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EDITORIALS

Behavior Change Fast and Slow: Changing Multiple Key Behaviors a Long-Term Proposition?

An intensive radio campaign in rural areas of Burkina Faso addressed multiple key behaviors to reduce child mortality, using a randomized cluster design. After 20 months, despite innovative approaches and high reported listenership, only modest reported change in behavior was found, mainly related to care seeking rather than habitual behavior such as hand washing. Various methodologic difficulties may have obscured a true greater impact. Analysis of the intervention after its full 35-month duration may reveal more impact, including on actual child mortality. Improving a number of key behaviors is essential to child survival efforts, and much of it may require strong and sustained efforts.

Glob Health Sci Pract. 2015;3(4):521-524
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Pre-eclampsia as Underlying Cause for Perinatal Deaths: Time for Action

Pre-eclampsia is a major underlying cause of late fetal and early neonatal death, accounting for somewhere between 1 in 10 and 1 in 4 perinatal deaths; it warrants greater efforts from the maternal-newborn community.

Stephen Hodgins
Glob Health Sci Pract. 2015;3(4):525-527
http://dx.doi.org/10.9745/GHSP-D-15-00350

Reduced Effectiveness of Contraceptive Implants for Women Taking the Antiretroviral Efavirenz (EFV): Still Good Enough and for How Long?

EFV clearly reduces effectiveness of implants. However, the reduced effectiveness still appears better compared with short-acting methods overall, at least for the initial period of implant use, and may be acceptable to many women. We need better data on effectiveness, especially over the long term and on whether ENG implants (Implanon) might be more effective than LNG implants (Jadelle). Communicating the risk of pregnancy to clients under these circumstances is very challenging. In the longer term, providing an alternative to EFV, such as dolutegravir, might solve this problem.

James D Shelton
Glob Health Sci Pract. 2015;3(4):528-531
http://dx.doi.org/10.9745/GHSP-D-15-00356

VIEWPOINTS

The Levonorgestrel Intrauterine System: Reasons to Expand Access to the Public Sector of Africa

The levonorgestrel intrauterine system has: (1) excellent effectiveness, (2) high satisfaction levels, (3) non-contraceptive benefits, and (4) potential to help reinvigorate interest in intrauterine contraception. The time is ripe for ministries and donor agencies to work together to make the product widely available across Africa.

David Hubacher
Glob Health Sci Pract. 2015;3(4):532-537
http://dx.doi.org/10.9745/GHSP-D-15-00178
The Levonorgestrel Intrauterine System: A Pragmatic View of an Excellent Contraceptive

The levonorgestrel intrauterine system (LNG IUS) has major advantages and could be a “game-changer” in improving contraceptive choice and use. It faces important challenges, however, including: (1) high commodity cost; (2) often-strong provider resistance to IUDs and difficult programmatic requirements; (3) need for demand creation, including assessing if markedly reduced menstrual bleeding is attractive to clients; and (4) the many requirements for introducing any new contraceptive. A good next step would be a well-focused and multifaceted “learning introduction” to assess the LNG IUS’s potential in several low-income countries, with rapid scale-up if results are promising.

Roy Jacobstein, James D Shelton
Glob Health Sci Pract. 2015;3(4):538-543
http://dx.doi.org/10.9745/GHSP-D-15-00330

ORIGINAL ARTICLES

The Saturation+ Approach to Behavior Change: Case Study of a Child Survival Radio Campaign in Burkina Faso

This randomized radio campaign focused on the 3 principles of the Saturation+ approach to behavior change: (1) saturation (high exposure to messages), (2) science (basing design on data and modeling), and (3) creative storytelling. Locally developed short spots and longer dramas targeted multiple child survival-related behaviors and were delivered entirely by local radio stations. Innovative partnerships with radio stations provided free airtime in return for training, equipment, and investment in solar power.

Joanna Murray, Pieter Remes, Rita Ilboudo, Mireille Belem, Souleymane Salouka, Will Snell, Cathryn Wood, Matthew Lavoie, Laurent Deboise, Roy Head
Glob Health Sci Pract. 2015;3(4):544-556
http://dx.doi.org/10.9745/GHSP-D-15-00049

Behavior Change After 20 Months of a Radio Campaign Addressing Key Lifesaving Family Behaviors for Child Survival: Midline Results From a Cluster Randomized Trial in Rural Burkina Faso

The radio campaign reached a high proportion of mothers, but the impact on self-reported behaviors at midline was mixed. Some reported episodic behaviors such as care seeking for diarrhea and obtaining treatment for fast/difficult breathing improved more in intervention than control areas, but there was little or no difference between areas in reported habitual behaviors, such as exclusive breastfeeding, complementary feeding, hand washing with soap, and use of bed nets.

Sophie Sarrassat, Nicolas Meda, Moctar Ouedraogo, Henri Some, Robert Bambara, Roy Head, Joanna Murray, Pieter Remes, Simon Cousens
Glob Health Sci Pract. 2015;3(4):557-576
http://dx.doi.org/10.9745/GHSP-D-15-00153
Barriers to Accessing Emergency Medical Services in Accra, Ghana: Development of a Survey Instrument and Initial Application in Ghana

Most respondents thought the number of ambulances insufficient and said they would rather use a taxi—perceived to be faster—in a medical emergency. Nevertheless, people generally had favorable attitudes of existing public ambulance services, although few knew of the toll-free emergency number and many thought it appropriate to use ambulances to transport corpses. Targeted public education, along with improved capacity of ambulance agencies to handle increased caseload, could improve use.

Nee-Kofi Mould-Millman, Sarah D Rominski, Joshua Bogus, Adit A Ginde, Ahmed N Zakariah, Christiana A Boatemaah, Arthur H Yancey, Samuel Kaba Akoriyea, Thomas B Campbell

Glob Health Sci Pract. 2015;3(4):577-590
http://dx.doi.org/10.9745/GHSP-D-15-00170

Monitoring and Evaluating the Transition of Large-Scale Programs in Global Health

Monitoring and evaluating large-scale global health program transitions can strengthen accountability, facilitate stakeholder engagement, and promote learning about the transition process and how best to manage it. We propose a conceptual framework with 4 main domains relevant to transitions—leadership, financing, programming, and service delivery—along with guiding questions and illustrative indicators to guide users through key aspects of monitoring and evaluating transition. We argue that monitoring and evaluating transitions can bring conceptual clarity to the transition process, provide a mechanism for accountability, facilitate engagement with local stakeholders, and inform the management of transition through learning.

James Bao, Daniela C Rodriguez, Ligia Paina, Sachiko Ozawa, Sara Bennett

Glob Health Sci Pract. 2015;3(4):591-605
http://dx.doi.org/10.9745/GHSP-D-15-00221

Sexual Satisfaction, Performance, and Partner Response Following Voluntary Medical Male Circumcision in Zambia: The Spear and Shield Project

Most men and their partners reported increased or the same levels of sexual pleasure and improved or no change in penile hygiene post-VMMMC. While half of men reported increased or no change in sexual functioning (orgasm, erections), one-third reported a decrease. Early resumption of sexual intercourse prior to complete healing was most closely associated with adverse outcomes, including decreased sexual functioning, satisfaction, and desire.

Robert Zulu, Deborah Jones, Ndashi Chitalu, Ryan Cook, Stephen Weiss

Glob Health Sci Pract. 2015;3(4):606-618
http://dx.doi.org/10.9745/GHSP-D-15-00163

Reducing Motor Vehicle-Related Injuries at an Arizona Indian Reservation: Ten Years of Application of Evidence-Based Strategies

Motor vehicle crashes decreased and seat belt use, including car seat use, increased in an American Indian and Alaska Native community through a multidisciplinary approach using strong partnerships among public health and law enforcement agencies; community outreach; mass media campaigns; and enactment and high-visibility enforcement of key laws, such as lowering the legal blood alcohol concentration limit for drivers and mandating use of occupant restraints.

Stephen R Piontkowski, Jon S Peabody, Christine Reede, José Velasco-Soltero, Gordon Tsatoke Jr, Timothy Shelhamer, Kenny R Hicks

Glob Health Sci Pract. 2015;3(4):619-629
http://dx.doi.org/10.9745/GHSP-D-15-00249
Family Planning Supply Environment in Kinshasa, DRC: Survey Findings and Their Value in Advancing Family Planning Programming

A series of facility-based surveys that mapped all sites providing family planning services and that assessed readiness to provide services, using mobile phones, was feasible in a low-resource setting, contributing to mobilization of partners and increased donor support. Between 2012 and 2013, readiness to provide services increased from 44% of sites to 63%. Three factors most associated with productivity: type of facility (clinics more than hospitals or health centers), more years in operation, and number of methods available.

Patrick Kayembe, Saleh Babazadeh, Nelly Dikamba, Pierre Akilimali, Julie Hernandez, Arsene Binanga, Jane T Bertrand
Glob Health Sci Pract. 2015;3(4):630-645
http://dx.doi.org/10.9745/GHSP-D-15-00298

FIELD ACTION REPORTS

Introduction of Mobile Health Tools to Support Ebola Surveillance and Contact Tracing in Guinea

An informatics system consisting of a mobile health application and business intelligence software was used for collecting and analyzing Ebola contact tracing data. This system offered potential to improve data access and quality to support evidence-based decision-making for the Ebola response in Guinea. Implementation challenges included software limitations, technical literacy of users, coordination among partners, government capacity for data utilization, and data privacy concerns.

Jilian A Sacks, Elizabeth Zehe, Cindil Redick, Alhoussaine Bah, Kai Cowger, Mamady Camara, Aboubacar Diallo, Abdel Nasser Iro Gigo, Ranu S Dhillon, Anne Liu
Glob Health Sci Pract. 2015;3(4):646-659
http://dx.doi.org/10.9745/GHSP-D-15-00207

Nurse Mentors to Advance Quality Improvement in Primary Health Centers: Lessons From a Pilot Program in Northern Karnataka, India

Trained nurse mentors catalyzed quality improvements in facility-based maternal and newborn care by: (1) encouraging use of self-assessment checklists and team-based problem solving, (2) introducing case sheets to ensure adherence to clinical guidelines, and (3) strengthening clinical skills through on-site demonstrations and bedside teaching. Inadequate leadership and staffing were challenges in some facilities. Some social norms, such as client resistance to referral and to staying 48 hours after delivery, also impact quality and mandate community mobilization efforts.

Elizabeth A Fischer, Krishnamurthy Jayana, Troy Cunningham, Maryann Washington, Prem Mony, Janet Bradley, Stephen Moses
Glob Health Sci Pract. 2015;3(4):660-675
http://dx.doi.org/10.9745/GHSP-D-15-00142
Behavior Change Fast and Slow: Changing Multiple Key Behaviors a Long-Term Proposition?

An intensive radio campaign in rural areas of Burkina Faso addressed multiple key behaviors to reduce child mortality, using a randomized cluster design. After 20 months, despite innovative approaches and high reported listenership, only modest reported change in behavior was found, mainly related to care seeking rather than habitual behavior such as hand washing. Various methodologic difficulties may have obscured a true greater impact. Analysis of the intervention after its full 35-month duration may reveal more impact, including on actual child mortality. Improving a number of key behaviors is essential to child survival efforts, and much of it may require strong and sustained efforts.

See related articles by Sarrassat and by Murray.

Some Behaviors Change Quickly

Human behavior is complex, often not completely rational, and profoundly influenced by social norms, structural constraints, opportunities, and habit. Yet we tend to approach behavior change interventions as discrete-in-time, “one-off” interventions. Of course some behaviors change remarkably readily. Think about the explosive adoption of cell phones globally. Or how use of plastic bags has plummeted in many jurisdictions in the United States (and in other countries), simply by adopting the “nudge” of levying a 5 cent charge on consumers.1

But Some Behaviors Change Slowly – the Case of Tobacco

Consider the reduction of smoking in the United States. It began with evidence emerging in the 1950s that led to a landmark US Surgeon General’s report in 1964.2 Efforts combatted tobacco industry assertions to try to deny and obscure the health effects and later were bolstered by recognition of tobacco as an addiction. Over the decades, evidence of the wide and varied harmful effects continued to mount. And when the harmful effects of secondhand smoke became recognized, it catalyzed a tipping point of strong social norms against smoking, since smoking could no longer be seen as harming only the smoker. All the while, public health initiatives ebbed and flowed. Rates of smoking declined steadily, but only gradually. A more recent breakthrough was targeting smoking prevention among adolescents. Thus, a package of interventions aimed at youth in New York City in the early 2000s combining higher cigarette taxes, prohibition of vending machines and tobacco sales near schools, strict enforcement of prohibition of sales to minors, and a very active mass media campaign produced a major drop in reported youth smoking.3 We need to recognize each behavior is different. Some such as those related to addiction and biologic drives can be particularly resistant to change.

Addressing Multiple Behaviors – The Innovative Saturation + Intervention in Rural Burkina Faso

Our global health community’s highly ambitious goals to end preventable child and maternal mortality4 mandate addressing a wide range of behaviors, both those that can be described as habitual (such as hand washing and proper nutrition) and episodic (for example, care seeking). Given the wide range of behaviors with major health consequences,5 it seems only practical to try to address them in some collective fashion and on a sustained basis, rather than as separate efforts.

This issue of GHSP presents a paper on the implementation of such an ambitious approach using intensive mass media (radio) in Burkina Faso and its separate evaluation.6,7 The intervention was unusual in identifying rural communities served by virtually only one radio station, allowing the project to randomize 7 such areas to receive intensive mass media behavior change messaging and 7 not to receive it. The campaign messaging was directed to a range of behaviors modeled to have the most potential impact on child mortality based on extensive formative research. It was distinguished by innovative and practical implementation including free airtime from radio stations in return for training, equipment, and investment in solar power,
Ending preventable child and maternal deaths mandates addressing a wide range of behaviors.

Behavior change efforts through a combination of methods and channels have been found to be more effective in some settings than mass media-only interventions.

Some behaviors may be inherently resistant to behavior change efforts or may require more time to change.

as well as story-based messaging (using both short spots and longer dramas) based on local, rapidly developed content. Notably, it did not intervene to improve service delivery.

Lukewarm Findings So Far

The separate midline evaluation (at 20 months) found a substantial proportion of the population reporting having heard the spots and dramas. And compared with the control areas, there were greater improvements in some key reported behaviors including saving money during pregnancy and care seeking/treatment for some conditions (diarrhea and possible pneumonia, two of the three leading causes of child death in Burkina Faso). But notably there were not significant comparative improvements in a variety of other behaviors including habitual behaviors such as hand washing or exclusive breastfeeding. Some support for impact came from a positive association between reported behavior change and exposure to “spot” messages though not to the dramas. And some corroboration of an effect on care seeking came from a marked relative increase in service utilization occurring in government primary care sites. The authors posit that care seeking may be easier to influence than habitual behaviors in this context, perhaps partly because onset of illness is more pressing and demanding of action. Conversely, habitual behaviors may be more entrenched and have cultural and structural limitations. It would be helpful to have some complementary qualitative evidence from the target population to see if their impressions were consistent with this hypothesis.

Might the True Impact Actually Have Been Greater Than Measured?

Very possibly. The intervention area actually showed marked improvements in quite a number of behaviors, including both habitual and care seeking ones, but so too did the control areas (Table). So the evaluation properly compared the changes in both to see where improvements in the intervention area might be greater—a “difference-in-difference” analysis—which produced the more muted results. But actually the randomized allocation may not have ensured comparability of the intervention and control arms. There were only 7 clusters in each arm, and as it turned out there were important differences between the 2 arms. Intervention areas were poorer, had a higher proportion of Muslim population, and were farther from health facilities. While the evaluators adjusted for these measured factors in their analysis, such adjustment does not ensure that there is no remaining confounding, since unmeasured differences may remain. Moreover, it appears likely there could have been some “contamination” of messaging into the control areas; it was later learned that in one area there was overlap of radio coverage. Also, a fairly high proportion of those in the control areas reported they recognized spots when played to them (although it seems very possible this may reflect courtesy bias or confusion with other radio messages). Yet another source potentially attenuating a measured benefit were the numerous health-promoting activities carried out in both intervention and control areas by other health programs during this time, including a very successful malaria bed-net distribution program. Finally, the baseline and midline surveys were carried out in different seasons of the year. All of these factors contributed to “noise” that could possibly have washed out to some extent a true effect of the intervention.

What Else May Have Limited Impact?

First, this was a mass media-only intervention. Behavior change efforts through a combination of methods and channels have been found to be more effective in some settings. And those who are most disadvantaged and could benefit most from behavior change may have had the least exposure to the mass media. Second, addressing multiple behaviors may present some limitations. Clearly each behavior does not receive nearly as much emphasis as it would in an intensive single-behavior approach, and although the intervention changed the theme of the spots weekly, it’s possible multiple, different messages might be confusing to some listeners. Next, in order to have substantial increased utilization of primary health services, care seeking needs to be matched by availability and quality of those services. Although the local primary health system was able to respond to some extent to the increase in demand, its capacity to handle increased demand must have been constrained in this resource-poor environment. Lastly, it may simply be that in this context, some behaviors are inherently resistant to this kind of behavior change effort. Or more time might be needed. Fortunately, the intervention continued for another 15 months, ending in January 2015. The endline analysis should tell whether indeed further shift in behavior occurred,
and to answer the ultimate question of whether there was an impact on actual mortality.

The good news though is that in both the intervention and the control areas, it appears that a number of key behaviors have been improving, perhaps in part because of the multiple other health intervention activities carried out in the overall area over time. It is useful to assess the impact of discrete behavior change interventions, but improving behavior over the long haul, probably resulting from multiple sources, seems the most reasonable approach for the most impact toward our global health goals. —Global Health: Science and Practice

### TABLE. Attributes, Midline Findings, and Issues Associated With the Burkina Faso Saturation+ Program

| Attributes                                                                 | Midline Findings                                                                 | Issues                                                                 |
|---------------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Randomized village clusters (7 intervention arms and 7 control arms)      | Substantial listenership (as reported)                                          | Substantial improvements in behavior seen in control areas             |
| Areas believed to be isolated from other mass media messaging (outside the “electric grid”) | Improvement in some care seeking behaviors, but mostly no difference compared with control areas | Large differences between intervention and control areas at baseline: intervention areas poorer, more likely Muslim, and farther from health facilities |
| Mass media only (radio)                                                   | Some dose effect seen based on “spot” messages but not dramas                   | Seasonal difference between timing of baseline and midline surveys     |
| Addressed multiple behaviors                                              | Increase in service site utilization corroborates the reported increases in care seeking | Contamination of exposure to radio messages in one control area         |
| Prioritized most important behaviors based on lives saved modeling        |                                                                                 | Various other health promoting activities occurred in both intervention and control areas |
| Extensive formative research                                              |                                                                                 | No qualitative data provided as yet to give further insights           |
| Short spots and interactive dramas (story-based)                          |                                                                                 | Mass media only                                                       |
| Aired multiple times per day (spots) or per week (dramas)                |                                                                                 | Many behaviors addressed; certain topics received more emphasis        |
| Potential to reach others besides primary caregivers                      |                                                                                 | No supply-side change limits service-related behavior                 |
| Local, rapidly developed, innovative content with quality control        |                                                                                 | More effect may take more time                                        |
| Partnerships with local stations resulting in cost-efficiencies           |                                                                                 |                                                                       |
| No efforts to increase or improve service delivery                        |                                                                                 |                                                                       |

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Pre-eclampsia as Underlying Cause for Perinatal Deaths: Time for Action

Stephen Hodgins

Pre-eclampsia is a major underlying cause of late fetal and early neonatal death, accounting for somewhere between 1 in 10 and 1 in 4 perinatal deaths; it warrants greater efforts from the maternal-newborn community.

The Global Maternal Newborn Health Conference held in Mexico City in October 2015 marks an important watershed in global efforts to reduce the burden of preventable maternal and newborn deaths, bringing together—as it did—what have been two fairly distinct technical communities (maternal and newborn) to tackle their shared challenges in a post-Millennium Development Goal era. With this broadening focus embracing both mother and fetus/newborn, it is an appropriate time to reflect on where we may be allowing things to fall through the cracks and how—with a more seamless effort—we can do better.

A first important observation is that although there has been growing attention in global health to maternal and newborn health and each of these areas has an active constituency, stillbirth remains relatively neglected. Yet it represents one of the starkest examples of global inequity. Risk of stillbirth is 10 times higher in South Asia and sub-Saharan Africa than it is in high-income countries. To focus our attention on where there is the greatest burden of preventable mortality, it can be helpful to reframe our view of mortality in a way that captures deaths late in pregnancy, during labor, and in the first hours and days after birth, recalling that globally it is estimated 73% of newborn deaths occur within 7 days of birth. Perinatal mortality comprises fetal deaths late in pregnancy (≥28 weeks gestation) and during labor, and newborn deaths through the first week after birth.

Role of Pre-eclampsia in Maternal Health

Pre-eclampsia and the life-threatening condition of eclampsia (seizures associated with this disorder) constitute an important contributor to the burden of bad maternal-newborn outcomes. Eclampsia/pre-eclampsia accounts globally for about 1 in 7 maternal deaths, with most (in high-mortality settings) resulting from eclampsia. In sub-Saharan Africa, 1 of every 1,500 pregnancies ends in a maternal death attributable to eclampsia/pre-eclampsia; in South Asia the proportion is about 1 in 3,000 (calculated from Kassebaum). The importance of the problem has been recognized within the maternal health community, and this is reflected in the emphasis it has placed on use of magnesium sulfate for care of women with eclampsia and severe pre-eclampsia, for example, as one of the Emergency Obstetrical Care “signal functions.”

Key Role of Pre-eclampsia in Perinatal Mortality

Although not very evident in global newborn strategy documents, eclampsia/pre-eclampsia makes a similarly important proportionate contribution to perinatal mortality, and this translates into a far larger number of deaths. This effect is mediated through compromised fetal nutrition and oxygenation resulting from utero-placental vascular insufficiency. According to data from a multicountry study conducted by the World Health Organization in Argentina, Egypt, India, Peru, South Africa, and Viet Nam, which included just under 8,000 pregnancies enrolled during antenatal care, eclampsia/pre-eclampsia was the primary obstetrical cause for 1 of 4 perinatal deaths, with similar proportions affected for stillbirths and early newborn deaths. In this study, data were captured until discharge or day 7 postpartum, whichever happened first. Stillbirths were included if they weighed ≥1,000 g or, if weight was unavailable, if they had reached 28 weeks gestation.

A more recently published and far larger hospital-based study (with more than 300,000 pregnancies) was conducted in 29 low- and middle-income countries. The study explored the relationship between severe, life-threatening maternal complications and perinatal deaths.
Pre-eclampsia and Perinatal Deaths

BOX. Effect of Pre-eclampsia on Fetal Growth

Pre-eclampsia is characterized by poor utero-placental circulation secondary to inadequate remodeling of the spiral arteries that occurs between weeks 8 and 18. There may be many routes to pre-eclampsia with different contributions from the mother and the placenta. Two individuals are involved, mother and baby, each with different genetic make-ups. Placental vascular dysfunction, which can be particularly significant in early-onset disease, compromises nutrition and oxygenation of the fetus and is associated with fetal growth restriction. 7

It found that such complications were the underlying obstetrical cause of 23% of macerated late fetal deaths, 28% of fresh late fetal deaths, and 21% of early neonatal deaths. 8 The most important category of such obstetrical causes for perinatal deaths was hypertensive disorders, with life-threatening eclampsia and pre-eclampsia underlying 7.5% of macerated late fetal deaths, 9% of fresh late fetal deaths, and 10% of early neonatal deaths.

These two studies differed in the epidemiology of their study populations and were not measuring antecedent cause in the same way (primary obstetrical cause vs. life-threatening maternal complication), but they give a similar picture of a very important contribution of eclampsia and severe pre-eclampsia to perinatal mortality, ranging from about 1 in 10 perinatal deaths up to 1 in 4 (again, depending on local epidemiology and the methodologies used). This puts the impact of pre-eclampsia into the same range as 3 of the 4 most important proximate causes of early newborn deaths (intrapartum complications, congenital anomalies, and sepsis). 11

Rates of perinatal deaths were similar in these two studies (12.5 late fetal and 9 early neonatal deaths per 1,000 births in Ngoc 8; 18 late fetal deaths and 8 early neonatal deaths per 1,000 births in Vogel 9) (Figure).

Maternal and newborn health communities must join forces to prevent maternal, perinatal, and newborn mortality attributable to eclampsia/pre-eclampsia.

LARGELY UNRECOGNIZED. WHY?

Despite the important contribution of eclampsia/pre-eclampsia to perinatal and newborn deaths, it has—for the most part—been absent from strategies elaborated globally to try to reduce the burden of such deaths. One could speculate this has been due in part to those in the newborn community seeing this problem as falling in the maternal health domain. On the maternal health side—as noted above—there has been attention to trying to ensure that when women arrive in hospital in a life-threatening state of eclampsia or severe pre-eclampsia they are appropriately treated with magnesium sulfate (though there is no evidence this helps reduce perinatal deaths). However, serious programmatic attention has not extended much further. This represents an important missed opportunity to achieve better outcomes.

WHAT’S NEEDED?

As Goldenberg has documented, 11 in the United States in 1930, eclampsia-attributable maternal deaths were at levels similar to the current burden in high-mortality settings in Africa and South Asia. Over the following half-century (before introduction of magnesium sulfate), such mortality was reduced by about 99%, with over 90% of that decline due to reduced incidence of eclampsia achieved by early identification of pre-eclampsia (through routine antenatal care screening) and timely delivery. The Goldenberg review documents the same historical pattern across high-income countries. To date, unfortunately, this important lesson has not been widely applied in program efforts in low- and middle-income countries.

But if we want to take a big chunk out of the wedge of maternal, newborn, and stillbirth mortality attributable to eclampsia/pre-eclampsia, maternal and newborn communities need to join forces and ensure a more comprehensive effort that includes:

• Systematic early identification of pre-eclampsia (requiring frequent antenatal contacts, particularly over the last 2 months of pregnancy, which cannot be achieved with the current 4-visit schedule)

• Timely delivery (before the woman reaches a life-threatening state)

• Effective management of those cases that progress to a life-threatening state (including appropriate use of magnesium sulfate and antihypertensive drugs, as well as appropriate medical support)

*Late fetal deaths were defined as deaths to fetuses weighing ≥1,000 g at birth, or if birthweight was unknown, ≥28 weeks gestation. Macerated late fetal deaths were late fetal deaths with signs of maceration, or tissue degeneration, at birth; fresh late fetal deaths were late fetal deaths with no signs of maceration at birth; and early neonatal deaths were deaths of a live-born neonate by discharge or day 7 of life.

†Prematurity accounts for a larger proportion.

7 Note that antenatal calcium supplementation is a promising preventive intervention in populations with low calcium intake, possibly reducing risk of neonatal death by up to 30% 12 and pre-eclampsia-specific maternal mortality by a similar proportion; however, dosage issues and implementation challenges remain.
Competing Interests: None declared.

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Reduced Effectiveness of Contraceptive Implants for Women Taking the Antiretroviral Efavirenz (EFV): Still Good Enough and for How Long?

James D Shelton

EFV clearly reduces effectiveness of implants. However, the reduced effectiveness still appears better compared with short-acting methods overall, at least for the initial period of implant use, and may be acceptable to many women. We need better data on effectiveness, especially over the long term and on whether ENG implants (Implanon) might be more effective than LNG implants (Jadelle). Communicating the risk of pregnancy to clients under these circumstances is very challenging. In the longer term, providing an alternative to EFV, such as dolutegravir, might solve this problem.

WHY REDUCED EFFECTIVENESS OF IMPLANTS IS AN IMPORTANT PROBLEM

The antiretroviral (ARV) efavirenz (EFV) is now recommended for first-line antiretroviral therapy (ART) by the World Health Organization (WHO). And since WHO now recommends ART for all people living with HIV, that makes virtually all the some 13 million women in sub-Saharan Africa living with HIV candidates for extended EFV use.

At the same time, contraceptive implants have many attractive features and are the fastest growing method of contraception in sub-Saharan Africa—taking a markedly increasing share of the contraceptive method mix. The reduced effectiveness of implants due to an interaction with EFV could result in many unwanted pregnancies among vulnerable women and undermine confidence in an outstanding contraceptive method.

HOW DOES EFV DECREASE EFFECTIVENESS OF IMPLANTS?

By reducing contraceptive hormone levels. The very high contraceptive efficacy of implants comes from consistent release of low but highly effective levels of progestin in the blood. However, EFV speeds up the normal degradation of contraceptive progestins including those in implants (though not that of the injectable DMPA), lowering the progestin blood levels by roughly half. Because blood levels are already quite low, such a large reduction can lead to levels below the threshold at which the implant’s typically very high effectiveness is assured. Moreover, the progestin blood levels with implants are highest very soon after insertion and normally decline over the multiple years of an implant’s use. Thus, with continued EFV (and implant) use, these still lower progestin levels are expected to increase the risk of pregnancy over time.

HOW MUCH DOES EFV REDUCE EFFECTIVENESS OF IMPLANTS?

Implants are normally extremely effective with a failure rate of less that 1% per year. Although the available studies on effectiveness of implants among women on EFV are limited, as shown in the Table, pregnancy rates for women on EFV are well above 1%. (Note data from the single Patel study are shown separately for the 2 types of implants.) The one exception is the small study of 25 women from Brazil, which found no pregnancies. Otherwise, the rates range from about 6% to 15%.

MIGHT ENG IMPLANTS BE MORE EFFECTIVE THAN LNG IMPLANTS?

The 2 leading implants are the single-rod Implanon, which releases the progestin etonogestrel (ENG), and the 2-rod Jadelle, which releases levonorgestrel (LNG). The primary mechanism for ENG and LNG implants is suppressing ovarian activity. Both are very highly effective, but the ENG implant is more effective than the LNG implant in suppressing ovarian activity.
For women taking EFV, the results presented in the Table suggest better pregnancy prevention for the ENG implant than for the LNG implant, with failure rates from 0% to 6% versus 7% to 15%, respectively. On the other hand, in the large retrospective study by Patel11 based on electronic records of clinic visits, while the failure rate was a bit better for those using the ENG implant (5.5%) than the LNG implant (7.1%), the rates are fairly similar. However, even in that study, the numbers of pregnancies, particularly for the LNG implant, were very few and confidence intervals very large, so this study result is still compatible with a substantial difference in effectiveness.

**TABLE.** Pregnancy Rates in Studies of Contraceptive Implants and the Antiretroviral Efavirenz

| Implant Type and Study | Methodology                          | No. of Women | No. of Pregnancies | Pregnancy Rate (95% CI) | Period of Use |
|------------------------|--------------------------------------|--------------|--------------------|-------------------------|---------------|
| LNG                    | Retrospective electronic database    | 191<sup>a</sup> | 6                  | 7.1 (1.5, 12.6)         | Unknown       |
|                        | Retrospective chart review           | 121          | 15                 | 10<sup>a</sup>          | 16.4 months   |
|                        | Prospective clinical                 | 20           | 3                  | 15                      | 48 weeks      |
| ENG                    | Retrospective electronic database    | 641<sup>a</sup>| 15                 | 5.5 (2.5, 8.4)          | Unknown       |
|                        | Prospective clinical                 | 25<sup>b</sup>| 0                  | 0                       | 3 years       |
| Known                  | Secondary analysis of prospective study | 9<sup>a</sup> | 1                  | 6                       | Unknown       |

Abbreviations: CI, confidence interval; EFV, efavirenz; ENG, etonogestrel; LNG, levonorgestrel.

<sup>a</sup> Estimated from data in publication.

<sup>b</sup> Believed to be predominantly EFV users.

FOR WOMEN TAKING EFV, HOW DOES THE REDUCED EFFECTIVENESS WITH IMPLANTS COMPARE WITH OTHER CONTRACEPTIVE METHODS?

For the initial time period at least, still generally better overall than the short-acting methods of oral contraceptives and injectables. The Patel study also assessed failure rates with other contraceptive methods for women taking EFV and found considerably higher failure rates with women using oral contraceptives and injectables compared with implants, though of course lower failure rates with IUDs and permanent methods.11 That higher risk with the short-acting methods was probably largely due to inconsistent use of pills and injectables. However, it is possible some of the women who reported use of a short-acting method, as recorded in the electronic database, may then have discontinued to become pregnant intentionally. But that seems unlikely to affect the overall finding that pregnancy rates for women taking EFV were better with implants than with injectables or pills.

WHAT DOES THIS EVIDENCE IMPLY FOR RECOMMENDATIONS ON USE OF IMPLANTS FOR WOMEN ON EFV?

Use of implants for women taking any ARV continues to fall under WHO Category 2, which is For women taking EFV, the ENG implant might be more effective than the LNG implant.

The antiretroviral efavirenz speeds up the degradation of progestins found in contraceptive implants.

Risk of pregnancy with continued EFV and implant use is expected to increase over time.

Pregnancy rates in women using EFV and implants generally range from 6% to 15%.

WHAT ABOUT THE EXPECTED INCREASE IN PREGNANCY RATES IN THE LATER YEARS OF IMPLANT USE WITH EFV?

Unfortunately we are largely in the dark, except that the pregnancy rates are bound to increase with longer duration of use. The blood level data suggest gradually declining levels of progesterin over time, but that provides little insight. Only the small Brazil study14 has data for as many as 3 years. In the Patel study,11 information on duration was not available in the electronic database. But use of implants most probably tended to be early use, since implant use has only been rapidly scaling-up in recent years.
The reduced contraceptive effectiveness when taking EFV and implants is still generally better overall than effectiveness of short-acting methods.

CONVEYING THIS EVIDENCE ON EFFECTIVENESS TO CLIENTS IS VERY CHALLENGING

The body of knowledge on the advantages and disadvantages of contraceptive methods is exceedingly complex, and realistically only the most important information can be conveyed to clients. Effectiveness is clearly important, but it is already difficult to convey. And our limited and imprecise evidence on effectiveness of implants for women on EFV, especially over the long term, makes communicating it even more complex. Moreover, we don’t know if the ENG implant might be a better choice over the LNG implant. Personally, if I were such a client who wanted an implant, if given the choice, I would likely select an ENG implant, since the effectiveness is unlikely to be worse and might be better. But of course other factors weigh in on any individual’s choice. Clearly we need more evidence.

NEW ARVS A POSSIBLE LONGER-TERM SOLUTION

One way out of this dilemma would be replacing EFV with another ARV that did not significantly reduce progestin blood levels. For example dolutegravir—an integrase inhibitor—has a number of advantages over EFV including apparently avoiding the way EFV reduces progestin blood levels.\(^{19-21}\) US guidelines already recommend such integrase inhibitors for first-line therapy, and EFV has been demoted to an alternative regimen.\(^{22}\) Dolutegravir is not widely available in developing countries as yet, though processes are in place hopefully to make it so in the coming years. Meanwhile, if and when it becomes available, preference for providing it to women choosing and using implants makes considerable sense.

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Contraceptive Implants and Efavirenz

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The Levonorgestrel Intrauterine System: Reasons to Expand Access to the Public Sector of Africa

David Hubacher

The levonorgestrel intrauterine system (LNG IUS) was developed in the 1970s. The product releases small amounts of progestin into the uterus and improves contraceptive action compared with earlier inert plastic devices. The first commercialized LNG IUS set a high standard for future contraceptive development. Relative to other reversible contraceptives, the LNG IUS has the highest effectiveness levels (combining the highest product continuation rates with over 99% efficacy). The duration of action is 5 years (likely more), and the product provides important non-contraceptive benefits related to how it thins the lining of the uterus and reduces menstrual blood loss; from these effects, it may alleviate and/or prevent iron deficiency anemia. However, because of historically high product cost and a variety of other reasons, the LNG IUS is not widely available to women in resource-poor settings.

The legacy product was first approved in Finland in 1990, in the rest of Europe in the 1990s, and in the United States in 2000; today it is registered in more than 100 countries, and 2014 revenue topped US$900 million (personal communication with Klaus Brill, Bayer HealthCare Pharmaceutical, June 30, 2015, citing the Bayer Annual Report 2014). Because of the product’s great success, even at a high retail price, other companies have recently developed similar technologies in the hopes of entering global markets with lower-cost products. Currently, 5 different pharmaceutical companies make an LNG IUS that was approved in Europe in 2014 and in the United States in 2015.

As of 2015, no major international donor agency has issued and executed a tender for purchasing the LNG IUS. Thus, the per unit cost for the public sector is unknown. For drugs to be purchased in large quantities by major international donor agencies, such as the US Agency for International Development (USAID) and the United Nations Population Fund (UNFPA), the products must first be approved by a stringent regulatory authority (e.g., an American, European, or Japanese authority) or by the World Health Organization (WHO) through its Prequalification Programme. Then, the products must be registered at the national level in recipient countries. Currently, only the legacy product meets these criteria for procurement; hopefully, one or more of the other products will soon be eligible as well. Together, these actions may foster eventual purchase of a low-cost product by an international donor agency.

In this paper, I provide a summary of the obstacles to interest in the LNG IUS. Then, I outline 6 main reasons why donor agencies should purchase the LNG IUS and why family planning programs should incorporate the method into their services.

OBSTACLES TO INTEREST IN THE LNG IUS

Aside from some temporary regulatory obstacles, international donor agencies and foundations have uncertainty over the “value added” with an LNG IUS. The uncertainty involves 3 interrelated issues: (1) high product cost, (2) belief that the current variety of other contraceptive commodities is sufficient, and (3) doubt that an LNG IUS can overcome program barriers to uptake that currently affect the copper intrauterine device (IUD). Each of these real or perceived (current or
Past) beliefs dampen enthusiasm for taking procurement and program action.

High product cost is a relative concept and a major barrier to LNG IUS procurement. The comparison with the copper IUD, which costs donors less than $1 per unit,7 severely limits any notions of purchase. It is hard to imagine that any LNG IUS will reach that price point in the foreseeable future. But the dogged view that the LNG IUS and copper IUD are interchangeable (for the reason that both products are placed in the uterus) is too simplistic; the products’ attributes are vastly different and will attract different users for different reasons. Some compare the LNG IUS to the subdermal implant. Implants currently cost donors $8–$9 per unit; this low price was established in 2013.8 However, in the 5-year period preceding this price reduction, the 2 largest donor agencies justified buying more than 8 million implants for approximately $20 each. Thus, while precedence exists to pay higher prices for new technologies, too many other factors prevent the LNG IUS from being procured.

Duration of use also plays into the cost calculations and comparisons. For example, the copper IUD lasts up to 12 years; this fact inappropriately drives perceptions that any new form of intrauterine contraception (i.e., the LNG IUS) needs to match that duration. Of note, the 3-year subdermal implant was not held to the standard of the 5-year implant, yet it has had substantial success and support. Sufficient interest in the LNG IUS may never materialize if donor agencies continue to compare it to the copper IUD or the subdermal implant.

Five primary contraceptive commodities currently make up the backbone of international donor support: injectables, pills, condoms, copper IUDs, and subdermal implants. From a donor perspective, this array enables couples to choose a contraceptive delivery system to suit a variety of personal preferences and needs. The subdermal implant is currently in high supply, due to the volume guarantee arrangement associated with the 2013 price reduction. Programs need to expand access to the product for the arrangement to be successful. If donors and foundations continue to view the 5 main contraceptives as sufficient, then the LNG IUS will never reach its full potential.

Finally, negative perceptions of the copper IUD and the struggles to establish even moderate levels of use in most African countries naturally dampen interest in another intrauterine product such as the LNG IUS. Many factors contribute to the poor uptake of the copper IUD. Previous failed efforts to stimulate uptake of the copper IUD should only be informative of the challenges for a new product, not predictive of a similar destiny.

SIX REASONS TO INVEST IN THE LNG IUS

The LNG IUS is a unique type of contraceptive that combines 2 key features: intrauterine placement and use of a proven and safe progestin. It will attract new users and stimulate programs. For the reasons outlined below, the LNG IUS should be procured by the international donor community.

1. Recently Placed on WHO’s Essential Medicines List

WHO recently placed the LNG IUS on the Essential Medicines List.9 Thus, in the eyes of WHO, the LNG IUS is now considered one of the most “efficacious, safe, and cost-effective medicines for priority conditions.”9 Priority conditions are “selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment.” Now, according to WHO, a health care system is not meeting basic needs without the LNG IUS on the formulary.

2. Well Accepted Worldwide

Worldwide, user satisfaction with the LNG IUS is consistently high. A study in 18 different countries in Asia and Europe found that 95% of LNG IUS users were satisfied with the product.10 Compared with the subdermal implant, the LNG IUS is often better tolerated. For example, in Australia, 3-year continuation rates of the LNG IUS and the etonogestrel subdermal implant were 73% and 53%, respectively.11 In the United States, the LNG IUS continuation rate at 24 months was found to be significantly higher than that of the subdermal implant (79% versus 69%, respectively).12 In the only head-to-head comparison of the levonorgestrel subdermal implant and the LNG IUS, the subdermal implant had a removal rate for irregular bleeding of 26.8% at 36 months compared with 3.3% for the LNG IUS.13 Prolonged bleeding consistently affected 20% to 40% of implant users at different follow-up times, but the problem did not exceed 10% for LNG IUS users.

Research in Africa also shows good prospects for the LNG IUS. In Kenya, 16% of family planning clients chose the LNG IUS when given the opportunity; only 3% wanted the copper IUD.14

While both the LNG IUS and the copper IUD are types of intrauterine contraception, they have vastly different characteristics and will thus attract different users.

According to WHO, a health care system is not meeting basic needs without the LNG IUS on the formulary.

Previous challenges with stimulating uptake of copper IUDs should inform new product rollout but should not be predictive of a similar destiny.
Kenyan providers cited non-contraceptive benefits (reduction of menstrual blood loss, alleviation of anemia) as important reasons for recommending the LNG IUS to clients. In a prospective cohort study, approximately 90% of women in Kenya were still using the LNG IUS after 12 months. A survey in South Africa found that 75% of respondents were positive toward a product such as the LNG IUS if it would reduce menstrual bleeding. In Ghana, LNG IUS users and providers had similar high opinions of the product. In Ghana and 8 other countries in sub-Saharan Africa, the International Contraceptive Access (ICA) Foundation has donated thousands of LNG IUS products since 2003.

3. Unique/Advantageous Delivery System and Important Non-contraceptive Benefits

No other hormonal method releases progestin directly into the uterus; this results in a predominately local effect with highly efficacious triple-action mechanisms on the cervix, endometrium, and ovaries to prevent pregnancy. Moreover, the level of levonorgestrel released from the LNG IUS is steady and slow, which minimizes side effects. In contrast, short-acting hormonal methods have abrupt dosing effects and higher levels of circulating hormones that create peaks and troughs of systemic levels; for many users, this causes intolerable side effects, leading to high discontinuation rates.

Non-contraceptive benefits also make the LNG IUS unique; the benefits are linked to how the LNG IUS shrinks the endometrium and minimizes uterine bleeding. The LNG IUS is a proven treatment for heavy menstrual blood loss and is more effective than all other non-hysterectomy approaches. The LNG IUS also decreases bleeding among women with uterine fibroids. Finally, the LNG IUS has very promising prevention actions against a number of conditions, including endometriosis, uterine fibroids, endometrial hyperplasia, endometrial cancer, and perimenopausal menstrual disturbances.

The LNG IUS may help anemic women; this is probably the most important potential non-contraceptive benefit for women in resource-poor countries. Through the mechanism of reducing menstrual blood loss, the LNG IUS can help anemic women retain up to 19 grams of iron each month. This amount, when accumulated over many months, might increase iron stores and prepare women for healthy pregnancy when the time comes. Anemia affects approximately 46% of women of reproductive age in sub-Saharan Africa and Southeast Asia, and it contributes to 20% of all maternal deaths. Prolonged anemia after pregnancy, short birth intervals, and even poor nutritional status prior to a first pregnancy increase the risks of poor health outcomes.

Because of these unique attributes, the LNG IUS is not interchangeable with the copper IUD. In Kenya, nearly a third of LNG IUS acceptors said they would have chosen a short-acting method if the LNG IUS were not available, and only 21% would have chosen the copper IUD. In the United States, approximately 80% of intrauterine contraceptive use is attributable to the LNG IUS and 20% to the copper IUD; the CHOICE study demonstrated that women overwhelmingly wanted the LNG IUS in a 4 to 1 ratio over the current copper IUD product.

4. Opportunity to Activate Some Countries

The best example of rapid uptake of the LNG IUS is from the United States. In this mature contraceptive market, the LNG IUS quickly reinvigorated interest in intrauterine contraception. Between 1995 and 2013, the proportion of all contraceptive users using intrauterine contraception in the United States rose from less than 1% to over 10%. Today intrauterine contraception is more popular in the United States than any new delivery system introduced since 1992, including the injectable DMPA (1992), the vaginal ring (2001), the patch (2002), and the etonogestrel subdermal implant (2006). The general rise in intrauterine contraceptive use was also seen in federally funded family planning programs, in which provision increased from 48,000 intrauterine contraceptive services in 1999 to more than 270,000 in 2011.

Ministries of Health recognize the importance of expanding access to long-acting reversible contraception, particularly since sterilization services are more difficult to provide. In the 1980s, many countries put the newly available copper IUD at the center of their family planning programs. Egypt, Mexico, Turkey, and Vietnam experienced tremendous fertility transition in one generation by making the IUD widely accessible. Today, Ethiopia's Ministry of Health is using health extension workers to make subdermal implants widely available; this may result in similar patterns of uptake that were observed in countries where the copper IUD became popular. Other countries will focus on the LNG IUS when it becomes available.
No one can predict which countries will launch the LNG IUS and make it successful, just as nobody predicted which countries would succeed with copper IUDs and implants. The international family planning community is ready to support the LNG IUS. At the biennial International Conference on Family Planning in Ethiopia in 2013, a small survey of 30 conference participants found that 100% of respondents with knowledge of the LNG IUS supported the idea of making the product available in public-sector clinics worldwide (personal communication with Heather Vahdat, FHI 360, November 11, 2014). When asked why they would support the introduction of an LNG IUS, responses fell primarily into 2 categories: benefits offered by the method (e.g., long-acting, fewer side effects, reduced bleeding) and support expansion of the method mix/choice for women.

5. Many Women in sub-Saharan Africa Want to Use Intrauterine Contraception

NGOs consistently show high uptake of IUDs in the same public-sector clientele where ministries fail. The difference is that NGO providers have the knowledge, skills, job expectations, and proper support to make IUD services available. For example, between 2008 and 2012 Marie Stopes International more than tripled the number of IUDs it provided in sub-Saharan Africa, from 69,087 insertions to more than 215,000.33,34 The interest in long-acting methods overall is growing.35 Introduction of the LNG IUS is a new opportunity for Ministries of Health and providers in the public sector to establish successful, demand-driven intrauterine contraception services. As demonstrated in the United States, a single intrauterine product with a proven track record and high acceptability can stimulate provision of services, even in the public sector. With a new product such as the LNG IUS, public-sector providers can develop the skills and confidence to insert IUDs and serve the clientele who currently have latent demand for services. Thus, the LNG IUS may be the easiest route to establish consistent access to the copper IUD.

6. Need for More Highly Effective Options

WHO lists IUDs (copper IUDs and the LNG IUS) and subdermal implants as the most effective reversible forms of contraception.36 Only subdermal implants and intrauterine contraception can compensate for lack of access to sterilization services. For spacing births, implants and intrauterine contraception eliminate the risks of unintended short birth intervals. In public-sector facilities throughout sub-Saharan Africa, the current array of contraceptive choices is imbalanced in favor of the least effective, short-acting options. Thus, women who need permanent or long-term protection face difficult challenges over many years. For many countries, the copper IUD has not contributed much toward reducing national levels of unintended pregnancy and fertility. New products such as the LNG IUS are needed to attract new users to highly effective, long-acting contraception. Adolescents also need more effective options like the LNG IUS. Preventing unintended pregnancy in this population (especially first pregnancies) can help young women achieve other goals they may have (e.g., education, employment). Consensus is building that long-acting reversible contraceptives should be easily available to sexually active young women.37,38

Summary

The LNG IUS is not just another, interchangeable contraceptive. This fact should help justify taking procurement and program action for the public sector in sub-Saharan Africa. For many decades, the obstacles to procurement appeared insurmountable. Today, however, international donors have better information and more opportunities to make large-scale procurement a reality. With renewed emphasis and funding for family planning, the timing couldn’t be better. Women in resource-poor countries will benefit tremendously from the LNG IUS; worldwide equity in access to the technology is needed.

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The Levonorgestrel Intrauterine System: A Pragmatic View of an Excellent Contraceptive

Roy Jacobstein, a James D Shelton b

The levonorgestrel intrauterine system (LNG IUS) has major advantages and could be a “game-changer” in improving contraceptive choice and use. It faces important challenges, however, including: (1) high commodity cost; (2) often-strong provider resistance to IUDs and difficult programmatic requirements; (3) need for demand creation, including assessing if markedly reduced menstrual bleeding is attractive to clients; and (4) the many requirements for introducing any new contraceptive. A good next step would be a well-focused and multifaceted “learning introduction” to assess the LNG IUS’s potential in several low-income countries, with rapid scale-up if results are promising.

See related article by Hubacher.

In this issue of Global Health: Science and Practice, Hubacher makes a good case for the levonorgestrel intrauterine system (LNG IUS) and why donors should purchase it for provision in African family planning programs.1 The LNG IUS is indeed an excellent contraceptive. It is highly effective, with only 2 pregnancies per 1,000 women in 1 year of typical use,2 a level of effectiveness 4 times that of the copper-containing IUD, and 35 and 70 times that of the injectable and pill, respectively. The LNG IUS also has very high satisfaction and continuation rates, and it confers important non-contraceptive—even therapeutic—benefits. And, like other long-acting reversible contraceptives (LARCs), it is suitable for all reproductive intentions (delaying, spacing, or limiting births). Both the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics have endorsed LARCs as “first-line” method choices for adolescents and young women.3 4 No wonder the LNG IUS is fueling a rise in IUD use in Europe and the United States. (Prevalence of IUD use is now over 6% in the United States, representing 9% of all modern method use among women aged 15–44.5)

Hubacher cites 3 obstacles to greater donor interest in the LNG IUS: high commodity cost; the belief that currently available method options are sufficient; and doubt about overcoming the barriers that the copper T 380A IUD (Cu T) often faces. He then advances 6 reasons why international donors should buy the LNG IUS: (1) it is on the World Health Organization’s (WHO’s) Essential Medicines List; (2) it is well accepted worldwide; (3) it has a “unique/advantageous delivery system” and important non-contraceptive benefits; (4) it will “activate” some countries; (5) many women in sub-Saharan Africa want to use intrauterine contraception; and (6) more highly effective options are needed.

To more fully consider Hubacher’s arguments, we address 5 somewhat overlapping aspects:

1. Cost Considerations

Costs—absolute commodity cost, commodity cost relative to similar methods (or methods occupying a similar niche), service delivery costs, and opportunity costs—are all, appropriately and necessarily, key considerations for donors, policy makers, and program leaders. Regarding commodity cost, it is relevant to recall that in the early days of implant availability, the public-sector commodity cost (for Norplant) was US$23.80 per set (in 1990 dollars). Today in 2015, thanks to donor volume guarantees to manufacturers, the unit cost of implants has been reduced by two-thirds, to $8.50 per set.6 It seems unlikely that the LNG IUS would be available at a unit cost to donors below the 2015 unit cost of implants. By contrast, the cost of the Cu T IUD to donors is as low as $0.35 per device.6 The funding implications of these large differentials in respective price points are seemingly also large. On the other hand, it could be argued that the lower commodity cost of the Cu T IUD is somewhat beside the point, because

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use of the Cu T (or any) IUD is below 1% in the majority of sub-Saharan African countries. Thus, in most of these countries, the LNG IUS would essentially be a new method for programs, and could be considered as such by policy makers, program leaders, and donors.

2. Categorization of the LNG IUS

Whether or not—and if so, in what respects—the LNG IUS is an IUD has a number of important dimensions and implications. Hubacher presents a good summary of how the LNG IUS and Cu T IUD differ. But there are also a number of important, programmatically relevant parameters in which the methods are similar. First, both devices require a skilled, unbiased, and motivated service provider in order for clients to receive the method. Second, both require pelvic examination for placement, often a limitation in traditional societies and low-resource settings. Third, both require accurate knowledge by clients—and the Cu T (the IUD generally made available by donors) has long faced a plethora of misunderstandings and myths. Fourth, despite the LNG IUS’s known benefit in reducing abnormally heavy menstrual bleeding and presumed positive effect on anemia, the reduced bleeding or frank amenorrhea it causes could be more problematic in traditional settings where sociocultural beliefs, prescriptions, and/or fears related to menstruation and amenorrhea are more common. None of this means the LNG IUS would not be a very good addition to a country’s method mix; only, rather, that these IUD-related barriers would need to be addressed.

3. Entrenched Service Provider Perspectives and Behaviors

Fostering “unlearning” among medical professionals, even when it is “evidence-based,” is often difficult and time-consuming.1,9 Service providers are not “empty vessels” waiting to have their minds filled with new knowledge, which, in turn, will prompt new behavior.10 They have their own “truths” and operate on the quite-reasonable general principle that, “What has worked for me has worked, so why change?”11 This is a major reason that updated service policies fail to diffuse into everyday service provision and that “research-to-practice” or adoption of “best practices” is generally slow going. Also, what may seem like “lack of provider motivation” is often a response to already-heavy workloads with no compensatory payment or relief from other existing duties in exchange for assuming additional ones. (Inserting IUDs is more time-consuming than provision of implants or short-acting resupply methods like injectables or pills—although removal of implants is more difficult than with IUDs.) Furthermore, in situations of low client demand, it can be difficult for trained providers to maintain their skills.

Changing providers’ specific understandings and behaviors regarding IUD provision can be particularly difficult. In our experience, providers often have exaggerated but deep-seated concerns related to the triad of sexually transmitted infections (STIs), pelvic inflammatory disease (PID), and infertility, as well as misunderstandings regarding eligibility, believing wrongly that a woman needs to be married or to have had a child to be eligible to receive an IUD.12 These impediments contribute to the low IUD use seen in a number of sub-Saharan African countries. So even as the LNG IUS is framed programmatically—as it should be—as a new and different method (albeit with the best features of the IUD and the pill), considerable program effort would be needed to ensure that provider biases and client perceptions do not generalize from the Cu T experience.

A possible programmatic remedy is suggested in Hubacher et al.’s recent study of the perspectives of 27 IUD service providers from Marie Stopes Kenya.13 These providers had positive attitudes toward both the Cu T IUD and the LNG IUS, and they behaved accordingly, providing 30,000 IUDs to Kenyan women in 1 year (mainly the Cu T, because of limited LNG IUS commodities, which were provided free by the International Contraceptive Access [ICA] Foundation, described below). Marie Stopes Kenya is a nongovernmental organization, however, and a “closed system” delivering family planning via fixed sites and mobile services (in private-public partnership with the Ministry of Health). It is able to employ family planning-dedicated providers selected not only for their service delivery skills but also for their positive attitudes and commitment to family planning, and then to supervise and reward them accordingly. Generalizability of this approach to the larger and more diffuse and resource-strapped African public sector itself might be limited.

4. Uncertain Extrapolation From Recent Experience in Europe and the United States

The recent rapid uptake of the LNG IUS in the United States and Europe may not necessarily be

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predictive of an LNG IUS trajectory in Africa. High-income countries have a more ample supply of service providers, contraceptive methods and services are much more widely and easily accessible to clients, women are more highly empowered and knowledgeable about their contraceptive options, and bias against the IUD is less (now, as opposed to the situation during the post-Dalkon Shield era of the 1980s and 1990s). Conversely, health workforce and health system constraints in sub-Saharan Africa, particularly for clinical method provision, are unfortunately widespread and problematic, as the recent Ebola outbreak has underscored. This reality is a chief reason that short-acting resupply methods of family planning predominate in the method mix of sub-Saharan African countries.

The recent marked increases in implant use in sub-Saharan Africa may also not be predictive of how the LNG IUS might fare, given the ways that provision of these 2 hormonally based methods differs. The implant needs no pelvic exam, does not face provider bias against it, and is more amenable to task shifting to lower cadres, including frontline community extension workers, as is being done in Ethiopia (for insertion). According to the UN’s 2015 multinational tabulations, no sub-Saharan African country has an IUD prevalence above 4%, only Guinea-Bissau and Kenya have levels above 3%, and the majority of countries have levels below 1%.7 By contrast, the implant’s prevalence is considerably higher: 11% in Kenya, 9% in Malawi, 8% in Burkina Faso, 7% in Ethiopia, and 6% in Rwanda.7

On the other hand, as Hubacher notes, the IUD has never received the extent of donor support and “buzz” in the international family planning community that has been accorded the implant since the Family Planning 2020 (FP2020) initiative and the donor volume guarantee. And yet, even absent that, the IUD’s share of modern method use in 2014–2015 surveys conducted by Performance Monitoring and Accountability 2020 (PMA2020) is 7% in Kenya,14 4% in Uganda,15 3% in Ethiopia,16 and 2% in Burkina Faso,17 confirming Hubacher’s point that some sub-Saharan African women will choose an IUD when it is made accessible.

5. Complexity of Introducing a New Method

Introduction of a new contraceptive method, with plans for its wider adoption and scale-up, is a complex process that requires considerable and sustained work.8 In addition to simple provision of the LNG IUS commodity by donors, introduction would require attending to many aspects of the health system: regulatory requirements; supply chain and logistics management; public- and private-sector service delivery policies and processes; counseling and skills training (the LNG IUS requires a different insertion technique than the Cu T IUD); side effects management; quality assurance; client perspectives and knowledge; provider perspectives and work situations; and community outreach and engagement.

HOW THEN TO ACHIEVE THE FULL POTENTIAL FOR THE LNG IUS?

In our view 5 things will be required for the LNG IUS to become widely accessible and used:

1. A commodity price comparable to that of contraceptive implants.
2. An introduction and ultimate scale-up plan that addresses the many considerations we’ve laid out above (assuming secure supply of needed LNG IUS devices).
3. Identifying, supporting, and otherwise “nurturing” a nucleus of “champions” to become advocates for the method itself and for its introduction at policy, program, system, and service provider levels.
4. Ensuring that the introduction effort is visible to policy makers and opinion leaders in the relevant government ministries, teaching and training institutions, service delivery systems, and professional organizations (medical, midwifery, and nursing), as well as to potential clients.
5. Robust outreach and demand creation efforts that include emphasizing the LNG IUS’s non-contraceptive benefits in reducing menstrual bleeding, i.e., it is not “just another IUD.”

Achieving scale-up of demand, availability, and access is a longer-term proposition, but one that should be initiated now. Well-conceived, adequately resourced, and well-implemented introduction should ideally start in several countries using import waivers where necessary to acquire the product in places where it is not currently registered. In order to facilitate that start, we describe LNG IUS product options and some of the pathways forward.

The ICA Foundation: Source of Limited Quantities of Free Product

The legacy LNG IUS product, Mirena, currently sells for well upwards of $400 in the United States,
which would be prohibitively expensive for public-sector provision in low-income countries. However, an LNG IUS device (with the same amount of hormone and mechanism of action as Mirena) is available free of charge from the ICA Foundation, a partnership between Population Council and Bayer Healthcare Pharmaceuticals.19 (One of this paper’s authors, RJ, serves as an Advisor to the ICA Foundation Board.) Upon request, the ICA Foundation provides free LNG IUS devices to governments, NGOs, and multilateral organizations. From 2004–2015, the Foundation donated more than 70,000 LNG IUS devices to 28 countries, 9 of them in sub-Saharan Africa (including for the introduction efforts in Ghana and Kenya that Hubacher describes3,13). (Information on how to access the LNG IUS can be found at http://www.ica-foundation.org/About_the_Programs/Application_for_New_Projects/.)

The ICA Foundation’s donations per country have typically been small, largely because the Foundation is unable to provide resources to support other needed aspects of wider introduction, e.g., the costs of shipment, registrations, or waivers, distribution and supply chain management, counseling and skills training, and demand creation. Thus, in the long run, this foundation might not be the best vehicle for a large scale-up of LNG IUS service delivery to tens of thousands (or more) interested clients. However, donations as large as 5,000 to 10,000 units could possibly be provided annually for initial scale-up efforts, concentrating such donations in 3 to 4 low-income countries that have demonstrated interest and with the capacity for larger-scale introduction than has yet occurred.

Liletta: The New Kid on the Block

Liletta, a low-cost alternative to the legacy product, is being made available by Medicines360.20 Approved by the US Food and Drug Administration (FDA) in February 2015, Liletta (known outside the United States as Levosert) contains the same amount of levonorgestrel as Mirena (52 mg), has the same mechanism of action, and releases the same small amount of hormone (20 μg/day) continuously into the uterus. Liletta is currently approved for 3 years of use, with ongoing trials underway to extend its labeled duration of effective use to at least 5 years. (Mirena is approved for 5 years of use.) Liletta does not yet have regulatory approval in low-income countries, nor does Medicines360 have a presence there, so linkage with donors and implementing partners would be essential for registration (or waiver), purchase, introduction, and scale-up—and it could be introduced in these countries now under a research framework.

THE WAY FORWARD: AN INITIAL “LEARNING” INTRODUCTION INITIATIVE

Although ultimate scale-up of the LNG IUS is a formidable goal, with substantial funding and implementation challenges, we believe the timing is right for smaller, well-focused introduction; demonstration activities to be launched now. These could assess the LNG IUS’s potential among donors, programs, providers, and clients alike. Such initial projects could access the free LNG IUS commodities now available from the ICA Foundation. Alternatively, devices soon to be available via Medicines360 could be used (as could products from other manufacturers, assuming comparable low commodity cost).

A key part of the introduction strategy would be to support activities in high-quality service delivery situations favorable to IUD provision, such as those using family planning-dedicated providers, mobile outreach service delivery, or social franchising, and with free or very low-cost service provision to clients. On the demand side, having careful evaluation of client acceptability, provider embrace, and method uptake and continuation would be essential in the context of wide contraceptive choice. Mindful of the Cu T’s difficulties, the LNG IUS should be framed as a “new” method, widely used and popular in high-income countries of Europe and North America. Along with high effectiveness and convenience, reduced bleeding and amenorrhea should be specifically promoted as potential advantages, with strong qualitative research to assess that messaging.

In Zambia, the dedicated provider approach, which entailed placement of 18 LARC providers in busy, urban-based, public-sector facilities, resulted in provision of 11,000 Cu T IUDs (and 22,000 implants) in 14 months.21 Use of dedicated providers and mobile service delivery over a 3-year span in Malawi led to uptake of more than 130,000 female sterilization procedures (generally more costly and time-consuming to provide than IUDs).22 In both situations, services were provided free of cost to clients, and the activities were conducted by an NGO in private-public partnership with the Ministry of Health, both important factors in such large uptake of clinical methods in low-resource settings. The new WHO guidance allowing immediate postpartum
provision of hormonal IUDs (and implants)\(^2\) and the almost universal (and largely unmet) demand for contraception in the 0- to 1-year postpartum period\(^2\) increases the potential importance of linking this introduction effort to busy maternity settings. These demonstration projects would need to address many of the implementation and scale-up requirements we have outlined earlier.

**What About Price?**

Price and aggregate commodity cost remain an unresolved sticking point to scale-up, as a 10- to 30-fold cost differential between the LNG IUS and Cu T IUD would understandably represent a large hurdle for policy makers and program funders. Securing a concentrated supply of LNG IUS devices in several countries via the free devices from the ICA Foundation could be a solid, albeit small, start. Hopefully, the imminent availability of Liletta as well as lower cost LNG IUS devices from other manufacturers will foster competition, and commodity cost will accordingly come down substantially. If initial introduction efforts are successful and quantities increase, that could also further decrease cost. And as with contraceptive implants, approaches like a volume guarantee could provide a major boost.

**CONCLUSION**

Under the conditions described above, the LNG IUS—such a highly beneficial, convenient, and potentially popular contraceptive—could become as widely chosen by women in sub-Saharan African countries as it is now by women in high-income countries of Europe and North America. Moreover, it seems likely that these efforts would also improve use of copper IUDs as well, as was the case in Kenya.\(^2\) Then the IUD would truly be “revitalized,” and women would have more highly effective options in the countries where we work.

In light of the LNG IUS’s considerable game-changing potential, and mindful of these qualifications and amplifications to Hubacher’s call to action, let’s mount a vigorous, well-focused, and multifaceted effort, now.

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The Saturation + Approach to Behavior Change: Case Study of a Child Survival Radio Campaign in Burkina Faso

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ABSTRACT

A 35-month cluster randomized controlled trial was conducted in Burkina Faso to test whether a radio campaign focused on child health, broadcast between March 2012 and January 2015, could reduce under-5 mortality. This paper describes the design and implementation of the mass media intervention in detail, including the Saturation + principles that underpinned the approach, the creative process, the lessons learned, and recommendations for implementing this intervention at scale. The Saturation + approach focuses on the 3 core principles of saturation (ensuring high exposure to campaign messages), science (basing campaign design on data and modeling), and stories (focusing the dramatic climax on the target behavior) to maximize the impact of behavior change campaigns. In Burkina Faso, creative partnerships with local radio stations helped us obtain free airtime in exchange for training and investing in alternative energy supplies to solve frequent energy problems faced by the stations. The campaign used both short spots and longer drama formats, but we consider the short spots as a higher priority to retain during scale-up, as they are more cost-effective than longer formats and have the potential to ensure higher exposure of the population to the messages. The implementation research synthesized in this paper is designed to enable the effective adoption and integration of evidence-based behavior change communication interventions into health care policy and practice.

INTRODUCTION

Between March 2012 and January 2015, Development Media International (DMI) implemented a 35-month mass media campaign in Burkina Faso and tested the impact of this intervention on child mortality through a cluster randomized controlled trial (RCT), funded by the Wellcome Trust and Planet Wheeler Foundation.1,2 The media intervention consisted of daily radio broadcasts (60-second spots and longer, interactive dramas) that targeted changes to multiple, key behaviors to improve child survival. We broadcast in 7 randomized geographic areas (clusters, which correspond to areas covered by local community FM radio stations) across Burkina Faso, with 7 additional clusters serving as controls. The RCT tested the impact of a mass media campaign alone; there was no supply-side intervention. This trial is the largest, most rigorous evaluation of a mass media intervention in a low-income setting. The independent evaluation is being led by the London School of Hygiene and Tropical Medicine (LSHTM) in partnership with Centre Muraz in Burkina Faso. Household surveys were conducted at baseline, midline, and endline to measure family behaviors and at baseline and endline to measure under-5 child mortality. The midline survey methods and midterm behavioral results have been published in a companion article in Global Health: Science and Practice.3 Effects on behaviors and child mortality at endline will be published as results become available.

The aim of this paper is to describe the implementation of our mass media intervention in detail. First we document the Saturation + principles and theory of change underpinning our approach. Then we describe
our implementation of the Burkina Faso campaign, its design, execution, our creative process, and how these components follow the Saturation + principles. Finally we discuss the lessons learned and our recommendations for implementing this intervention at scale. We believe this type of implementation science is crucial to enabling effective replication of evidence-based interventions. A lack of such information too often impedes the integration of research findings into health policy and practice.4

THE SATURATION + APPROACH

The media intervention tested in the trial was designed and implemented based on DMI’s Saturation + approach, which builds on existing communication principles for behavior change. It was developed following many years of experience in designing, implementing, and evaluating media campaigns.1

The Saturation + approach is a set of core transferable principles, grouped under the 3 main categories of saturation, science, and stories (Box 1). It is not intended to be a standard, one-size-fits-all method, but rather an approach designed to maximize the impact of campaigns. If successful, the trial will not prove that any mass media campaign can reduce child mortality. Rather, it will provide evidence of the impact of the specific Saturation + approach that underpins the media intervention being tested.

Saturation Theory

Intensity is key to any commercial advertising strategy, and yet it has been an underrated element of public health campaigning. Evidence suggests that achieving high exposure to messages is correlated with impact on behaviors.5 Although much of the existing evidence base comes from non-randomized evaluations (which may be affected by confounders), many of these studies make a strong case for the attribution of effects to their campaigns by showing that higher exposure is associated with incrementally higher impact on outcomes (dose-response effect).6 For example, the COMMIT media trial demonstrated correlation between exposure to the intervention “dose” and the reported effect “response” on smoking cessation.7

A recent systematic review of the effectiveness of mass media interventions for child survival in low- and middle-income countries reported that...
achieving adequate exposure is a key component of success, with campaigns needing to “reach substantial proportions of the target audience with enough frequency to be recalled.” Nearly one-third (31%) of the studies included in the review had achieved exposure of 61% to 100%, which has been shown to be a strong predictor of campaign success.

Another review of the impact of media campaigns on health behaviors proposed that investment in longer, better-funded campaigns is required to achieve frequent and widespread population exposure to messages, especially for habitual behaviors. Our own experience also indicates a link between the frequency of messaging and impact on behavior change. A particularly successful campaign targeted hand washing in Ethiopia, with messages broadcast up to 14 times per day for 3 years. Further analysis of data from both published studies (by Roy Head in consultation with the studies’ first author, Tansy Edwards) suggests significant reductions in observed dirty hands (decreasing from 74% to 26%) and a 20% reduction in the prevalence of trachoma in areas receiving radio messages alone without the use of antibiotics.

So how does exposure lead to behavior change? There are several theories about the mechanisms or pathways by which high exposure drives behavior change, summarized by Bob Hornik, including:

- **Learning.** People listen to the radio at different times each day and vary in their susceptibility or inclination to respond to a message. The more times a message is repeated, the more opportunities there are for people to hear and learn from the message when they are receptive to it.

- **Priming.** Repeated exposure to a message affects its pertinence, so a stronger weight is attributed to the message when deciding whether to adopt the behavior.

- **Creating social norms.** Repeated exposure to messages can create social expectations about behaviors. Such social norm pressures may persuade people to adopt behaviors.

- **Diffusion effect.** As more people are exposed to messages, more people will discuss these messages within their wider social networks, including people who have not seen or heard the media campaign.

- **Indirect impact on policy.** High exposure may alert policy makers to issues that are of public concern and thereby result in legislation or the implementation of policies that promote behavior change.

In the particular case of child mortality, there is another mechanism at work. The primary audience is mothers, and the motivation of mothers to protect their children is one of the strongest instincts in nature. While we know that knowledge alone is an insufficient instrument in, say, antismoking campaigns in which motivations are complex, it is safe to assume that virtually all mothers are highly motivated to protect their child with the proper knowledge of how to do so. Ensuring—through repeated broadcasts—that they are aware of danger signs and have the knowledge to protect their child will propel them further along the path to behavior change than less primal, instinct-driven behaviors. The broad theory of change or causal pathway by which we hypothesized that the Burkina Faso campaign would achieve impact is illustrated in Figure 1.

Bob Hornik, when summarizing his 2002 analysis of whether public health communication can change behaviors, suggested:

*Most of the innovative work in public health has focused on the problem of developing high quality messages. … This has been a good thing. At the same time, there has been less attention to the problem of exposure to those messages. … And that may be a crucial failing.*

Irrespective of the specific pathways through which high exposure drives behavior change, both evidence and theory (not to mention a century of experience from the advertising industry) suggest that high frequency of messaging is a crucial component of successful health communication campaigns. We therefore consider it a crucial component of the Saturation+ approach.

**IMPLEMENTATION OF THE BURKINA FASO CAMPAIGN**

In this section we describe in detail the design and execution of the media intervention tested in the RCT in Burkina Faso, within the Saturation+ framework. We have also produced an open-access Saturation+ handbook (http://www.developmentmedia.net/saturation-handbook). This tool is designed for use by other organizations that are delivering mass media behavior change campaigns. While our mass media campaigns focus on child survival and the handbook was written with this subject in mind, the principles described are applicable to campaigns addressing other health and non-health subjects.
**Saturation**

The broadcasting environment in Burkina Faso is unusual. Most people listen to local FM radio, rather than to the national station, because most output on the national station is in French (spoken by fewer than 1 in 5 rural Burkinabés) while the output of local FM stations is in the local languages. This environment makes it unusual. Most people listen to local FM radio, rather than to the national station, because most output on the national station is in French rather than to the national station, because most output on the national station is in French.

Radio penetration in Burkina Faso is also high. The 2010 Demographic and Health Survey (DHS) reported that 68.3% of households owned a radio (65.7% in rural areas) while only 16.2% of households owned a television (5.8% in rural areas). In preparation for the trial, DMI and Centre Muraz conducted a media survey in 2011 to measure radio penetration in 19 rural areas and to identify the stations with the greatest number of female listeners. We found that 75% of women surveyed listened to the radio at least once a week. It was clear that radio is the only form of mass media currently capable of reaching our primary target audience (mothers of children under 5 years, pregnant women, and mothers-to-be) as well as the secondary audience (people)

*Most people in Burkina Faso listen to local FM radio rather than to the national station, providing a uniquely suitable environment for an RCT.*

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**FIGURE 1. Theory of Change for the Saturation+ (Saturation, Science, and Stories) Mass Media Campaign in Burkina Faso**

**INTERVENTIONS**

**Saturation**
- Maximize reach of messages by targeting popular stations in well-understood languages.
- Strengthen capacity of broadcast partners.
- Develop multi-issue campaign, allocating airtime to each message based on seasonality & est. no. of lives saved.
- Identify key behavior change barriers through formative research, present to creative team, & test all materials before & after broadcast.
- Recruit experienced broadcasters for creative training & editorial management.
- Recruit & train highly creative local scriptwriters familiar with culture of audience.

**Science**
- Develop formative research findings & pretest results into creative process to produce messages that resonate with the audience. The emotional climax of dramas reflects key barriers to behavior change.
- Integrate formative research with creative local scriptwriters familiar with culture of audience.

**Stories**
- Recruit & train highly creative local scriptwriters familiar with culture of audience.

**OUTCOMES**
- Mothers & entourage hear spots & modules repeatedly (i). Mothers maintain improved household health behaviors (ii).
- Mothers adopt healthy behaviors. (iii).
- Mothers maintain improved household health seeking behaviors (iv).

**IMPACT**
- Child mortality reduced (v)

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**Assumptions:**
- A. Capacity strengthening of broadcast partner sensures radio stations remain on air and strengthens stations’ relationships with audience, increasing station commitment to broadcast spots 10 times/day.
- B. Investment in recruitment, training, and management of a creative team will result in high-quality scripts and spots.
- C. Mothers lack knowledge about healthy household and treatment-seeking behaviors but are highly motivated to keep their children healthy and protect their children’s lives.
- D. Cultural beliefs, family hierarchies, and community structures will not prevent the adoption of healthy behaviors because messages broadcast will directly address these barriers to change. (For example, spots will encourage mothers’ entourage to facilitate healthy behaviors.)
- E. Enough women are able to access and travel to a health facility.
- F. Enough health facilities have sufficient service provision to meet increased demand and provide an adequate equality of care.

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**Ongoing monitoring and evaluation of project**

- Rationale:
  - a. Repeated exposure to spots leads to increased awareness, knowledge, and behaviors.*
  - b. Evidence indicates that increasing coverage of key health behaviors and interventions leads to reductions in child morbidity and mortality.†

**Indicators:**
- i. Broadcasting of spots monitored by independent “trackers.”
- ii. Cross-sectional surveys & qualitative research investigate whether women have heard radio spots & modules.
- iii. Baseline, midline, & endline surveys of reported household behaviors.
- iv. Baseline, midline, & endline surveys of reported health-seeking behaviors.
- v. Baseline & endline measurement of child mortality.

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* Rationale articulated in Hornik, 2002.5
† Sources: Lancet Child Survival Series 2003; Steinglass R, Cherian T, Vandelaer J, Klemm RD, Sequeira J. Development and use of the Lives Saved Tool (LiST): a model to estimate the impact of scaling up proven interventions on maternal, neonatal and child mortality. Int J Epid. 2011;40(2);519-520; Fox MJ, Martorell R, van den Broek N, Walker N. Technical inputs, enhancements and applications of the Lives Saved Tool (LiST). BMC Public Health. 2011;11 Suppl 3; and Lassi ZS, Salam RA, Das JK, Bhutta ZA. Essential interventions for maternal, newborn and child health: background and methodology. Reprod Health. 2014;11 Suppl 1:S1.
who can directly influence the primary audience, in this case, the husbands and the mothers-in-law).

Saturation broadcasting can be achieved by paying the market-leading radio and television stations for airtime, but our experience is that it is much easier and cheaper to achieve saturation broadcasting if the broadcast industry is involved as a core partner. Unlike advertising agencies or governments, broadcasters have production capacity and airtime, the two vital ingredients of a media campaign. In the majority of our campaigns, we have negotiated free airtime in exchange for on-the-job training (working with each team to produce live evening programs) and for production expenses; the opportunity to secure better skills and advantage within a competitive media environment is usually enough incentive for broadcasters to partner with us. Our experience elsewhere has been that both private and public media organizations have been very willing partners. This was certainly the case in Burkina Faso.

The simplest way to achieve high intensity is to use short (e.g., 60-second) spots, as exemplified by the advertising industry. This format allows frequent daily broadcasts, across all peak listening times. It also allows us to produce precise health messages across a diversity of languages. The spots use emotion, humor, and dramatic techniques such as suspense to persuade our target audience to change behaviors. In our Burkina Faso campaign, we broadcast a new spot every week, played at least 10 times per day, over 35 months (from March 2012 to January 2015).

Exposure through multiple channels is also associated with greater impact. In countries with sufficient television penetration and/or higher literacy levels, other communication channels would strengthen the impact of a campaign. Due to low television coverage in rural Burkina Faso, our campaign was broadcast on radio alone. However, we used multiple formats to deliver our messages on the radio.

To be effective, longer formats also need to reach audiences frequently. Throughout the campaign, we broadcast 2-hour interactive programs, 5 nights per week, on each of our 7 partner radio stations (one in each intervention zone), representing a total of 70 hours per week of live radio in 6 different languages. We therefore needed to devise a format that could deliver health messages, was cheap, could be broadcast daily, could be produced “live” (which costs a fraction of pre-produced radio) and yet could be controlled centrally. Producing a pre-recorded soap opera, for example, in 6 different languages would be expensive and logistically very difficult. So we created a system of self-contained drama “modules” that were written in French in the capital city, sent on USB keys through local transport companies to our partner radio stations, and improvised live by local actors on location in their own language within their 2-hour shows. These were followed by phone-ins to allow listeners to comment on the issues raised. The modules were around 10 minutes each, with the remainder of the 2-hour program taken up by news, music, and discussion. They were aired in the evening, which our research found to be the peak time for radio listening among our target audience. This program format works well in a fragmented media environment, which is becoming the norm in most developing countries. These longer dramas and interactive shows can add value by creating role models, demonstrating life skills, or allowing on-air dialogue with the public. They also help us to build relationships with partner stations and can thereby help to ensure that our spots are broadcast at the intensity required.

In Burkina Faso we used a system of broadcast monitoring to verify whether stations had played the spots as they had agreed, at the frequency required, and to allow swift remedial action if they had not (in our experience this was usually due to inefficiency or genuine technical problems). We hired two independent monitors or “trackers” in each radio station’s coverage area to record when our materials were broadcast, and we collected their results by telephone weekly: The radio stations were not aware of the identity of the monitors, nor were the two monitors aware of each other. Radio station compliance during the RCT was extremely high, with stations reliably broadcasting an average of at least 10 spots every day. Where feasible, radio programming software can also be used to monitor and verify spot broadcasting. Data on our broadcasting intensity, by health topic and by format, are presented in the companion midline results paper.

**Science**

Data and modelling should underpin the key aspects of campaign design. We use data in our campaigns in several ways. First, we use data to quantify the geographic coverage, audience size, and market share of different media channels in different parts of the country, at different times of day, and with different demographic groups. It is often difficult to obtain these data, but it is essential if resources are to be allocated correctly.
In Burkina Faso, for example, we conducted a customized survey to estimate the market share and audience penetration of each radio station. We also use data to prioritize which messages can save the most lives per dollar spent. For this analysis, we use data on the mortality risk of different diseases, their susceptibility to behavior change, current levels of behavioral compliance, and the availability of key medical services. Our modeling work brings these data together, allowing us to predict the impact on mortality of each target behavior (using the Lives Saved Tool [LiST]17) and to weight campaign messages so that those predicted to save the most lives can be broadcast most frequently (Table).

For our campaign in Burkina Faso, where our primary aim was to reduce child mortality, we developed a message calendar based on the predicted impact of each behavioral message on under-5 lives saved. Our calendar also took into account seasonality, so that, for example, messages on seeking treatment for malaria were broadcast more frequently during the months when malaria transmission is typically highest. Each week of the year was assigned a message theme for spots; the theme of the longer modules changed daily but followed the same weighting as the spots (Figure 2).

The independent evaluation of our campaign included a baseline and a midline (as well as an endline) behavioral survey of 5,000 mothers of a child less than 5 years old, after 20 months of broadcasting. Using the midline results, we revised our message calendar to maximize the impact of the remaining months of the intervention. The revised message weightings were calculated by taking into account several factors, including the impact the campaign had already had on each behavior (from baseline to midline), the broadcast dose for each message (from baseline to midline), and the predicted impact of each behavior for the remainder of the campaign (from midline to endline, modeled using LiST). We suggest that impact data collected during a campaign (when available) should be used to adjust message weighting to optimize impact.

Message quality is also crucial, and qualitative research is a key element to ensuring this quality. Qualitative research includes formative research (to identify barriers to behavior change), pretesting of radio spots (to judge comprehension and appeal), and feedback research (to find out whether people have heard and understood the messages and what the remaining obstacles to behavior change are). The key, as argued below, is to link findings from such qualitative research as tightly as possible to the creative process.

We employed a team of in-house qualitative researchers, who conducted formative research at the start of our campaign. The research consisted of semi-structured individual interviews and focus group discussions with mothers and fathers of young children and influential members of their entourage (spouses, grandparents, co-wives), as well as individual interviews with key informants such as religious leaders, district medical chiefs, health center staff, midwives, and community health workers. For each health behavior, we synthesized this research into a 1-page message brief that presented the key behaviors to promote including:

- Contextual information about the behavior, including Ministry of Health policy and guidelines, and information drawn from guidance from the United Nations Children’s Fund (UNICEF) and the World Health Organization (WHO)
- Analysis of key decision makers within the target audience for the specified behavior

### Table

Lives Saved Model Predictions Used to Weight Messaging When Designing the Burkina Faso Radio Campaign

| Theme of Messages                      | No. of Lives Saved According to Modeling | Approximate No. of Months of Broadcasting |
|---------------------------------------|-----------------------------------------|------------------------------------------|
| ORT                                   | 3000+                                   | 6                                        |
| Malaria                               | 3000+                                   | 7                                        |
| Breastfeeding                         | 2000+                                   | 5                                        |
| WASH                                  | 2000+                                   | 4                                        |
| Pneumonia                             | 1000–1500                               | 4                                        |
| Extra care for low birth weight infants | 1000–1500                              | 3                                        |
| Complementary feeding                 | 500–1000                                | 3                                        |
| Maternal health                       | 500–1000                                | 3                                        |

Abbreviations: ORT, oral rehydration therapy; WASH, water, sanitation, and hygiene.

* Number of lives predicted to be saved if the campaign were implemented at national scale (not in the RCT intervention zones alone). These were the original model predictions at the start of the campaign. Message weightings were altered further during the course of the campaign.
Context-specific barriers to behavior change

An example message brief is provided in Box 2. We have found that reducing formative research down to a 1-page message brief for each target behavior is a critically important step in our creative process as it makes the research more accessible to the script writing team and helps to bridge the gap between research and creativity. Our team of scriptwriters drew on these message briefs to create dozens of scripts. The best of these went through a validation process involving creative staff in both Burkina Faso and London before being produced. We pretested the spots (for clarity, popularity, and understanding) in multiple languages using focus groups before selecting the spots and distributing them for broadcast. Pretesting is essential for ensuring messages are well received by the target audience. For example, we pretested a spot in which a character impersonating a diarrhea germ had a discussion with a baby. Our target audience could not grasp the concept of bacteria/germs nor of young babies talking, so they did not understand this spot. Although they seemed to comprehend the health message within the spot well, it was rejected after the pretest because the confusion around the story would detract from the take-home behavior. In contrast, we pretested a spot that featured a beneficial “genie” telling a mother and grandmother who are about to press and discard the mother’s colostrum that this first milk is full of nutrition and protects the newborn against illness. This spot was accepted at pretesting, as it was a better fit to the Burkinabé context, in which people are very familiar with stories of genies.

Our qualitative researchers also conducted post-broadcast feedback research using focus groups to provide an understanding of audience reactions to our messages and to find out whether and why people who hear our messages have changed their behaviors (or not). After each trip, our researchers fed back their findings to the creative team, forming a continual feedback loop. We used the information gathered through pretesting and feedback research to continually refine our message briefs and to tailor our messages to target existing barriers to behavior change.

Our qualitative research team also helped us to monitor the availability of commodities to ensure we were generating demand that was met by sufficient supply. Throughout the RCT, we maintained strong links with the Ministry of Health, WHO, UNICEF, and other organizations working in Burkina Faso to help us track supply-side initiatives and to ensure that our messages were consistent with government policies. Our research team was able to provide insight into the availability and quality of services available on the ground through their visits to health centers and by liaising with district medical officers. This was particularly important for the effectiveness of our treatment-seeking messages, which were service-dependent. Although our program comprised a demand-side intervention only, had we found there were significant, frequent stock-outs of the essential medicines required to treat serious childhood illnesses, we might have needed to reconsider our approach to messages promoting service-dependent behaviors. Supply-side constraints will need to be taken into consideration when interpreting the generalizability of this RCT’s findings to other settings. We have taken

| January 2013 | February 2013 | March 2013 | April 2013 | May 2013 | June 2013 | July 2013 | August 2013 |
|--------------|--------------|------------|------------|----------|-----------|-----------|-------------|
| PNEUM        | CF           | MAL        | ORT        | WASH     | BREAST    | MH        | ORT         | CF          | LBW       | MAL       | WASH     | ORT       | MH        | PNEUM      | WASH       |

Key: BREAST, early and exclusive breastfeeding; CF, complementary feeding; LBW, care of low birth weight infants; MAL, malaria prevention and treatment seeking; MH, maternal health: antenatal care attendance and delivery in a health facility; ORT, treatment seeking for diarrhea and use of oral rehydration solution and increased liquids; PNEUM, seeking treatment for pneumonia symptoms; WASH, water, sanitation, and hygiene.
BOX 2. Example of a One-Page Message Brief on Exclusive Breastfeeding From the Burkina Faso Radio Campaign

Breastfeed exclusively for the first six months of life

Behavior to promote

All mothers should breastfeed their babies exclusively for the first six months of life. The secret to having enough breast milk is to exclusively breastfeed. If you do not have enough milk for your baby, breastfeed more frequently and you will produce more milk. If you add other drinks/concoctions or food, including water, to your baby’s diet this will reduce your milk production.

Reasons

Breast milk production is dependent upon frequent breastfeeding. Interrupting breastfeeding by giving other liquids to a baby will decrease production of breast milk. Breast milk is the best and only food and the best and only drink that an infant needs for the first six months of life, even in hot and dry climates. Through breast milk, the baby receives defenses against diseases such as diarrhea and respiratory infections. Adding other foods or liquids can affect the health of a baby during the first six months of life, because these liquids or foods can be contaminated, which may cause diarrhea.

Barriers to behavior change

Sometimes mothers who breastfeed their babies are concerned when the baby wants to nurse more often than usual. They can attach this behavior to a lack of breast milk. A baby may want to nurse more often for several reasons: perhaps a phase of intense growth is happening; the baby might just be more hungry/thirsty; during an episode of illness babies may nurse more often; babies also may nurse more often when teething; or the baby may be in need of more comfort. A mother may interpret the cries of a baby as signs of hunger, which is often the case, but a baby may also cry because he is tired, or because he wants to burp or pass wind.

Mothers should understand that they can produce enough milk by breastfeeding more frequently. If they believe that their baby needs other liquids or supplementary foods, and they give these to their baby, they may reduce their milk production because if the baby breastfeeds less frequently, the mother will produce less milk. Other liquids/brews or foods do not help the baby, nor the mother, because these will increase the baby’s risk of illness and the mother will then have to spend even more time taking care of a sick baby.

Many people think that exclusive breastfeeding is not possible because they believe that breast milk alone is not a sufficient source of nutrition or water for babies. Because of this they add other food supplements or water to the baby’s diet. Water is given because they fear that a baby will “dry up” in Burkina Faso’s extreme heat. People compare breast milk to solid foods that adults eat and believe that a baby will be more thirsty because of the fat content of breast milk. Breast milk is not considered a source of water for the baby.

Decision and influencers

Mothers-in-law or aunts accompany expectant mothers before and after delivery. They have a strong influence on exclusive breastfeeding as they will advise mothers to add water, herbal potions, or other foods during the first six months. Like many others they also believe that it is beneficial to give babies “welcome water” and/or other liquids that stimulate the newborn’s appetite. These practices exist in most of Burkina Faso’s ethnic groups. The mother’s entourage can help by not insisting on the mother giving additional liquids or foods to a crying baby, but by giving the mother time to nurse until the baby is satisfied. Also the entourage has a great responsibility to ensure that pregnant women and mothers are well nourished.

Factors contributing to behavior change

Women attach great importance to breastfeeding. Children under six months are usually in close physical proximity to their mother (on their back) and thus breastfeeding is readily accessible and available. So, mothers can feed their baby when they need to and until the baby is done.

Water is the main component of breast milk (88%); it is particularly hydrating and quenches thirst. The other components (12%) are: carbohydrates, lipids, proteins, and micronutrients. At the start of feeding, breast milk contains a lot of water and minerals to hydrate. In the middle of a feed, proteins and lipids increase in quantity. At the end of each feed, fat is more concentrated in the milk and gives the baby a feeling of satiety. This signals the end of feeding for the baby. That is why it is necessary to breastfeed the baby for long enough at each breast.

Infants younger than six months are usually in close proximity to their mother. The infants are carried on their mothers’ backs and thus breast milk is immediately accessible and available. Many mothers place great emphasis on breastfeeding and breastfeed their babies up to two years of age. Most children under three years of age are breastfed.
supply-side availability into account in our scientific model, using the LiST tool to predict the impact of mass media campaigns on child morality in other settings.

An independent economic evaluation of the trial (led by LSHTM) will estimate the cost-effectiveness of our intervention and will provide further insight into the costs of implementation, household costs from increased health service use, and health system costs associated with increased care seeking.

As mentioned previously, details of the independent evaluation of this intervention on child mortality will be published separately. In general, since randomization of media interventions is rarely possible, we advocate the use of time-series or other quasi-experimental study designs to evaluate media campaigns and enable attribution of impact. It is important when designing an evaluation to carefully consider which outcomes will be measured, using health outcomes where feasible, and measuring knowledge, attitudes, and behavioral outcomes as indicators along the causal pathway of behavioral change.

Stories

Stories have resonated with human beings for thousands of years. We are drawn to drama in ways in which we are not drawn to data or facts. Stories allow us to identify emotionally with characters, and emotions—such as fear, status, and guilt—are powerful determinants of behavior. But how do stories work?

Creativity is often the “black box” in theoretical discussions: it is difficult to define or measure. Nevertheless it is possible to use systems to understand and then enhance the creative process. Understanding the structure of stories is important.

Virtually every Hollywood film conforms to a 3-act structure: Act I in which characters are given goals; Act II in which obstacles are thrown in front of the characters; and Act III in which the characters either change their goals or overcome the obstacles. This structure mimics life itself for most of us and also mimics the process of behavior change. The emotional turning point of most stories is at the end of Act II, the moment of decision for the main character when s/he must choose between competing emotions. Formative research, when conducted with this in mind, can therefore go further than simply identifying obstacles to behavior change (e.g., cost, inconvenience). It can identify the most important emotion (e.g., fear or guilt) that prevents people from complying and the most important emotion (e.g., love) that motivates people to comply. The conflict between those two emotions can then be made the centerpiece of a story’s dramatic climax at the end of Act II.

Choices about how we behave are often made in response to deep underlying human impulses to be accepted by others, to fit in with our peers, and to imitate people we respect. In Burkina Faso, both our spots and our longer-format programs were based on engaging stories and characters that reached out to the audience, helping them to feel empathy for the characters and their situations. Our stories aimed to move audiences to examine the health choices made in their own lives. Once people are thinking about making changes, the stories then provide concrete ideas about how to do that. Box 3 provides an example spot on the theme of exclusive breastfeeding.

Stories for public health programming must be driven by research, requiring the creative and research teams to work in close harmony—often a formidable challenge given that creative writers typically rely on their own judgment and imagination to create stories. This practical challenge is a microcosm of the wider challenge of bringing science and mass media together. One practical tool to enable collaboration is to develop succinct, 1-page message briefs that summarize the formative research, forming the foundation for the scriptwriters’ work. Another method is to send scriptwriters to help lead focus groups in the field, while also involving qualitative researchers in the radio production process. In Burkina Faso, we found that field visits motivated scriptwriters, provided new inspiration and ideas, and gave them valuable insight into the realities of rural Burkinabé life.

To maximize creativity and for quality assurance, we use multilevel systems of editorial control whereby, for example, 30 ideas per month are reduced to 6 for pretesting and to 4 for production. It is important that after pretesting, as well as after broadcast, qualitative research is fed back to scriptwriters. This feedback loop ensures an evolving creative process that continually responds to the target audience.

Grassroots recruitment of local scriptwriters is essential to develop a creative team that understands the language, context, and culture of the target audience. Rather than try to outbid other
NGOs for the existing talent pool, in Burkina Faso we advertised in university campuses, bars, and public meeting places and asked applicants to write and submit a story. This approach resulted in 600+ applications and, in our experience, yielded higher caliber staff than working through the existing NGO or media industries. We reviewed more than 600 scripts, interviewed 80 people, and hired 13 as scriptwriters. The hired scriptwriters had a diverse range of previous employment experience, ranging from teachers to a security guard, and originated from 8 regions of the country. Once hired, the team initially received training from experienced creative producers, and skills development was then sustained through weekly creative workshops.

LESSONS LEARNED AND RECOMMENDATIONS FOR SCALE-UP

A crucial but too often neglected task for any implementing organization is describing in detail the many lessons learned during the trial of an intervention and explaining how these can be addressed to enable scale-up. There has been a tendency for public health research to overlook the importance of reporting in detail exactly how and under which circumstances interventions work. Testing the efficacy of an intervention in controlled trial conditions does not provide policy makers with sufficient information to guide their investments under the complexities of real-world conditions. Here, we describe the key lessons learned during our campaign in Burkina Faso, along with suggested adaptations and recommendations for rolling it out at a national scale.

Cash payments for airtime are not necessarily the most useful incentives to develop partnerships with radio and television stations. Likewise, providing training and capacity building in exchange for airtime payments may not be feasible in some settings. We have found in Burkina Faso that solving the frequent energy problems that affect community radio stations—frequent power cuts, broken generators, and rising costs of energy supplies—by installing solar power is a more powerful incentive to ensure that stations remain committed to a campaign. Logistically it would not be possible to install solar power immediately in every community radio station involved in national scale-up. It would, however, be feasible to commit to installing solar power in all stations over perhaps the first 12 months of a national program. While this approach imposes a large upfront cost during the early stages of a campaign, it actually offers significant efficiency savings over paying for airtime. We believe that this would apply to those countries across Africa that have primarily locally based radio markets and where similar difficulties with energy supplies hamper the implementation of high-frequency saturation broadcasting campaigns.

The primary purpose of our campaign was to reduce child mortality, so all operational decisions

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BOX 3. An Example of a Short Spot About Exclusive Breastfeeding From the Burkina Faso Radio Campaign

“Saved by his Tears”

[sounds of baby crying each time his grandmother speaks, and laughing each time his mother speaks]

MOTHER-IN-LAW: [plaintive] Your baby is four months old now. His lips are dry. It's hot. Let me give him some water. [The cries of the baby get louder.] You see he's crying!

DAUGHTER-IN-LAW: Mother-in-law, I’m going to breastfeed him. There is enough water in my milk to quench his thirst; it also has all the nutrients he needs to grow strong until he’s six months. [baby's laughter] Other liquids could harm his health; they could put germs in his belly.

MOTHER-IN-LAW: No decoctions or water until he’s six months old! Impossible! I’m going to give him some water. [louder crying from baby] But ... it's strange how he's crying ... !

DAUGHTER-IN-LAW: Mother-in-law, compare my baby to Fanta's baby who is always sick. Fanta gives her baby other liquids and that makes him ill. Let my child drink my breast milk and you’ll see he’ll never be thirsty. [sounds of baby sucking followed by baby's laughter]

MOTHER-IN-LAW: [embarrassed] You’re right because your baby is healthy and growing up strong. I’m going to suggest to Fanta she does the same as you. That's what your baby is trying to tell me with his laughter. [more laughter from baby]
were designed to maximize our impact on that outcome rather than specifically targeted at building capacity. Despite capacity building not being our main objective, we built the capacity of radio station partners in several ways, through the provision of equipment, staff training, and technical support. Key lessons learned were the importance of maintaining close relationships with station managers and of regular site visits. This was crucial in ensuring that we were made aware of staff changes and power or equipment problems as soon as they occurred, thus preempting the danger of a station going off air.

Another tool to motivate media partners is providing them with impact data specific to their audience. Being able to feed back information to radio stations, showing them how their efforts have improved health outcomes in their area, is a powerful motivator. Furthermore, we have provided basic training in how this information can be used by the stations themselves to demonstrate their effect and sell their airtime to others, in order to build capacity and thrive in a competitive media market.

Taking a community radio intervention to scale in multilingual countries will inevitably require the translation and broadcasting of multiple messages. In Burkina Faso, for example, national coverage can be achieved by increasing our number of community radio station partners from 7 in the RCT to 29, taking the number of languages required from 6 to 12. Given this level of linguistic complexity, it is highly unlikely that qualitative research and pretesting of spots can be carried out in all languages. Despite this, we emphasize the importance of conducting formative and feedback research in as many languages and as many regions as is feasible. Wherever possible, we advocate training scriptwriters who speak local languages to assist the qualitative research team with pretesting and feedback research.

Financial constraints may prohibit the possibility of maintaining both spots and interactive program formats when scaling-up this intervention. The constituents of a Saturation+ media campaign will vary depending on available funding and a country’s media landscape. What we have tested in Burkina Faso was specifically designed and adapted to the media context there. Results from the midline quantitative evaluation published in the companion paper showed some suggestions of a positive correlation between exposure to the radio spots and behavioral outcomes (each additional week of broadcasting led to approximately a 1% additional behavior change). There was no evidence of this dose-response relationship with exposure to longer-format programs. Our qualitative research also found that although people reported learning from both program formats, they tended to express a preference for spots, as they are easy to understand, are concise, and are frequently heard, and they depict captivating stories. Additional studies specifically comparing media formats would be required to definitively test which are the most effective channels for changing each of our target behaviors.

Based on the available research and the exposure theory that underpins our Saturation+ approach, we consider spots to be the most important format to retain when scaling-up our intervention in Burkina Faso. Spots ensure that our messages are the most effective channels for changing each of our target behaviors. In certain contexts, such as those recovering from conflict, more significant time, effort, and investment in capacity building of media partners may be required, in order for radio and television stations to broadcast at the level of intensity that the Saturation+ approach requires. Supply-side availability and quality could also affect the feasibility and impact of adopting our approach in other settings. Nonetheless, when we model the potential impact of national campaigns, we are able to adjust for and take account of variation in media penetration and service availability between different countries.
Despite these limitations, the core principles that underlie the Saturation+ approach should still be applicable to most media campaigns and across different settings.

**CONCLUSION**

We have described the mass media intervention in Burkina Faso that was tested using a unique cluster RCT design, including the Saturation+ principles and theory of change underpinning our approach, the campaign design and execution, our creative process, and the generalizable lessons learned. We have considered how best to adapt and apply this intervention at national scale. We recommend using short spot formats that can be repeated multiple times throughout the day to achieve high-intensity saturation broadcasting. We also advocate investment in sustainable energy supplies for partner community radio stations rather than paying for airtime. Whatever the efficacy outcome of the trial, for its findings to be useful to implementers and policy makers alike, it is important that we have shared these details about exactly what the intervention consisted of, how it was implemented, and what did and did not work. Much emphasis is often (rightly) placed on the importance of robust impact evaluation of public health interventions. We have addressed this by conducting the RCT in Burkina Faso, the most rigorous evaluation of a mass media campaign in a developing country. The science of delivery warrants equivalent emphasis if results are to be replicable and actionable.

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Behavior Change After 20 Months of a Radio Campaign Addressing Key Lifesaving Family Behaviors for Child Survival: Midline Results From a Cluster Randomized Trial in Rural Burkina Faso

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The radio campaign reached a high proportion of mothers, but the impact on self-reported behaviors at midline was mixed. Some reported episodic behaviors such as care seeking for diarrhea and obtaining treatment for fast/difficult breathing improved more in intervention than control areas, but there was little or no difference between areas in reported habitual behaviors, such as exclusive breastfeeding, complementary feeding, hand washing with soap, and use of bed nets.

ABSTRACT

Background: In Burkina Faso, a comprehensive 35-month radio campaign addressed key, multiple family behaviors for improving under-5 child survival and was evaluated using a repeated cross-sectional, cluster randomized design. The primary outcome of the trial was postneonatal under-5 child mortality. This paper reports on behavior change achieved at midline.

Method: Fourteen community radio stations in 14 geographic areas were selected based on their high listenership. Seven areas were randomly allocated to receive the intervention while the other 7 areas served as controls. The campaign was launched in March 2012. Cross-sectional surveys of about 5,000 mothers of under-5 children, living in villages close to the radio stations, were conducted at baseline (from December 2011 to February 2012) and at midline (in November 2013), after 20 months of campaigning. Statistical analyses were based on cluster-level summaries using a difference-in-difference (DiD) approach and adjusted for imbalances between arms at baseline. In addition, routine health facility data were analyzed for evidence of changes in health facility utilization.

Results: At midline, 75% of women in the intervention arm reported recognizing radio spots from the campaign. There was some evidence of the campaign having positive effects on care seeking for diarrhea (adjusted DiD, 17.5 percentage points; 95% confidence interval [CI], 2.5 to 32.5; \( P = .03 \)), antibiotic treatment for fast/difficult breathing (adjusted DiD, 29.6 percentage points; 95% CI, 3.5 to 55.7; \( P = .03 \)), and saving money during pregnancy (adjusted DiD, 12.8 percentage points; 95% CI, 1.4 to 24.2; \( P = .03 \)). For other target behaviors, there was little or no evidence of an impact of the campaign after adjustment for baseline imbalances and confounding factors. There was weak evidence of a positive correlation between the intensity of broadcasting of messages and reported changes in target behaviors.

Routine health facility data were consistent with a greater increase in the intervention arm than in the control arm in all-cause under-5 consultations (33% versus 17%, respectively), but the difference was not statistically significant (\( P = .40 \)).

Conclusion: The radio campaign reached a high proportion of the primary target population, but the evidence for an impact on key child survival-related behaviors at midline was mixed.

BACKGROUND

The number of under-5 deaths worldwide has been reduced by 50%, from 12.7 million in 1990 to 6.3 million in 2013.1 Still, under-5 mortality risk remained above the Millennium Development Goal (MDG) target.
Behavior Change After a Radio Campaign in Burkina Faso

An innovative cluster randomized trial investigated whether a mass media campaign can change child survival-related behaviors at scale.

In Burkina Faso, Development Media International (DMI) implemented a 35-month community radio campaign, using the Saturation+ methodology, to address key family behaviors for improving under-5 child survival. An overview of the Saturation+ methodology is given elsewhere,11 and further details about the methodology and lessons learned during implementation of the DMI radio campaign are provided in a companion article in Global Health: Science and Practice.12 The campaign was evaluated using a repeated cross-sectional, cluster randomized design. Community radio stations were chosen as the delivery channel for the campaign as they are widely listened to in those rural areas where child mortality is highest and because, with their limited transmission range, a randomized design was possible. The use of television, which is broadcast nationally, would have made a randomized design difficult, if not impossible.

The primary objective of the trial was to investigate whether the Saturation+ approach to designing and implementing a mass media campaign can change behaviors on a scale large enough to result in measurable reductions in all-cause, postneonatal under-5 child mortality. To this end, household surveys were conducted in all clusters at 3 time points: at baseline, at midline, and at endline. At midline, the objective of the trial was to measure coverage of the campaign and to investigate changes in self-reported behavior achieved after 20 months of campaigning. The purpose of this article is to report on the midline results. Mortality reduction as well as behavior change achieved at endline will be reported separately when results are available.

METHODS

Setting

The population of Burkina Faso was estimated at 15.7 million people in 2010, of whom 77% lived in rural areas.13 Since 1990, the under-5 mortality rate has declined from an estimated 202 deaths per 1,000 live births to 186 deaths per 1,000 live births in 2000 and to 98 deaths per 1,000 live births in 2013.1 In 2013, malaria, pneumonia, and diarrhea accounted for an estimated 23%, 15%, and 10% of under-5 child deaths, respectively.14

The government is the main health service provider, and the country is organized into 70 health districts, each with 1 district hospital and 10 or more primary health facilities (Centre de Santé et de Promotion Sociale, or CSPS). The Integrated Management of Childhood Illness (IMCI) strategy was introduced in 2003.15 Since 2002, free antenatal care (ANC) has been offered in public health facilities, and in 2006 subsidies were introduced for child birth and emergency obstetric care.16 In 2005, artemisinin-based combination therapy (ACT) replaced chloroquine as the recommended treatment for uncomplicated malaria, and in 2010 ACT was introduced at the community level.17

Cluster Identification, Definition, and Randomization

In early 2011, we identified 19 distinct geographical areas using digital terrain maps and an engineer’s
modeling together with on-the-ground mapping of radio signal strength. Each geographical area contained one or more community FM radio stations, with little or no overlap of radio signal between areas.

We then performed a cross-sectional survey in each geographic area to assess women’s radio listenership. Fourteen areas with high levels of reported listenership (above 60% of women listening to the radio in the past week) were selected for inclusion in the trial, and, within each area, the radio station with the highest listenership was chosen as a potential partner to implement the campaign. High radio listenership was a key factor for the power of the trial given our assumption that the effect of the campaign would be directly proportional to the number of women listening to the radio.

Seven areas were then randomly allocated to receive the intervention and 7 other areas to serve as controls using pair-matched randomization based on geography and radio penetration rate (Figure 1). Specifically, we defined 3 radio listenership strata (from 61% to 70%, from 71% to 80%, and above 80%), and within each stratum, we paired the areas geographically closest to each other, one of which was randomly assigned to receive the intervention. Randomization was performed by SS and SC (both with the London School of Hygiene and Tropical Medicine), independently of DMI. Due to time constraints with implementing the campaign, randomization was performed before the baseline survey (see below) and therefore could not make use of behavioral and mortality data from the baseline survey. After randomization, DMI began formative qualitative research and capacity building with radio stations in the intervention clusters while the baseline survey took place. Broadcasting started at the end of the baseline survey.

For the purpose of the evaluation, the trial population in each area was restricted to the communities with limited access to television, who would consequently be more likely to listen to the radio. We therefore excluded the population living in the electricity grid, i.e., those living in the towns where the selected control and intervention community radio stations were located, as well as those living in villages within 5 km of the

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**FIGURE 1.** Pair-Matched Randomization of Clusters Based on Geography and Radio Penetration Rate

Adapted from Wikipedia.
Behavior Change After a Radio Campaign in Burkina Faso

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The radio campaign in Burkina Faso broadcast both short spots and longer dramas.

town, in villages with electricity, or in villages with a population above 5,000 inhabitants (and likely to be a priority for the national electrification program). Villages with poor radio signal strength were also excluded.

Using the last national census, we then identified sufficient eligible villages to provide a total population of about 40,000 inhabitants per trial cluster. The average number of villages per cluster was 34 and 29 in the control and intervention arms, respectively. With the exception of Kantchari intervention cluster (toward the East), the town with the community radio station was also the location of the regional or district hospital. The trial population also had access to primary health facilities in villages across each area. The trial was designed to detect, with a statistical power of 80%, a 20% reduction in all-cause, postneonatal under-5 child mortality.

**Brief Description of the Intervention**

DMI’s radio campaign launched in March 2012 and ended in January 2015. Women of reproductive age and caregivers of children less than 5 years old were the primary target of the campaign, which covered a wide range of behaviors along the continuum of care (Table 1). A full description of the theory of change—the Saturation + methodology—used to design the campaign and its implementation is provided elsewhere. Briefly, short spots of 1-minute duration were broadcast in the predominant local language approximately 10 times per day, and interactive long-format programs of 2-hours’ duration were broadcast 5 days per week. The spots were designed to be entertaining and informative and were developed and pretested based on qualitative formative research. Behaviors covered by spots changed weekly, while the long-format program changed daily, covering 2 behaviors a day.

At the time of the midline survey, no radio campaigns of comparable intensity were being broadcast in any of the clusters included in the trial. Various nutrition and sanitation programs were operating in similar numbers of clusters per arm, and community case management for malaria, pneumonia, and diarrhea was supported by the United Nations Children’s Fund (UNICEF) in one of the intervention clusters and one of the control clusters (Table 2).

**Behavioral Surveys**

Cross-sectional surveys were performed in all clusters at 3 time points: at baseline, from December 2011 to February 2012, before the launch of the campaign; at midline, in November 2013, after 20 months of campaigning; and at endline, between November 2014 and April 2015, at the end of the campaign. (Endline results will be reported separately.)

**Sampling**

At baseline, the behavioral survey was part of a larger survey conducted to estimate under-5 child mortality during the 2 years prior to the intervention. Due to cost constraints, the baseline survey was conducted in a simple random sample of half the villages included in each cluster. The average number of villages sampled per cluster were 17 and 15 in the control and intervention arms, respectively, with average populations per village of 1,359 inhabitants (range: 55 to 4,730) and 1,430 inhabitants (range: 83 to 4,702), respectively. In the sampled villages, a census was performed of all compounds to identify all women aged 15 to 49 years old and to collect pregnancy history data. The behavioral questionnaire was then addressed to a random subsample of about 5,000 mothers with at least one under-5 child living with them.

At midline, about 5,000 mothers were selected using a 2-stage sampling procedure. In each cluster, 9 villages were first drawn with probability proportional to size from villages surveyed at baseline. In each village, 100 women were then selected by simple random sampling using the census data collected at baseline, and the first 40 eligible and available women were interviewed.

The sample size of 5,000 mothers at each survey was calculated assuming a design effect of 2 with a view to providing an absolute precision of ±3% or better for behaviors relating to all children. The expected precision for behaviors related to childhood illness was ±6% for fever or diarrhea and ±10% for fast or difficult breathing.

**Questionnaires**

At baseline, a short interview with the household head addressed socioeconomic status and radio ownership. Interviews with women addressed their basic demographic characteristics, radio listenership, and family behaviors of relevance to child survival. Questions regarding maternal health referred to the last pregnancy of more than 6 months’ duration, and those regarding newborn health referred to the last live birth. Questions regarding nutrition, health care seeking...
TABLE 1. Target Behaviors and Broadcasting Intensity Up to the Month Preceding the Midline Survey (October 2013)

| Target Behaviors                                      | No. of Weeks for Short Spots | No. of Long-Format Modules |
|--------------------------------------------------------|------------------------------|---------------------------|
| Maternal health                                        |                              |                           |
| 4 or more ANC visits                                   | 3                            | 32                        |
| Saving money during pregnancy                          | 3                            | 32                        |
| Health facility delivery                               | 5                            | 25                        |
| Newborn health                                         |                              |                           |
| Breastfeeding initiation within 1 hour after birth      | 6                            | 25                        |
| First bath delayed for 24 hours or more after birth in low birth weight infants | 1                            | 7                         |
| Child nutrition                                        |                              |                           |
| Exclusive breastfeeding in 0- to 5-month-old children   | 5                            | 51                        |
| Complementary feeding in 6- to 11-month-old children   | 4                            | 29                        |
| Growth monitoring in 0- to 23-month-old children        | 4                            | 20                        |
| Health care seeking for childhood illnesses            |                              |                           |
| Health care seeking for fever                          | 10                           | 41                        |
| Health care seeking for pneumonia                      | 7                            | 43                        |
| Health care seeking for diarrhea                       | 12                           | 79                        |
| Diarrhea home treatment                                |                              |                           |
| ORS or increase in fluids for diarrhea                  | 12                           | 79                        |
| Bed net use                                            |                              |                           |
| Bed net use among under-5 children and pregnant women  | 6                            | 85                        |
| Sanitation                                             |                              |                           |
| Household latrine ownership                            | 2                            | 68                        |
| Safe disposal of children’s stool                       | 3                            | 68                        |
| Hand washing with soap                                 | 8                            | 55                        |

Abbreviations: ANC, antenatal care; ORS, oral rehydration solution.

Behavior Change After a Radio Campaign in Burkina Faso

for childhood illnesses, bed net use, and sanitation applied to the youngest child less than 5 years old. Illnesses were recorded using a recall period of 2 weeks preceding the interview.

At midline, socioeconomic status was not reassessed, and interviews with women used the same baseline questionnaire but with additional questions on radio ownership and recognition of the campaign. Spots broadcast in the last 2 weeks of October were played at the end of the interview, and women were asked whether they had listened to the long-format program by referring to its title. In the control clusters, the same method of recall was used with spots, and the title of the long-format program broadcast in the closest intervention cluster with the same language was mentioned. Interviews were performed using Trimble Juno SB Personal Digital
Assistants (PDA). Quality of data collection was monitored regularly, and repeat interviews were requested in cases of missing and/or inconsistent responses.

Routine Health Facility Data
Routine health facility data were obtained to complement self-reported data on service-dependent behaviors. The “Direction Générale des Etudes et des Statistiques Sanitaires” (DGESS) of the Ministry of Health of Burkina Faso provided monthly absolute numbers of pregnant women attending ANC, health facility deliveries, and all-cause under-5 child consultations in primary health facilities located in the trial clusters for 2011 and 2013.

Analysis
Change From Baseline in Self-Reported Behaviors
Analyses were performed on cluster-level summaries using a difference-in-difference (DiD) approach. With fewer than about 15 clusters per arm, cluster-level analyses are preferable to methods based on individual-level data. While generalized estimating equations (GEE) and random effects models have good asymptotic properties, they may not be robust when the number of clusters is small. The GEE approach...

| Cluster          | Nutrition        | Sanitation | Community Case Management |
|------------------|------------------|------------|--------------------------|
| **Intervention clusters** |                  |            |                          |
| Banfora          | El Mundo         | –          | –                        |
| Bogande          | NUTRIFASO program; GRET; Action Contre la Faim (ACF); Programme Alimentaire Modial (PAM) | SaniFaso | –                        |
| Djibo            | Croix Rouge (Red Cross) | Oxfam | –                        |
| Kantchari        | ACF; PAM         | ACF | –                        |
| Ouahigouya       | Terre des Hommes | –          | UNICEF                   |
| Sapouy           | –                | –          | –                        |
| Solenzo          | –                | –          | –                        |
| **Control clusters** |                  |            |                          |
| Boromo           | –                | SaniFaso program; WaterAid | –                        |
| Gayeri           | NUTRIFASO program; PAM | SaniFaso program | –                        |
| Kongoussi        | The Hunger Project | Plan International | UNICEF                   |
| Koudougou        | PAM              | –          | –                        |
| Nouna            | UNICEF           | –          | –                        |
| Po               | –                | –          | –                        |
| Pouytenga        | –                | Plan International | –                        |
tends to result in inflated type I errors in such situations, while the distributional assumptions of random effects models are difficult to verify without a large number of clusters.

For each target behavior (Table 1), in each cluster, the reported prevalence was estimated at baseline and midline, and the difference in prevalence between surveys calculated. The campaign began broadcasting in March 2012, so analyses of maternal and newborn-related behaviors at midline were restricted to pregnancies ending after June 2012 (thus allowing for at least 3 months’ exposure to the campaign). Linear regression was used to regress cluster-level differences in prevalence between surveys on the cluster-level baseline prevalence and the intervention status of clusters (intervention/control). The coefficient of the intervention variable thus provided an estimate of the DiD. Two-sided t-tests were performed to test the null hypothesis of no intervention effect. Adjustment for cluster-level baseline prevalence was used to account for the phenomenon of regression to the mean. In the absence of accurate estimates of the intraclass correlation coefficient, weighted analyses may be less efficient than unweighted analyses. All clusters were therefore given equal weight in the analysis, although the effective sample size in each cluster varied for behaviors applying to a subsample of women and their children (e.g., health care seeking and treatment). The matching procedure used for randomization was ignored as recommended for trials with fewer than 10 clusters per arm.

At midline, a third of women in the Gayeri control cluster (North-East) reported listening to the campaign’s radio station partner in the Bogande intervention cluster (Figure 1). All analyses were performed both on an intention-to-treat and per-protocol basis, the latter excluding all women interviewed in villages where contamination occurred.

Adjustment for Confounder Score
At baseline, the mean postneonatal under-5 mortality risk during the 2 years preceding the intervention was estimated at 113.1 per 1,000 children in the intervention arm versus 84.1 per 1,000 children in the control arm, a risk difference of 29.0 deaths per 1,000 children. To control for imbalance between arms, a confounder score was developed and used to obtain adjusted DiD estimates. Three covariates, particularly imbalanced between arms at baseline and expected to predict mortality, were combined using principal components analysis to produce a single cluster-level summary confounder score. These 3 covariates were the mean distance to the capital, as a proxy for general level of development (158 km versus 232 km in the control and intervention arms, respectively); the median distance to the closest health facility (2.5 km versus 6.3 km, respectively); and the baseline health facility delivery prevalence (81.8% versus 56.0%, respectively). After controlling for the confounder score, the mortality risk difference between arms at baseline was reduced from 29.0 to 4.1 per 1,000 children.

Analyses Restricted to Regular Listeners
Regular listeners were defined at baseline and at midline as women who reported listening to the radio in the past 7 days. A sensitivity analysis, restricted to these women, was performed using the methods described above.

Dose-Response Analyses
Three categories of radio ownership were defined to look for evidence of effect modification: no radio in the compound, radio in the compound, and radio in the household. In each cluster, the change in reported behavior prevalence from baseline was calculated by radio ownership category. A DiD analysis was performed including an interaction term between intervention status and radio ownership category. Cluster-specific random effects were included to account for the expected correlation in the change from baseline estimated for each radio ownership category in the same cluster.

To examine the relationship between broadcasting intensity and reported behavior change, DiDs for all target behaviors were plotted against broadcasting intensity. Intensity was measured as the number of weeks during which spots were broadcast from March 2012 to October 2013 and as the number of long-format modules during the same period. DiDs were then regressed on broadcasting intensity. The assumption that behaviors are independent of each other may not be true, and, therefore, no formal statistical tests were performed. The 95% confidence intervals (CIs) for the regression coefficients should be interpreted with caution as they may be too narrow.

Change From Baseline in Routine Health Facility Data
For each target service (ANC, deliveries, and all-cause under-5 child consultations), the absolute number of consultations at primary health
facilities located in the trial clusters was calculated by year and by cluster. For each cluster, the ratio of the absolute number of consultations in 2013 over the absolute number in 2011 was then calculated, and a 2-sided $t$ test was used to compare the mean ratio by arm.

**Ethics**

The study was approved by the ethical committees of the Ministry of Health of Burkina Faso and the London School of Hygiene and Tropical Medicine. The nature of the intervention precluded formal blinding of respondents and interviewers. Each interviewed woman recorded into the PDA her written consent to participate in the survey, which they were told was about their children’s health, without any mention of the radio campaign. The trial is registered at ClinicalTrials.gov (Identifier: NCT01517230).

**RESULTS**

At baseline, the census recorded 19,565 compounds, 40,156 households, and 47,737 women aged 15 to 49 years old in the sampled villages. Among women, 4% were absent at the time of the baseline survey, and 0.1% refused to participate. In total, 5,043 mothers were interviewed about their behaviors across the 14 clusters.

At midline, 8,098 women recorded in the baseline census were visited during the survey. In contrast to baseline, time for fieldwork in each village was much shorter and a higher proportion of women (20%) were absent the day of the visit (23% versus 17% in the control and intervention arms, respectively). Only 0.2% of women who were present refused to participate, 2% were less than 15 years old or more than 49 years old, and 18% did not have a child less than 5 years old; therefore, a total of 5,182 mothers were interviewed. The per-protocol analysis excluded 252 women from villages in Gayeri cluster where contamination occurred at midline.

**Baseline Sociodemographic Characteristics and Self-Reported Behavior Prevalence**

While several sociodemographic characteristics of interviewed mothers were similar across arms at baseline, there were some important differences (Table 3). In each arm, about 80% of mothers had lived 5 years or more in their village, their average age was 28 years, and nearly all were married, of whom 40% were in a polygamous union. Around 40% had 2 or more children aged less than 5 years old. The mean age of their youngest child was about 20 months. More Muslims and fewer Catholics/Protestants lived in the intervention arm than in the control arm (Muslims: 60% versus 47%, respectively; Catholics/Protestants: 26% versus 45%, respectively). The Mossi were the largest ethnic group in each arm, but other ethnicities varied across clusters. Only 16% and 10% of women in the control and intervention arms, respectively, had attended school. Households in the control arm tended to have higher socioeconomic status compared with the intervention arm. These sociodemographic characteristics remained stable at midline (Table 3).

At baseline, most service-dependent behaviors tended to be reported more commonly in the control arm than in the intervention arm (Figure 2), perhaps reflecting the difference in access to facilities between the 2 arms, with 40% of women in the control arm living less than 2 km away from a health facility compared with only 18% in the intervention arm (Table 3). In each arm, the proportion of sick children reported to have received treatment was quite low: a third or fewer children suffering from fever, fast/difficult breathing, or diarrhea received the appropriate treatment. Reported home-based behaviors at baseline were more similar between arms, though still tending to be better in the control arm (Figure 2). Early breastfeeding initiation and sanitation-related behaviors such as latrine ownership and safe disposal of stools were reported to be low at baseline, around a third or less. Other home-based behaviors, including saving money during pregnancy, exclusive breastfeeding, complementary feeding, and bed net use, were more common, reported by around 40% to 60% of mothers.

**Reach of the Radio Campaign**

At baseline, according to interviews with household heads, around two-thirds of women in each arm had access to a radio in their household (Table 3). At midline, around half of women in each arm reported access to a radio in their household. Although reported household radio ownership was lower than at baseline, close to 80% of interviewed women in the intervention arm had access to a radio, either in the compound or in the household, and 62% were regular listeners, i.e., they reported listening to the radio in the past 7 days (Figure 3).

In the intervention arm, 75% of women reported recognizing at least 1 of the 2 spots
| Sociodemographic characteristics | Control Arm<sup>a</sup> | Intervention Arm<sup>b</sup> |
|----------------------------------|------------------------|-----------------------------|
| **Baseline** (N = 2,567)        | Midline (N = 2,586)    |
| **Baseline** (N = 2,476)        | Midline (N = 2,596)    |
| Age, mean, y                     | 28.9                   | 29.2                        |
| Resident for 5 years or more in the village, % | 80.3                   | 86.4                        |
| Ethnicity, %                     |                        |                             |
| Mossi                            | 42.1                   | 30.1                        |
| Gourmantche                      | 11.5                   | 26.9                        |
| Gourounssi                       | 22.1                   | 3.2                         |
| Peuhl                            | 6.5                    | 17.0                        |
| Gouin/Karaboro/Turka             | 0.2                    | 13.9                        |
| Marka/Dafing/Dioula              | 8.4                    | 3.5                         |
| Bwaba/Bobo                       | 7.5                    | 3.3                         |
| Other                            | 1.6                    | 2.1                         |
| Religion, %                      |                        |                             |
| Muslim                           | 47.2                   | 60.1                        |
| Catholic/Protestant              | 45.0                   | 26.4                        |
| Animist                          | 7.8                    | 13.5                        |
| School attendance, %             | 15.6                   | 10.2                        |
| Income-generative activity in the past 2 weeks, % | 34.9                   | 29.3                        |
| Household socioeconomic status, %<sup>c</sup> |                       |                             |
| 1 (poorest)                      | 14.2                   | 18.8                        |
| 2                                | 16.6                   | 20.6                        |
| 3                                | 19.3                   | 20.2                        |
| 4                                | 21.8                   | 20.1                        |
| 5 (least poor)                   | 28.1                   | 20.3                        |
| Two or more under-5 children, %  | 39.4                   | 46.4                        |
| Married, %                       | 97.1                   | 98.3                        |
| Polygamous union, %              | 39.6                   | 40.3                        |
| Distance to the closest health facility, % |                       |                             |
| <2 km                            | 39.5                   | 18.3                        |
| 2–5 km                           | 33.2                   | 28.2                        |
| >5 km                            | 27.4                   | 53.4                        |

<sup>a</sup> - Baseline: refers to the initial data collection before the intervention.
<sup>b</sup> - Midline: refers to the data collected shortly after the intervention has been completed.
<sup>c</sup> - Household socioeconomic status: 1 (poorest) to 5 (least poor).
Table 3 (continued).

|                        | Control Arm<sup>a</sup> | Intervention Arm<sup>b</sup> |
|------------------------|-------------------------|------------------------------|
|                        | Baseline (N = 2,567)    | Midline (N = 2,586)          | Baseline (N = 2,476) | Midline (N = 2,596) |
| Radio ownership, %     |                         |                              |                       |                      |
| No radio               | 20.5                    | 35.1                         | 13.2                  | 21.9                 |
| Radio in the compound  | 16.7                    | 18.4                         | 22.3                  | 26.2                 |
| Radio in the household | 62.8                    | 46.4                         | 64.5                  | 51.9                 |

<sup>a</sup> At baseline: 36 missing values for age; 13 for number of children; 10 for ethnicity; 9 for socioeconomic status; 5 for residence, religion, school attendance, income-generative activity, and marital status; 8 for radio ownership. At midline: 4 missing values for radio ownership; 3 for age; 2 for religion and marital status; 1 for number of children, school attendance, and income-generative activity.

<sup>b</sup> At baseline: 23 missing values for age; 18 for socioeconomic status; 17 for number of children; 13 for radio ownership; 9 for religion; 7 for ethnicity; 6 for residence, school attendance, income-generative activity, and marital status. At midline: 3 missing values for radio ownership; 1 missing value for religion.

<sup>c</sup> Household socioeconomic status was measured only at baseline.

FIGURE 2. Prevalence of Target Behaviors at Baseline

| Service-dependent behaviors (%), 95% CI | Home-based behaviors (%), 95% CI |
|-----------------------------------------|----------------------------------|
| ORS-Diarrhea                            | HWWS                             |
| Antibiotic-Fast breathing               | Stools’ safe disposal            |
| ACT/QN-Fever                            | Latrine ownership                |
| Care seeking-Diarrhea                   | Bed net use-Pregnancy            |
| Care seeking-Fast breathing             | ITN use-Children                 |
| Care seeking-Fever                      | More liquids-Diarrhea             |
| Growth monitoring                       | Complementary feeding            |
| Facility delivery                       | Exclusive breastfeeding           |
| 4 or more ANC visits                    | 1st bath 24 h or more            |
|                                        | Breastfeeding within 1 h         |
|                                        | Savings-Pregnancy                |

Abbreviations: ACT/QN, artemisinin-based combination therapy/quinine; ANC, antenatal care; CI, confidence interval; HWWS, hand washing with soap; ITN, insecticide-treated bed net; ORS, oral rehydration solution.
played at the end of the interview, and 54% reported listening to the long-format program (Figure 3). Recognition of spots and of the long-format program was higher among regular radio listeners than among all women (88% for spots and 67% for the long-format program). In the control arm, 25% of women reported recognizing at least 1 of the 2 spots, and 18% reported listening to the long-format program (20% and 12%, respectively, when “contaminated” villages were excluded).

Change From Baseline in Self-Reported Behaviors

At midline, 43% of mothers overall reported that their child had suffered from one or more of the target childhood illnesses in the 2 weeks prior to interview. Period prevalence of these illnesses was similar in each arm: around 30% of children suffered from fever, 12% from diarrhea, and 8% from fast/difficult breathing. Most sick children for whom health care was sought went to a CSPS (92%). Only 10% went to a community health worker (CHW) and 2% or less to a hospital. Care seeking in private facilities was almost non-existent (6 cases only).

Table 4 presents the results of the intention-to-treat analysis, showing the prevalence of self-reported behaviors by arm at each survey and the corresponding “crude” and adjusted DiDs, i.e., the difference between arms in the change in prevalence from the baseline to the midline survey. Crude DiDs refer to the difference-in-difference without any adjustment for baseline prevalence or for confounder score.

Self-reported care seeking for diarrhea increased between baseline and midline by 17.5 percentage points more in the intervention arm than in the control arm, with some evidence for an effect of the campaign (adjusted DiD for baseline prevalence and confounder score, 17.5 percentage points; 95% CI, 2.5 to 32.5; P = .03) (Table 4). Self-reported treatment with oral rehydration solution (ORS) or increased fluids during an episode of diarrhea increased substantially in the intervention arm while it remained constant in the control arm (adjusted DiD for baseline prevalence, 14.9 percentage points; 95% CI, 2.0 to 27.8; P = .03), but the evidence for a difference between arms weakened after adjustment for confounder score (adjusted DiD for baseline prevalence and confounder score, 10.9 percentage points; 95% CI, -2.4 to 24.0; P = .11).

FIGURE 3. Radio Listenership and Campaign Recognition at Midline (%; 95% CI)

|                | Control arm | Intervention arm |
|----------------|-------------|------------------|
| Regular listeners | 50%         | 60%              |
| Spot recognition  | 15%         | 20%              |
| Long-format recognition | 40%       | 50%              |

Abbreviation: CI, confidence interval.
# TABLE 4. Changes From Baseline in Self-Reported Behaviors (Intention-to-Treat Analysis)

| Behaviors                                           | Control Arm | Intervention Arm | Crude DiD | Adjusted for Baseline Prevalence | Adjusted for Baseline Prevalence and Confounder Score |
|-----------------------------------------------------|-------------|------------------|-----------|----------------------------------|-------------------------------------------------------|
|                                                     | Survey      | No. (%)          | No. (%)   | DiD (95% CI)                     | P Value                                               |
| Maternal health                                     |             |                  |           |                                  |                                                       |
| 4 or more ANC visits                                | BS          | 2562 (50.8)      | 2470 (37.0) | 1.2 (-3.5 (-17.8, 10.9))         | .61                                                   |
|                                                     | MD          | 1012 (61.0)      | 1212 (48.4) | -5.6 (-23.7, 12.5)               | .50                                                   |
| Saving money during the pregnancy                   | BS          | 2562 (62.8)      | 2474 (56.4) | 8.8 (9.8 (1.0, 18.6))            | .03                                                   |
|                                                     | MD          | 1012 (67.4)      | 1212 (69.8) | 12.8 (1.4, 24.2)                | .03                                                   |
| Health facility delivery                            | BS          | 2562 (81.8)      | 2470 (56.0) | -1.3 (1.1 (-11.0, 13.2))         | .85                                                   |
|                                                     | MD          | 1012 (92.4)      | 1212 (65.3) | -1.0 (-12.6, 10.6)               | .85                                                   |
| Newborn health                                      |             |                  |           |                                  |                                                       |
| Breastfeeding initiation within 1 hour after birth  | BS          | 2556 (32.6)      | 2463 (26.8) | 6.1 (8.5 (-6.7, 23.6))           | .24                                                   |
|                                                     | MD          | 1003 (31.2)      | 1194 (31.5) | 9.0 (-16.9, 34.9)               | .46                                                   |
| First bath delayed for 24 hours or more after birth| BS          | 2556 (55.9)      | 2463 (49.3) | -7.4 (-5.5 (-16.3, 5.4))         | .29                                                   |
|                                                     | MD          | 1003 (66.0)      | 1194 (52.0) | -3.4 (-19.1, 12.4)              | .64                                                   |
| Health care seeking in a health facility or with a CHW (2 weeks prior to interview) | | | | | |
| Fever                                               | BS          | 735 (63.7)       | 637 (50.2)  | 6.3 (4.2 (-7.9, 16.3))           | .46                                                   |
|                                                     | MD          | 777 (73.1)       | 744 (65.9)  | 5.0 (-9.7, 19.6)                | .47                                                   |
| Fast/difficult breathing                            | BS          | 302 (56.6)       | 381 (44.4)  | 4.1 (-2.9 (-27.0, 21.2))         | .80                                                   |
|                                                     | MD          | 203 (70.9)       | 180 (62.8)  | 10.5 (-18.0, 39.1)              | .43                                                   |
| Diarrhea                                            | BS          | 559 (57.8)       | 514 (44.9)  | 12.4 (12.0 (-2.0, 26.1))         | .09                                                   |
|                                                     | MD          | 264 (65.5)       | 349 (65.0)  | 17.5 (2.5, 32.5)                 | .03                                                   |
| Treatment (2 weeks prior to interview)              |             |                  |           |                                  |                                                       |
| ACT or quinine IM/IV for fever                       | BS          | 735 (17.3)       | 639 (16.9)  | -1.4 (-4.1 (-12.7, 4.5))         | .32                                                   |
|                                                     | MD          | 797 (34.6)       | 766 (32.8)  | 0.0 (-11.5, 11.5)               | >.99                                                  |
| Antibiotic for fast/difficult breathing             | BS          | 302 (28.2)       | 382 (27.0)  | 12.6 (13.8 (-7.9, 35.5))         | .19                                                   |
|                                                     | MD          | 210 (33.8)       | 188 (45.2)  | 29.6 (3.5, 55.7)                | .03                                                   |
| ORS or more liquids for diarrhea                     | BS          | 560 (41.1)       | 516 (30.6)  | 24.4 (14.9 (2.0, 27.8))          | .03                                                   |
|                                                     | MD          | 274 (42.0)       | 354 (55.9)  | 9.5 (-5.6, 24.7)                | .19                                                   |
| Homemade solutions for diarrhea                     | BS          | 560 (6.8)        | 516 (6.8)   | 3.2 (3.3 (-6.2, 12.9))           | .46                                                   |
|                                                     | MD          | 275 (6.2)        | 362 (8.3)   | 3.2 (-10.5, 16.8)               | .62                                                   |
9.5 percentage points; 95% CI, -5.6 to 24.7; \( P = .19 \).

No messages were broadcast on homemade solutions, and their use remained constant between surveys, with fewer than 10% of mothers mentioning use of homemade solutions.

While the data on self-reported care seeking for fast/difficult breathing were inconclusive (adjusted DiD for baseline prevalence and confounder score, 10.5 percentage points; 95% CI, -18.0 to 39.1; \( P = .43 \)), the proportion of children with fast/difficult breathing who were reported to have been treated with an antibiotic showed a much greater increase between surveys in the intervention arm compared with the control

**Table 4 (continued).**

| Behaviors                          | Survey  | Control Arm No. (%) | Intervention Arm No. (%) | Crude DiD          | DiD (95% CI) | \( P \) Value | Adjusted for Baseline Prevalence and Confounder Score | Adjusted for Baseline Prevalence and Confounder Score |
|------------------------------------|---------|---------------------|--------------------------|-------------------|--------------|-------------|-----------------------------------------------------|-----------------------------------------------------|
| **Nutrition**                      |         |                     |                          |                   |              |             |                                                      |                                                      |
| Exclusive breastfeeding (day prior to interview, 0–5 months old) | BS      | 428 (44.6)          | 450 (42.4)              | -9.0              | -10.3 (-24.3, 3.6) | .13         | -8.7 (-28.2, 10.8)                                      | .34                                                  |
| Complementary feeding (day prior to interview, 6–11 months old) | BS      | 418 (55.5)          | 411 (49.9)              | 0.1               | -3.3 (-17.4, 10.7) | .61         | -10.0 (-27.6, 7.7)                                     | .24                                                  |
| Growth monitoring (past 6 months, 0–23 months old) | BS      | 1525 (59.7)         | 1615 (51.1)             | 0.4               | 0.1 (-11.1, 11.4)  | .98         | 2.6 (-17.3, 12.0)                                     | .70                                                  |
| **Bed net use**                    |         |                     |                          |                   |              |             |                                                      |                                                      |
| Children under an ITN the night prior to interview | BS      | 2567 (60.3)         | 2475 (58.5)              | -1.8              | -2.7 (-8.9, 3.5)  | .35         | -3.9 (-12.4, 4.7)                                     | .34                                                  |
| Women under a bed net during their last pregnancy | BS      | 2560 (65.6)         | 2468 (62.5)              | 3.9               | 2.1 (-5.3, 9.5)   | .55         | -0.6 (-10.6, 9.3)                                     | .89                                                  |
| **Sanitation**                     |         |                     |                          |                   |              |             |                                                      |                                                      |
| Household latrine ownership        | BS      | 2559 (19.5)         | 2458 (25.0)              | 1.9               | 0.0 (-11.2, 11.3) | >.99        | 6.0 (9.3, 21.4)                                      | .40                                                  |
| Safe disposal of children’s last stools\(^a\) | BS      | 2566 (14.1)         | 2475 (15.3)              | 0.9               | 0.2 (-6.4, 6.8)   | .95         | 2.4 (-7.0, 11.8)                                     | .58                                                  |
| Hand washing with soap the last time women cleaned their child who defecated | BS      | 2535 (37.5)         | 2401 (36.4)              | -0.3              | -1.6 (-21.0, 17.8) | .86         | -10.5 (-35.9, 14.9)                                   | .38                                                  |

\(^a\) Defined when the child used a latrine or when the stool was thrown into a latrine or buried.

**Abbreviations:** ACT, artemisinin-based combination therapy; ANC, antenatal care; BS: Baseline survey; CHW, community health worker; CI, confidence interval; DiD, difference-in-difference; IM/IV, intramuscular/intravenous; MD: Midline survey; ORS, oral rehydration solution.
The proportion of children with fast/difficult breathing reported to have received antibiotic treatment increased much more between surveys in the intervention arm than in the control arm.

arm (adjusted DiD for baseline prevalence and confounder score, 29.6 percentage points; 95% CI, 3.5 to 55.7; \( P = .03 \)).

There was no evidence for improved care seeking for fever (adjusted DiD for baseline prevalence and confounder score, 5.0 percentage points; 95% CI, -9.7 to 19.6; \( P = .47 \)) or for treatment of fever associated with the campaign (adjusted DiD for baseline prevalence and confounder score, 0.0 percentage points; 95% CI, -11.5 to 11.5; \( P > .99 \)).

While self-reported saving during pregnancy remained relatively constant between surveys in the control arm, it increased somewhat in the intervention arm (adjusted DiD for baseline prevalence and confounder score, 12.8 percentage points; 95% CI, 1.4 to 24.2; \( P = .03 \)).

Whereas the broad pattern of results with respect to care seeking and treatment for the targeted childhood illnesses was positive, there was no evidence of an intervention effect on feeding behaviors: early initiation of breastfeeding (adjusted DiD for baseline prevalence and confounder score, 9.0 percentage points; 95% CI, -16.9 to 34.9; \( P = .46 \)), exclusive breastfeeding (adjusted DiD for baseline prevalence and confounder score, -8.7 percentage points; 95% CI, -28.2 to 10.8; \( P = .34 \)), and complementary feeding (adjusted DiD for baseline prevalence and confounder score, -10.0 percentage points; 95% CI, -27.6 to 7.7; \( P = .24 \)).

For other target behaviors, including bed net use and sanitation, there was also no evidence that the campaign had an effect. Reported attendance to 4 or more ANC consultations, delivery in a health facility, bed net use, and latrine ownership increased in the intervention arm between surveys, but similar increases were observed in the control arm. Little or no change between surveys was observed in either arm in reporting of delayed bathing, growth monitoring, safe disposal of children’s stools, or hand washing with soap after cleaning a child’s bottom.

With respect to women living in “contaminated” villages (Gayeri control cluster) who were excluded from the per-protocol analysis, 80% belonged to the Gourmaniche ethnic group, 68% were Catholic or Protestant, 46% had 2 or more children less than 5 years old, 66% had access to a radio in their household, and 55% lived less than 2 km away from a health facility. Other sociodemographic characteristics were typical of other women in the control arm. Excluding these women from the analysis, confounder score-adjusted DiDs for self-reported care seeking for diarrhea, fast/difficult breathing, and fever tended to be higher than the adjusted DiDs from the intention-to-treat analysis (adjusted DiD for baseline prevalence and confounder score, 22.0 percentage points; 95% CI, 6.93 to 37.0; \( P = .01 \)); (17.3 percentage points; 95% CI, -10.3 to 44.9; \( P = .19 \)); and (14.3 percentage points; 95% CI, -1.1 to 29.6; \( P = .07 \)), respectively. For other behaviors, per-protocol analyses produced results similar to the intention-to-treat analyses (see supplementary material).

Analysis Restricted To Regular Listeners and Dose-Response Analyses

Restricting the analysis to regular listeners produced similar results to results among all women mentioned above (data not shown). There was no evidence that the effect of the campaign varied with radio ownership (data not shown), but tests for effect modification had very low power due to small numbers of observations for some behaviors.

There was some suggestion of a positive correlation between the intensity of spots and reported behavior change prior to adjustment for confounder score (regression coefficient, 0.8 percentage point increase per week of spot; 95% CI, -0.5 to 2.7) (Figure 4a). There was no evidence of correlation with the number of long-format modules broadcast (regression coefficient, 0.1 percentage point increase per week of spot) but resulted in a wider confidence interval (95% CI, -0.5 to 2.7) (Figure 4b).

Change From Baseline in Routine Health Facility Data

Table 5 shows the absolute numbers of consultations for targeted health services in 40 and 37 primary health facilities located in the control and intervention arms, respectively. There was no statistical evidence for a difference between the 2 arms for any of the indicators (\( P \geq .40 \)), although the observed increase in all-cause under-5 consultations was much greater in the intervention arm (33% increase between 2011 and 2013) than in the control arm (17% increase).

DISCUSSION

After 20 months, the radio campaign in Burkina Faso appears to have reached a high proportion of
FIGURE 4. Correlation Between Changes in Targeted Behaviors and Broadcasting Intensity (Intention-to-Treat Analysis)

a. Broadcasting Intensity of Short Spots

Regression coefficient (adjusted for confounder score), 0.9 (-0.5, 2.7); Correlation coefficient, 0.31.

b. Broadcasting Intensity of Long-Format Modules

Regression coefficient (adjusted for confounder score), 0.1 (-0.1, 0.2); Correlation coefficient, 0.13.

Abbreviations: ACT/QN, artemisinin-based combination therapy/quinine; ANC, antenatal care; DiD, difference-in-difference; HMS, homemade solution; HWWS, hand washing with soap; ITN, insecticide-treated bed net; ORS, oral rehydration solution.

Numbers in charts pertain to the targeted behaviors: (1) 4 or more ANC visits, (2) Savings-Pregnancy, (3) Facility delivery, (4) Breastfeeding within 1 h, (5) 1st bath 24 h or more, (6) Exclusive breastfeeding, (7) Complementary feeding, (8) Growth monitoring, (9) Care seeking: Fever, (10) Care seeking: Fast/difficult breathing, (11) Care seeking: Diarrhea, (12) ACT/QN-Fever, (13) Antibiotic-Fast/difficult breathing, (14) ORS/more liquids-Diarrhea, (15) HMS-Diarrhea, (16) ITN use-Children, (17) Bed net use-Pregnancy, (18) Latrine ownership, (19) Stools' safe disposal, (20) HWWS.
the primary target population, with 75% of mothers in intervention areas reporting recognizing spots played at the end of the interview. However, a relatively high proportion of women reported recognizing spots in the control arm, too (25%). Although “contamination” is known to have occurred in Gayeri control cluster, the distances to the closest intervention radio station preclude population-level contamination in the other control clusters. “Courtesy” bias and confusion with other radio programs may explain the reported recognition in the control clusters. Some women in the intervention arm who reported recognizing spots may also have answered with “courtesy” or confused them with other messages. Our findings are mixed with respect to the campaign’s effects on behavior. Among 19 target behaviors, there was some evidence of positive effects on self-reported appropriate family responses to diarrhea and fast/difficult breathing and saving money during pregnancy. Self-reported care seeking and home treatment for diarrhea increased more in the intervention arm, although there was no statistical evidence for the latter after controlling for confounder score. A relatively small number of mothers reported that their children had suffered from fast/difficult breathing and, consequently, results for behaviors related to this illness had wide confidence intervals. Nevertheless, the data are consistent with greater increases in self-reported care seeking and antibiotic treatment for this illness in the intervention arm, although there was no evidence that the radio campaign had an effect. While some behaviors appear to have changed little between baseline and midline in either arm, others appear to have improved to similar degrees in each arm. There is some evidence from other sources23 of increases in ANC attendance, facility delivery, exclusive breastfeeding, and care seeking for fever over recent years, although these changes are not always as rapid as those we observed. The similar increases reported in each arm in antimalarial treatment might also be explained by a seasonal variation in health care providers’ treatment practices, the baseline having been performed in the dry season and the midline in November shortly after the last rains. In the case of bed net use, the results likely reflect effective national distribution in the summer of 2013 before the midline survey took place. Bed net ownership was almost universal at midline, with 99% of women reporting living in a household with at least 1 bed net. Latrine ownership increases may reflect in part the effects of latrine construction programs in various clusters.

Why does the intervention appear to have had an impact on some behaviors but not others? First, intensity of the intervention is likely to be critical. Although the number of spots broadcast per day was high, on average 10 spots a day, and the long-format program was on air 5 days a week, the intensity allocated to each behavior varied substantially, from 1 week of spots for delayed bathing to 12 weeks of spots for management of diarrhea up to the month preceding the midline survey (Table 1). The dose-response analysis is consistent with those behaviors subject to the greatest number of weeks of spots tending to show the largest

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TABLE 5. Number of Attendances for Targeted Health Services in Primary Health Facilities Located in Control (N = 40) and Intervention (N = 37) Arms, Based on Routine Health Facility Data, 2011 and 2013

| Service                        | Control 2011 | Control 2013 | Intervention 2011 | Intervention 2013 | % Change From 2011 to 2013 | P Value |
|-------------------------------|--------------|--------------|-------------------|-------------------|---------------------------|---------|
| 4 ANC visits                  | 4,490        | 4,682        | 6,283             | 6,723             | 7                         | .75     |
| Health facility deliveries    | 10,054       | 10,105       | 11,911            | 12,928            | 9                         | .54     |
| All-cause under-5 child consultations | 67,172     | 78,265       | 78,892            | 104,535           | 33                        | .40     |
changes, although the statistical evidence for this is weak. There is no such pattern, however, for the number of long-format modules.

Another possible explanation for the mixed results may lie in the nature of the behaviors themselves. Changes may be difficult to achieve when they face habitual or normative practices that bear the weight of tradition and strong cultural beliefs. Such traditions and cultural beliefs are likely to vary from one setting to another. Perhaps more importantly, many preventive behaviors must be performed on a daily basis, with no immediately obvious benefit. Nutrition and hygiene-related behaviors, for example, share these characteristics and changing them may require more time and effort. This challenge to changing preventive behaviors may apply in many settings and across different behavior change approaches. In rural Burkina Faso, all behaviors for which we found some evidence for an intervention effect were episodic.

Michie et al. (2011) have proposed a framework for characterizing behavior change interventions. This includes a behavioral model, in which “motivation,” “capability,” and “opportunity” interact to determine behavior. According to this framework and given the theory of change underpinning DMI’s campaign, one might speculate that the following mechanisms explain the observed changes in behavior. DMI’s messages, rather than providing information alone, use health-related storylines, which provide examples for people to aspire to, imitate, and elicit either positive or negative feelings about target behaviors. By combining information and entertainment, the campaign may act not only through the “capability” component of behaviors (knowledge) but also through “motivation,” by affecting both emotional responses and analytical decision making. In addition, the immediate social circle of women and other members of their community were also exposed to the campaign. While husbands influence birth preparedness through permitting (or not) expenditures, female family members, such as mothers-in-law, aunts, or grandmothers, are frequently present at the time of birth, provide guidance during the first months of the baby’s life, and influence breastfeeding practices. Beside beliefs about disease etiology and perceived severity of illnesses, family members also influence decisions about whether and where to seek care in the event of childhood illnesses. By reaching a large audience, the campaign may also have triggered dialogue in the community and brought changes in the social norms or “social opportunity” component of behaviors, defined as the “cultural milieu that dictates the way people think about things.”

On the other hand, the “physical opportunity” component of behaviors, defined as the external conditions that make behavior change possible, was unaffected by the campaign and this needs to be considered when interpreting results. In 2010, Burkina Faso ranked 161 of 169 countries in UNDP’s Human Development Index with 44% of the population living below the poverty line and 77% living in rural areas. The poverty of the studied population is therefore likely to be an important barrier to changes in some behaviors, such as nutrition or sanitation-related behaviors. In addition, rural populations, largely dependent on subsistence agriculture, are vulnerable to food insecurity, the last crisis having occurred in 2012. In 2013, Burkina Faso ranked 65 of 78 on the Global Hunger Index. In this context, improving complementary feeding practices may require more practical support. Access to treatment is another potential limitation. For example, at midline, only 43% and 31% of surveyed villages in the control and intervention arms, respectively, had ORS available within the village itself (either at a primary health facility or through a CHW).

Finally, it should also be borne in mind that in this campaign exposure is largely passive, although the long-format programs did give listeners the opportunity to phone in. Other behavior change interventions have often used interpersonal communication that involves face-to-face interaction between health promoters and caregivers. Face-to-face encounters provide some opportunity to tailor information to caregivers’ needs and use persuasion and social influence. It has been suggested that programs in which mass media is part of a multifaceted intervention strategy are more likely to be successful than mass media alone. However, such programs are generally far more costly to implement effectively on a large scale.

Of the 32 evaluations of mass media campaigns identified by Naugle et al. (2014) that relied on “moderate” to “stronger” designs, all but 6 were reported to show some evidence of positive effects on child survival-related behaviors. However, only 2 evaluations reported using randomized designs, one of which randomized only 4 clusters, and the authors also note the
potential for publication bias. All but 6 evaluated programs that included interpersonal communication components, e.g., training of health workers or volunteers, or implementing community-based activities, but none was able to disentangle the impact of different components. The results of the 6 evaluations of programs that used mass media alone were generally consistent with positive effects but had important design limitations.

In Peru and the Philippines, vaccination coverage rates were reported to have improved by 10 to 20 percentage points following radio and TV campaigns, but no concurrent control data were available. In Central Java, Indonesia, a radio campaign was accompanied by improvements in reported fluid intake during diarrhea, but a similar change was observed in control areas; Hornik (2002) concluded that the change was probably unrelated to the campaign. In Bolivia, a new brand of nutritional supplement for women was promoted through a radio and TV campaign, with 11% of women at endline reporting having taken the supplement at least once. A radio and TV campaign, accompanied by SMS reminders, in Cameroon was associated with a 12 percentage point increase in bed net use among children under 5 years compared with the matched control group. Finally, Jaramillo (2001) reported a transient increase in the number of individuals being tested for tuberculosis in Cali, Colombia, coinciding with a TV and radio campaign. No such increase was seen in a control area, which did not receive the campaign.

Thus, the evidence base for the effectiveness of mass media in improving child survival, whether alone or with interpersonal components, is very limited, and it is impossible to make strong assertions about the relative impact of different strategies. To our knowledge, our study is the first cluster randomized trial to investigate and present evidence that a mass community radio campaign alone can change some health-related behaviors in a low-income setting.

Limitations
Several limitations of this study must be recognized. First, although clusters were randomly allocated to receive the intervention, there were some important differences at baseline between intervention and control arms. Baseline imbalance is not uncommon when only a few clusters are randomized, and we sought to control for these differences by creating a confounder score. However, we cannot exclude the possibility that this imbalance resulted in some bias in our comparisons of intervention and control clusters. Second, the evaluation largely relied on self-reported behaviors whose accuracy may be questioned. Some behaviors such as place of delivery, recognition of fever, and treatment with ACTs may be more accurately reported than behaviors occurring immediately after birth or recognition and antibiotic treatment of pneumonia. The length of the questionnaire, 40 minutes on average, may also have resulted in interview fatigue affecting women’s recall at the end of the interview. In addition, socially desirable behaviors may be overreported. When possible, we sought documentary evidence to reduce the probability of misreporting. For example, field-workers asked women whether they had a prescription or a package for any treatments given to their child. At both surveys, supporting evidence was available for about 70% of ACT treatments given to febrile children and oral antibiotics given to children with fast/difficult breathing. In addition, routine health facility data from the Ministry of Health are consistent with the observed changes from baseline to midline in self-reported service-dependent behaviors. Nevertheless, we cannot exclude the possibility that DMI’s campaign itself could have increased overreporting of target behaviors in the intervention clusters, although if reporting bias did occur to an important degree one might have expected to see positive results across a wider range of behaviors. Third, the power and precision of the trial is limited by the relatively small number of clusters that could be randomized, and this limits our ability to detect modest changes in behaviors. Fourth, the baseline and midline surveys were not performed at exactly the same period of the year, with the baseline performed between December and March and the midline survey performed in November. Seasonal variation in behaviors may explain some of the changes observed between baseline and midline but should not have confounded the comparison between intervention and control clusters. Fifth, although major co-interventions (Table 2) were implemented in similar numbers of clusters per arm, we did not collect data on their intensity and quality. Sixth, we excluded towns and large villages where access to television may limit the effect of a campaign delivered using local community radio stations. This exclusion limits, to some extent, the generalizability of our findings...
although it does not affect their internal validity (though it is unlikely that the addition of television messages would reduce the impact of the campaign). Lastly, we have examined multiple behaviors (19), but the differences between intervention and control arms were below the conventional cut-off point of \( P = .05 \) after adjustment for only some (3) of the behaviors. All these limitations mandate a cautious interpretation of our results.

**CONCLUSION**

DMI’s *Saturation*+ approach to designing and implementing a mass radio campaign had positive effects at midline on some maternal and child health behaviors such as saving money during pregnancy and appropriate family responses to diarrhea and fast/difficult breathing. However, there was no statistical evidence that the campaign had an effect on ANC consultations, facility delivery, delayed bathing, early initiation of breastfeeding, care seeking for and treatment of fever, bed net use, nutrition, or sanitation-related behaviors. Dose-response analysis of broadcasting intensity showed that behaviors associated with the greatest number of weeks of broadcasted spots tended to have the largest changes, although there is weak evidence of such an effect from a statistical perspective. The impact of the radio campaign on child mortality will be evaluated at endline.

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Barriers to Accessing Emergency Medical Services in Accra, Ghana: Development of a Survey Instrument and Initial Application in Ghana

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Most respondents thought the number of ambulances insufficient and said they would rather use a taxi—perceived to be faster—in a medical emergency. Nevertheless, people generally had favorable attitudes of existing public ambulance services, although few knew of the toll-free emergency number and many thought it appropriate to use ambulances to transport corpses. Targeted public education, along with improved capacity of ambulance agencies to handle increased caseload, could improve use.

ABSTRACT

Background: Emergency medical services (EMS) systems provide professional prehospital emergency medical care and transportation to help improve outcomes from emergency conditions. Ghana’s National Ambulance Service has relatively low public utilization in comparison with the large burden of acute disease.

Methods: A survey instrument was developed using Pechansky and Thomas’s model of access covering 5 dimensions of availability, accessibility, accommodation, affordability, and acceptability. The instrument was used in a cross-sectional survey in 2013 in Accra, Ghana; eligible participants were those 18 years and older who spoke English, French, or Twi. Although the analysis was mainly descriptive, logistic regression was used to identify factors associated with reported intention to call for an ambulance in the case of a medical emergency.

Results: 468 participants completed surveys, with a response rate of 78.4%. Few (4.5%) respondents had ever used an ambulance in prior emergency situations. A substantial proportion (43.8%) knew about the public access medical emergency telephone number, but of those only 37.1% knew it was a toll-free call. Most (54.7%) respondents believed EMTs offered high-quality care, but 78.0% believed taxis were faster than ambulances and 69.2% thought the number of ambulances in Accra insufficient. Many (23.4%) thought using ambulances to transport corpses would be appropriate. In two hypothetical emergency scenarios, respondents most commonly reported taxis as the preferred transportation (see table at end of abstract). Those aged 18–35 years were more likely than older respondents to prefer an ambulance (odds ratio [OR], 2.27; confidence interval [CI], 1.47 to 3.68), as were those with prior ambulance experience (OR, 1.75; CI, 0.98 to 3.09) (compared with those with no prior experience) and those who believed ambulances were safer than taxis (OR, 2.17; CI, 1.1 to 4.2) (compared with those who did not hold such beliefs).

Conclusions: Perceptions of public ambulance services in Accra, Ghana, are generally favorable, although use is low. Public health education to improve awareness of the toll-free medical emergency number and about appropriate use of ambulances while simultaneously improving the capacity of ambulance agencies to receive increased caseload could improve use of the EMS system.
**BACKGROUND**

Emergency medical services (EMS) are a community’s gateway to acute and emergency medical care for members of the public facing time-sensitive, condition-critical illness and injury. When implemented appropriately, EMS systems are an effective, frontline, public health intervention to reduce the disproportionately high morbidity and mortality in low- and middle-income countries. The formation of locally appropriate EMS systems in low-resource settings, to provide emergency care and transport, has been promoted by international bodies, such as the World Health Organization and the African Federation for Emergency Medicine. Thus, EMS systems, regardless of their state of development, play a critical role in the continuum of ensuing medical care. Emergency care usually begins in the community, when someone identifies a perceived emergency condition and attempts activation of the local EMS system. This ideally triggers a cascade of events resulting in a timely response of expertise, resources, and service directed to patient stabilization and/or safe emergency patient transportation to the nearest appropriate facility. The current norm in many low- and middle-income countries is, however ironic, to use a private vehicle or a taxi to transport the injured or ill person to the hospital, even when EMS has an active presence in these communities.

Across Africa, in-hospital and prehospital emergency care systems are being developed to serve diverse, multicultural, and multilingual populations of varying socioeconomic strata. For example, innovative programs in which motorbikes equipped with stretchers are activated in Malawi to transport emergency obstetric patients, and Ghana’s National Ambulance Service (NAS) provides professional crews and time-sensitive emergency transportation for patients. Ghana boasts one of sub-Saharan Africa’s thriving EMS systems. Formed in 2004, the NAS is comprised of a fully operational ambulance fleet with 160 basic life support-equipped ambulances and more than 1,200 emergency medical technicians (EMTs). It has a nationwide operational footprint, providing free emergency services to the citizens of Ghana. Within each of Ghana’s 10 regional capitals in 2013, NAS had at least 1 ambulance station and several ambulances staffed by a crew of trained EMTs. Accra, the national capital, had the largest NAS complement of ambulances and personnel, with 8 ambulances and approximately 100 EMTs. Still, the Accra ambulance-to-population ratio is approximately 1:250,000—a ratio that is 5–10 times below expert-recommended ratios for lower-income countries—and the mean response time is about 18 minutes. Injuries are the most common reason for public utilization of NAS services. Despite sustained growth of NAS over the past decade, annual reports have indicated low public utilization, which may be a contributor to continued poor outcomes of acute care. The reasons behind low utilization have not been studied sufficiently.

This study was undertaken to characterize and quantify the range of barriers—from the demographic and psychosocial to the financial, knowledge, and cultural barriers—that prevent Ghanaian citizens in Accra from appropriately accessing local EMS resources. In Accra, we hypothesized low public opinion of ambulance services, poor knowledge of ambulance access, and thus a strong public preference to use non-ambulance means of transport during medical emergencies.

**METHODS**

**Conceptual Approach**

Pechansky and Thomas provide a conceptual framework of 5 dimensions that affect patient access to or entry into health care systems: availability, accessibility, accommodation, affordability, and acceptability. Applications of this framework have elucidated causes for increased mortality pertaining to accessing emergency care, for emergency conditions such as sepsis and respiratory and obstetric emergencies.
The domain of content and relevant elements for our survey instrument were identified by a multidisciplinary research team, including experts in emergency care, EMS, African public health, and survey design, following discussions and a review of the literature. Desired attributes of the survey instrument included comprehensiveness, simplicity in execution, standardized oral administration, and ease of comprehension by respondents, independent of their sociopolitical, cultural, and geographic background. The survey was designed to be delivered on a tablet computer (Nexus 7, Google Inc., USA) using survey software (droidSurvey 2013, Google Inc., USA) to facilitate data collection. The research team developed survey questions for each element. Most of these questions were structured to enable quantitative categorization of responses. Due to the exploratory nature of this research, open-ended questions were also included to promote less-restricted responses and provide a richer explanation of issues raised by respondents.

Development and Validation of Survey Instrument

The research team defined the domain of the survey as all citizen-perceived barriers potentially impeding EMS access in low-resource sub-Saharan African settings. Relevant elements to the domain were screened in the context of Pechansky and Thomas’s domains of access (i.e., availability, accessibility, accommodation, affordability, and acceptability).

The survey instrument was written in English and designed to be orally administered to respondents by trained bilingual research assistants in English (the official language), French, or Twi (the most dominant local language). Each research assistant received more than 20 hours of training on the sampling technique and survey instrument, which included completing 15 supervised surveys each. The survey contained 8 main sections:

1. Respondent demographics
2. Prior experience(s) with EMS
3. Knowledge of ambulance function
4. Perceptions of ambulance performance
5. Hypothetical scenarios
6. Barriers to access
7. EMS educational intervention (in which we provided participants information about EMS)
8. Survey administration/logistics (e.g., interviewer name, location of survey, and language)

Of the 114 total questions, respondents were asked a maximum of 104, while 10 questions pertained to survey administration. The instrument had skip logic successfully embedded within it.

Early versions of the instrument underwent multiple rounds of revisions and sequential stages of validation. Three external survey experts provided feedback on its structure, including the syntax, grammar, and meaning of the chosen questions. Cognitive testing of a preliminary version of the instrument was performed in the United States (in Atlanta, Georgia, and in Ann Arbor, Michigan) and then in Ghana (in Accra and Kumasi) among 19 community members in total. During cognitive testing, feedback was provided on the meaning and clarity of questions, brevity, and ease of understanding and of responding to the survey. Pilot testing on the tablet computer was also conducted in Ghana, between April and June 2013, among 30 community members to ensure trouble-free data collection, to assess survey duration, and to resolve any impediments to conducting the survey.

According to the 49 community members and the 6 expert reviewers who participated in both phases of pilot testing and qualitative critique of the survey, the survey instrument passed face validity and content validity, and it was deemed

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**BOX. Five Dimensions of Access to Health Care**

- **Availability**: the relationship of the volume and type of existing services (and resources) to the clients’ volume and needs.
- **Accessibility**: the relationship between the location of supply of services (or resources) and the location of clients.
- **Accommodation**: the manner in which the services (or resources) are organized to meet the needs of clients and clients’ perceptions of the appropriateness of the way services are organized.
- **Affordability**: the relationship between the cost and perceived value of services and the clients’ ability to pay.
- **Acceptability**: the relationship of the clients’ perceptions and attitudes toward the service (or resources) to the actual characteristics of the service, as well as to the perceptions and attitudes of providers toward certain clients.

Source: Penchansky and Thomas.18
sound with regards to construct validity and translation. To test the instrument’s consistency when administered by different surveyors, the instrument was tested by multiple surveyors over 2 days: 2 survey administrators on day 1, and 3 survey administrators on day 2. Interrater reliability measurements of key variables yielded Krippendorff’s alpha scores between 0.66 to 1, suggesting good to excellent interrater reliability.22,23 Intrarater and test-retest reliability were non-applicable because the EMS educational intervention (an integral part of the survey mission) would skew respondents’ subsequent answers and introduce error into tests of reliability. All initially stated desired attributes were satisfied by the final design of the instrument.

Sampling
Surveys were conducted in a representative cross-section of the general public in Ghana’s capital city, Accra, from June to August 2013. Accra is a coastal city in southern Ghana, and the metropolitan area had a population of approximately 1.8 million in 2012, distributed over 173 square kilometers.24,25

The rationale for selecting Accra was that the Accra metropolitan area has the highest concentration of NAS ambulances and the highest population volume and density in Ghana.26,27 Therefore, Accra qualified as a high-yield survey site in which to reach an initial understanding of barriers to EMS access in the urban Ghanaian population.

To conduct balanced community-based random sampling, we replicated the population survey technique used in the 2003 and 2008 versions of the Ghana Demographic and Health Survey.28 In this approach, the Accra metropolitan area was divided into 11 geographic clusters, termed enumeration areas (Figure). To ensure valid statistical analysis could be conducted within each enumeration area, a target sample size of approximately 40 in each of the 11 areas was chosen, giving an overall sampling size of 440.

Two research assistants (JB, CA) were trained by the study’s lead investigators. The research assistants were fluent in English (both JB and CA), French (JB), and Twi (CA). In order to attain as broad a sample as possible, diverse areas including the road side, commercial areas, residential areas, schools, places of worship, and recreational areas were used as recruitment sites. By sampling every fifth person within each recruitment site and by using a goal of 6 to 8 interviews per site, an approximately equal number of people were interviewed within each enumeration area.

Inclusion and Exclusion Criteria
All persons 18 years of age and older, located within the 11 enumeration areas during our survey period, were eligible to participate after providing informed consent. Respondents who did not speak English, French, or Twi were excluded.

Data and Statistical Analysis
After we conducted the survey, we exported the data from the droidSurvey database into Microsoft Excel (2007, Redmond, WA). Quantitative data from closed-ended questions were cleaned and coded. Qualitative data from open-ended questions were reviewed by the authors and coded individually, into themes. Following initial coding, 2 authors (NM and SR) compared codes, discussed and resolved discrepancies, and categorized the codes into thematic areas. Missing data were noted as such, and no imputation was performed for missing variables. Cleaned and coded data were exported into a statistical software program, Stata (Stata Corp, College Station, TX), for analysis. Descriptive statistics were performed for quantitative data, using frequencies, means, and standard deviations (SDs), as appropriate.

In the survey, participants were presented with 2 hypothetical emergency situations and asked how they would prefer transport of the victim to the hospital. In the first scenario, the participant witnessed a pedestrian on the street struck by a car, implying accessibility to many private and commercial vehicles. In the second scenario, a relative was burned badly in a house fire, implying limited access to many private and commercial vehicles. The primary outcome for regression analysis was the response to the question, “If you saw a pedestrian hit by a car and they needed to go to a hospital immediately, how would you get them to the hospital?” Answers were categorized, then dichotomized to “ambulance” (combining the NAS ambulance and other ambulance options) and “non-ambulance,” then were analyzed using logistic regression.

An analytic model was developed to assess the effect of independent variables on this primary outcome variable. Independent variables in our model included respondent’s age, sex, education level, prior experience with ambulances, knowledge of local ambulance services, knowledge
of appropriate ambulance functions, and knowledge of the local emergency access number, all of which were assessed as part of the survey. To explore the relationship between independent variables and the outcome variable (decision to call an ambulance), descriptive cross tabs with chi-square analysis were performed. Variables were selected according to previous literature and the expert opinion of the authors. Variables that were found to be significant in bivariate analysis at the 0.1 level were entered into a multivariate model.

**Ethical Approval**
Ethical approval was obtained from the following human subjects committees: Colorado Multiple Institutional Review Board, University of Michigan Institutional Review Board, and the Ghana Health Service Ethical Review Committee.

**RESULTS**
Of 597 people who were approached, 468 completed the survey, yielding a survey response rate of 78.4%. Almost all (>90%) persons who refused participation did not give a reason for why they declined to consent. Respondents were sampled from all 11 enumeration areas, with between 38 and 57 respondents in each area. The majority of the respondents were surveyed in business locations (n=204, 43.6%), followed by the street (n=135, 28.8%) and residential
locations (n = 89, 19.0%). The remainder (n = 33, 7.1%) were surveyed in locations coded as “other,” mainly postgraduate schools, such as law school. Location data were missing for 7 participants (0.85%). Most of the surveys were conducted in English (n = 273, 58.3%), but a substantial proportion were translated (n = 195, 40.2%), virtually all in Twi (n = 184 in Twi, n = 1 in French, n = 10 not documented).

**Background Demographic Characteristics**
Slightly more than half of the participants who completed the survey were men (n = 248, 53.0%) (Table 1). The mean age was 34.9 years (SD, 12.9), with the majority (n = 277, 59.2%) of respondents between 18–35 years. The large majority (n = 448, 95.7%) resided in the Accra metropolitan area. Only 53 participants (11.3%) owned a car, but 453 (96.8%) owned a cell phone. About one-third (n = 159, 34.0%) of the respondents had attained post-secondary education.

**Prior Ambulance Use**
In the preceding 5 years, 350 (74.8%) respondents had had a personal experience and/or had witnessed an experience with either or both a medical (n = 246, 57.7%) or traumatic (n = 205, 47.1%) incident that required acute or emergency care. Of those prior incidents requiring acute or emergency care, 402 (89.1%) resulted in

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**TABLE 1. Demographic Characteristics of Survey Respondents, Accra, Ghana (N = 468)**

|                | No. (%) | No. (%) |
|----------------|---------|---------|
| **Sex**        |         |         |
| Male           | 248 (53.0) | 85 (18.1) |
| Female         | 220 (47.0) | 73 (15.6) |
| **Age, y**     |         |         |
| 18–35          | 277 (59.2) | 145 (31.0) |
| 36–50          | 128 (27.3) | 167 (35.7) |
| 51 +           | 63 (13.5) | 32 (6.8) |
| **Residence**  |         |         |
| Accra metropolitan area | 448 (95.7) | 66 (14.1) |
| Other          | 20 (4.3) | 26 (5.6) |
| **Cell phone ownership** |       |         |
| Yes            | 453 (96.8) | 42 (9.0) |
| No             | 15 (3.2) | 6 (1.3) |
| **Car ownership** |       |         |
| Yes            | 53 (11.3) | 231 (49.4) |
| No             | 415 (88.7) | 83 (17.7) |
| **Languages spoken** |       |         |
| Twi            | 413 (88.2) | 78 (16.8) |
| English        | 391 (83.5) | 37 (7.9) |
| Ga             | 220 (47.0) | 48 (10.3) |

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*Percentages do not total to 100%, given multilingual respondents.*
transportation to the hospital. Only 18 (4.5%) respondents had ever used an ambulance in the emergency situation (Table 2). The rest of respondents had used taxis (n = 195, 48.5%), private cars (n = 49, 12.2%), or other (n = 112, 27.9%) forms of transportation. Of the 18 respondents who recalled using an ambulance, 4 (22.2%) had called the public access emergency medical number and the rest (n = 14, 77.8%) had used alternative means to access the service (data not shown). In total, 69 (14.7%) respondents recalled being inside an ambulance in the past 5 years.

### Knowledge and Perceptions of Ambulance Services

Table 3 details respondents’ knowledge and perceptions of ambulance services in Ghana, according to their experiences.

| Type of Emergency | Injury, No. (%) | Illness, No. (%) | Total, No. (%) |
|-------------------|----------------|-----------------|---------------|
| **Type of transportation to hospital used** |                |                 |               |
| Ambulance         | 15 (9.6)       | 3 (1.2)         | 18 (4.5)      |
| Taxi              | 85 (54.5)      | 110 (44.7)      | 195 (48.5)    |
| Private car       | 22 (14.1)      | 27 (11.0)       | 49 (12.2)     |
| Tro-Tro (minibus) | 8 (5.1)        | 60 (24.4)       | 68 (16.9)     |
| Motorbike         | 4 (2.6)        | 0 (0.0)         | 4 (1.0)       |
| Walked            | 2 (1.3)        | 38 (15.4)       | 40 (10.0)     |
| Don’t remember    | 6 (3.8)        | 7 (2.8)         | 13 (3.2)      |
| Missing           | 14 (9.0)       | 1 (0.4)         | 15 (3.7)      |
| **TOTAL**         | 156 (38.8)     | 246 (61.2)      | 402 (100)     |

| How transportation was accessed | Injury, No. (%) | Illness, No. (%) | Total, No. (%) |
|---------------------------------|-----------------|-----------------|---------------|
| Waved down taxi                 | 5 (4.1)         | 0 (0.0)         | 5 (1.5)       |
| Someone waved taxi              | 14 (11.5)       | 0 (0.0)         | 14 (4.3)      |
| Walked to ambulance station     | 1 (0.8)         | 0 (0.0)         | 1 (0.3)       |
| Used own car/family drove       | 2 (1.6)         | 0 (0.0)         | 2 (0.6)       |
| Shouted/yelled for help         | 19 (15.6)       | 0 (0.0)         | 19 (5.8)      |
| Called known contact            | 4 (3.3)         | 30 (14.5)       | 34 (10.3)     |
| Sent someone to find transport  | 42 (34.4)       | 54 (26.1)       | 96 (29.2)     |
| Went myself to find transport   | 9 (7.4)         | 114 (55.1)      | 123 (37.4)    |
| Health care provider called     | 0 (0.0)         | 2 (1.0)         | 2 (0.6)       |
| Don’t remember                  | 11 (9.0)        | 6 (2.9)         | 17 (5.2)      |
| Missing                         | 15 (12.3)       | 1 (0.5)         | 16 (4.9)      |
| **TOTAL**                       | 122 (37.1)      | 207 (62.9)      | 329 (100)     |

*Respondents could have experienced either a traumatic (injury) or medical (illness) emergency or both.
| Availability                                                                 | No. (%)  | Affordability                                                                 |
|------------------------------------------------------------------------------|----------|-------------------------------------------------------------------------------|
| Knew at least one ambulance company                                           | 425 (90.8) | Respondents who knew of the public emergency number (n = 205) and thought the cost of calling that number was: |
| Knew about government ambulance service                                       | 213 (45.5) | Free (i.e., toll free)                                                        |
| Able to name the National Ambulance Service (NAS)                            | 26 (5.6)  | Same as a regular call                                                         |
| Thought the number of ambulances in Accra insufficient                        | 324 (69.2) | Less expensive than a regular call                                             |
| **Accessibility**                                                             |          | More expensive than a regular call                                             |
| Knew about public emergency access number                                     | 205 (43.8) | Did not know the cost                                                          |
| Knew public access number is 1-9-3                                            | 16 (3.4)  | More likely to call 1-9-3 in an emergency if the call was free                 |
| Expected NAS ambulance response time during peak traffic hours               |          | Thought the cost of government ambulance service was:                          |
| ≤ 15 minutes                                                                 | 165 (35.3) | Free                                                                          |
| Between 16 and 59 minutes                                                    | 271 (57.9) | Affordable                                                                     |
| ≥ 60 minutes                                                                 | 32 (6.8)  | Too expensive                                                                  |
| Expected NAS ambulance response time during non-peak traffic hours           |          | Thought the cost of private ambulance service was:                             |
| ≤ 15 minutes                                                                 | 311 (66.5) | Cheap                                                                         |
| Between 16 and 59 minutes                                                    | 154 (32.9) | Affordable/reasonable                                                          |
| ≥ 60 minutes                                                                 | 3 (0.6)   | Too expensive                                                                  |
| **Acceptability**                                                            |          | Did not know                                                                  |
| Identified at least one appropriate indication (as defined by NAS) for accessing an ambulance | 444 (96.3) | Believed ambulance technicians in Accra offered high-quality care              |
| Thought use of ambulance to transport corpses would be appropriate           | 108 (23.4) | Believed it is safer to go to the hospital by ambulance than by taxi in Accra |
| Thought ambulances in Accra were currently being used to:                   |          | Believed it is faster to go to the hospital by ambulance than by taxi in Accra |
| Transport persons with medical illnesses                                     | 223 (48.4) | Believed it is “better” to go to the hospital by ambulance than by taxi in Accra |
| Transport injured people                                                     | 161 (34.9) |                                                                               |
| Conduct interfacility transfers                                              | 90 (19.5)  |                                                                               |

* N = 461 as there were 7 missing responses.
to the 5 dimensions of access defined by Pechansky and Thomas.

**Availability**
213 (45.5%) respondents knew specifically about the government ambulance service, but only 26 (5.6%) correctly knew it was called the National Ambulance Service. The majority (n=324, 69.2%) thought there was an insufficient number of ambulances in Accra.

**Accessibility**
205 (43.8%) knew the existence of a public access medical emergency telephone number (1-9-3). During peak traffic hours, 165 (35.3%) of the respondents indicated that it would take a government ambulance (NAS) 15 minutes or less to arrive at the location of their incident, while 32 (6.8%) stated it would take 60 minutes or more.

**Accommodation**
To gauge participants’ perceptions of the client needs that ambulance services were currently organized to meet, we asked participants what they perceived ambulance services were currently used for in Ghana. Eight general themes emerged, centered around providing care and transportation to: (1) people with medical emergencies, (2) people with injuries, (3) burn victims, (4) obstetric patients in labor or with complications, (5) those with other emergency conditions, (6) patients requiring interfacility transportation, (7) provide general pre-hospital emergency care to the population, and (8) provide other specialized services. Participants most commonly reported that ambulances were currently used as transportation for medical illnesses (n=223, 48.4%), for injuries (n=161, 34.9%), and for interfacility transfers (n=90, 19.5%). A substantial number (n=108, 23.4%) thought ambulances should be used as hearses to transport dead bodies (but NAS policies do not permit or accommodate this). Selected responses from the open-ended question, “What are ambulances currently used for in Ghana?”, are listed in Table 4.

**Affordability**
Of those respondents who knew the existence of a public-access number for medical emergencies, only 76 (37.1%) knew it was a toll-free call. About one-third (n=167, 35.7%) of all the respondents indicated they would be more likely to call the 1-9-3 number in an emergency if they knew the call was toll free. When asked about their perceived cost of ambulances as a potential barrier, the majority of subjects indicated that government ambulances were free or affordable (n=249, 53.2%) and that private ambulances were too expensive (n=235, 50.2%).

**Acceptability**
The majority (n=256, 54.7%) believed the EMTs offer high-quality care, and most (n=403, 86.1%) believed it is overall “better” to go by ambulance in an emergency. However, the majority also thought taxis are faster than ambulances in Accra (n=365, 78.0%).

**Hypothetical Scenarios**
Of the 459 total responses to both hypothetical questions, 57 (12.4%) respondents reported they would call for an ambulance (either NAS or other) in both hypothetical scenarios (witnessing a pedestrian severely struck by a vehicle and a family member being burned badly in a house fire) (Table 5). The most common response was to use a taxi in both scenarios (n=225, 49.0%) while 21 (4.6%) stated they would take any available vehicle as a means of emergency transportation in both events.

An analytic model was developed in which the likelihood of calling an ambulance after witnessing a pedestrian-auto collision (outcome variable) was assessed as a function of respondent demographics of age, sex, education level, cell phone ownership, car ownership, prior ambulance experience, knowledge of ambulance function, knowledge of cost of the 1-9-3 call, and perception of ambulances (safe, fast, better). Age of respondent (in years) was found to be negatively associated with the likelihood of calling an ambulance (Table 6). This response was then categorized into 3 age variables: 18–35, 36–50, and over 51 years. Being between the ages of 18 and 35 (P=.01) and believing ambulances were safe means of emergency transport (P=.02) were significantly associated with reported likelihood of respondents to call for an ambulance in the case of an emergency. Prior experience with an ambulance (P=.06) was positively associated with likelihood of calling for an ambulance, but the association was not statistically significant. Those respondents aged 18–35 were 2.3 times as likely to call for an ambulance (odds ratio [OR], 2.27) as older respondents, and those who believed an ambulance is safer than a taxi were over 2 times as likely to report they would call for an ambulance (OR, 2.17) as those who did not hold such beliefs, while those who had personal experience with an ambulance were 75% more likely to report they would call for an ambulance than those with no prior experience.
(OR, 1.75). No other statistically significant association was discovered between any other variable and likelihood of calling an ambulance in the pedestrian injury scenario.

A similar regression was repeated using the second hypothetical scenario (in which a family member was burned in a house fire), with the respondents’ answers to how they would transport that patient to the hospital as the outcome variable, while maintaining the original independent variables (listed above). Results were similar (data not presented).

**DISCUSSION**

Although the significant burden of acute disease in Ghana suggests a large need for ambulance services, calls for ambulances from the public are

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**TABLE 4. Selected Responses About Current Use of Ambulances in Ghana According to Appropriateness of the Use**

| Appropriate Use of Ambulance                                                                 | Inappropriate Use of Ambulance                                                                 |
|---------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| “Because it is an emergency the ambulance is necessary since it will get to hospital faster than taxi.” | “I think the ambulance is to be for the dead … the sick and the injured should have their own special car.” |
| “Ambulances should be used to help those in need of health care, because we do not have enough hospitals and the ambulances can provide first aid.” | “For the corpse you can only use the ambulance, the police will arrest you if you take a dead body in another vehicle.” |
| “That is the job of the ambulance to save life because they have first aid in the ambulance to help you before getting to hospital.” | “For the pregnant women in labor it is better to go by taxi to get to the hospital quickly” |
| “Ambulances should be used to pick up the sick in the communities, but the government does not have enough so we use taxis.” | “It is not nice to put a corpse in a regular car.” |
| “The ambulance is supposed to be there for emergencies at home, schools, and everywhere.” | “That is what I have seen the ambulances do. I fear the dead so I could not be in the same car that has carried the dead so corpses should be carried in an ambulance.” |
| “Because there are not enough ambulances we only use the ambulance for emergencies, but if there were enough then we should use ambulances for critical illness.” | “The ambulance should be able to convey even those with mild sickness …” |

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**TABLE 5. Transportation Preferences in Hypothetical Emergency Scenarios: Concordance in Survey Responses to Both Scenarios (N = 459 Responses)**

| Preferred Transportation if Pedestrian Struck, No. (%) | Preferred Transportation if Family Member Burned, No. (%) |
|--------------------------------------------------------|----------------------------------------------------------|
|                                                        | NAS Ambulance | Other Ambulance | Taxi | Any Available Vehicle | Tro-Tro (minibus) | Total |
| NAS ambulance                                          | 5 (1.1)       | 1 (0.2)         | 4 (0.9) | 2 (0.4) | 0 (0.0) | 12 (2.6) |
| Other ambulance                                        | 18 (3.9)      | 33 (7.2)        | 37 (8.1) | 7 (1.5) | 0 (0.0) | 95 (20.7) |
| Taxi                                                   | 13 (2.8)      | 17 (3.7)        | 225 (49.0) | 41 (8.9) | 1 (0.2) | 297 (64.7) |
| Any available vehicle                                  | 0 (0.0)       | 7 (1.5)         | 19 (4.1) | 21 (4.6) | 0 (0.0) | 47 (10.2) |
| The car that hit the pedestrian                        | 0 (0.0)       | 1 (0.2)         | 7 (1.5) | 0 (0.0) | 0 (0.0) | 8 (1.7) |
| Total                                                  | 36 (7.8)      | 59 (12.9)       | 292 (63.6) | 71 (15.5) | 1 (0.2) | 459 (100.0) |

Abbreviation: NAS, National Ambulance Service.
disproportionately lower. Our study has elucidated contributing factors to this issue in Accra, where study participants most commonly indicated they would call a taxi—perceived to be faster than ambulances—in hypothetical traumatic emergency situations. The majority of participants thought there was an insufficient number of ambulances. Yet most participants had favorable opinions of existing ambulances, indicating they provided high-quality care and that they were safer and ultimately better than taxis. Only a minority, however, knew of the toll-free public access number, and many thought that ambulances should be used to transport corpses. With awareness of proper use of ambulance services and how to access it, along with adequate numbers of ambulances per population, use of ambulance services in emergency medical situations may improve. Our main findings, interpretations, and their significance are discussed below in the context of respondents’ prior experiences, preferences, and perceived barriers and facilitators.

Prior Emergency Medical Experiences and Use of Ambulance Services

Up to 75% of respondents reported experiencing a medical or traumatic emergency within the preceding 5 years. Among these, only about 5% had used an ambulance for emergency transportation to a health care facility. This is a lower proportion of ambulance use than was found in prior studies in Ghana that indicated ambulance use by the general population in 8% to 12% of emergencies. This difference may be accounted for by respondent recall bias, although we do acknowledge that emergency situations are often major life events and less likely forgotten; however, we have no way to assess to what extent participants were accurately recalling events. In addition, this study excluded cases of interhospital ambulance transfers, which are relatively common in Ghana and were included in prior studies. Nonetheless, the results confirm a generally low rate of ambulance access requests and utilization for medical and traumatic emergencies in a resource-constrained African setting.

Preferences for Modes of Emergency Transportation

When presented with the study’s hypothetical emergency injury scenarios (pedestrian hit by a car and person burned in a house fire), relatively few (12%) Ghanaians stated they would call for an ambulance in both scenarios, while 49% said they would rather use a taxi in both scenarios. These findings may be explained by the fact that 75% of respondents perceived taxis to be a “faster” form of prehospital transport than ambulances. Although there is no prior research assessing taxi response times in Ghana, given the ubiquitous presence of taxis and relative paucity of ambulances in 2013, it seems reasonable to assume a faster response time from the former. Paradoxically, respondents generally had favorable opinions of existing ambulance services in Accra: over half (55%) felt that EMTs offer “high-quality” care, 81% acknowledged that ambulances were in fact the “safer” form of emergency transport, and 86% affirmed that ambulances were ultimately the “better” way to be transported during emergencies. However, 69% of our sample felt the number of ambulances in the Accra metropolitan area insufficient. This leads to the inference that when an adequate number of ambulances exists, and citizens are made aware of this service, individuals (who appear to generally understand the appropriate indications to access an ambulance) may be inclined to actively seek access to them more often for primary, or scene, responses. Of note, given the high percentage of respondents who indicated some preference for taxis, a complementary, practical non-ambulance solution for safer emergency transport may include mass training of taxi drivers in first aid, appropriate destination hospital selection, and safe emergency transport (successfully demonstrated by Mock et al. in a small pilot study in Kumasi, Ghana, in the 1990s).

Perceived Barriers and Facilitators to Accessing Ambulances

Although 44% of respondents who knew the existence of a public access number in Accra, only 37% knew it was toll free, and 36% stated they would be more likely to call if they knew the call was free. Half believed NAS (the government ambulance service) was affordable, but very few

| TABLE 6. Likelihood of Calling an Ambulance in Hypothetical Pediatric-Pedestrian-Auto Collision: Results of Logistic Regression Analysis |
|------------------|------------------|------------------|
| **Personal experience with ambulance** | 1.75 (0.98, 3.09) | .06 |
| **Aged 18–35** | 2.28 (1.47, 3.68) | .001 |
| **Believe ambulance safer than taxi** | 2.17 (1.12, 4.19) | .02 |

**Abbreviations:** CI, confidence interval; OR, odds ratio.

When adequate numbers of ambulances exist and citizens are aware of the service, individuals may be more inclined to use ambulances.
(3%) knew it was a free service. Misperceptions about telephone access and cost of ambulance services are indicative of a general paucity of education among Ghanaians in Accra, and this is most likely generalizable to citizens across the nation. Issues within Ghana that focus on telephone-based access to emergency medical services through emergency medical dispatch are the subject of a parallel study by the investigators of this study.

We demonstrated that those with prior personal experience with an ambulance service, who were younger in age, or who believed ambulances to be a safer means of transport were more likely to report they would call for an ambulance in the event of a medical emergency.

Several previously hypothesized barriers were not perceived by our participants as obstacles to accessing EMS services, including poor knowledge of ambulance companies and appropriate indications to access ambulances. Over 90% of respondents were aware of the existence of at least one ambulance company in Accra, and about half knew specifically of NAS. Over 90% of surveyed citizens knew at least one appropriate indication for accessing an ambulance. Interestingly, 23% of respondents also inappropriately suggested that ambulances in Ghana should be used to transport corpses, a long-standing accepted practice in Ghana that was outlawed in 2012. This warrants special mention as many respondents felt ambulances were generally vehicles for transporting corpses, a common misperception that may prevent appropriate ambulance access. This deep-rooted sociocultural perspective may persist until this historic practice is completely aborted in Ghana and purposeful public information reverses the misperception.

Prior to this study, only one published report in the African emergency care literature was found that sought to assess barriers to accessing prehospital emergency care by a medically undifferentiated population. That study was undertaken in Libreville, Gabon, in 2009, where investigators conducted a brief 9-question oral interview of a small (N = 25) convenience sample of patients and visitors at a local emergency center. Qualitative results from this study indicated that misperceptions, lack of awareness, alternative forms of transport, and cost were all barriers to accessing prehospital resources. While our results support many of these findings, cost does not appear to be as substantial a barrier as in this previous study. Further, the majority of our study’s population had high awareness of the service and confidence in the service’s care and safety. However, the specifics about how to access the service, indicated by the low prevalence of awareness of the free public access phone number, reflect a population-based problem of access to care in Ghana.

Possible Interventions to Improve Use of Ambulance Services

If the culture of seeking formal emergency transportation and professional prehospital medical care does not shift among populations, EMS systems risk failing in their mission to save lives when time-sensitive expertise-driven care is required. Fortunately, our findings bear favorable implications for public health education as a means to appropriately improve access to and use of ambulance services in Ghana, given the preponderance of short-term modifiable factors. For example, focused public education about the toll-free number, ambulance safety, and response or transport times, delivered via media consumed by persons aged 18–35, may be one high-yield targeted method to improve appropriate public ambulance utilization, once adequate ambulance response units exist in the near future. This may be accomplished as part of public media campaigns and/or incorporated into school-based education. However, there has purposefully been no large-scale public educational efforts by the Ghana Ministry of Health or NAS given the small capacity of this ambulance service relative to its large jurisdictional responsibility.

It is noteworthy that while the development of an EMS system is important and prehospital care confers a survival benefit, there must be concurrent
improvement in in-hospital emergency care to synergistically improve patient outcomes. Emergency medicine is a recognized medical specialty in Ghana, and while specialist training has been ongoing in Kumasi, it is yet to commence in Accra where there is a paucity of emergency medicine specialist physicians.9,15

**Adaptation of the Survey Instrument**

While this survey instrument was designed for application in Ghana, plans are underway to adapt it to other African settings in which EMS leaders, administrators, and researchers desire to scientifically understand and quantify barriers to access of their local emergency medical services in order to increase the public’s appropriate use of EMS services.

**Limitations**

We do note heavier sampling in business and academic centers, which may have introduced a selection bias toward more-educated individuals, thereby making our sample less representative of the Accra population. Analysis of the Accra study population’s demographics indicate a high similarity to the general Ghanaian population; however, our conclusions are less generalizable to other urban areas in Ghana and least generalizable to non-urban areas in Ghana. Further, recall bias and decisions based on hypothetical emergency situations do not necessarily correlate with actual practice, and this is an unavoidable shortcoming in a survey.

**CONCLUSIONS**

Across Africa, EMS systems are developing rapidly in an effort to address the large burden of growing acute injury and endemic disease. This article describes the first known successful development and application of a robust community-based survey instrument to quantify the demographic, perceptual, and experiential factors that may prevent an African subpopulation from accessing critical EMS resources. Findings from this novel study indicate generally positive influencing citizens’ decisions to call for an ambulance. The present findings also support consieration of reconfiguring the public ambulance service to encompass trained taxi services as first-responders, which has been previously pilot tested in Ghana with operational and educational success.

Future work will include deploying the survey in rural Ghanaian settings and other African countries developing EMS systems.

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Monitoring and Evaluating the Transition of Large-Scale Programs in Global Health

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Monitoring and evaluating large-scale global health program transitions can strengthen accountability, facilitate stakeholder engagement, and promote learning about the transition process and how best to manage it. We propose a conceptual framework with 4 main domains relevant to transitions—leadership, financing, programming, and service delivery—along with guiding questions and illustrative indicators to guide users through key aspects of monitoring and evaluating transition. We argue that monitoring and evaluating transitions can bring conceptual clarity to the transition process, provide a mechanism for accountability, facilitate engagement with local stakeholders, and inform the management of transition through learning.

ABSTRACT

Purpose: Donors are increasingly interested in the transition and sustainability of global health programs as priorities shift and external funding declines. Systematic and high-quality monitoring and evaluation (M&E) of such processes is rare. We propose a framework and related guiding questions to systematize the M&E of global health program transitions.

Methods: We conducted stakeholder interviews, searched the peer-reviewed and gray literature, gathered feedback from key informants, and reflected on author experiences to build a framework on M&E of transition and to develop guiding questions.

Findings: The conceptual framework models transition as a process spanning pre-transition and transition itself and extending into sustained services and outcomes. Key transition domains include leadership, financing, programming, and service delivery, and relevant activities that drive the transition in these domains forward include sustaining a supportive policy environment, creating financial sustainability, developing local stakeholder capacity, communicating to all stakeholders, and aligning programs. Ideally transition monitoring would begin prior to transition processes being implemented and continue for some time after transition has been completed. As no set of indicators will be applicable across all types of health program transitions, we instead propose guiding questions and illustrative quantitative and qualitative indicators to be considered and adapted based on the transition domains identified as most important to the particular health program transition. The M&E of transition faces new and unique challenges, requiring measuring constructs to which evaluators may not be accustomed. Many domains hinge on measuring “intangibles” such as the management of relationships. Monitoring these constructs may require a compromise between rigorous data collection and the involvement of key stakeholders.

Conclusion: Monitoring and evaluating transitions in global health programs can bring conceptual clarity to the transition process, provide a mechanism for accountability, facilitate engagement with local stakeholders, and inform the management of transition through learning. Further investment and stronger methodological work are needed.

INTRODUCTION

The donor community has long been interested in the sustainability and fate of public health programs after donor funding is reduced.1,2 This interest has escalated recently, as a result of shifts in donor priorities and the resulting rapid reductions in, and often complete withdrawal of, external funding.

The process of transitioning financing and control of large-scale health programs from donors to local governments is not new. Among programs funded by the United States Government (USG), the transitions of large-scale
health programs have been called “graduations” and have been occurring at least since the 1980s with the graduation of family planning assistance programs in Latin America and the Caribbean.\(^{3,4}\) However, transitions are gaining both momentum and interest. For example, reauthorization of the US President’s Emergency Plan for AIDS Relief (PEPFAR) in 2008 reinforced the notion that transition must be handled carefully, with the introduction of Partnership Frameworks, which aimed to ensure PEPFAR programs were sustainable through a renewed focus on “country capacity, ownership and leadership.”\(^{5,6}\) Transitions of PEPFAR programs are ongoing in sites such as South Africa and the Caribbean and are expected to be initiated in other countries in the near future.

USG agencies are not the only ones to engage in such discussions. The Bill and Melinda Gates Foundation, The Global Fund to Fight AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance, are among several other global organizations with growing interest in the transition from donor assistance toward long-term sustainability. Gavi, for example, has recently revised its graduation policy, which outlines a process for phasing out Gavi support with time-limited catalytic investments to support graduation plans.\(^7\)

The discussion of phasing out donor support often comes after years, if not decades, of investments in strengthening service delivery and health systems and significant efforts to reduce the burden of disease. Poorly executed transitions risk reversing health achievements, negatively affecting services and outcomes for the beneficiary population. As ownership is transitioned from donors to local counterparts, clear accountability is needed to ensure transition is successful. However, with a few exceptions,\(^8\) transitions to date have been conducted on an ad-hoc basis, where lines of accountability for long-term sustainability between donors and local counterparts have not been clear and systematic, and purposeful monitoring of post-transition health outcomes was not prioritized by the aforementioned stakeholders.\(^2,4,9,10\)

Despite the high stakes involved in transition processes, there are relatively few documented examples of how the transition process was managed, of the effects of transition on the health outcomes of interests, or of monitoring and evaluation (M&E) of how the transition process itself was executed or managed. The US Agency for International Development (USAID) commissioned midterm\(^1,11,12\) and final\(^10,13\) evaluations for transition, and compilations of lessons learned,\(^2,6\) from selected Latin American and Caribbean countries that graduated from family planning assistance. However, few of these studies are rigorous evaluations, and most could be considered compilations of lessons learned through readily available qualitative and quantitative data sources. Further, most of these evaluations focused specifically on program-related outputs and outcomes. More recently, Gavi has sought to assess the readiness of graduating countries to assume responsibility for sustainable financing of the immunization process.\(^14\) Attention has also focused on the transitioning of health care worker support from PEPFAR to local funding.\(^15\) However, the frameworks to define and measure transition processes are few. Recent efforts to develop more systematic approaches to the M&E of transition include an evaluation of the sustainability of Gavi-funded immunization programs in Bosnia-Herzegovina (BiH) after the country became ineligible for Gavi funding,\(^16,17\) and efforts to prospectively monitor and evaluate the transition of the Gates-funded Avahan HIV prevention project in India to local ownership.\(^18-20\) To date, with the exception of the Avahan transition evaluation, none of the existing M&E activities has examined transition prospectively or throughout the entire transition process,\(^18\) and there have been no systematic efforts to develop an approach for the M&E of transition.

In this paper, we draw on our team’s experiences to develop an initial description of the key dimensions of health program transitions from donors to local counterparts. Furthermore, we make the case for why M&E of the transition process is important and propose a framework to facilitate the identification of different domains and dimensions to monitor and evaluate before, during, and after transition. Finally, we propose guiding questions linked to these domains, which can stimulate thinking around the potential indicators for the M&E of transition. We argue that the M&E of transition can help us obtain a deeper appreciation of how transition unfolds, as well as of the evidence necessary to refine our understanding of how transitions should be planned and managed. We focus on health programs whose goals are to be continued after the transition, unlike, for example, the transition of polio programming after polio eradication.

**METHODS**

Our paper takes a reflective “thought exercise” approach similar to that of Gilson et al.,\(^21\) whereby the content was generated in part through

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**There have been no systematic efforts to develop an approach to monitor and evaluate transitions of global health programs.**

**Poorly executed transitions of large-scale global health programs from donors to local governments risk reversing health achievements.**
author reflections on professional experiences and refined through discussion with other practitioners. Four authors (SB, DR, SO, LP) have had involvement in monitoring and evaluating the transition of health programs. SB, SO, and DR were involved with monitoring and evaluating the transition of Avahan’s HIV prevention program, and LP was involved in evaluating Gavi support to BiH, whose funding ended prior to the implementation of Gavi’s graduation policy.\(^{18-20}\) This direct involvement in the work allowed for insights on how M&E occurred during the transition process for different sorts of program transitions. In order to help ensure the broader generalizability of our recommendations, we also reviewed peer-reviewed and gray literature on transitions and on the M&E of transition.

Overall, to create the conceptual framework and guidance presented here, we:

- Based our initial thinking on the conceptual framework described in Bennett et al.\(^ {18}\) for monitoring and evaluating the transition of the Gates-funded Avahan project for HIV prevention.
- Searched the literature including peer-reviewed literature, gray literature, personal author collections, and papers recommended by experts to identify additional relevant sources that would inform the adaptation of the framework and our thinking about the M&E of transition.
- Conducted semi-structured interviews with individuals with experience in health program transitions (\(N=6\)); 5 respondents had first-hand involvement in USAID’s family planning graduation in Latin America, while based either at USG or within implementing partners; 1 respondent was engaged, at the time of the interview, in a CDC-funded activity to measure and monitor the transition of HIV care and treatment from international NGOs to local NGOs, and eventually to the country government.
- Adapted the Avahan framework\(^ {18}\) iteratively to develop a revised version informed by the literature, semi-structured interviews, and authors’ general experience with M&E of transitions, and developed guidance on approaching the M&E of transition.
- Obtained two rounds of feedback (27 June 2014, 12 September 2014) about the draft framework and guidance from a group of key informants (\(N=5\), separate from the interviewees noted earlier) with experience in health program transition; these informants were selected based on their recent engagement in the development of the Gavi graduation policy (\(n=1\)), their knowledge of the scaling down of PEPFAR activities in the Caribbean (\(n=2\)) and in Namibia (\(n=1\)), and their knowledge of M&E and possible sources of indicators that could be used to monitor or evaluate transition processes (\(n=1\)); all informants were associated with implementing, rather than funding, agencies. During both meetings, feedback was sought on how to package the available evidence around M&E of transition, the components of the proposed framework, and possible indicators and sources of indicators for each of the framework domains.
- Finalized the conceptual framework and guiding questions for this paper.

Ultimately, the final framework and approach presented here is meant to build on previous experiences in implementing and managing M&E of transitions, so as to present a guide for how those engaged in transition can think about the process, as well as for program evaluators and planners on possible approaches to the M&E of future large-scale health program transitions.

**FINDINGS**

Our findings are organized as follows. First, we present a conceptual framework highlighting potential transition domains, activities, and outcomes to be monitored or evaluated. Next, based on this framework, we describe possible approaches to the M&E of transition including reflections on timing and organization of M&E approaches. Finally, we suggest guiding questions and potential indicators that might be used to monitor and evaluate health program transition.

**Conceptual Framework**

The proposed conceptual framework (Figure) seeks to guide users through key aspects of monitoring and evaluating transition in a comprehensive fashion. It aims to be broad and inclusive of elements relevant to a large-scale health program transition, although we recognize that transitions take many forms and that the nature of transition drives which domains become pertinent for each particular case.
We conceive of transition as a process. Pre-transition activities set the parameters for transition including key factors such as the timeline, budget, and partners involved. Subsequent to these pre-transition activities, the transition entails a set of ongoing iterative processes that gradually shift program responsibility from the donor to the program recipient. Transitions may occur across one or more domains: leadership, financing, programming, and service delivery. Each of these domains is explained more fully in Table 1.

For each transition domain, we identified a set of relevant activities, which help to anchor the necessary responsibilities, rules, norms, and structures into the program recipient environment. Ultimately, these activities facilitate the delivery of program services by the recipient, at a level defined by the transition goals. These activities include:

**Sustaining a supportive policy environment:** Ideally transition plans are developed and executed in an environment where existing policies and involved stakeholders are committed and supportive of achieving the overall objective of the transition and of the health program. In practice, transitions can be politically motivated and implemented abruptly and are often met with resistance and/or disbelief. Therefore, it is crucial for transition planning to conduct activities strategically to build political commitment and support. In instances where leaders can be held accountable to their constituents, creating wide public support for a health program may encourage leaders to visibly support the sustainability and transition of a health program. In other instances, “soft” approaches such as strategic communication of benefits could be applied to influence powerful stakeholders. Signals of a supportive policy environment may include the post-transition program being embedded in national policy or specific program goals being reflected in national and/or subnational plans and budgets. Sometimes existing policies may undermine program sustainability; for example, existing policies inhibiting effective procurement processes would be a target for change.

**Creating financial sustainability:** The existence of secure and diversified funding is central to the sustainability of a health program. The burden of securing this funding is dependent on the context, but the responsibility may fall in part on the program recipients themselves as well as on donor agencies, and potentially on program beneficiaries. As there can be multiple donors and funding sources for a program, coordination is
central in organizing how funds are raised and shared. An understanding of a country and program’s current and future needs (e.g., using a resource plan) can better conceptualize the funding situation to key audiences.24 Ultimately, funding is related to contextual issues (economic conditions, political will, competing political/government priorities, capacity) and is affected by the donor landscape, where the presence of generous donors may discourage the acceptance of financial responsibility.25

**Developing local stakeholder capacity:** Shifting health program responsibility from donor to program recipient means that the capacity previously supplied by donors must be replaced or adapted according to the priorities and capacities of local actors. Ideally, developing local capacity and building ownership is a process initiated long before transition begins; however, in practice, this is not always the case. Organizational capacity assessments may diagnose existing competencies and identify areas in need of investment to reach sufficient capacity for sustaining the health program.26 When capacity is insufficient, capacity-building activities should be initiated to develop the necessary components to continually deliver program activities.26 Capacity goes beyond the idea of having the skills and tools to deliver program activities to also comprising staff, facilities, structures, and systems. A diverse range of activities to support this domain can be undertaken, depending on the needs and resources present.27

**Communicating to all stakeholders:** As the transition process inherently involves shifts in power and authority, it often faces considerable stakeholder resistance. Timely, transparent, and appropriately disseminated communication plays a key role in persuading stakeholders and forming a group of proponents to support transition. Communication helps to align expectations, forge common goals, and facilitate building positive relationships among key audiences. These activities can help to overcome common risks of transition, such as being overwhelmed by tension and confusion from misinformed audiences, as well as an overall resistance to transition.28 Communication of the transition plan needs to occur at multiple levels, from the donor to senior management, as well as from program recipient to frontline workers. Poor communication with frontline workers can create resistance due to shifting priorities or changing values.

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**TABLE 1. Transition Domains Explained**

| Transition Domain | Explanation |
|-------------------|-------------|
| Leadership        | High-level leaders must accept that the transition process is actually occurring, and health sector leaders need to provide political support for transition and for sustaining the program in its new environment post-transition. Political will and commitment are complex and context-specific and need to be built beyond individual leaders, who may be transient. High-level leadership needs to come from both within the health sector and from non-health sector actors, such as the Ministry of Finance. |
| Financing         | In order to ensure financial sustainability post-transition, the program recipient will need to identify and secure new sources of funding as prior sources of financial support are eliminated. Funding will likely come from multiple sources, and, as such, activities may include lobbying to secure funding from new sources and creating and altering financial mechanisms for improved sustainability. |
| Programming       | Responsibilities for program management, such as day-to-day operations, as well as staff management, funding, reporting requirements, monitoring and evaluation, and other administrative tasks, must be transitioned, to the extent that such functions were previously provided by donors. Capacity assessments can help diagnose competencies and signal the amount of capacity building and training required to transition programming. |
| Service delivery  | In instances where donors, and not local organizations, have been directly responsible for service delivery, the local program recipient may have to take responsibility for the logistics of service delivery, including human resources, commodity procurement, community outreach, and other elements related to the program services itself. |
**Aligning programs:** Programs may need to undergo a process of harmonization with existing services as they transition. This harmonization can include the adaptation of program services as well as the implementation of common arrangements for planning, management, financial reporting, and M&E, so as to integrate with the national program or host environment. Programs activities can be adapted, completely removed, or remain unchanged in accordance with the program recipient and health system context. The implementation of such alignment processes can constitute a significant task.

The 5 activity areas above are closely interconnected and reflect complex adaptive relationships that influence one another. For example, communicating transition plans to stakeholders is closely related to creating and sustaining a supportive policy environment, while the policy environment influences a program’s ability to secure funding and align programs with existing ones.

Together, these activities drive the transition of leadership, financing, programming, and service delivery forward so that program recipients can take full responsibility over these domains and over the health program as a whole. The intermediate result is the institutionalization of the program, by which we mean the development of policies, norms, and structures to sustain the program within the recipient organization’s health system. In total, a well-managed transition process enables the sustained delivery of program services and, hence, sustained health outcomes, even if there may be changes in who delivers services or the mechanisms through which they are provided. Ideally, a transition plan including a context-specific set of activities would be developed jointly in advance of transition and agreed upon between donors and recipient countries. Such a plan would clearly facilitate the M&E of transition, but historically such a document has been rare.

**Approaches to Monitoring and Evaluating Transition**

The conceptual framework described in this article can be used to:

- Identify the most relevant domains being transitioned
- Assess which activities might be prioritized for monitoring
- Formulate appropriate indicators for monitoring and evaluating transition using the proposed guiding questions explained below

The framework may also help program planners and evaluators to reflect on the question of when in the transition cycle it will be important to have measures of transition. As for many evaluations, determining the purpose of M&E is likely to be a critical first step. For example, if the M&E process is meant to help make course amendments to transition plans, then measures of readiness for transition (perhaps reflecting the extent to which transition activities have been implemented as planned, and how they have affected the 4 transition domains) may be key. Alternatively, if the purpose of M&E is to help hold key stakeholders, such as donors and local counterparts, accountable for what happens post-transition, then the focus of M&E may be on measures of institutionalization and service outcomes. For M&E that is designed to aid learning processes and cast light on what constitutes effective transition practice, it will likely be important to have measures of both transition activities and institutionalization and outcomes to allow investigation of how transition activities affect final outcomes. Regardless of the purpose of M&E, it will be important for program planners and evaluators to facilitate clear opportunities for stakeholder engagement (i.e., both donors and recipients), before, during, and after the transition.

Not all health program transitions will reflect all of the domains described in the conceptual framework. Table 2 describes the relevant domains for 3 different health program transitions with which we are familiar (Gavi graduation, USAID family planning transitions in Latin America, and the Avahan transition). The table illustrates that for some health program transitions (such as Avahan), all 4 of the transition domains will be relevant, whereas for others, such as Gavi, the focus may be on a more limited number of domains.

In an ideal situation, the monitoring of transition would begin prior to transition processes being implemented and continue for some time after transition has been completed. The pre-transition period would be used to engage key stakeholders and reach consensus on plans for transition and M&E of transition. This period may also be used for reflection on what type of transition will be taking place and over what timeline. During this period, donors and

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**The monitoring of transition should ideally begin prior to the implementation of transition and should continue beyond the completion of transition.**
### TABLE 2. Transition Types and Implications for Monitoring and Evaluation

| Transition Type | Gavi in Bosnia-Herzegovina | FP in Latin America | Avahan in India |
|-----------------|---------------------------|--------------------|----------------|
| **Transition Description** | From 2002 to 2011, Gavi supported the government of BiH to introduce the Hepatitis B and Hib vaccines, which were delivered through the government health system. BiH passed Gavi’s GNI per capita threshold in 2007, making it ineligible for new support, while Gavi fulfilled existing multyear commitments. The government of BiH assumed funding and planning responsibilities from Gavi when the funding ended, which was before Gavi developed a graduation policy. | Through USAID, the USG supported FP activities in LAC through financial and technical assistance beginning in the 1960s. In the mid-2000s, due to shifting donor priorities and improving FP indicators, countries were systematically "graduated" from FP assistance. Transition plans, typically spanning 2–5 years, were developed where funding and procurement was transitioned to local in-country organizations. | In 2005, the BMGF committed US$350 million to address the spread of HIV/AIDS in India, focusing on prevention for high-risk populations. The programs, in 6 states, offered services through cascading contracts with international and local NGOs. A planned and phased program transition took place between 2009 and 2012. |

| **Transition Domain** | Leadership | Financing | Programming | Service delivery |
|-----------------------|------------|-----------|-------------|-----------------|
| Leadership            | X          | X         | X           |                 |
| Financing             | X          |           | X           |                 |
| Programming           |             | X         | X           |                 |
| Service delivery      |             |           |             | X               |

| **Key M&E Dimensions** | Sustaining a supportive policy environment | Creating financial sustainability | Developing local capacity | Communicating among all stakeholders | Aligning programs |
|------------------------|------------------------------------------|---------------------------------|-------------------------|-------------------------------------|------------------|
|                        | X                                        | X                               | X                       | X                                   |                  |

Abbreviations: BiH, Bosnia-Herzegovina; BMGF, Bill and Melinda Gates Foundation; FP, family planning; GNI, gross national income; Hib, Haemophilus influenzae type B; LAC, Latin America and the Caribbean; M&E, monitoring and evaluation; USAID, US Agency for International Development; USG, United States Government.
Both quantitative and qualitative data are needed to fully understand the transition process and its effect on the wider health system.

BOX. Principles for Monitoring and Evaluating Health Program Transitions

- **Establish clear end goals.** Clear end goals are critical to guiding M&E plans. Stakeholders should clarify their vision for the future of the program and of its end goals with respect to service coverage and health outcomes.

- **Plan early.** Early planning allows for regular and consistent monitoring of the transition process, evaluation of transition preparation activities, and collection of baseline data to determine impacts post-transition.

- **Ensure program recipients are vested in M&E.** It is critical to engage all stakeholders and secure commitments from key actors regarding the use of M&E evidence. It is especially important for the program recipient to engage in the process to ensure access to data post-transition and also given their central role in acting upon M&E evidence.

- **Earmark funding for transition M&E.** Programmatic transition is distinct from programmatic service delivery and, as such, needs specific earmarked funding, as does the M&E of transition.

- **Protect the neutrality and independence of evaluators.** To promote acceptance of, and action on, M&E findings, all stakeholders need to view M&E results as unbiased and independent. External evaluators may help achieve this perception, but evaluation teams composed of donor and program recipient representatives may also be appropriate.

Potential program recipients should engage in open and transparent discussions to develop consensus around the program’s transition goals and M&E plans. This process should determine transition stakeholders, review the reasons for why transition is occurring, allocate a budget for transition activities, and ultimately create an agreed-upon transition and M&E plan. Based on transition experiences to date, it is not possible to recommend a more specific time frame for when M&E of transition should begin. Based on the authors’ experience, Avahan began its preparations for transition 2 years prior to the first wave of transition and 5 years prior to the main transition round. Gavi is currently looking to conduct transition assessments in countries as soon as their gross national income (GNI) per capita rises above the low-income country threshold, which, according to our observations, occurs roughly 5 years before graduation. The post-transition period is equally important and should be used to monitor sustainability of outcomes and identify potential unintended consequences. Our review of transition experiences has allowed us to reflect on key principles to be considered when monitoring and evaluating the transition process (Box).

Often the triggers for transition will influence the nature of the entire process and the time frame within which it is implemented. For example, donors may signal the need for transition on the basis of target indicators being met, or for political reasons. In other cases, program recipients may initiate transition planning as part of developing a sustainable program. Longer time frames facilitate better planning for transition and stronger transition M&E that, in turn, allow for deeper learning. However, not all transitions will take place under ideal circumstances, and sometimes they may be hurried, responding to political imperatives rather than to carefully determined and mutually agreed conditions. While all transition circumstances offer opportunities for monitoring and for learning, rapid transitions typically limit the scope for rigorous evaluation and may be associated with antipathy toward learning. The costs associated with the M&E of transition will vary according to the scope and scale of the exercise, varying from modest, highly focused efforts that address just one phase of the transition cycle (such as transition preparedness) through to more comprehensive M&E processes, spanning into the post-transition period.

Guiding Questions and Indicators

No set of indicators will be applicable across all types of health program transitions. Accordingly, rather than proposing a short list of indicators, we present guiding questions and selected illustrative indicators to be considered and adapted. We encourage the use of both quantitative indicators and qualitative investigation as complementary approaches necessary to fully explore transition. Quantitative indicators identify changes that have occurred due to transition, demonstrate trends, and track whether transition goals, objectives, and milestones are being met. Qualitative methods describe transition experiences, explain why changes have occurred and their repercussions, and indicate what feedback and adaptation are taking place. Such a qualitative investigation can be critical to understanding why unexpected effects are occurring or to identifying the underlying causes of poor transition performance.

The selection of indicators for monitoring should be driven primarily by the importance of what is being measured; the scientific soundness of the measure; and the feasibility of obtaining
data on the measure. In terms of importance, ideally the transition planning process will have developed a clear logic model (perhaps building on the conceptual framework presented here) that describes the anticipated linkages between transition preparation activities and outcomes. In such a context, it will be rational to tie the selection of indicators to the main constructs covered in this context-specific logic model, ensuring a balanced set of indicators across the different aspects of the transition identified as important. For example, using our conceptual framework, monitoring indicators could seek to capture a variety of pre-transition activities (such as development of a transition plan); aspects of the transition preparation process (such as measures of local stakeholder capacity, program alignment, communication, etc.); the extent of program institutionalization; and measures of outcomes (both service coverage and health outcomes) and how they are sustained over time. In situations where there is not a clearly defined transition plan, those planning the M&E of transition will need to piece together the pre-transition activities that would be underway to prepare for transition.

Health program evaluators are likely accustomed to measuring indicators related to health services and outcomes, and such data are often routinely collected as part of program M&E processes. However, the M&E of transition requires understanding of quantitative indicators that may lie beyond typical health program indicators and are likely to be scattered among different stakeholders and data sources. Table 3 lists possible quantitative indicators of transition M&E.18,33–36

Many of the guiding questions for quantitative indicators could also be explored through qualitative methods. We have included in Table 3 illustrative questions that can be used in semi-structured interviews or focus group discussions with key stakeholders who are either engaged in or affected by transition.

**DISCUSSION**

Based on our collective experiences of transition, including interviews and key informant discussions combined with a literature review, we developed a conceptual framework that broadly details how the transition process for large-scale health programs occurs and offers an approach to identifying what, beyond traditional M&E impact indicators, can be monitored throughout the transition process. The 4 domains of transition of leadership, financing, programming, and service delivery involve sets of activities to be considered during a transition process—from sustaining a supportive policy environment and creating financial sustainability to developing local stakeholder capacity, communicating the transition plan to all stakeholders, and aligning programs—which will require active and evidence-informed management. By monitoring and evaluating these activities during transition and using the resulting evidence for decision making, planners may gain a better sense of where attention needs to be focused or shifted during the transition process, making way for any necessary course correction.

While the ultimate goal of transition, namely, sustaining or enhancing services and outcomes, reflects constructs that health program evaluators are accustomed to measuring, other dimensions of transition may present challenges for evaluators. M&E of transition requires consideration of measures of factors that are much less commonly assessed in health program evaluations such as program alignment, the presence of a supportive policy environment, organizational capacity, and effective communication. Further, likely measures of these factors may be embedded in various data sources that are scattered across different stakeholders and often cannot easily be identified through routine M&E channels. Indeed, M&E of transition may require the development and implementation of special data collection tools.

Health programs typically emphasize rigorous and scientific M&E methodologies to ensure high data quality and accuracy. However, transition processes may differ in the sense that they rely heavily on the effective management of relationships between different stakeholders, most notably between donors and the recipient organization. Thus, when designing an approach for M&E, it may be beneficial and necessary to allow for a trade-off between scientifically rigorous data collection and quality metrics on the one hand and involvement of the right stakeholders on the other hand. Poor data collection processes or quality can gradually be improved, but there is no substitute for involving the right stakeholders from the outset.

The transition process is rarely easy as organizational change is occurring at various levels in a health program. Thus, introducing M&E as an additional component in the process of transition holds several challenges unique to the transition...
| Domain               | Guiding Questions                                                                 | Sample Indicators (obtained through quantitative and qualitative inquiry) |
|----------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| **CONTEXTUAL FACTORS** | To what extent is the political environment ready for a health program transition? | • Score on World Bank Governance Index                                   |
|                      |                                                                                  | • % government budget spent on health                                    |
|                      |                                                                                  | • % government budget spent on health program of interest                 |
|                      | To what extent is the economic situation ready for a health program transition?  | • GNI per capita                                                          |
|                      |                                                                                  | • USD per capita spent on health                                          |
|                      | To what extent is there community support for the health program to transition?  | • Civil society engagement in health program                              |
|                      | To what extent is the severity and scope of the health problem addressed by the program to transition? | • % geographic coverage of program                                        |
|                      |                                                                                  | • # deaths or cases averted due to health program                         |
|                      |                                                                                  | • % service delivery coverage target addressed by health program          |
|                      |                                                                                  | • # vulnerable populations reached by health program                      |
| **PRE-TRANSITION**   | To what extent has a core set of transition stakeholders been identified?         | • Donor and program recipient have agreed on key stakeholders for transition, including communities/beneficiaries, civil society, etc. |
|                      |                                                                                  | • Transition team representing key stakeholders has been established      |
|                      | To what extent has this core set of transition stakeholders agreed on transition objectives? | • % key stakeholders who have participated in transition planning events |
|                      | To what extent have the transition objectives been planned for, including monitoring and evaluation? | • Transition plan with M&E has been agreed upon and documented, including transition timelines |
|                      | To what extent have budget allocations been made for transition, including M&E of transition? | • % program recipient transition budget that has been funded              |
|                      |                                                                                  | • M&E transition budget available                                         |
| **TRANSITION**       | **Leadership**                                                                   | • Program is integrated into national policy or health plans              |
|                      | To what extent is there clear commitment from the political level for program service delivery over the long term? | • % leaders of affected communities who have been informed of transition plans |
|                      | To what extent is there transparent government leadership and management?         | • Guidelines allow exceptions to operating norms based on realities on the ground |
|                      |                                                                                  | • Clear lines of government accountability exist for the health program   |
### Table 3 (continued).

| Domain       | Guiding Questions                                                                                                                                                                                                 | Sample Indicators (obtained through quantitative and qualitative inquiry)                                                                                                                                 |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| **Financing**| To what extent do local stakeholders believe that the health program is a valuable and effective investment of their time and resources?  
To what extent have financial responsibilities been transferred from donor to program recipient?  
To what extent has program recipient secured adequate funding to sustain program? |  
% program activities integrated into local operational plans  
% program implementers who believe that program recipient has the same or higher level of commitment toward the program as the donor  
% implementers with an audit of their financial records  
% donor contribution to health program versus government funding  
Any recent or planned transitions from other donors working in health area  
% gap between estimated annual program costs and resources available |
| **Programming** | To what extent is there technical, managerial, and financial capacity within the program recipient to effectively deliver key health program services?  
To what extent have any shortages in capacity been identified?  
To what extent are training/capacity-building activities occurring or planned to address gaps in capacity? |  
% of required supervision sessions that occur  
% health program recipient staff qualified for financial management  
% supervisory or managerial position vacant at health program recipient  
Capacity needs assessment of program recipient has been conducted  
% training activities completed where capacity shortages were identified |
| **Service delivery** | To what extent are budgetary and financial systems aligned with those of the program recipients?  
To what extent are reporting structures aligned with those of the program recipients?  
To what extent are service delivery or procurement guidelines aligned with those of the program recipients?  
To what extent do the program M&E systems align with the host country’s M&E systems? |  
Overall budget and individual line items are reviewed and adjusted for alignment  
Reporting frequency of government and program recipients are aligned  
% reports that are complete upon submission  
% health facilities employing government procurement guidelines  
% donor indicators currently being reported to government health monitoring information system |
context. First, a lack of buy-in from program recipients can hinder M&E of transition as evaluators may be unable to access post-transition data to assess effects on service delivery and impact after transition. Second, breakdowns in the relationship between donor and program recipients may hinder the accessibility of those conducting M&E as the program is transitioning to the program recipient. Further, and similar to regular evaluations, it will be critical to have reliable baseline data for transition M&E, where it may be particularly important not to assume that performance of the program prior to transition was optimal. Third, although the resources for managing the transition process itself may be easier to obtain, dedicated financial and human resources for transition M&E may be more difficult to secure during a time of financial constraints. M&E of the post-transition period would be most difficult to manage. Donors might

| Domain                          | Guiding Questions                                                                 | Sample Indicators (obtained through quantitative and qualitative inquiry)                                                                 |
|---------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| INSTITUTIONALIZATION            | To what extent are the key features of the original service maintained in the program post-transition? | • % key features of the health program that continue post-transition • Budgets at national/district/facility level reflect funding necessary to support transitioned program • Budgeted funds are allocated and disbursed in a timely fashion. • Government standard operating procedures reflect modalities of the transitioned program • % key program administrators and implementers who view the program as a success |
|                                 | Is there a regular budget line and allocation to support implementation of this program? |                                                                                                                                           |
|                                 | To what extent is the program reflected in routine norms and guidelines?           |                                                                                                                                           |
|                                 | Is the health program viewed as a success by key administrators and program implementers? |                                                                                                                                           |
| SUSTAINED SERVICES AND OUTCOMES | To what extent is the program recipient controlling and managing delivery of essential program services? | • % health program services delivered through program recipient facilities • % clients who are satisfied with the program’s services • % program administrators and implementers describing same or improved quality of program services post-transition |
|                                 | How has the quality of program services changed?                                   | • # health facilities providing service before, during, and after the transition • Prevalence and incidence of health condition in question • Coverage of vulnerable populations reached by the health program |
|                                 | How has the coverage of program services changed after transition?                |                                                                                                                                           |
|                                 | How have key outcome indicators and key health outcome indicators relating to the health program changed? |                                                                                                                                           |
|                                 | How was the transition experience overall?                                        | • % program administrators and implementers who suggest the overall program changed significantly as compared with pre-transition • % program administrators and implementers describing the transition as smooth |
have limited resources and leverage to request support for and engagement in the M&E of the post-transition period, given the withdrawal of funding. Arrangements for access to M&E data post-transition should be ideally negotiated and agreed to during the pre-transition period, while the donor maintains influence on programming.

Fourth, different dimensions that are monitored during transition change at different speeds. Dimensions such as political commitment can change rapidly while others such as local stakeholder capacity change more predictably. Those involved in M&E need to consider what timelines are practical for data collection and analysis, as well as how often recommendations and feedback should be provided to stakeholders. Finally, there may be resistance to transition from within the donor organization, its implementing partners, and/or the program recipient organization. Transition shifts power and resources, creates additional work, and may bring about unwelcome shifts in organizational priorities. All of these factors may create resentment and negativity toward the transition process, and, by extension, to the M&E of transition.

**Limitations**

Our study faces several limitations. Our paper is based in part on author experience, creating the potential for biased interpretations and presentations. However, given the limited literature on the M&E of transition, we felt that integrating stakeholder interviews and consultations with our own experience in the field was critical in presenting a balanced final product. Also, although our framework is based on collective practical experiences, it has not been used prospectively in any program transition. Without having piloted the framework in the field, we are uncertain of the final utility of our thinking, and thus, we seek feedback on experience with applying this framework to monitor and evaluate health program transition. Finally, in this paper we focused our discussion on the transition of large-scale programs (e.g., family planning, immunizations) and did not explore the transition of small-scale projects.

**CONCLUSIONS**

Transition M&E can offer important benefits. The discipline of thinking through what transition entails and how best to describe and measure it can provide greater conceptual clarity to the whole transition process. M&E of transition can also help inform countries undergoing transition about how best to manage it—in terms of learning not only from other countries that have undergone the process but also from their own transitions over time. Such real-time learning through M&E can help identify potential problem areas before they manifest into more serious issues. M&E of transition may also provide an element of accountability for donors, allowing them to be assured that the transition process was executed with attention to detail and with overall sustainability of the program in mind. Finally, M&E of transition allows an opportunity to engage extensively with local stakeholders in the process of transition, ensuring that concerns and needs are appropriately shared as the program is being transitioned to local ownership.

Given the major shifts currently taking place in the development assistance landscape, ensuring effective health program transitions that sustain key health outcomes is likely to be a high priority for years to come. To date, M&E of transition processes has been relatively neglected, thus constraining the ability to learn from transition. Greater investments and stronger methodological work on the M&E of health program transition are needed. Piloting the proposed framework and other approaches for M&E transition would be one of the important first steps assisting our collective thinking about how to ensure that the accomplishments and health gains to date are not compromised during upcoming transitions.

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Sexual Satisfaction, Performance, and Partner Response Following Voluntary Medical Male Circumcision in Zambia: The Spear and Shield Project

Robert Zulu, Deborah Jones, Ndashi Chitalu, Ryan Cook, Stephen Weiss

Most men and their partners reported increased or the same levels of sexual pleasure and improved or no change in penile hygiene post-VMMC. While half of men reported increased or no change in sexual functioning (orgasm, erections), one-third reported a decrease. Early resumption of sexual intercourse prior to complete healing was most closely associated with adverse outcomes, including decreased sexual functioning, satisfaction, and desire.

ABSTRACT

Background: Voluntary medical male circumcision (VMMC) is an important HIV prevention strategy, particularly in regions with high HIV incidence and low rates of male circumcision. However, 88% of the Zambian male population remain uncircumcised, and of these 80% of men surveyed expressed little interest in undergoing VMMC.

Methods: The Spear and Shield study (consisting of 4 weekly, 90-minute sexual risk reduction/VMMC promotion sessions) recruited and enrolled men (N = 800) who self-identified as at risk of HIV by seeking HIV testing and counseling at community health centers. Eligible men tested HIV-negative, were uncircumcised, and expressed no interest in VMMC. Participants were encouraged (but not required) to invite their female partners (N = 668) to participate in the program in a gender-concordant intervention matched to their partners’. Men completed assessments at baseline, post-intervention (about 2 months after baseline), and 6 and 12 months post-intervention; women completed assessments at baseline and post-intervention. For those men who underwent VMMC and for their partners, an additional assessment was conducted 3 months following the VMMC. The ancillary analysis in this article compared the pre- and post-VMMC responses of the 257 Zambian men who underwent circumcision during or following study participation, using growth curve analyses, as well as of the 159 female partners.

Results: Men were satisfied overall with the procedure (mean satisfaction score, 8.4 out of 10), and nearly all men (96%) and women (94%) stated they would recommend VMMC to others. Approximately half of the men reported an increase or no change in erections, orgasms, and time to achieve orgasms from pre-VMMC, while one-third indicated fewer erections and orgasms and decreased time to achieve orgasms post-VMMC. Nearly half (42%) of the men, and a greater proportion (63%) of the female partners, said their sexual pleasure increased while 22% of the men reported less sexual pleasure post-VMMC. Growth curve analysis of changes in sexual functioning and satisfaction over time revealed no changes in erectile functioning or intercourse satisfaction, but there were increases in orgasm functioning, overall sexual satisfaction, and sexual desire. The majority (61% to 70%) of men and women thought penile cleanliness and appearance had improved post-VMMC. Of the 69% of men who reported having sexual intercourse at least once between having the procedure and their 3-month post-VMMC assessment, the large majority (76%) waited at least 6 weeks before resuming sex. Sexual intercourse prior to the 6-week healing period was associated with adverse events and lower levels of post-VMMC sexual satisfaction.

Conclusion: Both men and their partners can generally expect equal or improved sexual satisfaction and penile hygiene following VMMC. Future studies should consider innovative strategies to assist men in their efforts to abstain from sexual activities prior to complete healing.

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INTRODUCTION

Male circumcision has been practiced for nearly 4,500 years for religious, cultural, and medical reasons. It has also stimulated controversy among religious, cultural, and medical authorities, particularly with regard to its relevance in modern society. Voluntary medical male circumcision (VMMC), however, has recently been recognized as an important barrier to HIV infection in men (51% to 70% reduction in risk), and it has been recommended as an important HIV prevention strategy particularly in countries or regions with high HIV incidence and low rates of male circumcision, e.g., Eastern and Southern Africa. Lower rates of HIV infection resulting from medical circumcision in men would also reduce the risk of exposure to HIV infection among women, ultimately conveying an estimated 46% reduction in women’s risk of infection.

Despite these impressive statistics, the Zambia Sexual Behaviour Survey conducted in 2009 found that as many as 80% of uncircumcised Zambian men (i.e., 88% of the male population) expressed little interest in undergoing VMMC. Studies exploring reasons for men’s unwillingness to be circumcised have identified concerns related to potential effects of VMMC on sexual performance (e.g., erection, orgasm) and sexual pleasure, the risk of surgical pain, reluctance to abstain from sex for at least 6 weeks during recovery, and partners’ responses to the loss of the penile foreskin. Studies in Kenya, Uganda, South Africa, and Zambia have found the majority of men who had undergone VMMC were satisfied with the procedure. Further, studies in Kenya, Malawi, South Africa, and Tanzania have found that women report high sexual satisfaction with circumcised partners and believe that circumcision improves appearance, health, and hygiene. Additionally, research has found that female partners can influence men’s uptake of VMMC. However, no studies have examined the sexual satisfaction of Zambian women following their partners’ VMMC, nor their perceptions of post-VMMC penile hygiene or appearance.

The Spear and Shield project was a comprehensive sexual risk reduction and VMMC promotion intervention designed to promote VMMC for men initially uninterested in the procedure. This article examines the post-VMMC experience, including sexual satisfaction and performance, of the male study participants and their female partners. Given the controversies surrounding male circumcision and the disagreements concerning its effect on sexual performance and satisfaction for men and women, these data could offer definitive guidance to those considering undergoing the procedure, providing valuable information for HIV prevention strategies and implementation of VMMC programs.

METHODS

Study Procedures

The ancillary analysis presented in this article was conducted as a component of the Spear and Shield study, a prospective cluster-randomized 3-arm trial conducted in Lusaka, Zambia, between February 1, 2012 and October 31, 2014, to increase uptake of VMMC among Zambian men who were initially uninterested in undergoing the procedure. Thirteen Zambian community health centers (CHCs) were stratified according to size and volume of clients coming for HIV voluntary testing and counseling (HTC) and randomized to the experimental condition (5 clinics), the control condition (5 clinics), or the “observation-only” condition (3 clinics). Men attending HTC at the CHCs were enrolled in the study (N = 800; experimental, n = 400; control, n = 400) and given the option of inviting their female partners to participate (N = 668); no participants were recruited from observation-only sites. Men and women attended parallel group interventions either promoting VMMC for HIV prevention or a time-equivalent control condition.

The primary outcome measure for the study was VMMC uptake; of the 800 men enrolled, 257 men (experimental condition, n = 161; control condition, n = 96) underwent VMMC during the course of the study. Secondary outcomes included maintenance of sexual barrier use following VMMC, the acceptability of VMMC, female partner influence on VMMC uptake, and sexual satisfaction following VMMC. The analysis in this article focuses on sexual satisfaction and post-VMMC experiences of the 257 male study participants who underwent VMMC and the 159 female partners who completed post-VMMC questionnaires.

Study Sites and Participants

Three health care providers (nurses or clinic officers) from each of the 13 participating CHC clinics were trained over 10 days to perform male circumcisions using the dorsal slit method, according to VMMC training guides from the World Health Organization. VMMC training and supplies were provided to all clinics to ensure that
clients from all 13 sites had equal access to VMMC services. Two HTC counselors and/or nurses from each of the 10 experimental and control sites were trained to conduct either the Spear and Shield sexual risk reduction program (experimental condition: 4 weekly, 90-minute sexual risk reduction/VMMC promotion sessions) or a time-equivalent, video-based health educational program on malaria, tuberculosis, and waterborne disease prevention (control condition). The experimental and control clinics each recruited a total of 8–9 cohorts of 8–10 male participants, for a total of 80 male participants per site over the course of the study. Observation-only clinics did not recruit any participants or conduct assessments, but they collected monthly data on numbers of HTCs and VMMCs to measure secular trends in VMMC uptake over the course of the study. At recruitment onset, all clinics had trained staff available offering VMMC using the conventional dorsal slit method. (The minimally surgical Shang Ring method and the nonsurgical PrePex method were not available in Zambia at the time of this study.)

Screening, recruitment, and referral of study candidates were carried out by site HTC counselors as part of their post-test counseling activities. Since all candidates were voluntarily seeking HIV testing and counseling, and thus self-identified as at risk of HIV, the candidates were routinely advised of the availability of VMMC services for HIV prevention. Study recruitment targeted the approximately 80% of men identified by the 2009 Zambia Behavioural Health Survey as uninterested in VMMC.

Study assessors were notified by HTC counselors of potential study candidates; study assessors then obtained informed consent from eligible candidates and supervised assessments. Men and women provided consent individually in a private room in the study offices. Eligible male participants were 18 years of age or older, were not infected with HIV, were uncircumcised, and had no plans to undergo VMMC in the foreseeable future. Men were excluded if they were actively considering undergoing VMMC, were infected with HIV (WHO does not recommend circumcision for men with HIV), or had a complicating medical condition preventing VMMC.

All men were encouraged, but not required, to invite their female partners to enroll in a comparable VMMC promotional (or time-equivalent control) program for women. There were no recruitment or screening criteria for female partners, and only those invited by the enrolled men and who had consented to participate were enrolled. All participants were provided with refreshments and compensated for transportation to the site for each visit (about US$4/visit).

**Intervention**

Following enrollment, all participants completed a baseline assessment (see next section on Assessments) and then participated in either the experimental or control condition. The experimental condition—the Spear and Shield intervention—consisted of 4 weekly, 90-minute, manual-based, gender-concordant group sessions delivered to 8–10 participants per group. Examples of topics covered in the sessions included HIV prevention strategies, safer sex training in the correct use of male and female condoms, myths and facts about transmission of HIV and sexually transmitted infections (STIs), prevention of mother-to-child transmission, and cognitive behavioral training to improve problem solving in sexual communication and negotiation skills, including identifying and avoiding high-risk sexual situations. VMMC was highlighted in all sessions, which included a detailed description of risks and benefits of VMMC, visits from a peer who had undergone VMMC, and consultation with a VMMC provider who discussed the procedure and recovery. VMMC was discussed in the context of overall sexual risk reduction (e.g., use of condoms, reduction in sexual partners, and avoidance of high-risk environments involving sex, alcohol, and drugs). Men’s and women’s groups followed parallel topics, including gender-specific issues, for example, intimate partner violence and effects of VMMC on women’s health. The control condition was a time-equivalent, video-based health educational program on malaria, tuberculosis, and waterborne disease prevention. Both experimental and control conditions were delivered in local languages. Additional details on the Spear and Shield intervention have been published elsewhere.13, 14

**Assessments**

All men in the experimental and control conditions completed questionnaires at 4 fixed time points: baseline, post-intervention (about 2 months after baseline), 6 months post-intervention, and 12 months post-intervention. Female partners completed assessments at baseline and post-intervention. For those men who underwent VMMC and for their partners, if enrolled, an additional assessment was conducted at 3 months following the VMMC. All questionnaires were provided in local languages (Bemba, English, or
Nyanja), and all assessment data were collected using automated computer-assisted self-interviews (ACASI) in order to minimize social desirability bias. Participants were instructed how to use the ACASI system prior to administration, and a staff member was available to answer questions throughout the assessment.

Content of the Questionnaires

Demographics. Men and women completed a demographic questionnaire at baseline.

Sexual functioning and satisfaction. Men were assessed at all time points on sexual functioning and satisfaction using the International Index of Erectile Functioning (IIEF).26 The IIEF yields 5 subscales. The first 2, erectile functioning (the ability to achieve/maintain erections during sexual intercourse) and intercourse satisfaction (satisfaction with sexual intercourse) are rated 0 (no sexual intercourse), 1 (low), or up to 5 (high). Participants not engaging in sexual intercourse were excluded from these subscales. Orgasm functioning (the ability to achieve orgasm during sexual activity including intercourse, oral sex, or masturbation) is also measured from 0 (no sexual intercourse), 1 (low), or up to 5 (high); however, participants reporting no sexual intercourse were not excluded from this subscale, as other types of sexual stimulation are also measured. Overall satisfaction (satisfaction with sexual activity in general) and sexual desire are rated using a scale of 1 (low) to 5 (high).

Sexual risk behaviors. Men and women were also assessed on sexual risk behaviors over the last month at all time points.27 Among men, baseline sexual risk behaviors were combined to identify participants at “high risk” and “low risk” for HIV using latent class analysis; indicators of risk category included lifetime STI diagnosis, condom use, multiple partnering, use of drugs or alcohol before sex, and sex with a discordant partner or partner with an unknown HIV status. The analysis has been previously described, and the same risk groups have been used in this study.28

VMMC knowledge. VMMC knowledge was assessed among men and women at all time points using a measure adapted from a study in Uganda.12 Participants answered questions about the ability of VMMC to reduce their HIV risk (e.g., circumcision of a man without HIV reduces his chance of getting HIV; 1 = definitely false, 5 = definitely true) or to completely negate the risk of getting HIV (e.g., a circumcised man cannot get HIV; 1 = definitely false, 5 = definitely true). Items were combined into separate scales representing VMMC knowledge (4-item $\alpha = .58$) and VMMC misinformation (2-item $\alpha = .70$).29 Both scales were coded such that higher scores indicated more knowledge or misinformation.

Post-VMMC questionnaire. At 3 months post-VMMC, men completed an additional questionnaire addressing sexual function and satisfaction, the VMMC experience (including self-reported problems arising post-VMMC, i.e., infection, tearing, healing, pain), and resumption of sexual intercourse following VMMC. Participants were asked to evaluate their experience with VMMC, to indicate the length of time they waited prior to resuming sexual intercourse (if they had intercourse), and to report any problems or complications arising from the procedure. In addition, participants responded to descriptors associated with themselves as circumcised men, using a dichotomous response (1 = yes, 0 = no) to items including satisfaction, appearance, cleanliness, response from partner, and recommendation of VMMC to a friend. Women participating in the study completed a similar questionnaire following their partner’s VMMC; however, women were not assessed regarding complications, sexual function, or delaying intercourse.

Ethical Oversight

Prior to study initiation, ethical approval was obtained by the University of Zambia Research Ethics Committee and the Institutional Review Board at the University of Miami Miller School of Medicine. The Spear and Shield trial protocol is registered on Clinicaltrials.gov, number NCT01688167.

Statistical Analyses

Prior to the primary analyses, descriptive statistics (e.g., means, standard deviations, frequencies) were generated for demographic and VMMC satisfaction data. The primary analyses were a series of growth curves examining longitudinal mean subscale scores from the IIEF among men undergoing VMMC. Growth models are statistical models that can be used with repeated-measures data to understand the process of change; they attempt to estimate between-person differences in within-person change. (See Curran et al.30 for a concise, nontechnical overview of the growth curve modeling.) The growth models generated for this study included 5 measurement occasions
(baseline, post-intervention, 6-month follow-up, 12-month follow-up, post-VMMC) and accounted for the fact that participants completed the post-VMMC assessment at different times relative to baseline. Models included fixed and random intercept, linear, and quadratic time parameters; if the fixed quadratic parameter was not significant, quadratic terms were dropped from the model. In addition, models controlled for the number of attempts at sexual activity at each time point.

In addition to growth curve analyses, descriptive data from the 3-month post-VMMC assessment are presented for both men and their female partners, and Kappa coefficients were computed to examine agreement between partners on questions that were answered by both men and women. Finally, participants who waited the full 6-week healing period prior to resuming sexual intercourse were compared with those who did not wait, using t tests, the Wilcoxon signed rank test, and chi-square tests. All analyses were completed using SAS version 9.3 at a 2-tailed level of significance of \( P < .05 \).

**RESULTS**

**Demographics and Satisfaction With the VMMC Procedure**

A total of 977 men were screened for the broader Spear and Shield study; 800 men consented to be in the study and were enrolled. Of the 177 men who were not enrolled, 61 declined due to work or distance from the clinic, 28 were under age 18, 12 had planned to undergo VMMC, 18 were unwilling to participate, 7 were previously circumcised, 9 refused to consent, and 42 were disqualified because of their HIV serostatus. A total of 668 women were invited and elected to participate in the study. Additional details on participant recruitment and retention have been published elsewhere.\(^1\)\(^4\)

Male participants undergoing circumcision (N = 257) from the intervention and control arms were, on average, 26 years of age, and nearly three-quarters (74%) had at least 12 years of formal education (Table 1). Over half (57%) were unemployed, and 53% had an annual income of less than US$100. Over one-third (38%) reported being married or living with their partner, about one-third (34%) had at least 1 child, and two-fifths (40%) expressed desire for additional children. Female partners (N = 159) were similar in age (mean, 26 years), and 57% had at least 12 years of education. Most (72%) of the women were unemployed, and 57% reported an annual income of less than US$100. A higher percentage of women than men reported being married or cohabitating (47%), which is not uncommon in Zambia, where men and women often differ on the definition of marriage. Half of the women (52%) had at least 1 child, and 44% reported desire for at least 1 more child.

**Sexual Functioning**

Subscales of the IIEF were analyzed using longitudinal growth curves (Table 2). Domains of self-reported sexual functioning analyzed included erectile functioning and orgasm functioning. Examination of erectile functioning scores revealed that both the quadratic and linear time components of the growth curve were not significantly different from zero (\( P \) values of .08), and thus erectile functioning did not change over time. However, analysis of orgasm functioning scores over time did not change post-VMCC, but orgasm function increased.
showed a significant linear increase ($P < .001$) and a significant quadratic decrease ($P = .006$) over time, such that the predicted mean scores were 4.12, 4.81, and 4.99 at baseline, 6 months, and 12 months, respectively. Thus, orgasm functioning increased, but the rate of increase diminished over time (Table 2).

Data from participant assessments 3 months after their VMMC are summarized in Table 3. (One male participant was lost to follow-up following VMMC, thus the valid sample size for post-VMMC data is 256 men.) At post-VMMC, about half of the participants (49%) indicated they had an increased frequency of erections or no change (26% and 23%, respectively) compared with pre-VMMC, and about one-third (34%) reported a decrease (17% no opinion). Just over half (53%) of the respondents who had undergone VMMC reported increased orgasms or no change (33% and 20%, respectively), and one-third (33%) reported fewer orgasms (14% no opinion). Finally, about half (51%) reported increased time to achieve orgasm or no change (35% and 16%, respectively), and one-third (35%) reported less time to orgasm (14% no opinion).

### Sexual Satisfaction

Domains of sexual satisfaction analyzed included intercourse satisfaction, overall satisfaction, and sexual desire. Neither the quadratic nor linear growth curve components of intercourse satisfaction were significant ($P = .09$ and .84, respectively), thus intercourse satisfaction did not change over time. Examination of overall satisfaction revealed no quadratic change in time ($P = .42$); however, overall satisfaction increased linearly over time ($P = .007$; mean, baseline = 7.09, 6 months = 7.31, 12 months = 7.53). Finally, analysis of sexual desire showed a linear increase over time ($P = .001$) with a quadratic decrease ($P = .02$); estimated mean scores were 6.25, 6.67, and 6.79 at baseline, 6 months, and 12 months (Table 2).

Following VMMC, 57% of male participants reported that sexual activity was more pleasurable or that there was no change (42% and 15%, respectively), and 22% reported decreased sexual satisfaction (21% no opinion). Female partners also indicated their level of sexual satisfaction following their partner’s VMMC; most (79%) reported increased sexual satisfaction or no change (33% and 20%, respectively), and one-third (33%) reported fewer orgasms (14% no opinion). Finally, about half (51%) reported increased time to achieve orgasm or no change (35% and 16%, respectively), and one-third (35%) reported less time to orgasm (14% no opinion).

### Table 2. Growth Curve Analyses of International Index of Erectile Functioning Subscales Among Zambian Men Undergoing Voluntary Medical Male Circumcision

| Domain               | Quadratic Time $a$ | Linear Time | Baseline Mean Estimate $b$ | 6-Month Mean Estimate | 12-Month Mean Estimate |
|----------------------|-------------------|-------------|----------------------------|-----------------------|------------------------|
|                      | b (SE)            | P           | b (SE)                     | P                     |                        |
| Erectile functioning  | -.007 (.004)      | .08         | .068 (.039)                | .08                   |                        |
| Orgasm functioning    | -.007 (.002)      | .006        | .156 (.044)                | < .001                | 4.12                   | 4.81                   | 4.99                   |
| Intercourse satisfaction | .004 (.002)    | .09         | .003 (.017)                | .84                   |                        |
| Overall satisfaction  | -.002 (.003)      | .42         | .037 (.013)                | .007                  | 7.09                   | 7.31                   | 7.53                   |
| Sexual desire         | -.004 (.002)      | .02         | .093 (.028)                | .001                  | 6.25                   | 6.67                   | 6.79                   |

Abbreviation: SE, standard error.

$^a$ All models initially included both quadratic and linear growth curve components (i.e., fixed and random effects for time$^2$ and time); if the quadratic component was not significant, the model was refit using only a linear slope.

$^b$ Means were estimated using the fitted model for domains that significantly changed over time.

Note: Statistically significant parameters are noted in boldface.
### TABLE 3. Post-Voluntary Medical Male Circumcision (Post-VMMC) Sexual Functioning and Satisfaction Among Zambian Men (N = 256) and Female Partners (N = 159)

| Sexual Functioning       | Men          | Female Partners |
|--------------------------|--------------|-----------------|
| **Erections**            |              |                 |
| More                     | 67 (26%)     |                 |
| No change                | 58 (23%)     |                 |
| Fewer                    | 86 (34%)     |                 |
| No opinion               | 45 (17%)     |                 |
| **Orgasms**              |              |                 |
| More                     | 84 (33%)     |                 |
| No change                | 50 (20%)     |                 |
| Fewer                    | 85 (33%)     |                 |
| No opinion               | 37 (14%)     |                 |
| **Time to orgasm**       |              |                 |
| Increased                | 89 (35%)     |                 |
| No change                | 41 (16%)     |                 |
| Decreased                | 91 (35%)     |                 |
| No opinion               | 35 (14%)     |                 |
| **Sexual Satisfaction**  |              |                 |
| Increased                | 107 (42%)    | 99 (63%)        |
| No change                | 40 (15%)     | 25 (16%)        |
| Decreased                | 56 (22%)     | 21 (13%)        |
| No opinion               | 54 (21%)     | 14 (8%)         |
| **Appearance**           |              |                 |
| Better                   | 159 (62%)    | 97 (61%)        |
| No difference            | 52 (20%)     | 24 (15%)        |
| Worse                    | 39 (15%)     | 23 (15%)        |
| No opinion               | 6 (3%)       | 15 (9%)         |
| **Cleanliness**          |              |                 |
| Cleaner/easier to keep clean | 180 (70%) | 112 (70%)      |
| No difference            | 33 (13%)     | 22 (14%)        |
| Less clean/more difficult to keep clean | 34 (13%) | 18 (11%) |
| No opinion               | 9 (4%)       | 7 (5%)          |

All data are reported as No. (%).

*1* Male participant was missing all post-VMMC data.
(standard deviation, 2.7), and 96% of participants \((n = 245)\) indicated they would recommend VMMC to a friend. In addition, 94% \((n = 150)\) of female partners reported they would recommend VMMC, based on their and their partners’ experience with the procedure.

### Appearance and Cleanliness

Male participants undergoing VMMC were asked about the appearance of their penis post-VMMC; most \((82\%)\) reported that it looked better or neither better nor worse \((62\% \text{ and } 20\%, \text{ respectively})\), and \(15\%\) reported that it looked worse \((3\% \text{ no opinion})\). Female partners reported similar feelings about the appearance of their partner’s penis; the majority \((76\%)\) reported that it looked better or that there was no difference \((61\% \text{ and } 15\%, \text{ respectively})\), while \(15\%\) indicated that it looked worse \((9\% \text{ no opinion})\). There was \(77\%\) agreement between partners in post-VMMC penile appearance. In addition, most \((83\%)\) male participants reported increased penile cleanliness or no change following VMMC \((70\% \text{ and } 13\%, \text{ respectively})\), while \(13\%\) reported that it was harder to keep clean \((4\% \text{ no opinion})\). Most \((84\%)\) female partners reported increased cleanliness of their partner’s penis following VMMC or no change \((70\% \text{ and } 14\%, \text{ respectively})\), and \(11\%\) indicated that the penis was less clean \((4\% \text{ no opinion})\); \(64\%\) agreement between partners. The Figure presents a graphic representation of men’s and women’s responses concerning penile appearance and cleanliness.

### Early Resumption of Sexual Intercourse

Among men undergoing VMMC, \(178 \ (69\%)\) reported having sexual intercourse at least once between the procedure and their 3-month post-VMMC assessment. Of those sexually active men, \(135 \ (76\%)\) waited at least 6 weeks before resumption of intercourse following VMMC, but \(43 \ (24\%)\) did not wait.

To investigate factors associated with early resumption of sex, men who had sex but waited at least 6 weeks were compared with those who did not wait; results are presented in Table 5. In summary, early resumption of intercourse was associated with increased HIV risk behavior \((27\% \text{ of high-risk participants resumed sex early vs. } 10\% \text{ of low-risk participants}, P = .01)\) as well as with the increased risk of infection or tearing of the surgical incision; self-reported tearing of the incision was noted by \(15\%\) of participants and infection noted by \(11\%\); \(47\%\) of participants resuming sex early described infection or tearing vs. \(20\%\) of those waiting at least 6 weeks \((P < .001)\). Additionally, participants resuming sex early reported decreased orgasm functioning \((P < .001)\), overall satisfaction \((P = .001)\), and sexual desire at the post-VMMC visit \((P = .05)\) (Table 5). Demographics and VMMC knowledge did not impact early resumption of sexual intercourse.

### DISCUSSION

This study examined post-VMMC responses of Zambian men and their female partners. Overall, outcomes suggest VMMC was acceptable to both men and their partners.

Self-reported sexual functioning, including erectile and orgasm function, increased or was unaffected by VMMC. Overall sexual satisfaction, including satisfaction with intercourse, appeared better or unchanged among the majority of the male participants and their female partners. In fact, men and their partners expressed high

| TABLE 4. Agreement Between Zambian Partners on Sexual Satisfaction, Appearance, and Cleanliness Following Voluntary Medical Male Circumcision |
| --- |
| **Men** |
| **Women** |
| Increased/no change | Decreased/no change | Decreased (or Worse) | Kappa (95% CI) |
| Sexual satisfaction | 80 (68%) | 18 (15%) | 0.25 (0.04, 0.45) |
| Appearance | 104 (73%) | 15 (11%) | 0.10 (-0.09, 0.28) |
| Appearance/better/no change | 18 (13%) | 5 (3%) | 0.20 (-0.01, 0.42) |
| Cleanliness | 119 (80%) | 11 (7%) | 0.64 couples; for appearance, 142 couples; and for cleanliness, 148 couples. |

Most men reported waiting at least 6 weeks before resuming sex following VMMC.

Most men and women reported increased penile cleanliness following VMMC.
levels of agreement in their assessment of sexual satisfaction following VMMC. An increase in sexual satisfaction among women was also noted in a study in Turkey by Senkul et al.\(^{31}\) that found there was a delayed ejaculatory time in those circumcised. Senkul and colleagues suggested that delayed ejaculation in those who were circumcised should be regarded as an advantage rather than a complication. In a study in Canada, Payne et al.\(^{32}\) also evaluated sexual arousal and compared circumcised and uncircumcised men, obtaining similar results.

Contrary to men’s pre-VMMC concerns that circumcision may impair sexual performance, satisfaction, and pleasure, the findings from this study suggest that both men and their partners can expect equal or increased sexual satisfaction as well as improved penile hygiene following VMMC. Having women participate in VMMC programs also provides an opportunity to convey important information concerning how VMMC can protect women’s health, given the high rates of human papillomavirus (HPV) and cervical cancer in Zambia. It is not clear whether men and women agreed on circumcision because they shared the same attitudes or because they evolved to share the same views. Interventions to enhance VMMC uptake that include women will also assist women in better understanding how VMMC can impact their sexual satisfaction as well as their health.\(^{13,14,33}\)

Results from the Spear and Shield study\(^{13,14}\) and previous research suggest that women’s perceptions, attitudes, and opinions about VMMC may be important to men. Previous research by this team found that men were interested in knowing women’s preferences for the appearance of their penis, i.e., circumcised or uncircumcised. The majority of men felt the appearance of their penis had improved following VMMC, and there was a high level of agreement between male and female partners regarding this perception. The enhanced appearance of the penis was also noted in previous studies using the Shang Ring device in comparison with conventional VMMC methods (dorsal slit method in Zambia and forceps-guided method in Kenya). Prepex studies had similar results in comparison with surgical methods.\(^{34–37}\) Additionally, most men and women agreed that VMMC enhanced penile cleanliness; increased cleanliness may also play a role in stimulating arousal and may also be responsible for increased sexual satisfaction.

Prolonged abstinence from sexual activity is one of the principal reasons why clients are hesitant to undergo VMMC.\(^{6,38}\) In this study, complications were associated with premature resumption of sexual activity prior to adequate healing, highlighting the need for interventions to deter early resumption of sexual activity post-VMMC.\(^{39}\) Most of the participants who resumed sex prior to the recommended 6 weeks also had high-risk histories; this group also suffered a higher rate of self-reported post-surgical complications, including increased rates of post-surgical infection and decreased sexual satisfaction, as illustrated in Table 5. Although other factors could have played a role in poor surgical outcomes, e.g., wound care, cleanliness, and other post-surgery activities, it is clear that early resumption
| Demographic Characteristics | Waited at Least 6 Weeks (n = 135) | Did Not Wait at Least 6 Weeks (n = 43) | t/χ² | P Value |
|----------------------------|-----------------------------------|---------------------------------------|------|---------|
| Age, mean (SD), years      | 28.3 (8.4)                        | 26.4 (8.5)                            | 1.3  | .20     |
| Education level, No. (%)   |                                   |                                       | 2.1  | .15     |
| High                       | 103 (76%)                         | 28 (65%)                              |      |         |
| Low                        | 32 (24%)                          | 15 (35%)                              |      |         |
| Married/cohabitating, No. (%) |                                 |                                       | 1.8  | .18     |
| Yes                        | 66 (49%)                          | 16 (37%)                              |      |         |
| No                         | 69 (51%)                          | 27 (63%)                              |      |         |
| Wants (more) children, No. (%) |                                 |                                       | 2.9  | .09     |
| Yes                        | 64 (47%)                          | 14 (33%)                              |      |         |
| No                         | 71 (53%)                          | 29 (67%)                              |      |         |
| HIV risk category, b No. (%) |                                 |                                       | 6.7  | .01     |
| High                       | 12 (10%)                          | 11 (27%)                              |      |         |
| Low                        | 105 (90%)                         | 30 (73%)                              |      |         |
| Adverse Events             |                                   |                                       |      |         |
| Post-VMMC infection or tearing, No. (%) |               |                                       | 11.8 | <.001   |
| Yes                        | 27 (20%)                          | 20 (47%)                              |      |         |
| No                         | 108 (80%)                         | 23 (53%)                              |      |         |
| Sexual Satisfaction        |                                   |                                       |      |         |
| Erectile functioning, mean (SD) | 17.6 (6.5)                   | 17.7 (5.5)                            | 0.1  | .94     |
| Orgasm functioning, mean (SD)  | 5.8 (3.5)                        | 3.3 (3.4)                             | 4.1  | <.001   |
| Intercourse satisfaction, mean (SD)  | 7.4 (2.4)                       | 7.7 (1.7)                             | 0.7  | .48     |
| Overall satisfaction, mean (SD)  | 8.3 (2.2)                        | 6.5 (3.2)                             | 3.4  | .001    |
| Sexual desire, mean (SD)    | 6.9 (1.8)                         | 6.2 (2.1)                             | 2.0  | .05     |
| VMMC Knowledge             |                                   |                                       |      |         |
| Correct knowledge, mean (SD) | 11.8 (2.4)                       | 11.9 (2.5)                            |      | .71c    |
| Misinformation, mean (SD)  | 5.5 (2.2)                         | 6.0 (2.4)                             |      | .20c    |

Abbreviation: SD, standard deviation.

a Among men reporting at least one instance of sexual intercourse between the VMMC procedure and their 3-month post-VMMC assessment.

b The sample size of men with HIV risk designation comprised only 158 men because of missing items on the sexual risk behavior questionnaire.

c Wilcoxon's test.

Note: Statistically significant differences are noted in boldface.
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et al. 41 reported that some men resumed sex with future studies could explore by Mehta et al. 40 indicated that early sex did not which suturing is done. Although a meta-analysis when the conventional surgical method is used, as secondary healing, or secondary intention, is slower than primary healing, or primary intention, in which suturing is done. Although a meta-analysis by Mehta et al. 40 indicated that early sex did not increase likelihood of HIV acquisition, the study addressed those who had VMMC using conventional surgical methods in which wounds generally heal faster than when using device-based methods.34–37 Thus, increased attention should be devoted to assisting post-VMMC clients with delaying resumption of sexual intercourse for at least 6 weeks, especially when devices are used.34–37 Efforts to deter men from early resumption of sexual intercourse, for example, educational and reminder text messaging,40 have thus far not been successful. Hewett et al. 41 reported that some men resumed sex with stitches still intact. Additional research on this refractory issue is sorely needed.

Limitations

The primary limitation of this study was the relatively small amount of data collected from women, which prevented a comprehensive evaluation of the role of VMMC in women’s sexual satisfaction. In addition, although agreement between partners regarding penile appearance and cleanliness was high, the Kappa statistics were not statistically significant. This was very likely due to the low variability in those data, which resulted in a very high probability of agreement “by chance.”42,43 More finely grained questions should be considered to examine agreement between men and women on these issues. Additionally, self-reported problems arising post-VMMC were high and may have been misinterpreted by participants; the accuracy of these data would have been enhanced by clinical examination. Further, sexual satisfaction was not addressed in the intervention, and no differences between control and intervention conditions were noted in sexual satisfaction at baseline or follow-up. Though there was no reason to assume that the intervention would have had any impact on sexual satisfaction, future studies could explore the potential influence of VMMC interventions on sexual satisfaction. Finally, this study used a self-selected group of men seeking HIV testing at CHCs, assuming that these men would represent a level of HIV risk that is higher than in the general population. Future studies could further examine the impact of VMMC on sexual satisfaction in the general population.

CONCLUSION

Zambian men undergoing VMMC and their partners had a high degree of satisfaction with the procedure and its consequences in terms of sexual satisfaction, validating findings from previous research. Women’s opinions and preferences regarding VMMC may be valued by men, and scale-up of VMMC could be influenced by including women when introducing VMMC-promoting interventions. Premature resumption of sexual intercourse was associated with an increase in adverse events, underscoring the importance of further investigation to develop effective interventions to delay resumption of sex during the healing period.

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Reducing Motor Vehicle-Related Injuries at an Arizona Indian Reservation: Ten Years of Application of Evidence-Based Strategies

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Motor vehicle crashes decreased and seat belt use, including car seat use, increased in an American Indian and Alaska Native community through a multidisciplinary approach using strong partnerships among public health and law enforcement agencies; community outreach; mass media campaigns; and enactment and high-visibility enforcement of key laws, such as lowering the legal blood alcohol concentration limit for drivers and mandating use of occupant restraints.

ABSTRACT

Unintentional injury is a significant public health burden for American Indians and Alaska Natives and was the leading cause of death among those aged 1 to 44 years between 1999 and 2004. Of those deaths, motor vehicle-related deaths cause the most mortality, justifying the need for intervention at an American Indian Reservation in Arizona (United States). We describe motor vehicle injury prevention program operations from 2004 through 2013. This community-based approach led by a multidisciplinary team primarily comprised of environmental public health and law enforcement personnel implemented evidence-based strategies to reduce the impact of motor vehicle-related injuries and deaths, focusing on reducing impaired driving and increasing occupant restraint use. Strategies included: mass media campaigns to enhance awareness and outreach; high-visibility sobriety checkpoints; passing and enforcing 0.08% blood alcohol concentration limits for drivers and primary occupant restraint laws; and child car seat distribution and education. Routine monitoring and evaluation data showed a significant 5% to 7% annual reduction of motor vehicle crashes (MVCs), nighttime MVCs, MVCs with injuries/fatalities, and nighttime MVCs with injuries/fatalities between 2004 and 2013, but the annual percent change in arrests for driving under the influence (DUI) was not significant. There was also a 144% increase in driver/front seat passenger seat belt use, from 19% in 2011 before the primary occupant restraint law was enacted to 47% during the first full year of enforcement (2013). Car seat checkpoint data also suggested a 160% increase in car seat use, from less than 20% to 52% in 2013. Implementation of evidence-based strategies in injury prevention, along with employment of key program approaches such as strong partnership building, community engagement, and consistent staffing and funding, can narrow the public health disparity gap experienced among American Indian and Alaska Native communities.

INTRODUCTION

Between 1999 and 2004, unintentional injury was the leading cause of death among American Indians and Alaska Natives (AI/AN) ages 1 to 44 years in the United States.1 The impact of unintentional injury was even more acute for AI/AN in Arizona, for whom it was the leading cause of death for all ages during the same time period.1 The leading cause of unintentional injury death for AI/AN in Arizona was motor vehicle-traffic related, which accounted for 60.5% of all unintentional injury deaths.1 Nationally in 2005, the age-adjusted motor vehicle-related death rate among AI/AN was 2.01 times higher than among all races.8

Injuries—whether fatal or non-fatal—impose obvious impacts in AI/AN populations on the affected victims,
Unintentional injury is a leading cause of death among American Indians and Alaska Natives in the United States. Risk factors for motor vehicle-related injuries include low rates of occupant restraint use and high prevalence of alcohol-impaired driving.

families, and communities. However, injury can also have less obvious impacts. Due to the higher incidence of injury in younger age groups, fatal injury may involve premature death. Years of Potential Life Lost (YPLL) measures premature death before age 65 to illustrate lost potential productivity and income. Unintentional injury is the leading YPLL cause of death category for AI/AN, accounting for 28% of all YPLL causes of death, compared with 8% each for the next leading causes of heart disease and cancer. Injuries also pose an enormous economic burden among AI/AN populations. The lifetime costs of all injuries among AI/AN populations nationally in 2000 was estimated at over 2 billion dollars.

The Indian Health Service (IHS) has long recognized the problem that injury presents in AI/AN populations and has focused attention and resources on injury prevention activities. The US Centers for Disease Control and Prevention (CDC) has similarly recognized the injury problem in AI/AN populations and has collaborated with the IHS and with individual tribes. However, until relatively recently funding to support tribes to develop their own local infrastructures to address local injury problems based on the individual tribe’s needs was rare.

A focus of both the IHS Injury Prevention Program and the CDC’s National Center for Injury Prevention and Control is the implementation of effective injury prevention strategies that are evidence-based or that are considered best practices. Among AI/AN populations, appropriate attention has been focused on the prevention of motor vehicle-related injury. Risk factors for motor vehicle crash-related injuries and deaths in AI/AN communities include low rates of occupant restraint use and a high prevalence of alcohol-impaired driving. Accordingly, recommended effective strategies to prevent or reduce motor vehicle-related injury associated with low occupant restraint use and impaired driving include mandatory occupant restraint (child safety seats and seat belts) laws, enhanced enforcement campaigns such as occupant restraint checkpoints, lowering legal blood alcohol concentration (BAC) limits for drivers from 0.10% to 0.08%, sobriety checkpoints, and community-wide messaging about occupant restraint laws or mass media campaigns about alcohol-impaired driving. The “Guide to Community Preventive Services” is a systematic review of community-based interventions managed by the CDC. The systematic review process assesses large bodies of scientific literature by applying the scientific process to reduce bias in how conclusions are reached, improves the power and precision of results, and summarizes evidence about the effectiveness of specific interventions. This evaluation leads to recommended evidence-based interventions that have the greatest public health impact, allowing public health programs to focus on what works, rather than on determining, or guessing, what might work.

In 2004, the San Carlos Apache Tribe in Arizona received funding from the CDC to develop, implement, and evaluate a multiyear program using such effective strategies to combat impaired driving. Administratively located within the San Carlos Police Department, this Motor Vehicle Injury Prevention Program (MVIPP) expanded in 2010, with funding from the IHS under the Tribal Injury Prevention Cooperative Agreement Program (TIPCAP), to include strategies to increase occupant protection. Funding under TIPCAP ended in August 2015. In this paper, we describe the specific program intervention components, provide data to illustrate the impact of the program 10 years after it began operation, and offer reasons for its success.

PROGRAM IMPLEMENTATION

Setting
The San Carlos Apache Indian Reservation is located in east-central Arizona, 110 miles east of Phoenix, Arizona. During the program period, there were an estimated 10,000 to 12,000 tribal members residing on the reservation’s 2,812 square miles. According to the 2010 census, the unemployment rate was 64%, and about 41.5% of the population lived below the poverty line. There is an IHS hospital at San Carlos, which serves primarily as an outpatient facility, and a satellite clinic about 30 miles east in Bylas. The tribal police department has its headquarters in San Carlos, with a substation located in Bylas. The number of full-time police officers has fluctuated during the past 10 years, with a low of 12 and a high of 28.

Funding and Goals
The San Carlos MVIPP was originally funded in 2004 as one of four tribal pilot programs nationally. An MVIPP coordinator was hired in 2005. The MVIPP’s primary focus was on reducing alcohol-impaired driving, although it also conducted some
media messaging regarding occupant protection. The MVIPP also creatively used incentive programs for its police officers to encourage sustained participation and motivation. The MVIPP continued to receive the CDC funding at $70,000 per year for the 5-year life of the grant, and the CDC extended the original length of the grant from 4 to 5 years due to the pilot program’s success during the initial 2 years.

Due to the demonstrated success of the MVIPP in 2009, the San Carlos Police Department self-funded the program while it sought other funding options. The activities initiated during the 5 CDC-funded years continued during the 1 year of self-funding.

In 2010, the MVIPP received funding from TIPCAP in the amount of $65,000 per year for 5 years. The TIPCAP program had a similar intent as the earlier CDC program, namely to develop injury prevention programs based on effective strategies or best practices. As part of the TIPCAP grant, the MVIPP expanded its efforts to include strategies to increase occupant protection.

Following in approximate chronological order are the major MVIPP injury intervention components that have been accomplished from 2005 through 2013.

### Community Awareness and Outreach
The MVIPP developed a comprehensive media campaign in 2005 and 2006 that provided a foundation from which to operate for the duration of the program. Adopting a social marketing approach, the outreach made the public aware of the program and its activities. It used a variety of local media outlets to advertise its message about alcohol-impaired driving and occupant protection. These included paid advertisements in local newspapers, paid messages on the local cable access channel, messaging on the local casino marquee, and unpaid messaging via flyers provided to residents and posted on bulletin boards. Similar media outlets were used to advertise scheduled checkpoints. These culturally appropriate messages were derived from focus groups that we conducted with the public, and messages were advertised more frequently during tribal and national holidays in alignment with the Bureau of Indian Affairs Indian Highway Safety’s campaign and the National Highway Traffic Safety Administration’s campaigns.

An associated media campaign activity was the development and use of specific slogans and logos associated with the MVIPP. One logo (Figure 1) referenced the 390 Task Force, which coordinated and carried out the driving under the influence (DUI) checkpoints. The term “390” refers to the police code for an impaired driver. A second logo (Figure 2) incorporated a local, culturally significant design (featuring Mount Triplet) into an occupant restraint message. Both slogans and logos were printed on a variety of promotional items valued by the public, such as t-shirts, key chains, nylon drawstring bags, and travel mugs. Third-party funding sources (e.g., Federal Highway Administration, Arizona Department of Health Services, Inter Tribal Council of Arizona) also enhanced these campaigns throughout the project.

Media messages evolved to ensure the right information reached the target audience to help promote safe behaviors. Initial “don’t drink and drive” messages were revised to “don’t drink and drive, use a sober driver.” Messaging was clarified because police officers discovered during the first few DUI checkpoints that non-sober drivers would state they were the least intoxicated occupant of the vehicle and were therefore designated the most likely to drive safely.

The MVIPP participated in occasional community events, including health fairs, parades, and...
community meetings, to advertise the program and its activities.

DUI Enforcement

The MVIPP emphasis on impaired driving led to the development of a DUI task force, known as the 390 Task Force, which planned and organized the DUI checkpoints at various locations on the reservation. The high-visibility checkpoints used standard operating procedures for consistency, stopped all traffic during a specified time period to assess drivers’ levels of impairment, and involved the use of field sobriety tests and breath alcohol testers to assess alcohol impairment. The times of day and days of the week for the checkpoints were determined by anecdotal evidence contributed by the Task Force members and by police crash report data.

Some DUI checkpoints were conducted by San Carlos Police Department officers and support staff alone. Others were conducted with the assistance of regional enforcement partners, such as neighboring tribal police departments, neighboring city police departments, county sheriffs, the Arizona Department of Public Safety, and enforcement officers from the US Immigration and Customs Enforcement.

When police officer staffing levels or competing work priorities precluded the staff-intensive DUI checkpoints, saturation patrols were used as an alternative to checkpoints. Saturation patrols involved increased patrols at high-risk times in high-risk areas to identify impaired drivers, as well as to enforce all traffic safety laws.

Lower BAC Limit

Lowering the legal BAC limit for vehicle drivers from 0.10% to 0.08% is a recommended intervention to reduce alcohol-impaired driving. In 2007 the San Carlos Apache Tribe lowered the legal BAC to 0.08%. The MVIPP championed this legislation and significantly contributed to this decision.

Incentive Programs for Officers

The MVIPP coordinator used a variety of creative incentives—beyond overtime pay—to encourage and maintain police officers’ sustained participation and motivation in the program. Such incentives, valued by officers, included home-cooked meals before and during checkpoint events, awards of food and promotional items such as windbreakers and jackets to recognize exceptional participation and performance, an expense-paid trip to a national conference for the officer with the most DUI arrests in a calendar year, and recognition for outstanding performance in off-Reservation organizations such as Mothers Against Drunk Driving (MADD). These incentives were especially important during periods of shortages of police officers on staff.

Primary Occupant Protection Law

In November 2011, the San Carlos Apache Tribe enacted a primary occupant restraint law, to become effective in January 2012. The tribe was the fifth Arizona tribe to pass a primary law more stringent than the state’s secondary law. With primary laws, police officers may stop vehicles solely for seat belt law violations. In contrast, with secondary laws, officers must have another reason to stop a vehicle before citing an occupant for failing to wear a seat belt.

As part of planning the implementation of the new primary occupant restraint law, the MVIPP and San Carlos Police Department leadership realized the public needed time to adapt to the new law. Simultaneous to a media campaign, the San Carlos Police Department began a 3-month enforcement grace period, during which officers...
would stop drivers who were not wearing a seat belt but would only issue a warning citation. Public awareness via media outlets continued beyond the 3-month grace period.

Full enforcement of the new primary occupant restraint law began in late April 2012. At this time, anyone stopped by a police officer for not wearing a seat belt was issued a citation.

**METHODS**

Evaluation of the MVIPP was an integral part of its development. Several data elements were tracked throughout the operation of the program to measure its impact and are reported here. These included DUI arrests, total San Carlos Police Department-reported crashes, nighttime crashes, crashes involving injury or fatality, and nighttime crashes involving injury or fatality. A motor vehicle crash was any vehicle incident that involved a motor vehicle occupant, pedal cyclist, pedestrian, or other transport on a public highway, street, or road. Motorcycles, all-terrain vehicles, and other off-road vehicles, were not included unless a motor vehicle was also involved in the crash.

The number of DUI arrests and the total number of crashes are self-explanatory. The injury crashes and nighttime crashes were tracked since alcohol-involved crashes are associated with greater likelihood of injury, and alcohol-involved crashes are more frequent during nighttime hours. Due to variation throughout the year for times of sunrise and sunset, and to compensate for a relatively smaller number of crashes with a shorter nighttime period, we used a standard definition for nighttime as between 6:00 pm and 5:59 am.

Joinpoint Regression Analysis Software models were used to calculate trend changes in these key data elements. Joinpoint is statistical software for the analysis of trends using joinpoint models, i.e., models where several different lines are attached at the "joinpoints." Joinpoint models linear and non-linear trend lines, which can be used to best determine significant variations in data. We report one joinpoint relevant to our DUI arrest data. For each trend segment, the annual percentage change (APC) and corresponding P values were calculated.

We also tracked seat belt use to measure the impact of the primary occupant restraint law, which became effective in January 2012. We observed driver and front seat passenger seat belt use according to the local IHS observational seat belt survey protocol. The protocol standardizes how surveys are conducted to ensure local seat belt use surveys are reasonably consistent and provides guidance for the selection of observation locations, survey procedures, and data summary and reporting.

In 2013, 3 police-coordinated traffic checkpoints, which stopped all traffic at a particular location, provided an opportunity to obtain an estimate of car seat use for a sample of children in the stopped vehicles. It is important to note that these observations indicated only if a child was occupying a car seat; they did not assess car seat installation or optimal restraint use (e.g., child buckled in an age-and size-appropriate car seat).

Finally, knowledge, attitudes, and practices (KAP) surveys of the public were conducted in 2005, 2006, and 2008. KAP surveys were conducted to document the level of the public’s support of a lower BAC limit, a primary occupant restraint law, enhanced enforcement of new laws, and perceptions related to DUI and occupant restraints. Questionnaires were designed and piloted locally then administered by trained surveyors who completed 1 survey in 5 minutes or less. Occasionally, participant incentives such as free bottles of drinking water or t-shirts were provided. KAP survey locations were selected based on the high likelihood of being able to find a population primarily comprised of tribal members (e.g., grocery store, post office). We surveyed 200 participants in 2005, 139 in 2006, and 140 in 2008. In addition, a cost-benefit analysis of the San Carlos MVIPP, that included the program...
years 2005 through 2008, was conducted by a third party to estimate the value of the program’s effects.

**RESULTS**

**DUI Arrests and Motor Vehicle Crashes**

Table 1 shows the changes in data elements over time. The 2004 data serve as baseline measures, since the program received its initial funding in late 2004 but did not begin implementation of any program activities until early 2005.

Overall, the change in DUI arrests was non-linear—the trend for the first segment (between 2004 and 2009) was not significant nor was the trend for the second segment (between 2009 and 2013). The model with a joinpoint at 2009 is significantly better ($P = .02$) than the linear model, implying the DUI trend is not linear. The annual percentage change (APC) increased 9.08% per year until 2009, then decreased 14.95% per year afterwards, but neither change was statistically significant ($P = .12$ and $P = .09$, respectively).

However, the remaining outcomes regarding motor vehicle crashes were linear and significant, all decreasing about 5% to 7% per year. The number of total crashes, nighttime crashes, crashes involving injury/fatality, and nighttime crashes involving injury/fatality all generally dropped by substantial proportions from 2004. The APC for total MVCs was -6.34 ($P = .002$), for nighttime MVCs -7.43 ($P = .001$), for MVCs with injuries/fatalities -5.37 ($P = .01$), and for nighttime MVCs with injuries/fatalities -6.89 ($P = .02$).

**Occupant Restraint Use**

Data on driver and front seat passenger seat belt use reflect a 144% increase, from 19% before the primary occupant restraint law was enacted (2011) to 47% during the first full year of enforcement (2013) (Table 2). While the data in Table 2 depict observed seat belt use for a short 1-year time period before the law was enacted, observed seat belt use for the years 2004 through 2010 was consistently below 20%.

The tribe’s primary occupant restraint law also encompasses child car seat use. Efforts to assess the extent of car seat use prior to 2013 varied by methodology and venue. Many of these assessments involved voluntary car seat distribution or check events, which did not provide representative estimates of the population but found car seat use at less than 20%. In 2013, 3 police-coordinated traffic checkpoints that stopped all traffic at a particular location provided an opportunity to obtain a better estimate of car seat use for a sample of children in the stopped vehicles. In 2013, the combined observations from 3 checkpoints found that 52% of the children were in car seats. If we use 20% car seat use from previous years as the baseline measure, this reflects a 160% increase in car seat use since the occupant restraint law was enacted.

**Table 1.** Number of Driving Under the Influence (DUI) Arrests and Motor Vehicle Crashes (MVC) on the San Carlos Apache Reservation, 2004 to 2013

|                   | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | Annual Percentage Change | P Value |
|-------------------|------|------|------|------|------|------|------|------|------|------|--------------------------|---------|
| DUI arrests       | 308  | 385  | 411  | 391  | 468  | 533  | 359  | 392  | 375  | 213  | 9.08                     | .12     |
| Segment 1 (2004–2009) |      |      |      |      |      |      |      |      |      |      |                         |         |
| Segment 2 (2009–2013) |      |      |      |      |      |      |      |      |      |      | -14.95                  | .09     |
| Total MVCs        | 338  | 276  | 247  | 297  | 240  | 235  | 240  | 161  | 162  | 203  | -6.34                    | .002    |
| Nighttimea MVCs   | 146  | 102  | 98   | 121  | 107  | 107  | 91   | 68   | 63   | 68   | -7.43                    | .001    |
| MVCs with injuries/fatalities | 104  | 87   | 83   | 101  | 72   | 79   | 73   | 48   | 55   | 75   | -5.37                    | .01     |
| Nighttimea MVCs with injuries/fatalities | 51   | 33   | 39   | 39   | 39   | 46   | 31   | 22   | 21   | 26   | -6.89                    | .02     |

a 6:00 pm to 5:59 am.
Public Attitudes About Motor Vehicle Injury Prevention

KAP surveys revealed high levels of support for programs to prevent DUI. For example, in 2005 81% of KAP survey respondents were in favor of sobriety checkpoints, increasing to 93% in the 2008 KAP survey (Table 3). Nearly all (95%) survey respondents in 2006 thought there should be a child car seat safety law. Over time, more people reported seeing or being stopped at a DUI checkpoint in the past 12 months (increasing between 2005 and 2008 from 42% to 71% for seeing a checkpoint, and from 31% to 54% for being stopped at a checkpoint). Knowledge of appropriate designated drivers also increased, from 70% in 2005 stating a designated driver should have no drinks before driving to 86% in 2008.

Cost-Benefit Analysis

The cost-benefit conducted by an independent third party of program years 2005 through 2008 concluded that the MVIPP showed a lifetime cost-benefit ratio of 1:9.86, meaning that for every US$1 dollar spent to implement the program, there was almost $10 in savings from reduced medical and other costs.12

DISCUSSION

The San Carlos MVIPP clearly demonstrates the application of evidence-based injury prevention strategies is feasible and has a positive impact on public health in a Native American community. Use of such effective strategies as instituting DUI checkpoints to enforce sobriety laws, lowering the legal BAC limit for drivers, and passing and enforcing primary occupant restraint laws significantly reduced motor vehicle crashes, including those involving injuries or fatalities, and increased occupant restraint use, including car seat use. In 2013, the data on motor vehicle crashes suggest an upward turn, which may be due to reduced police officer staffing at the San Carlos Police Department.

Changes in DUI arrests over time were not statistically significant. However, the number of DUI arrests generally increased over the first several years of the project, but then the number declined or plateaued over the remaining project period. Possible explanations for this decline include that the San Carlos Police Department had significantly fewer sworn officers or that officers had multiple responsibilities other than traffic enforcement that competed with, and often negated, opportunities for involvement in DUI and/

### TABLE 2. Driver and Front Seat Passenger Seat Belt Use: Before and After Enactment of the Primary Occupant Restraint Law on the San Carlos Apache Reservation, 2011 to 2013

| Enforcement Phase (Time Period) | N  | No. Wearing Seat Belt | Percent Seat Belt Use (95% CI) |
|--------------------------------|----|-----------------------|--------------------------------|
| Pre-enactment of primary seat belt law (Jan to Dec 2011) | 445 | 86 | 19.3% (15.7, 23.0) |
| Enforcement grace perioda (Feb to Apr 2012) | 237 | 72 | 30.4% (24.5, 36.2) |
| Full enforcement of primary seat belt law (May to Dec 2012) | 822 | 354 | 43.1% (39.7, 46.5) |
| Full enforcement of primary seat belt law (Jan to Dec 2013) | 851 | 400 | 47.0% (43.7, 50.4) |

a Police officers stopped vehicles if occupants were not restrained but only issued warning citations.
or occupant protection checkpoints. On the other hand, the decline in DUI arrests could be related to increased awareness among community members about the danger of DUI or the risk of DUI arrest leading to less impaired driving incidents.

We believe several factors contributed to the program’s overall success:

- Extensive partnerships
- Technical expertise
- Program managed by a civilian employee within the police department
- Consistent staffing and funding
- DUI task force
- Use of incentives
- Community and stakeholder support

Although these factors are valuable assets individually, all of them combined likely led to the program’s significant success. Partners included federal agencies (e.g., Indian Health Service, the CDC, Bureau of Indian Affairs), multiple law enforcement agencies (tribal, city, county, state, federal), and a private marketing firm. A high level of local technical expertise existed. The public health staff involved with the program contributed expertise in the collection of qualitative and quantitative data, and in the management, analysis, interpretation, and presentation of that data. The law enforcement staff involved with the program contributed expertise in the development, enactment, and implementation of laws; with the enforcement of laws in general; and with specific enforcement operations such as DUI checkpoints.

The establishment of the MVIPP was the result of proactive foresight from the police department to become involved in a “prevention” effort. This highlights the point that not all prevention programs should or must be managed by a public health program to be successful. The department also hired a civilian (i.e., non-officer) full-time program coordinator who was able to dedicate all her talent and resources to implementing the interventions. Both the department and the coordinator possessed unwavering dedication to the project and to achieving its goals from the program’s inception.

The creation of a DUI task force within the police department emphasizes the department’s dedication to the issue. Reliable financial resources, through the multiyear funding cycles, enabled the program to function at a level necessary to implement the effective strategies. This included money for police officer overtime pay and the use of funding sources outside the department to procure equipment used at sobriety checkpoints.

Many of these factors are consistent with what Fell et al. identified as reasons for enforcement agencies to conduct sobriety checkpoints, including active local task forces who manage checkpoints, available financial and human resources whether from within law enforcement agencies or from outside sources, and support from the general public and officials to deter alcohol-impaired driving. The

| TABLE 3. Results From Knowledge, Attitudes, and Practices (KAP) Surveys of the Public, Motor Vehicle Injury Prevention Program, San Carlos Apache Reservation, 2005, 2006, 2008 |
|---------------------------------------------------------------|
| **KAP Survey Variable**                                      | **2005 (N = 200)** | **2006 (N = 139)** | **2008 (N = 140)** |
| In favor of sobriety checkpoints                              | 81%                | NA                | 93%                |
| Indicated it was “very important” to do something to reduce drinking and driving | 94%                | NA                | 97%                |
| Reported seeing a DUI checkpoint in operation in the past 12 months | 42%                | NA                | 71%                |
| Reported being stopped at a DUI checkpoint in the past 12 months | 31%                | NA                | 54%                |
| Reported seeing or hearing a message in the media about drunk driving in the past 12 months | 62%                | NA                | 73%                |
| Stated a designated driver should have no drinks before driving | 70%                | NA                | 86%                |
| Thought there should be a law requiring all children to ride in a car seat | NA                | 95%                | NA                |

Abbreviation: DUI, driving under the influence.
formation of impaired driving task forces or coalitions and support from local organizations for high-visibility law enforcement efforts, such as sobriety checkpoints, have been recommended elsewhere as well.\textsuperscript{14,15} We believe in addition to these elements, a major factor that promoted involvement in the checkpoints was the incentive program used to encourage and reward police officers of the DUI task force. Incentives included overtime pay, meals, and socializing among the task force prior to conducting sobriety checkpoints.

The support from tribal and police leadership was critical throughout the life of the program. Such ardent support was evident in the passage of the 0.08% BAC law and the primary occupant restraint law as well as the enforcement of these new laws. Support was also manifested in less obvious ways, such as police officer participation in injury prevention-focused training courses, conferences, and program activities such as DUI and occupant restraint checkpoints. We believe these interventions worked because they were championed by local leaders and because law enforcement and public health officials alike shared the common goal of reducing motor vehicle-related injuries, encouraging close collaboration on achieving this goal throughout the program period.

A novel element of the program’s data and monitoring strategy was not only to provide monitoring and evaluation updates to the funders but also to document the program’s approaches and share program successes and challenges with the broader public health community. For example, the program developed and presented several posters at the National Conference on Highway Safety Priorities – Lifesavers on topics ranging from overall program evaluation to unique program elements such as the police officer incentive program.\textsuperscript{16-23} We have found that such knowledge sharing activities offered several unexpected benefits (Box), and we recommend multifaceted community-based programs to consider incorporating such activities into their program evaluation.

**Strengths and Limitations**

A challenge that was overcome early in the program was the collection and management of data. Since the program coordinator received training in injury prevention and data management, she became the on-site data advocate within the police department. She worked closely with the officers to stress the importance of accurate and complete crash reports, and to emphasize the importance of the data they collect in measuring the impact of the MVIPP. She, in turn, collected and managed the collective crash data. This early emphasis on quality data resulted in the data component becoming a strength of the MVIPP. The data were used to demonstrate the program’s impact on several platforms: as feedback to the officers to reinforce the importance of their enforcement and data collection efforts, to police management and tribal leadership to demonstrate the value of the program in preventing injury, to the funding agencies to demonstrate the value of their investments, and to procure additional funds from multiple sources.

Data variables are police-reported only, with no verification by health care sources. While such verification through health care sources may be ideal, it was beyond the scope of local resources to combine with local emergency room data. This was recognized in a 2010 report that surprisingly determined police-reported MVCs were a more reliable data source than accessible local health care facility data sources because many MVC victims were evacuated directly from the crash site to health care facilities that provided a higher level of care.\textsuperscript{24}

A decrease in DUI arrests and increases in the 4 crash variables in 2013 (Table 1) coincided with a Support from tribal and police leadership was critical to the success of the injury prevention program.
very low San Carlos Police Department officer staffing level. While we believe the low officer staffing likely contributed to this 2013 data pattern, we cannot conclusively establish a causative effect. Regardless, a challenge for a small police department without a dedicated traffic enforcement unit is keeping focus on traffic enforcement during times of reduced police officer staffing, with competing law enforcement issues similarly requiring their attention.

Program sustainability beyond the time period we report in this paper is difficult to predict. However, continued collaboration among partners is likely and regardless of level of funding, interventions conducted may be scaled to meet local needs based on available resources (e.g., fewer DUI checkpoints, or low-manpower checkpoints, and increased saturation patrols).

CONCLUSION

The San Carlos Apache Tribe’s Motor Vehicle Injury Prevention Program is an exceptional example that supports the “Community Guide”s recommendations that a carefully planned, well-executed, multicomponent program, implemented in conjunction with community mobilization efforts, can reduce motor vehicle crashes and increase occupant restraint use. Key factors that contributed to the program’s success include strong partnerships between public health and law enforcement agencies, consistent financial resources over multiple years, and high-visibility enforcement of impaired driving laws.

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Family Planning Supply Environment in Kinshasa, DRC: Survey Findings and Their Value in Advancing Family Planning Programming

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A series of facility-based surveys that mapped all sites providing family planning services and that assessed readiness to provide services, using mobile phones, was feasible in a low-resource setting, contributing to mobilization of partners and increased donor support. Between 2012 and 2013, readiness to provide services increased from 44% of sites to 63%. Three factors most associated with productivity: type of facility (clinics more than hospitals or health centers), more years in operation, and number of methods available.

ABSTRACT

Background: Modern contraceptive prevalence was 14.1% in 2007 in Kinshasa, the capital city of the Democratic Republic of the Congo (DRC). Yet virtually nothing was known about the family planning supply environment.

Methods: Three surveys of health facilities were conducted in 2012, 2013, and 2014 to determine the number, spatial distribution, and attributes of sites providing family planning services. The 2012 and 2013 surveys aimed to identify the universe of family planning facilities while obtaining a limited set of data on “readiness” to provide family planning services (defined as having at least 3 modern methods, at least 1 person training in family planning in the last 3 years, and an information system to track distribution of products to clients) and output (measured by couple-years of protection, or CYP). In contrast, the 2014 survey, conducted under the umbrella of the Performance Monitoring and Accountability 2020 (PMA2020) project, was based on 2-stage cluster sampling. This article provides detailed analysis of the 2012 and 2013 surveys, including bivariate and multivariate analysis of correlates of readiness to provide services and of output.

Results: We identified 184 health facilities that reported providing at least 1 contraceptive method in 2012 and 395 facilities in 2013. The percentage of sites defined as “ready” to provide services increased from 44.1% in 2012 to 63.3% in 2013. For the 3-month period between January and March 2013, facilities distributed between 0 and 879.2 CYP (mean, 39.7). Nearly half (49%) of the CYP was attributable to implants, followed by IUDs (24%), CycleBeads (11%), and injectables (8%). In 2013, facilities supported by PEPFAR (n = 121) were more likely than other facilities to be rated as ready to provide services (P < .0001); however, PEPFAR-supported sites generated less CYP on average than sites supported by family planning implementing agencies (P < .0001). Multivariate analysis showed 3 variables were associated with CYP: type of health facility, length of time in operation, and number of contraceptive methods available. Clinics generated higher (3-month) CYP than hospitals and health centers by 65.3 and 61.5 units, respectively (P < .01). The mean CYP for facilities in operation for 4–6 years was 26.9 units higher (P < .05), and 50.2 units higher for those operating 7+ years (P < .01), than the reference group of facilities in operation for 1 year or less. For each additional method available at a facility, CYP increased by almost 8 units (P < .01).

Conclusions: Findings from these surveys suggest that lack of physical access is not the defining reason for low contraceptive use in Kinshasa, although it is highly likely that other service-related factors contribute to low service utilization. The results contributed to increasing the momentum for family planning in the DRC in many ways, including mobilizing partners to increase contraceptive access and increasing donor investment in family planning in the DRC.
INTRODUCTION

Kinshasa, the capital city of the Democratic Republic of the Congo (DRC), has a population of approximately 10 million people. The DRC is typcial of many sub-Saharan African countries with a high total fertility rate (6.6), although it is 4.2 in Kinshasa. Family planning efforts commenced in the country in the 1980s, but the DRC government did not begin to publicly demonstrate commitment to family planning until 2012. At that time, a number of government agencies and nongovernmental organizations (NGOs) were working in isolation to provide family planning services in different locations throughout the sprawling city of Kinshasa, but there was no master plan or even centralized listing of service delivery points (SDPs). In short, Kinshasa was a virtual black box in terms of the family planning service delivery environment.

Beginning in 2012, the Kinshasa School of Public Health in collaboration with the Tulane School of Public Health and Tropical Medicine conducted research to assess the availability of contraceptives in health facilities and other aspects of the family planning supply environment throughout Kinshasa. The latest Demographic and Health Survey (DHS) at that time (from 2007) showed the modern contraceptive prevalence rate (mCPR) in Kinshasa to be only 14.1%, a percentage similar to other capital cities in francophone Africa. Surveys since then have shown an increase in mCPR in Kinshasa—to 20.4% in the Performance Monitoring and Accountability 2020 (PMA2020) survey of 2014. This finding begged the question: was low mCPR an issue of supply (i.e., limited availability of contraceptive methods) or demand (lack of interest in using contraception)? The 2007 DHS indicated unmet need for family planning among married women in Kinshasa was 26.9% (19.9% unmet need for spacing births and 7.0% for limiting births). No comparable data existed on contraceptive availability.

The organization of family planning services in Kinshasa contrasts markedly to countries in which the government manages family planning services through a network of public sector health facilities. In the DRC, the central government supplies only 15% of the national health budget; donors contribute 23%, international NGOs 11%, corporations 8%, and the remaining 43% constitutes out-of-pocket payments, although even then the actual disbursement of funds is lower than the amount budgeted. In family planning as in other health sectors, the government pays for personnel and infrastructure while donor funding covers the vast majority of programmatic expenses, including training, commodities, behavior change communication, and related activities. Data from the National Health Account indicate that for reproductive health, the government covers less than 1% of the costs, donors 31%, international NGOs 1%, and households the remaining 68%. Donor funding in the DRC is channeled through international and local NGOs that provide family planning services through their own health facilities or that support family planning and reproductive health services in government facilities. As a result, the distinction between public and private sector facilities is often blurred.

The National Reproductive Health Program (Programme National de Reproduction de la Santé, PNSR) is mandated to establish national service delivery norms and oversee family planning activity throughout the country, yet for many years it lacked the financial, technical, and human resources to effectively advance family planning programming. Prior to 2012, it worked in loose collaboration with different implementing partner organizations (NGOs receiving donor funding to provide family planning services in Kinshasa and/or elsewhere in the country). As of 2012, 9 partner organizations supported family planning services in one or more of the 35 health zones of Kinshasa (Box). These NGOs generally coordinated with the Médecin Chef de Zone (chief medical officer of the zone), but no centralized database existed with the number or location of family planning SDPs in Kinshasa.

In June 2012, another source of support became available for family planning in Kinshasa: 4 projects supported by the US President’s Emergency Plan for AIDS Relief (PEPFAR) began to introduce contraception (counseling and methods) into their PMTCT (prevention of mother-to-child transmission) services. PEPFAR supported the training, and the US Agency for International Development (USAID), as an implementing arm of PEPFAR, supplied the full range of contraceptives. In 2013, PEPFAR declared family planning to be the second of four pillars for PMTCT, and by mid-2013, PEPFAR had integrated family planning into a second wave of facilities. Although the DRC has relatively low HIV prevalence in comparison with East and Southern African countries, it receives PEPFAR funding for HIV prevention and treatment. In mid-2012, 4 US government-funded projects expanded their PMTCT work to include family planning. Specifically, the projects identified...
health facilities where they could train personnel in contraceptive service delivery and supply them with commodities.

An essential first step to understanding contraceptive availability and eventually strengthening family planning programming was to determine the number and location of family planning SDPs in Kinshasa, a challenging task in a city of 10 million people that covers a landmass the size of the country of Lebanon. This initiative evolved into a series of 3 family planning facility-based surveys (in 2012, 2013, and 2014). Although the surveys differed in content, data collection mechanism, and sampling techniques, they have produced a wealth of data to inform programmatic decision making and to assess progress in family planning service delivery. In this paper, we describe results of the surveys, focusing on the 2012 and 2013 surveys in particular (as their methodology was more comparable than that of the 2014 survey), to demonstrate contraceptive availability, readiness to deliver family planning services, and performance of the facilities (level of output), as well as correlates of readiness to provide services and of output. In addition, the survey results provide information on the contribution of PEPFAR-supported sites to the family planning service delivery environment.

METHODOLOGY

Study Design and Sampling
We conducted facility-based surveys in Kinshasa in 2012, 2013, and 2014. (Data were also collected in 2015 but had not been officially released at the time of writing of this article.) See Table 1 for a summary of the methodological approach to each survey.

In 2012, we conducted a facility-based survey to identify, survey, and geocode the universe of health facilities and pharmacies that sold or distributed contraception free of charge, as a first step in defining the family planning supply environment in Kinshasa. Although the primary focus was on health facilities, we added pharmacies because they represented the source of contraception for almost half of modern contraceptive users in the 2007 DHS.4 To identify all possible health facilities, we drew up lists for each health zone, based on information obtained from the PNSR and implementing partners. Once at the health zone, we completed our listings with information provided by the health zone authorities. Data were collected using the conventional paper and pencil method; geographical coordinates were taken with an eTrex global positioning system (GPS) device using the WGS84 reference coordinate system.
In 2013, we conducted a follow-up survey using the same methodological approach as in 2012. The 2013 survey had 2 key objectives: (1) to update information on the universe of family planning sites, and (2) to evaluate the change in the percentage of 3-star sites (explained below). This survey did not include pharmacies because we discovered that the vast majority of pharmacies are in the private sector operating independently of the PNSR or NGOs working in family planning, and thus they were unlikely to be targets of family planning interventions. Also, the high use of pharmacies identified in the 2007 DHS was linked to the widespread use of condoms, but use of condoms for family planning had decreased from 62% of modern method use in 2007 to 30%–42% between 2013 and 2015, as other methods became available.\textsuperscript{1,5} We started with the listing of sites from the 2012 survey and added new sites that partner organizations were now supporting (including the PEPFAR-supported projects); we also conferred with health zone authorities. The 2013 survey used Android smartphones and the OpenDataKit application for both data collection and geocoding of sites. This open-source tool was programmed using XML forms tailored to collect family planning service indicators (such as number of trained staff or contraceptive methods available on that day) for each facility. In addition, the internal GPS for the smartphone automatically collected latitude and longitude data, thus recording the exact location of the facility. This innovative technology yielded rapid results (within a month of the completion of data collection), which brought further attention to the survey.

The 2014 survey differed markedly from the previous 2 surveys. Kinshasa was selected as a site for the PMA2020 survey project that uses a mobile-assisted data collection system to monitor family planning programs.\textsuperscript{5} Because the PMA2020 survey would be repeated at least annually in Kinshasa for multiple years, there was great interest in adopting this methodology. Key differences were the sampling approach and content of the questionnaire. Instead of capturing the universe of family planning SDPs, the PMA2020 survey was based on 2-stage cluster sampling, and the data were weighted accordingly. In the first stage, 58 enumeration areas were randomly selected (from the total of 335 in Kinshasa). During the second stage, one each of the following types of facilities was randomly selected per enumeration area: hospital, health center, health post, clinic, pharmacy, and kiosk. The difference between a health center and clinic is based on the level of care the facility offers and on the personnel operating it. A health center offers a minimum

### Table 1. Methodological Approaches to the 3 Facility-Based Surveys in Kinshasa, DRC

|                      | 2012                  | 2013                  | 2014                  |
|----------------------|-----------------------|-----------------------|-----------------------|
| Dates of data collection | Jan–Mar 2012          | Oct 2013–Jan 2014     | Aug–Sep 2014          |
| Approach to sampling of sites | Attempted to identify universe of family planning sites | Attempted to identify universe of family planning sites | Random sample of 58 enumeration areas; up to 6 SDPs per enumeration area |
| Type of facilities included | Health facilities (hospital, health center, health post, clinic) and commercial pharmacies | Health facilities (hospital, health center, health post, clinic); no pharmacies | Up to one each per enumeration area: hospital, health center, health post, clinic, pharmacy, kiosk |
| Mechanism for data collection | Pencil and paper | Smartphone | Smartphone |
| Length of questionnaire | Short | Short | Detailed |
| Used 3-star “readiness” rating | Yes | Yes | No |
| Geocoding of SDPs | Yes | Yes | Yes |

Abbreviations: DRC, Democratic Republic of the Congo; SDP, service delivery point.
package of services, including promotional and curative. A clinic offers more than the minimum package, including specialized consultations, interventions, and hospitalizations. Because not all enumeration areas had all 6 types of facilities, the actual number obtained per enumeration area ranged from 3 to 6. Regarding the content of the questionnaire, the PMA2020 survey included many more variables than the 2012 and 2013 surveys. Smartphones and the ODK system were used for both data collection and geocoding of sites.

**Data Collection**

Although the 2012 and 2013 questionnaires were purposely kept very short, they included 3 variables that were used to construct a very simple index of “readiness” to provide family planning services as a rough means of assessing differential levels of capacity among facilities. The 3 variables were:

1. Availability of at least 3 modern contraceptive methods
2. Availability of at least 1 person trained in family planning in the past 3 years
3. Availability of an information system that tracked distribution of products to clients

Facilities having all 3 items were labeled “3-star.” In a previous publication by the authors, we introduced this index as a 3-star rating of quality. However, given that service quality is more complex, we have renamed it “readiness” in this article. Although a crude indicator, it served a useful programmatic purpose of giving implementing partners 3 specific areas for improving service delivery at the sites they supported.

The 2013 survey also collected data on the number of commodities distributed during a 3-month period (January-March 2013) at each site, which were then converted to couple-years of protection (CYP) using established conversion factors. (CYP data were also collected in the 2012 survey, but the data were not of sufficient quality to include in this analysis.) CYP is a widely used measure of output in international family planning programs. Although it does not track individual users, it reflects the volume of activity at a given site and is useful for comparison purposes. To obtain a general sense of the distribution of methods provided in 2013, we calculated the percentage of method mix attributable to each method from the CYP data. We recognize the bias of calculating method mix based on CYP, since a method is given full credit for the protection it confers in the year it is delivered. For example, the conversion factor for 1 Jadelle implant is 3.8 years, the average duration of actual use based on research studies. However, the program gets all 3.8 years of credit in the year it is inserted. By contrast, methods whose protection lasts less than 1 year, such as the Depo-Provera injectable, never benefit from this bias. On the other hand, such methods provide a far lower duration of protection than longer-acting methods.

**Data Analysis**

Statistical analysis using Stata 13.0 package software consisted of bivariate and multivariate regression of data from the 2013 survey to test for factors as possible correlates of readiness (3-star rating) and of output (CYP). The 4 independent variables tested in the bivariate regression were: type of managing authority (private, faith-based, government, NGO), type of facility (health center, clinic, hospital), number of years in operation, and number of days per week in operation. Multivariate analysis was applied to test the relationship of 8 independent variables to the 3-month CYP. In addition to 4 aforementioned independent variables (type of facility, managing authority, number of years in operation, and number of days per week in operation), we also included type of support for each facility and the 3 variables that make up the readiness rating (number of methods, number of trained staff, and having an information system) in the model. We opted to test the 3 component parts of the readiness index as separate variables in the multivariate analysis to identify which was most strongly related to CYP. We also analyzed the contribution of external support (by a family planning implementing organization or by PEPFAR) to the family planning service delivery environment. Chi-square and t test and analysis of variance (ANOVA) were used to test the significance of associations between variables. A P value ≤ .05 was considered as evidence of association between 2 variables.

**Ethics**

The 2012 and 2013 facility-based surveys were approved by the Tulane Institutional Review Board (#238734 and #493349, respectively), as well as by the Ethics Committee of the Kinshasa SPH (ESP/CE/043/11 and ESP/CE/072/13).

**RESULTS**

**Facilities Offering Contraceptive Methods**

In 2012, we identified 184 health facilities (including hospitals, clinics, health centers, and health
posts), as well as 1,345 pharmacies, that provided at least 1 contraceptive method. In 2013, we found more than twice the number of health facilities (395) (Table 2). This doubling of sites is due to 3 main factors: addition of new sites by existing implementing partners; addition of sites by new PEPFAR-supported partners; and more intensive efforts by the research team to identify family planning sites within each health zone.

Health centers were the predominant type of health facility that offered family planning services in both 2012 (82.0%) and 2013 (76.5%). The 2014 data—representing the sample rather than the universe of facilities—nonetheless yielded a similar distribution by type of health facility to the previous years. (Data on pharmacies—available in the 2012 and 2014 surveys—are displayed in Table 1 but excluded from the narrative presentation of results, given the focus of this article on the other types of health facilities.)

Geocoding of the facilities in all 3 surveys allowed for spatial analysis of the distribution of family planning sites. Figure 1 shows the distribution of health facilities (excluding pharmacies) that were offering at least 1 contraceptive method in 2013. The concentration of facilities is far greater toward the center of Kinshasa than in the peripheral health zones. The number of health facilities that offered at least 1 method of contraception per health zone varied from 4 to 22. Taking into consideration population density, the number of health facilities offering at least 1 method of contraception per 100,000 population varied from 0.38 (Kokolo) to 17.57 (Gombo) per health zone. The map in Figure 2 shows these ratios at the health zone level for the entire city of Kinshasa. In downtown Gombo (the only health zone appearing in white), the high ratio of facilities per 100,000 results in large part from the low population density living in this largely administrative area of the city. In the surrounding health zones, the high population concentration results in a greatly reduced number of facilities offering family planning per 100,000 population. By contrast, in the very large semi-rural health zone located on the eastern periphery, one must take into consideration the distance factor. Although the number of facilities per 100,000 population is higher than in the center of Kinshasa, the vast landmass of these 2 eastern-most health zones means that the distances to the nearest health facility offering contraception can be as far as 25 kilometers for some people.

Types of Available Contraceptive Methods

All the facility-based surveys yielded information on the number and type of contraceptives

| TABLE 2. Number and Types of SDPs That Reported Offering Contraception in Kinshasa, DRC, 2012, 2013, and 2014 Facility-Based Surveys^a |
|---|---|---|---|
| SDP Type | 2012 | 2013 | 2014 |
| | No. | % of all health facilities^b | % of all SDPs^b | No. | % of all health facilities^b | % of all SDPs^b | No. | % of all health facilities^b | % of all SDPs^b |
| Health facilities (excluding pharmacies) | | | | | | | | | |
| Hospital | 23 | 12.5 | 1.5 | 72 | 18.2 | 10.6 | 17 | 21.5 | 10.6 |
| Clinic | 8 | 4.3 | 0.5 | 20 | 5.1 | 3.8 | 6 | 7.5 | 3.8 |
| Health center | 151 | 82.1 | 9.8 | 302 | 76.5 | 34.4 | 55 | 68.8 | 34.4 |
| Health post | 2 | 1.1 | 0.1 | 1 | 0.3 | 0.6 | 1 | 1.3 | 0.6 |
| Subtotal | 184 | 100.0 | 12.0 | 395 | 100.0 | 100.0 | 80 | 100.0 | 50.0 |
| Pharmacies | 1345 | – | 87.6 | – | – | – | 80 | – | 50.0 |
| Total SDPs | 1535 | – | 100.0 | – | – | – | 160 | – | 100.0 |

Abbreviations: DRC, Democratic Republic of the Congo; SDP, service delivery point.

^a The 2014 survey took a sample of SDPs, whereas the 2012 and 2013 surveys attempted to identify the universe of health facilities providing family planning. The 2013 survey did not include pharmacies.

^b That reported offering contraception.
At least half the sites had at least 3 modern methods available on the day of the survey. Condoms and injectables were the most frequently available methods in the facilities.

Available. In the 2012, 2013, and 2014 surveys, at least half the sites had at least 3 modern contraceptive methods available on the day of the visit. Although the rank ordering differed slightly, these methods comprised condoms, injectables, and pills.

Figure 3 presents the availability of specific methods in these health facilities in both 2012 and 2013 (with a different denominator to reflect the larger number of sites identified and surveyed in 2013). For every method measured in both surveys, availability increased between 2012 and 2013. Condoms and injectables were the most frequently available in both years, followed by pills and intrauterine devices (IUDs). By 2013, CycleBeads and implants were also offered in over half the facilities surveyed. Far less available were female sterilization and emergency contraception (16% and 14% of surveyed facilities, respectively, in 2013).

Readiness to Provide Family Planning Services

As reported elsewhere, the percentage of 3-star sites (those that had at least 3 modern contraceptive methods available, at least 1 person trained in family planning, and a functioning information system) increased from 44.1% in 2012 to 63.3% in 2013, reflecting measurable progress in readiness to provide contraception, especially considering the doubling in the number of facilities providing family planning between the 2 surveys.

Couple-Years of Protection Delivered (Output)

In 2013, the number of CYP distributed per facility for the 3-month period between January and March 2013 ranged from 0 to 879.2. Extrapolating the number of CYP for the 3-month period for
FIGURE 2. Number of Facilities per Health Zone Offering at Least One Method of Contraception per 100,000 Population, Kinshasa, Democratic Republic of the Congo, 2013

FIGURE 3. Availability of Specific Contraceptive Methods at Surveyed Facilities, Kinshasa, Democratic Republic of the Congo, 2012 and 2013

Abbreviations: EC, emergency contraception; IUD, intrauterine device. CycleBeads, female sterilization, and EC were not included in the 2012 survey.
the top-performing site to a full 12 months results in 3,517 CYP (879.2 CYP for 3 months = 293.1 CYP per month, multiplied by 12 months = 3,516.8 CYP per year). Some of the CYP was generated by long-acting methods, meaning that the protection from the method (e.g., an implant) would last beyond a single calendar year. Yet this number (3,517) quantifies the protection provided by this facility. In stark contrast, the mean CYP for the 3-month period across the 395 sites was 39.7, equivalent to roughly 158 couples protected in a 1-year period (39.7 CYP for 3 months = 13.2 per month, multiplied by 12 months = 158.4 CYP per year).

The top 10 facilities in terms of CYP performance represented less than 3% of the total number of sites, but they generated 31% of the total CYP for that period (data not shown in tables). On average, the top 10 facilities had more methods available (5.3) than did other facilities (3.6). The spatial distribution of these top 10 facilities is shown on the map in Figure 1, indicating a spread across the more concentrated population areas in the city (although distant to the outlying health zones).

Table 3 shows the percentage of method mix attributable to each method in 2013, calculated from CYP. Half the CYP corresponded to implants, followed by IUDs (24%), the Standard Days Method/Cyclebeads (11%), and 3-month Depo-Provera injectables (8%). Although the 2015 PMA2020 survey in Kinshasa showed male condoms to be the most frequently used modern method (by 35% of modern method users), condoms are often purchased in pharmacies or retail outlets, which were not visited in the 2013 facility-based survey.

Of note, one-third (33.4%) of the sites surveyed in 2013 reported zero CYP for the period January to March 2013 (that is, no reported distribution of contraceptive methods to clients). Facilities with no information system (78.6%) were more likely to have zero CYP than those with an information system (23.7%). Given the doubling in number of sites between 2012 and 2013, some sites surveyed at the end of 2013 may not have been operational in the beginning of that year during the period when this measure of CYP was taken. However, among 295 health facilities that had been offering family planning for at least 1 year, at least one-quarter (26.1%) reported zero CYP (data not shown).

### Correlates of Readiness to Provide Family Planning Services and of CYP

As shown in Table 4, 2 factors emerged as correlates of readiness in the bivariate analysis: type of facility and hours of operation. Managing authority and number of years in operation were not associated with readiness. Also shown in Table 4, 3 of the 4 tested factors emerged as correlates of performance (CYP output): type of facility, number of days per week in operation, and number of years in operation. It increased monotonically with the number of years the facility had been in operation. And it was higher among facilities open 4 to 6 days a week than among other facilities.

### The Entry of PEPFAR into Family Planning Service Delivery

The 2013 survey—conducted after PEPFAR had scaled-up its integration of family planning into PMTCT services—identified 121 health facilities supported by PEPFAR that reported providing family planning services. In comparison, 187 sites identified in the 2013 survey were supported by a family planning implementing organization (such as those listed in the Box) and 87 had no external support (Table 5).
Analysis of facility performance by type of support revealed that PEPFAR sites were more likely to be rated as 3 stars—suggesting readiness to provide family planning services—than other sites in Kinshasa (77.7% versus 56.9%, respectively). As shown in Figure 4, PEPFAR-supported sites were more likely than sites supported by traditional family planning organizations (61.3%) but more than sites receiving no external support (15.8) (Table 5).

**Correlates of CYP in a Multivariate Model**

As seen in the multivariate model (Table 6), 3 variables were associated with CYP: type of health facility, length of time in operation, and number of contraceptive methods available.
Clinics generated higher CYP than hospitals and health centers by 65.3 and 61.5 units, respectively (P < .01). The longer facilities had been in operation, the higher the level of mean CYP (by 26.9 more CYP for those operating 4–6 years [P < .05] and 50.2 more CYP for those operating 7 or more years [P < .01]), as compared with the reference group of facilities in operation for 1 year or less. In terms of number of methods available at the facility and CYP, for each additional method available, CYP increased by almost 8 units (P < .01).

## DISCUSSION

Our experience in the DRC shows that smartphone technology can be applied effectively to conduct facility-based surveys, even in a low-resource setting with notable infrastructure constraints. In addition to significantly improving the timeliness of the data collected, the digital data collection methodology also improved data quality (with automated skip patterns and response constraints limiting the number of missed or invalid answers), facilitated monitoring and communication through the daily updates on the online server, reduced survey costs, and built valuable skills among data collectors and supervisors. Despite the initial investment into the smartphones, extra batteries, and power banks, expenses associated with ODK totaled less than the printing, shipping, and data entry costs typical of paper surveys. Moreover, the growing popularity of smartphone-based data collection among development agencies means that our partners in the DRC received credit for spearheading these initiatives in a severely resource-constrained environment and after several more rounds of digital data collection (including the PMA2020 program described below), the country’s public health programs now have a trained cohort of supervisors and data collectors who can rapidly

### TABLE 5. Attributes and Performance of Facilities Providing Family Planning Services by Source of External Support, Kinshasa, Democratic Republic of the Congo, 2013

| Source of External Support | Total (N = 395) | FP Implementing Organization (n = 187) | PEPFAR (n = 121) | None (n = 87) | P Value |
|---------------------------|----------------|--------------------------------------|-----------------|-------------|---------|
| No. of years in operation, mean | 4.7 | 5.6 | 3.0 | 4.9 | .05 |
| No. of days per week of FP service delivery, mean | 4.8 | 4.9 | 4.7 | 4.7 | .15 |
| Type of facilities, % | | | | | |
| Hospital | 72 | 31 | 20 | 21 | .05 |
| Health center | 302 | 148 | 90 | 65 | |
| Clinic | 20 | 8 | 11 | 1 | |
| Achievement of elements in 3-star readiness index, % | | | | | |
| 3+ methods | 72.9 | 78.6 | 92.6 | 33.3 | < .001 |
| Staff trained in FP | 88.9 | 93.6 | 94.2 | 71.3 | < .001 |
| Basic information system | 82.3 | 90.4 | 87.6 | 57.5 | < .001 |
| All 3 elements | 63.3 | 71.7 | 77.7 | 25.3 | < .001 |
| CYP, Jan–Mar 2013, mean | 39.7 | 61.3 | 23.7 | 15.8 | < .001 |
| Zero CYP (no methods distributed), % | 33.4 | 20.9 | 43.0 | 47.1 | < .001 |

Abbreviations: CYP, couple-years of protection; FP, family planning; PEPFAR, US President’s Emergency Plan for AIDS Relief.
Facility-based surveys for family planning were conducted in 12 sub-Saharan African countries from 1989–97 by the Population Council under the Situation Analysis project. This model evolved into the Service Provision Assessment of the DHS, which has been carried out in some 10 African countries—most of which were conducted one time only in each country. With few exceptions (one being an article on Lesotho by Tuoane et al.), few family planning facility-based surveys have been published in the peer-reviewed literature. However, with the advent of PMA2020, data on family planning SDPs will become available on an annual basis from at least 9 African countries.

The major role played by the non-public sector in delivering family planning services highlights the longer-term challenge to the government of coordinating planning and budgeting. This analysis suggests a variation on the “total market approach” (whereby different sectors provide contraception for different segments of the population, based largely on ability to pay). However, it begs the question of what role the government can or should play in family planning programming going forward, especially given the current predominance of external organizations and funding. The government has become increasingly engaged in the issue of family planning. It needs to further pursue the objectives of the National Multisectoral Strategic Plan for Family Planning: 2014–2020 with emphasis on developing human resources, mobilizing financial resources, and procuring family planning products.

A key finding of this paper is the contribution of PEPFAR-supported family planning programming. The results of the 2013 survey demonstrated a

3 factors were associated with CYP: type of facility, length of time in operation, and number of contraceptive methods available.
readiness in PEPFAR-supported sites to provide services (as measured by the 3-star rating). However, the actual volume of services delivered (CYP) was lower than for sites supported by family planning implementing partners. This latter finding could reflect lack of interest, aptitude, and/or experience in family planning service delivery among staff trained primarily for HIV prevention and treatment. Alternatively, it may be a methodological artifact (the CYP data were collected for January–March 2013, during which point a number of PEPFAR facilities had just begun to integrate family planning with HIV). In fact, one-third of PEPFAR sites had been in operation for less than a year at the time of the 2013 survey (whereas only 15% of family planning sites were “new”). However, even if one compares only the sites in operation for at least 1 year, the mean CYP was higher among those supported by traditional family planning organizations (68) than among PEPFAR-supported sites (31) or no external support (21); data not shown in the tables. Of interest, the USAID Kinshasa Reproductive Health Advisor confirmed that the CYP data obtained in the 2013 survey for PEPFAR-supported sites were similar to the CYP numbers submitted by these same agencies to USAID (personal communication with Thibaut Mukaba, Family Planning/Reproductive Health Specialist, USAID/DRC, March 2015).

The case of Kinshasa can in no way be generalized outside Kinshasa. In particular, the findings could be very different in a country with high HIV prevalence, but they underscore the capacity of local facilities to scale-up family planning services if resources are made available, as was the case with PEPFAR funding in the DRC in 2013. However, in 2014 PEPFAR introduced a new strategy that places greater emphasis on treatment, and as a result family planning services will be discontinued at a number of sites previously supported with PEPFAR funding. These priority shifts will decrease access to family planning through health facilities in Kinshasa. Efforts are underway to identify new mechanisms for external support, with the withdrawal of PEPFAR funding for prevention activities.

The facility-based surveys conducted in Kinshasa do not answer the question of what would be the ideal number of family planning facilities in Kinshasa. (A parallel paper not yet published does analyze the spatial distribution of sites in Kinshasa.) However, results on the number of sites and on the average number of methods available per site do indicate that there are almost 400 health facilities and more than 1,500 pharmacies in the city where potential clients could obtain contraceptive methods, if they had the desire and means to do so.

In short, the findings suggest that lack of physical access to contraceptive methods is not

| TABLE 6. Multivariate Regression Analysis of Factors Associated With 3-Month CYP |
|---------------------------------|-----------------|-----------------|
|                                 | Mean CYP (SE)   |
| Managing authority              |                 |
| Government                      | 1 [Reference]   |
| NGO                            | 19.65 (1.34)    |
| Faith-based                    | 12.34 (0.93)    |
| Private                        | 5.36 (0.40)     |
| Other                          | 9.55 (0.18)     |
| Facility type                   |                 |
| Clinic                         | 1 [Reference]   |
| Hospital                       | -65.26 (2.79)** |
| Health center                  | -61.50 (2.86)** |
| Source of external support     |                 |
| No support                     | 1 [Reference]   |
| FP implementing agency         | 13.23 (0.99)    |
| PEPFAR                         | -18.91 (1.28)   |
| No. of years in operation      |                 |
| 0–1                            | 1 [Reference]   |
| 2–3                            | 13.72 (1.10)    |
| 4–6                            | 26.87 (1.97)*   |
| ≥7                             | 50.19 (3.43)**  |
| No. of days per week in operation |             |
| 1–3                            | 1 [Reference]   |
| 4–6                            | 19.16 (1.79)    |
| 7                              | 3.49 (0.25)     |
| Number of methods available    | 7.75 (3.06)**   |
| Number of trained staff        | 3.45 (1.28)     |
| Information system (yes/no)    | 8.06 (0.58)     |

Abbreviations: CYP, couple-years of protection; FP, family planning; PEPFAR, US President’s Emergency Plan for AIDS Relief; SE, standard error. * P < .05, ** P < .01, *** P < .001

When resources are made available, local facilities can scale-up services.
the defining reason for low modern contraceptive use in Kinshasa. In the 2015 PMA2020 survey, women aged 15–49 years not using contraception were more likely to give reasons other than service availability to explain their non-use: not at risk (44.7%), not married (39.8%), method or health-related concerns (19.3%), or opposition to use (11.9%); only 9 women (less than 1%) cited lack of knowledge/access to methods. Still, although not measured in these surveys, it is highly likely that other service-related factors also contribute to low service utilization, including quality of services, contraceptive stock-outs, and inconsistent pricing, among others.16

**Value of the Survey Results**

The findings from these facility-based surveys have contributed significantly to the increased momentum for family planning in the DRC since 2012 in multiple ways. Although we do not have concrete evidence demonstrating the link between the survey results and subsequent events, we believe the following activities can be plausibly linked to the survey work.

**Mobilization of implementing partners around a common objective of increasing contraceptive access and readiness.** Once the results from the 2012 survey were available, including static and interactive maps of SDPs throughout Kinshasa, the PNSR convened a meeting of the key donors for family planning in Kinshasa (USAID, UNFPA, and the Canadian Department of Foreign Affairs, Trade and Development) as well as implementing partners (listed in the Box) to review the findings. At this first meeting, the group, named the Kinshasa Family Planning Coalition, established the ambitious goal of increasing the percentage of 3-star sites in Kinshasa from 44% to 80%. The intervention to bring about this change was a series of quarterly meetings that focused on each of the 3 “stars” (range of methods, trained personnel, and functioning information system). The follow-up survey in late 2013 (then approximately 12 months away) would evaluate the extent of change. Although the follow-up survey showed an increase from 44.1% to only 63.3%, this measurable achievement in a relatively short period of time was highly motivational, and it created a new level of cohesion among family planning service providers in Kinshasa.3

**Development of an inventory of all family planning sites by implementing partner.** At the time of the 2012 survey, there was no central listing of family planning sites in Kinshasa, much less an inventory of which implementing partners supported which sites. Between the 2012 and 2013 survey, a spreadsheet was developed that showed every family planning facility listed by health zone and by implementing partner supporting that facility. If there had been a single managing authority responsible for all family planning sites (e.g., the Ministry of Health), this information would presumably exist. However, in a city where 10 different NGOs supported family planning service delivery without any formal coordination, this information linking family planning health facilities to specific implementing partners represented an essential step in defining the family planning supply environment. Moreover, it showed that some sites were supported by more than one partner organization (unbeknownst to them), while others had no supporting partner organization (which, once identified, could potentially be targeted to receive support in the future).

**Provision of feedback to implementing partners about their sites’ readiness to provide services and output.** Having linked family planning health facilities with implementing partners, the research team developed individual reports for each implementing organization. The report listed the name and address of the family planning facilities supported by each organization and provided information on the variables available from the 2013 survey: type of facility, managing authority, number of trained staff, and volume of each method in stock. Reports also gave the price that each facility charged for methods and the CYP measured for each facility. The director of the PNSR wrote a cover letter to each organization to reinforce the enhanced role of the PNSR in coordinating family planning activities in Kinshasa. Each implementing organization was free to use this information as it wished. Although we have no information on the extent to which organizations used these data for midcourse changes, these reports reflect the value of surveying the universe of family planning sites (instead of only a sample).

**Creation of heightened visibility for family planning in the DRC at the international level.** The static and interactive maps of family planning service delivery in Kinshasa were first presented publicly in November 2012 in Dar es Salaam, Tanzania, at a meeting titled “Using mobile technology to improve family planning and
health programs.” Given that francophone African countries have traditionally lagged behind anglophone African countries in all aspects of family planning programming, the audience took note that the DRC was using this cutting-edge technology to improve the evidence base of its programming, and the DRC won the Innovation Award (personal communication with Thibaut Mukaba, Family Planning/Reproductive Health Specialist, USAID/DRC, November 2012). Heightened visibility can lead to increased donor investment, as has occurred for family planning in the DRC.

Increase in donor investment in family planning. Although one cannot establish a definitive causal effect, the growing interest among donors in supporting family planning in the DRC can be partially linked to the strong evidence base that is now available for family planning service delivery in Kinshasa. For example, in 2014 the David and Lucile Packard Foundation funded a major family planning initiative for community-based distribution in Kinshasa, which used the maps from the 2013 survey in identifying health zones (and even areas within health zones) underserved for family planning. The Bill and Melinda Gates Foundation, which had provided seed funding for establishing this evidence base, has subsequently funded additional family planning activity in Kinshasa and Kongo Central.

Strengths and Limitations

Given the large increase in health facilities in Kinshasa reporting provision of family planning services between the 2012 and 2013 surveys (184 to 395), it is likely that the 2012 survey undercounted the number of sites. Specifically, in 2012 if the local health zone authorities informed the research team that a certain facility did not provide family planning, the research team did not visit that facility (which probably contributed to the undercount). However, as detailed in the results section, at least part of the increase can be attributed to the addition of new sites by PEPFAR-supported partners and by established family planning implementing agencies.

The 2012 and 2013 surveys were designed to obtain a few key variables from the universe of health facilities offering family planning in the 35 health zones of Kinshasa (in contrast to conducting a more comprehensive assessment of each facility based on a sample of family planning sites, as does the PMA2020 SDP module, which was conducted in Kinshasa in 2014 and 2015 and will continue forward in the coming years). In particular, because the 2012 and 2013 surveys collected relatively little data on each health site, the “3-star” rating system is based on only 3 variables (availability of methods, trained personnel, and information system).

By conducting surveys of “the universe” versus a sample of family planning sites in 2 consecutive years, we better appreciate the strengths and limitations of the 2 approaches. For example, the 2013 survey (“universe” approach) was extremely valuable for programmatic purposes. It provided site-specific information that could be fed back to implementing organizations for midcourse corrections and that could be used to answer such questions as which sites carried the implant in 2013 and how those sites were distributed across Kinshasa. Moreover, it captured a full picture of provision of family planning services in all health zones of Kinshasa. By contrast, the PMA2020 SDP survey yielded a sample of SDPs (including pharmacies, not included in the 2013 survey), which permits tracking of progress over time; moreover, PMA2020 allows for linking population-based data on contraceptive use among women residing in each enumeration area to data on access and service readiness at the facilities in the same enumeration areas.

CONCLUSION

This article forms part of an iterative series of quantitative and qualitative studies to understand the low mCPR in Kinshasa, DRC, and to inform family planning programming. It serves as an important reminder that physical access alone to health care services is just one part of the supply/demand equation. In the severely resource-constrained environment that is Kinshasa, the very existence and physical access to family planning SDPs is a necessary but not sufficient condition to the effective use of these services. Future research on contraceptive demand will yield further insights into the complex set of supply and demand factors that determine mCPR in Kinshasa, including financial, cultural, and social barriers.

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An informatics system consisting of a mobile health application and business intelligence software was used for collecting and analyzing Ebola contact tracing data. This system offered potential to improve data access and quality to support evidence-based decision making for the Ebola response in Guinea. Implementation challenges included software limitations, technical literacy of users, coordination among partners, government capacity for data utilization, and data privacy concerns.

ABSTRACT

Challenges in data availability and quality have contributed to the longest and deadliest Ebola epidemic in history that began in December 2013. Accurate surveillance data, in particular, has been difficult to access, as it is often collected in remote communities. We describe the design, implementation, and challenges of implementing a smartphone-based contact tracing system that is linked to analytics and data visualization software as part of the Ebola response in Guinea. The system, built on the mobile application CommCare and business intelligence software Tableau, allows for real-time identification of contacts who have not been visited and strong accountability of contact tracers through timestamps and collection of GPS points with their surveillance data. Deployment of this system began in November 2014 in Conakry, Guinea, and was expanded to a total of 5 prefectures by April 2015. To date, the mobile system has not replaced the paper-based system in the 5 prefectures where the program is active. However, as of April 30, 2015, 210 contact tracers in the 5 prefectures were actively using the mobile system to collectively monitor 9,162 contacts. With proper training, some investment in technical hardware, and adequate managerial oversight, there is opportunity to improve access to surveillance data from difficult-to-reach communities in order to inform epidemic control strategies while strengthening health systems to reduce risk of future disease outbreaks.

BACKGROUND

The longest and deadliest Ebola epidemic in history has prompted a historic global response in Guinea, Liberia, and Sierra Leone, the 3 countries affected most by Ebola. The epidemic began in December 2013 and has spread to 7 countries, causing, as of May 2015, more than 25,000 infections and almost 11,000 deaths.1

Controlling the epidemic requires a series of interventions: (1) community engagement; (2) identification of contacts; (3) contact monitoring for symptoms; (4) rapid lab confirmation of cases; (5) isolation and treatment of new cases; and (6) safe and dignified burials. Each activity is intrinsically complex, yet all need to be synchronized to stop transmission and control the outbreak.2 This challenge is compounded by the dynamic nature of an epidemic that is constantly evolving with transmission shifting to different environments. In this setting, real-time data become indispensable for guiding strategy, coordinating multiple interconnected interventions, and troubleshooting breakdowns in execution.

Lessons learned from the mobile health (“mHealth”) community demonstrate a possible opportunity to address some of these gaps. mHealth tools have been used in low-resource settings for a variety of applications, including strengthening access to data, managing health records, and improving the quality of health interventions.3-5 There have been selected instances in which mHealth tools have also been applied in emergency responses and for crisis management,6-8 but unfortunately quick adoption during times of emergency remains limited.
We established a real-time information system for contact tracing activities in Guinea. This system comprises a smartphone application that supports contact tracer workflow and enables rapid submission of surveillance data, which is linked to a business analytics and visualization software. Dashboards built on this platform facilitate access to the data by government response managers based in both prefecture-level offices and within the National Ebola Coordination Unit (NECU). The system allows for: (1) improved quality of work through built-in algorithms for contact tracers to follow; (2) real-time identification of contacts who have not been visited, allowing same-day intervention; and (3) stronger accountability of contact tracers through timestamps and collection of GPS points with their surveillance data. In this article, we describe the opportunities and challenges of deploying an mHealth system in response to an epidemic based on our experiences in Guinea during the Ebola outbreak.

**PROBLEM**

Contact tracing is the linchpin of epidemic control. It involves identifying all people who were exposed to someone with confirmed infection (termed “contact identification”) and monitoring them for the incubation period (21 days in the instance of Ebola). The purpose of the monitoring period is to diagnose and isolate contacts immediately if they develop symptoms (termed “contact monitoring”). With efficient contact tracing, the window of time during which an infected symptomatic person can transmit the disease is minimized, allowing for rapid disruption of human-to-human transmission.

In the current Ebola epidemic, contact tracing has been uniquely challenging due to the sheer numbers of cases and, thus, contacts; at one point, there were almost 4,000 contacts being monitored in Guinea spread over half of the country’s 33 prefectures. In addition, communities in affected countries are highly mobile, routinely traveling between different parts of the country. Furthermore, the communities may be resistant to contact tracing teams due to fear and stigma.

Contact tracing efforts in Guinea are conducted by contact tracers who are recruited locally and trained to monitor contacts in their community. Each contact tracer is required to visit their assigned contacts on a daily basis for 21 days to assess for symptoms of illness while also serving as a community resource for Ebola-related information. Contact tracers are managed by “close supervisors” who coordinate their activities and monitor whether contact tracers visit their assigned contacts through random household spot checks.

The current paper-based system proceeds as follows: The contact tracers use paper forms, based on internationally recognized templates, to record relevant information on the contacts they track daily. They then submit these forms to supervisors/field epidemiologists who collate them and enter the data into an Excel database. These data are aggregated at the prefecture level for review and submitted to national-level epidemiology teams for dissemination and analysis (Figure 1).

**FIGURE 1. Flow of Information Using Paper-Based Contact Tracing System in Guinea**

| Data Collection | Data Aggregation | Data Entry | Data Aggregation | Data Review & Report | Data Review & Report |
|-----------------|------------------|------------|------------------|----------------------|---------------------|
| • Visit Forms (Paper) | • Tally Daily Visits (Paper) | • Excel Database | • Excel Database | Prefecture Health Manager | National Response |
| Contact Tracer | Close Supervisor | Field Epidemiologist | Field Data Manager | Field Coordinator | |

Real-time data in emergency situations are indispensable for guiding strategy, coordinating interventions, and troubleshooting problems.

An mHealth application for contact tracing in Guinea was developed to facilitate rapid surveillance of and response to the Ebola epidemic.
TABLE 1. Limitations of Paper-Based Contact Tracing System

| Limitation                                      | Process Impact                                      |
|------------------------------------------------|-----------------------------------------------------|
| Paper-based contact tracing system creates delays between data collection and consumption. | Impedes rapid response and decision making around contact tracing strategy. |
| Human error is common with data entry, as is misunderstanding of data and communication gaps. | Data become unreliable, out of date, and inconsistent. |
| Efforts for data cleaning, data entry, and data compilation are time-intensive. | Takes away from time and resources needed for data analysis and troubleshooting. |

The paper-based system for contact tracing requires significant time and effort to enter, collate, and clean data, creating lag times in response.

CommCare is one of the few mHealth applications that allows longitudinal tracking of individual people over time.

This paper-based system and the time-intensive effort required for entering, collating, and cleaning data pose several limitations (Table 1). First, there is a time lag of 2 to 3 days for data collected by contact tracers to be processed and available for managers to use. Second, it is difficult to identify points at which mistakes may have been introduced during any step of the process. Third, this process requires significant time and energy by response teams devoted solely to data entry; drawing resources away from analyzing and acting on the issues presented.

Collectively, these limitations undermine the ability of response managers to accurately understand which contacts are going unmonitored, to evaluate the performance of different contact tracers, to pinpoint where and why lapses are occurring, and to troubleshoot breakdowns. For example, if a contact tracer missed a contact visit or a contact could not be located, response managers may not find out until a few days later. Furthermore, given the urgent nature of the epidemic, many contact tracers were rapidly deployed and inconsistently trained, potentially leaving gaps in performance. Given how pivotal effective contact tracing is for reducing transmission, these delays and problems have significant consequences for controlling the epidemic whereby new chains of transmission may go unrecognized.

SOLUTION

Implementation of the mobile contact tracing program involved 3 major stages:

1. Preparation
2. Deployment
3. Adaptation

Some steps within each stage ran concurrently.

The length of time and key partners involved in each step are summarized in Table 2. The head of the Surveillance Pillar of the NECU led the decisions about the locations and staggered timeline for deployment—beginning in Conakry, the country’s capital, and then expanding by prefecture according to Ebola caseload. A team of 3 West African global health experts, 2 experienced with information technology and 1 in health systems in crisis settings, was deployed to Conakry by the project headquarters in New York to manage local deployment, provide continuous quality improvement, and oversee maintenance of the program.

Stage 1: Preparation

Design of Application Software

We chose to use the Open Data Kit (ODK)-based software CommCare from Dimagi as the data collection tool for contact tracing activities. Although there were other mobile health options that were being considered for use in Guinea, there were several features of CommCare that guided our decision. CommCare is one of the few mobile health applications that allows longitudinal tracking of individual people over time—a feature critical for a surveillance system that required daily visits over a set period of time—and can also accommodate the reassignment of contacts and their history from one user to another if a contact tracer needs to be switched. Furthermore, with its algorithm-based decision support features, the software has been used to reinforce maternal and child health tracking in other projects managed by the implementation team since 2013. The implementation team’s familiarity with the software’s strengths and weaknesses was also a factor that contributed to the selection of the software, as it enabled rapid implementation and minimal software iteration. Key functions of CommCare that were leveraged for the program are summarized in the Box.

We created the contact tracing application using protocols that were publicly available from the US Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO),91 and then revised it in consultation with local United Nations (UN) agencies and government partners to reflect Guinea-specific procedures. The application consists of 3 forms that:

1. Register contact details upon first visit by the contact tracer
| Stage | Step | Approximate Time | Key Partners | Prerequisites for Deployment | Key Challenges |
|-------|------|------------------|--------------|-----------------------------|----------------|
| Preparation<sup>a</sup> | 1. Design of Application | 1 week | Dimagi | Vetted contact tracing protocols available from CDC, WHO, and GoG | Availability of standard contact tracing protocol |
| | 2. Development of Dashboards | 4 weeks | Tableau Foundation, Tableau consultants, Dimagi | Data requirements and desired indicators available from GoG and partners, Stable Internet and electricity available in country to access dashboards | Interoperability of Dimagi’s data infrastructure and Tableau system |
| Deployment<sup>b</sup> | 3. Procurement and Configuration of Equipment | 2 weeks | Ericsson, UNFPA, Blue Zones | Logistics protocols in place for accepting and processing equipment donations, Telecommunications network identified for highest coverage in different prefectures | Manpower to configure phones, Logisticians to help clear donated equipment, Cash flow availability for voice and data plans |
| | 4. Training of Trainers | 2 days<sup>b</sup> | UNFPA, GoG | Trainers pre-identified and hired by GoG | Quality of some trainers |
| | 5. Training of Contact Tracers and Supervisors | 2–3 days<sup>b</sup> | UNFPA, GoG | Contact tracers and supervisors pre-identified and hired by GoG, Contact tracers trained on contact tracing protocol, Supervisors trained on contact tracing protocol and supervision activities | Accountability of supervisors to supporting CommCare troubleshooting needs, Gaps in training on basic contact tracing protocols, Technological literacy level of some contact tracers |
| | 6. Deployment of Mobile Application | 1 day | UNFPA, GoG | Completion of contact tracer training, Distribution of smartphones, chargers, SIM cards, and other equipment to contact tracers, Contact tracer consent on proper-use protocols for smartphones and other equipment | Quality, timely make-up trainings for contact tracers who were not able to attend initial training and were still expected to monitor contacts using smartphones, Abuse of phone and/or data by contact tracers for personal use |
| Adaptation | 7. Data Validation | 1 day<sup>b</sup> | UNFPA, GoG | Contact tracing data from paper forms available and vetted | Availability of up-to-date paper-based data, Quality of data from paper-based databases |
| | 8. Modification of CommCare Application | 1 week<sup>b</sup> | Dimagi | Feedback on application content available from local partners and users based on use during pilot phase | Conversion of nuanced field protocols to automated skip logic and prompts, Distribution of heavy multimedia files, Coordination of updates where application was already deployed |
2. Follow-up with contacts daily for 21 days to monitor symptoms

3. Close the contact from the system once the 21-day period has been completed or for other reasons, e.g., the contact has been confirmed to have Ebola or has moved permanently to another area.

This application structure thus enables users to follow contacts for the duration of the disease’s 21-day incubation period. Additionally, the application recommends action steps based on data entered in the form. For example, if a contact develops symptoms, the application reminds the contact tracer that the contact should be immediately referred for testing and treatment (if positive). A contact tracer would then follow-up with the family and/or a supervisor to confirm the test results. If confirmed for Ebola, the diagnosis would inform the closing of the contact from the system; otherwise, the contact would only be closed after completing the 21-day monitoring period upon returning home. Audio and visual content translated into local languages was also added to support contact tracers for Ebola sensitization activities. During the initial deployment of the application, publicly available audio and visual sensitization resources from WHO, Doctors Without Borders, and the CDC were included. The application was later updated with multimedia content tailored to the Guinean context, developed by headquarters in New York in consultation with the local team, over the course of 3 months. Lastly, a training video module was included to provide contact tracers with ongoing assistance if they needed refresher information on how to use the system.

**Development of Dashboards**

To facilitate interpretation of the data collected in CommCare, the business intelligence software Tableau was integrated with the CommCare server. This software was recommended by Dimagi as a powerful analytic tool that could be integrated with CommCare. Once the key fields in the application were established, we began designing draft dashboards to visualize the data. Two sets of dashboards were established, developed by volunteer Tableau experts over the course of 1 month:

1. In one set, 3 dashboards depict aggregate indicators that are directly collected in each of the 3 forms, such as the relationship between...
2. The other set of 2 dashboards presents information on the performance of the contact tracers, including the number of visits conducted by each contact tracer per day (Figure 2).

We also designed a Key Performance Indicator (KPI) dashboard with the Tableau experts, which displays a summary of data for the past 7 days (Figure 3). Filters can be set by users to selectively display data according to time period, e.g., the past week or geographic zone (such as a sub-prefecture of interest), among other variables.

The link between the CommCare and Tableau software made by Dimagi’s engineers and the Tableau experts allows contact tracing data to be updated on the dashboards automatically every hour. Users can view the visualizations by logging into the secure online Tableau server. The underlying specifics of the data, i.e., the personally identifiable information for each contact registered in the system, are also viewable in Tableau for authorized users and are linked to the aggregate dashboards. Thus, if users with the appropriate permissions notice that many instances of resistance were reported in the past week, they can navigate from the aggregate graph directly to the details page, where the resistant contacts will be listed and can be identified for follow-up. Access to the Tableau server was granted to all government health staff managing surveillance activities at the prefectural and regional levels, to members of the NECU, and to any workers from partner organizations and agencies as requested by the NECU.

The system’s features thus enable surveillance managers to directly interact with and use the data to quickly identify trends and gaps. This rapid data intake and ease of interaction allows for faster response. This is in contrast with the paper system’s outputs that include: (1) daily, aggregate, static visuals for the NECU, and (2) inconsistently updated Excel files that capture paper-form entries, which require additional manual analysis to identify trends.

### Stage 2: Deployment

**Equipment Provision**

Ericsson donated an initial 1,000 Sony Xperia E1 phones, and the UN Mission for Ebola Emergency Response (UNMEER) then donated an additional 580 Samsung Galaxy S3 Neo and Motorola ATRIX phones. Solektra International donated Sunking Pro2 solar chargers to facilitate phone charging.
as well as 33 solar panels to enable regular access to power in the government offices where CommCare data are being used. The United Nations Population Fund (UNFPA) helped facilitate the purchase of SIM cards with a closed user group and 500 MB of data per month from Orange. Our implementation team also provided computers and USB modems to government staff as necessary, to ensure regular access to data.

Training of Trainers
Trainers were selected by the government and local UN agency partners from a pool of governmental health staff who supervise contact tracing activities. The first training of trainers (ToT) was conducted in Conakry by the local program staff in November 2014 and included approximately 17 trainers. The first half of the ToT included a didactic introduction to the phones and CommCare generally, while the second half of the ToT used blended learning techniques, incorporating multimedia, role-playing, and peer teaching to build expertise in using the CommCare application. Topics included contact registration, data input requirements for each form, GPS position collection, and form submission.

Training of Contact Tracers and Supervisors
Upon completion of the ToT, trainers were divided into pairs based on geographic area of supervision to
conduct 2-day trainings with contact tracers and close supervisors. Because contact tracers had already received training on basic contact tracing activities, this training focused on the mobile health application. The training started with a brief review of the importance of contact tracing, safety, Ebola danger signs, transmission, and prevention, as well as tips for respectfully engaging with households. Trainers then provided an overview of the purpose and structure of the CommCare application, the types of data collected in CommCare, how to use the application, and how the data would be used. The second day of the training served as a practicum during which trial phones were distributed for practice sessions. Following initial training, periodic refresher sessions have been conducted as needed, especially with the objective of engaging supervisors in troubleshooting and monitoring data quality issues reported by local staff. Table 3 summarizes the training schedule and numbers trained.

**Deployment of Mobile Application**

At the end of the contact tracer training, participants were given unique usernames and passwords for CommCare, phones, SIM cards, and phone accessories, and they were asked to sign proper phone use agreements. Contact tracers who were already monitoring contacts were prompted to begin using CommCare to register their contacts and record information from daily contacts.
contact monitoring visits in addition to the paper forms, which have remained the official reporting medium throughout the crisis. In certain prefectures, the training ended with the contact tracers registering all current contacts as a group. Contact tracers were also instructed through the application to obtain consent with each visit. To date, contact tracers in 5 prefectures—Boffa, Conakry, Coyah, Dubréka, and Forécariah—are using the CommCare system to monitor contacts of Ebola cases. As of May 2015, 210 contact tracers from the 5 prefectures were actively using CommCare to monitor more than 9,000 contacts collectively (Table 4).

### TABLE 3. Mobile Contact Tracer Program Deployment in Guinea as of May 2015

| Prefecture | Training Date(s) | Number of Contact Tracers Trained | Number of Supervisors Trained |
|------------|------------------|-----------------------------------|------------------------------|
| Boffa      | April 20–24, 2015| 72                                | 25                           |
| Conakry    | Nov 11–17, 2014  | 105                               | 13                           |
|            | Jan 20, 2015     | NA                                | 9                            |
|            | April 28–May 11, 2015 | NA                           | 38                           |
| Coyah      | Nov 30–Dec 2, 2014 | 27                            | 8                            |
| Dubréka    | Dec 5–9, 2014    | 36                                | 10                           |
| Forécariah | Mar 30–April 2, 2015 | 126                          | 30                           |
| **Total**  |                  | 366                               | 133                          |

Once the application was in use, the prefecture-based surveillance teams and our implementation team members began using the Tableau dashboards to monitor contact tracer activities. Initially, these surveillance teams mostly used the dashboards that focused on contact tracer performance, which functioned as a quick mechanism to see which contacts had not received daily visits. As the numbers of contacts has diminished and familiarity with the system has grown, prefecture-based teams are increasingly using the system to identify trends, for example, to investigate areas where resistance is high or zones where re-exposure to Ebola is frequent.

### Stage 3: Adaptation

#### Data Validation

To test the accuracy of the CommCare system, validation exercises compared CommCare raw data with paper-based contact tracing databases from the government for a given week for each commune or prefecture. When contacts could not be matched by first name, last name, age, and village, we would confer with the contact tracers and supervisors to understand the reasons for discrepancies.

During the first round of data validation for the 5 communes of Conakry, there was 78% agreement between the 2 databases. In response, we made programmatic adjustments to reinforce supervision and improve communication with partner organizations. For our second round of validation in Conakry, we reached 86% agreement. In general, missing data were attributed to 4 main deficiencies:
1. Training shortcomings/misunderstanding of the software
2. Miscommunication with partners who manage contact tracers
3. Misuse of phones
4. Errors in the reference database from the paper system

To address the first 3 deficiency categories, we changed hardware and SIM card management protocols and conducted targeted refresher trainings. Challenges from the fourth category highlighted potential weaknesses in the original paper system in which data entry errors, including duplicates, created misconceptions about contact numbers.

**Software Adaptation**

We refined the design of the application and the accompanying dashboards as the epidemic evolved, largely due to the lack of standardized contact tracing protocols and metrics agreed upon by all partners. Clearer standards from the outset could have accelerated the design process. Instead, the results of the validation exercises and feedback collected from the field were used to inform at least 3 software adaptations every 2 months for application content, logic, and prompts to better align with on-the-ground practices. For example, new options and alerts were added to the forms to reflect events in the community, such as a contact moving to a new area or being transferred to a health facility for testing. Rollout of these application updates was accompanied by refresher trainings by the local implementation team. We also iteratively designed the dashboards based on evolving end-user needs. For example, as frequent resistance from and movement of contacts continued to be a key challenge facing the Ebola response in Guinea, a new dashboard was developed to allow local surveillance teams to quickly identify contacts who were lost to follow-up (Figure 4).

**Deployment of Information Officers**

Centralized management of the mobile contact tracing system was not sufficient to ensure quality data collection by the contact tracers and routine data use by government staff and partners. In response to these capacity issues, information officers with experience in data analysis and community health programs were hired, trained, and deployed to local governmental health offices where Ebola surveillance activities are coordinated. Their initial training included an overview of the mobile contact tracing system and how to use the Tableau dashboards for monitoring data submissions by the contact tracers. The information officers’ responsibilities include basic troubleshooting of the mobile phones, daily review of data submissions, and communication of key trends to local response teams. They also train and support government office-based staff in using Tableau to manage the Ebola response.

**UNRESOLVED QUESTIONS AND LESSONS LEARNED**

Implementation of technology during an emergency outbreak is not without its challenges. The current iteration of the program is the result of a series of trials and corrective measures put in place to address the most common obstacles, detailed below.

**Software and Training Limitations**

While the CommCare software incorporates data submission and workflow features meant to be used in low-resource health contexts, it was not designed explicitly for emergency use. Additionally, the structure of the software created limitations in capturing nuances of complex contact tracing protocols. Furthermore, messy data from the field that required additional editing in the backend of CommCare was not easily accommodated in Tableau—which is more commonly used for commercial activities in developed settings. Tableau experts and Dimagi’s
engineers performed considerable troubleshooting remotely to refine and improve the connection between the 2 software programs. Finally, time limitations were also a challenge as the dashboards were built by Tableau experts who were volunteer consultants. Commissioning full-time Tableau consultants could have helped to shorten the time required to build the dashboards; however, they may not have had as much experience as the volunteer experts suggested by Tableau Foundation.

**ICT Challenges and Hardware Management Policy**

The availability of local staff to support phone configuration and hardware management was limited. Adjusting phone settings for language, date, and time and addition of application locking software and widgets for battery saving required between 10–15 minutes per phone. During the expansion phase, recruitment of local tech-savvy youth volunteers helped to accelerate the configuration of hundreds of phones.

After equipment was distributed, there were also limitations in implementing management policies for lost phones, data plan abuse, and phone storage. Because the contact tracers are co-managed by multiple entities including UN agencies, NGOs, and the government, coordination was necessary to create consistent policies that were agreed to and adopted by all local managers.

Finally, although the CommCare software could be used offline for data collection, access to the mobile network necessary for data submission was limited in the border regions of Forécariah prefecture, which affected 21 contact tracers. In these areas, we employed workarounds such as having the contact tracer submit data every few days when in locations with better network coverage or having the information officers directly request the data from the contact tracer via phone to enter themselves when necessary. An additional option, which has been used in previous projects but not in Guinea, is the manual transfer of data from the phone to an SD card, which could then be inserted to another phone for submission in areas with better network coverage.

**Use of Smartphones**

The quality of data submissions by contact tracers was an issue at the outset. There were occasional instances where users—often older generation—were unfamiliar with smartphones and therefore could not use the software effectively. For example, some contact tracers submitted data

![FIGURE 4. Contacts Lost to Follow-Up Dashboard](image)

This graph shows the number of days that have passed since contacts were available and visited by the contact tracer and were available at the household to be monitored for symptoms. (Note: Once a contact has not been seen for 3 or more days, they are considered lost to follow-up by surveillance management teams.) The column on the left indicates the sub-prefecture or commune where the contacts reside. The numbers in the colored boxes show the number of contacts who were unavailable for the daily contact tracing visit since 1 day ago (left column), 3 days ago (middle column), and 7 days ago (right column). The filters on the far right enable the user to restrict the data to contacts who reside in a specific region, prefecture, or sub-prefecture. The user can also click in an individual box to see the specific details for the contacts, i.e., the assigned contact tracer, name of the contact, source-case name, household head name, method of exposure, date the contact was registered, date the contact was last available to be monitored by the contact tracer, etc.
under test user accounts that were used for training, or they made spelling errors. To address this, older-generation contact tracers would sometimes be paired with younger, more tech-savvy contact tracers or would receive more one-on-one support from implementation team members.

In some cases, contact tracers used paper forms to first record information at the household, which was then entered into the phones after the visit. Although we did not systematically collect data on the frequency of this practice, comments from the field indicated that this would occur when contact tracers were concerned that the introduction of foreign technology could affect their trust with community members, who may have found the act of data collection, especially through unfamiliar equipment, strange or threatening.

There were also a few cases of contact tracers misusing data plans for personal purposes. Eventually, a solution was developed in which a fund for personal phone use was added, and if contact tracers exhausted their monthly data allotment, additional data would be supplied using their personal accounts to ensure continued CommCare data submission. A monthly auto-recharge system was also set up to ensure uninterrupted submission of data.

**Partnerships, Funding, and Coordination**

Coordination among partners was consistently a challenge that created difficulty in the identification of both contacts and contact tracers, access to paper-based data for validation, release of funds, integration of mobile contact tracing data with other Ebola response data, and cooperation with local supervisors who were managed by other organizations. International partners, including NGOs and UN agencies, expressed concern about the introduction of mobile phone technology for Ebola response purposes, citing poor literacy or possible network gaps as challenges. These apprehensions created significant delay in implementation and expansion despite having support and directive from the government lead of the Surveillance Pillar of the NECU. Validation exercises were conducted to address issues of data quality; however, presentations with partners were often delayed or canceled. Furthermore, the lack of clear leadership and coordination among partners, as well as the monthly rotation of leadership within key response organizations, created miscommunication and inconsistent messaging. To facilitate collaboration with other partners, our approach has been advocacy and transparency, offering to demonstrate the system and granting aggregate-level access to all agencies as requested by the government. Nevertheless, to date, the mobile system has not replaced the paper-based system in the 5 prefectures where the program is active, and many contact tracers still use both systems.

**Data Utilization**

While government staff members were especially enthusiastic about the wealth of data that could be used for supervision of contact tracers, actual use of the data was limited. Local government managers often had many competing interests and responsibilities, and thus relied instead on supervisors to report issues to them rather than exploring the data directly. While the corrective action of hiring information officers to be paired with government staff helped to increase the use of performance data, utilization of CommCare data to inform transmission trends and contact risk patterns has still been limited. It is important to recognize that the contact monitoring data being collected by this program are only one aspect of the response. Because each aspect of the response and the associated data are managed by different partners (i.e., call center, contact identification, contact monitoring, treatment centers, laboratories, safe burial teams), it is difficult to interpret broader trends from the contact monitoring data alone.

A government health manager in Conakry, Guinea, uses the Tableau dashboards to review new contacts registered in her commune.
Data Privacy and Ownership

As the data collected by CommCare contains protected health information as well as personally identifiable information, there were considerable concerns around data confidentiality. Although the Dimagi cloud server is compliant with the Health Insurance Portability and Accountability Act (HIPAA) and care was taken to ensure that data were shared in aggregate form, the national laws in Guinea around data privacy are still unclear. For this reason, datasets shared with partners have been mostly limited to aggregate indicators while government staff members have access to contact-specific details. Level of access has been determined by members of the NECU and facilitated by the implementing organization, which currently holds the end user license agreement with Dimagi per the government’s preference for ease of implementation. Formal transfer of data ownership to the government is in process and undergoing review by the NECU. There were also concerns from the government about data not being housed on a machine in country; for this reason a secondary local server was set up with a partner organization.

CONCLUSION

Use of a smartphone-based mHealth application to assist with Ebola contact tracing activities has demonstrated the potential to improve access to surveillance data for informing response strategy. There is also opportunity to extend this type of methodology to other pillars of the Ebola response to improve rapid access to data and integration of key indicators in the response chain. While there are inherent challenges in introducing technology in complex emergencies, the benefits of innovation to disrupt the status quo may be integral to controlling long-standing epidemics. This being said, careful consideration must be given to whether it is feasible and beneficial to implement new technology during an ongoing outbreak. When the decision is made to implement technology, it is critical to accompany the deployment with close managerial oversight to quickly correct data inconsistencies and to address challenges.

A formal government digital health information system currently does not exist in Guinea to allow for rapid health data collection and analysis, and thus the mobile contact tracing program cannot directly be absorbed into another system. However, the government and UN agencies in Guinea have expressed interest in using digital technology for longer-term surveillance, especially if embedded in a strong primary health care system. Certainly, the operational costs needed to bring a mobile health program to national scale would be substantial and have to be formally considered. Many of the resources and time required to set up this system were donated by partner agencies for Ebola-specific work. This initial investment in human resources, in-country technical expertise, and hardware for the program can certainly be leveraged and expanded to strengthen health systems.

With proper technical capacity and oversight, mobile technology has the potential to expand access to critical data from remote communities needed to control an outbreak. As we have learned from this Ebola epidemic, it is essential to acknowledge and plan for stronger information systems that can detect and report health trends and aberrations. Accurate and readily accessible data can help health surveillance officers quickly identify and contain outbreaks. Furthermore, a strong information system can not only serve to prevent emerging epidemics but also be adapted and leveraged for activities such as contact tracing in the event of a disease outbreak. Thus, investments in strong community-based information systems should be considered as integral for strengthening health systems and emergency preparedness to prevent future epidemics as tragic as the 2014–2015 West Africa Ebola outbreak.

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Trained nurse mentors catalyzed quality improvements in facility-based maternal and newborn care by: (1) encouraging use of self-assessment checklists and team-based problem solving, (2) introducing case sheets to ensure adherence to clinical guidelines, and (3) strengthening clinical skills through on-site demonstrations and bedside teaching. Inadequate leadership and staffing were challenges in some facilities. Some social norms, such as client resistance to referral and to staying 48 hours after delivery, also impact quality and mandate community mobilization efforts.

ABSTRACT
High-quality care during labor, delivery, and the postpartum period is critically important since maternal and child morbidity and mortality are linked to complications that arise during these stages. A nurse mentoring program was implemented in northern Karnataka, India, to improve quality of services at primary health centers (PHCs), the lowest level in the public health system that offers basic obstetric care. The intervention, conducted between August 2012 and July 2014, employed 53 full-time nurse mentors and was scaled-up in 385 PHCs in 8 poor rural districts. Each mentor was responsible for 6 to 8 PHCs and conducted roughly 6 mentoring visits per PHC in the first year. This paper reports the results of a qualitative inquiry, conducted between September 2012 and April 2014, assessing the program’s successes and challenges from the perspective of mentors and PHC teams. Data were gathered through 13 observations, 9 focus group discussions with mentors, and 25 individual and group interviews with PHC nurses, medical officers, and district health officers. Mentors and PHC staff and leaders reported a number of successes, including development of rapport and trust between mentors and PHC staff, introduction of team-based quality improvement processes, correct and consistent use of a new case sheet to ensure adherence to clinical guidelines, and increases in staff nurses’ knowledge and skills. Overall, nurses in many PHCs reported an increased ability to provide care according to guidelines and to handle maternal and newborn complications, along with improvements in equipment and supplies and referral management. Challenges included high service delivery volumes and/or understaffing at some PHCs, unsupportive or absent PHC leadership, and cultural practices that impacted quality. Comprehensive mentoring can build competence and improve performance by combining on-the-job clinical and technical support, applying quality improvement principles, and promoting team-based problem solving.

INTRODUCTION
In India, too many women and infants die from causes that are both preventable and easily treatable. The country accounts for 25% of all child deaths and 20% of all maternal deaths globally. Evidence points to the critical importance of ensuring high-quality care during labor, delivery, and the immediate postpartum period since maternal and child morbidity and mortality are linked to complications that arise during these stages. While maternal and infant mortality rates vary significantly by state within India, rural women and children often suffer the worst health outcomes.

India launched the National Rural Health Mission (NRHM) in April 2005 to tackle the high burden of maternal, neonatal, and child morbidity and mortality...
in its rural populations. Now known as the National Health Mission (NHM), the mission has invested in strengthening infrastructure, building capacity of service providers, and ensuring security of essential health supplies.5

Within this context, the Sukshema Project, funded by the Bill & Melinda Gates Foundation and implemented by Karnataka Health Promotion Trust (KHPT) and its partners comprising the University of Manitoba, St. John’s National Academy of Health Sciences, IntraHealth International, and Karuna Trust, developed a mentoring intervention to improve the quality of facility-based maternal and newborn care. Mentoring programs have been introduced in other contexts and countries, notably to support HIV/AIDS service provision,6,7 but the mentoring approach has not been widely applied to maternal and newborn health in India. Evidence suggests that performance problems require multifaceted interventions that go beyond one-time training.8 Comprehensive mentoring can respond to this need by combining on-the-job clinical and technical support, applying quality improvement principles, and promoting team-based problem solving.

The mentoring intervention described in this article focused on the rural poor in 8 priority districts in northern Karnataka that are among the poorest in the state (Figure 1). Although specific district-level data are unavailable, maternal and infant mortality levels in northern Karnataka are known to be higher than state and national averages. As Table 1 indicates, the proportion of institutional deliveries in 2012–2013 was lower in northern Karnataka (80%) compared with the state overall (89%). Nonetheless, the figures represent a marked improvement since 2007, when the government began efforts to increase institutional births. Births taking place in government facilities in Karnataka state rose from 33% to 52% over the 6-year period due to financial incentives provided under the NRHM.9,10

Given the growing demand for institutional births at government health facilities, the government of Karnataka adopted a strategy to bring maternity services closer to rural populations by upgrading primary health centers (PHCs) and reducing patient volume at higher-level referral facilities. PHCs are now the lowest level of facility expected to provide basic obstetric care in Karnataka.

The success of this close-to-community strategy is predicated on improved availability and quality of PHC services and capacity to manage referrals. In 2011, a situation analysis in the 8 intervention districts identified the need to improve PHC providers’ knowledge and competence in managing maternal and newborn care and to address facility-level factors such as drug stock-outs and lack of infrastructure. Findings revealed that providers did not follow best practices such as active management of the third stage of labor (AMTSL), use of a partograph, or essential newborn care.11 Moreover, labor augmentation, although not a recommended practice in facilities without capacity to conduct cesarean deliveries, was found to be very common. Some PHCs also lacked the drugs and equipment needed to provide delivery services and exhibited weak referral and follow-up systems.11

This article describes the experience of implementing a quality improvement intervention through mentoring in PHCs. It offers results from a qualitative assessment that identified and described program successes and challenges from the perspective of
mentors and PHC teams, including lessons learned and recommendations. The project also conducted a stratified random pre- and post-evaluation of the mentoring intervention that will be described in a future article. It is worth noting that the findings presented in this article are consistent with the findings of the quantitative evaluation.

**THEORY OF CHANGE AND INTERVENTION**

Our theory of change of the quality improvement intervention postulated that on-site mentoring would contribute to improved health worker performance and health care quality (including referral management) at PHCs, ultimately leading to better maternal and newborn health outcomes. The mentoring intervention, implemented between August 2012 and July 2014, integrated on-site clinical mentoring with facility-based quality improvement processes to support delivery of critical maternal and newborn care services at PHCs according to government guidelines. The project’s mandate was twofold: (1) to establish evidence of how mentoring affects quality of care, and (2) to demonstrate the process of scaling-up a mentoring program across the region.

We implemented a peer mentoring model by hiring and training a new cadre of 53 qualified nurses to mentor the PHC staff nurses who provide labor and delivery services. Salaries for the mentors were aligned with government pay scales so the state government could easily absorb them in the future if it chose to sustain the mentoring program.

The nurse mentors were recruited from northern Karnataka through job postings in local papers. Candidates were screened considering criteria such as qualifications, clinical experience, communication skills, abilities and inclination toward teaching and mentoring, and willingness to travel. Most of the candidates applying had 2 years of work experience, and very few had ever undergone training in skilled birth attendance outside their initial training. Almost all the nurse mentors recruited were diploma-level nurses. Most of the mentors had previously worked in small private clinics and hospitals, while 5 had worked as contract nurses in government hospitals prior to joining the project. All the mentors were recruited from within the districts as we wanted to determine if mentoring capacity could be developed locally.

Mentors participated in a 5-week initial training at St. John’s Medical College and Hospital in groups of 15 to 20. Nine trainings were conducted over a 15-month period as districts were phased into the program. The thrust of the training was to equip mentors with the competencies and tools required to support PHC staff in addressing clinical and systems gaps. To this end, the training updated trainees’ clinical skills in labor and delivery as well as in broader quality improvement and mentoring. The trainings were designed to be interactive and competency-based, with opportunities for trainees to learn and practice in the classroom setting using models and skill stations. Trainees also rotated through clinical settings to observe and practice what they learned in the classroom. The training was evaluated using pre- and post-test knowledge and skills tests and objective-structured clinical examinations.

At the conclusion of the training, mentors received backpacks containing reference materials, demonstration models, flip charts, and reporting formats to take on their PHC visits. Quarterly support visits by trainers from partner organizations (both doctors and nurses) were organized to provide further support to nurse mentors in the field. Mentors also participated in clinical postings and semiannual refresher trainings that helped them to gain confidence and competence in their role as mentors.

The mentoring intervention was scaled-up in 385 PHCs in 8 districts. These 385 PHCs provide

| TABLE 1. Trends in Institutional Deliveries, Northern Karnataka vs. Karnataka State |
|----------------------------------|----------------------------------|
| % Institutional Deliveries       | % Deliveries in Government Facility |
| 2007–08                         | 2012–13                          |
| Northern Karnataka (8 districts) | 50.4                             | 18.2                             | 18.2                             | 43.4                             |
| Karnataka state                 | 65.1                             | 89.0                             | 33.0                             | 51.8                             |

Source: Regression analysis of data from the District-Level Household and Facility Survey (DLHS)9 2007–08 and 2012–2013 based on methodology by Somayajulu et al.10

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30% of total deliveries in northern Karnataka. Two districts served as pilot sites and were also designated for the stratified random pre- and post-evaluation. In these pilot districts, only half of the PHCs received the mentoring intervention for the first year (August 2012–August 2013). (Information from this evaluation is being developed as a separate publication.) During the scale-up phase, we introduced the mentor program in the other 6 districts, 2 districts at a time (October 2012, December 2012, March 2013). By September 2013, soon after the completion of the evaluation, the intervention was also rolled out in the 54 PHCs of the control arm of pilot districts, thus saturating all the 24/7 PHCs in the region.

The mentors were responsible for mentoring staff in 6 to 8 PHCs within their assigned blocks in the district. Districts comprise an average of 7 blocks, and each PHC is sanctioned to have at least 1 medical officer (MO) and 3 staff nurses as well as other support staff. Typically, mentors lived within their assigned blocks so that their commuting distance was no more than 90 minutes to their facilities each way. Mentors who chose to live in the district headquarters had longer commutes to outlying blocks. In instances where the distance was greater, mentors spent the night at the facility rather than commuting back and forth. Mentors were responsible for organizing their own transport to facilities using common modes of local transportation (e.g., public bus, shared private van, or vehicles known as tempos). Mentors were introduced to the district government officials and supported by project staff in developing visit plans for their allocated facilities. They visited their designated PHCs 6 times in the first year.

The mentors spent 2 to 3 days at the PHC to provide clinical mentoring to staff nurses and also worked with other PHC staff to engage in team building and problem solving for quality improvement using a variety of tools and techniques. After 1 year, mentors adjusted the frequency of their visit schedule based on PHC clinical volume and the level of performance improvement still required. Some high-volume PHCs received monthly visits while PHCs with lower delivery loads received quarterly visits.

Figure 2 depicts a typical mentoring visit that begins with mentors explaining the purpose of the visit to PHC staff. Then the mentors work with PHC teams on quality improvement processes and provide clinical support to staff nurses. The mentors conclude the visit with a final debrief meeting with PHC leadership to share progress and action plans.

Mentors upgraded PHC provider skills through case reviews, case studies, mini-lectures, demonstrations, modeling of good practice, and bedside case discussions. During deliveries and postnatal care, mentors observed staff practices and provided guidance and assistance as needed. When staff were busy with routine duties, mentors used that time to conduct case sheet audits to identify provider gaps to subsequently address in one-on-one or group coaching. Drawing on quality improvement principles, mentors introduced self-assessment and action planning processes to all PHC staff to promote facility-based quality improvement. In this way, mentors also encouraged a team approach to address specific problem areas (e.g., equipment and supply logistics, infection prevention) and improve referral processes.

After each round of visits, mentors and other project staff met together as a team in each district to share experiences, review monitoring data, submit reports and expenses, and plan for future visits.

METHODS

The findings in this paper derive from a mix of qualitative methods, including structured observations of...
13 mentor visits, 9 focus group discussions (FGDs) with 38 mentors, and 25 interviews (individual and in small groups) with PHC staff and district health officials (Table 2). Mentor interviews, focus groups, and observations were timed to collect information after each round of mentor visits (e.g., first visit, second visit) to fully capture the progression of the intervention over time. Although the study was exploratory in nature, the use of multiple methods allowed for a thorough examination of themes and viewpoints from more than one perspective, providing a rich detailed description and analysis of the mentoring process, generating perceptions about the effectiveness of mentoring on service quality, and yielding suggestions for improving the mentoring program. Certain mentors in the pilot district were also interviewed more than once during the inquiry period to ascertain their perspectives on facility-level changes.

**Data Collection and Analysis**

We conducted 5 structured field visits between September 2012 and April 2014 to carry out observations and interviews in 13 PHCs in 6 districts. A senior technical advisor (EAF), not directly involved in the day-to-day operations of the mentoring program, conducted the interviews and observations with support from project staff. Data were collected using project-specific observation checklists and guides for the semi-structured interviews and focus group discussions. Interviews were not taped; however, detailed notes were taken by hand and later electronically transcribed into Microsoft Word. Data were analyzed using grounded theory,12 in which themes and subthemes emerge from the coding of text during the process of data reduction and analysis. The analysis captured a wide range of perceptions, represented through both shared and individual viewpoints in the results section below.

**FINDINGS**

Findings from the interviews and observations are organized into 3 major themes—program successes, changes in PHC quality, and program challenges—described below in detail and summarized in Table 3.

**Program Successes**

Nearly all the PHC staff interviewed appreciated the mentoring program and credited it with helping them improve service delivery. One MO stated:

> I am very happy with mentoring. We have made a lot of changes since mentors have come, and sisters’ [nurses’] knowledge has increased and they have learned more skills.

Factors contributing to program success included: (1) mentors’ ability to establish trust, (2) promotion of team-based assessment and problem solving, (3) continual strengthening of nurses’ clinical skills, and (4) support for use of case sheets.

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**TABLE 2. Summary of Qualitative Study Methods**

| Study Methods          | Participants                  | Number of Sessions/Participants                                                                 | Purpose                                                                                     |
|------------------------|-------------------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Mentor observations    | Trained mentors               | • 13 observations • 11 participants (2 observed twice)                                        | Document behaviors of mentors and their interactions with PHC staff                         |
| Focus group discussions| Mentors                      | • 9 focus groups • 56 participants in groups of 6–8 each (including 18 mentors interviewed more than once) | Gather mentor self-assessments and perceptions of the mentoring process and changes in PHCs |
| Individual and small-group interviews | PHC medical officers, staff nurses, pharmacists, district health officers | • 25 interviews • 25 participants (1–4 per session)                                            | Gather perceptions of the mentoring process and assess mentoring tools and procedures, challenges, successes, and PHC improvements |

Abbreviation: PHC, primary health center.
### TABLE 3. Key Findings About Nurse Mentoring Program in Northern Karnataka, India, Based on Qualitative Interviews and Observations

| Quality of Primary Health Centers: |   |   |
|-------------------------------|---|---|
| ✔ Areas Improving             |   |   |
| X Areas Resistant/Slower to Change |   |   |

| Clinical Practices |   |   |
|--------------------|---|---|
| ✔ Better understanding and use of AMTSL | Rapport and trust between nurse mentors and staff nurses |
| ✔ Diminished use of labor augmentation | Strengthening of nurses’ clinical skills through demonstrations, bedside teaching, case sheet reviews, and case studies |
| ✔ Routine administration of vitamin K |   |   |
| ✔ Use of radiant warmers for low birth weight newborns |   |   |
| ✔ Better understanding of how to handle complications such as newborn resuscitation and postpartum hemorrhage |   |   |
| X Postnatal check-ups at 15-minute intervals difficult to comply with |   |   |
| X Objections by MOs who were not updated with latest clinical guidelines |   |   |

| Availability of Equipment, Drugs, and Supplies |   |   |
|-----------------------------------------------|---|---|
| ✔ Procurement of needed equipment, drugs, and supplies | Quality improvement processes and tools, including team-based assessment and action plans |
| ✔ Creation of MNCH complication kits | Access to government untied funds to procure needed supplies |
| ✔ Replacement of damaged equipment |   |   |
| ✔ Increased availability of drugs and supplies |   |   |
| X Deficiencies in basic infrastructure harder to address |   |   |

| Referral Processes |   |   |
|--------------------|---|---|
| ✔ Improved appropriate identification and pre-referral management | Use of case sheets to identify complications requiring referral |
| ✔ PHCs posted referral directories | Case reviews and mentor reinforcement of referral guidelines |
| ✔ Nurses called referral facilities in advance more often |   |   |
| ✔ Nurses increasingly tracked referral outcomes |   |   |
| X Automatic referral without prior assessment continued in some instances | Understaffed facilities and overworked staff find it hard to perform complete pre-referral management |

| Infection Prevention |   |   |
|----------------------|---|---|
| ✔ Improved sterilization practices | Mentor reinforcement of infection prevention |
| ✔ Greater cleanliness in labor rooms | Demonstration of infection prevention practices with all nurses and cleaners |
| X Overall facility cleanliness still deficient |   |   |
| X Deficiencies in basic infrastructure (water, toilets) | Cleaning staff resistant to changing practices |

Abbreviations: AMTSL, active management of the third stage of labor; MNCH, maternal, newborn, and child health; MO, medical officer; PHC, primary health center.
Building Trusting Relationships
The ability of mentors to build rapport with mentees was crucial to the intervention’s acceptability. Rapport was largely achieved by introducing the mentors first to the district leadership and subsequently to the medical officers of the PHCs at the monthly meeting prior to rollout of mentoring visits. During the monthly meeting, the project’s district program manager described the goals and objectives of the mentoring program and the role of the nurse mentor in improving quality of care within the facilities. In addition, when the visit plans were made, the nurse mentors called the MO to ensure his/her presence at the first visit before actually making the visit. This preparatory work helped build initial rapport, which paved the way for the first visit. Acceptance was enhanced when there was sufficient advance communication with district and PHC leadership before the first mentoring visit about the program and its intent. Without this rapport, it would have been easy for PHC teams to perceive the mentors as outsiders coming in to inspect their facilities and report on them to higher authorities. In certain instances, the introduction at the monthly MO meeting did not take place (for example, when a local strike or other last-minute government priority caused the monthly meetings to be canceled) and only a circular was sent out to the PHCs by the district administration about the mentoring program. In these instances, some of the PHCs were initially reluctant to have mentors visit their facilities.

Mentors reported feeling like they often had to prove themselves in their first visits. In one instance, an MO spent 45 minutes asking a mentor technical questions before giving his PHC staff the green light to learn from her. Nonetheless, in most cases, mentors were able to build trust within the first few visits. As evidence, nurses and other PHC staff praised the mentors’ professionalism and interpersonal skills, describing mentors as “helpful,” “relaxed,” and “cooperative”:

Even if we are rude or stressed because we are busy, [the mentors] don’t react and are always at ease with us, which helps ease the tension.

Instilling Quality Improvement Processes
Many facility problems require staff to work together to identify solutions, yet this rarely happened prior to the mentoring intervention. Staff reported previously “working around” problems (such as drug shortages) rather than directly addressing them. Mentors emphasized the importance of service quality and introduced PHC teams to the idea that improvement is everyone’s responsibility.

Mentors reported that, for the most part, PHC staff willingly engaged with mentors in quality improvement meetings, remarking that they had rarely come together as a team before. As one nurse summarized, “The mentoring program has contributed to improved knowledge and better team work.”

To facilitate quality improvement efforts, mentors introduced a set of 8 self-assessment checklists (Box), designed around the principles of patient and provider rights to quality health care, an approach adapted from successful efforts elsewhere.13,14 (See supplementary material for copies of the full self-assessment checklists.) Mentors found that PHC teams were able to use the self-assessment tools to assess their performance, identify problems, and develop solutions. The mentors faced challenges in the beginning when the PHC staff were hesitant to fill out the checklists honestly, fearing the findings would be reported to higher officials; over a 3-month period, however, mentors developed sufficient rapport and trust, and staff saw the payoff from the self-assessment and action planning process as problems were resolved.

The role of the mentors as facilitators of the quality improvement meetings and self-assessment process was an integral part of the intervention design. It was expected that over time the PHC leaders would begin to drive quality improvement. Participation in the process helped build interest

**BOX. Content of Self-Assessment Checklists for Primary Health Centers**

1. Clients’ rights to safe and competent care
2. Providers’ rights to supplies, equipment, and infrastructure
3. Clients’ rights to access services and continuity of care
4. Clients’ rights to infection-free services
5. Providers’ rights to information, training, and development
6. Clients’ rights to privacy, confidentiality, dignity, comfort, and expression of opinion
7. Clients’ rights to information and informed choice
8. Providers’ rights to facilitative supervision and management

See the supplementary material for copies of the full checklists used in the nurse mentoring program in Karnataka, India.
in and appreciation of self-assessment among PHC staff that may contribute to its longer-term sustainability.

In interviews, mentors and PHC staff noted that the process of reviewing and developing action plans had become an entrenched part of the mentoring visits. In several instances, MOs took immediate action to resolve problems identified. In facilities where the leadership position was vacant (unfortunately a common occurrence) or where the MO did not participate fully in the team meetings, problems were less likely to be resolved. In those instances, the lack of leadership also appeared to demotivate staff from making even those improvements that were within their purview to implement.

Increase in Knowledge and Skills
Staff nurses credited mentor support with increasing their knowledge and skills in labor, delivery, postpartum care, and newborn care. Nurses pointed out that mentors had helped them become more systematic and thorough in providing care. One nurse stated:

Mentoring has helped in better understanding in a stepwise manner how to conduct deliveries. Having someone explain these steps is very beneficial.

Another nurse commented:

We didn’t know much before, and now the mentor tells us how to do each thing and explains why we do these things. The mentor reminds us about things we forget.

To facilitate clinical capacity building, mentors followed a semi-structured plan during each visit to ensure coverage of critical topics. The mentors used training models (pelvic model and newborn doll) to carry out demonstrations, providing staff nurses with opportunities to practice skills such as newborn resuscitation. Mentors also provided bedside teaching and demonstrations with pregnant and recently delivered PHC clients. This happened more often in high-volume facilities, but, over time, opportunities for bedside mentoring arose in nearly all PHCs. Case sheet reviews and case studies were other primary teaching approaches.

Use of Case Sheets
Given findings of poor provider knowledge of and adherence to government skilled birth attendant (SBA) guidelines, the project introduced a multipurpose case sheet that functioned as a clinical record, job aid, and teaching tool. An existing government case sheet was not well used and lacked explicit guidance on patient care. The mentor-supported case sheet used a checklist concept derived from evidence that checklists can reduce errors and improve compliance with clinical guidelines.15 The case sheet included supplemental complication case sheets that guided providers on diagnostic criteria and treatment protocols for complications such as prolonged labor, postpartum hemorrhage, and pre-eclampsia. (See supplementary material for a copy of the case sheet.)

As a teaching tool, the case sheets helped mentors focus discussions on compliance with clinical guidelines. The case sheet mechanism also facilitated retrospective case reviews, allowing mentors to refer to cases for teaching purposes despite not being physically present for most PHC deliveries. Finally, the case sheets served as a tool for mentors and PHC staff to monitor changes in quality of care. During each mentoring visit, mentors conducted a case sheet audit and identified and discussed areas for improvement with staff.

Some staff, particularly senior staff nurses, were reluctant to use the case sheets, perceiving them as time-consuming, unnecessary, or a change from long-held practices of not documenting anything. Nurses in busier PHCs also found it challenging to consistently use case sheets as intended in real time and sometimes deferred filling them in until after the delivery. Promoting consistent and correct use of case sheets required active implementation and support from the mentors.

A nurse mentor (left) in Karnataka, India, explains how to complete and use patient case sheets with staff nurses (right).
sheets was, therefore, a major undertaking for the mentors. With continued encouragement, staff became more accustomed to the case sheets, grew to appreciate their value as a job aid, and completed them for most patients.

Changes in PHC Quality
PHC staff and mentors pointed to noticeable improvements in the PHCs since the mentoring program began. Key areas most often noted included improved clinical practices, improved availability of equipment and supplies, and strengthened referral processes.

Clinical Improvements
Mentors noted that staff nurses seemed to better understand and practice AMTSL after the first few mentoring visits. Mentors and PHC nurses also reported that the practice of labor augmentation had diminished. Nurses began giving vitamin K more routinely and using radiant warmers for low birth weight newborns. In numerous instances, mentors also were able to intervene and teach nurses how to handle complications. In one case, when a nurse did not know how to do resuscitation with a bag and mask, the mentor stepped in and saved the newborn’s life. In another case, a PHC nurse called a mentor for help with a postpartum hemorrhage situation. Over the phone, the mentor guided her through the steps outlined on the complication case sheet, and the nurse was able to manage and refer the patient. Since then, nurses in that facility have handled postpartum hemorrhage cases on their own.

Of note, a clinical practice slow to improve was postnatal care. Models of postnatal care provision at the community level in India have demonstrated that simple interventions, such as thermal care and exclusive breastfeeding, can have a significant impact on neonatal survival.16 Although these practices are included in the postnatal care guidelines for PHC nurses, mentors noted that postnatal care was often not practiced to standard, and the postnatal care portion of the case sheet was the section most often left incomplete. Both mentors and nurses commented that it was difficult to comply with the guidelines requiring postnatal check-ups at 15-minute intervals, particularly in high-volume facilities with competing demands on nurses’ time. Mentors estimated that only about half of the PHCs communicated postnatal care messages correctly, and they commented that “just reminding staff to give [correct] messages is not enough.” In low-volume PHCs, compliance with postnatal guidelines was easier, as evidenced by one PHC where staff made and posted their own postnatal care charts in the local language.

Despite widespread demonstrated improvements in clinical practice, mentors noted that a small number of PHCs remained “outliers” due to the facilities’ MOs. Mentors described a few MOs who were unwilling or slow to discourage labor augmentation. Similarly, a few MOs objected to the use of vitamin K and would not allow nurses to administer it. Mentors also noted occasional MO concerns about the use of magnesium sulfate. Although nurses provide the vast majority of maternal care at PHCs, they cannot act against MO advice.

Improved Availability of Equipment and Supplies
Mentors and PHC staff pointed to improvements in labor rooms and drug supplies as some of the first signs of quality improvement. Many of the changes listed below were instituted by the third or fourth mentoring visit:

- Less congestion and greater cleanliness in delivery rooms
- Replacement of rusty delivery sets
- Replacement or repair of radiant warmers
- Increased availability of oxygen and generators
- Advance preparation of emergency drug kits to ensure availability of drugs and supplies needed for complications
As a result of mentoring, most PHCs procured or repaired autoclaves for sterilization. Mentors also trained nurses on practices such as preparing and using chlorine solutions. However, while mentors noted that labor rooms were cleaner and sterilization more common, overall cleanliness in the facilities remained deficient even after multiple visits. Although the mentors involved custodial staff in PHC team meetings and many participated willingly, the substandard levels of hygiene and cleanliness may represent ingrained attitudes and practices that are challenging to change. A combination of organizational and behavioral changes may be required to bring about stronger improvements.

**Strengthened Referral Processes**

Timely access to emergency maternal and newborn services can reduce a significant proportion of maternal and newborn deaths. Since PHCs have limited ability to provide more than basic obstetric care, strong referral linkages to higher-level first referral units (FRUs) are critical. Fortunately, Karnataka has a relatively well-functioning ambulance service, which makes emergency transportation to referral hospitals less of a barrier than in other parts of India.

Nurse mentors and facility teams promoted interventions to improve referral processes and ensure continuity of care for referred cases, including:

- Using the complication case sheets to identify cases needing referral
- Generating an updated referral directory and referral plan for each facility
- Using referral registers more effectively
- Improving provider communication with referral facilities
- Improving communication with community-based junior health assistants (JHAs) and accredited social health activists (ASHAs) upon discharge to ensure proper follow-up

Mentors noted that staff nurses’ ability to identify and handle cases needing referral had improved. One nurse explained, “Earlier we forgot to ask about presenting complaints, but we do so more easily now with the case sheet.” Another nurse reported receiving a call from an obstetrician-gynecologist at a referral hospital praising her for administering magnesium sulfate before referring the patient. Still another nurse described her increased comfort with initial management of complications:

> Now we are more confident to manage complications and do referrals. Before, we had knowledge but not confidence. . . . Now we manage and inform the referral facility and do follow-up.

The general aim of the complication case sheets and the accompanying emphasis on referral management was to decrease automatic referrals of patients without assessment. Improvement in this area remained a work in progress, even after numerous mentor visits. Mentors observed that nurses referred normal deliveries out of PHCs without assessment if patients asked too many questions, if nurses did not want to be disturbed at night, or if patients lacked antenatal care lab work and the nurses did not wish to do the tests. On the other hand, nurses reported that patients often objected to being referred due to perceptions that the referral facility would be less personal, more costly, and more inconvenient. Observations confirmed that providers had to convince families to go to higher-level facilities. Moreover, PHC staff and mentors noted that many FRU-designated hospitals were not able to provide appropriate advanced care because they lacked specialty staff and equipment. As a district health officer conceded:

> There will be no use in improving the skills at the PHCs in diagnosing and referring cases if they don’t get good care once referred.

**Program Challenges**

The qualitative inquiry identified 4 broad sets of challenges relating to high-volume PHCs, PHC leadership, facility staffing, and cultural practices.
Busy facilities required more mentoring support than low- or moderate-volume facilities.

especially important for the project to ensure that those high-volume facilities provided quality services. Yet we learned that busy PHCs require more support than low- or moderate-volume facilities. The mentors noted, for example, that it was more difficult to engage with staff in busy PHCs. Nurses with many patients to treat also were less likely to fill out case sheets or follow protocols. In busy PHCs, mentors had to seize individual teaching opportunities whenever a staff nurse was free, often being disrupted in the process. This meant that the high-volume PHCs needed a more intense focus by the mentors.

Over time, project staff adjusted the mentoring approach to make the most efficient use of resources and to better target high-volume PHCs. Specifically, the project intensified mentoring support in high-volume PHCs while reducing the frequency (and duration) of mentor visits to quarterly visits rather than bimonthly visits to PHCs that consistently reported low delivery loads. In high-volume PHCs, 2 experienced mentors began to jointly visit the facility for 3 days every month in lieu of every 2 months by a single mentor. The joint visits allowed the 2 mentors to divide up responsibilities and engage with busy PHC staff on the job. Mentors reported observing improvements in staff performance after this revised strategy was implemented. The more frequent visits also helped encourage staff to use the case sheets more often.

Most nurses and MOs in high-volume facilities expressed satisfaction with the more frequent support from 2 mentors. One nurse stated:

"Earlier we didn’t give importance to the mentor as we were very busy and it was hard to give attention. Now one mentor can help with outpatient department and labor and the other mentor can teach, so it works much better."

Lack of PHC Leadership

Not surprisingly, mentors noted the greatest quality improvement in facilities that had supportive, full-time MOs. Where the MO was indifferent, absent, or available only part-time, the ability of the mentoring program to improve quality of care was limited. In PHCs with inadequate leadership, it proved particularly difficult to encourage a sense of teamwork, as expressed by a nurse in a high-volume PHC who lamented the uncaring attitude of the MO demoralized staff. From this nurse’s perspective, the MO was not interested in improving quality and would not attend group meetings or address identified problems. She noted:

"Nobody bothers about us. We ask [the] pharmacist and medical officer for supplies and nothing happens. They don’t agree to sit together to solve problems."

Inadequate Facility Staffing

Many PHCs do not operate with the full complement of nurses or other technical staff such as laboratory technicians and pharmacists. PHC staffing guidelines call for 3 nurses to provide 24-hour coverage regardless of patient volume. In the evening and overnight, just 1 staff nurse is on duty. In PHCs that handle high outpatient and delivery volumes, nursing staff are often overstretched and unable to give sufficient time and attention to women in labor or postnatally. Another complicating factor is that it is not uncommon for at least 1 of the 3 nurses to be away for training, marriage leave, maternity leave, or other reasons. One of the PHCs visited was operating with just 1 staff nurse. Understaffed facilities and overworked staff were perhaps most in need of, but least able to, benefit from mentor support.

Cultural Practices

Some barriers to improved maternal and newborn outcomes derive from social norms and community

| Volume Level |
|--------------|
| Low (0–19 deliveries/month) | Moderate (20–39 deliveries/month) | High (≥ 40 deliveries/month) |
| No. (% of PHCs) | 298 (77%) | 67 (17%) | 20 (5%) |
| No. (% of deliveries) | 2800 (50%) | 1710 (31%) | 1060 (19%) |
practices. Case sheet reviews and interviews indicated that mothers, especially second gravida or more, often come to PHCs only when they are in advanced active labor or fully dilated because they fear automatic referral if they come earlier. However, late arrival limits opportunities to monitor the progress of labor, identify and manage complications, or make timely and needed referrals.

Women delivering in PHCs are expected to remain for 48 hours after delivery as this is the critical window in which maternal and newborn complications most often develop. Interviews suggested that few women remain in the facility that long. The project’s situation assessment identified a number of reasons for shorter stays. First, many facilities lack basic amenities such as functioning toilets, security, or meals. Second, mothers and family members frequently do not understand the rationale for remaining for 48 hours and want to return home to avoid additional transportation costs, to attend to household responsibilities, and to participate in home-based rituals. Even when women remain for the recommended duration, they may not receive postnatal care and support from PHC staff according to guidelines.

Mentors worked with PHC teams to identify and address some of the facility-based barriers discouraging longer stays. Through the team-based quality improvement process, some PHCs arranged for meals and other amenities. However, mentors indicated that these improvements did not appreciably increase the duration of post-delivery stays in any of the PHCs over the course of the mentoring intervention.

DISCUSSION

The mentoring intervention supported district and facility efforts to improve the quality of care in PHCs to ensure that women coming to this level of facility receive skilled birth attendance and that complications are identified, managed, and referred when needed. The prior situation analysis found many gaps in service quality stemming from providers’ lack of knowledge and skills in conducting normal deliveries or recognizing and managing maternal and newborn complications. Most PHCs also lacked the equipment, supplies, and drugs needed to deliver care according to guidelines. The quality improvement program offered an opportunity to provide tailored support to PHC staff to address these clinical and system-level gaps through on-site mentoring, use of team-based assessment tools and problem solving techniques, and use of case sheets to promote adherence to clinical guidelines.

Building Capacity of Nurse Mentors

Considerable effort was required to build the mentors’ clinical capacity and expertise, both at the beginning and throughout the project. First, Karnataka had a limited number of senior nurses with the required skills willing to serve as mentors in multiple locations. Many of the nurses who applied and were hired were, therefore, young, relatively inexperienced, and lacked strong clinical backgrounds in maternal and newborn care. Nevertheless, sourcing candidates from the local area was important to demonstrate the scalability and sustainability of a mentoring program. At a professional level, candidates found the new career opportunity of mentor to be interesting and felt they could add value in providing teaching and training—an element of the position that held appeal for many applicants. At the same time, we learned that clinical skills could be taught and that it was critical to recruit outgoing candidates who enjoyed interacting with people; communication skills were harder to instill if not initially present.

The 5-week mentor training was sufficient to refresh basic knowledge and skills, but mentors needed further on-the-job support and reinforcement through clinical practice and refresher trainings to fully develop their clinical competence and confidence. The project sought to build in a 5-day clinical posting every quarter for all mentors, but finding adequate clinical sites to provide mentors with practical training in labor and delivery posed a significant challenge. This was because hospital staff who did not know the mentors or their level of competence were reluctant to allow trainees to practice their skills. Ultimately, the project developed relationships with a few district and teaching hospitals and rotated mentors through their labor rooms for clinical practice. Each mentor observed 5 deliveries and conducted at least 5 deliveries during the week they were posted, which they recorded in a logbook. High-volume hospitals proved to be a good place to observe complicated obstetric cases, providing mentors with a better understanding of their presentation and management. Unfortunately, these facilities did not always follow correct guidelines and best practices, so mentors were supervised by the technical specialists of the project to help them avoid picking up non-evidence-based practices. The project also supplemented clinical
postings with refresher training and on-the-job support from senior clinicians who periodically accompanied mentors on PHC visits to help the mentors grow as effective mentors over time.

**Acceptance of Nurse Mentors by Facility Staff**

The mentoring concept is a generally unknown and untested strategy to improve quality of care in India, especially in primary-level facilities. Because of the lack of familiarity with the mentoring concept, we were not sure whether mentors would be accepted by the PHC teams to which they were assigned. The findings from this qualitative assessment furnish positive evidence that the majority of PHC teams interviewed perceived the mentors as helpful. Mentors were able to effectively communicate the purpose of their support in such a way that PHC teams did not feel threatened or blamed. The supportive, collegial tone that mentors brought to their interactions with staff nurses, as well as the respect they showed for MOs, created the basis for forming trusting relationships—an essential ingredient in a successful mentoring program. Because the mentors had no supervisory authority over the PHC teams, nurses were able to respond to them as colleagues rather than authority figures. The perception of mentors as a trusted resource also allowed PHC teams to be open about facility problems.

Nurses and MOs receive preceptor support during the clinical postings that are part of nursing or medical education, but this type of support is not typically available once a health professional is posted to a facility. Moreover, traditional training interventions do not provide follow-up support to ensure transfer of learning once a health worker returns to her workplace. The mentors’ support filled this gap. In fact, many nurses stated that they found mentoring to be better than attending one-time training. The continuity of the mentoring relationship provided the opportunity for ongoing learning and sharing of experiences, and the mentors’ ability to observe and assist nurses over time helped ingrain clinical skills and adherence to guidelines into daily nursing practice. In addition, PHC nurses frequently contacted mentors in between clinic visits to seek advice, confirm diagnoses or treatment decisions, or confer about other issues.

**Frequency of Mentor Visits**

The frequency of the mentor visits generally seemed adequate and appropriate. The visits were frequent enough to establish relationships and trust, yet spaced apart enough to provide time for staff to practice newly learned skills. The duration of each visit was adjusted over time. Early in the program, it became apparent that a 2-day visit did not allow sufficient time for mentors to cover topics planned for that visit or to interact with all staff given shift schedules and duties. Extending the visits to 3 days afforded mentors extra time to work within the circumstances encountered in each PHC and to reach all staff. We also learned that busy PHCs benefit from more frequent (monthly) visits to instill and reinforce changes in provider practices. Since high-volume PHCs provide a greater contribution to overall deliveries, intensifying support in these facilities can help maximize outcomes. In less busy PHCs, staff had more leisure to absorb and adopt practices into their routines and only required visits every quarter after 1 year of support. To plan a program at this scale, it is important to have guidelines on frequency and duration of visits to manage mentors’ time, but it is also important to allow mentors some autonomy and the ability to adjust visit schedules in accordance with facility circumstances.

**Team-Based Quality Improvement Approach**

Although mentors worked most closely with the PHC staff nurses, they were also able to catalyze a team-based approach to improving quality of maternal and newborn care that went beyond what could be accomplished in one-time quality improvement training. The self-assessment guide and action plan tools helped give focus to these team meetings and ensured that the meetings were action-oriented and identified actual problems. It is not clear, however, whether these tools would have been as useful without the facilitation provided by the mentors. On their own, PHC teams tended not to identify deficiencies, but when the mentors probed and asked follow-up questions, team members conceded the need for improvements. Recognizing this tendency for bias, the involvement of a more objective third party such as the mentors appears to contribute to a more effective self-assessment process.13

The intervention design required the mentors to prompt PHCs to fill out the self-assessment tools a few times a year. As PHCs made improvements, they identified fewer gaps in subsequent rounds of assessment. Modifying the self-assessment checklists over time might prevent the assessment process from becoming too routine, and additional
self-assessment tools could go into more detail on quality standards after basic gaps are addressed. For example, more detailed assessments could address patient-centered care and patient-rights concepts at a deeper level. The fact that PHC teams were comfortable using the self-assessment checklists also suggests that a comparable mechanism could be leveraged to explore issues beyond maternal and newborn care.

**Teaching Models and Tools**

Mentors’ ability to use a variety of teaching methodologies helped PHC nurses build their skills and confidence. Nurses appreciated mentors’ effective use of simple models to do demonstrations and observe return demonstrations. Working alongside nurses providing patient care also introduced opportunities for reinforcing guidelines. The mentors proved adept at identifying and taking advantage of teaching opportunities that spontaneously presented themselves but at the same time used the semi-structured mentoring plans to ensure that they covered all critical topics. Additionally, the case sheet proved useful as both a teaching aid and a way for mentors to discuss and review cases. As a job aid, the case sheet provided guidance to nurses for normal and complicated cases. At the same time, introducing a new tool into nurses’ work routines was challenging, and mentors had to continually reinforce the importance and value of the case sheet. The systematic approach to patient assessment and reporting that the case sheets demanded was new to many nurses; some nurses took to it while others were ambivalent and saw it as an added burden. We do not know if case sheet use would continue in the absence of mentors encouraging and monitoring its use. If the case sheet mechanism is adopted by others for use at scale, it will be important to build in adequate training and support structures to help providers use the case sheets as intended. It is not sufficient to simply distribute the case sheets and expect providers to use them.

**Challenges to Improving Quality of Care**

Despite a high level of acceptance by most PHCs, mentors’ ability to prompt changes in quality of care was limited by factors beyond their control. For example, mentors’ good intentions could be undermined if the MO was not in favor of the program or the PHC lacked full-time leadership. Instances of MO opposition underscore the need to orient MOs on the latest guidelines and convince them to support adherence to guidelines. Mentors also found it harder to promote changes in PHCs that were understaffed for the volume of patients they handled, leaving staff too busy to engage with the mentors. Mentors cannot fix the underlying problem of staff shortages, a situation that is only likely to improve if the authorities take action to revise their staffing policies and better align number of staff to patient volume. Tools such as the World Health Organization’s Workload Indicators of Staffing Need (WISN) could help identify staffing requirements aligned to workload.20,21

Other factors that stand in the way of improved maternal and newborn health are deeply rooted in cultural and social norms over which mentors and PHC teams have limited influence. Women’s tendency to arrive late in labor, to resist referral if required, and to object to staying 48 hours after delivery are just some examples. There was little evidence, even anecdotally, that improvements in the quality of care provided at PHCs might mitigate these cultural factors. Community-level interventions are needed to raise awareness of the importance of seeking care and recognizing and acting on danger signs. Similarly, the assessment’s findings regarding the complexities of effectively managing and making referrals indicate that both community and health system factors need to be strengthened to fully improve access to quality referral services.

**Scalability and Sustainability of the Nurse Mentoring Approach**

Given its dual focus on clinical support and systems strengthening, the nurse mentoring intervention is a comprehensive approach to improving the quality of intrapartum care at the facility level. Mentors work with PHC staff to address the multifaceted processes that must be aligned and integrated within a facility to improve maternal and newborn health outcomes. The nurse mentoring intervention was piloted at sufficient scale and generated evidence of improved quality across the high-priority districts. The scalability of this type of intervention is particularly relevant to Indian and other similar contexts that have shown considerable progress in increasing the percentage of facility-based births. Unless these facilities are able to provide quality care, countries will fall short of achieving improved maternal and newborn health outcomes.20,21 Yet at the same time the public health sector in India faces challenges in filling positions of doctors and specialists, so exploiting the available
nursing workforce to improve service quality can be a viable option.

Evidence of the scalability and sustainability of this mentoring approach is promising. In India and globally, more government leaders are becoming champions for quality improvement within government health systems, yet to develop a culture of quality at all levels within government will take time. Public-private partnership models in which governments work with NGOs or professional organizations may be one approach to scaling-up and sustaining a mentoring program. In India, state governments often have the resources through NHM to pursue such models if they choose to do so. For example, the Karnataka experience was adopted in another state of India, Uttar Pradesh, which is implementing the nurse mentoring program in 25 high-priority districts of the state with government funding and donor-provided technical support.

Beyond wholesale adoption of this model, elements of the mentoring program are also incorporated in recent Government of India guidelines that call for the establishment of skill labs and training of nurse mentors to provide on-site mentoring support to trained staff in maternal and newborn care. The most recent national quality assurance guidelines also include aspects of setting-up quality improvement committees within facilities and use of self-assessment and action planning for addressing systems gaps—the same approaches that we found useful in the mentoring intervention. These developments are timely and acknowledge the need for quality improvement processes and on-site support in enhancing provider skills and performance and, ultimately, health outcomes. Growing recognition among India’s health experts on the need for strengthening the capacities of nurses and midwives through ongoing support and mentorship and a focus on quality improvement offers promise for sustaining these interventions within the existing government health system.22–25

CONCLUSION

Implementation of the mentoring intervention demonstrated the ability of mentors to work with facility-level staff to identify gaps and improve the quality of maternal and newborn services in rural PHCs in northern Karnataka. The mentors used quality improvement processes and tools, such as self-assessment checklists, to encourage PHC teams to drive the improvement process themselves, and they drew on a number of teaching methodologies to strengthen staff nurses’ clinical skills including on-site demonstrations, bedside teaching, and case sheet reviews. The program was implemented at scale in a short period of time, staff were accepting of mentors and the guidance they provided, and mentors demonstrated their ability to increase staff nurses’ capacity and confidence in areas such as active management of the third stage of labor and routine administration of vitamin K. In many PHCs, nurses reported being better able to provide care according to guidelines and to handle maternal and newborn complications. Facilities were also better organized, equipped, and supplied to deliver quality services, and referral procedures improved. Challenges encountered in some facilities included inadequate commitment of senior personnel at the district and PHC levels and inadequate staffing levels. Overall, the evidence gathered holds out the promise that comprehensive mentoring can be an effective intervention for improving the quality of facility-based maternal and newborn care.

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