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# GLOBAL HEALTH: SCIENCE AND PRACTICE

2018 | Volume 6 | Number 4

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**Global Health: Science and Practice** (ISSN: 2169-575X) is a no-fee, open-access, peer-reviewed journal published online at [www.ghspjournal.org](http://www.ghspjournal.org). It is published quarterly by the Johns Hopkins Center for Communication Programs, 111 Market Place, Suite 310, Baltimore, MD 21202. The journal is made possible by the support of the American People through the United States Agency for International Development (USAID). The Knowledge for Health (K4Health) Project is supported by USAID's Office of Population and Reproductive Health, Bureau for Global Health, under Cooperative Agreement #AID-OAA-A-13-00068 with the Johns Hopkins University. GHSP is editorially independent and does not necessarily represent the views or positions of USAID, the United States Government, or the Johns Hopkins University.

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Cover caption: A girl receives the HPV vaccine at her school in the Southern Province of Rwanda. © 2012 Christine McNab/WHO.

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Jose G. Rimon II, Amy O. Tsui

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Kate H. Rademacher, Tabitha Sripipatana, Anne Pfitzer, Anna Mackay, Sarah Thurston, Ashley Jackson, Elaine Menotti, Hayley Traeger

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Dawn Greensides, Judith Robb-McCord, Angeline Noriega, James A. Litch

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Julie H. Hernandez, Pierre Z. Akilimali, Mbadu Fidèle Muanda, Annie L. Glover, Jane T. Bertrand

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Gillian Eva, Geeta Nanda, Kate Rademacher, Anna Mackay, Omaye Ngedu, Anne Taiwo, Leila Dal Santo, Mariya Saleh, Lucky Palmer, Tracey Brett

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David Mabirizi, Bayobuya Phulu, Wuletaw Churfo, Samson Mwinga, Greatjoy Mazibuko, Evans Sagwa, Lazarus Indongo, Tamara Hafner

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Allison Annette Foster, Marjorie Kabinga Makukula, Carolyn Moore, Nellisiwe Luyando Chizuni, Fastone Goma, Alan Myles, David Nelson

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Rena Eichler, Susan Gigli, Lisa LeRoy

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Fude Takayoshi, Sakiko Yamaguchi, Amelita M. Pangilinan, Makoto Tobe, Shogo Kanamori

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Eliningaya Kweka, Aneth Mahande, Johnson Ouma, Wycliffe Karanja, Shandala Msangi, Violet Temba, Lucille Lyaruu, Yousif Hemeidan

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## EDITORIAL

# Antenatal Corticosteroids: *Primum non nocere*

Steve Hodgins<sup>a</sup>

Efforts continue—building on work of the UN Commission on Life-Saving Commodities for Women and Children—to expand use of antenatal corticosteroids in low-resource settings. We argue that until more is known on the balance of benefit versus harm, such promotion should be suspended.

➔ See related article by Greensides.

Corticosteroids are a synthetic version of the stress hormone cortisol. As such, they have manifold effects across systems and functions of the body including renal, vascular, endocrine, central nervous system, skin, gut, and—of most relevance for their use for imminent preterm labor—growth and development and immunological function (and, therefore, response to infection).

We have evidence for the protective efficacy of antenatal corticosteroids, dating back to animal studies in the 1960s and clinical trials beginning in the 1970s. Roberts and Dalziel's Cochrane reviews<sup>1</sup> summarize the findings of these trials (mainly from high-income countries), notably that treatment with antenatal corticosteroids prior to imminent preterm birth, compared with placebo or no treatment, is associated with:

- 32% lower neonatal mortality (relative risk, 0.69; 95% confidence interval, 0.59 to 0.81; N=7188; 22 studies, from the 2017 review), and
- reduced risk of respiratory distress syndrome, intraventricular hemorrhage, necrotising enterocolitis, and systemic newborn infection in the first 48 hours of life.

On the strength of such evidence, corticosteroids have been a mainstay of preventive treatment for preterm birth in high-income countries for decades. Use in low- and middle-income countries (LMICs) has been much less widespread, and evidence much sparser. However, anticipating that such use could have particular benefit in settings with high newborn mortality, there have been prominent efforts at the global level to promote use in LMICs—dating from 2012—reflected in the World Health Organization's (WHO's) *Born Too Soon* report,<sup>2</sup> the focus on antenatal corticosteroids by the UN

Commission on Life-Saving Commodities for Women and Children,<sup>3</sup> and several prominent papers published at the time.<sup>4,5</sup>

## ■ WORRIES ABOUT EFFICACY AND SAFETY IN LOW- AND MIDDLE-INCOME COUNTRIES

Over the same period as this recent big advocacy push, the Global Network for Women's and Children's Health Research, funded by the National Institute of Child Health and Human Development, was also conducting a large (N=99,742), multi-country, pragmatic trial (called ACT) in Argentina, Guatemala, India, Kenya, Pakistan, and Zambia, encouraging wider use of antenatal corticosteroids for imminent preterm birth, including in peripheral-level health services. The results, first published in October 2014,<sup>6</sup> came as a shock.<sup>7</sup> In the intervention arm, neonatal mortality was 12% *higher* than in the comparison arm, corresponding to more than 150 excess deaths, mainly in bigger newborns, presumably most born at or near term. However, even in those in the lowest 5% by birthweight—among whom no overall mortality effect was seen—this may well reflect a mix of individuals benefited and harmed. The clearest evidence of an adverse mortality effect was in the 2 African sites<sup>8</sup> (although mortality was also elevated in the Indian sites); in addition to higher mortality, these African sites also showed almost a doubling of risk of possible severe bacterial infection among newborns in the intervention arm. Note, also, that stillbirths increased to approximately the same degree as newborn deaths, although evidence<sup>9</sup> for a causal role of antenatal corticosteroids in risk of stillbirth is less robust.

## ■ RESPONSE TO THE NEW EVIDENCE

In the wake of release of these findings, momentum for expanding use of antenatal corticosteroids in LMICs slowed markedly, though not to a complete halt. The UN Commission on Life-Saving Commodities for Women and Children continued its work<sup>10</sup>—somewhat

<sup>a</sup>Editor-in-Chief, Global Health: Science and Practice Journal, and Associate Professor, School of Public Health, University of Alberta, Edmonton, Alberta, Canada.

Correspondence to Steve Hodgins (shodgins@ghspjournal.org).



more cautiously than before—supporting increased use in LMICs. But WHO did issue new, more explicit guidelines in 2015,<sup>12</sup> specifying the full set of conditions that need to be met for safe use (i.e., for the probability of benefit to be greater than the probability of harm), notably:

- Accurate gestational age dating and competent assessment determining imminent preterm birth (i.e., within 1–7 days)
- No evidence of maternal infection
- Adequate care at childbirth and for preterm newborns, including thermal care, nutrition/fluids, infection treatment, and care for respiratory complications (including safe oxygen use)

## ■ HOW IMPORTANT ARE THESE REQUIREMENTS?

### Ensuring Accurate Selection and Timing Based on Accurate Estimation of Gestational Age

From the results of the ACT trial,<sup>6</sup> excess mortality was seen only among those in the highest 75% by birthweight. This group would have included few newborns in the target gestational age of <34 weeks, but mainly a mix of mistimed administration and pregnancies exposed to antenatal corticosteroids at an appropriate gestational age but continuing on to term or near term before delivering. There had already been an indication in secondary analyses done by Roberts<sup>1</sup> that for this later gestational age group, the probability of harm could exceed probability of benefit. The recently published, U.S.-based Antenatal Late Preterm Steroids (ALPS) trial,<sup>13</sup> on antenatal corticosteroids for late preterm gestation (34 weeks 0 days, to 36 weeks 5 days), documented a reduced risk of respiratory complications of prematurity. However, it found no impact on mortality and an increased risk of neonatal hypoglycemia (and evidence from elsewhere suggests this effect may be more severe for mothers of low body mass index<sup>14</sup>). The relevance of these findings for LMIC settings is unclear. Although mortality risk is markedly lower in this older gestational age group than among those <34 weeks at birth, they are far more numerous and therefore still account for a large number of deaths in LMICs. It certainly appears that in the older gestational age group, in LMIC settings similar to the ACT trial, probability of harm from antenatal corticosteroids exposure exceeds probability of benefit. So, accuracy of

both gestational age dating and assessment of imminence of birth appears to be quite important.

### Challenges in Assessing Gestational Age Especially Late in Pregnancy

In the ACT trial settings, obstetrical ultrasound was generally unavailable. Investigators made a serious effort to ensure that participating health workers had training and equipment to enable them to competently estimate gestational age based on last normal menstrual period and fundal height, within the limitations of the method. However, numerous studies<sup>15</sup> have found that such clinical assessment of gestational age is associated with greater error than first trimester ultrasound.

The most accurate ultrasound dating is by first trimester crown-rump length (accurate to within  $\pm 3$  to 8 days).<sup>16</sup> In the second and third trimester, the most accurate estimates are by an index of several measurements.<sup>15</sup> Currently, the standard is based on femur length and head circumference. According to a recent study by Papageorgiou using this index,<sup>17</sup> accuracy in the third trimester can be  $\pm 14$  days or slightly more.

So, competently done clinical assessment using last normal menstrual period and fundal height can yield accuracy within about 2 weeks, if done in the first trimester, but accuracy declines with gestational age. Competently done ultrasound in the first trimester, using crown-rump length, gives the greatest accuracy. Ultrasound done later in pregnancy is less accurate, with imprecision of 14 days or more in the third trimester.

In principle, one way of improving targeting of antenatal corticosteroids would be to make competent obstetrical ultrasound more widely available in LMICs. However, effectiveness and feasibility of such a strategy was tested in the FirstLook study, which documented that although it was possible to get good-quality assessments, there were significant challenges even with robust technical support.<sup>18</sup>

In summary, ensuring appropriate timing of administration—which depends on accurate gestational age estimation—matters. But in many LMIC settings, it's highly problematic to get accurate dating.

### Ruling Out Maternal Infection

A second condition specified in the new WHO recommendations is that maternal infection be ruled out. Given evidence from the ACT trial of higher

**Corticosteroids have been a mainstay of preventive treatment for preterm birth in high-income countries for decades.**

**In the ACT trial conducted in 6 LMICs, use of antenatal corticosteroids was associated with 12% higher risk of neonatal mortality.**

**In many LMICs, it's highly problematic to get accurate gestational age dating.**

**Accuracy of gestational age dating and assessment of imminence of birth appears to be quite important for the safe use of antenatal corticosteroids.**

rates of maternal infection and potentially severe infection in the newborns in the intervention arm, it would appear appropriate to insist on carefully ruling out maternal infection before administering antenatal corticosteroids. However, it's not clear that had such provisions been more robust in the ACT trial, they would have been sufficient to ensure safe use.

### Standard of Care for Preterm Newborns

The WHO guidelines also specify—as a requirement for safe use—that the service delivery environment be capable of providing adequate care for preterm newborns, including appropriate thermal care, managing feeding and fluids, and care of respiratory complications (including safe oxygen use). The fact that a health facility is considered capable of providing emergency obstetrical care (including cesarean delivery) is no guarantee that it also has the capability of providing adequate care for preterm newborns and their complications. Furthermore, while we can expect that having such capability would contribute to reducing mortality risk, this is only one of a full set of conditions to be met for safe antenatal corticosteroids use. In settings where the other conditions are not met (e.g., accurate gestational age dating using first or second trimester ultrasound), even when antenatal corticosteroids are used in highly functional tertiary-level health facilities, one cannot necessarily be confident that the probability of benefit would exceed probability of harm.

### Other Potentially Relevant Contextual Differences Between High-Income and Low- and Middle-Income Countries

Although not mentioned in the WHO guidelines, other authors<sup>8</sup> have pointed out that not only does the service delivery environment differ between high-income countries and LMICs, but there may also be relevant epidemiologic differences that can influence the balance of benefit versus harm (and, indeed, there may be important differences *between* LMIC settings, for example, between South Asia and sub-Saharan Africa). Notably, there may be relevant differences in microbiological exposures and nutritional factors and associated responses in the mother and fetus. More needs to be learned before we can be confident of the results to be expected using this treatment across varied epidemiologic settings.

### ■ ADDRESSING UNCERTAINTIES

Several authors have recently pointed to uncertainties with regard to the balance of benefit

versus risk in LMICs. Jobe and Goldenberg<sup>19</sup> comment, on antenatal corticosteroids: “an effective therapy in high-resource environments may be ineffective or harmful in low-resource environments.” In the recently updated Cochrane review by Roberts et al.,<sup>1</sup> the authors conclude that it would be particularly relevant to explore effectiveness versus possible harms in low-resource settings, using adequately powered prospective trials. And this call is echoed in Vogel's report<sup>20</sup> on the conclusions of expert meetings convened by WHO in 2015 and 2016. In response to such calls for further trials (including in older gestational-age pregnancies), funds have been committed for 2 new trials in LMICs to be implemented under WHO: ACTION I (testing antenatal corticosteroids use <34 weeks gestation)<sup>21</sup> and ACTION II (34 to 36 weeks).<sup>22</sup>

### ■ AWAITING NEW EVIDENCE, WHAT SHOULD BE OUR STANCE IN LMIC SETTINGS?

From what was documented in the article in this issue of GHSP by Greensides et al.,<sup>11</sup> it is pretty clear that conditions for safe use—as specified in the current WHO recommendations—are *not* consistently being met in the countries surveyed. It is certainly plausible that current use of antenatal corticosteroids in these settings could be resulting in more deaths caused than prevented.

In our view, global leaders in maternal and newborn health need to communicate more clearly: if we cannot be confident that all essential conditions for safe use are met, antenatal corticosteroids may *increase* rather than reduce risk of newborn death. On the principle of *primum non nocere*—first, do no harm—we should not promote use of antenatal corticosteroids in LMIC settings unless or until we have robust evidence that expectation of benefit exceeds expectation of harm.

**Funding:** None.

**Competing Interests:** None declared.

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**Primum non nocere: Until we have better evidence on the balance of effectiveness and safety, we should not promote antenatal corticosteroids in LMICs.**

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**First Published Online:** December 20, 2018

**Cite this article as:** Hodgins S. Antenatal corticosteroids: primum non nocere. *Glob Health Sci Pract*. 2018;6(4):620–623. <https://doi.org/10.9745/GHSP-D-18-00461>

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## EDITORIAL

## Time to Evolve Beyond Prototypical Community-Based Distribution (CBD) of Contraception?

CBD efforts have a definite role in a variety of country programming contexts. However, contemporary efforts need to strive for an expanded method mix, strong support and motivation of CBD agents, and robust integration with existing health systems.

➔ See related article by [Hernandez](#).

In this issue of GHSP, Hernandez and colleagues present a notable description of how their process evaluation of a large community-based distribution (CBD) program in the capital city of the Democratic Republic of the Congo (DRC), Kinshasa, led to major improvements in that program.<sup>1</sup> We compliment the authors for forthrightly detailing the weaknesses they observed in the original design of the AcQual program and the reasonable changes they subsequently have made. Nevertheless, the experience offers the opportunity to ask what might be the proper role for similar CBD efforts in the future.

Community-based distribution of contraception has had a number of variations, including:

- Whether agents are volunteers or paid (or retain proceeds from sales of the contraceptives),
- Which contraceptive methods they provide,
- Whether agents are expected to actually visit clients in their homes, and
- Whether CBD programs should focus just on contraception or include other health interventions.

Historically, CBD programming was pivotal, especially in the 1970s and 1980s, in demonstrating that a substantial proportion of women would use contraception if it were readily available, getting contraception to some extent out of the “medical model” and helping to jump-start and advance family planning efforts in early programs. Yet since then, many countries have made marked progress socioeconomically and have made major improvements in their health programs. Moreover, more contraceptive options, notably the popular implants and injectables (including subcutaneous DMPA), are much more widely available, and other successful service delivery modes—notably mobile

outreach service delivery; social marketing in drug shops, pharmacies, and community outlets; and social franchising of private health clinics—have evolved to reach geographically dispersed clients.

But importantly the overall global health agenda is vastly larger going forward. Accordingly, the much broader concept of “community health worker” in its many variants and with a correspondingly broader health intervention mandate has taken root and occupies a key place in many low- and middle-income country programs. A good reference on best practices for community health workers for family planning is the High Impact Practice brief.<sup>2</sup>

The original CBD model undertaken by Hernandez et al. was “prototypical” in some ways. It focused only on contraception, relied on volunteer CBD agents (albeit they retained some of the proceeds of contraceptive sales), had only a very limited set of methods that the agents could provide (male condoms, oral contraceptives, and CycleBeads for the Standard Days Method), and was funded by external donors. Simply getting family planning moving more in the DRC is laudable. And to be sure, the program designers faced some constraints and made accommodations toward synchrony with the ongoing public-sector system. They had policy limitations as to what methods the agents could provide. They used existing contraceptive supply chain and service delivery records. And they linked the CBD agents with existing clinical family planning services.

As described by Hernandez et al., it is fairly evident, however, that in its original form, the project was far from successful. They describe a variety of shortcomings, to a large extent related to the challenging environment and systems they worked in. Thus, total annual couple-years of protection (CYPs) provided by the CBD agents were only roughly 36,000. Consider the contrast with other successful family planning efforts in the DRC:

- Social marketing efforts in the DRC registered 1.95 million CYPs in 2017<sup>3</sup>



- Successful provision of injectables by nursing students<sup>4</sup>
- Highly successful provision of long-acting reversible methods, especially implants<sup>5</sup>
- PMA2020 surveys in Kinshasa showing dominant and growing use of injectables and implants,<sup>6</sup> documenting that substantial progress is being made through other service delivery channels

Changes proposed for the upcoming iteration of the program—AcQual 3—appear reasonable, especially in terms of allowing the CBD agents to provide subcutaneous DMPA. And the AcQual experience seems likely to have contributed to the adoption of such progressive family planning policies in the DRC. The extent to which AcQual 3 will be more successful in this challenging environment remains to be seen. It should be recognized, however, that implementation will involve considerable effort, and interaction with other health programming and the long-term sustainability within the government system is unclear.

It is axiomatic in family planning programming that (1) when more contraceptive methods are available and (2) clients have more programmatic modalities from which to choose, more clients' needs will be satisfied and overall programming will be more successful. Still, undertaking any additional service delivery modality entails considerable effort and cost. And alignment with other health interventions and consideration of long-term sustainability is key.

Accordingly, consideration of if, where, when, and how to embark on a new family planning CBD effort calls for careful and considerable thought and selectivity. —*Global Health: Science and Practice*

**Competing Interests:** None declared.

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**Cite this article as:** Time to evolve beyond prototypical community-based distribution (CBD) of contraception?. *Glob Health Sci Pract*. 2018;6(4):624–625. <https://doi.org/10.9745/GHSP-D-18-00462>

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## VIEWPOINT

## Regaining Momentum in Family Planning

Jose G. Rimon II,<sup>a</sup> Amy O. Tsui<sup>b</sup>

Since the launch of the Family Planning 2020 initiative 5 years ago, 46 million more clients in the 69 poorest countries are using modern contraception—a tremendous accomplishment, albeit behind schedule to reach the 2020 global goal of 120 million. Family planning continues to be innovative, and as reflected in the recent 2018 International Conference on Family Planning in Rwanda, there is a newfound momentum behind the movement and a new generation of young leaders with powerful ideas, creativity, and passion who are stepping up to help propel family planning onward.

The 1994 International Conference on Population and Development in Cairo established that family planning should be considered a core part of reproductive health care and that women have the right to decide whether, when, and how many children to have. Yet for almost 2 decades post-Cairo, family planning's visibility receded and remained in the shadows of other global health issues, such as HIV/AIDS, malaria, and tuberculosis.<sup>1,2</sup> The field, however, quietly persisted, developing new contraceptive formulations, testing approaches to expand service delivery, broadening stakeholder interest, and engaging with private-sector networks. Family planning's reemergence was assisted with the start of the series of International Conferences on Family Planning (ICFP), the first of which took place in 2009, organized by Johns Hopkins University's Bill & Melinda Gates Institute for Population and Reproductive Health and the host country government of Uganda. ICFP 2009 drew in more than 1,200 attendees, when only 300 were anticipated. The momentum of interest in family planning continued with ICFP 2011 in Senegal, attended by more than 2,200 professionals.

As the world's largest scientific and programmatic conference dedicated to family planning, ICFP brings together researchers, policy makers, ministers, advocates, practitioners, media, and youth to share knowledge and best practices. The conference takes place every 2 years, and each time is cosponsored by a different host country partner, a core group of organizers, and more than 50 agencies comprising the ICFP international steering committee. It offers a regular convening platform around which family planning stakeholders can share

the latest evidence, exchange insights on best practices, and plan opportunities to network.

The year 2012 saw the London Summit on Family Planning, a landmark gathering of the family planning movement, organized and cohosted by the Bill & Melinda Gates Foundation, the United Nations Population Fund (UNFPA), and the UK Government's Department for International Development (DFID). The London Summit gave rise to Family Planning 2020 (FP2020), an initiative which has galvanized and tracked global and national family planning commitments and achievements toward the goal of enabling 120 million more women and girls to access voluntary family planning by 2020. Total spending on family planning in the FP2020 focus countries in 2016 reached US\$3.4 billion, with less than half (48%) coming from donors and one-third from domestic governments.<sup>3</sup>

Since 2012, ICFP 2013 was held in Ethiopia and ICFP 2016 in Indonesia, both with more than 3,000 attendees. The second London Summit followed in 2017. These events further energized global interest in and commitment to family planning. The field has recently seen the development of several technical and programmatic innovations, such as contraceptive delivery to rural areas by community health workers (task shifting) and mobile teams, access to self-administered subcutaneous Depo-Provera injectables, social franchising to harness the capacity of private provider networks, post-abortion family planning, and immediate postpartum family planning.<sup>4</sup> These high-impact practices have evolved through technical consensus among implementing organizations in the family planning field and widely shared at each ICFP.

<sup>a</sup>Bill & Melinda Gates Institute for Population and Reproductive Health, Department of Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA.

<sup>b</sup>Department of Population, Family and Reproductive Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA.

Correspondence to Jose G. Rimon II (jrimon@jhu.edu).

### ■ PROGRESS IN FAMILY PLANNING GLOBALLY

The 2018 ICFP, recently held in November in Kigali, Rwanda, continues to capture and reflect the momen-



tum of the family planning community. It was attended by more than 4,000 participants from 119 countries and the largest-ever contingent of more than 600 youth. At this latest meeting, the FP2020 progress report for 2018 was released, which noted that as of July 2017, more than 317 million women and girls in the world's 69 poorest countries were using modern contraceptives.<sup>3</sup> That is an increase of 46 million since the FP2020 partnership was launched 5 years earlier and about 30% higher than the historic trend in new users. Yet the gains are not up to expectations. The report confirms the sobering reality that, although some countries may meet their individual goals, the family planning community is not on track to meet the 2020 global goal.

Still, the results are encouraging. Progress has been made; the curve is bending upward. There are observers in the community who believe that current achievements are underreported, that estimates are not adequately reflecting recent gains with real- and near-time data. The Indian government has expanded its provision of sponsored methods and introduced injectables and a weekly pill, as well as postpartum delivery of the intrauterine device (IUD), into the public health system. Service statistics seem to indicate an upsurge in postpartum family planning, especially with IUD use.<sup>5</sup> In Nigeria, data from the Performance Monitoring and Accountability 2020 (PMA2020) project suggest that the modern contraceptive prevalence rate (mCPR) among married women was 16% in 2016 and reached 19% in 2018,<sup>6</sup> a rise since the 2013 Demographic and Health Survey estimate of 10%.<sup>7</sup> PMA2020 data for both Burkina Faso and Uganda show an average increase in mCPR of 2 percentage points per year over the last 3 to 4 years.<sup>8,9</sup> A rapid and substantial uptick in implants in sub-Saharan Africa is also detectable; a recent study shows contraceptive implants to be the main driver of increases in mCPR in 11 sub-Saharan African countries over the last 4 to 8 years.<sup>10</sup>

## ■ CRUCIAL CONTRIBUTIONS OF FAMILY PLANNING TO DEVELOPMENT GENERALLY

While the family planning field has been advancing in its efforts, it has been evident to the rest of the world that the planet needs family planning. It is a cornerstone of the Sustainable Development Goals, a key to the quest for universal health care, and a way for countries and regions to prosper. The ICFP 2018 theme, "Investing for a Lifetime of Returns,"

references family planning's impressive returns on investment, in terms of the economy, education, empowerment, and the environment, not just the health benefits of reduced maternal morbidity and mortality and under-5 and infant mortality.<sup>11</sup> Well-known is family planning's ability to spur economic progress in the context of the benefits of demographic dividend, which has been documented to have contributed at least 33% of the economic growth in East Asia.<sup>12</sup> Family planning has also been established as the second-best "buy" for development by the Copenhagen Consensus, an independent think tank. Their research concludes that the long-term economic and health benefits of achieving universal access to contraception are worth US\$120 for each \$1 spent on family planning.<sup>13</sup> A recent analysis found that India and Nigeria could save \$89.7 billion and \$12.9 billion, respectively, by satisfying current unmet need for family planning by 2030.<sup>14</sup> A study led by noted environmentalist Paul Hawken estimates that investments in family planning will reduce carbon emissions by nearly 60 gigatons through 2050; family planning combined with girls' education is considered the most effective means of mitigating climate change.<sup>15</sup>

## ■ CONTINUED PROGRESS

While FP2020 stakeholders may not reach their goal by 2020, the needs of the remaining 73 million and more women and girls will eventually be met. This will in turn provide a strong foundation for achieving universal access to family planning by 2030. The critical question is how does one get there from here? Will the same thinking that brought the family planning community this far take it forward? Or are new ways of thinking, a fresh vision for the family planning field, needed?

In our view, there is a need to challenge current successful approaches: more "positive disruptions," more business unusual rather than business as usual. An analysis of the international family planning movement in 2005 called out 4 possible courses of action<sup>16</sup>:

- Forming strategic alliances.
- Redefining the family planning message to mobilize and strengthen support.
- Improving service delivery to broaden public acceptance and contraceptive method use.
- Nurturing new leadership.

As recounted above, the first 3 have materialized since 1994. For the fourth, a breakthrough at the 2018 Kigali conference was the new generation

**The International Conference on Family Planning is the world's largest scientific and programmatic conference dedicated to family planning.**

**The 2018 conference in Kigali, Rwanda, was attended by the largest-ever contingent of more than 600 youth.**

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**As one youth expressed at the International Conference on Family Planning, ultimately universal access will not be driven by donors or governments but by the individual decisions of women and men.**

of family planning leaders—the young people who brought powerful ideas, creativity, and passion there. They were a force to be reckoned with: they organized a sold-out youth pre-conference and a youth plenary during the main conference, made a strong showing on the scientific program and during special events, and even wrote an original new family planning song, “We are Family,” and performed it live at the closing ceremony. One youth attendee expressed a powerful idea—that ultimately, universal access will not be driven by donors or even governments but by the individual decisions of women and men, acting in their own self-interest and collectively becoming a movement, creating norms of behavior that are self-sustaining and transforming the “vicious cycle of poverty into a virtuous cycle of development.”

The future of family planning, and the planet, is already in the hands of the young people. This gives us confidence that the next decades will see amazing progress in family planning.

**Funding:** None.

**Competing Interests:** None declared.

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**Received:** November 29, 2018; **Accepted:** December 5, 2018

**Cite this article as:** Rimon JG II, Tsui AO. Regaining momentum in family planning. *Glob Health Sci Pract*. 2018;6(4):626–628. <https://doi.org/10.9745/GHSP-D-18-00483>

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## COMMENTARY

# A Vaccine Against Cervical Cancer: Context for the Global Public Health Practitioner

Mary Carol Jennings,<sup>a</sup> Anagha Loharikar<sup>b</sup>

Many low- and middle-income countries are moving to introduce HPV vaccine into their national immunization programs. To improve coverage, equity, and sustainability, public health officials and practitioners can use planning and implementation lessons learned, including successful school-based delivery strategies, innovative approaches to reach out-of-school girls, best practices for communication and social mobilization, and integration of services to reduce delivery cost. Policy makers, donors, and global partners should continue to consider ways to drive down costs of vaccine procurement.

## CERVICAL CANCER BURDEN AND HPV VACCINE RECOMMENDATIONS

As countries move to add primary prevention to their strategies to combat death and morbidity associated with cervical cancer, many practitioners in immunization as well as experts in non-communicable and communicable diseases will benefit from keeping up-to-date with recent developments in practice and implementation regarding human papillomavirus (HPV) vaccine delivery.

Persistent infection of cervical epithelial cells with “high-risk” carcinogenic types of HPV causes 99% of the estimated 530,000 global cases<sup>1</sup> of cervical cancer that occur each year<sup>2,3</sup>—the majority of which occur in low- and lower-middle-income countries,<sup>4</sup> where screening and treatment programs are not typically robust. HPV types 16 and 18 cause 70% of cancer globally; the contribution of 5 more high-risk HPV types accounts for 90% of the global cervical cancer burden.<sup>5</sup>

Three HPV vaccines are currently on the global market: a bivalent product (protecting against HPV types 16 and 18), a quadrivalent product (protecting against HPV types 6, 11, 16, 18), and a nonavalent product (protecting against HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58).<sup>4</sup> These vaccines are close to 100% efficacious at preventing HPV infection from the HPV types they target directly,<sup>6</sup> with additional cross-protection against other HPV types.<sup>7,8</sup> Multiple clinical trials, particularly of the bivalent and quadrivalent products (the first market entrants), have also demonstrated close to 100% efficacy

in protecting against cervical intraepithelial neoplasia caused by HPV types covered by these vaccines.<sup>9–12</sup> All 3 vaccines offer a similar, positive safety profile.<sup>4</sup>

The World Health Organization (WHO) recommends all countries include HPV vaccine in their national immunization schedule. WHO recommends 2 doses of HPV vaccine for girls ages 9–14 years, separated by a minimum interval of 6 months, and 3 doses of HPV vaccine for girls ages 15 years and over.<sup>4</sup> Vaccination during pregnancy is not recommended<sup>4</sup>; however, accumulating safety evidence suggests no increased risk of adverse pregnancy outcomes.<sup>13</sup> Immunocompromised youth, including anyone with HIV, should be vaccinated with 3 doses. Of note, neither HIV nor pregnancy testing are indicated as a prerequisite for receiving the vaccine.<sup>4</sup> WHO recommends that, if feasible, countries vaccinate multiple age cohorts (e.g., 9–14 year-olds) in the first year of introduction. The existence of a cervical cancer screening or treatment program is not a prerequisite for vaccine introduction.<sup>4</sup>

We offer this commentary in the hope of focusing dialogue between and among public health practitioners and public health officials on key recent developments in the planning and implementation of HPV vaccination programs.

## SUPPORT FOR HPV VACCINE INTRODUCTION

Gavi, the Vaccine Alliance provides support for vaccine introduction and immunization programs in eligible countries; country eligibility for support from Gavi is chiefly determined by the gross national income (GNI) per capita, which determines the level of co-financing and nature of vaccine program support available.<sup>14</sup> Between 2012 and 2016, both Gavi and vaccine

<sup>a</sup>International Vaccine Access Center, Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA.

<sup>b</sup>Vaccine Introduction Team, Global Immunization Division, U.S. Centers for Disease Control and Prevention, Atlanta, GA, USA.

Correspondence to Mary Carol Jennings (marycaroljennings@jhu.edu).

**School-based vaccine delivery models have effectively achieved high coverage for girls in school but pose an equity challenge for out-of-school youth.**

manufacturers funded sub-national demonstration projects in countries around the world to better understand how to feasibly and sustainably deliver HPV vaccine to adolescents, a relatively new target age group that does not routinely access health services, especially in low- and middle-income countries. Gavi-eligible countries needed to demonstrate successful vaccination to this new target age group prior to requesting funds for national HPV vaccine introduction. Starting in 2017, Gavi shifted its focus from demonstration programs to national introductions, aiming to scale up early lessons learned and to accelerate progress toward the goal of protecting 40 million girls from cervical cancer by 2020 in Gavi-eligible countries.<sup>15</sup> Following WHO recommendations, Gavi enacted policy to support vaccination of multiple age cohorts in the first year of program implementation for Gavi-eligible countries. However, due to current global vaccine shortage, some countries have been advised to target a single age group for the first year of introduction, with the potential to vaccinate multiple age cohorts in the future, as supply allows. Demonstrating experience in delivering the vaccine to adolescents is no longer a prerequisite for support of national implementation in these countries.

Following WHO's change in HPV vaccine policy and Gavi's shift in program support, many Gavi-eligible countries are moving rapidly to introduce HPV vaccine into their national immunization programs.

## ■ PROGRAMMATIC CONSIDERATIONS FOR HPV VACCINE INTRODUCTION AND IMPLEMENTATION

Achieving high vaccination coverage through a routine immunization program among adolescent girls necessitates innovative delivery strategies and communication efforts.

Among 45 low- and middle-income countries surveyed in 2016 after having completed HPV vaccine demonstration programs or national introduction, most (87%) used primarily a school-based delivery strategy.<sup>16</sup> While the majority (96%) of programs reporting data successfully achieved first-dose vaccination coverage of at least 70% among the target age group, only 83% of programs reporting data attained the same milestone for complete series coverage.<sup>16,17</sup> The use of a school-based delivery strategy for other relevant vaccines has been successfully implemented in some countries<sup>18</sup>—for example, for second-dose measles vaccine at

school entry<sup>19</sup> and vaccines against tetanus, diphtheria, and pertussis.<sup>20,21</sup> The use of school health programs to deliver other health services, such as vitamin A supplementation and deworming medications,<sup>22</sup> is a well-established practice. However, while teachers can feasibly be trained to distribute tablets or medications, an injectable vaccine requires additional health worker involvement that can be disruptive or resource-intensive for national immunization programs to provide in the school setting.

Using a school-based vaccine delivery platform has effectively achieved high coverage for girls in school but poses an equity challenge for out-of-school youth, many of whom have poor access to health services and screening later in life.<sup>23</sup> Despite the use of fixed-site and targeted outreach strategies to reach out-of-school girls in demonstration projects,<sup>16</sup> few data-driven strategies to deliver HPV vaccines to out-of-school-girls have been designed and implemented, and fewer rigorously tested.<sup>16,24,25</sup> Even in populations with high primary school enrollment, there may be poor school attendance among 9–14 year-olds. Unless social mobilization efforts are undertaken to ensure enrolled girls attend school on vaccination days, vaccination coverage will likely be low.<sup>26,27</sup>

To continue to build successful HPV vaccination programs, several types of stakeholders must be engaged in the program planning process. Regardless of how and where the vaccine is delivered, education stakeholders need to be involved in program planning and communication, as the adolescent age group is largely enrolled in primary school. Other key stakeholders include adolescent and youth service providers, community service organizations, local women's groups, family planning and reproductive health advocates, cervical cancer specialists, gynecology organizations, and HIV prevention and treatment groups. Vaccine delivery may also be a promising service for integration with other development or health services for girls, such as nutrition, economic empowerment, menstrual hygiene, and disease prevention, so stakeholders who are experts in those programs may be involved.

While at least 11 countries around the world, including Australia and the United States of America, routinely vaccinate boys with HPV vaccine, achieving high coverage among girls is a more cost-effective vaccination strategy in low- and middle-income countries than a “gender-neutral” vaccination strategy that immunizes both girls and boys.<sup>4</sup> Countries can certainly choose to also vaccinate boys if this strategy is



deemed financially and politically feasible; however, Gavi is currently only providing donor funding for vaccination of girls ages 9–14 years.

The current context of most countries focusing on vaccinating girls illuminates the importance of having a clear communication and social messaging campaign in place, with a realistic and nimble crisis communication strategy that can be activated quickly if rumors emerge.<sup>16</sup> Vaccinating only girls can lead to rumors about the vaccine impacting fertility. Many countries have found that best practice is to have media, and well-trained media spokespersons, involved early in the planning, well ahead of vaccine introduction activities.

Although delivering vaccines to girls nationwide requires a different scale of resource commitment than a demonstration program, a number of potentially generalizable communication lessons can be drawn from studying programs that have implemented HPV vaccination to date.<sup>16</sup> Program evaluations have shown how important it is for vaccination programs to be jointly “owned” by both the immunization program as well as educational institutions, for consent, social mobilization, logistics, and monitoring. Data from prior evaluations demonstrate that opt-out consent processes are generally acceptable and follow the consent format of other routine immunizations. Using an opt-in consent process can lead to rumors and misconceptions, but this may be mitigated by face-to-face communication with parents and communities.<sup>27</sup> Experience responding to rumors and negative stories in the media has shown program implementers that social mobilization should happen well ahead of vaccine introduction.

Our understanding of best practices continues to evolve, highlighted by some best-case examples from Rwanda and Bhutan. In 2011, Rwanda became the first low-income country in the world to introduce HPV vaccine into its national program, and with strong leadership from its First Lady, partnership with industry, and effective, evidence-based mobilization efforts, has consistently reported between 93% and 96% full-course coverage.<sup>28,29</sup> Bhutan, a lower-middle-income country and another early adopter, introduced HPV vaccine into its national immunization program in 2010, and with country ownership, a strong public-private partnership, an evidence-based and flexible delivery strategy, leadership from schools, and a proactive approach to media engagement, thereafter achieved consistent complete series coverage of over 90% among targeted

12-year-old girl cohorts, using a school-based delivery strategy.<sup>17</sup>

Although adolescence is arguably one of the healthiest periods of the life course, investment in this population, and inquiry into which services can be successfully and cost-effectively bundled with HPV vaccination, offers significant opportunity for impact.

## ■ ECONOMIC CONSIDERATIONS FOR LOW- AND MIDDLE-INCOME COUNTRY INTRODUCTIONS

### Cost-Effectiveness

Overall, validated and relatively sophisticated economic models predict that HPV vaccination is very cost-effective in most countries, particularly in low-income countries.<sup>30</sup> Introducing an expensive new vaccine constitutes a significant investment on behalf of a government, with vaccine cost accounting for approximately half of the total cost of procurement and delivery.<sup>31</sup> Delivery costs reported across demonstration programs and delivery strategies ranged from US\$1.11 to \$9.21 per dose.<sup>27</sup> Bhutan spent US\$2.40 to deliver each HPV vaccine dose in a well-documented 2010 evaluation of its national program.<sup>17</sup> In Tanzania, a 2012 analysis estimated a delivery cost using a periodic school-based campaign delivery strategy of US\$3.09 per dose; this cost estimate was in addition to the cost of vaccine,<sup>32</sup> and the program was categorized as a very cost-effective intervention.<sup>33</sup>

**Robust economic models predict that HPV vaccination is very cost-effective in most countries, particularly in low-income countries.**

### Resources to Support New Vaccines for Low- and Middle-Income Countries

All 3 HPV vaccine products on the global market are currently WHO-prequalified; as of August 2018, the quadrivalent and bivalent products are approved for Gavi funding support to eligible countries. Gavi provides a vaccine introduction grant as part of its initial start-up package to a country to cover operational costs and social mobilization efforts. Gavi-eligible countries can also procure the prequalified HPV vaccines for US\$4.60 per dose (bivalent product) and US\$4.50 per dose (quadrivalent product).<sup>15</sup> However, as country economic indicators (i.e., GNI) improve to the point that they are no longer eligible for Gavi funding, countries must budget an incrementally larger share of the costs each year until they entirely self-fund both vaccine procurement and delivery costs. For countries whose economic indicators (i.e., GNI) improve to the point that they are no longer eligible for Gavi funding, as well as for middle-income

countries that were never Gavi-eligible, these recurring programmatic and procurement costs represent a significant portion of national immunization budgets. Depending upon the vaccine, manufacturers may agree to continue offering Gavi-negotiated prices to countries for a selected number of years after transition. However, we note the critical need for donor mechanisms to ensure that middle-income countries can introduce HPV vaccines, and that transitioning countries can sustain new introduction decisions.

### Innovations and Potential Shifts in Cost

Looking forward, new developments may be able to reduce HPV vaccine procurement and delivery costs. The eventual market entry of vaccines manufactured by companies based in low- and middle-income countries and owned by local entities may create the same downward pressures on prices as we have seen with multiple other medicines and biologics.<sup>34,35</sup> One of the key barriers to development of such low-cost second-generation HPV vaccines is the lack of standardized and widely accessible laboratory serology tests and assays to assess how new vaccines perform against the currently licensed vaccines. An initiative intended to standardize and evaluate new laboratory tests—developed by a variety of institutions—to address this gap was established at the beginning of 2017 at the U.S. National Cancer Institute.<sup>36</sup>

Other factors may also play a role in reducing expected costs of program implementation. For example, an analysis by Gavi and WHO anticipates that national programs will harness economies of scale much more effectively than small demonstration programs were able to do.<sup>31</sup>

Data on whether a 1-dose schedule confers adequate levels of protection show promise,<sup>37–40</sup> but the science available does not yet provide definitive guidance for policy.<sup>4,41,42</sup> The U.S. National Cancer Institute is currently conducting a large randomized controlled trial to evaluate the efficacy of a single-dose regimen in Costa Rica, with availability of results targeted for 2023.<sup>42,43</sup>

### Relationship to Cervical Cancer Screening and Treatment

As countries introduce and scale up HPV vaccination programs, cervical cancer screening remains important for women who do not get vaccinated as children and for women who may have been infected with a high-risk HPV type that is not included in the vaccine. As national stakeholders in cancer and chronic diseases come together

with immunization programs and their advisory bodies to make policy on HPV vaccination, they have an important opportunity to also inform their national policies on cervical cancer screening and surveillance programs.

**Acknowledgments:** The authors wish to acknowledge Terri Hyde, Kim Fox, Abigail Shefer, and Lauri Markowitz for reviewing and providing input on drafts of this commentary.

**Funding:** None.

**Disclaimer:** The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry.

**Competing Interests:** None declared.

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**National HPV vaccination programs will likely harness economies of scale much more effectively than small demonstration programs.**



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**Peer Reviewed**

**Received:** June 21, 2018; **Accepted:** September 26, 2018; **First Published Online:** November 20, 2018

**Cite this article as:** Jennings MC, Loharikar A. A vaccine against cervical cancer: context for the global public health practitioner. *Glob Health Sci Pract*. 2018;6(4):629–634. <https://doi.org/10.9745/GHSP-D-18-00222>

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## COMMENTARY

# A Global Learning Agenda for the Levonorgestrel Intrauterine System (LNG IUS): Addressing Challenges and Opportunities to Increase Access

Kate H. Rademacher,<sup>a</sup> Tabitha Sripipatana,<sup>b</sup> Anne Pfitzer,<sup>c</sup> Anna Mackay,<sup>d</sup> Sarah Thurston,<sup>e</sup> Ashley Jackson,<sup>f</sup> Elaine Menotti,<sup>b</sup> Hayley Traeger<sup>g</sup>

The LNG IUS is one of the most effective forms of reversible contraception and has important noncontraceptive benefits but is currently not used at scale in any Family Planning 2020 focus country. A global working group developed a shared learning agenda to answer critical questions, harmonize approaches, avoid duplication, and facilitate introduction of the method within the context of informed choice.

## ■ BACKGROUND

The levonorgestrel intrauterine system (LNG IUS) is one of the most effective forms of reversible contraception with efficacy rates similar to subdermal implants and copper intrauterine devices (IUDs).<sup>1</sup> The LNG IUS is also associated with a number of important noncontraceptive health benefits, including treatment for menorrhagia (heavy menstrual bleeding) and uterine fibroids and potentially for anemia.<sup>2–4</sup> In addition, as a result of the localized release of hormones and relatively low systemic blood levels compared with other hormonal methods, the side effects for the LNG IUS may be less pronounced than side effects with other hormonal contraceptives.<sup>5,6</sup> (See [Box 1](#) for a summary of the method's advantages.)

The LNG IUS has proved to be a popular choice with women in developed countries where the method is available, and it has helped revitalize the IUD market in some settings.<sup>7</sup> Mirena, the 5-year LNG IUS product currently manufactured by Bayer Healthcare Pharmaceuticals Inc., was first introduced in the United States in 2000. At that time, less than 2% of women in the United States using contraception were using an IUD. Currently, almost 12% of contraceptive users have an IUD, and in 2014, 74% of women with an IUD were using a hormonal product.<sup>8</sup> In 2015, the World Health Organization added the LNG IUS

to its *Essential Medicines List*.<sup>9</sup> Despite this and despite the method's advantages—which have been further described by colleagues (Hubacher<sup>7</sup> and Jacobstein and Shelton<sup>10</sup>) previously in this journal—the method is not currently available at scale outside of the commercial sector in any of the Family Planning 2020 (FP2020) focus countries,<sup>11</sup> and thus access to the larger population for this method is limited in these settings.

In this commentary, we review current challenges to LNG IUS access in low- and middle-income countries (LMICs). We then describe an introduction coordination platform that was launched in 2015 to help address these challenges and answer critical questions about the LNG IUS through a shared global learning agenda. We also discuss some of the advantages and disadvantages of this type of method-specific coordination platform and provide a call to action for other organizations that are considering introducing or scaling up the LNG IUS.

## ■ BARRIERS TO ACCESS

### Product Costs

Historically, the high cost of LNG IUS commodities has been a primary barrier to public-sector procurement in international settings, and therefore to inclusion in the contraceptive method mix in national family planning programs.<sup>7,10</sup> Mirena is offered on a very limited basis in private, for-profit settings in some developing countries. Recent market assessments conducted in Kenya, Madagascar, Nigeria, and Zambia have documented prices of Mirena to clients in urban settings ranging from US\$60 to \$400.<sup>12–15</sup> In this price range, the method is prohibitively expensive for most women in LMIC markets.

An unbranded LNG IUS product manufactured by Bayer Healthcare is available for free by application

<sup>a</sup>FHI 360, Durham, NC, USA.

<sup>b</sup>United States Agency for International Development (USAID), Washington, DC, USA.

<sup>c</sup>Jhpiego, Baltimore, MD, USA.

<sup>d</sup>Marie Stopes International, New York, NY, USA.

<sup>e</sup>Population Services International, Washington, DC, USA.

<sup>f</sup>Seconded to WCG Cares by Population Services International, Seattle, WA, USA.

<sup>g</sup>USAID Global Health Fellows Program, Public Health Institute, Washington, DC, USA. Now with IBM Global Business Services, Washington, DC, USA.

Correspondence to Kate Rademacher (krademacher@fhi360.org).

**BOX 1. Summary of Advantages of the LNG IUS**

- Highly effective contraceptive method
- Long-acting and reversible
- Rapid return to fertility after removal
- Can lead to reduced menstrual bleeding and cramping
- Localized release of hormones and relatively low systemic blood levels compared with other hormonal methods (side effects for the LNG IUS may be less pronounced)
- Removal can be easier than implant removals
- Noncontraceptive health benefits including treatment of heavy menstrual bleeding and potential reduction in iron-deficiency anemia
- May help protect against endometrial and cervical cancer
- No further action or supplies required once the LNG IUS is inserted
- Can be used immediately postpartum and post-abortion (Note: Manufacturers' labels for LNG IUS products do not currently include an indication for immediate postpartum insertions. However, the World Health Organization's *Medical Eligibility Criteria for Contraceptive Use* categorizes immediate postpartum insertion [ $<48$  hours] of the LNG IUS as a category 1 [no restrictions] in non-breastfeeding women and as a category 2 [benefits outweigh the risks] in breastfeeding women.)

**The LNG IUS is not currently available at scale in any of the FP2020 focus countries.**

**New, more affordable LNG IUS products are starting to become available in some FP2020 markets.**

through donations made by the International Contraceptive Access (ICA) Foundation, a private-public partnership between Bayer Healthcare and the Population Council. Since 2005, approximately 125,000 units have been donated through this mechanism in 36 countries.<sup>16</sup> However, these donated units have generally been used to support small-scale pilot activities rather than to facilitate access through the health system on a regional or national scale. In addition, the ICA Foundation's LNG IUS product is registered in only a few countries, which means that a regulatory waiver must be secured when importing the product in most LMICs.

The landscape may be changing as new LNG IUS products become more available globally (Table). A new LNG IUS distributed by Medicines360, a non-profit pharmaceutical company, was approved by the U.S. Food and Drug Administration in 2015,<sup>17</sup> and the company is currently working with partners to register the product in FP2020 countries under the trade name Avibela. In early 2018, this product was approved in Madagascar and Zambia, and additional registrations are pending.<sup>18</sup> The international public-sector procurement price for Avibela will vary by volume between US\$12 to \$16 per unit; for an order of 100,000 units, the public-sector price will be approximately US\$15 per unit.<sup>12</sup>

A recent assessment of the direct service delivery costs of various family planning methods per couple-years of protection (CYP) (inclusive of the cost for commodities, supplies, and provider time for insertion, resupply, and/or removal) demon-

strated that at US\$15 per unit, the cost per CYP of the LNG IUS compared favorably with that of other contraceptive methods commonly procured in FP2020 countries.<sup>12</sup> This analysis used the assigned CYP factor of 3.3 years for an LNG IUS labeled for 5 years of use<sup>19</sup>; however, emerging evidence suggests that the duration of effectiveness of the LNG IUS is at least 7 years.<sup>20</sup> In addition, Medicines360's clinical trial for the product is ongoing and will follow women for up to 10 years.<sup>21</sup> If the duration of use is extended for the method, the CYP factor will increase and the cost per CYP will decrease even further.

Despite this, past experience with other methods demonstrates that even if a method is cost-effective over its duration of use, high upfront commodity costs can still be a barrier to procurement by donors and governments.<sup>22</sup> Similar to the LNG IUS, contraceptive implants were not scaled up in LMICs for many years, partly because of high commodity costs. However, since the introduction of a more affordable 2-rod implant, Sino-implant (II)/Levoplant, and after the launch of the Implants Access Program—which was supported by a consortium of donors to lower the price of the 2-rod implant (Jadelle) and the 1-rod implant (Implanon/Nexplanon) and to support programmatic efforts to scale up access—implant use has grown rapidly in a number of FP2020 countries.<sup>23</sup>

The more affordable pricing for implants, which can be procured now by donors and governments for US\$6.90 to \$8.50 per unit in FP2020 countries, has set a new bar, which could impact expectations

**TABLE.** Overview of LNG IUS Products Approved by a Stringent Regulatory Authority<sup>a</sup>

Supplier	SRA-Approved LNG IUS Product	Availability and Pricing in FP2020 Countries
Bayer Healthcare	Mirena <sup>b</sup>	Mirena is provided commercially through private health care clinics in some developing countries on a very limited basis. Pricing between ~US\$60–\$400 has been documented in recent market assessments in urban settings in Kenya, Madagascar, Nigeria, and Zambia. <sup>12–15</sup>
International Contraceptive Access (ICA) Foundation	Unbranded LNG IUS product	Through a public-private partnership between Bayer HealthCare and Population Council, a free unbranded LNG IUS product is provided by donation. Registered in several countries; brought in via regulatory waivers in other countries.
Medicines360	Sold in the United States under trade name Liletta; being registered in FP2020 countries under the trade name Avibela	The public-sector price to distributors for Avibela will vary by volume between US\$12–\$16; for an order of 100,000 units, public-sector transfer price will be approximately \$15/unit. As of mid-2018, registered in Madagascar and Zambia.

Abbreviations: FP2020, Family Planning 2020; LNG IUS, levonorgestrel intrauterine system; SRA, stringent regulatory authority.

<sup>a</sup> In addition to the products listed in the table, there are several LNG IUS products that are being introduced in a limited number of FP2020 countries that are not currently approved by an SRA. As of 2018, there are no LNG IUS products that have been prequalified by the World Health Organization.

<sup>b</sup> Bayer Healthcare also manufactures the LNG IUS products Skyla and Kyleena. However, these products are not yet available in low- and middle-income countries, and therefore are not discussed here.

for pricing of the LNG IUS. In addition, copper IUDs are available for procurement for programs in FP2020 countries for less than US\$0.50 per unit.<sup>24</sup> (These prices do not reflect downstream costs such as import fees or shipping and distribution costs. Also, the actual cost to clients varies by service delivery outlet.) Interviews with key opinion leaders in several countries have indicated that if the upfront commodity cost of the LNG IUS remains substantially higher than that of other methods, particularly of implants, introduction and scale-up may remain challenging.<sup>12–15</sup>

### Demand and Service Delivery Considerations

As stakeholders consider whether to procure the LNG IUS for public-sector programs and/or invest in a global price reduction strategy, additional evidence is needed regarding the potential value of adding the LNG IUS to the method mix within countries. Stakeholders recognize that contraceptive commodity costs are only one factor impacting access and use. In the case of the LNG IUS, awareness and demand for the method would need to increase and potential supply-side barriers would need to be addressed for availability and uptake to expand substantially.<sup>7,10</sup>

Notably, while use of contraceptive implants has risen dramatically over recent years in sub-Saharan Africa, voluntary uptake of the copper IUD remains low with no country in the region having an IUD prevalence above 2%.<sup>23,26</sup> A number of barriers limit voluntary uptake of the copper

IUD, which may impact the potential of the LNG IUS as well. These factors include persistent myths and misperceptions about the IUD among potential clients and providers (for example, the incorrect belief that the method cannot be used by nulliparous women or that it causes infertility); the need for a pelvic exam; lack of provider competence and/or confidence in IUD insertion; a hesitancy among some providers to devote the extra time and effort required for IUD insertion relative to other contraceptive methods; lack of instruments and supplies; and low demand among women, which also reinforces supply barriers.<sup>27</sup> Despite these challenges, there have also been some recent notable successes with copper IUD demand generation and provision, and use of the method has increased modestly in some countries in recent years.<sup>23,28–30</sup> A key question about the LNG IUS is how the method would be positioned in relation to both the copper IUD and implants, given the similarities between the methods (e.g., all 3 require a certain level of provider training and skills; both the copper IUD and the LNG IUS require a pelvic exam and intrauterine insertion) and their differences (e.g., the LNG IUS is associated with reduced menstrual bleeding while the copper IUD is often associated with heavier menstrual bleeding).

There is an emerging body of evidence about use of the LNG IUS in LMICs. For example, a recent study of LNG IUS users in Kenya found high satisfaction and continuation rates. Among

**The LNG IUS may face similar barriers to uptake as the copper IUD.**



**Emerging evidence from several sub-Saharan African countries finds positive perceptions of the LNG IUS among users and providers.**

671 postpartum women offered a range of methods, 16% chose the LNG IUS.<sup>31</sup> After 1 year of use, 89% of LNG IUS users were still using the method and 87% reported being very satisfied; these rates were comparable with those among users of implants.<sup>32</sup> A separate qualitative assessment in Kenya documented experiences among early adopters of the Mirena and their male partners; a key finding was that women's main reason for choosing the LNG IUS was their perception that the method had fewer side effects compared with other contraceptive methods.<sup>33</sup> A recent study in Nigeria documented perceptions of the method among clients, providers, and key opinion leaders in the country. In sites where the LNG IUS was introduced, the method represented less than 1% of all long-acting reversible contraceptives provided during the project time frame. Yet in qualitative interviews with LNG IUS users, providers, and key opinion leaders, the majority of respondents reported positive perceptions of the method. Findings from the study suggested that a comprehensive approach that addresses both demand- and supply-side factors will be required to gain traction with the method, and that while affordability of LNG IUS commodities is a prerequisite, lower prices alone will likely not be enough to translate into demand or uptake of the method at scale.<sup>34</sup>

Moving forward, additional evidence is needed to inform potential future introduction of the LNG IUS, especially to address the unresolved questions about demand. This will be particularly important given limited budgets and competing priorities as countries work to scale up the contraceptive methods they already have available. Specifically, questions remain about what demand generation and provider training strategies would be required to overcome potential barriers to uptake and whether the LNG IUS would be cost-effective compared with other long-acting reversible methods, especially if more resources are required to increase awareness and demand for the LNG IUS than are required for other methods. Governments and donors also want to know whether the method would primarily attract new users and/or "switchers." Preliminary research in Kenya and Nigeria found that among switchers, a portion of LNG IUS users shifted from using short-acting resupply methods.<sup>32,34</sup> If this outcome is replicated elsewhere, it will have important public health implications given that long-acting reversible methods like the LNG IUS have higher effectiveness and continuation rates than short-acting methods.<sup>35</sup> In

addition, more evidence is needed about women's perceptions and experiences of menstrual bleeding changes associated with the LNG IUS,<sup>36</sup> as well as the potential impact of the method's non-contraceptive benefits including its potential to prevent or treat anemia.<sup>7</sup>

## ■ DEVELOPMENT OF A GLOBAL LNG IUS LEARNING AGENDA

In 2015, a product introduction coordination platform, the LNG IUS Working Group, was convened by the United States Agency for International Development (USAID) with the goal of facilitating the introduction of high-quality, affordable LNG IUS products in developing countries in order to increase the range of highly effective contraceptive options available to women, within the context of informed choice. The LNG IUS coordination platform includes donors, suppliers, research agencies, and training and service delivery organizations that are currently supporting LNG IUS introduction and/or evaluation activities. The platform was formed to address the following objectives:

- Understand potential demand and use dynamics among different populations (such as new users and switchers), continuation rates, and client and provider perspectives of the method.
- Identify if and how the challenges that have impacted use of the copper IUD in many settings could be overcome by the LNG IUS, given the similarities and differences between the 2 methods.
- Identify effective strategies to generate awareness and demand for the LNG IUS including how to communicate method attributes in relation to attributes of other methods.
- Assess programmatic models in different service delivery channels.
- Evaluate willingness-to-pay for the LNG IUS among different market segments.
- Increase coordination among service delivery groups by sharing country introduction plans, service delivery approaches, and regulatory resources.
- Contribute to the global family planning community by making LNG IUS provider training materials, counseling materials, and job aids widely available.

As a first step, the group collaborated on development of a shared global learning agenda related

**Members of the LNG IUS Working Group developed a shared global learning agenda for the LNG IUS.**



to the LNG IUS. While the creation and use of a learning agenda is increasingly common in the development sector,<sup>37</sup> we are not aware of any other formal efforts to collaborate with a diverse group of stakeholders to develop research and evaluation priorities for the LNG IUS in international settings. A primary goal of the process was to harmonize approaches and avoid duplication. Implementing partners in the group collaborated to develop a first draft of an LNG IUS learning agenda. Donors then further refined the list based on priorities and available resources. Next, the draft was shared with the larger LNG IUS Working Group, including LNG IUS manufacturers, for additional feedback and revision. The full learning agenda was approved and adopted by the LNG IUS Working Group in 2016 (Box 2). At the same time, members of the working group also recognize that the learning agenda is a “living document.” It is regularly revisited by the group and can be revised and updated as further evidence emerges from the field and/or when additional priorities are identified.

## ■ IMPLEMENTATION OF THE GLOBAL LNG IUS LEARNING AGENDA

Since its adoption in 2016, the LNG IUS learning agenda has been used in several ways:

- **Learning agenda questions were prioritized by donors and implementing agencies and used to inform investment and programming decisions.** The subcommittee of implementing agencies as well as donors involved with the LNG IUS Working Group each ranked the learning agenda questions in order of priority and relevance for their respective institutional strategies. This exercise was useful to identify how priorities differed among stakeholders and to facilitate further discussion among the group’s members. The learning agenda also informed donor decisions for new research studies and maximized opportunities to leverage support among funders.
- **Research and service delivery groups coordinated to support data collection in pilot programs.** Members of the LNG IUS Working Group recognized that if all pilot programs introducing the LNG IUS could ask similar questions of women choosing the method as part of routine data collection, the impact of evaluation efforts could be increased. FHI 360 modified 3 questions that had been included in a research study in Kenya conducted

by Hubacher and colleagues<sup>31,32</sup> (Box 3). Service delivery groups including Jhpiego, Marie Stopes International, Population Services International, and WCG Cares then incorporated the questions into their pilot introduction efforts, with providers administering the questions in Kenya, Madagascar, Nigeria, Zambia, and Zimbabwe. Data were then compiled in a single dashboard so results could be compared and discussed. The dashboard will be updated on a regular basis as new data become available; the current version is available online through the Knowledge for Health platform.<sup>38</sup> There were some challenges with implementation of this approach across countries and projects. For example, there were some discrepancies with how country programs implemented the questions (e.g., whether respondents were instructed to select a single answer to a question or whether multiple response options were possible). In addition, not all providers were willing or able to systematically collect the data from LNG IUS users given limited time and resources. Moving forward, it will be important to address these challenges and ensure that all groups more fully align on how the questions are asked. Despite the limitations to date, the approach has been successful in allowing programs to compare preliminary data about women’s perspectives across various service delivery contexts.

## ■ ADVANTAGES AND DISADVANTAGES OF GLOBAL COORDINATION PLATFORM

The LNG IUS Working Group brings together partners that are supporting introduction and evaluation of the LNG IUS in pilot settings such that information shared during the meetings can be used immediately. In addition to providing a forum to define and implement the global learning agenda, the LNG IUS Working Group offers a platform to share updates and lessons from the field, training resources, and regulatory materials. The group has also facilitated approved sharing of LNG IUS product stock in country and provided an opportunity for members to co-develop client-centered counseling materials, such as a new job aid for providers about menstrual bleeding changes.<sup>39</sup> In addition, the meetings serve as a platform for donors and manufacturers to obtain updates from multiple service delivery partners at the same time, allowing for an appreciation of the full scope of introduction activities and more

**BOX 2. Global Learning Agenda for the LNG IUS****Learning Agenda Questions****A. Client Demand**

1. What are the profile(s) of the clients who will use this product?
  - a. Is there or would there be demand for this product among sub-populations with high unmet need for family planning (e.g., women in lower wealth quintiles, postpartum women, adolescents, post-abortion clients)?
  - b. Will introduction of the LNG IUS help reach new family planning users (i.e., current non-users)?
  - c. To what degree will introduction of the LNG IUS result in “switching” and from what other methods (e.g., from short-acting methods)?
2. Does the LNG IUS have the potential to ‘revitalize’ the IUD market in FP2020 countries?
  - a. Will demand for the LNG IUS be higher than demand for the copper IUD has been?
3. Would introduction of the LNG IUS increase family planning use overall/increase contraceptive prevalence rate(s)?
  - a. Can scale-up of this product help meet FP2020 goals?
4. How do continuation rates of the LNG IUS compare to continuation rates of other LARCs in multiple contexts?
5. Does immediate postpartum access to the LNG IUS increase use of postpartum family planning overall?

**B. Marketing**

6. What are effective demand creation strategies with different populations and in different sectors?
7. How can promotion of family planning including the LNG IUS be integrated into other health sectors such as nutrition programs or menstrual hygiene management programs?

**C. Service Delivery**

8. How can we overcome barriers that have impacted provision of the copper IUD at the service delivery level when introducing the LNG IUS?
9. What are health care providers’ perceptions of this product?
10. What are effective service delivery models for LNG IUS provision? How does it differ by context, channel, and/or user group?
  - a. What are effective provider training strategies for the LNG IUS?

**D. Noncontraceptive Attributes**

11. How does knowledge of noncontraceptive attributes of the LNG IUS affect uptake and use?
  - a. What noncontraceptive attributes are most attractive to women in different contexts?
  - b. What noncontraceptive attributes are seen as most beneficial by providers in different contexts?
12. What are perceptions of amenorrhea among providers and various clients segments?
13. Can scale-up of the LNG IUS help reduce rates of anemia?

**E. Cost-Effectiveness and Pricing**

14. To what extent is the LNG IUS cost-effective compared to other family planning methods including other LARCs?
15. What is the willingness-to-pay for the LNG IUS among different populations of clients and different stakeholder groups?

Abbreviations: FP2020, Family Planning 2020; IUD, intrauterine device; LARCs, long-acting reversible contraceptives; LNG IUS, levonorgestrel-releasing intrauterine system.

immediate identification of common challenges that their input and resources can help resolve. The regular meetings also provide an opportunity to identify the evidence and funding gaps to shape existing project work plans and design future activities with an understanding of the key questions in the field that are not currently being investigated.

While the coordination platform has proved to be useful to participant organizations, it faces challenges that the group openly acknowledges. Suppliers with a product approved by a stringent

regulatory authority are key partners in the LNG IUS Working Group, and they are not always able to share commercially sensitive information, especially among other suppliers. As such, some information and negotiation goes on in separate confidential meetings not open to the larger group. This limits the inclusion of all working group members in some planning activities; however, it ensures the continued involvement of manufacturers in this platform. The LNG IUS Working Group also includes service delivery and

### BOX 3. Coordinated Data Collection Approach Among LNG IUS Working Group Members in Multiple Countries

Three questions were adapted from a previous research study in Kenya<sup>31,32</sup> and were incorporated into programs where LNG IUS introduction activities funded by USAID were underway. In each project, a woman receives comprehensive counseling based on informed choice. If she chooses the LNG IUS, she is asked to consent to answer a version of the following 3 questions:

1. Can you briefly tell me the reasons you chose the LNG IUS today instead of another method?
2. If the LNG IUS had not been available today, what method, if any, would you have chosen instead?
3. How did you first find out about the LNG IUS?

Versions of these questions were administered by providers in Kenya, Madagascar, Nigeria, Zambia, and Zimbabwe. Data were then compiled by members of the LNG IUS Working Group in a single dashboard so results could be compared. The dashboard will be updated on an ongoing basis. The current version (as of November 2018) is available online in the IUD Toolkit on the Knowledge for Health platform.<sup>38</sup>

research partners that are potentially competing against each other for donor resources or a share of the LNG IUS market in countries. The donors involved have to be cognizant of the competitive nature of the work. For example, they must stay informed of when there are procurements being bid that may impact the working group participants' relationships while still holding partners accountable for coordination to ensure that LNG IUS introduction and evaluation efforts are as cost-effective and efficient as possible given limited resources.

## CONCLUSION

The implementation of a method-specific introduction coordination platform has allowed for the creation of a tailored learning agenda with input from diverse stakeholders. The LNG IUS is being introduced in contexts of informed choice, where it is one method among a range of contraceptives that country programs offer. There are learning gaps specific to the LNG IUS that have made coordination and collaboration useful for service delivery groups, research partners, manufacturers, and donors. Lessons from implementing this type of method-specific platform and global learning agenda model could be applied to other issues<sup>40</sup> or other product introduction efforts.

At the same time, this type of single-method introduction coordination platform comes with costs as well as benefits. There are other new contraceptive methods being introduced in FP2020 countries, and the level of effort required for a single-method coordination group may not be needed or warranted in all cases. In addition, while the LNG IUS Working Group aims to apply experiences with scaling up access to other

underused methods—such as implants and subcutaneous injectables—a platform that focuses on more than one method could further increase coordination and learning.

Given the positive attributes of the LNG IUS and the potential benefits of adding it to the contraceptive method mix in LMICs, country-level stakeholders should consider if and when to introduce the method into family planning programs. At the same time, considering the potential programmatic challenges as well as unanswered questions such as the potential demand for the method if price barriers were removed, the new global learning agenda for the LNG IUS is a call to action for other entities engaged in LNG IUS introduction or research. We encourage other implementers and researchers to document and publish LNG IUS introduction experiences in LMICs, including uptake data, and to administer standardized monitoring and evaluation questions where possible. Rigorous research and program evaluations are essential, as are coordinated country-level introduction efforts, to better understand the potential impact of expanding access to this highly effective, potentially popular—yet now largely unavailable—contraceptive option.

**Acknowledgments:** The authors thank the members of the LNG IUS Working Group including staff from Bayer Healthcare, the Bill & Melinda Gates Foundation, the Children's Investment Fund Foundation, DKT International, FHI 360, Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) consortium members, ICA Foundation, International Planned Parenthood Federation, Jhpiego, Marie Stopes International, Medicines360, Pathfinder, Population Council, Population Services International, the United Nations Population Fund (UNFPA), USAID (the Office of Population and Reproductive Health and the Center for Innovation and Impact), and WCG Cares.

**Funding:** This paper was made possible by the support of the American People through the United States Agency for International Development (USAID).

**A single-method introduction coordination platform comes with costs as well as benefits.**

**Disclaimer:** The contents of this paper are the sole responsibility of the authors and do not necessarily reflect the views of USAID, the United States Government, FHI 360, Jhpiego, Marie Stopes International, Population Services International, or WCG Cares.

**Competing Interests:** Co-authors Sarah Thurston and Anna Mackay are currently or were previously members of the ICA Foundation Board of Trustees. Ashley Jackson is an incoming deputy member on the ICA Foundation Board.

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#### Peer Reviewed

**Received:** October 3, 2018; **Accepted:** November 19, 2018

**Cite this article as:** Rademacher KH, Sripipatana T, Pfitzer A, et al. A global learning agenda for the levonorgestrel intrauterine system (LNG IUS): addressing challenges and opportunities to increase access. *Glob Health Sci Pract*. 2018;6(4):635–643. <https://doi.org/10.9745/GHSP-D-18-00383>

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## ORIGINAL ARTICLE

# Antenatal Corticosteroids for Women at Risk of Imminent Preterm Birth in 7 sub-Saharan African Countries: A Policy and Implementation Landscape Analysis

Dawn Greensides,<sup>a</sup> Judith Robb-McCord,<sup>b</sup> Angeline Noriega,<sup>c</sup> James A. Litch<sup>d</sup>

Countries have put in place some elements necessary for safe and effective antenatal corticosteroid (ACS) use, but significant challenges remain including: ensuring accurate gestational age determination, establishing clear treatment guidelines, strengthening provider capacity, incorporating obstetric indications for ACS use in national essential medicines lists, and collecting and using ACS-related data in the HMIS. Most importantly, the quality of maternal and newborn care, including specialized newborn care, needs improvement to ensure a strong foundation for the safe and effective use of ACS.

➔ *Résumé en français à la fin de l'article.*

## ABSTRACT

**Background:** Every year approximately 15 million babies are born prematurely and nearly 1 million die due to preterm birth complications. Evidence shows that antenatal corticosteroids (ACS) can be used to improve preterm birth outcomes in particular clinical settings. We conducted a policy and implementation landscape analysis of ACS use for women at risk of imminent preterm birth in 7 low-income countries.

**Methods:** A study framework and situation analysis tool were developed based on the World Health Organization (WHO) recommendation for ACS use among women at risk of preterm birth. The study was conducted in the Democratic Republic of the Congo, Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania, and Uganda. Primary data were collected through key informant interviews. Secondary data were gathered from publicly available sources, a survey of health management information system indicators, and demographic data from the Every Premie—SCALE country profiles for preterm and low birth weight prevention and care.

**Results:** All 7 countries are using ACS for women at risk of imminent preterm birth. The majority of countries include language on ACS use in clinical protocols or standard treatment guidelines; however, none include language on accurately measuring gestational age. For 2 of the 5 countries with national standards for ACS use, the upper gestational age limit for ACS use exceeded the WHO recommendation of 34 weeks. There are gaps in national guidance on how to determine if a woman is at risk of imminent preterm birth. Few countries include guidance that indicates ACS is contraindicated in the presence of infection. The majority of countries reported that facilities providing ACS meet comprehensive emergency obstetric and newborn care standards, and all countries reported the availability of some form of special newborn care or neonatal intensive care units at facilities providing ACS.

**Conclusions:** Countries recognize challenges to access to high-quality maternal and newborn care that fulfill clinical care preconditions required for safe and effective ACS use. Key informants recommended support for clinical guidelines and provider training on ACS use, inclusion of obstetric indications for dexamethasone and betamethasone in national essential medicine lists, collecting and using ACS-related data, and improving the quality of maternal and newborn care, including specialized newborn care.

## BACKGROUND

Each year approximately 15 million babies are born prematurely (before 37 weeks of gestational age) and nearly 1 million die due to complications of preterm birth.<sup>1</sup> Prematurity is the leading cause of newborn deaths in the first 4 weeks of life and the leading cause of death among children under age 5 around the world.<sup>2</sup>

<sup>a</sup>Independent consultant, Johannesburg, South Africa.

<sup>b</sup>Every Premie—SCALE/Project Concern International, Washington, DC, USA.

<sup>c</sup>Independent consultant, Portland, OR, USA.

<sup>d</sup>Every Premie—SCALE/Global Alliance to Prevent Prematurity and Stillbirth (GAPPS), Seattle, WA, USA.

Correspondence to Dawn Greensides (dawn@greensides.com).



Preterm birth is also a prominent cause of disability and ill health later in life.

In addition to essential newborn care and other more specialized postnatal care interventions, there is a body of evidence to support the use of specific maternal health interventions to improve preterm birth outcomes. These include magnesium sulfate, antibiotics for preterm labor, tocolytics, and a reduction in elective, early cesarean deliveries. Use of antenatal corticosteroids (ACS) for fetal lung maturation in select pregnant women who are at risk of imminent preterm birth is also widely acknowledged as an effective, evidence-based intervention to improve preterm birth outcomes.

The timely use of ACS for the management of preterm labor—before 34 weeks of gestation in high-resource settings with neonatal intensive care unit (NICU) services and with high certainty of gestation age estimation—has been associated with a 34% reduction in respiratory distress syndrome, 46% reduction in intraventricular hemorrhage, 54% reduction in necrotizing enterocolitis, and, overall, a 31% reduction in newborn mortality.<sup>3–5</sup> Additional benefits include reduced length of hospital stay, lower rate of intensive care admissions, and reduced cost of care.<sup>3–5</sup>

Cochrane reviews have reported no benefit, and the potential for harm to newborns, when ACS is administered after 34 weeks of gestation, and an increased rate of puerperal sepsis.<sup>3–5</sup> A World Health Organization (WHO) survey of facilities in 29 countries published in 2014 reported that more than 25% of ACS use occurred at gestational ages at which benefit is controversial or harmful.<sup>6</sup> The Antenatal Corticosteroid Trial, a multicenter trial of ACS for management of preterm labor from 24 to 36 weeks of gestation in 6 lower-middle-income countries, reported increased newborn mortality and increased serious maternal infections in the intervention group, compared with the control group that received traditional care in peripheral health care settings with limited technology and without newborn intensive care.<sup>7</sup>

Guidance on the minimum requirements of maternal and newborn clinical support for safe and effective ACS use has been limited. The *WHO Recommendations on Interventions to Improve Preterm Birth Outcomes* (2015) made a strong recommendation in support of ACS use for women at risk of imminent preterm birth from 24 weeks to 34 weeks of gestation when 5 conditions are met<sup>8</sup>:

1. Accurate gestational age assessment
2. Preterm birth is imminent (within 7 days)

3. No clinical evidence of maternal infection exists
4. Adequate childbirth care is available
5. Adequate preterm newborn care is available

ACS is 1 of 13 lifesaving commodities identified in 2012 by the United Nations Commission on Life-Saving Commodities (UNCoLSC) for maternal, newborn, and child health. Projections made in 2012 indicated that the lives of an estimated 6 million women and children could be saved by 2017, if countries invested in these commodities and promoted health systems strengthening for improved access to and use of these commodities.<sup>9</sup>

The Reproductive, Maternal, Neonatal and Child Health Trust Fund supported 8 countries to implement the UNCoLSC recommendations. These 8 countries were designated as the “Pathfinder” countries in 2013. The UNCoLSC engaged the Pathfinder countries and established expert technical reference teams to advance the commission’s agenda. The technical reference teams created technical working groups, spanning the 13 commodities and 10 recommendations, in order to focus on specific aspects of their agendas. The technical reference teams and related technical working groups advanced the UNCoLSC’s recommended actions for 3 to 4 years and drew to a close in June 2016.

A multi-country analysis of health system bottlenecks and potential solutions for coverage of ACS found that 9 or more of 11 countries (more than 75%) in Africa and Asia reported very major or significant bottlenecks for health information systems (11 countries), essential medical products and technologies (9 out of 11 countries), and health service delivery (9 out of 11 countries).<sup>10</sup> This survey highlighted the need for more specific information on the current use of ACS in Africa and Asia.

Because of the positive evidence supporting ACS use, low-resource countries are moving forward with its implementation to prevent preterm birth complications, which have contributed dramatically to newborn and under-5 mortality. This article presents findings of a policy and implementation landscape analysis of ACS use for women at risk of imminent preterm birth in 7 of the 8 Pathfinder countries: Democratic Republic of the Congo (DRC), Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania, and Uganda (excluding Senegal). The UNCoLSC Newborn Health Technical Reference Team commissioned the analysis and Every Premie—SCALE, a cooperative agreement

**Use of antenatal corticosteroids for fetal lung maturation in select pregnant women at risk of imminent preterm birth is widely acknowledged as effective to improve preterm birth outcomes.**

**Five specific conditions are required for the safe and effective use of ACS, as recommended by WHO.**

funded by the United States Agency for International Development (USAID), implemented it.<sup>11</sup>

This landscape analysis is intended to direct the attention of national and local stakeholders to important issues related to the safe and effective use of ACS in low-resource settings. Identifying these crucial needs can be pivotal in influencing policy change and driving responsive intervention development and implementation. Although the analysis did not enable us to scrutinize the actual quality of implementation, it provided valuable information regarding the framework for implementation in these 7 countries.

## METHODS

The study team used a framework and situation analysis tool to focus on public-sector services in 7 countries for this landscape analysis. We included the following UNCoLSC Pathfinder countries in the study: the DRC, Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania, and Uganda. However, Senegal was omitted from the study due to a lack of response from in-country stakeholders.

### Data Collection

We used primary qualitative research methods to collect information about ACS use through key informant interviews. Secondary quantitative data were gathered from publicly available sources in the 7 countries, including national standard treatment guidelines, essential medicines lists, drug formularies, national strategies and plans, national road maps, programmatic reports, and intrapartum protocols. If any of these sources were not readily available, we reached out to in-country contacts to obtain them where possible. See [Table 1](#) for examples of select documents reviewed in each country. Secondary data were further supplemented by the 2015 *Health Management Information System Maternal and Newborn Health Indicator Survey*,<sup>12</sup> conducted in 23 of USAID's priority maternal and child health countries. Demographic data from the Every Premie—SCALE country profiles for preterm and low birth weight prevention and care,<sup>13</sup> published in 2015, were also included as a fourth component. Additional secondary data were obtained from the most recent global Countdown to 2015 reports<sup>14,15</sup> and a WHO survey on behalf of the UNCoLSC.<sup>16</sup> We summarized the relevant information on the use of ACS in each country and used it to validate information provided by the key informants. Data

collection and verification occurred from February to June 2016.

Interview questions were based on the 5 WHO conditions for safe ACS use and included whether or not ACS is in use in each country and at what level of care, and the availability of clinical guidelines to determine if a woman is at risk of imminent preterm birth, the presence of maternal infection, gestational age parameters for ACS use, and how to establish accurate measures for gestational age during pregnancy. In the analysis we also looked at the availability of comprehensive emergency obstetric care services and special newborn care services, including the availability of NICUs.

The key informant questionnaire focused on national-level ACS policy and implementation and was derived from a framework that laid out the overall objectives of the landscape analysis and key research questions. The framework was shared with members of the ACS Technical Working Group (under the UNCoLSC Newborn Health Technical Reference Team) for their review and input. Key informants were queried on the strengths of implementation as well as existing challenges and barriers.

Knowledgeable local and global experts nominated key informants in each of the Pathfinder countries, providing a purposeful sample. At least 1 key informant for every country was a senior-level ministry of health representative. Additional informants, if available, came from organizations working closely with the ministry of health for the respective country. In 7 of the 8 Pathfinder countries, key informants participated in interviews. Despite several attempts to reach suggested key informants in Senegal, efforts were unsuccessful. Senegal was therefore omitted from the study.

The study team conducted interviews with 1 to 4 key informants in each of the 7 countries. Representatives from each country had relevant experience and information regarding the use of ACS for women at imminent risk of preterm labor and were able to provide valuable insights.

Whenever possible, we conducted key informant interviews by phone or in person during a 4-week period between April 6 and May 6, 2016. We used a structured questionnaire with 29 defined questions for the key informant interviews. The questions promoted discussion and allowed for follow-up and clarification by the interviewer. Each interview took approximately 45 minutes. Three participants received an electronic copy of the written questionnaire to record their written responses due to challenges related

**We interviewed key informants, including at least 1 senior ministry of health official in each country.**

**TABLE 1.** Examples of Select Documents Reviewed by Country

Country	National Document
DRC	<ul style="list-style-type: none"> <li>• Maternal, Newborn, and Child Standards of Health User Manual, April 2015</li> <li>• Integrated Maternal, Newborn, and Child Standards for Health, Volume 2: Obstetric Emergency Care, April 2012</li> <li>• Obstetric Care Training and Neonatal Emergency Facilitators Guide, May 2012</li> </ul>
Ethiopia	<ul style="list-style-type: none"> <li>• FMOH STGs for Primary Hospitals, 2014</li> <li>• FMOH STGs for General Hospitals, 2014</li> <li>• FMOH STGs for Health Centers, 2010</li> <li>• FMOH Management Protocol on Selected Obstetrics Topics for Health Centers, 2014</li> <li>• FMOH Basic Emergency Obstetric and Newborn Care Training Manual, 2013</li> </ul>
Malawi	<ul style="list-style-type: none"> <li>• Malawi STGs Incorporating Malawi Essential Medicines List, 2015</li> <li>• Malawi National Reproductive Health Service Delivery Guidelines, 2014–2019</li> <li>• Participants Manual in Integrated Maternal and Neonatal Care, 2015</li> <li>• Reproductive Health Unit Obstetric Management Protocols</li> </ul>
Nigeria	<ul style="list-style-type: none"> <li>• Report of Expert Consensus Panel on the use of ACS, October 2014</li> <li>• MOH National Strategic Health Development Plan 2010–2015</li> <li>• “Saving One Million Lives” Accelerating improvements in Nigeria’s Health Outcomes through a new approach to basic services delivery, 2012</li> </ul>
Sierra Leone	<ul style="list-style-type: none"> <li>• Basic Package of Essential Health Services for Sierra Leone 2015–2020, 2015</li> <li>• Reproductive, Newborn and Child Health Strategy 2011–2015</li> <li>• Maternity Africa: Policies and Guidelines for Intrapartum Postnatal and Neonatal Care</li> <li>• Essential Obstetric and Newborn Care: Practical Guide for Midwives, Doctors With Obstetrics Training and Health Care Personnel Who Deal With Obstetric Emergencies, 2015</li> </ul>
Tanzania	<ul style="list-style-type: none"> <li>• Administration of Antenatal Corticosteroids in Pre-Term Labour, July 2015, Guidelines</li> <li>• Standard Treatment Guidelines and Essential Medicines List, Fourth Edition, 2013</li> <li>• Health Sector Strategic Plan July 2015–June 2020</li> </ul>
Uganda	<ul style="list-style-type: none"> <li>• MOH Uganda Guidelines, 2012</li> <li>• MOH Uganda Clinical Guidelines and Essential Medicines and Health Supplies List for Uganda, 2012, Addendum 2: RMNCH Lifesaving Commodities</li> <li>• Essential Medicines and Health Supplies List for Uganda, 2012</li> </ul>

Abbreviations: ACS, antenatal corticosteroids; DRC, Democratic Republic of the Congo; FMOH, Federal Ministry of Health; MOH, Ministry of Health; RMNCH, reproductive, maternal, newborn, and child health; STG, standard treatment guidelines.

to language or telephone connection issues. The questionnaire was also professionally translated into French for key informants from the DRC who preferred to provide written responses in French. See [Table 2](#) for the number of key informants and method of interview by country.

## Data Analysis

In every case possible, we verified the key informant interview data using country-level documents obtained from the desk review. However, verification of key informant data was

not possible for reported care practices or the quality of those practices, such as adequate childbirth care and preterm newborn care.

The study team made every effort to identify all of the available secondary information for review and analysis in each country. Although it is possible that we missed documents or did not identify a more up-to-date version, our team used multiple sources to identify the most current and relevant materials to mitigate this risk. In the case of inconsistencies between the raw data provided from the Countdown to 2015 reports,<sup>14,15</sup> the WHO survey on behalf of the UNCoLSC, and the

**TABLE 2.** Number of Key Informants and Method of Interview by Country

Country	Number of Key Informants	Method of Interview
DRC	2	Phone interviews and written questionnaire
Ethiopia	1	Phone interview
Malawi	2	In-person interviews
Nigeria	1	Phone interview
Sierra Leone	4	Phone interviews and written questionnaire
Tanzania	1	Written questionnaire
Uganda	1	In-person interview

Abbreviation: DRC, Democratic Republic of the Congo.

**Corticosteroids were on the national essential medicines lists for all 7 countries, but not for obstetric indications.**

secondary data obtained through the desk review, the study team attempted to contact the authors of the Countdown to 2015 and WHO reports to obtain more information on the protocols used for their surveys to resolve inconsistencies.

## ■ RESULTS

### ACS Use

ACS was approved for use at tertiary facilities in the DRC (based on information obtained from key informant interviews), Ethiopia,<sup>20</sup> Malawi,<sup>22</sup> Nigeria (key informant interview), Tanzania,<sup>24</sup> and Uganda.<sup>25</sup> A pre-referral first dose was also approved in Ethiopia, Tanzania, and Uganda before a patient transfers to a higher-level facility; however, key informant data indicated that ACS was not actually being implemented at lower-level facilities. See Table 3 for a list of countries

and approved levels of care for ACS use, actual levels of care, and indications for use.

Corticosteroids were on the national essential medicines lists for all countries, but they were not listed for obstetric indications in any of the 7 countries.

### WHO Recommendations for the Safe and Effective Use of ACS Policy, Clinical Protocols, and Guidelines

National-level policies and guidelines provide a critical foundation when adopting a new health care intervention. Each of the 7 countries had either a national ACS policy or guidelines, with indicated ACS use ranging from preterm labor alone to threatened preterm birth including severe preeclampsia/eclampsia, preterm premature rupture of membranes, and antepartum hemorrhage.

**TABLE 3.** ACS Use by Country: Level of Care, Indications for Use, and Pre-Referral Dose Authorization

Country	Level of Care Approved for ACS Use	Level of Care Where ACS Actually in Use	Indications for Use	Pre-Referral Dose Allowed
DRC	Tertiary and maternity hospitals	Tertiary and maternity hospital in capital only	pPROM, eclampsia, preterm labor	No
Ethiopia	Referral, general, primary hospitals, and health centers	Tertiary and secondary hospitals	Preterm labor	Yes
Malawi	Central and district hospitals	Central and district hospitals	Preterm labor	No
Nigeria	Tertiary hospitals	Tertiary hospitals	Preterm labor	No
Sierra Leone	Tertiary hospitals including district referral hospitals	Tertiary and district referral hospitals	None	No
Tanzania	Hospitals, health centers	Hospitals	Preterm labor	Yes
Uganda	Hospitals, health centers IV, III, and II	Hospitals, health center IV	pPROM and “risk of preterm delivery”	Yes

Abbreviations: ACS, antenatal corticosteroids; DRC, Democratic Republic of the Congo; pPROM, preterm premature rupture of the membranes.

Based on our review of the most current clinical protocols and standard treatment guidelines in each of the 7 countries, there was variability among the countries on the inclusion of the 5 conditions for safe and effective use of ACS as stated in the *WHO Recommendations on Interventions to Improve Preterm Birth Outcomes*.<sup>8</sup> See Table 4 for a summary of the 5 conditions and their inclusion in national clinical protocols or standard treatment guidelines by country.

### Gestational Age Assessment

The national-level guidance on gestational age criteria for use of ACS varied between countries, ranging from 24 to 37 weeks, 28 to 34 weeks, and less than 34 weeks, with no minimum gestational age required. The DRC, Ethiopia, and Tanzania had national-level criteria for gestational ages that were appropriate for the safe use of ACS. Nigeria and Sierra Leone did not have a nationally standardized gestational age range, but key informants in Sierra Leone reported a commonly accepted gestational age range between 28 and 35 weeks. At the time of this writing, Nigeria was reportedly in the process of revising the standard treatment guidelines to include a gestational age of 30 to 34 weeks; however, current national clinical standards do not reflect this update. Importantly, Malawi and Uganda had national-level guidance for gestational age criteria that exceeded the 34-week upper limit. See Table 5 for gestational age parameters for ACS use and source by country.

None of the 7 countries had national-level guidance on how to calculate gestational age relevant to preterm labor. In the Ethiopian *Management Protocol on Selected Obstetrics Topics for Health Centers*,<sup>17</sup> there is information on how to determine gestational age, but it is found in the section on post-term pregnancy only.

### Risk of Imminent Preterm Birth and Maternal Infection

Ethiopia was the only country to include language in its standard treatment guidelines on how to determine if a woman is at risk of imminent preterm birth. Only the clinical standards and guidelines in the DRC, Ethiopia, and Uganda indicated that ACS use is contraindicated in the presence of maternal infection. Nigeria was in the process of revising their standard treatment guidelines and reportedly planned to include how to assess gestational age and how to determine whether there is clinical evidence of infection, but the updated guidelines following this survey did not include this language.

**National-level guidance on gestational age criteria varied between countries, from no minimum up to 37 weeks.**

### Adequate Childbirth Care and Preterm Newborn Care

The majority of countries included language in their clinical protocols or standard treatment guidelines emphasizing the availability of adequate childbirth care. The DRC, Ethiopia, Malawi, Sierra Leone, Tanzania, and Uganda reported that facilities providing ACS met comprehensive emergency

**TABLE 4.** Inclusion of WHO Care Conditions Required for ACS Use in National Clinical Protocols or Standard Treatment Guidelines, by Country<sup>a</sup>

	WHO Condition for ACS Therapy				
	Gestational Age Can Be Accurately Undertaken	Preterm Birth Is Considered Imminent	No Clinical Evidence of Maternal Infection	Adequate Childbirth Care Is Available	Adequate Preterm Newborn Care Is Available
DRC	No	No	Yes	Yes	Yes
Ethiopia	No	Yes	Yes	Yes	Yes
Malawi	No	No	No	Yes	Yes
Nigeria	No	No	No	Yes	Yes
Sierra Leone	No info	No info	No info	No info	No info
Tanzania	No	No	No	Yes	No
Uganda	No	Yes	Yes	Yes	Yes

Abbreviations: ACS, antenatal corticosteroids; DRC, Democratic Republic of the Congo; WHO, World Health Organization.

<sup>a</sup> Yes: WHO condition included in country protocols or guidelines; No: WHO condition not included in country protocols or guidelines.



**TABLE 5.** Gestational Age Parameters for ACS Use and Source by Country

Country	Gestational Age Criteria	Source
DRC	28–34 weeks	National-level document <sup>19</sup>
Ethiopia	28–34 weeks	National-level document <sup>20,21</sup>
Malawi	<34 weeks 28–34 weeks 24–37 weeks	National-level document <sup>22,23</sup> (Note: Criteria varied between national documents available for review.)
Nigeria	30–34 weeks	Key informant, no national-level document
Sierra Leone	28–35 weeks	Key informant, no national-level document
Tanzania	28–34 weeks	National-level document <sup>24</sup> (Note: ACS could be provided as low as 24 weeks if birth is at a well-equipped facility with a specialist available to manage the premature newborn.)
Uganda	32–37 weeks	National-level document <sup>25</sup>

Abbreviations: ACS, antenatal corticosteroids; DRC, Democratic Republic of the Congo.

obstetric and newborn care standards. Nigeria stated that some, but not all, tertiary facilities providing ACS met comprehensive emergency obstetric and newborn care standards. Malawi reported that facilities authorized to provide pre-referral first-dose ACS at lower levels of the health care system met basic emergency obstetric and newborn care standards.

All countries reported that the preterm newborn care interventions recommended by WHO for safe and effective ACS use were available at facilities providing ACS, although they were not specifically stated as *required* to be in place to provide ACS. Key informant data also indicated that because these interventions were not required nor defined by the ministry of health, the availability, content, and quality of preterm newborn care interventions varied widely across facilities and countries. See Table 6 for preterm newborn care interventions that were reportedly available by country.

All countries reported the availability of some form of special newborn care or the availability of NICUs. Wide variation existed among countries regarding the availability of NICUs where ACS is given. Only the DRC and Tanzania required a NICU to be in place in order to give ACS; however, Tanzania also reported that NICUs were often not available in facilities providing ACS. The DRC and Nigeria reported that NICUs were always present in facilities providing ACS, and Ethiopia, Malawi, and Uganda reported that NICUs were available in facilities that most often provided ACS. Sierra Leone's key informants reported that NICU care

was available at 1 hospital only in Freetown and was limited in terms of quality of care.

### ACS Prescription and Administration

In the DRC, Ethiopia, Nigeria, Tanzania, and Uganda, only high-level clinical practitioners such as doctors, including obstetrician-gynecologists, were nationally authorized to prescribe ACS. In addition to doctors, Malawi reportedly had medical or clinical officers prescribing ACS (key informant interview), and Ethiopia had a cadre of graduates from a masters in emergency surgery and obstetrics program who were also reportedly able to prescribe ACS (key informant interview). Nurses and midwives were allowed to administer ACS with clinical oversight but could not prescribe it in the DRC, Ethiopia, Malawi, Tanzania, and Uganda. In Ethiopia nurses and midwives at the health center level were also authorized to prescribe and administer a pre-referral first dose of ACS.

Sierra Leone did not have national guidance for ACS prescriptive authority or administration, but a key informant reported that doctors, including obstetrician-gynecologists, had prescriptive authority, and clinical health officers, medical officers, and midwives could administer ACS with clinical oversight.

### Clinical Training

Secondary data elaborating on the inclusion of ACS in health personnel preservice and in-service training were limited. Key informants in Ethiopia,

**Wide variation existed among countries regarding the availability of NICUs where ACS is given.**

**TABLE 6.** Preterm Newborn Care Interventions Recommended by WHO for Safe and Effective ACS Use Reported by Key Informants as Being Available at Facilities Providing ACS, by Country

Preterm Newborn Care Interventions					
Country	Resuscitation	Thermal Care	Infection Prevention and Treatment	Feeding Support	Safe Oxygen Use
DRC	<ul style="list-style-type: none"> <li>• Bag and mask</li> </ul>	<ul style="list-style-type: none"> <li>• Skin-to-skin contact/ KMC</li> <li>• Incubators (not prevalent)</li> </ul>	<ul style="list-style-type: none"> <li>• Handwashing</li> <li>• Antibiotics</li> <li>• Separate unit for sick babies</li> </ul>	<ul style="list-style-type: none"> <li>• NG tube</li> <li>• Daily weight monitoring</li> <li>• Daily intake monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Oxygen mixer</li> <li>• Oxygen titration</li> <li>• Pulse oximetry</li> </ul>
Ethiopia	<ul style="list-style-type: none"> <li>• Bag and mask</li> </ul>	<ul style="list-style-type: none"> <li>• Drying, cleaning, wrapping</li> <li>• Skin-to-skin contact/ KMC</li> <li>• Radiant warmers/ incubators</li> </ul>	<ul style="list-style-type: none"> <li>• Handwashing</li> <li>• Antibiotics</li> <li>• Sterilization of equipment</li> </ul>	<ul style="list-style-type: none"> <li>• Exclusive breastfeeding</li> <li>• Expressed breast milk</li> <li>• NG tube</li> <li>• Daily weight monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Oxygen titration</li> <li>• Oxygen concentrator</li> </ul>
Malawi	<ul style="list-style-type: none"> <li>• Bag and mask</li> </ul>	<ul style="list-style-type: none"> <li>• Skin-to-skin contact</li> <li>• Incubators (some available)</li> </ul>	<ul style="list-style-type: none"> <li>• Handwashing</li> <li>• Antibiotics</li> <li>• Separate ward for sick babies</li> </ul>	<ul style="list-style-type: none"> <li>• Expressed breast milk</li> <li>• NG tube</li> <li>• Daily weight monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Oxygen mixer</li> <li>• Oxygen titration</li> <li>• Pulse oximetry</li> </ul>
Nigeria	<ul style="list-style-type: none"> <li>• Bag and mask</li> </ul>	<ul style="list-style-type: none"> <li>• KMC</li> <li>• Incubators (at general hospitals)</li> </ul>	<ul style="list-style-type: none"> <li>• Antibiotics</li> <li>• Aseptic technique</li> <li>• Separate ward for sick babies</li> </ul>	<ul style="list-style-type: none"> <li>• Breastfeeding and all feeding alternatives</li> <li>• NG tube (general and teaching hospitals)</li> </ul>	<ul style="list-style-type: none"> <li>• Pulse oximetry</li> </ul>
Sierra Leone	<ul style="list-style-type: none"> <li>• Bag and mask</li> </ul>	<ul style="list-style-type: none"> <li>• Dry, warm, stimulate</li> <li>• KMC</li> </ul>	<ul style="list-style-type: none"> <li>• Antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>• Expressed breast milk</li> <li>• Formula</li> <li>• NG tube</li> <li>• Daily weight monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Oxygen mixer</li> <li>• Pulse oximetry</li> </ul>
Tanzania	<ul style="list-style-type: none"> <li>• Bag and mask</li> </ul>	<ul style="list-style-type: none"> <li>• Skin-to-skin contact</li> <li>• Incubators</li> </ul>	<ul style="list-style-type: none"> <li>• Handwashing</li> <li>• Antibiotics</li> <li>• Separate ward for sick babies</li> </ul>	<ul style="list-style-type: none"> <li>• Expressed breast milk</li> <li>• NG tube</li> <li>• Daily weight monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Oxygen mixer</li> <li>• Oxygen titration</li> <li>• Pulse oximetry</li> </ul>
Uganda	<ul style="list-style-type: none"> <li>• Bag and mask</li> </ul>	<ul style="list-style-type: none"> <li>• Skin-to-skin contact</li> <li>• Incubators (limited supply and irregular power supply)</li> </ul>	<ul style="list-style-type: none"> <li>• Handwashing</li> <li>• Antibiotics</li> <li>• Separate ward for sick babies</li> </ul>	<ul style="list-style-type: none"> <li>• Expressed breast milk</li> <li>• NG tube</li> <li>• Daily weight monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Oxygen mixer/ concentrator (limited use due to irregular power supply)</li> </ul>

Abbreviations: ACS, antenatal corticosteroids; DRC, Democratic Republic of the Congo; NG, nasogastric; KMC, kangaroo mother care; WHO, World Health Organization.

Nigeria, and Uganda reported that ACS was included in their preservice clinical training materials. In addition, the DRC, Ethiopia, Malawi, Sierra Leone, Tanzania, and Uganda reported having ACS in their in-service clinical training materials. All countries listed training and capacity building for health care providers on ACS as an area of identified need for their programs. No information was collected on the content or compre-

hensiveness of either ACS preservice or in-service training materials or actual provider training.

### Health Metrics for ACS Use

None of the countries in the landscape analysis had an existing indicator for ACS use in their health management information system (HMIS). However, Ethiopia, Malawi, Nigeria, Tanzania, and Uganda had each proposed a

**None of the countries had an existing indicator for ACS use in their HMIS, but 5 of the countries had proposed one for future use.**

**All but 1 country captured data on proxy indicators related to 5 preconditions for the safe and effective use of ACS.**

national indicator for ACS to be integrated into their HMIS. Ethiopia, Malawi, and Tanzania had a nationally proposed indicator for ACS specifying “women less than 34 weeks receiving ACS.” Other proposed indicators included stock-out of ACS in the past month, hospitals providing ACS, women receiving steroids with delivery between 24 and 27 weeks of gestation, women receiving steroids with delivery between 28 and 34 weeks of gestation, and women in preterm labor receiving at least 1 dose of ACS before delivery.

Analysis of the 2015 *Health Management Information System Maternal and Newborn Health Indicator Survey* data revealed that 6 of the 7 countries (the DRC, Ethiopia, Malawi, Nigeria, Tanzania, and Uganda) captured data on a range of proxy indicators related to the 5 WHO preconditions for the safe and effective use of ACS.<sup>12</sup> These included the number of antenatal care (ANC) visits (4 or more), maternal complications (preeclampsia/eclampsia) diagnosed in ANC, preterm birth as a complication diagnosed in labor and delivery, maternal complications diagnosed in labor and delivery (preterm premature rupture of membranes and antepartum hemorrhage), maternal gestational age measured in labor and delivery, maternal blood transfusion, essential newborn care including breastfeeding within 1 hour of birth and immediate skin-to-skin contact, and newborn resuscitation in labor and delivery.

Each of the 7 countries was capturing the number of ANC visits and all but Nigeria captured gestational age (in weeks) in ANC. Malawi had an indicator for the diagnosis of preeclampsia/eclampsia in ANC, and Ethiopia, Malawi, and Tanzania had indicators for the diagnosis of antepartum hemorrhage in labor and delivery. The DRC was the only country with an indicator for active management of the third stage of labor, and both Malawi and Tanzania had indicators for cesarean delivery as a method of delivery. All countries but Nigeria had an indicator for breastfeeding within 1 hour of birth, and only Uganda had an indicator for immediate skin-to-skin contact as part of essential newborn care. Nigeria was the only country with an indicator for referral to Kangaroo Mother Care for postnatal care as part of managing newborn complications.

**All national guidelines included language on ACS, but did not address how to assess gestational age or how to determine if a woman is at risk of imminent preterm birth.**

### **Lessons Learned, Strengths, Opportunities, and Challenges**

Key informants shared their country-specific views on lessons learned, strengths, opportunities, and challenges regarding the implementation of

ACS in their countries (Table 7). Reported reasons for not implementing ACS at all levels of care where approved in the 7 Pathfinder countries included “inadequate newborn care at lower levels of care,” “ACS is not available,” “guidelines for ACS are not available at lower levels of care,” “staff at lower-level facilities are not adequately trained to provide ACS safely,” and “safety concerns due to outcomes of recent trials.”

## **DISCUSSION**

Nearly 2.2 million preterm births and approximately 195,000 direct preterm child deaths occur annually across the 7 Pathfinder countries highlighted in this analysis.<sup>13</sup> Countries are responding to preterm birth as a public health priority and are moving to implement evidence-based interventions within national maternal and newborn health programs. ACS is one intervention for improved preterm birth outcomes. The safe and effective use of ACS, however, relies on the availability and quality of care across the continuum of care—from provision during preterm labor to childbirth and preterm newborn care—to improve newborn survival while limiting the risk of resultant maternal and newborn complications.

The *WHO Recommendations on Interventions to Improve Preterm Birth Outcomes*, based on a comprehensive review of evidence, provide necessary guidance for the safe and effective implementation of ACS for women at risk of imminent preterm birth from 24 weeks to 34 weeks of gestation when 5 conditions are met: (1) accurate gestational age assessment, (2) preterm birth is imminent (within 7 days), (3) no clinical evidence of maternal infection exists, (4) adequate childbirth care is available, and (5) adequate preterm newborn care is available.<sup>8</sup> Further guidance on accurately estimating gestational age by WHO was made available in 2016. According to the *WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience*, an ultrasound scan before 24 weeks of gestation (early ultrasound) is recommended for all pregnant women to accurately estimate gestational age.<sup>18</sup>

Each of the 7 countries included in this study was implementing ACS for women at risk of preterm birth and the majority of countries included language in their clinical protocols or standard treatment guidelines regarding the use of ACS. However, none of the countries included language on how to accurately assess gestational age, and there were gaps in national-level guidance or criteria for how to determine whether a woman is

**TABLE 7.** ACS Implementation Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informants

<b>Lessons Learned</b>	<ul style="list-style-type: none"> <li>• ACS should be added to the EML for obstetric use</li> <li>• Intervention needs to be cost-effective</li> <li>• Need comprehensive package, not just guidelines</li> <li>• Stakeholders need to be informed of new WHO recommendations</li> <li>• Policies, guidelines, preservice education, in-service education, and regulatory bodies all need alignment</li> <li>• Need increased community awareness of preterm birth</li> </ul>
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• Ministry of health involvement and ownership</li> <li>• Guidelines and policies exist for most countries</li> <li>• Strong political will and partner support exist for this intervention</li> </ul>
<b>Opportunities</b>	<ul style="list-style-type: none"> <li>• Expand standards and guidelines to include assessment (i.e., how to determine who should receive ACS)</li> <li>• Need studies of ACS impact at scale</li> <li>• Partner commitment, political will</li> <li>• Strengthen quality of ANC</li> <li>• Increase community awareness to reduce delay in diagnosis</li> </ul>
<b>Challenges</b>	<ul style="list-style-type: none"> <li>• Inadequate training and capacity building</li> <li>• Inadequate information available to safely scale up the intervention in low-income countries</li> <li>• Delay in diagnosis of preterm labor</li> <li>• ACS not in preservice training</li> <li>• Poor supply chain</li> <li>• Lack of trained health care workers</li> <li>• No specific implementation guidelines for new WHO recommendations</li> <li>• Lack of diagnostics such as ultrasound to determine gestational age</li> <li>• Many deliveries are occurring at lower-level facilities where it is not appropriate to provide ACS</li> </ul>

Abbreviations: ACS, antenatal corticosteroids; ANC, antenatal care; EML, essential medicines list; WHO, World Health Organization.

at risk of imminent preterm birth. The range of gestational age criteria for ACS use varied across countries, and only 3 countries aligned with the WHO recommendation of an upper limit of 34 weeks. At the same time, only a few countries included guidance indicating that ACS is contraindicated in the presence of infection. Existing standard treatment guidelines did, however, emphasize the need for adequate childbirth care and preterm newborn care when using ACS.

ACS provision matched to the appropriate level of care facility is a major challenge for the safe and effective use of ACS. There was general agreement among the Pathfinder countries that ACS should be provided within a comprehensive package of maternal and newborn care that includes consistently available specialized (advanced) newborn care. Specific newborn care interventions listed as conditions for ACS use in the *WHO Recommendations on Interventions to Improve Preterm Birth Outcomes* are resuscitation,

thermal care, infection prevention and treatment, feeding support, and safe oxygen use.<sup>8</sup> The majority of countries reported that facilities providing ACS met comprehensive emergency obstetric and newborn care standards and all countries reported the availability of some form of special (advanced) newborn care or the availability of NICUs. However, countries reported that there was great variability in the quality and availability of these services across their health systems.

Access to health facility care with competent health care providers for maternal and newborn health in many low-income countries remains a persistent challenge and complicates the availability of the safe provision of ACS. According to the available population-based survey data, births at health facilities ranged from a low of 10% in Ethiopia to a high of 91% in Malawi, with an unweighted average of 31% across the 7 countries—leaving great room for improvement.<sup>13</sup>



HMIS indicators measuring the use of ACS were lacking in the Pathfinder countries, although most countries had proposed a national indicator for ACS use to be integrated into their HMIS. There were no suitable proxy indicators included in any of the countries' HMIS that are related to the 5 WHO preconditions for the safe and effective use of ACS. The 2015 *WHO Recommendations on Interventions to Improve Preterm Birth Outcomes*<sup>8</sup> outlines these preconditions for use of ACS and should prompt the development of suitable proxy indicators.

Countries recognized that challenges remain in terms of consistent and high-quality maternal and newborn care that meet required clinical care preconditions to safely and effectively provide ACS. The evidence of benefit and harm associated with ACS use calls for caution to ensure that preconditions are met at service delivery points before providing ACS for threatened preterm birth. Each country identified specific areas to improve ACS implementation, for example, reestablishing gestational age guidelines to meet international recommendations, qualifying the type of providers and level of facility that can prescribe and administer ACS, the design and release of new standard treatment guidelines to direct ACS implementation, and developing e-learning curricula for ACS.

Key informants recommended continued support for several implementation components, including clinical guidelines for ACS use, inclusion of obstetric indications for dexamethasone and betamethasone in national essential medicines lists, strengthening the capacity of providers to safely provide ACS, measuring and collecting ACS-related data, and attention to the quality of childbirth care (comprehensive emergency obstetric and newborn care) and preterm newborn care. Key informants thought it would be useful to conduct in-depth facility-level quality of care surveys to more comprehensively evaluate the safe and effective implementation of maternal and newborn health services, including ACS use.

Emphasis was also placed on ways to address the need for accurate gestational age assessment, including making pregnancy test kits available in ANC to confirm pregnancy early before palpation is possible, ensuring the availability of ultrasound equipment in ANC, training ANC providers to use ultrasound technology for early assessment of fetal gestational age, and improving ANC provider competency to perform abdominal palpations and measure fundal height. Country representatives welcomed support for up-to-date technical briefs, training material, educational tools, and job aids.

Previous work on health system barriers to the uptake of ACS for preterm birth among 11 countries was implemented as part of the Every Newborn Action Plan process.<sup>10</sup> The countries included in the ACS health system bottlenecks analysis that overlapped with countries in this landscape analysis are the DRC, Malawi, Nigeria, and Uganda. Findings highlighted in this landscape analysis that were also prioritized in the bottlenecks analysis include the need for clear guidelines on ACS use, the inclusion of ACS for fetal lung maturation on essential medicines lists, improved provider competency in the use of ACS, and defining indicators to track and monitor the use of ACS.

## Study Limitations

Due to the limited time and resources available for this study, we interviewed 1 to 4 key informants in each country. We recognize that this is a small number of key informants; however, study participants were not intended to be a representative sample of perspectives but rather to serve as key informants to provide essential information on current national policy, including supporting government documents. The key informants were nominated by knowledgeable local and global content experts, providing a purposeful sample. Interviews may not be representative of all views, or even the dominant view.

In every case possible, we verified the key informant interview data using country-level documentation obtained in the desk review. Verification of key informant data was not possible for care practices or the quality of those practices, such as adequate preterm newborn care and childbirth care. For Sierra Leone, the national-level standard treatment guidelines and the updated essential medicines list were unavailable.

This landscape analysis focuses on public-sector services and does not reflect the implementation of ACS in private-sector health facilities in the 7 countries.

Inconsistencies existed between the raw data provided from the Countdown to 2015 reports,<sup>14,15</sup> the WHO survey on behalf of the UNCoLSC,<sup>16</sup> and the secondary data obtained through the desk review. The research team attempted to gain information on how the raw data were gathered and validated but was unable to gain clarification on the protocols used by the Countdown and WHO/UNCoLSC surveys.

**Most facilities providing ACS met comprehensive emergency obstetric and newborn care standards and all had some form of advanced newborn care or NICUs.**



## CONCLUSIONS

The goal for ACS as an intervention within national maternal and newborn health programs is to improve health outcomes related to preterm birth. There are benefits and risks to the use of ACS, and implementation in low-resource settings must ensure consistently available, high-quality maternal and newborn health services and interventions that are safe and effective and adhere to the principle of “first do no harm.” This analysis has identified crucial needs for the safe and effective use of ACS at service delivery points that must be addressed by national and local stakeholders, for example, providing guidelines and means for accurately assessing gestational age and guidance on how to determine if a woman is at risk of imminent preterm birth. Ideally, the information provided in this analysis and ensuing conversations will meaningfully add to the global and national exchange regarding the safe and effective expansion of ACS and, ultimately, inform comprehensive programming for improved preterm birth outcomes.

**Acknowledgments:** Many thanks to PATH for developing and administering the contract for this work. The authors would like to acknowledge and thank the key informants from each of the 7 participating UNCoLSC Pathfinder countries, including but not limited to: Dr. Laetitia Mavinga (DRC), Dr. Lisani Tadesse (Ethiopia), Mrs. Eneles Kachule (Malawi), Dr. Bose Adeniran (Nigeria), Dr. Alimamy Philip Koroma (Sierra Leone), Dr. Hussein Kidanto (Tanzania) and Dr. Jesca Nsungwa Sabiiti (Uganda). We would also like to thank Kate Kerber for her engagement in the design and review of the study framework and data collection tools and Lisa Hedman at WHO, Bennett Nemser at UNICEF, and Jane Briggs at Management Sciences for Health for sharing WHO, Countdown, and UNCoLSC data sets for our secondary data collection and analysis. Special acknowledgment goes to Barbara Rawlins and her team at the USAID-funded Maternal and Child Survival Program for working with us to extract information relevant to this study from their multi-country HMIS survey.

**Funding:** The USAID Bureau for Global Health, Office of Maternal and Child Health and Nutrition and the UNCoLSC Newborn Health technical reference team provided funding for this landscape analysis.

**Competing Interests:** None declared.

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## En français

### Corticostéroïdes anténatals chez les femmes présentant un risque de naissance prématurée imminente dans sept pays d'Afrique subsaharienne : Analyse des politiques et de leur mise en œuvre en contexte

Les pays ont mis en place certains éléments nécessaires à une utilisation efficace et sûre des corticostéroïdes anténatals (ACS), mais de nombreux défis demeurent, notamment : la garantie de la détermination de l'âge gestationnel, l'élaboration de directives claires en matière de traitement, le renforcement des capacités des prestataires, l'inclusion d'indications obstétriques pour l'utilisation des ACS dans les listes nationales de médicaments essentiels, ainsi que la collecte et l'utilisation de données liées aux ACS dans les systèmes de gestion des informations de santé (HMIS). Plus important encore, la qualité des soins prodigués aux mères et aux nouveau-nés, y compris les soins néonataux spécialisés, doit être améliorée afin de disposer d'une assise solide pour l'utilisation efficace et sûre des ACS.

## RÉSUMÉ

**Contexte :** Quinze millions de bébés environ naissent prématurément chaque année et près d'un million meurent à la suite de complications liées à une naissance prématurée. Il a été établi que les corticostéroïdes anténatals (ACS) peuvent être utilisés pour améliorer les issues associées à la naissance prématurée dans certaines conditions cliniques. Nous avons effectué une analyse des politiques et de leur mise en œuvre en contexte concernant l'utilisation des ACS chez les femmes présentant un risque de naissance prématurée dans sept pays à faible revenu.

**Méthodes :** Le cadre de l'étude et l'outil d'analyse de la situation ont été élaborés en se fondant sur les recommandations de l'Organisation mondiale de la Santé (OMS) relatives à l'utilisation des ACS chez les femmes présentant un risque de naissance prématurée. L'étude a été réalisée en République démocratique du Congo, en Éthiopie, au Malawi, au Nigeria, en Sierra-Leone, en Tanzanie et en Ouganda. Les données primaires ont été collectées au cours d'entretiens réalisés auprès d'informateurs clés. Les données secondaires ont été recueillies en se fondant sur les sources disponibles publiquement, une étude des indicateurs des systèmes de gestion des informations de santé et des données démographiques provenant des profils Every Premie-SCALE des différents pays relatives aux soins des bébés présentant une insuffisance pondérale à la naissance et à la prévention de celle-ci.

**Résultats :** Les 7 pays ont recours aux ACS pour les femmes présentant un risque de naissance prématurée imminente. La majorité des pays inclut un libellé spécifique à l'utilisation des ACS dans les protocoles cliniques ou les directives thérapeutiques standard. Toutefois, aucun pays n'inclut de référence à la mesure précise de l'âge gestationnel. Dans deux des cinq pays disposant de normes nationales en matière d'utilisation des ACS, la limite d'âge gestationnel supérieur applicable à l'utilisation des ACS excédait la recommandation de l'OMS qui est de 34 semaines. Il existe des lacunes dans les directives nationales sur la manière de déterminer si une femme court un risque de naissance prématurée imminente. Peu de pays précisent dans leurs directives que les ACS sont contre-indiqués dans le cas d'une infection. La majorité des pays ont indiqué que les établissements de soins fournissant des ACS satisfont aux normes en matière de soins néonataux et obstétricaux d'urgence complets. De même, tous les pays ont signalé la présence d'unités de soins néonataux spéciaux ou de soins intensifs pour nouveau-nés dans les établissements dispensant les ACS.

**Conclusions :** Les pays reconnaissent les défis que posent l'accès à des soins maternels et néonataux de haute qualité qui remplissent les conditions préalables requises en termes de soins cliniques pour permettre une utilisation efficace et sûre des ACS. Certains informateurs clés ont recommandé l'élaboration de directives cliniques et la formation des prestataires de service à l'utilisation des ACS, l'inclusion des indications obstétriques du dexaméthasone et du bétaméthasone dans les listes nationales de médicaments essentiels, la collecte et l'utilisation des données liées aux ACS, ainsi que l'amélioration de la qualité des soins maternels et néonataux, y compris les soins spécialisés prodigués aux nouveau-nés.

## Peer Reviewed

**Received:** May 15, 2018; **Accepted:** October 2, 2018; **First Published Online:** December 20, 2018

**Cite this article as:** Greensides D, Robb-McCord J, Noriega A, Litch JA. Antenatal corticosteroids for women at risk of imminent preterm birth in 7 sub-Saharan African countries: a policy and implementation landscape analysis. *Glob Health Sci Pract*. 2018;6(4):644-656. <https://doi.org/10.9745/GHSP-D-18-00171>

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## ORIGINAL ARTICLE

# Evolution of a Large-Scale Community-Based Contraceptive Distribution Program in Kinshasa, DRC Based on Process Evaluation

Julie H. Hernandez,<sup>a</sup> Pierre Z. Akilimali,<sup>b</sup> Mbadu Fidèle Muanda,<sup>c</sup> Annie L. Glover,<sup>a</sup> Jane T. Bertrand<sup>a</sup>

Midterm process evaluation results indicated that design and implementation failures hindered the program's success, notably: (1) the short-acting methods provided by community-based distributors (CBDs) offered limited choice; (2) the nominal revenue retained from selling the methods provided limited motivation for the volunteer CBDs; and (3) the model was poorly coordinated with the existing clinical service system, partly because of challenging systems issues. In the revised model, the CBDs will also provide subcutaneous injectables and emergency contraceptive pills, retain more revenue from contraceptive sales, and have better interaction with the existing system including conducting monthly mini-campaigns to increase visibility and attract more clients.

➔ *Résumé en français à la fin de l'article.*

## ABSTRACT

In a context where distance, user fees, and health staff shortages constitute significant barriers to accessing facility-based family planning services, the use of community-based distributors (CBDs) as counseling and contraceptive providers has been tested in several resource-constrained environments to increase family planning uptake. In the capital city of the Democratic Republic of the Congo (DRC), Kinshasa, a massive CBD program (AcQual) has been implemented since 2014, with lackluster results measured in terms of the low volume of contraceptives provided. A process evaluation conducted in 2017 assessed the fidelity of implementation of the program compared with the original AcQual design and analyzed gaps in provider training and motivation, contraceptive supplies, and reporting and monitoring processes. Its objective was to identify both theory and implementation failures in order to propose midcourse corrections for the program. The mixed-method data collection focused on the CBDs as a pivotal component of the AcQual program with 700 active CBDs interviewed. In addition, 10 in-depth interviews were conducted with clinical personnel, local health program managers, and project partners to identify gaps in the AcQual implementation environment. Issues with CBDs' performance, knowledge retention, and commitment to program activities, as well as gaps in contraceptive supply chains and insufficient monitoring and supervision processes, were the main implementation failures identified. Inappropriate method mix offered by the CBDs (condoms, pills, and CycleBeads only) and chronic overburdening of health care staff at the local level compounded these issues and explained the low volume of contraceptives provided through AcQual. Midcourse corrections included a more structured schedule of activities, stronger integration of CBDs with clinical providers and health zone managers, expansion of the mix of contraceptives offered to include subcutaneous injectables and emergency contraceptive pills, and clarifying reporting and monitoring responsibilities among all partners. Findings from this process evaluation contribute to the limited knowledge base regarding "unwelcome results" by examining all the intervention components and their relationships to highlight areas of potential failures, both in design and implementation, for similar CBD programs.

## BACKGROUND

Family planning need in the Democratic Republic of the Congo (DRC) and its capital, Kinshasa, are among the highest in the world. Despite the progress achieved since the country's commitment to the Family Planning (FP2020) initiative in 2012, average fertility rates are high (6.6 per woman, according to the 2013–2014 Demographic and Health Survey) and

<sup>a</sup>Global Health Management and Policy, Tulane University School of Public Health and Tropical Medicine, New Orleans, LA, USA.

<sup>b</sup>Kinshasa School of Public Health, University of Kinshasa, Kinshasa, Democratic Republic of the Congo.

<sup>c</sup>Programme National de Santé des Adolescents (PNSA), Kinshasa, Democratic Republic of the Congo.

Correspondence to Julie Hernandez (hernanjulie@gmail.com).

**The AcQual project design centered on community-based distributors providing condoms, pills, and CycleBeads in their communities at minimal cost to increase access to family planning.**

modern contraceptive prevalence remains low (7.8%).<sup>1</sup> In Kinshasa, the estimated unmet need for contraceptives among all women (i.e., the percentage of women who do not want another child for at least 2 years but are not currently using modern contraceptives) is 22.6%.<sup>2</sup> This figure has been partially attributed to the lack of access to quality health facilities that can provide family planning services to women living in Kinshasa. Distance to facilities, frequent stock-outs, costs, and overburdened health care staff are indeed key obstacles to health care access in the DRC.<sup>3,4</sup>

Based on service delivery mechanisms designed and tested since the 1970s in numerous sub-Saharan African countries,<sup>5</sup> including the DRC,<sup>6</sup> to expand access to family planning services, the AcQual (“Access and Quality”) project is a large-scale community-based contraceptive distribution program designed and implemented to address some of these gaps. Its ultimate objective is to increase contraceptive uptake in Kinshasa (and later in Kongo Central). AcQual 1 was initially launched in 27 of the 35 health zones in Kinshasa in February 2014, then expanded in 2016 as AcQual 2 to cover 33 health zones (and an additional 12 health zones in Kongo Central, not covered in this study). The purpose of this article is to present findings of a process evaluation of the AcQual model as it was implemented between 2014 and 2017. It also describes how the community-based distribution model was redesigned to address the findings from the process evaluation.

## ■ PROGRAM DESCRIPTION

### Context for Role and Deployment of CBDs in AcQual 1 and 2

Under AcQual, local health zone authorities recruited community-based distributors (CBDs) among volunteers who were often already involved in immunization or nutrition activities in their neighborhood. The only criteria for selection were neighborhood residence and completion of at least primary school. Two in-country implementing partners—the Association pour le Bien-Être Familial (ABEF), the International Planned Parenthood member affiliate in the DRC, and SANRU, a local faith-based organization involved in health care provision to marginalized Congolese communities since the 1980s—trained these individuals to provide family planning counseling and selected contraceptives (male condoms, oral contraceptive pills, and CycleBeads for use with the Standard Days

Method) to previous and new family planning users living in their communities. Family planning clients who wanted methods not provided by the CBDs or who were experiencing side effects could be referred to nurses, also trained under the AcQual program, at nearby health facilities. The Health Zone Central Office (Bureau Central de la Zone de Santé, or BCZS), as the operational branch of Ministry of Health (MOH) programs in the DRC, and AcQual implementing partners shared the responsibilities for contraceptive resupply, reporting, and supervision of the distribution activities.

The intervention design centered on the CBDs, with the assumption that their roots and capacity to circulate in their communities would decrease the barriers associated with distance to facilities. It was thought that cost issues would be limited by the absence of registration or prescription fees typically charged by facilities in the DRC and the heavily discounted price of the contraceptives provided by the CBDs. The CBDs’ familiarity with the community was seen as a stepping stone to recruit new modern contraceptive users who may otherwise have concerns about visiting a facility for family planning services. In addition, CBDs were encouraged to complete outreach activities (such as group discussions or canvassing), individual counseling, and referral to facilities, thus acting as a bridge to widen the pool of potential family planning users in their communities. However, because AcQual was designed to be integrated into the existing national health system of the DRC, to the extent possible, certain design choices had to be made to remain within the existing programmatic and policy boundaries. For example, in contrast to the situation in Ethiopia,<sup>7</sup> it was agreed that the MOH in the DRC could not realistically offer a salary to the CBDs (considering that they pay regular public health facility employees sporadically). Similarly, given that the CBDs were not clinically trained, the range of methods they could provide was limited to pills, condoms, and CycleBeads, since in the DRC only doctors and nurses are typically permitted to provide injectables, implants, and intrauterine devices. Finally, reporting tools were designed to match those already used in the National Health Information System to avoid duplicating efforts, and it was decided that health zone staff and nurses at referral facilities would receive a portion of the contraceptive sales to increase buy-in chances.



## Initial Non-Systematic Monitoring

In the spring of 2016, the AcQual 2 team launched a non-systematic monitoring effort involving BCZS and facility visits, informal interviews with a convenience sample of about 60 CBDs, and a review of routine statistics. (This internal evaluation process was not part of a research activity submitted for approval to Tulane's Institutional Review Board but emerged organically during routine field visits to the project sites in Kinshasa. AcQual partners invited all CBDs and nurses operating in the health zone to be present during these visits and similar questions were asked during each of these sessions.)

The internal review raised some concerns about the seemingly low quantities of contraceptives (converted to couple-years of protection or CYPs) provided by the project's CBDs and facilities. Comparisons with the success of other community-based delivery strategies implemented between 2015 and 2016 in the DRC, such as use of medical and nursing school students to provide the subcutaneous injectable depot medroxyprogesterone acetate (DMPA-SC), under the brand name Sayana Press,<sup>8</sup> further accentuated these concerns. The "focus group style" discussions with the CBDs about their experiences, motivations, and concerns with AcQual and the interviews with BCZS personnel supported a grounded theory approach to highlight several, non-mutually exclusive factors that could explain these lower-than-expected results for AcQual providers:

- The CBDs were not as active as initially expected.
- Frequent stock-outs may have resulted in reduced activity and missed opportunities for contraceptive provision.
- The CBDs may have distributed larger quantities of contraceptives that were underreported in AcQual monthly statistics.
- Some of the barriers to family planning use may not have been addressed adequately in the AcQual design.

## Design of the Formal Midterm Process Evaluation

To better understand the respective importance of these factors on the project's main objective to increase the modern contraceptive prevalence rate (mCPR) in Kinshasa and Kongo Central, the research team designed a midterm process evaluation. While midterm program evaluations often focus on measuring results obtained, without

trying to analyze the actual implementation of the intervention intended to produce those results, the study described in this article specifically examined how the different components of the program were implemented.

Although there are few existing formal guidelines for process evaluations,<sup>9</sup> the study framework typically proposes "to assess the quality, accuracy and fidelity to theoretical design and the relationships between the main program components."<sup>10</sup> This approach further enables program managers to clarify if unexpected or disappointing results are the product of "implementation" failure (the intervention design was appropriate, but the implementation was incorrectly or insufficiently conducted) or "theory" failure (the intervention was not adequately designed to address the issue).

The study examined the following components of the AcQual project design in terms of quality, accuracy, and fidelity:

- AcQual was designed to increase coverage of family planning services at the community level by deploying CBDs throughout Kinshasa.
- Once recruited, trained, and deployed, these CBDs had to be ready and able to provide quality family planning services to the populations living in their communities.
- The CBDs also needed to be continuously supplied with contraceptive methods to meet the needs and preferences of women living in their communities.
- CBDs and nurses at AcQual facilities had to be aware of the referral system and of their role in managing family planning clients counseled for clinical methods or management of side effects.
- Finally, ABEF and SANRU needed to properly monitor and supervise the CBDs to ensure that they received proper technical support, remained committed to AcQual activities, and reported routine service statistics in an accurate and timely manner.

The overall objective of the process evaluation was to identify gaps in the implementation of these components and/or unexpected responses to the intervention design from all actors involved, in order to formulate recommendations for mid-course corrections.

## METHODS

The process evaluation used a mixed-methods design involving both quantitative and qualitative

**An internal review 2 years into the project revealed low quantities of contraceptives provided by the community-based distributors.**

**A process evaluation was conducted to identify any potential implementation failures or design failures.**



data, and findings were triangulated through routine reports and project documentation review. Key process indicators to assess the effectiveness and fidelity of AcQual implementation were defined in terms of:

- Levels of activities of the CBDs
- Volume of CYPs provided
- Frequencies of stock-outs
- Completeness and timeliness of routine statistics reports
- Frequency and quality of supervision
- Overall community and facility providers' satisfaction and engagement with the project

Because the CBDs were such a crucial component of the AcQual program, assessing their characteristics, performance, commitment, and satisfaction with their role in AcQual activities was central to the process evaluation. The research team thus proceeded to obtain a complete listing of all CBDs trained by ABEF and SANRU since the start of the project (N=870) and to systematically interview all who were still declaring themselves active with AcQual and who agreed to participate in the study. The CBD questionnaires were designed to collect multiple factors that could influence the CBDs' performance in contraceptive delivery, including socio-demographic characteristics such as gender, age, education, matrimonial status, number of children, and employment status (as proxies for burden on CBDs' time), knowledge and competence as family planning service providers, values and attitudes toward family planning provision, and commitment to the AcQual project.

In addition, the research team interviewed the 73 nurses trained under AcQual to handle referrals to fixed health care facilities, as well as the Chief Medical Officers and Community Activity Coordinator from the managing offices of the 33 health zones where AcQual CBDs were operational.

All quantitative surveys were administered electronically using the smartphone-based application OpenDataKit (ODK) and submitted to a protected server where the data were aggregated and extracted by the research team in the United States. This process allowed for an extremely quick turnaround in the evaluation results: the study was fielded in April 2017 and the results were presented at a dissemination meeting in July 2017.

Survey data from CBDs and nurses were triangulated with systematic review of the monthly

reports available at the BCZS for the January–March 2017 period. Members of the research team visited each BCZS and documented the number of CBD monthly reports available compared with the number expected per AcQual reporting design (i.e., each CBD was expected to submit 2 reports every month, 1 report on services delivered and the other report on contraceptive stocks and flows).

Finally, the research team conducted 10 in-depth interviews with AcQual partners at the national level (MOH personnel and ABEF/SANRU representatives) and international level (UNFPA and DKT International, who were in charge of contraceptive supplies for the project).

Data collection for the process evaluation was approved by Tulane University Institutional Review Board (1029926-OTH) as well as by the Ethics Committee of the Kinshasa School of Public Health (#ESP/CE/014/2017).

## ■ RESULTS

Of the 870 CBDs trained by AcQual partners since February 2014, 105 (12.1%) were no longer active (including 88 lost to follow-up and 7 deceased), 65 (7.5%) were still active but refused to be interviewed, and 700 (80.5%) declared they were still active and consented to be interviewed.

Overall, the number of days worked and CYPs distributed by active CBDs based on recall for the last month were low. CBDs declared “doing something related to the AcQual project” on average 8 days per month. When asked for the quantities of each contraceptive they remembered distributing over the past month, the mean quantity of CYPs provided amounted to 3.8, with a median of 1.3 (less than 1 set of CycleBeads per month). In addition, a quarter (25.3%) of the CBDs declared having distributed no contraceptives at all in the previous month.

The following findings break down the dimensions of AcQual 2 implementation that were believed to be crucial for CBDs to provide high quantities of contraceptives and quality family planning services at the community level, and they identify gaps in both model design and implementation.

### Adequate Coverage for Family Planning Service Provision

AcQual trained and deployed 3 CBDs per health area in 303 of the 381 (73.5%) health areas of the city. The project also trained an additional

**The project trained and deployed 3 community-based distributors per health area in nearly three-quarters of Kinshasa's health areas.**

73 nurses at referral facilities (2.2 per health zone on average). Thus, AcQual reached its stated objective to cover at least 70% of all health areas in Kinshasa. Based on population data provided by the Congo National Institute of Statistics, the average number of CBDs was 12.1 per 100,000 people at the health zone level (with a median of 9.3).

### Inadequate Readiness to Provide Quality Family Planning Services

All CBDs had been recruited and were operating in their own neighborhood and, following AcQual design, almost all (99.3%) had completed at least primary school, with 70.7% having completed high school or higher education levels. More than half (57.1%) were unemployed and one-third (33.8%) were already involved as community health workers for other programs. The average age of the AcQual CBDs was 45.9 years old, with 82.4% of them being over 35 years old. When asked about their main motivation to volunteer in AcQual, 42.1% of the CBDs expressed a desire to “help their community,” while 33.8% indicated that they were already involved in health outreach activities and 22.9% said they wanted to acquire new competences. Less than 1% initially mentioned money as a motivator.

The CBDs gave unanimously positive reviews to the training they received. However, results from the 15-question family planning knowledge test included in the questionnaire were mediocre, with 32% of the CBDs scoring below average and between a quarter and a third holding incorrect information for pregnancy screening, CycleBeads use, and medical eligibility for the pill. Compounding these poor knowledge levels, personal values (approximated by level of comfort in providing contraceptives to certain populations) may have hindered their level of activity: while 96.1% and 84.4% of the CBDs declared being “somewhat or very comfortable” with providing contraceptives to men and unmarried women, respectively, a quarter of them (23.4%) felt “somewhat or very uncomfortable” selling contraceptives to youth under 18 and almost half (47.4%) declared being “somewhat or very uncomfortable” providing family planning services to youth under 15. (Considering that this question has a strong desirability bias, the actual figures may possibly be higher.) Overall, 78.3% of the CBDs would have liked a refresher training, particularly on how to recruit new acceptors and how to refer women to facilities for management of side effects.

### Recurring Stock-Outs

Contraceptive stock-outs were one of the most prevalent issues reported by the CBDs. More than three-quarters (77.3%) had experienced at least 1 stock-out since the beginning of the project, with 75.4% stating that they were “sometimes or often” stocked out of condoms, and about half declaring being “sometimes or often” stocked out of pills (48.2%) and CycleBeads (46.2%) (Table 1). In addition, only 46.7% of the CBDs reported currently having at least one family planning counseling material (e.g., flyers, print job aids).

The relatively rarer occurrence of stock-outs for pills and CycleBeads could be indicative of a lower demand for these types of contraceptives, a hypothesis compounded by CBDs’ perception of women’s preferences in their community. According to them, less than a quarter of all women would prefer to use CycleBeads (23.6%), the pill (21.7%), or condoms (18.9%) as their main contraceptive method. The perceptions of the CBDs are consistent with results from recent population surveys that show higher levels of use of implants, injectables, and emergency contraception.<sup>2</sup> Qualitative data extracted from the CBD interviews indicated their frustration with their inability to offer these methods, which can be delivered in the DRC only by medically trained health care staff.<sup>7</sup>

### Weak Interaction With Clinical Services

The reported disconnect between the methods provided by the CBDs and the existing demand from potential family planning users could have been corrected within the AcQual project design, as long as the referral system to AcQual health facilities was operational and effective. The majority of CBDs (89.8%) stated that they had referred “some” or “several” women to a health structure since the beginning of the project, with 71.1% indicating they referred women to the facility designated by AcQual partners during the training. In the majority of cases, women were referred because they wanted a method not provided by the CBD (Table 2). The second most frequently cited referral reason, mentioned by 29.9% of CBDs, was management of side effects.

Only half of the nurses (54.7%) could identify “all or most” of the CBDs operating in their health zone. But a higher percentage (62.8%) stated that they interacted between once a week and once a month with some CBDs in their health zone, which may indicate that nurses tend to always interact with the same individuals, while others remain under their radar.

**Contraceptive stock-outs were one of the most prevalent issues reported by the community-based distributors.**

**In the majority of referral cases, community-based distributors reported that women were referred because women wanted a method they could not provide themselves.**

**TABLE 1.** Contraceptive Stock-Outs and Resupplies Reported by CBDs, Kinshasa, DRC, 2014–2017

	Condoms	COCs	POPs	CycleBeads
Stocked out often	41.4%	20.3%	22.7%	24.2%
Stocked out sometimes	34.0%	30.3%	23.1%	22.6%
Stocked out once	10.0%	13.1%	11.3%	13.7%
Never stocked out	14.6%	36.2%	42.9%	39.6%
Reported the stock-out	81.3%			
Resupplied	74.9%	70.4%	58.3%	57.2%

Abbreviations: CBDs, community-based distributors; COCs, combined oral contraceptives; DRC, Democratic Republic of the Congo; POPs, progestin-only pills.

Overall, the work of CBDs was perceived as mutually beneficial (by 96.6% of the CBDs and 87.1% of the nurses). Among the 7.1% of referral nurses holding “very negative” opinions of the work of CBDs, most were concerned with clinical errors made by CBDs in administering contraceptive methods and deceitful attitudes of CBDs who, as one nurse described, “present themselves as ‘doctors’ when they have not received adequate training.”

### Weak Support and Supervision of Community-Based Distributors

For AcQual to reach its stated objectives, the project needed to monitor and supervise CBD activities for the purpose of providing adequate technical support, ensuring CBD retention and motivation, limiting contraceptive stock-outs, and ensuring the completeness and timeliness of routine service statistics monitoring. The latter was another weak point of AcQual implementation with only 32.5% of the monthly reports being available at the BCZS for the January–March 2017 period. Only 48.4% of the CBDs were aware that there were 2 forms to be completed each month (one for family planning services and the other for contraceptive stocks, following the formats and requirements of the National Health Information System in the DRC), and 46.9% reported difficulties in completing and transmitting their reports to the BCZS each month. The main reasons mentioned for this situation were the absence of clients (21.2%) and the lack of time to complete (14.4%) or deliver (15.4%) the report to the BCZS. With 93.8% of the CBDs reporting in hard copy, distance and transportation costs, especially in the vast semi-rural health zones at Kinshasa’s periphery, were significant barriers to routine statistics transmission.

Conversely, 55.4% of the CBDs declared being out of blank forms to complete future reports. The BCZS staff interviewed during the evaluation pointed out that some of these statistics might be purposefully underreported since the CBDs are supposed to share the profits from contraceptive sales with both the BCZS and the AcQual partners. This situation might explain why 34.9% of the BCZS staff declared that the CBDs “rarely” or “never” reported their contraceptive sales.

In addition, while the CBD overall declared being “satisfied” or “very satisfied” (27.8% and 63.2%, respectively) of their relationship with the BCZS, the reported interaction between them seemed to vary significantly from one health zone to the next. The large majority (82.3%) of the CBDs declared attending at least one monitoring meeting at the BCZS, but just over half (56.9%) of BCZS staff did not know how many of these meetings were held over the past 6 months. In addition, 1 in 6 BCZS staff indicated that no monitoring meetings had been organized and only 4.6% declared that all 6 monthly meetings took place as planned under AcQual guidelines. At the next level of supervision (AcQual implementing partners, ABEF and SANRU), only a third (36.6%) of the CBDs recalled ever interacting with staff from these organizations after the training phase was completed. The numbers were higher for BCZS staff (83.3%), who would normally be visited by ABEF/SANRU at least once a month to provide service statistics reports and manage contraceptive resupply. However, when asked about the support they received from AcQual partners, 12.1% of the BCZS staff declared that it was “not very good” and 21.2% said that it was “not good at all.”

The overall perception of the project by its main implementing partners remained positive

**TABLE 2.** Assessment of the AcQual Referral System by CBDs and Facility-Based Nurses, Kinshasa, DRC, 2017

	CBDs	Nurses
Can identify counterpart in referral system	88.4%	54.7%
Frequency of interactions between CBDs and referral facilities		
Often	13.7%	31.4%
Sometimes	34.3%	31.4%
Rarely	42.6%	8.6%
Never	7.3%	27.1%
Reasons for referral to facilities		
Method not provided by CBD	83.9%	67.1%
Management of side effects	29.9%	40.0%
Preference for health facilities	11.3%	22.9%
Method provided by CBD but stocked out	9.1%	17.1%
Implants/IUD removal	—	21.4%
Other	7.4%	—
Does not know	3.3%	—
Perceived approval of CBD activities by health facility personnel		
Very positive	96.6%	70.0%
Somewhat positive		17.1%
Somewhat negative	2.1%	0.0%
Very negative		7.1%
Does not know	1.2%	5.7%

Abbreviations: CBD, community-based distributor; DRC, Democratic Republic of the Congo; IUD, intrauterine device.

with 78.4% of the BCZS staff and 97.2% of the CBDs declaring being “satisfied” or “very satisfied” with their AcQual experience. However, qualitative comments at the end of both surveys listed recurring complaints about lack of adequate support and incentives. Multiple CBDs complained that:

*[We] are asked to perform a very difficult job almost pro bono. [...] We don't have equipment, like rain boots and umbrella, we don't get much contraceptives and we don't have a salary or enough recognition to motivate us. [...] Even just one of these things would improve our work. [...] We also need new people to be involved. It's been three years for us and sometimes it feels like AcQual abandoned us a little.*

## DISCUSSION AND RESULTING CHANGES TO THE ACQUAL MODEL

A recent article published in the *Lancet*, “A call for transparency in the evaluation of global maternal

health projects,”<sup>11</sup> pointed out “the incongruity between successes—invariably reported at discrete program level—and the collective lack of progress in global maternal mortality” and suggested that underreporting of “unwelcome findings” in project evaluations might be partially responsible for this discrepancy. The findings presented in this article highlight both unwelcome “theory failures” and “implementation failures” that have hindered AcQual success in increasing access to quality family planning services at the community level.

The results specifically pointed toward 2 types of issues: (1) gaps specific to AcQual design or implementation that were not anticipated or controlled for when the project started, and (2) systemic issues related to the DRC health care delivery system that would require a broader, multipronged approach beyond the scope of AcQual to improve upon.

Considering the large body of existing literature on community health workers,<sup>12–15</sup> some of the evaluation findings were not particularly



surprising (e.g., lack of long-term commitment of volunteers, non-paid CBDs and their poor integration with health facilities). However, at the time it was initiated, AcQual was the first CBD program implemented in Kinshasa after a 20-year hiatus, and it was designed in close collaboration with the MOH, with the ultimate objective to become part of the national family planning service delivery system. Some of the project features were thus selected to avoid further burdening an already resource-constrained health system but were not always capable of compensating existing gaps.

Crucially, the initial assumption that the percentage of contraceptive sales going to the CBD would be a sufficient motivation to compensate their “volunteer” status and for them to be proactive in family planning service provision in their community was undermined by the purposefully low price of the contraceptives, along with the absence of incentives to report service statistics. In many cases, the benefits received from the monthly contraceptive sales could not cover the costs of public transportation for CBDs to attend monitoring meetings at the health zone office. Competing interests also compounded this situation since the CBDs are also often serving as health extension workers for other projects (e.g., immunization or HIV/AIDS prevention) that remunerate them directly.

In addition, existing medical norms in the DRC de facto limited the range of methods offered by AcQual CBDs, which did not match women’s preferences for mid- to long-acting reversible methods such as injectables and implants. CBDs and other AcQual partners further perceived this as a missed opportunity since the higher retail price of these contraceptives could have supported a stronger commitment of the CBDs to community provision.

Finally, the routine provision model encouraging CBDs to provide contraceptives “whenever they had an occasion in the course of their daily lives in the community” proved haphazard in practice, in terms of unequal levels of CBD activities and gaps in the contraceptive resupply and reporting chains. In this regard, the process evaluation also provided evidence for all AcQual partners to acknowledge and discuss necessary organizational changes, including the identification and replacement of unproductive CBDs, the retraining of active CBDs (including value clarifications for family planning service provision to specific segments of the population such as youth and unmarried women), the formalization of reporting chains and supervision responsibilities

from the BCZS to the AcQual managerial team at Tulane International, and the reallocation of budget items to increase coverage for monitoring and supervision activities.

### AcQual 3 Redesign

More crucially, findings from the process evaluation informed design and implementation changes that led to a revised CBD model (AcQual 3) to be implemented in Kinshasa and Kongo Central in 2019–2021. In particular, CBDs are now organized into a more rigorous family planning service provision schedule around monthly mini-campaign events known as *Samedi PF* (“Family Planning Saturday”), which brings AcQual 3 closer to the campaign days/advanced provision strategies implemented by national and international partners in the DRC as their main strategy for community-based contraceptive provision. The *Samedi PF* are expected to create a focal event that will help engage CBDs by gathering several community-based providers in one location (typically a market place) and thus potentially attract more clients. Moreover, these events will increase CBDs’ visibility in the community by introducing them as local resources for family planning counseling and methods and provide them with an opportunity to report their service statistics, obtain contraceptives resupplies, and receive supervision without additional transportation costs.

In addition, the revenue from contraceptive sales is now going entirely to the CBDs to create a stronger financial incentive to participate in AcQual activities. This change should be complemented by the expansion of the method mix offered by CBDs, which in AcQual 3 will include DMPA-SC (Sayana Press) and emergency contraceptive pills, both in high demand and retailed at higher prices than other community-level methods. The addition of these 2 methods to the CBDs’ method mix stems from separate Tulane-led research outlining the opportunities for community-based provision of these methods,<sup>16,17</sup> and illustrate how pilot studies and operational research (such as this process evaluation) can be leveraged to improve program design and implementation.<sup>18</sup>

However, some of the challenges identified in the midterm evaluation are partially beyond the scope of a single project such as AcQual. Chronic shortages and gaps in the contraceptive supply chain are a recurring issue in the DRC, particularly with the increase in demand for contraception

**The short-acting methods that the community-based distributors could provide did not match women’s preferences for mid- to long-acting reversible methods.**

**In the revised project model, the method mix offered by community-based distributors has been expanded to include subcutaneous injectables and emergency contraceptive pills.**



over the past few years. Facility and community-based health workers tend to be overburdened by health care duties and multiple demands on their time for reporting project and program data.<sup>19</sup> Despite the efforts engaged to closely integrate AcQual activities to public health programs implemented at the health zone level (e.g., relying on the BCZS for CBD recruitment, involving the MOH in their training, using standard forms for service statistics reporting), the project's activities, contraceptive resupply protocols, and reporting demands created redundancies and competing demands on health staff's already limited time and energy. Future efforts and modifications to the AcQual approach should address "increasing government ownership and leadership, limiting external inputs, and institutionalizing interventions within existing structures."<sup>20</sup>

## Limitations

The existing literature on process evaluations converges on the absence of a systematic framework<sup>9,10</sup> and the overwhelming and possibly redundant amount of information they tend to generate. This study focused on comparing the actual performance of the program to the model of how it was expected to function. In doing so, the research team measured fidelity to design and the providers' readiness to serve, perceptions, and level of satisfaction but did not capture other dimensions that process evaluation may capture such as client exposure and satisfaction.

Moreover, the lack of data on the performance of each individual CBD (measured by volume of contraceptive distributed) forced the research team to rely on ad hoc quantitative indicators created for this evaluation (number of days worked, volume of methods provided, and knowledge score) based on recall data provided by the CBDs themselves, which may be biased either toward overreporting (desirability bias) or underreporting (if they believed this would lead to more direct support or if they did not report sales to keep the benefits) their contraceptive distribution activities. The very gaps recorded in the reporting and supervision of family planning service provision may also be contributing to this perceived poor performance of the CBDs.

In addition, the focus on CYPs as a measure of AcQual successful implementation ignores dimensions of service quality (screening of family planning clients and adequate counseling) that are crucial not only to method adoption but also to long-term use.

Finally, this focus on CYPs may be overlooking other important aspects of the CBDs' work to

promote access to contraceptives (e.g., outreach, individual counseling) and increase knowledge of, and demand for, family planning services in the community.

## CONCLUSION

The family planning supply environment in Kinshasa has been evolving rapidly since 2012.<sup>21–23</sup> Multiple national and international partners now overlap, and sometimes compete for, contraceptive delivery using diverse pricing strategies, intervention scales, and clinical or community service points. As a result, the attribution of the slow but steady increase in mCPR in Kinshasa to a specific project or program is impossible, and AcQual is no exception. However, the preference given to a process evaluation for the project, and the presentation of its results to all family planning partners operating in Kinshasa in July 2017, offered an opportunity to isolate and assess intervention components that may be shared by other projects and programs (e.g., use of different cadres of community health workers, social marketing approach of contraceptive pricing) and to clarify their interaction and identify environmental factors and responses associated with variation in the project outcomes.

In the case of AcQual 2, in addition to systemic gaps in the DRC health care system, both theory failures (inappropriate method mix and inadequate incentive scheme to maintain CBDs' commitment) and implementation failures (contraceptive logistics gaps and insufficient monitoring and supervision of CBDs' activities) were responsible for the poor outcomes in terms of CYPs provided. Once these failures were identified, Tulane and its partners used the evaluation's findings to inform key design and implementation changes to the model, now AcQual 3, which is currently under implementation in the DRC (2019–2021).

While there are now growing concerns over scaling up and sustainability of community-based family planning provision models in resource-constrained environments, process evaluations such as the one presented in this article are an important contribution. They highlight how scientific evidence, donor strategies, and national or local situations inform initial design choices, which after field testing may prove inadequate. Innovation and lessons shared from other projects can help correct some of the identified gaps. However, the realistic integration of these models to existing national health systems (beyond the successful piloting of self-contained and resource-intensive projects),

requires inventive compromises between strengthening the most effective components of the model and adapting to chronic failures of these systems.

**Acknowledgments:** The authors are grateful to the David and Lucile Packard Foundation for support of the work described in this article. In particular, we recognize Tamara Kreinin, Coley Gray, Kristina Kastler, and Amy Iftekhar.

**Funding:** David and Lucile Packard Foundation (Grant # 2017/65766).

**Competing Interests:** None declared.

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## En français

### Évolution d'un programme à large échelle de distribution à base communautaire de contraceptifs à Kinshasa, RDC, sur la base d'une évaluation de processus

Les résultats de l'évaluation de processus à mi-parcours ont indiqué que des lacunes dans la conception et la mise en œuvre du programme ont limité sa réussite, en particulier : (1) les méthodes à courte durée d'action offertes par des distributeurs à base communautaire (DBC) ne représentaient qu'un choix limité ; (2) le revenu symbolique tiré de la vente des méthodes n'étaient pas suffisant pour motiver les DBC volontaires ; et (3) le modèle était mal coordonné avec l'offre de services cliniques existante, partiellement à cause des challenges posés par le système sanitaire. Dans le modèle révisé, les DBC fourniront également des contraceptifs injectables sous-cutanés et des pilules contraceptives d'urgence, recevront un meilleur revenu de la vente des contraceptifs, et leurs activités seront mieux intégrées avec le système sanitaire, y compris par le biais de mini-campagnes mensuelles qui permettront d'accroître leur visibilité et d'attirer potentiellement plus de client(e)s.

## RÉSUMÉ

Dans un contexte où l'éloignement, les frais cliniques, et les ressources humaines limitées constituent des barrières significatives à l'accès des services de planification familiale dans les structures de santé, l'utilisation de distributeurs à base communautaire (DBC) comme prestataires de conseils et de contraceptifs a été testée dans plusieurs environnements dont les ressources sont limitées, afin d'accroître l'adoption de la planification familiale. Dans la capitale de la République Démocratique du Congo (RDC), Kinshasa, un large programme de DBC (AcQual) a été mis en œuvre depuis 2014, avec des résultats médiocres en termes des volumes de contraceptifs fournis. Une évaluation de processus menée en 2017 a mesuré la fidélité de la mise en œuvre du programme par comparaison avec le design original d'AcQual et a analysé les lacunes concernant la formation et la motivation des prestataires, l'approvisionnement en contraceptifs, et les processus de supervision et de rapportage. L'objectif de l'évaluation était d'identifier les échecs de conception comme de mise en œuvre du programme afin de proposer des corrections à mi-parcours. La méthode mixte de collecte des données s'est concentrée sur les DBC, dans la mesure où ils sont une composante centrale du programme AcQual, et 700 DBC actifs ont été interviewés. De plus, 10 entretiens en profondeur ont été menés avec les personnels cliniques, les gestionnaires des programmes de santé locaux, et les partenaires du projet afin d'identifier les lacunes organisationnelles pesant sur la mise en œuvre d'AcQual. Les principaux problèmes identifiés avaient à voir avec les performances des DBC, leur niveau de connaissance, et leur implication auprès des activités du programmes, ainsi qu'avec des lacunes dans les chaînes d'approvisionnement en contraceptifs et des insuffisances dans les processus de supervision et de rapportage. La gamme contraceptive proposée par les DBC (limitée aux préservatifs, pilules et colliers du cycle) s'est révélée inadéquate et la surcharge de travail chronique pesant sur le personnel de santé au niveau local a aggravé ces problèmes tout en expliquant les faibles volumes de contraceptifs fournis par l'intermédiaire d'AcQual. Les corrections à mi-parcours incluent un calendrier plus structuré des activités, une meilleure intégration des DBC avec les prestataires cliniques et les responsables des zones de santé, une expansion de la gamme des contraceptifs offerts, qui inclue désormais les injectables sous-cutanés et les pilules contraceptives d'urgence, et une clarification des responsabilités de supervision et de rapportage parmi les partenaires. Les conclusions de cette évaluation de processus contribuent à la base limitée des connaissances sur les « résultats malvenus » en examinant l'ensemble des composantes de l'intervention et leurs relations pour mettre en évidence les zones d'échecs potentiels, en matière de conception comme de mise en œuvre, pour des programmes similaires de DBC.

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## Peer Reviewed

**Received:** June 1, 2018; **Accepted:** November 24, 2018

**Cite this article as:** Hernandez JH, Akilimali PZ, Muanda MF, Glover AL, Bertrand JT. Evolution of a large-scale community-based contraceptive distribution program in Kinshasa, DRC based on process evaluation. *Glob Health Sci Pract*. 2018;6(4):657-667. <https://doi.org/10.9745/GHSP-D-18-00205>

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## ORIGINAL ARTICLE

# Unpacking the “Black Box”: How an SMS-Based Continuing Medical Education Intervention Improved Medical Knowledge Among HIV Clinicians in Vietnam

Maia R. Nofal,<sup>a\*</sup> Nafisa Halim,<sup>a\*</sup> Bao Ngoc Le,<sup>b</sup> Lora L. Sabin,<sup>a</sup> Anna Larson Williams,<sup>a</sup> Rachael Bonawitz,<sup>a</sup> Ha Viet Nguyen,<sup>b</sup> Tam Thi Thanh Nguyen,<sup>c</sup> Christopher J. Gill<sup>a</sup>

Daily SMS quizzes sent to medical practitioners seem to act as a stimulus for further self-study when paired with access to additional readings and online courses, improving medical knowledge as a result.

## ABSTRACT

**Background:** A mobile-based continuing medical education (mCME) intervention implemented over 6 months between 2016 and 2017, consisting of daily SMS multiple choice quizzes and access to online daily readings and CME courses, was shown to be effective in increasing medical knowledge among HIV providers in Vietnam. We hypothesized this improvement was a result of “lateral learning,” a process in which the daily SMS quizzes acted as a stimulus for interacting with other study materials.

**Methods:** We explored how study materials directly provided by the intervention—the daily readings and the online CME courses—and independent study behaviors, such as using medical textbooks and reviewing national guidelines, contributed to medical knowledge as measured by baseline and endline exams. At baseline, there were 53 participants each in the intervention and control groups (N=106). Using linear regression models, we estimated the association between intervention-prompted and independent study behaviors and endline test scores. We also conducted a series of interaction analyses to test the extent to which the effect of daily quiz performance on endline test scores depended on use of the intervention-prompted or independent study materials. Finally, we estimated the proportion of variance in endline test scores explained by each of the intervention-prompted behaviors.

**Results:** The average medical knowledge test score among all participants was 46% at baseline and 54% at endline. Among the intervention group, 82% of the daily quizzes were answered, although only about half were answered correctly. Responding to the daily quizzes ( $\beta=0.24$ ;  $P=.05$ ), quiz performance ( $\beta=0.42$ ;  $P<.001$ ), and accessing daily readings ( $\beta=0.22$ ;  $P=.06$ ) were statistically significantly associated with higher endline test scores. While accessing the online CME courses and some of the independent study behaviors, such as use of medical textbooks, had positive associations with endline test scores, none reached statistical significance. Quiz performance explained 51% of the variation in endline test scores. Interaction analysis found that quiz performance had a stronger, but not statistically significant, association with endline test scores when both daily readings ( $\beta=0.87$ ;  $P=.08$ ) and online CME courses ( $\beta=0.25$ ;  $P=.09$ ) were accessed more frequently.

**Conclusion:** In mCME interventions, daily SMS quizzes can effectively act as a stimulus for uptake of study behaviors when paired with access to relevant readings and online courses. While further investigation is needed to more fully understand the role of outside study materials, we believe this model has the potential for further use in Vietnam and other low-resource settings.

## INTRODUCTION

In 2009, the Vietnamese government passed a law requiring medical practitioners to participate in continuing medical education (CME) to maintain their licensure.<sup>1,2</sup> Given the costs and complexity of tradi-

tional in-person CME workshops, the Vietnamese Ministry of Health (MOH) selected distance learning as the optimal strategy for supporting the quality of its clinical workforce.<sup>3–6</sup>

Between 2014 and 2017, in partnership with the Vietnamese MOH and Hanoi Medical University, we developed, tested, evaluated, and refined a mobile CME (mCME) intervention using short message service (SMS) to improve the medical knowledge of clinicians in Vietnam.<sup>7,8</sup> In the final iteration of the intervention (mCME version 2.0), conducted over a 6-month period between 2016 and 2017, the intervention group

<sup>a</sup> Department of Global Health, Boston University School of Public Health, Boston, MA, USA.

<sup>b</sup> Consulting, Researching Community Development (CRCD), Hanoi, Vietnam.

<sup>c</sup> Center for Population Research Information and Databases (CPRID), General Office for Population and Family Planning, Ministry of Health, Hanoi, Vietnam.

\* Contributed equally.

Correspondence to Nafisa Halim (nhalim@bu.edu).



received an SMS with a multiple choice question once daily along with a reply congratulating for correct answers or encouraging better luck next time while providing the correct answer. In all cases, the intervention group received a daily hyperlink to technical readings related to the quiz question, typically 13 paragraphs in length, and invitations to participate in online CME courses hosted by Hanoi Medical University. The control group received a weekly SMS without any medical content that simply reminded them that they were a study participant, and did not receive the links to daily readings or invitations to take the CME courses. However, both the intervention and control group were introduced to the online CME courses at baseline, were given access to the courses, and were encouraged to take them on their own schedule. At the end of the experiment, intervention participants significantly outperformed the controls on the endline examination.<sup>9</sup>

We theorized that the intervention group’s SMS messages served as stimuli to motivate broader learning, a process that we called “lateral learning,” but that is arguably a pedagogical adaptation of the Health Belief Model.<sup>10,11</sup> The Health Belief Model posits that individuals are likely to change behavior if they believe that they are self-efficacious or that they can successfully complete the behavior of interest despite barriers.<sup>12</sup> Individuals’ self-efficacy is a by-product of 4 factors: the individuals’ perception that they are susceptible to a condition (perceived susceptibility), which could have severe consequences (perceived severity), and the individuals’ belief that the behavior of interest would lead to more benefits (perceived benefits) than costs (perceived barriers).<sup>12,13</sup> Also, the model talks about cues to action, which are referred to as those factors that serve to stimulate or prompt behaviors.<sup>14</sup> Cues to action set in motion the process of behavior change, and without any cues, an individual may delay a behavior change despite perceptions of susceptibility, severity, and benefits outweighing barriers.<sup>14</sup>

The goal of this analysis was to better understand how the different components of the mCME version 2.0 intervention, alone or in combination, contributed to medical knowledge gains—in other words, unpacking the “black box” (Figure). Specifically, we addressed the following questions:

1. Did the mCME version 2.0 intervention improve the endline exam scores by encouraging uptake of intervention-prompted study behaviors?
2. Did the mCME version 2.0 intervention improve the endline exam scores by encouraging uptake of independent study behaviors outside of those directly prompted by the intervention?

## METHODS

### Study Design Overview

Full details of the mCME methodology have been published previously.<sup>8,9</sup> The intervention, conducted over a 6-month period between 2016 and 2017, consisted of sets of daily SMS quiz questions, linked readings, and invitations to participate in online CME courses on the same topics, clustered thematically into 15 modules covering a range of clinical topics in clinical HIV/AIDS care. The daily SMS quiz questions were developed in English, which were then translated into Vietnamese for delivery. All other intervention components were developed and delivered in Vietnamese. The control group had access to the online CME courses but did not receive the daily SMS quizzes or other messages encouraging self-study. In total, 106 HIV clinicians participated in the study (n=53 in the intervention group, n=53 in the control group).

### Data, Measures, and Variables

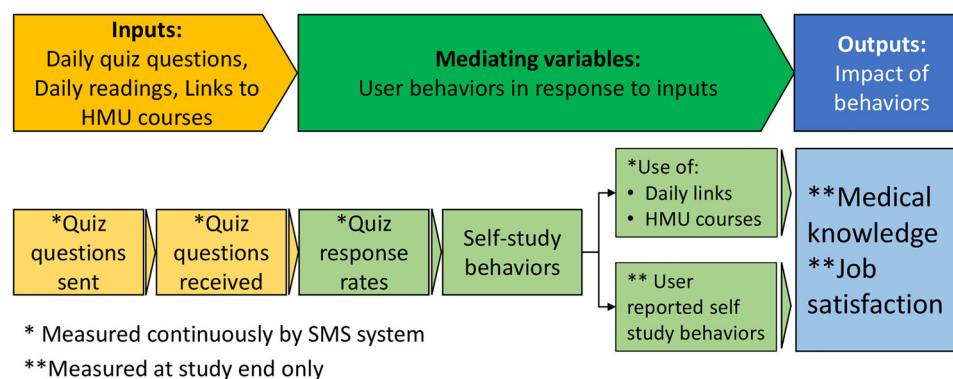
*Outcome variables:* Our outcome variable was HIV knowledge at the endline examination. We measured HIV knowledge through a 100-item standardized, multiple choice test focused on aspects of HIV care covered in the 15 online CME courses.

*Intervention-prompted behaviors:* Data were captured in real time on participants’ use of the daily quizzes; their performance on the daily quizzes; access of the daily hyperlinked readings; and access of the online CME courses.

*Independent study behaviors:* Outside of using the study materials directly provided through the intervention, we were interested in how the intervention affected the uptake of additional study materials. We defined the use of these study materials as “independent study behaviors.” These were behaviors that were not directly encouraged by the intervention but may have had a significant impact on the participants’ endline score. To assess this, we collected self-study behaviors via a survey administered at the endline evaluation. This survey assessed levels of engagement (4 or more times/week; 1–3 times/week; 1–3 times/month; <1 time/month) and changes (more, less,

**In an mCME intervention, we theorized medical quizzes sent via SMS to clinicians served as stimuli to motivate broader learning, a process we called lateral learning.**



**FIGURE.** Logic Model of Lateral Learning for the mCME Intervention in Vietnam

Abbreviations: HMU, Hanoi Medical University; mCME, mobile continuing medical education; SMS, short message service.

The mCME intervention implemented in Vietnam was hypothesized to function as a pedagogical analog to the Health Belief Model. In the intervention, the stimuli were the daily text messages and the desired initial outputs were a change in self-study behaviors, which were also a hypothesized mediator of acquired medical knowledge. As in the Health Belief Model, the potency of the stimuli were contingent on the willingness of a given individual to respond by investing their time and energy to self-study.

or the same, compared with before the mCME study) pertinent to 6 types of study habits:

1. Using medical textbooks.
2. Consulting with colleagues.
3. Researching information online using Google or another web browser to refresh clinical knowledge.
4. Using websites developed specifically for medical professionals.
5. Reviewing the official guidelines for HIV practice issued by the Vietnamese MOH.
6. Reviewing scientific research papers from the medical literature.

*Control variables* included baseline exam scores on the HIV knowledge examination and a number of sociodemographic attributes. Similar to the endline exam, baseline exam scores were based on a multiple choice test of medical knowledge. While the baseline and endline exams covered the same 15 thematic areas covered in the online CME courses, the exam questions were not repeated. Further, we adjusted for participants' gender and age collected via self-report at baseline. Gender was measured as a binary variable with female as the reference category, and age was measured as a continuous variable.

## Data Analysis

Attempting to answer our 2 research questions, we estimated the extent to which endline test scores

were associated with intervention-prompted and independent study behaviors. All regression models were adjusted for gender, age, years of experience in HIV-care provision, and baseline test scores. The sample size included in the analysis depended on whether the endpoint pertained to the full cohort (intervention and control participants, N=106), or solely the intervention group at baseline (n=53) or the intervention group retained at endline (n=48).

To answer our first question, how the 4 components of the intervention (SMS quizzes, quiz performance, daily readings, and online CME courses), affected gains in medical knowledge, we fit 6 adjusted linear regression models to estimate the association between intervention-prompted behaviors and endline test scores, one model for each of the 4 intervention-prompted behaviors and 2 models for all 4 together. To address our second question, how the intervention affected independent study behaviors in order to affect gains in medical knowledge, we fit 4 adjusted linear regression models, 2 to test the independent study behaviors as effect mediators and 2 to test the differential effects of independent study behaviors by intervention status.

Finally, we conducted 2 additional analyses to further explore our core findings pertinent to intervention-prompted behaviors. First, we tested the extent to which the effect of quiz performance on endline test scores may depend on utilization of daily readings, online CME courses, or self-study resources. For that, we conducted a series of

**TABLE 1.** Sociodemographic Characteristics and Test Scores of Study Participants (N=106).

	Value
Female, %	56.0
Age, years, mean (SD)	41.2 (9.5)
Highest clinical degree, No. (%)	
CBPA	3 (2.8)
CK1	57 (53.8)
CK2	1 (0.9)
MD	45 (42.5)
Years of experience providing HIV care to patients, mean (SD)	4.2 (4.9)
Number of patients typically seen each daily, No. (%)	
1–2	62 (58.5)
3–4	13 (12.3)
5–7	12 (11.3)
8–11	8 (7.6)
12+	11 (10.4)
Baseline scores, mean (SD)	46.4 (11.9)
Intervention group	44.6 (12.4)
Control group	48.2 (11.2)
Endline scores, <sup>a</sup> mean (SD)	54.2 (12.1)
Intervention group	55.0 (11.7)
Control group	53.4 (12.5)
% change in scores between baseline and endline, <sup>a</sup> mean (SD)	19.6 (30.9)
Intervention group	25.6 (32.4)
Control group	13.5 (28.2)

Abbreviations: CBPA, community-based physician’s assistants; CK1, first-level specialization/specialist; CK2, second-level specialization/specialist, SD, standard deviation.

<sup>a</sup> Sample size at endline consisted of 95 individuals (n=48 in the intervention group, n=47 in the control group).

interaction analyses. Second, we estimated the proportion of variance in endline test scores explained by each of the intervention-prompted behaviors. All analyses were conducted in SAS 9.4.

## RESULTS

### Descriptive Results

On average, the mCME study participants (intervention and control group combined) were 41 years

of age and had 4 years of experience in HIV care. Most (56%) were women. The mean medical knowledge test score among both groups combined was 46% at baseline and 54% at endline (Table 1). As noted in the report of the primary study findings,<sup>9</sup> the small sample size precluded precise measurement of impact on medical knowledge.

Among the intervention participants over the 6-month study period, on average 82% of the daily quizzes delivered were answered, although only about half of them were answered correctly (Table 2). The timing of the SMS had no effect on participation in daily quizzes: participants were as likely to respond to daily quizzes regardless of whether the SMS was sent in the morning or in the afternoon (82% for 9 am vs. 81% for 1 pm).

The daily hyperlinked readings sent with each quiz had lower participation rates than the daily quizzes, only 20% on average. Of the 53 HIV clinicians assigned to the intervention arm, 41 accessed between 1% and 89% of the hyperlinks while 12 never accessed the hyperlinks. The timing of the SMS had an impact on participants’ access of the daily hyperlinks: a greater percentage of participants accessed the daily hyperlinks when the SMS was sent in the morning than in the afternoon (23% for 9 am vs. 13% for 1 pm).

Across both the intervention and control groups, 43% of study participants ever accessed the online CME courses throughout the intervention period. Among the intervention group only, 60% of the study participants ever accessed the online CME courses. In addition, the intervention group accessed the CME courses more times (134 times) than the control group (27 times).

Among the 6 independent study behaviors queried on the endline survey, using medical textbooks and reviewing the Vietnamese HIV guidelines were the most frequently used study strategies (Table 2). Consulting with colleagues and reading scientific papers were the least commonly used self-study behaviors. On average, participants from both groups used 3.62 study resources a week. Most participants also said that they used medical textbooks, researched online, visited medical websites, and reviewed the HIV guidelines more than they had before the study.

Notably, clinicians could engage in these behaviors irrespective of study arm and not all clinicians answered all questions. The variables capturing change in self-study behaviors were based on the questions asked in the endline survey on clinicians’ self-assessment of their self-study behavior compared with before the intervention.

**On average, 82% of the daily quizzes were answered, but only about half were answered correctly.**

**TABLE 2.** HIV Clinicians' Participation in Intervention-Prompted and Independent Study Behaviors

	Value
<b>Intervention-Prompted Study Behaviors Among Intervention Group (n=53)</b>	
% of SMS quizzes answered, mean (SD)	81.9 (23.1)
% of SMS quizzes correctly answered, mean (SD)	52.0 (20.5)
% of daily hyperlinks accessed, mean (SD)	18.1 (21.8)
Ever accessed online CME courses, <sup>a</sup> % (SD)	60.4 (49.4)
<b>Independent Study Behaviors Among Intervention and Control Groups Combined<sup>b</sup></b>	
Used medical textbooks (ref: 1–3 times/month or <1 time/month)	61.7 (48.9)
Consulted with colleagues (ref: 1–3 times/month or <1 time/month)	44.7 (50.0)
Researched online (ref: 1–3 times/month or <1 time/month)	56.8 (49.8)
Researched website for medical professionals (ref: 1–3 times/month or <1 time/month)	55.3 (50.0)
Reviewed HIV guidelines (ref: 1–3 times/month or <1 time/month)	61.1 (49.0)
Reviewed scientific papers (ref: 1–3 times/month or <1 time/month)	42.6 (49.7)
More use of medical textbooks than before (ref: the same or less)	62.8 (48.6)
More consultation with colleagues than before (ref: the same or less)	43.2 (49.8)
More research online than before (ref: the same or less)	60.2 (49.2)
More visits to researched medical websites than before (ref: the same or less)	56.8 (49.8)
More frequent review of HIV guidelines than before (ref: the same or less)	62.4 (48.7)
More frequent reviews of scientific papers than before (ref: the same or less)	50.5 (50.3)
Total number of study resources used 1–3 or 4 or more times/week, mean (SD)	3.6 (2.7)

Abbreviations: CME, continuing medical education; SD, standard deviation; SMS, short message service.

<sup>a</sup> Among the entire study group (intervention and control group combined), 43.4% (SD=49.8) ever accessed the online CME courses.

<sup>b</sup> Sample size for the intervention and control group varied slightly for each indicator, from 93 to 95 individuals, depending on how many respondents answered each question.

**All intervention-prompted study behaviors were positively correlated with baseline test scores.**

## Bivariate Results

All intervention-prompted study behaviors were positively correlated with endline test scores (Table 3, Column 1). Baseline test scores had a positive correlation with only quiz participation and performance (Column 2). Further, endline test scores had the strongest correlation ( $r=0.36$ ) with quiz performance (Column 1, Row 4), and quiz performance had a stronger correlation with endline ( $r=0.36$ ) than baseline test scores ( $r=0.11$ ). Further, quiz performance had a strong positive correlation with quiz participation ( $r=0.83$ ) and a moderately strong positive correlation with access of daily readings ( $r=0.56$ ).

## Modeling Results

### *Associations Between Intervention-Prompted Behaviors and Endline Test Scores*

Table 4 presents the standardized regression coefficients, which captured the relative association

with endline test scores of each of 4 intervention-prompted behaviors, alone (Models 1–4) and combined (Models 5–6). In Model 1, increased quiz participation predicted an increase in endline test scores ( $\beta=0.24$ ;  $P=.05$ ). The percentage of SMS quizzes that participants answered correctly was more strongly predictive of endline test scores: Based on Model 2, a 1 standard deviation increase in the percentage of SMS quizzes that participants answered correctly was associated with nearly a half-point increase in endline test scores ( $\beta=0.42$ ;  $P<.001$ ). The percentage of daily readings accessed, as demonstrated by Model 3, had a positive association with endline test scores when considered alone ( $\beta=0.22$ ;  $P=.06$ ). Similarly, whether or not the participants ever accessed the online CME courses had a positive association with endline test scores in Model 4 ( $\beta=0.16$ ), but the association was not statistically significant ( $P=.19$ ). In the combined models, we included quiz participation and performance

**TABLE 3.** Correlation Coefficients for Intervention-Prompted Study Behaviors and Baseline and Endline Test Scores (n=48)

	(1)		(2)		(3)		(4)		(5)		(6)		(7)		(8)		(9)	
	Endline Test Scores		Baseline Test Scores		Average % of SMS Quizzes Answered		Average % of SMS Quizzes Correctly Answered		Average % of Daily Readings Accessed		Ever Accessed Online CME Courses		Years of Experience in HIV Care Provision		Age		Male	
	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>	<i>r</i>	<i>P</i>
(1) Endline test scores	1.00																	
(2) Baseline test scores	0.59	<.001	1.00															
(3) Average % of SMS quizzes answered	0.17	.26	0.04	.81	1.00													
(4) Average % of SMS quizzes correctly answered	0.36	.01	0.11	.47	0.83	<.001	1.00											
(5) Average % of daily readings accessed	0.20	.18	−0.004	.98	0.38	.01	0.56	<.001	1.00									
(6) Ever accessed online CME courses	0.04	.81	−0.08	.57	0.45	.002	0.35	.01	0.30	.04	1.00							
(7) Years of experience in HIV care provision	0.16	.28	−0.07	.65	−0.16	.28	−0.09	.56	−0.002	.99	−0.19	.20	1.00					
(8) Age	−0.13	.39	−0.09	.53	0.13	.36	0.26	.08	0.14	.36	0.07	.63	0.33	.02	1.00			
(9) Male	−0.12	.41	−0.11	.45	0.19	.20	0.16	.27	−0.17	.26	0.06	.66	0.15	.30	0.23	.11	1.00	

Abbreviations: CME, continuing medical education; SMS, short message service.

alternatively, given their strong correlation ( $r=0.83$ , Table 3). When mutually adjusted in Models 5–6, only the percentage of SMS quizzes that participants answered correctly was predictive of endline test scores: as in Model 2, a 1 standard deviation increase in the percentage of SMS quizzes that participants answered correctly was associated with nearly a half-point increase in endline test scores ( $\beta=0.43$ ). In terms of model fitness, Model 2 had the best fit, explaining 51% of variation in endline test scores.

### Associations Between Independent Study Behaviors and Endline Test Scores

Table 5 presents the associations between independent study behaviors and endline test scores among all participants (Models 1–2); intervention participants only (Model 3); and control participants only (Model 4). In Model 2, we tested the extent to which the association between the intervention status and endline test scores (Model 1) was mediated by independent study behaviors. Additionally, we present the associations between independent study behaviors and endline test scores for intervention participants and control

participants by way of assessing the extent to which associations varied by intervention status.

After adjusting for baseline test scores (which were lower among the intervention than control participants) along with additional controls (Model 1), intervention participants achieved higher endline test scores suggesting that the intervention led to improvement in medical knowledge among HIV clinicians ( $\beta=0.11$ ), but the result was not statistically significant ( $P=.22$ ). The relative association of the intervention grew somewhat stronger when independent study behaviors were added to the model (Model 2) ( $\beta=0.15$ ;  $P=.11$ ). Independent study behaviors appeared to act as moderators of the overall effect of the intervention on endline test scores—when considering the strength of association of the intervention, the regression coefficient increased when independent study behaviors were added to the model.<sup>15</sup>

Among the intervention participants (Model 3), ‘use of medical textbooks’ ( $\beta=0.07$ ;  $P=.69$ ), ‘researched online’ ( $\beta=0.26$ ;  $P=.11$ ), and ‘reviewed scientific papers’ ( $\beta=0.21$ ;  $P=.15$ ) had positive but not statistically significant associations with endline test scores. On the other



**TABLE 4.** Associations Between Intervention-Prompted Study Behaviors and Total Endline Test Scores (n=48)

	Model 1: Predictor, Quiz Participation		Model 2: Predictor, Quiz Performance		Model 3: Predictor, Daily Readings		Model 4: Predictor, Online CME Courses		Model 5: All Predictors Except Quiz Performance <sup>a</sup>		Model 6: All Predictors Except Quiz Participation <sup>a</sup>	
	B (SE)	P	B (SE)	P	B (SE)	P	B (SE)	P	B (SE)	P	B (SE)	P
Average % of SMS quizzes answered	0.24 (0.06)	.05							0.16 (0.07)	.27		
Average % of SMS quizzes correctly answered			0.42 (0.06)	.004							0.43 (0.08)	.005
Average % of daily readings accessed					0.22 (0.06)	.06			0.14 (0.07)	.28	−0.03 (0.07)	.81
Accessed online CME courses (ref: never)							0.16 (2.89)	.19	0.05 (3.16)	.71	0.03 (2.78)	.79
Male (ref: female)	−0.11 (2.81)	.38	−0.12 (2.51)	.28	−0.01 (2.83)	.92	−0.07 (2.84)	.57	−0.06 (2.97)	0.62	−0.13 (2.74)	.28
Age	−0.18 (0.16)	.15	−0.27 (0.15)	.02	−0.19 (0.17)	.14	−0.16 (0.17)	.21	−0.20 (0.17)	0.11	−0.27 (0.16)	.03
Years of HIV care provision	0.31 (0.30)	.02	0.34 (0.27)	.004	0.26 (0.29)	.04	0.29 (0.31)	.03	0.31 (0.31)	.02	0.34 (0.28)	.005
Baseline test score	0.57 (0.11)	<.001	0.53 (0.10)	<.001	0.59 (0.11)	<.001	0.60 (0.12)	<.001	0.58 (0.11)	<.001	0.53 (0.11)	<.001
Adjusted R <sup>2</sup>	0.40		0.51		0.40		0.37		0.39		0.49	

Abbreviations: CME, continuing medical education; SE, standard error; SMS, short message service.

<sup>a</sup>Model 5 includes Quiz Participation, Daily Readings, Online CME Courses, and controls while Model 6 includes Quiz Performance, Daily Readings, Online CME Courses, and controls. Quiz Participation and Quiz Performance were not included in the same model together due to high collinearity.

hand, ‘consulted with colleagues’ ( $\beta=-0.23$ ;  $P=.11$ ), ‘researched website for medical professionals’ ( $\beta=-0.14$ ;  $P=.41$ ), and ‘reviewed HIV guidelines’ ( $\beta=-0.002$ ;  $P=.99$ ) had negative correlations, although these correlations also were not statistically significant. Among the control participants (Model 4), ‘consulted with colleagues’ ( $\beta=0.18$ ;  $P=.35$ ), ‘researched online’ ( $\beta=0.12$ ;  $P=.69$ ), and ‘researched websites for medical professionals’ ( $\beta=0.40$ ;  $P=.14$ ) had positive associations with endline test scores, while ‘used medical textbooks’ ( $\beta=-0.35$ ;  $P=.16$ ), ‘reviewed HIV guidelines’ ( $\beta=-0.15$ ;  $P=.45$ ), and ‘reviewed scientific papers’ ( $\beta=-0.03$ ;  $P=.89$ ) had negative associations. None of these associations were statistically significant.

**Quiz performance had a stronger association with endline test scores when both daily readings and online CME courses were accessed more frequently.**

#### **Additional Analyses** *Associations Between Endline Test Scores and Interactions Between Quiz Performance and Independent Study Behaviors*

Of all potential variables, the percentage of SMS quizzes answered correctly was the best predictor of endline test scores (Table 4). To better

understand this association, we tested the extent to which the effects of quiz performance on endline test scores depended on accessing the daily readings, online CME courses, or self-study resources. Therefore, we conducted a series of interaction analyses: we constructed 8 interaction terms (percentage of quizzes answered correctly multiplied with each of 8 variables including daily readings, online CME course usage, and the 6 independent study behaviors) and used each interaction (e.g., percentage of SMS quizzes correctly answered \* used medical textbooks) along with original terms (e.g., percentage of SMS quizzes correctly answered; used medical textbooks) as covariates in adjusted regression models.

Quiz performance had a stronger association with endline test scores when both daily readings and online CME courses were accessed more frequently, suggesting that use of multiple elements of the intervention had added benefits (Table 6). HIV clinicians scored higher endline test scores when they more frequently accessed daily readings ( $\beta=0.87$ ;  $P=.08$ ) or visited online CME course websites ( $\beta=0.25$ ;  $P=.09$ ) as well as better performed in daily quizzes. None of the interactions

**TABLE 5.** Associations Between Independent Study Behaviors and Total Endline Scores

	Model 1 Predictor, Intervention Status (n=95)		Model 2 Independent Study Behaviors as Potential Mediators of Intervention Effect (n=91)		Model 3 Independent Study Behaviors as Predictors of Endline Scores Among Intervention Group (n=47)		Model 4 Independent Study Behaviors as Predictors of Endline Scores Among Control Group (n=44)	
	$\beta$ (SE)	P	$\beta$ (SE)	P	$\beta$ (SE)	P	$\beta$ (SE)	P
Treatment status (ref: control)	0.11 (2.08)	.22	0.15 (2.09)	.11				
Used medical textbooks (ref: 1–3 times/month or <1 time/month)			–0.11 (3.11)	.41	0.07 (3.95)	.69	–0.35 (5.47)	.16
Consulted with colleagues (ref: 1–3 times/month or <1 time/month)			–0.12 (2.57)	.28	–0.23 (3.18)	.11	0.18 (4.56)	.35
Researched online (ref: 1–3 times/month or <1 time/month)			0.20 (3.32)	.19	0.26 (3.89)	.11	0.12 (6.56)	.69
Researched website for medical professionals (ref: 1–3 times/month or <1 time/month)			–0.04 (3.11)	.80	–0.14 (3.84)	.41	0.40 (6.07)	.14
Reviewed HIV guidelines (ref: 1–3 times/month or <1 time/month)			–0.09 (2.70)	.45	–0.002 (3.81)	.99	–0.15 (4.37)	.45
Reviewed scientific papers (ref: 1–3 times/month or <1 time/month)			0.17 (2.46)	.12	0.21 (3.13)	.15	–0.03 (4.56)	.89
Male (ref: female)	–0.25 (2.12)	.01	–0.28 (2.16)	.005	–0.15 (2.71)	.23	–0.55 (4.67)	.01
Age	–0.02 (0.12)	.86	0.11 (0.13)	.32	–0.07 (0.19)	.66	0.23 (0.19)	.19
Years of HIV care provision	0.15 (0.24)	.12	0.12 (0.23)	.24	0.23 (0.33)	.11	0.04 (0.37)	.83
Baseline test score	0.50 (0.09)	<.001	0.55 (0.09)	<.001	0.62 (0.12)	<.001	0.47 (0.16)	.01
Adjusted R <sup>2</sup>	0.31		0.34		0.42		0.26	

Abbreviation: SE, standard error.

between quiz performance and each of 6 independent study behaviors were statistically significant suggesting that the effect of quiz performance on endline test scores was not conditional on independent study behaviors.

#### **Percentage of Total Explained Variances Attributable to Intervention-Prompted or Independent Study Behaviors**

Finally, within the intervention group, we considered how much of the total variance in endline test scores was explained by each of the intervention-prompted or independent study

behaviors considered (Table 7). We report on intervention-prompted study behaviors only. For this analysis, we fit a model of endline test scores using gender, age, years of experience in HIV care provision, and baseline score as covariates (Model 1), and report the total variance explained by Model 1 (adjusted R<sup>2</sup>=0.36). Next, we fit Model 2, adding to Model 1 the percentage of SMS quizzes correctly answered, and report the total variance explained by Model 2 (adjusted R<sup>2</sup>=0.51). Third, we calculated the proportion of the total variance explained by the percentage of SMS quizzes correctly answered [ $((\text{Adjusted } R^2 \text{ of Model 2} - \text{Adjusted } R^2 \text{ of Model 1}) / \text{Adjusted } R^2 \text{ of Model 1}) * 100$ ].

**TABLE 6.** Associations of Interactions Between Quiz Performance and Study Behaviors With Total Endline Scores

	Model 1 (n=48)		Model 2 (n=48)	
	B (SE)	P	B (SE)	P
% of SMS quizzes correctly answered	0.18 (0.08)	.04	0.11 (0.09)	.24
% of daily readings accessed	−0.64 (0.37)	.09		
Accessed online CME courses (ref: never)			−13.81 (8.06)	.09
% of SMS quizzes correctly answered * % of daily readings accessed	0.87 (0.48)	.08		
% of SMS quizzes correctly answered * accessed online CME courses			0.25 (0.15)	.09
Age	−1.88 (2.85)	.51	−0.92 (2.76)	.74
Years of HIV care provision	−0.28 (0.16)	.09	−0.30 (0.16)	.08
Baseline test score	0.49 (0.11)	<.001	0.52 (0.11)	<.001
Intercept	36.67 (9.15)	<.001	37.69 (9.51)	<.001
Adjusted R <sup>2</sup>	0.44		0.43	

Abbreviations: CME, continuing medical education; SE, standard error; SMS, short message service.

100]. We followed the same procedure for the remaining 8 intervention-prompted or independent study behaviors. The percentage of total variance explained by intervention-prompted study behaviors ranged between 3% and 43%. SMS quiz performance explained the highest variance in endline test scores, further supporting that this aspect of the intervention-prompted study behaviors was the most important to the success of the intervention. Among the remaining intervention-prompted behaviors, the percentage of daily readings accessed explained more variation in endline test scores than gender, age, years of experience in HIV care provision, and baseline test scores alone: 40% as opposed to 36%, and 10% of that variability was attributable to the percentage of daily readings accessed. Finally, accessing the online CME courses explained 1% more of the variability in endline test scores than gender, age, years of experience in HIV care provision, and baseline score alone, and 3% of that variability could be attributed to the online CME courses.

## DISCUSSION

The mCME intervention improved the knowledge of HIV clinicians in Vietnam by increasing the use of intervention-prompted study behaviors, namely, performance on the daily quizzes

and accessing daily linked readings, but potentially also accessing the online CME courses. Unprompted changes in study behavior (i.e., searching for information outside of the embedded materials provided in the intervention itself) also may have played a role in improving clinicians' knowledge. In other words, the intervention was effective because it helped the participants to be better, more diligent, and more engaged students.

Starting from the high-level observation that the mCME version 2.0 intervention was effective at motivating study behaviors and led to gains on the endline exam compared with control participants, the analysis presented in this article furthers our insight into the likely mechanisms that mediated this result. Analysis of the intervention-prompted behaviors was facilitated by the click data tracked by software provided by the Vietnamese MOH. This allowed accurate measurement of accessing the quizzes, daily readings, and online CME courses. We found that performance on the daily quizzes most consistently predicted endline test performance, which strongly supports the strategy of using SMS quiz questions to motivate study behaviors. A key insight is that participation in the quizzes was less predictive than how well individuals performed on the quizzes. Because all our analyses controlled for

**Our findings support the strategy of using SMS quiz questions to motivate study behaviors.**

**TABLE 7.** Percentage of Total Explained Variances Attributable to Intervention-Prompted Study Behaviors (n=48)

	Adjusted R <sup>2</sup>	% of Adjusted R <sup>2</sup> Attributable to:		
		% of SMS Quizzes Correctly Answered	% of Daily Readings Accessed	Accessed Online CME Courses
Model 1. Gender, age, years of HIV care provision, baseline test scores	0.36			
Model 2. % of SMS quizzes correctly answered, gender, age, years of HIV care provision, baseline test scores	0.51	43		
Model 3. % of daily readings accessed, gender, age, years of HIV care provision, baseline test scores	0.40		10	
Model 4. Accessed online CME courses, gender, age, years of HIV care provision, baseline test scores	0.37			3

Abbreviations: CME, continuing medical education; SMS, short message service.

baseline scores, we know that quiz performance was not a result of the participants' baseline knowledge. Because participation is a requirement to assess quiz performance, this suggests individuals who simply answered the SMS quiz question did not improve endline scores as much as individuals who used study resources to help answer the questions correctly.

Moreover, some of these factors interacted in synergistic ways. The daily readings and online CME courses mediated the strong performance on the daily quiz questions. When provided in conjunction with the SMS quizzes, students who accessed these 2 resources, particularly the daily readings, demonstrated improved performance on the quizzes and were the most successful on the endline exam relative to the rest of their cohort. This yields a conclusion that is in some sense very intuitive: the mCME version 2.0 intervention worked among those individuals who were cued by the daily quizzes into investing time into studying, and worked less well among students who only answered the SMS quiz question. As such, this largely supports the lateral learning model that guided this research project, which assumed that learning would largely result from investments of study time rather than from knowledge acquired directly from the daily quiz questions themselves. Since the control participants had the same opportunities to engage in self-study but rarely did so in practice, we can conclude that the daily prompts from the SMS quizzes were an effective way of motivating self-study,

and that this strategy yielded meaningful results in terms of mastery of clinical knowledge.

Nonetheless, with all the intervention-prompted behaviors and demographic factors included in the analysis, only 43% of the total variance in endline score changes could be explained. Naturally, this leads us to study behaviors outside of those directly provided by the intervention—the independent study behaviors.

The independent study behaviors may have had a significant impact on endline scores. These data remain challenging to analyze because we could only ask about a limited number of self-study behaviors. Much of our analysis did not show statistically significant differences between the intervention and control groups, likely due to limitations in sample size. Additionally, these data were all taken from a single endline survey, which could not capture longitudinal changes in study strategies over the course of the intervention. Despite limitations in using surveys, data from the self-study behaviors we measured show distinct differences in study behaviors between the 2 groups. Resources that were associated with higher endline scores in the control group were often associated with lower endline scores in the intervention group and vice versa, suggesting that the intervention did not simply prompt higher usage of study resources but may actually have changed the way in which the participants approached the material or used their resources.

While it is impossible to know for certain why the intervention changed study habits, it is

**Daily readings and online CME courses mediated the strong performance on the daily quiz questions.**



possible that exposure to many example questions along with easy access to good resources such as the online CME courses and daily hyperlinked readings provided insight into how the material was tested and allowed motivated students to better utilize reliable sources of information, such as scientific papers, over less reliable sources, such as consulting with colleagues or searching for information on Google. Some of these study behaviors actually appeared to be counterproductive, including general Google searches or consulting with co-workers for information.

The independent study behaviors still only explain a portion of the residual variance in end-line scores. That should be no surprise: there are myriad ways in which individuals can study, and not all of these were captured by our survey. Nor are the semi-quantitative and subjective reporting of measured behaviors a perfect measure of study intensity. In future mCME studies, more thorough investigation into these independent study resources might better reflect changes in lateral learning that may have taken place as a result of the intervention. Future mCME studies should have a larger sample size for a more thorough assessment of lateral learning mechanisms.

## CONCLUSION

We conclude that mCME is a useful approach to improve clinicians' clinical knowledge and may be particularly useful in resource-limited settings where access to and/or support for in-person CME courses are limited. The mCME strategy is portable since the methodology can be applied to any content area, user group, or geography.<sup>9</sup> Further, the mCME strategy is feasible; the groups supporting the mCME program will have to make available the software itself and the content that is to be broadcast, and participants will have to own a smartphone and have access to a mobile network.<sup>9</sup> These technology-related requirements are seldom barriers in resource-limited settings since SMS messages nowadays use a fraction of the bandwidth required for media files and can function even where bandwidth is constrained.<sup>9</sup> The success of the mCME version 2.0 intervention in Vietnam suggests that lateral learning, or the process of engaging in learning outside of the intervention but in response to the intervention, mediated the improvement in medical knowledge.<sup>3</sup> Unpacking the “black box” has helped us to evaluate the underlying mechanisms by which mCME can improve medical knowledge.

**Acknowledgments:** We wish to thank the following Vietnamese organizations and individuals for their support and collaboration in the mCME project: from the Vietnam Authority for AIDS Control at the Vietnamese MOH, Dr. Tran Ninh; from Hanoi Medical University, Ms. Le Thi Thanh Binh; from the Center for Population Research, Information and Databases at the MOH, who developed the mCME software and hosted the intervention on their servers, Ms. Nguyen Thi Thanh Tam, Mr. Nguyen Duc Tam, Mr. Phan Van Dan, Mr. Vo Duc Tri, and Mr. Vu Ngoc Lam; from the Hai Phong Provincial Center for AIDS Control, Dr. Nguyen Duy Hung and Dr. Dao Viet Tuan; from the Quang Ninh Provincial Center for AIDS Control, Dr. Le Thi Hoa and Ms. Nguyen Ngoc An; from the Thai Nguyen Provincial Center for AIDS Control, Dr. Le Ai Kim Anh and Ms. Ho Thi Quynh Trang; and from the Infectious Diseases Department at Bach Mai Hospital, Dr. Pham Thi Thanh Thuy. A particular note of thanks to our excellent operations team at Consulting, Research for Community Development, Ms. Tra Kim Anh and Ms. Ha Quynh Anh.

**Funding:** Funding for the mCME project was provided by the Fogarty International Center at the U.S. National Institutes of Health (1R21-TW009111). Funding for mCME version 2.0 was provided as a supplement to the main award, with the stipulation that it focus on issues related to HIV/AIDS. The funders played no role in the conduct, analysis, or reporting of this study.

**Competing Interests:** None declared.

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**Peer Reviewed**

**Received:** August 8, 2018; **Accepted:** November 2, 2018

**Cite this article as:** Nofal MR, Halim N, Le BN, et al. Unpacking the “black box”: how an SMS-based continuing medical education intervention improved medical knowledge among HIV clinicians in Vietnam. *Glob Health Sci Pract.* 2018;6(4):668–679. <https://doi.org/10.9745/GHSP-D-18-00298>

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## ORIGINAL ARTICLE

# Experiences With the Levonorgestrel Intrauterine System Among Clients, Providers, and Key Opinion Leaders: A Mixed-Methods Study in Nigeria

Gillian Eva,<sup>a</sup> Geeta Nanda,<sup>b</sup> Kate Rademacher,<sup>c</sup> Anna Mackay,<sup>d</sup> Omaye Negedu,<sup>e</sup> Anne Taiwo,<sup>e</sup> Leila Dal Santo,<sup>b</sup> Mariya Saleh,<sup>f</sup> Lucky Palmer,<sup>e</sup> Tracey Brett<sup>g</sup>

Between September 2016 and December 2017, Marie Stopes International Organisation Nigeria introduced the LNG IUS in 16 Nigerian states to increase method choice. Just under 1,000 devices were inserted, representing less than 1% of all long-acting reversible contraceptives provided. Qualitative feedback from opinion leaders, providers, and LNG IUS users found important benefits to users and suggested coordinated demand- and supply-side activities, including user champions and supportive providers to generate interest in the method, would be needed for successful scale-up.

## ABSTRACT

**Background:** The levonorgestrel intrauterine system (LNG IUS) is one of the most effective contraceptive methods, and it has noncontraceptive health benefits, including treatment for women with heavy menstrual bleeding. In 2016, Marie Stopes International Organisation Nigeria (MSION) expanded LNG IUS provision through training and support to 9 mobile outreach teams, 105 social franchise clinics, and 20 public-sector providers in 17 states. Information about the LNG IUS was added to awareness-raising materials, and community mobilizers provided information on the LNG IUS alongside other voluntary family planning methods.

**Methods:** In 2016, Marie Stopes International, MSION, and FHI 360 examined clients' and providers' experiences with the LNG IUS to assess the potential for further scale-up of the method as part of a comprehensive approach to family planning in Nigeria. A mixed-methods approach was used including analysis of routine service data, supplemental data specific to LNG IUS clients, and in-depth interviews with LNG IUS clients, providers, and key opinion leaders.

**Results:** Just under 1,000 LNG IUS were inserted from September 2016 to December 2017 in 16 states in channels supported by MSION, representing 0.4% of all long-acting and reversible contraceptive (LARC) services provided by the participating providers during this time frame. The vast majority (82%) of LARCs provided were implants. A small pool of providers was responsible for providing almost half of the LNG IUS services. Common reasons for women choosing the LNG IUS were reduced menstrual bleeding (61%), long-acting duration (52%), effectiveness (49%), and discreetness (42%). Almost 80% of the users first heard about the method from a provider. Almost all users and providers reported positive experiences with the method, noting the noncontraceptive benefits and fewer side effects compared with other methods. All providers who were interviewed said they would continue offering the LNG IUS. Several key opinion leaders mentioned a total market approach incorporating both public and private sectors would be needed to successfully scale up the LNG IUS.

**Conclusion:** Reduced menstrual bleeding and fewer side effects compared with other methods were identified as important attributes of the LNG IUS by clients, providers, and key opinion leaders. Challenges to uptake of the LNG IUS include difficulty with introducing a new method within a busy service delivery infrastructure and limited awareness and demand-generation activities on the LNG IUS specifically. A comprehensive product introduction approach with coordinated demand- and supply-side activities may be required for this method to reach its full potential.

## BACKGROUND

The levonorgestrel intrauterine system (LNG IUS), a long-acting and reversible contraceptive (LARC) method, is one of the most effective forms of contraception available and has important noncontraceptive health benefits, such as treatment for heavy menstrual bleeding and potential alleviation of anemia in some women. Possible side effects include acne, headaches,

<sup>a</sup> Marie Stopes International, Washington, DC, USA.

<sup>b</sup> FHI 360, Washington, DC, USA.

<sup>c</sup> FHI 360, Durham, NC, USA.

<sup>d</sup> Marie Stopes International, New York, NY, USA.

<sup>e</sup> Marie Stopes International Organisation Nigeria, Abuja, Nigeria.

<sup>f</sup> FHI 360, Abuja, Nigeria.

<sup>g</sup> FHI 360, Johannesburg, South Africa.

Correspondence to Gillian Eva (Gillian.eva@gmail.com).

breast tenderness, and weight gain.<sup>1,2</sup> First introduced nearly 30 years ago, the LNG IUS has been popular in countries where it is available, but access to the method in low- and middle-income countries (LMICs) has been very limited, largely due to the current high price of the product.<sup>3,4</sup> New, more affordable LNG IUS products are starting to become available globally, and early introduction efforts are underway in several LMICs,<sup>5</sup> including Nigeria. Introduction of new contraceptive methods has the potential to increase voluntary contraceptive use<sup>6</sup> and gives women and men a better chance of finding a method that suits them.

As part of the global Family Planning 2020 (FP2020) initiative launched in 2012, the government of Nigeria has committed to reducing unmet need for family planning and increasing modern contraceptive prevalence to 27% among all women by 2020,<sup>7</sup> compared with a prevalence of 11% in 2013.<sup>8</sup> Data from the 2013 Nigeria Demographic and Health Survey indicated that 13% of all women (ages 15 to 49) in Nigeria had an unmet need for family planning.<sup>8</sup> Family planning use varies widely across states, with the modern contraceptive prevalence rate ranging from 5.9% in Kano to 23.3% in Lagos, according to 2017 Performance Monitoring and Accountability 2020 (PMA2020) data.<sup>9</sup> Recent targeted initiatives in both the public and private sectors have led to increased voluntary uptake of LARCs (particularly implants) in Nigeria, including among lower-income women and women living in the more rural and conservative northern states<sup>10</sup> who often have limited or no access to family planning.

According to the 2013 Nigeria Demographic and Health Survey, the copper intrauterine device (IUD) comprised a small portion (5%) of Nigeria's overall contraceptive method mix,<sup>8</sup> and use of the LNG IUS is too low to be included as a separate method in national surveys. Mirena, the 5-year LNG IUS product distributed by Bayer HealthCare Pharmaceuticals Inc., is available on a limited scale in the commercial sector, at a cost to clients (including insertion) ranging from US\$90 to US\$275 in private clinics in Abuja, according to a recent assessment.<sup>11</sup> Several other LNG IUS products are starting to be introduced in Nigeria, including Emily (HLL Lifecare Ltd.), Eloira (Pregna International Ltd.), and AVIBELA (Medicines360) (information is from personal communications with respective suppliers of LNG IUS products, January 2018). In addition to these commercial products, a free, non-branded LNG IUS product is donated by the International

Contraceptive Access (ICA) Foundation, a public-private partnership between Bayer HealthCare Pharmaceuticals Inc. and the Population Council. This product is being offered by several organizations across the country including Marie Stopes International Organisation Nigeria (MSION).

Small-scale LNG IUS introduction pilots led by several service delivery groups have been underway for some time in Nigeria. However, to our knowledge, this is the first formal research to be conducted about the experiences of LNG IUS users and providers within the country. Using evidence from MSION's LNG IUS program, this article aims to explore the perceptions and experiences of early adopters of the LNG IUS, LNG IUS providers, and key opinion leaders. The results identify both challenges and opportunities with method introduction and can help inform further introduction and scale-up of the method in Nigeria and beyond.

## ■ PROGRAM DESCRIPTION

MSION supports high-quality family planning counseling and a range of voluntary contraceptive services, including LARCs and permanent methods, through a network of delivery points across 33 states in Nigeria. In underserved rural areas, MSION expands the contraceptive choices available in public facilities by offering voluntary LARCs and permanent methods through 12 mobile outreach teams and by training public-sector providers in LARC provision, while in peri-urban areas MSION supports the BlueStar network of 253 social franchise clinics (usually small, private clinics staffed by a mid-level provider). In 2017, MSION provided more than 2 million voluntary family planning services (not including condoms or emergency contraception), of which almost 1 million were voluntary LARC services.

The ICA Foundation donated 1,400 LNG IUS units to MSION between 2010 and 2014 (these were programmed through routine service delivery) and a further 3,000 units in 2016–2017. With this additional donation and with funding from the United States Agency for International Development (USAID) in 2016, MSION expanded LNG IUS provision through training and support to 9 mobile outreach teams, 105 social franchise clinics, and 20 public-sector providers. This period of expanded provision in 2016–2017 is referred to in this article as “the program.” Activities under the program included training 136 providers and 12 MSION supervisors on LNG IUS provision, generating awareness of the method among potential users via outreach by community mobilizers, and

**Marie Stopes International Nigeria expanded LNG IUS provision in 2016 through training and support to mobile outreach teams, social franchise clinics, and public-sector providers.**



monitoring of service provision. Providers from 17 states across Nigeria were trained, with LNG IUS services ultimately delivered in 16 states. Social franchise clinics were selected that had high volumes of family planning services and an experienced family planning provider trained in provision of LARCs including IUDs, covering 13 states (Abia, Anambra, Benue, Cross River, Delta, Ebonyi, Edo, Enugu, Imo, Lagos, Ogun, Ondo, and Oyo). Nine mobile outreach teams were included, covering 7 states (Abuja in the Federal Capital Territory, Benue, Cross River, Gombe, Lagos, Osun, and Sokoto). Public-sector providers were trained in 5 states (Benue, Cross River, Ogun, Ondo, and Oyo). Marie Stopes International (MSI) and MSION partnered with FHI 360 to examine experiences with provision and use of the LNG IUS in these settings among both clients and providers during the program period, and to assess the potential for further scale-up of the method more broadly.

The providers selected for involvement in the program included a mix of nurses, midwives, and doctors. They took part in a 3-day training between April and November 2016 that covered history taking, general family planning counseling, steps on infection prevention, and demonstration of insertion and removal of the LNG IUS using models and practicing with clients who wanted the LNG IUS. Trainers or supervisors observed all providers inserting LNG IUS with clients, either during the training or during a follow-up observation in a facility, before reaching competency as determined by MSI global clinical standards. Technical competence was monitored during routine clinical follow-up visits every 2 months.

Following the training, the LNG IUS was introduced alongside other family planning methods through mobile outreach teams, social franchise clinics, and public-sector providers supported by MSION. As with other contraceptive services, there was no charge for the LNG IUS provided through mobile outreach or at public-sector facilities. Social franchise clinics charged a consultation fee of 2,000 to 3,000 Naira (US\$6 to \$8) for LNG IUS services during the first year of the program, which was reduced to 1,500 Naira (US\$4) in October 2017 to make the cost of the LNG IUS comparable with implant and copper IUD services, which range from 1,000 to 2,000 Naira (US\$3 to \$6).

Information about the LNG IUS was added to existing awareness-raising materials, including flip charts and posters. In addition, community

mobilizers already providing family planning information at the community level were trained to provide information about the LNG IUS, including duration of use, side effects, risks including conditions that might render the use of the method inadvisable, and effectiveness, as well as the non-contraceptive benefits of the method.

Providers received a small number of products once they achieved competency and could request more as needed, with additional supplies delivered by MSION within 1 week of the provider's request. There were no reported LNG IUS stock-outs during the program. Since the end of the program in December 2017, MSION's trained providers continue to offer donated LNG IUS as part of a broader method mix.

## METHODS

We used a mixed-methods approach to evaluate experiences with and attitudes toward the LNG IUS, drawing on different data sources, including routine MSION service data, supplemental data specific to LNG IUS clients, and qualitative in-depth interviews with LNG IUS clients, providers, and key opinion leaders (Table 1). We also included results from MSION's 2017 client exit interviews for comparative purposes.

Ethical approval was received from the Nigerian Institute of Medical Research, the MSI independent Ethics Review Committee, and FHI 360's Office of International Research Ethics.

### Routine MSION Service Data and Supplemental LNG IUS Client Data

The research team used routine MSION service data on the number of family planning services delivered, which MSION collected throughout the program via paper forms at all facilities involved in LNG IUS introduction. We also collected supplemental data from LNG IUS clients at the time of service, through 4 mobile outreach teams and at 47 social franchise clinics, using paper-based questionnaires. The questionnaires included questions about women's reasons for choosing the LNG IUS, how they heard about the method, what method they would have chosen if the LNG IUS had not been available that day, and sociodemographic characteristics (age, parity, education level, and marital status).

MSION conducted client exit interviews with a sample of MSION clients after they received a service from MSION between November 8 and November 29, 2017, in order to capture sociodemographic characteristics. Client exit interviews

**TABLE 1.** Data Sources

Data Source	Frequency	Participants
Routine MSION service data	Collected by providers at time of service on ongoing basis	All MSION family planning clients
Supplementary LNG IUS client data	Collected by providers at time of service as part of LNG IUS program	Sample of LNG IUS clients (N=388)
MSION client exit interview data <sup>a</sup>	Collected by MSION annually	Sample of MSION LARC clients (N=692)
In-depth interviews	Conducted in 2017	LNG IUS clients (N=33) LNG IUS providers (N=32) Key opinion leaders (N=17)

Abbreviations: LARC, long-acting reversible contraception; LNG IUS, levonorgestrel intrauterine system; MSION, Marie Stopes International Organisation Nigeria.

<sup>a</sup> Used for comparison purposes, not part of LNG IUS study protocol.

are part of MSION's routine monitoring and evaluation activities and were not part of the study protocol; as such, they were not necessarily conducted at the sites where LNG IUS services were offered. We have included them to provide broad comparisons among LNG IUS users and other MSION LARC clients. For outreach, we conducted the client exit interviews in the same states as the LNG IUS rollout, plus Kano state. For social franchise, they were conducted in the same states as the LNG IUS rollout, excluding Anambra, Ebonyi, and Imo states.

Our indicators of interest included the following: sociodemographic characteristics of LNG IUS users, why women chose to use it, what alternative method they would have used, and how they initially found out about the LNG IUS. Where appropriate, we explored differences by service delivery channel and with other LARC users, using chi-square ( $\chi^2$ ) tests or *t* tests as applicable. Descriptive data analysis was conducted using SPSS version 22,<sup>12</sup> using univariate and bivariate analysis.

### Qualitative Interviews With LNG IUS Clients and Providers

Between March and October 2017, we interviewed LNG IUS clients and providers to document their experiences using and providing the LNG IUS, respectively, attitudes toward the method including advantages and disadvantages, and potential considerations for expanding access to the method. Semistructured interview guides were used for all interviews.

A sub-sample of LNG IUS clients who had given permission to be contacted at the time of service was invited to participate in an in-depth interview

3 months after the clients received the LNG IUS. Interviews were conducted in person at a health facility convenient to the woman, in English and other local languages, based on the respondent's preference. We initially aimed to reach 40 to 50 women from across the delivery channels, estimating that these numbers would be sufficient to identify major themes<sup>13</sup> and take into account feasibility constraints related to financial and time considerations. Participants were recruited via convenience sampling. Ultimately, due to time constraints and challenges reaching women, we interviewed a total of 33 women.

Providers who were trained on provision of the LNG IUS and had provided the method in one of the participating facilities were similarly recruited via convenience sampling, with the aim of reaching 20 to 30 providers, assuming these numbers would be sufficient to identify major themes.<sup>8</sup> Interviews were conducted in English at the provider's facility. We interviewed 32 providers.

We obtained informed consent from all participants before initiating the in-depth interviews. LNG IUS clients were compensated 2,000 Naira (US\$6) for transportation costs. Providers did not receive compensation for participation. We audio-recorded all in-depth interviews (except for 2 client interviews and 1 provider interview in Edo state that were documented with detailed notes) and transcribed them, translating into English when applicable. We analyzed the in-depth interview data thematically using NVivo version 11,<sup>14</sup> first coding the data according to a framework derived from themes in the interview guide and emerging themes from the interview data, then developing memos related to the larger themes and emerging sub-themes.

**Most of the 115 providers in the program delivered fewer than 10 LNG IUS services, while 9 providers delivered just over half of all LNG IUS insertion services.**

### Qualitative Interviews With Key Opinion Leaders

Between January and September 2017, we conducted interviews with key opinion leaders to document their perceptions of the LNG IUS and attitudes about opportunities and challenges associated with further introduction and scale-up of the LNG IUS more broadly within Nigeria. Key opinion leaders were identified by local FHI 360 and MSION staff based on their experience and expertise in the field of reproductive health in Nigeria and, in some cases, with LNG IUS provision. Seventeen interviews were conducted with individuals including representatives from government institutions, NGOs, academic institutions, donor groups, and procurement organizations. Opinion leaders who were interviewed did not receive compensation. All interviews were conducted in English either in person (n=15) or by phone (n=2). Four respondents declined to be audio-recorded; in these cases, detailed written notes of the interviews were taken. In all other cases, interviews were audio-recorded and transcribed. Results were analyzed thematically in Microsoft Excel by categorizing responses according to a framework based on themes from the interview guide.

## RESULTS

Between September 2016 and December 2017, the 9 trained mobile outreach teams, 76 of the 105 trained social franchise providers, and 7 of the 20 trained public-sector providers delivered 990 LNG IUS insertions. Almost all clients received LNG IUS services at either a social franchise clinic (53.0%, n=525) or through mobile outreach (44.5%, n=441). A small number received the method through participating public-

sector facilities (2.4%, n=24); these cases are not included in the following analysis. The rate of voluntary uptake of the method was fairly consistent throughout the program period.

Most (83%, n=95) of the participating providers delivered fewer than 10 LNG IUS services during the 16-month program, while 9 providers (8%) (4 mobile outreach teams and 5 social franchise clinics) provided on average 58 LNG IUS services each (ranging between 24 and 89). These 9 providers delivered just over half (52.5%) of all LNG IUS insertion services.

LNG IUS services represented 0.4% of all voluntary LARC services provided by the participating mobile outreach teams and social franchise clinics that provided at least 1 LNG IUS service during this time frame: 0.7% among the social franchise clinics and 0.3% among the mobile outreach teams (Table 2). The majority of LARCs provided were implants (82.3%)—88.2% of LARCs provided in mobile outreach settings were implants and 69.4% of LARCs provided in social franchises were implants.

### LNG IUS Client Sociodemographic Characteristics

Sociodemographic data were available for 29.6% of LNG IUS clients (n=286), although some of these women did not answer all of the questions related to sociodemographic characteristics.

According to this sub-sample, the mean age for LNG IUS clients was 34.0 years (standard deviation [SD]=6.5). Almost half (47.2%; n=134) of LNG IUS clients in the sample were 35 years or older; 69.5% (n=146) of LNG IUS clients had completed secondary education or higher. The vast majority of LNG IUS clients in the sub-sample were married (93.8%; n=259), and these LNG

**TABLE 2.** Voluntary LARC Provision in Facilities Participating in LNG IUS Introduction Program, Nigeria, September 2016–December 2017

	Social Franchise No. (%)	Mobile Outreach No. (%)	Total No. (%)
Implants	54,720 (69.4)	151,943 (88.2)	206,663 (82.3)
IUDs	23,649 (30.0)	19,889 (11.5)	43,538 (17.3)
LNG IUS	525 (0.7)	441 (0.3)	966 (0.4) <sup>a</sup>
Total	78,894 (100)	172,273 (100)	251,167 (100)

Abbreviations: IUDs, intrauterine devices; LARC, long-acting reversible contraception; LNG IUS, levonorgestrel intrauterine system.

<sup>a</sup>Public-sector figures on provision of other LARCs were not available so the 24 LNG IUS provided through public-sector facilities are not presented in this table.

IUS clients had on average 4.4 children (SD=2.6) (n=272).

MSION's 2017 client exit interviews were conducted with 692 LARC clients (91 IUD clients and 601 implant clients). To provide a broad comparison point, we compared client exit interview data with the service delivery data collected for LNG IUS users, and we found that the profile of the clients choosing LNG IUS (for whom we have sociodemographic data) differed in a number of ways from MSION's average LARC client profile. LNG IUS clients were more highly educated (29.5% of LNG IUS clients had education beyond secondary school, compared with 7.6% of MSION LARC clients [ $\chi^2=44.7$ , degrees of freedom ( $df$ )=3,  $P=.000$ ]); older (mean age of LNG IUS clients was 34 years, compared with 30 years for MSION LARC clients [ $t=9.031$ ,  $df=960$ ,  $P<.001$ ]); and had more children (4.4 on average compared with 3.8 for MSION LARC clients [ $t=3.401$ ,  $df=958$ ,  $P=.001$ ]). The vast majority of all clients were married, but LNG IUS clients were more likely to be married (93.8% of LNG IUS clients were married compared with 89.1% of MSION LARC clients [ $\chi^2=5.103$ ,  $df=1$ ,  $P=.02$ ]).

### Supplemental LNG IUS Client Data

Due to challenges in getting all providers to systematically collect the supplemental data specific to LNG IUS clients, these data were collected from only 38% (n=400) of LNG IUS clients during the program period—from 47 social franchise clinics (285 clients), 4 mobile outreach teams (103 clients), and 3 public-sector providers (12 clients). The 12 clients from the public sector were not included in the analysis, leaving a sample of 388 cases in the analysis.

### Reasons for Choosing the LNG IUS

LNG IUS clients were asked, after they had chosen the method, why they chose the LNG IUS (Table 3). Multiple responses were possible and responses were offered spontaneously.

The most commonly mentioned reasons for choosing the LNG IUS were: reduced menstrual bleeding (61.4%); long duration of effectiveness ("it lasts for a long time") (52.0%); effectiveness (48.9%); and discreetness ("nobody will know") (41.7%). Reduced menstrual bleeding was mentioned by 91.3% of mobile outreach clients but only 51.5% of social franchise clients.

**TABLE 3.** Reasons for Choosing the LNG IUS (N=326)<sup>a</sup>

Reason <sup>a</sup>	No. (%)
Reduced menstrual bleeding	197 (61.4)
It lasts for a long time	167 (52.0)
Effective	157 (48.9)
Nobody will know	134 (41.7)
It is convenient/don't need to do anything	100 (31.3)
Won't affect future fertility	98 (30.7)
Few side effects	86 (26.9)
Recommended by friend or family	63 (19.7)
Don't want more children	59 (18.5)
Want to delay pregnancy for at least 2 years	54 (17.0)
Can use while breastfeeding	51 (16.0)
Affordable here	39 (12.3)
Other	11 (3.3)
Not sure	3 (0.9)

Abbreviation: LNG IUS, levonorgestrel intrauterine system.

<sup>a</sup> Source: Supplementary LNG IUS client data collected at time of service. 326 women gave at least 1 response to this question; the women could provide multiple responses and responses were offered spontaneously.

### Method of Choice if the LNG IUS Were Unavailable

Women who chose the LNG IUS were asked what method, if any, they would have chosen if the LNG IUS had not been available (data not shown). The majority of clients who gave a response to this question (n=332) would have chosen another LARC (78.9%, n=262): either a copper IUD (49.7%, n=165) or an implant (29.2%, n=97).

Thirteen percent of clients (n=43) would have chosen a short-acting method and 3.9% (n=13) would have chosen a traditional method. Only 2 clients (0.6%) stated that they would have gone elsewhere for an LNG IUS, and 10 (3.0%) reported that they would not have used any method if the LNG IUS were not available.

### Initial Source of Information About the LNG IUS

In a multiple-response question on the source of clients' information about the LNG IUS, with answers given spontaneously, most clients who responded to this question (n=347) mentioned first hearing about the LNG IUS from a health

**One of the most cited reasons for choosing the LNG IUS at time of service delivery was the potential of reduced menstrual bleeding.**



**TABLE 4.** First Source of Information About the LNG IUS (N=347)<sup>a</sup>

First Source of Information	No. (%)
From clinic staff today	189 (54.4)
Friend/family member	97 (28.0)
From clinic staff on another day	49 (14.1)
Community health worker/volunteer	40 (11.5)
Referred by other health provider	38 (11.0)
Poster/flyer	15 (4.3)
Other	7 (2.0)

Abbreviation: LNG IUS, levonorgestrel intrauterine system.

<sup>a</sup> Source: Supplementary LNG IUS client data collected at time of service. 347 women gave at least 1 response to this question; the women could provide multiple responses and responses were offered spontaneously.

care provider, either on the day of service (54.4%), on another day (14.1%), or through a referral from another health care provider (11.0%) (Table 4). Mobile outreach clients were more likely to have learned about the method from clinic staff on the day they received the method (96.0%) versus social franchise clients (36.4%) who received LNG IUS information through more diverse sources—37.6% of social franchise clients heard about the method from a friend or family member, and 15.1% heard about it from a community health worker (CHW) or volunteer.

### Qualitative Interviews With LNG IUS Clients and Providers

We interviewed 33 women (24 from social franchise clinics; 2 from public-sector facilities; 7 through mobile outreach teams), 30 of whom were currently using the LNG IUS and had been for at least 3 months. Three had recently discontinued use. Sociodemographic information about the in-depth interview participants is shown in Table 5. We also interviewed 32 health care providers (28 female and 4 male) who were mostly nurses and midwives. Data on LNG IUS insertions were available for 24 providers. Among these providers, the number of LNG IUS insertions ranged from 1 to 40, with an average of 7 insertions.

### Women's Reasons for Choosing the LNG IUS

The most common reason given for choosing the LNG IUS was that a health care provider recommended it.

*They said it will work well with my body. I might forget to take the pills and I don't like injection. So that's why I prefer it.* —User, age 28, 2 children

Some women also chose the LNG IUS because they wanted a method that could help with heavy bleeding or fibroids.

*From what she [the provider] said, I prefer it, because it will control the bleeding and it also reduces the date [length of bleeding], because I told her, I have heavy flow for 7 days and she said it will reduce the flow.* —User, age 30, 3 children

*She actually told me that it reduces fibroid ... I was diagnosed with multiple fibroids and I've been afraid of undergoing the surgery ... so I started using this herbal method, it wasn't working, and then she [the provider] told me about this method, that it reduces fibroids, so that was why I had it inserted.* —User, age 37, 1 child

Some participants also chose the LNG IUS because they had negative experiences with other contraceptive methods.

*I had taken [the] injectable for 6 months but blood was coming out and it didn't stop at all. That's the reason I chose another one [type of method].* —User, age 34, 3 children

### Providers' LNG IUS Insertion Experiences

All providers expressed confidence in their current ability to insert the LNG IUS; however, 13 of the 32 providers mentioned experiencing challenges, typically during their first insertion. Challenges included difficulty using the insertor, difficulty inserting in women with fibroids, forgetting to pull back the string, difficulty inserting in women with a small or anteverted uterus, and difficulty inserting when patients were not menstruating (because the cervix was perceived as being too tight). One provider indicated that she had carried out a total of 5 insertions:

*I had a challenge with some that had a huge uterine fibroid ... the LNG IUS couldn't sit in there so I had to send her for scanning ... she ended up taking Jadelle [implants]. I wouldn't want to insert something that I wasn't confident of where I wanted it to be.* —Provider, social franchise, Edo

### Perceptions of the LNG IUS Among Clients and Providers

In general, method satisfaction was high among the current users interviewed, with all 30 saying

**Satisfaction was high among LNG IUS users, with all 30 who were interviewed saying they intended to continue using the method.**



**TABLE 5.** Sociodemographic Characteristics and Family Planning Use of LNG IUS Clients (N=33)<sup>a</sup>

Sociodemographic Characteristics	Women
Age, years, mean	33.8
Marital status, No.	
Married	27
Not married	2
Number of children, mean	3.2
Education, No.	
None/some or completed primary	9
Some or completed secondary	12
Post-secondary	8
Currently using the LNG IUS, No.	30
Recently removed the LNG IUS, No.	3
Previously used family planning, No.	24
Family planning methods ever used, No. <sup>b</sup>	
Condoms	5
Pills	5
Injectables	14
Implants	8
Copper IUD	8
Other	2
Desire for future children, No.	
Yes	17
No	9
Maybe	3

Abbreviations: IUD, intrauterine device; LNG IUS, levonorgestrel intrauterine system.

<sup>a</sup> Source: In-depth interviews with LNG IUS clients.

Sociodemographic data and data on desire for future children are missing for 4 women.

<sup>b</sup> Not mutually exclusive.

they intended to continue using the method, and 28 stating they would recommend the LNG IUS method to their friends—7 of whom had already done so.

*I think after this one I will still insert it again, and I also encourage some other women to go for it, especially those that are having problems with other methods, I encourage them to go for this one.* —User, age 43, 6 children

When asked about perceived advantages with LNG IUS use, women most often mentioned that they liked not experiencing any side effects while using the method as compared with other

methods. “It works well for my body” was a sentiment frequently cited by users.

*I’m comfortable, I like it, it does not give me any problem, not any health problem that some women will say—head pain, back pain, leg pain—all these things, I did not experience anything.* —User, age 43, 6 children

In some cases, women were also happy that the method regulated or reduced their menstrual bleeding and that they did not experience any pain when using the method:

*I am very okay with it. There is no excessive bleeding compared to the last one. It did just like they told us. I am satisfied 100%.* —User, age 52, 4 children

Three women specifically cited the discreet nature of the method as a perceived advantage. Nine users had something negative to say about the method, including that they did not like the initial spotting that occurred post-insertion, being able to feel the string, and having irregular menstruation or amenorrhea.

Of the 3 women who had discontinued use, 2 were due to involuntary expulsion and the third was not satisfied with the method’s side effects, which, for her, included headaches, general body pains, and continuous bleeding.

Provider perceptions of the method included clinical advantages, particularly for women with heavy bleeding or fibroids, the contraceptive effectiveness of the method, and the ability of the method to reduce menstrual bleeding and cramps.

*One of the advantages just as I’ve always said is bleeding, you know it has tendency to reduce menstrual flow . . . then also another advantage it has, especially those that did not take permission from their husband. You know when they do something inside, their husband will not know, I think that is another advantage.* —Provider, mobile outreach, Nasarawa State

All providers said they would continue offering the method. The main reasons providers cited for continuing to offer the LNG IUS were the method’s noncontraceptive benefits, fewer side effects compared to other methods, and positive testimonies from clients.

*Number one is the report I have been getting from my clients. I will no more be getting those reports of “Madam, this thing is giving me bleeding” and if your client come to you like those, even those ones that are not coming for family planning, if you send somebody for scan and you are told that she has little, little fibroid, if you know this thing [LNG IUS] can help shrink it, you*

**Providers liked the clinical advantages of the LNG IUS, including its contraceptive effectiveness and its ability to reduce bleeding, cramps, and fibroids.**

**Key opinion leaders acknowledged the advantages of the LNG IUS but also expressed concerns about high commodity costs of currently available products.**

*have solved her problem now. So, I will continue with it. I love this new method, I love it.* —Provider, social franchise, Anambra

Most providers had nothing negative to say about the method, as illustrated by a mobile outreach provider from Abuja: “It doesn’t have any disadvantages. Rather it has more advantages.” Perceived disadvantages that were mentioned included the cost, mentioned by 2 providers, and bleeding changes, mentioned by 4 providers. Three providers mentioned expulsions of the method, particularly with their first insertions, as another disadvantage of the method.

### **Perspectives on Method-Related Bleeding Changes Among LNG IUS Clients**

Among the 12 women who reported having reduced bleeding, most said they were comfortable with lighter periods. In some cases, women clarified that while they were happy with reduced bleeding, they would have been opposed to amenorrhea. Among the 7 women who reported amenorrhea, 2 were not happy with this change, but all others mentioned they were comfortable with not bleeding. These women noted that they were either counseled about the possibility of amenorrhea or they preferred not bleeding.

*With the method I had before, it comes for 5 days and it will be heavy but since I did this one it is very scanty, like blood stain on pants on the third or fourth day and it will not rush as usual. We have been told that there is no cause for alarm. . . . I have accepted it. It has no [negative] reaction in the body.* —User, age 32, 4 children

### **Qualitative Interviews With Key Opinion Leaders**

All of the key opinion leaders reported being familiar with the method before the interview. When asked what method attributes they believed would be most attractive to women, almost all mentioned reduced menstrual bleeding. For example, one key opinion leader said:

*For LNG IUS specifically, I think you also need to highlight the fact that it can play a significant role in reducing menstrual blood flow, which can be such a nuisance for many women.*

Other attributes commonly mentioned included the method’s long-acting duration, high effectiveness, noncontraceptive clinical health benefits, and reduced menstrual cramps and pain. One respondent noted:

*Well, the product has its advantages . . . giving women the choice to make both contraceptive and noncontraceptive choices at the same time—killing 2 birds with 1 stone.*

When asked about disadvantages and barriers to wider use of the method, the most common response was high commodity costs, mentioned by 14 of the 17 key opinion leaders. Other barriers frequently mentioned included a shortage of trained providers and heavy provider workloads, low availability of the method, and the invasiveness of the insertion procedure, especially compared with implants. For example, one key opinion leader said:

*The insertion method through the vagina may not be acceptable to some groups of women, especially where there is the option of the less invasive implants.*

The majority of key opinion leaders felt that demand for the LNG IUS would increase if new, more affordable products were introduced. For example, one said, “If it’s made more affordable, yes, it will improve access and certainly uptake will increase.” However, several respondents indicated that price could remain a challenge relative to the copper IUD; for example, one respondent said, “The main barrier [with the LNG IUS] is the competition with copper IUD in terms of pricing.” Several key opinion leaders noted that many clients and providers have a preference for implants over copper IUDs, which could also influence demand for the LNG IUS.

*I don’t think the reduction in price on its own can cause an increase in demand. I think the preference for implants generally over IUDs or intrauterine systems has much more to do [with other factors] than just the cost because the implants are much more expensive than copper T IUD but they are much more popular if you look at the uptake.*

When asked what segments of the population would be most likely to use the LNG IUS if new, more affordable options were available, the most common response was women who are seeking clinical benefits of the method, with 12 respondents mentioning this group.

*I think the niche for LNG IUS is for treatment of those menstrual abnormalities in addition to contraception.*

Recommended strategies to increase voluntary uptake of the method included health care provider training, demand creation, stakeholder engagement, and commodity security.

*The challenge is making sure that the providers are well trained, the method is available at all times, and*

*the women are aware of it. . . . I think these are the challenges; once we solve them, there won't be any problem.*

Several key opinion leaders noted the importance of expanding access to the method in both the public and private sectors:

*If you use the total market approach, yes! It will thrive better in the private sector and social marketing sector—where women would want to pay for the services not necessarily where it is free. . . . And then to get the consensus of the government to include it within the basket of commodities available in the public health facilities, it will help to increase access to it.*

Key opinion leaders also acknowledged the importance of government involvement and support for scale-up of the method.

*It won't be widely available if it is only in the private sector, if it is not one of the products that the Federal Ministry of Health procures for distribution. . . . Only the government can actually scale up this and make sure that it is widely available.*

## ■ DISCUSSION

Just under 1,000 women in 16 states of Nigeria had an LNG IUS inserted between September 2016 and December 2017 by MSION-supported providers, representing less than 1% of the voluntary LARCs delivered by these providers during the time frame. This outcome was similar to results from a pilot introduction of the ICA Foundation product by Marie Stopes Kenya, which documented low uptake of the LNG IUS compared with other LARCs.<sup>15</sup> For MSION, it proved challenging to introduce a new method through a service delivery infrastructure focused on expanding access to existing LARCs and that often experienced an overwhelming demand for previously unavailable methods, such as implants, in rural settings. Nigeria is experiencing increased implant use in line with broader trends across sub-Saharan Africa.<sup>16</sup> The barriers preventing similar uptake of IUD use, such as common misconceptions about the method among both clients and providers,<sup>17</sup> may be even more acutely relevant for the lesser-known LNG IUS. Several key opinion leaders noted that women and providers may prefer implants over the LNG IUS even if the method were more affordable and widely available, because for women who want a long-acting hormonal method, the implant is better known and is seen as a less invasive procedure.

FHI 360 is currently working with partners to conduct additional market research to better understand potential demand for the LNG IUS in Nigeria.

There were also specific supply- and demand-side factors that may have limited LNG IUS uptake. One major challenge was that efforts to generate demand for LNG IUS were limited. Awareness-raising activities were integrated into existing materials and channels, and additional emphasis was not given to the LNG IUS, partly due to staff concerns about appearing to “promote” one method over another. This is reflected in the low proportion of users who had heard about the LNG IUS from community mobilizers or other awareness-raising activities. According to the 2017 MSION client exit interviews, 54.2% of MSION clients knew which method they wanted before coming for the service, demonstrating the importance of community-level awareness raising, especially for a new and lesser-known method such as the LNG IUS. Recommendations from friends and family played an important role for LNG IUS social franchise clients, with almost 40% hearing about the LNG IUS from friends or family, suggesting a valuable role for LNG IUS “satisfied users” in awareness-raising and demand-creation activities.<sup>18</sup> This indicates that uptake may remain low until there is a critical mass of voluntary early adopters, which will require more demand-side activities and a longer time frame than were possible for this program. Our analysis found some differences between MSION LARC clients and women choosing the LNG IUS, which could be explained in part by the high proportion of implant users among MSION LARC clients, who are typically younger and less educated than IUD users. Further research is planned to assess different characteristics of LNG IUS adopters compared with other family planning users, which could assist with more nuanced demand generation and forecasting efforts.

On the supply side, a small pool of providers (40% of mobile outreach teams and 7% of social franchise clinics) were responsible for delivering almost half of all LNG IUS delivered during the program period. Further evaluation is needed to ascertain the extent to which this was due to provider-side factors (e.g., expertise and motivation) or environmental factors (e.g., location and type of clientele served by these providers), but this finding is in line with other similar research, including an assessment of introducing postpartum IUD services (with the copper IUD) in Rwanda, which found that having engaged

**Challenges related to generating demand for LNG IUS may have limited uptake of the method.**

**LNG IUS insertions made up less than 1% of all voluntary LARCs delivered during the 16-month time frame.**

providers and managers was a critical factor for success.<sup>19</sup> The important role the provider played in LNG IUS uptake is also reflected in the findings from the qualitative interviews—that women’s main reason for choosing the LNG IUS was based on provider recommendation. Similarly, providers were reported as the primary source of information for the LNG IUS for almost 80% of LNG IUS clients; in mobile outreach settings, which serve more rural populations where LNG IUS awareness is likely to be very low, this rose to 99%.

These and other similar findings<sup>20</sup> suggest that at least in the initial product introduction phase, training and supervision investments should be targeted at those most likely to become “provider champions” who may build momentum around LNG IUS provision and demonstrate the potential of the LNG IUS to their peers as part of a comprehensive approach to voluntary family planning. There is also a need for additional research to further understand providers’ perspectives on who they view as appropriate clients for the LNG IUS. Interviewed providers emphasized the clinical benefits of the LNG IUS for women with heavy bleeding or fibroids, and this may lead them to view the LNG IUS as a “niche” service for women presenting with these issues. If this were the case, implementers could consider adapting provider counseling training to emphasize that the LNG IUS can be used by multiple different client groups to meet their contraceptive needs. Future training should also be informed by the qualitative findings from some providers on some initial difficulties with LNG IUS insertion.

Most LNG IUS adopters reported that they would have chosen another LARC if the LNG IUS had not been available (MSION-supported providers are known within Nigeria to be able to provide LARC services, so it is unsurprising that women seeking services from these providers would have a preference for LARCs). However, 20% of LNG IUS adopters indicated that they would have used a short-acting or traditional method, or not used any method, if the LNG IUS had not been available. This is in line with findings from a study of LNG IUS users in Kenya<sup>21</sup> and suggests that for a sizable minority of women, the addition of the LNG IUS to the family planning service mix may lead them to switch from a less effective, short-acting method of family planning.

The most cited reason for choosing the LNG IUS in the supplemental LNG IUS client data was

the potential of reduced menstrual bleeding (61%). Reduced menstrual bleeding was cited as a reason for use by over half of social franchise LNG IUS clients and almost all (93%) of mobile outreach LNG IUS clients, a notable difference that is worth further investigation. This finding was also reflected in the qualitative interviews, where women frequently mentioned choosing the method because they were told that it could help reduce menstrual bleeding (as well as treat fibroids). Although most users who experienced reduced bleeding or amenorrhea were happy with the change, a small number were not. This finding is supported by Polis and colleagues (2018) who found that women’s reactions to contraceptive-induced menstrual bleeding changes can vary widely.<sup>22</sup> Moving forward, there is a need for additional evidence regarding whether reduced or no bleeding associated with use of the LNG IUS is something that different segments of women perceive as an advantage or disadvantage<sup>23</sup>; for women who would welcome this attribute, it could be emphasized in targeted demand-generation efforts.

Overall, the majority of interviewed LNG IUS users reported positive experiences with the method. A perceived lack of side effects was the most frequently mentioned advantage. This finding is similar to results from qualitative interviews with Mirena users in Kenya, which documented that women’s main reason for choosing the LNG IUS as their family planning method was the perception that the method had fewer side effects compared with other contraceptive methods.<sup>24</sup> Since the most common reason for non-use of contraception among women in developing countries is concern about side effects and health risks,<sup>25</sup> this is also a product attribute that should be included in counseling and demand-creation efforts.

Several key opinion leaders noted the importance of a total market approach to product introduction, which would require support and engagement from the Federal Ministry of Health as well as a coherent strategy of introduction across the public and private sectors in order to maximize access for women. Most key opinion leaders felt that demand for the method would increase if more affordable products were introduced. However, all LNG IUS services under the MSION program were free or subsidized, and no change in uptake was seen during the 3 months when the price was dropped in social franchises. This suggests that product affordability alone, although an important prerequisite, will not be

**The addition of the LNG IUS to the family planning method mix may lead some women to switch from a less effective, short-acting method.**



sufficient to generate voluntary LNG IUS uptake at scale, as discussed elsewhere.<sup>4</sup>

## Limitations

Our study had important limitations. Despite concerted efforts by MSION, the supplemental data specific to LNG IUS clients were collected by providers for only 38% of LNG IUS clients and were systematically missing for certain providers. Sociodemographic data were available for only 30% of clients. Furthermore, provider-collected data may be subject to bias as the user may offer the response they believe the provider wants to hear or may be unwilling to respond negatively.

The target sample size for in-depth interviews of clients at mobile outreach and public-sector sites was not met. As a result, we addressed the general themes around the LNG IUS as developed in our protocol, but we were unable to draw comparisons across different channels. The low number of public-sector clients also meant that we were unable to offer insights on LNG IUS delivery through the public sector—an unfortunate gap because the public sector would be a key delivery channel for any LNG IUS scale-up.

The client sample for both routine data and qualitative data was limited to those who had used the method, so we could not report on the perspectives of women who did not choose the LNG IUS. Similarly, the perspectives of women who had discontinued the method were not well represented in the sample of qualitative interviewees. Finally, the perspectives of the key opinion leaders interviewed may not be representative of other stakeholders' perspectives or adequately predict the potential of the method if it is scaled up in Nigeria.

## CONCLUSION

MSION's experience, along with feedback from the providers, LNG IUS users, and key opinion leaders, suggests that the LNG IUS has attractive benefits for users, but that without adequate demand-generation activities, supportive providers, and satisfied clients to generate interest, initial uptake may remain low. As such, a holistic and multi-stakeholder approach with an affordable product and coordinated demand- and supply-side activities, including cultivating a body of provider and user champions, may be required for this method to reach its full potential in Nigeria and other similar settings.

**Acknowledgments:** Thanks to the women who took the time to take part in the in-depth interviews, to the providers for collecting the additional data, and to MSION for supporting the rollout and data collection. The design of the assessment was informed by an LNG IUS working group convened by USAID in 2015. Thanks also to Julia Byington, Kathryn Church, and Megan Elliott at Marie Stopes International, Aurelie Brunie, Laneta Dorflinger, and Markus Steiner at FHI 360, and Marguerite Farrell and Elaine Menotti at USAID for reviewing previous drafts of this article.

**Funding:** This paper was made possible in part by the support from the American People through the United States Agency for International Development (USAID) through the Support for International Family Planning and Health Organizations (SIFPO) 2: Sustainable networks project, Cooperative Agreement No. AID-OAA-A-14-00036, and from the Bill & Melinda Gates Foundation.

**Disclaimer:** The contents of this article are the responsibility of the co-authors and do not necessarily reflect the views of USAID, the United States Government, the Gates Foundation, Marie Stopes International, or FHI 360.

**Competing Interests:** None declared.

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#### Peer Reviewed

**Received:** June 28, 2018; **Accepted:** October 9, 2018

**Cite this article as:** Eva G, Nanda G, Rademacher K, et al. Experiences with the levonorgestrel intrauterine system among clients, providers, and key opinion leaders: a mixed-methods study in Nigeria. *Glob Health Sci Pract*. 2018;6(4):680–692. <https://doi.org/10.9745/GHSP-D-18-00242>

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## ORIGINAL ARTICLE

# mLearning in the Democratic Republic of the Congo: A Mixed-Methods Feasibility and Pilot Cluster Randomized Trial Using the Safe Delivery App

Nancy E. Bolan,<sup>a</sup> Larry Sthreshley,<sup>b</sup> Bernard Ngoy,<sup>b</sup> Faustin Ledy,<sup>b</sup> Mano Ntayingi,<sup>b</sup> Davis Makasy,<sup>b</sup> Marie-Claude Mbuyi,<sup>c</sup> Gisele Lowa,<sup>b</sup> Lynne Nemeth,<sup>a</sup> Susan Newman<sup>a</sup>

Health worker knowledge and self-confidence in basic emergency obstetric and newborn care (BEmONC) increased significantly 3 months after introduction of the Safe Delivery App in intervention facilities compared with controls.

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

## ABSTRACT

**Background:** Substandard delivery care has been widely documented as a major cause of maternal mortality in health facilities globally. Health worker learning via mobile devices is increasing rapidly; however, there is little evidence of mLearning effectiveness. This study sought to determine the feasibility, acceptability, and potential effect of the Safe Delivery App (SDA) on health workers' practices in basic emergency obstetric and newborn care (BEmONC) in the Democratic Republic of the Congo (DRC). The Theoretical Domains Framework was used to guide this research.

**Methods:** Eight BEmONC facilities in central DRC were randomized to either an mLearning intervention or to standard practice (control). Maternal and newborn health workers in intervention facilities (n=64) were trained on the use of smartphones and the French version of the SDA. The SDA is an evidence-based BEmONC training resource with visual guidance using animated videos and clinical management instructions developed by the Maternity Foundation and the Universities of Copenhagen and Southern Denmark. Knowledge on postpartum hemorrhage (PPH) and neonatal resuscitation (NR) and self-confidence in performing 12 BEmONC procedures were assessed at baseline and at 3 months post-intervention. Eighteen qualitative interviews were conducted with app users and key stakeholders to assess feasibility and acceptability of mLearning and the use of the SDA. Maternal mortality was compared in intervention and control facilities using a smartphone-based Open Data Kit (ODK) data application. One smartphone with SDA and ODK was entrusted to intervention facilities for the study period, whereas control facilities received smartphones with ODK only.

**Results:** The analysis included 62 health workers. Knowledge scores on postpartum hemorrhage and neonatal resuscitation increased significantly from baseline among intervention participants compared with controls at 3 months post-intervention (mean difference for PPH knowledge, 17.4 out of 100; 95% confidence interval [CI]=10.7 to 24.0 and 19.4 for NR knowledge; 95% CI=11.4 to 27.4), as did self-confidence scores on 12 essential BEmONC procedures (mean difference, 4.2 out of 48; CI=0.7 to 7.7). Increases were unaffected by health worker cadre and previous smartphone use. Qualitative interviews supported the feasibility and acceptability of the SDA and mLearning, and the potential for it to impact maternal and neonatal mortality in the DRC.

**Conclusion:** Use of the Safe Delivery App supported increased health worker knowledge and self-confidence in the management of obstetric and newborn emergencies after 3 months. SDA and mLearning were found to be feasible and acceptable to health workers and key stakeholders in the DRC.

## INTRODUCTION

Health worker clinical performance is often inadequate in low- and middle-income countries (LMICs).<sup>1</sup> Substandard services in delivery and emergency obstetric and newborn care (EmONC) have been widely documented as a major cause of maternal and newborn mortality in health facilities globally.<sup>2</sup> Worldwide,

<sup>a</sup> College of Nursing, Medical University of South Carolina, Charleston, SC, USA.

<sup>b</sup> IMA World Health, Kinshasa, Democratic Republic of the Congo.

<sup>c</sup> Pathfinder International, Kinshasa, Democratic Republic of the Congo.

Correspondence to Nancy E. Bolan (Nancy.e.Bolan@gmail.com).

approximately 830 women die daily from preventable causes related to pregnancy and childbirth,<sup>3</sup> and almost 2 million newborns die in the first week of life every year.<sup>4</sup> LMICs accounted for approximately 99% (302,000) of global maternal deaths in 2015, with sub-Saharan Africa alone accounting for about 66% of deaths (201,000).<sup>5</sup>

The Democratic Republic of the Congo (DRC), the largest country in sub-Saharan Africa, has one of the highest maternal mortality ratios in Africa (846 maternal deaths per 100,000 live births).<sup>6</sup> A woman's lifetime risk of maternal death, or the probability that a 15-year-old woman will eventually die from a maternal cause, is estimated to be 1 in 24 in the DRC, compared with 1 in 3,300 in high-income countries.<sup>5</sup> Neonatal deaths, or deaths before 28 days of life, are estimated at 29 per 1,000 live births in the DRC.<sup>4</sup> Worldwide, disparities in maternal and child health outcomes largely reflect inequalities in access to quality health services.<sup>3</sup>

Deficits in health worker knowledge and skills are linked to suboptimal patient outcomes in low-resource settings.<sup>7–9</sup> Maternal care providers demonstrate low levels of EmONC knowledge, despite varying years of provider experience, and poor clinical management skills of postpartum hemorrhage (PPH).<sup>2,10–12</sup> PPH is the leading cause of maternal mortality worldwide,<sup>13</sup> and PPH management is 1 of the 7 “signal functions” of basic EmONC (BEmONC), or key medical interventions that must be provided by all skilled birth attendants. An outreach gap exists wherein health workers in peripheral health facilities are not properly trained to manage obstetric emergencies.<sup>14</sup> Additionally, in low-volume settings, emergencies do not occur sufficiently often for providers to become experienced in obstetric complication management.<sup>15</sup>

A basic strategy for changing health worker behavior and strengthening clinical performance is promoting continuing education (CE) or continuous professional development.<sup>16</sup> However, for many health workers, access to relevant up-to-date learning opportunities is difficult or impossible, particularly in hard-to-reach or peripheral settings where maternal and newborn mortality are highest.<sup>10,17,18</sup> However, the availability and use of mobile phones is increasing rapidly in LMICs,<sup>19</sup> as is learning via mobile devices or mLearning. Given the costs and logistical challenges of providing in-person, conventional CE training programs peripherally, the use of mobile phones and other mobile electronic devices holds promise as new mechanisms to reach more remote health care workers with up-to-date

information.<sup>20</sup> Most of the studies examining mLearning, however, are of poor methodological quality and few have evaluated the effects on client health outcomes.<sup>21–23</sup>

This mixed-methods feasibility and pilot cluster randomized controlled trial (RCT) sought to determine the feasibility, acceptability, and potential impact of a recently developed evidence-based mLearning training tool, known as the Safe Delivery App (SDA), on knowledge, self-confidence, and practice of facility-based health workers in maternal and newborn health in the DRC. The trial also sought to refine intervention delivery in the DRC and strengthen study procedures required to conduct a robust large-scale trial in the future. The Theoretical Domains Framework guided this study, which views health professional behavior change as key to increasing the uptake of evidence into health care practice.<sup>24</sup>

## METHODS

### Study Design

This feasibility pilot study was a cluster RCT with the health care facility as the unit of randomization. The study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting pilot and feasibility trials.<sup>25</sup> Using mixed-methods convergent parallel design,<sup>26</sup> the principal investigator (PI) conducted qualitative semistructured interviews with app users and key stakeholders.<sup>27</sup> Additionally, selected patient outcomes were compared pre- and post-intervention. The DRC Institutional Review Board (IRB) housed at the Protestant University of Congo (UPC) provided ethical clearance for the study in April 2017, as did the Medical University of South Carolina (USA) IRB.

### Setting

The study took place over 3 months (April–July 2017) in 2 health zones (Alunguli and Kindu) in the province of Maniema, an under-resourced area in central-eastern DRC with weak infrastructure and some of the poorest maternal and newborn health outcomes in the country.<sup>6</sup> Ten health care facilities constituted sites eligible for cluster randomization owing to their being accessible by vehicle and being designated as EmONC centers supported by the Access to Primary Health Care Project (ASSP). ASSP, led by IMA World Health (IMA), an international NGO, is a health systems strengthening and primary care

**The use of mobile phones holds promise to reach more remote health care workers with up-to-date information.**

redevelopment project funded by the UK government. The project is carried out in collaboration with the Congolese government and an array of local and international partners to revitalize the country's health system in targeted health zones, fight disease, and improve key health indicators, particularly related to maternal and child mortality.<sup>28</sup> As designated EmONC centers, the 10 facilities (1 hospital and 4 health centers per zone) have received EmONC commodities and equipment, and personnel have participated in EmONC trainings.

### Randomization

Identified facilities were stratified by type into hospital or health center categories (Figure). In the hospital category, 1 facility was selected randomly for intervention, using an urn filled with labeled papers, from the matched group of 2 facilities. One health center was excluded due to being non-functional. In the health center category, 3 centers were chosen randomly from among the

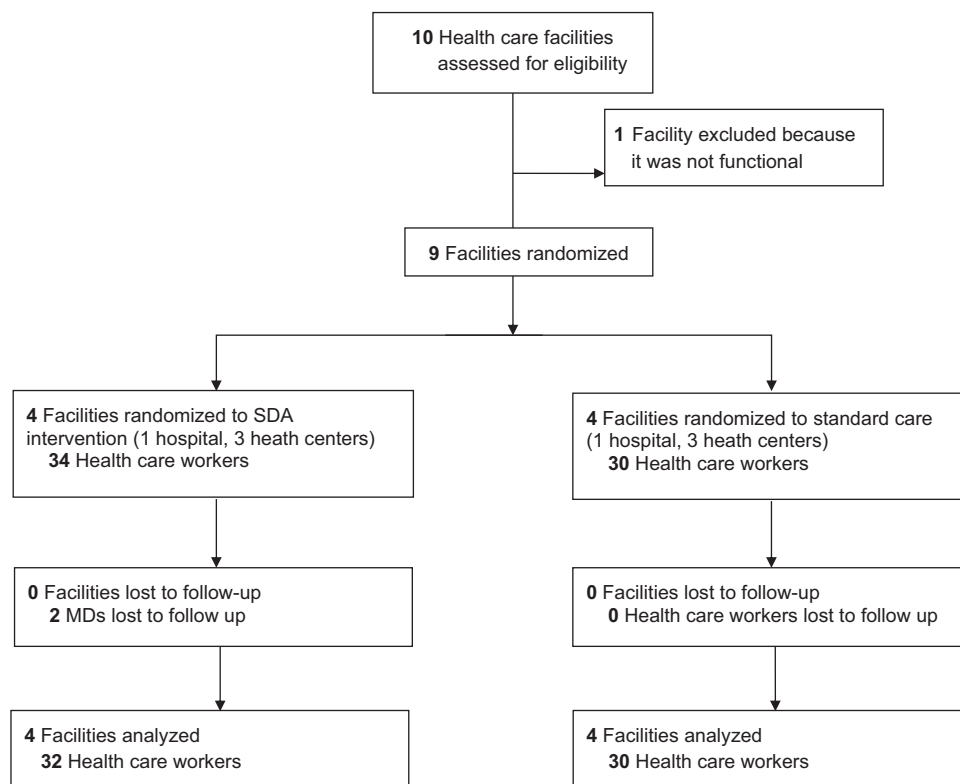
7 matched health centers for intervention and 3 for control, giving a total of 4 intervention and 4 control facilities (N=8).

### Participants

Medical doctors (MDs), nurses, and midwives working in the selected facilities who manage deliveries and newborn care were invited to participate in the study. The study population included 64 health care workers at the 8 selected health care facilities (Figure). Attrition included 2 individuals (MDs) in the intervention group who completed the pretest but were unable to participate in the posttest due to ill health. For this mixed-methods study, the PI conducted qualitative semistructured interviews with 2 categories of professionals for a cumulative total of 18 interviews. The first category of professionals consisted of 10 key stakeholders in Kinshasa (national capitol) and Kindu (capitol of Maniema Province), and the second category comprised 8 app users. For key stakeholders, the researcher used "snowball

**The study included medical doctors, nurses, and midwives working in the DRC who manage deliveries and newborn care.**

**FIGURE.** CONSORT Flow Diagram



Abbreviations: CONSORT, Consolidated Standards of Reporting Trials; MD, medical doctor.



sampling,” which relies on the personal networks of the persons the researcher taps into for referrals to other key persons.<sup>29</sup> Key stakeholders included educational, policy, program and health service leaders in the field. App users were identified as a convenience sample from among users trained on the app from the study facilities in Kindu.<sup>26</sup> All study participants provided verbal consent after they were informed about the purposes of the study during a site visit by the research team and were given IRB-approved written information (“Information for Participants Sheet”), assuring the confidentiality of all information obtained during the study and informing them of their right to withdraw from the study at any time without any effect on their employment status. The study participants and the clinic staff were not masked because the intervention required overt participation. Facilities were randomized rather than individuals to avoid contamination among health care workers in the same facility.<sup>14</sup>

### Intervention

The SDA is a training tool and job aid developed by the Maternity Foundation, University of Copenhagen, and the University of Southern Denmark. It was designed to reinforce the capability and confidence of health care workers in low-income countries on how to manage basic obstetric and neonatal emergencies. The content of the app is based on global clinical BEmONC guidelines and has been validated by an international group of global health experts.<sup>15</sup> The SDA can be downloaded free of charge for iPhone at <https://itunes.apple.com/dk/app/safe-delivery/id985603707?mt=8> and for Android at <https://play.google.com/store/apps/details?id=dk.maternity.safedelivery>.

The SDA conveys knowledge and skills via animated videos and instructions on key procedures. It also contains information on essential drugs for BEmONC. All features and functions are designed for low-literacy, low-income settings and work completely offline once downloaded. The 10 instruction films include the 7 signal functions of BEmONC as well as 3 additional essential procedures (infection prevention, management of infection in newborns, and active management of the third stage of labor). In this study, the French version of the SDA was pre-downloaded to Android smartphones in the DRC capital, Kinshasa, due to poor Internet connectivity in the pilot region (Kindu, Maniema), and 1 smartphone was allocated per facility. An Open Data Kit (ODK) data collection instrument, purposefully designed by the PI and study authors for this study,

was also loaded onto the smartphones to collect information on BEmONC vital statistics and signal function execution, beyond what was normally captured in the District Health Information System 2 (DHIS 2) (to be referred to as the health information system, or HIS), and was to be entered manually by facility staff daily.

Staff in participating facilities received explanation of the nature and purpose of the trial. Intervention health care workers received a half-day training session on the use of the smartphone, SDA, and ODK, with joint app video viewing and discussion. At the non-intervention health care facilities, the health care workers provided standard care without the assistance of the SDA. However, training was conducted for the smartphone-based ODK data collection, as data were collected at control facilities in the same manner as at intervention facilities during the study period. To ensure equal possibilities to provide standard care, the availability of a minimum package of drugs and equipment was ensured by ASSP in both groups of facilities. For the 3-month study period, the smartphone with SDA was available to all maternity providers at the intervention facilities. Solar panel battery chargers were given to all 8 facilities with the smartphones to ensure consistent ability to charge. Providers were instructed to use the SDA as often as they wished and that the phone should be made available to the team on duty at all times. Ministry of Health supervisors were tasked with visiting intervention and control facilities weekly to remind providers to use the app and/or the ODK.

### Theoretical Framework

The Theoretical Domains Framework, which positions health professional behavior change as key to increasing the uptake of evidence into health care practice, was used to guide this research.<sup>24</sup> The initial aim of this framework was to simplify and integrate a number of behavior change theories to provide a theoretical lens through which to view the cognitive, affective, social, and environmental influences on provider behavior.<sup>30–31</sup> Explanatory constructs from 33 theories of behavior change were reduced and grouped into 14 theoretical construct domains, each of which consists of a grouping of theoretical constructs, which are proposed as potential mediators of behavior change (Table 1).<sup>30–31</sup> The Theoretical Domains Framework provides a useful conceptual basis for assessing implementation problems of evidence-based care and understanding provider behavior-change

**The Safe Delivery App conveys knowledge and skills via animated videos and instructions on key BEmONC procedures.**

**The Theoretical Domains Framework reduces and groups explanatory constructs from 33 theories of behavior change into 14 theoretical construct domains.**

**TABLE 1.** The Theoretical Domains Framework With Definitions and Component Constructs<sup>30</sup>

Domain	Construct	Domain	Construct
<b>1. Knowledge</b> (an awareness of the existence of something)	Knowledge (including knowledge of condition/scientific rationale) Procedural knowledge Knowledge of task environment	<b>8. Intentions</b> (a conscious decision to perform a behavior or a resolve to act in a certain way)	Stability of intentions Stages of change model Transtheoretical model and stages of change
<b>2. Skills</b> (an ability or proficiency acquired through practice)	Skills Skill development Competence Ability Interpersonal skills Practice Skill assessment	<b>9. Goals</b> (mental representations of outcomes or end states that an individual wants to achieve)	Goals (distal/proximal) Goal priority Goal/target setting Goals (autonomous/controlled) Action planning Implementation intention
<b>3. Social/professional role and identity</b> (a coherent set of behaviors and displayed personal qualities of an individual in a social or work setting)	Professional identity Professional role Social identity Identity Professional boundaries Professional confidence Group identity Leadership Organizational commitment	<b>10. Memory, attention, and decision processes</b> (the ability to retain information, focus selectively on aspects of the environment, and choose between 2 or more alternatives)	Memory Attention Attention control Decision making Cognitive overload/tiredness
<b>4. Beliefs about capabilities</b> (acceptance of the truth, reality, or validity about an ability, or talent that a person can put to constructive use)	Self-confidence Perceived competence Self-efficacy Perceived behavioral control Beliefs Self-esteem Empowerment Professional confidence	<b>11. Environmental context and resources</b> (any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behavior)	Environmental stressors Resources/material resources Organizational culture/climate Salient events/critical incidents Person-environment interaction Barriers and facilitators
<b>5. Optimism</b> (the confidence that things will happen for the best or that desired goals will be attained)	Optimism Pessimism Unrealistic optimism Identity	<b>12. Social influences</b> (those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviors)	Social pressure Social norms Group conformity Social comparisons Group norms Social support Power Intergroup conflict Alienation Group identity Modeling
<b>6. Beliefs about consequences</b> (acceptance of the truth, reality, or validity about outcomes of a behavior in a given situation)	Beliefs Outcome expectancies Characteristics of outcome expectancies Anticipated regret Consequents	<b>13. Emotion</b> (a complex reaction pattern, involving experiential, behavioral, and physiological elements, by which the individual attempts to deal with a personally significant matter/event)	Fear Anxiety Affect Stress Depression Positive/negative affect Burn-out
<b>7. Reinforcement</b> (increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	Rewards (proximal/distal, valued/not valued, probable/improbable) Incentives Punishment Consequents Reinforcement Contingencies Sanctions	<b>14. Behavioral regulation</b> (anything aimed at managing or changing objectively observed or measured actions)	Self-monitoring Breaking habit Action planning

processes.<sup>24</sup> In this research, the Theoretical Domains Framework influenced the design of interview questions to explore the specific content of these domains in relation to barriers and facilitators to the use of the SDA, mLearning, and CE implementation in the DRC. It was also used as the coding framework for analysis.

## Outcomes and Measures

The primary outcomes of the pilot SDA trial were self-confidence and knowledge scores by the health care workers. Self-confidence and knowledge data collection instruments were developed, tested (in English), and translated into French by the Maternity Foundation in Copenhagen. Reliability and validity measures have not yet been published for these measures; this study will contribute to the assessment of the measures. Self-confidence scores were assessed for 12 essential BEmONC services. Knowledge scores were assessed for 2 key BEmONC services, management of PPH and neonatal resuscitation (NR) at baseline and at 3 months post-intervention. Additionally, baseline demographic characteristics were collected for the health workers in intervention and control groups.

Births, maternal deaths, obstetric complications, and execution of BEmONC signal functions were assessed in intervention and control clusters post-intervention using a smartphone-based ODK application designed for this study by the researchers and piloted with the SDA, as part of an examination of study procedures for a future adequately powered RCT. ODK-generated data were compared with hand-collected statistical data from health facility registers and with HIS data.

Feasibility and acceptability of the SDA were assessed through qualitative semistructured interviews with app users. Key stakeholder perspectives on the use of mLearning more broadly in the DRC were also assessed.

## Data Collection

Data collection was conducted in parallel in the intervention and control facilities using the same methods at baseline and 3 months after the training intervention. Measures were taken prior to the training of facility-based providers on the SDA and included:

- Demographic data of participant health workers (pre-intervention only)
- Provider self-rated self-confidence in handling 12 essential procedures of BEmONC

- Provider knowledge of 2 key BEmONC services: management of PPH and NR

All data were collected on paper in a classroom setting; knowledge scoring was provided by the SDA. Results were entered in Microsoft Excel and subsequently transferred and analyzed in SPSS (version 23). Three months after the SDA introduction, self-confidence and knowledge were measured a second time in the classroom using the same data collection instruments.

The PI developed 2 qualitative interview guides for the 2 qualitative target groups (SDA users and key stakeholders) using the theoretical construct domains of the Theoretical Domains Framework<sup>31</sup> to guide the questions (Table 1). Semistructured interviews were audio recorded by the PI with 8 SDA users and 10 key stakeholders after the 3-month study period. SDA users were asked about the feasibility and acceptability of using the SDA and barriers and facilitators to its use. Key stakeholders were asked about the feasibility and acceptability of the use of mLearning and CE in the DRC more broadly, as well as barriers and facilitators to the implementation of CE.

Facility-based reporting of selected health outcomes collected with the use of the ODK was compared with data reported in the HIS and with data collected by hand-review of health facility registers by the PI. Data were collected by hand at baseline for the 3 months prior to the intervention and then at 3 months post-intervention for comparison. The ODK app was developed for this research study and piloted during the study period in the 8 intervention and control facilities. The ODK data were entered by the health workers into mobile phones provided by the project immediately post-delivery/event and were available online (after uploading) for consultation from any location.

## Statistical Analysis

Descriptive summary statistics were analyzed on demographic data including age, gender, profession, educational level, years of experience, number of deliveries performed in the past month, and previous use of smartphone. Given that this was a feasibility study, power calculations were not made in choosing the sample size for the pilot trial. However, the study team did gear the sampling strategy to achieve a minimum sample size of 30 for both intervention and control groups to support the use of parametric statistical tests.

T-tests examined within-subject differences on test scores pre- and post-intervention, (where

the dependent variable was the score on self-confidence and knowledge tests within the intervention and control groups) and between-group differences in change in self-confidence and knowledge (where the dependent variable was the mean difference in change on scores for the 2 groups). Confidence intervals (CIs) and effect size were calculated. To test for potential confounding, between-group differences were calculated to examine the role of gender on test scores and the role of previous smartphone use. One-way analysis of variance (ANOVA) was used to examine test scores analyzed by the 3 health professional cadres (nurses, midwives, and MDs) across both intervention and control groups. The criterion for significance for all analyses was set at  $P < .05$ . All data were entered into Microsoft Excel and analysis was performed using SPSS (version 23).

## Qualitative Analyses

Data coding for both target groups was carried out deductively by the PI, using the 14 domains from the Theoretical Domains Framework (Table 1) as the coding framework for content analysis, in order to interpret meaning from the content of the qualitative data.<sup>30–31</sup>

Quantitative and qualitative data were interpreted and merged together, noting both the quantitative statistical results and qualitative quotes or themes that supported or refuted the quantitative results.<sup>27</sup>

## RESULTS

### Quantitative Data

#### Background Characteristics

The analysis included 62 health care workers: 32 in intervention and 30 in control groups. Table 2 shows that the participating health care workers included 26 clinical nurses and midwives (81.3%) in intervention groups and 20 (66.6%) in control groups; the remaining workers were medical doctors (18.8% intervention and 33.3% control, respectively). The average age was similar, 41.3 years and 44.2 years in the intervention and control groups, respectively. There were more women in the intervention groups ( $n=26$ , 81.3%) than the control groups ( $n=11$ , 36.7%). The control groups had less delivery experience than the intervention groups, with 13 workers (43.3%) conducting 5 or fewer deliveries during the previous month and 10 (33.3%) conducting more than 10 deliveries, in comparison

with 5 (15.6%) and 21 (65.6%) workers, respectively, in the intervention groups. Similarly, 12 workers (40.0%) had more than 10 years of experience in the profession in the control groups, compared with 17 (53.1%) in the intervention groups. Fourteen intervention health care workers (43.8%) and 9 control health workers (30.0%) had tried using a smartphone before the study.

### Baseline Knowledge and Self-Confidence Scores

Mean knowledge scores for PPH management were similar at baseline for health workers in the intervention and control groups at 47.8 (standard deviation [SD]=16.8) and 47.5 (SD=14.7), respectively, out of 100 total points (Table 3). BEmONC self-confidence mean scores were also similar at baseline in intervention and control groups at 30.3 (SD=8.7) and 31.4 (SD=10.8), respectively, out of 48 total points. In contrast, mean baseline NR knowledge scores were lower among health care workers in the intervention group (40.8, SD=17.5) compared with the control group (50.9, SD=16.6) (out of 100 points).

### Pre-Post Differences in Knowledge and Self-Confidence Scores

We found a significant association between the SDA intervention and health care workers' knowledge on both PPH and NR knowledge, as well as on BEmONC self-confidence, 3 months after baseline (Table 3). The mean increase in PPH knowledge from pre- to post-test was statistically significantly larger in the intervention group compared with the control group (18.9, SD=14.6 vs 1.6, SD=11.4, respectively;  $P < .001$ ). Similarly, the mean increase in NR knowledge from pre- to post-test in the intervention group was statistically significantly larger compared with the increase in the control group (16.8, SD=14.6 vs -2.5, SD=16.9, respectively;  $P < .001$ ), despite lower baseline scores in the intervention group. Overall self-confidence scores on 12 essential EmONC procedures also significantly improved compared with those of controls after 3 months (mean difference, 4.2 out of 48; CI=0.7 to 7.7;  $P=.02$ ). Significant differences in the self-confidence of intervention participants were found pre- and post-test on 5 essential BEmONC procedures out of 12: manual vacuum aspiration, preeclampsia/eclampsia, prolonged labor, PPH, and manual placenta removal (Table 4).

### Analysis of Potential Confounders

In exploring potential confounders, comparison of PPH and NR mean knowledge scores by provider

**The Safe Delivery App had a significant effect on health workers' knowledge of postpartum hemorrhage and neonatal resuscitation, and on their BEmONC self-confidence.**



**TABLE 2.** Demographic Characteristics of Study Groups<sup>a</sup>

	Intervention (n=32)	Control (n=30)
<b>Age, years, mean</b>	41.3	44.2
<b>Gender, No. (%)</b>		
Male	6 (18.8)	19 (63.3)
Female	26 (81.3)	11 (36.7)
<b>Professional cadre, No. (%)</b>		
Nurses	22 (68.8)	14 (46.6)
Midwives	4 (12.5)	6 (20.0)
MDs	6 (18.8)	10 (33.3)
<b>Years of experience in profession, No. (%)</b>		
1–5	3 (9.4)	6 (20.0)
6–10	12 (37.5)	12 (40.0)
>10	17 (53.1)	12 (40.0)
<b>No. of deliveries past month, No. (%)</b>		
0–5	5 (15.6)	13 (43.3)
6–10	6 (18.8)	7 (23.3)
>10	21 (65.6)	10 (33.3)
<b>Experience with smartphone, No. (%)</b>		
Tried using one	14 (43.8)	9 (30.0)
Never tried using one	18 (56.3)	21 (70.0)

Abbreviation: MD, medical doctor.

<sup>a</sup>The intervention and control group each comprised 4 health care facilities.

gender across the intervention and control groups combined showed that there were significant differences along gender lines in the pre-test for both PPH and NR; however, there were no differences between men and women for either post-test (Table 5). Mean pre-test knowledge scores for men across both intervention and control groups were statistically significantly higher for both PPH and NR knowledge (53.9, SD=13.8 and 53.6, SD=15.9, respectively) compared with women's scores (43.4, SD=15.6 and 40.3, SD=16.9, respectively) ( $P=.008$  for PPH differences between men and women and  $P=.003$  for NR differences between men and women). In contrast, men in the post-test had similar mean scores compared with those of the women on both tests. The mean increase in PPH knowledge from pre- to post-test among women was statistically significantly larger compared with the increase among men (13.8, SD=17.3 vs. 5.7, SD=11.8, respectively;  $P=.046$ ). Similarly, the mean increase in NR

knowledge among women was statistically significantly larger compared with the increase among men (12.0, SD=19.0 vs. 0.8, SD=15.7, respectively;  $P=.02$ ).

Analysis of test scores by previous smartphone experience showed significant differences for mean PPH scores on both pre- and post-tests across both intervention and control groups combined, wherein people with previous smartphone experience scored statistically significantly higher on the PPH pre- and post-tests ( $P<.05$ ) (Table 5). Although providers who had smartphone experience scored slightly higher on the NR pre- and post-tests, there was no significant difference. Similarly, there was no significant difference in mean change in PPH and NR knowledge from pre- to post-test among those experienced with smartphones and those who had never used them.

ANOVA tests were employed to examine differences in test score results by health professional cadre using a breakdown of all participants across

**TABLE 3.** Within- and Between-Subject Differences in Mean Knowledge and Self-Confidence Scores Pre-and-Post Intervention

	Intervention (n=32)	Control (n=30)	Difference Between Intervention and Control	95% CI	P Value	Cohen's d
<b>PPH knowledge scores (out of 100)</b>						
Pre, mean (SD)	47.8 (16.8)	47.5 (14.7)	0.3	(-7.8, 8.3)	.95	
Post, mean (SD)	66.7 (14.8)	49.1 (15.6)				
Pre-post difference, mean (SD)	18.9 (14.6)	1.6 (11.4)	17.4	(10.7, 24.0)	<.001	1.6
95% CI for pre-post difference	(13.7, 24.2)	(-2.6, 5.8)				
P value for pre-post difference	<.001	.46				
Cohen's d for pre-post difference	1.2					
<b>NR knowledge scores (out of 100)</b>						
Pre, mean (SD)	40.8 (17.5)	50.9 (16.6)	-10.1	(-18.7, -1.4)	.02	-0.6
Post, mean (SD)	57.7 (15.3)	48.3 (17.3)				
Pre-post difference, mean (SD)	16.8 (14.6)	-2.5 (16.9)	19.4	(11.4, 27.4)	<.001	1.2
95% CI for pre-post difference	(11.6, 22.1)	(-3.8, 3.8)				
P value for pre-post difference	<.001	.42				
Cohen's d for pre-post difference	1.0					
<b>BEmONC self-confidence scores (out of 48)</b>						
Pre, mean (SD)	30.3 (8.7)	31.4 (10.8)	-1.1	(-6.1, 3.9)	.66	
Post, mean (SD)	34.0 (8.9)	30.9 (8.7)				
Pre-post difference, mean (SD)	3.8 (6.6)	-0.4 (7.2)	4.2	(0.7, 7.7)	.02	0.6
95% CI for pre-post difference	(1.4, 6.2)	(-8.6, 2.3)				
P value for pre-post difference	.003	.74				
Cohen's d for pre-post difference	0.4					

Abbreviations: BEmONC, basic emergency obstetric and newborn care; CI, confidence interval; NR, neonatal resuscitation; PPH, postpartum hemorrhage, SD, standard deviation.

both intervention and control groups together into 3 cadres (nurses, midwives, and MDs) (Table 6). The ANOVAs indicated significant group mean differences for the 3 cadres only for the NR pre-test. For both NR and PPH pre-tests, MDs had the highest scores, followed by midwives and then by nurses. In both post-tests, nurses scored higher than midwives, with MDs scoring the highest. This difference reflects positively on the internal validity of the measurement instruments to distinguish differences between cadres.

### Patient Outcomes

In terms of patient outcome data, birth and maternal mortality figures were collected by register review of hand-entered data in the 8 study facilities. These data were triangulated

with data collected by mobile phones using the ODK application and the monthly HIS reporting. ODK-generated data corresponded well with hand-collected register data; however, the HIS data differed from the ODK and register data. Patient adverse events were too few to compare statistically, given the small number of facilities and months in the study period, as well as infrequent occurrence of maternal death. Obstetric complication and BEmONC signal function execution data collection was piloted with the ODK, but is not collected systematically by the facility registers and is not captured by the HIS reporting; therefore, these data were not possible to triangulate. Since the ODK was only introduced with the intervention (in May 2017), we were not able to compare ODK data pre- and post-test.

**TABLE 4.** Differences in BEmONC Self-Confidence Scores (on a Scale of 4 Points) Among the Intervention Group, Pre- and Post-Intervention

BEmONC Procedures	Pre-	Post-	Pre-Post Difference	P Value
	Mean (SD)	Mean (SD)		
MVA	2.1 (1.3)	3.0 (1.2)	0.88	.003
D&C	2.7 (1.2)	2.6 (1.3)	−0.03	.90
Preeclampsia/eclampsia	2.0 (1.2)	2.4 (1.4)	0.41	.03
AMTSL	3.5 (0.7)	3.7 (0.5)	0.22	.09
Prolonged labor	2.7 (1.1)	3.1 (0.8)	0.47	.007
Vacuum extraction	1.7 (1.4)	1.8 (1.3)	0.19	.45
PPH	2.6 (1.2)	3.1 (0.9)	0.50	.03
Manual placental removal	2.8 (1.0)	3.1 (1.1)	0.31	.04
Septicemia	2.2 (1.2)	2.5 (1.3)	0.34	.08
NR	3.0 (0.8)	3.0 (0.9)	0.00	1.00
Danger signs in newborns	2.6 (1.0)	2.9 (1.0)	0.31	.11
Severe infection of newborn	2.4 (1.1)	2.6 (1.0)	0.19	.31

Abbreviations: AMTSL, active management of the third stage of labor; D&C, dilation and curettage; MVA, manual vacuum aspiration; NR, neonatal resuscitation; PPH, postpartum hemorrhage.

### Qualitative Data

Responses for SDA users were coded to 8 out of 14 domains:

- Knowledge
- Skills
- Belief about capabilities
- Reinforcement
- Intentions
- Emotion
- Memory/attention/decision processes
- Environmental context and resources

Key stakeholder responses were mapped to these same 8 domains, plus 2 additional domains (social/professional role and identity, beliefs about consequences), since the discussion took into account the broader issues and context of CE in the DRC. The scope of analysis was limited to the above domains.

### Interviews With SDA Users

The 8 interviewees discussed how use of the SDA was feasible and acceptable. They perceived a positive effect on their knowledge, skills, belief about capabilities/confidence, intentions, memory/attention/decision processes, and emotion

(Table 7). Many noted that it helped to “hear and see [the information] at the same time.” One respondent said, “We did things blindly before with what we learned in school and it wasn’t enough.”

Respondents reported changes in their intentions, belief about capabilities, and memory/attention/decision processes, which led them to change their management of BEmONC, including now taking vital signs, using uterine massage and bimanual compression in PPH, using controlled cord traction during the third stage of labor, giving intravenous fluids and misoprostol for PPH, and using the partogram. One respondent said, “It changed our old habits.” The respondents discussed observed changes in patient outcomes as a result of using the SDA and how this reinforced their new practices, such as: “There are no more deaths from PPH now.” “All the children are saved with using the Ambu bag for NR.” “Now we see less fever in children after NR when we give antibiotics.” “PPH resolves if you use what is in the video.” “With info in the video for NR, you see the newborn coming back. It’s really encouraging.”

In terms of emotion, one participant said: “[The videos] are amusing and relaxing. It’s good for educating adults. There is variety.” Another said: “The animated graphics were interesting. Other trainings, they talk and talk.” The interviewees stated that they consulted the app

**TABLE 5.** Within- and Between-Subject Differences in Knowledge Scores Pre- and Post-Intervention (Among Intervention and Control Groups Combined), Analyzed by Gender and Smartphone Experience

	Men (n=25)	Women (n=37)	Difference Between Men and Women	95% CI	P Value	Cohen's d	Never Used Smartphone (n=39)	Experienced Smartphone (n=23)	Difference Between Smartphone Experience	95% CI	P Value	Cohen's d
<b>PPH knowledge scores (out of 100)</b>												
Pre, mean (SD)	53.9 (13.8)	43.4 (15.6)	10.5	(2.8, 18.3)	.008	0.72	43.0 (14.5)	55.6 (14.6)	12.6	(5.0, 20.3)	.002	.87
Post, mean (SD)	59.6 (15.3)	57.2 (18.9)	2.5	(-6.6, 11.6)	.588		53.8 (17.2)	65.6 (15.7)	11.8	(3.0, 20.5)	.009	.72
Pre-post difference, mean (SD)	5.7 (11.8)	13.8 (17.3)	8.1	(0.1, 16.0)	.046	0.56	10.9 (17.8)	10.0 (11.6)	0.85	(-7.5, 9.2)	.84	
95% CI for pre-post difference	(0.9, 10.6)	(8.0, 19.5)					(5.1, 16.6)	(5.0, 15.0)				
P value for pre-post difference	.02	<.001					.001	<.001				
Cohen's d for pre-post difference	0.37	0.80					0.69	0.66				
<b>NR knowledge scores (out of 100)</b>												
Pre, mean (SD)	53.6 (15.9)	40.3 (16.9)	13.3	(4.8, 21.9)	.003	0.81	43.9 (17.5)	48.7 (18.0)	4.7	(-4.6, 14.0)	.31	
Post, mean (SD)	54.4 (14.8)	52.3 (18.3)	2.1	(-6.7, 10.9)	.634		51.5 (17.8)	55.9 (15.0)	4.3	(-4.5, 13.2)	.33	
Pre-post difference, mean (SD)	0.8 (15.7)	12.0 (19.0)	11.2	(2.1, 20.4)	.02	0.66	7.6 (19.4)	7.2 (17.0)	.40	(-9.4, 10.2)	.94	
95% CI for pre-post difference	(-5.7, 7.2)	(5.6, 18.3)					(1.3, 13.9)	(-0.1, 14.6)				
P value for pre-post difference	.81	<.001					.02	.05				
Cohen's d for pre-post difference		0.68					0.43	0.44				

Abbreviations: CI, confidence interval; NR, neonatal resuscitation; PPH, postpartum hemorrhage; SD, standard deviation.

frequently (reinforcement), both as a learning tool and in various obstetric and neonatal emergencies as a job aid. The app topic most consulted by the respondents was PPH management (n=8). Participants preferred watching the animated videos, as compared with the written app features, and many of the providers interviewed had not consulted the other features in the app. After the PPH video, the other videos most frequently watched by the respondents were on topics related to active management of the third stage of labor (n=5), NR (n=4), eclampsia (n=2), newborn care (n=2), septicemia (n=1), manual vacuum aspiration (n=1), manual extraction of the placenta (n=1), and prolonged labor (n=1).

In terms of barriers to implementation of the SDA and BEmONC guidelines, participants cited environmental context and resources, particularly the poor practice environment, lack of consistent

medications, equipment, electricity, and poor salary. One respondent said, "Availability of material would help us to manage better: uniforms, tops, shoes, eye protective equipment, aprons, soap. We work in our own clothes and shoes, we risk to contaminate our children." Another said, "We have needs for certain materials to carry out work properly: long gloves and lights [maternity ward has no power]." "We earn nothing. Put yourself in our place. We work hard for nothing."

### Interviews With Key Stakeholders

Data from semistructured interviews with 10 key stakeholders mapped to all of the same domains noted with the SDA users, plus an additional 2 domains (social/professional role and identity and beliefs about consequences) (Table 8).<sup>30-31</sup> Respondents supported the feasibility and acceptability of mLearning and the potential for it to

**The app topic most consulted by the respondents was PPH management.**



**TABLE 6.** Knowledge Scores Pre- and Post-Intervention (Among Intervention and Control Groups Combined), Analyzed by Health Worker Cadre

	Scores, Mean (SD)				F	P Value	P Value for Paired Comparisons <sup>a</sup>		
	Nurses (n=36)	Midwives (n=10)	MDs (n=16)	All Cadres (N=62)			Nurses–Midwives	Nurses–MDs	Midwives–MDs
Pre-tests									
PPH	44.4 (16.8)	48.8 (14.1)	54.1 (12.3)	47.6 (15.7)	2.197	.12	—	—	—
NR	41.1 (18.5)	47.5 (11.8)	54.9 (15.5)	45.7 (17.7)	3.747	.03	—	.02	—
Post-tests									
PPH	56.9 (17.6)	53.2 (17.5)	64.1 (16.7)	58.2 (17.5)	1.428	.25	—	—	—
NR	53.4 (15.1)	42.8 (21.2)	59.0 (15.6)	53.2 (16.9)	3.046	.055	—	—	.04

Abbreviations: MD, medical doctor; NR, neonatal resuscitation; PPH, postpartum hemorrhage; SD, standard deviation.

<sup>a</sup> Significant for Tukey's HSD (honestly significant test).

have an impact on maternal and neonatal mortality. Many respondents noted that health workers often have no access to CE and that the same people are sometimes selected many times for training. One respondent reported, "There is a poor distribution of opportunity to get CE. There is limited training for hard-to-reach areas and for lower professional cadres." Another interviewee noted, "eLearning can train more people at lower cost."

Respondents noted that current trainings are often too theoretical, are not necessarily relevant to the daily work of health workers, are not of interest, and don't do a good job of enhancing knowledge, skills, or changing belief about capabilities or intentions to change behavior. One respondent said, "Generally, there is a weak development of competence of personnel with current continuing education." Another said, "We must change training approaches to those that facilitate learning. Approaches aren't adapted to the current era, using written modules and lectures. People don't read the modules." One service leader said, "Trainings are too theoretical via lectures; the essential notions aren't mastered and trainees aren't able to apply the knowledge to a case."

To combat infrequent access to training or self-directed learning opportunities, mLearning was noted to provide the opportunity for reinforcement of learning and to be more interesting (emotion, memory/attention/decision processes): "New technology fascinates people and they want to try it. It responds to a need or desire for learning." "New technology should be encouraged, especially for remote areas." "Audiovisual makes it more interesting and one can experience it alone or in a

group. Approaches must change from written info to interactive self-learning options."

In terms of barriers to mLearning or CE, responses centered on the domain of beliefs about consequences, and noted the lack of incentives or requirements for CE, amidst the general lack of national and regional planning and tracking capacity for CE. One interviewee noted, "There is no link between CE and career progression." Others said, "CE must meet a need, fill a gap, and lead to a change in employment status or a concrete change." "We need an accreditation system for CE, so that people have to take CE with a systematic plan of courses required for different fields." One respondent noted, "mLearning should be linked with post-training monitoring and supervision and it should be connected to performance contracts." Another said, "We must encourage health workers to do better." Interviewees also noted that many deficiencies centered on the domain of environmental context and resources, highlighting the contextual gaps that result in poor care such as lack of accountability for poor practice, insufficient remuneration for health workers, lack of drugs, equipment, and supervision. One respondent noted the differences between what people are taught and the reality of the environment: "challenges are linked to logistics: electricity, equipment."

### Triangulation of Quantitative and Qualitative Data

Qualitative interviews identified many positive benefits to the use of the SDA and mLearning in

the DRC context, particularly in terms of making evidence-based, up-to-date global BEmONC guidelines available to health workers via an exciting mLearning app. Access to information was noted to be especially critical to those who are often devoid of learning opportunities such as those in remote areas and lower-level cadres. However, interviewees noted that even for those who have been trained in the past, the SDA and mLearning offer the opportunity to learn important knowledge and skills and change behavior via the use of a more modern, more captivating approach that appeals to all health personnel. This reinforces our quantitative results of significantly increased knowledge and self-confidence scores (which directly mirror the 2 domains of knowledge and beliefs about capabilities) across all 3 health professional cadres (MDs, nurses, midwives) after 3 months of SDA use. The increases were unaffected by previous smartphone use, reinforcing that mLearning can be used to train any health worker.

Qualitative responses further elucidated barriers to mLearning and CE that are well known to key stakeholders in the DRC, such as environmental and contextual barriers and lack of resources (Table 8). The policy context, including lack of accountability and incentivizing measures (beliefs about consequences) and gaps in professional identity, mutually reinforce the environmental context and resource gaps, contributing substantially to poor quality of care by health care providers and high mortality indicators for mothers and newborns.

## ■ DISCUSSION

Learning via the SDA was feasible and acceptable for health workers in the context of the DRC. mLearning, more broadly, was assessed by our sample of key stakeholders in the DRC to be feasible, acceptable, and a potential solution to health workers' problems of accessing up-to-date learning resources in hard-to-reach settings. A pilot trial with the French-language version of the SDA in the DRC led to a significant increase in health care workers' knowledge scores for PPH and NR management and in BEmONC self-confidence scores in intervention as compared with control participants, irrespective of previous smartphone use or professional cadre of the health worker.

This study supported findings by Lund et al.<sup>14</sup> regarding the significant effect of the use of the SDA with skilled birth attendants in Ethiopia in terms of significantly increased knowledge and

skill scores of health workers on neonatal resuscitation and a non-significant 24% reduction in perinatal mortality. The trial reported in this article did not test BEmONC skill scores given the smaller nature of the feasibility study. Similarly, this trial was unable to determine the impact of the SDA on patient outcomes with sufficient power, given the small sample size and short duration of the study combined with relatively infrequent occurrence of maternal death. However, the research team did assess the feasibility of study procedures for a future larger well-powered study in the DRC.

Despite being unable to demonstrate 2 key needs for mHealth trials in LMICs identified in systematic reviews,<sup>21–23</sup> namely, trials with patient outcomes as a primary outcome and longer-term trials, this study did assess the feasibility, acceptability, and potential efficacy of using the SDA to improve the quality of BEmONC in the largest francophone African country. It also proposed a potential means of addressing the challenge of inadequate access to up-to-date evidence-based training and reference materials for health workers in hard-to-reach areas and for health worker cadres that often miss out on training opportunities in the DRC. The advantages of the SDA are that it is self-explanatory, available in many languages, is open source and free for download, and, once installed on the mobile device, does not need network coverage to function.

Conventional training of skilled birth attendants in BEmONC has proved effective to improve health care outcomes.<sup>11,32,33</sup> However, health care workers in hard-to-reach settings are often not able to participate in such trainings and are unable to access other learning resources.<sup>10,17,18</sup> Systematic reviews on mHealth show that mobile phone applications are increasingly being used in LMICs to disseminate information to health care workers.<sup>34</sup> Other pilot studies have shown related eLearning strategies to be potentially as effective as traditional training strategies.<sup>20</sup> These findings also support those of other studies that the use of electronic tools is perceived as an opportunity for improving health worker quality of care with effects on health care workers' motivation,<sup>35</sup> self-efficacy,<sup>36</sup> and enthusiasm.<sup>37</sup> The Theoretical Domains Framework proposes domains of influence or constructs for health worker behavior change that mirror these concepts, with domains such as belief about capabilities, intentions, and emotion as being critical determinants of behavior change.<sup>30–31</sup>

Lessons from this feasibility study to improve future study procedures suggest that future trials

**The Safe Delivery App is open source, free, and available in many languages.**

**Learning via the Safe Delivery App was feasible and acceptable for health workers in the DRC.**

**TABLE 7.** Qualitative Interview Results With SDA Users in Intervention Facilities (n=8)

Domains	Illustrative Quotes
Knowledge	<p>“When we hear and see [the information] at the same time it teaches a lot.”</p> <p>“We did things blindly before with what we learned in school and it wasn’t enough.”</p>
Skills	<p>“Training gave us the skills to use the app.”</p>
Beliefs about capabilities	<p>“We see that misoprostol is effective [for PPH].”</p> <p>“Had many PPH deaths before . . . PPH resolves if you use what is in the video.”</p> <p>“Now we see less fever in children after NR when we give antibiotics.”</p> <p>“With info in the video for NR, you see the newborn coming back. It’s really encouraging.”</p>
Reinforcement	<p>“We watched videos about every 3 days during free time at maternity [ward] alone or with maternity team. Also used during a case of manual removal of placenta and MVA.”</p> <p>“One can re-watch the video as many times as one wants.”</p>
Intentions	<p>“It changed our old habits”</p> <p>“Now we take vital signs and use the partogram during delivery.”</p> <p>“Before for AMSTL we put the baby off to the side; now we put baby skin-to-skin and encourage breastfeeding.”</p> <p>“We aspirated all babies; now we only aspirate when we need to.”</p> <p>“Before we held the baby upside down after delivery and gave mouth-to-mouth brutally if needed; now we use the Ambu bag, which gives a good result. We learned that we must position the baby and the mask in order to do NR.”</p> <p>“Before for respiratory distress we did mouth to mouth and gave hydrocortisone IM, no antibiotics, and saw high rate of fever. Now, we give antibiotics, and we see less fever.”</p> <p>“Before we didn’t do uterine massage or use misoprostol or IV fluids for PPH management; now we use massage, misoprostol, and IV fluids . . . with good results.”</p> <p>“Now we do uterine massage [with PPH] and use a urinary catheter, and we see the uterus contracts.”</p> <p>“Before we pushed the uterus down during 3rd stage; now we support the uterus and use controlled traction on the cord.”</p> <p>“Now with premature rupture of membranes we give antibiotics.”</p>
Memory, attention, and decision processes	<p>“mLearning with the app is good, the learner sees the information, hears it and then can do it themselves. It helps participants to remember the visual images or auditory information.”</p>
Environmental context and resources	<p>“Only 2 of us were trained back in 2012 but need others to be trained, and we need formative supervision more often.”</p> <p>“Need uniforms, tops, shoes, eye protective equipment, aprons, soap. We work in our own clothes and shoes, we risk to contaminate our children.”</p> <p>“We earn nothing—12,700 Francs per month. Put yourself in our place. We work hard for nothing.”</p>
Emotion	<p>“It’s amusing and relaxing. It’s good for educating adults. There is variety.”</p> <p>“App should be made more widely available—in pediatrics and the operating room.”</p> <p>“Animated graphics were interesting. Other trainings, they talk and talk.”</p> <p>“We are very happy with the intervention. It’s very encouraging.”</p>

Abbreviations: AMSTL, active management of the third stage of labor; IM, intramuscular; IV, intravenous; MVA, manual vacuum aspiration; PPH, postpartum hemorrhage; NR, neonatal resuscitation; SDA, Safe Delivery App.

of mLearning in the DRC would benefit from an additional means of data collection for mortality and other critical BEmONC data, such as through the use of the ODK data collection instrument designed for this study or dedicated data collection staff on-site. Researchers found that data collected by hand-review of health facility registers and

ODK data collected daily via mobile phone were comparable, but differed from monthly HIS reporting. Although not the primary question in our research, interview data revealed possible explanations for discrepancies in data collected from these different sources including under-reporting of mortality in the HIS by health

**TABLE 8.** Qualitative Interview Results With Key Stakeholders (n=10)

Domains	Illustrative Quotes
Knowledge	<p>“Trainings are theoretical via lectures. They teach too many things at the same time and they rush through the material. Learners have trouble prioritizing and leave with confusion; meanwhile the essential notions aren’t mastered and they aren’t able to apply the knowledge to a case. Providers have been trained before but it’s as if they have never been trained. It would be better to have more practical training.”</p> <p>“CE should incorporate adult learning principles, and it should be continuous/regular.”</p> <p>“Hospital/workers are often ‘subjected’ to trainings that they haven’t planned . . . should be included in planning in response to priority gaps/needs.”</p> <p>“Must present things that are relevant to what they [health workers] do—where they get practical info and can see the gestures.”</p> <p>“SDA renders learning operational.”</p>
Skills	<p>“There is a weak development of competence of personnel.”</p> <p>“Care has become mechanized and based on memorized protocols, so they [health workers] have a difficult time analyzing situations.”</p> <p>“Providers were able to put into practice new things learned [from the SDA] such as using the side of the hand for manual extraction [of the placenta] and bimanual compression for PPH.”</p> <p>“Should be conducted in real work conditions to combat the gap between what one knows and what one does.”</p> <p>“mLearning also teaches people how to use technology.”</p>
Social/professional role and identity	<p>“[Health workers] use what they have to treat patients, but they are not going to look something up or get additional info.”</p> <p>“Must create a way for people to share information. Maybe form a club (to discuss with an animator/trainer). If the program is personalized, even better—get points, get certificate [must be linked to the employer].”</p>
Beliefs about capabilities	<p>“Imposing CE is only of limited value, when the boss isn’t there . . . they won’t do it.”</p> <p>“Inspiring them to the benefits of CE would be more motivating than sanctions.”</p>
Beliefs about consequences	<p>“No accountability related to malpractice.”</p> <p>“CE regulations/requirements are where the country needs to go to make a change.”</p> <p>“[Employers or] Ministry should have tracking capability related to CE to be able to identify persons in need of training and needed training.”</p> <p>“Must assure career path for health workers based on regular evaluation.”</p> <p>“Must lead to a change in employment status/have a concrete change.”</p>
Reinforcement	<p>“mLearning is interesting to reinforce learning since the tool is available at all times and the provider can view the information many times.”</p> <p>“Ideal if someone [trainer] follows the process to enrich the application [give retro-information and ensure that needs are covered in the app], and to answer questions.”</p> <p>“SDA should be made available in all health zones with post-training supervision . . . would decrease maternal and neonatal mortality.”</p>
Intentions	<p>“For remote settings, eLearning is interesting—self-directed learning, and should measure if they acquire competencies/can be certified, and put in place a system for them to be encouraged to do this.”</p>
Memory, attention, and decision processes	<p>“The images allow people to learn with more stimulation and attention. The visual memory can fix the memory of the information for longer.”</p> <p>“When time passes after a training, you forget.”</p> <p>“If people are motivated they may retain info better.”</p>
Environmental context and resources	<p>“Better working conditions [salaries, supervision, environment] would push people.”</p> <p>“Poor distribution of opportunity to get CE training. Limited training for hard-to-reach areas and for lower health worker cadres (A3, A2).”</p> <p>“For CE, programs/partners decide subject, may repeat subjects already covered, same people always go to the trainings and are missing from work.”</p> <p>“No clear CE policy. Who chooses the subjects? And must be defined who participates and what one gets from it. Needs a clear policy, training should be programmed and budgeted . . . so that employers recognize the training and has it planned/budgeted for their facility.”</p> <p>“eLearning can train more people at lower cost.”</p>
Emotion	<p>“Seeing the images is more interesting than just talking theoretically.”</p> <p>“Approaches must change from written info to interactive self-learning options.”</p> <p>“New technology fascinates/attracts people and they want to try it; it responds to a need.”</p>

Abbreviations: CE, continuing education; PPH, postpartum hemorrhage; SDA, Safe Delivery App.

**The recently updated version of the Safe Delivery App incorporates additional features to measure learning and motivate the user, such as game-like features.**

workers for a variety of reasons such as incomplete compilation of HIS data using only certain registers (maternity) rather than all related hospital registers where maternal or newborn deaths would be recorded (such as emergency, gynecology, and pediatric services), or omission in reporting deaths given that HIS data are only collated on a monthly basis and recording may be done retrospectively. Under-reporting of adverse outcomes was mentioned to be deliberate on occasion, due to fear of punishment by health authorities, or financially motivated. Such factors would clearly complicate the measurement of patient outcomes in an eventual follow-up study using HIS data alone in the DRC unless certain remedial measures are taken to improve mortality data quality.

Future work could also benefit from use of the recently updated version of the SDA, which incorporates additional features to measure learning and to motivate the user through game-like features, where learners must gain a certain number of points to move to the next learning level and are certified once they achieve the top score. These features might exponentially increase the benefits of the SDA intervention by providing incentives and rewards, and promoting motivation and self-empowerment, thereby touching on domains such as emotion, reinforcement, and belief about capabilities. These features would rely on Internet connectivity and bandwidth, which remain out of reach for individuals in many contexts due to poor connections or lack of financial access, despite rapid increases of the use of wireless communication in many developing countries.<sup>34</sup>

The implications of this study are that the SDA and other mLearning interventions likely increase the ability of health workers to provide improved quality of care during obstetric and neonatal emergencies as well as improved routine obstetric and newborn care. Evolving policies for continuing education in the DRC and similar contexts should consider the integration of mLearning as an approach for training and as a job aid for EmONC in order to reduce maternal and newborn mortality, as well as considering the integration of mLearning tools for other priority and emergent health problems. Challenges to implementation of quality EmONC care, posed by gaps in the environmental context and resources, as well as the regulatory and accountability environment, must be considered and addressed alongside other programmatic measures such as quality improvement initiatives to target health system weaknesses.

## Limitations

The small sample size of this study limited findings by reducing the power of the study. In terms of design limitations, 8 facilities were randomized in this study, rather than individuals, to avoid contamination of the intervention group to the control group,<sup>14</sup> and researchers did note disparities between the intervention and control groups in the gender, professional cadre composition, and previous experience of the health workers. Additionally, blinding of intervention and control clusters was impossible owing to the nature of the intervention, which increased the risk for information bias. It is possible, however, that some control participants accessed the SDA in intervention facilities, since the facilities were all in relatively close geographic approximation. Other limitations included that the study team was unable to consistently track SDA use during the study, given that this capability was not completely developed at the time of intervention. Access to such data would enrich results and analysis of the association between SDA use and changes in measures in future research.

## CONCLUSION

The SDA and mLearning was found, through both qualitative and quantitative methods, to be feasible and acceptable to health workers and to key stakeholders in the DRC, the largest francophone African country. SDA use was associated with increased health worker knowledge on PPH and NR management 3 months after introduction and increased health worker self-confidence overall in the management of obstetric and newborn emergencies. These results contribute to the growing body of knowledge on mHealth in low-income countries where the quality of care is challenged by lack of continuing education programs.

**Acknowledgments::** We would like to thank the Ministère de la Santé Publique, DRC; The Maternity Foundation; Drs. Stine Lund and Bjarke Sorensen, University of Copenhagen; Dr. Peter Johnson, Jhpiego; Dr. Martina Mueller and Rebeca Mueller, Medical University of South Carolina; and Steven Fountain and Chris Kalonji, IMA World Health.

**Funding:** IMA World Health.

**Competing Interests:** None declared.

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### mLearning en République Démocratique du Congo : Un Essai Randomisé Pilote par Groupe Utilisant des Méthodes Mixtes à l'Aide de l'Application « Safe Delivery »

Les connaissances des professionnels de santé et leur confiance en soi dans les soins obstétricaux et néonataux d'urgence de base (SONU-B) se sont significativement améliorées trois mois après l'introduction de l'application « Safe Delivery » dans les établissements de santé d'intervention par rapport aux établissements témoins.

#### RÉSUMÉ

**Contexte :** Le manque de qualité des soins à l'accouchement a été largement documenté comme cause majeure indirecte des décès maternels dans les établissements de santé au niveau mondial. Bien que l'apprentissage des professionnels de santé via des téléphones mobiles (mLearning) augmente rapidement, il existe peu de preuves de l'efficacité du mLearning. Cette étude visait à déterminer la faisabilité, l'acceptabilité et les effets potentiels de l'application « Safe Delivery » (SDA) sur les pratiques des professionnels de santé en matière de soins obstétricaux et néonataux d'urgence de base (SONU-B) en République Démocratique du Congo (RDC). Le « Cadre des Domaines Théoriques » a été utilisé pour guider cette recherche.

**Méthodes :** Huit établissements de santé de SONU-B situés dans le centre-est de la RDC ont été sélectionnés de façon randomisée pour recevoir une intervention de mLearning ou être établissements témoins. Les professionnels de santé en charge de la santé maternelle et néonatale dans les établissements d'intervention (n = 64) ont été formés à l'utilisation des smartphones et à la version française de la SDA. La SDA est une ressource de formation en SONU-B basée sur des preuves empiriques. Il s'agit d'une application visuelle qui utilise à la fois des vidéos et des instructions de prise en charge clinique développées par la Maternity Foundation et les universités de Copenhague et du Danemark du Sud. Les connaissances sur l'hémorragie du post-partum (HPP) et la réanimation néonatale (RN) ainsi que la confiance en soi pour l'exécution de 12 procédures SONU ont été évaluées au départ et trois mois après l'intervention de mLearning. Dix-huit entretiens qualitatifs ont été menés avec les utilisateurs de l'application SDA et les principales parties prenantes afin d'évaluer la faisabilité et l'acceptabilité du mLearning, ainsi que l'utilisation de la SDA. La mortalité maternelle a été comparée dans les établissements d'intervention et les établissements témoins à l'aide d'une application de données Open Data Kit (ODK), qui utilise également les smartphones. Des smartphones avec les applications et ODK ont été confiés aux établissements d'intervention pour la période de l'étude, tandis que les établissements du groupe témoin n'ont reçu que des smartphones avec ODK.

**Résultats :** L'analyse a porté sur 62 professionnels de santé. Les scores de connaissances sur l'hémorragie du post-partum et la réanimation néonatale ont augmenté de manière significative par rapport aux valeurs initiales chez les participants à l'intervention par rapport aux participants témoins trois mois après l'intervention. En effet, la différence moyenne pour les connaissances sur l'HPP est de 17,4 sur 100 (intervalle de confiance [IC] 95% = 10,7 à 24,0) et de 19,4 pour les connaissances sur RN (IC 95% = 11,4 à 27,4). De plus, les scores de confiance en soi pour 12 procédures SONU ont également significativement augmenté (différence moyenne 4,2 sur 48, IC 95% = 0,7 à 7,7). Les améliorations n'ont pas été affectées par le profil des professionnels de santé ni l'utilisation antérieure du smartphone. Des entretiens qualitatifs ont confirmé la faisabilité et l'acceptabilité de la SDA et du mLearning, ainsi que le potentiel impact de ces approches sur la mortalité maternelle et néonatale en RDC.

**Conclusion :** L'utilisation de l'Application « Safe Delivery » a permis d'accroître les connaissances des professionnels de santé et leur confiance en soi dans la prise en charge des urgences obstétricales et néonatales après trois mois. La SDA et le mLearning ont été jugés faisables et acceptables pour les professionnels de santé et les principales parties prenantes en RDC.

#### Peer Reviewed

**Received:** July 23, 2018; **Accepted:** November 6, 2018

**Cite this article as:** Bolan NE, Sthreshley L, Ngoy B, et al. mLearning in the Democratic Republic of the Congo: a mixed-methods feasibility and pilot cluster randomized trial using the Safe Delivery App. *Glob Health Sci Pract.* 2018;6(4):693-710. <https://doi.org/10.9745/GHSP-D-18-00275>

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## ORIGINAL ARTICLE

# Introduction of Subcutaneous Depot Medroxyprogesterone Acetate (DMPA-SC) Injectable Contraception at Facility and Community Levels: Pilot Results From 4 Districts of Uganda

George Odwe,<sup>a</sup> Kate Gray,<sup>b</sup> Annet Kyarimpa,<sup>c</sup> Francis Obare,<sup>a</sup> Grace Nagendi<sup>d</sup>

Over 1 year, the NGO-led project provided more than 14,000 units of DMPA-SC, mostly in community settings and to a substantial proportion (43%) of young women. The share of injectables increased significantly, as did the volume of all methods provided, including short-acting, long-acting, and permanent methods.

## ABSTRACT

Reproductive Health Uganda (RHU), a local NGO, introduced subcutaneous depot medroxyprogesterone acetate (DMPA-SC, brand name Sayana Press) in 4 districts of Uganda between April 2016 and March 2017. RHU trained public and private facility providers on all family planning methods including DMPA-SC; trained community health workers (known as village health teams, VHTs) to give family planning counseling, provide short-acting methods including DMPA-SC, and make referrals for long-acting and permanent methods; conducted mobile outreach and raised awareness of family planning; and provided family planning commodities. We used a retrospective cross-sectional evaluation design drawing on data from (1) in-depth interviews with 32 facility- and community-based providers; (2) key informant interviews with 7 policy makers and program staff; and (3) family planning program statistics from 4 RHU clinics, 26 mobile outreach sites, and 40 VHTs in 4 study districts. Data collection took place between April and June 2017. Over 12 months, 14,273 units of DMPA-SC were provided in RHU clinics, by mobile outreach teams, and by VHTs. DMPA-SC units were mostly administered in community settings either by VHTs (70%) or at mobile outreach events (26%). A substantial proportion (43%) of DMPA-SC units were administered to young people (<25 years), a significantly higher proportion compared with other methods provided to this age group through the project ( $P<.001$ ), except condoms. In addition, a greater proportion of DMPA-SC units provided at the community level by VHTs were used by young people (45%) compared with units provided at outreach (36%) or in clinics (35%). Overall, injectables (DMPA-SC and intramuscular DMPA combined) came to represent 43% of all contraceptive methods provided, up from a baseline of 20%. This shift occurred despite significant increases in the volume of all other methods provided ( $P<.001$ ). Qualitative data revealed various factors that facilitated introduction, including comprehensive training, commodity availability, strong referral links, and early community engagement. RHU's experience supports the viability of community-based delivery of DMPA-SC and identifies opportunities to strengthen this approach. There is further evidence that DMPA-SC may be popular with young people, especially in community settings.

## INTRODUCTION

An estimated 214 million women and girls in low- and middle-income countries (LMICs) would like to stop having children or delay their next birth for at least 2 years but are not using a modern contraceptive method and are therefore at risk of unintended pregnancy.<sup>1</sup> Limited access to family planning services and restricted method choice have been cited as main reasons for high levels of unmet need for contraception in LMICs.<sup>2</sup> In an effort to increase the availability of

a range of contraceptive methods, and in doing so, potentially attract new voluntary family planning users, a new injectable contraceptive known as subcutaneous depot medroxyprogesterone acetate (DMPA-SC) has been developed.<sup>3</sup>

DMPA-SC is a 3-month, progestin-only injectable contraceptive containing 104 mg of DMPA per 0.65 ml dose that is administered into certain fatty areas under the skin. Sayana Press (a brand of DMPA-SC developed by Pfizer) combines the drug and needle in a single pre-filled Uniject system (a trademark of Becton, Dickinson and Company), designed only for single use. The single-unit design makes DMPA-SC easy to transport and simple to administer as providers do not have to draw a measured dose into the syringe from a vial.<sup>4,5</sup> These features make it suitable for community-based distribution and for women to administer themselves, thus avoiding

<sup>a</sup>Population Council, Nairobi, Kenya.

<sup>b</sup>International Planned Parenthood Federation, London, United Kingdom.

<sup>c</sup>Reproductive Health Uganda, Kampala, Uganda.

<sup>d</sup>International Planned Parenthood Federation, Africa Region, Nairobi, Kenya.

Correspondence to George Odwe (godwe@popcouncil.org, godweus@gmail.com).

**The single-unit design of Sayana Press makes it easy to transport and simple to administer.**

the need for them to travel to a health facility.<sup>6</sup> In 2018, the World Health Organization (WHO) included DMPA-SC in its revised *Essential Medicines List*.<sup>7</sup> DMPA-SC is currently approved for use in a number of sub-Saharan African countries including Burkina Faso, Niger, Senegal, and Uganda.<sup>8</sup>

To date, the bulk of evidence on DMPA-SC has come from high-quality research trials on the method's acceptability, efficacy, and safety. However, there is still much to learn about different models and approaches for DMPA-SC rollout and scale up. In 2016/2017, Reproductive Health Uganda (RHU)—a member association of the International Planned Parenthood Federation—implemented a 1-year project to increase learning on provision of DMPA-SC at the facility and community levels. The project, also known as the Sayana Press Learning Project, was implemented in 4 districts of Uganda—Kabale, Kabarole, Mbale, and Mbarara.

Estimates from the 2016 Uganda Demographic Health Survey show that about 41% of pregnancies in Uganda are unintended.<sup>9</sup> Teenage pregnancy is also highly prevalent—approximately 25% of adolescent girls aged 15–19 in Uganda have begun childbearing.<sup>9</sup> However, the modern contraceptive prevalence rate (mCPR) is modest at 35% among married women aged 15–49 years.<sup>9</sup> The Ugandan government has made commitments to the Family Planning 2020 (FP2020) initiative to improve access to family planning services, with the goal of reducing unmet need for family planning from 38% to 10% and increasing mCPR to 50% by 2020.<sup>10</sup> To help achieve these targets, Uganda is implementing a community-based health strategy allowing community health workers, known as village health teams (VHTs) in the country, to provide both family planning information and selected services including injectable contraceptives and other short-acting methods (condoms and oral pills) in their community.<sup>11–15</sup> In 2014, the Ugandan government launched a pilot introduction of DMPA-SC through the VHT program across 28 districts to accelerate achievement of FP2020 goals. RHU was one of a range of partners involved in this initial pilot introduction of DMPA-SC and served as the first private-sector NGO clinic entry point for the DMPA-SC pilot in Gulu district, northern Uganda.

In this article, we document RHU's experience in introducing DMPA-SC services in 4 other districts of Uganda through various models, consisting of static clinics, community-based distribution through VHTs, and mobile outreach in remote communities by a team of trained providers. We also share lessons learned from RHU's experience

in supporting the rollout of DMPA-SC from the perspective of key informants involved in the project including service providers, project staff, and government officials. The findings can inform policy makers and program implementers in other countries on how to introduce DMPA-SC into the range of available methods.

## ■ PROJECT DESCRIPTION

### Study Setting

RHU is a Ugandan NGO with a network of 17 clinics across the country that offer integrated sexual and reproductive health information and services including comprehensive family planning, testing and treatment for HIV and other sexually transmitted infections, and cervical cancer screening. RHU provides these integrated services through clinic-based providers, mobile outreach teams, and community resource persons, including VHTs. RHU implemented the Sayana Press Learning Project from April 2016 through March 2017 in collaboration with the Ministry of Health (MOH), mainly in partnership with public-sector facilities (health centers) in remote settings. In selecting project districts, RHU prioritized (1) districts with well-established RHU clinics offering a full range of voluntary family planning services and capacity to support local public-sector facilities and community health workers during the pilot, and (2) districts where no other DMPA-SC implementation had taken place through other pilots. [Table 1](#) presents current reproductive health indicators for the sub regions where study districts are located.

[Table 2](#) lists programmatic inputs. In order to achieve integration of DMPA-SC into the family planning service delivery structure at the community level and strengthen family planning services in static clinics, RHU provided support in 5 key areas: training; demand creation; commodity supply; partnerships and collaboration; and service delivery at community and facility levels.

### Training

A total of 42 facility-based providers, mainly nurses, midwives, and clinical officers, primarily from public-sector facilities with outreach sites as well as from RHU's own facilities, were trained on DMPA-SC using modules developed by PATH. Public-sector providers also received refresher training on all family planning methods to be able to support mobile outreach services in their respective facility sites. In addition, RHU recruited 40 active VHTs (10 in each study district) and

**RHU provided support in training, demand creation, commodity supply, and service delivery in order to integrate DMPA-SC into family planning services at the community and facility levels.**



**TABLE 1.** Reproductive Health Indicators for Study Districts, Uganda, 2016

District	Subregion	TFR	Teenage Pregnancy (%)	mCPR (%)	Unmet Need for Family Planning (%)
Mbale	Bugisu	5.6	28.2	43.2	22.1
Kabarole	Toro	5.4	30.3	37.4	41.3
Mbarara	Ankole	4.9	18.9	36.2	44.5
Kabale	Kigezo	4.6	15.5	43.2	NA
<b>National</b>		<b>5.4</b>	<b>24.8</b>	<b>34.8</b>	<b>31.9</b>

Abbreviations: NA, not available (due to small numbers of data); mCPR, modern contraceptive prevalence rate; TFR, total fertility rate. Source: UBOS and ICF (2018).<sup>9</sup>

trained them for 7 days using the MOH's national curriculum for VHTs and DMPA-SC training modules developed by PATH. The VHTs' training was aimed at improving their knowledge, skills, and competencies on counseling family planning clients on all methods; provision of short-acting methods including DMPA-SC; community mobilization; reporting; and referrals. To ensure service quality, RHU clinical staff conducted monthly supportive supervision meetings with VHTs participating in the project. At these meetings, existing MOH tools were used to assess and strengthen VHT skills.

### Demand Creation

RHU supported VHTs to mobilize communities to attend outreach events and to provide information about family planning when visiting households in their communities. In addition, RHU providers conducted family planning health education sessions at health centers during outreach visits. The project also used the media (mainly radio talk shows), billboards, and community dialogue sessions to increase access to information about family planning, including DMPA-SC.

To update community stakeholders about the family planning services available through the project and to ensure community acceptance of planned activities, the project team held meetings with community leaders from project districts prior to implementation. Information about DMPA-SC was shared with participants during these stakeholder workshops.

### Commodity Supply

In line with standard supply-chain processes in Uganda, public health facilities in project districts received commodities from the Ugandan National Medical Stores. Like all NGO partners that

collaborated with the MOH to deliver family planning services in Uganda, RHU received contraceptive commodities including DMPA-SC via the Uganda Health Marketing Group (UHMG) and distributed them to all its service delivery points in the participating districts.

### Partnerships and Collaboration

RHU was a member of the DMPA-SC coordination group that spearheaded the rollout of DMPA-SC services nationally. Members of the DMPA-SC coordination group met on a monthly basis to track DMPA-SC introduction progress, identify and respond to emerging challenges, and make decisions about national DMPA-SC introduction. The coordination group included representatives from the MOH and other NGOs implementing DMPA-SC rollout activities in other districts. Members of the coordination group complemented each other to support DMPA-SC activities. For example, RHU adopted the DMPA-SC educational and training materials developed by PATH to train providers.

### Service Delivery

RHU implemented the Sayana Press Learning Project within the existing family planning service delivery structures, via 3 principal channels: VHTs, static clinics, and mobile outreach. **At the community level**, the project supported integration of DMPA-SC into family planning service delivery via:

- **40 VHTs (10 from each district)**, who provided comprehensive family planning counseling; delivered DMPA-SC along with other short-acting methods to women in their homes and in community settings; and referred clients interested in long-acting methods to mobile health units, RHU clinics, or public-sector static clinics. To enable them to travel

**DMPA-SC was provided through 3 principal channels: village health teams, static clinics, and mobile outreach.**



**TABLE 2.** Sayana Press Learning Project Activities by Service Delivery Channel, Uganda, April 2016–March 2017

	Service Delivery Channels			
	VHTs	Static Clinic		
		Public Sector	RHU Clinics	Mobile Outreach
<b>Number supported</b>	40 VHTs (40% men, 60% women; 10 VHTs per district selected from existing cadre of active VHTs)	26 clinics with outreach site <ul style="list-style-type: none"> <li>• Kabale (9)</li> <li>• Kabarole (4)</li> <li>• Mbale (6)</li> <li>• Mbarara (7)</li> </ul>	4 clinics (1 RHU static clinic per project district)	Mobile outreach conducted in 26 public-sector clinic sites
<b>Service delivery</b>	<ul style="list-style-type: none"> <li>• Comprehensive family planning counseling, information, and awareness raising</li> <li>• Short-acting methods (DMPA-IM, DMPA-SC, oral contraceptives, condoms)</li> <li>• Referral to mobile outreach teams, RHU clinics, or public-sector clinics for long-acting methods and other SRH services</li> </ul>	<ul style="list-style-type: none"> <li>• Comprehensive family planning counseling and information</li> <li>• Short-acting methods (DMPA-IM, DMPA-SC, oral contraceptives, condoms)</li> <li>• Long-acting methods (implants and IUDs)</li> <li>• Permanent methods (tubal ligation and vasectomy)</li> <li>• Other SRH services (including HIV and STI testing/treatment and cervical cancer screening)</li> </ul>		
<b>Trainings</b>	All 40 VHTs received a 7-day training on: <ul style="list-style-type: none"> <li>• Comprehensive counseling on all methods (including DMPA-SC)</li> <li>• Provision of DMPA-SC</li> <li>• Provision of other short-acting methods</li> <li>• Referral processes</li> <li>• Project data collection</li> </ul>	42 facility-based providers (nurses, midwives, and clinical officers) drawn from public-sector facilities with outreach site and RHU facilities received a 2-day training on: <ul style="list-style-type: none"> <li>• Comprehensive counseling on all methods including DMPA-SC</li> <li>• Provision of DMPA-SC</li> <li>• Refresher training on all family planning methods</li> </ul>		
<b>FP supplies and equipment</b>	VHTs obtained FP commodities from RHU clinics in project districts	FP commodities provided through the NMS	All FP commodities (including DMPA-SC) provided through UHMG	All FP commodities and equipment provided by RHU outreach teams
<b>Additional support provided</b>	<ul style="list-style-type: none"> <li>• Monthly supportive supervision provided by RHU clinical staff</li> <li>• Comprehensive counseling on all methods including DMPA-SC</li> </ul>	NA	NA	NA
<b>Demand creation</b>	<ul style="list-style-type: none"> <li>• 1 stakeholders' meeting involving 118 participants (including district health officers and religious and community leaders) drawn from all 4 project districts</li> <li>• Educational outreach by RHU providers or VHTs about importance of family planning method through door-to-door mobilization, group information sessions, IEC materials, and media (mainly TV and radio programs)</li> </ul>			

Abbreviations: DMPA-IM, intramuscular depot medroxyprogesterone acetate; DMPA-SC, subcutaneous depot medroxyprogesterone acetate; FP, family planning; IEC, information, education, and communication; IUD, intrauterine device; NA, not applicable; NMS, National Medical Stores; RHU, Reproductive Health Uganda; SRH, sexual and reproductive health; STI, sexually transmitted infection; UHMG, Uganda Health Marketing Group; VHT, village health team.

within their communities and to clinics to restock family planning commodities, VHTs received a monthly transportation allowance of approximately 30,000 Ugandan shillings (about US\$8 at 2018 exchange rates). In

setting this allowance, the project used standard RHU rates for 2015/2016, which were lower than the rate paid by comparable NGOs but higher than the government rate of US\$3 per month.

- **Mobile outreach teams**, who provided a mix of long- and short-acting family planning methods (including DMPA-SC). Each team consisted of 1 driver, at least 1 VHT to mobilize communities, and a mix of RHU outreach clinical staff and project-trained public-sector service providers—mainly nurses and midwives.

**At the facility level**, providers at RHU and government static clinics provided all family planning services including long-acting methods and DMPA-SC as a new method.

## METHODS

We used a retrospective cross-sectional evaluation design, drawing on both qualitative and quantitative data. Data collection took place from April to June 2017 in the 4 project districts.

Qualitative data were collected through in-depth interviews with 20 VHTs (5 per project district) and 12 facility-based health workers (4 from RHU clinics and 8 from public-sector facilities) to assess their experiences and their perceptions of enablers of and barriers to DMPA-SC service provision. Only providers who participated in the program were eligible for inclusion. In addition, we conducted 7 key informant interviews (2 national and 4 district-level policy makers and 1 program staff) to assess how the project was implemented and to seek their views on the feasibility of scaling up DMPA-SC services. Key informants were selected based on their role in the intervention. Written informed consent was obtained from all participants before conducting the interviews. Interviews were audio-recorded, transcribed, and translated into English when necessary.

Quantitative data were based on family planning service statistics extracted from RHU's static clinics, VHTs, and mobile outreach activities in the study districts. For each service delivery channel (i.e., static clinics, VHTs, and outreaches), information was collected on the number of family planning services provided by age category of recipients (below 25 years and 25 years or older). Family planning service data were captured using standard registers, which had been adapted to include DMPA-SC as a new family planning method. At the community level, VHTs captured family planning client records using VHT registers, which were submitted to RHU facilities on a monthly basis. Prior to the start of the project, RHU trained VHTs and RHU's facility-based providers on data collection, storage, and reporting procedures. Data from each service delivery unit were entered into RHU's District Health Information Software



During an RHU outreach event in Kabarole district, Uganda, a provider shows women waiting for family planning services what Sayana Press looks like and provides information about the method. © 2016 Irene Kugonza/RHU.

(DHIS), which is a centralized platform. Information Management Assistants based at RHU clinics in each project district were responsible for data management and quality assurance across all service delivery points. In addition, monthly data quality assessment visits to RHU facilities were conducted by headquarters staff. We did not capture family planning data from the public health facilities in project sites as DMPA-SC had not been integrated into the MOH management information system by the time of this evaluation.

We downloaded family planning data into Microsoft Excel, and then exported the data to Stata version 11 for analysis. Quantitative data analysis involved generating descriptive statistics, mainly via cross-tabulations and frequencies, and conducting test on proportions of family planning services to examine whether there were any significant changes between the 6-month period prior to project implementation and the second 6-month period of project implementation (i.e., months 7 through 12 of project implementation). We used Impact 2 (version 5) to calculate couple-year of protection (CYP) estimates.<sup>16</sup> We analyzed qualitative data using content analysis by coding the data and identifying common themes based on the interview guides.

## Ethical Clearance

Ethical approval for the study was obtained from the Population Council's Institutional Review Board (Protocol 762) and The AIDS Support Organization

(TASO) Research Ethics Committee in Uganda (TASOREC/38/16-UG-REC-009). The Uganda National Council for Science and Technology (UNCST) granted administrative permission for the research (SS4225).

## RESULTS

### Volume of DMPA-SC Units Provided

A total of 14,273 units of DMPA-SC were distributed by VHTs, at RHU clinics, and through mobile outreach in project districts between April 2016 and March 2017 (Table 3). The mean number of units administered across all project sites and through all service delivery points (excluding public-sector static clinics) was 1,189 units per month, with a high of 1,757 units distributed in

March 2017 and a low of 200 units during the first month of implementation (April 2016).

There were some fluctuations in the monthly distribution of DMPA-SC during the project period (Figure 1). These fluctuations could be attributed mainly to program challenges such as delays by VHTs in replenishing their family planning stocks and delays in disbursement of funds to RHU and implementation teams.

### Volume of Family Planning Methods Provided

Table 4 presents the number of all family planning methods delivered during the 12-month project period and for 6 months before the project began. A total of 82,254 family planning methods, representing approximately 24,500 CYPs, were

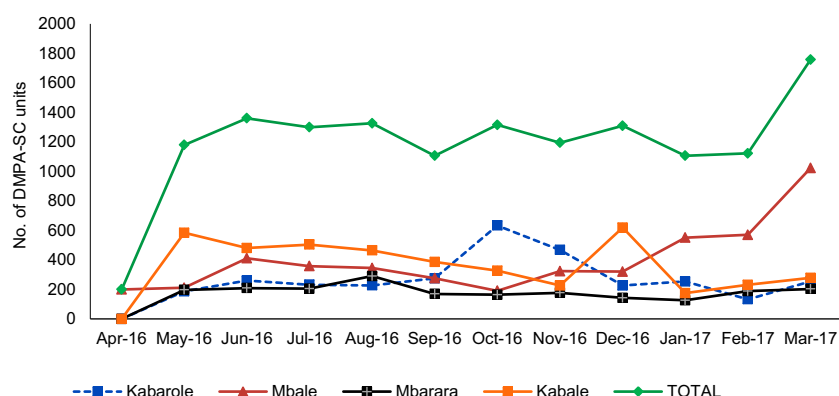
**More than 14,000 units of DMPA-SC were distributed over the 12-month project period.**

**TABLE 3.** Number of DMPA-SC Units Provided by Project District and Service Delivery Channel, Uganda, April 2016–March 2017

District	Service Delivery Channel			Total No.	Monthly Average No.
	Clinics No. (%)	Outreach No. (%)	VHTs No. (%)		
Mbale	131 (2.7)	1060 (22.2)	3589 (75.1)	4780	398
Kabarole	110 (3.5)	881 (28.0)	2157 (68.5)	3148	262
Mbarara	87 (4.2)	405 (19.6)	1579 (76.2)	2071	173
Kabale	267 (6.2)	1388 (32.5)	2619 (61.3)	4274	356
<b>Total</b>	<b>595 (4.2)</b>	<b>3734 (26.2)</b>	<b>9944 (69.7)</b>	<b>14,273</b>	<b>1189</b>

Abbreviations: DMPA-SC, subcutaneous depot medroxyprogesterone acetate; VHT, village health team.

**FIGURE 1.** Monthly Trends in the Number of DMPA-SC Units Provided by District, Uganda, April 2016–March 2017



Abbreviation: DMPA-SC, subcutaneous depot medroxyprogesterone acetate.

**TABLE 4.** Volume of Family Planning Methods Provided Before and During the Intervention by Contraceptive Method, 4 Districts of Uganda

Method	6 Months Before Intervention (Oct 2015–Mar 2016) No. (%)	First 6 Months of Intervention (Apr 2016–Sep 2016) No. (%)	Second 6 Months of Intervention (Oct 2016–Mar 2017) No. (%)	Total No.
Pills <sup>a</sup>	2303 (10.8)	3378 (8.4)	3216 (7.6)	8897
DMPA-IM	4292 (20.0)	9115 (22.7)	11,933 (28.3)	25,340
DMPA-SC	—	6470 (16.1)	7803 (18.5)	14,273
Implants	1926 (9.0)	2140 (5.3)	2262 (5.4)	6328
IUD	217 (1.0)	280 (0.7)	254 (0.6)	751
Permanent methods <sup>b</sup>	21 (0.1)	94 (0.2)	123 (0.3)	238
Condoms <sup>c</sup>	12,662 (59.1)	18,646 (46.5)	16,540 (39.3)	47,848
<b>Total</b>	<b>21,421 (100.0)</b>	<b>40,123 (100.0)</b>	<b>42,131 (100.0)</b>	<b>103,675</b>
<b>Total CYPs</b>	<b>7073</b>	<b>11,491</b>	<b>13,009</b>	<b>31,573</b>

Abbreviations: CYP, couple-years of protection; DMPA-IM, intramuscular depot medroxyprogesterone acetate; DMPA-SC, subcutaneous depot medroxyprogesterone acetate; IUD, intrauterine device.

<sup>a</sup>Includes combined oral contraceptives and progesterone-only pills.

<sup>b</sup>Includes tubal ligation and vasectomy.

<sup>c</sup>Includes both male and female condoms.

delivered during the 12 months of project implementation. This translates to a mean of 6,854 units (2,042 CYPs) per month, up from a mean of 3,570 units (1,179 CYPs) per month during the 6 months prior to project implementation, representing a substantial growth in the volume of methods provided across all sites. There were also notable and significant increases in the volume of each individual method provided through the project, including condoms (male and female), oral contraceptives, contraceptive implants, intrauterine devices (IUDs), and permanent methods ( $P < .001$  for all methods).

### Injectables' Share of the Family Planning Market

The increase in the share of injectables (DMPA-IM and DMPA-SC) was far greater than for other methods. The volume of injectables provided increased from 4,292 units during the 6 months before the project began (DMPA-IM only), to 15,585 units during the first 6 months of the intervention, and further to 19,736 during the second 6 months of project implementation (DMPA-IM and DMPA-SC combined during project implementation). As a result, there were notable changes in the mix of family planning methods provided across project sites, with injectables

growing to represent a significantly larger proportion of methods provided during the first and second 6 months of project implementation (43%) than before implementation (20%) (Table 4).

### Methods Provided by Service Delivery Channel

The vast majority of all short-acting family planning methods provided through the project were delivered at the community level, either by VHTs or through mobile outreach clinics (Figure 2). The majority of implants (86%) and IUD insertions (59%) were also accessed in the community, at mobile outreach sites. DMPA-SC services were overwhelmingly provided at the community level by VHTs (70%) or through mobile outreach services (26%).

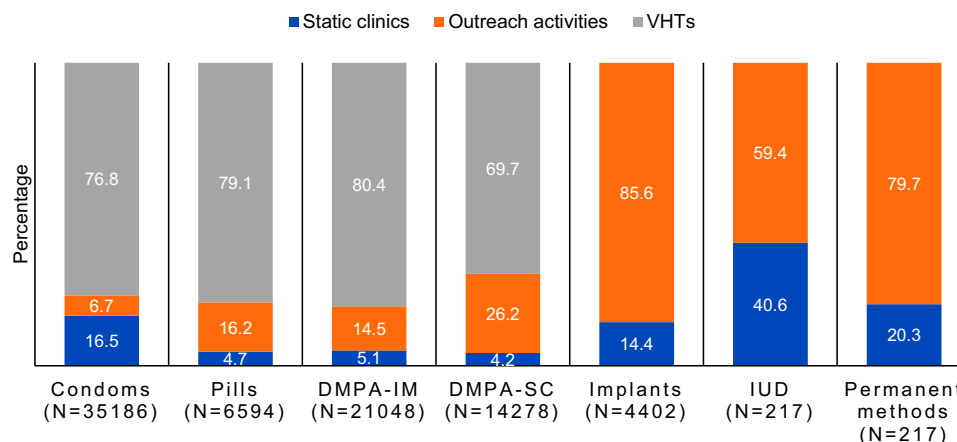
### Age Profile of Clients by Family Planning Method

Overall, 42% of family planning services provided through the project across all project sites were delivered to young people (aged below 25). However, there were significant variances between methods. Notably, a significantly higher proportion of DMPA-SC units (43%) were administered to young people than units of DMPA-IM (37%), oral contraceptives (38%), implants

**There were significant increases in the volume of all family planning methods provided through the project.**

**A significantly higher proportion of DMPA-SC units were administered to young women compared with other methods, except condoms.**



**FIGURE 2.** Percentage Distribution of Family Planning Methods by Service Delivery Channel, 4 Districts of Uganda, April 2016–March 2017

Abbreviations: DMPA-IM, intramuscular depot medroxyprogesterone acetate; DMPA-SC, subcutaneous depot medroxyprogesterone acetate; IUD, intrauterine device; VHT, village health team.

Note: Pills include combined oral contraceptives and progestin-only pills; condoms include male and female condoms; and permanent methods include tubal ligation and vasectomy.

(22%), or IUDs (17%) (Table 5). Further analysis of DMPA-SC services by age and service delivery channel revealed that VHTs served a higher proportion (45%) of young DMPA-SC clients than static clinics (35%) or mobile outreach (36%) (results not shown).

**TABLE 5.** Percentage Distribution of Family Planning Clients by Age and Method, 4 Districts of Uganda, April 2016–March 2017

Method	Age Category		Total (N)
	<25 Years (%)	≥25 Years (%)	
Pills	38.4	61.6	6594
DMPA-IM	36.8	63.2	21,048
DMPA-SC	42.6	57.4	14,273
Implants	21.6	78.4	4402
IUD	16.9	83.1	534
Permanent methods	2.3	97.7	217
Condoms	48.1	51.9	35,186
<b>All methods</b>	<b>42.1</b>	<b>57.9</b>	<b>82,254</b>

Abbreviations: DMPA-IM, intramuscular depot medroxyprogesterone acetate; DMPA-SC, subcutaneous depot medroxyprogesterone acetate; IUD, intrauterine device.

Note: Pills include combined oral contraceptives and progestin-only pills; condoms include male and female condoms; and permanent methods include tubal ligation and vasectomy.

## Enabling Factors for the Provision of DMPA-SC at the Community Level

From qualitative interviews, we identified several factors that enabled introduction of DMPA-SC.

### Training and Supportive Supervision

Facility- and community-based providers recalled receiving comprehensive training on DMPA-SC and also responded positively to training on counseling skills for other methods as part of promoting voluntary family planning services.

*We were taught comprehensive family planning methods including Sayana Press. About Sayana Press, we were taught about the size of injection, its strength, its user-friendliness compared to other injectables, storage, side effects, how it works. ... I think we covered a comprehensive package of Sayana Press. (Male facility-based provider, 10 years' experience)*

However, some providers felt that refresher training on DMPA-SC would add value and enable them to solidify their learning.

*The training was adequate; however, they should have organized another training so that they can refresh us properly. As a people, we may be forgetful or there may be something that we have not done the right way. So, if they come and organize a refresher meeting then you*



*can correct your mistakes. (Female, VHT, 17 years' experience)*

Most VHTs considered supervision important for strengthening their skills, improving quality of services, and building confidence among community members.

*Yes, the in-charge of [facilities] is supporting us so much. When he comes to the ground [with other staff] for outreaches, people get to know that I am not doing it alone as an individual. So, we are supported. When we are trained in class, we assume we understand everything, but he comes and reminds you of how to prepare the drugs for administration. (Female, VHT, 10 years' experience)*

### Reliable Commodity Supplies and Linkages

A reliable supply of family planning commodities was considered essential for providing DMPA-SC and other family planning services. Most VHTs indicated that there were no challenges with DMPA-SC stock-outs and other materials or supplies necessary for its provision during project implementation.

*From the time [DMPA-SC] was introduced, it has never been out of stock. I usually come here [RHU clinic] to request for it and it is provided, so there has not been any problem. (Female, VHT, 22 years' experience)*

The strong relation between VHTs and facilities was considered important for enabling commodity resupply and referral of clients for long-acting methods.

*First of all, it's a teamwork; I always work well with [health care providers] at the health center. We understand each other and also I see there is a lot of cooperation because they always call me and give me assignments and I am always willing to help. (Male, VHT, 7 years' experience)*

### Community Acceptance

Early engagement with, and sensitization of, community stakeholders was identified as beneficial to the smooth introduction of DMPA-SC.

*I know about Sayana Press and we attended the district entry meeting where SP [Sayana Press] was introduced to the district. Because this is a new method, we needed to be aware. The orientation meeting gave us much information and knowledge. (Key informant interviewee, District Health Officer)*

### Providers' View on Workload

Many providers felt that DMPA-SC expanded the range of available family planning methods without significantly affecting their workload. DMPA-SC is similar to DMPA-IM, which is already being provided by active VHTs in their communities. Some facility-based providers reported that because DMPA-SC is easier to administer than DMPA-IM and implants, its introduction had actually enabled them to serve more clients in less time.

*Family planning has long been there, and we have been providing family planning services to people, so Sayana Press is not any different. It is not complicated to administer. It is normal with us and we give it to people who want it easily. It is not any different from any other family planning method. (Female VHT, 10 years' experience)*

*It has reduced the workload because it is very easy to give.... It is very easy to give compared to Depo Provera and these other methods like Implanon. It has reduced our workload. (Female facility-based provider, 4 years' experience)*

### Barriers to the Introduction of DMPA-SC

Interviews with the key informants also identified a range of inhibiting factors.

#### Inadequate Number of Trained Service Providers

Some key informants indicated that the number of community-based health workers trained to provide injectable contraceptives was still inadequate to meet the rising demand.

*Only a few of us were trained. Some VHTs in some sub-counties were not trained in family planning services, so we cover bigger areas and sometimes we are not able to reach some areas. Hence, people in those areas miss out on those services. It is important to increase the number of VHTs to publicize family planning services. (Female, VHT, 5 years' experience)*

#### Lack of Transportation

High demand, large catchment areas, and poor transport connections left VHTs feeling stretched.

*I am skilled and comfortable providing it [DMPA-SC] to people who need it. I also want to provide it to other people in far places only if I get [transport] facilitation. This acts as a barrier to me.... lack of transport facilitation to reach women in the far areas. (Female, VHT, 10 years' experience)*

**Community health workers were positive about the addition of DMPA-SC service delivery to their responsibilities.**

## ■ DISCUSSION

This study documents the experience of an NGO in introducing DMPA-SC at the facility and community levels in 4 districts of Uganda. A number of themes emerge from the quantitative and qualitative data collected through the project.

### The Viability of Community-Based Distribution of DMPA-SC

More than half of all methods, and 96% of DMPA-SC units, provided through the project were delivered at the community level outside of static clinics—either by VHTs or through mobile outreach teams. On average, each VHT provided 21 units of DMPA-SC per month, equating to an estimated 62 CYPs and 22 unintended pregnancies averted per VHT, per year. In the absence of service statistics from public health facilities, we do not have a complete picture of where clients accessed family planning services across all project districts. However, RHU's experience demonstrates that strengthening VHTs' capacity through training and ensuring continuous supply of contraceptive commodities can result in the provision of a high volume of family planning services at the community level.

### Potential for DMPA-SC Introduction to Increase the Share of Injectables in the Ugandan Method Mix

Project data showed that there was a shift in the mix of family planning services provided during the project period, with injectables growing to represent 43% of all methods provided compared with just 20% prior to implementation. Project-level service data from a small number of service outlets (4 RHU static clinics, 40 VHTs, and 26 outreach sites) cannot be interpreted in the same way as population-based sample data such as from the Demographic and Health Surveys. However, the observed shift in the comparative balance of methods provided at the service level does provide insight into how the introduction of DMPA-SC could potentially further increase the share of injectables within the method mix in Uganda once it is rolled out nationally. Injectable contraceptives have become the most commonly used modern methods in a number of sub-Saharan African countries.<sup>18</sup> The use of injectables has risen to about 15% to 20% of married women, equaling about 40% of all contraceptive use, with this percentage even higher in some countries.<sup>19–21</sup>

Importantly, while the introduction of DMPA-SC has the potential to impact the relative share of

injectables within the method mix, this would not necessarily equate to a decline in the uptake of other methods in absolute numbers. Within the RHU project, for example, there was a significant increase in the volume of *all* contraceptive methods provided at project sites including long-acting methods. Furthermore, there is evidence to suggest that DMPA-SC has the potential to reach new acceptors of family planning.<sup>8</sup> However, more rigorous research is needed on the possible impact of DMPA-SC introduction on the uptake of other methods.

It is important that, as with any new method, programmers use the introduction of DMPA-SC as an opportunity to reinforce access to a full range of methods. For example, programmers may consider giving community- and facility-based health workers refresher training on *all methods* when they are introducing DMPA-SC; strengthening links between service delivery points to enable referral for long-acting methods; and ensuring continuous availability of all contraceptive commodities across the family planning delivery system. These approaches, adopted by RHU in this project, were widely welcomed and identified through stakeholder interviews as enabling factors to the introduction of DMPA-SC.

### The Apparent Popularity of DMPA-SC Among Young People

Project data on the proportion of family planning services provided by client age group reinforces existing evidence that DMPA-SC is attractive to young people.<sup>8,22</sup> Nearly half (43%) of all DMPA-SC units administered were provided to clients below 25 years of age—a significantly higher proportion than for all methods, except condoms. Other studies have found that DMPA-SC is popular among young people because of its convenience, the potential for discreet use without partner/parental detection, and the lower reported side effects than with some other methods.<sup>13,23,24</sup> Service data show that a greater proportion of VHT clients were young (47%) than static clinic clients (35%) or mobile outreach clients (36%). This could suggest that it is easier or more comfortable for young people to access contraceptives via VHTs, away from formal health settings.

### Both Supply- and Demand-Side Factors Facilitated Provision of DMPA-SC Services

From qualitative interviews, we identified several factors that enabled introduction of DMPA-SC at

**96% of DMPA-SC units provided through the project were delivered at the community level.**

**The share of injectables in the method mix grew from 20% at baseline to 43% at the end of the project.**

**Our pilot results reinforce that DMPA-SC is attractive to young people.**

the community level that may be of note for programmers and policy makers. VHTs and facility-based providers valued the comprehensive family planning training; consistent availability of contraceptive commodities; and strong referral links (between public and NGO providers, and from VHTs to static facilities). Key informant interviews also found that engagement of community leaders before service delivery began was an important enabling factor.

However, a number of barriers and challenges remain. VHTs reported that the transport allowances they received through this project were insufficient to cover the cost of traveling to visit clients and to restock commodities at static clinics. There is need to review VHT support packages to better enable them to effectively do their work. In addition, the project trained only a limited number of active VHTs (10 in each district). Inadequate number of trained VHTs limited provision of DMPA-SC in the community. A 2015 study estimated that there were 179,175 VHTs in Uganda—30% of whom did not have basic training at that time.<sup>25</sup> As national rollout plans for DMPA-SC progress, training VHTs, and training them *at volume*, will likely become a major priority and challenge for government and partners alike.

## Study Limitations

The project provided significant support in the form of training to the public sector to enable comprehensive service delivery in static facilities. However, due to the absence of data from public-sector facilities, the data presented do not offer a full picture of the intervention. Analysis is therefore limited to the volume of methods provided at RHU clinics, through mobile outreach, and by VHTs.

The absence of unique client identifiers across all service delivery points also limits analysis in several ways. First, it was not possible to identify how many individual clients were served by the project, and we should expect that a proportion of clients were provided with a method on multiple occasions during the course of the project, particularly users of short-acting methods including DMPA-SC. The absence of unique client identifiers across some service delivery platforms also means that it was not possible to track switching between methods.

Interviewees were purposively identified based on their role in the intervention and could have been tempted to offer positive views of the program. Given that some participants reported

challenges, however, the selection process did not appear to bias the qualitative data collection to only those with positive views.

## CONCLUSIONS

As questions about safety, efficacy, and acceptability of DMPA-SC are satisfactorily answered through rigorous research,<sup>26–28</sup> programmers and policy makers turn their attention to operational questions about how DMPA-SC can be rolled out effectively to increase access to and reach those most in need. RHU's experience gives insight into one NGO's experience in introducing DMPA-SC at the community level in non-trial settings. The project focused heavily on community distribution through VHTs, which appears to have been an effective strategy for increasing service delivery and reaching young people. The views of project stakeholders in Uganda offer insight into how program teams, nationally and internationally, can roll out DMPA-SC to effectively reach those in most need of voluntary family planning.

**Funding:** The project, also known as the Sayana Press Learning Project (SPLP), was funded by the United States Agency for International Development (USAID) through the Sustainable Networks Project (SIFPO2) and implemented by Reproductive Health Uganda (RHU) in collaboration with the Ugandan Ministry of Health (MOH) from April 2016 to March 2017.

**Disclaimer:** The opinions expressed in the paper are solely those of the authors and do not necessarily reflect the views of the funding agency.

**Competing Interests:** None declared.

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#### Peer Reviewed

**Received:** March 23, 2018; **Accepted:** September 17, 2018; **First Published Online:** November 14, 2018

**Cite this article as:** Odwe G, Gray K, Kyarimpa A, Obare F, Nagendi G. Introduction of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) injectable contraception at facility and community levels: pilot results from 4 districts of Uganda. *Glob Health Sci Pract*. 2018; 6(4):711–722. <https://doi.org/10.9745/GHSP-D-18-00117>

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## ORIGINAL ARTICLE

# Implementing an Integrated Pharmaceutical Management Information System for Antiretrovirals and Other Medicines: Lessons From Namibia

David Mabirizi,<sup>a</sup> Bayobuya Phulu,<sup>b</sup> Wuletaw Churfo,<sup>c</sup> Samson Mwinga,<sup>b</sup> Greatjoy Mazibuko,<sup>b</sup> Evans Sagwa,<sup>b</sup> Lazarus Indongo,<sup>c</sup> Tamara Hafner<sup>d</sup>

Integrating patient and commodity data into one system while maintaining specialized functionality has allowed managers to monitor and mitigate stock-out risks more effectively, as well as provide earlier warning for HIV drug resistance.

## ABSTRACT

The success of the Namibian government's "treatment for all" approach to control and stop the country's HIV epidemic is dependent on an uninterrupted supply of antiretrovirals (ARVs) for people living with HIV. The public health system in Namibia, however, was constrained by an inefficient paper-based pharmaceutical information system resulting in unreliable and inaccessible data, contributing to persistent stock-outs of ARVs and other essential pharmaceuticals. This article describes the incremental implementation of an integrated pharmaceutical management information system to provide timely and reliable commodity and patient data for decision making in Namibia's national antiretroviral therapy (ART) program and the Ministry of Health and Social Services (MoHSS). The system has 4 inter-linked information tools: (1) the Electronic Dispensing Tool (EDT) that manages the dispensing and inventory of antiretrovirals at service delivery points; (2) the EDT national database, which facilitates the flow, storage, and collation of ART data at the central level; (3) the Facility Electronic Stock Card used to manage pharmaceutical stocks and report inventory movement data to the national level; and (4) the Pharmaceutical Management Information Dashboard that integrates all 3 tools plus the warehouse management tool used by the central and regional medical stores into 1 dashboard that serves as a platform for the analysis and dissemination of pharmaceutical information throughout the health system. Implementing the pharmaceutical management information system was a prolonged and complicated process, with key challenges related to user acceptance and human resource constraints. The integrated pharmaceutical management information system enables Namibia to collect more than 90% of transactional commodity and patient dispensing data from more than 85% of all ART sites. Health managers use information from the system for medicine quantification decisions and to improve pharmaceutical service delivery. The MoHSS and its partners in the national ART program use the information for monitoring the World Health Organization early warning indicators for HIV drug resistance; ART defaulter tracing; and for planning, reporting, and research purposes. Namibia's pharmaceutical management information system demonstrates the feasibility and benefits of integrating related tools while maintaining their specialized functionality to address country-specific information and inventory management needs.

## INTRODUCTION

Namibia, an upper middle-income country, is one of the world's most sparsely populated countries. Access to health services is partially constrained by the country's vast geography and the distribution of its population—two-thirds of the population live in sparsely settled rural areas and it is estimated that rural

households are 114 minutes away from the nearest public health facility.<sup>1</sup> A shortage of skilled health personnel, including pharmacy staff, coupled with a fragmented health information system in some areas,<sup>2,3</sup> made it difficult for the Ministry of Health and Social Services (MoHSS) to effectively manage decentralized health services across the country's 14 regions.

HIV/AIDS is a leading cause of morbidity and mortality in Namibia. The number of people aged 15 years and older living with HIV is estimated at 260,000, or 12.3% of the total population.<sup>4</sup> The Namibian government has adopted numerous policies and guidelines to control the HIV epidemic, such as the World Health Organization (WHO) "Treatment for All" approach, which has resulted in high testing and treatment coverage leading

<sup>a</sup> Pharmaceuticals and Health Technologies Group, Management Sciences for Health, Arlington, VA, USA.

<sup>b</sup> Systems for Improved Access to Pharmaceutical and Services (SIAPS) Program, Management Sciences for Health, Windhoek, Namibia.

<sup>c</sup> Division of Pharmaceutical Services, Ministry of Health and Social Services, Windhoek, Namibia.

<sup>d</sup> SIAPS Program Consultant, Aarhus, Denmark.

Correspondence to David Mabirizi (dmabirizi@msh.org).



**The integrated pharmaceutical management information system incorporates components of logistics management information systems but also includes dispensing, patient, and treatment data to facilitate decision making.**

to the near elimination of mother-to-child transmission of HIV.<sup>5</sup> The government has also decentralized antiretroviral therapy (ART) services beyond district hospital and health center pharmacies to include outreach sites, community-based dispensing and prescription refill, and nurse-initiated and nurse-managed ART sites.<sup>6</sup> The key objective of the 2010–2016 national strategic framework for HIV and AIDS was to achieve universal access to care and treatment for people living with HIV.<sup>7</sup> These objectives and strategies are ultimately aimed at achieving the broader global goal of 90-90-90, requiring 90% of HIV patients knowing their HIV status, 90% accessing ART, and 90% achieving viral suppression.<sup>8</sup> To achieve these objectives, Namibia's public health system faces the challenge of sustainably ensuring uninterrupted access to antiretrovirals (ARVs) for 90% or more people living with HIV.

The uninterrupted supply of ARVs requires timely availability of accurate patient and commodity information for decision making. The decentralization of health services brings new challenges in retrieving patient and medicine information from service delivery points. A 2006 assessment found that the lack of computerized information systems was a severe constraint on the management of pharmaceuticals and the tracking of ART defaulters in Namibia.<sup>9</sup> An earlier assessment found that the paper-based system used at service delivery points—including tertiary, regional, and district hospitals and health centers—was inefficient, contributing to prolonged patient waiting times and a high dispensing workload.<sup>10</sup> Patient and stock data collected were unreliable, late, and inaccessible for decision making, and some hospitals and health center pharmacies did not routinely collect commodity consumption and stock data.<sup>10</sup> The MoHSS tried unsuccessfully to improve pharmaceutical inventory management by mandating the use of stock cards in health facilities (MoHSS Circulars 25 and 61). At the regional level, pharmacists routinely lacked access to accurate information and had challenges using the limited information available. In addition, no mechanism for collating and analyzing ART data existed at the central level.

The lack of a system to manage pharmaceutical information meant that ARV quantifications were based on predefined inventory level maximums and minimums, which did not account for current consumption trends or other relevant information.<sup>10</sup> This led to persistent ARV stock-outs and created an urgent need for an information system to ensure a consistent supply of ARVs to its

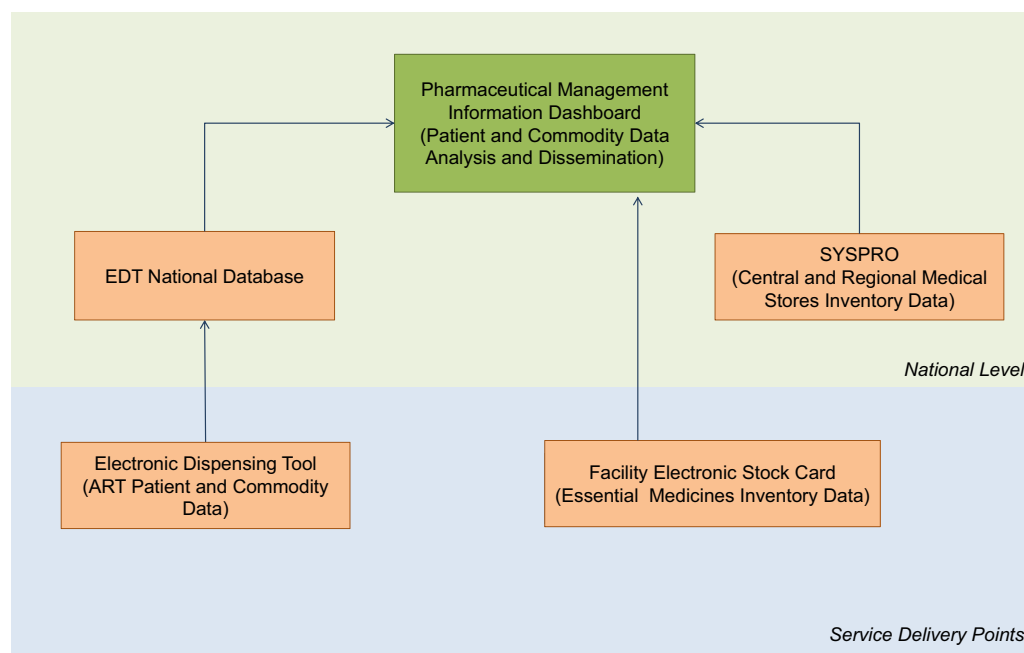
growing population of people living with HIV.<sup>11</sup> The findings and recommendations from the assessments<sup>9,10</sup> informed the initiation of a now decade-long technical assistance program in Namibia to strengthen pharmaceutical information management for the national ART program and pharmaceutical service delivery.

This article describes the incremental implementation and integration of a pharmaceutical management information system in Namibia to ensure uninterrupted access to ARVs for people living with HIV. The pharmaceutical management information system incorporates components of logistics management information systems (LMIS), but it also includes dispensing, patient, and treatment data, and selected pharmaceutical system performance indicators. The incorporation of these varied sources of data facilitates evidence-based decision making regarding inventory management, resource allocation, pharmaceutical policy, and other aspects of the performance of pharmaceutical service delivery.<sup>12</sup> An effective pharmaceutical management information system can enhance the availability of and access to information for decision making in Namibia's national ART program and in the Division Pharmaceutical Services (DivPhS) of the MoHSS.

## ■ INTERVENTIONS

Between 2007 and 2017, the Strengthening Pharmaceutical Systems (SPS) and Systems for Improved Access to Pharmaceutical and Services (SIAPS) programs, funded by the United States Agency for International Development (USAID), supported the MoHSS with the development and implementation of 4 interlinked pharmaceutical information tools: (1) the Electronic Dispensing Tool (EDT) manages the dispensing and inventory of ARVs at service delivery points; (2) the EDT national database facilitates the flow, storage, and collation of ART data at the central level; (3) the Facility Electronic Stock Card (FESC) is used to manage pharmaceutical stocks and report inventory movement data to the national level; and (4) the Pharmaceutical Management Information Dashboard—a web-based inventory management tool—integrates all 3 tools plus SYSPRO, an inventory management tool used by central and regional medical stores. The dashboard serves as a platform for the analysis and dissemination of pharmaceutical information throughout the health system (Figure 1).

The intervention approach was incremental and evolved to meet the emerging needs of the

**FIGURE 1.** Components of Namibia's Integrated Pharmaceutical Information System

Abbreviations: ART, antiretroviral therapy; EDT, Electronic Dispensing Tool.

pharmaceutical system and the national ART program. The intervention started in 2007 with the implementation of the EDT at service delivery points. In 2010, the EDT national database was installed at the central level at the MoHSS. The intervention continued with the implementation of FESC at service delivery points. Finally in 2016, the Pharmaceutical Management Information Dashboard was implemented. **Box 1** provides a summary of the system components.

An estimated US\$4 million was invested over the 10-year period in developing and implementing the pharmaceutical management information system in Namibia. The estimated cost includes software development (20%); capacity building—mainly training, mentoring, and supportive supervision of MoHSS staff at facility, regional, and national levels (50%); equipment (25%); and costs related to data transfer (5%). The SIAPS program covered the initial set-up costs and the Namibian government provided support for human resources and infrastructure. The MoHSS, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the U.S. Centers for Disease Control and Prevention (CDC) contributed to the purchase of equipment for setting up the system.

### Collection and Collation of Patient and Commodity Data *Electronic Dispensing Tool*

The EDT was implemented in 2007 at service delivery points to manage the dispensing and inventory of ARVs. ARV prescription filling is the primary source data for EDT, which captures ART uptake patterns (patients that are new, active, and lost to follow-up), patients' pill counts and appointment keeping, medicines coverage, and availability of ARVs at the health facility. These data enable better monitoring of patients' adherence to medications and WHO early warning indicators for HIV drug resistance. The intervention started with the identification of "quick adopters"—pharmacists and pharmacy assistants who were technologically interested in using computers and electronic tools. The EDT was first piloted at 10 district-level and referral hospitals over a 3-month period in 2007, and then rolled out to 20 hospitals and large health centers in the next 6 months. Within 1 year, all 34 hospitals and 2 high-volume health centers were using the EDT.

In Namibia, 6 of 10 people live in rural communities with limited access to ART services.<sup>13</sup> The government therefore adopted a decent-

**Within a year, all 34 hospitals and 2 high-volume health centers were using the Electronic Dispensing Tool to manage the dispensing and inventory of ARVs at service delivery points.**

**BOX 1.** Description of Components of the Pharmaceutical Management Information System

- **Electronic Dispensing Tool (EDT).** The EDT is a health facility desktop software for antiretroviral therapy (ART) pharmacy management and reporting. The tool captures ART patient demographic data, dispensing history, and antiretroviral inventory data including stock orders, receipts, issues, and stock taking. It registers daily transactions and produces monthly ART reports that feed into the Pharmaceutical Information Dashboard.
- **EDT National Database.** The EDT National Database is the central repository that aggregates all facility-level individual EDT data sets.
- **Facility Electronic Stock Card (FESC).** The FESC is a simple electronic stock control card. It records data on stock taking, ordering, receiving, issuing, and adjustment of each stocked pharmaceutical item and generates monthly summary stock status reports that feed into the Pharmaceutical Information Dashboard.
- **SYSPRO.** SYSPRO is a proprietary commercial Enterprise Resource Planning software used to manage inventory, supplier and health facility order processing at the central and regional medical stores.
- **Pharmaceutical Management Information Dashboard.** The Pharmaceutical Management Information Dashboard is a web application for collating and visualizing aggregated ART, other essential medicines and commodities, and information on pharmaceutical system performance indicators from various sources including the EDT and the FESC.

ralized ART model—nurse-initiated and nurse-managed services at primary health care clinics—to bring ART services closer to these rural communities. The paper-based reporting systems used at these sites had discrepancies in the number of patients accessing treatment and most of the patients were falsely tagged as lost to follow-up in the EDT national database. These inaccurate data negatively affected ART program planning at the national level.

To address data and patient management challenges in rural areas, SIAPS adapted EDT to a portable handheld device referred to as a mobile EDT (mEDT).<sup>11</sup> In 2013, pharmacy staff and other health workers were trained on capturing ARV dispensing and stock data during outreach activities in communities using the mEDT. Mobile EDT devices were also deployed for use at smaller primary health care clinics where computerization was not feasible. After 2 years of implementation, a patient referral module was implemented that enabled district hospitals to refer patients downwards to outreach sites and smaller clinics to pick up refills using mEDT. A total of 61 mEDTs have since been deployed and 70 health workers at 51 primary health care sites in select regions with high HIV prevalence have been trained to use the mEDT. Each mEDT is affiliated with a designated main (parent) EDT site. The data collected through mEDT are periodically synchronized with the EDT at the main site. Pharmacy staff were initially trained and later retrained on the collection, collation, and interpretation of the EDT data for their health facilities and districts.

**Electronic Dispensing Tool National Database**

The EDT national database was implemented in 2010 to aggregate and summarize EDT data at the central level.<sup>11</sup> Encrypted data from EDT at service delivery points are automatically transmitted through low-cost mobile telecommunication 3G devices directly to the national database. This reduces the expense of the physical transfer of data from the facilities to the central level and eases the burden of producing paper reports. The national database facilitates a national backup of data from service delivery points and the quick generation of up-to-date data sets for analysis and evidence-based decision making.

**The Facility Electronic Stock Card**

The intervention continued with the implementation of the FESC at health facilities. Based on the experience with the EDT, the MoHSS expressed the need for an electronic tool to help improve the management and availability of other essential commodities in the health system. In response, SIAPS supported the development of the FESC and its implementation in 51 service delivery points—pharmacies at 35 hospitals, 6 health centers, and 10 clinics. Following the implementation of the FESC in 2016, 138 pharmacy staff were trained on how to use the FESC for managing inventory and generating and interpreting LMIS reports. The FESC captures pharmaceutical stock and inventory transaction data, automatically computes average monthly consumption and minimum and maximum stock quantities, and provides suggested ordering quantities. The FESC

**The program adapted the Electronic Dispensing Tool to a portable handheld device to reach communities in rural areas.**

also includes a module for making positive and negative adjustments and explaining the reason for such adjustments. It generates LMIS reports summarizing stock status, issue by item, issue by facility, receiving, and Central Medical Stores (CMS) service levels to a specific facility.

### Analysis and Dissemination of Patient Dispensing and Commodity Data Pharmaceutical Management Information Dashboard

In 2016, the Pharmaceutical Management Information Dashboard was implemented to serve as a platform for the analysis and dissemination of information from the other tools and to improve access to information for decision making. Although the EDT and national database existed, information was still not easily accessible for decision making. Pharmaceutical and program managers relied on quarterly reports manually generated by DivPhS for information about patients and commodities in the national ART program. Information access was further constrained by having to submit requests to DivPhS for specific information from the national database. The MoHSS had implemented SYSPRO, a proprietary commercial Enterprise Resource Planning software, at the CMS in 2001, and later at the 2 regional medical stores. The central and regional medical stores use SYSPRO to manage inventory, supplier procurement order, and health facility order processes, but program managers and facility-level managers had no readily available information about stock levels of essential medicines at the medical stores. Concurrent with the implementation of FESC, SIAPS supported the implementation of the Pharmaceutical Management Information Dashboard, which consolidates data from SYSPRO, the EDT, FESC, and EDT national database to automatically compute selected indicators and generate standardized reports summarizing commodity and patient information (Figure 1).

The dashboard has 3 modules: ART, essential medicines and clinical supplies, and service performance. The ART module provides summary reports including the number and trend of active patients and new patients accessing HIV treatment, retention and adherence rates, and early warning indicators of HIV drug resistance (Box 2). The service performance module provides information on 22 essential pharmaceutical service performance indicators that describe the status of pharmaceutical service delivery nationwide. Reports from FESC feed into the essential commodities

#### BOX 2. Summary of Reports Available on the ART Module of the Pharmaceutical Management Information Dashboard

##### Commodity-Related:

- ARV stock status at national, regional, district, and facility levels
- National ARV stock pipeline
- National ARV stock status by risk category
- ARV stock status trend by risk category of facilities with a stock-out of HIV tracer commodities
- Value of ARV expiries and damages
- Percentage of facilities with a stock-out of key items

##### Treatment-Related:

- Trend in backbone ARV used to initiate ART
- Regimens used to initiate ART
- ARVs consumption trends
- Consumption trends for the top 5 ARVs

##### Patient-Related:

- Percentage of patients at risk of medicine shortages and stock-outs
- Trend of patients on ART
- ART patient uptake by region
- ART patients by regimen
- Comparative trend of patients on ART
- ART patients by regimen category
- Patients by duration on treatment
- Patients distribution by age group
- Monthly patient status

##### Retention and Adherence:

- Adult and pediatric patient adherence to ART by pill count
- National (aggregate) adherence to ART by pill count
- Trend in retention rates
- ART Retention and loss to follow-up rates
- Retention rates on ART by region
- Retention rates on ART for patients by facility
- Number of pickups per day
- Regimen switch

module, which provides an overview of stock status for essential medicines and clinical supplies at district-level facilities across the country.

A key feature of the dashboard is an incorporated early warning system to alert supply chain managers of potential stock-outs of medicines, vaccines, and clinical supplies. This makes it easier for managers to identify potential stock-outs or overstocking, and it triggers commodity redistribution to avoid stock-outs or expiries. More than 50 standardized reports are available on the dashboard. One of the most important reports is the national ART



**The Pharmaceutical Management Information Dashboard consolidates 4 information tools and provides an early warning system to alert managers of potential stock-outs.**

stock status, which is disaggregated by risk levels (stock-out, potential stock-out, understock, satisfactory, and overstock). As shown in Figure 2, this risk profile allows easy visualization of stock status nationally for a defined time period. ART stock-out rates can also be displayed geographically for a given month or as a time series. Depending on the indicator or report, users can customize data aggregation by period, facility, region, commodity group, or patient group. For example, trends in new and active ART patients can be disaggregated into adult and pediatric patients and by gender.

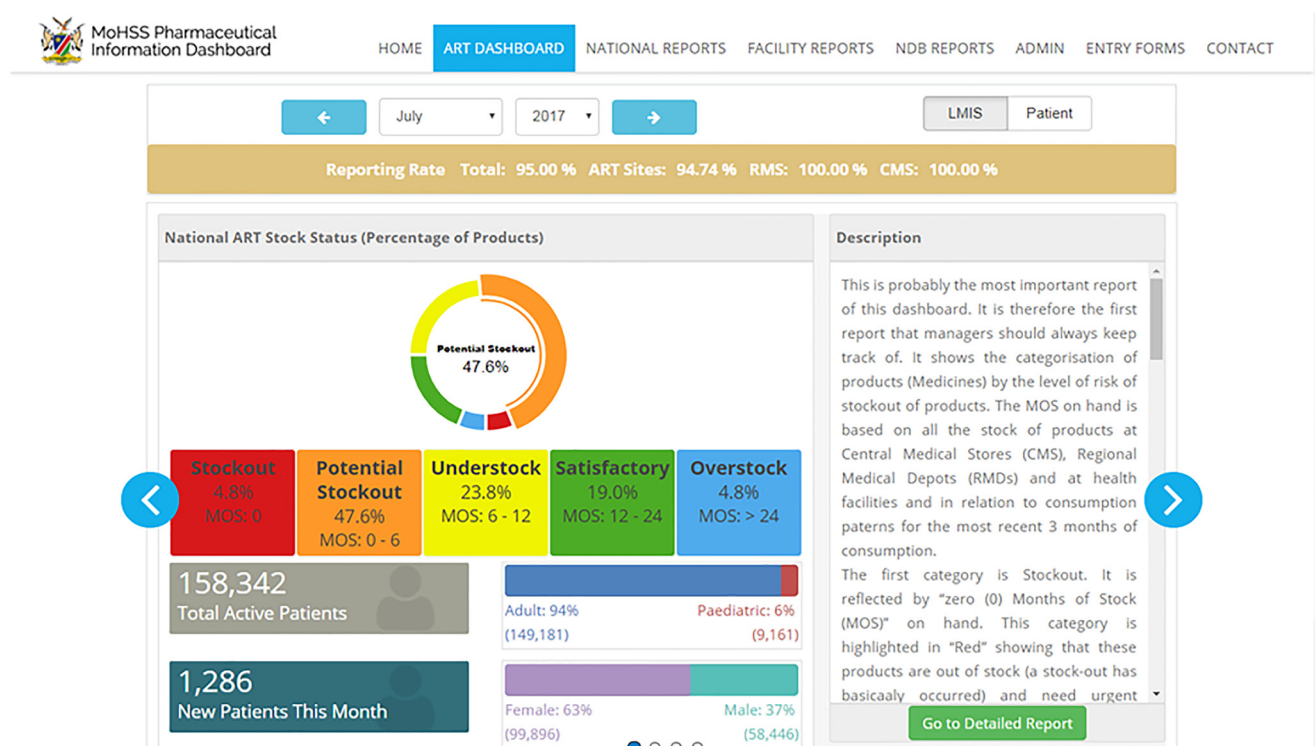
Training technical and program managers on the use of the dashboard was a critical component of the dashboard implementation in 2016. At the national level, managers from DivPhS, Directorate of Special Programs, and partner organizations were oriented on the type of data available and accessing and using these data for decision making. At the regional level, SIAPS conducted quarterly workshops on EDT, FESC, and the dashboard to enable regional management teams to understand

the purpose of the tools, strengthen their competency in supervising the use of the tools, and using the information generated by the tools for making decisions at the regional and district levels. Clinical mentors in the national ART program were also trained to strengthen their capacity to use information from the dashboard for clinical and programmatic decision making. The ART Logistics Pharmacist in DivPhS, with technical support from SIAPS, served as the dashboard administrator, approving user access and using activity logs to monitor dashboard access and use.

## METHODS

Our article relied on a desk review of documents produced by SIAPS and its predecessor programs, including assessment and technical reports relevant to Namibia's national ART program. In addition, we reviewed data and reports from the Pharmaceutical Management Information Dashboard to summarize average reporting rates and trends. A literature

**FIGURE 2.** Screenshot of ART Module of the Pharmaceutical Management Information Dashboard Reporting the National ART Stock Status, July 2017



Abbreviation: ART, antiretroviral therapy.

search was conducted with Google Scholar and PubMed for peer-reviewed publications on HIV treatment and care that included analysis of data from the EDT. Keywords in various combinations included Namibia, antiretroviral (\*ARV, ART), HIV, drug resistance, HIVDR, and electronic dispensing tool (\*EDT). Information from these sources was used to develop a narrative of the implementation process, the challenges, and some of the lessons learned. SIAPS technical staff reviewed drafts of the narrative and provided input as needed for correction and clarification.

## RESULTS

With the dashboard, Namibia has successfully achieved integration of all its pharmaceutical information tools (Figure 1). This integrated pharmaceutical management information system enables Namibia to collect more than 90% of commodity and patient dispensing data from more than 85% of all ART sites within 15 days of each month. With proper and consistent reporting and use, technical service and program managers can access patient and commodity data with only a 1-month lag. Below are some examples of how information from the pharmaceutical management information system is used at service delivery points and at regional and national levels.

### Service Delivery Points and Regional Levels

Pharmacy staff in 64 ART facilities currently use the EDT to manage more than 160,000 patients. Pharmacy staff, including nurses and community health workers, use mEDT to track 12,293 patients, which is approximately 10% of ART patients in Namibia who are managed at nurse-initiated and nurse-managed sites. Between April 2017 and March 2018, the average ART module reporting rate to the dashboard was 97% (Table), with 10% of facilities submitting late reports.

FESC, which was more recently introduced, is still gaining traction. Some facilities have demonstrated efficiency gains with consistent use of the tool.<sup>14</sup> However, other facilities have failed to use the tool consistently to track stock levels, or they are submitting reports late or inconsistently. The average FESC reporting rate for facilities to the dashboard between April 2017 and March 2018 was 61% (Table), with 50% of facilities reporting late. Reporting rates and usage are expected to increase as users become more familiar with FESC. Regardless, there has been an improvement in inventory control and quantification—the percentage of facilities with stock within minimum

**TABLE.** Facility Reporting Rates on the Dashboard, April 2017 to March 2018

Month	ART (%)	FESC (%)
April 2017	100	62
May 2017	89	49
June 2017	98	54
July 2017	100	62
August 2017	95	65
September 2017	100	73
October 2017	95	62
November 2017	95	62
December 2017	100	73
January 2018	98	62
February 2018	98	57
March 2018	97	55
<b>Average</b>	<b>97</b>	<b>61</b>

Abbreviations: ART, antiretroviral therapy; FESC, Facility Electronic Stock Card.

and maximum levels increased from 16% in 2011 to 67% in 2018.<sup>15,16</sup> The pharmaceutical information tools, along with other factors, contributed to this improvement.

Regional pharmacists are expected to use the EDT and FESC for dispensing and inventory management in their capacity as pharmacists for the regional hospitals. Regional pharmacists also serve an administrative function by ensuring support to service delivery points, managing the flow of data to the national level, and ensuring the use of the tools at service delivery points. Functions related to data management at the regional level have not been clearly defined, which has constrained information use for decision making at this level.

### National Level

DivPhS managers use the information for improving service delivery and making quantification and procurement decisions. Consumption and stock level data from the dashboard were critical inputs for the latest ARV quantification done for the period October 2016 to March 2019. The dashboard has filled a critical information gap for DivPhS managers at the national and regional levels for monitoring stock levels. Before the dashboard, the CMS had no access to comprehensive information about stock levels at regional medical

**The average rate of facilities reporting ART module information to the dashboard was 97%.**

stores and at service delivery points. The CMS had to call individual facilities for stock counts when it needed to know stock levels across the country and few facilities reported any stock on hand when ordering new stock. There was no structured way of compiling stock status at the facility level for meaningful discussions and designing strategies at the national level. That information is now readily available on the dashboard.

In cases where there is an impending stock-out or change in treatment guidelines, managers can use the dashboard to identify regions or facilities with stock levels above the maximum buffer stock needed and redistribute accordingly to avert a stock-out or avoid wastage. Pharmacists across the country have formed an interactive group on the WhatsApp social media platform where they discuss their analysis of reports from the dashboard, enabling them to easily locate and redistribute stock. However, managers are still adapting to the nascent dashboard and learning to make full use of its capabilities to incorporate the data in daily practices and decision making. Further, the CMS has been beleaguered by recent human resources shortages, which have limited their use of the information and dashboard in general.<sup>17</sup>

Within the national ART program, the MoHSS and its partners have been using information from the tools for ART defaulter tracing, planning, reporting, and operational research. The EDT is the most reliable source of information on ART adherence in Namibia. The data are used to identify ART patients lost to follow-up for patient tracing in the Namibia Adherence and Retention Program.<sup>18</sup> Namibia uses the EDT system to monitor timely pill pick-up, retention in care, pharmacy stock-outs, and dispensing practices—all HIV drug resistance early warning indicators. The annual monitoring of early warning indicators has led to public health recommendations and action on increasing defaulter tracing, improving ART record systems, and scaling up differentiated models of care.<sup>19</sup> MoHSS clinical managers also use data to inform decisions regarding adherence, treatment guidelines, and decentralization of ART programs. They use the distribution of ART regimens to monitor the number of patients maintained on failed treatments and to identify potential noncompliance with standard treatment guidelines. They also use the new and total ART patient data to identify high congestion sites and inform decisions in the clinical mentor program and the decentralization of the national ART program.

The Research, Monitoring and Evaluation Unit in the Directorate of Special Programs and the

Joint United Nations Programme on HIV/AIDS (UNAIDS) use the EDT data to formulate estimates on HIV prevalence and incidence in Namibia. These estimates are used for various internal and external reporting and planning purposes.<sup>4,20</sup> USAID and the CDC use the data, including the ARV refill and number of newly initiated ART patients data, to estimate ART retention when developing country operational plans for the U.S. President's Emergency Plan for AIDS Relief.<sup>20,21</sup> UNAIDS also uses the data from EDT to track progress on United Nations Assembly commitments to HIV and to help identify focus population groups for expanding treatment and adherence at the regional and global levels. The use of EDT data has contributed to Namibia being identified as a country in the Eastern and Southern Africa region on target to reducing the number of people newly infected with HIV and dying from AIDS-related causes.<sup>22</sup>

Fourteen peer-reviewed articles using EDT data have been published and some are linked to decision making in the national ART program (Box 3). An assessment of HIV drug resistance early warning indicators has led to changes in recordkeeping and the strengthening of adherence and monitoring.<sup>24</sup> The MoHSS and researchers have used EDT data to investigate adverse reactions associated with zidovudine, tenofovir, and nevirapine.<sup>23–25</sup> The findings from the nevirapine study contributed to the MoHSS revising its treatment guidelines and stopping the use of nevirapine-containing ART to initiate treatment of pregnant women with high baseline CD4 cell counts.<sup>25</sup>

**Namibia uses the Electronic Dispensing Tool to monitor HIV drug resistance early warning indicators.**

## ■ CHALLENGES AND LESSONS LEARNED

Migrating from a paper-based pharmaceutical management information system to an electronic system was a prolonged and complicated process with challenges related to behavioral, technical, and organizational factors. These challenges are highlighted in the sections that follow, along with lessons learned.

### Gaining User Acceptance of the Tools

Negative attitudes toward technology and resistance to change were perhaps the biggest challenges. In the beginning, there was no culture of using computerized information technology to provide care in the health system and some health workers were not in favor of abandoning the paper-based system. Further, health workers

**BOX 3.** Peer-Reviewed Publications Using Electronic Dispensing Tool Data

- Hong SY, Jonas A, Dumeni E, et al. Population-based monitoring of HIV drug resistance in Namibia with early warning indicators. *J Acquir Immune Defic Syndr*. 2010;55(4):27-31. [CrossRef](#). [Medline](#)
- Corbell C, Katjita I, Mengistu A, et al. Records linkage of electronic databases for the assessment of adverse effects of antiretroviral therapy in sub-Saharan Africa. *Pharmacoepidemiol Drug Saf*. 2012;21(4):407-414. [CrossRef](#). [Medline](#)
- Hong SY, Jerger L, Jonas A, et al. Medication possession ratio associated with short-term virologic response in individuals initiating antiretroviral therapy in Namibia. *PLoS One*. 2013;8(2):e56307. [CrossRef](#). [Medline](#)
- Jonas A, Gweshe J, Siboleka M, et al. HIV drug resistance early warning indicators in Namibia for public health action. *PLoS One*. 2013;8(6):e65653. [CrossRef](#). [Medline](#)
- McQuide PA, Kolehmainen-Aitken RL, Forster N. Applying the workload indicators of staffing need (WISN) method in Namibia: challenges and implications for human resources for health policy. *Hum Resour Health*. 2013;11(1):64. [CrossRef](#). [Medline](#)
- Sagwa E, Ruswa N, Musasa JP, Mantel-Teeuwisse AK. Adverse events during treatment of drug-resistant tuberculosis: a comparison between patients with or without human immunodeficiency virus co-infection. *Drug Saf*. 2013;36(11):1087-1096. [CrossRef](#). [Medline](#)
- Hong SY, Fanelli TJ, Jonas A, et al. Household food insecurity associated with antiretroviral therapy adherence among HIV-infected patients in Windhoek, Namibia. *J Acquir Immune Defic Syndr*. 2014;67(4):e115-e122. [CrossRef](#). [Medline](#)
- Jonas A, Sumbi V, Mwinga S, et al. HIV drug resistance early warning indicators in Namibia with updated World Health Organization guidance. *PLoS One*. 2014;9(7):e100539. [CrossRef](#). [Medline](#)
- Hong SY, Jonas A, DeKlerk M, et al. Population-based surveillance of HIV drug resistance emerging on treatment and associated factors at sentinel antiretroviral therapy sites in Namibia. *J Acquir Immune Defic Syndr*. 2015;68(4):463-471. [CrossRef](#). [Medline](#)
- Kalemeera F, Mengistu AT, Gaeseb J. Tenofovir substitution in Namibia based on an analysis of the antiretroviral dispensing database. *J Pharm Policy Pract*. 2015;8(1):14. [CrossRef](#). [Medline](#)
- Asefa W, Tsegaye D, Dalebout S, Ahmed E. Improving adherence to antiretroviral therapy in Namibia. *Health Aff (Millwood)*. 2016;35(12):2348. [CrossRef](#). [Medline](#)
- Kalemeera F, Mbango C, Mubita M, Naikaku E, Gaida R, Godman B. Effect of changing from first- to second-line antiretroviral therapy on renal function: a retrospective study based on data from a single health facility in Namibia. *Expert Rev Anti Infect Ther*. 2016;14(8):777-783. [CrossRef](#). [Medline](#)
- Kalemeera F, Mengistu AT, Gaeseb J. Assessment of the nevirapine safety signal using data from the national antiretroviral dispensing database: a retrospective study. *J Pharm Policy Pract*. 2016;9:5. [CrossRef](#). [Medline](#)
- Mutenda N, Bukowski A, Nitschke AM, et al. Assessment of the World Health Organization's HIV drug resistance early warning indicators in main and decentralized outreach antiretroviral therapy sites in Namibia. *PLoS One*. 2016;11(12):e0166649. [CrossRef](#). [Medline](#)

were not accustomed to using data for decision making. As such, health workers and managers did not consider use of the electronic system as a priority or as an advantage. The paper-based system was the official system for audit and accountability purposes and provided no incentive for adopting the electronic system.

From the start of the implementation, SIAPS identified pharmacists and pharmacy assistants who were interested in using computers and electronic tools and empowered them as early adopters and ambassadors of the tools. The tools were developed with substantial input from pharmacy staff, which created ownership and interest in the success of the tools. Further, tool development took into account existing processes and procedures of collecting and reporting pharmaceutical information. The progressive implementation of the tools facilitated substantial stakeholder involvement and gradual user adoption without staff being overwhelmed.

Political will and ownership from the government were critical enabling factors in gaining user acceptance of the integrated pharmaceutical management information system. The system evolved over time to address specific needs identified by the MoHSS, which generated immense political support and ownership of the tools by the ministry. The EDT became an integral part of ART dispensing at service delivery points, and an indispensable source of timely and reliable data for the national ART program and pharmaceutical managers. The early success of the EDT created an environment conducive to engage stakeholders at all levels for the implementation of FESC and the dashboard. Engagement with the MoHSS minister and permanent secretary, in particular, and their leadership and political commitment were pivotal in the successful adoption and implementation of the tools. The tools gained legitimacy when the MoHSS leadership adopted them as the official systems for audit and accountability purposes, with DivPhS owning

**Political will and ownership from the government were critical enabling factors in gaining user acceptance of the integrated pharmaceutical management information system.**



and managing the tools. Continuous engagement with the MoHSS; alignment of the tools to government priorities, process, and systems; and a persistent effort to sustain interest and leadership were critical for building political will and government ownership, which in turn encouraged acceptance of the tools.

### Strengthening Human Resource Capacity

Namibia has depended heavily on foreign pharmacy staff because of a national shortage of trained health workers. As a result, a high pharmacy staff turnover and low technical capacity of available staff resulted in lack of human resources being a key challenge. SIAPS adopted a multipronged approach to address this human resource challenge. To strengthen the technical capacity of the pharmacy staff, SIAPS worked with the MoHSS to conduct regular trainings on the tools, complemented with continuous mentorship through supportive supervisory visits to pharmacy staff at all health facilities.<sup>15,16</sup> To build institutional memory and overcome challenges related to high staff turnover, SIAPS added a video training module to the EDT to provide new users with a step-by-step orientation. Further, all the tools have a simple user-friendly interface, which facilitates tool adoption among all cadres of health workers. The simplicity of the EDT, for example, means that mentorship from colleagues is sufficient to help new pharmacy staff quickly learn and use the tool for dispensing without formal training.

To address the bigger challenge of pharmacy staff shortages, SIAPS collaborated with local training institutions for pharmacists and pharmacist assistants, incorporating the tools into the curricula and extending training to the different cadres of pharmacy staff. This has increased the pool of potential recruits who are familiar with the tools and have the technical capacity to use them effectively for patient management. It is clear that training users has to be an ongoing process and should be incorporated in the preservice curriculum to ensure sustainability of the tools.

### Financial and Technical Sustainability

Substantial costs were associated with the procurement, installation, and maintenance of the equipment and software required for the integrated pharmaceutical management information system. Development partners funded the initial procurement, development and installation of the system hardware and software, and the Namibian government agreed to take over the

full cost of operating and maintaining the system once SIAPS support ended. Reductions and restrictions on budgetary allocations to the MoHSS, however, meant that the government was unable to fully finance the system. USAID therefore provided temporary support to give the MoHSS more time to fully absorb the costs. The financial sustainability of the system will depend on the MoHSS's success in getting future budget requests approved.

The MoHSS's centralized information technology (IT) department took over installation and maintenance of the system. However, no staff in the MoHSS IT department was assigned specific responsibility for the administration and technological support for pharmaceutical information tools implemented by the project. Further, the DivPhS at the national level, which owns and manages the tools, had no IT personnel to service and maintain the tools. The DivPhS therefore had little capacity to handle the technical management of the tools at the national level while the districts and regions had limited support for health information systems. SIAPS partially addressed this issue by seconding and transitioning IT staff to the MoHSS to provide dedicated support for the tools. SIAPS also collaborated with local academic institutions to train both pharmacy and IT students to strengthen the technical capacity of potential recruits for maintaining the tools.

Limited Internet connectivity in some public-sector pharmacies across the country, software problems, the lack of IT staff at the MoHSS dedicated to the tools, and the lack of a structured replacement plan for broken or obsolete computers and printers in the facilities continue to present technical challenges. At the start of the intervention, poor Internet connectivity in some regions hampered the use of the tools and the electronic transmission of data was a substantial challenge. Internet connectivity was improved through a partnership with a local telecommunications company, which automated data transmission on a simple, low-cost, secure, and efficient wireless area network platform using 3G devices that were widely available across Namibia. The transmission of ART and FESC data is currently dependent on a reliable Internet network. The MoHSS has rolled out new integrated local networks. The sustainability of the pharmaceutical management information system will partially depend on the MoHSS's ability to maintain and update the system's equipment and software, fund Internet service for the facilities, and ensure access to the new local network.

## Interoperability and Integration

In 2012, 61 health information system tools, with varying degrees of functionality and use, were operating within the Namibian health system.<sup>2</sup> Most of these systems were, and still are, unable to share data. The pharmaceutical management information system therefore serves as an example of how Namibia can work toward integrating its other tools. However, this fragmentation also presents challenges for the sustainability and integration of the pharmaceutical management information system in the broader national health information system. There is also an ongoing e-Governance initiative through which the Namibian government has been using information technologies, including integrated local networks and mobile computing, to expand service delivery to citizens and improve coordination and communication between government departments. The MoHSS's ability to integrate the tools into the e-Governance initiative could help mitigate some of the fragmentation problems.

## Continuous Monitoring and Data Quality

The success and sustainability of the pharmaceutical management information system hinge on the quality of the data and the required human resources and technical capacity to maintain the system and support its use. The ART logistics pharmacist serves as the administrator for the dashboard and follows a data verification and monitoring protocol, which includes sending reminders to facilities to submit facility-level reports. In the early stages of dashboard implementation and adoption, data requested by MoHSS managers and development partners to analyze the various trends associated with treatment interventions and stock status helped to identify gaps and errors in the data. Identification of any errors and gaps further prompted the pharmacist to follow up with the relevant facilities for clarification and requests for additional data, which over time helped to improve the quality of the data on the dashboard. Further, this feedback process between pharmacists, health staff and program managers, and facilities demonstrated the usability of the tool and contributed to facility-level ownership of the tools.

FESC and EDT were developed to capture real-time transactional data with regular automated electronic updates to the national database. Further, the database query has a predefined list of commonly required and critical reports that are easily retrievable and customizable to respond to

key information needs and support decision making. Data are now readily available on the dashboard with only a 1-month lag, allowing managers clear visibility of the consumption and stock level trends throughout the country. The real-time data capture and automated updates help to eliminate much of the workload and task shifting associated with compiling and submitting reports. However, the suboptimal use of FESC threatens the quality of data in the pharmaceutical management information system. Going forward, the MoHSS needs to clarify roles and responsibilities for pharmaceutical information use and actively promote the use of information in decision making, including at the regional level. The MoHSS must also allocate the resources necessary to increase the technical capacity and human resources needed to manage and use the integrated system. National-level ownership of the tools cannot be over-emphasized, but without facility-level ownership and use, the tools' sustainability and data quality will be undermined.

## System Replication

SIAPS has supported the implementation of similar but less comprehensive systems in other countries. In Bangladesh, the SIAPS program supported the Directorate General of Family Planning to implement an electronic logistics management information system, which enables health program managers to monitor stock levels at the facility level and identify stock-out risks.<sup>26</sup> Similarly, SIAPS supported the Mali Ministry of Health, Sanitation, and Hygiene to develop and implement a pharmaceutical web-based dashboard called OSPSANTE for capturing, tracking, and aggregating patient and health commodity data.<sup>27</sup> As in Namibia, the systems in Bangladesh and Mali combine patient and commodity data, making data more accessible and visible for the management of pharmaceutical products. The systems have contributed to the reduction of stock-outs and improved medicines availability. These examples demonstrate that the approach used in Namibia is replicable in low-income countries, not only for ART but also other pharmaceutical products and health programs. The partnership with the local telecommunications company in Namibia to automate electronic data transmission using a 3G wireless area network is worth considering in low-resource settings with limited Internet connectivity and good 3G or mobile telecommunications data coverage.

**A feedback process between pharmacists, health staff and program managers, and facilities demonstrated the usability of the tool and contributed to facility-level ownership.**

## Limitations

This article has several limitations. It does not include many quantifiable measures to demonstrate a direct effect of the implementation and use of the tools (particularly FESC and the dashboard) on pharmaceutical service delivery and the national ART program outcomes. FESC and the dashboard are still being institutionalized and the pharmaceutical management information system has yet to undergo a full assessment that includes direct measures. As a result, the article focuses on the implementation and integration of the system and the lessons learned from that process and less on outcome measures. However, this article demonstrates how the integrated information system has streamlined the collection, collation, and analysis of pharmaceutical information and the resulting improvements in the availability and accessibility of pharmaceutical information for evidence-based decision making at the different levels of the health system. The lessons learned from the implementation process will help to inform strategies adopted by practitioners and policy makers aiming to improve the management of pharmaceutical information.

## CONCLUSIONS

The management of pharmaceutical information is critical for improving population health outcomes. The collection and use of health and logistics data facilitate accurate quantification and procurement of medicines and financial planning, thus ensuring an uninterrupted supply of pharmaceutical products. This in turn helps improve access to medicines and contributes to better health outcomes. Namibia's integrated pharmaceutical management information system seamlessly merges patient and commodity data and creates a common information platform for decision making. The system has improved the availability and visibility of pharmaceutical information in Namibia, contributing to more reliable quantifications and facilitating better inventory management of ARVs and other pharmaceutical products. Further, the system provides a reliable means for managing ART patients and monitoring ART adherence and HIV drug resistance early warning indicators. The incremental implementation of the tools resulted in a simple and practical system that meets the specific and emerging needs of the national ART program and the MoHSS. Ultimately, this type of integrated system makes it easier to identify discrepancies between commodity supply and demand and can strengthen

transparency and accountability in the pharmaceutical system. Despite some of the challenges highlighted, the implementation of the integrated pharmaceutical management information system in Namibia demonstrates a feasible approach for integrating separate existing information tools at different levels of the system while maintaining their unique functions.

**Acknowledgments:** The authors are grateful to Alemayehu Lemma Wolde (SIAPS Program, Management Sciences for Health, Namibia), Harriet R. Kagoya (SIAPS Program, Management Sciences for Health, Namibia), Rosalia Indongo (USAID, Namibia), Mahmudul Islam (SoftWorks), and all pharmacy and nursing staff in Namibia who have contributed to improving the pharmaceutical management information system in Namibia.

**Funding:** This work was supported by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, which is funded by the U.S. Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021.

**Disclaimer:** The contents are the responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government.

**Competing Interests:** None declared.

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## Peer Reviewed

**Received:** April 27, 2018; **Accepted:** November 13, 2018

**Cite this article as:** Mbirizi D, Phulu B, Churfo W, et al. Implementing an integrated pharmaceutical management information system for antiretrovirals and other medicines: lessons from Namibia. *Glob Health Sci Pract*. 2018;6(4):723-735. <https://doi.org/10.9745/GHSP-D-18-00157>

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## FIELD ACTION REPORT

# Strengthening and Institutionalizing the Leadership and Management Role of Frontline Nurses to Advance Universal Health Coverage in Zambia

Allison Annette Foster,<sup>a</sup> Marjorie Kabinga Makukula,<sup>b</sup> Carolyn Moore,<sup>c</sup> Nellisiwe Luyando Chizuni,<sup>d</sup> Fastone Goma,<sup>b</sup> Alan Myles,<sup>e</sup> David Nelson<sup>f</sup>

Through a 12-month blended learning program, nurses and nurse-midwives leading low-resource health facilities at the community level improved their capacity to engage community members, increased their ability to lead frontline teams, strengthened their skills and confidence in technology use, and optimized investments in the community health system to achieve high-quality services.

## ABSTRACT

In Zambia, nurses and nurse-midwives lead more than half of rural facilities and guide primary health care delivery. Based on a formative assessment, the Ministry of Health (MOH) determined that improved leadership capacity and management skills of facility heads would help maximize the potential of Zambia's community-level investments. In support of these efforts, the Primary Health Care to Communities (PHC2C) initiative designed and tested a 12-month blended learning program for a certificate in leadership and management practice (CLMP) to build leadership and management competencies of rural facility heads, including increasing their ability to lead frontline teams and strengthening their skills and confidence in technology use. The CLMP was created with leadership from the MOH, technical guidance from the University of Zambia, and expertise from PHC2C partners IntraHealth International, Johnson & Johnson, and mPowering Frontline Health Workers. In total, 20 nurse facility heads and 5 district nurse supervisors in 20 rural facilities across 5 districts were selected to test the course content and delivery approach. A mixed-methods approach, including evaluation of facility heads' presentations on community health improvement projects, focus group discussions with community members, and key informant interviews with nurses, clinical officers, and other stakeholders, was used to assess the results. Findings suggested that the facility heads had successfully strengthened their leadership and management competencies, increased their ability to lead frontline teams, and strengthened their skills and confidence in use of technology, including using a WhatsApp community of practice for support and consultation with other colleagues, with demonstrated improvements in the quality and accessibility of services. Based on assessment results and lessons from the test intervention, the Zambian government has committed to institutionalize CLMP as a national continuing professional development program, required for nurses posted to lead rural facilities. The planning, design, and implementation of this program offer an example to other countries and global actors of how nurses empowered with competence and confidence can play a significant role in coordinating the maze of community actors and navigating the complexities of community health systems to advance primary health care and universal health coverage.

## BACKGROUND

In 2018, we celebrated the 40th anniversary of the Alma Ata Declaration and confirmed that primary health care at the community level remains the cornerstone of improved population health. To achieve Goal

3 of the Sustainable Development Goals, countries must invest resources in primary health care to advance universal health coverage.

In Zambia, nurses and nurse-midwives still lead over half of rural facilities and guide primary health care delivery in almost all facilities. Nurses ultimately need to manage their own clinical workloads and lead task shifting, task sharing, and delegation of responsibilities among facility staff, community health workers, and community volunteers. Facility staff typically include clinically trained nurses of various levels and community health assistants (CHAs)<sup>1</sup>—a cadre of community health workers added to the frontline team between 2010 and 2012 who have been trained by the government and put on payroll. They

<sup>a</sup>IntraHealth International, Washington, DC, USA.

<sup>b</sup>University of Zambia, Lusaka, Zambia.

<sup>c</sup>mPowering Frontline Health Workers, Jhpiego, Washington, DC, USA. Now with FHI 360, Washington, DC, USA.

<sup>d</sup>University of Zambia, Lusaka, Zambia. Now with FHI 360, Lusaka, Zambia.

<sup>e</sup>Independent consultant, The Lee, Buckinghamshire, UK.

<sup>f</sup>IntraHealth International, Chapel Hill, NC, USA.

Correspondence to David Nelson (dnelson@intrahealth.org).

provide households with health sensitization, health promotion and education, counseling, and some primary care, and are supervised by the clinical staff. Community health workers also include community-based volunteers—village members who have had various levels of training, most often from external projects, have varying levels of capacity, and who provide additional support to households, including HIV peer-to-peer counseling, counseling to pregnant mothers, and escorting pregnant mothers to facilities for delivery. Other community volunteers contribute their support through neighborhood health committees.

Head nurses need the ability to assign clinical tasks to the providers best suited to execute them and assess how best to delegate tasks among front-line team members to optimize existing skills. Facility heads must also integrate CHAs into front-line health teams and maximize the impact of CHAs and other community health workers, through guidance and oversight to the full front-line team and by building bridges with the community. This relationship with the community includes engaging with them to solve health challenges, partnering with them to build awareness of disease prevention and encourage healthy lifestyles, and community members working with the facility to improve service quality, reduce morbidity and mortality, and improve population health. Some facility heads also recruit village leaders to endorse or require healthy behaviors among households and mobilize direct assistance of community members for tasks such as building and furnishing maternity homes.

The capacity of nurses to lead community health effectively will determine the quality and safety of the services delivered and returns realized. Yet nurses heading rural facilities have not received updated scopes of practice that reflect leadership activities or additional training to prepare them for the broader responsibilities that come with heading a rural facility. Further, nurses who are deployed to lead these rural facilities have not been awarded updated titles recognizing the significance of their role or commensurate salary increases.

Zambia is striving to optimize investment dollars to meet community health needs and to ensure that its community systems can sustain health initiatives within national budgets and maintain achievements toward reaching the Sustainable Development Goals. The Ministry of Health (MOH) has leveraged development funding from the United States Agency for International Development (USAID), the UK Department for International Development (DFID), the United Nations Children's Fund

(UNICEF), and other donors to integrate CHAs into the MOH staff as part of its effort to improve community health and advance universal health coverage. However, the MOH and its partners have faced difficulties in assimilating CHAs with the rest of the community team. They determined that better supervisory support and management from facility heads and district supervisors was needed to maximize the potential of the CHA investment.

Nurses have reported inadequate practical training in supervisory and management skills in their preservice education. Limited access to technologies and heavy workloads at under-staffed facilities have made it hard for nurses to access continuing professional development (CPD) opportunities to strengthen management competencies. Even intermittent workshops posed a challenge because of the time nurses are away from situations where they are urgently needed. It has been shown that workshop training without follow-up fails to demonstrate sustainable results over time.<sup>2</sup>

## ■ PROGRAM DESCRIPTION

In support of Zambia's efforts to strengthen the community health system, the Primary Health Care to Communities (PHC2C) initiative designed and tested a blended learning program in 2016–2017 to build leadership and management competencies of rural facility heads. Guided by evidence from a 2015 formative assessment,<sup>3</sup> the MOH requested that the University of Zambia (UNZA), a PHC2C partner, and the professional councils define a program to develop greater leadership and management capacity among nurses and nurse-midwives leading low-resource facilities. (See the [Figure](#) for competencies defined through the formative assessment.)

With the MOH leading the process, a competency-based, blended learning program for a certificate in leadership and management practice (CLMP) was created through technical guidance from UNZA and input from PHC2C partners IntraHealth International, Johnson & Johnson, and mPowering Frontline Health Workers. The ultimate aim of this program is to advance universal health coverage by improving the quality, accessibility, safety, equity, and utilization of care. The specific objectives of the program are to:

- Improve the leadership and management competencies of facility heads.
- Increase the ability of facility heads to lead front-line teams toward improving quality of care.

**Nurses have reported inadequate practical training in supervisory and management skills in their preservice education.**

**A blended learning program to build leadership and management competencies of rural facility heads was designed and tested in 2016–2017.**

**FIGURE.** Tasks, Important Practices, and Recommended Competencies of Facility Heads**How does the ‘in-charge’ lead quality care delivery?**

<b>Basic Activities</b> “What tasks do you carry out and what are you responsible for?”	<b>Effective Practices</b> “Which in-charge practices are important to improve the quality of care?”	<b>Recommended Competencies</b> “What competencies are needed to better prepare the in-charge to effectively lead their team?”
Assess, screen, and diagnose Manage referrals Prescribe and dispense medicines Oversee operations, budgets, and supply chain Oversee staff and volunteers Document and report Interface with neighborhood health committee (NHC) and community-based volunteers Directly report to District Health Management Team Responsive 24 hours a day	Prioritize and delegate tasks Build cooperative teams Train, mentor, and supervise staff Build community relationships Engage NHC in decisions Motivate and integrate volunteers Resolve conflicts Remain clinically up-to-date	Deliver respectful care Respond to community needs Manage facility repairs Teach, motivate, retain, mentor Ensure delivery of quality care Leverage position for influence Monitor performance M&E: data management and application Use tech for info management, training, M&E Negotiate with community Provide services Manage medicines Independent decision making Delegation and assignment of tasks

Abbreviations: M&E, monitoring and evaluation; NHC, neighborhood health committee.

- Strengthen the skills and confidence of nurses in using technology.
- Equip nurses to better lead frontline teams in advancing universal health coverage, measured through improved service quality and access.

### Course Design

A new feature of this training, in the context of nurses working at the community level in Zambia, is its blended learning design. Short-term workshops alone lack the ongoing practice and guidance required to apply learning in context

and sustain gains through changed practice. Self-guided or distance in-service programs, even those with intermittent in-person meetings or workshops, are often short-term and lack the oversight of participating supervisors. Finally, most in-service programs train one group of providers without engaging the broader team of staff and volunteers with whom they may need to work to apply new concepts and practices.

The CLMP program is designed to bring the nurses and nurse-midwives leading primary health care teams together with their district manager supervisors in a joint learning endeavor. As described in the CLMP's Facilitator's Guide (<http://health-orb.org/resource/view/certificate-in-leadership-and-management-practice#files-notice>), each of the in-person trainings features a pre-orientation with the district nurse managers and includes those managers in the training itself. Monthly calls, facilitated discussions, and monthly reviews of workbook exercises keep nurse managers involved in the coursework, using and reinforcing their supportive supervision roles. The aims of this inter-professional/cross-cadre training design are to:

- Strengthen supervisory and leadership skills among the supervisors while building leadership skills of the facility heads.
- Lay the groundwork for sustainability such that both management and frontline team leadership understand the same objectives and develop the same skills.
- Strengthen the relationships between the supervisors and the nurses, which are commonly weak in rural settings.
- Broaden the understanding and recognition of the potential leadership value that nurses can provide on the frontline if equipped with the training in those capacities.

Further, this joint participation in the program helps to ensure that training aligns with national policies and district guidelines and requirements, strengthening the oversight and accountability mechanisms of the national community health system.

The bulk of the learning in the 12-month program is spent in the workplace and engages community members, volunteers, and facility staff, including any additional clinical staff at the facility, CHAs, and environmental health technicians in a variety of learning exercises. These exercises are integrated with everyday work practices to ease workloads, improve efficiencies, and bring changes that facility heads, their teams, and their clients can

see. The length of the program and its integration into service delivery activities allows time for new practices to become habit and perspectives and attitudes to be internalized. Course instructors for the test intervention came from UNZA and other PHC2C partners. This team led delivery of the course with ongoing input from technical advisors from the MOH, the UNZA School of Medicine, the Zambian Union of Nurses Organization (ZUNO), the General Nursing Council, and the Health Professionals Council of Zambia.

The first 9 months of the course revolve around a community health improvement project, designed so that nurses and their teams can apply knowledge and skills gained through the learning experience to achieve a goal together that improves delivery of a particular service in their community. The project is identified through consultation by the head nurse with facility staff, volunteers, and community members about which service improvement would mean the most to them. Several nurses reported that this exercise offered a fresh introduction to village leaders (e.g., village chief, council headman, council members), who were important later in supporting the work of the frontline team. Examples of projects included increasing enrollment in antenatal care (ANC), improving the quality of services for facility deliveries, and increasing uptake of testing for HIV and other sexually transmitted infections.

Facility staff of all cadres, including CHAs, as well as volunteers and community members join the facility heads in the development, implementation, and monitoring of the community health improvement project, with ongoing guidance from the district supervisors. These district managers, in turn, learn to provide more hands-on support and to recognize the potential of the head nurses to help them advance service indicators, community health, data management, and evidence building. The last 3 months of the program are devoted to completing the community health improvement project, evaluating the results, and preparing a final presentation for the course graduation event. The community health improvement project demonstrates the results of the training and the capacity of the facility head to build and sustain a cohesive, effective team to deliver high-quality, accessible care. The project also serves as an accountability mechanism, bringing the community and the MOH together as collectively responsible for the performance of their own health system.

**The first 9 months of the course revolve around a community health improvement project.**

**The bulk of learning in the 12-month blended learning program is spent in the workplace.**



**The training structure incorporates peer-to-peer learning components and ongoing communication activities, including a WhatsApp discussion group between nurses and managers.**

The training structure incorporates peer-to-peer learning components and ongoing communication activities. As described in the CLMP Facilitator's Guide, the learning process requires that nurses use their mobile phones (all of which were owned or acquired by the course participants themselves) to participate in learning group discussions facilitated by their nurse managers during which they use WhatsApp to call their assigned "call partner" (another facility head) each week to complete that week's training assignment. This activity strengthened peer-to-peer relationships between the nurses, most of whom did not know each other prior to the course even when they were working in the same district. It also strengthened a community of practice among facility heads that had not existed before and through which nurses gain confidence not only in their own capacity as leaders in their health zone or catchment area but also in the support system they have from one another. Studies have shown that the use of social media as a part of learning improves the learning while contributing to retention of frontline health workers in low-resource posts.<sup>4</sup>

The program also incorporates UNZA Mobile, a mobile application that supplements workbook reading and cross-cadre activities and reinforces learning through audio and visual tools, research links, and review exercises. UNZA Mobile is based on the OppiaMobile application and allows students to access video, audio, and text-based tools without an active network connection. When students join in-person quarterly workshops, the content for the subsequent quarter is downloaded to their UNZA Mobile app because many of the course participants live in rural areas where access to phone connections is poor. As technology and infrastructure continue to improve in Zambia, students will be able to download this content on their own. The mobile application is designed to engage students instantly and add variety to the learning process, accommodating multiple learning modalities while building self-guided research habits. Further, interaction with the mobile application is intended to raise nurses' level of self-assurance in technology use beyond social texting and voice communication.

## ■ ASSESSMENT METHODOLOGY

Twenty facilities (rural health centers and health posts) across 5 districts in 2 provinces were selected to test the course content and delivery approach for viability of operationalization, appropriateness for uptake, and effectiveness in building leadership and management competen-

cies in nurses, as well as to gauge how the program reinforced community and service delivery processes, health system operational mechanisms, and national and district policies. Twenty nurse facility heads (18 of whom completed the course) and 5 district nurse supervisors participated in the test cohort.

A mixed-methods approach was used to assess the results of the test intervention:

- The community health improvement projects provided the primary means of evaluating facility heads' ability to better lead frontline teams toward improving quality of care. During project presentations, results of the training were demonstrated by the head nurse's ability to describe the improvement process, identify the competencies they had used and how they had applied them, clarify contributing roles of various frontline team members, and show measurable improvement toward meeting the need or closing the gap prioritized by their project. (See [Supplement 1](#) for the final community health improvement project presentations made by program participants and [Supplement 2](#) for the goals and results by facility.)
- Nine months into the program, program advisors gathered with UNZA training facilitators, General Nursing Council representatives, and district managers to assess the progress of the training. Students were asked to present progress on their community health improvement projects to gauge (1) whether they had used peer-to-peer support, engaged community members to solve problems, and applied the problem-solving tools imparted during the training; and (2) how their own management skills had been employed to guide coordination of roles to accomplish tasks and move forward. The students' ability to describe the process and explain progress made was used as an indicator of autonomy and accountability, 2 leadership characteristics addressed in the course curricula. Each nurse also discussed additional areas of service improvement being pursued. Clarifying questions were posed regarding competencies gained, used, and demonstrated. (See [Supplement 3](#) for case examples.)
- We conducted a qualitative retrospective assessment during the last quarter of the program at 18 facilities through focus group discussions and key informant interviews. A

total of 54 focus group discussions were conducted (3 per facility), with a range of 13 to 20 participants in each group (neighborhood health committee members and community volunteers). Key informant interviews (n=23) were conducted with nurses, clinical officers, CHAs, and environmental health technicians working at each of the 18 facilities. The assessment focused on whether staff, volunteers, and community members had seen changes in the management practices of the facility head, increased teamwork among staff and volunteers, and improved services to clients. (See [Supplement 4](#) for assessment questionnaires.)

## ■ RESULTS

### Facility Heads Improved Leadership and Management Competencies

During the course's third-quarter workshop, head nurses were asked to present examples of where they were applying newly gained competencies from their training. Observations of the program instructors, validation by the district managers of the nurses' achievements to date, and the nurses' responses to unstructured interview questions suggested that the nurses had successfully gained and strengthened leadership and management competencies and were able to apply them toward achieving health outcome goals and improvement objectives. (See [Supplement 3](#) for case examples.)

One example is the facility head's application of quality improvement practices at the Chibombo District's Mwanjuni health post. With members of her frontline team (and without direct project support), the facility head developed referral cards that CHAs and volunteers use to track the effectiveness of their counseling of women for early ANC enrollment. The CHAs and volunteers give the cards to pregnant women after visiting their homes and tell the women to bring the cards to the facility when they come for their ANC visit. The cards enable the facility head to track how many women the CHAs are visiting, cross-checking with registry information, and how many women referred are coming to the clinic. The nurse uses the cards to document which houses are being visited and which CHAs and volunteers are most effective in applying what they have learned about advocating for early ANC enrollment. It also demonstrates a low-cost solution that was feasible within the health facility's limited budget.

### Facility Heads Increased Ability to Lead Frontline Teams

The community health improvement projects showed that nurses were able to build collaboration among the different cadres in the frontline team to identify gaps, prioritize needs, plan and implement strategies to address needs, and improve the quality of care delivered to the community. Through the projects, the head nurses demonstrated their leadership as they were able to articulate their improvement goals, their SMART (specific, measurable, attainable, realistic, and timely) objectives for attaining those goals, and the indicators they defined to monitor and demonstrate improvement. As part of the presentation, the facility heads were able to explain the specific roles and responsibilities of their frontline team members in contributing to the improvement plan, and how tasks had been shifted and responsibilities shared. Facility heads articulated the leadership and management competencies they had applied through the process and how those competencies contributed to the project achievement.

**Nurses were able to build collaboration among the different frontline team cadres to identify gaps, prioritize needs, plan and implement strategies, and improve the quality of care.**

### Nurses Strengthened Skills and Confidence in Technology Use

Less than half of the participants owned a smartphone when they began the program. By the third in-person meeting, 90% of the participants had traded their feature phones to invest in smartphones. All students learned to download applications, access and organize files, and incorporate the WhatsApp social communications tool into work and learning.

The training participants also gained experience and confidence using computer programs. The community health improvement project required that all students develop a PowerPoint presentation to demonstrate their final results. Some nurses developed these presentations on facility or personal computers; others without access to computers wrote up their presentations and used study time allotted during the workshops to transfer their work into PowerPoint on colleagues' computers. Nurses having trouble with their presentations received help from their supervisor and peers. At the outset of the training, only 2 participants were comfortable using PowerPoint. By the third in-person meeting, only 2 were still unable to use the computer programs and functions on their own. The rest of the students, at varying speeds, were able to maneuver through

presentation slides and apply shortcuts to update tables and graphs.

All of the students were comfortable using mobile phones to call and text, but initially only a few used their mobile phones to connect with colleagues for support and consultation. However, the nurses soon began to use the WhatsApp community of practice not only to fulfill their course requirement to discuss weekly questions posed by their district managers and socialize with each other but also as a network of support for their work. On at least 2 occasions, a nurse faced a difficult health care challenge while alone in their facility. Without any other support available, the nurse in distress reached out to the community of practice and found technical guidance and moral support to steer through the necessary steps in responding to the critical health need. One of these times, a woman arrived at a facility in the middle of the night with obstructed labor, and the enrolled nurse was the only health care provider immediately available. The second event occurred when a man was brought to a facility unconscious and there was no evidence as to the cause or the needed response. In both cases the patient was successfully treated due to the network of colleagues that were ready to provide their expertise through the community of practice.

### Nurses Enhanced Capacity to Lead Teams to Advance Universal Health Coverage

The community health improvement project presentations and findings from the qualitative retrospective assessment indicated that communities where head nurses had completed the training saw specific improvements in the quality and accessibility of services—2 of the 4 characteristics of universal health coverage as defined by the World Health Organization.<sup>5</sup> Examples of measurable improvements reported for individual facilities through the projects included (1) increasing testing of HIV-exposed infants at 18 months from 60% to 83%; (2) increasing ANC coverage before 14 weeks from 35% to 62%; and (3) increasing the number of fully immunized children under age 1 from 6% to 80%. (See [Supplement 2](#) for a table of project goals and results by facility.)

Efficiency of service delivery is 1 of 6 domains of quality care, as described by the Institute of Medicine.<sup>6</sup> Toward efficiency, nurses reported delegation and shifting of tasks as one of their main learnings in describing the competencies they applied in their community health improvement projects. Over and over again, nurses told

how the training had empowered them to work better with the members of the team, inside and outside their facility, to divide the work among everyone and to assign roles and responsibilities. Further, the PHC2C team coordinated with the Clinton Health Access Initiative, which had developed a training for CHA supervisors to better guide CHAs on filling out reports and following the government's CHA policies. As the MOH had invested in both programs, PHC2C worked with the MOH and Clinton Health Access Initiative to incorporate elements of the CHA supervisor training into the CLMP to maximize and sustain the benefits of both trainings.

Nurses reported their appreciation of integrating training on reporting skills and CHA policies with training on how to be more effective supervisors through coaching, mentoring, and teaching. As described by the nurses, their improved ability to shift tasks among the team members and provide quality and safety oversight enabled them, as clinically trained providers, to use their time more wisely, see more clients, and achieve population health targets. Community members and facility staff echoed this improvement as a result of the training and noted their own increased motivation and engagement with a clear role that had meaning in contributing to the health of their community.

*We teach and mentor now with the community-based volunteers and they can't just keep quiet anymore. If they see something wrong in the community, they will come to us and say, "We don't know how you're going to handle this but there is such a case in our community." —Community health assistant, Kabweza Rural Health Post*

Timely services is another Institute of Medicine domain of high-quality care. Clients from Mwanjuni, Momboshi, and Chisamba facilities specifically noted shorter wait times and a more effectively run facility due to delegation of duties by the head nurse to the frontline team.

*The community is happy with the services because of the way we are working. It is better this year than last year because [now] they don't wait long to come and register for antenatal [care] and a lot have given birth at the clinic. —Neighborhood health committee member, Mugurameno District*

Accessibility to respectful care and high-quality services is increased by shorter wait times, improved services, and greater confidence of the community in the facility. Confidence of clients demonstrates patient-centered care, which translates not only into

**Examples of measurable improvements reported for facilities included increasing testing of HIV-exposed infants at 18 months, increasing ANC coverage before 14 weeks, and increasing the number of fully immunized children under age 1.**

the care that the community member receives at the point of service but also in the inclusion and engagement of community members in improving the quality of care. Community-based volunteers and neighborhood health committee members described a clear increase in their own collaboration and the nurses' increased outreach to the community, evidenced by the nurses coming into the community physically and inviting community members to share their thoughts and participate in plans to improve services. Staff described that the head nurse shared coaching and mentoring techniques to use with clients and community members and reported that using these techniques had built more trust and confidence in the community to come to them with problems.

During focus group discussions, community members described changes they had seen in the way that nurses and their staff treated clients. For example, a community volunteer from the Kafue Mission Health Center told how the nurse explained to the volunteers that if they wanted to improve care, they needed to listen to the people they were caring for. The nurse wanted to better understand why women were not coming to enroll in antenatal care when they knew they were pregnant. She went into the community and sat with women to listen to their concerns. What she found was that some women were afraid to register with the clinic because the father was not their husband, and they thought they would be required to name the father. The head nurse then instructed all volunteers to be sure to explain to the community members that when they come to enroll in ANC, they do not have to be married or name the father. They can feel safe.

During the formative assessment, some clients had complained that head nurses and staff shouted at patients, treated them with disrespect, and never listened to their problems. In the post-training retrospective assessment, community members noted specifically that they had seen improvements in the way that the head nurse and the other facility providers communicated with clients.

*In the past nurses used to shout at the patients, but this time there is nothing; and the community appreciates that. The staff here has been told not to shout at the patients because they came to serve the community. And this improvement, we saw it this year. — Neighborhood health committee member, Chisamba Rural Health Center*

## ■ DISCUSSION

The CLMP program is designed to be sustainable in several aspects. The job requirements of the district supervisor include the supervision and coaching of facility heads and participation in the program, for which they also earn CPD points. The training allows nurses and nurse-midwives to fulfill their relicensure requirements with the council, and to gain the additional title of head nurse in charge. Environmental health technicians and clinical officers are also motivated to pursue the course as their councils recognize it for their CPD units. The MOH recognizes the need and value of improved leadership and management capacity to strengthen primary care delivery and build stronger community systems.

### Key Factors for Optimizing Success

The planning, design, and implementation of this program may offer an example to other countries and global actors of how investments in community systems can be optimized and global goals can be realized in local contexts, and of the commitment and accountability that is required to foster sustainable return on investments. Key factors for success follow.

#### Country Ownership

The intervention met a country need and responded to priorities defined by health authorities and recognized by relevant actors.

#### Country–Community Alignment

Community engagement is an important part of successful health system designs that respond to community needs and advance health-seeking behaviors. A variety of interventions have been implemented to increase and institutionalize community engagement, including social accountability mechanisms, neighborhood committees, quality assurance, and community development groups. We designed this intervention to reflect community voices and engaged community input throughout the process to ensure responsiveness to community needs and community requests for improvement. The program helps to build skills and expectations in the community on how to interact with health facility staff as part of routine work practices and see themselves as part of the frontline team accountable for service quality and health outcomes. It also builds skills and practices among the nurses for collaborating with community leaders and integrating community



contributions within the roles and responsibilities of their teams. Further, key stakeholder participation—namely district and provincial management, professional councils, and unions and associations—bridged the gap between community voices and central government awareness.

### Scale

The approach to this program, from its initial development to its implementation, was designed to enable institutionalization at a national level. Partners, both those leading in the country and those providing peripheral experience or resources, followed development principles that were inclusive, evidence-based, contextualized, viable, and flexible:

- **Inclusive:** Key stakeholders, from the community to the government, were engaged from the initial verification of evidence to the interpretation and application of that evidence to recommendations and decision making.
- **Evidence-based:** Evidence-based strategies ensured that the interventions were designed to fit the need and that indicators monitored reflected the expectations of the communities served and quality standards of the health system.
- **Contextualized:** The intervention was shaped to respond to the national infrastructure, health systems mechanisms, and cultural mores of the environment.
- **Viable:** Tools, mechanisms, and training delivery design were all integrated within systems structures, practices, hierarchies, and resources. Succession of program ownership was factored in from the beginning so that removing external support did not end the program.
- **Flexible:** Internal and external partners collaborating on program development remained flexible in applying previous experience and expectations so that individual or even collective agendas would not obstruct needs to adapt the program throughout its initial testing.

**At the end of the test intervention, the MOH approved scaling up the blended learning program.**

At the end of the test intervention in 2017, the MOH approved scaling up the CLMP program, with financial support, and linked CLMP completion and certification to an elevated title for nurses and nurse-midwives. The MOH has also reorganized the establishment of positions and salaries, although the rural facility “in-charge” position is not yet funded by the Public Service Management Division. As of this writing, ZUNO is negotiating

for a salary increase upon CLMP completion and assumption of increased leadership responsibilities.

Based on the learning from this experience, the MOH has encouraged all local institutions to provide in-service leadership training for nurses and midwives working in rural facilities, and it has approved the CLMP as a national CPD program, required for all nurses posted to lead primary health care services at rural health facilities (centers and posts). Institutionalization is being led through UNZA as part of its CPD offerings for relicensure, to be sustained through student payments and annual district budget funds earmarked for CPD. UNZA is also seeking to reduce implementation costs through support from stakeholders such as ZUNO. In January 2019, UNZA will roll out the CLMP to 3 additional provinces—Eastern, Luapula, and North Western—targeting 25 to 30 rural facilities in each where service quality indicators are low. ZUNO has committed financial support to supplement existing provincial support for students who need assistance to take the training.

In addition, the UNZA School of Nursing Sciences has incorporated elements of the CLMP into its updated preservice curriculum for the Bachelor of Science degree program in public health nursing to strengthen the leadership and management component. An updated curriculum, including a community engagement component and community health improvement project model, is planned for implementation by the 2019 academic year. The School of Nursing Sciences hopes to link the improved preservice curricula more closely to CPD with the support of the MOH.

### Maximizing and Optimizing Resources

Throughout the planning, development, and implementation of the program, country leadership guided budget decisions so that all program elements would remain financially viable within the national resource structure. The existing management structure provided mentoring and supervision of the nurses during their work, without additional support from the project. Phones and computers were not provided. To make it easier in the future to provide closer supervision of students, preceptors from referral hospitals have been added to the design. The preceptors, students who are completing their degrees during their in-service clinical practice, will receive credit toward the completion of their course by facilitating the online community of practice discussions,

participating in the bi-monthly nurse-supervisor calls, and checking workbook exercises. This additional layer of support will not cost the MOH or students, but it will help to give preceptors broader supervisory experience while gaining course credit, and will provide additional on-the-ground mentoring in between the nurses' monthly check-ins with the district managers.

The program was also designed to complement other implementation projects going on in the catchment areas. For example, we aligned training on documentation and reporting with new guidelines on how reporting should be done with CHAs and the greater participation of neighborhood health committees and incorporated the MOH's CHA supervisor training in our supervision, teaching, coaching, and mentoring module. Another key measurement of success was the program's contribution to helping community actors sustain and advance the improvements made in their own communities. For example, nurses applied their skills to advance the MOH program to expand maternity homes as part of Zambia's plan to increase facility deliveries. In one case, the facility head used her negotiation skills to recruit the village leaders' support in galvanizing contributions from community members to complete the facility's maternity home, which had been delayed due to limited resources. In presenting this work in her community health improvement project, the facility head described how she had employed some of the approaches learned through the CLMP for mobilizing resources and combined that skill with some of the tools learned for community engagement to assume responsibility for her own facility and demonstrate some autonomy and leadership in achieving the goal even without the help of external funds or district intervention.

### **Holistic Approach to Capacity Building**

Although this program aims to develop competencies in one cadre—nurses or nurse-midwives leading low-resource facilities—it is also designed to build the skills and knowledge of actors across the frontline team, including community members. Program developers understood that vertical interventions focusing on a specific disease or system can create imbalances in the system. Therefore, the intervention was designed to be holistic and to strengthen the system's capacity horizontally by strengthening roles for nurses in leadership and management.

### **Limitations**

The small sample size of the test intervention limits the reliable applicability of the results across larger populations, and the scope and 12-month length of the intervention precluded assessment of longer-term quantitative improvements in services. While some community health improvement projects documented measurable improvements in HIV/AIDS, maternal and child health, or sexual and reproductive health services, these cannot be considered significant until continued or stabilized over an additional 12 months.

### **■ IMPLICATIONS FOR REPLICATION**

Designing a fit-for-purpose workforce, meaning a well-integrated team of health workers that is prepared to respond to the needs of the population it serves, requires that countries remain flexible and responsive in education and training. Building capacity stretches far beyond preservice education and in-service training—it is a continuous journey in which various actors in the health system must learn to work together and supervision and management must support professional growth, development, and advancement. Building these skills and attitudes must start in preservice education, by establishing an understanding among clinical professionals of their roles as leaders and managers.

It is in these roles that providers can move services further toward patient-centered care, using the soft skills that are so essential in building responsive, accountable teams and are borne through engagement and interdependence among the clinical providers, the community health workers, and the community population. As Odugleh-Koluv and Parrish-Sprowl<sup>7</sup> advocate:

*Health systems and communities are in continuous and interdependent action. If community engagement becomes a focus for UHC efforts, it could finally push the health sector from an almost exclusively transactional model into one that recognizes that health and well-being are co-produced, and that empowers both health-care providers and communities. This means that governments, donors and researchers have to address institutional culture and invest in so-called soft skills . . .*

In its approach to community health, Zambia may provide an example for other countries of the region and beyond. When developing strategies to leverage community health workers and strengthen the community health system, it has considered the entire system and how a fit-for-

purpose workforce best brings together communities, volunteers, and health facility staff as a cohesive frontline team. Using existing resources and working within national systems and mechanisms, the Zambian government is committed to institutionalizing a program that will continue to strengthen leadership among community providers, build sustainability and resilience within the community system, and improve services toward achieving Sustainable Development Goal 3. Maximizing potential of community-level leadership will go a long way toward realizing people-centered, accountable community health systems that provide access to high-quality care for all.

**Acknowledgments:** The authors gratefully acknowledge the numerous contributions of the PHC2C global and national advisory groups. Global Advisory Group members include Michael Bzdak (Johnson & Johnson), Lesley-Anne Long (formerly of mPowering Frontline Health Workers), Gail Tomblin Murphy (Dalhousie University WHO/PAHO Collaborating Center for Health Workforce Planning and Research), Judith Shamian (International Council of Nurses), Laura Hollod (Johnson & Johnson), Carolyn Moore (formerly of mPowering Frontline Health Workers), and Stembile Mugore (IntraHealth International). Zambian Stakeholder Advisory Group members include Mujajati Aaron (Health Professions Council of Zambia); Dorothy Chanda (University of Zambia); Judith Chipili (General Nursing Council); Kanekwa Chisense and Elias Siamatanga (Ministry of Health); Rita Kalomo and Liseli Sitali (Zambia Union of Nurses Organization); Bertha Kaluba (Midwives Association of Zambia); Caroline Phiri (Ministry of Health, formerly with Ministry of Maternal Health and Community Development); and Emily Measures, Salome Temba, and Nikhil Wilimink (Clinton Health Access Initiative). Paul Ngwakum (UNICEF) provided leadership and guidance throughout the development, delivery, and harmonization of the work with broader partners in community systems strengthening and with the Ministry of Health. Maureen Corbett and Rebecca Kohler of the IntraHealth executive team provided leadership and guidance throughout, and have long engaged collaboratively with partners and colleagues in Zambia and globally. Alice Liu, Alex Kellerstrass, and Alex Little of mPowering Frontline Health Workers provided technical assistance in developing

workbooks and the UNZA Mobile app, and adapting materials for online access. Nathan Heidt of Positive 6 designed the workbooks. Charity Kapenda and Dorothy Chanda of the University of Zambia provided technical input into the design, implementation, and assessment of the program and remain long-time advocates for supporting the frontline team (Thunder, Thunder, Thunder!). Claire Viadro (previously of IntraHealth) contributed to the research during the formative assessment. Nadia Leveque (previously of IntraHealth) provided invaluable support in program management and logistics.

**Funding:** Johnson & Johnson.

**Competing Interests:** None declared.

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## Peer Reviewed

**Received:** February 9, 2018; **Accepted:** November 6, 2018

**Cite this article as:** Foster AA, Makukula MK, Moore C, et al. Strengthening and institutionalizing the leadership and management role of frontline nurses to advance universal health coverage in Zambia. *Glob Health Sci Pract*. 2018;6(4):736-746. <https://doi.org/10.9745/GHSP-D-18-00067>

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## FIELD ACTION REPORT

# Implementation Research to Strengthen Health Care Financing Reforms Toward Universal Health Coverage in Indonesia: A Mixed-Methods Approach to Real-World Monitoring

Rena Eichler,<sup>a</sup> Susan Gigli,<sup>b</sup> Lisa LeRoy<sup>c</sup>

Implementation research enabled stakeholders to formulate questions, assess implications of research results that informed changes in regulations and payment at the primary care level, and strengthen monitoring capacity. While the national health insurance system had some impact on performance of primary care facilities, individual providers remained unsatisfied because payment was largely based on factors outside of their control such as tenure and position, rather than their contributions to improved performance.

## ABSTRACT

Universal health coverage reforms are complex and impact numerous processes, institutions, and individuals. To know whether reforms are being implemented as planned and working as envisioned, policy makers and managers need information and insights on bottlenecks. The United States Agency for International Development (USAID) provided support to build implementation research (IR) capacity and to conduct cycles of research to help Indonesia understand how its single-payer national insurance reform, Jaminan Kesehatan Nasional (JKN), was affecting primary care. Two cycles of IR in Indonesia focused on effects of JKN financing on primary care, as determined through a consultative process with stakeholders at national and district levels. This process generated questions relevant for implementers and policy makers and strengthened government interest in findings. Research was conducted in 5 diverse districts, and methods included key informant interviews, focus groups, document review, health worker surveys, and analysis of service delivery data. Cycle 1 findings showed an uneven understanding of JKN regulations, unequal implementation readiness, and limited evidence of improved productivity. JKN capitation payments did not increase health worker satisfaction or motivate additional effort. Informed by these findings, regulations were rewritten and the capitation payment formula was redesigned to include payment conditional on performance. Cycle 2 found that health workers experienced increased workloads because of increased enrollment in JKN and the requirement that people access primary care before being referred to higher levels of care. In addition, health workers indicated they did not experience the payment system to be fair. Instead of payment being conditional on performance, they indicated it was primarily determined by education and tenure, with only some districts incorporating a small payment component based on behaviors, such as attendance, and performance. The health workers said they preferred to be paid based on achieving primary care targets. Conducting IR so that questions are relevant and the process of finding and sharing answers is timely and cost-effective requires high-level skills, but support to build IR capacity has potential to make a lasting impact.

## BACKGROUND

Universal health coverage (UHC) reforms are complex and impact numerous processes, institutions, and individuals in health systems. To know whether reforms are being implemented as planned and working as envisioned, policy makers and managers need information and insights on bottlenecks. In Indonesia, the

United States Agency for International Development (USAID) provided local capacity-building support to conduct implementation research (IR) to understand how health reforms were working for primary health care and to inform revisions. This article describes how IR was applied in Indonesia, shares lessons learned and trade-offs to consider when launching IR, and discusses why support for building IR capacity is a worthwhile investment.

IR in health can be defined as “a type of health policy and systems research concerned with the study of clinical and public health policies, programs, and practices, and aims to understand not only what is and is not

<sup>a</sup>Broad Branch Associates, Washington, DC, USA.

<sup>b</sup>Broad Branch Associates, Washington, DC, USA. Now with Kantar Public, Washington, DC, USA.

<sup>c</sup>Abt Associates, Cambridge, MA, USA.

Correspondence to Rena Eichler (rena.eichler@broadbranch.org).



working, but also how and why implementation is going right or wrong, and testing approaches to improve it.”<sup>1</sup> IR focuses on practical and actionable issues and on complex and real-world settings. It involves implementers in shaping the research to meet their needs and relies on mixed methods to answer research questions. IR benefits both policy makers and implementers as a way to quickly identify and respond to implementation challenges by helping to answer questions such as:

- Is the initiative being implemented as planned?
- What factors are hampering implementation?
- Does the initiative translate into the expected changes in the system?
- Are there unintended consequences (either positive or negative)?
- What actions should be taken to improve implementation?

To our knowledge, IR has not been used in complex system-wide health reform efforts; however, we are aware of its application to scaling up health interventions<sup>3</sup> and delivery strategies.<sup>4,5</sup>

In January 2014, Indonesia began implementing a national health insurance initiative aimed at covering the country’s entire population by 2019. BPJS (Badan Penyelenggara Jaminan Sosial), Indonesia’s social insurance administration organization, integrated existing insurance programs for the poor, civil servants, police, military, and formal sector workers into 1 single-payer national health insurance scheme, known as Jaminan Kesehatan Nasional (JKN). In addition, the vision was to integrate more than 300 district-level insurance schemes into JKN, and for all non-poor informal sector workers to enroll. If Indonesia attains these ambitious goals, it will have the largest single-payer insurance system in the world.

As with any ambitious health financing reform, implementation of JKN is challenging and not all effects can be anticipated. With its emphasis on actionable and prospective learning in real-world settings, IR can strengthen the chances of policy makers and implementers to successfully pursue universal health coverage. The purpose of the IR described in this article was to (1) strengthen local capacity in Indonesia to conduct IR and (2) provide crucial information for policy makers and other decision makers at the national and district levels about whether JKN was being implemented as intended and bringing about desired changes in primary care. Primary care was selected as the technical health area of

focus because of its important to the entire health system. Policy and decision makers and managers can use the findings to monitor and strengthen operational processes, review policy decisions, and clarify roles and responsibilities to ensure progress toward reform and enable attainment of their goal to provide universal health coverage in Indonesia by 2019.

## METHODS

The research sites consisted of 5 districts in 4 provinces: East Jakarta (Jakarta Province), Jember (East Java Province), Tapanuli Selatan (North Sumatra Province), and Jayapura and Jayawijaya (Papua Province). These 5 districts exhibited strong local political commitment to JKN and were among USAID’s priority districts for reproductive, maternal, and child health, tuberculosis, and HIV. They represented both urban and rural areas and were part of the Center for Health Policy and Management’s (CHPM’s) Health Policy Network, a network of universities across Indonesia. Before the research began, an assessment was conducted to review other studies on JKN and to identify gaps.

An important feature of the IR conducted in Indonesia was its participatory nature.<sup>2</sup> CHPM and the Ministry of Health (MOH) Center for Health Finance and Insurance, supported by the Health Finance and Governance project team, facilitated an IR launch workshop with national- and district-level stakeholders in February 2016. The workshop used a root cause analysis method that unpacked the underlying processes and behavioral reactions that were expected to lead to anticipated benefits of JKN, which resulted in primary care as the priority focus of the IR.

Then, through a consultative process key stakeholders, including national and local policy makers and implementers, contributed to defining the IR questions, which broadly focused on the effects of JKN financing on primary care. Cycle 1 assessed how JKN regulations on capitation fund management at the primary health center level were being interpreted and implemented and implications for effectiveness of JKN. BPJS pays health centers a monthly per capita payment to deliver a package of services to JKN members. For public facilities, regulations mandate 60% of capitation funds for health staff supplemental payments and 40% for operational costs. Private primary care facilities have full discretion over how capitation funds are used. These capitation funds were

hypothesized to motivate staff to provide improved primary care services, enhance productivity, and control costs by managing referrals. The operational costs component was hypothesized to improve availability of inputs and enhance outreach. Cycle 2 sought to investigate health worker satisfaction with capitation payments and identify opportunities to strengthen the links between capitation and behaviors that lead to improved service delivery.

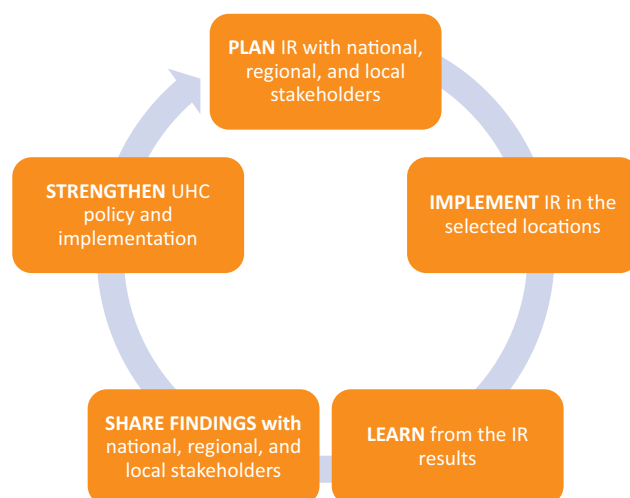
Each cycle of research took approximately 1 year to complete and included engaging stakeholders, determining priority questions, launching field work, conducting analysis, and sharing results (Figure). Cycle 1 began in February 2015 and ended in December 2016, and Cycle 2 began during the Cycle 1 dissemination workshop in December 2016 and ended in December 2017. Specifically, to understand whether JKN capitation funds were being managed and used as intended, CHPM conducted focus groups and in-depth interviews with district health and government officials and health facility teams in the 5 target districts, complemented by document review, collection of administrative data on service delivery, and health worker satisfaction surveys (Table). Following the data collection and analysis phase in Cycle 1, stakeholders discussed the findings, identified whether and which corrective measures needed to be taken to improve implementation, and identified questions for Cycle 2.

At the end of each of the 2 research cycles, the IR team at CHPM organized national- and district-level workshops to share findings and facilitate discussions with university partners and stakeholders. National-level decision makers valued learning about the challenges of implementing JKN from district leaders, and district leaders appreciated the opportunity to provide input to national decision makers. District leaders valued learning about how JKN was being operationalized in their communities and how other districts were interpreting and operationalizing JKN policies and regulations. Following national workshops, CHPM staff traveled to each district to meet with the local university partner and district stakeholders to discuss district specific findings.

### Partners and Stakeholders

The USAID-funded Health Finance and Governance Project used a competitive process to select the Center for Health Policy and Management (CHPM) at the University of Gadjadara, to engage with stakeholders, carry out capacity building training, and conduct research. CHPM was selected because it had the following capabilities: (1) convening power and credibility to engage national- and district-level policy and decision makers to shape research and act on the findings, (2) capacity to learn from cycles of research that would strengthen JKN

**FIGURE.** Implementation Research Cycle



Abbreviations: UHC, universal health care; IR, implementation research.

**TABLE.** Number of Interviews and Focus Groups by Implementation Research Cycle and District

District	Cycle 1		Cycle 2	
	Interviews	Focus Groups (Participants)	Interviews	Focus Groups (Participants)
South Tapanuli	8	1 (15)	7	4 (29)
East Jakarta	26	1 (8)	15	4 (30)
Jember	24	1 (10)	18	4 (56)
Jayapura	15	1 (9)	14	6 (25)
Jayawijaya	13	1 (20)	9	3 (33)
Total	86	5 (62)	63	21 (173)

implementation at the primary care level, and (3) capacity to build local IR capabilities.

CHPM's government counterpart was the MOH Center for Health Finance and Insurance, which was chosen because they had a history of leading multi-entity working groups, had the mandate to focus on health financing and the impact of JKN on service delivery, had legal but not necessarily actual access to data from BPJS—the Indonesian entity that pays providers for services covered through the national insurance program, and they were receptive to engaging with CHPM to steer the consultation and dissemination process. Other stakeholders, selected because of national- and district-level leadership and policy and management roles, were the MOH Directorate of Primary Care, BPJS, Ministry of Home Affairs, Ministry of National Development Planning, and district health and political leadership.

### Strengthening Local Capacity in Implementation Research

CHPM conducted training sessions to build local capacity to conduct IR. CHPM trained 5 teams and 35 individuals from the staff and faculty of the Health Policy Network universities—University Sumatera Utera (North Sumatera Province), University Negeri Jember (East Java Province), and University Cendrawasih (Papua Province)—to conduct surveys, interviews, and focus groups; transcribe and analyze data; prepare briefs for district stakeholders; and present findings. Those trained both directly conducted the research and trained students and other faculty to conduct the implementation research. The capacity-building sessions enabled local individuals to conduct IR and communicate policy and programmatic findings across Indonesia.

In addition, CHPM conducted webinars and presentations on IR that reached 1,634 additional

stakeholders comprised of district- and national-level decision makers, academics, and students.

## FINDINGS AND CORRECTIVE MEASURES

### Cycle 1

Findings from Cycle 1, assessing how capitation fund management regulations were being interpreted, revealed uneven understanding of national, provincial, and district regulations that impacted implementation of JKN at the primary care level. Another challenge identified was diverse readiness among districts and regions to manage JKN. For example, districts differed in their degree of use of capitation funds. Facilities in one district failed to use 36% of capitation funds because of imperfect understanding of procurement regulations, and in another district, facilities failed to use 17% of capitation funds because of challenges with procurement processes and under-spending for outreach.

Staff surveys, interviews, and focus groups indicated that additional payments from capitation payments did not increase health worker satisfaction or motivate additional effort. Only 25% of doctors reported being satisfied with their income since introduction of JKN, whereas 43% reported being unsatisfied. One reason for doctor dissatisfaction was that additional payments received from capitation were not perceived to compensate for additional workloads, and another reason was that JKN forced them to work full shifts, which limited their ability to earn private-practice income.

The capitation payment system was found to have little impact on improving performance at either the facility level or the individual level. Findings from respondent interviews indicated that the additional income from capitation

**Research findings revealed uneven understanding of JKN regulations, unequal implementation readiness, and limited evidence of improved productivity.**

incentivized staff to show up for work, but there was limited evidence of improved performance. However, both quantitative and qualitative data indicated that preventive and promotive services increased in volume and quality.

In response to the finding of uneven understanding of regulations, the MOH held a meeting, together with the Ministry of Home Affairs, that was attended by 514 district health officers to understand the sources of misunderstanding, according to a conversation with Dr. Doni of the Health Finance and Insurance Unit of the Indonesia MOH (December 18, 2018). One outcome was that regulations were rewritten to be more user-friendly. Findings about weak incentive effect of capitation payments contributed to the redesign of the capitation payment to condition a portion on facility performance.

## Cycle 2

In 2017 the calculation for facility-level capitation payments was changed to a per capita basis as well as performance on 3 indicators: contact rate, referrals, and chronic disease management. Health promotion activities, including home visits, outreach services, exercise programs, and chronic disease care, increased due to the availability of funds to cover operational costs, including medicines and supplies, and potentially because of these new performance-based capitation payment rules. These changes contributed to improved ability to deliver priority services at the primary care level, but health workers remained unsatisfied. Our research sought to uncover the reasons why.

Findings from Cycle 2 showed that health workers did not find that additional income from capitation adequately compensated for the increased workload under JKN. The health workers perceived the allocation of payments to individuals to be unfair. Instead of health worker contribution to service delivery or population health, individual worker payments were primarily determined by immutable characteristics such as education attained, tenure, and position. Only some districts incorporated a small payment component that was determined by behaviors (e.g., attendance) and performance indicators (e.g., numbers of community visits and medical procedures).

The health workers indicated a preference for an incentive system based on service delivery accomplishments, such as measures of health promotion, preventive service delivery, and meeting quality standards. They also recommended adjusting

payment for infectious disease risk and service area size. In addition to financial remuneration, health workers would like to be rewarded with opportunities for training and advancement. Finally, they recommended penalties for poor performance such as demotions, allowance reductions, and dismissal.

## LESSONS

It is not possible to comprehend how changes in systems, processes, payment rules, and roles and responsibilities are functioning without asking those who are affected. To answer many of those questions, a mixed-method approach is needed, which requires researchers to have both qualitative and quantitative skills. IR has the potential to be a powerful tool for understanding complex reform processes, but conducting IR so that the questions are relevant, the process of finding answers is cost-effective, and information is shared with policy makers so that timely action can be taken requires high-level skills.

External donors can support countries to build capacity to conduct IR and to use research findings to inform refinements. This support has potential to make a lasting impact that exceeds the tenure of any time-limited project. What follows are some lessons learned, challenges confronted, and trade-offs to consider.

### Communicating Controversial Findings

Because IR aims to understand what is and is not working smoothly, findings have the potential to be controversial. It was more effective to initially communicate IR findings through a series of one-on-one meetings than in group meetings with national and district stakeholders. Without advance preparation, some stakeholders were defensive in larger meetings. One-on-one meetings are time-consuming but we found them to be a necessary part of the process of ensuring that IR findings contribute to strengthening the health system.

**Because implementation research findings can be controversial, one-on-one meetings were an effective first step to precede group meetings.**

### Institutional Arrangements for Implementation Research

The institutional arrangements to conduct IR can impact its effectiveness. In Indonesia, an independent third-party university was selected to facilitate the IR process and to conduct the field research. The MOH was the key government stakeholder and convener of multi-stakeholder meetings on IR findings. However, both CHPM and the MOH reflected that it may be more effective for a government research unit to conduct IR



**Implementation research is in a nascent stage in Indonesia, but policy makers, managers, and researchers recognize its value.**

directly or for the government to manage contracts with external entities to conduct this research, according to discussions with Dr. Laksono of CHPM (December 13, 2018) and with Dr. Doni of the Health Finance and Insurance Unit of the Indonesia MOH (December 18, 2018). One reason is that the MOH may be more receptive to findings that elements of the reforms are not working if the findings come from an internal unit. On the other hand, research conducted by a respected university may have more credibility than research conducted by a government team. The internal MOH research unit requested training on how to conduct IR from CHPM. In addition, a regulation was passed in 2018 that specifies that the internal MOH research group must be involved in all research in the health sector to ensure that research is policy relevant.

Deciding which key government stakeholders to include is not always obvious and selection may be influenced by external donor history. When support for IR began in Indonesia, USAID had a well-developed relationship with the MOH and a weaker relationship with BPJS. The MOH expressed interest in being a stakeholder and because they understood how to work with USAID external support, the MOH was selected as the key government partner. However, the role of BPJS as the strategic purchaser of health services solidified during the IR period, so there may have been a missed opportunity to focus the IR on whether key BPJS processes were functioning as intended.

### Capacity to Conduct Qualitative Research

Capacity to conduct qualitative research is critical for conducting IR that aims to understand how and why reforms may or may not be working at the service delivery level. Managing qualitative research in multiple districts with interviews and focus groups with multiple stakeholders generates volumes of transcripts that need to be coded and analyzed. Building capacity to conduct the qualitative research that is foundational to IR is a priority for low- and middle-income countries that aim to assess and refine the roll out of their UHC reforms.

### Time to Institutionalize Implementation Research

Institutionalizing IR takes time. It takes time to identify the right stakeholders and to develop relationships with them and it takes time to prioritize questions and to implement fieldwork.

This groundwork has begun in Indonesia and stakeholders are now discussing issues that were not the focus of conversations before the IR. A process of communication has been stimulated that cuts across national institutions and between national and district levels. The MOH has expressed interest in steering IR and has passed regulations requiring that research in the health sector must be policy relevant. While IR is in a nascent stage in Indonesia, policy makers, managers, and researchers recognize its value.

## CONCLUSION

Any country that introduces reforms to a complex health system needs to monitor whether processes are being understood and implemented as intended and whether the policies and systems are working as expected. In essence, this is sound management. It is “taking the temperature” of processes and systems so that there is regular information about aspects that need tweaking or changing. Leaders and managers operate with the hope that policies are working as intended, but IR supplies the information required to confirm that those hopes are realities.

**Acknowledgments:** Deep appreciation to Shita Dewi, Dr. Laksono and the CHPM team for their hard work, Kelley Laird of Abt Associates for her support, Laurel Hatt of Results for Development for guidance in the initial stages of this work, to Zohra Balsara and Edhie Rahmat of the Indonesia USAID Mission for their leadership and support, and Joseph Naimoli and Kristina Yarrow for their vision of the potential value of IR and their encouragement.

**Funding:** USAID.

**Disclaimer:** The authors' views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development (USAID) or the United States Government.

**Competing Interests:** None declared.

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**Peer Reviewed**

**Received:** August 30, 2018; **Accepted:** November 1, 2018; **First Published Online:** December 13, 2018

**Cite this article as:** Eichler R, Gigli S, LeRoy L. Implementation research to strengthen health care financing reforms toward universal health coverage in Indonesia: a mixed-methods approach to real-world monitoring. *Glob Health Sci Pract*. 2018;6(4):747-753. <https://doi.org/10.9745/GHSP-D-18-00328>

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## TECHNICAL NOTE

# Revisiting the Facility-Based Delivery Rate Formula in the Philippines for Better Local Health Governance and Services

Fude Takayoshi,<sup>a</sup> Sakiko Yamaguchi,<sup>b</sup> Amelita M. Pangilinan,<sup>c</sup> Makoto Tobe,<sup>d</sup> Shogo Kanamori<sup>e</sup>

When calculating local facility-based delivery rates, the standard measure based on place of birth excludes residents' facility births outside the municipality. In contrast, counting the facility births of all residents—regardless of whether they take place within or outside their home municipality—provides a more accurate population- or residence-based measure of use of services for that catchment area. This residence-based measure offers local governments a better understanding of coverage gaps by taking into account place of residence rather than place of birth.

Data on health care-seeking behaviors are instrumental for identifying gaps in access to health services, an issue particularly important in the maternal and child health field as reflected in the United Nation's Sustainable Development Goals. However, lack of basic data, including data on health care services coverage at the community level, is an identified barrier to effective policymaking.<sup>1</sup>

The facility-based delivery (FBD) rate is an essential indicator because improving facility-based delivery with skilled birth attendants is an important strategy for lowering maternal mortality.<sup>2</sup> Globally, the formula to compute the FBD rate from routine health information data is a simple one: the number of FBDs in a population divided by the total number of deliveries. However, at the community level, this formula might need to be redefined and clarified in terms of who should be counted in the numerator and denominator.

In the Philippines, the country's public health information system, the Field Health Services Information System, mandates the FBD rate to be occurrence-based, meaning that only deliveries that occur in a given place are counted:

Occurrence-based FBD rate =

$$\frac{\text{Number of FBD cases that occurred in the municipality}}{\text{Number of deliveries that occurred in the municipality}}$$

As a basis for reporting, Barangay Health Workers (community health volunteers who provide health promotion and education) are tasked to track all pregnancy cases in their designated *barangays* (smallest administrative unit) through routine household visits, and nurses and midwives are in charge of filling out a register with individual information and place of delivery based on information obtained from the Barangay Health Workers and facility data. This register routinely captures 3 different scenarios of both facility- and home-based deliveries.

- A. Residents' deliveries within municipality
- B. Residents' deliveries outside municipality
- C. Non-residents' deliveries within municipality

From this paper register, health workers report to the Field Health Services Information System by manually adding the numbers in Scenarios (A) and (C) for the denominator of the FBD rate. Likewise, FBD cases are extracted from this denominator and used as the numerator. Scenario (B), residents' deliveries outside the municipality, are not counted in either the denominator or the numerator.

In the Philippines' decentralized health system, local government units, such as provinces, municipalities, and *barangays*, have significant local autonomy and responsibility for managing and providing health care services.<sup>3</sup> A problem arises when the occurrence-based FBD rate is officially employed as a proxy of the health care-seeking behaviors of pregnant women living in a municipality or *barangay*.

Take the Cordillera Administrative Region as a case in point. This ethnically diverse and mountainous region in the north-central part of Luzon has a population of 1,722,006 (as of 2015) and comprises 6 provinces and 1 chartered city.<sup>4</sup> Besides cultural factors, geographic

<sup>a</sup>Koei Research & Consulting Inc., Tokyo, Japan.

<sup>b</sup>Department of Psychiatry, McGill University, Montreal, Quebec, Canada.

<sup>c</sup>Cordillera Administrative Regional Office, Department of Health, Baguio City, Benguet, Philippines.

<sup>d</sup>Japan International Cooperation Agency, Tokyo, Japan, and Research Center for Health Policy and Economics, Hitotsubashi Institute for Advanced Study, Tokyo, Japan.

<sup>e</sup>Department of Community and Global Health, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan, and Department of Health, Manila, Philippines. Correspondence to Fude Takayoshi (fude.takayoshi@gmail.com).

and economic barriers remain challenging problems to resolving unequal distribution of maternal and child health care, particularly access to health care facilities.<sup>5,6</sup>

In this area, pregnant women often cross the municipal boundaries to access health care services. Because of the mobility associated with their delivery practices, many health workers and mayors empirically know that the occurrence-based FBD rate is not suitable for local health planning. In response, a maternal and child health project, the Project for Cordillera-wide Strengthening of the Local Health System for Effective and Efficient Delivery of Maternal and Child Health Services (MCH-CAR) (2012–2017) supported by the Japan International Cooperation Agency, redefined the FBD rate formula from occurrence-based to residence-based by including in the numerator and the denominator all the deliveries of a municipality's residents, regardless of whether they occurred within or outside the home municipality:

$$\text{Residence-based FBD rate} = \frac{\text{Number of live birth FBD cases among residents of the municipality}}{\text{Number of live births among residents of the municipality}}$$

Note that the 2012 version of the Field Health Services Information System guideline indicates that both live births and stillbirths should be counted when computing the (occurrence-based) FBD rate.<sup>4</sup> However, it is customary for field staff in practice to count only the live births. Therefore, to be consistent and comparative, the project team in collaboration with government counterparts counted only live births to compute both occurrence- and residence-based FBD rates.

Figure 1 illustrates the potential difference obtained with the 2 formulas when considering 10 residents giving birth in 1 year, with 2 of the 10 delivering in a facility within the municipality, 6 delivering in a facility outside the municipality, and 2 delivering at home within the municipality. With the occurrence-based calculation, in which only the deliveries occurring within the municipality are counted, one obtains a 50% FBD rate (2 facility deliveries within the municipality/4 total deliveries). With the residence-based calculation, in which all residents' deliveries are counted, even those occurring outside the municipality, one obtains an 80% FBD rate (8 facility deliveries within and outside the municipality/10 total deliveries). The focus of attention and investment for a local



Typical mountainous scenery of Cordillera Administrative Region, Mankayan Municipality, Benguet Province, Philippines. ©2013/Amando Francisco Jr., MCH-CAR Project.

government unit to address a 50% FBD rate is quite different than if the FBD rate were 80%.

How feasible is it to apply this new equation? There is one favorable factor in the Cordillera Administrative Region: rural communities have close-knit social networks and are supportive of Barangay Health Workers doing rigorous pregnancy tracking. However, some health workers initially had difficulty distinguishing clearly between the 2 different definitions, and retraining them was required. To compute the residence-based FBD rate, they needed to pay closer attention to Scenario (B) while excluding Scenario (C).

Figure 2 shows the discrepancy between the 2 definitions in 13 municipalities for 2012 in 1 of the 6 provinces of the Cordillera Administrative Region, Benguet. The occurrence-based FBD rates did not provide a good population-based measure of service coverage in 7 of the municipalities (Itogon, Tuba, Sablan, Tublay, Bakun, Kabayan, and Kibungan). By inference, those low FBD rates could imply to policy makers—particularly those who do not understand how the occurrence-based FBD rate is calculated—that 62% (Tuba) to 100% (Sablan) of the deliveries were home-based, because the rates disregard the deliveries outside the residents' home municipality. Women in these 7 municipalities routinely travel to deliver in neighboring municipalities where hospitals are located.

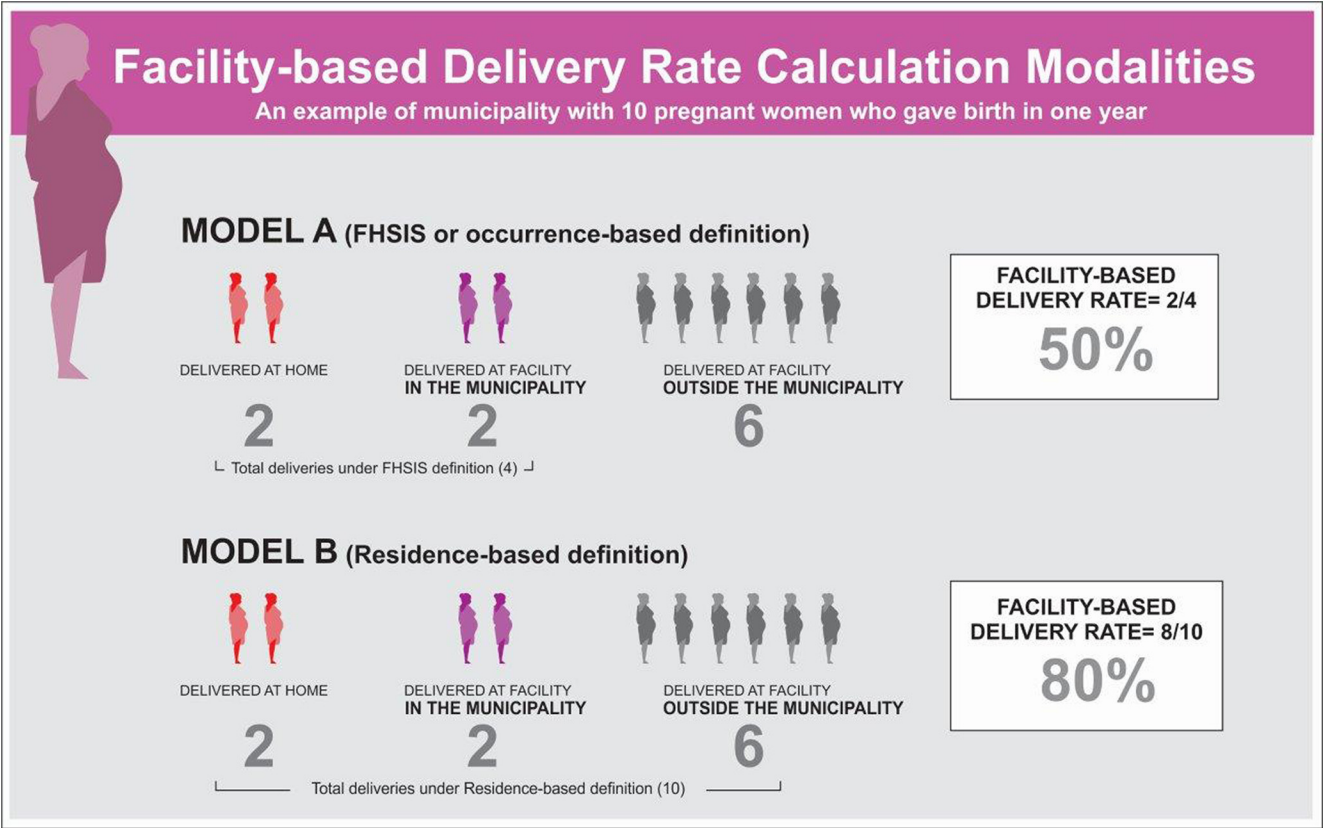
The extreme case is Sablan, which is adjacent to the chartered city. Because there were no birthing facilities in Sablan in 2012, the occurrence-based FBD rate was necessarily 0%. However, when factoring in the 93 pregnant women living

**The occurrence-based FBD rate is not suitable for local health planning.**

**The residence-based FBD rate takes into account all deliveries of a municipality's residents, regardless of whether they occurred within or outside the home municipality.**

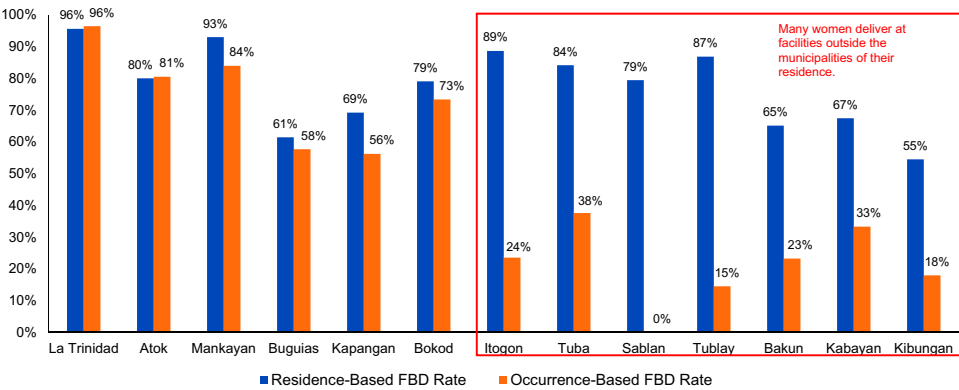


**FIGURE 1.** Comparison of Occurrence-Based With Residence-Based Computations of the Facility-Based Delivery Rate



Abbreviation: FHSIS, Field Health Services Information System.

**FIGURE 2.** Facility-Based Delivery Rates of 13 Municipalities in Benguet Province, Philippines, 2012, by Computational Method



Source: MCH-CAR project<sup>7</sup> and Department of Health [Philippines].<sup>8</sup>

in Sablan who delivered at facilities outside their home municipality and the 24 women who delivered at home, the residence-based FBD rate becomes 79%.

These results highlight that in this context low occurrence-based FBD rates in a municipality do not necessarily reflect low performance, or a high number of home-based births. Rather, the low FBD rates might point to the availability of hospitals and birthing centers outside the municipality. While building birthing facilities in all municipalities might seem an ideal health care solution, that is not necessarily the most effective way to distribute the limited health care resources of local government units.

Today, the Department of Health in the Cordillera Administrative Region continues to use residence-based data for its annual work and financial plan. With the redefined rate, local government units are able to capture their residents' delivery practices more precisely and tailor health policies to fit local needs more accurately. Further, using the redefined rate helps local officials identify geographical areas at relatively high risk by *barangay*. Understanding pregnant women's delivery practices and their mobility is crucial for effective health policymaking. This project experience highlights that revisiting nationally employed definitions of maternal and child health indicators may contribute to better local health governance and health care services.

**Funding:** None.

**Competing Interests:** None declared.

#### Peer Reviewed

**Received:** July 13, 2018; **Accepted:** November 20, 2018

**Cite this article as:** Takayoshi F, Yamaguchi S, Pangilinan AM, Tobe M, Kanamori S. Revisiting the facility-based delivery rate formula in the Philippines for better local health governance and services. *Glob Health Sci Pract*. 2018;6(4):754-757. <https://doi.org/10.9745/GHSP-D-18-00256>

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## SHORT REPORT

# Novel Indoor Residual Spray Insecticide With Extended Mortality Effect: A Case of SumiShield 50WG Against Wild Resistant Populations of *Anopheles arabiensis* in Northern Tanzania

Eliningaya Kweka,<sup>ab</sup> Aneth Mahande,<sup>c</sup> Johnson Ouma,<sup>d</sup> Wycliffe Karanja,<sup>d</sup> Shandala Msangi,<sup>b</sup> Violet Temba,<sup>b</sup> Lucille Lyaruu,<sup>b</sup> Yousif Himeidan<sup>d</sup>

The new SumiShield 50WG insecticide, which possibly has longer duration of effectiveness than other indoor residual spray (IRS) formulations, has potential as an alternative IRS product for malaria vector control, particularly where resistance to other formulations has developed.

## ABSTRACT

**Background:** Resistance of malaria vectors to different classes of insecticides has been reported in malaria-endemic areas. Identifying new indoor residual spray (IRS) compounds that are effective against resistant vector populations is a high priority in managing insecticide resistance.

**Method:** A biological efficacy trial was conducted in the field from August 2016 to February 2017 to determine the efficacy of SumiShield 50WG, a new insecticide class, against wild *Anopheles arabiensis*. Indoor surfaces of 20 houses in Mabogini ward in the rural district of Moshi in northern Tanzania were sprayed with SumiShield 50WG. Bio-efficacy monitoring was conducted monthly for 6 months after the spray application. In addition, susceptibility tests were conducted by exposing mosquitoes to papers treated with permethrin 0.75%, pirimiphos-methyl 0.25%, and clothianidin 2% (SumiShield 50WG). Representatives from each household included in the study were surveyed about possible side effects or problems faced since the spray. Regression probit analysis was used to calculate knock-down times while the chi-square test was used to compare the mortality effect for mosquitoes.

**Results:** The SumiShield 50WG insecticide maintained optimal efficacy in the field setting for the duration of the 6-month study period, with 100% mortality of mosquitoes by 144 to 168 hours post-exposure to treated surfaces. Susceptibility tests showed some variation in tolerance to the tested insecticide-treated papers, particularly between SumiShield 50WG and pirimiphos-methyl. The knock-down times for 50% and 95% of the mosquitoes when exposed to SumiShield 50WG-treated test paper were 45.81 minutes and 83.85 minutes, respectively, and 67.77 minutes and 105.81 minutes, respectively, for the pirimiphos-methyl-treated papers. There were no short-term adverse side effects reported by households sprayed with SumiShield 50WG.

**Conclusion:** The findings of this study suggest that SumiShield 50WG is a viable IRS insecticide for malaria vector control in Tanzania, especially in areas where pyrethroid resistance is a concern.

## INTRODUCTION

Despite the general decline in malaria transmission, malaria remains a major cause of morbidity and mortality in many tropical countries including Tanzania.<sup>1,2</sup> Malaria vector control campaigns have

been advocating the use of indoor residual spray (IRS) and long-lasting insecticidal bed nets (LLINs) to reduce malaria transmission.<sup>3–5</sup> The scale-up of LLINs in Tanzania has been successful, with coverage of 75% and up to 100% in some parts of the country, mostly in the Lake Zone regions (Kagera, Mara, Mwanza, and Shinyanga).<sup>6–8</sup> However, the IRS program in Tanzania has faced many challenges, as is the case in other countries around the world.

IRS programs have been implemented worldwide since the 1950s and have been shown to decrease vector density, leading to a decline in malaria transmission in various settings.<sup>9,10</sup> The different wall types in malaria-

<sup>a</sup>Department of Medical Parasitology and Entomology, School of Medicine, Catholic University of Health and Allied Sciences, Mwanza, Tanzania.

<sup>b</sup>Mosquito Section, Division of Livestock and Human Health Disease Vector Control, Tropical Pesticides Research Institute, Arusha, Tanzania.

<sup>c</sup>Mabogini field station, Division of Livestock and Human Health Disease Vector Control, Tropical Pesticides Research Institute, Moshi, Tanzania.

<sup>d</sup>Africa Technical Research Centre, Vector Health International Ltd., Arusha, Tanzania.

Correspondence to Eliningaya J. Kweka (eliningaya.kweka@tpri.go.tz).

endemic areas, however, have hindered the performance and effectiveness of sprayed insecticides.<sup>11,12</sup> Another challenge is that malaria vectors have developed, and continue to develop, resistance against most classes of insecticides sprayed. Studies conducted in several malaria-endemic countries including Tanzania show that resistance has developed against organophosphates,<sup>13,14</sup> pyrethroids,<sup>13,15,16</sup> and carbamates.<sup>13,17</sup> To sustain the gains achieved in malaria control and ensure continued success of IRS, programs must identify compounds from new classes of insecticides with long-lasting efficacy and ensure they are used judiciously and according to the Global Plan for Insecticide Resistance Management (GPIRM) that was coordinated by the World Health Organization's (WHO's) Global Malaria Programme.<sup>18</sup>

In searching for an innovative insecticide replacement, a new IRS compound called SumiShield 50WG, containing the neonicotinoid insecticide clothianidin, has been developed. This formulation, manufactured by Sumitomo Chemical Co. Ltd, Tokyo, Japan, is expected to retain its bio-efficacy for much longer than many other existing IRS products. This study evaluated the bio-efficacy of SumiShield 50WG against wild resistant populations of *Anopheles arabiensis* in northern Tanzania.

## METHODS

### Study Setting

This study was conducted in Mabogini ward in the rural district of Moshi, which is located on the southern foothills of Mount Kilimanjaro in northern Tanzania.<sup>19</sup> In this area, rice is grown on more than 400 hectares of land under an irrigation scheme, making the area conducive for breeding malaria vectors. Malaria transmission occurs throughout the year albeit with low parasitemia<sup>20–23</sup> and a low entomological inoculation rate.<sup>24</sup> The predominant mosquito species in the area are *An. arabiensis* and *An. funestus*.<sup>4,16,25–27</sup> For a detailed description and map of the area, refer to Lowassa and colleagues (2012).<sup>26</sup>

Twenty houses with different types of wall surfaces (i.e., walls made of brick, burnt brick, or mud) sprayed with SumiShield 50WG were selected for 6 months of follow-up. The spray application was conducted over a 4-day period, and the houses were at least 10 meters apart. This study took place from August 2016 to February 2017.

### Calibration of the Sprayers

The spray team used in total 6 8-liter Hudson X-Pert sprayers. The nozzles of the sprayers were checked first per guidelines from the WHO Pesticide Evaluation Scheme (WHOPES).<sup>28</sup> The flow rate of the constant flow valve used for the 6 sprayers ranged between 760 to 790 ml/minute at a tank pressure of 55 psi. This range was within the WHOPES-recommended flow rate of 681 to 832 ml/minute. The hardness of the water used in the field ranged from 0.0 to >4.0 mg/m<sup>3</sup>, and the pH from 5.5 to 7.0 mg/m<sup>3</sup>, as measured at different points over the 4-day spray period. Any water used for mixing of the products or for washing the sprayer was filtered using a double layer of new polyester cloth and a water sieve.

### Indoor Residual Spraying Procedures

Indoor residual spraying was conducted following WHO standard procedures described elsewhere.<sup>29</sup> Briefly, SumiShield 50WG was applied according to label claims with a targeted dosage of 300 mg active ingredient per m<sup>2</sup>. Household items such as furniture and other utensils were gathered into the middle of rooms to expose the wall surfaces for spraying. All room walls in each house were uniformly sprayed. The time spent to spray each house depended on the number and size of the rooms as well as the house content, but in general the spray operators did not take more than 30 minutes per house.

### Assessment of Spray Quality and Uniformity

Two methods were used to assess the spray accuracy: (1) calculating the actual volume sprayed by weighing the sprayer before and after spraying and determining the area sprayed, and (2) analyzing the active ingredient content sprayed on filter paper attached to the surface sprayed as described by WHO.<sup>29</sup>

For the first method, the empty sprayers were weighed and the weight recorded. Water and the insecticide formulation were then added and weighed before and after spraying each house. The volume sprayed was determined by subtracting the weight of sprayer and contents after spraying from the weight of the depressurized sprayer and contents before spraying. The surface sprayed was measured for the selected houses. The sprayed dose in mg per m<sup>2</sup> was calculated as  $[sprayed\ volume \times mg\ active\ ingredient\ per\ liter] / surface\ area\ sprayed$ .

For the second method, 3 points were selected in 1 room in each sprayed house and labeled with

**To sustain the gains achieved in malaria control, programs must identify compounds from new classes of insecticides and ensure they are used judiciously.**

**This study evaluated the bio-efficacy of SumiShield 50WG, a new IRS compound, against wild resistant populations of *Anopheles arabiensis* in northern Tanzania.**



**Standard WHO cone bioassays were conducted on the walls of treated houses at monthly intervals for 6 months after the spray application to assess residual efficacy.**

masking tape as low (2 feet from the floor), middle (4 feet from the floor), and high (6 feet from the floor). Three filter papers were then fixed at these 3 points on a separator at a distance from the wall to prevent insecticide running down the wall and contaminating the paper. After spraying the surface, chemical analysis of the filter papers was carried out in 1 of 2 laboratories: Health & Crop Sciences Research Laboratory (HCRL), Takarazuka, Japan, or the Africa Technical Research Centre (ATRC), Arusha, Tanzania.

### Cone Bioassays

Standard WHO cone bioassays were conducted on the walls of treated houses at monthly intervals for 6 months after the spray application to assess residual efficacy. The F1 *An. arabiensis* offspring reared from field-collected larvae were used in cone bioassays. Ten 4-day-old unfed female mosquitoes per cone were exposed to the walls of houses sprayed with SumiShield 50WG. At monthly intervals, in each selected room a total of 40 mosquitoes were exposed for 30 minutes and collected in paper cups as 4 replicates of 10 mosquitoes per cup.<sup>29</sup> In all assays in the field, knocked-down and live mosquitoes were recorded at 60 minutes and mortality was observed at intervals of 24 hours post-exposure, up to 168 hours (7 days) post-exposure. After exposure, the female mosquitoes were placed in 150 ml cups (10 mosquitoes per cup), with sugar solution provided, and maintained in a climatic chamber for 24 hours at 27° Celsius  $\pm$  2° Celsius and 80%  $\pm$  10% relative humidity. Field experiments were conducted monthly to monitor the bio-efficacy of insecticides in each treated house included in the study.

### Susceptibility Tests

Susceptibility tests were conducted using the standard WHO protocol.<sup>30</sup> The treated papers used were permethrin 0.75% (treated with technical-grade permethrin with cis:trans ratio of 40:60, Lot: GBPRTG052E), pirimiphos-methyl 0.25% (treated with technical-grade pirimiphos-methyl, Lot: SZBC010XV), and clothianidin 2% (treated with SumiShield 50WG, Lot: 16940015056Y). Mosquito larvae were collected from lower Moshi rice-irrigated fields and reared in the insectary until they emerged and reached 4 days old. They were exposed to insecticide-treated papers for 1 hour, and mortality was recorded at 24 hours post-exposure and, for the clothianidin-treated papers only,

up to 168 hours post-exposure. A total of 600 mosquitoes were tested for each insecticide.

### Chemical Analysis of Filter Papers

The filter papers for residual dose monitoring were extracted in organic solvents and analyzed for clothianidin content by high performance liquid chromatography. The active ingredient contents were divided by the area of the sprayed filter paper to obtain the dose per m<sup>2</sup>. The chemical content in the filter papers was analyzed by either HCRL in Japan or ATRC in Tanzania. The laboratories used the same protocol that had been validated using filter paper samples treated with the target dose at HCRL.

### Side Effects

The study team surveyed head of households from the 20 treated houses to ask about all possible side effects or problems faced since the day the house was sprayed. All mentioned cases, if any, were recorded.

### Data Analysis

Data were analyzed using PASW (Predictive Analytics Software) Statistics version 18 (SPSS Inc., Chicago, IL). Descriptive tests were deployed for data analysis to obtain the confidence intervals and mean of difference. Microsoft Excel 2016 spreadsheets were used to calculate percentage mortalities for field mosquitoes. Regression probit analysis was used to calculate the KDT<sub>50</sub> (knock-down time for 50% of the mosquitoes) and KDT<sub>95</sub> (knock-down time for 95% of the mosquitoes) while the chi-square test was used to compare the mortality effect for mosquitoes 24 hours post-exposure to the 3 insecticides in the susceptibility tests.

## RESULTS

### Spray Quality and Uniformity

Analysis of the chemical content of the filter papers for the sprayed houses showed that the correct dose was sprayed, with the average being 363.4 mg/m<sup>2</sup> (Table 1). The acceptable range is 300 mg/m<sup>2</sup>  $\pm$  25%. The residual doses obtained by chemical analysis and by volume measurement were generally similar from one house to another (Figure 1).

### Susceptibility Tests

Susceptibility tests for the wild population of *An. arabiensis* showed some variation in tolerance to the tested insecticide-treated papers, particu-

TABLE 1. Active Ingredient of Clothianidin (SumiShield 50WG) Sprayed on Filter Papers<sup>a</sup>

Formulation	Clothianidin Content (mg/m <sup>2</sup> )					% RSD
	Upper	Middle	Lower	Mean	SD	
SumiShield 50WG	334.5	384.9	368.7	363.4	165.4	45.5

Abbreviations: RSD, relative standard deviation; SD, standard deviation.  
<sup>a</sup> Results were pooled from tests of 12 houses performed by the Health & Crop Sciences Research Laboratory in Takarazuka, Japan, and 16 houses performed by the African Technical Research Centre in Arusha, Tanzania.

larly between SumiShield 50WG and pirimiphos-methyl. Specifically, the knock-down times for 50% and 95% of the mosquitoes when exposed to the SumiShield 50 WG-treated test paper were 45.81 minutes and 83.85 minutes, respectively (Table 2). The permethrin-treated papers showed similar results. However, the pirimiphos-methyl-treated papers had higher knock-down times: 67.77 minutes for 50% of the mosquitoes and 105.81 minutes for 95% of the mosquitoes. The 24-hour mortality was not statistically significant among the 3 insecticides tested ( $X^2=0.0942$ ;  $P=.95$ ) (Figure 2). The susceptibility of wild population of *An. arabiensis* to permethrin and pirimiphos-methyl was monitored for 24 hours only, but for

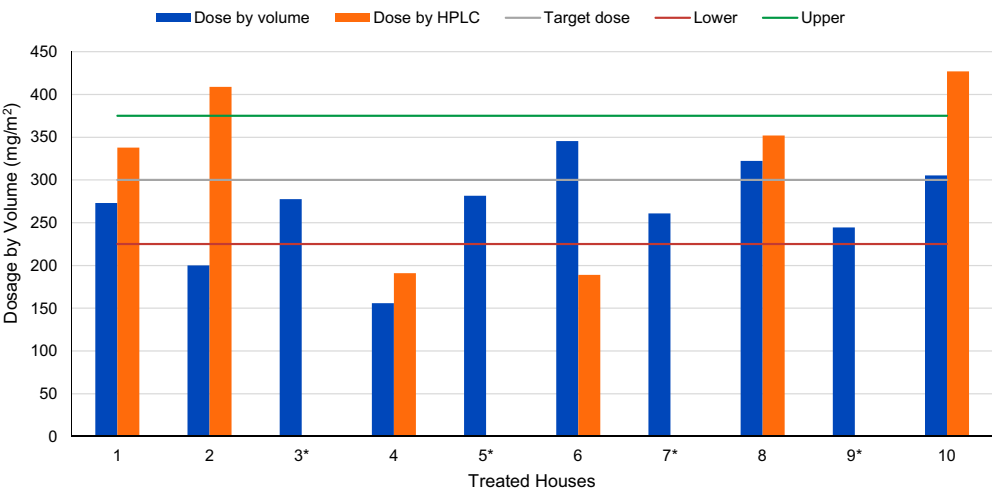
clothianidin mortality was monitored for 168 hours as it has additional delayed mortality effect beyond the first 24 hours exposure. At each 24-hour period from 48 hours post-exposure to 168 hours post-exposure, 100% of the mosquitoes exposed to SumiShield 50WG were fully susceptible to the insecticide (Figure 2).

100% of mosquitoes exposed to SumiShield were susceptible within 168 hours of exposure.

Residual Efficacy of SumiShield 50WG From Bioassays

The residual efficacy of SumiShield 50WG was observed to be constant for 6 months, with 100% mortality of mosquitoes when tested 168 hours after exposure to treated surfaces including mud and concrete (Figure 3).

FIGURE 1. Assessment of Spray Accuracy by Volume Measurement and Chemical Analysis, Moshi, Tanzania



Abbreviation: HPLC, high performance liquid chromatography.  
Due to constraints with performing analysis of the collected specimens, assessment of spray quality was performed on only 10 of the 20 treated houses.  
\* HPLC data are missing for 4 of the treated houses.

TABLE 2. Knock-Down Times (in minutes) for the Insecticide-Exposed Mosquitoes, by Insecticide Type

Insecticide	KDT <sub>50</sub> (95% CI)	KDT <sub>95</sub> (95% CI)
SumiShield 50WG	45.81 (44.34, 47.35)	83.85 (80.81, 87.24)
Permethrin	47.73 (45.79, 49.75)	85.77 (82.45, 89.45)
Pirimiphos-methyl	67.77 (64.84, 70.88)	105.81 (101.46, 110.61)

Abbreviations: CI, confidence interval; KDT, knock-down time.  
Note: Mosquitoes were exposed to each insecticide for 1 hour.

Side Effects and Community Acceptability of SumiShield 50WG

In all houses sprayed, none of the household members was recorded to have had any adverse effects (e.g., sneezing or itching) related to SumiShield 50WG spray application up to 6 months later. All community members whose houses were involved were interviewed (n=20), and all found the SumiShield 50WG trial application acceptable and reported being willing to participate in the next round of spraying.

DISCUSSION

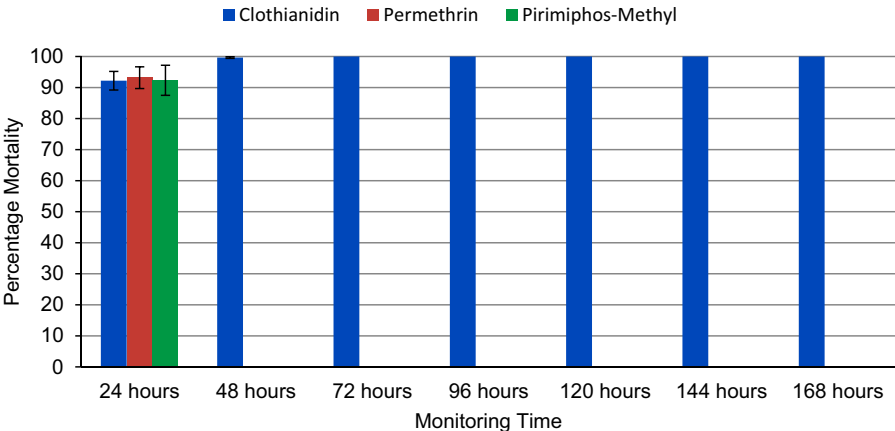
In this study, the new SumiShield 50WG IRS compound was found to be effective against field populations of *An. arabiensis*. While initial mortality of exposed mosquitoes was low, we observed and documented an increasing kill effect over time, reaching 100% mortality at 144 to 168 hours post-exposure. This new

compound holds great promise in vector control as it has higher efficacy than other IRS formulations.<sup>31–34</sup> In addition, the residual efficacy of 6 months shown for SumiShield 50WG is higher than reported for other compounds in previous studies in malaria-endemic regions.<sup>35–37</sup> The bio-efficacy observed against the wild-resistant population of *An. arabiensis* is similar to other studies using SumiShield 50WG conducted in Africa and Asia at the community level.<sup>32–34</sup>

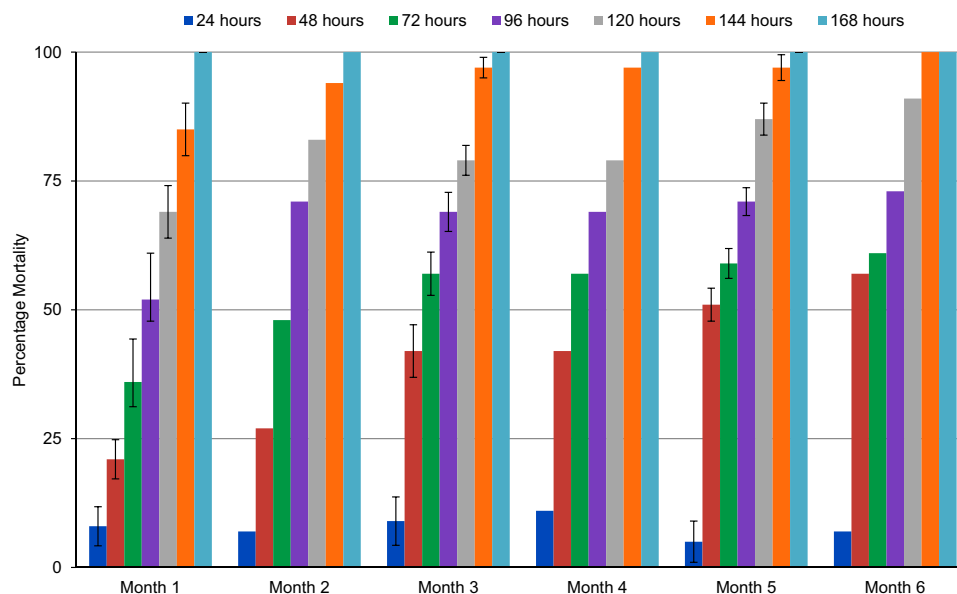
The efficacy of SumiShield 50WG was shown to be above the WHO-recommended mortality cut-off point of 80% for the entire 6-month trial period, and no decline in mortality was observed throughout this period against the wild-resistant population of *An. arabiensis*. These findings demonstrate a better efficacy of SumiShield 50WG than that previously observed in studies with pyrethroids, organophosphates, carbamates, and organophosphates.<sup>5,13,16,38–40</sup> The efficacy of SumiShield 50WG against wild populations

SumiShield 50WG holds great promise in vector control as it has higher efficacy than other IRS formulations, including long-lasting residual efficacy.

FIGURE 2. Susceptibility of *Anopheles arabiensis* to Clothianidin (SumiShield 50WG), Permethrin, and Pirimiphos-Methyl by Post-Exposure Time<sup>a</sup>



<sup>a</sup> Only clothianidin-treated papers were monitored beyond 24 hours because it has extended mortality effects.

**FIGURE 3.** Residual Efficacy of SumiShield 50WG: Percentage Mortality of Mosquitoes After Exposure for 30 Minutes in Cone Bioassays on Treated Surfaces

of *An. arabiensis* is attributed to it being non-repellent—unlike other insecticides such as pyrethroids—which increases the possibility of the vector getting the peak lethal dose of the insecticide from the treated surfaces. Similar responses have been shown by other studies evaluating SumiShield 50WG.<sup>32–34</sup>

The bio-efficacy and residual effect of SumiShield 50WG reported from this field study in Tanzania has shown that the product retains maximum mortality efficacy for 6 months while other IRS compounds used in Tanzania were found to have sharply decreased mortality from the fourth to the sixth month.<sup>5,29,32–34,40</sup> Therefore, SumiShield 50WG provides the potential for longer residual protection as it consistently maintains its residual activity once applied. With complete coverage, SumiShield 50WG provides a lethal dose to mosquitoes that land on sprayed surfaces, with complete mortality effects observed at 144 to 168 hours after exposure.<sup>2,29,32–34</sup> SumiShield 50WG was very effective on both concrete and mud surfaces tested under the field conditions of the lower Moshi region of Tanzania.

## CONCLUSION

The findings of this study suggest that SumiShield 50WG is a suitable alternative IRS insecticide for

rotational use in malaria vector control in Tanzania, including all endemic areas, particularly where resistance to the existing organophosphorus IRS formulation has started to develop.

**Acknowledgments:** We wish to thank everyone who contributed to the accomplishment of this study, in particular the technical staff members of Tropical Pesticides Research Institute (TPRI) for their diligence and patience while undertaking the experiments. We thank Mr. Agustino Mtui for very effective coordination with community members during the field trials and the National Institute of Medical Research (NIMR) and Amani Research Centre for providing the spray pumps used in the study. We also appreciate the Africa Technical Research Centre and Vector Health International Ltd for their technical consultations during preparation and spraying time and Sumitomo Company, UK for providing SumiShield 50WG.

**Funding:** Sumitomo Chemical Co., Ltd.

**Competing Interests:** The authors declare receiving a grant from Sumitomo Chemical Co., Ltd., the company that manufactures SumiShield 50WG, to conduct this study, but the company had no role in the analysis or reporting of the study results nor with the conclusion made.

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#### Peer Reviewed

**Received:** June 7, 2018; **Accepted:** November 13, 2018

**Cite this article as:** Kweka E, Mahande A, Ouma J, et al. Novel indoor residual spray insecticide with extended mortality effect: a case of SumiShield 50WG against wild resistant populations of *Anopheles arabiensis* in northern Tanzania. *Glob Health Sci Pract*. 2018;6(4):758–765. <https://doi.org/10.9745/GHSP-D-18-00213>

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## CORRECTION

## Corrigendum: Daru et al., Decentralized, Community-Based Treatment for Drug-Resistant Tuberculosis: Bangladesh Program Experience

➔ See *corrected article*.

In the article, “Decentralized, community-based treatment for drug-resistant tuberculosis: Bangladesh program experience,” by Paul Daru et al. (Volume 6,

Number 3), the results section of the Abstract incorrectly cited the baseline percentages of patients who died and were lost to follow-up as 34%. These baseline figures have been corrected to 14%, per the data reported in the Table and main body of the article.

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**Cite this article as:** Corrigendum: Daru et al., Decentralized, community-based treatment for drug-resistant tuberculosis: Bangladesh program experience. *Glob Health Sci Pract.* 2018;6(4):766. <https://doi.org/10.9745/GHSP-D-18-00398>

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Knowledge for Health Project  
Johns Hopkins Bloomberg School of Public Health  
Center for Communication Programs  
111 Market Place, Suite 310  
Baltimore, MD 21202  
Phone: 410-659-6134  
Fax: 410-659-6266  
Email: [editorialoffice@ghspjournal.org](mailto:editorialoffice@ghspjournal.org)  
Web: [www.ghspjournal.org](http://www.ghspjournal.org)

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