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Victor K Barbiero

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Caution on corticosteroids for preterm delivery: learning from missteps

Stephen Hodgins^a

An important new study in lower-level health facilities in low- and middle-income countries found an increased risk of neonatal deaths with corticosteroid use in pregnant women with imminent preterm birth, in contrast with the positive results previously found in high-income countries. The surprising finding demonstrates that *context matters*. The increase appears largely due to steroids administered in cases that were *not* actually preterm, probably due to inaccurate pregnancy dating and challenges with diagnostic capacity. Promoting public health often requires decisions based on less-than-perfect evidence, but we must be vigilant about gathering and assessing new evidence and ready to change strategies.

Globally, preterm birth, along with pneumonia, is the leading cause of death among children under 5.¹ The use of corticosteroids for cases of imminent preterm birth has significantly reduced the burden of such deaths in high-income countries. Numerous studies have confirmed important effects, particularly in reducing risk of respiratory distress syndrome (RDS) through its action on production of lung surfactant. A 2006 Cochrane review found a 31% reduction in risk of neonatal death, across 21 studies conducted in middle- and high-income countries.² On the strength of this substantial evidence, corticosteroids for this indication have been included among the interventions that are the focus of the UN Commission on Life-Saving Commodities for Women and Children,³ adding to the momentum to expand use of this intervention in lower-income settings with less sophisticated health services.

NEW EVIDENCE

As part of this effort to extend the use of steroids, a very large multicountry, cluster-randomized trial was conducted recently, testing a strategy to push such services more peripherally to the community, health center, and district hospital levels. Findings were published by Althabe and colleagues this year on October 15 in the *Lancet*.⁴ The results come as something of a shock.

In this 6-country study (with sites in Argentina, Guatemala, India, Kenya, Pakistan, and Zambia),

99,742 pregnant women were enrolled. In the intervention arm, 6,109 women received steroids (dexamethasone). The main outcome tracked was neonatal mortality, measured overall and among those in the lowest 5% by birth weight (as a proxy for preterm births, which couldn't be reliably determined for the whole cohort). Overall neonatal mortality was 12% higher in the intervention arm (relative risk [RR]=1.12, 95% confidence interval [CI]=1.02–1.22), and the stillbirth rate was similarly elevated. Among those in the lowest 5% by birth weight, mortality was the same in intervention and control arms (RR=0.96, 95% CI=0.87–1.06). Risk of maternal infection was also increased; among those with births in the lowest 5% by birth weight, infection was reported in 10% of the women in the intervention group vs. 6% in the control group (odds ratio [OR]=1.67, 95% CI=1.33–2.09).

NET HARM? HOW COULD THAT BE?

The elevated risk in overall newborn mortality appears to have been largely due to administration of dexamethasone in cases that were actually *not* preterm at the time of delivery. There had been previous hints of safety issues for cases delivering at or near term; the Cochrane review found elevated mortality for steroid-exposed cases going to term or near-term compared with controls, with borderline statistical significance.² Results of the new study confirm this elevated risk. There had also been suggestive evidence in the Cochrane review of elevated risk of *maternal* infection, which was confirmed by the new study.

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

Why the detrimental effects among those delivering later? One can only speculate. But corticosteroids directly or indirectly influence virtually all major systems in the body. They have effects on: stress response; metabolism; renal function; cardiovascular and endocrine functions; muscle and bone; central nervous system functions; eyes and skin; gut function; and—*perhaps of most relevance to this situation*—growth and development and inflammatory and immune response (with consequences for vulnerability to infection).⁵ It's not hard to imagine that some combination of such effects from steroid exposure in late pregnancy—when risk of RDS is much reduced—could result in net harm.

IS THERE NO BENEFIT TO PRETERM NEWBORNS AFTER ALL?

The results of the new study did not show net benefit among those in the bottom 5% by birth weight. But this weight category is a mixed bag, comprising virtually all those born at <34 weeks gestation (ie, those who were actually preterm) but also a significant number of growth-restricted term or near-term newborns. The lack of a measured beneficial effect among those in the bottom 5%, taken as a group, could mask a situation in which there was a real benefit among those actually preterm at birth, but this was offset by an elevated risk among those born at or near term. Furthermore, even among those genuinely preterm, there may have been an attenuation of a real effect: since the study sites generally lacked the capacity to adequately manage complications in preterm newborns, those born very premature (say, <28 weeks gestation) may not have experienced lower mortality even if their risk of RDS was reduced with the dexamethasone treatment.

WHAT HAVE WE LEARNED?

Our strategic stance had been: *Push this intervention further out; save more newborn lives*. In hindsight, although the potential benefits of corticosteroids are substantial, this experience argues for more consideration of safety, given the particular vulnerability of fetal life and the potent and manifold effects of these drugs.

Possible risks had not received much attention in the published literature. In none of the 21 trials summarized in the Cochrane review was there disaggregated analysis of steroid-exposed cases that went on to deliver at or near term. Only by

obtaining additional data not included in the original paper by Liggins⁷ (one of the trials summarized in the review) did the authors of the Cochrane review have sufficient data to do this secondary analysis. But this was one sub-analysis of many dozens done in the review; in the face of an overwhelmingly positive picture from the analysis as a whole, this potentially worrying suggestion of adverse effects was not flagged for special attention in the discussion or conclusions of the review. We overlooked a small grey cloud in an otherwise clear blue sky. Following publication of the protocol for the Althabe study, there was no published objection to the design on the basis of safety. Only in spring 2014, by which time study enrollment was closed, was a note of alarm first rung in the published literature.⁶

These findings serve as a reminder that “effect sizes” cannot be considered context-free. In this case, they are a function of the interaction between *agent* (dexamethasone), *host* (with its responses driven in part, for example, by nutritional status and infectious and parasitic exposures), and the service delivery *environment* (notably, capacity to manage complications).

In public health, all decisions, even decisions to do nothing, have consequences. As a general rule, we have to make decisions based on less-than-perfect evidence. Then, as we proceed, we need to keep our critical faculties alert, continue to gather evidence, and, when required, be ready to revisit previously drawn conclusions in the light of new evidence. With use of antenatal corticosteroids, we have reached such a juncture.

WHAT NOW?

At this point, clearly, the global newborn community will need to sharply adjust its stance on steroid use for management of pregnant women facing imminent preterm delivery. The World Health Organization is expected, in the near future, to issue new, more explicitly conservative guidelines.

The imperative of extending the benefits of this efficacious intervention to lower-resource settings remains. But it is now evident that corticosteroid use needs to be restricted to clinical settings where it can be ensured the drug is given only for cases that will deliver preterm (<34 weeks gestation). This is not necessarily an easy standard to meet. Accurate dating requires early antenatal contact and, ideally, obstetrical ultrasound. Diagnosis of imminent preterm delivery also requires sound diagnostic capability. Furthermore, to derive full

The lack of measured benefit among very low birth weight newborns may reflect real benefit among those genuinely preterm, offset by an elevated risk among those born at or near term.

Corticosteroid use should be restricted to clinical settings where it can be ensured the drug is given only for preterm deliveries.

benefit from this intervention, close monitoring and appropriate care needs to be reliably available to manage common life-threatening complications of prematurity. This requirement, also, is not necessarily easy to meet. Even tertiary care centers categorized as providing level-2 newborn care may be stretched quite thin and may struggle to meet such requirements.

It is inevitable that new evidence will come along from time to time that calls into question previous decisions or strategies, as it has in this case. As public health professionals, we need to be ready to learn from our missteps, adjust our perspectives, and change strategy in the face of such evidence.

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It's not Ebola ... it's the systems

Victor K Barbiero^a

The 2014 Ebola outbreak in West Africa demonstrates key deficiencies in investment in health systems. Despite some modest investment in health systems, our field has instead largely chosen to pursue shorter-term, vertical efforts to more rapidly address key global health issues such as smallpox, polio, malaria, and HIV/AIDS. While those efforts have yielded substantial benefits, we have paid a price for the lack of investments in general systems strengthening. The Ebola deaths we have seen represent a small portion of deaths from many other causes resulting from weak systems. Major systems strengthening including crucial nonclinical elements will not happen overnight but should proceed in a prioritized, systematic way.

BACKGROUND

The sensational media coverage of Ebola virus disease (EVD) has turned world attention to the crisis in West Africa and the potential spread of EVD to other African countries and beyond. Ebola has been responsible for not only substantial numbers of deaths but also major disruptions to the entire health systems and economies of the countries involved.

While EVD is in the limelight, we should also consider the epidemiology and disease burdens that drive most of the mortality and morbidity in low- and middle-income countries. For example, each month about 66,000 children die from diarrhea worldwide.¹ Thus, an investment in broader systems strengthening makes sense. Poor health systems, inadequate access to skilled and equipped providers, and the challenges of motivating positive behavior change compound the difficulty of control efforts for Ebola, diarrhea, and other diseases. But systems are neither perfect nor foolproof. The recent Ebola cases in Dallas, Texas, are a testimony that weaknesses exist even in the most sophisticated systems. However, strong systems will mitigate epidemic outbreaks and reduce endemic disease burdens. Strong systems save lives.

Global health leaders have called for major efforts to stop the 2014 EVD outbreak. All recommendations focus on infection containment and therapy.² All have an underlying investment in systems strengthening and behavior change. Jim Yong Kim, President of the World Bank, stated, "Now we are witnessing the results of our acceptance of the status quo," and has urged a commitment to systems strengthening.³ He outlines a 4-point strategy consisting of:

1. Support to health workers
2. Improved clinical and diagnostic infrastructure
3. Expanded information, education, and communication (IEC)
4. General infrastructure support

If the Bank's commitment is over the long term, it represents a sea change in global health programming and will promote stronger routine prevention and care across low- and middle-income countries. The Centers for Disease Control and Prevention likewise endorses a longer-term systems approach to EVD.⁴

SMART SYSTEMS STRENGTHENING

Much of the problem with Ebola is behavioral, coupled with an underlying deficiency in primary and secondary health care systems. Stopping the outbreak and mitigating future outbreaks depends on improved infrastructure at primary and secondary facilities, as well as rapid behavioral changes including better patient care-seeking behavior, the modification of funeral practices, and the avoidance of bush meat harvesting and consumption. What's needed is flatter, more prevention-focused systems that center on smart primary health care along with more upstream emphasis on things such as health-positive behavior, water, sanitation, and hygiene (WASH), and addressing adverse cultural practices. Implementing organizations and others recognize the need for health systems strengthening but require bi- and multilateral donors to dedicate specific, significant, and sustained resources to help build those systems.^{5,6}

Functional platforms established by long-term investments in family planning, HIV prevention and control, polio eradication, the expanded program for immunization, and malaria control can serve as a

^a *Global Health: Science and Practice*, Associate Editor.

BOX: SYSTEM STRENGTHENING INPUTS

- Increased numbers of trained, equipped, and compensated personnel
- Supplies, equipment, commodities, and improvements to, and maintenance of, physical plant infrastructure
- Sustainable water, sanitation, electricity, and waste disposal for all facilities
- Appropriate data management and data-based decision-making
- Supply chain management
- Improved access to prevention and curative care for clients
- Effective management at all levels of the system
- Improved behavior change
- Increased engagement of the private sector in service delivery

foundation for strengthening systems sustainably. Savvy leaders and programmers can capitalize on these opportunities in the near and long terms. Systems strengthening synergies exist within present global health priorities such as laboratory strengthening, human resource development/technical training, logistics/supply chain management, behavior change/IEC, and monitoring/evaluation.⁷

Clearly, systems require an immense amount of specific and sustained inputs and prioritized, strategic approaches. Priorities include a focus on primary preventive and curative care, building on existing platforms, especially HIV/AIDS and family planning, and focusing on positive behavior change. Technical inputs are broad and complex (Box). But systems also require less tangible inputs that concern quality, access, culture, traditional beliefs, education, private-sector engagement, accountability, policy dialogue, and public perceptions concerning fear and distrust of the health care system itself.

By definition, systems are interdependent and all elements need strengthening. However, key priorities in lower-income countries include financing, equipping the health workforce, infrastructure support, effective management, and functional partnerships between the public and private sector.

The legacy of vertical programs is that they have built systems platforms to some extent. If we capitalize on those platforms, we can strengthen the systems more broadly. It will take creative programming and piggybacking inputs across the various, more vertical programs that exist today.

Let's not let the momentum and awareness generated by this Ebola outbreak go to waste. Let's strike while the iron is hot and proceed to support better health systems to help mitigate future Ebola outbreaks while limiting the other major health problems rampant in the developing world. We must be proactive rather than reactive.

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Breaking new ground in family planning communication

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The Urban Reproductive Health Initiative, funded by the Bill & Melinda Gates Foundation and implemented in 4 countries of Africa and Asia, is breaking new ground in the field of family planning communication. Two articles in this issue of GHSP describe and evaluate the initiative’s communication efforts after about 2 years of implementation.

Endogeneity Addressed Through a Longitudinal Design

The first article, a broader evaluation across all 4 sites led by Speizer of the Measurement, Learning & Evaluation (MLE) project at the University of North Carolina, indeed found impact of exposure to various program efforts (such as recalling a radio program or receiving information at a community event) on contraceptive method use.¹ However, a perennial problem in such evaluations of communication efforts is concern about “endogeneity”—that is, that people who are more aware or proactive may be more likely *both* to being exposed (or to remember being exposed) to such efforts and also to adopting family planning. Because the longitudinal evaluation design included interviewing many of the same women twice (at baseline and midterm), this endogeneity would have remained fairly constant over time within the same individual. In a sense, women serve as their own controls. By using the technique of comparing 2 complementary statistical approaches, “fixed effects” and “random effects” models, and finding that they gave similar results, the authors conclude such endogeneity was not likely a problem in this situation.

Changing Ideation to Improve Contraceptive Use

The paper by Krenn and colleagues on the Nigerian Urban Reproductive Health Initiative is notable because they used communication and a client-centered approach as the leading part of the comprehensive family planning

program, and they also describe a much deeper and richer dive into the Nigeria program.² The programmers promoted and measured a set of positive “ideational” constructs related to family planning, such as individuals’ knowledge and attitudes toward family planning but also their perceptions of the attitudes of key people in their social network, such as peers, partners, and religious leaders, as well as self-efficacy to use contraception. The project had marked impact on a number of these factors, such as women’s perception that their peers supported family planning. And positive changes in ideation were associated with increases in contraceptive use.

Beyond these groundbreaking communication efforts, the Urban Reproductive Health Initiative, of course, includes a major “supply side” component as well. The Nigeria program found increases in contraceptive use overall. Thoughtfully adapting to the local context, the program identified a gap in services in slum neighborhoods and instituted a mobile service outreach model to serve those areas. Notably by the end of the reported time frame, such mobile outreach was accounting for about half of the family planning clients served by project-supported clinics. Clearly, both supply and demand are important. We look forward to more findings from this important initiative in the future. – *Global Health: Science and Practice*

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A better future for injectable contraception?

- Provision of injectables through drug shops appears practicable and can contribute a marked share of family planning services.
- A potential longer-acting injectable providing at least 6 months of protection appeals to programmatic professionals.
- Subcutaneous administration of DMPA offers major injectable improvements over the current intramuscular approach.
- Ironically, while injectable use will inevitably grow, better choice and wider availability of other methods—especially of long-acting and permanent methods—will reduce injectables’ overall share.

PLUSES AND MINUSES OF INJECTABLES

Injectables are a leading method in much of the developing world. They have many advantages for the client, the provider, and the system (Table). All the same, the dominant injectable DMPA (depot medroxyprogesterone acetate) in its current intramuscular (IM) form has some pretty important drawbacks—notably, side effects, higher blood levels than needed for most of the 3-month duration, provider bias, possible role in HIV acquisition, and requirement for repeated visits that are a burden

to both the system and the client. Despite DMPA’s high popularity, continuation rates with DMPA are rather poor. After 1 year of starting DMPA, only about 50% of women, on average, are still using the method—rates similar to those of condom and oral contraceptive users.¹

PROVISION BY DRUG SHOPS

A number of studies have previously shown that community health workers can provide injectables safely and effectively.² Thus, it should come as no great

TABLE. Advantages and Disadvantages of Current Intramuscular DMPA Injectable

Advantages	Disadvantages
<ul style="list-style-type: none"> • Highly effective • Coitally independent • Possible to use without partner’s knowledge • Lasts a full 3 months • 1-month grace period for reinjection • Safe and suitable for nearly all women • Relatively low cost • Easy for providers • Somewhat easy and convenient for clients • Amenable to community-based distribution 	<ul style="list-style-type: none"> • Bleeding side effects • Weight gain^a • Reduced bone density (temporary) • Not advised during early breastfeeding by WHO • Delayed return to fertility • Higher initial blood dosage than needed for efficacy • Requires repeated visits • System burden (eg, supply chain, staff time) • Provider bias (eg, reluctance to offer it to young women) • Poor continuation • Implicated for possible increased HIV risk

^a Weight gain may be perceived as positive by some women.

surprise, as described in the paper by Akol and colleagues,³ that the same is true when drug shops in peri-urban areas of Uganda are properly enlisted to provide them. In fact, a technical consultation in 2013 concluded that, with appropriate training and monitoring, drug shop operators can screen and counsel clients for DMPA effectively and administer DMPA injections safely.⁴ What is actually extremely notable, however, is that in the Akol study the convenience and quality of drug shop provision led the drug shops to reach a substantial share of overall family planning users in their areas, apparently mostly injectables users.

VIRTUES OF A 6-MONTH INJECTABLE

One potential major improvement would be a 6-month injectable, which has long been an objective of contraceptive developers. As described by McKenna and colleagues,⁵ in this issue of *Global Health: Science and Practice*, renewed efforts are underway to develop such a 6-month product. Using qualitative methods, the authors explore the potential acceptability and program considerations for one. Perhaps not surprisingly, they find a strong interest among providers, policy makers, and program implementers. Moreover, their findings emphasize the issues involved in introduction of even such a minor change in technology, such as regulatory approval, training, and supply chain adjustments. Interestingly, many providers were not aware that the current 3-month DMPA-IM allows for a 1-month “grace period,” during which clients can receive a reinjection. That indicates we need to work harder to achieve better client satisfaction and continuation even with the current DMPA injectable.

SUBCUTANEOUS DMPA APPEARS BETTER THAN THE CURRENT INTRAMUSCULAR APPROACH

How might such a 6-month approach be possible? Readers may be aware that a new approach to the 3-month DMPA is provided by Sayana Press, which is administered subcutaneously via the Uniject one-time-use injection system. Its proprietary DMPA formulation provides a lower hormonal dose (104 mg vs 150 mg), resulting in lower but still highly effective MPA blood levels without such a high

initial peak that is seen with DMPA-IM. Notably, based on studies of the impact on ovarian activity, it appears likely that Sayana Press itself, despite the lower dose, is actually effective for 4 months with a 1-month grace period.⁶ Unfortunately, a major drawback to Sayana Press is its significantly higher cost.

Fortuitously, it appears that a special formulation of DMPA may not be needed for subcutaneous (SQ) administration. Ironically, the current IM formulation when given subcutaneously provides better, more even, and sustained blood levels of the drug.⁶ So one major approach toward a 6-month injectable is to assess what SQ dosage of the current IM DMPA formulation might be needed to achieve the full 6 months (plus 1-month grace period) duration of action.

MORE CHOICE AND DIVERSITY OF METHODS REMAIN CRUCIAL

Whatever the advances toward a better injectable, it remains clear that practical access to a wide variety of methods remains limited for many women and couples. That is particularly true for the long-acting and permanent methods of implants, IUDs, and sterilization, but it is also true of emergency contraception and the Standard Days Method. The fact that use of implants is growing by leaps and bounds⁷ shows the field is making progress. Continuing to expand access to such a broad variety of methods remains the lynchpin of achieving the Family Planning 2020 goals.⁸ —*Global Health: Science and Practice*

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COMMENTARY

The future of routine immunization in the developing world: challenges and opportunities

Angela K Shen,^a Rebecca Fields,^b Mike McQuestion^c

Vaccine costs in the developing world have grown from < US\$1/child in 2001 to about \$21 for boys and \$35 for girls in 2014, as more and costlier vaccines are being introduced into national immunization programs. To address these and other challenges, additional efforts are needed to strengthen 8 critical components of routine immunization: (1) policy, standards, and guidelines; (2) governance, organization, and management; (3) human resources; (4) vaccine, cold chain, and logistics management; (5) service delivery; (6) communication and community partnerships; (7) data generation and use; and (8) sustainable financing.

BACKGROUND

Four decades ago in 1974, the World Health Organization (WHO) launched the Expanded Programme on Immunization (EPI). The EPI blueprint laid out the technical and managerial functions necessary to routinely vaccinate children with a limited number of vaccines, providing protection against diphtheria, tetanus, whooping cough, measles, polio, and tuberculosis, and to prevent maternal and neonatal tetanus by vaccinating women of childbearing age with tetanus toxoid. The purpose of EPI was simple and straightforward—to deliver multiple vaccines to all children through a simple schedule of child health visits.¹ At the time, basic health systems in most lower- and lower-middle income countries (LLMICs) were weak to nonexistent. Vaccine coverage levels among children younger than 1 year of age were less than 5%.² By 1990, most LLMICs had institutionalized immunization programs based on the EPI blueprint. In 1991, the global target of vaccinating 80% of the world's children was declared to have been met, saving millions of lives. The capacities and capabilities of countries built through the EPI blueprint were responsible for such significant gains.²

Since then, more vaccines have been added to national immunization schedules, and the contribution of immunization programs to ongoing declines in infant

and child mortality has increased commensurately.^{3,4} As of 2014, WHO has recommended that all immunization programs add vaccines against hepatitis B, *Haemophilus influenzae* type b, *Streptococcus pneumoniae*, rotavirus, rubella, and human papillomavirus (in girls). However, the full benefits of these vaccines has yet to be realized. WHO estimates 29% of deaths among children 1–59 months of age are vaccine-preventable.⁵ This gap is due largely to systems weaknesses in immunization programs that can be improved. With the addition of new vaccines, the complexity and costs of routine immunization increase.^{2,3,6,7} More vaccinations to protect against more diseases requires additional and better communication between health workers and caregivers as well as greater cold chain capacity. New vaccines and doses that expand immunization beyond infancy extend the benefits of vaccines across the life spectrum into adolescence and adulthood. Moreover, health systems in general are becoming more complex as new programs and services are added.

Fulfilling the vision of EPI requires sustained investments in routine immunization.⁸ Since its inception, expanded immunization has been a continuous and progressive story building on the fundamental managerial and technical health systems building blocks of leadership and governance; financing; service delivery; health workforce; products, vaccines, and technologies; and information systems. Additionally, the economic benefits of immunization are significant. Healthier individuals are, in the long term, more productive contributors to a country's wealth, particularly as countries rapidly transition from high to lower mortality levels.⁹

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29% of deaths among children 1–59 months old are vaccine-preventable.

Routine immunization both depends upon and effectively strengthens the health systems through which they are delivered.

Despite substantial success, there remain numerous challenges to the ultimate effectiveness of routine immunization. These fall into the following programmatic areas: (1) policy, standards, and guidelines; (2) governance, organization and management; (3) human resources; (4) vaccine, cold chain, and logistics management; (5) service delivery; (6) communication and community partnerships; (7) data generation and use; and (8) sustainable financing. This paper describes experiences and challenges in these areas. There is much to learn from decades of valuable experience in immunization that can potentially be applied to the “bigger picture” of primary health care. Investment in routine immunization has the potential to both optimize the programs that deliver the benefits of lifesaving vaccines and bolster the underlying health systems on which they rest.

WHAT IS ROUTINE IMMUNIZATION?

Routine immunization is the foundation through which countries provide access to lifesaving vaccines and control and eradicate vaccine-preventable diseases.^{2,3,6,8} It is the process of timely vaccination on a regular basis with vaccines considered important for a given country to reduce morbidity and mortality. This process is enabled by a country’s health system and maintained through a set of management subsystems needed to continuously supply the full complement of scheduled vaccines, monitor their safety, control population coverage, and measure their epidemiological impact. Essential components of immunization systems align with fundamental health systems components and function within the context of broader health and social welfare systems.

A strong routine immunization platform has the potential to benefit the overall health system by generating policy and financing innovations, robust logistic and cold chain systems, and skilled human resources, particularly in the areas of management, surveillance, and regulation. Routine immunization creates opportunities to educate parents about the benefits of vaccines and other health services. Engaging the community in planning, financing, and delivering the program can increase equity and build trust in the government’s ability to deliver immunizations. Immunization trust can lead to generalized trust and rising expectations for other government services.¹⁰ The development challenge is to ensure

the investments materialize, are sustained, and result in quality and reliable immunization programs that help drive the broader socio-economic development of countries.

The continued success of routine immunization depends on the availability of vaccines as well as the human, financial, and material resources needed to effectively deliver and use them. To achieve and maintain a country’s immunization objectives, adequate resources must be forthcoming every year for an ever-expanding birth cohort. Ideally, those resources are obtained in sustainable fashion. Dependence on support from external partners, with their shifting institutional priorities, results in precarious management and uneven performance.¹¹ An enabling environment, even in the poorest countries, depends on the political will of decision-makers. Paradoxically, political will declines if funding allocations are based strictly on morbidity and mortality burdens. This may put a high-performing immunization program at a disadvantage for securing the funding it needs to sustain high performance.¹²

CHALLENGES TO ROUTINE IMMUNIZATION AND LESSONS LEARNED

The programmatic goal of routine immunization is to ensure that vaccination services are accessible, available, acceptable, and affordable to users in an efficient and effective manner. At a time when health systems weaknesses are highlighted by outbreaks of measles¹³ and, more recently, Ebola virus disease, current platforms including routine immunization investments provide potential to help strengthen systems sustainability.¹⁴

Despite the maturity of EPI, immunization systems as part of broader health systems have become fragile as they face new challenges and struggle to balance country needs with the achievement of global coverage goals and accelerated disease control efforts (eg, polio eradication, measles elimination). We describe some of these prominent challenges and successful approaches in the context of 8 core components of routine immunization (Figure 1):

- Policy, standards, and guidelines
- Governance, organization, and management
- Human resources
- Vaccine, cold chain, and logistics management
- Service delivery

- Communication and community partnerships
- Data generation and use
- Sustainable financing

Establishing Policies, Developing Standards, and Providing Guidelines

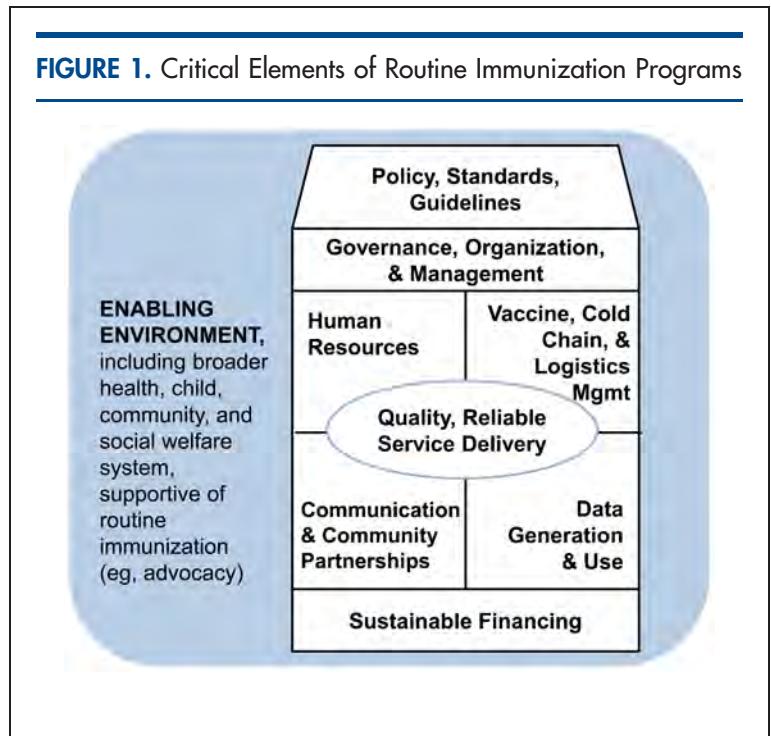
From the advent of EPI, WHO has played a critical supporting role to countries, particularly LLMICs. WHO generates global-level policies, standards, and technical guidance for immunization and actively helps countries (member states) introduce and adapt them as appropriate. WHO has no direct policy-setting authority at the country level; each country is expected to establish its own immunization policies, standards, and guidelines.

National policymaking capacity varies considerably across LLMICs. Concerted efforts have been made in recent years to establish and formalize National Immunization Technical Advisory Groups (NITAGs). Comprised of top biomedical, academic, and clinical professionals, the primary function of NITAGs is to guide the development of national immunization policies, guidelines, and standards and to inform program decision-making, including recommendations on vaccine introduction and immunization schedules. Moreover, their recommendations should be evidence-based and generated through transparent processes.¹⁵ Such advisory bodies have long existed in industrialized countries but are new to LLMICs. As of 2012, 38 of 102 LLMICs reported to WHO that they had NITAGs that met 6 process criteria: legislative or administrative basis for the advisory group, formal terms of reference, diverse expertise/representation (eg, pediatrics, public health, epidemiology) among core members, number of meetings per year, circulation of the agenda and background documents at least 1 week prior to the meeting, and mandatory disclosure of any conflict of interest.¹⁶ Progress toward these process indicators strengthen NITAGS, an important tool in strong national immunization programs.

In the absence of a NITAG, de facto policies sometimes emerge in the form of recommended practices and procedures that appear in training materials, supervisory checklists, and data management and reporting tools.

NITAGs are distinct from Interagency Coordinating Committees (ICCs), which are mechanisms to coordinate immunization partner inputs.

FIGURE 1. Critical Elements of Routine Immunization Programs



NITAGs are both a technical resource and deliberative body. They support national authorities and decision-makers to make evidence-based decisions, for example, on whether to introduce a new vaccine. As NITAGs evolve, they mirror immunization program development. Their advice helps managers set priorities and strategies tailored to epidemiological needs and programmatic capacities.

Regulation and oversight is another area central to well-functioning routine immunization platforms. Many LLMICs rely on the WHO vaccine prequalification process and UNICEF procurement mechanisms to ensure purchase of safe vaccines. A growing number of countries are increasing their investments in national regulatory authorities (NRAs) and associated regulatory systems (eg, laboratories). Strong NRAs are necessary if countries are to self-procure and ensure a reliable supply of quality vaccines.¹⁷

Building Strong Governance, Organization, and Management

National governments typically have the responsibility for leading and overseeing routine immunization. However, immunization is best seen as a shared responsibility of individuals, communities, and governments. Many other partners may be involved. For example, the public sector is often responsible for purchasing

routinely recommended vaccines and providing these to both public and private-sector providers (nonprofit and for-profit).¹⁸ Maintaining active representation from all partners and keeping the focus on routine immunization has been a continuing challenge. External partners tend to be most concerned with accomplishing specific, time-limited events, such as mass campaigns, new vaccine launches, or training events. In the most dependent LLMICs, financing and technical support for routine immunization is closely geared to these externally mandated outputs.

Strong managerial and technical leadership is required to manage the many partners and functions involved in national immunization programs.

In most countries, the national immunization program provides managerial and technical leadership and serves a wide array of functions, including developing standards and guidelines; securing vaccine supply and distribution; preparing training materials and supervisory tools and implementing training; developing and carrying out communication strategies; planning the introduction of new vaccines; organizing immunization campaigns; collecting, analyzing, and providing reports on vaccine coverage, disease surveillance, and budget execution; and maintaining relationships with external agency counterparts. In some countries, these functions are fragmented, split among different units or divisions of the health ministry or even across multiple ministries. This affects the efficiency and effectiveness of program functions and linkages.

Increasingly, health systems are being decentralized. Subnational health teams, often at the district level, are responsible for managing and providing the fully array of basic health services, including immunization. In principle, decentralization makes routine immunization more robust by bringing the management of services closer to the populations being served. In practice, immunization and other decentralized public services often suffer from a dearth of capable managers.¹⁹ According to the 2013 WHO-UNICEF report based on the Joint Reporting Form (used by every member country to report annually on immunization program indicators, such as coverage levels, wastage rates, and expenditures), there were more than 5,000 health districts (or similar subnational units) in WHO's Africa Region alone. A common problem is that authority and responsibility for immunization are divided in decentralized health systems. District-level managers are charged with optimizing immunization and other health services down to community levels. For immunization this includes maintaining herd

Immunization programs are growing in complexity, increasing the need for a well-trained health workforce.

immunity and controlling disease outbreaks. In low-resource settings, subnational decision-making processes are complex, mediated by both technical and political considerations and further challenged by constrained resources.²⁰ Efforts at the national level to control funding for certain key services, including immunization, are sometimes misunderstood or viewed as contradictory to the very principles of decentralization.^{21,22}

Some approaches to improving governance, organization, and management of routine immunization include:

- **Interagency coordinating committees:** In most LLMICs, a government-led ICC for immunization harmonizes planning and resource allocation to the programs from all major stakeholders. This forum provides a mechanism to improve coordination, collaboration, and cooperation among partners and the government, with varied success. In many LLMICs, external partners dominate the planning and resource allocation for routine immunization. Final decisions regarding input coordination, collaboration, and cooperation should be made by the host government.
- **Linkages:** Key technical and advisory bodies for routine immunization (NITAGs, NRAs, ICCs) need to be linked. Moreover, these institutions must coordinate their work with other disease control programs and analogous bodies at the health system level.
- **Pushing down to district levels:** Detailed microplans at the district level are recommended by WHO, outlining difficulties in accessing certain communities and subgroups. The plans cover delivery groups and strategies, how to reach such groups, including resource needs (equipment and staff) and means of monitoring these plans.

Human Resources for Health: The People Factor

The growing complexity of immunization programs increases the need for a well-trained, capable health workforce. Technical skills must be adequate to administer an increasing number of vaccines to more children and expanded age groups. Management and supervisory skills become increasingly important as vaccine costs rise and financial and data management responsibilities increase. There are more opportunities

for error, and the errors are costlier in terms of health risks to children and to the integrity of the entire immunization program. In many places, vaccinators represent the lowest tiers of health workers authorized to provide injections. Under such circumstances, task shifting of vaccine administration to community health workers or volunteers is not legal or appropriate. Despite the growing skill demands, the same basic approach to immunization training has been in use for more than 30 years. This usually takes the form of short, offsite, in-service training courses, often delivered through cascade training in which those providing the training may be experts in the subject matter but not in training techniques, or vice versa.

Promising areas in which to invest to build the capacity and professional development of an appropriately trained health cadre include:

- **eHealth:** eHealth or mHealth technologies and processes have been shown to improve health worker capacity and effectiveness in other programs.²³ With a global deficit of trained health workers²⁴ and the rapid expansion of mobile phone networks in many LLMICs, the application of eHealth/mHealth to improve health communication and decision-making by health professionals (and clients) is increasingly recommended and feasible. E-learning opportunities can also support training needs and enhance learning.
- **Preservice training:** Some countries are working to improve immunization training, including preservice training. The aim is to build a foundation, at the outset of health workers' careers, which includes not just knowledge and skills but also professional values that directly affect routine immunization performance. These values include appreciating the importance of immunization data and understanding how to use them to improve management. Another value is to be respectful of the child caregivers such that they have a positive experience and return to complete the vaccination schedule.
- **Supervision:** Regular supervisory visits provide opportunities to reinforce good practices and values to improve services.

Vaccine, Cold Chain, and Logistics Management

Cold chain and logistics management systems have been prominent features of the EPI blueprint

from the onset. System requirements have expanded drastically over the past several years with the introduction of new vaccines and the frequent mass campaigns to control, eliminate, or eradicate specific diseases, such as polio, measles, rubella, and tetanus. While such initiatives tend to be well-resourced, the strain they place on the supply chain system are substantial and often under-recognized, particularly at subnational levels.^{25,26} The most visible impact of new vaccine introduction is an increase in the volume of products that need to be stored, transported, and tracked, as well as the need for more storage capacity due to the increased use of single-dose vials.

Successful cold chain and logistics management requires attention to many considerations. Adequate fuel and transport are necessary to ensure continuous running of cold chain equipment, which itself must meet international standards. Fuel and maintenance costs are often underestimated, and decisions to fund them are usually made by local governments, which may have other priorities. The resources that are allocated are sometimes diverted to other uses. Taken together, these circumstances lead to unreliable delivery of supplies and vaccine stock-outs. In addition, maintaining vaccines at proper temperatures has become more complex than in the past as some new vaccines are inactivated by exposure to freezing while other vaccines (those that have been in use for decades) are damaged by heat exposure. With the unit cost of newer vaccines far more expensive than those of the "original" complement of EPI vaccines, poor vaccine-handling practices have large financial consequences.

Managing the movement of vaccine products and supplies has largely been taken for granted over the decades, and a renewed interest in supporting this key element provides tangible opportunities to build efficient and effective systems to protect and handle the investments in vaccines.²⁵ We are seeing new investments in:

- **Tools to support forecasting:** Tools for forecasting and monitoring of vaccines, supplies, and equipment stock help address a host of problems, from outdated inventory and inadequate storage space to inadequate stock and unmaintained equipment. Fortunately, new tools, such as improved supply chain and logistics management information systems, are becoming available.²⁷ But they

Introduction of new vaccines requires additional capacity of the supply chain system to handle the higher volume of products.

will only improve program performance if the required financing is in place and resources are correctly allocated and managed.

- **Vaccine technologies:** New developments are needed in this area to help countries meet increasing demands, including non-syringe delivery mechanisms and thermostable vaccines.⁶

Quality and Reliable Service Delivery To Reach Every Child

Global coverage for the third dose of the diphtheria, tetanus, and pertussis vaccine (DTP3) increased from 73% in 2000 to 82% in 2008 but has remained stalled since then, hovering around 83%.²⁸ Within-country variations are substantial, even in countries with high nationwide coverage.²⁹ Data from the Demographic and Health Surveys from several African countries show that coverage is consistently lower in the poorest wealth quintile than in the

highest quintile (Figure 2). The children who are missed tend to be those most in need of the protection that immunization confers.

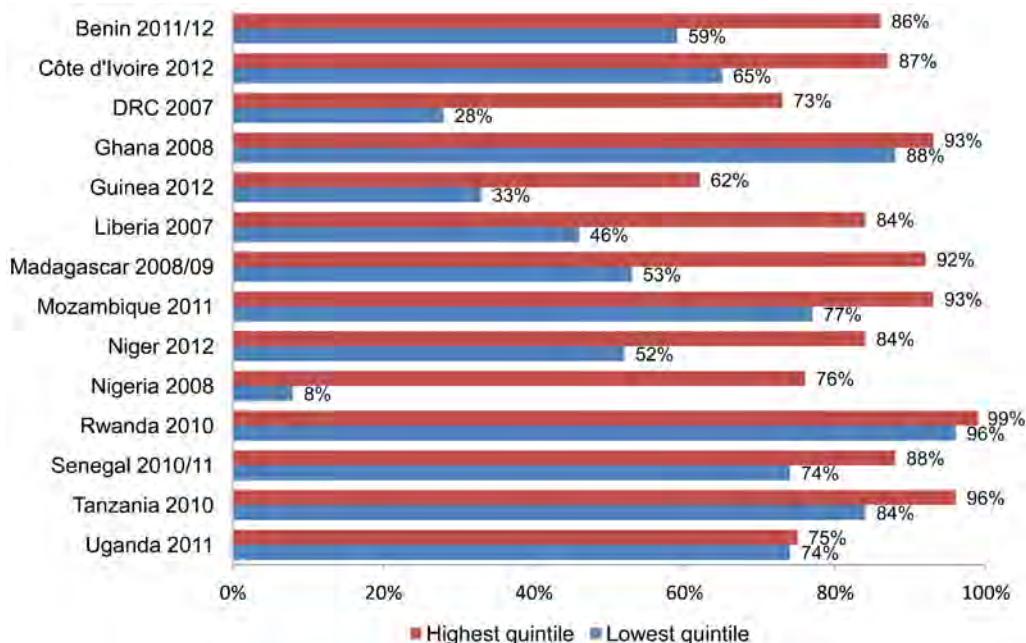
Routine immunization typically employs two service delivery strategies, fixed and outreach. Fixed immunization takes place within health facilities while outreach entails visits to sites as far as 5–15 kilometers from the facilities. More resources are typically allocated for the former, leaving resource gaps for the latter.

Some approaches and strategies to improve the equity of services to efficiently and effectively deliver vaccines to every child include:

- **Finding the under-vaccinated (have not completed all recommended vaccinations) and unvaccinated (have not received any vaccinations):** Here again, microplanning—the detailed planning by individual health facilities and districts of how to reach all vaccine-eligible children in the catchment area—is essential for improv-

Immunization coverage is consistently lower among the poor than among their wealthy counterparts.

FIGURE 2. DTP3 Coverage for Lowest and Highest Wealth Quintiles in 14 African Countries, 2007–2012



Abbreviations: DRC, Democratic Republic of the Congo; DTP3, third dose of the diphtheria, tetanus, and pertussis vaccine.

Source: Demographic and Health Surveys.³⁰

ing equity in immunization.³¹ Good planning requires knowledge of specific target populations, which is a serious challenge. As overall vaccine coverage levels rise, microplanning increasingly focuses on reaching hard-to-reach populations, whether defined in geographic, socioeconomic, cultural, or other terms.

- **Health worker–client interaction:** Not only must vaccinations be given properly and safely but the services must also be accessible and appealing enough for caregivers to bring their children for repeated visits. Under pressure to achieve low vaccine wastage rates for some vaccines such as measles, providers sometimes turn mothers away if they feel that not enough children have come to an immunization session to justify opening a multi-dose vial of vaccine. This has resulted in children being vaccinated too late or too early and contributes to high drop-out rates because of the added inconvenience it imposes on caregivers. Supporting health workers to balance the challenge of effectively and efficiently providing services is an important strategy to improving the delivery of services.

Communication and Community Partnerships

Educating and mobilizing the public to support immunization and to use immunization services is central to EPI. In practice, this requires health workers and other trusted individuals to keep caregivers informed of where, when, and how many times they need to bring children for vaccination. Caregivers consistently cite health workers as their most important source of information on immunization, yet health workers receive limited training and supervision on interpersonal communication skills and its importance.

The acceptability of immunization is highly variable worldwide. For example, non-acceptance of immunization, or “vaccine hesitancy,” is a common problem in Europe,³² where vaccine-preventable diseases are not commonly encountered due to the success of immunization efforts. Particular groups disseminate misinformation, for example, linking the measles, mumps, and rubella (MMR) vaccine to autism.³³ Challenges have ranged from isolated episodes of non-acceptance (due to religious, ethical, or medical considerations) to active mobilization against immunization

programs driven by political or conspiratorial arguments.³⁴

In LLMICs, demand for immunization is generally high and closely related to the availability of vaccines and quality of services,⁶ with non-acceptance limited to certain subpopulations. Revitalizing investments in communication to provide key information and direct the attention of caregivers and decision-makers to immunization is important.^{34,35} Non-use of services is sometimes attributed to mothers’ distrust of immunization.³⁶ Other reasons include perceived poor quality, unreliability, and inaccessibility of services.^{3,37–39} Persuading these populations to accept vaccines is complex. Knowing about vaccination, although important, does not lead to vaccine acceptance. Locally adapted and appropriate communication strategies are needed to address the sociocultural and political influences that impact immunization behavior.³⁴

Waisbord and Larson (2005) identified 4 key challenges confronting immunization programs³⁴:

1. Children do not get vaccinated if caregivers do not know the value of vaccines, when children need to be immunized, and where vaccines are administered.
2. Children do not get vaccinated when communities are excluded and beyond the reach of immunization services.
3. Children do not get vaccinated if caregivers do not trust the safety of vaccines.
4. Children do not get immunized when vaccines are not available.

Empirical results show that partnering with the community to develop communication strategies helps build trust and acceptance of vaccines and improve the quality, convenience, and use of vaccination services.³⁴

The active participation of communities in planning and carrying out outreach services has been shown to be associated with vaccination coverage increases in 3 countries.⁴⁰ In addition, in East Timor, India, and Nepal, community participation in monitoring immunization coverage within their own villages has contributed to service improvements. The involvement of nongovernmental organizations in maintaining a community scorecard on primary health care services was associated with an improvement in immunization coverage in Uganda.⁴¹ In Kenya, a process of community dialogue between community mem-

Caregivers consistently cite health workers as their most important source of information on immunization.

Involving communities in immunization programs has proved to build trust and acceptance of vaccines.

bers and health personnel was so successful that it was added to the essential package of services.^{20,42}

Generation and Use of Quality Immunization Data

The generation of high-quality immunization data is important to informing programmatic decisions. The two main sources of vaccine coverage data are periodic population-based surveys, such as Demographic and Health Surveys (DHS) and Mixed Indicator Cluster Surveys, and routine administrative reports. Maintaining and improving the quality of routine immunization data is a constant challenge. Survey-based and administrative vaccine coverage figures for a given country or district are often discrepant. Routine administrative reports usually overestimate coverage relative to surveys. WHO/UNICEF coverage estimates from the Joint Reporting Form are often lower than official country-reported figures.^{43,44}

One key problem is the inaccuracy of denominator (population) data, which are often based on outdated census data or inaccurate projections that do not reflect recent growth or population movement. Other common problems include double-counting of doses given, the mixing of doses given to older children with doses given to infants, and the fabrication of reports in order to achieve targets.⁴⁵

Some approaches that have proved to be successful are:

- **Home-based immunization records such as vaccination or child health cards:** These are necessary for the accuracy of population-based surveys,⁴⁶ and they serve as the cornerstone of vaccination programs at the local level. Health workers and caregivers are taught to value this document and that it should be requested and reviewed at every contact point between the caregiver and health worker. Yet home-based immunization records remain unavailable as they can often be out of stock and heavily underused. Of 23 DHS surveys conducted in Africa between 2010 and 2013, the median availability of cards was 68%, with only 28% and 29% of children having cards in Nigeria and Ethiopia, respectively.^{47,48}
- **Better tools for data collection and analysis:** Better data can lead to better decisions and better health outcomes. For

example, the use of vaccine registries can improve the accuracy in determining both the denominator for target populations and who and where the “unreached” are.

- **Expanded disease surveillance activities:** Frontline health workers routinely report cases of notifiable diseases, including vaccine-preventable diseases. In active surveillance systems, each facility must report the presence or absence of these cases, ideally on a weekly basis, more often realistically in many countries on a monthly basis. These raw data are fed into epidemiological surveillance systems, and the data are pooled and analyzed at higher levels.
- **Local use of programmatic data:** Routine immunization programs typically generate a wealth of data on programmatic indicators that can be used to improve program performance and services. Regular monthly and quarterly review meetings to examine such information at facility and district levels have been shown to improve routine immunization program performance.^{40,49} Data on cold chain functioning, frequency and place of immunization sessions, drop-out rates, and other indicators can be used by local health personnel to evaluate their own performance, identify gaps, and implement corrective actions to improve services.
- **Information feedback:** High-functioning immunization programs provide regular feedback reports to all levels of the health system, summarizing program outputs, cold chain performance, disease trends, and outbreak control activities. Feedback is essential to encourage the active participation of all health workers in the process of data collection and preservation of the integrity of the data for program and policy decision-making.

Sustainable Vaccine and Immunization Financing

The benefits of vaccines extend beyond those accruing to the person being immunized. Immunization also reduces the potential transmission of bacteria and viruses to others not yet vaccinated. This herd immunity effect protects the unvaccinated, provided a threshold number of people are immunized and rendered immune. Eliminating epidemic childhood diseases reduces curative care costs⁴ and makes countries more

If enough people are vaccinated and rendered immune, immunization then also provides herd immunity, protecting the unvaccinated from disease.

attractive places in which to invest. These and other externalities—in particular, the herd immunity that immunization creates—qualify immunization as a public good, one that must be rationalized among other competing health interventions for government resources.

Immunization, like other preventive services, sometimes falls victim to its own success, especially in low-resource settings. When coverage is continually high and outbreaks of vaccine-preventable diseases are averted (thereby reducing the vaccine-preventable disease burden), immunization demand may drop and policy makers and decision-makers may turn their attention and allocate resources to other interventions.⁸ The drop in resources for routine immunization usually results in a drop in coverage. Often the impact of these policies is not seen for a year or two. Immunity levels wane and vaccine-preventable disease outbreaks return, incurring higher containment costs and political threats to governments.

In many LLMICs, immunization budgets are currently insufficient to sustain programs and incorporate the new, costlier vaccines, although there is fiscal space to absorb costs.⁵⁰ New vaccines have added both tremendous benefit and costs to the original EPI blueprint.⁷ For example, the Gavi/UNICEF cost of the human papillomavirus (HPV) vaccine to protect girls against cervical cancer is about US\$4.50 per dose, with 3 doses recommended (total cost \$13.50). In 2001, the total cost of the original set of 6 WHO-recommended vaccines was under US\$1 (Figure 3). With the introduction of a combination 5-in-1 pentavalent vaccine in 2005, children became protected against 2 additional vaccine-preventable diseases, and the total vaccine costs increased to about \$11. In 2014, the total cost of 11 WHO-recommended vaccines reached approximately \$21, with an additional \$13.50 to vaccinate girls against HPV. Looking forward, adding an inactivated polio vaccine (IPV) to support the polio eradication efforts will add \$1.26 to the schedule, bringing the total vaccine costs to about \$23 for boys through age 18 and to \$36 for girls. Note that prices vary by brand of vaccine and vaccine presentation (eg, multi-dose vials, liquid formulation). Delivery costs, estimated by Lydon and colleagues (2014), add about \$25 per child, bringing the total delivery costs to fully immunize a child to around \$50 to \$60.^{7,51} These delivery costs are most likely underestimates.

Some current approaches toward sustainably financing immunization include:

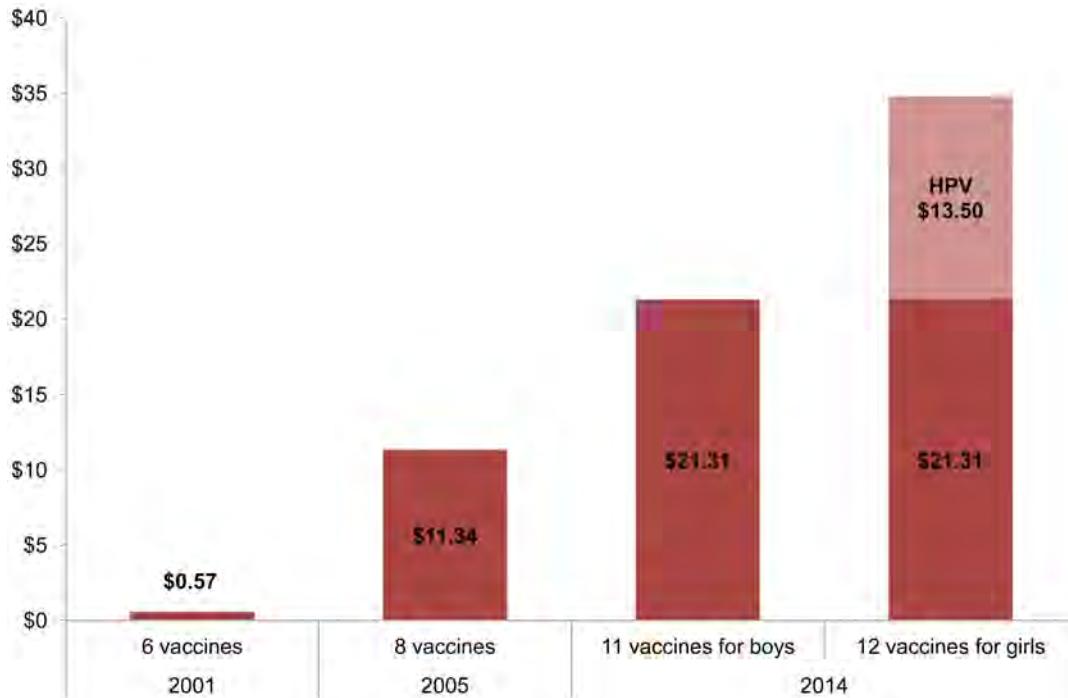
- **Establishing legal frameworks:** Increasing national immunization budgets and protecting those budgets through legislation helps countries achieve country ownership. Current work toward establishing legal frameworks for immunization financing provides a foundation for sustainably financing immunization. For example, Nigeria, Africa's most populous country, more than doubled its immunization budget from 2010 to 2012 and passed a new national health bill that includes a provision explicitly guaranteeing public immunization financing.⁵²
- **Tracking immunization program expenditures:** Immunization program expenditures are notoriously hard to track. Improved resource-tracking down to district levels provides the basis to improve budget and resource allocation. Between 2006 and 2013, government spending on routine immunization per surviving infant remained relatively flat while health per capita and gross national income generally rose, data from Gavi eligible countries show (Figure 4). To compound this picture, the cost of newer vaccines has been rising, from about US\$0.57 per child in 2001 (for 6 antigens) to approximately \$21 per boy and \$35 per girl in 2014 (for 11 antigens), as mentioned earlier (Figure 3). The current nominal cost of the vaccines alone to vaccinate 1 child is equivalent to or exceeds the amounts many LLMICs have spent on all their public health programs combined, which has ranged, on average, from \$21 to \$24 per capita since 2010 (Figure 4).

GAVI AND GRADUATION

Financing vaccine purchase and immunization delivery programs is increasingly challenging, particularly to LLMICs unaccustomed to such high health spending. Gavi, an innovative financing mechanism created in 2000 to accelerate access to new and underutilized vaccines, pre-pays production costs for the newer WHO-recommended vaccines directly to manufacturers and provides grants to the 73 poorest LLMICs to finance procurement and introduction of the vaccines into the routine system. The vaccines are procured through UNICEF's Supply Division, which, independently of Gavi, is the world's

It could cost up to an estimated US\$60 to vaccinate 1 child when taking into account both delivery and vaccine costs.

FIGURE 3. Vaccine Costs per Child (US\$) for Routinely Recommended Vaccines^a From Birth Through Age 18, 2001, 2005, 2014



Abbreviation: HPV, human papilloma virus.

Source: UNICEF contract prices as of May 8, 2014.⁷ Costs based on lowest-available price to UNICEF.

^a The 2001 WHO-recommended vaccination schedule comprised 4 vaccines containing 6 antigens: diphtheria, tetanus, pertussis (DTP); measles; polio; and bacille Calmette-Guérin (BCG). In 2005, 2 more antigens were added: hepatitis B (Hep B) and *Haemophilus influenzae* type b (Hib). In 2014, rotavirus, pneumococcal conjugate, rubella, and HPV were added to the schedule, bringing the total number of WHO-recommended antigens to 12.

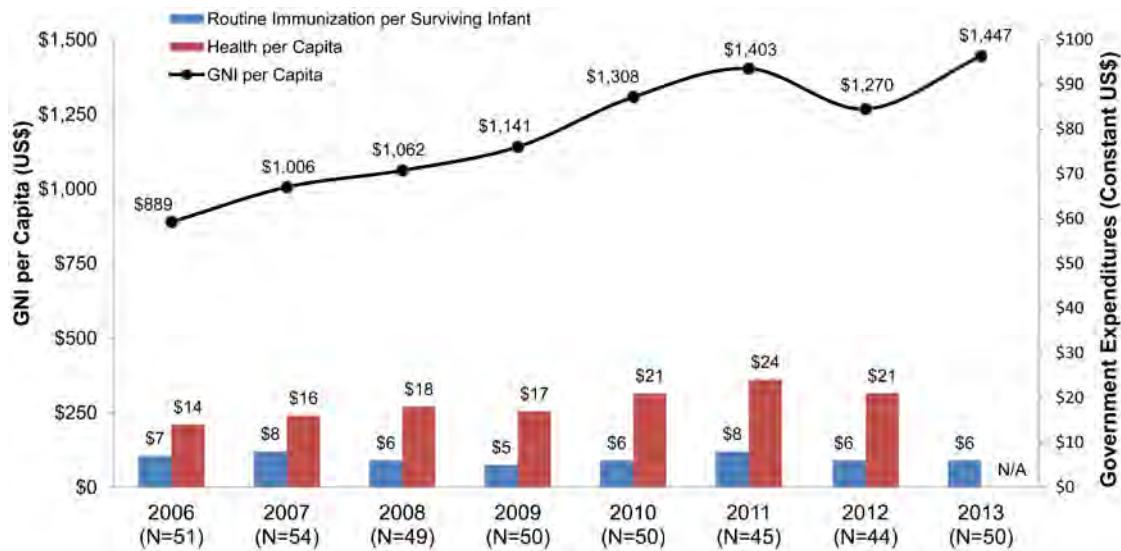
Notes: The WHO-recommended target group for HPV vaccination is girls ages 9–13 years. HPV vaccination of boys is optional but not recommended in resource-constrained settings. WHO recommends all countries introduce at least 1 dose of inactivated polio virus (IPV) into their immunization schedules by the end of 2015, which will add an additional \$1.26 to the schedule.

largest vaccine procurer. About half of UNICEF-procured vaccines currently go to countries not supported by Gavi.⁵⁷ Another example of a collective vaccine procurement mechanism is the Pan American Health Organization’s Revolving Fund, a collective bargaining mechanism of pooled procurement for the WHO region of the Americas.⁵⁸

In the 73 poorest LLMICs, Gavi finances nearly all the newer vaccines. By 2015, the first 20 countries will begin graduating from Gavi eligibility as their per capita gross national incomes already exceed the Gavi funding threshold (US\$1,500 in 2010, adjusted in 2014 to \$1,570). Upon graduation,

the countries will need to self-finance all their vaccines.¹⁷ Although Gavi facilitates this transition, countries will face global market vaccine prices, joining some 40 middle-income countries that were never eligible for Gavi support. The uncertainty of future vaccine prices is an impediment to planners and legislators, particularly as they write new or revise existing vaccine legislation obligating their governments to finance the programs. The domestic investment case in countries is often not properly developed. That said, countries are graduating from Gavi assistance at a time when they are experiencing robust economic growth. Assuming continued economic growth, countries, with political support

FIGURE 4. GNI per Capita and Government Expenditures on Health per Capita and on Routine Immunization per Surviving Infant Among Reporting Gavi-Eligible Countries



Abbreviations: GNI, Gross National Income; N/A, not available.

Source: Routine immunization expenditures extracted from the WHO/UNICEF Joint Reporting Form, Immunization Financing Database,⁵³ Indicator 6500. Expenditures reported in local currency were converted to US\$ using the midyear exchange rate. Surviving infant populations derived from the UN Population Division Online Database.⁵⁴ GNI per capita (Atlas method) expressed in US\$ and extracted from the World Bank.⁵⁵ Government expenditures on health extracted from the WHO National Health Account Database.⁵⁶

All values in population-weighted constant (2013) US\$. The following country-years were excluded from the analysis: Bhutan 2007, Uganda 2011, and Uzbekistan 2006, 2009.

and commitment, could fully finance their own programs.⁵⁹

Prerequisites for sustainable financing include:

- **Data:** Cost-effectiveness studies are needed for each vaccine to inform decisions to introduce into national immunization schedules.⁵¹ Few LLMICs have the necessary research expertise to carry them out.
- **Effective national procurement and regulatory authorities:** National procurement and regulatory bodies have a role to ensure that governments purchase safe, effective vaccine products at the lowest possible cost.¹⁷ Investments in the ability of countries to manage procurement and supply are important to countries nearing graduation.¹⁷ This is largely because, depending on the source of vaccine (ie, procurement through a United Nations Agency, self-procurement, or domestic

vaccine producer), countries need to strengthen the management of procurement including product pricing strategies. National regulatory functions vary depending on procurement mechanisms. At a minimum, countries must have a regulatory system for market authorization, licensing activities, and pharmacovigilance in order to procure vaccines for use in immunization programs. This function is separate from vaccine procurement duties. (If countries self-procure vaccines, their regulatory authority must be able to perform two additional functions—lot release and laboratory access. If a country produces vaccines domestically, they must also perform regulatory inspections and regulatory oversight of clinical trials.)

- **Public finance systems:** Performance of public finance systems must be adequate to efficiently handle the increased immunization

program budgets, and managers must be adept enough to demonstrate value for money.⁶⁰

WHERE DO WE GO FROM HERE?

Ultimately, any vaccine, whether part of the original EPI blueprint or new, is only as effective as the health system that delivers it. To reach every child, it will be essential to address inequities in access to vaccines (often masked by high national coverage), strengthen the fragility of underlying health systems, and invest directly in routine immunization. Countries have pledged to achieve ownership of their immunization programs by finding sustainable financing solutions and developing needed institutional innovations. If the resulting country and external partner investments materialize, immunization services will reach all children, continuously, using locally appropriate strategies.⁶¹

However, EPI's history shows that without continued and sustained investments in long-term development approaches, gains can be lost.^{2,62} With the push to universal immunization in the 1980s, the global solidarity to accelerate coverage resulted in unprecedented increases in coverage for the basic set of EPI vaccines by the end of 1990. However, the focus on increasing coverage, as opposed to building sustainable and equitable health care systems, was evident as coverage stagnated throughout the 1990s, with global and regional averages masking lower local coverage, particularly in the African region where coverage levels for fully immunized children are under 50%.⁶² The reason for this is not only weaknesses in the health system and lack of continued investment in routine immunization but also the underlying funding pressures that divert resources away from routine immunization. Investments to strengthen routine immunization systems have been limited, instead mediated through broader bilateral or multi-lateral health system strengthening strategies or as a side benefit of specific disease control initiatives.⁶²

Countries have made undeniable progress and significant advances in routine immunization over the last 40 years. It is costing more to save a life from vaccine-preventable diseases than before, but that is because there are more lifesaving vaccines now and immunization is saving more lives than ever before. We are at a time when new and future vaccines will be on

the order of dollars versus cents, and recurrent costs to support delivery and administration of vaccines must be factored into the budget equation, whereas it had not been in the past. Over the past 4 decades, progress has clearly been made in building the 8 critical components of routine immunization. Expanding these lessons to support the primary health system provides opportunities to address the constant barriers that choke the primary health care system. Transformative changes are required to support and manage a trained and skilled workforce, shore up infrastructure weaknesses, and improve data and information needs. These areas are not new cries for attention.¹⁴ Addressing these underlying deficiencies that underpin primary health care systems are investments in the future dividend of a nation's health and productivity.

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COMMENTARY

Strategies to reduce risks in ARV supply chains in the developing world

Chris Larson,^a Robert Burn,^b Anja Minnick-Sakal,^c Meaghan O'Keefe Douglas,^d Joel Kuritsky^e

Key strategies of the main ARV procurement program for PEPFAR to reduce supply chain risks include: (1) employing pooled procurement to reduce procurement and shipping costs and to accommodate changing country needs by making stock adjustments at the regional level, and (2) establishing regional distribution centers to facilitate faster turnaround of orders within defined catchment areas.

BACKGROUND

Between September 2005, when the United States Agency for International Development (USAID) awarded the Supply Chain Management System (SCMS) project, and August 2014, the SCMS project delivered over US\$1.9 billion in HIV/AIDS commodities, approximately \$1.1 billion of which were antiretroviral (ARV) drugs to support the treatment of people with HIV and AIDS. This total sum of ARVs accounted for approximately two-thirds of the ARVs delivered with funding from the US President's Emergency Plan for AIDS Relief (PEPFAR).¹ The SCMS project is led by the Partnership for Supply Chain Management, with 13 private-sector and nongovernmental partners.²

One of the primary challenges to achieving a reliable, cost-effective, and secure supply chain of HIV/AIDS commodities has been the high cost of commodities. The US Department of Health and Human Services and the US Food and Drug Administration (FDA) made a significant initial response to the issue of cost in May 2004, when they introduced a new initiative to facilitate global ARV manufacturers' access to an expedited product review and inspection process. This tentative approval process to determine the quality of ARVs produced by manufacturers anywhere in the world was designed to increase access to high-quality medications globally. Under this initiative, if products meet the FDA's quality assurance standards, they are eligible for purchase under PEPFAR.³

As generic products obtained approval for use under PEPFAR, stakeholders began to procure more generic ARVs and fewer branded ones, resulting in rapid and substantial savings to PEPFAR. A 2010 study estimated that **between 2005 and 2008 PEPFAR saved over US\$323 million by procuring approved generic ARVs instead of equivalent-branded ARVs.**⁴

As of September 30, 2013, 6.7 million people were receiving antiretroviral treatment through the PEPFAR program—up fourfold from 1.7 million in 2008.⁵ Addressing demand-side challenges while simultaneously mitigating supply risks (production and shipping delays) as well as cost risks has been essential to meeting the needs of antiretroviral therapy (ART) programs and ensuring that a stable supply of ARVs is available to patients.

This article describes the practices employed by USAID and the SCMS program to mitigate ARV supply chain risks. From the program's experience in numerous PEPFAR countries, the risks can be grouped into 3 categories of supply, demand, and cost (Table).

The program's risk mitigation approaches represent integrated supply chain strategies that take advantage of economies of scale to improve cost and quality. In particular, **pooled procurement and the use of regional distribution centers (RDCs)** are common strategies across the 3 risk categories, illustrating the interconnectedness of risks. For example, inaccurate forecasting (demand risk) may lead to under-procurement (supply risk), eventually resulting in the need for a costly emergency order (cost risk) to remedy a product stock-out.

SUPPLY RISKS

Production and shipping delays can result in product stock-outs when goods are not delivered according to

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TABLE. ARV Supply Chain Risks and Corresponding Risk Mitigation Strategies by the SCMS Project

Risk Category	ARV Supply Chain Risks	Risk Mitigation Strategies
Supply	<ul style="list-style-type: none"> • Production delays • Shipping delays 	<ul style="list-style-type: none"> • Multiple-source procurement • Pooled procurement • Use of RDCs • Flexible product specification
Demand	<ul style="list-style-type: none"> • Expanding treatment programs • Inaccurate and/or delayed demand forecasting and supply planning • Burdensome procurement procedures 	<ul style="list-style-type: none"> • Frequent update and review of supply plans • Regional aggregation of country forecasts and supply plans for pooled procurement • Restocking RDCs based on analysis of likely demand (as opposed to firm orders)
Cost	<ul style="list-style-type: none"> • High per-unit product costs • High shipping costs 	<ul style="list-style-type: none"> • Pooled procurement based on aggregate demand plans • Freight consolidation and ocean shipping

Abbreviations: ARV, antiretroviral; RDC, regional distribution center; SCMS, Supply Chain Management System.

Between 2005 and 2008, PEPFAR saved over an estimated US\$323 million by procuring approved generic ARVs instead of branded ones.

the supply plan and, hence, are not available for scheduled in-country distribution. These stock-outs can lead to ART interruption for patients if the needed ARV drugs are not consistently available. Country-specific procurements are scheduled according to a multilateral, agreed-upon supply plan, designed to maintain inventory levels across the in-country supply chain.

According to SCMS procurement data, between 2007 and 2012, manufacturers of generic ARVs delivered their products on time to the contractually agreed-upon destination (the RDC or a country's central medical store) 50% to 70% of the time. Orders were considered on time if they arrived at their destination within 14 days of the projected delivery date in the price quote. Of the orders arriving late (greater than 14 days after the projected delivery date), two-thirds were provided within 1 month of the originally agreed-upon delivery date.⁶ In order to improve the delivery performance due to production or shipping delays to the recipient countries the program developed the following strategies to mitigate supply risks.

These 4 strategies are:

1. Multiple-source procurement
2. Pooled procurement based on projected demand
3. Use of RDCs
4. Flexible specifications for presentation of ARVs (appearance of packaging, quantities

Pooled procurement among neighboring countries reduces procurement and shipping costs.

per package, instructions printed in multiple languages) to facilitate common product use across multiple countries

1. Multiple-Source Procurement Mitigates Production and Shipping Delays

Based on the best-value approach that is embodied in USAID procurement regulations, ARV procurements are usually awarded concurrently to multiple vendors on a tender-by-tender basis. The benefits of doing so are twofold. First, the risk and consequence of sudden production or delivery failures by a single vendor are mitigated by the completion of orders for the same product by other vendors. Second, it is the opinion of the authors that the participation of multiple vendors leads to an ARV marketplace that is competitive and growing in capacity to supply these products to an increasing number of patients on ART. Starting in 2009, the program began to issue the vast majority of its tenders as multiple-source tenders.

2. Pooled Procurement Maximizes Product Availability and Reduces Costs

Pooling (combining) the procurement for common ARVs across PEPFAR-supported countries based on their supply plans maximizes the availability of these ARVs and reduces procurement and shipping costs for a number of reasons:

- Economies of scale are attained for manufacturing and shipping.

- Fewer tenders and orders need to be processed, reducing transactional costs for both the buyer and the manufacturers.
- Minimum batch volumes imposed by manufacturers before beginning production are reached more rapidly, thus avoiding production delays.
- The capacity of shipping containers can be maximized fully, particularly when pooled products are shipped to RDCs.

The pooled procurement process also allows vendors and recipients to plan ahead strategically. For example, when countries place orders at least 6 months before they need the goods, ocean freight can be used rather than more expensive air freight. Additionally, by pooling procurement, SCMS can negotiate reduced aggregate tendering rates. The program issues approximately 8 planned tenders to the market per year, of large aggregate volumes each time. This process increases the program's negotiating power with vendors, improving the chances of obtaining the best price available, in contrast to an annual tender process, which allows only for a single negotiation. Using a continuous retendering and buying strategy throughout the year also allows the program to take advantage of price declines in the market.

By combining demand forecasts with procurement history from multiple countries (normally within the same region), SCMS can hedge against forecast errors. The combined forecast is shared quarterly with manufacturers, suppliers, other implementing partners, and nongovernmental organizations, such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria, the Clinton Health Access Initiative, and the United Nations Children's Fund (UNICEF).

To illustrate the cost savings from the pooled procurement model, the authors have prepared the comparison below between the 2013 annual tender process in an East African country and the pooled procurement price in 2013 for two high-volume fixed-dose combination (FDC) ARVs (Figure 1). The pooled procurement price for the adult formulation of Lamivudine/Nevirapine/Zidovudine (150/200/300 mg dispensed in 60 tabs) and for the pediatric equivalent (30/50/60 mg dispensed in 60 tabs) trended below the East African country's annual tender price, with modest differences at the start and a widening gap throughout the year 2013. This is an illustrative example of the potential benefit of frequent

tendering, founded on pooled procurement, which enables the buyer to capture price decreases throughout the year.

3. Use of Regional Distribution Centers Speeds the Order-to-Delivery Process

The program has established 3 RDCs to provide intermediate warehousing and regional distribution for 11 other PEPFAR-supported countries in sub-Saharan Africa (Figure 2). For example, the RDC in Pretoria, South Africa, serves Botswana, Mozambique, Namibia, Zambia, and Zimbabwe. The 3 distribution centers, in turn, have supplied 40 countries with HIV/AIDS commodities and have enabled the program to effectively increase the availability and timely shipment of generic ARVs.

One strategy for operating efficient RDCs involves holding common, high-volume generic ARVs in multimarket, pharmaceutical-grade distribution centers to facilitate more rapid turnaround of orders originating within the defined catchment region, reducing delivery time and improving on-time delivery to clients. This model has been used in the private sector as well.⁷ Between 2007 and 2012, the RDCs delivered 90% of orders on time. In contrast, between 50% and 70% of orders arrived on time with direct delivery from a vendor during the same time period (Figure 3).⁶ The RDCs are independent, commercial enterprises, which serve commercial and public sectors, ensuring their sustainability. The costs associated with RDC warehousing services have averaged 2.89% of the value of the ARVs delivered.

RDCs can also be leveraged to substantially reduce lead time—the time interval between the order and receipt of commodities. Analysis conducted in 2011 showed that partner country programs requesting emergency shipments (ie, shipments with a requested delivery date of less than 60 days from the order date) received delivery in an average of 28 days from RDCs, out of RDC stock, compared with an average of 72 days directly from manufacturers.⁶ This means that these intermediate storage facilities not only have sped up delivery but also have fulfilled urgent orders from stock positions when the minimum time frame for delivery could not otherwise have been met by manufacturers.

By managing the inventory of ARVs strategically at the RDCs, the program has been able to mitigate many supply and demand risks. Many factors are considered to ensure sufficient RDC stock levels. First, we anticipate demand from countries, which is determined by the ARV

Using a continuous retendering strategy throughout the year for large aggregate volumes increases the program's negotiating power and allows it to take advantage of price declines in the market.

Between 2007 and 2012, 90% of orders fulfilled by regional distribution centers were delivered on time compared with only 50%-70% of orders fulfilled directly by vendors.

Regional distribution centers can be leveraged to substantially reduce lead time.

FIGURE 1. 2013 Pricing (US\$) for Adult and Pediatric Formulations of Fixed-Dose Combination Antiretroviral Drugs,^a Pooled Procurement vs Annual Tender^b



^a Adult formulation: Lamivudine/Nevirapine/Zidovudine 150/200/300 mg dispensed in 60 tabs; pediatric formulation: Lamivudine/Nevirapine/Zidovudine 30/50/60 mg dispensed in 60 tabs.

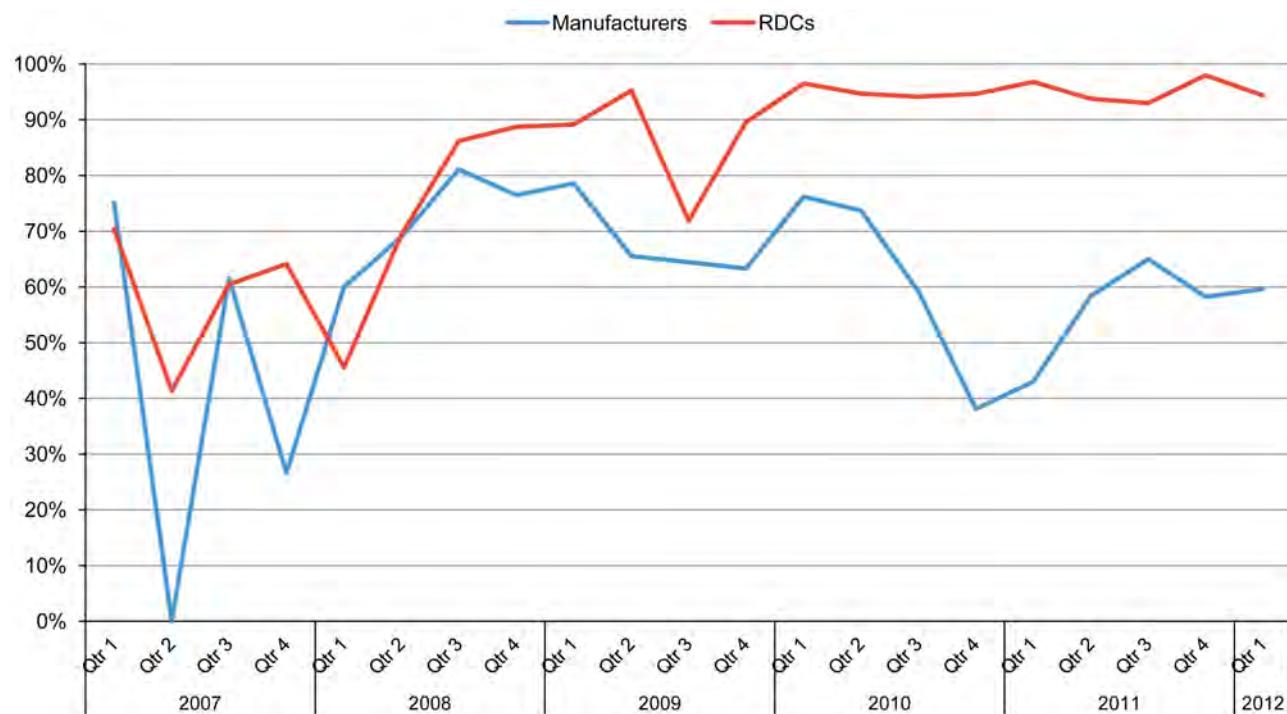
^b Pooled procurement across PEPFAR-supported countries; annual tender in an East African country.

FIGURE 2. Catchment Area of Regional Distribution Centers



To support global pooled procurement and reduce turnaround times for delivery of ARVs, the Supply Chain Management System project established 3 regional distribution centers (RDCs) in Ghana, Kenya, and South Africa. These facilities hold strategic stock, provide regularly scheduled shipments to neighboring countries, and expedite emergency orders to prevent stock-outs. To provide a sustainable resource, the RDCs were established as independent commercial enterprises, attracting major private-sector pharmaceutical clients.

FIGURE 3. Proportion of ARV Shipments Delivered On Time, Manufacturers Versus SCMS Regional Distribution Centers, January 2007–March 2012



Abbreviations: ARV, antiretroviral; RDC, regional distribution center; SCMS, Supply Chain Management System.

supply plans developed by each country as an outcome of ARV commodity forecasts.⁸ Supply plans also consider factors related to attributes of the market place for generic ARVs, such as lead time, manufacturer delivery performance, historical demand, the need to make stock available for emergency requirements, and product transitions due to revisions to treatment guidelines. Finally, supply plans are also informed by market dynamics issues, such as active pharmaceutical ingredient shortages, formulation production capacity constraints, new product entrants, and increasing options for fixed-dose combinations.

4. Flexible Specifications Facilitate Product Use in Multiple Countries

The program encourages manufacturers to register a common presentation for a given ARV formulation across multiple countries whenever possible, which allows the program to procure and ship a single product to most African

countries. In the majority of cases, the single presentation uses labels and inserts printed in both English and French. This common presentation strategy has come to dominate the ARV procurements made by the program; in 2013, 77% of the ARVs procured by the program by volume were of the common presentation with English/French labeling.

DEMAND RISKS

The authors define demand risks as operational matters at the client, program, or country level that impact the timely and cost-effective processing of ARV orders through the national and donor systems.

Producing accurate national demand forecasts is challenging, which can result in orders that may not reflect the country's actual need. On the one hand, under-forecasting can result in product scarcity, increasing the likelihood of stock-outs and creating the need for costly

emergency orders. It also substantially increases the use of high-cost air shipping—the normal transportation mode for emergency orders. In contrast, orders placed sufficiently in advance of their desired delivery date can be shipped via ocean, with savings of more than 60% when compared with the cost of air freight. To ensure on-time delivery of the most common fixed-dosed combination and single-dose formulation ARVs shipped via ocean, a minimum lead time of 6 months is needed. This lead time can extend up to 9 months, as supply constraints and demand variations come into play.

Conversely, over-forecasting can result in excess stocks that expire before use. This increases costs of storage and handling as well as the cost of properly disposing of the unused product. Additional common challenges to timely, accurate procurement include delays in finalizing and submitting orders and coordination issues between donors and recipients.⁸

To mitigate these demand risks, the program has employed a combination of strategies:

1. Regularly updating country forecasts and supply plans
2. Regionally aggregating supply plans for pooled procurement (noted above as a measure that also maximizes supply-side product availability)
3. Restocking RDCs based on analysis of likely demand, rather than on firm orders from clients

1. Frequently Updated Country Supply Plans Improve Orders and Reduce Stock Imbalances

The program assists PEPFAR-supported countries in establishing 12–18 month supply plans, which are updated every 3 months and are based on reported product consumption. Delivery quantities for planned shipments can thus be continuously revised to reflect a more accurate picture of demand and to respond to changes in consumption trends, ultimately attempting to avoid both stock-outs and overstocking of commodities.

2. Aggregating Supply Plans for Pooled Procurement Enables Stock Adjustments at the Regional Level

Taking the additional step of aggregating the supply plans of all countries within a region

further mitigates supply risks linked to forecasting weaknesses, because adjustments can be made closer to the country program, as opposed to the very beginning of the supply chain. For example, if one country in a region adjusted its supply plans to reflect greater ARV requirements and another country in the same region concurrently experiences reduced demand, the relevant RDC could transfer excess from the latter to meet the increased needs of the former without ever having to order new supplies from manufacturers.

3. Restocking Regional Distribution Centers Based on Likely Demand Allows for Flexibility at the Country Level

The program also uses aggregated supply plans to plan advanced ARV procurements delivered to the RDC in bulk shipments using ocean freight, which saves significant funds. The quantities from these shipments can then be broken down for distribution to countries in the same regions as the RDC. The RDC also allows for flexibility with clients by increasing or reducing delivery quantities of a product to a given country each quarter to align with changes in actual consumption where that data are available. Private-sector companies practice this sort of strategic inventory management by holding a certain amount of stock depending on the forecast and lead time associated with each product or component pieces, enabling the companies to fill orders quickly.⁹

COST RISKS

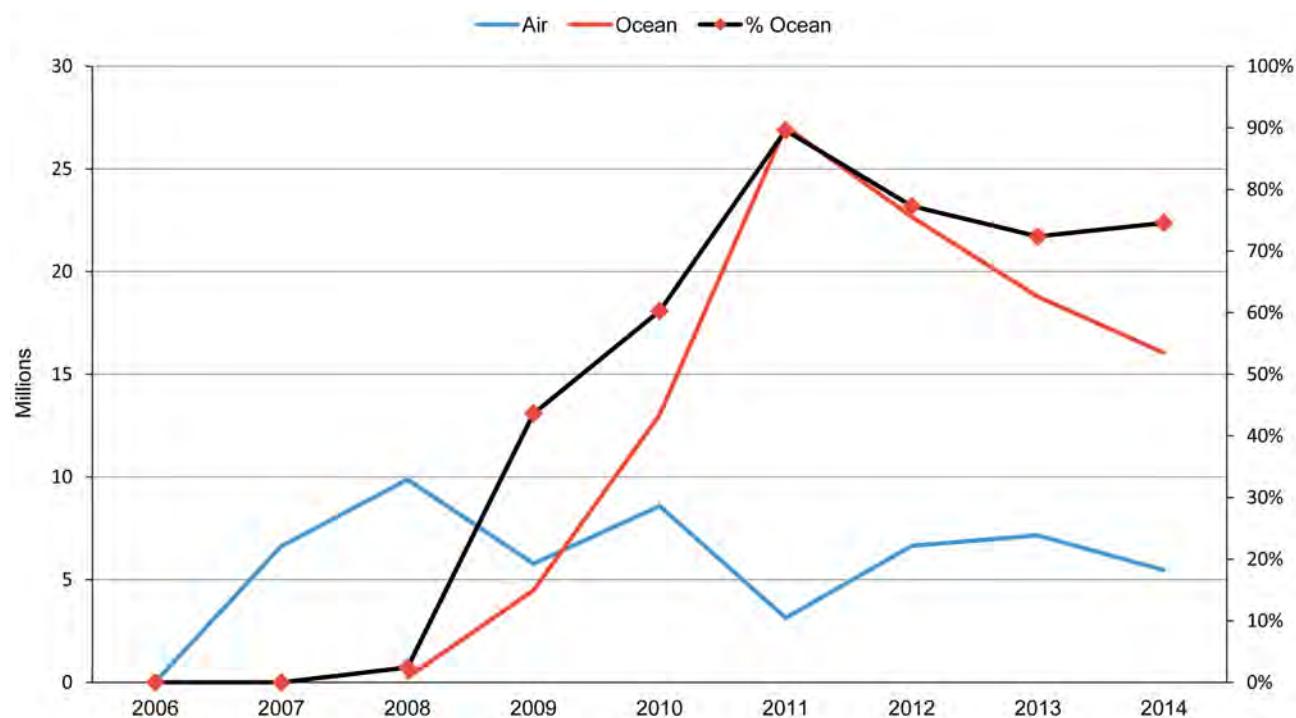
Cost risks may generally be divided into risks related to the unit cost of ARVs and risks related to shipping and storage. In short, efforts described above to reduce supply and demand risks through regionally aggregated planning, procurement, and intermediate storage also have a considerable effect on reducing costs throughout the supply chain.¹⁰

1. Pooled, Frequent Procurement Lowers Product Units Costs

Economies of scale obtained through pooled procurement create the opportunity for cost savings in the ARV supply chain.^{10,11} However, this is not only the result of reducing the number of demand-side transactions required to obtain the same quantity of products for multiple countries. Economies of scale are also achieved on the supply side, as manufacturers are asked to

Pooled procurement provides an opportunity for cost savings through economies of scale.

FIGURE 4. Number of Bottles of ARVs Transported by Air and Ocean and Proportion of Ocean Shipments, 2006–2014



Abbreviation: ARV, antiretroviral.

respond to fewer requests for proposals overall, since the program covers multiple countries in a single order. This reduces costly workloads associated with preparing separate outbound orders, export customs entries, transaction records, and invoices.

2. Freight Consolidation Reduces Shipping Costs

The strategy of the program for transporting ARVs focuses on meeting client country requirements at the lowest possible cost without compromising product integrity. This means balancing the use of ocean and air freight for manufacturer-to-country shipments. Air freight is the best choice when urgency is needed to avoid stock-outs, treatment interruptions, and significant program disruptions; otherwise, optimizing available lead time for orders allows for lower-cost shipment by ocean, which the program seeks whenever possible. In addition, road freight rather than air can be used on key lanes for

intra-Africa movements. The program strives to consolidate as many orders as possible into as few shipments as practical, leveraging the process to facilitate lower-cost modes of transport.

As shown in Figure 4, the proportion of ARV shipments transported via ocean to country programs increased from less than 10% in 2007 and 2008 (before we fully implemented the transport strategy) to over 75% between 2011 and 2014.⁶ The program estimates that between January 2007 and September 2011, USAID saved US\$34 million by leveraging lower-cost transportation to meet client countries' ARV needs.⁶

CONCLUSION

Through the use of supply chain risk mitigation strategies, particularly by pooling procurement and using regional distribution centers, the program has reduced ARV demand, supply, and cost risks. Among other key impacts, these strategies

Between 2007 and 2011, the project saved an estimated US\$34 million by leveraging lower-cost transportation.

have resulted in better central-level stock management in PEPFAR-supported countries, improved on-time delivery, and increased cost savings through ocean freight. There are other challenges affecting the in-country ARV supply chain related to human resource capacity, in-country distribution of commodities to treatment sites, reporting and ordering, and storage and infrastructure capacity, which international partners and host countries are addressing collaboratively.

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A stewardship approach to shaping the future of public health supply chain systems

Alan Bornbusch,^a Todd Dickens,^b Carolyn Hart,^c Chris Wright^c

Guiding Principles: (1) Governments should see themselves as stewards of supply chains, providing vision, guidance, and oversight, not necessarily as operators of supply chains. (2) Governments should not be afraid to leverage the multiple supply chain actors and diverse options available; these can be woven into a coherent, integrated system, providing flexibility and reducing risk. (3) Governments will need new skills in leadership, regulation, market research, contract design, oversight of outsourced providers, financial analysis, and alliance-building.

Picture this: *You are the Minister of Health, responsible for supporting the health of your citizens. Your mandate—your business—is to make sure their needs for services, supplies, and information are met to maintain or recover their health and to live productively in their communities. Lives depend on it, the economy depends on it, and your country depends on it. Part of that mandate is ensuring people can access affordable, quality drugs and other health products, but this is difficult and costly. The citizens you serve—your customers—are from every socioeconomic level and are scattered all over the country, many in very difficult-to-reach areas. And there are larger trends afoot that pose challenges and opportunities for you. How will you lead the effort to ensure an effective supply chain system?*

The global health community has until recently focused much of its attention on achieving relatively near-term goals, such as the 2015 Millennium Development Goals and the Family Planning 2020 goals. However, there is now growing interest in achieving longer-term end games that look a generation into the future, such as attaining universal health coverage, achieving an AIDS-free generation, and ending preventable child and maternal deaths. For those concerned with ensuring access to health commodities, these longer-term visions require a hard look at the supply chain systems of today: How well have they adapted to today's realities? And what must begin now in order to equip them to take advantage of future opportunities and to meet future challenges?

In the commercial sector, every successful enterprise asks similar questions. The answers begin with *knowing your business* and knowing that *your supply chain strategy serves your business strategy*. Taking a business approach means: Understanding your customers' needs and the resources you have available to meet those needs. Understanding your options for supply chain services. Knowing when it is in your comparative advantage to develop in-house capabilities and when to seek those capabilities elsewhere. Contracting with those that have the expertise you need and negotiating rates that provide good value and good services. Managing those contractors and monitoring customer satisfaction. Staying flexible and changing what does not work.

Our view is that this business approach can serve the public health sector as well as it serves the commercial sector. Incorporating it into the broader stewardship responsibilities of government is necessary if public health supply chain systems are to effectively adapt to changing development contexts.

CHANGING DYNAMICS

In just the last decade, low- and middle-income countries (LMICs) have seen significant economic growth,¹ with many experiencing economic transitions. This growth has presented opportunities for health financing, expansion of the retail market, and increases in private-sector logistics capacities. The mass penetration of mobile telecommunications is powering a revolution in access to information and enabling better management and greater transparency in supply chain systems. Changing demographics are helping to drive these developments, with continued

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Governments' core competency is not in operating supply chains but in being stewards of supply chains to ensure they achieve results.

population growth, a younger population eager for opportunity, and increased urbanization that is concentrating markets. Within the public health sector, the traditional emphasis on communicable diseases has yielded significant gains, while looming priorities will change to address noncommunicable diseases such as cancer, diabetes, asthma, and cardiovascular disease that disproportionately affect LMICs.² Decentralization of government services has increased the complexity of health services with a multitude of new stakeholders, financing options, and decision-makers. New donors and global initiatives have expanded funding sources. Health care consumers, civil society, and development partners are all demanding better performance and cost-effectiveness.

Meanwhile, configuration and management of public health supply chain systems has changed only gradually. These systems strain under the vastly increased volume of products brought by billions of dollars' worth of investments in vaccines, medicines, and supplies to prevent, diagnose, and treat diseases, support family planning programs, and more.³ Some investment has focused on strengthening existing in-country supply chains and creating alternative supply channels to compensate for underperforming systems or to respond to larger reforms in government services or the health sector. These investments have prevented collapse and have yielded gains in overall performance in terms of commodity availability. Millions of lives have been improved, and millions of deaths averted. However, these performance gains are tenuous, as are the health outcomes, unless public health leaders take a more business-like approach to challenge the status quo and ask of today's supply chain systems: "Is what we have today working as well as it needs to, and will it work for tomorrow?"

NEW OPPORTUNITIES, NEW PERSPECTIVES

The people responsible for public health supply chain systems—working in ministries, donor agencies, nongovernmental organizations (NGOs), technical agencies, etc—must expand their perspectives of their own roles as well as of the mission and composition of the supply chain systems they support. There are 3 guiding principles to keep in mind:

1. A government's role is one of stewardship in achieving common development goals.

Governments in particular must understand first and foremost that their core competency is *not* in operating supply chains, which has been their traditional role in centralized systems (Figure 1). Instead they must see themselves as *stewards* providing vision, guidance, and oversight to ensure that supply chains achieve results—serving the needs of customers to improve and maintain people's health. Stewardship does not require direct control of services and facilities; rather, stewards are responsible for engaging and orchestrating different partners to achieve common development goals.

2. Multiple players and diverse supply chain options can now contribute to public health outcomes.

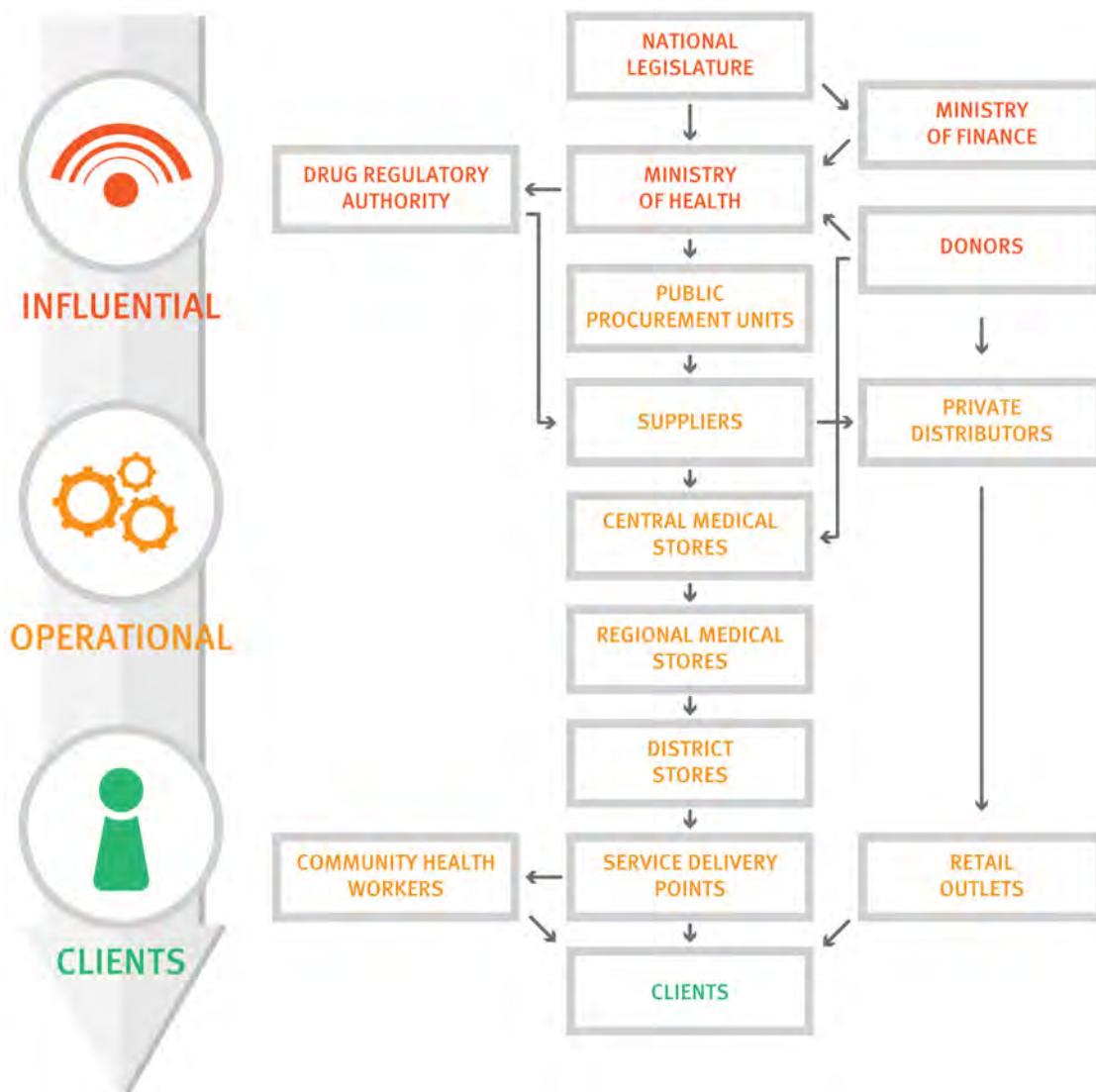
Stewards must expand their concept of what "supply chains" look like and embrace an increasing diversity of players. Traditional government-operated public health supply chains are an oversimplification and are becoming a thing of the past. In most countries today, the reality is that public health supply chain *systems* encompass multiple supply chains and involve a multi-sectoral range of public, private, faith-based, and NGO facilities and distributors; diverse operational agencies and practices; and people from many organizations and professions (Figure 2). Such complexity can become overwhelming but when well-understood (viz the overlay in Figure 2) and managed, these diverse supply chains and supply chain actors can be woven into a rationally integrated system (Figure 3). This can give stewards flexibility and prudent redundancy in funders, suppliers, distributors, procurement arrangements, and even in quality assurance, reducing risks of supply disruption and better serving all customers.⁴

3. Supply chains support broader public health outcomes.

Stewards must understand the intended impact of public health supply chains not simply in terms of distributing products but also in improving health outcomes and even broader development goals, such as increasing productivity and reducing poverty. The cost-benefit analysis of alternative supply chain models

Public health supply chain systems today encompass multiple supply chains and diverse players.

FIGURE 1. The Traditional Centralized Government-Operated Supply Chain



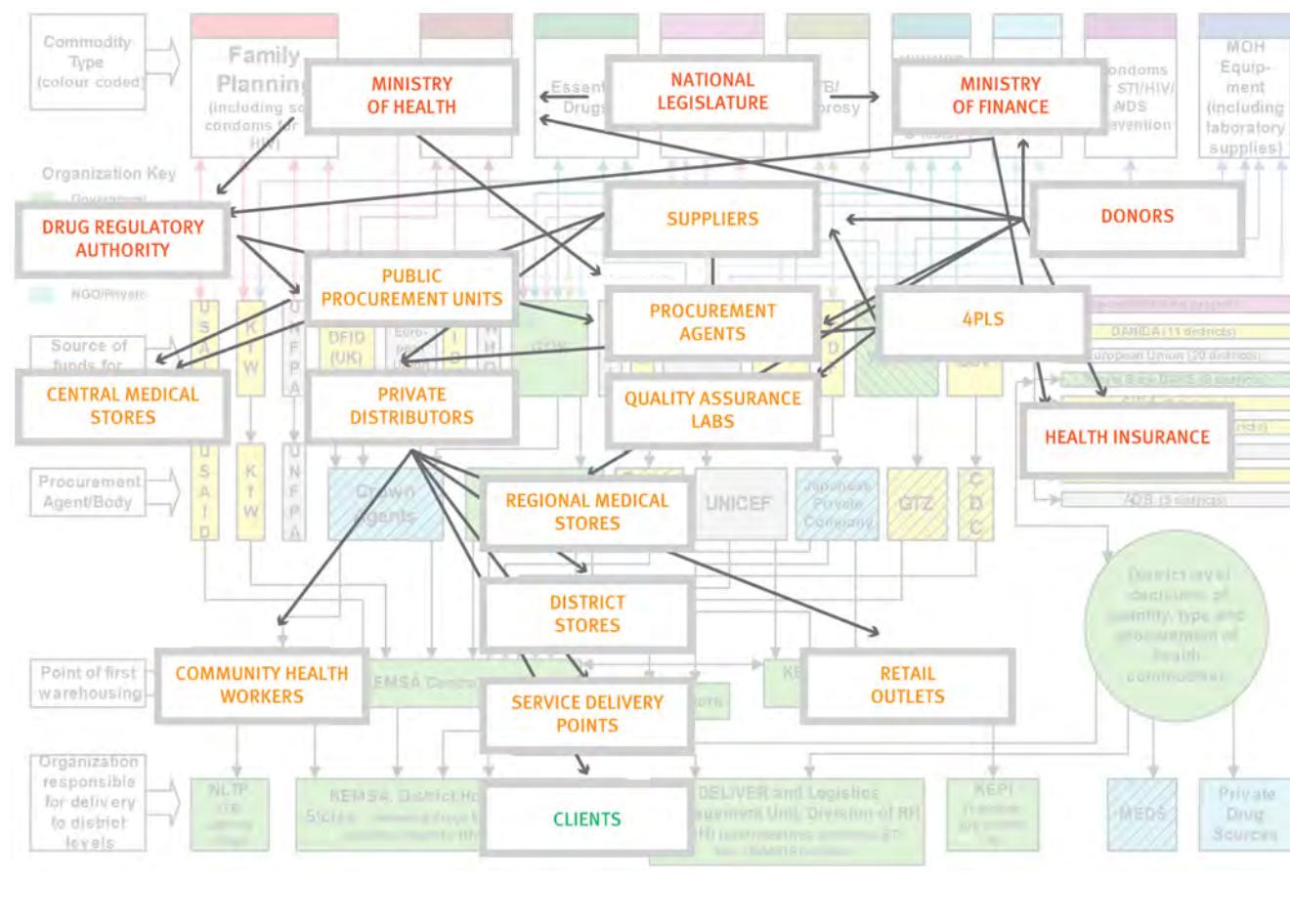
should expand to take into account these broader “bottom line” considerations.

EVOLVING TOWARD STEWARDSHIP, 3PLs, AND 4PLs

Ministries of health have traditionally operated public-sector supply chains through central medical stores and ministry motor pools.⁵ The norm has been control of supply chain *functions* through ownership of supply chain *assets*—people,

warehouses, vehicles, etc— in order to fulfill the social and political mandate of making medicines and other health commodities available. However, many governments have neither the expertise to operate efficient supply chains nor the career structures to enable professionalism and promote performance among supply chain workers. Yet the public sector is often reluctant to outsource to third-party logistics providers (3PLs) in the private sector, fearing loss of control or perceiving

FIGURE 2. Public Health Supply Chain Systems Today Comprise an Ecosystem of Operational and Influential Actors



Color coding as in Figure 1 (red, influential; orange, operational; green, clients).

Source: Adapted from Kinzett and Gelfed (2001).¹⁴

Outsourcing supply chain functions is increasingly common in low- and middle-income countries.

higher cost, conflict of interest, or misaligned motives.⁶ In addition to those fears, a very real impediment to effective outsourcing is a lack of contract management capacity within government. But just as supply systems need to evolve—from ad hoc activities to more organized approaches and finally to well-integrated systems⁷—stewards of the health sector must also evolve with them.

Outsourcing is increasingly common throughout LMICs for functions such as storage, transport, and procurement, and there are numerous instances of successful private-sector engagement in public health supply systems. Commercial or NGO 3PLs and distributors

supply both public and private facilities in Kenya, Malawi, Mozambique, Nigeria, South Africa, Tanzania, Uganda, Zimbabwe, and other countries. For procurement, many governments use services offered by UN agencies and private firms. A fourth-party logistics (4PL) strategy,⁸ for the design, optimization, and operation of supply chains, is increasingly recognized as a good investment in the public sector; 4PLs function as system integrators that coordinate quantification, plan and conduct procurement, and manage freight forwarders, customs clearance, and other 3PLs—essentially taking responsibility for end-to-end supply chain operations on behalf of a client.

FIGURE 3. An Integrated Supply Chain System



In an integrated supply chain system, people, functions, levels, and actors are linked and managed as an interconnected system.

At the same time, public agencies can or must fulfill some key roles. For example, e-procurement services for health commodities have been established in Chile⁵ and Indonesia,⁹ where the health minister credits the new service with reducing prices by 40%.¹⁰ Procurement has been decentralized in Bolivia, Colombia, and Ecuador, but the ministry of health (or its equivalent) prequalifies suppliers based on quality and reliability, and local/regional governments are allowed to procure only from prequalified suppliers.¹¹ Greater autonomy of central medical stores, outsourced management, or competition from alternative agencies has improved customer service in Botswana,⁵ Burkina Faso,¹² Chile, and Uganda.⁵ Among their many important responsibilities, national drug regulatory authorities play an important role in quality assurance (QA) for pharmaceuticals in both the public and private sectors. But where capacity is limited, functions like QA testing can be outsourced, as has been done in Tanzania for some locally procured and distributed medicines.¹³

Effective stewardship of a more diverse supply ecosystem requires not only new perspectives on roles but also new skills and capacities. These include the leadership to articulate a common vision, effective regulation, a robust capacity for market research, contract design, award and management and oversight of outsourced providers, expertise in modeling and financial analysis, and adept alliance-building among partners. Good stewardship also requires commitment to good governance—transparent procurement of goods and services, clear specifications and service-level agreements, and timely payment.

Let's be clear—adopting a stewardship role does not involve a reduction in responsibility. There can be no effective public health supply chains without the public sector playing its stewardship role across the policy and operational spectrum. Certain functions remain essential public responsibilities: regulating pharmaceuticals, setting essential medicines policy, defining benefits and services, crafting an overall supply system vision and strategy, overseeing public expenditure, and providing oversight of the health system in general.

POSITIONING SUPPLY CHAINS FOR THE FUTURE OF PUBLIC HEALTH

Effective supply systems must be able to respond to changes in health priorities, demographics,

Effective stewardship of a diverse supply ecosystem requires new skills, including leadership, regulation, and oversight.

Certain supply chain functions remain essential public responsibilities, such as regulating pharmaceuticals and setting essential medicines policy.

Effective supply systems must be nimble—they must be able to respond to changing development contexts.

manufacturing, technology, and financing. In short, they must be *nimble*. Governments typically are *not* nimble. But with appropriate skills, a good understanding of their stewardship responsibility, and a strategic vision of their health sector goals, governments can reengineer their public health supply systems to better serve their mandate and their business. Every country context is different, and no single combination of public and private engagement, nor any single approach, can be applied everywhere. But these principles are universal:

- **Know your business.** It is public health. The bottom line is saving and improving lives, which should be as powerful a motivator for rethinking supply systems as profit is in the commercial sector.
- **Focus on what only you can do.** Concentrate on your core competencies to be a steward (versus a provider) of public health.
- **Learn from the commercial sector.** Ensure leadership at the highest levels for rethinking your supply system, creating change, and pursuing continuous improvement.
- **Embrace diversity.** Identify and leverage the ecosystem of supply chain actors from the public, private, and semi-private sectors to get the job done well and efficiently.

Business leaders the world over recognize that cost-effective supply chains are essential and have given them the strategic vision and operational resources they require. Their success can be seen in the manufacturing, agriculture, technology, pharmaceutical, and retail sectors and can be measured on the bottom line. The same techniques that have achieved so much in commerce can be applied by public-sector stewards to the business of public health, strengthening supply chains that will lead to better health and better lives for men, women, and children.

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ORIGINAL ARTICLE

Demand generation activities and modern contraceptive use in urban areas of four countries: a longitudinal evaluation

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Demand generation activities that were significantly associated with increased use of modern contraception in India (Uttar Pradesh), Kenya, Nigeria, and Senegal included: (1) community outreach activities, such as home visits and group discussions about family planning; (2) local radio programs; and (3) branded slogans and print materials circulated widely across the city. Television programming was also significant in India and Nigeria. Exposure to more activities may increase women's likelihood of using contraception.

ABSTRACT

Family planning is crucial for preventing unintended pregnancies and for improving maternal and child health and well-being. In urban areas where there are large inequities in family planning use, particularly among the urban poor, programs are needed to increase access to and use of contraception among those most in need. This paper presents the midterm evaluation findings of the Urban Reproductive Health Initiative (Urban RH Initiative) programs, funded by the Bill & Melinda Gates Foundation, that are being implemented in 4 countries: India (Uttar Pradesh), Kenya, Nigeria, and Senegal. Between 2010 and 2013, the Measurement, Learning & Evaluation (MLE) project collected baseline and 2-year longitudinal follow-up data from women in target study cities to examine the role of demand generation activities undertaken as part of the Urban RH Initiative programs. Evaluation results demonstrate that, in each country where it was measured, outreach by community health or family planning workers as well as local radio programs were significantly associated with increased use of modern contraceptive methods. In addition, in India and Nigeria, television programs had a significant effect on modern contraceptive use, and in Kenya and Nigeria, the program slogans and materials that were blanketed across the cities (eg, leaflets/brochures distributed at health clinics and the program logo placed on all forms of materials, from market umbrellas to health facility signs and television programs) were also significantly associated with modern method use. Our results show that targeted, multilevel demand generation activities can make an important contribution to increasing modern contraceptive use in urban areas and could impact Millennium Development Goals for improved maternal and child health and access to reproductive health for all.

INTRODUCTION

Family planning helps save lives and can improve human welfare substantially. It prevents unintended pregnancies that may lead to abortion, limits the closely spaced and higher-order births most likely

to lead to maternal death, and reduces pregnancies that might result in infants being born with HIV infection.^{1–5} Family planning can lower fertility rates even in the poorest countries, making it more feasible to achieve long-term national goals related to universal education, poverty reduction, and improved environmental conditions.^{1,2}

Because of these manifold benefits, family planning is central to reaching the Millennium Development Goals (MDGs), specifically MDG Target 5.B, which is to attain universal access to reproductive health by 2015. This goal will continue beyond the MDG 2015 deadlines; in 2012, the global community launched the FP2020 initiative to reach 120 million new contraceptive users in developing countries by 2020.^{3,6}

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Countries that have made commitments under the FP2020 initiative are currently designing country-level strategies to increase access to and use of family planning.

Strong evaluation evidence is needed to inform these country-level family planning strategies. To date, much of the evidence is focused on short-term program outcomes (eg, with 6–18 month follow-up) and on geographically small programs or programs targeting specific groups.^{7,8} Some notable exceptions are the Matlab and Navrongo demographic surveillance sites that support longitudinal assessment of long-term impact,^{9–11} but these studies are based in rural settings. Rigorous, longitudinal evaluation evidence of family planning programs in urban settings is lacking.

As the world becomes more urbanized, cities—and slums within cities—are growing rapidly in high-fertility countries, resulting in an increased need to provide family planning and health services in urban settings.¹² While urban residents tend to have better access to and use of health services and better health outcomes, this “urban advantage” does not emerge across all urban residents.^{13,14} In particular, the urban poor tend to have larger family sizes, have less knowledge of and access to family planning methods and services, and are less likely to use contraception than wealthier urban residents.^{15,16} For example, in Uttar Pradesh, India, Speizer and colleagues¹⁵ showed that the urban poor were less likely than their wealthier counterparts to use family planning; among those who were using it, the poor were more likely than the wealthy to use sterilization. This suggests that the urban poor use spacing methods less and have less choice than wealthier urban residents. This disadvantage among the urban poor has been shown in multiple sub-Saharan African settings as well.¹⁶ Furthermore, in some cases, the urban poor have family planning and fertility indicators that are as modest as or are worse than their rural counterparts.¹⁶

To address the need for family planning in rapidly urbanizing areas, particularly among the urban poor, in 2009 the Bill & Melinda Gates Foundation launched the Urban Reproductive Health Initiative (Urban RH Initiative) in 4 countries: India (Uttar Pradesh), Kenya, Nigeria, and Senegal. The underlying goal of the Urban RH Initiative is to increase modern contraceptive use by 20 percentage points in targeted urban areas, particularly among the urban poor. Each country program aims to meet the following 5 key

objectives related to the supply, demand, and advocacy environments:

- Develop cost-effective interventions for integrating quality family planning with maternal and newborn health, HIV and AIDS, postpartum, and postabortion care programs (supply)
- Improve the quality of family planning services for the urban poor, with emphasis on high-volume clinical settings (supply)
- Test novel public-private partnerships and innovative private-sector approaches to increase access to and use of family planning by the urban poor (supply)
- Develop interventions for creating demand for and sustaining use of family planning among marginalized urban populations (demand)
- Increase funding and financial mechanisms and promote a supportive policy environment for ensuring access to family planning supplies and services for the urban poor (advocacy)

The locally designed programs of the Urban RH Initiative are being evaluated independently by the Measurement, Learning & Evaluation (MLE) project, which is led by the University of North Carolina at Chapel Hill Carolina Population Center in collaboration with the International Center for Research on Women. Findings from the MLE project will inform future family planning and reproductive health programs in the target countries and globally.

This article provides a summary of the Urban RH Initiative country programs, focusing on the demand creation activities, along with midterm (2-year) longitudinal evaluation results of the effect of the demand creation activities on modern contraceptive use.

URBAN RH INITIATIVE INTERVENTIONS

In each of the 4 countries, a consortium of local and international organizations have engaged together to increase modern contraceptive method use in target urban sites over the 4 to 5-year project period. [Table 1](#) presents a summary of key details about the country programs, including the initial intervention cities and the delayed intervention cities where the programs began after midterm (ie, start date about 2 years later). Country-level programmatic strategies to meet the above supply, demand, and advocacy objectives were informed by baseline quantitative and qualitative data from

The urban poor are less likely to use family planning than their wealthier counterparts.

TABLE 1. Summary of Urban Reproductive Health Initiative Country Programs

Country	Project Name, Lead, and Website	Initial Intervention Cities	Delayed Intervention Cities	Key Programmatic Strategies at Launch
India (Uttar Pradesh)	Urban Health Initiative (UHI), FHI 360, http://uhi-india.org/	<ul style="list-style-type: none"> Agra Aligarh Allahabad Gorakhpur 	<ul style="list-style-type: none"> Moradabad Varanasi 	<p>Demand Generation</p> <ul style="list-style-type: none"> Interpersonal communication: home visits by peer educators to provide women and men information, counseling, and referral; focus on LAPMs for pregnant women Mid-media: street plays, road shows, magic shows (low exposure) Mass media: radio and television with targeted messages <p>Supply Side Activities</p> <ul style="list-style-type: none"> Postpartum service integration: targeted FP information, counseling, and promotion during pregnancy and postpartum; ensure supplies and provider competencies to offer LAPMs Postabortion service integration: provide FP counseling and services during postabortion care Expand service delivery and quality <ul style="list-style-type: none"> Expand method choice Improve technical and client-provider interaction skills of providers Public-private partnerships <ul style="list-style-type: none"> Partnerships with Janani and other high-volume private facilities Strengthen routine and fixed day services for poor from slum communities Social marketing of condoms and pills <p>Advocacy</p> <ul style="list-style-type: none"> Focus on policy, advocacy, scale <p>Demand Generation</p> <ul style="list-style-type: none"> Generate demand by addressing social norms and barriers that inhibit FP use <ul style="list-style-type: none"> Community mobilization Wide distribution of print project materials Local and mass media, including radio and television shows targeted to urban poor and young audiences <p>Supply Side Activities</p> <ul style="list-style-type: none"> Improve quality and accessibility of FP services through integration of services. Focus on facilities: close to slum/informal settlements; with high-volume attendance; and with high usage from slum/informal settlements Ensure contraceptive security throughout the life of the project and beyond by addressing poor forecasting and developing electronic stock-out reporting system Engage formal and informal private sector: work with selected private nurses and clinical officers to offer high-quality and low-cost comprehensive FP services <p>Advocacy</p> <ul style="list-style-type: none"> Advocacy for improved policy environment Capacity building and sustainability: build capacity of local implementing partners, policy makers, private and public-sector providers to respond to FP/RH goals and needs
Kenya	Tupange ("Let's Plan"), Jhpiego, www.tupange.or.ke/	<ul style="list-style-type: none"> Nairobi Kisumu Mombasa 	<ul style="list-style-type: none"> Kakamega Machakos 	<p>Demand Generation</p> <ul style="list-style-type: none"> Generate demand by addressing social norms and barriers that inhibit FP use <ul style="list-style-type: none"> Community mobilization Wide distribution of print project materials Local and mass media, including radio and television shows targeted to urban poor and young audiences <p>Supply Side Activities</p> <ul style="list-style-type: none"> Improve quality and accessibility of FP services through integration of services. Focus on facilities: close to slum/informal settlements; with high-volume attendance; and with high usage from slum/informal settlements Ensure contraceptive security throughout the life of the project and beyond by addressing poor forecasting and developing electronic stock-out reporting system Engage formal and informal private sector: work with selected private nurses and clinical officers to offer high-quality and low-cost comprehensive FP services <p>Advocacy</p> <ul style="list-style-type: none"> Advocacy for improved policy environment Capacity building and sustainability: build capacity of local implementing partners, policy makers, private and public-sector providers to respond to FP/RH goals and needs

TABLE 1 (continued).

Country	Project Name, Lead, and Website	Initial Intervention Cities	Delayed Intervention Cities	Key Programmatic Strategies at Launch
Senegal	L'Initiative Sénégalaise de Santé Urbaine (ISSU) ("Senegal Urban Reproductive Health Initiative"), IntraHealth International, www.facebook.com/santeurbaine	<ul style="list-style-type: none"> Dakar Guédiawaye Pikine Mbao 	<ul style="list-style-type: none"> Mbour Kaolack (outside the region of Dakar) 	<p>Demand Generation</p> <ul style="list-style-type: none"> Outreach workers identifying FP needs Theater to promote discussion on a topic Small group discussions led by midwives with users to discuss FP-related topics Engagement of religious and community leaders to participate in and lead FP discussions Radio and television using public, private, and community-level stations <p>Supply Side Activities</p> <ul style="list-style-type: none"> Integration of FP into MCH services including postpartum and postabortion care <ul style="list-style-type: none"> Train providers to use cost-effective and evidence-based service delivery systematic screening tool to identify unmet FP needs Expand availability and quality of long-acting FP services in health facilities <ul style="list-style-type: none"> Train providers; ensure stock reliably available Integrate trained midwives into facilities to increase access to and availability of FP on a regular basis Outreach through mobile clinics targeting poor areas Social franchise strategies to increase access through the private sector <ul style="list-style-type: none"> Use Blue Star to increase access to FP in existing private-sector services
Nigeria	Nigerian Urban Reproductive Health Initiative (NURHI), Johns Hopkins Center for Communication Programs, www.nurhi.org/	<ul style="list-style-type: none"> Abuja Ibadan Ilorin Kaduna 	<ul style="list-style-type: none"> Benin City Zaria 	<p>Advocacy</p> <ul style="list-style-type: none"> Advocacy to create a favorable policy environment <p>Demand Generation</p> <ul style="list-style-type: none"> Social mobilization: interpersonal communication activities to encourage discussion and reduce barriers of miscommunication and social stigma to normalize FP, undertaken in various settings including markets, special events; spread of branded items in numerous community settings Media: radio and television at the state and local levels; use local-language slogans for specific city radio programs; radio magazine entertainment-education program <p>Supply Side Activities</p> <ul style="list-style-type: none"> Improve quality and integrate high-volume facilities: train providers, ensure stock, improve facility environment including quality standards Test novel public-private partnerships: Family Planning Providers Network trains, markets, and supplies providers with what they need to provide appropriate FP services and networks the providers together <ul style="list-style-type: none"> Clinical services: performance improvement to ensure that clinical providers offer full menu of methods with quality counseling and integrated services Patent Medicine Store/pharmacist: provide information, basic counseling, and non-clinical FP methods as first-line providers <p>Advocacy</p> <ul style="list-style-type: none"> Advocacy to promote FP discussions in public forum and to encourage acceptance at all levels

Abbreviations: FP, family planning; LAPMs, long-acting and permanent methods; MCH, maternal and child health.

each country (and city); this led to use of various media forms and messages and service delivery strategies designed specifically for the different contexts.

In **India**, the Urban Health Initiative (UHI) implemented the following demand creation interventions:

- Interpersonal communication activities, including home visits by peer educators (particularly to homes in slum communities) to provide family planning information, counseling, and referral to all women and men as well as to promote long-acting and permanent methods to women who had recently become pregnant
- Radio and television programs with targeted family planning messages to promote women's control over family planning, men's adoption of sterilization for a happy family, and the importance of long-acting and permanent method use after childbirth
- Some mid-media activities, including street plays, road shows, and magic shows; these activities are not assessed in this article as they were undertaken predominately in one city with low overall exposure

The demand creation activities of the **Kenya** Urban RH Initiative (Tupange) focused on addressing social norms and barriers that inhibit family planning use through:

- Community mobilization activities including distribution of consortium-developed print materials, such as posters, leaflets, and comic books
- Mass media activities using focused radio and television shows that targeted the young and poor. For example, one of the Kenya project partners developed the *Jongo Love* program, a 24-episode radio drama series set in a fictional urban slum in Kenya, called Jongo, featuring the complex lives and relationships of residents and relating these to the reproductive choices they make. This series aired in Kenya just before implementation of the midterm survey.

In **Senegal**, the in-country consortium, l'Initiative Sénégalaise de Santé Urbaine (ISSU), implemented numerous types of demand creation activities targeting women and men, such as:

- Augmentation of a cadre of community outreach workers who identified family planning needs and counseled and referred women to family planning services

- Small group discussions on family planning-related topics led by project-engaged midwives
- Engaging and training religious and community leaders to become family planning champions and to lead family planning discussions in their local communities and at religious events
- Community theater to promote discussions on family planning topics within the community and between the community and religious leaders
- Radio and television programs aired on local public and private stations

The **Nigerian** Urban RH Initiative (NURHI), because it is based on the theory that creating demand for family planning will drive supply and consequently lead to long-term sustainability of program activities, developed numerous demand generation activities that together are thought to influence behavior change. These activities include:

- Social mobilization through interpersonal communication activities that encourage discussion about family planning and reduce barriers, myths, miscommunication, and social stigma against family planning. These activities are undertaken at numerous venues such as markets, association meetings, and special events including naming ceremonies, freedom ceremonies, graduation events, Christmas/Eid celebrations, and weddings.
- Mass media with a particular focus on local and state-level radio programs that promote local-language family planning slogans and messages, radio magazine entertainment-education programs (radio shows with various magazine elements, such as listener interviews and "ask the expert" segments), and television spots that promote the program's family planning messages and slogans
- Program brand/slogans/logos were used across program activities (not just on the radio and television) and were also spread to the community through badges worn by health care providers, umbrellas exhibited at the market, posters/displays in health facilities, and t-shirts, bracelets, and other items that were distributed extensively

The demand generation activities across the countries had 3 main themes: (1) fostering dialogue about family planning; (2) increasing

BOX. Illustrative Themes of Family Planning Messages in Urban RH Initiative Programs

Foster dialogue about family planning at numerous venues

- Model fertility and family planning discussions between couples (television, radio shows, posters)
- Model and promote family planning discussions with providers (posters, buttons, pamphlets)
- Train religious leaders to discuss family planning in groups and one-on-one (especially with men)
- Encourage young people to talk to providers and peers about family planning (radio dramas and programs)
- Promote wider societal discussion of family planning (mass events, radio, television)

Increase social approval for family planning

- Model healthy and happy families (radio dramas, television, posters)
- Promote role of family planning in responsible parenting (radio dramas, television, posters)
- Promote family planning for healthy timing and spacing of pregnancies (outreach events, radio, television)
- Develop and focus on one's life goals and family planning's role in achieving those goals (radio drama, comic book, outreach)
- Recognize and address reproductive choices of young people, poor people, and women (radio, television, outreach)

Improve knowledge and perceptions of family planning methods

- Address potential contraceptive side effects, myths, and misconceptions (leaflets, booklets, radio dramas, discussion groups)
- Promote postpartum family planning use and adoption of long-acting methods (radio talk shows, facility health talks)
- Increase knowledge of method choice and sources of methods (leaflets, radio, television, outreach)

social approval for family planning; and (3) improving knowledge and perceptions of family planning methods (Box). Not all countries promoted all the messages included in the box, but most countries promoted messages from each of the 3 main themes.

DATA AND VARIABLES

In each country, the MLE study design involves collecting longitudinal data from a representative sample of women prior to program implementation (baseline), at midterm (2 years after baseline), and at endline (4 years after baseline). In India, Kenya, and Nigeria, the baseline and midterm surveys were conducted in 2010 and 2012, respectively, and the endline survey will occur in 2014. In Senegal, each survey round occurred/will occur 1 year later (ie, 2011, 2013, and 2015). This article presents the baseline and midterm longitudinal evaluation results of the demand creation activities.

At **baseline** in each country, the MLE project used a 2-stage sampling design to obtain a representative sample of women from each of the initial and delayed intervention cities. In the first stage, for the 3 African countries, representative samples of primary sampling units (PSUs) in project cities were selected based on a sampling frame from the most recent census. In India, where the most recent census was nearly 10 years old, the MLE team developed a sample frame based on geographic location of residence designed to ensure adequate representation of the urban poor and selected a representative sample of PSUs for each study city. (Details of the geographic-based sampling approach used in India are provided elsewhere.¹⁷) For details of sampling and stratification of PSUs in each country, see the study reports.^{18–21} At the second stage of selection, following listing and mapping of each PSU, a systematic random sample of households was selected for interview.

TABLE 2. Number of Women Interviewed in Baseline and Midterm Surveys, by Country

Country	Baseline, No.	Midterm, No. (% of Eligible Subsample Interviewed)	Samples for Longitudinal Analysis
India (Uttar Pradesh)	17,643	5,790 (85.8%)	4,029 women interviewed at both baseline and midterm and who, at baseline, were in union, had not been sterilized, and had not had a hysterectomy
Kenya	8,932	3,207 (56.1%)	3,205 women interviewed at both baseline and midterm, regardless of their marital status at either time period, with non-missing data
Nigeria	16,144	4,331 (64.6%)	4,303 women interviewed at both baseline and midterm, regardless of their marital status at either time period, with non-missing data
Senegal	9,614	2,744 (80.7%)	1,538 women interviewed at both baseline and midterm and who were in union at baseline

Source: Measurement, Learning & Evaluation project baseline^{18–21} and midterm^{22–25} surveys of the Urban RH Initiative country programs.

Within selected households, all eligible women were interviewed at baseline. All women ages 15–49 years at the time of survey were eligible; the women had to be in union in India but not in the 3 African countries. Representative samples from each city were obtained (Table 2). Descriptions of the baseline samples can be found in the baseline country-level reports.^{18–21} All data collection activities were approved by the Institutional Review Board at the University of North Carolina at Chapel Hill and by the respective in-country ethics review boards.

At **midterm**, we tracked all women but interviewed only a subsample of them (Table 2).^{22–25} The donor reduced the size and scope of the midterm survey to obtain rapid results that the programs could use to implement midcourse corrections. Thus, the midterm evaluation focused on the demand generation activities because program activities to improve quality of and access to family planning services had not yet been implemented by midterm at wide enough scale to influence outcomes. These supply side measures will be included as part of the endline evaluation in 2014/2015. In collaboration with each country consortium, the MLE team designed a midterm survey that captured the full extent of demand generation activities being undertaken in each country, including information about women's exposure to mass media, mid-media, and interpersonal communication activities.

For copies of the baseline and midterm questionnaires, see the MLE project website at: www.urbanreproductivehealth.org/.

The primary outcome of interest in this analysis is modern contraceptive method use in each study country. Modern methods were defined as female or male sterilization, intrauterine devices (IUDs), implants, injectables, oral contraceptive pills, emergency contraception, condoms, the Lactational Amenorrhea Method, and other modern methods including spermicides, diaphragms, and the dermal patch, as applicable in each country.

For the longitudinal analysis presented in this article, we used slightly different study samples based on country-specific considerations (Table 2). For example, in Senegal, the analysis sample excluded women who were not in union at baseline because there is little non-marital sexual activity in the Senegalese context.

This article includes descriptive characteristics of the women interviewed at both time periods for each study country. The main demographic variables included in all multivariate models were age group, education, wealth status, religion, and, for Kenya and Nigeria only, marital status. Wealth group was created within country across cities based on household assets at each time point using principal components methods as done in the Demographic and Health Surveys.²⁶ Thus, the wealth measures presented are based on the urban sample and provide a representation of which women were the poorest (and richest) in the urban areas under study.

The key exposure variables were country-specific variables related to specific program activities encompassing community activities, radio

and television programming, print materials, and engagement of religious leaders.

All descriptive analyses are weighted using country-specific weights. These weights adjust for uneven probabilities of selection and non-response.

Estimation of multivariate models of the impact of women's recall of program exposure on modern contraceptive use by country used samples within which each woman had two observations—one from baseline and one from midterm. Estimation involved random effects logistic regression of an indicator for each woman's modern contraceptive use as of the panel (baseline or midterm) taking into account her background characteristics and program exposure as of that panel. Program exposure was, by definition, zero at baseline in nearly all cases (with the exception of one program component in India that had already been started by baseline), while for midterm the woman's actual empirically observed program exposure was used. Estimation thus exploited two panels of longitudinal data. Random effects were used to control for the correlation of each woman's observations between baseline and midterm.

The longitudinal data and estimation design has several advantages. First, it simply admits more variation in the key variables allowing for generally more precise estimation of the parameters of the model. Second, the longitudinal design also permits examination of the possible endogeneity (sometimes referred to as "confounding") of the program exposure variables. Endogeneity involves possible correlation between interviewee recall of program exposure and some other unobserved determinants of modern contraceptive use that were not measured in the surveys, with the potential result that estimates of the impact of recall on modern contraceptive use will be biased. There are many potential unobserved determinants that might introduce such correlation (eg, cultural norms, preferences), but let us focus on health motivation as an example. If more motivated individuals are more likely to recall program exposure and to use contraception, then the intervening but unobserved motivation variable can lead to a misleading positive relationship between recall of program exposure and contraceptive use. Fortunately, one type of test of endogeneity can be exploited in the longitudinal data setting. The test involves comparison of results from an

efficient estimator (ie, lower sample-to-sample variation in estimates) that does not correct for possible endogeneity of program exposure (random effects is such an estimator) with a less efficient estimator that does correct for the potential endogeneity of program exposure (fixed effects is the classic choice in the longitudinal data setting). Put simply, if the estimates yielded by the two models are similar, this suggests endogeneity is not playing a major role and any observed impact on contraceptive use is likely due to women's recall of program exposure.

RESULTS

Baseline Demographic Characteristics

Table 3 presents the baseline demographic characteristics of the matched analysis sample by country. In Senegal and Uttar Pradesh, India, where the samples were of women in union, the analysis sample was older with fewer women in the 15–19 and 20–24 age groups. The samples in Kenya and Nigeria were somewhat more evenly distributed across the age groups.

Women in Senegal had the least formal education; 43% had no education or only Quranic education. India had a mixed educational distribution—about a quarter of women had no education (27%) and more than 60% had secondary or higher education. In Nigeria, about three-quarters of women had secondary or higher education, while in Kenya two-fifths had only primary education and more than half have secondary or higher; these relatively high education levels reflect the focus on major urban areas in this analysis.

Across the countries, the wealth groups calculated for these urban areas were nearly evenly split; the wealth groups were created as quintiles, so it is expected that about 20% would be in each category.

Senegal had the highest percentage of Muslims (94%) of the 4 countries. In Nigeria, about half the population was Muslim, and the remaining half were Christian (Protestant or Catholic). In Kenya, the majority of the women were Protestant (64%); Catholics were the next most common religious group (22%), followed by Muslims (12%). In India, the majority of the women were Hindu (81%), and the remainder were predominately Muslim.

The study's longitudinal design has several advantages, namely that it can correct for possible endogeneity (or confounding) of the program exposure variables.

TABLE 3. Baseline Demographic Characteristics of the Matched Baseline–Midterm Analysis Samples,^a by Country (%)

Characteristic	India (UP) (N=4,029)	Kenya (N=3,205)	Nigeria (N=4,303)	Senegal (N=1,538)
Age group				
15–19	3.48	9.42	16.17	3.99
20–24	18.75	25.15	15.21	14.42
25–29	24.28	23.64	18.65	18.49
30–34	21.84	15.97	16.52	19.92
35–39	15.73	12.33	14.39	18.38
40+	15.93	13.51	19.06	24.80
Education				
None/Quaranic	26.95	7.13	10.13	42.93
Primary	8.70	36.73	13.78	39.64
Secondary	36.99	39.80	48.49	15.67
Higher	27.35	16.34	26.70	1.77
Missing	0.00	0.00	0.89	0.00
Wealth group				
Poorest	22.50	16.76	14.49	15.49
Poor	21.44	19.66	17.92	22.53
Middle	18.90	21.26	19.95	26.43
Rich	19.11	21.67	22.41	19.28
Richest	18.05	20.64	25.22	16.27
Religion				
Hindi	80.98			
Catholic		21.96	5.05	
Protestant		63.86	42.01	
Muslim	19.01 ^b	12.04	52.23	94.11
Other ^c				5.89
No religion		2.08	0.05	
Missing		0.06	0.66	
Marital status				
Never married	NA	25.71	30.11	NA
In union	NA	63.37	65.83	NA
Separated/divorced/widowed	NA	10.91	4.07	NA

Abbreviation: NA, not applicable (sample includes only women in union); UP, Uttar Pradesh.

^a The matched analysis sample comprised, in India, women in union and not sterilized at baseline; in Kenya and Nigeria, all women; and in Senegal, women in union at baseline.

^b Includes "other" category.

^c Includes Christian and "other" categories.

Finally, in Kenya and Nigeria (where all women were included in the samples), about a quarter were never married, and the remainder were predominately currently in union (63% in Kenya and 66% in Nigeria).

Program Exposure Variables at Midterm

Table 4 presents the country-specific exposure variables at midterm. In each country, there are different levels of reported recall of exposure to each Urban RH Initiative activity.

TABLE 4. Percentage of Women^a Recalling Exposure to Specific Program Activities at Midterm, by Country

Program Activity	India (UP)	Kenya	Nigeria	Senegal
Exposure to CHW in the last 3 months	22.52			
Ever saw any UHI TV program ^b	41.52			
Ever heard any UHI radio program ^b	5.32			
Attended FP/Tupange meeting in the last year		11.49		
Saw Tupange leaflet in the last year		32.58		
Saw Tupange poster in the last year		43.16		
Saw Shujazz comic book in the last year		16.94		
Heard <i>Jongo Love</i> radio program in the last year		16.29		
Saw episode of <i>Matatu</i> TV program in the last year		22.33		
Heard or seen "NURHI" in the last year			23.01	
Ever heard of language-specific NURHI radio programs			28.96	
Heard NURHI phrases/slogans ^c in the last year			30.91	
Ever listened to language-specific NURHI radio programs			56.55	
Seen NURHI puzzle logo in the last year			26.81	
Received info on FP/birth spacing at a community event ^d in the last year			20.85	
Heard general FP messages on the radio in last 3 months			63.38	
Saw FP on TV in last 3 months (NURHI was only group with TV advertisements during project period)			59.29	
Heard at least 1 ISSU radio program in the last year				40.57
Saw at least 1 ISSU TV program in the last year				66.43
Participated in at least 1 ISSU community activity in the last year				22.31
Heard an FP radio advertisement in the last year				47.59
Heard religious leader speak favorably about FP in the last year				27.18

Abbreviations: CHW, community health worker; FP, family planning; ISSU, l'Initiative Sénégalaise de Santé Urbaine; NURHI, Nigerian Urban Reproductive Health Initiative; UHI, Urban Health Initiative; UP, Uttar Pradesh.

^a The matched analysis sample comprised, in India, women in union and not sterilized at baseline; in Kenya and Nigeria, all women; and in Senegal, women in union at baseline.

^b The midterm questionnaire for India asked specifically about 3 UHI spots: (1) *Sambhal lunga*, about a wife taking control and going to see a doctor and to use a contraceptive method; (2) *Munna*, in which a husband adopts male sterilization after talking to a doctor and has a happy married life afterwards; and (3) *Kishon Mein*, a story about a couple who adopts female sterilization at the time of delivery because they don't want any more children. Each was asked related to TV and radio exposure separately.

^c Includes "Get it Together"; "Know, Talk, Go"; "No Dulling"; and attending a family planning meeting led by someone wearing a program t-shirt.

^d Includes association meetings, naming and freedom ceremonies, graduation events, Christmas/Eid celebrations, and weddings.

In India, more than 40% of women recalled exposure to a UHI television program whereas 23% reported exposure to a community health worker (CHW) and only 5% to a UHI radio program.

In Kenya, the most common Tupange demand generation activity known by the women was the print media, comprising the Tupange leaflets (33%) and posters (43%). Among the remaining activities (including the comic book and radio and television programs), between 16%–22% of women reported exposure. Only 11% of women reported exposure to Tupange-led group/club/professional association meetings where family planning was discussed. Notably, in Kenya, the midterm questionnaire did not ask specific questions on exposure to community outreach workers; this oversight will be corrected at endline.

In Senegal, more than two-thirds of women recalled exposure to the ISSU television program and more than 40% recalled exposure to an ISSU radio program and a family planning radio advertisement. Close to a quarter of women recalled exposure to community activities (22%) or heard a religious leader speak favorably about family planning (27%).

Finally, in Nigeria, radio was a common source of general family planning information (64%), as well as language-specific NURHI radio programs (57%). Likewise, more than half of women reported at midterm that they recalled seeing family planning television advertisements. During the observation period (eg, 2010–2012), NURHI was the only group airing family planning messages on television. Among the other NURHI demand generation activities, between

20% and 30% of women were exposed to the logo, slogans, and community events.

Contraceptive Use at Baseline and Midterm

Table 5 presents the percentage of women using a contraceptive method (no method use, traditional method use, and modern method use) at baseline and midterm in each study country. Because our focus in this analysis is contraceptive adoption by midterm, we are particularly interested in the changes between the two time periods.

In India, we include two baseline measures: the distribution of use at baseline among women in the matched baseline–midterm analysis sample comprising women who were in union and not sterilized at baseline (ie, women with whom the family planning program could have an impact) as well as the baseline distribution of use among *all* women in union surveyed at midterm (to provide an accurate portrayal of baseline use in these Indian cities since sterilization is the most commonly used method). At baseline, in the full midterm sample (that includes some women who were sterilized at baseline), the prevalence of modern method use was 49% (Table 5, footnote b). Among the remaining women, about a third were non-users and 17% traditional method users. In the analysis sample, the percentage using at baseline was lower at 37%, and the percentages of women who were non-users and traditional method users were higher (39% and 24%, respectively) (Table 5). By midterm, the percentage of the analysis sample that was using a modern method (38%) was similar to the percentage using at baseline.

TABLE 5. Contraceptive Method Use Among Surveyed Women^a at Baseline and Midterm, by Country

Type of Method	India		Kenya		Nigeria		Senegal	
	Baseline ^b	Midterm	Baseline	Midterm	Baseline	Midterm	Baseline	Midterm
No method	39.10	37.12	50.99	46.46	68.89	61.29	71.04	66.12
Traditional method	24.24	25.32	4.23	7.81	7.83	8.92	2.94	2.36
Modern method	36.66	37.56	44.78	45.73	23.28	29.79	26.02	31.52

^a The matched analysis sample comprised, in India, women in union and not sterilized at baseline; in Kenya and Nigeria, all women; and in Senegal, women in union at baseline.

^b In India, when considering all women in union (including those who were sterilized at baseline) who were surveyed at midterm (N=5,790), at baseline, 48.91% were using a modern method, 17.19% were using a traditional method, and 33.89% were not using a method.

For Kenya, like India, the aggregate percentage of women using modern contraception between baseline and midterm remained about the same at 45%–46% among women surveyed at baseline and midterm. Use of traditional methods increased slightly between baseline and midterm.

In Nigeria and Senegal, modern contraceptive use increased by about 6–7 percentage points between baseline and midterm (Nigeria, 23% to 30%; Senegal, 26% to 32%). Traditional method use changed little in these two countries.

Overall, the results of modern method use in Table 5 are difficult to interpret because some women are aging in the follow-up period and thus are becoming more (or less) likely to use a modern method; multivariate analyses are needed to control for these aging effects as well as other factors such as education and wealth.

Multivariate Analyses: Is Program Exposure Associated With Modern Contraceptive Use?

The results of the multivariate random effects logistic regression models are presented in figures that show odds ratios (ORs) and their significance for the key program exposure variables by country. (Estimation results from corresponding fixed effects models were similar, indicating that endogeneity of the key exposure variables was likely not a problem and thus are not reported in favor of the more precise random effects estimates.) In all countries, the models controlled for age group, education, wealth, religion, and city of residence. In Senegal, the models also controlled for general family planning messages in the mass media but this was not found to be significant. In Kenya and Nigeria, marital status was included in the model since the analysis sample includes women who are in union as well as those who are not (never married, separated, or divorced). A small number of other country-specific control variables are also included in the models.

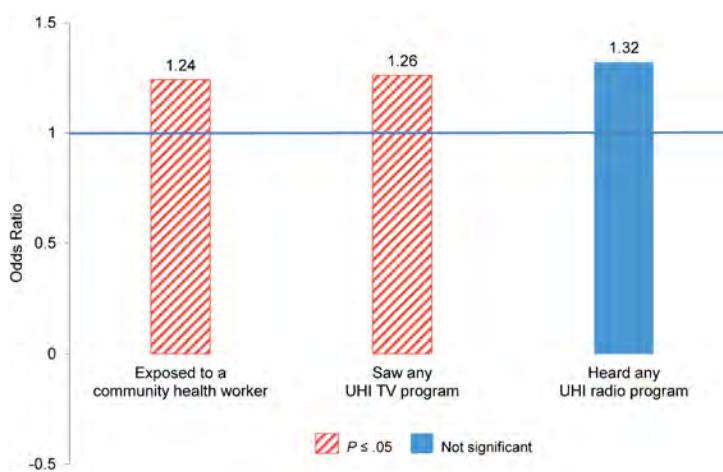
Figure 1 demonstrates that in India, women who recalled exposure to a CHW (OR=1.24; $P \leq .05$) and to any UHI television program (OR=1.26; $P \leq .05$) were significantly more likely to be modern method users at midterm than women who did not recall such exposure. While the odds ratio for UHI radio programs is large (OR=1.32), it was not significant in the random effects models. This may be related to low overall recall of exposure to radio programs, as shown in Table 4.

In Kenya, exposure to Tupange leaflets and brochures was significantly associated with modern contraceptive use between baseline and midterm (OR=1.37; $P \leq .05$) (Figure 2). In addition, exposure to Tupange's *Jongo Love* radio program was marginally significant (OR=1.29; $P \leq .10$).

In Senegal, women who reported participating in at least one ISSU-supported community activity, comprising a community conversation, a small group discussion, or outreach worker visits, were significantly more likely to be modern method users at midterm than women who did not report participating in any community activity (OR=1.62; $P \leq .05$) (Figure 3). This significance is notable given that it is the demand generation activity with the lowest reported exposure (22%). The other factor found to be marginally significant in Senegal is recalling hearing at least one ISSU-sponsored radio program in the last year (OR=1.35; $P \leq .10$). In these results, we did not find an effect of exposure to a religious leader speaking favorably about family planning on women's modern method use. However, in results not shown, when models were run using men's midterm data examining men's method use and attitudes

In India, exposure to UHI television programs was significantly associated with modern method use.

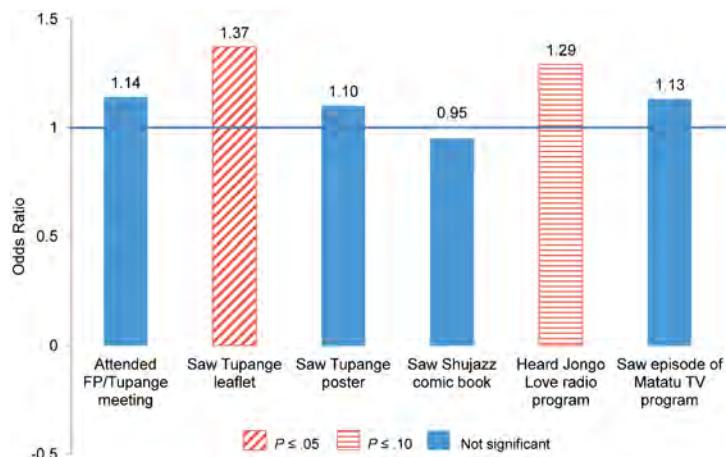
FIGURE 1. Odds Ratios From Random Effects Analysis of Demand Factors Associated With Modern Method Use Among Women in Union and Not Sterilized at Baseline in India



Abbreviation: UHI, Urban Health Initiative.

Model controls for age group, education, wealth, religion, city of residence, and other country-specific variables.

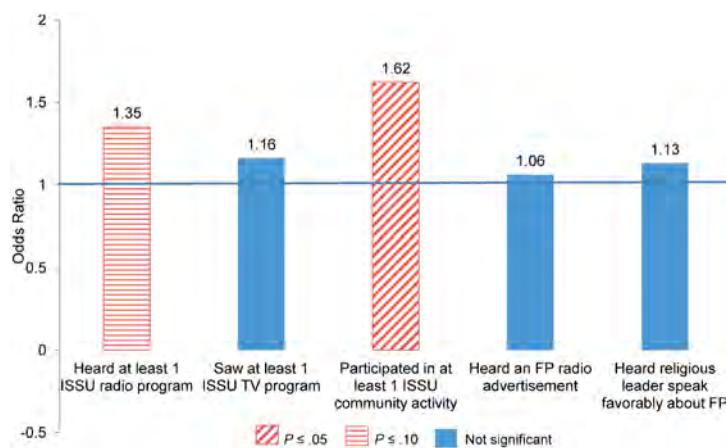
FIGURE 2. Odds Ratios From Random Effects Analysis of Demand Factors Associated With Modern Method Use Among Women in Kenya



Abbreviation: FP, family planning.

Model controls for age group, education, wealth, religion, city of residence, marital status, and other country-specific variables.

FIGURE 3. Odds Ratios From Random Effects Analysis of Demand Factors Associated With Modern Method Use Among Women in Union in Senegal

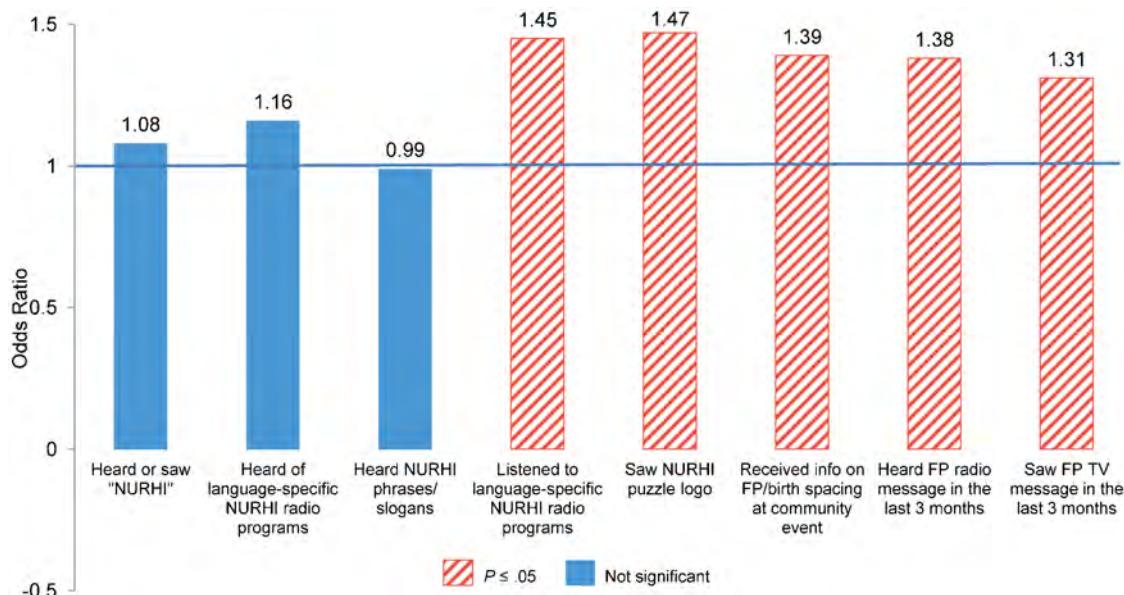


Abbreviations: FP, family planning; ISSU, l'Initiative Sénégalaise de Santé Urbaine.

Model controls for age group, education, wealth, religion, city of residence, and other country-specific variables.

toward family planning, we found that those men who recalled exposure to religious leaders speaking favorably about family planning were more likely to report family planning use as well as to have favorable family planning attitudes than men with no reported exposure to religious leaders ($P \leq .05$).

In Nigeria, women who recalled ever listening to local-language NURHI radio programs were significantly more likely to be modern method users at midterm than women who did not recall listening to these radio programs ($OR=1.45$; $P \leq .05$) (Figure 4). In addition, women who were familiar with the NURHI puzzle logo, a colorful logo that included the “Get It Together” slogan as part of the program branding, were also significantly more likely to be modern method users at midterm ($OR=1.47$; $P \leq .05$). The puzzle logo is used on all types of program materials, including on television, signs at health facilities, posters, and umbrellas. Women who recalled receiving information on family planning at any of the measured community events including association meetings, naming ceremonies, freedom ceremonies, graduation events, Christmas or Eid celebrations, and weddings, were significantly more likely to be modern method users at midterm than women who did not recall participating in these community events ($OR=1.39$; $P \leq .05$). Finally, women who recalled exposure to family planning messages on television in the last 3 months (considered to be NURHI television messages) were significantly more likely to be modern method users at midterm than women who did not recall exposure ($OR=1.31$; $P \leq .05$). A similar effect was found for exposure to general family planning messages on the radio ($OR=1.38$; $P \leq .05$), although this may have included non-NURHI radio activities as well. As noted earlier, the NURHI program has a strong focus on demand generation activities and theorizes that the multiple demand generation activities build upon one another. In results not shown, when women’s recall of exposure to demand generation activities are summed, those women who reported exposure to more activities were significantly more likely to be users of modern contraception at midterm than those exposed to fewer activities. This supports NURHI’s overall program theory of change. Similar results were found in analyses that summed up the key Tupange demand generation activities (also not shown).

FIGURE 4. Odds Ratios From Random Effects Analysis of Demand Factors Associated With Modern Method Use Among Women in Nigeria

Abbreviations: FP, family planning; NURHI, Nigerian Urban Reproductive Health Initiative.

Model controls for age group, education, wealth, religion, city of residence, marital status, and other country-specific variables.

DISCUSSION

To date, there is little rigorous evaluation evidence of family planning programs targeting urban areas due to difficulties in identifying comparison groups. These findings, which use longitudinal data from women in 14 initial program implementation cities, are a first step in informing future family planning programs in urban settings. Of note are the different study contexts. India and Kenya started at higher levels of modern contraceptive use than Nigeria and Senegal, but the types of contraceptive methods used were different in the countries, particularly among the urban poor. Most poor users in India used female sterilization whereas most poor users in Kenya used injectables.^{18–21} In Nigeria and Senegal, family planning use is lower overall than in India and Kenya, with a common reliance on injectables in both countries as well as on condoms in Nigeria and on pills in Senegal.

Several interesting and informative results about demand generation activities emerge from

our analysis. First, in each country where community outreach was measured, women who were exposed to community activities were significantly more likely than their counterparts who were not exposed to such activities to be modern method users at midterm. These findings are robust in the sense that models (ie, fixed effects) that explicitly correct for the potential endogeneity of program exposure (specifically, recall) offered similar results. In urban settings, it appears that interpersonal communication activities are important strategies for encouraging family planning use. Given that there continue to be a large percentage of women in urban settings that have myths and misconceptions about family planning,^{18–20} interactions with peers and health workers may be an influential strategy to change these problematic attitudes.

Second, local radio programs were also an effective means to encourage women to use family planning. Local radio programs were found to be significant in all 3 African countries but not in India, although the television programs in India that had the same themes (and greater exposure)



A roadside market umbrella in Mapo district in Ibadan, Nigeria, branded with the "Get it Together" NURHI puzzle logo, encourages people to "know" about family planning, "talk" with their partner about it, and "go" for family planning services.

as the radio programs were significant. Local radio programs were able to address specific concerns of urban, and particularly urban poor, populations as was done through Tupange's *Jongo Love* program in Kenya and through NURHI's radio magazine entertainment-education programs in Nigeria.

Television was also significant in India and Nigeria. In urban Nigeria, there is widespread access to television (about 89% of women in study cities watched television¹⁹) and thus can be an important approach to influence attitudes about and discussion of family planning topics in urban Nigerian settings.

In Kenya and Nigeria, specific program slogans and materials blanketed across the cities were found to be associated with increased modern method use. Program branding was less common in India and Senegal where the consortia worked to align their actions more closely with their respective government programs. These are strategic decisions that may be related to long-term program sustainability and that need to be made based on the country and urban context of future programs.

Notably, in Senegal, where religious leaders play an important role in daily life, we did not find an effect of exposure to religious leaders on women's contraceptive use. That said, in results not shown, recall of exposure to religious leaders was significantly related to men's reported approval and use of family planning. In a context such as Senegal, where more than 90% of the population is Muslim, it seems that working with influential religious leaders is an important strategy to influence contraceptive use directly

among men and indirectly among women through their husbands.

Each Urban RH Initiative country program used the results of the midterm evaluation to make midcourse corrections. For example, UHI in India put greater emphasis on CHWs and community outreach activities in slum areas. Also, consortium-led television activities in Kenya and Senegal were dropped while radio programming in Nigeria and Senegal was continued or expanded. In addition to the fact that television programming is expensive, in Kenya and Senegal, reported exposure to television did not have an effect on contraceptive use. In Senegal, ISSU's television program was aired a small number of times on a limited number of television stations but on stations and times that had high coverage. The television programs did lead to high exposure, but they did not necessarily lead to discussion of family planning and to program impacts. On the other hand, the local radio programs that aired numerous times in Senegal were more effective, even with lower overall exposure. In Kenya, the main television program aired, called *Matatu Sema Kitu*, was an interactive show in matatu (taxis) that aimed to foster dialogue about family planning. While there appears to have been wide viewership estimated by the program, the activity did not have a significant effect on contraceptive use.

Limitations

This analysis is not without limitations. First, because the midterm evaluation was seeking quick results for midcourse corrections, we did not obtain supply side information to determine whether short-term changes in quality and access to family planning may have influenced the results. Second, because we did not collect midterm data in the delayed intervention sites, we lack variation in the exposure variables that comes with comparison sites. Third, from the available data, it is not possible to know whether exposure preceded family planning use or vice versa; thus, the focus of this analysis is on associations rather than on causality. Fourth, the data do not permit an assessment of the *quality* of the CHW (or community event) interactions; this requires more in-depth, qualitative data. Fifth, the information on program exposure is based on respondent recall of family planning programs and messages. It is possible that other women were exposed but were already using family planning or, on the other hand, were exposed but

Working with influential religious leaders may be an important way to influence contraceptive use directly among men and indirectly among women through their husbands.

not interested in family planning and thus did not report recalling the messages. Future analyses that examine women's (and men's) ability to recall key messages, intensity of exposure, and length of exposure would be informative for understanding the relationships between demand generation activities and modern method use. Finally, because smaller numbers of women were surveyed at midterm than initially intended, it was not possible to examine the full scope of transitions in modern contraceptive use (adoption, discontinuation, switching, and non-use). The 2014/15 endline evaluation will survey a larger sample and permit a more refined assessment of contraceptive use patterns over time as well as of the association of changes in family planning use with program activities.

CONCLUSION

Targeted demand generation activities can make an important contribution to increasing modern contraceptive use in urban areas and could impact Millennium Development Goals for improved maternal and child health and access to reproductive health for all. These demand generation activities can be undertaken at multiple levels including community-level activities such as outreach by a health worker, a family planning worker, or a religious leader. Radio programs and, in particular, local radio programs that target key urban populations including younger and poorer groups are also likely to be successful at increasing modern method use.

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ORIGINAL ARTICLE

Using behavior change communication to lead a comprehensive family planning program: the Nigerian Urban Reproductive Health Initiative

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Greater exposure to a comprehensive family planning program in urban Nigeria that emphasized demand generation and communication theory was associated with improved ideation among women (their beliefs, ideas, and feelings about family planning), and more positive ideation was associated with greater contraceptive use, especially among the poor. Improving providers' knowledge, attitudes, and skills was also key. By the end of the observation period, outreach through mobile service delivery contributed nearly one-half of the project clinics' family planning services.

ABSTRACT

Background: The Nigerian Urban Reproductive Health Initiative (NURHI), a 6-year comprehensive family planning program (2009–2015) in 4 cities, intentionally applies communication theories to all program elements, not just the demand generation ones, relying mainly on a theory called ideation—the concept that contraceptive use is influenced by people's beliefs, ideas, and feelings and that changing these ideational factors can change people's behavior.

Program Description: The project used multiple communication channels to foster dialogue about family planning, increase social approval for it, and improve accurate knowledge about contraceptives. Mobile service delivery was started in the third year to improve access to clinical methods in slums.

Methods: Data from representative baseline (2010–11) and midterm (2012) surveys of women of reproductive age in the project cities were analyzed. We also used propensity score matching to create a statistically equivalent control group of women not exposed to project activities, and we examined service delivery data from NURHI-supported clinics (January 2011–May 2013) to determine the contribution of mobile services to total family planning services.

Results: Three years into the initiative, analysis of longitudinal data shows that use of modern contraceptives has increased in each city, varying from 2.3 to 15.5 percentage points, and that the observed increases were predicted by exposure to NURHI activities. Of note is that modern method use increased substantially among the poorest wealth quintiles in project cities, on average, by 8.4 percentage points. The more project activities women were exposed to, the greater their contraceptive use. For example, among women not using a modern method at baseline, contraceptive prevalence among those with no exposure by midterm was 19.1% vs. 43.4% among those with high exposure. Project exposure had a positive dose-response relationship with ideation, as did ideation and contraceptive use. By the end of the observation period, mobile services were contributing nearly 50% of total family planning services provided through NURHI-supported clinics. Propensity score matching found that the increase in contraceptive use in the 4 cities attributable to project exposure was 9.9 percentage points. Intention to use family planning in the next 12 months also increased by 7.5 to 10.2 percentage points across the 4 cities.

Conclusion: Demand-led family planning programs, in which demand generation is the driving force behind the design rather than the conventional, service delivery-oriented approach, may be more suitable in places where expressed demand for contraceptives is low.

INTRODUCTION

With a population of 169 million, Nigeria has some of the poorest measures of reproductive health in Africa, including an estimated maternal mortality ratio of 630 deaths per 100,000 live births

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NURHI uses communication methodologies to adapt each program activity and places more emphasis on demand generation activities than most other comprehensive family planning programs.

and an infant mortality rate of 69 per 1,000 live births.¹ The Government of Nigeria has committed to improving these indicators as part of the Millennium Development Goals (MDGs). For MDG 5 (improve maternal health), a pillar of achievement is increasing the contraceptive prevalence rate (CPR), a core driver of maternal and reproductive health.²

The Nigerian Urban Reproductive Health Initiative (NURHI), a comprehensive family planning program encompassing supply, demand, and advocacy interventions, aims to increase voluntary use of contraceptives by 20 percentage points in 4 large Nigerian cities (Abuja, Ibadan, Ilorin, and Kaduna), with the underlying goal of improving the health of Nigerian women and children. The program began in 2009 and is now in its sixth and final year of implementation. It is led by the Johns Hopkins Center for Communication Programs, in partnership with the Association for Reproductive and Family Health and the Center for Communication Programs Nigeria as well as other local organizations for specific implementation needs.

Similar projects are underway or have recently concluded in India (Uttar Pradesh), Kenya, and Senegal. All are funded by the Bill & Melinda Gates Foundation, and all use a similar basic structure built on the documented elements of successful family planning programming,³ although context, strategy, and implementation are very different in each country. The 5 objectives common to all the country initiatives are to:

- Integrate family planning into other health services
- Improve the quality of family planning services
- Build private-sector partnerships
- Increase demand for family planning
- Advocate an improved policy environment

NURHI and the other country initiatives are evaluated by an external evaluation project called the Measurement, Learning, & Evaluation (MLE) project. MLE has conducted baseline and midterm surveys to measure the impact of NURHI, and a final evaluation will be available in early 2015. For more information on the initiatives in India, Kenya, and Senegal, see the MLE website (www.urbanreproductivehealth.org), which is designed to share the learning from these programs.

The project's activities, which included performance improvement at facilities, training providers

in contraceptive provision, and ensuring efficient and effective commodity logistics systems, will be familiar to anyone who has designed and implemented a comprehensive family planning program; what NURHI has done differently than most programs is to use communication methodologies to adapt each activity—even the service delivery ones—and to put serious and sustained effort and resources into demand generation activities.

The NURHI initiative was designed based on the hypothesis that *when demand for family planning rises, supply will rise to meet the demand over time*. NURHI defines demand for family planning as the desire and ability among women and/or men to take action to plan their families. Our hypothesis does not imply that one can leave the supply side to itself; it simply reframes the often unstated but very real assumption built into some large-scale family planning programs that *if you build it, they will come*.

Creating demand for family planning was clearly a priority in Nigeria, as just a fraction of women were articulating a desire and need for family planning. For example, in the 2008 Nigeria Demographic and Health Survey,⁴ the national CPR for modern methods was 10.5% (with less than 2 percentage points of growth since the 1999 survey⁵) and 39% of women cited opposition to contraceptive use, but 20% had an unmet need and 21% intended to use contraception in the future. While designing the NURHI project, the Bill & Melinda Gates Foundation shared with program designers an overview of its 2008 reproductive health strategy, in which it estimated through its own calculations that “demand issues comprise 70% of the problem and, therefore, are an even larger driver for achievement of our goals.”

Furthermore, there are adequate sources of short-acting contraceptive methods in parts of the country, including through the nonprofit health sector (the public sector and nongovernmental organizations) and through a robust and entrepreneurial for-profit health care sector that includes patent medicine vendors (who serve as frontline health care providers for a large percentage of Nigerians), pharmacists, and an array of small to large-scale health facilities (general and maternity clinics and hospitals). Interestingly, the majority of family planning users in Nigeria already purchase their contraceptives from the nonclinical private sector.⁶ In NURHI's urban sites, the primary issue was thus not a lack of sites that could provide family planning services, but

rather than no one was asking for them. This was supported by the baseline survey, which found that under 1% of women in the 4 intervention cities cited cost, distance, or access as a reason for not using family planning.⁶

The purpose of this article is to describe the activities designed and implemented by NURHI to meet the project's stated objectives and to illustrate how having a demand lens influenced programming decisions in ways that other family planning programs probably would not have considered. We also present findings about the project's outcomes at midterm, primarily from the MLE evaluation surveys.

INTERVENTION DESIGN AND COMPONENTS

In this section, we introduce the theoretical foundation that underpins the NURHI project and describe in some detail each component of the project, including its formative research, demand generation activities, service delivery interventions, and advocacy activities. The research, strategies, and materials used to design and implement NURHI can be found at www.nurhitoolkit.org.

Theoretical Foundation

NURHI's overall design and strategy are driven by the project's *theory of change*. NURHI understands the barriers to contraceptive use in its intervention cities to be primarily ones of knowledge, attitudes, and social norms, and the causal pathway to improve the CPR is through changes in these factors at each level of society, from the individual up through communities, service sectors, and the policy environment. Communication is the driver of this change at every level, from demand creation at the individual level, to supportive supervision and training in interpersonal communication at the provider level, to advocacy at the policy level.

In developing strategies for demand generation, service delivery interventions, and advocacy, NURHI has made use of a communication theory called *ideation*. Ideation is the concept that people's actions are influenced strongly by their beliefs, ideas, and feelings ("ideational factors") and that changing them can change behavior, including contraceptive behavior (Figure 1).⁷ Some of these ideational factors are personal, such as what a person knows about family planning and how they think it will affect them. Others reflect social norms, such as what people believe other people will think of them if they use family planning. The

more positive ideational factors a person holds, the greater the likelihood the person will adopt the desired behavior.

While ideation has often been applied to designing demand generation interventions in family planning, we also applied the basic ideas of ideation to designing our service provision activities. We examined service providers' ideas, beliefs, and feelings about family planning, and adapted service delivery interventions to address them. For example, among the "ideas and feelings" that service providers hold is the common belief that women should not use family planning if they only have 1 or 2 children or if they are young, beliefs that pose a barrier to quality family planning provision. Ideation also includes knowledge, which, for a service provider, would encompass skills in clinical care.

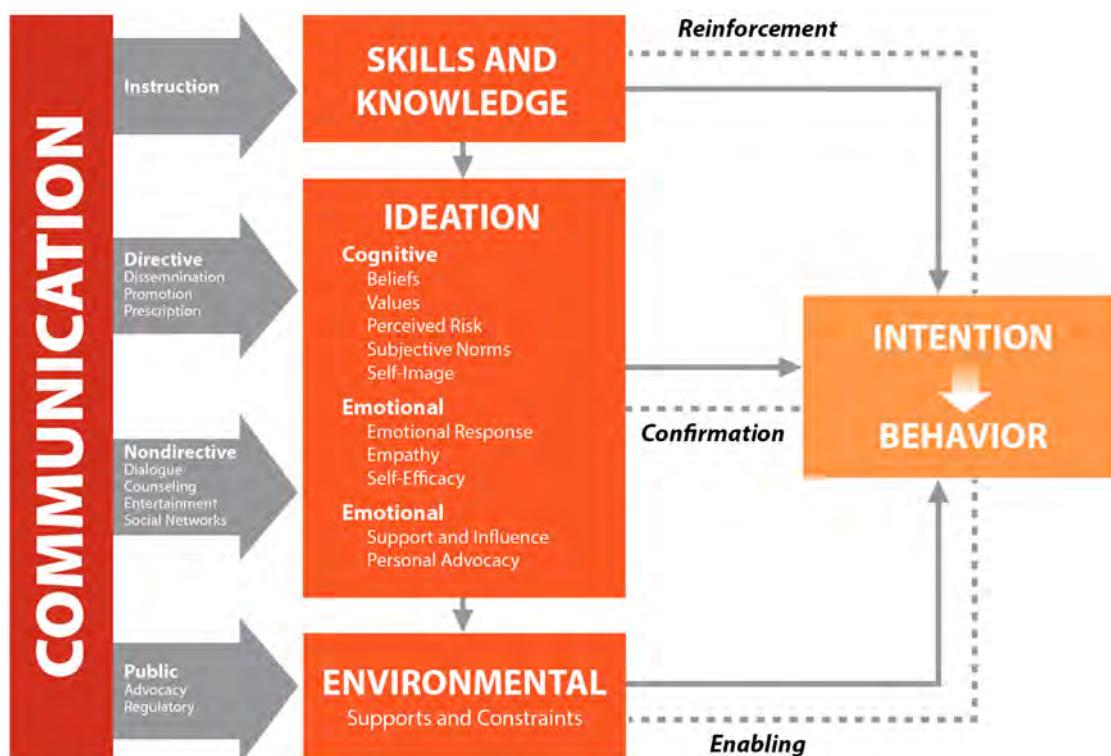
Formative Research

Reflecting our theory of change, we designed the formative research to explore potential barriers to contraceptive use related to knowledge, attitudes, and social norms, and to pay specific attention to ideational factors in both qualitative and quantitative research. The full set of formative research included a household baseline survey with men and women; focus group discussions with men and women (contraceptive users and non-users) and family planning providers of different cadres; a facility assessment survey; and a family planning social mapping survey in 3 of the project cities.

The NURHI project team worked with the MLE evaluation team to tailor the instruments used in the **baseline and midterm surveys** to measure indicators important to this communication-infused program. Questions were tailored to measure ideational factors (partner communication, beliefs and attitudes, correct knowledge, perceptions of peer support, self-efficacy, and perceptions of religious approval), which, taken together, are used as an index predictive of contraceptive use; changing these factors contributes to increased contraceptive use. We also tailored the evaluation to add a baseline survey of men, because although men are not family planning clients for most methods, they are integral to the decision-making process and NURHI needed information about their beliefs, needs, and desires.

Qualitative research with users and non-users as well as with service providers was used to complement the baseline survey findings.

The communication theory of ideation holds that people's behaviors are influenced by their beliefs, ideas, and feelings and that changing these ideational factors can change behavior.

FIGURE 1. Ideation Model of Communication

Source: Health Communication Capacity Collaborative (2014).⁸

The research with the providers uncovered and described the biases they held against certain types of clients and methods. Focus groups with men and women explored their beliefs, motivations, fears, and perceptions of use and non-use.

A number of important findings emerged from these quantitative and qualitative research methods (Box). Taken together, we concluded that a major barrier to contraceptive use in the project cities was fear and bias. NURHI's interpretation of these data is that people approve of family planning as a concept but believe individual methods are risky. Service providers believe it is their role to uphold social norms around family size, marriage, and spousal consent. These are major challenges, but ones that can be addressed using communication approaches—by encouraging people to talk about family planning and helping to make it a normal part of life, by providing accurate information about the safety of

contraceptive methods, and by helping providers use their clinical knowledge, rather than their personal values, in the counseling room. NURHI designed the project's demand generation, service delivery, and advocacy interventions to achieve these goals (Figure 2).

Demand Generation

NURHI's demand generation strategy for women and men focuses on demedicalizing and demystifying the practice of family planning, including fostering dialogue around family planning—in the home, on the street, at work, in the clinic, in the media; increasing understanding, appreciation, and social approval for planning one's family; improving knowledge and perceptions of family planning methods; and reinforcing existing contraceptive use and reducing discontinuation.¹³

The initial strategy included a 3-phase approach: Phase 1 was designed to increase access

In urban Nigeria, people approve of family planning as a concept but believe particular methods are risky.

BOX. Formative Research Findings Guide Program Design

The baseline survey provided the following essential information that guided the design of program interventions:

- Contraceptive prevalence was low in the 4 project cities, ranging from 19.6% in Kaduna to 33.3% in Ibadan. The majority of modern contraceptive users were using short-acting methods; for example, in Ibadan only 5.4% of married women used 1 of 3 long-acting or permanent methods available (sterilization, IUDs, implants).
- Most women cited no intention to use family planning in the next year (for example, in Ibadan only 7.5% of non-users intended to use contraceptives in the future). The main reasons women gave for not using contraception related to either being pregnant or wanting to be pregnant (36.7% of women in Abuja fit this profile) or having no/infrequent sex (36.2% in Abuja). This indicated to NURHI that a major challenge was to help people think about the benefits to spacing their children and planning their families.
- Fear of specific methods and misconceptions about their side effects was a major non-fertility related reason for not using contraception (in Kaduna, for example, 13.8% of women said they did not use contraceptives due to fear of side effects). The majority of women and men stated that they approved of family planning as a practice, but they held fearful and negative views of actual available methods.
- Despite high levels of awareness of contraceptives (over 90% of women knew of at least 1 method and where to get it), there was limited knowledge of clinical methods (IUDs, implants, and sterilization). Qualitative research showed that what “knowledge” there was of these methods was generally based on myths and misconceptions and contributed to fear of these methods.
- Of women who were using a method, most were using short-acting methods through private-sector pharmacies and drug shops rather than clinical methods from clinics or hospitals with a trained provider. This point dovetails with those above: Women did not know of clinical methods and what they did “know” was negative. Furthermore, women may not have seen access as a barrier because they were not trying to access clinical methods, where services may not be readily available.
- Women and men did not report discussing family planning, contraceptives, or their desired number of children. Spousal discussion is strongly predictive of family planning use,⁹ and so lack of discussion is a barrier.
- While women said religious approval was important, and some felt that their religion did not approve of family planning, a majority of women believed that they could use a contraceptive method despite religious disapproval, a surprising finding. Gender preference was also prevalent but not predictive of non-use, another surprising finding that shaped program interventions.

Qualitative research provided in-depth understanding of the barriers to family planning use:

- Focus groups with service providers showed that the providers had biases and myths and misconceptions about family planning that reflected those of the larger city populations. In particular, service providers believed women should have many children and should not use contraceptives to space them until they have already had a large family. They also disliked providing services to young women, unmarried women, and women with few children. The following quotes from in-depth interviews with service providers illustrate these medical barriers¹⁰:

We do not provide family planning to unmarried young girls because it can make them promiscuous.

—Female, 24 years old, middle income, head of nursing at a private clinic in Kaduna

I don't like attending to youth because of their involvement in what they are not due for. Also, I don't like attending to the unmarried people.

—Female, 18–29 years old, owner of patent medicine store in a slum in Ibadan

Furthermore, sometimes providers perpetuate biases and myths about contraception to potential family planning users. One 21-year-old married woman from Ibadan with 1 child said, “The advice given to us in the hospital is that the IUD is risky.”

- A survey of service providers at clinics and hospitals showed that they restricted access to certain methods based on a woman’s age, marital status, or parity rather than on medical eligibility. For example, 48% of providers restricted

access to injectables if they felt a woman has not had enough children; 60% restricted access to IUDs if a woman is not married; and 30% restricted access to pills without spousal consent.¹¹

- Focus groups with women and men found that a major barrier to family planning use was the need for women to obtain their husband's permission to use family planning, but women found it difficult to start a conversation about family planning with their husbands. Both men and women, in general, approved of planning one's family. However, men felt it was the women's responsibility to begin the family planning discussion, and women felt it was the men's responsibility, and so the conversation was not happening.
- Women and men described the need to plan a family as a way to ensure one had only the number of children one could "cater for," meaning feed, clothe, house, educate, and love. People saw children as a blessing and a gift but also as a great responsibility; they described this responsibility as the reason for supporting family planning. A 24-year-old married woman from Ibadan with 2 children and middle socioeconomic status explained¹²:

Having too many children is not good. Everyone knows his capacity, and I think it is necessary to limit your childbirth to what your capacity can take you. God will not come down from heaven to help.

- Aside from condoms, people viewed contraceptives as highly medical, requiring medical tests and a perfect fit with one's anatomy. Hormonal and clinical methods were seen as risky—more risky than giving birth to many children. A 30-year-old married man from Ibadan with 1 child and middle socioeconomic status described this fear, which was rooted in misconceptions about contraception¹¹:

I will advise her [his wife] not to do it. Family planning is very dangerous to a person's health. Great caution needs to be exercised.

- Women and men engaged in a social mapping exercise, which enabled the NURHI team to identify community locations that were key points for social interaction that could be used for social mobilization purposes, including markets, places of worship, and schools. It also generated information on commonly used and preferred service delivery points where NURHI could invest in quality improvement, commodity supply, and other service delivery interventions. As this exercise was qualitative and not comprehensive, preferred service delivery sites in NURHI project cities were also identified through the baseline survey.

to basic family planning information and to heighten awareness of family planning; Phase 2 meant to deepen understanding, discussion, and exploration around the concept of family planning and about specific methods; and Phase 3 was designed to increase the level and localization of communication efforts but was subsequently rolled in with Phase 2 based on timing issues.

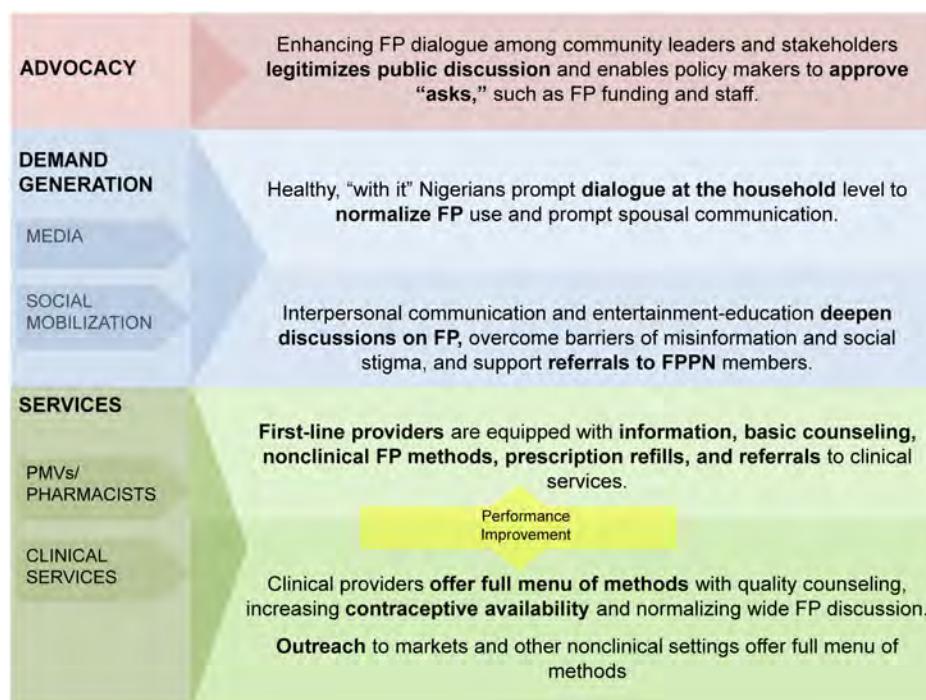
From the outset, NURHI's demand side activities have been orchestrated to mutually reinforce one another, in addition to being closely integrated with the service delivery and advocacy objectives. We use multiple communication channels, based on the theory that communication interventions have a synergistic impact, so that hearing or seeing messaging through more than one medium has more impact than hearing or seeing messaging in just one way. Furthermore, the communication activities operate at different levels of the socio-ecological environment, from the individual up through the community and to the policy environment, with messaging designed to address essential cognitive, emotional, and

normative ideational factors. The main NURHI demand generation activities consist of mass media, entertainment-education, social mobilization, and integrated branding with a memorable, colorful puzzle logo and tagline that helps tie all program activities together under one identity. The tagline is "Know. Talk. Go.", meaning "know" your family planning options, "talk" to your partner, and "go" for services.

Mass Media

A media campaign featuring the overarching puzzle logo and the "Know. Talk. Go." tagline uses radio and TV spots and print materials (eg, posters, umbrellas, flyers, t-shirts) to get the word out. Some of the scenes or materials illustrate partner communication; others show barbers or hairdressers discussing family planning with their friends in an open and easy way or couples going to clinics for services, allowing NURHI to model healthy, happy family planning users. For example, in one spot, a couple gets the happy news they are expecting a second child soon after stopping their contraceptive method,

NURHI employs multiple communication channels to spread the program's messages more effectively.

FIGURE 2. Nigerian Urban Reproductive Health Initiative (NURHI) Interventions

Abbreviations: FP, family planning; FPPN, Family Planning Providers Network; PMVs, patent medicine vendors.

refuting the myth of impaired fertility with contraceptive use.

Entertainment-Education

A 30-minute weekly radio magazine program (a radio show with various magazine elements, such as listener interviews and call-in “ask the expert” segments) was also produced and broadcast in each project city. These programs include additional content about contraceptive methods, they address myths and misconceptions, and they model discussion of family planning between spouses and with providers. In the initial plans, NURHI had expected to produce one program that could be translated for each location. However, to fully localize it to the specific city context, ultimately a unique program was designed for each site although the format remained consistent. The second phase of the radio programs integrates a live call-in component, with a quiz and an opportunity to ask questions to an “on-air” expert. Radio listening groups, formed within

the city environment, are convened on a weekly basis by social mobilizers to listen to and discuss the content of the programs, thus deepening the dialogue, reflection, and understanding of family planning.

Social Mobilization

NURHI social mobilizers were chosen not for their expertise in health but for their expertise in talking to people and making connections in their slum communities. In Nigeria, these are hairdressers, barbers, and tailors. Working through professional associations and community-based organizations, NURHI recruited mobilizers from these professions, trained them in family planning, and equipped them with materials, including “Know. Talk. Go.” referral cards. In addition to leading the radio listening groups, they talk to their clientele in their shops about family planning, mobilize clients for family planning outreach services, and discuss family planning at key life events, such as graduations and naming ceremonies. They are



A poster produced by the NURHI project for the “Get It Together” campaign encourages partners to discuss family planning together.

“72-Hour Clinic Makeovers” not only improved facility conditions but also engaged facility staff to value family planning.

now widely sought out by community members, as their participation is considered highly prestigious. This focus in the community has been critical to personalizing the agenda, making family planning a socially acceptable topic, and providing a bridge between the community members and the services. The mobilizers are not paid, which is both a strength and an ongoing challenge for retention and commitment. Recognition of their role and contribution to the well-being of others in the community has inspired many of the mobilizers to continue with the work.

Service Delivery

NURHI’s service delivery component is based on best practices in service integration and quality

improvement,^{3,14} but with the added dimension of treating service providers as an audience for behavior change. The formative research identified key biases among providers related to their attitudes toward family planning, the provision of specific methods, and the women who seek services. Many providers lacked basic family planning knowledge and, in many instances, the technical competency to provide particular services. As NURHI launched and program staff spent time in clinical facilities, it also became apparent that the decrepit family planning facilities (lack of privacy for clients, lack of running water, leaking roofs, dirty floors and walls) were not just an issue of hygiene or safety; they also indicated to providers how little family planning mattered to hospital administrators, which was demotivating to staff.

The issue of **decrepit facilities** is illustrative of how we approached a supply intervention (renovating the facilities) with a demand lens. NURHI viewed the decrepit facilities as an indicator of the ideas and feelings (the ideation) of stakeholders, policy makers, the larger community, and service providers, specifically that they lacked motivation for and did not value family planning. The solution therefore involved advocacy with local stakeholders, engagement with facility administrators, participation of facility staff in the renovation process (coined as the “72-Hour Clinic Makeover”), and a launch of a “new and improved” family planning facility that built support for the providers in their community. It is important to note that the facility renovations generally entailed a coat of fresh paint, scrubbing, connecting a sink to the hospital’s water line, and making sure contraceptive commodities and equipment were on hand—not, in most cases, major costs or construction.

NURHI also applies a demand lens to improving **counseling sessions between providers and clients**, which we consider to be critical episodes of interpersonal communication. We have ensured that provider training sessions include ample time and priority for interpersonal communication and counseling. In addition, we have made sure that providers have the tools they need to counsel their clients well to provide voluntary, free choice of methods, and we have developed those materials to seamlessly integrate with demand generation outside the clinic walls. For example, counseling materials and job aids were part of the overall NURHI communication approach, with consistent branding, creative

approach, and messaging so that both clients and providers would associate what happens inside the clinic with the television, radio, and interpersonal communication they were exposed to in the community.

Finally, our **selection of service sites** for the project's clinical interventions was informed by communication approaches by first considering, through the baseline household survey, women's preferences, needs, and behaviors regarding where they access health services. We matched that input with sites with a high volume of clients and also asked women where they spent time in their community, so we had an idea of where we could reach women outside of the clinic. Using this information, we selected service delivery points for clinical quality improvement, almost all of which were public-sector facilities where clinical services were available, plus a broad network of mostly private, nonclinical service delivery sites where providers expressed interest in family planning. We connected all of these providers through a new branded network called the "Family Planning Providers Network" to ensure access to the full basket of services in every project city. We also adopted and adapted a clinical service outreach model to fill a gap in clinical services in slum neighborhoods, in which we provide services on advertised days in tents in markets and in small health posts with no regular family planning providers. These outreach visits are linked to our demand generation work, by using social mobilizers to promote the outreach events and make referrals to them.

Advocacy

In NURHI's view, policy makers and traditional and religious leaders—as well as service providers—are important audiences in need of communication and "demand generation" just as much as the general public. The difference is in the kind of information they need and in how they can access that information.

Baseline research showed that hearing a religious leader voice support for family planning was an important ideational factor for women and men in Nigeria.⁶ NURHI enlists prominent leaders of multiple faiths to speak publicly and in the media about family planning. The project also developed advocacy kits for each city's policy makers, many of whom are motivated to make progress toward the MDGs, that synthesized baseline data at the city level and highlighted MDG-related trends and how family planning could



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A couple attends a family planning counseling session in Ibadan, Nigeria.

impact them. In each city, we also formed advocacy groups that included all interested partners working to improve family planning, and these groups oversaw the development and use of the advocacy kits and took ownership for progress.

While funds for family planning are often allocated in State and Local Government Area budgets, the funds are often not released so that family planning coordinators and facilities can actually use them. Through intensive communication and mentoring, NURHI staff coached government staff in the intricacies of local-level budgeting, requesting processes, and spending decisions, with the result that modest amounts of funding began flowing in many Local Government Areas, where the funds had been previously "stuck."

METHODS

Data on the outcomes of the NURHI project come primarily from analysis of the MLE baseline and midterm surveys. The surveys are representative of men and women of reproductive age in each NURHI project city. The same women were interviewed for the baseline and midterm surveys, providing a unique longitudinal sample in which sophisticated analytical techniques could be applied to have greater confidence that results of the project could be attributed to exposure to the interventions.¹⁵ (The men's survey was cross-sectional, however.) The baseline survey of

Outreach through mobile service delivery provided access to clinical methods in hard-to-reach slum neighborhoods.

NURHI enlists prominent faith leaders to speak publicly and in the media about family planning.

women and men was conducted in 2010–2011 and the midterm survey of women in 2012.^{6,16}

We also conducted additional analysis of the MLE data using a technique called propensity score matching (PSM). This technique allowed us to estimate the probability (propensity) that a woman will be exposed to the program activities and to create an unexposed control group that is statistically equivalent to those exposed. Using PSM, we estimated what the CPR *would have been* among the women exposed to the NURHI project had they not been exposed to it. The difference between the CPR of the women exposed to the NURHI project and the estimated CPR of those same women had they not been exposed is considered the treatment effect of the intervention.

Finally, we performed secondary analysis of the MLE data to determine whether there was a positive relationship between communication activities and ideation (factors such as beliefs, spousal discussion, perceived peer behavior, perceived self-efficacy, and personal advocacy), and whether there was a positive relationship between ideation and contraceptive use. Specifically, 32 ideational items were measured across 3 domains: cognitive, emotional, and social interaction. The items included aspects of contraceptive awareness (12 items), myths and rumors about contraceptives (8 items), perceived self-efficacy to take action regarding contraceptive use (7 items), and approval of leaders talking about family planning (2 items), as well as descriptive norms about contraceptive use in one's community, personal advocacy for family planning, and perceived social support for personal use of contraceptives. The resulting scores were then categorized into quintiles denoting women's overall level of ideation: very low (8 items or fewer), low (9–10 items), medium (11–12 items), high (13–15 items), or very high (16 or more items).

In addition to exploring the effect of demand generation activities on contraceptive use, we also examined service delivery data from NURHI-supported clinics between January 2011 through May 2013 to determine the proportion of clinic-provided family planning services attributed to outreach visits.

RESULTS

Program Exposure

The MLE midterm survey measured people's exposure to various NURHI messages and strategies and computed overall exposure to the

NURHI program by summing up people's exposure to multiple items. Overall program exposure is presented in 4 categories:

1. No exposure
2. Low (knew of 1 or 2 NURHI activities)
3. Medium (knew 3–6 activities)
4. High (knew 7 or more activities)

About 80% of women in the 4 project cities reported some exposure to the NURHI project: 24% reported low exposure, 32% medium, and 25% high, with the remaining 19% reporting no exposure.¹⁶

Myths and Misconceptions

Between baseline and midterm, the percentage of women who believed in myths or had misconceptions about contraception declined. For example, the percentage of women who believed incorrectly that "contraceptives are dangerous to your health" dropped by 17 percentage points in Ilorin, from 37.4% to 20.4%, and by about 15 percentage points in Ibadan, from 57.1% to 42.2%.¹⁶ Similarly, the percentage who believed that "contraceptives can harm your womb" decreased by 15.7 percentage points in Ilorin, from 33.6% to 17.9%; by 12.5 percentage points in Ibadan, from 49.8% to 37.3%; and by 9 percentage points in Abuja, from 33.4% to 24.1%.¹⁶

Intention to Use Contraception

In each project city, there was a significant upward trend in the percentage of women intending to use contraception. For example, in Abuja and Ibadan, the percentage of women who intended to use contraception in the next 12 months increased significantly by 10 percentage points in each city, from 13.9% to 23.5% in Abuja and from 7.5% to 17.7% in Ibadan (Figure 3). In Ilorin and Kaduna, intention to use increased significantly by nearly 8 percentage points in each city.

Contraceptive Use at Baseline and Midterm

Between baseline and midterm, use of modern methods among married women increased in each city, although the change varied widely between the 4 cities (Table 1). For example, in Abuja, 31.9% of married women were using modern contraception at baseline; the percentage increased slightly at midterm to 34.2%, but the change was not statistically significant. On the other hand, in Kaduna, the modern CPR increased

Women's ideation scores were based on 32 variables across cognitive, emotional, and social interaction domains.

Intention to use contraception in the future increased in each project city.

by 15.5 percentage points between baseline and midterm, from 19.6% to 35.1% ($P < .001$).

One factor in those differences is the difference in the modern CPR at baseline between the cities. In Kaduna, for example, the low level of contraceptive use (19.6%) at the start of the project may have represented pent-up need for access to family planning services, resulting in the notable improvement at midterm. The cities differ demographically, politically, culturally, and religiously, and these factors may also have contributed to the different results in each city. It is interesting to note, however, that the modern CPR in the 4 cities at midterm is similar (between 34.2% and 36.9%), whereas the rates were more variable at baseline (between 19.6% and 33.3%). In addition, of note is that the modern CPR increased substantially among the poorest wealth quintiles in NURHI project cities, on average, by 8.4 percentage points.¹⁷

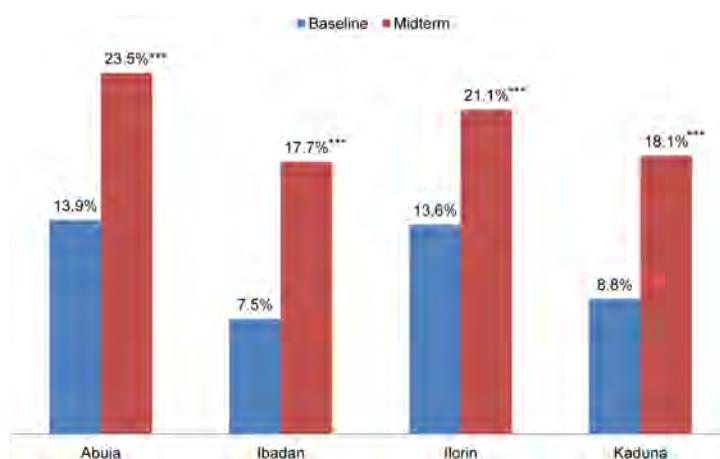
Contraceptive Use by Level of Exposure to the NURHI Program

Longitudinal data from the MLE baseline and midterm surveys show that (reported) exposure to several of the NURHI communication interventions was significantly associated with higher levels of contraceptive use. The greatest effects were associated with exposure to the local-language radio entertainment-education programs, social mobilization activities, and television spots.¹⁵

Analysis of CPR data by women’s reported level of exposure to NURHI project activities shows that, among married women not using a modern method at baseline, 19.1% were using contraception at midterm among those reporting no exposure to NURHI activities compared with 32.1% among those with low exposure (Figure 4). Contraceptive prevalence increased positively and linearly with greater exposure (medium exposure, 34.6%; high exposure, 43.4%).

We used propensity score matching to better understand whether changes in behavior (contraceptive use) were attributable to exposure to NURHI’s demand generation activities. This analysis showed that the CPR among the matched control group would have been 25.9% had the women not been exposed to the NURHI program, compared with the actual (observed) CPR of 35.8%. These data suggest that the increase in contraceptive use (ie, the treatment effect) attributed to exposure to the program was 9.9 percentage points.

FIGURE 3. Percentage of Women Not Currently Using Contraception Who Intend to Use a Method in the Next 12 Months at Baseline (2010/11) and Midterm (2012), by NURHI Project City



*** $P < .001$.

Ideational Factors and Contraceptive Use

Analysis of longitudinal data from the baseline and midterm surveys also finds that 9 of 10 measured ideational factors increased significantly. For instance, the percentage of women who perceived there was peer support for family planning increased significantly from 22.8% to 42.4% ($P < .001$) between baseline and midterm (Table 2). Similarly, the percentage of women who had positive attitudes toward family planning rose from 53.7% to 70.9% ($P < .001$).

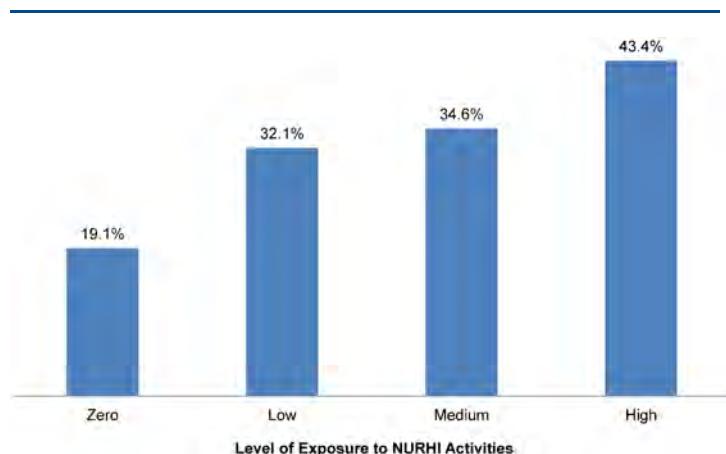
Contraceptive prevalence increased positively and linearly with greater exposure to NURHI activities.

TABLE 1. Modern Contraceptive Prevalence Rate Among Married Women, at Baseline and Midterm, by NURHI Project City

City	Baseline	Midterm	Percentage Point Change
Abuja	31.9%	34.2%	+2.3
Ibadan	33.3%	36.9%	+3.6*
Ilorin	26.9%	34.9%	+8.0***
Kaduna	19.6%	35.1%	+15.5***

* $P < .05$; *** $P < .001$.

FIGURE 4. Contraceptive Prevalence at Midterm Among Married Women Who Were Not Using a Modern Method at Baseline, by Level of Exposure to NURHI Activities, N=1,992



Significance of differences across groups: $P < .001$.

The data also show that level of exposure to program activities had a positive dose-response relationship with these ideational factors. For example, the percentage of women who perceived there was peer support for family planning increased by 6.2 percentage points among women reporting no program exposure, and the percen-

tage increased significantly and linearly with each level of exposure: from a 17.9 percentage point increase among women with low exposure to a 26.7 percentage point increase among women with high exposure (Figure 5).

Furthermore, analysis of CPR data by women's level of ideation shows that the more positive ideational factors that women had, the greater their contraceptive use. Among women not using a modern method at baseline, 15.9% of those with very low ideation at midterm were using contraception compared with 28.2% of those with medium ideation and 47.3% of those with very high ideation (Figure 6).

Contribution of Clinical Outreach

Figure 7 shows the contribution of clinical outreach to the total number of clients served by the high-volume sites where NURHI has trained and supported providers. Between 2009 and 2011, the NURHI project worked with selected public-sector sites to improve their facilities and quality of services. In the third year of the project (2012), NURHI began dispatching family planning outreach staff to hard-to-reach slum areas. Between January 2011 and May 2013, the number of family planning users served by NURHI-supported facilities steadily increased, from about 1,000 users per month to about 7,000 total users in May 2013 (Figure 7). In 2012, when NURHI started conducting outreach visits, the outreach visits contributed, on average, about 15% of these total family planning users, and the share increased to 31% in the fourth year of the project. At the end of the observation period, outreach visits were contributing nearly half of total clinical services supported by NURHI. Note that the full number of contraceptive users is better represented by data from the midterm survey since women access many sources for family planning, including private-sector providers such as pharmacists and drug shop owners.

DISCUSSION

While changes to the contraceptive prevalence rate in the cities where NURHI works have been variable, sophisticated analysis of the longitudinal data indicate that NURHI's demand generation activities are indeed significantly associated with increased contraceptive use in the cities. In particular, the data support the theoretical foundation on which NURHI was based—that is, the communication theory that holds that



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Members of a radio listeners' club listen to and discuss the family planning radio magazine and drama, *Second Chance*, produced by NURHI.

TABLE 2. Ten Ideation Factors at Baseline and Midterm That Predict Contraceptive Use

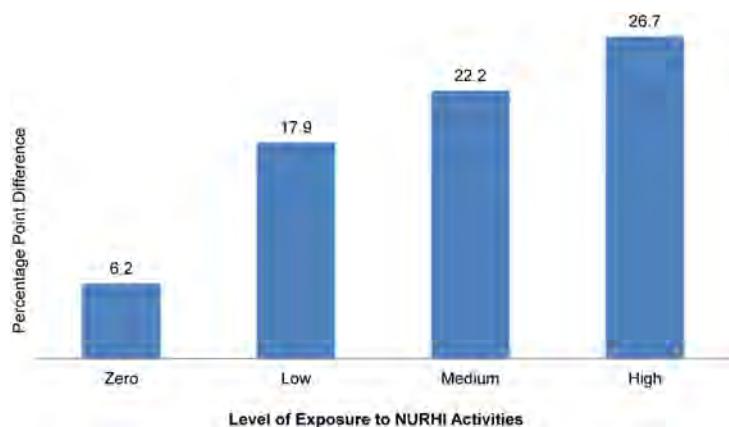
Ideation Factor	Description	Baseline	Midterm	Significance of Change
Contraceptive methods knowledge	Percent of married or cohabiting women with knowledge of at least 3 modern methods	55.5%	69.2%	$P < .001$
Beliefs/attitudes about family planning	Percent of married or cohabiting women with highly positive attitudes toward family planning	53.7%	70.9%	$P < .001$
Attitudes toward government officials talking about family planning	Percent of married or cohabiting women who approved of government officials speaking publicly about family planning	83.0%	91.4%	$P < .001$
Attitudes toward religious officials talking about family planning	Percent of married or cohabiting women who approved of religious leaders speaking publicly about family planning	58.6%	72.2%	$P < .001$
Spousal communication	Percent of married or cohabiting women who discussed the number of children with spouse during the last 6 months	29.8%	30.8%	Not significant
	Percent of married or cohabiting women who needed spousal permission to use family planning	75.4%	77.4%	Not significant
Perceived peer behavior	Percent of married or cohabiting women with most friends using a modern contraceptive method	8.2%	17.6%	$P < .001$
Perceived self-efficacy	Mean score for perceived self-efficacy to take relevant actions in favor of contraceptive use (range, 0–6)	3.1	3.6	$P < .001$
Family size preferences	Percent of married or cohabiting women who indicated wanting families of 3 or fewer children	14.7%	17.4%	$P < .05$
Perceived peer support	Percent of married or cohabiting women who perceived peer support for family planning	22.8%	42.4%	$P < .001$
Personal advocacy	Percent of married or cohabiting women who encouraged friends to go for family planning services	17.1%	24.2%	$P < .001$

changing ideational factors, such as knowledge, attitudes, and beliefs, increases the chances of changing people's behavior. Women's use of contraception at midterm increased linearly with increasing levels of ideation. Similar findings have been reported in Bangladesh, Burkina Faso, and the Philippines.^{18–20} Ideational factors can be thought of as *positive* risk factors, similar to how certain behaviors are risk factors for disease. For example, just as obesity, diet, exercise, and genetics are all risk factors for heart disease, ideational factors are "risk factors" for the positive behavior of family planning. And just

as with risk factors for heart disease, the more factors a person has, the more likely that person is to have the outcome, in this case, contraceptive use. When designing family planning programs, this means that program planners can consider the entire scope of ideational factors that are predictive of contraceptive use and select a group of factors to target that are: (1) currently not prevalent, so there is room for growth, and (2) amenable to change. Ideal family size, for example, is an important ideational factor, but it may not always be feasible for programs to address for both practical and political reasons.

The more positive ideational factors that women had, the greater their contraceptive use.

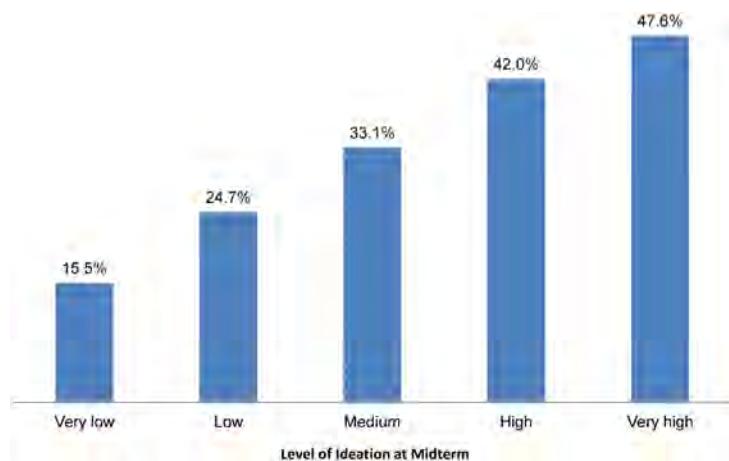
FIGURE 5. Change in Perceived Peer Support for Family Planning Between Baseline and Midterm, By Level of Exposure to NURHI Activities, N=4,331



Significance of change in perceived peer support is $P < .05$ for zero exposure and $P < .0001$ for low, medium, and high levels of exposure.

Data from the NURHI project also demonstrate that using a combination of communication channels, such as mass media, interpersonal, and

FIGURE 6. Contraceptive Prevalence at Midterm Among Married Women Who Were Not Using a Modern Method at Baseline, by Level of Ideation at Midterm, N=1,992



Significance of differences across groups: $P < .001$.

communication channels, enhances the effect of communication interventions. Exposure to more NURHI communication activities was associated both with higher levels of ideation among women and with higher levels of contraceptive use. In this way, communication works like a drug, with a dose-response effect.²¹ As the “dose” (number of communication activities to which a person is exposed) increases, so does the impact on ideation and contraceptive use. It is not simply that more exposure to the same communication increases response, but that exposure to multiple channels of communication increases response. This is one reason why NURHI was designed with television, radio, social mobilization, and clinic-based communication interventions—to maximize the types of interventions people experience. Another reason to use multiple communication channels is to maximize the chance of exposure in general, as no one channel reaches everyone. In addition, different channels have different uses, for example, radio is useful for modeling change through entertainment-education while interpersonal communication helps to deepen knowledge; together, the messages communicated through multiple channels become mutually reinforcing.

Intention to use contraceptives is an important indicator for NURHI, because it gives an indication of likely future users—women who might not be ready to use contraception now due to pregnancy or other factors but who want to plan their families. In each NURHI project city, there was an upward trend in the percentage of women saying they intended to use contraception in the next 12 months. In an analysis of data from 27 Demographic and Health Surveys conducted between 1993 and 1996, for each 1% increase in intention to use contraception, there was nearly a 1% rise in contraceptive adoption.²²

Clinical outreach through mobile services played an important role in improving contraceptive use. Women responded enthusiastically to having family planning services brought to their own neighborhoods. By the end of the observation period, nearly one-half of the services provided by NURHI-supported public-sector clinics came from these outreach visits. Mobile service delivery has shown great success in other projects.²³ In the urban slums supported by NURHI, women do, technically, have access to family planning facilities within a reasonable distance. But NURHI’s mobile services put the convenience and needs of family planning users first, by having service providers travel to them,

FIGURE 7. Family Planning Users Served by NURHI-Supported Clinics and Through Associated Outreach Visits, January 2011–May 2013



On average, outreach visits contributed, in the third year of the project, 15.2% of total family planning services provided by NURHI-supported clinics and 31% in the fourth project year.

rather than expecting women to travel to the service provider.

Many large-scale family planning programs tend to be “service-led,” that is, informed by a service-delivery and health systems strengthening approach. Such a program would typically be managed by a partner known for its service delivery expertise and budgeted with service delivery absorbing the majority of program funds, with service delivery needs setting the tone and pace of the project. If supported adequately by demand generation and other high-impact practices,⁶ the service-led approach may be the appropriate design for a given context. However, given that demand generation and communication interventions have been shown to increase family planning use in Nigeria and elsewhere,^{24–26} it is worth exploring whether an alternative project strategy is effective.

An alternative strategy is for a “demand-led” program, such as that of the NURHI project, which was designed with demand generation as its driving force. What does it mean for a family planning project to be demand-led rather than service-led? It means that from the outset of design, program planners put potential and current family planning users at the forefront, along with their barriers and challenges to using

family planning and their desires and hopes. With that insight as a starting point, the demand-led project would *then* design the appropriate systems, supplies, provider inputs, and communication interventions needed to serve the potential and current users. While using this approach, NURHI has come to see the locus of the program as the space between husband and wife, or between romantic partners, rather than at the clinic. The catalyst happens in the home; the rest of the (very substantial) work involves making sure the couple is supported and enabled, both in the community and in the clinic, to plan their family.

We cannot yet assert whether the demand-led approach is effecting the CPR *faster* than the standard approach, but we can say that it is working. The NURHI hypothesis is that at some point, when CPR has reached a high enough level, family planning will become an ordinary part of family life, and people will feel that their community supports it to such an extent that demand for family planning will be self-maintaining. It is at that point that demand will truly drive supply, leading to sustained demand with providers working to meet it. That does not mean that no further investment will be needed when this occurs; health systems must be

By May 2013, outreach visits were contributing nearly half of total clinic family planning services supported by NURHI.

A “demand-led” family planning program puts potential and current family planning users at the forefront and uses demand generation as its driving force.

Investing in making family planning a social norm will lead, in time, to self-sustaining levels of demand for contraception.

funded. But NURHI does believe that an investment in making family planning a social norm—whereby women perceive contraceptive use is ubiquitous, approved, and supported by family, community, and influential leaders—will lead, in time, to a level of demand that will prevent the CPR from falling back down to the low levels now common in some countries such as Nigeria. We have not gotten there yet, but we are headed in the right direction.

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ORIGINAL ARTICLE

Strengthening government management capacity to scale up HIV prevention programs through the use of Technical Support Units: lessons from Karnataka state, India

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A Technical Support Unit of managerial and technical experts, embedded in but distinct from the government, provided support in 5 key areas: strategic planning; monitoring and evaluation; supportive supervision; training; and information, education, and communication. This model likely contributed to effective and rapid scale up of Karnataka state's HIV prevention program. A clear mandate, close collaboration, and well-defined roles were keys to success.

ABSTRACT

Scaling up HIV prevention programming among key populations (female sex workers and men who have sex with men) has been a central strategy of the Government of India. However, state governments have lacked the technical and managerial capacity to oversee and scale up interventions or to absorb donor-funded programs. In response, the national government contracted Technical Support Units (TSUs), teams with expertise from the private and nongovernmental sectors, to collaborate with and assist state governments. In 2008, a TSU was established in Karnataka, one of 6 Indian states with the highest HIV prevalence in the country and where monitoring showed that its prevention programs were reaching only 5% of key populations. The TSU provided support to the state in 5 key areas: assisting in strategic planning, rolling out a comprehensive monitoring and evaluation system, providing supportive supervision to intervention units, facilitating training, and assisting with information, education, and communication activities. This collaborative management model helped to increase capacity of the state, enabling it to take over funding and oversight of HIV prevention programs previously funded through donors. With the combined efforts of the TSU and the state government, the number of intervention units statewide increased from 40 to 126 between 2009 and 2013. Monthly contacts with female sex workers increased from 5% in 2008 to 88% in 2012, and with men who have sex with men, from 36% in 2009 to 81% in 2012. There were also increases in the proportion of both populations who visited HIV testing and counseling centers (from 3% to 47% among female sex workers and from 6% to 33% among men who have sex with men) and sexually transmitted infection clinics (from 4% to 75% among female sex workers and from 7% to 67% among men who have sex with men). Changes in sexual behaviors among key populations were also documented. For example, between 2008 and 2010, the proportion of surveyed female sex workers in 9 districts reporting that they used a condom at last intercourse rose from 60% to 68%; in 6 districts, the proportion of surveyed men who have sex with men reporting that they used a condom at last anal sex increased from 89% to 97%. The Karnataka experience suggests that TSUs can help governments enhance managerial and technical resources and leverage funds more effectively. With careful management of the working and reporting relationships between the TSU and the state government, this additional capacity can pave the way for the government to improve and scale up programs and to absorb previously donor-funded programs.

INTRODUCTION

Scaling up national public health programs requires governments to have strong coordination, management, and technical capacity. A wide range of skills is needed to develop and issue policies, strategies, and implementation guidelines; manage and administer funds; procure commodities; manage systems and human resources; implement programs; provide technical

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and managerial support to programs; and monitor and evaluate them. However, in most settings, resource-limited or not, governments are often unable to act effectively across such a wide spectrum of program needs, because they lack either the human resources and the broad range of needed skills or the appropriate structures and processes. The Government of India’s HIV prevention programming illustrates both this issue and a potential solution: insourcing expertise and skills from the private and nonprofit sector through a Technical Support Unit (TSU) to provide rapid, flexible support in a way that government systems cannot always manage.

In this article, we describe the background to the formation of TSUs in India, and show how a TSU was formed in the state of Karnataka, how it worked, and what the results were. This article consolidates the experience of stakeholders involved in the design and implementation of technical assistance in India, including government, donors, and implementing partners.

SCALING UP HIV PREVENTION IN INDIA

The Government of India conceptualizes its HIV/AIDS response in 5-year strategic plans called the National AIDS Control Programme (NACP).¹ The government’s third such program (NACP-III), which ran from 2007 to 2012, prioritized HIV prevention among key populations, including female sex workers and men who have sex with men, as one of its main pillars, because of the disproportionately high rate of infection within these groups and the possibility of HIV transmission from members of these groups to members of the more general population.² Two-thirds of the budget was allocated to prevention programming, with the goal of scaling up the number of prevention interventions to ensure high levels of coverage.^{3,4} In the context of NACP-III, scaling up referred to increasing coverage of key populations so that they all had access to HIV prevention programs as well as to increasing the quality of these programs.

To facilitate this scale up, NACP-III called for decentralized planning and implementation of the program. While the national body (the National AIDS Control Organisation, or NACO) was responsible for setting policies and guidance, responsibility for implementation in each of the then 28 Indian states fell to each State AIDS Prevention and Control Society (SACS). As part of the national strategy, program implementation was outsourced

to nongovernmental organizations (NGOs) and community-based organizations (Figure 1), which were directly contracted by the SACS. These were known as intervention units. Outsourcing implementation to NGOs in the health sector is common in India and not limited to HIV/AIDS programs. The SACS, however, was ultimately responsible for the state’s performance and for ensuring that the response achieved adequate scale and coverage.

A key strategy of the national government under NACP-III was to strengthen program management and technical capacity of the SACS.^{2,5} A lesson learned during the previous national strategy period, NACP-II (2000–2006), was the importance of supportive supervision—direct and intensive technical and management support of interventions—and constant capacity building of the SACS and NGOs to improve the coverage and quality of services. The state government was well-equipped to perform its core skills of administration, procurement, release of funds, and audits. However, it lacked key technical and program management skills to implement the programs. The SACS, in particular, lacked both the human resources and the skills needed to manage such programs, particularly as delivered by a network of intervention units.

FIGURE 1. India’s Strategy for Sourcing Capabilities to Accelerate Scale Up of the HIV Prevention Program Among Key Populations



Abbreviations: CBOs, community-based organizations; NGOs, nongovernmental organizations.

The national government mandated state AIDS agencies to form Technical Support Units to strengthen their management and technical capacity.

In the early 2000s, some Indian states had experimented with Project Management Units—externally funded groups of experts who helped government teams with program design, evaluation, and reporting. NACO recognized the value of these units, but they had been formed on an ad hoc basis, so the government decided to standardize the approach. NACP-III conceptualized Technical Support Units (TSUs), including roles and responsibility, structure, and skills, and it mandated their formation for most states across the country to help with scaling up HIV prevention programming (Figure 1). Most TSUs were funded directly by the federal government, while a few were supported by donor agencies.

THE MANDATE, FUNCTION, AND STRUCTURE OF TSUs

TSUs are management units contracted by NACO and embedded within the SACS to provide technical and management support to the implementation of HIV prevention programs among key populations. Each TSU is comprised of experts from the private and nonprofit sector. The TSU is responsible for all technical aspects of the program, while administrative functions (procurement and finances) remain with government staff. The TSU ensures that national policies and strategies are implemented at the state level by working in close coordination with the SACS and providing capacity building and direct implementation support to intervention units. While the overall aim of the TSU is the same as that of the SACS—to support HIV prevention among key populations—it focuses on specific areas to ensure program scale and coverage and complements the skill set found within the SACS (Figure 2). It also ensures that program planning and implementation are evidence-driven and improves program accountability by strengthening monitoring and evaluation (M&E) systems.

The TSU model is different from a traditional model of providing technical support to governments by seconding staff. Crucially, the staff of each TSU is not part of the SACS itself; instead, each TSU is separate from—although closely interconnected with—the preexisting government department (Figure 3). The TSU has its own team leader, who is responsible for day-to-day operations but accountable to the head of the government department. This separate structure enables the unit to respond quickly to changing conditions on the ground.

THE LOCAL CONTEXT: KARNATAKA STATE

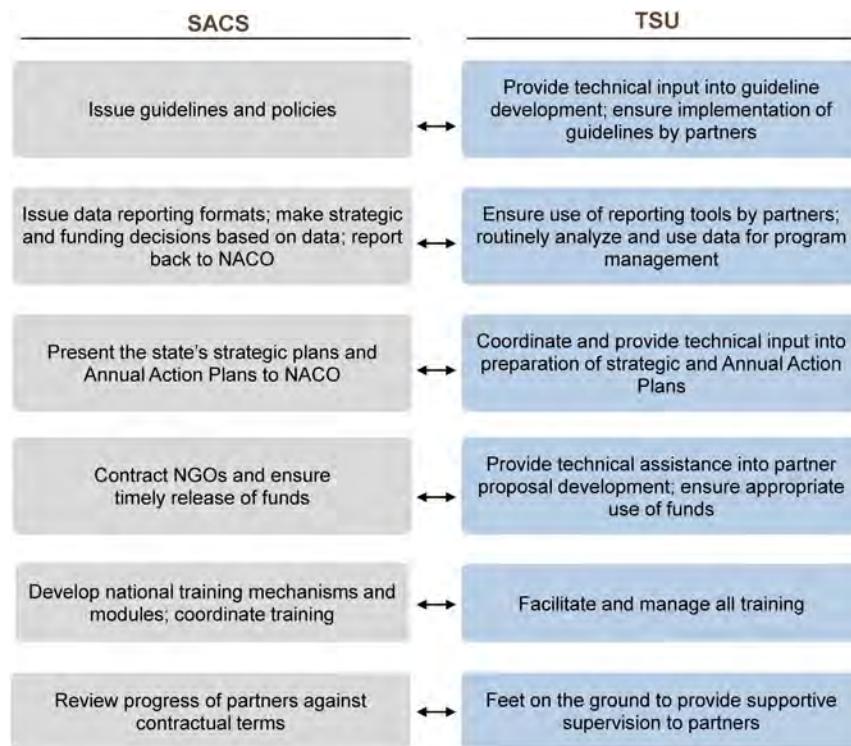
Karnataka, with a population of 61 million, is one of India's 6 high-priority states for HIV prevention. In 2007, HIV prevalence among attendees of public antenatal clinics in Karnataka was 0.86% (a proxy for overall HIV prevalence).⁶ The epidemic is largely driven by unprotected sex between approximately 78,000 female sex workers and their clients (particularly long-distance truck drivers and migrant workers, who are considered “bridge” populations that could enable further transmission of HIV to the wider population), as well as by unprotected sex between about 25,000 men who have sex with men.⁷ In 2007, HIV prevalence among female sex workers in Karnataka (measured primarily at sentinel surveillance sites at antenatal clinics) was 5.3%.⁶ However, in 5 districts of the state surveyed as part of an integrated behavioral and biological assessment, HIV prevalence among female sex workers ranged from 9.5% to 34.2%, and among men who have sex with men in 1 district, prevalence was 19.5%.⁸

Under NACP-III, Karnataka's SACS, called the Karnataka State AIDS Prevention Society (KSAPS), was responsible for HIV prevention, care, and treatment programming across the state, including prevention programming among key populations in 10 of the state's 30 districts. The remaining 20 districts were covered by the Avahan program funded by the Bill & Melinda Gates Foundation.⁹

KSAPS had significant structural limitations, including frequent turnover of senior staff and just 6 departmental heads responsible for all aspects of HIV programming. Moreover, these departmental heads were mainly preoccupied with administrative tasks, leaving them little or no time to provide technical and managerial support to programs or to offer direct support in the field. When NACP-III began in 2007, the state was implementing 18 prevention interventions in its 10 districts. However, it reached only 5% of the approximately 21,000 female sex workers in these districts regularly, and coverage of the around 7,000 men who have sex with men was inadequately documented. Furthermore, routine program monitoring indicators were not being collected or reported from all the interventions. There was a clear need to bolster the capacity of KSAPS to translate national guidance and strategy into action on the ground,¹⁰ by increasing coverage of key and bridge populations with prevention services, improving the quality of the programs, and ensuring that

Each Technical Support Unit is comprised of experts from the private and nonprofit sector with a complementary skill set to that found in the state government.

FIGURE 2. Complementary Roles of the State AIDS Prevention and Control Society and Technical Support Unit



Abbreviations: NACO, National AIDS Control Organisation; NGOs, nongovernmental organizations; SACS, State AIDS Prevention and Control Society; TSU, Technical Support Unit.

program indicators were collected and reported for performance monitoring and accountability. In accordance with the national strategy, NACO established a Technical Support Unit in Karnataka in 2008.

ESTABLISHING THE TECHNICAL SUPPORT UNIT IN KARNATAKA

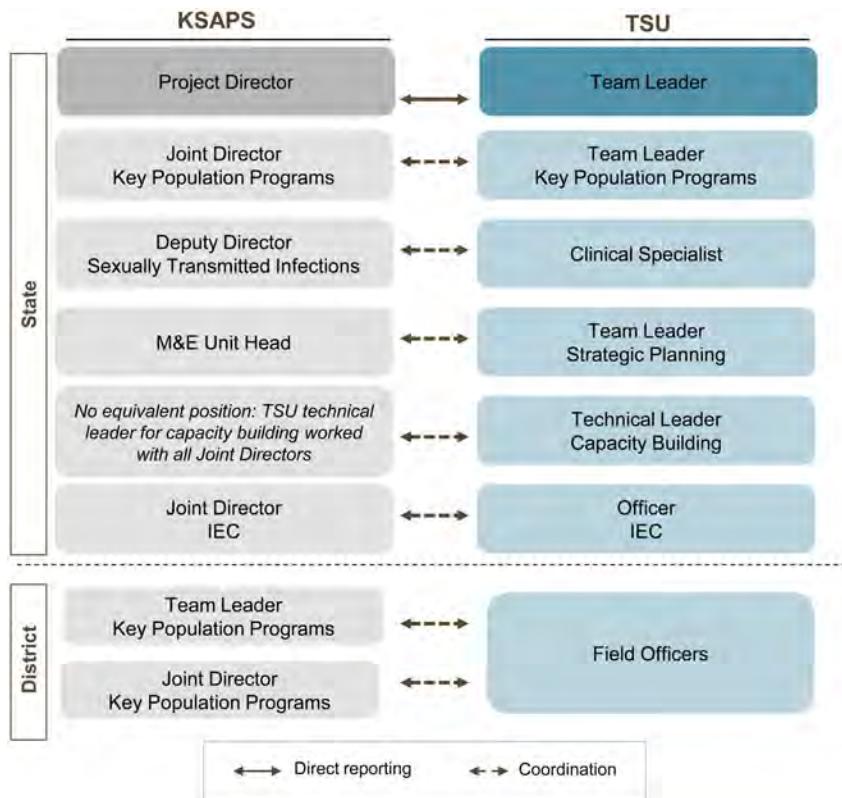
Following a Request for Applications, NACO awarded the contract to form a TSU to India Health Action Trust (IHAT), an organization affiliated with Karnataka Health Promotion Trust, which was implementing the Gates-funded interventions in 20 districts of Karnataka.

The Bill & Melinda Gates Foundation provided NACO with funding for the first 4 years of the TSU, but the TSU was fully accountable to the state and national government. IHAT signed a Memorandum of Understanding with KSAPS to

clarify the TSU's initial roles and responsibilities. KSAPS and NACO reviewed IHAT's contract annually for performance, with the opportunity to reassess goals and objectives. Once the TSU staff had been hired in consultation with the state government, IHAT took primarily a backseat role in order to ensure the TSU's profile as part of the government rather than an as an external organization and in order to make collaboration easier.

The TSU's 18 staff were hired from the private and nongovernmental sectors for their managerial and technical expertise. Senior staff were hired from the Avahan program because of their expertise and experience in Karnataka and to enable a quick transfer of lessons from Avahan, which had achieved greater program coverage in the 20 districts it covered than the KSAPS interventions had in the other 10 districts. Field-level staff were hired from the open market. Positions and salaries were set by the national

FIGURE 3. Coordination Between the Karnataka State AIDS Prevention Society and the Technical Support Unit



Abbreviations: IEC, information, education, and communication; KSAPS, Karnataka State AIDS Prevention Society; M&E, monitoring and evaluation; TSU, Technical Support Unit.

government. Given the technical and managerial experience of the staff and in order to attract high talent, salaries were slightly higher than government salaries for corresponding positions in KSAPS.

The TSU staff included:

- A team leader to provide overall supervision and guidance
- A strategic planning officer to guide strategy and develop annual plans
- Key population program officers and an advocacy officer to provide supervision and guidance to the implementing NGOs
- Clinical program officers to provide technical support to the clinical components of the programs
- Capacity-building officers to design training

- A program officer for information, education, and communication (IEC)
- An M&E officer to assist field agencies with collecting, uploading, and analyzing monitoring data and to support survey design and implementation

The program officers were placed in districts across the state to make it easier for them to supervise the implementing agencies. The remaining TSU staff worked in the same offices as the KSAPS staff so that the two teams could work in an integrated manner. Reporting relationships between the TSU and KSAPS also facilitated this integration. The TSU's team leader reported primarily to the head of KSAPS and also had a "dotted line" of reporting to NACO's own national-level TSU. The reporting

Most of the Technical Support Unit staff were embedded in the state government office to facilitate close collaboration.

relationship to the head of KSAPS ensured ownership of the TSU's work at the state level, while contact with the national TSU helped ensure that national guidance was translated to the state level. Overall, this reporting arrangement, along with regular reviews of the unit's activities at both the state and national government levels, facilitated coordination and good relations between all the bodies. Below the leadership level, TSU staff reported to the TSU team leader and not to KSAPS staff, but the TSU's technical and program officers worked closely with KSAPS officers (Figure 3).

While sharing the same strategic goals, KSAPS was largely responsible for the administrative side (procuring NGOs to run interventions, releasing funding, conducting audits), while the TSU was responsible for the technical side. The two entities thus complemented each other and operated as one to fulfill the HIV prevention mandate of the state.

TSU SUPPORT

The TSU provided support in 5 key areas, regardless of whether the prevention interventions for key populations were government- or donor-run:

1. Assisting in strategic planning for management, scale up, and monitoring
2. Building and rolling out a comprehensive M&E system for the state
3. Providing direct supportive supervision to intervention units
4. Facilitating training
5. Assisting with IEC

Strategic Planning

The TSU provided technical input to the state government's Annual Action Plans for HIV prevention, treatment, care, and support.¹¹ These plans, submitted by KSAPS to NACO for review and approval, contain the targets, budget, and implementation strategy for the upcoming year. The TSU also helped the KSAPS program officers develop activity plans for each department within KSAPS, to ensure timely implementation and use of funds.

One of the TSU's primary areas of support was to map the districts to identify where there were gaps in coverage and advise KSAPS on how to allocate funds and interventions accordingly. These

mapping exercises estimated the denominator of key and bridge populations across the state by typology, defined service areas, recommended locations of sexually transmitted infection (STI) clinics where they would be most accessible to key population members, and set targets to maximize contacts by peer educators. Peer educators are members of key populations recruited to provide outreach to other key population members—namely, to deliver HIV prevention information and commodities and encourage clinic attendance. The peer educators are selected for their knowledge of their communities and their credibility and trust within them, which make them better able to reach their peers than outreach workers who are not members of key populations.¹²

Where mapping showed the need for new interventions, it was the responsibility of KSAPS to procure an NGO. Once the NGO was contracted, the TSU would help the NGO develop its proposal, work plan, and financial plan, as well as support the program for scale up.

Monitoring and Evaluation

The TSU's role in M&E was to improve data systems so that outputs and program performance could be tracked and accountability systems put in place. The TSU worked with the implementing NGOs to ensure that nationally designed planning and monitoring tools were implemented across the state and that reporting took place on a routine basis. One example is the microplanning tools specially designed to be used by peer educators (including those with no literacy skills) to plan and record their contacts with individual key population members and detail all services provided. Linking outreach with clinical reporting helped the implementing partners understand their performance and use data for decision-making.

The TSU monitored the output of core NACP-III indicators, developed a performance monitoring dashboard for KSAPS leadership, and routinely analyzed and presented data to KSAPS. This allowed for accountability at two levels: (1) the NGOs were accountable to KSAPS, and (2) KSAPS, in turn, was accountable to NACO for overall performance.

The TSU also developed and implemented behavioral surveys (polling booth surveys) to monitor behavioral outcomes of programs, conducted periodic reviews of the NGOs on fiscal and programmatic areas, and updated KSAPS on progress. Official annual evaluations of each intervention were conducted by KSAPS,

One key activity of the Technical Support Unit was a district mapping exercise to identify gaps in program coverage.

with input on performance monitoring from the TSU.

Supportive Supervision

Through its key population officers based in the field and clinical program officers, the TSU provided direct, intensive technical and management support to the interventions. Program officers were decentralized and spent 1–3 days a month with each intervention unit for which they were responsible. They provided support to clinical services, linkages to other services, monitoring systems and reporting (as described earlier), and community mobilization. TSU staff also ensured that KSAPS supplied commodities (including condoms, lubricant, and IEC materials) to the interventions in a timely manner and that implementing NGOs provided adequate documentation and reporting.

Facilitating Training

The TSU capacity-building officer worked closely with the KSAPS counterpart to identify training institutions and resource people for staff of the intervention units, design training modules and materials, develop an annual training calendar, and evaluate trainings. The TSU trained the staff of STI clinics (referral, static, and outreach) that were contracted by KSAPS, to ensure that they

provided appropriate examinations and testing for members of key populations and treated them respectfully. Recruitment and training of peer educators was an additional focus to increase program coverage.

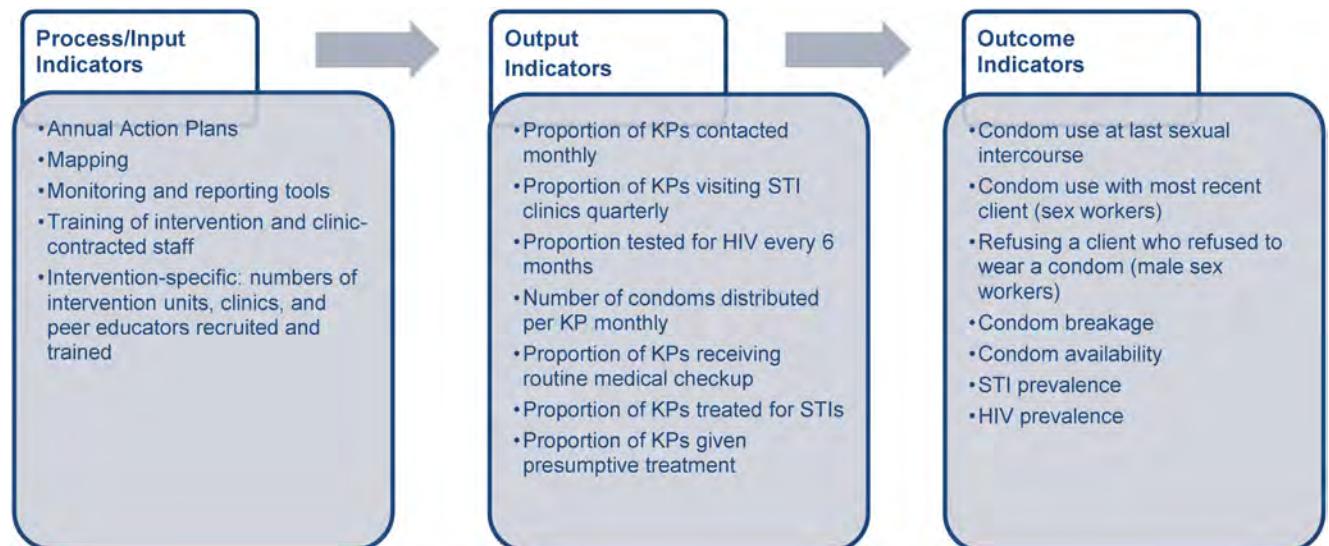
Information, Education, and Communication

The communications officer supported KSAPS in the design and overall rollout of IEC campaigns for HIV, and especially for key populations. The communications officer also supported the NGOs in rolling out IEC materials at the field level.

METHODS

We used the results framework for KSAPS and the TSU to assess the effectiveness of the TSU and state government’s joint efforts in scaling up HIV prevention programming in Karnataka (Figure 4). Specifically, we focused on 3 types of indicators to measure success: process/input, output, and outcome. KSAPS monitoring data provided information on process indicators, including the number of intervention units, STI clinics, and peer educators. Program monitoring data provided information on key output indicators that give an indication of program coverage; examples of such indicators are the proportion of female sex workers and men who have sex with

FIGURE 4. Results Framework for the Karnataka State AIDS Prevention Society and Technical Support Unit, Selected Indicators



men who were contacted monthly by the program, the proportion of these key population groups who regularly visited STI clinics and HIV testing and counseling centers, and the number of condoms distributed to these groups. Finally, to monitor changes in key sexual and health-seeking behaviors among key population groups (ie, outcome indicators), the TSU implemented polling booth surveys with female sex workers and informal confidential voting interviews with men who have sex with men. A polling booth survey is a group interview method in which individuals give anonymous responses through a ballot box, while informal confidential voting interviews blend face-to-face interviews with anonymous voting methods.^{13–15} See the **Box** for sample indicators measured in the polling booth surveys with female sex workers. These approaches are more suitable than conventional interviewing and surveying methods to collect information on sensitive and personal issues, such as sexual behaviors, particularly among low-literacy populations.

RESULTS

Process Indicators

The TSU's assistance in **strategic planning with KSAPS through the Annual Action Plans** contributed to the state government's success in increasing the overall KSAPS budget from US\$8.0 million in 2007–2008 to \$13.1 million in 2011–2012. Over the same period, the portion of the state budget allocated to prevention interventions among key populations tripled, from \$0.7 million to \$2.1 million, partly because the TSU-facilitated mapping exercises revealed higher numbers of key population members. Planning for the transition of the donor-funded intervention units to KSAPS management also required additional funds.

The TSU also ensured that national **reporting** formats were implemented. In 2007–2008, only 56% of intervention units in the 10 KSAPS districts had been reporting on a monthly basis, but within 2 years 100% were doing so with TSU-provided training and support, using the national government's comprehensive set of indicators. This, in turn, helped KSAPS understand gaps in programming and develop plans for comprehensive state coverage.

The combined efforts of the TSU and KSAPS led to a **significant improvement in coverage** of key populations in Karnataka through increases in the number of intervention units and STI clinics. Between 2007–2008 and 2008–2009, the number of

BOX. Indicators Measured in Polling Booth Surveys With Female Sex Workers

- Condom use at last sexual intercourse with:
 - Clients (paying new or occasional clients)
 - Regular clients (paying regular clients)
 - Lovers (nonpaying lovers of the female sex workers who do not live with them)
 - Husbands or cohabiting partners (nonpaying husband or live-in partner)
- Sex without a condom
- Condom breakage
- Barriers to using condoms
 - Partner's choice
 - Influence of alcohol
 - Condoms not available
 - Client offers more money for sex without condoms
- Anal sex
- Risk perception
- Experience of violence
- HIV testing
- Knowledge of antiretroviral therapy
- Experience of sexual violence in the past year

With assistance from the Technical Support Unit, the Karnataka state government's budget increased from US\$8 million to \$13 million within 4 years.

intervention units in the 10 districts overseen by KSAPS increased from 9 to 26. The number of STI clinics (static, referral, and outreach) in these districts grew from 16 in 2007–2008 to 211 in 2011–2012. In the 4 years from 2009, KSAPS increased its coverage beyond these 10 districts, taking responsibility for the 27 preexisting Gates-run intervention units and adding new units to encompass all districts in the state. As a result, between 2008–2009 and 2012–2013, the number of intervention units managed by KSAPS increased almost fourfold to 126. The ability to absorb donor-funded programs without compromising coverage and quality was key to the long-term sustainability of HIV prevention among key populations throughout the state.¹⁶

In the initial 10 districts overseen by the Karnataka state government, the number of STI clinics grew from 16 to 211 between 2007 and 2012.

Meanwhile, the number of peer educators for female sex workers statewide increased from 345 in 2008–2009 to 621 in 2011–2012, and for men who have sex with men, from 86 to 326.

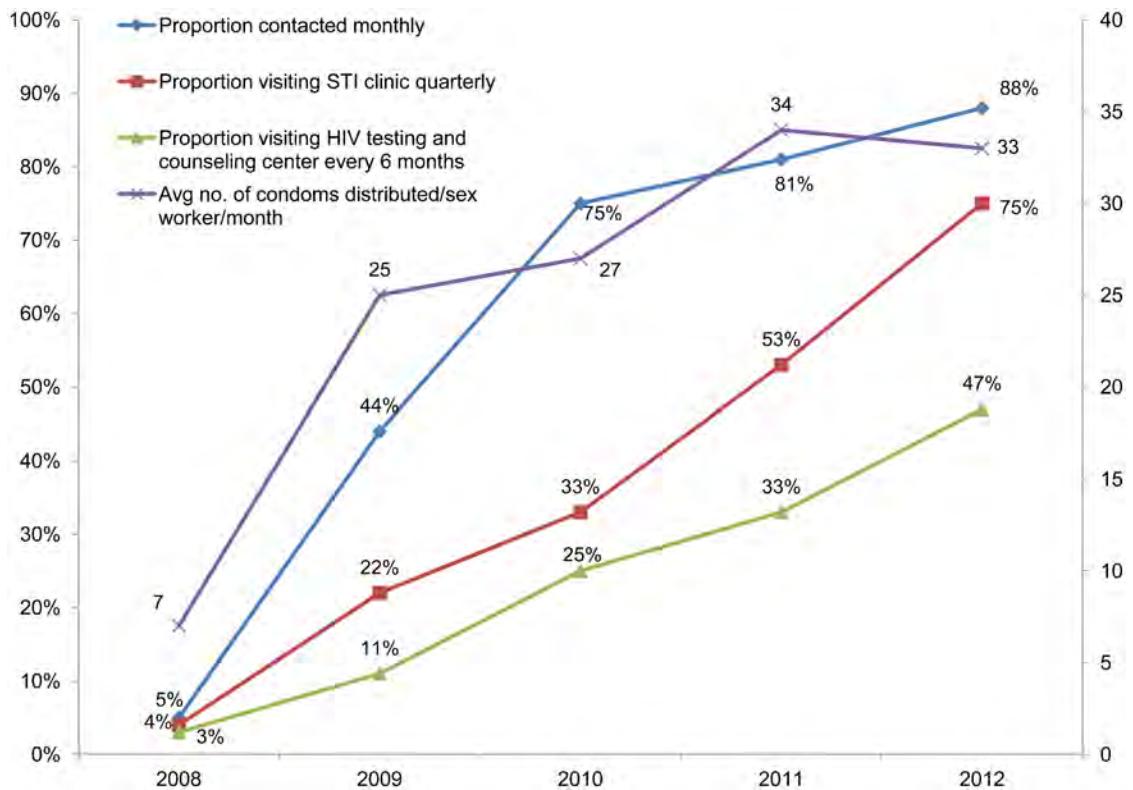
Output Indicators: Program Coverage

The increased number of peer educators was associated with enhanced program coverage and an improvement in output indicators for both female sex workers and men who have sex with men. For example, the proportion of female sex workers contacted monthly by the program increased from an average of 5% in 2008 to 88% in 2012 (Figure 5); among men who have sex with men, the increase was from an average of 36% in 2009 to 81% in 2012 (Figure 6). (The target

set by NACO for both populations was 80%.) By 2012, 75% of female sex workers and 67% of men who have sex with men were visiting an STI clinic quarterly. Although these levels were below the NACO target of 80%, they increased considerably from the 2008 levels of 4% and 7%, respectively. The proportion of female sex workers visiting an HIV testing and counseling center every 6 months increased from 3% to 47% between 2008 and 2012, while for men who have sex with men, the corresponding increase was from 6% to 33%. The average number of condoms distributed monthly per female sex worker in 2012 was 33, above the NACO target of 32, and the corresponding figure for men who have sex with men was 25, exceeding the target of 24. (Lubricants were

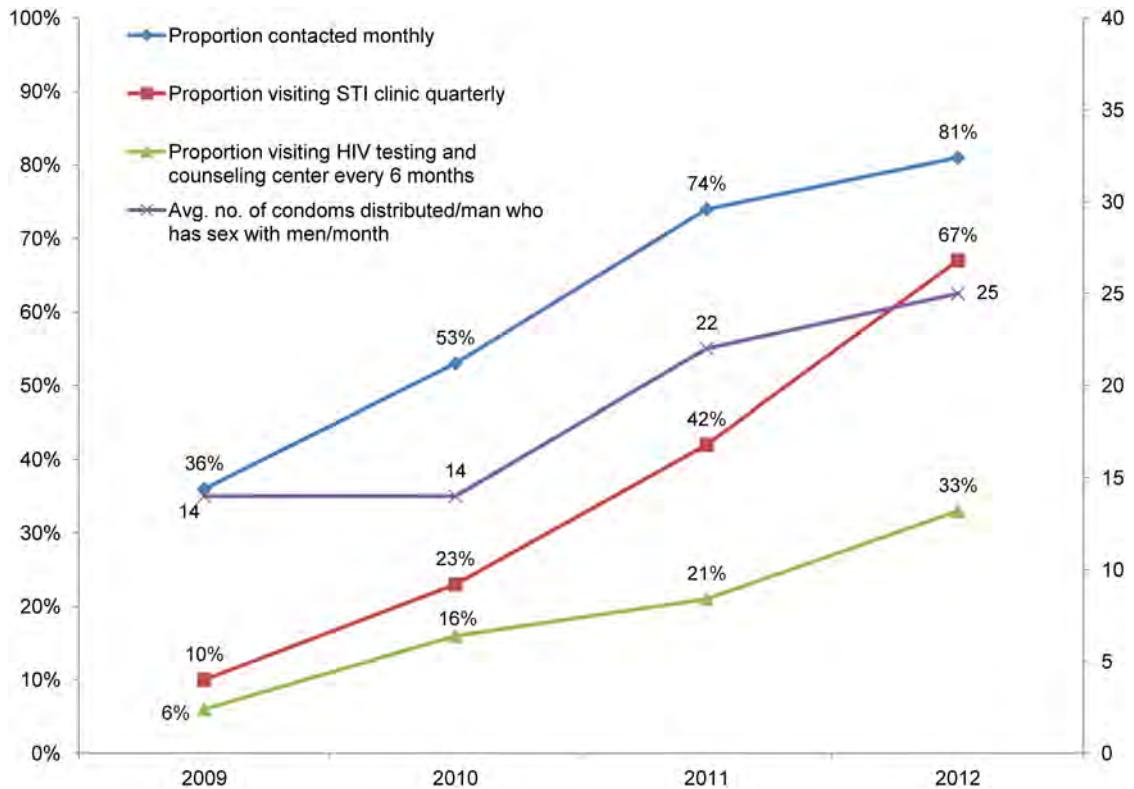
Monthly contact with female sex workers by the state program increased from 5% to 88% between 2008 and 2012.

FIGURE 5. Coverage of Mapped Female Sex Workers (N= 20,806) by State Government HIV Prevention Programs, 10 Districts of Karnataka, 2008–2012



Targets: 80% of mapped number contacted monthly; 100% visiting STI clinic quarterly; 100% receiving HIV test every 6 months; average of 32 condoms per female sex worker distributed monthly.
 Source: Karnataka State AIDS Prevention Society monitoring data.

FIGURE 6. Coverage of Mapped Men Who Have Sex With Men (N=7,054) by State Government HIV Prevention Programs, 10 Districts of Karnataka, 2009–2012



Targets: 80% of mapped number contacted monthly; 100% visiting STI clinic quarterly; 100% receiving HIV test every 6 months; average of 24 condoms per man who has sex with men distributed monthly.
 Source: Karnataka State AIDS Prevention Society monitoring data.

also distributed along with condoms, although NACO did not require recording this.)

Outcome Indicators: Sexual Behaviors

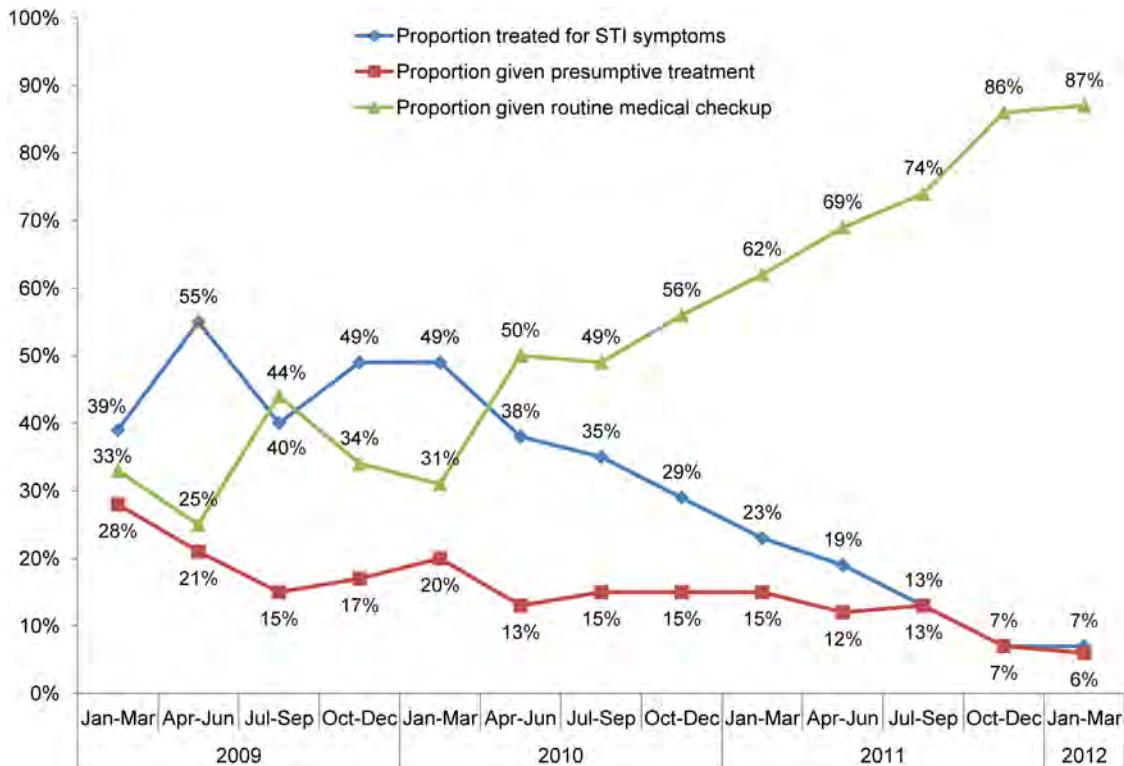
In 9 of the 10 KSAPS program districts, the overall proportion of female sex workers reporting that they used a condom at last intercourse rose from 60% in 2008 to 68% in 2010; over the same period, the proportion reporting that their most recent client used a condom grew from 71% to 78%. The percentage of female sex workers reporting that a condom broke the last time they tried to use one declined from 26% to 14%, and those prevented from using a condom at last sex because it was not available fell from 27% to 20%. Program data showed that while the

proportion of female sex workers receiving routine medical checkups increased substantially from 33% in the first quarter of 2009 to 87% in the first quarter of 2012, the proportion treated for STI symptoms declined from 39% to 7% over the same period (Figure 7).

Between 2008 and 2010, the proportion of men who have sex with men in 6 program districts who reported using a condom at last anal sex increased from 89% to 97%, and the percentage using a condom at last anal sex with their regular male partner rose from 76% to 86%. The proportion of male sex workers refusing to have anal sex because a client refused to use a condom rose from 45% to 72%. As with female sex workers, the proportion of men who have sex with

Sexual behaviors of key populations, such as using a condom at last sex, improved over time.

FIGURE 7. Medical Treatment of Female Sex Workers by State Government HIV Prevention Programs, 10 Districts of Karnataka, 2009–2012



Source: India Health Action Trust monitoring data.

men being treated for STI symptoms declined, from 30% in the second quarter of 2009 to 4% by the beginning of 2012, even as the proportion receiving routine medical checkups grew from 14% to 85% over the same period (Figure 8).

DISCUSSION

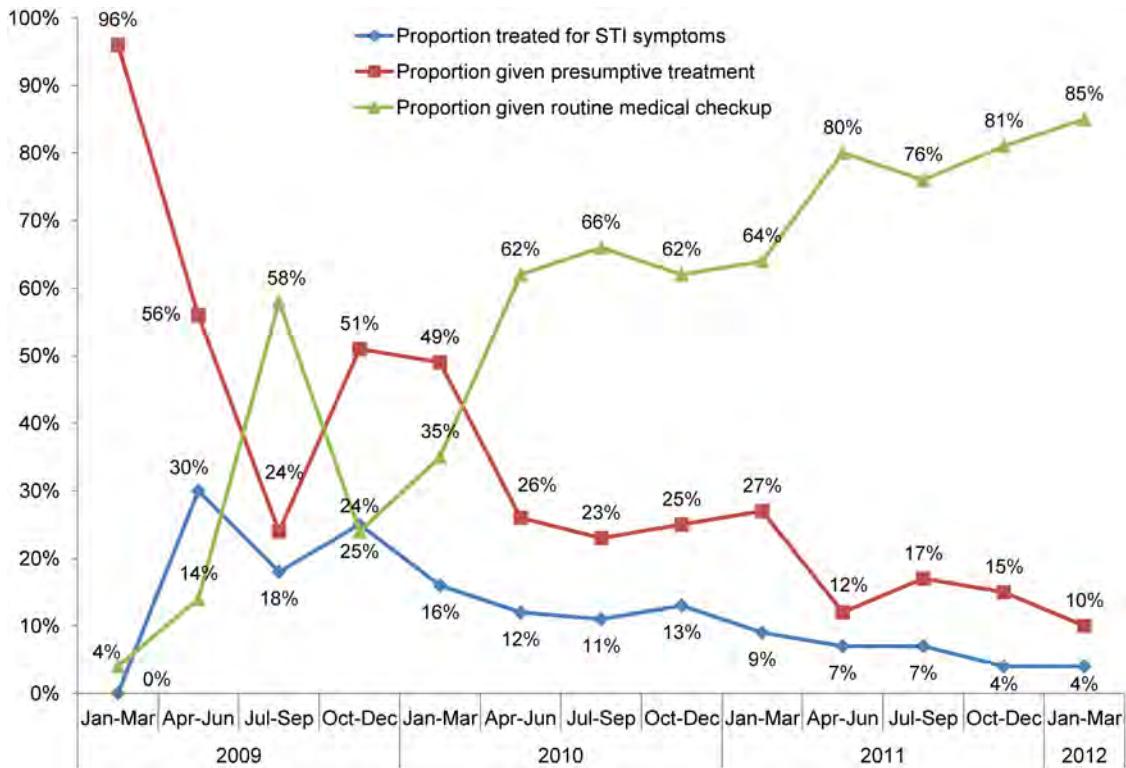
The Technical Support Unit likely contributed to the improved outcomes of the state government HIV prevention program.

Because of the complexity of the programming environment in Karnataka, with multiple actors including KSAPS, the TSU, and the Bill & Melinda Gates Foundation, among others, it is not possible to attribute statewide HIV prevention outcomes directly to the TSU’s work. However, in the 10 districts overseen by KSAPS, there were changes after the TSU was established, and it seems reasonable to infer that the technical assistance given by the TSU may have contributed to KSAPS’ success in improving outcomes.

The TSUs are part and parcel of the national strategy to rapidly scale up HIV prevention programs among key populations, and they are integral to implementation of the strategy. In Karnataka, the experience has been that a TSU of experts with clear deliverables and systems for close coordination with the government has ensured a common sense of mission and cohesion.

We would like to emphasize that the increased outputs described earlier likely occurred as a result of the collaboration between the TSU and KSAPS. The results should therefore not be seen as due to the success of the TSU alone, but rather as progress for the state as a whole, using an innovative management model designed to enhance the effectiveness of components of the national government’s plan. These components included increased funding, a strengthened reliance on M&E systems, and scale up of interventions to improve coverage.

FIGURE 8. Medical Treatment of Men Who Have Sex With Men by State Government HIV Prevention Programs, 10 Districts of Karnataka, 2009–2012



Source: India Health Action Trust monitoring data.

A number of lessons can be drawn from the Karnataka experience that may be applicable in other contexts where TSUs are being considered.

Clearly Define the Mandate, Roles, and Responsibilities for the TSU, As Well As Indicators of Success

The formation of TSUs in each Indian state was mandated by the national government, but a Memorandum of Understanding between IHAT (the agency contracted to establish the TSU) and the state government was essential to ensure that both sides understood what the TSU was to do—and, just as importantly, what it was not to do. A Memorandum of Understanding gives the TSU legitimacy, protects it from political or bureaucratic changes within the state government, and allows it to stay focused on its work and deflect additional demands.

In order to be viewed as an unbiased party, the TSU cannot be involved in any decisions about selecting NGOs to implement programs. Its focus should remain on providing technical support once the implementing NGOs have been chosen. Nevertheless, because the TSU’s role often involves asking challenging questions and taking difficult decisions about the NGOs, it can be susceptible to political pressure. The Memorandum of Understanding, together with regular reviews at the state and national level, ensures that such matters can be arbitrated when necessary.

Choose the Right Organization to Manage the TSU

The organization contracted by the national government to hire, train, and compensate the TSU staff must have the appropriate skills and experience in the area of HIV prevention management. It

should also have the political maturity required to navigate the complexities of placing staff within the government system and to work with state government officials to create an enabling environment for the TSU to work effectively.

Do Not Lose Sight of the TSU's Role in Supporting the Government

A TSU can only succeed if its relationship with the government agency is mutually supportive and noncompetitive. The unit must be sanctioned at the highest political levels, and it should be seen as a catalyst to help achieve shared program goals. The TSU's leader should report to the highest state government official to ensure it gets appropriate visibility and support. However, the TSU should not forget that its role is to provide support to the government and that ultimate decision-making power must rest with the government.

Clearly defined roles and relationships enhance the TSU's productivity and make it more effective than the ad hoc placement of experts in individual government departments. By working to create an environment of trust, the TSU helps to ensure that its staff will be consulted by state agency staff before they make decisions. Having the TSU staff in the same building as the agency builds this trust and helps the state agency staff feel that they have joint ownership of the TSU's work.

A related point is the need to be sensitive to concerns about salary differentials between the TSU and the government unit. Attracting high levels of technical ability from the private and nongovernmental sectors at competitive rates implies that TSU staff often earn more than their government counterparts, which may cause resentment and can interfere in having a productive partnership. These sensitivities may be mitigated if the TSU does not try to garner praise for itself and shares the credit for any accomplishments with the government.

Be Sensitive to Costs and Value Added

Particularly in resource-constrained settings, a TSU may be an effective way to leverage government funding to ensure scale and quality in programming. In 2012–2013, the KSAPS prevention budget was US\$3.7 million (out of a total budget of \$14.3 million), of which \$0.7 million (19%) was allocated to the TSU. This helped ensure that the remainder of the prevention budget was spent as effectively as possible.

Governments are often under pressure to produce “quick wins,” so the TSU should aim to

demonstrate quickly that it adds value to the government's work. One such area in Karnataka was monitoring, an area that is often weak in programs and one in which it therefore may be possible to produce rapid improvements. Setting up a data collection, analysis, and reporting system to measure outcomes helped the government value the TSU for the knowledge and skills that it brought and for the value that it added to the overall HIV prevention program. One example is the use of polling booth surveys to monitor outcomes, and we would further recommend the adoption of such surveys by TSUs in other states as well.

There were other, less tangible but valuable benefits to the TSU. Although it was not in the remit of the TSU staff to train their government counterparts, they found that by being embedded in the government offices and working alongside them, the TSU staff indirectly helped build the capacity of their government colleagues. Occasionally going beyond the strict terms of the mandate to help government colleagues can build a great deal of goodwill. In Karnataka, although the TSU was focused on HIV prevention programs among key populations, it helped the government write guidelines on STIs (for both key and general populations) and helped develop an HIV capacity-building plan as well as broad IEC activities.

In addition, given the high turnover and staff vacancies that frequently affects government programs, a TSU can offer the additional value of institutional memory, helping to provide much-needed continuity and stability for implementing agencies as well as helping to foster their success.

Understand Insourcing of Skills as Integral to Building Sustainable Government Health Systems

Some critics assert that “sourcing-in” the key functions of the government to staff who are not core government employees delays much-needed efforts to build health systems and is not sustainable in the long run. We would argue that TSUs should rather be seen as part of a broad approach to strengthening systems and to expanding existing government capacity to manage and scale up health programs. Any such approach should take into consideration the degree of urgency for program implementation, the feasibility of the models for the given context and problem, and the available timeframe for addressing issues of sustainability. In India, the national program discerned an urgent need to

Cultivating a mutually supportive and noncompetitive relationship between the Technical Support Unit and the state government agency is crucial.

Technical Support Units should be seen as part of a broad approach to strengthening systems.

improve the range and depth of technical expertise in the states, and it decided that working to strengthen capacity among existing SACS staff would take too long. In low-, middle-, and high-income countries, the private sector often subcontracts other agencies to perform key skills that they might otherwise not be equipped to do. We see no reason why government systems should not be equally creative in their approach, given the complex range of skills needed for health programs.

We agree that sustainability is a major issue that needs to be addressed, and we propose two ways to look at this issue. The first question should be: Will the TSU be required on an indefinite basis, or is the need for it time-limited? In the case of India, TSUs were acknowledged as critical structures that enabled the scale and quality of HIV prevention programs that was needed for the duration of NACP-III (2009–2012). The second question is: If the TSU is needed for the long term, will the functions it carries out be required at the same level of intensity, or is it possible to move to a less intense model? TSUs have been retained as part of NACP-IV, although in some states, including Karnataka, only a reduced core of staff was maintained, since scale had already been achieved and the emphasis is now mostly on maintaining quality. So, for example, the ratio of field staff to the number of prevention units was reduced from 1:10 to 1:15. Although most of the TSUs in India are now funded by the national government through the World Bank, the Karnataka TSU continues to be funded by the Bill & Melinda Gates Foundation.

It is worth noting that the TSU model not only continues as a national policy within HIV programming in India but also has been adapted for other health programs both within India (such as maternal and child health in the states of Bihar and Uttar Pradesh and for the national immunization program) and externally, such as the Kenyan government's HIV program.

Limitations

We recognize that it is not possible to conclusively attribute the improvements in prevention coverage and service provision among key populations to the formation of the TSU (and as we have indicated earlier, we would not seek to do so, since the TSU and KSAPS worked closely together). A comprehensive evaluation of the TSU is beyond the scope of this article, and a randomized controlled trial of technical assistance was never designed in India and is not feasible. Such a trial

would have required comparing Karnataka with a state of a similar size and demographic profile that had no TSU, but all such states in India were mandated by the national government to adopt TSUs at the same time as Karnataka.

CONCLUSION

The scale up of national health programs requires a broad continuum of capabilities, including policy guidance, budgetary planning and disbursement, technical and managerial support for the implementation of programs, and monitoring and evaluation. In many low- and middle-income countries, it is a challenge to cover this range of skills adequately within a single government agency, but without such capacity it is difficult to scale up programs while maintaining quality. The experience in Karnataka state in India suggests that TSUs—a deliberate partnership with expertise from the nonprofit and private sectors—can be an effective way of enabling rapid scale up while maintaining program quality. A comprehensive and comparative analysis of all TSUs in India is warranted and would be highly valuable to the development field.

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ORIGINAL ARTICLE

Policy and programmatic considerations for introducing a longer-acting injectable contraceptive: perspectives of stakeholders from Kenya and Rwanda

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Unique attributes of a longer-acting injectable would likely appeal to both existing injectable users and new clients, both for spacing and for limiting births, and allow health systems to operate more efficiently. Considerations for enhancing successful introduction of this potential new method include keeping the cost low, expanding access through community-based distribution, and training providers to improve practices about injectables in general.

ABSTRACT

Background: More than 40 million women use injectable contraceptives to prevent pregnancy, and most current or previous injectable users report being satisfied with the method. However, while women may find injectables *acceptable*, they may not always find them *accessible* due to stock-outs and difficulties with returning to the clinic for reinjections. FHI 360 is spearheading efforts to develop a longer-acting injectable (LAI) contraceptive that could provide at least 6 months of protection against pregnancy. This article addresses systems-level considerations for the introduction of a new LAI.

Methods: We conducted qualitative case studies in Kenya and Rwanda—two countries that have high levels of injectable use but with different service delivery contexts. Between June and September 2012, we conducted in-depth interviews with 27 service providers and 19 policy makers and program implementers focusing on 4 themes: systems-level barriers and facilitators to delivering LAI services; process for introducing an LAI; LAI distribution approaches; and potential LAI characteristics. We also obtained electronic feedback from 28 international family planning opinion leaders.

Results: Respondents indicated strong interest in an LAI and thought it would appeal to existing injectable users as well as new family planning clients, both for spacing and for limiting births. Providers appreciated the potential for a lighter workload due to fewer follow-up visits, but they were concerned that fewer visits would also decrease their ability to help women manage side effects. The providers also appreciated the 1-month grace period for follow-up LAI injections; some seemed unaware of the latest international guidance that had increased the grace period from 2 weeks to 4 weeks for the currently available 3-month injectable. The majority of policy makers and program implementers were supportive of letting community health workers provide the method, but many nurses and midwives in Kenya had reservations about the approach. At the policy level, respondents indicated that obtaining regulatory approvals before introducing the new method could be costly and time-consuming. Manufacturing and procurement decisions could also affect cost and availability.

Conclusions: Successful introduction of a potential longer-acting injectable may be enhanced by considering broader systemic issues, including managing cost to the health system and users, expanding access through community-based distribution, and training providers on the latest service delivery guidelines.

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BACKGROUND

Between 1995 and 2005, use of injectable contraceptives more than doubled worldwide, from 12 million married women to over 32 million.¹ Currently, more than 40 million women use injectables to prevent pregnancy.² In studies of current and previous injectable

users, more than three-quarters of women report being satisfied with the method, mainly due to its inherent product characteristics: It requires relatively few visits to a health care facility, provides discreet contraceptive protection, is less user-dependent than methods such as condoms or oral contraceptive pills, and requires less invasive medical procedures than methods such as intrauterine devices (IUDs) or implants.^{3–7}

While women may find the injectable *acceptable*, they may not always find it *accessible*. Multiple factors ultimately affect clients' ability to obtain and continue using contraceptive methods, including policy and service delivery guidelines, recommendations and decisions about appropriate target populations, pricing, and product distribution mechanisms. Logistical issues at the systems, facility, and individual levels may also impede access and continuation, causing clients to unintentionally disrupt or discontinue contraceptive adherence. Specifically, commodity stock-outs at facilities can be common, and clients may also have difficulty returning to the clinic for reinjections. Similarly, when women return late for their follow-up appointments, they are sometimes denied a reinjection, even when they are within the approved grace period.^{3–5,8–13}

A project led by FHI 360 with funding from the Bill & Melinda Gates Foundation is underway to develop an innovative injectable contraceptive that could provide at least 6 months of protection from pregnancy. Building on the popularity of existing 1- and 3-month injectables, a longer-acting injectable (LAI) could address some of the access-related barriers that contribute to discontinuation and could provide women with greater contraceptive choice.

During the first phase of the LAI development initiative, we used qualitative methods in Kenya and Rwanda to explore acceptability, potential demand, and policy and delivery issues related to a new LAI. Kenya and Rwanda were selected because injectables are by far the most popular family planning method in both countries.^{8,14} Despite widespread acceptability and use, several contextual factors differ between the two countries, providing useful diversity in a case-study approach. For example, the method mix differs with a higher percentage of women in Kenya than in Rwanda using long-acting methods. In addition, Rwanda has a large public-sector distribution network and well-established community-based distribution (CBD) programs that cover the entire country. In contrast, Kenya

has complementary public and private markets, and while a CBD system for administering the DMPA injectable has been piloted and permitted through recent policy change, it has yet to be fully integrated into current national programs.^{7,8}

In this article, we identify potential barriers and opportunities related to the introduction of an LAI at the policy, health system, clinic, and client levels. A companion paper published in *Global Health: Science and Practice* described the preferences of opinion leaders, providers, and potential users for a range of potential characteristics of an LAI.¹⁵

METHODS

Between June and September 2012, we conducted in-depth interviews (IDIs) with 19 policy makers and program implementers and 27 service providers in Kenya and Rwanda (Table 1). In addition to nurses and midwives from mostly urban areas, service providers included community health workers (CHWs) recruited from private- and public-sector clinics in peri-urban and rural areas who provide injectables. Policy makers and program implementers represented local and international government and private/nongovernmental family planning programs at a variety of levels. Some of the policy makers worked at nongovernmental organizations (NGOs) as policy analysts or on developing family planning and other reproductive health policies with their colleagues from government. Program implementers included NGO directors and senior program officers, government program directors, and program managers.

The IDIs followed a guide that focused on 4 themes:

1. Systems-level barriers and facilitators to contraceptive delivery services in general and as related to a possible LAI
2. Steps needed to introduce an LAI into existing programs and facilities
3. Possible new LAI distribution approaches
4. Exploration of LAI characteristics identified in the target product profile (TPP)

The TPP is used to inform product development and identifies both desired and minimally acceptable targets related to effectiveness, the target user population, side effect profile, dosage and delivery mechanism, cost, and other aspects (Box 1). LAI characteristics from the TPP were emphasized with all interviewees.

Commodity stock-outs and difficulty returning to the clinic for reinjections can impede access to injectables.

Development of a longer-acting injectable that could provide at least 6 months of pregnancy protection is currently underway.

BOX 1. Target Product Profile for a Longer-Acting Injectable Contraceptive

Goals for this new method:

- 99% effective in preventing pregnancy when used correctly
- Indicated for women of all reproductive ages*
- No contraindications—can be used immediately after birth and does not interfere with breastfeeding*
- Return to fertility when stopping the method similar to that among women who have stopped using a nonhormonal contraceptive method
- New dose every 6 months with a 1-month grace period*
- Given in the arm
- Side effects no worse than those associated with currently available hormonal methods/injectables*
- Can be stored in warm, humid climates*
- Costs US\$4 or less per year in public-sector programs*
- Single-dose, prepackaged, disposable injection system
- Can be provided by trained community health workers*

* Characteristics addressed in this article.

TABLE 1. Profile of In-Depth Interview Respondents from Kenya and Rwanda (N=46)

Role in the Health System	Kenya		Rwanda		Totals
	Public Sector	NGO/Private Sector	Public Sector	NGO/Private Sector	
Program implementers	2	5	1	2	10
Policy makers	2	3	2	2	9
Service providers					
Nurses/midwives					
Rural	–	–	1	–	1
Peri-urban	7	–	2	–	9
Urban	2	3	1	2	8
CHWs					
Rural	–	–	6	–	6
Peri-urban	3	–	–	–	3
Urban	–	–	–	–	–
Totals	16	11	13	6	46

Abbreviations: CHWs, community health workers; NGO, nongovernmental organization.

In addition, reproductive health specialists from FHI 360 identified 67 international opinion leaders with expertise in family planning for an open-ended email-based survey about the perceived need and important characteristics for an LAI as well as potential challenges related to LAI development and introduction. Respondents were asked to identify additional opinion leaders and to provide their contact information; 28 individuals were identified through this mechanism, for a total of 95. Of the 95 whom we contacted, 28 responded (Table 2). Survey responses were organized into a matrix by topic.

RESULTS

Below, we discuss stakeholder perspectives in 4 main areas: (1) health systems-level considerations for LAI introduction; (2) opportunities and barriers for introduction at the clinic level; (3) distribution mechanisms to ensure wide access to the method; and (4) identification of potential LAI users.

IDIs were conducted by male or female interviewers in English, French, or the local language (as preferred by the participant). Interviewers used illustrations depicting each TPP characteristic to facilitate discussion. IDIs were audio-recorded and then translated into French or English and transcribed. The documents were then uploaded into NVivo9, and the information was coded by multiple coders and reviewed for reliability. To analyze the data thematically, we wrote detailed memos describing subthemes related to each main code, including each TPP characteristic. We also created Excel matrices to examine variations in subthemes by country and participant type. The study was approved by FHI 360's Protection of Human Subjects Committee and by the institutional review boards in both countries.

TABLE 2. Profile of International Opinion Leaders Responding to Email-Based Survey (N=28)

Characteristics	No. of Respondents
Type of Organization	
NGO (international and based within the US)	14
International organization (UN, etc)	3
University	4
Donor	5
Government	1
Clinical services	1
Countries	
Global (work in > 1 country)	18
Brazil	1
Guinea	1
Jordan	2
Malawi	1
Nigeria	1
Uganda	2
United States	2

Partnering with a manufacturer with low labor costs and proximal shipping distances could help keep the cost of a new longer-acting injectable low.

Health Systems-Level Considerations
When asked about the decision-making and planning processes required to introduce a new contraceptive product, respondents noted that regulatory processes, manufacturing and procurement, and cost were the main considerations that could affect access to and eventual uptake of a new LAI.

Regulatory Policy Approvals

Six of the 28 opinion leaders responding to the email-based survey mentioned the need to obtain regulatory approvals before introducing a new contraceptive, with several pointing out that the process is often lengthy and costly. Similarly, 6 of 9 policy makers in Kenya and Rwanda stated that potential users' access to new drugs is significantly affected by the series of international and country regulatory approvals (eg, prequalification from the World Health Organization [WHO], addition to international and country-level Essential Medicines Lists). Additionally, 6 policy makers and program implementers in the

two countries indicated such a product would first need a small-scale pilot introduction to assess programmatic feasibility, safety, and acceptability, which could pose a potential obstacle to swift introduction.

Supply Chain Management: Manufacturing, Procurement, and Associated Costs

Logistics involving the supply chain, specifically manufacturing, procurement, and associated costs, were concerns for a number of the IDI and survey respondents. Several Kenyan and Rwandan program implementers explained that their country's reliance on international-level decisions for procuring contraceptive commodities commonly led to delays in their arrival in-country. Six opinion leaders suggested that the price (and subsequently, cost to users) of a new LAI could be reduced if it were manufactured in a country with low labor costs and proximal shipping distances. One opinion leader from a global NGO said that product developers "should target low-cost manufacturing to keep costs low [and should] not license to [a] high-cost manufacturer," and another was adamant that the rights to an LAI "should rest in 'public hands' such that several manufacturers can produce it without hindrance."

Three Kenyan policy makers and program implementers noted that current procurement processes were sometimes lengthy and could potentially delay any future introduction efforts for an LAI; similarly, program implementers and policy makers in both countries noted the numerous steps and governing bodies involved in moving from initial product introduction to making the method available to women in the country. The country director for an NGO in Kenya stated:

That's the problem; we don't have a local manufacturer ... we're not like India where they're manufacturing almost all their family planning commodities so they can at least deliver it quickly to where it's needed.

Similarly, 8 service providers in Kenya suggested that the shelf life of any LAI should be at least 3 years, with some specifying that this would enable the product to withstand the lengthy overseas procurement and local distribution processes.

Funding Contraceptive Commodities

One-third of Kenyan policy makers and program implementers and one-half of the Rwandan counterparts pointed out that the cost of an LAI would largely determine accessibility. They

explained that most contraceptives are procured using government or donor funds, which could translate to limited stocks in the event of a shortage of donor funds or Ministry of Health (MOH) allocations. Twelve opinion leaders mentioned in their open-ended responses that an LAI should be affordable to procurement agencies, with a price point similar to or less than currently available injectable products. Additionally, a few respondents in Kenya and Rwanda mentioned that decisions about what contraceptives to include in the national method mix is a process driven by available resources, taking into account funding, cost, and the variety of methods available; therefore, introducing a new method might involve reducing financial allocations for other existing methods.

Interestingly, this differs somewhat from the user perspective as reported more fully in the companion paper by Tolley and colleagues,¹⁵ wherein potential users ranked cost as one of the least important issues. Potential users' perspectives on cost were influenced by whether their country provides contraceptives for free in the public sector; potential users in Kenya, where paying for contraceptives through social marketing or the private sector is relatively common, were more willing to pay for an LAI than those in Rwanda.

Clinic-Level Barriers and Opportunities

Some LAI characteristics could affect service provision at the clinic level, which would, in turn, affect potential users' access to an LAI. The TPP used in the interviews specified a dosing schedule of 2 reinjections per year; a grace period, or reinjection window, of 1 month; and that the LAI should not require cold chain transportation and storage.

Overall, providers felt an LAI would fit into existing programs well, both because they thought that clients would be interested in the method type and duration and because they perceived that certain product characteristics could help relieve them of job-related stress. While providers did acknowledge that there may be initial difficulty or learning curves in time management, clinic workflow, and side effect management, they remained mostly positive about the potential of an LAI to enhance both client and provider satisfaction.

Dosing Schedule and Follow-Up Appointments

According to WHO guidance, the grace period for follow-up injections for the currently available

3-month injectable is 4 weeks, during which time women do not require additional contraceptive protection.¹⁶ Before WHO updated this guidance in 2008, the approved grace period was 2 weeks. In Kenya and Rwanda, some providers seemed unaware of this updated guidance because they thought the 1-month grace period for the LAI TPP was significantly different from the current reinjection window.

Most service providers in Kenya (12 of 15) agreed that a 6-month duration for the method would be desirable, while an additional few added that effectiveness up to 1 year would also be desirable. In Rwanda, 4 providers mentioned that everyone—women, providers, facilities—would benefit from a dosing schedule with fewer follow-up appointments.

Providers described a variety of ways in which they manage reinjection windows for injectables. While some providers in the two countries allow women the full grace period in which to return for reinjection, other providers intentionally advise women that the grace period is much shorter than what it really is or do not mention a grace period at all to ensure that women return on time. The majority of respondents in both countries thought that 4 weeks would give women sufficient flexibility to get to a facility or CHW for LAI reinjections. In Rwanda, 10 providers reported that they have problems with women returning late for follow-up injections, and 7 providers felt that a 4-week grace period would enable them to maintain continuation for more women. One CHW explained:

It [the seemingly longer grace period] is really good because [currently] if we count 2 weeks that a mother hasn't respected her appointment, we can't give her the method. If now it's a month, we are lucky, we will be sure that the service that we provide is impeccable.

In Kenya, 4 policy makers and 3 program implementers were concerned that discontinuation rates might be higher for an LAI (compared with currently available contraceptives) if side effects could not be managed properly as a result of longer periods between clinic visits. A Kenyan provider worried that clients would suffer side effects for longer periods of time without obtaining assistance if the reinjection schedule did not require clients to return as frequently. One provider worried about irreversibility in the event of severe side effects:

Many of the respondents in Kenya and Rwanda thought cost would be the determining factor in accessibility to a new longer-acting injectable.

Some respondents worried that longer periods between clinic visits for reinjections would make it difficult to manage side effects properly.

My concern would be if I inject the client and then we have this bleeding or somebody develops maybe blood pressure and maybe the drug will take a year or maybe 2 years [respondent's understanding of the potential duration of effectiveness], what will happen in between?

Several providers in Kenya—and several potential users themselves (see Tolley et al, 2014¹⁵)—noted that the irreversibility of an LAI could be problematic, either in relation to side effect management or if a woman changed her fertility intentions; both providers and users suggested that a way to reverse the drug could be important and useful. Conversely in Rwanda, only 1 respondent, a service provider, thought that side effects would be more difficult to manage with a lengthened dosing schedule.

Workload and Learning Curve for Providers

In both countries, most respondents thought that providers' workload would decrease with introduction of an LAI because of longer intervals between injections. A provider from Rwanda remarked favorably that workload is sometimes substantial but would lessen with the introduction of an LAI:

Work will decrease because the frequency of clients will also decrease ... we will do our work better because sometimes it happens that we don't do our work like we should because of the pressure of a line of people waiting outside the door. But when they are fewer, you can put your things in order without problems.

Most respondents agreed that longer intervals between injections would reduce the burden on the health care system.

Six opinion leaders agreed that an LAI would reduce the burden on the health care system because of longer intervals between reinjections.

However, several service providers from both countries mentioned that their workload might initially increase due to a perceived steep learning curve, as users would need to be educated about the method, many women would want to try it, and increased monitoring paperwork might be needed for a new method. As policy makers and program implementers pointed out, the high client volume many providers confront already favors administration of injectables over longer-acting methods, since from the providers' perspective, it is generally faster and simpler to give a woman an injection than to perform the more involved procedures required of IUDs and implants.

Storage and Stock-Outs

All respondents in both countries agreed that an LAI with no cold chain storage requirements was essential to ensure that a product could feasibly reach more users. In an open-ended question about important product characteristics, 9 opinion leaders also raised this as a priority. In Rwanda, all service providers volunteered that the ability to store an LAI without refrigeration would ensure wide access to the method. A CHW from Rwanda remarked:

What's really good is that we, community health workers, we don't have refrigeration ... so for us, a good medicine is one that we can use without difficulty and one in which we can have confidence in how it is stored. If you give CHWs medicines that require a fridge, it's expected that there would be many [commodity] losses.

Respondents acknowledged that stock-outs can limit access for potential users by delaying the initiation or continuation of a method, with stop-gap measures (such as condoms) providing less effective pregnancy prevention. Although not related directly to a TPP characteristic, several Kenyan and Rwandan providers reported that good record-keeping and planning help to avoid stock-outs at the clinic level and could also be applied to an LAI to ensure consistent access.

Distribution Mechanisms to Enhance Access

The TPP of the LAI included a goal of product distribution by CHWs. Respondents had differing levels of experience with CBD of family planning methods; their opinions about CBD of an LAI tended to be based on provider type and their familiarity with CBD programs. Respondents were divided about the possibility of self-injection of an LAI.

Community-Based Distribution

CBD of injectables has been ongoing in Rwanda since 2010, with a specific focus on rural areas, and most Rwandan respondents were positive about the program. With the exception of 3 providers, Rwandan respondents felt that a properly trained CHW should have a role in providing an LAI, especially for rural women. One nurse at a rural health center noted:

It's also an advantage for the women who live far from health centers, and also it helps approach more people and sensitize them [to family planning] since we don't do field visits.

A few Rwandan providers objected to CHWs providing an LAI, and they further expressed that CHWs did not have enough training to administer injections in general.

Although CBD of injectables is not widely available in Kenya, all but 2 policy makers and program implementers were very supportive of delivering an LAI through community-based mechanisms; they projected that task sharing with CHWs would save time both for clients and for facility staff and would better serve rural areas. Several policy makers and program implementers mentioned current pilots or earlier programs in which contraceptives were successfully provided at the community level. One government official stated:

It's not happening now, but it's likely to happen; there are efforts to scale it down to the community level by training the community health workers on the safety of injections and to provide those services in the hard-to-reach areas, and especially [places] where we're facing challenges of retaining or recruiting [staff from] medical training colleges.

However, only one-quarter of providers in Kenya envisioned this possibility. Common concerns about CBD of an LAI, or of any injectable, elucidated by nurses and midwives in Kenya (the largest provider group in the sample) included worries that CBD workers would not have adequate safe-injection training, proper resources to dispose of used needles, or the ability to manage side effects. One provider explained:

A community health worker may inject well, but when it comes to the biology ... in case of any side effects that need explanation, a community health worker may not be in a position to assist appropriately.

Among international opinion leaders, 6 mentioned that an LAI could ideally be administered by CHWs, with only 1 opinion leader expressing concern for potential confusion among CHWs when having to distinguish between the different types of injectables (ie, between the 3-month injectable and an LAI).

Self-Injection

With the introduction of Sayana Press, a DMPA product prepackaged in a single-use Uniject injection system administered subcutaneously, self-injection of injectable contraceptives may be feasible in the future. Respondents in both Kenya and Rwanda were divided on whether

self-injection of an LAI would be a good option for women. In Rwanda, 5 respondents agreed that self-injection could work, with caveats; 6 respondents strongly disagreed; and 2 respondents were non-committal. In Kenya, 9 respondents were not supportive of the idea, while 4 were fully supportive, and 6 others pointed out both advantages and disadvantages to the approach. There was no clear pattern by job function in either site.

Providers who agreed with the idea saw the potential for reduced workload for providers and tended to relate self-injection of a contraceptive to self-injection of insulin by patients with diabetes; they reasoned that if people with diabetes could be trained to self-inject and could manage their fears about injection, so could contraceptive users:

That would be very interesting because it would decrease the work [at the facility]. People could follow their [family planning] program without coming to the hospital. If we trained them like we do for those who have diabetes ...

Providers who disagreed foresaw problems with infection prevention, insecure storage of the product at women's homes, improper management of contraindications and side effects, and women's fear of the pain of injection as an inhibitor of timely and correct injections. A CHW, laughing in response to the question, explained:

Women are afraid of injections, they wouldn't dare do it themselves. And then they might keep it at their house without using it like they do sometimes with other medications. If there is no follow-up like we do, then all the women would surely get pregnant.

In open-ended email responses, 2 opinion leaders suggested that self-injection was an ideal characteristic for an LAI and specified a preference for a subcutaneous self-injectable via the Uniject delivery device.

Perspectives About Potential LAI Users

A TPP goal is to develop an LAI that could be used by all women of reproductive age—regardless of age or parity and without any contraindications—but especially by women immediately after childbirth and by breastfeeding mothers.

In general, respondents in both countries thought that while a wide range of women would be interested in an LAI, current satisfied injectable users might be logical early adopters who might switch to an LAI because it would be

Many nurses and midwives in Kenya worried that community health workers would not be able to provide injectables safely and effectively.

similar to the 3-month injectable but more convenient.

Most Kenyan policy makers and program implementers, along with 6 providers, stated that women who wanted to space their children would be especially interested in an LAI. However, Rwandan respondents envisioned an LAI to be used more for limiting births than for spacing births, and especially among women who have less familiarity and comfort with other longer-acting methods commonly used for limiting such as IUDs and implants.

Several respondents in both countries mentioned that an LAI would be advantageous because it would fill what they saw as a gap between currently available short-acting and long-acting methods. The potential for cost savings to women and couples if a 6-month product were priced approximately the same as a 3-month product was also noted by some respondents.

Respondents also acknowledged that certain subpopulations of potential users might be particularly interested in or appropriate for an LAI. In both countries, almost all service providers and several country-level stakeholders saw the need for an injectable product that could be used immediately after childbirth. Respondents differed a bit on their attitudes toward the use of an LAI by adolescent girls. Respondents in both countries acknowledged that school-aged girls are already interested in injectables but are often not having their contraceptive needs met for a number of reasons. There was some concern from Kenyan respondents about parental consent for minors or the potential for young women using the injectable to disregard using condoms to protect against sexually transmitted infections. In Rwanda, respondents were particularly supportive of adolescent use of an LAI with no contraindications; for some service providers, their support was driven by an inaccurate belief that the 3-month injectable is contraindicated for young women because of its perceived potential for sterility in women who do not have proof of fertility through previous pregnancy.

Few providers in either country were well-versed about whether the pharmaceutical formulation of hormonal contraception could increase susceptibility to and transmission of HIV infection, although policy makers and program implementers were familiar with recent WHO guidance and MOH statements released on the matter. Also, when asked about HIV, some respondents in both countries acknowledged the lack of HIV

prevention inherent to a non-barrier method. Some respondents also understood questions about HIV and hormonal contraception as whether an LAI could be used by women with HIV. Their responses reflected their opinions about whether women with HIV should have children, or they mentioned the potential interaction between hormonal methods and drugs typically taken by women with HIV (eg, antiretrovirals, tuberculosis treatment).

Policy maker, program implementer, and provider perspectives on overall interest in and acceptability of the product, as well as appropriate target user types, were generally consistent with potential users' interest as presented in the companion paper by Tolley et al.¹⁵ Generally, both potential users and other respondents ranked effectiveness as a very important characteristic for a potential LAI, prioritized a predictable return to fertility, and preferred a delivery system with a single, prepackaged disposable injection. Potential users were actually less concerned about side effects than were providers, perhaps reflecting providers' anticipation or worry that side effects of an LAI would require more of their time or would be more difficult to manage.

DISCUSSION

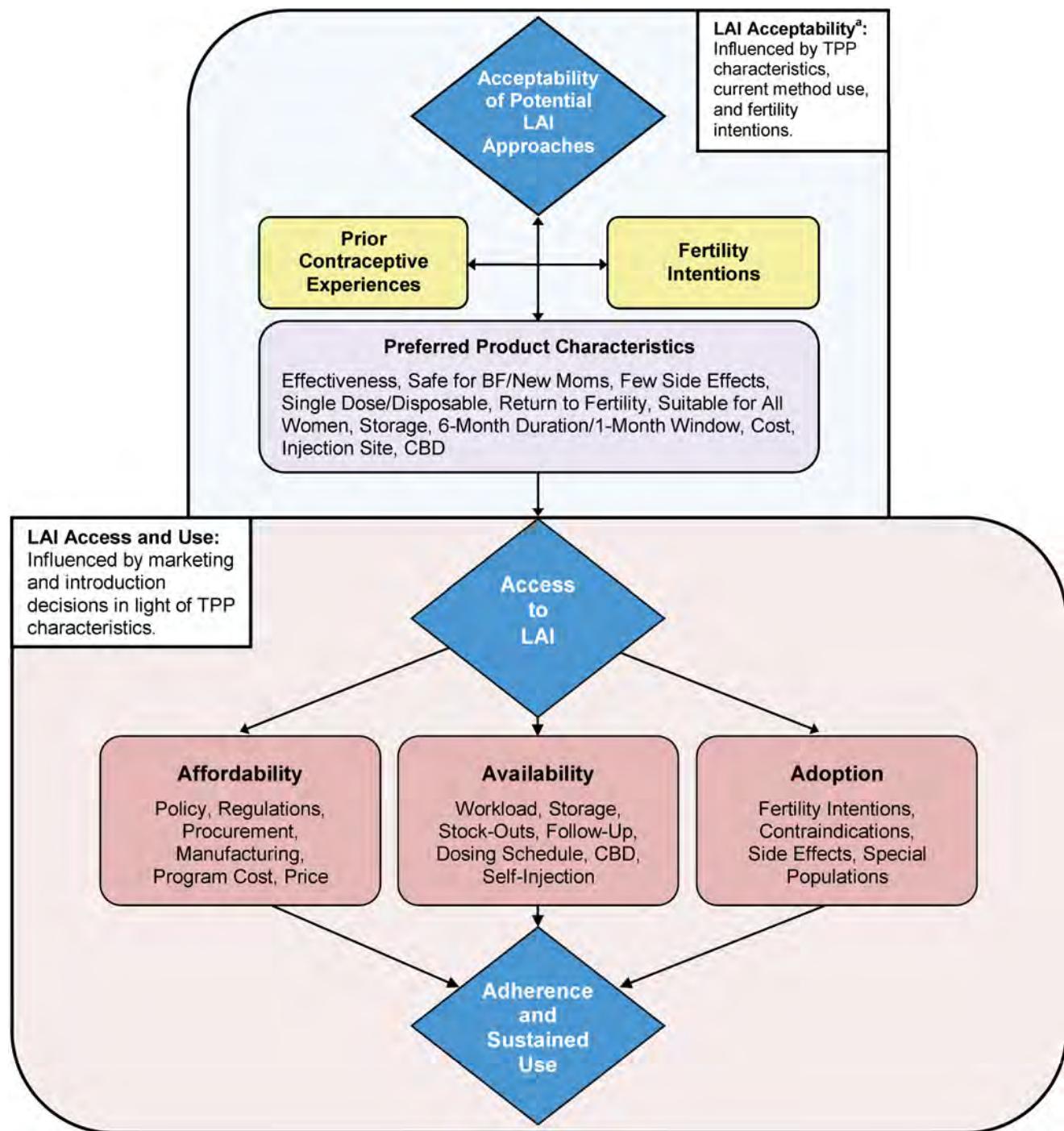
Both international and country-level stakeholders play a pivotal role in shaping access to and demand for new contraceptive products. A representative sample of such key stakeholders identified a number of possible barriers to and opportunities for increasing access to an LAI at the policy, facility, distribution, and user population levels. Using the access "architecture" proposed by Frost and Reich,¹⁷ their insights are organized into 3 distinct components (affordability, availability, and adoption) that, when taken together, comprise the conceptual model showing foundation for access to an LAI (Figure).

Affordability: Policy, Regulatory Bodies, and Manufacturers as Pivotal Components

Delays with regulatory approvals, challenges with procurement, or a lack of partnerships with low-cost manufacturers could hinder cost-effective product introduction and scale-up. These systemic issues could influence pricing, procurement, cost to the health system, and eventual availability of an LAI, which respondents viewed as larger issues than acceptability of the product among clients (Box 2). Although most respondents, especially

Several respondents thought a longer-acting injectable would fill a gap between currently available short-acting and long-acting methods.

FIGURE. Affordability, Availability, and Adoption: Systems-Level Considerations for Enhancing Access to an LAI



Abbreviations: BF, breastfeeding; CBD, community-based distribution; LAI, longer-acting injectable; TPP, target product profile.
^a For full version of the "Acceptability" portion of this figure, see Tolley et al, 2014.¹⁵

BOX 2. Key Take-Away Messages for Introducing a Longer-Acting Injectable

Acceptability. Service providers, program implementers, and policy makers from Kenya and Rwanda were interested in introducing an LAI into their health care systems and believed that women would find the method acceptable. They also felt that an LAI would fill a gap in the current method mix—especially for women desiring a method with duration somewhere in between that of the long-acting reversible contraceptives (IUDs and implants) and other short-acting methods (including the 3-month injectable).

Cost. Cost to health systems is a major consideration in the introduction of a longer-acting injectable. The up-front cost for getting the method approved, training staff on method provision, and establishing distribution processes should be balanced with the likely efficiencies experienced by overburdened health systems. Such efficiencies include a reduction in the number of reinjection visits that providers must deliver as well as the potential for decreased contraceptive discontinuation rates.

Community-based distribution. Community-based distribution and other innovative distribution mechanisms for an LAI would have a sizeable impact on enhancing potential users' access to the method.

Allowing CHWs to provide the longer-acting injectable could expand access to the method while also ensuring a manageable workload for clinicians.

those at the policy and program levels, believed that an LAI would fit into the national method mix well, procurement price could determine whether a product could be provided through public-sector programs. One question that remains is whether a 6-month injectable contraceptive has the potential to attract new family planning users or whether the current market for injectables will be “cannibalized” by the new LAI, thus resulting in little overall change in contraceptive prevalence rates at the country level. Still, even if a 6-month injectable does not attract high numbers of new family planning users, it is likely that an LAI would improve compliance and continuation rates among those who switch from existing injectables.¹⁸ Understanding these dynamics better could influence both forecasting for procurement and supply chain management.

Cost—to both the health care system and to the end-user—could be lowered by partnering with a manufacturer in an emerging market (eg, Brazil, China, or India), but not without considering the potential trade-off in real or perceived product quality. Other considerations are prioritizing an extended shelf life for the drug, ensuring early policy and program planning to guarantee adequate public-sector budgetary

allotment, and fully involving the public, private, and social marketing sectors in a comprehensive introduction strategy to reach potential users.

Creative strategies should be employed by product development groups, donors, governments, and distributors to guarantee access to a low-cost product among target populations in low-resource settings. Effective approaches that have been used with other contraceptives include, but are not limited to, public-sector pricing agreements with distributors, partnerships with manufacturers from emerging markets, and agreements brokered by donors that guarantee funding for set volumes of product in exchange for a lower price per unit.¹⁹ Additionally, attempts to make registration processes more efficient should be considered. Ongoing early regional harmonization efforts are underway, which may assist in fast-tracking product registration approvals.²⁰ Also, local registration partners can help navigate country-specific regulations and advocate product approval.²¹

Availability: Service Delivery and Distribution Mechanisms

The potential for a shortage of human resources to meet the demand for an LAI is a valid concern that should be examined. Task sharing with CHWs could be a feasible way to enhance service delivery and ensure that clinic-based health workers maintain a manageable client load. Additionally, disseminating updated guidelines on injectable service provision would help address some of the workload concerns among facility-based providers. For example, WHO's 2008 change to the approved reinjection window for the currently available injectable from 2 weeks to 4 weeks should allow more women the flexibility to receive a timely reinjection without the addition of extra appointments—and thus, provider time—to rule out pregnancy before receiving a reinjection.

To allay provider or client concerns about side effect management given longer periods between doses of the LAI, provider training could be expanded to include proper counseling for clients, and referral systems could be reviewed with providers, or new ones created. Training could build on the similarities to existing injectable products (eg, same mode of administration, contraindications, main counseling issues), while concurrently emphasizing the unique characteristics of this particular method. Ultimately, the introduction of an LAI could also be a timely opportunity to introduce

relevant information about the LAI and other injectable methods in order to make providers' jobs less burdensome.

Additionally, policy and program planning for CBD distribution of an LAI, in both the public and private/social marketing sectors, should be addressed early to ensure no delays if and when a new method is introduced. For instance, while this study was being conducted, CBD in Kenya had already been piloted but policy had not yet been changed. If pilot testing shows that access to injectables can be enhanced, policy makers and program managers will want to align national policy and clinical guidelines with usage and distribution for all injectables, including a potential LAI, to increase access for those in need. A particular focus may also be needed on sensitizing mid- and higher-level providers to the benefits of CBD, given that we saw reluctance about CBD from the sample of nurses and midwives in Kenya. Their reluctance may be partially due to fears about losing responsibility and status if CHWs were allowed to provide some of the same services that nurses and midwives currently provide.

Some respondents were supportive about self-injection as a possibility for potential LAI users. Although CBD might be a more viable option initially, alternate channels for service provision such as self-injection should still be considered. When CBD of contraceptives was first introduced, sensitization of all stakeholders and communities and proper training of providers led to many successful CBD programs; the introduction of self-injection of injectable contraceptives could follow a similar path.¹³ Patients with diabetes provide a case in point that people can safely self-inject and manage their fears about injections, which could be emphasized to both providers and users alike. Still, insulin is a very different product, requiring daily injection as opposed to twice-yearly injection of an LAI. Opposition to self-injected contraception might also be based on the misperception that women would need to self-inject with an intramuscular delivery device (instead of a subcutaneous device). Better education about self-injection of contraceptives could potentially alleviate provider reservations.

Adoption: Drawing on the Preferences of Potential Users

Policy makers, program implementers, providers, and international opinion leaders overwhelmingly had high interest in an LAI and believed that

women would as well, particularly if side effects and contraindications were minimized (for the views of potential users themselves, see Tolley et al, 2014¹⁵). Respondents had clear characterizations of the types of women they saw as potential users—women who already use the 3-month injectable, women who want immediate protection after childbirth and while breastfeeding, spacers in Kenya, and limiters in Rwanda. In some cases, however, these characterizations were partly based on inaccurate or questionable assumptions. These inaccurate characterizations draw attention to the nuances and potential pitfalls of relying on higher-level decision-makers to understand the needs and preferences of a user population. While providers and other stakeholders certainly have a role to play in assessing user population composition and in reaching that population, they are not immune to misperceptions that can hamper women's acceptance of a product. This again highlights the necessity of addressing the introduction of a new method with a holistic approach that considers user perspectives and lived experiences as well as those of providers, program managers, and policy makers. As women's health is a large focus of health systems, and health systems are largely guided by higher-level decisions, programs could enhance their effectiveness by more regularly and systematically "checking the pulse" of users in order to retain a more accurate depiction of user preferences and beliefs.

Also, most respondents from this sample expressed enthusiasm for a product that could be used immediately after birth. However, current WHO guidelines do not recommend initiation of progestin-only methods, including injectables, until 6 weeks postpartum.^{22,23} If an LAI could be administered after childbirth while women are still at a facility or via a postnatal checkup by a CHW, it would help to ensure that women receive timely and extended protection from rapid repeat pregnancies, therefore increasing healthy birth spacing. Modeling studies comparing possible disadvantages of administering injectables and/or other progestin-only methods immediately following childbirth to potential benefits of reducing morbidity and mortality associated with rapid repeat pregnancies could be potentially useful in steering guidance revisions. This might be a powerful consideration if substantial decreases in unintended pregnancies combined with decreased method discontinuation were resultant from guideline revisions.

Limitations

This study has several limitations. First, the study had a small sample size; in-depth interviews were conducted in only two countries, and the research used a qualitative design, limiting its generalizability. However, as is true with many qualitative studies, data collection was intended to provide a more in-depth understanding of interest in an LAI, including factors that influence product introduction and potential barriers to access. Second, the sample of opinion leaders was not a representative sample; it was determined via self-selection and therefore some bias is possible. Additionally, as the study was designed to assess the acceptability of key characteristics of a hypothetical LAI, responses collected from participants may have been limited by key informants' lack of knowledge of all facets of product introduction processes. Building on this initial research, future studies that focus on LAI introduction could determine more generalizable estimates for preferred product characteristics or identify most common health systems factors by including a larger sample with expanded country inclusion.

CONCLUSIONS

Stakeholders in Kenya and Rwanda—two countries with markedly different service delivery environments—were overall enthusiastic about a potential LAI. They thought the method would fill a special niche in their countries' method mix, with the unique attributes of the LAI promoting adoption among potential users both for spacing and for limiting births and to both current injectable users and new family planning clients. Messaging about the method will need to balance similarities of the LAI to other injectables with the LAI's distinctive characteristics. Introduction of a new LAI would be a timely opportunity to offer provider training on the new method as well as refresher training on all types of injectables to ensure providers are aware of and are using the most up-to-date service delivery guidelines. However, use of an LAI by women will largely be dictated by affordability and availability of the method. Creative strategies should be employed to ensure a low-cost product, for example, by partnering with manufacturers from emerging markets, arranging public-sector pricing agreements with distributors, and making registration processes more efficient. In addition, allowing all cadres of health care providers, including CHWs, to administer the product can help ensure wider access to the method.

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ORIGINAL ARTICLE

Getting closer to people: family planning provision by drug shops in Uganda

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Private drug shops can effectively provide contraceptive methods, especially injectables, complementing government services. Most drug shop clients in 4 peri-urban areas of Uganda were continuing users of DMPA; had switched from other providers, mainly government clinics, because the drug shops had fewer stock-outs and were more convenient (closer location, shorter waiting time, more flexible hours); and were satisfied with the quality of services. The drug shops provided a substantial part of the total market share for family planning services in their areas.

ABSTRACT

Background: Private-sector drug shops are often the first point of health care in sub-Saharan Africa. Training and supporting drug shop and pharmacy staff to provide a wide range of contraceptive methods and information is a promising high-impact practice for which more information is needed to fully document implementation experience and impact.

Methods: Between September 2010 and March 2011, we trained 139 drug shop operators (DSOs) in 4 districts of Uganda to safely administer intramuscular DMPA (depot medroxyprogesterone acetate) contraceptive injections. In 2012, we approached 54 of these DSOs and interviewed a convenience sample of 585 of their family planning clients to assess clients' contraceptive use and perspectives on the quality of care and satisfaction with services. Finally, we compared service statistics from April to June 2011 from drug shops, community health workers (CHWs), and government clinics in 3 districts to determine the drug shop market share of family planning services.

Results: Most drug shop family planning clients interviewed were women with low socioeconomic status. The large majority (89%) were continuing family planning users. DMPA was the preferred contraceptive. Almost half of the drug shop clients had switched from other providers, primarily from government health clinics, mostly as a result of more convenient locations, shorter waiting times, and fewer stock-outs in drug shops. All clients reported that the DSOs treated them respectfully, and 93% trusted the drug shop operator to maintain privacy. Three-quarters felt that drug shops offered affordable family planning services. Most of the DMPA clients (74%) were very satisfied with receiving their method from the drug shop and 98% intended to get the next injection from the drug shop. Between April and June 2011, clinics, CHWs, and drug shops in 3 districts delivered equivalent proportions of couple-years of protection, with drug shops leading marginally at 36%, followed by clinics (33%) and CHWs (31%).

Conclusion: Drug shops can be a viable and convenient source of short-acting contraceptive methods, including DMPA, serving as a complement to government services. Family planning programs in Uganda and elsewhere should consider including drug shops in the network of community-based family planning providers.

INTRODUCTION

Drug shops are privately owned medicine outlets that are legally permitted to sell only nonprescription medications. Unlike pharmacies, drug shops

are not required to employ trained pharmacists. Drug shops are often the first line of health care in sub-Saharan Africa,¹ and, in countries such as Uganda that have high rates of maternal mortality and morbidity, they can play an important role in providing basic health care.²

Training and supporting drug shop and pharmacy staff to provide a wide range of contraceptive commodities and information is one of several promising high-impact practices in family planning,³ especially in light

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of evidence that paraprofessional health workers can safely administer injectable contraceptives in addition to providing oral contraceptive pills and condoms.⁴ However, more information is needed to fully document implementation experience and impact.

Private-sector drug shops are more readily found in underserved rural trading centers and peri-urban areas than in towns and cities, making them important players in increasing access to and use of family planning at the community level. In addition, as a private enterprise, drug shops are less likely than public-sector health facilities to suffer from commodity stock-outs and thus are potentially a sustainable source of contraceptive methods.⁵ Recognition of the utility of drug shops in providing short-acting contraceptive methods is growing in Africa.^{6–8} The recent introduction in Uganda and elsewhere of Sayana Press, a subcutaneous formulation of DMPA (depot medroxyprogesterone acetate), increases the prospects for non-clinic provision of DMPA and may catalyze policy action in favor of DMPA provision in drug shops.^{9–11}

In Uganda, where only 23% of currently married women use a modern contraceptive method but 34% of such women have unmet need for family planning,¹² drug shops could play an important role in increasing access to family planning in hard-to-reach areas. A large proportion of family planning users (45%) obtain their methods from the private medical sector. Drug shops and pharmacies provide methods to 5.5% and 3.1% of users, respectively.¹² At 14% prevalence, intramuscular DMPA remains the method of choice for many women in Uganda.¹²

Drug shops in Uganda are regulated by the National Drug Authority (NDA), which mandates drug shops to sell only unrestricted or unclassified medicines. Within this policy, drug shops offer oral contraceptive pills and condoms.¹³ Administration of intramuscular DMPA is not included within the NDA policy, but in practice drug shops do provide DMPA.² Drug shops depend on the commercial private sector to maintain their medicines supply chain, obtaining their supplies from large wholesale pharmacies who, in turn, procure contraceptives from social marketing or other commercial suppliers.

Under the STRIDES for Family Health project in Uganda, funded by the United States Agency for International Development (USAID), private drug shops were included, beginning in 2010, in efforts to expand the method mix of available

contraceptives in Luwero and Nakasongola districts in central Uganda and in Mayuge and Bugiri districts in east-central Uganda. Uganda has 112 districts, with an average of 216,315 people in each district.¹⁴ By September 2011, 139 drug shops in the 4 selected districts had been identified and recruited by FHI 360, a STRIDES subcontractor, to provide family planning products and services. With the approval of the Ministry of Health (MOH), drug shop operators (DSOs) affiliated with these establishments were trained to counsel clients and administer DMPA injections.

In 2012, the PROGRESS (Program Research for Strengthening Services) project, a 5-year USAID-funded project implemented by FHI 360, carried out an enhanced evaluation to assess the contribution of drug shops to family planning service provision in the 4 selected districts of Uganda. Specifically, the evaluation estimated the market share of contraceptive method uptake of all methods provided by the drug shops and documented clients' level of satisfaction, perceptions of quality of care, counseling received, and intention to continue using drug shop family planning services.

PROGRAM DESCRIPTION

DSO Training

Between September 2010 and March 2011, we held 4 training workshops, one for each district, led by a national trainer closely assisted by the district officer in charge of family planning and reproductive health. In each workshop, we taught a maximum of 35 DSOs how to provide family planning methods, with an emphasis on DMPA, through several adult learning methodologies, including group discussions, demonstration and return demonstration (participants demonstrating back to the trainers what had just been demonstrated to them), and role play simulations. The training content included counseling clients to support informed choice, screening clients, procedures for ensuring infection prevention and injection safety, medical waste disposal, and referring clients for other methods or for complications. Each workshop was restricted to 2.5 days based on the assumption that the participants had some medical background and would already have some knowledge about family planning methods and their provision. Since the DSOs already knew how to provide intramuscular injections, we did not include a clinic practicum

Drug shops are increasingly recognized as important providers of short-acting contraceptive methods.

session. However, all participants were required to demonstrate competency with injections during classroom demonstrations.

The training was based on the following resource materials: *Family Planning: A Global Handbook for Providers* (www.fphandbook.org); a manual on initiating clients on DMPA developed by FHI 360; and family planning provider checklists. At the end of the training, we provided each participant with the following resource guides:

- Provision of Injectable Contraception Services Through Community-Based Distribution: Implementation Handbook
- Checklist for how to be reasonably sure a client is not pregnant
- Checklist for screening clients who want to initiate DMPA
- Checklist for screening clients who want to initiate combined oral contraceptives
- Family Planning Methods: A Flip Chart for Community Health Workers

(For full-text access to the first 4 resources, see the Community-Based Family Planning Toolkit at: <https://www.k4health.org/toolkits/communitybasedfp/training>; the last resource is available at: https://www.k4health.org/sites/default/files/FP_Flipchart_Community_Health_Workers.pdf.)

DSOs completed a written pre- and post-training questionnaire. The average score at pretest was 28%, with a range of 20%–53%. At posttest, the average score was 71%, ranging from 40%–98%. Overall, the evaluations revealed that the participants had limited knowledge of the full range of contraceptive methods.

Supportive Supervision of the DSOs

Following training, the DSOs returned to their shops and began to administer DMPA with supportive supervision from the district health management team and FHI 360 staff. The aim of supportive supervision was to enhance the DSOs' skills, collect data, and troubleshoot any problems. Supportive supervision was conducted through quarterly DSO meetings (at which time, DSOs were retrained by district staff if necessary), field visits from FHI 360 staff, and independent visits from the District Assistant Drug Inspector (DADI).

We later amended the supervision strategy to deploy the DADI with other district health management team members or FHI 360 staff to foster trust between the drug inspectors and drug

shops. Prior to this project, the DADI's role was to enforce the NDA Policy by closing drug shops that were not in compliance with the law. In our experience, when the drug shop owners saw the DADI's vehicle in the village, the owners would close the drug shops, preventing the drug inspectors from conducting their supervision visits. Deploying the inspectors with other project staff helped change the perception of the DADI's role.

Data Reporting

Data were collected on numbers of new and revisit family planning clients, clients counseled, and contraceptive products distributed. Initially, the DSOs were supposed to submit these data directly to the district's health management information system (HMIS). However, the DSOs had little motivation to submit the data since they did not receive public-sector commodities or transport or other allowances from the government. Therefore, FHI 360 collected and submitted the data to the districts on behalf of the DSOs, which helped ensure data accuracy prior to submission.

Logistical Support to Drug Shops

To increase the incentive for drug shops to provide family planning, FHI 360 provided them with logistical support, comprising a storage cupboard for records and supplies, files and record books for recording family planning service data, counseling guides, and a job aid on the USAID family planning compliance requirements. We also labeled and branded the drug shop with the MOH family planning symbol, the name of the drug shop, and USAID and project logos. The drug shops provided socially marketed contraceptives and sold them at the retail price recommended by the social marketing agency. FHI 360 did not have any role in ensuring family planning commodity availability at the drug shop.

METHODS

DSO and Client Interviews

We randomly selected 54 drug shops from the list of 139 eligible shops to participate in the evaluation. Between July and August 2012, we approached the 54 drug shop owners and collected information on their age, sex, level of education, and highest professional qualifications achieved. We asked them to recruit, over a 6-week period, interested family planning clients (men and women) to participate in a cross-sectional survey. We aimed to recruit a minimum of 510 family

TABLE 1. Distribution of Study Participants and Other Characteristics by District, Uganda

	Bugiri	Mayuge	Luwero	Nakasongola	Total
Total population in 2002 ^a	237,441	324,674	341,317	127,064	
No. of drug shop owners interviewed	16	14	12	12	54
No. (%) of drug shop family planning clients interviewed	181 (30.9)	168 (28.7)	112 (19.2)	124 (21.2)	585 (100.0)
No. of government clinics in the evaluation subcounties ^b	11	8	13	N/A	32
No. of community health workers in the evaluation subcounties ^b	30	30	30	N/A	90

^a Data from the 2002 Uganda Population and Housing Census.¹⁴

^b Family planning service statistics from government clinics and CHWs were used for the market share analysis.

planning clients, allowing us to estimate the client satisfaction rate with a 95% confidence interval within 5% precision. Drug shop operators were asked to keep track of client refusals to assess if the response rate dropped substantially (below 85%) to flag potential biases in the sample.

All clients recruited by the DSOs were interviewed, resulting in a sample of 585 clients (Table 1). Using a structured questionnaire, we interviewed these clients to assess their contraceptive method use and perspectives of, and satisfaction with, drug shop-provided family planning services. Information gathered by interviewers was entered and managed in Epi Data, version 3.1. We used clients' reports of contraceptive use to calculate the proportion of interviewees who were new to family planning and to DMPA use. A new family planning client was defined as any client who was using contraception for the first time ever. We performed frequencies and cross-tabulations to assess data on client satisfaction and perceptions of quality of care, as well as limited bivariate analyses to assess whether satisfaction, quality of care, counseling, or method/service point switching were associated with drug shop characteristics and settings.

Analysis of Service Statistics

We also conducted a comparative retrospective review of service statistics from drug shops, community health workers (CHWs), and government clinics to determine the drug shop market share of family planning services. A list of all the clinics, drug shops, and CHWs in the project

subcounties was obtained from the district health office. Information on family planning uptake from CHWs and drug shops was available from project monitoring records while information from clinics, including private clinics and hospitals, was obtained from HMIS records at the district health offices. Data from these 3 major sources of supply were entered into Excel to compute the family planning market share of drug shops. Market share calculations were based on data from 3 of the 4 selected districts that had the data disaggregated by subcounty, and the calculations spanned the 3 months (April, May, and June 2011) for which complete data from all sources were available. To calculate the drug shop market share, we computed the total number of couple years of protection (CYPs) delivered by drug shops as a proportion of all CYPs from all sources in subcounties that had participating drug shops.

RESULTS

Background Characteristics of DSOs and Clients

Of the 54 DSOs we approached, 76% were female. Their average age was 37 years, and the majority (92%) had a background in health care as a nurse, midwife, clinical officer, or nursing aide (data not shown).

The DSOs contacted 585 of their family planning clients, all of whom agreed to participate in the evaluation. The large majority (90%) of the clients were female, and most were of reproductive age with an average age of 28.8 years (range, 13–52 years) (Table 2). The clients had, on average,

The large majority of the drug shop operators we interviewed had a medical background.

TABLE 2. Background Characteristics of Drug Shop Family Planning Clients, N=585

Characteristics	
Sex, %	
Female	90.1
Male	9.9
Age, ^a mean (range), y	28.8 (13.0–52.0)
Marital status, %	
Single	10.3
Married	66.5
Unmarried, living together	15.7
Separated/divorced/widowed	7.5
No. of children, ^a mean (range)	3.4 (0.0–13.0)
Highest level of education completed, %	
Did not attend school	6.5
Kindergarten/nursery school	24.8
Primary	43.1
Secondary or higher	25.4
Missing	0.2
Works for money, %	
Yes	77.9
No	15.1
Missing	7.0
Type of work, %	
Running a shop/stall/business	44.3
Farming	24.1
Housewife	12.0
Other	12.6
Missing	7.0
Socioeconomic status, %	
Very low	30.3
Low	29.9
Medium	31.4
High	8.4
Desires a baby in the future, %	70.6

^a Data are among 584 clients (missing data for 1 client).

3.4 children (range, 0–13), and 71% of them desired a child in the future. More than half of the clients were married (67%) while 16% were cohabiting, 10% were single, and 8% were separated, divorced, or widowed. One-quarter had attained secondary school education or higher, while 31% had not received any formal schooling.

The majority of clients (78%) worked for money; 44% ran small-scale businesses (eg, retail shops, food market stalls, secondhand clothing stores, and other types of retail business) and 24% practiced farming. Despite being involved in income-generating activities, 60% were categorized as low or very low socioeconomic status and only 8% were categorized as having a high socioeconomic status.

Family Planning Use

About 11% of all interviewed drug shop clients were new family planning clients (Table 3). Most (79%) of the drug shop clients were using DMPA while 10% were using oral contraceptives and 11% were using condoms. The trend was similar among new family planning clients, with 79% choosing DMPA, and 9.7% each for condoms and pills (Figure 1).

Among the 29% of clients who were method switchers (n=170), the most commonly cited reason for switching was side effects (41%), followed by excessive or prolonged bleeding (24%) (Table 4). Nearly 1 client in every 5 cited issues related to logistics or adherence to the method as reasons for switching methods.

Almost half of all drug shop clients (47%) had received their last contraceptive method supply elsewhere and were considered to have switched providers. Of those who had switched providers, the majority (66%) had switched from a government clinic/health center. Among those switching from a government location or a pharmacy, the most cited reason for switching providers was the convenient location of the drug shop (43%), while 12% mentioned that there was a shorter waiting time at the drug shop (Table 5). Other reasons mentioned with almost equal frequency were flexible hours of operation/better service (11%) and fewer stock-outs (10%) at the drug shop compared with clinics and health centers.

Ninety-two percent of the DMPA clients intended to get another injection. Among these, almost all (98%) mentioned the drug shop as the location of their next injection. Of the 10 clients who did not want to go to the drug shop, half cited money as the barrier (data not shown).

TABLE 3. Contraceptive Methods Used by Drug Shop Family Planning Clients, N=585

Characteristic	Percent
Method received at drug shop	
DMPA injectable	78.6
Condoms	10.9
Oral contraceptive pills	10.2
Implants ^a	< 1%
Ever use of family planning (FP)	
Used FP in the past, same method as current	60.3
Used FP in the past, different method from current	29.1
First-time user	10.6

^a One client reported that she received an implant from a drug shop operator.

TABLE 4. Reasons for Switching Methods Among Family Planning Clients Reporting Use of a Different Method in the Past, n=170

Reasons ^a	Percent
Side effects	41
Excessive/prolonged bleeding	24
Logistics/adherence	18
Couples' discussion/preference	14
Other	12

^a Total does not sum to 100% because clients could choose more than 1 reason.

Client Satisfaction and Perceptions of Quality of Care

Client reports of satisfaction and quality of care were positive. All clients (100%) reported that the DSOs treated them respectfully, and 93% trusted the DSO to maintain privacy (Table 6). About three-quarters felt that drug shop family planning services were affordable.

Among the surveyed DMPA users (n=460, or 79% of the sample), about three-quarters were very satisfied with the method (Table 6). In addition,

96% would recommend the drug shop to a friend for family planning services, reflecting the overall high level of satisfaction with DMPA services from drug shops.

Client satisfaction with services was higher with female drug shop operators (74%) than with male (24%), although this difference was not statistically significant. Clients of female DSOs were significantly more likely to report the DSO had discussed side effects than clients of male DSOs (48% vs. 14%, respectively; $P < .05$)

Most DMPA users were very satisfied with the method.

FIGURE 1. Client Method Choice at Drug Shops for New and Continuing Users, Selected Districts of Uganda, N=585

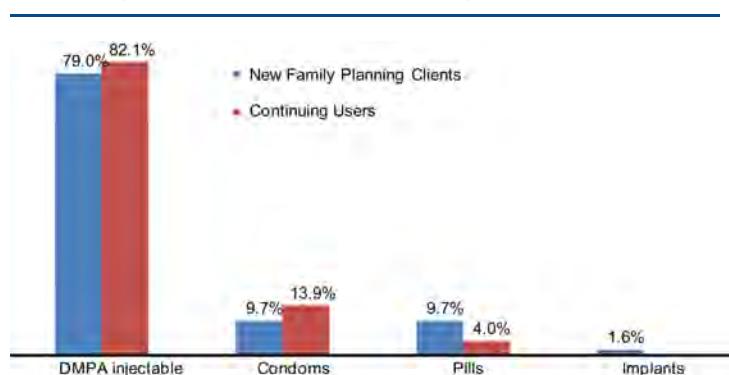


TABLE 5. Reasons for Switching to the Drug Shop Among Clients Who Switched From Pharmacies or Government Facilities, n=184

Reasons ^a	Percent
Convenient location	43
Shorter wait time	12
Flexible hours of operation/better service or cost	11
Fewer stock-outs	10
Other	10
Missing	22

^a Total does not sum to 100% because clients could choose more than 1 reason.

TABLE 6. Client Perceptions of Quality of Care and Client Satisfaction, N=585

Characteristic	Percent
Friendliness of DSO	
Talked to client in a friendly way	89.1
Did not talk to client much	8.7
Talked to client in a unfriendly way	2.2
DSO treated client with respect	100.0
Trust the DSO will protect privacy	
Yes	93.3
No	1.2
Do not know	5.3
Missing	0.2
Feel family planning DSO services are affordable	
Yes	75.6
No ^a	21.7
Missing ^a	2.7
Will continue to go to DSO for family planning services	
Yes	94.0
No	5.5
Missing	0.5
Satisfied with the way the DSO provided the method	
Yes	99.0
No	1.0
Satisfied with DMPA ^b	
Very much satisfied	73.9
Somewhat satisfied	22.2
Not at all satisfied	3.3
Missing	0.6
Always go to same DSO for DMPA ^b	
Yes	90.0
No	9.8
Missing	0.2

Abbreviations: DSO, drug shop operator; DMPA, depot medroxyprogesterone acetate.

^a Many of the clients with "no" or "missing" responses had received services for free.

^b Data among DMPA users only (n=460).

(Table 7). It is important to note, however, that there were many more female than male drug shop operators in the sample.

Drug Shops' Market Share of Family Planning Services

Data from selected subcounties in 3 districts for April 2011 through June 2011 show that, overall, clinics, CHWs, and drug shops delivered equivalent proportions of CYPs to the community, with drug shops leading marginally at 36%, followed by clinics (33%) and CHWs (31%) (Figure 2). Variations existed within districts, with drug shops in Bugiri district enjoying the largest market share in that district (44%) and drug shops in Luwero district having the least market share (26%).

DISCUSSION

Based on reports from the clients we interviewed, we found that drug shops serve more continuing than new family planning users, suggesting that drug shops may be better placed to resupply existing family planning users. We also found that almost half of all interviewed drug shop clients had received their previous method resupply elsewhere, mainly from government clinics. This switching behavior was attributed largely to more convenient locations, fewer stock-outs, and flexible hours and shorter waiting time at the drug shops than in clinics. These findings reflect nationwide statistics, which show that waiting time at government clinics is more than 6 times that at private clinics and that, at any given time, one-third of government health facilities are likely to face stock-outs of key health commodities, including DMPA.¹⁵

These findings suggest that drug shops, which are usually located in peri-urban areas where access to family planning and other health services is not as problematic as in rural areas, likely provide existing family planning users more convenience in resupplying their methods. Unmet need for family planning as a result of limited access to services, on the other hand, is largely a rural phenomenon. Another study in Uganda found that CHWs are more likely to serve *new* family planning users as a consequence of their placement in rural communities.⁵ Drug shops with trained providers can play an important role in peri-urban areas as an alternative source of contraceptive methods in cases where government clinics cannot meet client demand due to stock-outs or to geographical distance from users.

We also found that the quality of family planning services reported by drug shop clients was high. Clients unanimously agreed that the DSO treated them respectfully and almost all trusted the DSO to maintain their privacy. Perceived quality of services is considered to be a predictor of client satisfaction with services,^{16,17} which was indeed the case in our study. For DMPA, in particular, almost all clients indicated an intention to get their next injection from the drug shop. This is consistent with comparatively high satisfaction with private health care services found elsewhere.¹⁸⁻²⁰ This high level of satisfaction, combined with the short waiting time, flexible hours, and convenient location as reasons for switching providers, suggests that drug shops are an acceptable provider of family planning, and particularly of DMPA resupply. In October 2014, the Ministry of Health in Uganda convened stakeholders to discuss the evidence on drug shops as a first step toward influencing policy change to allow DMPA provision in drug shops.

This proposition is reinforced by our finding that, drug shops, CHWs, and clinics deliver roughly equivalent amounts of CYPs to clients. However, there were differences in the drug shops' share of the family planning market among the 3 districts, with drug shops leading the market share in one district and having the least market share in another district. When we compared our market share findings with findings from a national assessment of the Uganda health system, we did not find the drug shop market share was related to the strength of the health systems in the 3 districts or to rural-urban differences in the 3 districts. This limits our ability to make inferences about the comparative strength of drug shops as a stakeholder in the general family planning market. Rather, this finding underscores the complementary role of the government and private sector in meeting people's family planning goals within the context of the total market approach to family planning.

The overall 36% market share of drug shops in the 3 districts included in our evaluation contrasts starkly with national data from the 2011 Uganda Demographic and Health Survey, which reports that only 3% of women get their methods from pharmacies and about 6% get them from drug shops.¹² The reason for the disparity might be that DMPA provision in drug shops was a focus of the STRIDES project. Drug shop operators were trained in the safe provision of DMPA and provided with job aids and supportive supervision; thus, they

TABLE 7. Client Satisfaction and Reports of Counseling Received (%), by Sex of Drug Shop Operator (DSO),^a N=585

Characteristic	Services Received by:		P Value
	Female DSOs	Male DSOs	
Satisfaction with family planning services received at DSO			.54
Satisfied/somewhat satisfied	74.1	24.4	
Not at all satisfied	1.0	0.5	
DSO discussed:			
<i>Side Effects</i>	48.2	13.5	.04
Advantages	42.9	13.2	.48
Disadvantages	28.4	8.7	.75
Warning signs	42.1	12.7	.47
Would continue to go to DSO for family planning services	70.8	23.7	.74

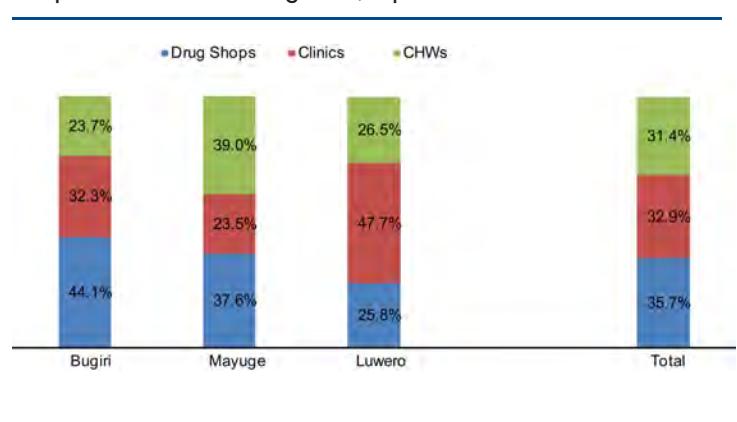
P < .05 was considered statistically significant (shown in italics).

^a The majority of the DSOs were women (42 female DSOs vs. 12 male DSOs).

were both empowered and motivated to counsel clients about DMPA and provide the method.

Finally, 3 drug shop clients of every 10 whom we interviewed did not want to have any more

FIGURE 2. Market Share of Family Planning Services^a Provided by Clinics, Community Health Workers (CHWs), and Drug Shops in 3 Districts of Uganda, April–June 2011



^a Measured by couple-years of protection delivered by each source.

children. These are women for whom a more effective long-acting or permanent method of contraception might be suitable. This finding emphasizes the need for family planning programs to bring long-acting reversible contraception and permanent methods closer to clients. It also raises the prospect of drug shops as sources of information and referral for such methods.

Strengths and Limitations

The quality and availability of data had an impact on our market share analysis. The market share analysis relied on HMIS records for family planning service provision data from clinics, but the HMIS did not always have such data. In addition, the market share analysis required data by subcounty, but in some cases, drug shop data were not disaggregated by subcounty and therefore could not be used in the analysis. Also, in some months (September 2010–March 2011), CHWs in some districts were not active, yielding no data. Thus, the market share analysis used data from only 3 months (April, May, and June 2011) for which complete data from all sources were available.

In addition, our sample of drug shop clients was a convenience sample drawn by asking the DSOs to invite their clients to participate in the survey. Therefore, the sample is not representative of all drug shop clients. In addition, there is a possibility that the DSOs invited only clients they considered to be satisfied clients, which would introduce a bias. However, since a large number of clients enrolled, the effect of this bias is probably not large.

CONCLUSION

Drug shops can be a viable and convenient source of short-acting contraceptive methods, including DMPA injectables, particularly for continuing users but also for new family planning clients. Together with government services, drug shops and other private-sector providers offer complementary roles in meeting people's family planning needs and should be included in the network of community-based family planning providers in Uganda.

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SHORT REPORT

Maternal mental health in Amhara region, Ethiopia: a cross-sectional survey

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Poor mental health, including suicidal thoughts, affects a substantial proportion of surveyed women who are up to 2 years postpartum in the Amhara region of Ethiopia. Opportunities for integrating basic psychosocial mental health services into maternal and child health services should be explored.

ABSTRACT

Background: Postpartum common mental disorders (CMD) such as depression and anxiety are increasingly recognized for their burden in low-resource countries such as Ethiopia. However, the magnitude of postpartum CMD in Ethiopia is not well-established. This short report describes the mental health status of women who had given birth in the last 24 months in the Amhara region of Ethiopia.

Methods: A cross-sectional survey was conducted among 1,319 women aged 15–49 years old who had a delivery in the previous 24 months from 30 randomly selected *kebeles* (smallest administrative unit in Ethiopia) across Amhara region. The survey included the Self-Reporting Questionnaire (SRQ-20) developed by the World Health Organization—a CMD screening instrument that includes 20 yes/no questions on depression, anxiety, and somatic symptoms experienced in the last 30 days. We used 2 cutoff scores to determine probable cases of mental disorder: (1) 4/5 (≤ 4 “yes” responses=non-case, ≥ 5 “yes” responses=case) based on a study that validated the SRQ-20 against a diagnostic tool in Butajira, Ethiopia, and (2) a more conservative and commonly used 7/8 cutoff.

Results: Among the 1,294 women who completed the full survey including the SRQ-20, 32.8% had probable CMD using the 4/5 cutoff score versus 19.8% using the more conservative 7/8 cutoff. About 15% of the women responded affirmatively that they had had suicidal thoughts.

Conclusion: Poor mental health was common among the surveyed women who had given birth in the past 24 months in Amhara region, Ethiopia. Integrating mental health care into maternal and child health services could potentially alleviate the burden of CMD among women in the extended postpartum period.

INTRODUCTION

Mental disorders during and after pregnancy are increasingly recognized for their burden in low- and middle-income countries (LMICs)—for both the disability among the affected women and the asso-

ciated impact on their children.^{1–4} A review of studies on postpartum common mental disorders (CMD), which include depression and mixed depressive, anxious, and somatic symptoms, among women in LMICs revealed a weighted mean prevalence of 19.8%.¹ In Africa, another systematic review found a weighted mean prevalence of 18% for depression among postpartum women and 14% for anxiety.² Risk factors for postpartum CMD include poverty, marital status (unmarried), marital conflict, family conflict, higher parity, adverse reproductive health outcomes (eg, unintended pregnancy, pregnancy complications, stillbirth), and lack of social support.^{1,2}

The magnitude of postpartum CMD in Ethiopia is not well-established. Estimates for depression during and after pregnancy have ranged from

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9% to 20%,^{9,10} and for postpartum CMD, the estimates have been as high as 33%.¹¹ Understanding the postpartum CMD burden is important for informing mental health services and policies.

In order to reach postpartum women suffering from disabling depression, anxiety, or somatic disorders, global guidance promotes integrating mental health services into maternal and child health (MCH) care platforms.⁵ In many contexts, integration must extend beyond facility-based services because many women lack access to such services. For example, in the Amhara region of Ethiopia, 89% of women deliver at home and 93% do not receive a postpartum checkup within 41 days after delivery.⁶

To improve access to services for many of the poorest and most remote Ethiopians, the government established the Health Extension Program, which includes a cadre of trained health extension workers (HEWs) who provide community-based services.⁷ Per government guidelines, HEWs are at least 18 years old, are women (except in pastoralist areas), have at least a 10th grade education, and are nominated and selected at the local level.⁷ Each *kebele* (smallest administrative unit in Ethiopia, similar to a ward) has 1 health post (lowest level of primary care) with 2 HEWs who provide a variety of health services, including the pregnancy continuum of care. The HEWs conduct home visits, hold community conversations on health topics, and distribute health-related commodities. In theory, they also have mental health training to screen people for mental health problems and refer them for services, and they are tasked with mental health prevention, promotion, and ongoing community-based care.⁸ Diagnosis and treatment for mental disorders is offered at the next level of care (health centers), staffed by health officers and nurses.

This report describes the mental health status of Ethiopian women up to 2 years postpartum in the Amhara region. The mental health data are from a study undertaken by the Amhara Regional Health Bureau and FHI 360 whose main purpose was to identify factors associated with postpartum family planning use; the study hypothesized that mental health was one such factor but did not find an association between mental health status and postpartum family planning uptake.¹²

METHODS

A cross-sectional survey was conducted among 1,319 women aged 15–49 years old who had delivered within the previous 24 months, from 30 randomly selected *kebeles* across Amhara region. Participants were recruited from 3 randomly selected zones, comprising East Gojjam (n=389), South Wollo (n=385), and North Gondar (n=390), as well as 1 additional zone, Bahir Dar (n=130), which was purposefully selected for urban representation. Data collectors approached local health workers, including HEWs, at the selected *kebeles* to generate lists of women who had delivered within the last 24 months regardless of whether the delivery took place at a health facility or at home. In addition, the selected women were asked if they knew any other women who had delivered within the last 24 months in their area.

The survey included the Self-Reporting Questionnaire (SRQ-20) developed by the World Health Organization (WHO), which is a CMD screening instrument that includes 20 yes/no questions on depression, anxiety, and somatic symptoms experienced in the last 30 days.¹³ Each of the 20 questions is scored 0 (no) or 1 (yes), with the total score ranging from 0 to 20; a cutoff score is used to determine probable cases of mental disorder or poor mental health. The SRQ-20 has been used extensively in Ethiopia among various populations as well as across Africa.^{10,14–16} For this study, we obtained an Amharic-translated and pretested version of the SRQ-20 from colleagues who used it with a perinatal population.¹⁰

We received ethical approval from the Protection of Human Subjects Committee at FHI 360 and the Institutional Review Board at the Amhara Regional Health Bureau. Participants provided oral informed consent. All interviews were conducted at participants' homes (usually outside to ensure confidentiality during the interview). Participants who responded affirmatively to the suicidal ideation item or to ≥ 10 questions were referred to local health services.

A total of 1,294 nonpregnant women who had given birth in the previous 24 months completed the survey including the SRQ-20. We present CMD prevalence estimates using 2 different SRQ-20 cutoff scores. The first is a 4/5 cutoff score (ie, ≤ 4 "yes" responses=non-case, ≥ 5 "yes" responses=case), which we selected based on an unpublished study that validated the

About 20% of postpartum women in developing countries have common mental disorders.

The WHO Self-Reporting Questionnaire is a simple and commonly used tool to screen for common mental disorders.

SRQ-20 against a diagnostic tool in antenatal clinics in semi-rural areas around Butajira, Ethiopia. The study found an optimal cutoff score of 5 or more with 80% sensitivity and specificity (personal communication with Dr. Charlotte Hanlon, Addis Ababa University, 2014 Apr 2). Another study using the SRQ-20 with perinatal women in Ethiopia found conflicting evidence for optimal cutoff scores.¹⁰ We therefore also present SRQ-20 data using a 7/8 cutoff, which has been commonly used in other studies around the world.¹⁸ The bivariate association between mental health and relationship status was conducted using Pearson's chi-square test and adjusted for clustering at the *kebele* level.

RESULTS

20% to 33% of the surveyed women in Amhara region had poor mental health.

Among the 1,294 surveyed women, 32.8% had probable CMD using the 4/5 SRQ-20 cutoff score (responding affirmatively to 5+ items). Using a more conservative cutoff of 7/8 (responding affirmatively to 8+ items), 19.8% had probable CMD.

Probable CMD by zone using the 7/8 cutoff was 24.1% in North Gondar, 15.2% in East Gojjam, 19.5% in South Wollo, and 21.5% in Bahir Dar.

About 15% of surveyed women had had suicidal thoughts.

A sizable proportion of women (n=187, or 14.5%) responded affirmatively to the question, "Have you thought of ending your life?", indicating the recent burden of suicidal thoughts among this population (Table).

Unmarried women (n=120, or 9.3% of the total sample) were significantly more likely than married women to experience poor mental health ($P < .0001$). In this sample, unmarried women were primarily widowed, separated, or divorced.

Internal reliability of the SRQ-20 was excellent (Cronbach's alpha=0.92).

DISCUSSION

This study highlights the substantial levels of mental distress and probable CMD among the surveyed women who had delivered in the past 24 months in Amhara region, Ethiopia, including unmarried women. A recent review of CMD prevalence studies conducted in Ethiopia reveals that depression and the broader category of CMD have been measured with a range of instruments in various populations, making specific contextual comparisons challenging.¹⁹ Our estimates are somewhat higher than those from other studies in Ethiopia conducted among women of

reproductive age and among the general population, suggesting that women up to 2 years postpartum may potentially be at elevated risk of CMD compared with a general population of women of reproductive age.^{19,20} More research is needed, however, to explore this potential relationship further since several limitations with the study design limit our ability to draw firm conclusions. Furthermore, it is worth reiterating that the SRQ-20 captures a range of mental distress symptoms, more inclusive than depression alone. Nonetheless, it is clear that a substantial proportion of women in this study were experiencing mental health problems, including suicidal thoughts, for which services are urgently needed.

The global health field has called for integrating mental health care into priority health care platforms, and specifically for integrating maternal mental health care into MCH services.^{5,21} Given the low rates of facility-based postpartum checkups in Amhara region and nationally, access to HEWs for mental health prevention activities and referral for more serious mental health problems during the extended postpartum period is vital. Ethiopia's national mental health strategy mandates the integration of mental health services into the primary health care system, and it emphasizes self-care and use of HEWs for promotion and prevention activities to increase awareness, reduce stigma, and increase use of mental health services.⁸ Given the high rates of probable CMD among women up to 2 years postpartum, mental health services could potentially be integrated into MCH services offered by providers based at local health posts and/or by HEWs, such as at childhood immunization and well-child visits. The possibility of HEWs providing simple psychosocial interventions, such as screening for maternal mental distress, basic counseling, and facilitating establishment of support groups, could be further explored and tested in Ethiopia.²²

Limitations

This study used a convenience sample of women identified through local health care providers, which excluded very remote communities that could not be reached by vehicle, and therefore may not be representative of the entire Amhara region. Also, while our focus was on mental distress in the postpartum period, which is usually defined as the first 12 months after childbirth, our sample consisted of women who

TABLE. SRQ-20 Results for Probable Mental Disorder/Poor Mental Health in the Past 30 Days Among Women With a Delivery in the Past 24 Months, by Relationship Status, Amhara Region, Ethiopia

SRQ-20 Questions	Total Sample (N=1,294)	Married (n=1,174)	Unmarried (n=120)
	No. responding "yes" (%)		
1. Been nervous, tense, or worried	320 (24.8)	271 (23.1)	49 (40.8)
2. Frightened easily	265 (20.5)	236 (20.1)	29 (24.2)
3. Generally felt unhappy	247 (19.2)	203 (17.4)	44 (37.0)
4. Found it difficult to make decisions	149 (11.5)	120 (10.2)	29 (24.2)
5. Had headaches quite often	519 (40.1)	466 (39.7)	53 (44.2)
6. Had problems thinking clearly	204 (15.8)	174 (14.9)	30 (25.2)
7. Found it difficult to enjoy daily activities	186 (14.4)	146 (12.5)	40 (33.3)
8. Often lost interest in things	152 (11.8)	117 (10.0)	35 (29.2)
9. Felt tired easily	402 (31.1)	355 (30.3)	47 (39.2)
10. Experienced loss of appetite	312 (24.2)	287 (24.5)	25 (21.0)
11. Problems with sleep	278 (21.6)	243 (20.8)	35 (29.4)
12. Had uncomfortable feelings in stomach	310 (24.0)	282 (24.1)	28 (23.3)
13. Often experienced shaking of hands	139 (10.8)	126 (10.8)	13 (10.9)
14. Felt tired all the time	359 (27.8)	322 (27.5)	37 (30.8)
15. Cried more than usual	194 (15.1)	159 (13.6)	35 (29.2)
16. Daily activities suffered	140 (10.8)	118 (10.1)	22 (18.5)
17. Thought of ending life	187 (14.5)	154 (13.2)	33 (27.5)
18. Felt unable to play a useful part in life	170 (13.2)	147 (12.6)	23 (19.2)
19. Experienced poor digestion	258 (19.9)	220 (18.7)	38 (31.7)
20. Felt worthless	160 (12.4)	129 (11.0)	31 (25.8)

Abbreviation: SRQ, Self-Reporting Questionnaire.

All variables had ≤ 6 missing responses. Percentages are based on non-missing data.

had delivered within the past 24 months, which limits our ability to associate the mental distress estimates within the conventionally defined postpartum period. Our ability to draw firm conclusions about the occurrence of CMD specifically within the postpartum period is further limited because the study did not include a comparison group of women who had not given birth. However, the sample of women who were up to 24 months postpartum represents an extended postpartum period, and thus the

estimates from this study add to the literature on maternal CMD.

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STORY FROM THE FIELD

Courage is not the absence of fear: responding to the Ebola outbreak in Liberia

Linda Meta Mobula^a

Since the onset of the Ebola outbreak in West Africa in February 2014, the World Health Organization estimates that more than 370 health care workers have been infected with Ebola virus disease (EVD), and 216 have since died.¹

During the height of the Ebola epidemic, I had the unique opportunity of working at the Ebola Case Management Center of the Eternal Love Winning Africa (ELWA) hospital in Monrovia, Liberia. About a third of all patients with Ebola admitted to ELWA were health care workers.² Some of these brave individuals had worked tirelessly, treating Ebola patients while fully aware that they could become infected themselves. Others were likely exposed to EVD at their respective government health facilities, unaware that their patients had Ebola. Exposure to Ebola patients outside of an Ebola management center increases one's risk of contracting the illness, especially since there are no infection control measures in place for protection.

A famous quote from author Ambrose Hollingworth Redmoon (born James Neil Hollingworth) goes³:

Courage is not the absence of fear, but rather the judgment that something else is more important than fear. The timid presume it is lack of fear that allows the brave to act when the timid do not. But to take action when one is not afraid is easy. To refrain when afraid is also easy. To take action regardless of fear is brave.

Redmoon's assertion describes perfectly the bravery of those who have sacrificed their lives to treat an illness with no known scientifically proven cure. In my time serving at ELWA, as more health care workers became infected, fewer reported to duty, leading to a further shortage of personnel. I, too, experienced fear that I or my other colleagues would become infected as I watched several of my coworkers contract Ebola. In

fact, I would sometimes have dreams at night that I had symptoms, prompting me to check my temperature in the middle of the night—sometimes several times. Each time I came into contact with bodily fluids of a patient with Ebola, I realized that I was putting myself at risk of contracting the disease. Despite this, I overcame my fears and continued to provide medical care to my patients, which included my own coworkers.

Fear of contracting Ebola was compounded by fear for personal safety; many times there were protests from local residents who were concerned about having a treatment center in their community. I was also cognizant that individuals who used to be child soldiers during Liberia's civil war earlier in the decade were now adults. I feared that the violence surrounding ELWA would soon escalate, making it impossible for patients to receive medical care. On my last day at ELWA, the treatment center was brimming with



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Dr. Linda Mobula and Dr. Nathalie McDermott wearing full personal protective equipment in the ELWA Ebola Case Management Center in Monrovia, Liberia.

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Gloves, boots, and goggles drying after decontamination with chlorine in the courtyard at the ELWA Ebola Case Management Center in Monrovia, Liberia.

Providing compassionate care to patients with Ebola while wearing full personal protective equipment proved to be extremely challenging.

patients in every bed and there were a limited number of health care workers providing vital medical care while dozens of protesters stood outside chanting and shouting; the challenges in providing patient care were insurmountable.

Fear of EVD is not anything new to me. As a child, I grew up in the Democratic Republic of the Congo and was there during the 1994 Ebola outbreak in Kikwit, 250 miles away from Kinshasa, where I lived. I recall clearly that the population in Kinshasa feared that the outbreak would spread; thus, Kikwit residents were quarantined. Little did I know, 20 years later, I would experience fear of Ebola in a completely different context.

But fear was not the only challenge in fighting the Ebola epidemic. Given the high case fatality rate, health care workers were repeatedly forced to face the death of those whose lives they had worked so hard to preserve. Every morning, I recall coming to the clinic and receiving the update that a patient my team had cared for had succumbed to EVD overnight. I remember vividly the mother of one of my patients looking into my eyes and pleading with me, "Please save my son. He is my only son. Don't let him die." Ebola shows no such justice. Her son passed away two days later—his mother's worst fears were realized, and I was devastated.

As a physician, I have always aspired to provide compassionate care to each of my

patients. Providing such compassionate care to patients with Ebola while wearing full personal protective equipment (PPE) proved to be extremely challenging. When health care providers are covered with PPE, it is difficult for patients to perceive their caregivers' emotions or to understand their body language. As there is no guarantee of recovery with Ebola, one of the few opportunities I had to demonstrate empathy to my patients was through my own verbal communication and nonverbal behavior, such as nodding or looking into the eyes of my patients with concern. Touching patients more than required for administering treatments, even while wearing full protective gear, was not advisable.

I often wondered if these communication barriers constructed by the PPE caused additional distress to patients. Already in physical isolation, afflicted with a deadly illness, and unable to witness the attitude and emotions of their health care provider, patients were mentally and emotionally isolated. To see the face of their health care provider obscured by a mask and hood only contributed to their trepidation. Furthermore, because of isolation requirements, many patients' sense of loneliness was magnified, as they died alone without family members nearby.

When my time at ELWA came to an end, I struggled to leave Monrovia knowing that the outbreak would not be contained any time soon. As a matter of fact, given the challenges of implementing infection control measures nationwide, I feared that the situation would soon escalate into a humanitarian emergency.

A myriad of factors have led to an inadequate response to this horrendous outbreak, from the lack of public health and health care delivery infrastructure to the persistence of unsafe burial practices and an environment of mistrust. Today, many Liberians believe either that Ebola does not exist or that patients with the disease are being experimented upon at clinics. In order to contain this outbreak, we must have a thorough understanding of cultural practices. And to overcome the mistrust, it is paramount that we use credible voices from Liberian communities to reinforce health promotion messages that are tailored to Liberian culture.

Despite these challenges, I have faith and am hopeful that the international community will come together and create a clear plan of action to prevent the loss of thousands of lives. I applaud the bravery of my Liberian colleagues, as well as those from Samaritan's Purse, Médecins Sans Frontières, and Serving in Mission, who have

To overcome community mistrust, we must use credible community voices to reinforce health promotion messages that are tailored to the specific culture.

engaged Ebola from the beginning and continue to provide care despite many obstacles.

This is a unique opportunity for the international community to combine our technical expertise in public health, medicine, disaster management, and social science to better understand and address barriers that are preventing an effective response to the Ebola outbreak of 2014. It is also an opportunity to review how we can build the health infrastructure in low- and middle-income countries to prevent a disaster of this proportion from recurring.

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