider in the private sector (6.2) compared with the public sector (5.8), and a much wider range of providers inserting voluntary PPIUDs: from 4 to 8 voluntary PPIUDs per provider per month in the public sector to between 1 to 13 PPIUDs provided in the private sector (Figure 5).

Although the number of providers trained by PSI-Mali has increased over time, the data show that the number of providers actively providing voluntary PPIUDs each month fluctuates. In some months, trained providers provide no PPIUD services at all, despite no reported stockouts during the pilot period. This finding was also observed during site visits. The most recent analysis of DHS data on birth seasonality in Mali shows

FIGURE 5. Average Monthly Voluntary PPIUDs per Active Provider, by Public and Private Facilities



Abbreviation: PPIUD, postpartum intrauterine device.

births highest in April and June and lowest in January.[22] While January 2016 and 2017 had the lowest total number of PPIUD insertions, overall patterns of insertions and births are not correlated, suggesting that birth seasonality might be a contributing factor but not a strong driver of the monthly insertion numbers.

Calculating the average monthly number of active providers who inserted PPIUDs in 2016 and 2017, reveals that, on average, 18.8 private providers and 5.9 public providers actively provided voluntary PPIUD insertions, regardless which approach was used. This represents only a small proportion of providers who have been trained in PPIUD insertions. Provider-level analysis also reveals that the same providers can fluctuate between being "active" and "inactive," with few consistently providing voluntary PPIUDs each and every month.

Provider Perceptions of Service Trends

Although not specifically related to the dedicated inserter, but to PPIUD insertions more generally (including with forceps), providers identified supply- and demand-side drivers and barriers associated with PPIUD use or non-use. Based on their experiences of providing PPIUD, their main perceptions were:

- **Wider site orientation increases access to PPIUDs:** Increasing the number of staff at a facility who can counsel women during ANC visits and delivery, or assist with voluntary PPIUD insertions, can contribute to increased access to PPIUDs.
- **ANC visits are an essential time to counsel women:** Providers reported that counseling women during ANC sessions was more likely to result in voluntary postplacental PPIUD insertions; however, if counseling was done in early labor or postpartum, women were less likely to choose this method.
- **Community sensitization increases acceptance of the IUD:** Providers believed that community sensitization caused a shift in the acceptance of the IUD, in general, as a method of family planning and had an impact on the uptake of voluntary PPIUDs.
- **Provider availability influences PPIUD service availability:** Providers reported that in public facilities, the high volume of deliveries, the quick turnover of new mothers in the delivery suites, and the relatively low number of providers trained in PPIUD insertions to date, meant that access to PPIUD is often restricted.
- **Retention and relocation of public-sector providers creates challenges for PPIUD availability:** Providers believed that public-sector staff or provider rotation, retirement, or sick leave can all negatively influence the continuous availability and provision of voluntary PPIUD services.
- **Demand-side barriers hinder uptake of voluntary PPIUD:** Providers reported the most common reasons for non-use of the PPIUD were husband opposition to family planning, women changing their mind post-delivery—having selected a PPIUD during ANC visits—because of fear of pain or wanting to discuss it with their husbands first, women preferring to wait 40 days to resume sexual activity and consider all family planning methods, and myths and negative perceptions about IUDs.

Demographic Characteristics of PPIUD Users

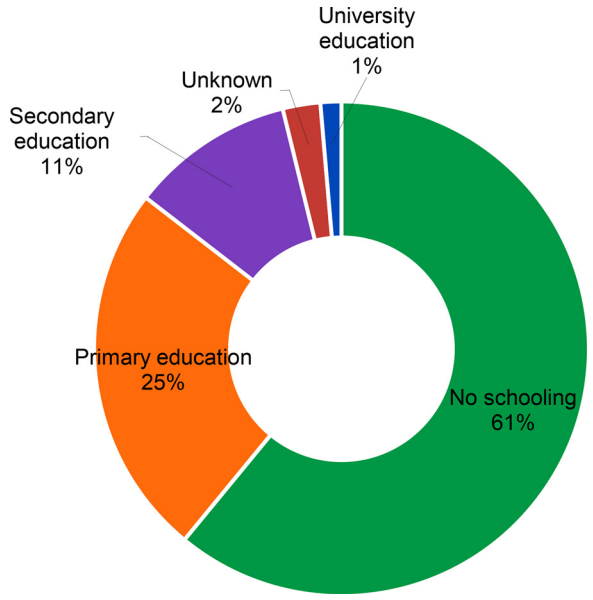
In 2017, 86% of women adopting a voluntary PPIUD had either no or only primary education.

Based on 2017 client data, most women adopting a voluntary PPIUD had either no education (61%) or primary education only (25%) (Figure 6). There were some differences in education status between public- and private-sector PPIUD clients; private-sector clients were less likely to have had no schooling and more likely to have primary and secondary education than clients accessing services in the public sector. The large proportion of women with no or little schooling accessing voluntary PPIUDs in both the public and private sector suggests that over the course of the dedicated PPIUD inserter pilot program service delivery successfully reached women of lower socioeconomic status, using education status as a proxy measure.

In 2017, although the proportion of women adopting a voluntary PPIUD was highest in the 30-to-39-year age group, over half (51%) of all women choosing a PPIUD were under the age of 30 (Figure 7). Almost half (46%) of clients in the public sector were aged 30 to 39 years compared to the private sector, where there was a much more even distribution across the age groups 20 to 24, 25 to 29, and 30 to 39 years.

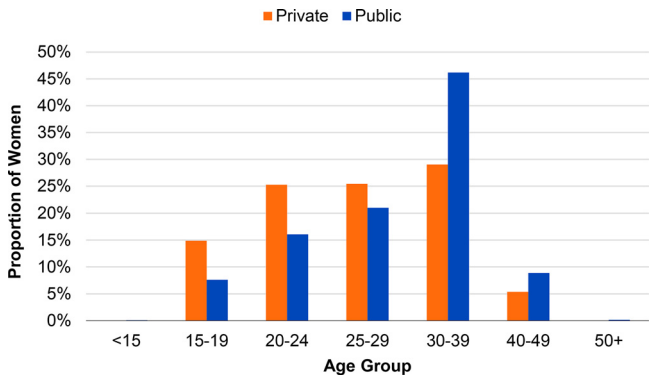
The reasons for the differences in client age require further exploration. Based on interviews with some public providers, one explanation could be that multiparous women are more often identified as possible candidates for counseling for voluntary PPIUD in the public sector, while the private sector considers that all women of reproductive age may be interested in the PPIUD. Information regarding client parity was available in

FIGURE 6. Education Status of Voluntary PPIUD Clients, 2017



Abbreviation: PPIUD, postpartum intrauterine device.

FIGURE 7. Age of Women Choosing a PPIUD, by Sector, 2017



Abbreviation: PPIUD, postpartum intrauterine device.

health-facility level registers but not available through internal management information system data and, therefore, was not included in this analysis.

Multiple confounding factors identified during the pilot phase may have influenced voluntary PPIUD uptake.

DISCUSSION

Since the introduction of the dedicated PPIUD inserter in Mali, the insertion technique has proved to be popular among service providers interviewed who consider it easier, faster, more convenient, and less risky than the conventional IUD inserted with forceps. Whether provider acceptability of the dedicated inserter has directly contributed to an increase in service results remains unclear due to multiple confounding factors identified during the pilot phase that may have influenced voluntary PPIUD uptake.

Nevertheless, it can be considered that provider preference for and confidence with the inserter's use can contribute to reducing potential supply-side barriers. Historically, peaks in voluntary PPIUD services have coincided with training sessions for providers. This might suggest a potential downturn once trainings were reduced; however, since the program entered a more natural phase in August 2017, when trainings have reduced, the results have revealed stable or increasing numbers of monthly voluntary PPIUD services. While service trends in PPIUD service provision in the private facilities during the pilot phase steadily increased, they remained unpredictable for the public sector. They have, however, shown the potential of increasing access to PPIUD if providers are trained, confident, and motivated to provide the service. This was demonstrated during the training phases of providers; their motivation to qualify as a provider of the PPIUD with the dedicated inserter could be a contributing factor to the boost in figures. Despite the number of public and private providers trained on the dedicated PPIUD inserter, only a small proportion actively provide voluntary PPIUDs each month. This suggests that not all trained providers are operating at their full potential each month, perhaps due to factors such as a limited demand for PPIUD services or competing priorities other than PPFP counseling within maternity units.

The large volume of deliveries in public-sector facilities in Mali demonstrates an opportunity to increase voluntary PPIUD access at scale, but a number of supportive factors—supplies, supportive supervision, and community sensitization—need to be in place to ensure uninterrupted delivery to all women, of all ages and parities. If providers in the public sector feel overstretched with their existing workload, consideration for how to ensure providers have the time, capacity, and motivation to integrate and sustain a new service is needed.

While public facilities have a much greater number of deliveries, private facilities are providing voluntary PPIUDs to a much higher proportion of postpartum women, and more evenly across age groups. Further research is required to fully understand what is behind the differences between voluntary PPIUD uptake in public versus private facilities. A recent study in Nigeria identified strong uptake in private-sector facilities where 41% of women delivering chose a voluntary PPIUD.[21] Once the determinants of strong uptake are better understood, there may be scope to apply learnings between sectors.

The dedicated PPIUD inserter may contribute to reducing some of the supply-side barriers that inhibit access to voluntary PPIUD services due to the inserter's acceptability among providers. However, this alone cannot increase uptake of postpartum contraception or of voluntary PPIUD as a proportion of the method mix. Integration of a new service into an already overstretched health system does not come without challenges. Further, Mali continues to face important demand-side barriers not only for PPIUD provision but also for the voluntary IUD and family planning in general, especially among men. Additional efforts are required to provide comprehensive information on birth spacing and family planning options at a community level. The importance of integration of PPFP services into different maternal health services was echoed by providers, with ANC identified as a critical time to counsel women on their PPFP options, especially for PPIUDs. Importance of PPFP counseling during all ANC sessions—for women of all ages and parity—should be stressed in future trainings and continue to be observed during onsite supervision visits. Understanding of the number of women who do not attend ANC sessions or return to facilities for postnatal care is equally important. PPFP strategies should include components to reach women in their homes or communities with PPFP information and referral pathways, or by integrating PPFP counseling into other maternal, infant, and child health services.[24,25]

PSI-Mali will continue to support the providers it has trained in the private and public sectors to provide quality, voluntary PPIUD services within the context of broad method choice to women in a critical stage of their reproductive life. Results from the dedicated inserter pilot program demonstrate the potential for this service to be scaled up, in order to enable women in Mali to achieve their fertility intentions and support their health and the health of their families.

The large volume of deliveries in public-sector facilities shows an opportunity to increase voluntary PPIUD access at scale, but a number of supportive factors need to be in place to ensure uninterrupted delivery to all women.

Limitations

Due to the limited scope of the case study, only a small number of providers could be interviewed. While they provided invaluable insights for PSI on the experiences of the dedicated PPIUD inserter and the drivers of voluntary PPIUD uptake, they were not considered to be a representative sample of PSI-trained providers, and therefore generalizable conclusions cannot be drawn. Additionally, the providers were all based in Bamako, the

capital city; future research would benefit from including providers from other regions. Some of the calculations included in this case study are based on best-available information, such as the number of deliveries per facility, which are tallied manually in institutional log books and are, therefore, subject to potential human error.

CONCLUSION

The dedicated PPIUD inserter has been widely accepted and preferred by providers in Mali and, where implemented, has potentially contributed to reducing some of the supply-side barriers associated with PPIUD services. While not directly attributable to the introduction of the dedicated inserter alone, voluntary PPIUD insertions have increased since its introduction, suggesting the potential for the dedicated PPIUD inserter to enhance access to PPIUD, given that only a small proportion of trained providers actively provide voluntary PPIUD insertions each month.

Further research is required to understand the impact of potential confounding factors to voluntary PPIUD uptake, the difference in trends between the public and private sectors, and client perspectives of the dedicated PPIUD inserter. However, the Mali pilot demonstrates notable acceptability and preference for the dedicated PPIUD inserter among a key constituent group who enable access to this important postpartum method, namely, providers. With continued support to providers, coupled with ongoing efforts to address demand-side barriers to PPIUD, and family planning more broadly, the dedicated PPIUD inserter could play an important role in responding to the high unmet need for postpartum women in Mali. On a global level, the lessons learned from Mali will inform the rollout of the dedicated PPIUD inserter taking place in 12 other countries. With increasing support for the scale up and integration of the dedicated PPIUD inserter in the pilot countries, and the WHO and United Nations Population Fund product prequalification processes underway, substantial potential exists for the dedicated PPIUD inserter to expand PPFP options, reduce unmet need for PPFP, and contribute to reducing maternal, infant, and child mortality.

By continuing to support providers and addressing demand-side barriers to PPIUD, the dedicated PPIUD inserter could play an important role in responding to the high unmet need for postpartum women in Mali.

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Competing Interests: Dr. Blumenthal reports he is named on a pending patent for the PPIUD Inserter without financial involvement relative to being so named.

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En français

Aider les femmes post-partum au Mali à réaliser leurs intentions en matière de fertilité: perspectives de l'introduction du dispositif d'insertion dédié au DIU post-partum

Dans cette contexte d'introduction pilote, les prestataires formés ont déclaré une acceptation et une préférence plus élevées pour le dispositif d'insertion dédié par rapport à l'insertion post-partum conventionnelle avec forceps, suggérant le potentiel du dispositif d'insertion dédié à élargir l'accès aux DIU post-partum

RÉSUMÉ

Contexte : Le Mali a l'un des taux de mortalité maternelle les plus élevés du monde, associé à l'un des taux les plus faibles d'utilisation de contraceptifs modernes. Près d'un quart des 750 000 naissances annuelles du pays surviennent dans les 24 mois suivants une naissance, ce qui augmente les risques pour les mères et les bébés. Près de 70 % des femmes en post-partum ont un besoin de planification familiale non satisfait. En 2016, Population Services International Mali (PSI-Mali) a introduit un applicateur spécialisé du dispositif intra-utérin du post-partum (DIUPP) pour remplacer la technique d'utilisation des forceps pour l'insertion du DIUPP ; ceci dans le but d'aider à résoudre ce déficit important de la planification familiale. Méthodes : Une approche à méthodes mixtes a été utilisée pour évaluer les résultats du programme et les expériences des prestataires formés par PSI qui utilisent l'applicateur spécialisé du DIUPP dans 5 établissements de santé à Bamako. Au total, 10 entretiens avec des informateurs clés ont été menés chez les prestataires, de même que 4 entretiens avec des informateurs clés du personnel opérationnel et clinique de PSI-Mali impliqué dans la formation et le soutien des prestataires. Des données supplémentaires ont été collectées à partir d'enquêtes sanitaires de district et de registres d'établissement. Les données secondaires englobaient la documentation de 2011 à 2017, avec les chiffres de prestation de services du DIUPP qui ont utilisé l'applicateur spécialisé sur la période pilote de mars 2016 à décembre 2017. Les données primaires ont été collectées au Mali en juillet 2017.

Résultats : Entre mars 2016 et décembre 2017, PSI-Mali a formé 134 prestataires du secteur public et privé sur l'applicateur spécialisé du DIUPP et fourni plus de 3 500 DIUPP volontaires. Sur les 1 840 DIUPP volontaires fournis en 2017 uniquement, 67 % ont été fournis par des établissements formés à l'utilisation de l'applicateur spécialisé du DIUPP. Les prestataires ont exprimé une préférence pour l'applicateur (par rapport à l'utilisation de forceps) en raison de sa facilité, de sa rapidité, et ont perçu les risques plus faibles d'infection associés. Les données de service des 5 établissements visités ont révélé une moyenne générale d'adoption du DIUPP de 7,3 % des accouchements en 2017. Bien que les établissements privés aient considérablement moins d'accouchements que les établissements publics (600 à 900 contre 20 à 30 respectivement), une proportion beaucoup plus élevée de femmes qui accouchent dans les établissements privés ont choisi un DIUPP. Les prestataires ont également évoqué d'autres obstacles du côté de l'offre et du côté de la demande continue qui empêchent l'adoption du DIUPP.

Conclusion : L'acceptation par les prestataires de l'applicateur spécialisé du DIUPP peut aider à réduire certains des obstacles du côté de l'offre qui empêchent les femmes d'accéder aux méthodes de planification familiale du post-partum. L'applicateur spécialisé du DIUPP pourrait jouer un rôle important en réponse au besoin élevé non satisfait de planification familiale chez les femmes en post-partum au Mali avec en synergie : un soutien continu aux prestataires ; des efforts continus pour résoudre les différences dans les tendances de service entre les secteurs et les obstacles du côté de la demande du DIUPP et de la planification familiale de manière plus générale.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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ORIGINAL ARTICLE

Global Health Competency Self-Confidence Scale: Tool Development and Validation

Cynthia Stuhlmiller,[a] Barry Tolchard[b]

The scale, designed to measure students' self-assessment of their confidence in 11 competency domains before and after participating in global placements, was found to be reliable and correlated well with an earlier validated scale.

ABSTRACT

Background: Global health education in tertiary institutions worldwide is at an all-time high. Until recently, most evaluations of student learning from a global exposure was in the form of a reflective paper with little information that would enable standardized assessment of the competencies gained. In 2015, the Consortium of Universities for Global Health (CUGH) published a set of interprofessional global health competencies that were drawn upon to create a Global Health Competency Self-Confidence Scale and workbook. This study reports the development and validation of the scale and its implications for global health education.

Methods: In total, 126 graduate students from a university in New York State participated in the validation process of the Global Health Competency Self-Confidence Scale—an 11-domain, 22-item competency self-assessment to measure the level of confidence of students before and after undertaking a global learning experience. The team used factor analysis to compare the scale to the Global Health Competency Survey for content validity and reliability.

Results: Reliability and validity of the scale was determined. An exploratory factor analysis identified 4 standalone components as: (1) Ethical and Professional Practice, (2) Capacity Strengthening and Planning, (3) Structural and Social Determinants of Health, and (4) Strategic Analysis. The scale showed excellent internal consistency (Cronbach's alpha=0.92) and test-retest reliability (reliability (r)=0.455; $P<.001$). Concurrent validity was established.

Conclusion: The Global Health Competency Self-Confidence Scale contributes to a further consolidation and refinement of competency groupings into components of global health education and offers a scale to assess student learning in global placements.

INTRODUCTION

For decades, preparation and training for academic health disciplines has been informed by an ever-evolving discipline-specific set of criteria that defines the knowledge, skills, and attitudes students are required to demonstrate before they are credentialed and, if relevant, licensed for practice.[1,2] The role of institutional accrediting bodies is to ensure that the institutions offering educational degrees or certifications maintain a defined set of standards based on established course competencies that will produce capable graduates of that discipline.[3] While most academic health profession curricula have increasingly incorporated content to address cultural diversity and differences, as they impact practice, 2 key movements over the past decade have contributed to the current explosion in student- and academic-driven global health education: globalization and interprofessional education.

Globalization is, in part, a result of policies promoting the international marketplace that have increased global travel, education, and employment. Technologies of the Internet and mass communication have enabled events around the globe to be witnessed as they happen, exposing the world to a range of cultures and experiences. This exposure has also highlighted the plight of peoples with poor health conditions resulting from political and economic factors and has fueled student interest and activism in understanding and addressing health disparities.

The move toward interprofessional education has been in response to demands for the health industries to provide better coordinated care and reduce errors created by inadequate communication across the disciplines. While each health discipline retains its separate scope of practice, evidence has shown that greater efficiencies and better health outcomes are achieved when health professions work together.[4] Accordingly,

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recommendations to integrate interprofessional core competencies into curricula are needed to inform and support accreditation and credentialing processes.[5–9] In their review of global health competencies, Sawleshwarkar and Negin[10] examined the competencies needed to support "academic global health"—a term coined by Wernli[11]—and the integration of health care, international health, and public health.[10,11] Harmer and colleagues' analysis of global health education in the United Kingdom resulted in the identification of 16 core competencies for medical and non-medical students.[12]

Academic global health has become a cross-cutting theme at universities, including not only the health sciences but also the fields of architecture, environmental science, law, anthropology, media studies, and political science. The contributions of these disciplines are essential to collaborative and comprehensive problem solving. To meet the growing demand for a transdisciplinary approach to global health education, the Consortium of Universities for Global Health (CUGH) was founded in 2008. Based in Washington, DC, CUGH is composed of 169 academic institutions and other organizations from around the globe that work together to seek solutions to health problems. As an interprofessional endeavor, CUGH members work together to share knowledge and resources and to partner in research and service initiatives.[13]

One of CUGH's earliest aims was to define the field of global health and examine the structure, content, and competencies of global health education programs. In 2013, the CUGH Global Health Competency Subcommittee was formed to develop a standardized set of interprofessional global health competencies to guide curricula development and evaluation. Their work established a common understanding of what educators should expect from students across all disciplines undertaking a global learning experience[14] and a common definition of global health as[15]:

> *an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide. Global health emphasizes transnational health issues, determinants, and solutions; involves many disciplines within and beyond the health sciences and promotes interdisciplinary collaboration; and is a synthesis of population-based prevention with individual-level clinical care.*

After a rigorous national expert consultation process across health disciplines and professional organizations, the subcommittee generated a comprehensive list of 82 competencies across 12 domains. The competencies were then assigned to 4 levels that corresponded with educational intent: (1) Global Citizen (as basic preparation for students pursuing any field related to global health); (2) Exploratory (students contemplating a future in global health); (3) Basic Operational (for moderate time in the field, which has 2 sublevels that focus on either discipline-specific skills [practitioner-oriented] or program development, planning, evaluation, policy, and so on [program-oriented]); and (4) Advanced Level (for a career in global health).[14]

The subcommittee then collapsed the 4 levels into 2, combining the 2 interprofessionally focused levels (1 and 2) and the 2 discipline-specific levels (3 and 4). During the final step, the subcommittee assigned competencies to either of the 2 new levels: Level 1 Global Citizen or Level 2 Basic Operational Program-Oriented. With further refinement, they published a set of 13 competencies across 8 domains for the Global Citizen level and 39 competencies across 11 domains for the Basic Operational Program-Oriented level. The competencies and domains of the Global Citizen level are contained within competencies and domains of the Basic Operational Program-Oriented level.[14]

CUGH was formed in 2008 to support academic and other institutions to improve global health through collaborative education, service, research, and advocacy.

Construction of the Competency Measurement Tool

While global health competency skill assessment measures have been developed, most are discipline specific to medicine,[16,17] nursing,[18] and rehabilitation.[19] The aim of our study was to translate the CUGH competencies into a measurement tool to assess perceived competency attainment from global exposure for students of all disciplines. Drawing directly from the final set of CUGH competencies, we identified the competencies most relevant to our university students who undertake short- and longer-term global immersive experiences. Our university enrolls nearly 30,000 students, approximately one-third of whom are undertaking graduate studies. The demand for more globally experienced graduates means that universities need to provide more international learning opportunities to students. To address that, our university has dozens of ongoing initiatives that engage hundreds of undergraduate and graduate students participating from a range of disciplines including nursing, dental medicine, medicine, public health, engineering, environmental science, business, and education.

While the original objective was to prepare students at the Global Citizen level, because of our student demographics, we chose to also retain the other 3 domains of the Basic Operational Program-Oriented level (capacity strengthening, program management, and strategic analysis) to accommodate students with longer experiences but also prompt short-term student participants to think beyond their experience. After further revising and consolidating the CUGH domains and competencies, we proposed the following 11 domains:

1. Global Burden of Disease
2. Globalization of Health and Health Care
3. Social and Environmental Determinants of Health
4. Capacity Strengthening
5. Collaboration, Partnering, and Communication
6. Ethics
7. Professional Practice
8. Health Equity and Social Justice
9. Program Management
10. Sociocultural and Political Awareness
11. Strategic Analysis

Each domain included 2 key competencies, resulting in a 22-item learning assessment scale, which we called the Global Health Competency Self-Confidence Scale. As an example, the subcommittee identified Domain 1 as the Global Burden of Disease, and Competency 1a as the ability to "Describe the major causes of morbidity and mortality around the world, and how the risk for disease varies with regions."

To evaluate student experiences based on the newly defined domains and competencies, we converted each selected competency into a self-rated measure of confidence. The scale asks students to rate, for example, their level of confidence in such statements: "I can describe the basic causes of morbidity and mortality and their variations between high-, middle-, or low-income regions, and where the host community that I will be spending time with fits into the global picture." Reponses are rated using a 4-point Likert scale ranging from not confident at all (1) to completely confident (4). We found this approach to be consistent with scales used by behavioral scientists who employ Likert-interval levels of measurement.[20,21] In short, the Global Health Competency Self-Confidence Scale was designed to measure and compare the level of confidence of each student before and after a global learning experience.

We developed the Global Health Competency Self-Confidence Scale to measure and compare the level of confidence of students before and after undertaking a global learning experience.

Agreeing on common concepts and language is crucial when working across disciplines. For example, we distinguish between "confidence" as a personal belief in one's self and ability to succeed and "competence" as the knowledge and skills a learner possesses.[22–23] In many fields in medical and nursing education, there is a known discordance between the self-report of confidence (or self-efficacy) to succeed and competence in terms of knowledge and/or skills. The self-evaluation of confidence therefore is not intended to assess the possession of the requisite knowledge and skills, but rather promote reflection and analysis of practice. Asking a student to assess their confidence pre-exposure to placement can help identify areas of concern to address with the student. Students and educators may choose to develop additional materials and resources to help build student confidence in the areas they are likely to be most motivated to do so. A post-exposure assessment includes a more direct test of competence under the same domains. Knowledge and ability could be tested as self-report and confirmed through formal testing, such as objective structured practice observations.

METHODS

Stages of Validation of the Scale

Building on the work of Churchill[25] and Hinkin,[26] the scale-validation approach uses a 7-step process for designing valid and reliable scales:

Step 1: Item generation – The items were derived and amended from the published CUGH interprofessional global health competencies.[14]

Step 2: Content adequacy assessment – The content was determined by national and international experts who reviewed the consolidated items for content validity.

Step 3: Questionnaire administration – The scale was administered to 126 participants to test its validity and to make sure the questions were answered consistently. Similar studies have found that in most cases, a sample size of 100 observations should be sufficient to obtain an accurate solution in exploratory and confirmatory factor analysis.[27] The participants also completed another scale, the Global Health Competencies Survey (GHCS) 17-item subscale on knowledge and interest in global health and health equity,[28] to establish concurrent validity. This survey was

developed in 2011 and is considered a predecessor of the work undertaken by the CUGH Competency Subcommittee to expand and refine the competencies.[28]

Step 4: Construct validity – Exploratory factor analysis was undertaken to evaluate the performance of items and decide if they individually and collectively contributed to the aim of the scale. This determined the quality of the factor structure by statistically testing the significance of the overall model (e.g., distinction among scales), as well as the relationships among items and scales.

Step 5: Internal consistency assessment – After dimensionality of the scale was established, reliability was calculated using the commonly accepted measure for assessing a scale's internal consistency, Cronbach's alpha, which indicates how well the items measured the same construct. After the exploratory factor analyses had been conducted and all "bad" items were examined for removal, the internal consistency reliabilities for each item were calculated.

Step 6: Concurrent validity – Content validity (Step 2) and internal consistency reliability (Step 5) were examined to provide supportive proof of concurrent validity. Further evidence of concurrent validity was accomplished by examining the extent to which the scale correlated with other measures designed to assess similar constructs (convergent validity).

Step 7: Use – Use of the scale is discussed in more detail at the end of this article.

Measures

The GHCS 17-item knowledge and interest in global health and health equity subscale[25] was used in conjunction with the new proposed competency scale. The GHCS subscale uses a 3-point Likert scale rated from "not at all confident" to "very confident," and is reported as having good reliability and validity.[28]

Testing Participants

Paper copies of the study materials were provided in an envelope and distributed to students by an instructor. In total, 126 students participated in the testing process, initially completing the scale to test response consistency and the GHCS subscale to establish construct and criterion-related validity. Fifteen minutes proved to be more than enough time to complete both scales. The retest of the scale was repeated 2 days later by the same cohort of students. Assuming that no global experience was undertaken by the student in the intervening 48 hours, we expected their first and second answers to each scale item to match or be close. Students protected their privacy by choosing a unique number that only they would know but allowed the research team to match their test and retest results. Two points of demographic data were also collected: age and gender. Because the test sample size was relatively large, providing age and gender information did not lead to the identification of individual students. All scales were delivered to the principle investigator in a sealed envelope for data entry into an SPSS file.

Data Analysis

Exploratory factor analysis was performed to determine if items adequately contributed to the scale. Cronbach's alpha was used to determine the reliability of the scale, and a bivariate Pearson's correlation was used to determine test-retest reliability as well as concurrent validity.

Ethical Considerations

The University Human Research Institutional Research Board approved administering the scale to university students (approval 1627). A script was developed for faculty to introduce and gain consent with a cohort of university students as a sample of convenience. Consent was indicated by each student through their agreement to complete and submit the scales. To maintain confidentiality, a personal number was selected by each student and was used to match the test and retest.

RESULTS

Study Population

The student population was composed of 45.2% women and 54.8% men. The mean age of participants was 24.12 years, with a standard deviation of 2.13 years and range of 22 to 37 years.

Content Validity

The scale was devised using CUGH interprofessional global health competencies.[14] These competencies had been evaluated in a number of settings as discussed in the introduction of this article. Once the items for the scale had been selected, a panel of 6 experts—3 global health practitioners with 15 to 20 years of experience each and 3 academics who were CUGH members with extensive experience developing and leading global health education programs in low- and middle-income countries—were asked to confirm

A panel of 6 experts were asked to confirm the consistency of the scale's items with CUGH competencies.

if the items were consistent with the CUGH competencies. All agreed this was so.

Face Validity

The same panel of experts examined the first draft of the scale to establish the clarity of wording, the suitability to the target student audience, and the general layout and style of the scale. With minor amendments, the panel responded favorably to each domain and item on the scale and made the decision to proceed.

Construct Validity

A principal component analysis was run on the 22-item scale. The suitability of principal component analysis was assessed prior to analysis. Inspection of the correlation matrix showed that all variables had at least 1 correlation coefficient greater than 0.3. The overall Kaiser-Meyer-Olkin (KMO) measure was 0.85 with individual KMO measures all greater than 0.7—classifications of "middling" to "marvelous" according to Kaiser.[29] Bartlett's Test of Sphericity was statistically significant (chi-square=1701.947; degrees of freedom=231; $P<.001$), indicating that the data were likely factorizable.[30]

Although principal component analysis revealed 5 key components, visual inspection of the scree plot showed only 4 met the interpretability criteria.

Principal component analysis revealed 5 components that had eigenvalues greater than 1, which explained 35.0%, 13.4%, 11.1%, 5.0%, and 4.7% of the total variance, respectively. Visual inspection of the scree plot indicated that 4 components met the interpretability criterion and should be retained.[31]

The Global Health Competency Self-Confidence Scale was shown to have concurrent validity when compared with a related scale.

The 4-component solution explained 64.6% of the total variance. A varimax orthogonal rotation was employed to aid interpretability, with the rotated solution exhibiting "simple structure."[32] The interpretation of the data was consistent with the construct the scale, which was designed to measure with strong loadings for ethical, professional, and collaborative partnership items on component 1, capacity strengthening and planning items on component 2, structural and social determinants of health items on component 3, and strategic analysis items on component 4. Component loadings and communalities of the rotated solution are presented in Table 1. The factor analysis was re-run with the second completion of the scale and the same components were produced.

Internal Consistency

The scale showed excellent reliability on first administration (Cronbach's alpha [α]=0.92) and on second administration (α=0.93). Taking each component as a subscale, the reliability was excellent (ethical, professional, and collaborative partnership, α=0.88; capacity strengthening and planning, α=0.88; structural and social determinants of health, α=0.83; and strategic analysis, α=0.90). There was no difference in Cronbach's alpha with gender or age. Test-retest reliability was excellent (r=0.693; $P<.001$). There were no floor or ceiling effects present in the sample. Overall, participants were generally confident of their ability to work in global health situations. The mean and standard deviations from each competency item are presented in Table 2.

Participants were reported being "somewhat" to "mostly" confident, with a mean for all items of 2.26 (range, 1.65 to 3.28). Participants were most confident in items related to professional and collaborative working.

Concurrent Validity

A Pearson bi-variate correlation between the scale and the previously validated GHCS subscale produced a high level of correlation (r=0.455; $P<.001$). In this study, the validated GHCS subscale had a Cronbach's alpha of 0.874; therefore, the new scale could be seen to measure the overall construct of the study.

DISCUSSION

We modified the CUGH interprofessional global health competencies to produce the 22-item Global Health Competency Self-Confidence Scale, which was shown to be reliable on single admission and test-retest. When compared with the GHCS 17-item knowledge and interest in global health and health equity subscale, the Global Health Competency Self-Confidence Scale was shown to have excellent concurrent validity. Finally, when the Global Health Competency Self-Confidence Scale was tested for factorability, it passed all necessary assumptions to perform an exploratory factor analysis. The initial extraction using principal component analysis revealed 5 components with eigenvalues above 1. However, using the visual inspection method of the scree plot, a 4-component solution was considered best.

Overall, exploratory factor analysis indicated that the competencies measured what they were designed to do. However, we suggest that the domains could be collapsed from 11 down to 4 components, as indicated in Table 1. Reducing the domains to 4 components does not diminish the importance of each domain; instead, it helps

TABLE 1. Exploratory Factor Analysis (Test 1)

	Global Components			
Domains	**Component 1: Ethical, Professional, and Collaborative Partnership**	**Component 2: Capacity Strengthening and Planning**	**Component 3: Structural and Social Determinants of Health**	**Component 4: Strategic Analysis**
D1. Global burden of disease				
D1.1			0.551	
D1.2			0.576	
D2. Globalization of health and health care				
D2.1			0.753	
D2.2			0.751	
D3. Social and environmental determinants of health				
D3.1			0.776	
D3.2			0.695	
D4. Capacity strengthening				
D4.1		0.629		
D4.2		0.555		
D5. Collaboration, partnering, and communication				
D5.1	0.793			
D5.2	0.811			
D6. Ethics				
D6.1	0.744			
D6.2	0.734			
D7. Professional practice				
D7.1	0.653			
D7.2	0.658			
D8. Health equity and social justice				
D8.1	0.486			
D8.2		0.713		
D9. Program management				
D9.1		0.700		
D9.2		0.723		
D10. Sociocultural and political awareness				
D10.1		0.772		
D10.2		0.687		
D11. Strategic analysis				
D11.1				0.801
D11.2				0.814

Extraction method: Principal Component Analysis. Rotation method: Varimax with Kaiser Normalization. Refer to Table 2 for a full list of the 2 competencies included under each of the 11 domains.

TABLE 2. Mean and Standard Deviations for Individual Items

Domains	Mean (SD)
D1. Global burden of disease	
D1.1 I can describe the basic causes of morbidity and mortality and their variations between high-, middle-, or low-income regions and where the population I will be spending time with fits into the global picture.	1.84 (.73)
D1.2 I can describe the efforts to reduce health disparities in global health and specifically for my population of study.	1.98 (.70)
D2. Globalization of health and health care	
D2.1 I can describe the major models or systems of health care and where my population of study fits in these systems and the effect it has on the health of the people.	1.71 (.72)
D2.2 I can describe the major trends and influences in the global availability and movement of health care workers in my study population.	1.65 (.63)
D3. Social and environmental determinants of health	
D3.1 I can list the major social, economic, and structural determinants of health, their effects on access and quality of health services, and their relationship to mortality and morbidity generally and specifically in my population of study.	2.09 (.76)
D3.2 I can describe how cultural context influences perceptions of health and disease generally and specifically in my population of study.	2.31 (.72)
D4. Capacity strengthening	
D4.1 I can collaborate with my host or partner organization to assess knowledge, skills, and resources needed to enhance the organization's operational capacity.	2.31 (.82)
D4.2 I can identify strategies to strengthen community capacity that may help reduce health disparities.	2.16 (.81)
D5. Collaboration, partnering, and communication	
D5.1 I am able to build trust, communicate, and work effectively with partners and within the team.	3.22 (.81)
D5.2 I am able to exhibit values and skills that demonstrate respect for and awareness of unique cultures, values, roles/responsibilities, and expertise of other professionals and groups who work in global health and with my population of study.	3.28 (.81)
D6: Ethics	
D6.1 I can demonstrate an understanding of and an ability to resolve common ethical issues and challenges that arise when working in diverse contexts, vulnerable populations, and low-resource settings.	2.86 (.81)
D6.2 I can demonstrate an awareness of local and national codes of ethics relevant to the environment of my study population.	2.64 (.90)
D7: Professional practice	
D7.1 I am able to articulate barriers to health and health care in low-resource settings locally and internationally.	2.53 (.80)
D7.2 I am able to adapt my discipline-specific skills and practice in this setting.	2.72 (.90)
D8: Heath equity and social justice	
D8.1 I am able to engage marginalized and vulnerable people/populations in making decisions that affect their health and well-being.	2.54 (.79)
D8.2 I am able to identify and evaluate the global economic trends, forces, and policies that influence global health indicators.	1.96 (.73)
D9: Program management	
D9.1 I am able to plan, implement, and evaluate an evidence-based program.	2.12 (.80)
D9.2 I am able to apply project management techniques throughout program planning, implementation, and evaluation.	2.19 (.80)
D10: Sociocultural and political awareness	
D10.1 I can describe the roles and relationships of the major entities influencing global health and development.	1.90 (.64)
D10.2 I am able to identify and evaluate potential causes (micro and macro) of marginalization and inequity related to global health.	1.96 (.76)
D11: Strategic analysis	
D11.1 I can conduct a community needs assessment.	1.94 (.76)
D11.2 I can conduct a situational analysis and design context-specific health interventions based on a situational analysis.	1.78 (.74)

Abbreviation: SD, standard deviation.

educators and curriculum writers to better target domains relative to their importance for their students. All original competency pairs fell into the original domains with the exception of Domain 8.1 "engagement in marginalized communities" and Domain 8.2 "identifying global trends." These domains are different, in that one is an action and the other is evaluative. A future rendition of the tool may drop both items or reword the items to match each other in terms of response style: e.g., both are evaluative, or both are action. However, we decided to move these items under the 2 new components they fell under: Domain 8.1 would move under the new Component 1 (ethical and professional practice) and Domain 8.2 would move under the new Component 2 (capacity strengthening and planning) as identified by the exploratory factor analysis.

The final 4 components generated were:

- **Component 1. Ethical, Professional, and Collaborative Partnership** – This is composed of 3 competencies and item 8.1 from the health equity and justice competency. These items represent aspects of global health practice either within disciplines or interprofessionally.
- **Component 2. Capacity Strengthening and Planning** – This is also composed of 3 competencies and item 8.2 from the health equity and justice competency. This component identifies the need to work collaboratively within communities while being aware of the local socio-political environment.
- **Component 3. Structural and Social Determinants of Health** – This is composed of 3 competencies, all 3 specific to the understanding of global health concerns in context to the local scene.
- **Component 4. Strategic Analysis** – This is composed of 2 competencies under the same name. This competency aims to ascertain an understanding of how to demonstrate change in global health practices.

In line with the principles of exploratory factor analysis, the intention is to reduce data to a smaller set of variables to explore the underlying theoretical structures of the phenomenon under scrutiny. Therefore, decisions made about grouping individual items is dictated by this process. In this case, the aim of the analysis was to understand how the competencies work together in a mutually inclusive manner that does not reduce the importance of each domain. The final solution described in the factor analysis indicates where each domain is important and with which domains this importance has an influence. For example, while Domain 5, Collaboration, Partnership, and Communication, now falls under Component 1, Ethical, Professional, and Collaborative Partnership, the domain continues to have the same level of importance as a standalone construct while influencing the ethics and professional practice domain. The presence of this domain in the component is to provide curriculum writers and education providers an opportunity to deliver the domains more effectively, ensuring students meet the competencies specific to their needs. This finding is supported by a large employers' study, which indicated that 85% believed such preparation was being poorly met especially in courses concentrating on nonclinical global skills.[33]

Workbook and Resource Manual

To accompany the scale, we created a workbook and resource manual based on the validated scale competencies to guide student learning. The content of the resource manual was drawn from the recently published CUGH Global Health Education Competencies Tool Kit but is organized to align with our scale.[34] The workbook directs students to investigate each competency item of the scale as pre-departure preparation. For example, the first domain, global burden of disease, asks students to:

1. Describe the basic causes of morbidity and mortality and their variations between high-, middle-, or low-income regions. Where does your host community fit into this global picture?
2. Describe efforts to reduce global health disparities and specifically for my host community.

The resource manual then links students to relevant sections of the CUGH Global Health Education Competencies Tool Kit.[34]

Because the validation process resulted in the consolidation of domains and competences into 4 components while also giving each component the ability to stand on its own, the workbook was organized accordingly. For example, under Component 1, Ethical and Professional Practice, students would be directed to focus on collaboration, partnering, communication, ethics, professional practice, health equity, and social justice, and the corresponding competencies in the Tool Kit resources.

The scale and workbook have been distributed to a number of universities worldwide that engage

The aim of the analysis was to understand how the competencies work together in a mutually inclusive manner that does not reduce the importance of each domain.

in global learning and are interested in collaborating on continuing research to further evaluate the scale and workbook.

Limitations

The obvious limitation of this study is in selection and reduction of items drawn from the 39 CUGH competencies to produce the 22-item scale. While a pragmatic approach was taken to consolidate and reduce the number for our purposes, the removal of items means that some specific competencies may not have been captured. For example, the CUGH Domain 3, Social and Environmental Determinants of Health, has a third competency that required students to be able to "describe the relationship between access to quality of water, sanitation, food, and air on individual and population health." Knowledge of this relationship may be a major factor in some global learning situations. However, in this case, we would expect students to address the relationship in their exploration of Domain 3.1, where they are directed to examine the social, economic, and structural determinants of health for their population of study. As acknowledged by Jorgest and colleagues, the CUGH interprofessional competencies are a work in progress and recommendations to develop and validate tools to assess outcomes are needed.[14] This was an aim of our project.

CONCLUSION

As the field of global health continues to expand, educators have an unprecedented luxury of selecting from educational and knowledge management products and resources that are freely and readily available.[35] With global academic collaboration at an all-time high, it makes sense to build on rapidly evolving practices, especially those related to standardizing competency evaluation. This study extends the work of CUGH, contributes to a further consolidation and refinement of competency groupings into components of global health education, and offers a scale to assess student learning. Instructors can develop programs to target specific learning objectives and direct students to 1 or more of components of study though the use of a workbook, learning resources, and assessment system. The scale also enables students to learn from their experiences and understand the breadth and depth of knowledge and skills required to be a competent global health practitioner, enabling them to adjust their learning focus to areas in which they are most deficient. Through the CUGH Tool Kit, they benefit from easy access to the wide range of learning resources amassed by global health experts.

With global academic collaboration at an all-time high, it makes sense to build on rapidly evolving practices related to standardizing competency evaluation.

This work can also play a role in accrediting global health programs by ensuring a common set of standard competencies are assessed. Considering that global health includes an examination of health across nations, the scale and materials can be used to guide local and national service learning endeavors and direct students to compare and contrast conditions around the globe.

We are currently involved in an evaluation study of the scale, workbook, and learning resources. A number of global health academics, CUGH members, and researchers from around the world have asked to use these materials and, in return, have been invited to submit their de-identified findings to a shared cloud-based repository so we can learn more about competency assessment and work together toward strengthening the field. For example, in a discussion about further engagement of host countries, CUGH has convened a competency assessment subcommittee, and we are developing observed structured clinical exams to address the self-confidence to action conundrum. It is an exciting time to be involved in global health education and practice. Contributors to the rapidly evolving science are to be commended on their generosity to share in the effort to develop first-class practitioners.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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ORIGINAL ARTICLE

Helping Babies Breathe, Second Edition: A Model for Strengthening Educational Programs to Increase Global Newborn Survival

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The revised neonatal resuscitation curriculum updates not only the science of resuscitation but also the educational and implementation approaches needed to further enhance neonatal survival, including promoting ongoing practice to retain skills and linkages with quality improvement initiatives.

ABSTRACT

Background: Helping Babies Breathe (HBB), a skills-based program in neonatal resuscitation for birth attendants in resource-limited settings, has been implemented in over 80 countries since 2010. Implementation studies of HBB incorporating low-dose high-frequency practice and quality improvement show substantial reductions in fresh stillbirth and first-day neonatal mortality. Revision of the program aimed to further augment provider and facilitator skills and address gaps in implementation with the goal of improving neonatal survival.

Methods: The Utstein Formula for Survival—Medical Science X Educational Efficiency X Local Implementation = Survival—provided a framework for the revisions. The 2015 Neonatal Resuscitation Consensus on Science and Treatment Recommendations by the International Liaison Committee on Resuscitation informed scientific updates, which were harmonized with the 2012 World Health Organization Basic Newborn Resuscitation Guidelines. Published literature and program reports, consensus guidelines on reprocessing equipment, systematic collection of suggestions from frontline users, and responses to a semistructured online questionnaire informed educational/implementation revisions. Links to maternal care were added. Draft materials underwent Delphi review and field testing in India and Sierra Leone. An Utstein-style meeting of stakeholders identified key actions for successful implementation.

Results: Scientific revisions included expectant management of infants with meconium-stained amniotic fluid, limitation of suctioning, and initiating and continuing effective ventilation until spontaneous respirations. Frontline users (N=102) suggested augmented simulation methods to build confidence and competence and additional guidance for facilitators on implementation. Users identified a need for sufficient practice during the workshop, systematized ongoing practice, and enough simulators for participants. Field trials refined approaches to self-reflection, feedback and debriefing, and quality improvement. Utstein meeting stakeholders validated the importance of quality improvement and use of data to improve outcomes.

Conclusions: The second edition of HBB provides a newer paradigm of learning for providers that incorporates workshop practice, self-reflection, and feedback and debriefing to reinforce learning as well as the promotion of mentorship and development of facilitators, systems for low-dose high-frequency practice in facilities, and quality improvement related to neonatal resuscitation.

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INTRODUCTION

Intrapartum-related events—also known as birth asphyxia—occur between the beginning of labor and the delivery of the placenta; they are a major cause of neonatal morbidity and mortality and the primary cause of intrapartum stillbirths.[1,2] Although neonatal resuscitation is an intervention that has the potential to save newborn lives and reduce injury,[3–5] widespread and effective implementation has been challenging. Helping Babies Breathe (HBB) is a global curriculum for neonatal resuscitation specifically designed to simplify and demystify the resuscitation steps.[6–8] The skills-

based curriculum focuses on enhancing birth attendants' understanding and basic resuscitation skills through active learning with simulation, emphasizing practice with peers to develop teamwork, good communication, and reflective learning with self-improvement. Indeed, HBB challenges the previous assumption that equated resuscitation with neonatal intensive care and instead promotes the idea that basic neonatal resuscitation should be available to every baby, wherever they are born.

The first edition of the HBB curriculum was developed by the Global Implementation Task Force, which was founded in 2006 and consisted of stakeholders brought together by the American Academy of Pediatrics (AAP) to develop a standardized, simplified neonatal resuscitation curriculum based on the same evidence as the Neonatal Resuscitation Program.[8–11] Informed by global expertise in education and neonatal care, the resulting educational program focused on active learning with simulation and pictorial materials. The curriculum, designed to harmonize with the World Health Organization (WHO) Basic Newborn Resuscitation Guidelines (then under revision) and the 2010 Consensus on Science and Treatment Recommendations (CoSTR) by the International Liaison Committee on Resuscitation (ILCOR),[12,13] underwent 2 rounds of Delphi review to build consensus between qualified external experts.[14] It was then field tested in Bangladesh, India, Kenya, Pakistan, and Tanzania before being revised and released.[9,10,15]

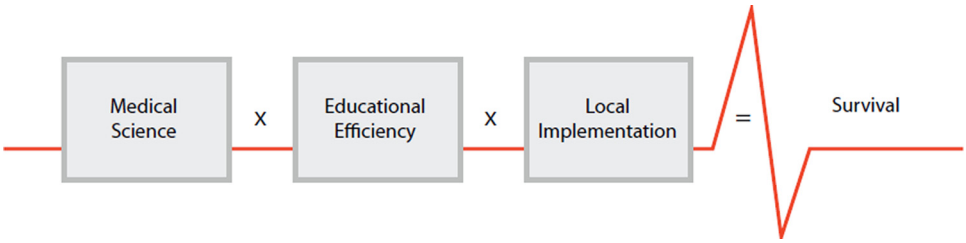
In 2010, a public-private partnership, the HBB Global Development Alliance (GDA), was created. The 5 founding member organizations—AAP, Laerdal, National Institute of Child Health and Human Development, Save the Children, and the United States Agency for International Development (USAID)—believed that by working together they could help reduce neonatal morbidity and mortality. These educational and neonatal care experts began to design a curriculum, develop implementation plans, and coordinate training efforts for an educational program to strengthen the knowledge and skills of birth attendants who care for mothers and babies in low-resource settings.[9] Since rollout of the program in 2010, HBB workshops have taken place in more than 80 countries—with the curriculum translated into 27 languages—and an estimated 500,000 providers trained.[9,16] Before and after studies of regional or facility-based HBB training in Africa and Asia have shown substantial decreases in very early neonatal mortality, stillbirth rates, and asphyxia-related morbidity and mortality when provider education was coupled with facilitated ongoing practice, quality improvement assessments, and local ownership of the program that integrated the content into routine clinical practice.[17–20]

While these successes were celebrated, analysis of the published literature and the experience of implementing partners of the HBB GDA highlighted elements of the educational package and implementation approach that needed strengthening. Without systematic, integrated, and sustained activities, the trainings by themselves were unlikely to result in longstanding change,[11,16,21] and the first edition of the HBB curriculum did not contain guidance on these issues. For example, case reports describing the implementation of the HBB curriculum in Bangladesh and Malawi demonstrated improvements in the provision of neonatal resuscitation, but a lack of improvement in neonatal mortality when the program was implemented widely, but incompletely, without a plan for ongoing exposure, practice, and quality improvement efforts.[11,22] Conversely, concerted efforts to include ongoing practice and quality improvement assessments in studies performed in Africa and Asia demonstrated further reductions in neonatal mortality after HBB training.[18,20,23] Lessons learned during the first 5 years of program implementation indicated that adaptation of materials for local contexts must be facilitated and systematic ongoing practice—extending beyond the duration of a training workshop—should be embraced.[18,24,25] Furthermore, achieving impact at the population level requires integration of the curriculum into the regional health system, with integration of adapted educational materials into comprehensive preservice and in-service education packages, mechanisms for supply and logistics management, and linkages with ongoing quality improvement initiatives to effect change and document outcomes.

Evolving evidence and further acknowledgment of the challenges of implementation and sustainability were incorporated into the second edition of the HBB curriculum and are outlined here. The goals of this process were to further improve neonatal care by promoting the most current science, augmenting educational effectiveness, and suggesting expanded implementation strategies. Through documenting the process by which the inputs for revision were incorporated into the new edition, we intend to provide a model

Since rollout of the Helping Babies Breathe program in 2010, workshops have taken place in >80 countries, with an estimated 500,000 providers trained.

FIGURE 1. The Utstein Formula of Survival



Adapted with permission from Søreide et al.[27]

for continuous improvement of perinatal education programs.

METHODS

Inputs for Revisions

In 2015, an Utstein-style meeting of key stakeholders focused on previous implementation of the HBB curriculum to determine what key actions were essential for effective dissemination of educational programs for neonatal and maternal survival, such as the Helping Babies Survive and Helping Mothers Survive programs. The framework for improving survival worldwide is summarized in the Utstein Formula for Survival, based on the consensus of international experts, which states that survival is the product of medical science, educational effectiveness, and implementation (Figure 1).[26,27] Although the development of the first edition of the HBB curriculum focused on the design of the educational program, adding the components of the Utstein Formula for Survival to the second edition helped provide a framework for identifying changes that resulted from an additional focus on enhanced educational effectiveness, skills retention, and the importance of coordination with national resources and leadership. The framework also identified 2 key challenges: sustainability and wide implementation. The inputs that aided the revisions are described in further detail below.

Resuscitation Science

The goal of the HBB curriculum is to bring the latest in resuscitation science to low-resource settings. To that end, the 2015 ILCOR CoSTR was formed to provide a system for evaluating scientific updates.[28] For the first time, the 2015 ILCOR CoSTR used the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) approach for evaluating evidence to rate guidelines recommendations, based on the strength of the evidence.[29] The most recent changes in resuscitation processes identified by the 2015 ILCOR CoSTR review were further harmonized with the revised WHO *Guidelines on Basic Newborn Resuscitation*.[12]

During the evaluation process, the committee also reviewed the evidence supporting delayed cord clamping. New experimental evidence and human data from low-resource settings demonstrated increased neonatal morbidity and mortality with cord clamping prior to onset of respiration.[30–32] Feedback from user experience revealed a frequent overreliance on suctioning, whether the infant was breathing or not; delays in the initiation of ventilation; and frequent interruptions in ventilation when the infant was not yet breathing.

The committee also recognized that a single provider may often be caring for the mother–infant pair and that little evidence was available on how to co-manage the 2 patients if both were critically ill. Improved linkages between neonatal care and maternal care were made, including, for example, the preparation of oxytocin before birth.

Researchers in Kenya expressed concern that improper or incomplete disinfection of resuscitation equipment was a contributing factor in spreading infection.[33] They reported that non-HBB-trained personnel were often involved in reprocessing the equipment for future use, which was being done improperly, potentially affecting the safety and functionality of the equipment.[33] They noted that a workable field guide did not exist that would provide recommendations about reprocessing of used resuscitation equipment.

Educational Effectiveness

The dissemination of the HBB curriculum, as noted earlier, was global, with numerous facility-

based studies of doctors, nurses, and midwives indicating that uptake of both knowledge and skills improved immediately after an HBB workshop.[15,24,34–36] However, published reports also mentioned the deterioration of skills after HBB workshops, which mirrored the experiences of other resuscitation training programs.[24,37,38] For the effective performance of these lifesaving skills to impact neonatal mortality and stillbirth rates, providers need to be able to perform basic resuscitation and bag-mask ventilation, if needed, within "The Golden Minute" after birth.

Numerous studies since the release of the first edition of the curriculum indicate that a system of ongoing practice or refresher training can be effective for the maintenance of resuscitation skills.[39] Many key lifesaving skills, such as bag-mask ventilation, require more practice time, focus, and supervision than could be provided during the usual 1-day workshop.[24] While the exact frequency of practice and refresher training required to maintain proficiency for each type of provider is unknown, it is clear that ongoing low-dose high-frequency practice can improve performance and competency.[18,23,25,40,41] Importantly, the incorporation of debriefings and case reviews after real-life delivery room situations, and a quick review of bag-mask ventilation in low-dose high-frequency sessions, for example, at the beginning of a shift, improved early neonatal mortality and decreased stillbirth rates in facility-based settings in Africa and Asia.[18,23]

Studies also indicated that it was important to consider past experience of the providers, as different cadres of providers such as physicians likely had some past experience with neonatal resuscitation training and simulation, whereas nurses did not.[41] Furthermore, researchers noted differences between who was able to perform these skills in real-life scenarios, despite similar performances during simulation exercises. The concept of ongoing practice, even when studied in rural providers—such as village midwives and birth attendants—1 year after their initial HBB training, showed retention of basic resuscitation skills with ongoing practice and/or refresher trainings and reductions in fresh stillbirth and early neonatal mortality rates.[38,42,43]

Finally, additional input from frontline users also noted that the skills assessments—in particular, the objective structured clinical evaluations (OSCEs)—were cumbersome, confusing, and potentially biased. These assessments were often used in both summative and formative evaluation but were not always implemented in a learner-focused fashion, which allows learners to self-reflect and learn from their experience.

Implementation and Sustainability

After gathering information from published literature and program reports, the HBB GDA published a summary of the first 5 years of HBB implementation, with a clear message that gaps in quality of care would need to be overcome by more than just additional or continued provider training.[11] To that end, USAID and WHO designed frameworks for characterizing gaps in quality of care for mothers and babies and strategies to overcome the gaps in care.[44,45] The WHO framework described 6 strategic areas where evidence-based approaches could guide interventions to improve care, including the development of clinical guidelines, standards of care, effective interventions, measures of quality of care, relevant research, and capacity-building practices.[45] The newly formed Quality of Care Network, linked to the WHO framework, focuses on the tenets of quality, equity, and dignity to drive quality of care and access to care for all.

Lifesaving skills, such as bag-mask ventilation, often require more practice time, focus, and supervision than can be provided in a single-day workshop.

Themes of effective implementation included linking workshops to existing health care programs and leaders in order to promote local ownership and planning for training-of-trainers cascades, with an emphasis on early exposure through preservice education. The Utstein-style meeting formulated 10 essential action points for national dissemination and implementation of the Helping Babies Survive and Helping Mothers Survive program materials and training (Box).

To gather additional perspectives from frontline HBB users, we developed a 59-question

Pilot testing of Helping Babies Breathe 1st Edition in Dar es Salaam, Tanzania. © 2010 Eileen Schoen/American Academy of Pediatrics.

BOX. Essential Action Points for National Helping Babies Breathe and Helping Mothers Survive Implementation

1. At the country level, establish a maternal, newborn, and child health alliance with public, private, and nongovernmental partners
2. Form a functional working group for advocacy, planning, training, and monitoring at the country level; through the working group, identify gaps in the current system, establish performance standards, set specific goals, and develop a financial plan to implement and sustain the program(s)
3. Develop a plan for nation-to-facility levels training, which achieves high-quality coverage of providers in both public and private facilities
4. Provide appropriately adapted learning materials, equipment, and supplies simultaneously with training
5. Identify and support local leaders and champions
6. Set up local systems for frequent, brief refresher training, debriefing, and audits
7. Support the function of facility-level perinatal quality improvement teams
8. Collect and report local data on a standardized set of indicators of basic processes of care and patient outcomes
9. Develop a system for looped reporting and feedback to/from all levels of the health system and the working group
10. Engage and empower health care providers, famlies, and the broader community in the initiative

Reproduced from Ersdal HL, Singhal N, Msemo G, et al (2017).[26]

semistructured online survey. The invitations to participate were sent via email, and the online survey generated 102 responses. The primary respondents were physicians (65%), professionals based in North America (77%), and global HBB facilitators (93%). When asked about the most important change needed to make sure all babies receive help to breathe, respondents answered better confidence and skills in those trained (66%), rather than training greater numbers of providers (33%). When asked about the 3 most important ways to ensure that providers could perform their skills, respondents identified sufficient time for practice during the workshop (91%), enough mannequins to reach the goal ratio of 1 mannequin per 2 participants (54%), and a system for ongoing practice after the workshop (87%). To better support HBB facilitators, respondents ranked facilitating the first course with experienced trainers (68%), improving ways to assess that learners have the required skills (64%), and more instruction/practice on how to facilitate the course (51%) as their 3 highest choices.

Respondents identified sufficient time for practice during workshops and a system for ongoing practice after workshops as key ways to improve provider skills.

Delphi Review and Field Trials

The draft materials underwent Delphi review by 20 individuals recruited from frontline users and program managers. Consistent messages from Delphi reviewers included the need to strengthen facilitator advice before, during, and after the workshop; to emphasize systems of ongoing practice and quality improvement after the workshop; and to more strongly link HBB with the Helping Mothers Survive suite of programs. Further inputs from the maternal care community suggested that elements of maternal care could be integrated within HBB, recognizing that care for the mother and baby is often the task of a single provider.

A revised version of the materials underwent field testing in India and Sierra Leone. In India, experienced master trainers, familiar with the first edition materials, and novice participants were trained with the new materials. In Sierra Leone, a group of novice participants was trained to be master trainers, and then observed as they trained a group of providers. At both sites, focus group discussions were performed to obtain qualitative feedback about the new materials and the overall educational program. The interviews were audio recorded, transcribed, and then subjected to thematic analysis by independent reviewers.

Ethical Considerations

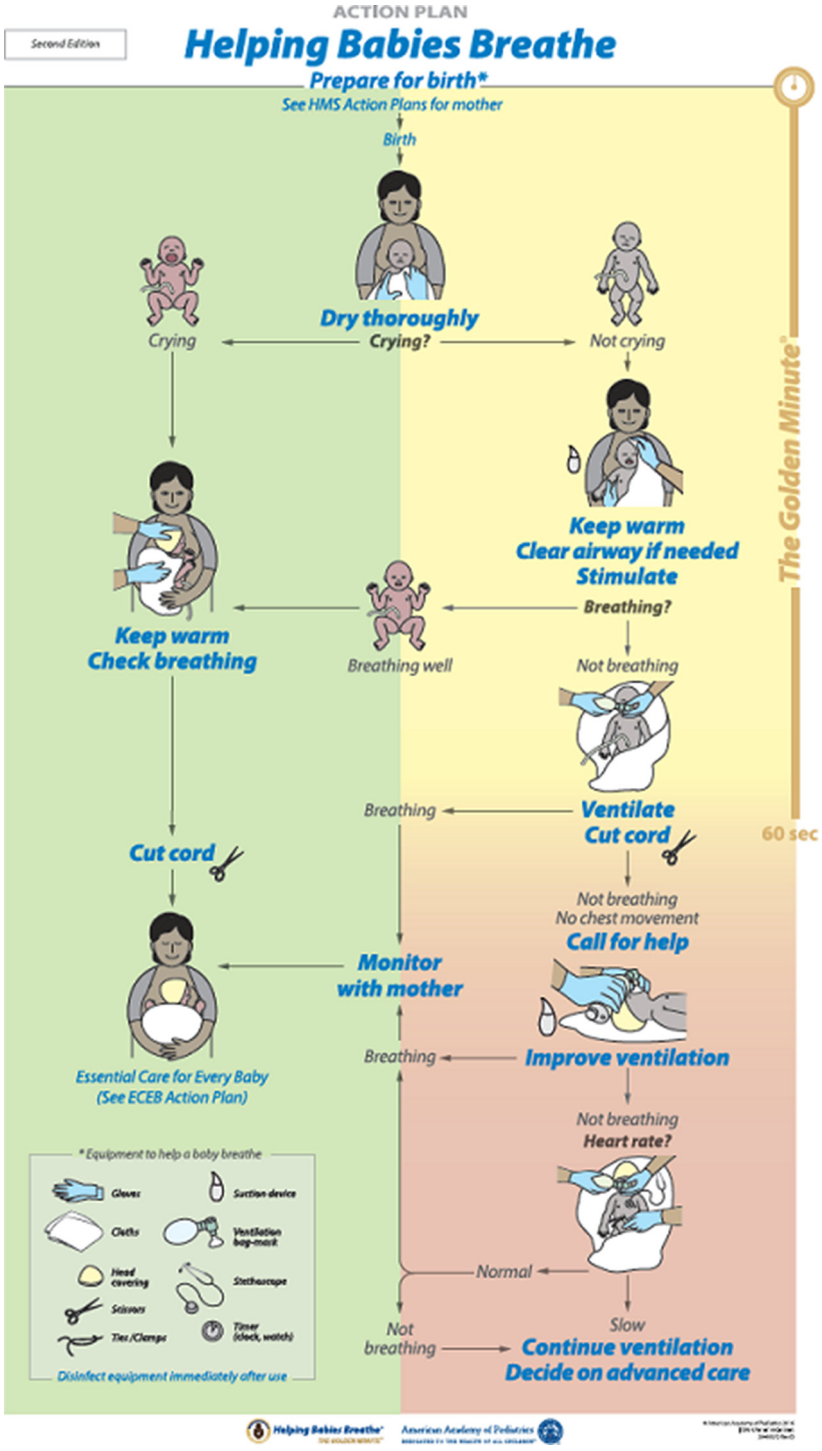
Ethical approval for the semistructured survey was obtained from the Cincinnati Children's Hospital Medical Center Institutional Review Board. For the India field trial, ethical approval was obtained by the Colorado Multiple Institutional Review Board and the Institute Ethics Committee of the All India Institute of Medical Sciences, in New Delhi, India. Ethical approval for the field trial in Sierra Leone was obtained from the Committee for the Protection of Human Subjects at the Theodore Geisel School of Medicine.

RESULTS

Resuscitation Science

A summary of the differences between the first and second editions is available on the Helping Babies Survive website (hbs.aap.org) (Supplement).The scientific changes identified in the 2015 ILCOR CoSTR[28] informed new recommendations in the second edition of the HBB action plan (Figure 2). New recommendations included that no suctioning

FIGURE 2. Helping Babies Breathe Second Edition Action Plan



Abbreviations: ECEB, Essential Care for Every Baby; HMS, Helping Mothers Survive.

Source: Niermeyer S, Kamath-Rayne B, Keenan W, Little G, Singhal N, Visick M, eds. (2016).[7] Reprinted with permission from the American Academy of Pediatrics.

New recommendations focus on drying and stimulating babies immediately after birth regardless of the presence of meconium-stained fluid, which reduces the number of babies requiring bag-mask ventilation.

is needed before drying babies born through meconium-stained amniotic fluid, whether the babies were vigorous or not.[28] In particular, attention to drying and stimulating the baby after birth resulted in fewer babies requiring bag-mask ventilation.[23,46] The second edition further deemphasized the use of oropharyngeal suctioning overall, and stated clearly that it was not needed for infants unless they failed to cry after thorough drying and secretions were seen in the airway. Given the strong evidence for delayed cord clamping, it continued to be incorporated into the second edition action plan (Figure 2). However, a new option was included to initiate ventilation prior to cutting the cord,[30] with the advice that a facility should determine in advance how they plan to sequence these events, depending on the number of providers at a birth and their ability to ventilate the baby on or by the side of the mother. Similar to the seventh edition of the Neonatal Resuscitation Program, which is also based on the 2015 ILCOR CoSTR, the second edition action plan emphasized providing effective ventilation, with rapid assessment of chest movement and initiation of corrective steps to improve ventilation.[7]

Finally, to provide recommendations on disinfection and reprocessing of equipment, PATH conducted an evidence-based review of reprocessing basic neonatal resuscitation equipment in resource-limited settings (Supplement).[47] In the absence of sufficient available evidence, the organization made recommendations based on best available evidence at the time and, when evidence was not available, selected experts from the Neonatal Resuscitation Working Group of the United Nations Commission on Life-Saving Commodities for Women and Children to come to a consensus opinion. These recommendations included steps for preparation, pre-disinfection, high-level disinfection or sterilization, and post-disinfection storage of equipment until next use. Second edition materials that support the new recommendations include a new job aid that presents the steps in a pictorial fashion[48] and the action plan that specifically recommends that providers "[d]isinfect [equipment] immediately after use" (Figure 2).

Educational Effectiveness

As a result of the studies showing that ongoing practice was required to retain resuscitation skills, the second edition of the HBB curriculum extends the educational scope of the program beyond a single training to a system of ongoing practice with peer/near-peer support in order to empower providers to change behavior. Birth attendants articulated the need to be equipped with not only technical skills but also a way of reflecting on their own actions and interacting with peers to improve performance.[32] A page in the second edition facilitator flip chart is devoted to a discussion of devising a system of ongoing practice after an initial HBB workshop (Supplement).[7] Given the positive effect of debriefings and case reviews after difficult resuscitations, these activities were incorporated as advice toward building the system of ongoing practice. Developing this kind of system was also tied to the concept of supportive supervision that HBB facilitators must provide after the conclusion of an HBB workshop. Low-dose high-frequency practice, associated with decreases in early neonatal and stillbirth mortality, is encouraged. New facilitators are empowered to mentor their learners and leadership at health facilities to oversee the establishment of a system for practice and to supervise peer-to-peer support during practice. Stronger advice is provided for facilitators for this new expanded role.

Further revision of the OSCEs included adding 5 questions that prompt HBB provider to self-reflect on their performance, formulate a plan for improving their behaviors or practices for the next resuscitation, and receive feedback from peers or facilitators. In this way, the OSCEs became more learner-centered and could be used as both a summative and formative evaluation of performance.[49] These questions also serve the same purpose when used after actual resuscitations.

Implementation and Sustainability

Given the broader emphasis on implementation, quality improvement, and linkages to existing health care systems as well as the expanded role of facilitators to mentor and oversee these actions, the second edition provides additional advice for the facilitator. Each page in the facilitator flip chart has background information and educational advice to guide the facilitator in techniques for active learning.[7] The new flip chart emphasizes local implementation with a focus on what the facilitator needs to know and do before, during, and after a course (Supplement), provides a timeline of actions a facilitator should perform when planning a course, and strongly encourages facilitators to integrate their workshops within local health care programs as they plan a training-of-trainers cascade. The flip chart stresses the importance of building and maintaining good relationships with existing

in-country programs that already are working toward reducing newborn deaths, as they will be crucial to achieving a broader coverage of skilled birth attendance and sustained implementation. Furthermore, the flip chart serves as a guide to better support facilitators, who now find themselves in a potentially expanded role, not only enabling learning but also facilitating linkages with clinic leadership for ongoing practice and quality improvement efforts within health facilities.

Anecdotally, a typical HBB course concludes with much enthusiasm about the new concepts learned and how these will be implemented in the workshop participant's home facility. Two pages in the second edition were designed to harness and channel provider enthusiasm into specific steps they can incorporate into their facility in order to improve care. A page entitled "Commit to making a difference" uses the revised action plan to point out potential process and outcome indicators that can be used to track improvement (Supplement). It was designed to introduce the process of quality improvement and link neonatal resuscitation to institutional or health system improvement initiatives, without using the daunting jargon that typically accompanies implementation science. The participants are challenged with 3 questions: "What are you going to do differently?" "What will you no longer do?" "How are you going to make these changes happen?" Finally, the flip chart includes a small group exercise where participants can review the information they record on each baby born in their facility, identify potential steps they can take to improve care, and gain insight into how to track whether the changes were successful.

To further aid in accessibility, the teaching materials—in multiple translations—are available online and freely downloadable at hbs.aap.org. Recognizing the difficulty in obtaining and/or printing new batches of teaching materials, the AAP has made available advice on how local providers can adapt their first edition HBB materials to teach the updated concepts. Given the expanded role of facilitators, the AAP created a webinar (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/helping-babies-survive/Pages/Webinars.aspx) and Global Health Media Project (globalhealthedia.org) produced videos to further promote, educate, and support ongoing mentorship and oversight for systems of practice, quality improvement, implementation, and updated resuscitation practices. Furthermore, AAP and Jhpiego collaborated on a set of implementation briefs that discuss the guiding principles for implementing the Helping Mothers Survive and Helping Babies Survive programs together in a twinned approach, including a focus on competency, simulation, and case-based learning, appropriately spaced brief periods of content delivery, team-focused and facility-based training, ongoing practice of skills after initial training, peer facilitation of practice, results tracking, and comprehensive quality improvement efforts to change service delivery.[50]

The flip chart emphasizes that facilitators should enable learning but also facilitate linkages with clinic leadership for ongoing practice and quality improvement.

Delphi Review and Field Trials

Given that frontline birth attendants often care for both the mother and the newborn, Delphi reviewers called for better integration of care between the mother and infant. The second edition action plan (Figure 2) explicitly acknowledges that maternal and neonatal care are part of the same sequence by including references to the Helping Mothers Survive program and to preparing oxytocin in the "Prepare for birth" section.

Of the 24 participants in the India field trial, 22 felt well-prepared to be a facilitator after the course.

The India field trial, which occurred at the All India Institute of Medical Sciences in New Delhi in June 2016, involved a group of 6 participants with prior training in the first edition HBB curriculum and 18 novice participants. Asking the 3 questions about the "Commit to making a difference" page solicited many answers to identify gaps in care that could be improved. Of the 24 participants, 22 felt well-prepared to be a facilitator after the course. Thematic analysis from qualitative interviews from 3 focus group discussions revealed several strengths of the revised curriculum, with the most effective key themes being the interaction with facilitators, workshop structure, quality improvement, and course content (Table). Participants liked the course emphasis on hands-on learning, rather than lectures, and felt that the small group size allowed participants more time to practice skills and observe and learn from each other's mistakes. They noted that small groups allowed for more personalized interaction with the facilitator, who then was able to give each participant genuine feedback, and felt this made a huge difference in the uptake of the material. The participants commented that the facilitators were able to handle multiple groups at once, provoke discussion, and receive constructive feedback. Further strengths included the new addition of instruction on quality improvement, which now challenged participants to reflect on their own practices and consider how they could improve. They found the quality improvement material empowered individuals to see what they could do to bring change to

TABLE. Key Training Themes in Qualitative Analysis From Helping Babies Breathe Second Edition Field Testing in India

Themes	Subthemes	Selected Comments
Most Effective Themes		
Facilitators	Provoke discussion Feedback One-on-one interaction	"The facilitator could give feedback, genuine feedback."
Workshop structure	Emphasis on doing rather than lecturing Small group size Time for practice, observation, and learning from each other's mistakes Enough equipment for everyone to practice with Networking with others outside of their area to discuss their practice similarities and differences	"I think it uses everybody's time more effectively. I think working in small groups . . . that was the beauty of the program."
Quality improvement	Reflection of each individual's practice and how to improve Worked well with rest of workshop structure	"[B]ecause we train so many people, and we impart knowledge and skills, and it is individual improvement which is looked at. That session for the first time, looked at the individual and what he/she will do to bring change to their unit."
Content	Clear and concise presentation of information Action plan was a helpful summary Flip chart serving as a written guide for facilitating	"Planning of the flip chart and implementation guide has been incorporated. That was the one thing which everyone wanted. While you are organizing and conducting a workshop, what you need to do, and what our facilitators should do, is now written."
Least Effective Themes		
Content	Suggestive or ambiguous language such as "may" or "could" Time to read and review material prior to the course Complexity of content for peripheral clinics	"If it is meant mostly for peripheral settings, where resources are scarce, and I think the messages have to be direct and loud, that message is not obvious. Because you can say from this what is most important? It doesn't strike."
Format	Presentation of material (color coding, font size, binding of flip chart)	
Integration	How to ensure implementation at facility after training Skills would not be maintained unless practiced and refresher courses available Administrative support of the program at their facility Buy-in from local leaders	"Otherwise we go through the same cycle of doing the workshop, but having no impact." "There has to be some time, some kind of timeline, that every day or alternate day, or once a week they have a practice session of this duration. And the unit in charge should be made responsible for this action."
Unrealistic expectations	Difficult to implement with low resources Supply chain Facility where workshop held versus reality in periphery Overemphasis of skin-to-skin care Concerns about resources and space Lack of experience with quality improvement	"[How to do skin-to-skin care] is all very vague, and therefore it may not be taken up well. So more clarity on that and the pictures need to be done." "Quality is considered a very special thing. It is something that is a luxury for people who have a lot of resources. This is their mindset. Because in a source limited situation, quality cannot be done. This is the mindset. So how to change that mindset?"

their facility. Even so, participants were concerned that some individuals in peripheral clinics may not see the value in quality improvement, because quality was perceived as a luxury that was only for places that have the resources to effect change. Participants felt that the content was presented and displayed in a clear and concise manner, and that the flip chart contained more guidance for facilitation and more instruction on how to organize and conduct a workshop.

The Sierra Leone field trial occurred in August 2016 at Kabala District Health Management Facility in Koinadugu district and consisted of 24 participants from nearby facilities with no prior exposure to the HBB curriculum. Participants were professionally diverse and included midwives, public health nurses, hospital matrons, a community health officer, and maternal and neonatal health aides. The training was conducted in 2 stages, with 12 participants learning the HBB

curriculum in each stage. Four participants in the first stage were selected to become master trainers, who subsequently trained the remaining 12 participants in the second stage. Following the trainings, written evaluations were administered and participants were invited to join focus group discussions. Written evaluations demonstrated that the participants valued hands-on practice, small-group discussion, and interaction with the facilitators. In focus group discussions, participants noted that certain common practices would be reevaluated, such as routine suctioning and emphasis on resuscitation with chest compressions. New master trainers felt comfortable using the materials to impart the knowledge and skills to their learners, but they felt that giving feedback was a skill they needed to improve, and they noted that their learners needed to become accustomed to feedback as part of the learning process. Observations of AAP master trainers showed that these new master trainers from Sierra Leone reverted back to lecturing rather than facilitating discussion about the newly included topics of quality improvement and "what the facilitator needs to know and do." The new master trainers themselves noted that more time was needed after the initial HBB workshop to better understand these concepts.

Final Revisions

After the field trials, the inputs were all critically reviewed by program leadership. Careful language had to be chosen to convey the role of suctioning and to stimulate discussion and an evidence review regarding equipment reprocessing. While the quality improvement content was well received and the ideas and energy toward quality improvement were self-initiated after workshop, the concepts needed to be further simplified and further coaching was considered beneficial to help accelerate the work. Additional input from global leaders and implementers was used to strengthen the recommended advice for facilitators before, during, and after the workshop to make linkages with existing health care systems, plan for systems of ongoing practice, and engage in quality improvement.

Field testing of Helping Babies Breathe 2nd Edition with MNCH aides in Kabala, Sierra Leone. © 2016 Erick Amick/American Academy of Pediatrics.

DISCUSSION

The global community must remain committed to introducing practices that will accelerate the reduction of overall neonatal mortality in order to meet the goals of the Every Newborn Action Plan.[21] These goals include achieving national neonatal mortality rates of less than 10 neonatal deaths per 1,000 live births with the aim of achieving global neonatal mortality rates of less than 7 neonatal deaths per 1,000 live births, all by 2035.[21] Despite all efforts to decrease neonatal mortality, recent data show that neonatal mortality has declined at a slower rate than overall childhood mortality, which has resulted in neonatal mortality now accounting for 46% of overall under-5 childhood deaths.[51]

Neonatal resuscitation is an important intervention with the potential to save newborn lives. HBB addresses not only the science of resuscitation but also the key steps to improve educational efficiency and health care delivery that are essential to improving neonatal survival. HBB has been combined with the Essential Care for Every Baby, Essential Care for Small Babies, and Improving Care for Mothers and Babies curricula

New master trainers felt that giving feedback was a skill they needed to improve and something learners needed to become accustomed to.

By combining HBB, Essential Care for Every Baby, Essential Care for Small Babies, and Improving Care for Mothers and Babies curricula, a single suite of Helping Babies Survive programs was created to address the needs of both mothers and babies.

to create a suite of Helping Babies Survive programs.[52–54] The Helping Babies Survive programs use similar effective educational approaches that emphasize facilitated learning and promote continued practice and quality improvement to further enhance survival and decrease neonatal morbidity.[52–54]

The process for creating the second edition of HBB included reflection that the impact of the program encompassed more than just medical science and extended to the other 2 components of the Utstein Formula for Survival—educational efficacy and local implementation. Since the release of the first edition, gains in newborn survival have been achieved and essential lessons learned regarding the importance of ongoing practice for retention of skills and quality improvement to enhance and ensure evidence-based practices were occurring at the individual and facility levels. Further feedback from front-line users have been incorporated to make the educational program more accessible and provide guidance to facilitators, program managers, and policy makers on the importance of incorporating interventions such as quality improvement and systems of ongoing practice for maintenance of resuscitation skills.

The challenge now is to ensure that the updated science and the concepts of ongoing practice and quality improvement reach all health workers attending deliveries and that the materials continue to be easily accessible to all. Since the release of the first edition of the HBB curriculum in 2010, an impressive number of providers around the world have been trained in the skills of basic neonatal resuscitation. While broad coverage and widespread dissemination are still essential, the second edition emphasizes that continued follow-up, ongoing practice, and quality improvement are critical to improving outcomes and further decreasing neonatal mortality. The AAP remains committed to ensuring the most up-to-date recommendations are available to all users; the AAP hosts the Helping Babies Survive website (hbs.aap.org) where downloads of the updated HBB materials—in addition to the other Helping Babies Survive curricula—are freely available as well as information sheets that describe how to adapt first edition materials to stay current with the most recent recommendations. National health leaders and ministries can use the materials to update national clinical guidelines to reflect the most recent resuscitation science, as these are highlighted on the website.

The expanded role for facilitators also deserves further attention; their efforts at catalyzing behavior change in the areas where they are working begin with facilitating an HBB workshop and continue as they support practitioners to maintain their skills after the workshop is over. HBB facilitators now work with local clinical leadership to establish a system for ongoing mentorship, committed supervision, and policies that support neonatal resuscitation training as an organizational routine. Additional tools to assist facilitators are under development by the AAP Helping Babies Survive Planning Group.

The Helping Babies Survive programs have demystified some of the practices related to newborn care and made them easily accessible to local providers all over the world. This innovative model of education has successfully transmitted current resuscitation science and has expanded to address provider behavior change and delivery system quality improvement. The capacity to change patient outcomes has been demonstrated in both small- and large-scale trials. The programs have achieved many successes, including champions who have created ongoing systems of practices at peripheral facilities, country facilitators who have originated national training-of-trainers cascades, academics and clinicians who have included Helping Babies Survive programs in preservice curricula, nurses and midwives who have been empowered to improve care, and researchers who have created data collection systems to monitor the success or challenges to implementation.

However, in order to truly impact neonatal mortality, additional steps need to be taken to address sustainability in order to make high-quality effective neonatal resuscitation a permanent part of the health system. Achieving impact at the population level will require integration into the national health system, with incorporation of adapted educational materials into comprehensive preservice and in-service education packages, mechanisms for supply and logistics management, and linkages with quality improvement initiatives to effect change and document outcomes. Furthermore, neonatal resuscitation is only one aspect of overall essential newborn care. In order to reduce neonatal mortality, improved essential newborn care and supportive care for small and sick newborns will be crucial. Care of the newborn within the continuum of perinatal care also calls for investments in maternal care to prevent asphyxia and reduce preterm birth and associated morbidities. Ongoing efforts on the part of governments and stakeholders to bring

coverage and quality of neonatal resuscitation to scale have the potential to achieve impact on global neonatal mortality.

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REVIEW

Use of Mid-Upper Arm Circumference by Novel Community Platforms to Detect, Diagnose, and Treat Severe Acute Malnutrition in Children: A Systematic Review

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Limited studies suggest that with robust program inputs caregivers and CHWs can correctly use mid-upper arm circumference to detect severe acute malnutrition (SAM) and that properly trained and supported CHWs can treat uncomplicated SAM in communities.

ABSTRACT

Background: A stubborn persistence of child severe acute malnutrition (SAM) and continued gaps in program coverage have made identifying methods for expanding detection, diagnosis, and treatment of SAM an urgent public health need. There is growing consensus that making mid-upper arm circumference (MUAC) use more widely accessible among caregivers and community health workers (CHWs) is an important next step in further decentralizing SAM care and increasing program coverage, including the ability of CHWs to treat uncomplicated SAM in community settings.

Methods: We conducted a systematic review to summarize published and operational evidence published since 2000 describing the use of MUAC for detection and diagnosis of SAM in children aged 6–59 months by caregivers and CHWs, and of management of uncomplicated SAM by CHWs, all outside of formal health care settings. We screened 1,072 records, selected 43 records for full-text screening, and identified 22 studies that met our eligibility criteria. We extracted data on a number of items, including study design, strengths, and weaknesses; intervention and control; and key findings and operational lessons. We then synthesized the qualitative findings to inform our conclusions. The issue of treating children classified as SAM based on low weight-for-height, rather than MUAC, at household level, is not addressed in this review.

Findings: We found evidence that caregivers are able to use MUAC to detect SAM in their children with minimal risk and many potential benefits to early case detection and coverage. We also found evidence that CHWs are able to correctly use MUAC for SAM detection and diagnosis and to provide a high quality of care in the treatment of uncomplicated SAM when training, supervision, and motivation are adequate. However, the number of published research studies was small, their geographic scope was narrow, and most described intensive, small-scale interventions; thus, findings are not currently generalizable to public-sector health care systems.

Conclusions: Scaling up the use of MUAC by caregivers and CHWs to detect SAM in household and community settings is a promising step toward improving the coverage of SAM detection, diagnosis, and treatment. Further research on scalability, applicability across a wider range of contexts, coverage impact, and cost is needed. The primary use of MUAC for SAM detection should also be explored where appropriate.

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INTRODUCTION

Of the approximately 16.4 million children aged 6–59 months worldwide estimated to experience severe acute malnutrition (SAM), roughly 7% to 13% receive treatment each year.[1,2] While the growth of community-based management of acute malnutrition (CMAM) programs has considerably increased coverage of treatment for SAM over the past decade, continued gaps in coverage and a persistence of SAM have made identifying strategic methods for expanding access to care, and finding the means to leverage these methods at scale, an urgent public health need.[3]

The use of mid-upper arm circumference (MUAC) by health care providers to detect SAM was inextricably linked to the initial success of CMAM and is likely to remain an accurate, simple, affordable, and acceptable tool to facilitate further scale up of SAM detection and management. In the standard protocol for measuring MUAC to screen for acute malnutrition, a health care provider bends the child's left arm to locate and mark the midpoint. Then the arm is relaxed straight, the MUAC tape is wrapped around the midpoint, and the circumference of the arm is recorded to the nearest 1 millimeter.[1,2,4] The platform for detecting, diagnosing, and treating SAM has typically been within CMAM programs in clinic settings; the merits and limitations of MUAC as an indicator of nutritional and mortality risk in such settings have been well described and debated in the literature.[3,5,6]

Despite the word "community" being part of the CMAM acronym, there is seldom a measurement component at the household level. Currently, the standard protocol is being revisited with simpler, alternative protocols in mind, often involving MUAC measurement by community members and caregivers in household and community settings and/or integrating MUAC measurement into other existing platforms, such as part of growth monitoring activities, health campaigns, emergency services, and integrated community case management (iCCM) programs. Expanding the role of community health workers (CHWs) to include detection, diagnosis, and even treatment of uncomplicated SAM is also being explored as an element of decentralizing SAM care. CHWs work in the communities where they reside; we use the term inclusively, referring to both paid and volunteer workers, those working full time, and those working on an ad-hoc basis. CHWs have a decades-long history of successfully diagnosing and treating childhood illness, but their potential for addressing the burden of acute malnutrition remains largely untapped.[7]

The prospect of MUAC-focused management strategies led by caregivers and community members has great potential for enhancing public health impact by facilitating community sensitization and early treatment of affected children, reducing late-stage clinical complications and hospitalizations, and increasing coverage of CMAM programs.[8] The primary objectives of this systematic review are therefore to summarize the published and operational evidence describing (1) the use of MUAC by caregivers and CHWs in community settings for the detection and diagnosis of SAM, (2) the treatment of SAM by CHWs in community settings, and (3) health platforms where MUAC use and SAM management have been successfully integrated.

METHODS

This systematic literature review was conducted according to standards set by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[9]

Studies were eligible for review if they met the following criteria:

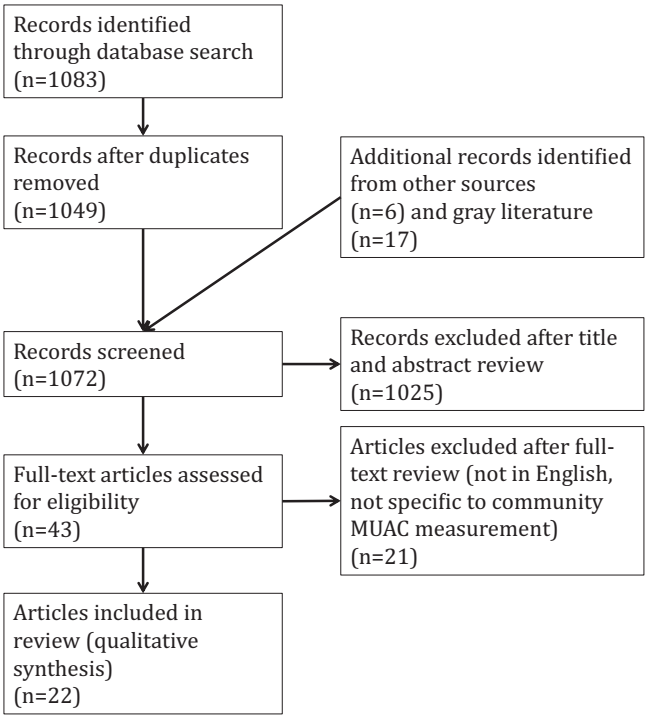
1. The study population included caregivers of children aged 6–59 months with acute malnutrition or those susceptible to acute malnutrition, or CHWs working in the field of acute malnutrition, and
2. The study occurred in a community setting, such as a household or communal space (not in clinics, hospitals, health posts, outreach sites, CMAM sites, or other formal health care settings), and
3. MUAC was used to detect, diagnose, or monitor child anthropometric status, and
4. Outcomes included effectiveness or quality of care provided by CHWs to children with SAM, timeliness of SAM detection or treatment, changes in SAM treatment coverage, operational program descriptions, or other related operational or health outcomes, and
5. Date of publication was 2000 onwards (from the time CMAM programs became operational).

Observational studies, experimental studies, intervention studies, and reviews were all eligible for inclusion. Excluded studies included those that were not available in English, those that did not directly address CHW or caregiver use of MUAC, those that occurred within clinic or hospital settings, and studies of infants younger than 6 months as MUAC is not currently a recommended indicator for acute malnutrition screening in that age group.

Five information sources were used for this review: A database search of peer-reviewed publications was conducted between September 15 and October 15, 2017, using PubMed and Google Scholar; the gray literature was searched on Emergency Nutrition Network (ENN) and Coverage Monitoring Network (CMN) websites between October 15 and October 30, 2017); records from the bibliographies of studies found in our database searches were retrieved between October 15 and October 31, 2017; and lastly, suggestions of relevant sources from experts in the field, including unpublished or operational materials, were received between September 15, 2017, and March 5, 2018.

Our electronic search strategy used the following terms and queries: "community health

FIGURE. Flow Diagram of Selection Process



worker" AND "acute malnutrition" OR "SAM" OR "MUAC"; "reliability" AND "community health worker" AND "anthropometry"; "community screening" AND "malnutrition" AND "child"; "family MUAC"; "MUAC" AND "community diagnosis" OR "community detection"; "acute malnutrition" AND "community detection" OR "community diagnosis"; "MUAC" AND "integration"; "MUAC" AND "health system"; "MUAC" AND "vaccination"; "home-based therapy" AND "SAM"; home-based therapy'" AND "acute malnutrition".

The study selection process included 4 steps. First, a list of potential studies was compiled via our database search and from expert sources. Second, titles and abstracts were screened based on the eligibility criteria, and third, eligible articles were selected for full-text reading and further screening. The bibliographies of full-text articles were also screened for additional articles that were eligible for inclusion. Finally, articles that met the criteria were submitted for data extraction. For published literature, a standardized form was used for simultaneous data retrieval and data entry of the following items: record reference, objective of study, study design, study population, intervention, control (if any), key findings, operational lessons, study strengths and weaknesses, and comments. For gray literature sources, the reference, organizational source and setting, the objective of the document, and key messages were recorded. Data were extracted by one author and reviewed by second authors. We synthesized the findings of the included studies by summarizing key findings, identifying trends across studies, and noting operational challenges faced during implementation. Disagreements were mutually resolved between all authors. Both the published and the operational materials informed our conclusions, with recognition that individual studies may be biased toward publication of positive results.

RESULTS

We screened 1,072 records and selected 43 records for full-text screening. We included 22 studies in the review (Figure). A brief summary of each of the 22 studies reviewed is presented in Table 1 (published literature, n=11) and Table 2 (operational materials, n=11). Of the published studies reviewed here, 10 were observational studies describing existing or experimental use of MUAC within communities, and 1 was a randomized control trial evaluating an integrated model for acute malnutrition care. All studies reviewed were conducted in rural settings. Studies included those with paid and volunteer CHWs. The operational materials included 5 reports describing existing community MUAC programs, 3 reports of new tools being developed to facilitate community MUAC use, 1 stakeholder report describing MUAC integration modalities, 1 observational study of community MUAC use, and 1 summary of a randomized control trial to evaluate new acute malnutrition care protocols.

The studies identified for this review fall into 4 broad, but not mutually exclusive categories:

1. Caregiver detection of SAM using MUAC
2. CHW diagnosis of SAM using MUAC
3. CHW treatment of SAM
4. Integration of MUAC use and/or SAM care into other platforms

Our results and the discussion are organized around these categories.

Caregiver Detection of SAM Using MUAC in Community Settings

We identified 3 research studies of caregiver detection of SAM using MUAC tapes (Niger[10,11])

TABLE 1. Summary of Published Research Studies Included in Review (n=11)

Reference	Objective	Thematic Category and Platform	Design, Training, and Remuneration	Key Findings
Alé et al. 2016[11]	To compare the efficacy and cost-effectiveness of maternal measurement of child MUAC and edema with CHW measurement (Niger)	Caregiver detection, CHW diagnosis (Community platform, rural)	Design: Intervention efficacy study with 2 experimental groups comparing the performance of 12,893 mothers with 36 CHWs Training and remuneration: 30-minute group training plus follow-up individual training for mothers, 6 hours theoretical and 2 hours practical training for CHWs. CHWs were part of established national network and may have been volunteers (payment unknown).	Mothers' MUAC measurements were in agreement with those of health workers more frequently than those made by CHWs (risk ratio 1.88, $P<.0001$). Case detection was earlier in the mothers' group (median MUAC of cases 1.6 mm higher than CHW group), with fewer children requiring inpatient care relative to the CHW group.
Alvarez-Moran et al. 2017[19]	To assess CHW capacity to evaluate, classify, and treat uncomplicated cases of SAM, and to appropriately refer complicated cases, as part of an integrated iCCM package (Mali)	CHW diagnosis and treatment, Integration (iCCM/community platform, rural)	Design: Cross-sectional observational study (no comparison group) of 17 CHWs assessing 125 children Training and remuneration: CHWs had a median of 6 months of job training; no additional training for this study. CHWs were part of Mali's established network and received a salary according to national regulations.	CHWs assessed MUAC correctly in 97% of children, assessed edema correctly in 78%, administered medical treatment correctly in 75% of SAM cases, and managed RUTF supplies correctly in 100% of cases.
Amthor et al. 2009[22]	To describe a rapidly adapted home-based SAM therapy approach in which village health aids diagnosed and treated SAM (MUAC and/or edema) in the context of a food crisis with inadequate health system support (Malawi)	CHW diagnosis and treatment (Emergency community platform, rural)	Design: Retrospective descriptive study of the clinical outcomes of 826 children with SAM who received treatment at home from village health aids Training and remuneration: 5 hours of training plus 5 days job shadowing a nurse. Village health aids were part of an established network; payment unknown.	Recovery rates of children with SAM treated by village health aids were high (94%), without any intervention by medical professionals aside from training. quality of care.
Blackwell et al. 2015[10]	To determine whether minimally trained mothers could identify children with SAM, using either arm and without measuring the specific midpoint (Niger)	Caregiver detection (Community platform, rural)	Design: Nonrandomized non-blinded evaluation study of 2 experimental groups (103 mother-child pairs using simplified protocol and CHWs using standard protocol) Training: Intended to be 5 minutes with each individual, was instead done communally. CHWs were part of a nationally established network and may have been volunteers (unknown).	Mothers' ability to classify GAM and SAM had high sensitivity (>90% of GAM and >73% of SAM cases correctly identified as such) and high specificity (>80% of GAM and >98% of non-cases correctly identified as such). The simplified protocol (either arm and visual ascertainment of midpoint) performed as well as the standard protocol.
Grant et al. 2018[12]	To test the sensitivity of 3 MUAC classification devices when used by caregivers/mothers (Kenya)	Caregiver detection (Community platform, rural)	Design: Prospective nonrandomized clinical diagnostic trial comparing the performance of 3 "Click-MUAC" devices and an MUAC insertion tape across 21 health facilities and 1,040 mother-child pairs Training and remuneration: NA	All devices yielded high sensitivity (>93%) for detecting SAM. Sensitivity for SAM was highest (100%) with the standard MUAC insertion tapes. Specificity was also high for all devices (>96%), with no significant differences observed between the insertion tape and the "Click-MUAC" devices.

Continued

TABLE 1. Continued

Reference	Objective	Thematic Category and Platform	Design, Training, and Remuneration	Key Findings
Linneman et al. 2007[23]	To assess clinical outcomes of children with acute malnutrition receiving home-based RUTF therapy from community health aids in an operational setting (Malawi)	CHW diagnosis and treatment (Community platform, rural)	Design: Observational study of 3 intervention groups with varying levels of decision-making and SAM treatment authority given to community health aids (12 health centers, >3,000 children with acute malnutrition) Training and remuneration: 1 month plus 4 days job shadowing a nurse. Community health aids were part of an established network; payment unknown.	SAM cases who received treatment from community health aids had the same rate of recovery (90%) as those treated by medical professionals (87%). Note that community health aids appear to have delivered some of the care under supervision in clinic settings.
Maust et al. 2015[27]	To evaluate an integrated MAM/SAM program in terms of coverage, number of children treated, and recovery of children (Sierra Leone)	Integration (Integrated CMAM platform, rural)	Design: Cluster randomized controlled trial with an intervention group (integrated protocol using MUAC for admissions and discharge, RUTF used for MAM and SAM) and a control (standard protocol using W/H Z, RUTF for SAM, and FBFs for MAM) Training and remuneration: NA	Coverage of the integrated program was higher (71% compared with 55% using standard protocol), and recovery rates were comparable (83% vs. 79%).
Nyirandutiye et al. 2011[28]	To evaluate integration of MUAC screening into National Nutrition Week activities (Mali)	Integration (National Nutrition event platform, rural)	Design: Cross-sectional survey of health centers (2) and interviews with health center staff (45), CHWs (17), and caregivers (1543) Training and remuneration: MUAC training was incorporated into event training; CHWs were unpaid volunteers.	Integrating MUAC screening into other activities led to a greater proportion of kids screened (52% of eligible children) than via community screening (5%) or via health center screening (22%), and was viewed as beneficial by caregivers and health care providers. Screening rates were low in clinics, even where staff had been trained in the CMAM protocol.
Puett et al. 2012[20]	To assess the quality of CHW care of uncomplicated SAM cases, including technical competence and acceptability, as part of an iCCM health platform (Bangladesh)	CHW diagnosis and treatment, Integration (iCCM/community platform, rural)	Design: Observational cohort study of 55 CHWs who provided SAM care, and focus group discussions with 29 caregivers whose children received SAM care from CHWs Training and remuneration: 2 days plus monthly refresher trainings. CHWs were part of an established network and received payment.	Trained and supervised CHWs delivered high-quality care to uncomplicated SAM cases; they correctly assessed MUAC and advised caregivers of children with SAM appropriately (90% of cases were managed error-free). Antibiotics correctly administered in 90% of pertinent cases. See also Puett et al. 2013[21] and Sadler et al. 2011.[25]
Puett et al. 2013[21]	To assess the cost-effectiveness of SAM management (diagnosis and treatment) by CHWs as part of a community nutrition program, compared with inpatient treatment (Bangladesh)	CHW diagnosis and treatment, Integration (iCCM/community platform, rural)	Design: Nonrandomized intervention study of 724 SAM cases treated by CHWs in the community and 633 SAM cases treated as inpatients Training and remuneration: 2 days plus monthly refresher trainings, CHWs were part of an established network and received payment.	CHWs delivered the full spectrum of SAM identification and treatment at a lower overall program cost than inpatient treatment. Supervision was the greatest expense in the CHW group (40% of total, compared with 28% of total budget in inpatient group). See also Puett et al. 2012[20] and Sadler et al. 2011.[25]

Continued

TABLE 1. Continued

Reference	Objective	Thematic Category and Platform	Design, Training, and Remuneration	Key Findings
Rogers et al. 2017[24]	To assess the quality of care for uncomplicated SAM by female health workers (Pakistan)	CHW diagnosis and treatment, Integration (iCCM/community platform, rural)	Training: Observational cross-sectional study of 17 female health workers providing care for 61 cases of uncomplicated SAM Training and remuneration: 3 days plus a refresher 3–6 months later. CHWs were part of an existing network and received salaries according to national regulations. They did not receive additional pay for the added SAM care responsibilities.	MUAC and edema were correctly measured for 57% and 88% of children, respectively. 68% of cases received correct medical and nutrition treatment, but only 4% also received key nutritional counseling messages.

Abbreviations: CHW, community health worker; CMAM, community-based management of acute malnutrition; FBF, fortified blended flour; GAM, global acute malnutrition; iCCM, integrated community case management; MAM, moderate acute malnutrition; MUAC, mid-upper arm circumference; NA, not available; RUTF, ready-to-use therapeutic food; SAM, severe acute malnutrition; W/H Z, weight-for-height z score.

or alternative MUAC devices (Kenya[12]) that indicate that caregiver-focused approaches are reliable and feasible.

Blackwell et al. (2015) found that mothers were capable of using standard MUAC tapes to classify SAM cases with >73% sensitivity and >98% specificity in a pilot study in Niger; this was comparable with CHW performance of 80% and 96%, respectively.[10] Mothers responded positively to being engaged in monitoring their child's nutritional status, and their comprehension of how MUAC classification corresponded to admission (or exclusion) from SAM treatment programs improved. The simplified MUAC protocol—measurement of either arm, at a midpoint ascertained visually—performed as well as the standard protocol.[10,13] In a follow-up study in Niger, Alé et al. (2016) observed that in areas where caregivers were using MUAC tapes to detect SAM in their own households in Niger, the median MUAC of SAM cases admitted to outpatient therapeutic programs was significantly higher than in areas where CHWs were doing the screening.[11] There were also fewer complicated cases and hospital admissions among mother-referred cases.

Most recently, Grant et al. (2018) compared the performance of 3 prototype "Click-MUAC" devices with an improved MUAC insertion tape ("UniMUAC" tape) among caregivers in Kenya.[12] The 3 prototypes, which resembled plastic cuffs and tapes, had internal circumferences of 115 mm or 115–125 mm and were hoped to improve case-finding sensitivity over the standard MUAC insertion tapes. Each of the prototypes yielded high sensitivity (>93%) and specificity (>98%), but the UniMUAC tape was superior in both sensitivity (100%) and level of agreement between caregiver, health facility staff, and data collection staff measurements (98%) when screening for SAM.

Operational Findings

ALIMA, the nonprofit that runs the Niger-based programs detailed earlier, has expanded its "Family MUAC" programs to Burkina Faso, Chad, and Mali.[14,15] Action Against Hunger piloted "MUAC Mothers" programs in India and Mauritania with mixed results. In their India pilot, approximately 30% of mothers trained to use MUAC tapes measured their children in the 7 months following training. In Mauritania, more than 6,000 mothers were trained in both MUAC use and edema detection; outcomes were not available at the time of review.[16] Several other organizations (Médecins Sans Frontières, GOAL, Concern, World Vision, International Red Cross, International Medical Corps, Cooperazione Internazionale, and Valid International) are in the process of adopting and adapting Family MUAC (also known as "Mother MUAC" and "MUAC Mothers") programming,[17] and tools to improve caregiver training and monitoring are in development.[18]

CHW Detection and Diagnosis in Community Settings

We found evidence supporting high CHW capacity to accurately diagnose SAM using MUAC in 3 studies of 2 interventions in Bangladesh and Mali[19–21] Two studies presented mixed evidence from Niger and Pakistan,[11,13] and two from

TABLE 2. Summary of Operational Materials Included in Review (n=11)

Reference	Organizational Source and Setting	Thematic Category	Type of Document	Objective of Document
ACF 2017[42]	Action Against Hunger (DRC, Kenya)	Caregiver detection, CHW diagnosis	Description of program/ materials	To describe a simplified, standardized MUAC bracelet under development for testing in the DRC and Kenya.
Bailey 2018[26]	Multiagency (Chad, Kenya, Yemen, Pakistan, Jordan)	Integration	Pilot study (results not yet published)	To summarize the protocol being used by the ComPAS study. The ComPAS study, currently underway as of the writing of this article, aims to integrate the treatment of MAM and uncomplicated SAM by using one product (RUTF) in doses that correspond to growth at each stage of treatment, and using MUAC and edema as the only metrics for admission, monitoring, and discharge.
CMN 2015[34]	Coverage Monitoring Network (no specific setting)	Integration	Advocacy	To advocate for the integration of MUAC into other health and nutrition activities, including vaccination campaigns, well-baby clinics, and water and sanitation programs.
Emary 2017[18]	World Vision (Mauritania)	Caregiver detection	Description of program/ materials	To describe qualitative and quantitative tools developed for training and monitoring "Mother-Led MUAC" programs in Mauritania.
Friedman and Wolfheim 2014[35]	Multiagency (no specific setting)	CHW diagnosis and treatment	Description of program/ materials	To identify and describe models for how CHWs currently incorporate SAM screening, referrals, and treatment into their work. While there is evidence supporting CHW capacity to conduct all SAM-related activities, there are outstanding questions regarding the conditions that foster success, as well as the optimal mix of iCCM and nutrition-related responsibilities.
ALIMA 2017[15]	ALIMA (Niger, Burkina Faso, Mali, Chad)	Caregiver detection	Description of program/ materials	To describe the expansion of "Family MUAC" concepts in Burkina Faso, Chad, Mali, and other locations.
MSF 2017[43]	Médecins Sans Frontières (no specific setting)	Caregiver detection, CHW diagnosis and treatment	Pilot study	To report on lab testing of an alternative MUAC strap for use with adult and child populations. Initial testing of the strap using a standardization process (not on humans, but on differently sized cylinders) showed it to be more accurate and have a higher sensitivity than the standard UNICEF strap. The next step is to test the straps on children in a field setting.
Sadler et al. 2011[25]	Save the Children/ Feinstein International Center (Bangladesh)	CHW diagnosis and treatment	Research study	To report outcomes of SAM cases receiving CHW care in Bangladesh (some results also published, see Puett et al. 2012[20] and Puett et al. 2013[21]). Coverage, weight gain, and recovery were high (89%, 6.7 g/kg/day, and 92%, respectively). The use of multiple pathways to care within the CHW model—use of MUAC, monthly growth monitoring sessions, home visits to sick children, and use of a "watch list" to monitor sick children—facilitated high coverage of screening and diagnosis. See also Puett et al. 2012[20] and Puett et al. 2013.[21]
Sayadi 2016[17]	CMAM Forum (multiple settings)	Caregiver detection	Description of program/ materials	To connect agencies interested in adopting "Mother-Led MUAC" programs (Action Against Hunger, Médecins Sans Frontières, GOAL, Concern, World Vision, International Red Cross, International Medical Corps, and Cooperazione Internazionale).
Sessions 2017[16]	Action Against Hunger (India, Mauritania)	Caregiver detection	Pilot study	To describe 2 pilot studies of the "MUAC Mothers" approach. In India in 2015, 61 caregivers were trained to measure MUAC and given information about how to proceed if they classified their child as having MAM or SAM. Seven months after training, approximately 20 were using the tapes actively; the remaining 41 had misplaced, forgotten how to use the tapes, or not participated in measuring. In Mauritania in 2016, CHWs provided training for more than 6,000 mothers on MUAC use, screening for edema, and what to do if a child got a red, yellow, or green reading.

Continued

TABLE 2. Continued

Reference	Organizational Source and Setting	Thematic Category	Type of Document	Objective of Document
Tesfai 2015[14]	International Rescue Committee (multiple settings)	CHW diagnosis and treatment	Description of program/ materials	To describe tools to enable low-literacy CHWs to diagnose and treat uncomplicated SAM. Piloted tools include use of MUAC-only for admission and monitoring, the use of visual materials (color-coded RUTF dosage charts, scales that indicate RUTF dose, and use of icons to facilitate registration and monitoring), and alignment with iCCM vocabulary and tasks. Field tests have been conducted in Chad, India, Mali, and South Sudan.

Abbreviations: CHW, community health worker; CMAM, community-based management of acute malnutrition; ComPAS, Combined Protocol for Acute Malnutrition Study; DRC, Democratic Republic of the Congo; iCCM, integrated community case management; MAM, moderate acute malnutrition; MUAC, mid-upper arm circumference; NA, not available; RUTF, ready-to-use therapeutic food; SAM, severe acute malnutrition; UNICEF, United Nations Children's Fund.

Malawi indicated success but did not report specific measured outcomes.[22,23]

CHWs used standard MUAC approaches to diagnose SAM with a high level of accuracy and reliability, and they found it to be a straightforward tool in work by Alvarez-Moran et al. in Mali (2017).[19–21] Alvarez-Moran et al. (2017) found that CHWs correctly assessed MUAC in 97% of children.[19] In Bangladesh, Puett et al. (2012) observed that CHWs completed MUAC measurements correctly >96% of the time.[20]

We found mixed evidence of CHW MUAC measurement in 2 other studies, one from Niger and one from Pakistan. Alé et al. observed that mothers' MUAC classifications agreed more often with nurses' than those made by CHWs in Niger: mothers' measurements agreed with nurses' 75% of the time, contrasted with only 40% of the time between CHWs and nurses. CHW performance in this case was not described as deficient, despite the discrepancy when compared with caregiver performance.[11] Rogers et al. (2017) report that MUAC was correctly measured for just 57% of children in their study from Pakistan.[24] While the authors concluded that CHWs are capable of accurate SAM diagnosis, they speculated that the low rate of correct MUAC measurements was due to operational constraints and low CHW motivation.

CHW Treatment of SAM in Community Settings

We identified 5 published research studies from Bangladesh, Malawi, and Mali that report consistently successful outcomes of programs or pilot studies of CHW-managed SAM diagnosis and treatment at the household level.[19–23] The findings of these studies, which span clinical outcomes of SAM cases, quality of care provided, and cost-effectiveness, indicate that CHWs are capable of providing high-quality, effective care for uncomplicated SAM at a lower cost than inpatient care models, given adequate operational support and supervision.

CHWs provided correct medical care for uncomplicated SAM cases in 75% of cases and managed RUTF supplies correctly for all cases studied by Alvarez-Moran et al. (2017) in Mali.[19] The majority (80%) of cases were concluded to have received high-quality treatment, defined by Alvarez-Moran as meeting essential indicators across 5 dimensions of care (interface with caregiver, evaluation, classification, treatment, and counseling). Similarly, in Puett's 2012 Bangladesh study, 90% of SAM cases were managed without error; the addition of SAM management to CHWs' regular responsibilities did not appear to affect quality of care or clinical outcomes.[20] (See also Sadler 2011.[25]) Both Puett et al. (2012) and Alvarez-Moran et al. (2017) determined that high levels of supervision likely contributed to the high quality care they observed in Bangladesh and Mali, respectively.[19,20]

Amthor et al. (2009) and Linneman et al. (2007) focused on clinical outcomes of SAM cases receiving treatment from CHWs in Malawi; given the high SAM recovery rates (94% and 89%), we presume that the quality of care they received from CHWs was adequate.[22,23]

We found evidence of unsatisfactory CHW management of SAM in 2 instances, one in the study by Alvarez-Moran et al. in Mali (2017) and in work done by Grant et al. in Pakistan (2018).[19,24] Alvarez-Moran et al. (2017) found in Mali that for some tasks, such as administering antibiotics, CHW performance was deficient.[19] Similarly, in

the study by Rogers et al. (2018) in Pakistan, quality of CHW care for SAM was not provided at a consistently high level. While 68% of uncomplicated SAM cases received the correct medical and nutritional care (RUTF, antibiotics, and folic acid), only 4% of cases received the full package of medical and nutritional care and nutritional counseling messages. This low compliance was attributed to operational challenges—namely stock outages—and low CHW motivation owing to lack of extra remuneration.[13] Nonetheless, and important to note, is the fact that the clinical outcomes of SAM cases in the Pakistan study were noninferior to traditional facility-based models. In other words, failure to deliver the full package of care did not result in low performance or SAM recovery outcomes relative to other care modalities.

Operational Findings

There are ongoing efforts to create tools that facilitate SAM diagnosis and treatment by low-literacy CHWs in Chad, India, Mali, and South Sudan. These include the use of visual materials for RUTF dosage and icons to enable reliable case documentation and monitoring.[14] Simplified dosage protocols that do not depend on measuring child weight, as described in Phase 1 of the Combined Protocol for Acute Malnutrition Study (ComPAS) in Chad, Jordan, Kenya, Pakistan, and Yemen, will also facilitate CHW treatment.[26] How to safely combine low-literacy tools with the ability to administer antibiotics, assess for danger signs, and refer appropriately when needed requires further exploration.

Integration of MUAC Use and/or SAM Care Into Other Platforms

Our search yielded 2 published research studies that explicitly described examples of MUAC screening and/or SAM care integration into existing health and/or nutrition platforms. Maust et al. (2015) tested the effectiveness of an integrated treatment program for SAM and moderate acute malnutrition (MAM) in Sierra Leone, which relied on the sole use of MUAC as the indicator used for admissions, monitoring, and discharge, and on RUTF as the sole treatment food. They found the exclusive use of MUAC to be conceptually and logistically simpler, and their results of high coverage (71%) and recovery rates (83% for SAM) are promising.[27] Other studies (ComPAS) are underway to examine the effectiveness of similar joint protocols in other settings.[26]

Nyirandutiye et al. (2011) reported on the use of MUAC during National Nutrition Week activities in Mali; the event typically has 80% to 90% coverage nationwide and is a promising partner platform for SAM screening and referrals. The difference in screening coverage was substantial: 52% of eligible children (those in the 6–59-month age range) were screened during the event, compared with 22% screened at health centers and 5% screened in the community in the months following the event.[28] The discrepancies in screening rates suggest that both facility and community-based SAM screening have considerable room for improvement: half of the children with acute malnutrition in their survey had been at a health center within the previous 4 months, but only a quarter of them had been assessed for malnutrition.

Operational Findings

The gray literature provides additional support for different models of integration, some of which are already operational and others that are still hypothetical. Friedman and Wolfheim (2014) describe the current range of operational models, 2 of which pertain to SAM screening, referrals, and treatment by CHWs in community settings. In one model, CHWs assess and refer SAM cases as part of iCCM, and in a second model they also provide treatment[29]; we found evidence supporting the success of both models in Bangladesh and Niger in the course of our review.[11,20,25]

DISCUSSION

Caregiver Detection of SAM Using MUAC in Community Settings

Caregiver-focused models for detecting and classifying SAM using MUAC have potential for increasing coverage and detecting acute malnutrition earlier than standard MUAC protocols. Given the rapid expansion of simplified protocols for caregiver-led pilots and programs, the evidence base is likely to broaden in the next few years. While it is too early to assess the sustainability of caregiver MUAC programs, there is some evidence of high variation in the level of involvement and activity that mothers invest following training. For example, at ALIMA's initial site in Niger, 60% of mothers in the project area have been trained and >70% of CMAM admissions are now referred by mothers.[15] In contrast, 7 months after an MUAC Mothers training in India, only 30% of mothers reported having ever measured their

children.[16] Understanding how to best motivate and engage caregivers to participate in MUAC measurements and addressing any barriers or stresses created by this responsibility are important questions going forward.

Further simplification of MUAC protocols may hold additional potential in increasing effective community/caregiver MUAC use in other settings. Potential simplifications include embracing "classification" rather than "measurement," the use of wider color-banded MUAC tapes, the use of either arm for measurements, and/or visually locating the arm midpoint.[10]

CHW Detection and Diagnosis of SAM Using MUAC in Community Settings

Most of the available evidence supports the ability of CHWs to reliably measure MUAC to the standard necessary for SAM screening. It is worth noting that although MUAC is widely considered a simple indicator for measurement and interpretation, there are examples where the metric was not accepted by CHWs and/or not accurately measured by community workers in the context of growth monitoring and basic anthropometric training[30–32] (not included in this review as they did not meet inclusion criteria).

Thus, despite widespread assertions of the simplicity of MUAC, some users—CHWs, nurses, and other health professionals included—find measuring MUAC to be a challenging task. This may partially explain why screening rates and detection of SAM cases remain low even at clinics where staff have been trained in CMAM protocols.[28] If the findings by Blackwell et al. (2015) hold true, further simplifying the MUAC protocol may address issues of familiarity and understanding of MUAC among health care providers and caregivers alike.[10]

CHW Treatment of SAM in Community Settings

Most studies reviewed here indicate that CHWs are capable of performing the tasks associated with SAM diagnosis and treatment when supervision, training, and motivation are satisfactory. However, little has been published to describe the effectiveness on child outcomes or coverage relative to standard approaches. One consistent message across studies of CHWs and SAM treatment, both in the published and the gray literature, is the importance of quality training, regular refresher trainings, and high levels of supervision to ensuring sustained CHW motivation, activity, and effectiveness.[19,24,25] The cost of supervision is likely to constitute a large proportion of overall program costs, particularly when implementing a new CHW-led program. Notably, there is evidence that in countries with a well-established CHW network, rapid implementation of CHW-led SAM care in an emergency setting may be highly feasible and effective.[22]

Integration of MUAC Use and/or SAM Care Into Other Platforms

Several studies indicate that the use of MUAC by caregivers and CHWs is a missing link in the integration of SAM care into other platforms, be it integration with MAM programming;[27,33] integration into nutrition or health-focused events such as nutrition weeks, vaccination campaigns, nutrition events, water, sanitation, and hygiene (WASH) programming, or well-baby clinics;[28,34] or incorporating MUAC assessment and treatment into existing iCCM programs.[35] As many of the studies reviewed in this article suggest, and as reported by a study of the integration of SAM care into Niger's national health system, the complexity of acute malnutrition intervention protocols (multiple indicators, treatment types, locations, and steps in care) hinders integration.[36] Integrating SAM care successfully does not necessarily require integrating every aspect of its treatment, nor is integration a solve-all for inadequate resources or staff.[37] The optimal mix, or level of mixing, between MUAC use, SAM care, and other activities will likely vary widely depending on context, content, and complementarity of joint activities, among other factors.

Study Limitations

As with most systematic reviews, this review is subject to publication bias. Published research on MUAC use is likely biased in favor of successful programs; as a result this review may be missing important lessons learned from pilot programs and trials that did not show an apparent positive impact of caregiver or CHW use of MUAC for SAM detection, diagnosis, and/or treatment. Nonetheless, our review did yield work reporting negative outcomes (see Rogers et al. 2017[13]). Most of the studies reviewed here are observational rather than interventional, so inference is limited. Furthermore, most of the published evidence describes intensively delivered, small-scale interventions, and is not readily generalizable to larger scale, public-sector health care systems.

With few exceptions, the studies reviewed here contain little information about the demographic and socioeconomic characteristics of study participants. The absence of this contextual information, the narrow geographic scope of the available studies, and variation in how/whether training and remuneration were delivered limits our ability to generalize findings. Differences in settings, cultures, training protocols, and populations will have implications for the usefulness and acceptability of MUAC.

The issue of treating children classified as SAM based on low weight-for-height, rather than MUAC, at household level, is not addressed in this review. There is evidence that MUAC and weight-for-height do not detect the same children;[38] however, there is also strong evidence that MUAC is a better predictor of children at high risk of death.[5,39] While community studies demonstrate that MUAC is better at predicting mortality, children with low weight-for-height still remain at risk.[5] Some studies have reassessed MUAC cutoffs in order to better capture children classified as SAM by current weight-for-height criteria.[40] Others argue that MUAC and weight-for-height identify different children at risk and both should be retained as independent criteria.[41]

We did not address the differences between MUAC and other metrics or implications for the screening, diagnostic, or treatment models reviewed here. Vulnerable children not detected by MUAC alone still need care and should not be overlooked in efforts to scale up and integrate SAM care. Efforts to determine MUAC cutoffs that are sensitive to other metrics—such as low weight-for-height—do exist (see Fiorentino et al. 2016[40]). Determining the impact of CHW treatment programs on children with low weight-for-height will be necessary if an MUAC-focused model is to be rolled out at scale.[8]

CONCLUSIONS

There is a limited but growing amount of evidence describing the use of MUAC for detection, diagnosis, and treatment of SAM by caregivers and CHWs in community settings. The number of published research studies is small, their geographic scope is narrow, and most describe intensive, small-scale interventions and pilot studies. As such, findings should not yet be extrapolated to other settings. From our review of published research studies, case studies, and operational materials, we can conclude the following:

- Caregivers are able to use MUAC to detect SAM in their children with little apparent risk and many potential benefits to early case detection and coverage.
- CHWs are able to diagnose SAM and provide high-quality treatment with increased coverage, particularly when using simplified protocols and when supported by strong supervision. Without adequate supervision, training, and/or remuneration, the quality of care is likely to suffer. The correct administration of antibiotics by CHWs as well as the ability to detect and refer for danger signs requires further consideration. There is currently only limited evidence on SAM treatment outcomes using this approach, and little consideration of the impact on other child health outcomes under the remit of CHWs.
- While most practitioners consider MUAC relatively simple, it still requires good training and community advocacy in settings where it is unfamiliar. Ongoing research into simplified protocols, modified MUAC tapes, MUAC-based RUTF dosages, and low-literacy treatment tools will all support diagnosis and treatment of SAM by CHWs at household level. The available literature indicates that improvements in coverage are likely when SAM management protocols are simple and the proposed platform for integration is composed of complementary nutrition-related activities.
- In recognizing the benefit of MUAC as a community tool, it is important to recognize that current MUAC criteria do not select for all high-risk children, including low weight-for-height children, and the optimal approach will vary across different contexts. More research is needed to identify different options to identify these high-risk children in the community and ensure successful diagnosis and treatment.

In conclusion, scaling up the use of MUAC to detect SAM in communities is a promising step toward greater coverage and use of existing CMAM services. Given adequate operational support, training, and supervision, the quality of care for self-referred and/or CHW-treated cases is likely to be comparable with current health worker and CMAM models. Further research regarding scalability and applicability of community MUAC use across a wide range of contexts is needed and warranted. In some contexts, the use of MUAC as the primary criterion for detection, diagnosis, and

discharge may be appropriate and should be explored further.

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SHORT REPORT

Childbirth and Early Newborn Care Practices in 4 Provinces in China: A Comparison With WHO Recommendations

Tao Xu,[a] Qing Yue,[a] Yan Wang,[a] John Murray,[b] Howard Sobel[b]

In the 10 hospitals studied, we found that hospital policies, protocols, and interventions only partially align with WHO early newborn care recommendations, and that many hospitals still use outdated and non-medically sound practices.

ABSTRACT

Objectives: As a part of the process of implementing Early Essential Newborn Care (EENC) in China, which are evidence-based interventions recommended by the World Health Organization (WHO), we sought to understand whether current hospital policies are consistent with WHO-recommended standards and what factors influence their use. Data from the study will help inform policy changes needed to support the introduction of evidence-based childbirth and early newborn care practices effectively and to inform further scale up of EENC nationwide.

Methods: Ten randomly selected hospitals in 4 early-introducing provinces participated in the study. We collected data from 20 simulated delivery scenario observations and focus group discussions and individual interviews with 10 hospital management staff. Policies, protocols, and guidelines related to childbirth and newborn care practice were also collected and reviewed at each hospital. Additionally, a survey was emailed to 15 childbirth and newborn experts from the 4 selected provinces and completed by 13. Data were compared with WHO EENC evidence-based standards to calculate the agreement rates. Barriers to introducing evidence-based guidelines were identified in focus groups and key informant interviews, then combined into common categories.

Findings: Hospital policies were not consistent with WHO recommendations in 10 (59%) of the 17 delivery and early newborn care practices. Delayed cord clamping was recommended by 30% of hospital protocols and prolonged skin-to-skin contact by 13%, neither of which were observed in the delivery simulations. Kangaroo mother care (KMC) for stable preterm babies was required in only 17% of the hospitals; no preterm babies had KMC initiated, with all immediately separated from their mothers and admitted to neonatal intensive care units. Newborn resuscitation equipment was required to be placed within 2 meters of the delivery bed in 84% of hospital protocols, but was prepared in only 40% of cases. Immediate drying after birth was required in 48% of hospital protocols, but was initiated in only 20% of observed cases.

Conclusions: Current childbirth and early newborn care policy and practice in China is not aligned with WHO recommendations for some major interventions. To make it easier and safer for hospital workers to practice EENC, expert working groups and national policies must be established to address inconsistencies and cultural beliefs and provide a strong, evidence-based set of guidelines for hospitals and health workers to follow.

INTRODUCTION

With an estimated 16 million babies born annually, China has achieved remarkable progress reducing deaths among children under 5 over the past 2 decades. Between 1991 and 2015, the under-5 mortality rate of Chinese children declined by 80% from 79.2 to 10.7 per 1,000 live births and infant mortality declined from 50.2 to 8.1 per 1,000 live births.[1] By 2015, the newborn mortality rate was 5.4 per 1,000 live births, which represented over half of all child deaths.[1] Despite these reductions, the number of children under 5 dying each year remains close to 200,000, the majority of whom are born in remote rural areas without adequate care and support. In 2011, the World Health Organization (WHO) estimated that institutionalizing simple, low-cost interventions during childbirth and the early newborn period could prevent at least 22% of reported Chinese newborn deaths.[2]

Since the World Summit for Children in 1990, China has invested in strengthening policy and legislation for improving the child health system[3,4] by enacting the *Law of the People's Republic of China on Maternal and Infant Health Care*[5] and developing the *Measures for the Implementation of Law of the People's Republic of China on*

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Maternal and Infant Health Care[6]. Based on these 2 documents, the central government developed specific maternal and child health (MCH) action plans—the *National Program of Action Plan for Women Development in China (2011–2020)*[7]and the *National Program of Action Plan for Children Development in China (2011–2020)*[7]—that identify 10-year obj-ectives, main indicators to measure and meet, and strategies for improving women's and children's health, education, protection, and rights. While these documents covered a wide range of issues, quality early essential newborn care (EENC) was not mentioned.

To improve quality of care during delivery and in the newborn period, 8 countries collaborated with WHO/WPRO to develop a regional action plan to implement and scale up EENC interventions.

Progress on improving the quality of care around delivery and in the early newborn period has been slower than other aspects of child health and recognized as an area that needs renewed attention.[8] To that end, in 2013, China and 7 other countries, collaborated with the WHO Western Pacific Regional Office (WHO/WPRO) to develop and adopt the *Action Plan for Healthy Newborn Infants in the Western Pacific Region (2014–2020)*.[9] This plan outlines an approach for implementing and scaling up a package of evidence-based EENC interventions recommended by WHO that have been demonstrated to reduce newborn mortality from the 3 most important causes: prematurity, birth asphyxia, and sepsis (Table 1). The EENC approach focuses on improving the quality, reach, and demand for facility-based maternal and newborn services using a systems-based approach to improve health worker practices.[10] All 8 of the countries have since taken important steps in the areas of policy, planning, coordination, and program implementation. This has included local adaptation and endorsement of the *Early Essential Newborn Care Clinical Practice Pocket Guide*,[10] the coaching/training of health facility staff on EENC, and institutionalization of approaches to improve the quality of practices in hospitals related to childbirth and the immediate newborn period.[11]

In 2015, the National Health and Family Planning Commission (NHFPC) in China began prioritizing the introduction of EENC, beginning with improving quality of hospital care in 4 early-implementation provinces. Preliminary discussions with senior hospital staff found that hospital newborn health protocols often vary considerably within and across facilities. Prior to the implementation of EENC in China, we sought to first understand what protocols were being used in hospitals in the 4 early-implementation provinces, whether current policies were consistent with WHO-recommended standards, and what factors influence their use. The aim of these data was to inform the policy changes needed to support the introduction of evidence-based delivery and early newborn care practices effectively and to inform scale up to other regions of the country.

METHODS

We conducted the study between December 2015 and April 2016 using observations of simulated deliveries, focus group discussions with the simulation participants, individual interviews

TABLE 1. Core EENC Interventions

Population		Intrapartum Care	Newborn Care
All mothers and newborn infants	The First Embrace	• Labor monitoring (partograph)	• Immediate drying • Immediate skin-to-skin contact • Appropriately timed clamping and cutting of the cord • Exclusive breastfeeding • Routine care (eye care, vitamin K, immunizations, weighing, and examinations)
At-risk mothers and newborn infants	Preterm and LBW infants	Preterm labor Elimination of unnecessary inductions and cesarean deliveries • Antenatal steroids • Antibiotics for preterm PROM	• Kangaroo mother care • Breastfeeding support • Immediate treatment of suspected infection
	Sick newborn infants	Obstructed/prolonged labor Fetal distress • Assisted delivery • Cesarean delivery	Not breathing at birth • Resuscitation Suspected sepsis • Antibiotic treatment

Abbreviations: EENC, Early Essential Newborn Care; LBW, low birth weight; PROM, pre-labor rupture of membrane.

with hospital management staff, a key informant survey mailed to Neonatal Resuscitation Program (NRP) instructors, and a desk review of hospital protocols.

Study Sites

The study was conducted in Beijing, Shaanxi, Sichuan, and Inner Mongolia provinces. The NHFPC chose these 4 provinces because they are representative of provinces with different economic development statuses. In each province, 1 city and 1 county within this city were randomly selected. At each level—provincial, city, and county—1 hospital was randomly selected, for a total of 10 selected hospitals. Since Beijing is a municipality directly under the central government, only city- and county-level hospitals were selected.

Simulated Delivery Observations, Focus Group Discussions, and Interviews

We conducted 2 simulated deliveries in each of the 10 hospitals selected, for a total of 20 simulated deliveries, and health care provider focus groups and interviews to assess current practices. We used scenario assessments instead of actual deliveries for 2 reasons: (1) we could not get permission from pregnant women to observe their actual deliveries, and (2) we believed that using simulated cases would be an easier and less stressful way for health care providers to demonstrate their routine practices.

Six staff members—2 midwives, 2 obstetricians, and 2 pediatricians—were selected randomly in each hospital to join a delivery simulation session and a focus group discussion. The sessions were conducted in a delivery room, or a room set up like a delivery room, and had 2 components. First, the facilitator asked a midwife and an obstetrician to demonstrate management of a routine normal delivery—dividing tasks according to the routine protocol—using a manikin infant, delivery kits, and other delivery room supplies. The facilitator observed and scored the tasks performed using a standard EENC skills review method and checklist, with 1 participant playing the role of the mother and the others conducting the delivery.[12,13] Core practices reviewed were based on WHO recommendations and included in the EENC clinical coaching approach.[14] The practice scenario was repeated for management of a non-breathing baby requiring resuscitation. Second, facilitators conducted a focus group discussion to identify steps that were inconsistent with WHO recommendations and probed why staff used these practices, what factors influenced the practices, what barriers impeded changing practices, and how compliance with standards was monitored.

A simulated delivery scenario of a breathing baby was conducted in 1 hospital in Sichuan, China. © 2016 Tao Xu/National Center for Women and Children's Health, Chinese Center for Disease Control and Prevention

Simulated delivery scenarios, followed by focus group discussions, were used to assess current hospital and health worker practices without jeopardizing the health and safety of delivering mothers and their newborns.

In addition to the simulated delivery observations and the focus group discussions, 1 hospital management staff at each hospital was interviewed (N=10) about how the implementation of delivery and early newborn care policies was conducted, including how the hospital monitored adherence to hospital protocols and what was done if protocols were not followed. All observations, focus group discussions, and individual interviews were recorded for data management and analysis.

Key Informant Mail Survey

A survey was emailed to 15 national NRP instructors in the 4 provinces to collect data on delivery and early newborn care policies, protocols, and guidelines. The group of NRP instructors included national and provincial health bureau managers, MCH program officers, and childbirth and newborn care specialists. A survey questionnaire was developed and distributed via email; respondents were asked to return the completed survey via email. The questionnaire asked respondents to compare WHO recommendations on key practices to current childbirth and newborn care practices, policies, and recommendations; describe how adherence to protocols within hospitals is monitored; and identify perceived barriers and

challenges to implementing WHO-recommended guidelines.

Desk Review of Hospital Protocols

At each of the hospitals, current policies, protocols, and guidelines related to childbirth and newborn care practice were also collected and reviewed. The documents reviewed included both practice guidelines (e.g., clinical procedures and standards) and management procedures (e.g., frequency of reporting of data, accreditation mechanisms). If protocols referred to primary sources, such as medical society recommendations, textbooks, or adapted international guidelines, these were also reviewed.

Data Analysis

Data on the policies, protocols, and guidelines were extracted and entered into a Microsoft Office Excel 2013 file that allowed comparisons with WHO EENC evidence-based standards. Agreement rates for each practice or intervention were calculated by dividing the number of hospitals with protocols consistent with WHO recommendations by total number of hospitals. Each health care provider focus group discussion and interview was transcribed into a Microsoft Word 2013 file. Focus group and interview notes and transcripts were reviewed to summarize and compare the hospital protocols with WHO recommendations. Findings on accreditation mechanisms for current hospital protocols and perceived barriers to change current protocols were summarized across all hospitals and combined into common categories.

Hospital protocols and observed practices were consistent with only 41% of the 17 WHO-recommended delivery and early newborn care practices.

Ethical Approval

Institutional ethics approval to conduct the study was obtained from the institutional review board at the National Center for Women and Children's Health at the Chinese Center for Disease Control and Prevention (NCWCH). Informed consent was obtained from all health care providers participating in observations and interviews.

RESULTS

Background Characteristics of Study Hospitals

Ten hospitals from 4 provinces were sampled. Site visits with desk review of policies, focus group discussions, individual interviews, and delivery observations were conducted at those hospitals. Thirteen of 15 mail survey questionnaires were returned. Respondents included 5 pediatricians, 3 obstetricians, 3 midwives, and 2 MCH program officers.

The number of annual deliveries and the number and type of staff available to provide delivery services varied greatly between hospitals (Table 2). In 9 of the hospitals, at least 1 midwife and 1 obstetrician are routinely present at each delivery, with the midwife practicing delivery under the supervision of the obstetrician. At 1 hospital, no midwives were available prior to 2015 and deliveries were conducted by obstetricians. Most hospitals had at least 1 nurse to help in the delivery room. Pediatricians were usually only present in delivery rooms for high-risk pregnancies or if they were called to help with emergency cases.

Comparison of Hospital Protocols and Practices With WHO Recommendations

A review of hospital protocols—by self-report through the survey and onsite review by study staff—revealed that hospital protocols were consistent with WHO guidelines for 7 (41%) of the 17 delivery and early newborn care practices, including routine use of the partograph, use of corticosteroids for women of 24 to 34 weeks' gestation at risk of preterm birth, optimal timing technique for cord cutting, use of oxytocin for active management of the third stage of labor, routine administration of hepatitis B and bacillus Calmette-Guérin vaccines, and delayed bathing until at least 24 hours after birth (Table 3). Despite this, we also discovered that protocols for 10 practice areas were not consistent with WHO recommendations. None of the hospitals had policies on immediate and thorough drying after birth, delayed cord clamping, and dry-cord care. Less than 50% of hospitals had a policy on birth position and companion of choice during childbirth (38%), immediate and thorough drying after birth (48%), delayed cord clamping (30%), prolonged skin-to-skin contact (13%), delayed routine care until after the first breastfeeding (17%), and kangaroo mother care (KMC) for all newborns less than 2000 grams (17%).

The practices of hospital staff who were observed in routine delivery scenarios were consistent with WHO recommendations in the same 7 practices areas noted for hospital protocols (Table 3). The other 10 practice areas were never or rarely practiced in observed delivery scenarios, regardless of the hospital protocol. Practices never conducted in practice scenarios included

TABLE 2. Characteristics of Hospitals Included in the Study, China, December 2015

Province and Hospital	No. of Deliveries in 2014	No. of Obstetricians	No. of Pediatricians	No. of Midwives
Beijing				
Beijing MCH	17,250	68	15	65
Beijing University People's	2,343	16	17	12
Shaanxi				
Shaanxi Provincial MCH	13,338	111	81	55
Shangluo City MCH	1,845	18	12	9
Luonan County MCH	2,653	6	5	8
Sichuan				
Sichuan Provincial MCH	6,327	114	59	28
Liangshan City MCH	1,818	35	30	23
Inner Mongolia				
Inner Mongolia Provincial MCH	8,522	33	16	28
Wuhai City MCH	6,064	25	18	3
Nanhai County	394	6	4	4

Abbreviation: MCH, maternal and child health.

immediate and thorough drying after birth, immediate skin-to-skin contact of adequate duration, delayed cord clamping, absence of routine suction, and delaying routine tasks until after the first breastfeeding. Although delayed cord clamping was recommended by 30% of hospital protocols and prolonged skin-to-skin contact by 13%, neither were practiced in any case observations at the 10 hospitals, with hospital staff completing routine care (eye care, weight, and height) immediately after birth before skin-to-skin contact. Similarly, KMC for stable preterm babies was required in 17% hospitals; no preterm babies had KMC initiated, with all immediately separated from the mother and admitted to neonatal intensive care units. Newborn resuscitation equipment was required to be placed within 2 meters of the delivery bed in 84% of hospital protocols but was only prepared in 40% of cases. Immediate drying (within 5 seconds of birth) was required in 48% of hospital protocols but was initiated in only 20% of observed cases.

Barriers to Improving Hospital Protocols for Delivery, Childbirth, and Early Newborn Care

Several potential barriers to introducing evidence-based guidelines were identified in focus group discussions with simulation participants and key informant interviews with NRP instructors. The results are summarized below.

Clinical Protocols and Guidelines

Each province has developed an MCH plan and the measures for administration of midwifery techniques guidelines. These provincial policies regulate the certification of delivery services, required preservice and in-service trainings and qualifications for providers, accreditation mechanisms and regulations, basic equipment and facility requirements, and content of services for the different levels of hospitals. However, none of these guidelines provide detailed clinical practice standards or protocols on immediate childbirth and early newborn care, leaving hospitals to look to other resources. For example, the *Guide for Prevention and Treatment of Postpartum Hemorrhage*[15], developed by the Chinese Medical Society, provides detailed protocols for techniques such as cord clamping and the use of oxytocin, and an NRP guideline was developed for the NHFPC-led China NRP program. As a result, participants indicated that hospitals have to develop their own protocols based on the textbooks and guidelines available to them, which, in turn, has

Key barriers to improving hospital protocols included the lack of a standardized evidence-based set of clinical protocols and guidelines, supported by peer-reviewed literature and aligned with a system of evaluation.

TABLE 3. Number and Proportion of Hospitals With Delivery and Immediate Newborn Protocols and Practices Consistent With WHO Recommendations by Assessment Method, China, December 2015

Intervention	Protocol Self-Report via Mail Survey (n=13) No. (%)	Protocol Onsite Hospital Review (n=10) No. (%)	Observed Delivery Practice (n=10) No. (%)
Companion and position of choice for all deliveries	5 (39)	3 (30)	3 (30)
Maternal and fetal monitoring during labor including use of the partograph	13 (100)	10 (100)	10 (100)
Corticosteroids for women of 24 to 34 weeks' gestation who are at risk of preterm delivery	13 (100)	10 (100)	10 (100)
Bag and mask resuscitation kit available for every delivery, positioned within 2 meters of delivery bed	11 (85)	6 (60)	4 (40)
Drying started within 5 seconds after birth	7 (54)	4 (40)	2 (20)
Dried the baby thoroughly (wiped the eyes, face, head, front, back, arms, and legs)	0 (0)	0 (0)	0 (0)
No routine suctioning	0 (0)	0 (0)	0 (0)
Delayed cord clamping performed 1 to 3 minutes after birth, after cord pulsations have stopped	4 (31)	3 (30)	0 (0)
Clamp/tie placed at 2 cm, forceps at 5 cm from umbilical base	13 (100)	10 (100)	10 (100)
No placing substances on the cord stump	0 (0)	0 (0)	0 (0)
Skin-to-skin contact for a minimum of 90 minutes for newborns without complications	3 (23)	0 (0)	0 (0)
Intramuscular oxytocin given to mother within 1 minute	13 (100)	10 (100)	10 (100)
All routine newborn care (e.g., eye care, vitamin K, immunizations, and examinations) delayed until after a full breastfeeding	2 (15)	2 (20)	0 (0)
First dose of hepatitis B vaccine given within 24 hours of birth	13 (100)	10 (100)	10 (100)
Single dose of BCG vaccine given within 24 hours of birth	13 (100)	10 (100)	10 (100)
No bathing of the newborn until at least 24 hours after delivery	13 (100)	10 (100)	10 (100)
KMC for preterm babies weighing ≤2000 g at birth, including feeding with breast milk and monitoring for complications	3 (23)	1 (10)	0 (0)

Abbreviations: BCG, bacillus Calmette-Guérin; KMC, kangaroo mother care.

led to inconsistent protocols and practices across the different hospitals.

Systems of Accreditation and Legal Status of Protocols

While national- and provincial-level MCH service evaluation standards are currently available, they only focus on basic principles and requirements, not core evidence-based practices. Hospitals are evaluated every 3 or 4 years by provincial authorities. If the basic standards are not met, the hospital may be prohibited from providing MCH services the following year. If an individual staff member is found not to be practicing protocols, he or she may be disciplined by verbal criticism, deduction of wages, suspension of license, or a lawsuit, depending on the severity. Most hospital staff believe they should follow domestic textbook recommendations and Medical Society guidelines because these are officially sanctioned, and have legal status in case of medical disputes.

Understanding of the Evidence Base Supporting New Practices

Peer-reviewed journal articles used for WHO GRADE recommendations, for example, are felt to be important to explain key practice steps such as prolonged skin-to-skin contact, delayed cord clamping, non-use of suction except for non-breathing babies born with meconium staining and dry cord care. This is particularly important for explaining why new evidence-based recommendations are different from those used previously. For example, the previous duration for skin-to-skin contact recommended in baby-friendly hospital guidelines was 30 minutes, not

90 minutes. Similarly, many staff believed that applying disinfectants and covering the cord stump is important to prevent sepsis, and would like to see relevant data on this issue. In two hospitals, staff were concerned that mothers may not be able to safely hold babies in skin-to-skin contact and may drop them; in some cases there was concern that this position may be associated with an increase in the risk of asphyxia.

Cultural Beliefs and Practices

A number of cultural practices and beliefs held by families, particularly grandparents, prevent evidence-based practices from being applied including early separation of the newborn from the mother so the newborn can be shown to other family members, concerns that skin-to-skin contact with the mother is dangerous, a desire to bathe the newborn early, and beliefs that keeping the cord stump uncovered will allow "cool breezes" to pass through the cord stump into the newborn's body and cause illness.

Facility Support for New Practices

Maintaining skin-to-skin contact for 90 minutes, or until the first breastfeeding, usually requires the assistance of postnatal care staff who may not be familiar with the how and when to initiate each technique and for how long. Breastfeeding counseling, in particular, is essential for initiating the first feed. In some cases, staff members were concerned that beginning new practices would increase the workload for midwives or nursing staff and wanted clarification on how responsibilities would change.

DISCUSSION

Our findings suggest that although China has no national EENC guidelines, many childbirth and newborn health care protocols and practices were evident in various documents at the hospital level. However, technical protocols related to childbirth and newborn health care were fragmented, outdated, and developed through a nonscientific guideline development process, and over half were not consistent with WHO guidelines. Because the EENC recommendations are new and not included in current protocols, facilities were not expected to adhere to them. To introduce EENC in China, implementers must recognize the need to identify necessary support for and changes in hospital policy, organization, accreditation mechanisms, and cultural beliefs.

Since 2013, the Chinese NHFPC has been working with the United Nations Children's Fund (UNICEF) China to develop a newborn survival framework and service package, as the government response to the WHO and UNICEF Every Newborn Action Plan. The central and provincial health authorities have developed various policy documents that, for example, regulate the certification of delivery service, required preservice and in-service trainings and qualifications for providers, accreditation mechanisms and regulations, requirements for basic equipment and facilities, and a description of services for different levels of hospitals. In May 2018, the NHPFC issued the *Healthy Child Action Plan (2018–2020)*,[17] and newborn health is one of the key areas that needs to be strengthened. These government documents do not, however, provide detailed technical protocols on childbirth and newborn health care interventions. Instead, hospitals have had to adopt and develop their own technical protocols based on textbooks, medical society guidelines, or experience learned from others. As a result, these hospital protocols were inconsistent in their scientific foundations and clinical procedures. In addition, although a description of childbirth and immediate newborn care was available in the hospital documents we examined, the technical procedures were fragmented and not presented or implemented in a systematic manner. To address policy and practice inconsistencies within and across hospitals in the country, a national guide on childbirth and early newborn care is needed.

Many of the technical childbirth and newborn health care protocols used by the hospitals studied were limited, outdated, and did not use a strict evidence-based guideline development process.

In 1988, less than half of all women in China gave birth in hospital; within 20 years, hospital births became almost universal.[18] This change is, in part, due to the government discouraging community midwifery and introducing a safe motherhood program that encourages hospital delivery in 2000.[19] The Chinese NHFPC is now focusing on improving the quality of in-hospital maternal and child health care, especially the quality of care during and immediately after birth. WHO estimates that full implementation of EENC in the Western Pacific Region could prevent at least 50,000 newborn deaths each year.[9] Central to EENC is the concept and practice of "The First Embrace," a protected and prolonged skin-to-skin cuddle between mother and newborn, which allows proper warming, feeding, and cord care. The EENC protocol also includes the care of high-risk newborn infants, including preterm and low birth weight babies, and of sick newborn infants.[10]

Despite of these proven effective interventions, many inappropriate interventions are still

practiced in hospitals that interfere with the baby's ability to adapt and feed well, such as unnecessary suctioning, immediate cord clamping, and delayed drying. These outdated practices increase the risk of delayed fetal-to-newborn circulatory adjustments, infection, breathing problems, hypothermia, anemia, acidosis, coagulation defects, brain hemorrhage, and trauma.[9] Many newborns are distressed, hypothermic, and exposed to dangerous bacteria because they are separated from their mother.[10] The first breastfeeding is often delayed because of an incorrect sequencing of actions taken immediately after birth.[7] In our study, less than half of the hospital protocols we reviewed were consistent with WHO recommendations for procedures related to childbirth and immediate newborn care, such as immediate drying after birth, no routine suctioning, delaying cord clamping, skin-to-skin contact, no placing substances on the cord stump, and KMC for stable preterm babies. In addition, the abovementioned key practice areas were never or rarely practiced in observed delivery scenarios, regardless of the hospital protocol.

One recently published UNICEF reviews identified problems and bottlenecks in the health system to provide newborn care.[20] Our research results support these findings and identified more specific barriers that health workers face introducing and practicing EENC in their facilities. First, there is no detailed national clinical practice guidelines for the management of routine delivery, childbirth, and immediate newborn care. As a result, policies and practices within and across hospitals were often not consistent. The knowledge on textbooks and experiences from other health workers were often outdated and harmful, and preservice and in-service trainings usually did not include sufficient instruction on quality EENC. As a result, many health workers were unaware that simple steps could protect newborn infants. Second, the protocols used must have legal validity for medical disputes and malpractice cases. The development and adoption of national evidence-based guidelines must therefore be initiated and approved by academic authorities or at the NHFPC level before being implemented in hospitals and incorporated into an effective accreditation mechanism. Third, the documents used for the evidence base should be made available to all stakeholders, including health workers and families of newborns. New practices need to be supported by an evidence base to secure widespread support from staff. In addition, the role of traditional and cultural beliefs must also need to be recognized, as they can influence how and why parents make certain decisions. Thus, capacity building activities should go beyond training and focus on coaching, which focus on methods for improving awareness of the importance of evidence-based practices. Last, insufficient coordination between obstetric and pediatric care complicates newborn care.[21] Changes in facility support and the organization of work are required to support revised practices and to ensure that new practices are understood and adopted by all. For example, closer collaboration is needed between staff present at delivery who may currently divide or share tasks, particularly those tasks that obstetrics or midwifery staff may not traditionally feel is their responsibility, such as identifying whether a newborn is stable and able to be placed into immediate skin-to-skin contact and starting immediate newborn bag and mask resuscitation for non-breathing newborns.

The development and adoption of national evidence-based guidelines must be initiated and approved at the national level before being implemented in hospitals and incorporated into an effective accreditation mechanism.

Neonatal deaths in the Western Pacific Region declined slowly between 1990 and 2015.[9] This was largely because of the widespread, outdated, and harmful health care provider practices.[11] Through collaborative efforts with WHO and UNICEF, it is clear that countries in the region share many similar problems and barriers when scaling up EENC interventions. The results of this study may help countries working to ensure evidence-based policies and practices are used to improve their quality of skilled childbirth care.

CONCLUSION

China has been working closely with various partners to prioritize newborn health by developing a national action plan and technical guideline that aligns with WHO recommendations. However, at the moment, hospital policies, protocols, and interventions only partially align with WHO recommendations. To make EENC easier and safer for hospital workers to practice, expert working groups and national policies must be established to address inconsistencies and cultural beliefs and provide a strong, evidence-based set of guidelines for hospitals and health workers to follow.

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SHORT REPORT

Local Sourcing and Supplier Development in Global Health: Analysis of the Supply Chain Management System's Local Procurement in 4 Countries

Prashant Yadav,[a] Sarah Alphs,[b] Clinton D'Souza,[c] Gordon Comstock,[d] Iain Barton[c]

Local suppliers reported that after doing business with PEPFAR's global procurement and distribution project for essential HIV/AIDS medicines and supplies, they achieved revenue and asset growth, improved their quality standards, acquired new contracts with other businesses, and hired more employees.

ABSTRACT

From 2006 to 2014, Supply Chain Management System (SCMS), the global procurement and distribution project for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), distributed over US$1.6 billion worth of antiretroviral drugs and other health commodities, with over US$263 million purchased from local vendors in 14 countries in sub-Saharan Africa. A simple framework was developed and 39 local suppliers from 4 countries were interviewed between 2013 and 2014 to understand how SCMS local sourcing impacted supplier development. SCMS local suppliers reported new contracts with other businesses (77%), new assets acquired (67%), increased access to capital from local lending institutions (75%), offering more products and services (92%), and ability to negotiate better prices from their principles (80%). Additionally, 70% (n=27) of the businesses hired between 1 and 30 new employees after receiving their first SCMS contract and 15% (n=6) hired between 30 and 100 new employees. This study offers preliminary guidance on how bilateral and multilateral agencies could design effective local sourcing programs to create sustainable local markets for selected pharmaceutical products, laboratory, and transport services.

BACKGROUND

Amidst a growing concern about sustainability of global health aid, and in a context of increasing focus on aid-recipient countries taking over their health budgets, the development of national program capacity has been attracting considerable policy interest.[1–5] There is a strong interest in identifying viable institutional frameworks and policy options that can help countries graduating from foreign development assistance for health to effectively manage their health systems with local implementing partners.[2] Many donors and development agencies, especially the United States Agency for International Development (USAID), have an increased focus on how to make programs more effective, more enduring, and less costly through procurement reform, sustainable partnerships, and local solutions.

This imperative for greater sustainability and higher value for money is most pronounced in the procurement and distribution programs run as part of global health initiatives such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR); the Global Fund to Fight AIDS, Tuberculosis, and Malaria; and Gavi, the Vaccine Alliance. USAID had initiated a strategy to increase local procurement with an intent to promote sustainability and country ownership of its programs.[6] These trends are based on a hypothesis that local procurement—the practice of purchasing goods and/or services through local suppliers—can help achieve sustainability and build the capacity of local market actors and institutions.

In 2005, USAID under PEPFAR established the Supply Chain Management System (SCMS) to provide a reliable, cost-effective, and secure supply of products for HIV/AIDS programs in PEPFAR-supported countries. Between 2006 and 2014, SCMS distributed US$1.6 billion worth of antiretroviral drugs and other health commodities to various countries. One of the cornerstones of SCMS's mission is a commitment to developing the procurement and distribution capacity of host-country governments and local NGOs, and selecting the most appropriate procurement strategies for each product and geography. In tune with this strategy, SCMS sourced

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over US$263 million of its overall spending during this period from local suppliers in 14 African countries.

When commercial companies seek local suppliers, the reason is typically to reduce costs and meet local content requirements.[7,8] While local purchasing by global multinationals has shown the benefits of lowering costs and achieving economic benefits,[6] local procurement may not work for all product and geographical markets. In low- and middle-income country settings, the number of local suppliers who can meet the standard for quality and reliability required for producing pharmaceuticals and laboratory supplies are extremely limited. As a result, intermediaries who add cost markup without contributing to value addition sometimes get added into the value chain. While increased cost was of some concern, the key goals of the SCMS local sourcing initiative were not necessarily cost savings but sustainability and local capacity enhancement.

The goal of this study was to understand the impact of SCMS local sourcing on long-term development of a high-quality local supplier base. While supplier development has been extensively studied in the commercial sector[9] and to some extent in high-income country public-sector procurement,[10] it has not been studied systematically for public/NGO purchasers operating in international health settings. This study aimed to understand how local sourcing impacts supplier development and long-term market health. Our contribution sheds new light on how bilateral and multilateral agencies could design effective local sourcing programs to create sustainable local markets for selected pharmaceutical products, laboratory, and transport services.

METHODOLOGY

The commonly used methodology in economic literature to assess broader intersectoral economic impact of an intervention is Input-Output Analysis.[11] Input-Output Analysis looks at the interdependencies of industries or economic sectors and estimates to what extent positive or negative economic shocks affect a country's economy.[11] While this type of analysis provides a useful way to assess overall economic impact, it does not capture firm specific managerial impacts that are at the core of our study. Another important way to assess impact is the concept of Shared Value,[12,13] which assesses the gains to each stakeholder. Our study objectives were to understand the strategic, managerial, and economic implications for organizations that were part of the SCMS local vendor network. We developed a simple framework of measurement that was clear, practical, and grounded in the country context where this work was carried out.

Global commercial companies often seek local suppliers to reduce costs and meet local production standards.

Through their relationship with SCMS, local suppliers benefitted from increased revenue, additional resources to expand operations, and received training and technical support to help their businesses improve and grow.

The most direct impact measured was the increase in business revenue for the suppliers when SCMS procures a product or service from them. This revenue increase leads to further economic activity, including the creation of additional jobs at the supplier. Furthermore, as suppliers expand to meet additional or new needs, they potentially acquire additional assets, such as a warehouse, a forklift, or laboratory equipment. In addition, as part of the local sourcing initiative, SCMS provided training, helped create standard operating procedures, and enforced strict quality standards on the suppliers. This could improve suppliers' ability to better serve other customers and increase their competitiveness in seeking business with other companies. A clear predictable revenue stream from SCMS may also enable suppliers to access capital at better terms from banks and financial institutions. We used a 3-part framework of potential direct, intermediate, and long-term impact to assess the overall impact of SCMS on its suppliers (Figure 1) and surveyed sampled firms to help answer the 8 questions embedded within the framework. We measured this using the indicators described in the Table.

We developed a survey and interview guide to assess these and additional changes in the supplier's economic position, relationships, and capacity over time (Supplement). The methodology did not include any control group—specifically, local firms that did not receive a SCMS contract—and was strictly based on comparisons before and after receiving a contractual award from SCMS.

Sample Selection

Analysis of SCMS spending revealed that more than 90% of SCMS spending with local vendors between fiscal years 2009 and 2011 was in 8 countries (of 14): Côte d'Ivoire, Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Tanzania, and Zambia. We sampled 50% of the 8 countries based on logistical/geographical clustering. The study was carried out in Ethiopia, Kenya, Mozambique, and Tanzania. Instead of interviewing and obtaining records from every single vendor in each of these countries, the below was used as inclusion criteria for vendors:

1. Contract award value over US$15,000.

FIGURE 1. Impact Assessment Framework

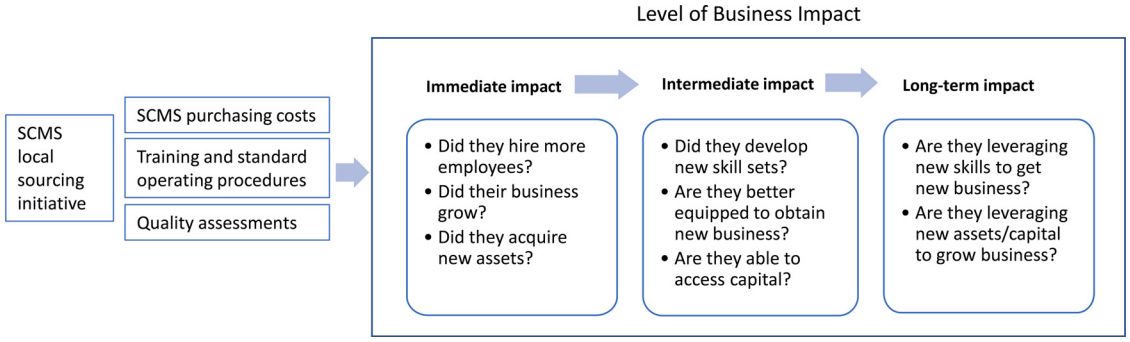


TABLE. Indicators for Impact Assessment

Impact	Indicator	Data Source
Revenue	Annual revenue pre-/post-SCMS award	Supplier company records
Business output/productivity	# training programs conducted Good storage practices Access to working capital	Supplier company records and interview
Assets (e.g., vehicles)	# of assets obtained/sold locally	Supplier company records
Employment	# of additional jobs created post-SCMS award	Supplier company records
Market competitiveness	# of contracts obtained post-SCMS award	Supplier company records and interview
Range of services offered	# and types of services offered post-SCMS award	Supplier interview

Abbreviation: SCMS, Supply Chain Management System.

2. Supplied at least 1 order to SCMS between 2006 and 2013.
3. Representation from different industries, such as laboratories, pharmaceutical, information and technology services, logistics, and warehousing.
4. Representation of both smaller and larger businesses.

A total of 39 vendors across all 4 countries were interviewed. The interviews were carried out over the period of May 2013 through January 2014.

Local suppliers ranged from small office suppliers to large pharmaceutical or laboratory companies.

Profile of Local Suppliers

The local suppliers spanned from small vendors of office supplies or maintenance services to large pharmaceutical and laboratory supply companies. Before delving into understanding the impact of local procurement, it is necessary to understand who the local suppliers are, how long they have been in business, and how many employees they have.

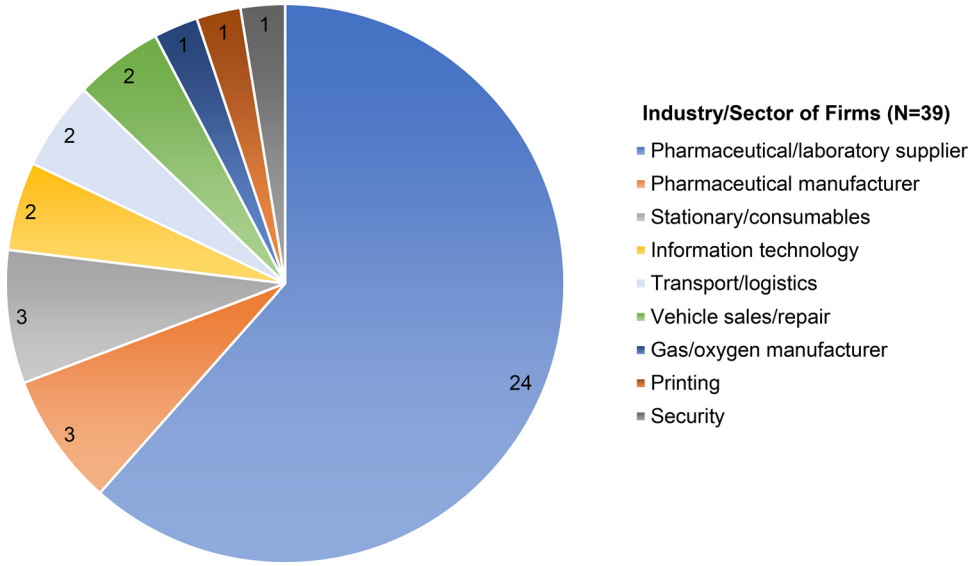
Job Function of Respondents

Survey- and interview-based business impact studies often rely on interviews with line staff who have a limited understanding of strategic issues, such as the development of new service offerings. For this study, the research team interviewed respondents with managerial and strategic experience who were at the leadership level at each supplier. More than 20 of the respondents were chief operating officers or owners of the firm, which gave us an understanding of how local sourcing has transformed their business.

Industry of Local Supplier

A large portion of money spent at the local level was on suppliers of pharmaceuticals and

FIGURE 2. Industry/Sector of Firms in the Sample



laboratory services or reagents. Of the vendors interviewed (N=39), 24 were suppliers of laboratory, medical supplies, and pharmaceuticals (Figure 2).

Age of Business

Of the 39 local suppliers interviewed, 27 had been in operation for 5 years or more at the time of the interview. This demonstrates that a majority of the local vendors are established firms and are not new players that have created only to serve SCMS.

Size of Business

The reported median annual revenue of local suppliers was between US$1 million and US$5 million, with some earning as high as US$30 million through US$49.9 million (Figure 3).

The distribution of the size of the businesses varied considerably by the industry. All of the pharmaceutical and laboratory suppliers (n=24) reported an annual revenue greater than US$1 million, with many earning up to and over US$20 million. Stationary suppliers tended to be smaller, with 2 of them having revenue less than US$500,000 each year. Vendors supplying vehicles, including forklifts and trucks, were the largest vendors by type, with 2 reporting an annual revenue of over US$10 million. As noted in the sampling framework, only local businesses with a contract award over US$15,000 were included in the study, which slightly biased this sample toward larger companies.

Number of Employees

SCMS local vendors interviewed included a balanced mix of smaller businesses with less than 25 employees and larger businesses with over 200 employees (Figure 4).

Branches

Of the 39 businesses interviewed, 24 said they had a branch in another location. Multi-locational businesses have a larger footprint, allowing them to provide services not only in the capital city but also in other parts of the country.

Number of Customers

The sampled businesses represented a balanced mix of companies that ranged from having less than 50 customers to having more than 500.

Vendor's Total SCMS Contract Award Values

SCMS provided the research team with the values of contracts awarded to vendors in Ethiopia, Mozambique, and Tanzania. Among these vendors (n=28), 26 were awarded contracts with a total value over US$100,000. The majority of vendors received contract awards valued between US $100,000 and US$500,000 (Figure 5).

FIGURE 3. Annual Revenue (in US$) of Firms in the Sample

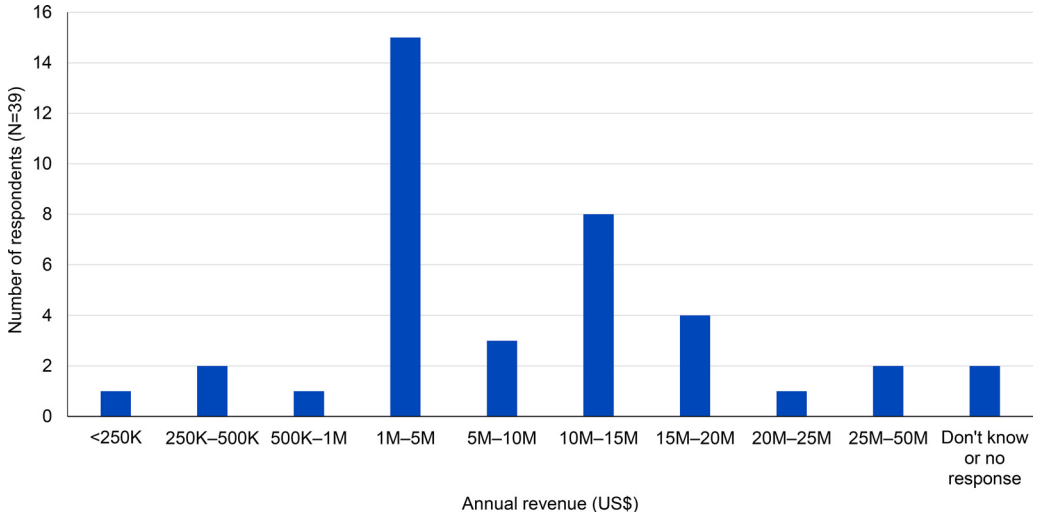
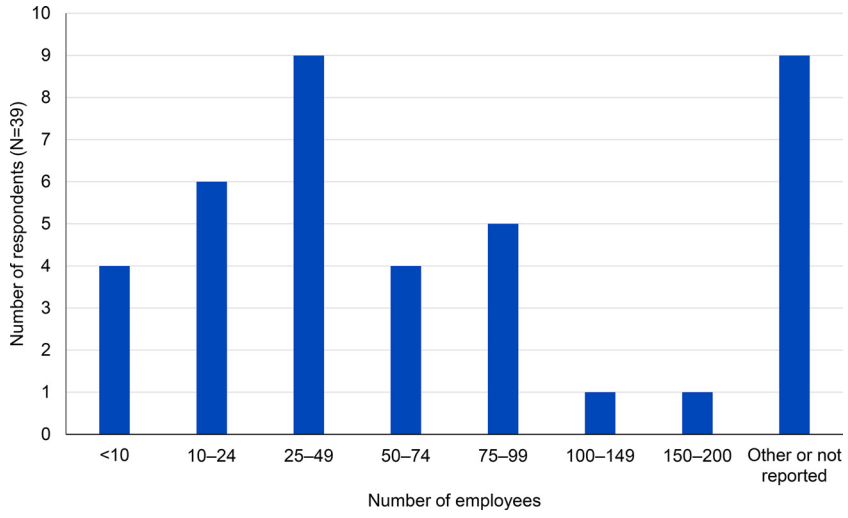


FIGURE 4. Number of Employees in Respondent Firms



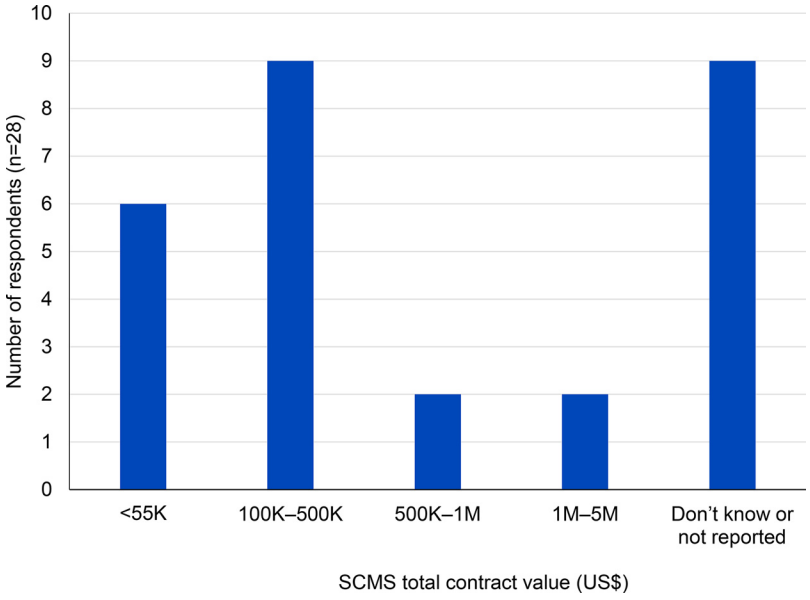
The distribution of contract value varies considerably by the industry in which local vendors operate. In total, 3 manufacturers received contracts valued over US$500,000; 8 of the pharmaceutical and laboratory suppliers (distributors) received contracts between US$100,000 and US$500,000, 7 received contracts valued between US$500,000 and over US$10 million, and 1 received a contract valued less than US$50,000; and 2 of the suppliers supplying stationary and other office consumables received contracts valued less than US $50,000.

RESULTS

Revenue Growth

Almost all (n=36) of the 39 businesses interviewed reported that their company had experienced growth since their first contract with SCMS.

FIGURE 5. Distribution of SCMS Total Contract Value (US$) to Firms in the Sample



Abbreviation: SCMS, Supply Chain Management System.

Note: Kenya respondents were not included. When provided a range, the average of the range is included in this analysis.

Labor Changes and Employment Generation

A majority (n=33) of the firms reported an increase in the number of employees after receiving a contract from SCMS. Of the 33 firms, 27 hired between 1 and 30 new employees after receiving their first SCMS contract and 6 hired between 30 and 100 new employees (Figure 6). Employee salaries have a trickle down/multiplier effect on the local economy.

Asset Growth

A majority (n=36) of the 39 firms interviewed reported an increase in asset ownership after their first SCMS contract. The most commonly acquired assets were warehouse space, commercial vehicles, and additional office space (Figure 7). These are generic assets that can be effectively leveraged for other clients. The majority (n=25) of respondents reported acquiring new assets over US$100,000 (Figure 8).

Overall Impact of SCMS Business

When the respondents were asked to reflect on the impact of SCMS on their businesses, about half (n=19) of 39 businesses interviewed said that SCMS had positively impacted their business, 2 reported that working with SCMS negatively impacted their business, 3 reported both positive and negative impacts, and 9 said that SCMS had no impact on their business (Figure 9). Of the 19 firms who reported that a contract with SCMS had a positive impact on their business, 8 stated that doing business with SCMS improved their reputation, enabling them to win new clients.

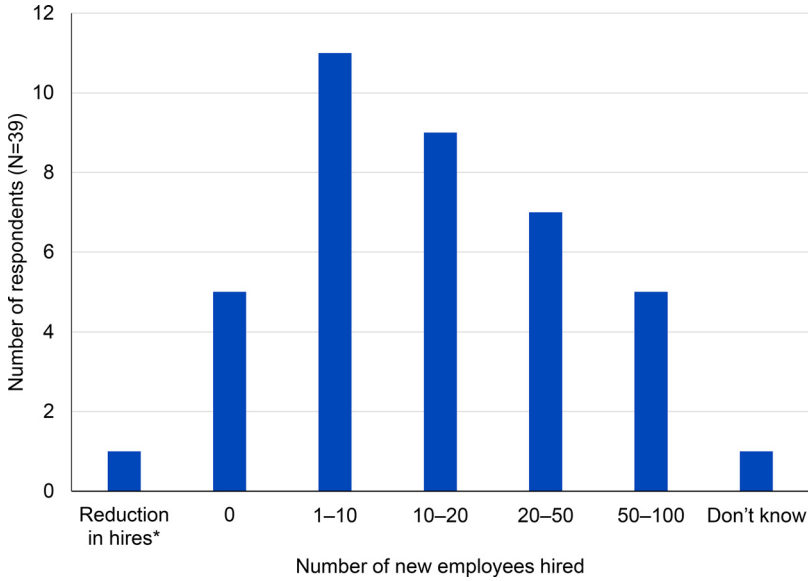
A majority (84.6%) of the firms reported an increase in the number of employees after receiving a contract from SCMS.

Of the 2 vendors who reported that working with SCMS negatively impacted their business, the first cited that delayed payments from SCMS constrained their company financially and the second reported that working with SCMS had negatively impacted their company's reputation when facility-level stock-outs of a product they had supplied to SCMS were attributed to their business.

A total of 9 vendors responded that SCMS had no impact on their business. We analyzed these vendors in greater detail to understand the underlying reasons for their lack of growth. We found that nearly all (n=7) of the firms did not have any active contracts with SCMS in 2013 and that their earlier contracts were mostly one-off procurement arrangements. Of the 2 remaining firms, 1 was in financial distress with significant debt due to outstanding payments from large clients, including the national government, and did not

About half (48.7%) of 39 businesses interviewed said that SCMS had positively impacted their business.

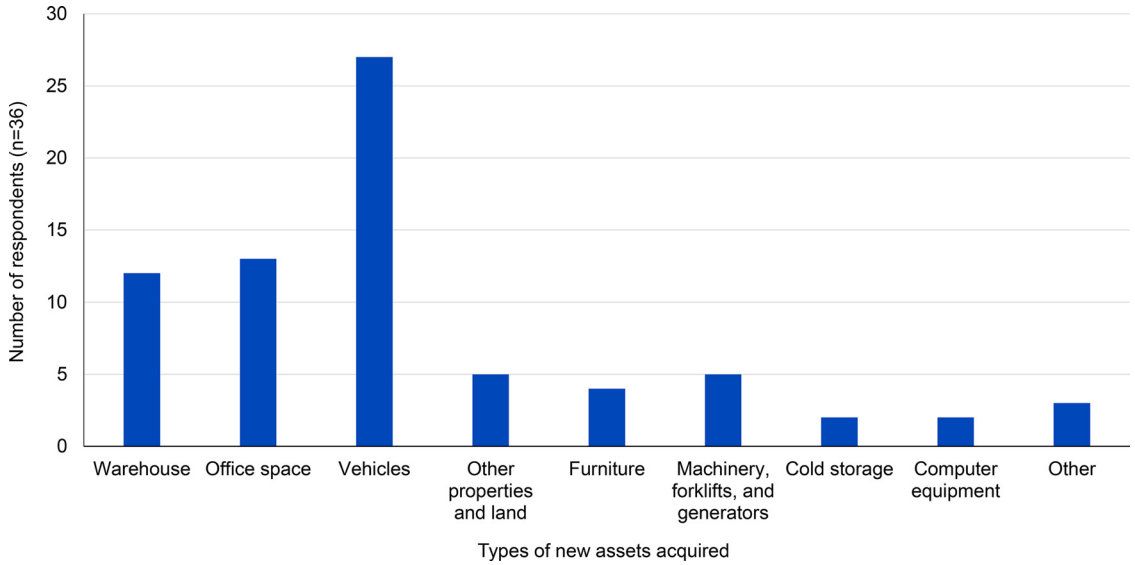
FIGURE 6. Number of New Employees Hired After Contract With SCMS



Abbreviation: SCMS, Supply Chain Management System.

* 1 firm reported a decrease in their employees after the start of SCMS contract.

FIGURE 7. Types of New Assets Acquired[a] After Start of SCMS Contract



Abbreviation: SCMS, Supply Chain Management System.

[a] More than 1 response was allowed.

FIGURE 8. Estimated Value (in US$) of New Assets Acquired

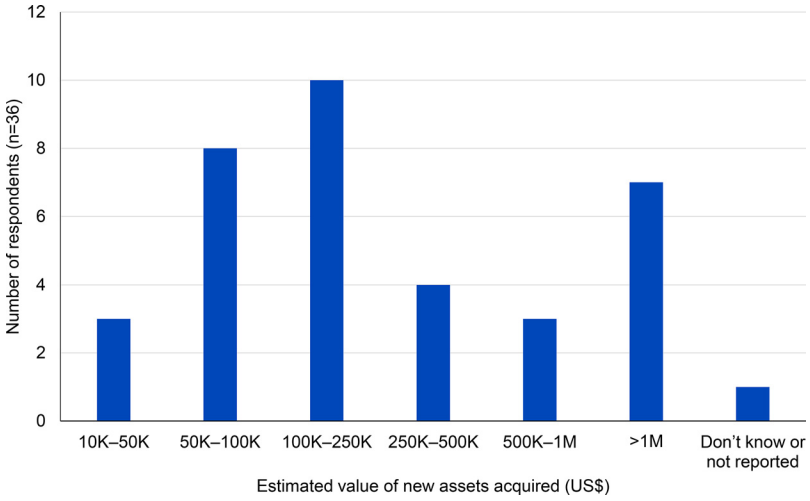
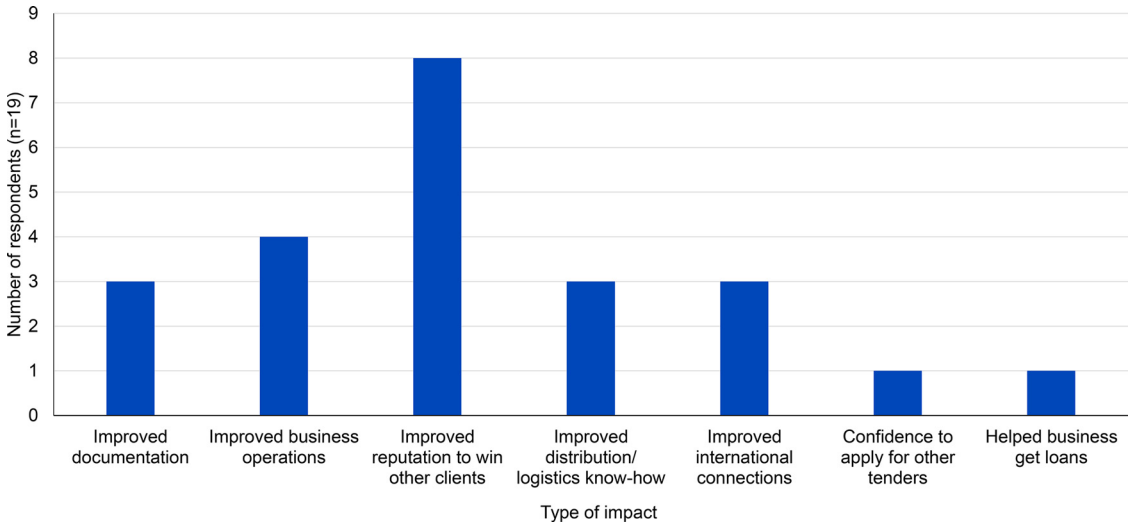


FIGURE 9. Type of Impact[a] of SCMS Contract on Firm's Business



Abbreviation: SCMS, Supply Chain Management System.

[a] More than 1 response was allowed.

attribute its financial issues to SCMS. The other was a large well-established business that had received its first contract with SCMS in 2013, but had many larger clients than SCMS.

DISCUSSION

When large global firms source from local suppliers it provides a powerful channel through which the global firm's knowledge and skills can be diffused directly to the local suppliers, or indirectly to local firms through a spillover effect.[7,14,15] However, sometimes it is difficult or impossible to find local suppliers who meet the international quality standards or capability requirements needed to expand the supply chain. Supplier development should be a key part of public and NGO procurement in such markets.

The results of this study show that, in most cases, local suppliers under the SCMS local sourcing initiative increased employment, achieved revenue and asset growth, improved their quality standards, and became more equipped to acquire new customers. Admittedly, some of this growth would have occurred due to overall growth in the economy/sector. Furthermore, firms with effective business processes, strong management, good governance, and a past record of growth were more likely to grow faster than their peers. Given SCMS's selection criterion for local vendors favors firms with such attributes, it became harder to establish to what extent their growth was due to SCMS contracts and know-how and how much would have occurred irrespective of those 2 factors.

Local suppliers need capital to continually upgrade the quality, breadth, and depth of the services they offer. In order to meet global standards and further grow their businesses, local suppliers require sufficient capital to invest in buildings, machinery, equipment, trucks, and product inventory. High interest rates, lack of longer-term loans, and the absence of credit records hinder the ability of small- and medium-sized suppliers to survive and grow. About a quarter (n=29) of the 39 local SCMS vendors in this study reported that their access to capital from local lending institutions increased after they began doing business with SCMS. This shift results from the predictability of demand and greater confidence by local banks in suppliers with track record of doing business with a large international firm. Evidence shows that alleviating working capital constraints substantially enhances business sustainability.[16] To that end, supplier financing solutions that can provide greater access to capital and further enhance the growth of local suppliers need to be explored. Commercial companies often conduct a supplier sustainability gap analysis, which helps to identify the constraints current suppliers are facing in leveraging their enhanced capabilities to further grow and diversify their business. This type of analysis can help bilateral and multilateral agencies, host country governments, and their implementing partners identify opportunities and work together to design local supplier development programs. A key challenge to this approach is that when local suppliers are uncompetitive, forcing local sourcing through "local content requirements" can lead to high-cost production of low-quality products. A more appropriate policy intervention is to create investment vehicles that allow stronger linkages through which productivity know-how can be diffused from global firms to local companies.

Programs should adopt a strategic approach to local supplier development and use key performance metrics to measure growth and impact.

A supplier sustainability gap analysis helps commercial companies identify the constraints faced by their suppliers to further grow their business.

Our findings show that local supplier development of smaller firms would require the buying group to provide a support role through coaching, mentoring, and other methods of transferring business know-how. For more established local firms (such as the ones in this study sample), the buying group's key role is their ability to provide predictable demand, guaranteed financial flows, and the reputational benefits of doing business with a large global firm (Figure 9). Local supplier development is an effort- and resource-intensive activity that requires substantial staff time to be devoted to finding, auditing, and selecting local suppliers, and then mentoring or coaching their staff to improve their business processes.

Due to the frequent use of formal tendering in public procurement, public buyer–supplier relationships often do not have an explicit supplier development component built into them. Organizations such as SCMS and the USAID Global Health Supply Chain Program – Procurement and Supply Management Project (GHSC-PSM) have more flexibility in their sourcing and procurement practices to embed supplier development into their programs. To realize local sourcing objectives, specifically local firm growth, local economic impact, and program sustainability, multi-year programs/initiatives should adopt a strategic approach to local supplier development. They should also build in key performance metrics into health commodity procurement to measure the factors related to improving the quality of local labor force, local firm growth, and local economic impact.

As a large share of health commodity procurement transitions to national government financing, it is important to embed local supplier development programs into the transition plans. It remains unclear if some of the benefits to local firms—such as easier access to local credit because of a fixed contract with a global organization or the reputational benefits associated with doing business with a global organization—would be as relevant when their main customer becomes the national government instead of a group like SCMS or GHSC-PSM. These are crucial areas of market and supplier development that require further examination.

CONCLUSION

This study offers preliminary guidance on how bilateral and multilateral agencies could design

effective local sourcing programs to create sustainable local markets for selected pharmaceutical products, laboratory, and transport services. Further investigation is required to better understand the procurement pathways that lead to local suppliers investing in new assets, institutionalizing new quality standards, recruiting new employees, or creating new service offerings.

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Competing Interests: CD, GC, and IB are employees of SCMS. SA received travel assistance to visit 4 countries for the study. PY reports no competing interests.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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FIELD ACTION REPORT

Adaptation of the Training Resource Package to Strengthen Preservice Family Planning Training for Nurses and Midwives in Tanzania and Uganda

Stembile Mugore,[a] Mercy Mwanja,[b] Vumilia Mmari,[c] Alphonce Kalula[d]

Lessons learned when adapting the evidence-based global family planning training resource package included the need to: (1) engage key nursing and midwifery educators for buy-in; (2) update the technical skills of educators in contraceptive technology and competency-based training methods; and (3) adapt to the local context including condensing the global content for the time-limited preservice education context.

ABSTRACT

Background: Tanzania and Uganda have high total fertility and maternal mortality rates, and low contraceptive prevalence rates. High-quality preservice family planning education for nurses and midwives can improve the quality of sexual and reproductive health care, thereby improving health outcomes.

Description of Intervention: In 2015, we worked with relevant stakeholders in Tanzania and Uganda through a series of surveys, assessments, and workshops to adapt modules of the Training Resource Package for Family Planning (TRP), an evidence-based global resource, to improve the quality of preservice family planning education for nurses and midwives. With support, a wide range of stakeholders, including policy makers, program managers, educators from nursing and midwifery training institutions, and representatives from professional associations, identified relevant TRP modules and adapted them to each country's context to inform and develop their own lesson plans in accordance with national policies, guidelines, and standardized preservice education templates.

Lessons Learned: Important lessons from the adaptation process include the following: (1) engage relevant ministries of health and education, professional associations, and regulatory councils at each step of the process to increase the acceptability and utility of the TRP; (2) use a context-specific process for adaptation of the TRP, as not one process will fit the needs of all countries; and (3) include nursing and midwifery educators in the adaptation process to create an established pool of trainers who can then cascade the TRP to other educators in their respective schools. Overall, participants in both countries expressed challenges with incorporating competency-based teaching methods into their curricula because they were unfamiliar with such approaches themselves and with reducing the extensive TRP content to fit within the time constraints for preservice education.

Conclusion: Adaptation of an evidence-based global family planning training resource in Tanzania and Uganda resulted in substantive changes to the curricula of the reproductive health preservice course unit that will support nurses and midwives to provide quality, rights-based family planning services.

BACKGROUND

The modern contraceptive prevalence rate in Tanzania and Uganda, 32% and 35%, respectively, is low relative to that in high-income countries, whereas the maternal mortality rate, 556 and 336 per 100,000 live births, respectively, is high.[1,2] Tanzanian women have, on average, 5.2 children, and Ugandan women 5.4.[1,2] Across both countries, approximately 1 in 4 women has an unmet need for contraception.[1,2] Quality family planning services provided by well-trained, competent health workers can lead to increased uptake of contraception and reductions in unintended pregnancies, in turn leading to improved health outcomes.

Preservice education (i.e., training and instruction provided to health professionals in an educational setting before they begin their careers) is an important building block for equipping health workers with the skills and knowledge necessary to provide high-quality care.[3] Preservice education is often more cost-effective than in-service training because preservice education usually trains large swathes of health workers at once.[4]

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The skills and knowledge imparted during high-quality preservice education can also be more sustainable than during in-service training, as participants may be more receptive to training when they are learning the bedrock skills for their future careers.[4]

Despite its importance, data suggest that the quality of preservice family planning education in Tanzania and Uganda is subpar. For example, a 2013 survey of 70 nursing and midwifery professionals across East, Central, and Southern Africa revealed that many of the nursing and midwifery schools in these countries have limited materials and technical expertise.[5] As one 2014 study of 35 preservice schools in Tanzania concluded, "Pre-service FP [family planning] teaching in Tanzania is theoretical, poorly guided, and skewed toward short-acting methods; a majority of the schools are unable to produce competent FP service providers."[6]

DESCRIPTION OF INTERVENTION

We worked with relevant stakeholders in Tanzania and Uganda to improve the quality of preservice family planning education for nurses and midwives. Stakeholders included the East, Central, and Southern Africa Community (ECSA), an organization focused on improving health across this region, as well as the Tanzanian and Ugandan governments. We focused on nurses and midwives because they comprise the majority of the professional health workforce.[7] In Tanzania and Uganda, approximately 200 public and private schools train the 2,400 to 3,000 nursing and midwifery students who graduate each year.[4]

Preservice education, which usually trains large swathes of health workers at once, is often more cost-effective than in-service training.

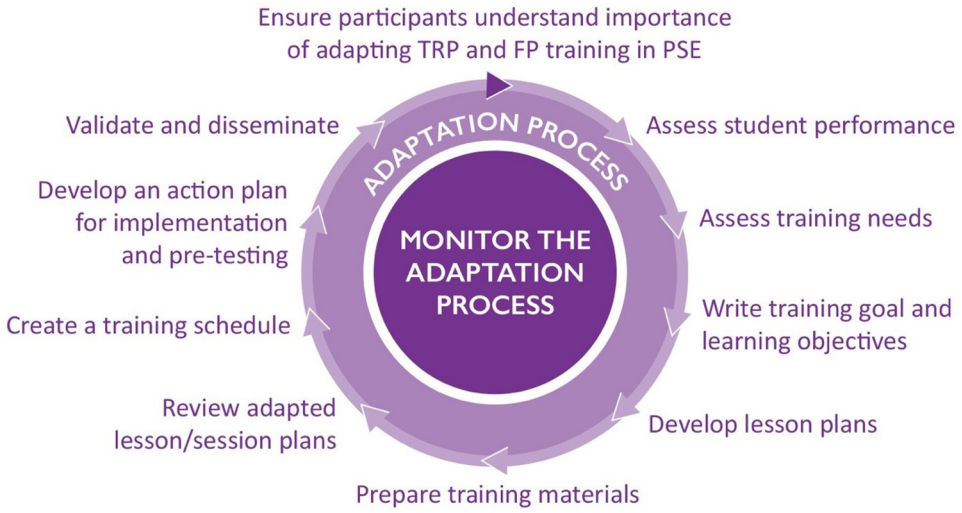
To enhance the quality of preservice family planning education for these cadres of health workers, we adapted the Training Resource Package for Family Planning (TRP)—a comprehensive set of family planning curricula—to meet the needs of the 2 countries, and supported use of the adapted curricula during preservice education (Figure).

The Training Resource Package for Family Planning

Developed in 2012 by the U.S. Agency for International Development (USAID), the United Nations Population Fund (UNFPA), and the World Health Organization (WHO), along with a number of sexual and reproductive health organizations, the TRP contains 13 modules, each outlining a particular topic. The topics include information on contraceptive methods, comprehensive contraceptive counseling, information on side effects, and youth-friendly contraceptive services (Box). Each module comes with a lesson plan, PowerPoint presentations, and additional resources and activities that instructors might find useful for relaying information to students. The TRP is available for free online and can be accessed at: https://www.fptraining.org/. The TRP uses the

We worked with relevant stakeholders in Tanzania and Uganda to improve the quality of preservice family planning education for nurses and midwives.

FIGURE. Illustrative Representation of the TRP Adaptation Process



Abbreviations: FP, family planning; PSE, preservice education; TRP, Training Resource Package for Family Planning.

BOX. List of Modules Included in the Training Resource Package for Family Planning

1. Benefits of Family Planning
2. Combined Oral Contraceptives
3. Condoms – Female
4. Condoms – Male
5. Contraceptive Implants
6. Emergency Contraceptive Pills
7. Emergency Contraceptive Pills Training for Pharmacists
8. Family Planning Counseling
9. Intrauterine Devices
10. Lactational Amenorrhea Method
11. Progestin-Only Injectable Contraceptives (Injectables)
12. Standard Days Method
13. WHO's Family Planning Guidance Documents and Job Aids

most up-to-date technical information to inform the content of its modules.

Our process, results, and lessons learned are further detailed in the following sections.

Dissemination Through ECSA

In September 2014, ECSA held its 5th quadrennial general meeting in Harare, Zimbabwe, which was attended by representatives of ECSACON (ECSA's nursing- and midwifery-focused arm), development partners, nursing and midwifery educators, regulatory councils, professional associations, service delivery managers, providers, and students. The theme of this meeting was increasing access to quality nursing and midwifery care across ECSA's member states (i.e., Kenya, Lesotho, Malawi, Mauritius, Swaziland, United Republic of Tanzania, Uganda, Zambia, and Zimbabwe).

A survey of nurses and midwives from ECSA countries revealed that countries dedicated insufficient time to comprehensive family planning training and that training focuses on provision of short-acting methods.

In the days preceding the meeting, we hosted a half-day workshop with educators from ECSA member states during which we disseminated the TRP, demonstrated its use for in-service training, and discussed adaptation for preservice education. Participants at this half-day preconference workshop included tutors from preservice education of nurses and midwives, representatives of regulatory councils and professional associations, students, service delivery managers from ECSA and nonmember countries Botswana, Namibia, and South Africa. We demonstrated how to access the TRP online and oriented them on how it is structured. Participants reviewed the TRP counseling module and engaged in role-play exercises to demonstrate the module.

After the workshop, between December 2014 and July 2015, participants applied their learning, sharing the TRP with colleagues, reviewing curricula and training methods, and identifying ways to strengthen family planning training at individual institutions. Some of the participants attempted to use the TRP as is and faced challenges with reducing the time and aligning the content with what is expected in preservice education. As a result, it was recommended to hold workshops in specific countries to align the TRP with their preservice education standards and to develop lesson plans.

Participants from Lesotho, South Africa, Tanzania, Uganda, and Zimbabwe asked that we support them to implement the TRP to strengthen family planning training in their countries. The participants also suggested that in any future trainings, we upload the TRP content to flash drives so that participants can access the modules even when there is no Internet.

Analyzing Content of Preservice Education in ECSA Countries

After the workshop, we developed a questionnaire based on WHO's *Core Competencies in Adolescent Health and Development for Primary Care Providers*,[8] and asked nurses and midwives from ECSA countries to complete it between February and April 2015. The questionnaire assessed treatment of family planning, youth sexual and reproductive health, and gender in curricula; the capacity of schools to teach family planning; teaching methods used; time allocated for both classroom instruction and practicum; and preparation of educators to teach family planning. A survey of nurses and midwives from ECSA countries revealed that countries dedicated insufficient time to comprehensive family planning training and that training focuses on provision of short-acting methods. Moreover, training was conducted mostly through lectures, rather than practicums, which is widely considered to be a less effective training modality. Based on this information, and with guidance from ECSACON, we chose to support the adaptation of the TRP for preservice education with nursing and midwifery preservice educators from schools in Tanzania and Uganda. Tanzania was in the process of reviewing preservice curricula and Uganda had plans to update preservice curricula—which were long past due for review.

Assessing Tanzanian and Ugandan Preservice Education

Once we selected Tanzania and Uganda, in May 2015, we conducted a more detailed review of preservice family planning education in these 2 countries. We held discussions with ECSA and

representatives of nursing and midwifery councils and preservice education program managers in Tanzania and Uganda, and we conducted a desk review of preservice curricula and resources. The desk review consisted of relevant websites including those of Johns Hopkins University's Knowledge for Health Project, Human Resources for Health's Global Research Center, the Global Health Workforce Alliance, implementing partners known to have supported preservice education programs, and ECSA and ECSACON. Following the online search, country-specific documents were requested from Tanzania and Uganda, such as scopes of practice, curricula for in-service and preservice education, and family planning and reproductive health policies and guidelines.

Across both countries, nursing and midwifery councils accredit and regulate nursing and midwifery schools and determine curricula content. Content must then be approved by committees, which are typically composed of policy makers, educators, regulatory councils, content experts, and professional associations. Curricula must be reviewed and updated every 5 years, or as needed, based on changes in policies and new technology. Approved curricula are disseminated to the schools. Individual educators then design each training session using a standard template provided by the preservice training units of the Ministry of Health or Ministry of Education, leading to lack of standardization of the content taught, time allocated to teach family planning, and training methodology used. Both countries allocate 40 hours to the entire reproductive health module, which includes family planning, sexually transmitted infections, HIV/AIDS, adolescent and youth sexual and reproductive health, and postabortion care.

While training standards in Tanzania and Uganda specify that curricula have to be competency-based, educators in both countries tend to have limited experience in use of such training methods. However, both countries cited that educators have limited experience in use of competency-based training methods and tend to depend instead on lectures. The Tanzanian preservice family planning curriculum was updated in 2015, but Uganda's curriculum had not been revised for many years, some parts for more than a decade.

Workshops

In 2015, we organized 2 workshops in each country. During these initial workshops, we disseminated the TRP, oriented participants on its structure, and distributed *WHO's 2015 Medical Eligibility Criteria (MEC)*[9] *and the USAID High Impact Practices*.[10]

The first planning workshop in each country was 3 days long and attended by key stakeholders, including preservice education policy makers, family planning program managers, educators from nursing and midwifery training institutions, and representatives from professional associations and curricula-development committees. The aim of this initial workshop was to disseminate the TRP, foster country ownership, and identify gaps in preservice family planning education curricula that could be addressed through application of the TRP. Participants arrived at recommendations for improvement of preservice family planning education based on the country's policies and standards, including family planning knowledge, attitudes, and skills to be developed during preservice education and job expectations post-graduation. At the initial workshop, participants then developed the design and schedule for the subsequent 5-day adaptation workshop; for example, they decided which TRP modules should be used to demonstrate adaptation of the TRP. The demonstration modules were selected based on what content the educators felt they and their students needed to know more about, and what content needed an update within the curricula. Participants also developed the schedule and methodology for the adaptation process.

The second 5-day workshop in each country focused on adapting the selected TRP modules. The workshop included a broader set of participants to adapt the TRP: educators from public- and accredited private-sector schools for nursing and midwifery, regulatory councils, professional associations, in-service family planning trainers, and service providers from practicum training sites. Those who attended the 3-day planning workshop served as co-facilitators during the 5-day workshop. We documented our lessons learned for other program implementers to use when adapting the TRP to local contexts.

In both countries, we established an online community of practice to allow participants to interact with one another and support continued learning. However, we recognized that the limited Internet connectivity in Uganda would somewhat hamper these participants' ability to engage.

While training standards in Tanzania and Uganda specify that curricula have to be competency-based, educators in both countries tend to have limited experience in use of such training methods.

Tanzania

We held the Tanzanian 3-day planning workshop in July 2015. Participants decided on the following objectives for the 5-day adaptation workshop: (1) adapt the TRP to validate the newly updated

family planning content; (2) demonstrate how to adapt the TRP using the counseling module as an example; (3) update the knowledge and skills of participants on family planning; (4) conduct contraceptive technology update; (5) demonstrate use of competency-based training methods; and (6) develop session plans for the updated curricula family planning module.

Participants in the adaptation workshop used the TRP to develop lesson plans in accordance with national policies and guidelines in the standard templates.

The Ministry of Health and Social Welfare led the 5-day workshop, and 33 participants attended including educators from the nursing and midwifery training institutions, universities, and local ECSACON country representatives. We showed participants how to access and use the TRP online and on flash drives. In-service family planning master trainers from the Ministry of Health presented sessions on the WHO's MEC and the TRP's counseling module, demonstrating use of competency-based training methods. Participants then adapted the existing curricula according to the TRP content. Table 1 shows the changes to the curriculum in Tanzania after the workshop.

We demonstrated how the trainers could adapt the TRP to inform their own lesson planning. To allow participants to practice, we divided them into groups of 3 and randomly assigned them a topic (e.g., balanced family planning counseling). Participants in the adaptation workshop used the TRP to develop lesson plans in accordance with national policies and guidelines in the standard templates. Once developed, participants presented their lessons to others and received feedback. Some adopted the session training materials and PowerPoint presentations directly from the TRP. Others removed slides that they felt were too advanced for their students. Still others made small modifications to the TRP based on their knowledge of students' needs and what is already taught through preservice education (e.g., communication skills, anatomy and physiology of the male and female reproductive organs). All participants used the TRP to create comprehensive lesson plans. Participants reported that they would have liked to have had more time to

TABLE 1. Changes to the Tanzanian Curriculum Before and After the TRP Workshop

Before Curriculum Review (2009)	FP Curriculum Content and Learning Outcomes Revised After the TRP Workshop (July 2015)
Learning Outcomes	**Learning Outcomes**
• Provide FP services in the community	• Provide FP services according to guidelines and protocols
Content Outline	**Content Outline**
• Define FP	• Define FP
• Identify advantages of FP	• Identify myths and misconceptions related to FP methods
• Explain various methods of FP	• Explain advantages of FP
• Counsel clients on FP methods	• Describe short- and long-acting reversible contraceptive methods
	• Explain elements of FP service delivery
	• Take obstetric and gynecological history
	• Perform physical examination
	• Counsel the client on informed choice
	• Screen client for medical eligibility for contraceptive choice
	• Initiate the chosen contraceptive method (oral contraceptive, injectable, implant, intrauterine devices, and natural and barrier methods)
	• Plan for a follow-up visit
	• Refer for permanent methods (vasectomy, tubal ligation) when appropriate

Abbreviations: FP, family planning; TRP, Training Resource Package for Family Planning.

develop lessons plans and practice session delivery for the whole family planning module.

In Tanzania, all participants had a laptop, so while we provided flash drives with the TRP modules included, participants primarily accessed the TRP online. Participants expressed satisfaction with the TRP itself, especially its ease of use and the many resources included with it. Overall, they preferred didactic teaching methods, rather than practicum methods. They suggested that in future sessions, facilitators might spend more time demonstrating role-play and other competency-based methods before they asked participants to do so. Lastly, they found adaptation a challenge, reporting difficulty reducing the exhaustive TRP content to fit within the allotted 20 hours of time for family planning training.

Since the workshops, the National Pre-Service Education Coordinating Unit of the Ministry of Health and the Nurses Council aligned competencies in the diploma nursing and midwifery curricula with global standards, using the TRP as a benchmark. The National Council for Technical Education (NACTE) approved the updated curricula. The Coordinating Unit then organized workshops to orient 139 educators representing training institutions for nurses and midwives in Tanzania.

Uganda

In December 2015, we hosted the 3-day planning workshop and subsequent 5-day adaptation workshop in Uganda. Based on feedback from participants, we then added a third, 2-week workshop where participants from the 5-day workshop reconvened to develop lesson plans that used Uganda's standardized template for preservice education. During the workshops, these lesson plans, along with supporting materials, were compiled into a *Trainers' Reference Guide for Family Planning Pre-service Education for Nurses and Midwives*, further described below.

During the 3-day workshop, participants decided on the following objectives for the 5-day workshop: (1) review the TRP to ensure its alignment with national policy; (2) update the preservice modules on contraceptive technology and competency-based training methods; and (3) standardize lesson planning.

Thirty-two representatives of nursing and midwifery schools, the Uganda Nursing and Midwives Council, the Uganda Nursing and Midwifery Examination Board, and ECSA attended the 5-day workshop in Uganda. The Nursing and Midwifery Examination Board, which is under the Ministry of Education, was included instead of the Ministry of Health (as in Tanzania), because in Uganda the Ministry of Education has jurisdiction over preservice education. Participants spent the first few days of the Ugandan workshops reviewing the nursing and midwifery curricula to determine content gaps and needs. As the curricula had not been reviewed since 2003, participants viewed the TRP workshops as a useful opportunity to undertake a thorough curricula review of the entire reproductive health course unit's family planning objectives and content. We disseminated the TRP online and on flash drives. Based on the recommendations from the 3-day workshop to use modules with content that would be new to most of the participants, we demonstrated use of the TRP using modules on emergency contraceptive pills and the Standard Days Method. The use of role-plays and demonstration enhanced participants' learning and reinforced competency-based training methods.

In small groups, participants cross-checked existing preservice curricula against the reproductive health unit family planning standards, in-service training curricula, and TRP content. During this examination, they revised learning objectives and updated knowledge, skills, and attitudes to be developed during preservice education. They then developed the content outline, resulting in a much more comprehensive curriculum (Table 2).

Once the objectives of the family planning curricula and content on knowledge, skills, and attitudes were established, the small groups allocated time to each objective, developing lesson plans and incorporating competency-based training methods. In Uganda, few participants had computers, so hard copies of the TRP modules were printed and distributed to participants to use in their small groups.

Participants provided valuable feedback. Some workshop participants found it challenging to adapt the extensive TRP content into the limited time allotted for preservice education. They suggested that we develop more explicit guidance on how to use the TRP to develop preservice education lesson plans. Disseminating the TRP to all schools in the country would be helpful, participants said, in standardizing training content.

Some workshop participants found it challenging to adapt the extensive TRP content into the limited time allotted for preservice education.

In July 2016, a follow-up, 2-week workshop was organized in Uganda to adapt the TRP to develop lesson plans. During this workshop, we worked with participants to adapt the TRP to

TABLE 2. Changes to the Ugandan Curriculum Before and After the TRP Workshop

Before Curricula Review (2005–2008)	Revised Objectives, Competencies, and Content After the TRP Workshop (December 2015)
NURSING	**NURSING AND MIDWIFERY**
FP Objectives	**Objectives**
• Describe all FP methods	• Identify clients for FP/RH services
Competencies	• Communicate and promote FP/RH effectively to different population groups
• Provide all FP methods	• Counsel clients for voluntary informed choice
Content Outline	• Provide clients with oral pills, progestin-only injectables, ECPs, implants, IUDs, SDM, Cervical Mucus Method, and barrier methods according to national FP/RH guidelines
• Define FP	• Integrate FP with other services including MNCH, STIs, and HIV/AIDS
• History of FP	• Identify clients with FP/RH complications
• Benefits and disadvantages of FP	• Manage clients with FP/RH complications
• Management of FP services	• Manage FP clients with STIs and HIV/AIDS
MIDWIFERY	• Refer clients to other FP/RH services appropriately
FP Objectives	• Document, manage, and utilize data related to FP/RH
• Assess clients for different FP methods	**Content Outline**
• Explain FP services	• Define FP
Competencies	• Benefits of FP
• Counsel clients on FP	• Rights-based FP/RH service delivery
Content Outline	• Counseling for FP and voluntary informed choice
• History of FP	• Cultural beliefs and practices related to FP
• Benefits and disadvantages of FP	• Methods of FP/contraceptive technology (oral pills, progestin-only injectables, ECPs, implants, IUDs, SDM, Cervical Mucus Method, condoms – male and female, other barrier metohds)
• Management of FP services	• Medical Eligibility Criteria for contraceptive methods
• Monitoring and evaluation of FP services	• Provision of FP methods
	• Elements of successful FP monitoring, FP/RH service delivery
	• Provision of FP for special groups (adolescents, postpartum clients, postabortion care, HIV/AIDS, ending mother-to-child transmission of HIV, men)
	• Myths and misconceptions of FP

Abbreviations: ECPs, emergency contraceptive pills; FP, family planning; IUDs, intrauterine devices; MNCH, maternal, newborn, and child health; RH, reproductive health; SDM, Standard Days Method; STIs, sexually transmitted infections; TRP, Training Resource Package for Family Planning.

develop the *Trainers' Reference Guide for Family Planning Pre-service Education for Nurses and Midwives*. The Reference Guide includes a series of predesigned lesson plans that used Uganda's standardized template for preservice education; PowerPoint presentations; handouts; and knowledge evaluation questions that could be adapted to develop pre-post knowledge tests, quizzes, and skills assessment checklists. The Reference Guide includes guidelines for practicum training,

development of practicum training sites, and preparation for practicum training. The Trainers Reference Guide is aligned with the TRP, and cognizant of the time allocated to family planning classroom teaching. Based on recommendations from the 2015 workshops, participants were given more time to practice delivering their sessions. They "pretested" lesson plans and used feedback from facilitators and peers to inform revisions. They added some lesson plans that are not part of the TRP, such as the family planning/reproductive health policies, guidelines, and strategies, and sessions on "family planning concepts" and permanent methods for enhanced knowledge on country context and links between family planning and maternal, newborn, and child health.

Since developing the lesson plans, the National Curriculum Development Committee and educators who had attended the TRP workshops reviewed the certificate and diploma nursing and midwifery preservice education curricula, enabling the TRP to be a reference document. The lesson plans and Reference Guide have been disseminated to training institutions. The training institutions conducted workshops with other educators who had not attended the TRP workshops facilitating use of the lesson plans. The educators found the lessons plans to have sufficient content for preservice education.

RESULTS AND OBSERVATIONS

Adaptation of the TRP in Tanzania and Uganda resulted in substantive changes to the curricula of the reproductive health course unit that will support nurses and midwives to provide quality, rights-based family planning (Table 1 and Table 2). In both countries, we asked participants to take pre-post knowledge tests to assess knowledge gained throughout the course of the workshop. The pre-post tests showed significant gains in family planning knowledge: the average pretest score was between 30% and 40%, and the average post-test score increased to more than 80%.

Sustainability

Six months post-workshop, we checked in with workshop participants to assess whether the TRP was still in use. In Tanzania, educators who had attended the workshop were using the TRP and had shared the TRP and adapted lesson plans with their colleagues. The Ministry of Health had used the TRP as a reference to develop curricula for the country's newly formed community health worker cadre. Workshop participants were using the TRP resources and tools (most notably, the PowerPoint presentations) in their classrooms; however, they reiterated the challenge of reducing content from the TRP to fit within the allotted amount of time for preservice family planning training. Because the Uganda lesson plans were developed within the time allotted to the reproductive health course unit, educators in Uganda did not experience the same challenge as those in Tanzania. However, they did express challenges in using competency-based training due to large class sizes and lack of adequate training resources, such as anatomic models. In Uganda, participants reported using the TRP and again affirmed the value of the Trainers' Reference Guide, which helped to standardize learning and contained lesson plans. Although educators who attended the workshops shared the TRP and adapted lessons with their colleagues, we do not know how the resources are being used by schools that were not part of the workshops.

Our workshops revealed some areas for improvement within the TRP. Any future revisions may consider adding content to address the following topics in greater depth:

- Basic foundational concepts for family planning service delivery, such as the meaning of healthy timing and spacing of pregnancy and rights-based family planning
- Strategies for deconstructing myths and misconceptions about family planning
- Recordkeeping and health data management including data use to improve family planning service delivery
- Gender and adolescent and youth sexual and reproductive health

Lessons Learned

Through the process of adapting the TRP, we learned several lessons that may be useful to other implementers as they implement the TRP in their own countries.

- The process of reviewing the TRP with key stakeholders is a learning opportunity. Implementers of preservice education programs should organize content review workshops with educators and representatives of relevant ministries, allowing sufficient time for participants to identify and discuss in detail differences in their existing curricula and the TRP.
- Similarly, productive relationships with ministries of health and education, regulatory

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Inclusion of nursing and midwifery educators in the adaptation process helped to create an established pool of trainers who could then cascade the TRP to other educators.

councils, and professional associations in each country proved invaluable for rolling out the TRP adaptations. Inclusion of nursing and midwifery educators in the adaptation process helped to create an established pool of trainers who could then cascade the TRP to other educators.

- Adaptation of the TRP for preservice education should be context specific. Adaptation is a complex process and not one process will fit the needs of all countries. It is therefore important for stakeholders involved in the adaptation process to have a thorough understanding of country context.
- Our experience reinforced our belief that high-quality preservice education is a crucially important element of building nurses' and midwives' foundational skills. But educators are only as good as the tools and resources available to them. It is critically important that educators' skills in contraceptive technology and competency-based training methods be routinely updated and they are equipped with technically accurate textbooks.

CONCLUSIONS

Strengthening preservice family planning education for nurses and midwives can improve health outcomes for women, newborns, infants, and children. Quality preservice family planning education for nurses and midwives is therefore a "best buy" for countries seeking to reduce maternal, newborn, and child mortalities and morbidities. A global analysis conducted by UNFPA in 2014 concluded that midwives, when educated to international standards, have the competencies to deliver 87% of the 46 essential reproductive, maternal, and newborn health services needed by women and newborns.[11] The TRP, as an evidence-based tool, can be applied and adapted globally to improve the quality of family planning service delivery and respond to the need to improve the global health workforce.

Next Steps

Based on our experience in Tanzania and Uganda, we developed 2 useful tools for those interested in replicating the process described in this article. The first is a *How-To Guide* for adaptation of the TRP to improve preservice family planning education (see https://www.e2aproject.org/publication/guide-adaptation-training-resource-package-family-planning-improve-pre-service-education/). The *How-To Guide* contains detailed steps elaborating the adaptation process, including examples of adapted training modules. The second is a *package of modules*—one for preservice family planning education and one for preservice education on adolescent and youth sexual and reproductive health and gender (see https://www.e2aproject.org/publication/training-resource-package-pre-service-education-family-planning-adolescent-youth-sexual-reproductive-health/). Adolescent and youth sexual and reproductive health is taught in its own standalone unit in both countries, but the broader curricula do not discuss age biases in family planning service provision. The modules contain lesson plans and supporting materials that can be used by educators to teach essential family planning, adolescent and youth sexual and reproductive health, and gender competencies to nurses and midwives during the time allotted for preservice family planning education.

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FIELD ACTION REPORT

Decentralized, Community-Based Treatment for Drug-Resistant Tuberculosis: Bangladesh Program Experience

Paul Daru,[a] Refiloe Matji,[b] Hala Jassim AlMossawi,[b] Krishnapada Chakraborty,[b] Neeraj Kak[b]

Shifting from hospital- to community-based management of drug-resistant TB, increased treatment enrollment, reduced treatment initiation delays, improved follow-up and adherence, and lowered treatment failure, and was associated with higher cure rates and lower mortality.

ABSTRACT

Background: Bangladesh is a highly populous country where the prevalence of drug-resistant tuberculosis (DR-TB) is growing. With the rapid increase in DR-TB notifications through GeneXpert technology, it was imperative to come up with a new treatment strategy that could keep up with the increase of patients diagnosed.

Intervention: Intervention was designed to support national transition of DR-TB management of World Health Organization-approved long course (20-to-24-month regimen) treatment from a hospital-based approach to the decentralized model of community-based programmatic management of DR-TB (cPMDT). In close coordination with the Ministry of Health and Family Welfare and National TB Program, patients were initiated into treatment at hospitals and then transferred to community-based care. A cadre of directly observed therapy providers supported treatment at the household level, supervised by the outpatient DR-TB teams.

Methods: We conducted a descriptive pre- and post-intervention study of all 1,946 DR-TB patients enrolled in treatment nationwide between May 2012 and June 2015. Data were collected from hospitals, patient cards, district records, and diagnostic laboratories through the National TB Program. Intervention results were assessed in comparison with the baseline (2011) indicators.

Results: During the intervention period, treatment enrollment of 1,946 diagnosed DR-TB patients through the national program increased from 50% in 2011 to 100% in 2015. The delay between diagnosis and treatment initiation decreased from 69 days in 2011 to 6 days in 2014. Most (95%) of the patients completed all scheduled follow-up smear and culture tests. By the sixth month of treatment, 99% of patients had negative smear conversion and 98% had negative culture conversion. The treatment success rate increased from 70% in 2011 to 76% in 2015 at the end of the intervention period. The results also indicate a decline between baseline and endline from 14% to 9% for patients died, 14% to 10% for loss to follow-up, and 2% to 0% for treatment failure.

Conclusions: Community-based management is an effective approach for increasing access to quality-assured DR-TB treatment. Using existing structures and resources, the intervention demonstrated that favorable treatment outcomes can be achieved and sustained by treating patients with DR-TB at their homes.

BACKGROUND

Treatment for drug-resistant tuberculosis (DR-TB)—which includes both rifampicin-resistant TB (RR-TB) and isoniazid and rifampicin-resistant TB (MDR-TB)—is currently available to only 22% of the estimated cases globally.[1] While progress has been made to increase the number of DR-TB patients identified and reported, treatment programs continue to be hampered by waitlists and poor outcomes. The shift to decentralized, community-based care for DR-TB patients has been recommended as a means to increase the number of patients who access treatment by freeing up personnel and infrastructure at treatment-initiating sites.[2] The effectiveness of ambulatory or community-based treatment for DR-TB has been demonstrated in a variety of settings and, under most conditions, to produce better outcomes than centralized hospital-based care.[3–6] Decentralized treatment has a high level of acceptability among patients,[7] contributes to a reduction in the number of patients lost to follow-up,[8] and is less expensive than inpatient treatment.[5] Leveraging resources and properly using existing health system structures can ensure a scalable and sustainable model for lasting impact.

Bangladesh is a densely populated country with a high burden of TB. Although the country has a relatively low prevalence of DR-TB, estimated at 1.6% among new TB cases and 29% among retreatment patients,[9] the epidemic continues to grow, especially in younger urban populations.[10] Although the National TB Program

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(NTP) started a pilot DR-TB treatment program in 2008, which was scaled up nationally by 2010, widespread availability of the treatment has lagged. The limited number of DR-TB beds in hospitals has caused long delays in treatment initiation of diagnosed patients, increasing the risk of infection and adverse treatment outcomes. With the rapid increase in the detection of drug-resistant TB by GeneXpert technology, it was imperative to come up with a new strategy that could reduce the need for hospital beds and provide diagnosed patients with quicker access to treatment.

THE INTERVENTION

Principal barriers to the management of DR-TB cases in the pre-intervention stage included centralized treatment initiation with prolonged hospital stays up to 8 months, limited number of hospital beds for DR-TB patients, poor patient monitoring, and a lack of psychosocial support. In 2012, with support from the United States Agency for International Development (USAID) TB CARE II project, the Ministry of Health (MOH) of Bangladesh and NTP launched the community-based programmatic management of DR-TB (cPMDT) initiative to ensure access to DR-TB treatment for the increasing number of rifampicin-resistant patients confirmed with GeneXpert MTB/RIF assay testing (Cepheid, Sunnyvale, CA, USA). The cPMDT model implemented in Bangladesh was based on outpatient care of DR-TB cases after an initial and relatively short hospital treatment. The model employs patient-centered approaches to comprehensively address the various needs of DR-TB patients and improve DR-TB treatment outcomes. The key mechanisms of the model include home-based directly observed therapy (DOT), a community-based sputum collection and transportation mechanism, and a package of psychosocial support.

The framework for cPMDT was introduced to support the transition and management of DR-TB treatment from the hospital-based approach to community-based care. The framework outlined policy changes and redefined diagnostic and treatment guidelines, based on a reduced duration of inpatient treatment from the previous 6 to 8 months to less than 2 months. Through a participatory process, a standard operating procedure (SOP) for cPMDT was developed, incorporating lessons from programs in other countries and reflecting national and global guidelines.[1,11] The SOP endorsed by the MOH and NTP provided step-by-step guidance on how to organize, implement, and monitor community-based care for DR-TB, including program planning, monitoring, and supervision. MOH and NTP, with TB CARE II team support, developed a detailed implementation plan that defined roles for DR-TB teams, outlined training curricula, and identified financial sources to roll out the program.

The project provided financial allowances to DOT providers to cover transportation costs for ensuring delivery of daily DOT and nutritional supplements to patients to promote treatment adherence. The intervention covered 38 districts and 4 city corporations. The remaining districts of the country were covered by Damien Foundation for implementation of a short-course (9 to 12 months) regimen for treatment of DR-TB cases. The cPMDT intervention supported GeneXpert testing nationwide while all diagnosed patients in Damien Foundation districts were enrolled in to the short-course treatment.

Moving Treatment to the Community Level

The major change within the cPMDT approach was the decentralization of DR-TB service delivery from national-level hospitals to upazila-level (sub-district-level) health facilities to improve access to DR-TB services. The outpatient DR-TB teams formed at each upazila assume a central role in management of DR-TB patients at the community level. These teams are headed by the upazila health and family planning officer and consist of several members, including medical officers, the TB and leprosy control assistant, and support staff. In the last 3 years, NTP, with the project support, has formed upazila outpatient DR-TB teams in all the upazilas under the 38 cPMDT districts and has completed training of 2,340 team members on the programmatic management of DR-TB.

Upazila outpatient DR-TB teams trained selected health workers to provide daily DOT and manage DR-TB patients.

The cPMDT framework was introduced to support the transition and management of DR-TB treatment from hospital- to community-based care.

The upazila outpatient DR-TB team is responsible for the selection and training of DR-TB DOT providers who are officially designated to provide daily DOT and manage DR-TB patients. DOT providers are selected from the existing pool of public health workers. In areas where no public health workers are available, the program recruits and trains pharmacists and community workers from NGOs. A total of 590 health workers were trained as DOT providers during the project period.

Since DR-TB management capacity has been developed at the community level, MOH and NTP introduced new hospitalization and discharge criteria that recommend that DR-TB patients be

transferred to cPMDT if they tolerate prescribed treatment well and sputum smear conversion is confirmed based on weekly testing. By applying these criteria, hospitals are able to discharge a majority of DR-TB patients after 4 to 8 weeks of treatment. Before discharging the patient, the treatment-initiating hospital begins the process of transferring care by notifying the respective upazila outpatient DR-TB team. The outpatient DR-TB team then identifies and trains a DR-TB DOT provider who is committed to supporting the patient and is considered acceptable to the patient. A patient transferred to community-based care now receives their daily dose from the DOT provider in their household. The outpatient DR-TB teams provide clinical support to the patient, supervise the DOT provider, and make monthly visits to monitor patient compliance with the treatment. At the subdistrict and district levels, the teams conduct monthly patient monitoring visits and provide clinical support to the patient as needed.

The psychosocial support component of the cPMDT model focuses on counseling, nutritional support, and vocational training.

Sputum Collection and Transportation

Patients transferred to community-based services need regular access to sputum testing for monitoring their response to the treatment regimen. Within cPMDT program, sputum collection points were set up at upazila public laboratories offering microscopy services. Sputum samples are sent to a reference lab for culture on a monthly or quarterly basis, or as needed. The system has improved patient compliance with follow-up sputum testing and has eliminated the need for patients to travel to reference lab. The system also supports transportation of sputum collected from presumptive DR-TB cases for GeneXpert testing at reference labs.

Provision of Home-Based DOT

Providing patient-centered care at community level is a key element of the cPMDT model. During the treatment period, DOT providers visit each patient daily to administer injections and supervise intake of medicine according to the patient's tailored regimen. To ensure quality of care, each DOT provider is responsible for no more than 2 patients. Each DOT session is used as an opportunity for contact screening among household members and counseling on adherence, adverse events, infection prevention and control, and social support. DOT providers also monitor side effects and refer patients to upazila health complex (UHC) for any additional clinical support. Monthly clinical assessments are scheduled at the local UHC, and patients receive reminders about their routine visit schedule from their DOT providers.

Psychosocial Support

TB patients who come from socioeconomically vulnerable groups are at increased risk of defaulting treatment.[12] Research has shown that psychosocial and nutritional support are crucial for supporting and improving patient compliance with treatment.[13] At the largest national chest disease hospital where most of the patients were initiated to treatment, psychosocial support to DR-TB patients, an essential component of the cPMDT model, focuses on counseling, nutritional support to patients, and vocational training. The aim of these activities is to boost patient morale to adhere to and complete the treatment. At the hospital, counseling sessions are planned for every DR-TB patient and conducted in a group setting—individual sessions are also available for patients who need additional support. The patient counseling at the community level is conducted by DOT providers during home visits. Family members of the patient are also counseled on how they could extend ongoing psychological support to the patient. As per national guidelines, each patient enrolled in community-based treatment receives a monthly stipend to promote adequate nutrition and to help cover the transportation costs of their monthly follow-up visits to the hospital. Cash transfers to patients are done through mobile banking services, which eliminates the risk of corruption and malpractice. Hospitalized patients have the opportunity to receive vocational training on tailoring, which they could use to create income opportunities. Mostly women benefited from this training.

Monitoring and Supervision

Upazila outpatient DR-TB teams manage the monitoring and supervision of DOT providers and DR-TB patients. They conduct monthly reviews of the performance of the DOT providers, which includes checking the patient card to verify home visits, administration of daily DOT, completeness of patient information recorded, and availability of drugs. They also make monthly visits to patient homes to monitor treatment compliance, assess patient management needs, and take follow-up actions. The upazila teams are, in turn, supported by teams at the district and divisional levels.

mHealth Monitoring

In 2013, an mHealth application was introduced that provides a platform for the real-time monitoring of home visits and administration of daily doses by the DOT providers. Since then, each DOT provider has been equipped with a smartphone to access the Android-based application, which includes a personalized patient list and guides the provider to record key actions during each visit. Each record includes a time-and-location stamp to promote accountability, which enables supervisors to conduct online monitoring of the DOT status of every patient daily so that immediate action can be taken if any DOT was missed.

METHODS

Between May 2012 and June 2015, we conducted a descriptive pre- and post-intervention analysis of 1,946 DR-TB patients enrolled in 20-to-24-month treatment regimen in decentralized DR-TB care in Bangladesh. Aggregated data were collected from the NTP management information systems, which includes data from diagnostic laboratories, treatment-initiating hospitals, patient cards, and district DR-TB records to follow patients along the cascade of care and to measure the time between diagnosis and treatment initiation. Sputum and culture conversion data were routinely collected to monitor treatment adherence, efficacy, and progress. Data pertaining to training of service providers, patient enrollment in to cPMDT, and patient's compliance with DOT were retrieved from the TB CARE II project monitoring records and reports. Intervention results were assessed in comparison with the baseline (2011) indicators.

Aggregated data on treatment enrollment and outcome of DR-TB patients were downloaded into a Microsoft Excel spreadsheet. Simple quantitative analyses were performed to calculate year-wise diagnosis of patients by GeneXpert, treatment enrollment, and outcome including sputum conversion for baseline and intervention period. TB CARE II project data, maintained on a Microsoft Excel spreadsheet, were used to calculate the number of patients transferred to cPMDT for treatment and median number of days for treatment initiation delays. Treatment outcome data were analyzed for patients who completed DR-TB treatment during the scale-up of community-based care to examine the proportions of patients who were cured or completed treatment, lost to follow-up, died, or had treatment failure.

Data quality and completeness were strictly maintained by regular monitoring and supervision visits by the project field staff. Data were also regularly checked during joint monitoring visits by teams comprising representatives from NTP, the World Health Organization (WHO), and project staff. Moreover, the quality and completeness of the data were ensured by conducting regular data quality assurance assessments. No major data collection and management issues were observed except for delays updating culture results and treatment outcomes. All data collection and analysis were conducted according to international principles of maintaining privacy and confidentiality of personal information.

DOT providers use smartphones to access specific patient records and record key actions during patient visits.

RESULTS

The transfer of DR-TB patients enrolled in 20-to-24-month treatment regimen into community care began in May 2012, and steadily increased with the geographic expansion of the cPMDT approach. The percentage of patients transferred to cPMDT increased from 21% in 2012 to 100% in 2015. This increase aligns with the annual increases in the number of DR-TB cases notified and initiated into treatment nationally. Overall, treatment initiation of patients into both long and short courses diagnosed with DR-TB increased from 77% in 2011 before cPMDT to 100% in 2015, which coincided with the transfer of all DR-TB patients into cPMDT (Figure 1).

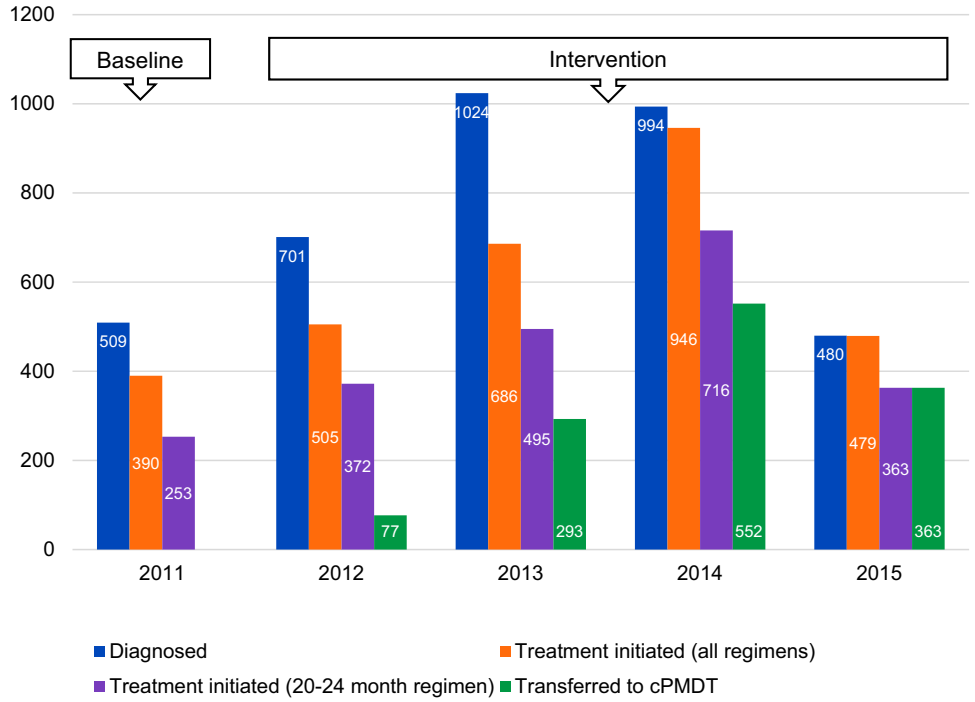
Analysis of data comparing treatment initiation delay for DR-TB patients in the long course between pre- and post-cPMDT intervention showed that the median number of days lapsed between diagnosis and treatment initiation decreased from 69 days in 2011 to 15 days in 2012, 11 days in 2013, and 6 days in 2014 (Figure 2).

The delay between diagnosis and treatment initiation decreased from 69 days in 2011 to 6 days in 2014.

Almost all (95%) of the patients completed all routine follow-up smear and culture tests, which were used to monitor patient response to treatment, specifically if and when culture conversion occurred. Of these patients, 93% were smear negative by the third month and 99% by the sixth month. Culture conversion was negative for 79% of the patients by the third month and 98% by the sixth month after treatment initiation (Figure 3).

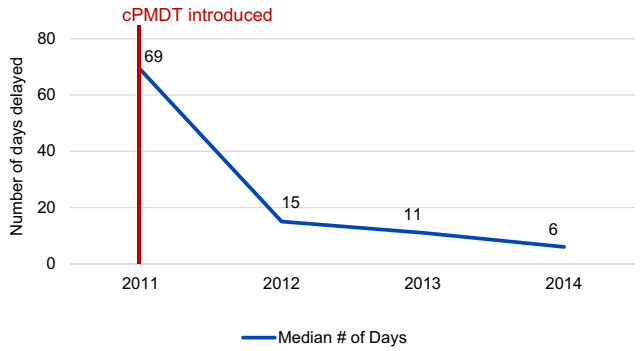
Year-wise breakdown of data shows a gradually improving trend in treatment outcomes throughout the intervention period. Out of the 1,946 confirmed DR-TB patients enrolled into long-course treatment, 1,433 (74%) patients

FIGURE 1. Trends in Diagnosis and Treatment Initiation, Bangladesh, 2011–2015



Abbreviation: cPMDT, community-based programmatic management of drug-resistant tuberculosis.

FIGURE 2. Trend in the Length of Delay Between DR-TB Diagnosis and Treatment Initiation, Bangladesh, 2011–2014



Abbreviation: cPMDT, community-based programmatic management of drug-resistant tuberculosis; DR-TB, drug-resistant tuberculosis.

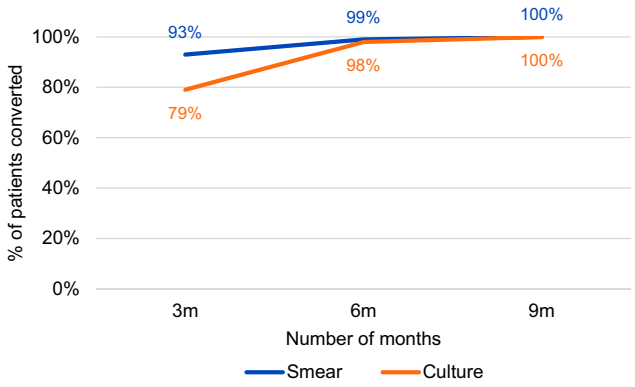
The treatment success rate increased from 70% in 2011 to 76% in 2015.

were successfully treated, 244 (13%) patients died, 222 (11%) patients were lost to follow-up or their data were unavailable, and 9 (0.5%) patients experienced treatment failure. From 2011 to 2015, the treatment success rate increased from 70% to 76%, while the proportions of patients who died (14% to 9%), were lost to follow-up (14% to 10%) and had treatment failure (0%) decreased (Table 1).

DISCUSSION

The cPMDT program was a completely new approach to DR-TB patient care and management

FIGURE 3. Sputum and Culture Conversion Rates of DR-TB Patients After Treatment Initiation, Bangladesh



Abbreviation: DR-TB, drug-resistant tuberculosis.

TABLE. Trend in Treatment Outcomes of DR-TB Patients During Transition to cPMDT, Bangladesh, 2011–2015

	Baseline	Intervention				
	2011 (n=240)[a] No. (%)	2012 (n=372)[b] No. (%)	2013 (n=495)[b] No. (%)	2014 (n=716)[b] No. (%)	2015 (n=363)[c] No. (%)	Total (N=1,946) No. (%)
Cured/completed	168 (70.0)	271 (72.8)	376 (76.0)	510 (71.2)	276 (76.0)	1433 (73.6)
Died	34 (14.2)	42 (11.3)	59 (11.9)	109 (15.2)	34 (9.4)	244 (12.5)
Lost to follow-up	34 (14.2)	50 (13.4)	52 (10.5)	82 (11.5)	38 (10.5)	222 (11.4)
Failure	4 (1.7)	3 (0.8)	5 (1.0)	1 (0.1)	0 (0.0)	9 (0.5)

Abbreviations: cPMDT, community-based programmatic management of drug-resistant tuberculosis; DR-TB, drug-resistant tuberculosis.
[a]All non-cPMDT patients with 6 to 8 months hospitalization.
[b]cPMDT + non-cPMDT patients.
[c]All cPMDT patients; data from January to June 2015 only.

for Bangladesh. To decentralize the management and integration of service delivery with the local health care system, the initiative had to develop a national consensus on the new community-based framework for management of DR-TB and to facilitate the policy changes needed to redefine the diagnostic and treatment guidelines. Strong advocacy efforts were needed from national- and local-level stakeholders—from policy planners, program managers, and clinical experts from NTP, MOH, local Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) partners, and chest disease hospitals and medical associations to community leaders and health workers—to address the concerns and ambivalence about increasing access to DR-TB services in the local context and to develop buy-in at both levels.

Before the introduction of the cPMDT program in Bangladesh, most MDR-TB patient treatment had been managed at the central hospital. The expansion of treatment to communities through the public sector provided the opportunity to significantly expand the number of DR-TB patients on treatment while maintaining high treatment quality leading to positive patient outcomes.

As the number of DR-TB cases detected continued to rise, mainly due to increased use of the GeneXpert diagnostic platform, the overall treatment initiation of DR-TB patients through both long- and short-course regimens started to rapidly

increase—from 50% in 2011 to 100% in 2015. The proportion of DR-TB patients who initiated the long-course regimen, which was the intervention focus, increased from 67% in 2011 to 76% in 2015. The remaining 24% were enrolled in the short-course regimen supported by the Damien Foundation. Of the 1,946 DR-TB patients who initiated treatment between 2012 and 2015, 1,285 (66%) received and completed treatment in their communities. This change was crucial, as it eliminated the backlog of patients awaiting treatment initiation—a major concern in the pre-cPMDT stage—and the associated risk of infection at the facility and community levels.

While there are few published studies associating poor treatment outcomes with delayed treatment initiation, evidence of programmatic changes leading to shorter treatment initiation delays does exist.[14] Prior to the introduction of cPMDT, the median wait time between diagnosis and treatment initiation was 69 days in 2011. In 2014, the median wait time decreased to 6 days. Several factors contributed to this change. The transfer of patients to their communities after about 2 months of hospitalization enhanced the capacity of treatment-initiating hospitals to rotate a single bed for up to 6 patients a year, compared with 1.5 patients in previous years. Additionally, expanding the number of treatment-initiating hospitals at regional headquarters, increasing the number of hospital beds allocated to DR-TB patients, and increasing the efficient management and coordination of processes related to treatment initiation, release, and transfer of patients to community added speed to each step, reducing delay while increasing access to treatment for more patients.

Increased resources are needed through government revenue funds, the Global Fund, international donors, and local private entities to effectively sustain the DR-TB initiative.

Sputum culture conversion is an important interim indicator of the efficacy of MDR-TB treatment as well as an important predictor for treatment outcome.[15] Monthly culture monitoring is essential for early detection of treatment failure in patients with MDR-TB.[16] The project routinely tracked culture and smear conversion of patients to identify delayed converters and provide additional treatment support to them. Data analysis showed that 95% of the patients in community-based care complied with the requirement to have smear and culture tests done monthly and, after sputum conversion, culture tests done quarterly. Within 6 months of treatment, smear and culture conversion rates for patients reached 99% and 98%, respectively. The keys to ensuring patient compliance with the follow-up test requirements, were the decentralization of treatment to the community level and real-time monitoring of patients through a web-based mHealth application.

Compared with global averages, DR-TB patients in Bangladesh experienced better treatment outcomes. The treatment outcome data, measured at the end of the project in 2015, showed a treatment success rate of 76%, which is much higher than global average of 54%.[17] Only 10% of the Bangladesh patients were lost to follow up compared with 21% globally[17]; and 0.5% patients in Bangladesh experienced treatment failure compared with 8% globally.[17] In 2015, all 363 DR-TB patients received and completed treatment in their respective communities. The project results suggest that community-based care of DR-TB patients can achieve high levels of treatment adherence and favorable treatment outcomes.

A systems strengthening approach with a focus on integrated service delivery was a major consideration for financial sustainability of the cPMDT intervention. The intervention was planned consciously to avoid building a parallel system that would be difficult to sustain after the end of the project. However, the system will require additional resources to support recurring costs for continued training of service providers, procurement of drugs for treatment of DR-TB, provision of financial allowances to DOT providers and patients, quality assurance, and monitoring and supervision. The MOH and NTP are cognizant of the additional resource needs and expect to secure greater allocation of revenue funds from the government to cover certain costs. The monthly stipend to DOT providers and patients, initially supported through USAID funds, has already been shifted to the Global Fund. Stronger advocacy efforts are needed to mobilize more resources through the Global Fund, international donors, and local private sector entities to effectively continue and expand the DR-TB initiative.

Challenges and Lessons Learned

As a new approach for Bangladesh, the cPMDT project had to overcome several challenges, most of which were addressed through consistent effort and effective coordination with NTP, WHO, and other local-level partners. Effective planning and coordination for rolling out the program to the community level required a considerable effort to train and mobilize hundreds of skilled personnel at the upazila and community levels to manage and monitor patients integrated with the existing

health care system. Establishing well-functioning outpatient DR-TB teams that would be responsive to their new roles and responsibilities for management of DR-TB patients seemed to be a big challenge. The participation and combined effort from the local health authority, DR-TB hospitals, and NTP were essential to overcome those challenges. The existing health care system was not ready to take full responsibility for sustaining the initiative without external vigilance and support. The project's facilitative role, including close monitoring of field activities, was key to ensuring that patients were transferred without delay to the community and that they remained adherent to the treatment regimen.

Limitations

The study presented here has several limitations. Because we had to rely on the routine data collected by NTP for the national DR-TB program, which did not disaggregate cPMDT and non-cPMDT patients, we were unable to directly compare results between the two groups making it difficult to determine the impact of cPMDT model on the treatment outcome of DR-TB patients. We were also unable to compare results of sputum conversion between pre- and post-intervention because the data prior to the intervention were not available.

A concurrent health system strengthening effort may have also impacted the results of the intervention. During the cPMDT implementation, inpatient facilities were improved and the number of hospital beds for DR-TB treatment increased through a separate health system strengthening program, contributing to increasing national capacity for and access to DR-TB treatment.

CONCLUSION

The implementation of cPMDT in Bangladesh has greatly increased the proportion of DR-TB patients enrolled in treatment, reduced the delay in treatment initiation, and improved treatment adherence and outcomes among patients. The model demonstrates that cPMDT is an effective approach for increasing access to and providing quality-assured DR-TB treatment. A high cure rate with minimal default and failure is achievable by treating patients in their homes, where they feel more comfortable and receive family support. As detection of DR-TB cases continues to increase with the use of rapid diagnostic technologies, stronger systems for decentralized patient management are needed to accommodate treatment needs. Unless hospitalization is necessary for clinical reasons, treatment of DR-TB patients in the community from the first day is the way Bangladesh can mitigate the severe clinical, social, and economic consequences of DR-TB for individuals and communities.

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The cPMDT initiative has strengthened Bangladesh's health system by increasing the number of patients enrolled in treatment, reducing treatment delay, and improving patient adherence and outcomes.

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INNOVATION

Menstrual Bleeding Changes Are NORMAL: Proposed Counseling Tool to Address Common Reasons for Non-Use and Discontinuation of Contraception

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A new family planning counseling tool uses the simple mnemonic device "NORMAL" to help family planning counselors and providers communicate to their clients key messages about menstrual bleeding changes associated with use of hormonal contraception and the copper IUD.

BACKGROUND

In 2017, an estimated 214 million women of reproductive age living in low-resource settings wanted to avoid pregnancy but were not using a modern method of contraception.[1] Data from Demographic and Health Surveys conducted between 2005 and 2014 reveal that almost one-third of women cite concerns about side effects or fear of health risks as a reason for non-use of modern contraception.[2] In addition, nearly 40% of women who want to avoid pregnancy report they used a contraceptive in the past but discontinued use because of method-related issues.[3] Evidence shows that menstrual bleeding changes associated with contraceptive use contribute to both discontinuation rates and non-use of contraception.[4–10] Many women fear that menstrual changes—such as heavier bleeding, prolonged bleeding, irregular bleeding, spotting, and absence of bleeding (amenorrhea)—can lead to negative health consequences, including infertility. In addition, women often perceive that menstruation is a natural sign of femininity; they worry absence of bleeding is a sign of pregnancy; and they fear a build-up of "dirty" or "bad" blood in their bodies. Unsurprisingly, changes in menstrual bleeding are known to impact women's daily lives and relationships with their partners.[10–18]

Helping women understand the typical bleeding changes associated with the use of modern contraceptive methods could lead to greater acceptance of these changes, increased method uptake, improved satisfaction, and higher continuation rates.[10,19] In particular, both health care providers and contraceptive users should understand that changes to menstrual bleeding—including absence of bleeding—due to the use of contraceptive methods will not negatively impact women's health.[20,21] A clearer understanding of potential bleeding changes associated with a given contraceptive method and anticipated lifestyle implications may also help women make well-informed decisions about the specific method that best meets their needs.[22]

In addition, amenorrhea and oligomenorrhea (infrequent bleeding) associated with certain hormonal contraceptive methods can have important noncontraceptive health benefits as well as lifestyle advantages for some women.[20,21] Positioning noncontraceptive attributes as having potential advantages for women, rather than characterizing all menstrual bleeding changes as unpleasant side effects, could potentially lead to increased demand for and satisfaction with hormonal contraceptive methods.[23]

Despite the potential advantages of providing high-quality counseling on these topics to family planning clients, it is unclear the extent to which this happens in the field and what impact these types of messages might have on method uptake or continued use. A recent review by Polis et al.[10] found few studies that have evaluated whether counseling clients on changes to menses influences method choice or improves continuation rates. The authors noted that development of a counseling tool could help health care providers better communicate with clients about potential bleeding changes associated with contraceptive use. The work described here was undertaken to address this gap.

CURRENT LANDSCAPE: EXISTING MESSAGES IN INTERNATIONAL TRAINING AND COUNSELING MATERIALS

As a first step, to better understand what current guidance is available to health care providers on how

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Understanding the potential bleeding changes associated with various contraceptive methods and potential lifestyle implications could help women make well-informed decisions about the specific method that best meets their needs.

A new counseling tool uses the simple mnemonic device "NORMAL" to help providers remember important messages about menstrual bleeding changes associated with contraception.

to counsel women about menstrual bleeding changes and contraceptive use, we reviewed counseling, training, and reference materials developed and commonly used by international family planning programs (Table).[24–34] Two clinicians independently reviewed each resource to evaluate if and how menstrual bleeding changes were addressed. They examined 6 parameters to determine whether providers were instructed to (1) describe bleeding changes clients should expect with specific contraceptive methods; (2) compare typical bleeding changes among different contraceptive methods; (3) reassure women about menstrual bleeding changes, either general or detailed reassurance; (4) describe strategies to manage inconvenient menstrual changes; (5) provide basic information about menstruation and/or menstrual hygiene; and (6) explain the potential health benefits of oligomenorrhea or amenorrhea. In addition, reviewers also noted whether providers were instructed to describe typical menstrual changes before or after a client selected a specific contraceptive method, and whether tailored information was included for special populations, such as youth or postpartum women. The information was evaluated for 4 contraceptive methods—implants, injectables, the copper intrauterine device (IUD), and the levonorgestrel intrauterine system (LNG IUS)—because of the high likelihood of these methods to change menstrual bleeding patterns.

A key finding from the assessment was that menstrual bleeding changes are insufficiently addressed in the resources reviewed. In general, common bleeding changes, such as heavier or decreased bleeding, and the potential benefits of reduced or no bleeding are addressed in all of the resources evaluated; however, these topics either do not receive much emphasis or little detail is provided. Although resources often instruct providers to reassure women that bleeding changes are not a sign of illness, global evidence demonstrates that women's concerns about bleeding changes are more varied and nuanced.[10] As such, family planning counselors need to be able to provide clients with general information about bleeding changes as well as communicate information tailored to clients' individual concerns. Results from the assessment of training, counseling, and reference materials are summarized in the Table.

PROPOSED TOOL

To address gaps in existing guidance and training materials, a multidisciplinary project team from FHI 360 and Population Services International (PSI) developed a simple set of counseling messages about menstrual bleeding changes associated with contraceptive use. The objective of this project, which was funded by the United States Agency for International Development (USAID), was to develop a resource that health care providers could easily incorporate into counseling sessions without substantially increasing time or effort requirements. The primary goals of the tool are to prompt providers to (1) educate women on bleeding changes associated with use of contraception, (2) address common misconceptions and fears about menstrual changes, and (3) increase women's awareness of the potential advantages of reduced menstrual bleeding and/or amenorrhea.

The tool uses the simple mnemonic device "NORMAL"—Normal, Opportunities, Return, Methods, Absence of Menses, and Limit—to help practitioners remember brief messages about menstrual bleeding changes associated with hormonal contraception and the copper IUD and address typical concerns and questions women often have. The NORMAL tool prompts providers to address the following 6 points:

1. **NORMAL – Changes to your menses are NORMAL when you use a contraceptive method.** With this point, providers are encouraged to describe the different types of bleeding changes that women can expect—specifically, changes in volume, duration, and predictability of menses—with use of hormonal contraception and the copper IUD. Providers are also instructed to tell clients that menstrual changes can vary over time with continued use of hormonal contraception.[33]
2. **OPPORTUNITIES – Lighter or no menses can provide OPPORTUNITIES that may benefit your health and personal life.** Providers are prompted to inform clients of the potential health benefits and lifestyle advantages associated with reduced bleeding or amenorrhea. For example, all hormonal contraceptives offer some protection from iron-deficiency anemia, and some methods—such as oral contraceptive pills and the LNG IUS—are used as effective treatments for heavy menstrual bleeding (menorrhagia).[33] Also, the absence of bleeding or infrequent bleeding can be convenient for women by increasing their ability to participate in educational or work activities, lowering financial

TABLE. Content Related to Menstrual Bleeding Changes in Key International Family Planning Counseling and Training Resources

		Messages/Content Evaluated							
Resource/Lead Organization(s)	**Contraceptive Method**	**Type of Expected Bleeding Changes**	**Comparison of Bleeding Changes Among Different Methods**	**When to Address Bleeding Changes**	**Type of Reassurance Provided[a]**	**Strategies to Manage Bleeding Changes and Associated Symptoms**	**Overview of Function and Biological Process of Menstruation**	**Potential Benefits of Oligomenorrhea or Amenorrhea**	**Expected Bleeding Changes for Special Populations[b]**
The Balanced Counseling Strategy Plus: A Toolkit for Family Planning Service Providers Working in High HIV/STI Prevalence Settings[24]/ Population Council	Implants	Y	Y	After method initiation	2	N	N	Y	N
	DMPA injectable	Y	N	After method initiation	1	N	N	Y	N
	Copper IUD	Y	N	After method initiation	2	N	N	N/A	N
	LNG IUS	Y	N	After method initiation	2	N	N	Y	N
Training Resource Package for Family Planning[25c]/ USAID, WHO, and UNFPA	Implants	Y	N	Before method initiation	2	N	N	Y	N
	DMPA injectable	Y	N	Before method initiation	3	Y	N	Y	N
	Copper IUD	Y	N	Before method initiation	2	Y	N	N/A	Y
Providing Long-Acting Reversible Contraception (LARC) Learning Resource Package (Modular/Facility-Based)[26d]/MCSP, Jhpiego	Implants	Y	N	Before method initiation	2	Y	N	Y	Y
	Copper IUD	Y	N	Before method initiation	2	Y	N	N/A	N
	LNG IUS	Y	N	Before method initiation	2	Y	N	Y	Y
Pathfinder Family Planning Resources[27–32c]/ Pathfinder	Implants	Y	N	Before method initiation	3	Y	N	Y	N
	DMPA injectable	Y	N	Before method initiation	2	Y	N	Y	Y
	Copper IUD	Y	N	Before method initiation	2	Y	N	N/A	Y
Family Planning: A Global Handbook for Providers, 3rd ed.[33]/WHO and K4Health Project, Johns Hopkins CCP	Implants	Y	N	Before and after method initiation	3	Y	N	Y	N
	DMPA injectable	Y	N	Before and after method initiation	3	Y	N	Y	N
	Copper IUD	Y	N	Before and after method initiation	2	Y	N	N/A	N
	LNG IUS	Y	N	Before and after method initiation	2	N	N	Y	N

Continued

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Resource/Lead Organization(s)	Contraceptive Method	Messages/Content Evaluated							
		Type of Expected Bleeding Changes	Comparison of Bleeding Changes Among Different Methods	When to Address Bleeding Changes	Type of Reassurance Provided[a]	Strategies to Manage Bleeding Changes and Associated Symptoms	Overview of Function and Biological Process of Menstruation	Potential Benefits of Oligomenorrhea or Amenorrhea	Expected Bleeding Changes for Special Populations[b]
LNG IUS Training Manual for Family Planning[34e]/ICA Foundation	LNG IUS	Y	Y	Before method initiation	2	Y	N	Y	N

Abbreviations: CCP, Center for Communication Programs; DMPA, depot medroxyprogesterone acetate; ICA, International Contraceptive Access; IUD, intrauterine device; LNG IUS, levonorgestrel intrauterine system; K4Health, Knowledge for Health; MCSP, Maternal and Child Survival Program; UNFPA, United Nations Population Fund; USAID, United States Agency for International Development; WHO, World Health Organization.

[a] 1=none; 2=general "no harm" message; 3=detailed "no harm" message.

[b] Special populations include youth and postpartum women.

[c] Method-specific information on the LNG IUS is not included in this resource.

[d] Method-specific information on DMPA is not included in this resource.

[e] Information about the LNG IUS is not included in all resources because it is not widely available in developing countries. The ICA Foundation donates free LNG IUS units and has LNG IUS training resources for providers on their website. The ICA Foundation materials were reviewed for information on the LNG IUS specifically and did not include information on implants, DMPA, or the copper IUD.

costs and the burden of menstrual hygiene management, and reducing disruption of sexual activity.[21,35]

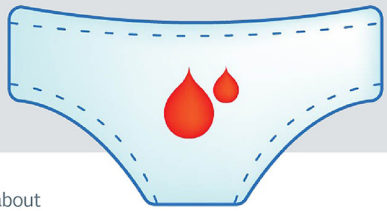
3. **RETURN – Once you stop using a method, your menses will RETURN to your usual pattern, and your chances of getting pregnant will RETURN to normal.** Providers are encouraged to reassure women that menstrual bleeding changes are not permanent and will not harm their future fertility. For most contraceptive methods, fertility will return rapidly after use of contraception is discontinued. In the case of injectable contraception, return to fertility will likely be delayed for several months after stopping use.[33]
4. **METHODS – Different contraceptive METHODS can lead to different bleeding changes.** Providers should ask a woman about her preferences regarding bleeding changes when she is selecting a method. Bleeding profiles differ across methods, and women's preferences should inform a tailored counseling approach and be incorporated into deciding which method to select.[22]
5. **ABSENCE OF MENSES – If you are using a hormonal method, ABSENCE OF MENSES does not mean that you are pregnant.** Providers should reassure users of hormonal contraception that they should not assume absence of menstrual bleeding is, by itself, a sign of pregnancy. If a woman has other signs of pregnancy while using a hormonal method, or if she misses her menses while using copper IUD, she should talk with her provider or take a pregnancy test.[33]
6. **LIMIT – If changes to your menses LIMIT your daily activities, there are simple treatments available.** If a woman perceives bleeding changes as unpleasant or worrisome, she should be encouraged to talk with her provider about options before she decides to discontinue a method. For example, irregular or heavy bleeding may interfere with women's daily lives or increase their menstrual hygiene management burden.[10] Simple treatment options are available that can help alleviate troubling physical symptoms.[33,36] Additional education and reassurance can also be helpful.[37]

Evidence shows that use of acronyms and mnemonic devices can improve clinical practice in a range of fields, and that the introduction of simple evidence-based checklists and job aids for family planning providers can lead to increased contraceptive use in low-resource settings.[38–41] Two mnemonic devices have been commonly used in international family planning programs to

FIGURE. NORMAL Counseling Tool

MESSAGES TO CLIENTS USING CONTRACEPTION

Changes to Menses are **NORMAL**



Many women have misconceptions about changes to menses (periods) that occur with use of hormonal contraception or the copper IUD. Use this simple tool to help your clients understand that changes to their menses when they use a hormonal contraceptive method or the copper IUD are **NORMAL**. Provide your clients with evidence-based information about method-specific changes that may occur. In addition, in each counseling session, reassure your clients about these changes and discuss the potential benefits of reduced bleeding and amenorrhea. Use the **NORMAL** acronym to address these points with them.

N — **NORMAL** — Changes to your menses are **NORMAL** when you use a contraceptive method. With hormonal methods, menses could become heavier or lighter, occur more frequently or when you don't expect it, or you could have no menses at all. Changes to your menses may also be different over time.[1] With the copper IUD, menses could become longer and heavier, but remain regular; spotting could also occur during the first few months after IUD insertion.

O — **OPPORTUNITIES** — Lighter or no menses can provide **OPPORTUNITIES** that may benefit your health and personal life.

R — **RETURN** — Once you stop using a method, your menses will **RETURN** to your usual pattern, and your chances of getting pregnant will **RETURN** to normal.[2]

M — **METHODS** — Different contraceptive **METHODS** can lead to different bleeding changes. Let your provider know what types of bleeding changes you would find acceptable.

A — **ABSENCE OF MENSES** — If you are using a hormonal method, absence of menses does not mean that you are pregnant. If you have another symptom of pregnancy or if you missed your menses while using the copper IUD, talk to your health care provider or use a pregnancy test.[3]

L — **LIMIT** — If changes to your menses **LIMIT** your daily activities, there are simple treatments available. Talk to your provider.[4]

Illustration credit: Period emoji, Plan International UK. https://plan-uk.org/act-for-girls/break-the-taboo-vote-for-your-favourite-period-emoji

[1] In addition to these points, provide method-specific information about potential changes to menses both before and after a client selects a hormonal contraceptive method.
[2] If applicable, inform your client that when using injectable contraception (e.g., DMPA), return to fertility will likely be delayed after discontinuing the method. For other methods, return to fertility will be immediate.
[3] If applicable, inform your client that when using oral contraceptive pills, absence of menses can be a sign of pregnancy. Absence of menses during the first month after initiation of the implant or progestin-only injectables may also be a sign of pregnancy (e.g., when the method was initiated as part of the Quick Start, without pregnancy being ruled out with reasonable certainty). Tell your client to return to the clinic if she is unsure of her pregnancy status.
[4] Treatment for heavy/prolonged bleeding due to hormonal methods include a 5-day course of ibuprofen or another NSAID (except aspirin), or a 21-day course of COCs or ethynyl estradiol. Treatment for bleeding associated with the copper IUD includes a 5-day course of tranexamic acid or NSAIDs (except aspirin). In most cases, however, providing supportive counseling and/or reassurance to clients is sufficient.

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Abbreviations: COCs, combined oral contraceptives; DMPA, depot medroxyprogesterone acetate; IUD, intrauterine device; NSAID, nonsteroidal anti-inflammatory drug.

The NORMAL tool may help enhance acceptability of modern contraceptive methods, reduce discontinuation rates among current users, and increase use among women with unmet need for contraception.

train providers on appropriate sequencing of counseling steps: GATHER, which stands for Greet, Ask, Tell, Help, Explain, and Return, and REDI, which stands for Rapport building, Exploration, Decision making, and Implementing the decision.[42,43] The NORMAL tool complements these frameworks as well as other commonly used counseling approaches.

Research has demonstrated that when delivering information about a health intervention, there is a risk of inadvertently reinforcing misconceptions among the target population.[44,45] As such, all messages included in the NORMAL tool are framed in positive language that avoids repeating inaccurate information. Although only a subset of contraceptive methods was included in the initial review of international counseling and training resources described earlier, the NORMAL tool was designed to be relevant and applicable for all hormonal methods and the copper IUD. Providers who use the tool are instructed to use it both before and after a client selects a contraceptive method; they are also prompted to remind their clients to return for additional counseling and/or treatment if they have concerns about bleeding changes after method initiation.

In 2017, the team that developed the NORMAL tool solicited feedback on a preliminary draft from private- and public-sector health care providers in Haiti and Zambia during family planning training workshops, and from PSI and FHI 360 reproductive health staff in Nigeria and Zambia during project meetings. The format and content of the tool were then revised based on the input received. A final version of the NORMAL tool (Figure) is also available in French, Portuguese, and Spanish; the term "NORMAL" is used in all 3 translated versions, with minor adjustments to ensure the translated content is accurate and appropriate. (To download the English and translated versions, see www.fhi360.org/resource/normal-counseling-tool-menstrual-bleeding-changes-job-aid.) Because the tool is meant to prompt providers to address key points and is not intended to be a script that is read verbatim, the expectation is that providers will be able to address the same topics using local languages with clients.

NEXT STEPS

Changing women's knowledge and attitudes about menstrual bleeding changes associated with contraceptive use may enhance acceptability of modern contraceptive methods, reduce discontinuation rates among current users, and increase use among women with unmet need for contraception. The NORMAL counseling tool is designed to reduce common myths and misconceptions among women, improve women's knowledge of bleeding changes, and increase women's interest in the noncontraceptive benefits associated with oligomenorrhea or amenorrhea. This tool could be incorporated into facility- or community-based provision of family planning, and could be included in preservice and on-the-job training for providers.

Before the tool is implemented on a wide scale, additional research is needed to further evaluate the feasibility and effectiveness of incorporating the NORMAL tool into family planning counseling sessions, women's comprehension of these messages, and the ultimate impact on changing providers' and women's attitudes and behaviors. In 2018, the NORMAL tool will be evaluated as part of a USAID-funded study in Malawi. Additionally, development of the tool was based on the initial review of counseling and training tools developed by international groups; an important next step would be to review national family planning guidelines and training curricula to determine if and how menstrual bleeding changes are addressed in those documents. Following that review, national stakeholders could be encouraged to incorporate the NORMAL tool into these resources, pending positive evaluation results.

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UPDATE

Update of: Sarma et al., Effectiveness of SMS Technology on Timely Community Health Worker Follow-Up for Childhood Malnutrition: A Retrospective Cohort Study in sub-Saharan Africa

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UPDATE

Update of: Kheang et al., Malaria Case Detection Among Mobile Populations and Migrant Workers in Myanmar: Comparison of 3 Service Delivery Approaches

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UPDATE

Update of: Ndiaye et al., High-Risk Advanced Maternal Age and High Parity Pregnancy: Tackling a Neglected Need Through Formative Research and Action

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UPDATE

Update of: Marks et al., Review of Grain Fortification Legislation, Standards, and Monitoring Documents

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UPDATE

Update of: Subramanian et al., Increasing Contraceptive Use Among Young Married Couples in Bihar, India: Evidence From a Decade of Implementation of the PRACHAR Project

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UPDATE

Update of: Koffi et al., Engaging Men in Family Planning: Perspectives From Married Men in Lomé, Togo

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We have added French translations of the abstracts for a number of articles from the June 2018 issue (Volume 6, Number 2) in which the content focused on countries where the official language is French. This has affected the page numbering of these and subsequent articles. The new citations are as follows:

- Ouedraogo Y, Furlane G, Fruhauf T, et al. Expanding the single-visit approach for cervical cancer prevention: successes and lessons from Burkina Faso. Glob Health Sci Pract. 2018;6(2):288–298. https://doi.org/10.9745/GHSP-D-17-00326. *(French translation of the abstract added)*
- Harvey SA. Observe before you leap: why observation provides critical insights for formative research and intervention design that you'll never get from focus groups, Interviews, or KAP Surveys. Glob Health Sci Pract. 2018;6(2):299–316. https://doi.org/10.9745/GHSP-D-17-00328
- Koffi TB, Weidert K, Ouro Bitasse E, et al. Engaging men in family planning: perspectives from married men in Lomé, Togo. Glob Health Sci Pract. 2018;6(2):317–329. https://doi.org/10.9745/GHSP-D-17-00471. *(French translation of the abstract added)*
- Subramanian L, Simon C, Daniel EE. Increasing contraceptive use among young married couples in Bihar, India: evidence from a decade of implementation of the PRACHAR Project. Glob Health Sci Pract. 2018;6(2):330–344. https://doi.org/10.9745/GHSP-D-17-00440
- Sarma S, Nemser B, Cole-Lewis H, et al. Effectiveness of SMS technology on timely community health worker follow-up for childhood malnutrition: a retrospective cohort study in sub-Saharan Africa. Glob Health Sci Pract. 2018;6(2):345–355. https://doi.org/10.9745/GHSP-D-16-00290
- Marks KJ, Luthringer CL, Ruth LJ, et al. Review of grain fortification legislation, standards, and monitoring documents. Glob Health Sci Pract. 2018;6(2):356–371. https://doi.org/10.9745/GHSP-D-17-00427
- Ndiaye K, Portillo E, Ouedraogo D, Mobley A, Babalola S. High-risk advanced maternal age and high parity pregnancy: tackling a neglected need through formative research and action. Glob Health Sci Pract. 2018;6(2):372–383. https://doi.org/10.9745/GHSP-D-17-00417. *(French translation of the abstract added)*
- Kheang T, Lin MA, Lwin S, et al. Malaria case detection among mobile populations and migrant workers in Myanmar: comparison of 3 service delivery approaches. Glob Health Sci Pract. 2018;6(2):384–389. https://doi.org/10.9745/GHSP-D-17-00318
- Choi Y, Short Fabic M. Monitoring progress in equality for the Sustainable Development Goals: a case study of meeting demand for family planning. Glob Health Sci Pract. 2018;6(2):390–401. https://doi.org/10.9745/GHSP-D-18-00012

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