Editorials

Taking Exception
Reduced mortality leads to population growth: an inconvenient truth

Reduced mortality has been the predominant cause of the marked global population growth over the last 3/4 of a century. While improved child survival increases motivation to reduce fertility, it comes too little and too late to forestall substantial population growth. And, beyond motivation, couples need effective means to control their fertility. It is an inconvenient truth that reducing child mortality contributes considerably to the population growth destined to compromise the quality of life of many, particularly in sub-Saharan Africa. Vigorous child survival programming is of course imperative. Wide access to voluntary family planning can help mitigate that growth and provide many other benefits.

James D. Shelton
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Urban health: it's time to get moving!

The global health community should mainstream urban health and implement urban health programs to address the triple health burden of communicable diseases, noncommunicable diseases, and injuries in low- and middle-income countries.

Victor K. Barbiero
Glob Health Sci Pract. 2014;2(2):139-144
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Commentaries

Getting family planning and population back on track

After a generation of partial neglect, renewed attention is being paid to population and voluntary family planning. Realistic access to family planning is a prerequisite for women’s autonomy. For the individual, family, society, and our fragile planet, family planning has great power.

Malcolm Potts
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Viewpoints

Local markets for global health technologies: lessons learned from advancing 6 new products

Key components to support local institutional and consumer markets are: supply chain, finance, clinical use, and consumer use. Key lessons learned: (1) Build supply and demand simultaneously. (2) Support a lead organization to drive the introduction process. (3) Plan for scale up from the start. (4) Profitability for the private sector is an absolute.

Dipika Mathur Matthias, Catharine H Taylor, Debjeet Sen, Mutsumi Metzler
http://dx.doi.org/10.9745/GHSP-D-13-00131
Are pregnant women prioritized for bed nets? An assessment using survey data from 10 African countries

Women of reproductive age are generally more likely to sleep under an insecticide-treated net (ITN) than other household members. Universal coverage increases ITN use by all family members, including pregnant women. However, BCC efforts are needed to achieve desired levels of bed net use, which is especially important for pregnant women.

Emily Ricotta, Hannah Koenker, Albert Kilian, Matthew Lynch
http://dx.doi.org/10.9745/GHSP-D-14-00021

The quality–coverage gap in antenatal care: toward better measurement of effective coverage

The proportion of pregnant women receiving 4 or more antenatal care (ANC) visits has no necessary relationship with the actual content of those visits. We propose a simple alternative to measure program performance that aggregates key services that are common across countries and measured in Demographic and Health Surveys, such as blood pressure measurement, tetanus toxoid vaccination, first ANC visit before 4 months gestation, urine testing, counseling about pregnancy danger signs, and iron-folate supplementation.

Stephen Hodgins, Alexis D’Agostino
http://dx.doi.org/10.9745/GHSP-D-13-00176

Preferences for a potential longer-acting injectable contraceptive: perspectives from women, providers, and policy makers in Kenya and Rwanda

High effectiveness, predictable return to fertility, and a single, prepackaged, disposable delivery system ranked high. Side effects were generally acceptable to women if they did not last long or disrupt daily activities. Cost was considered important for providers but not so much for most potential users.

Elizabeth E Tolley, Kevin McKenna, Caroline Mackenzie, Fidele Ngabo, Emmanuel Munyambanza, Jennet Arcara, Kate H Rademacher, Anja Lendvay
http://dx.doi.org/10.9745/GHSP-D-13-00147

Rising cesarean deliveries among apparently low-risk mothers at university teaching hospitals in Jordan: analysis of population survey data, 2002-2012

Cesarean deliveries nationally in Jordan have increased to 30%, including substantial increases among births that are likely low risk for cesarean delivery for the most part. This level is double the threshold that WHO considers reasonable.

Rami Al Rifai
http://dx.doi.org/10.9745/GHSP-D-14-00027
Medical barriers to emergency contraception: a cross-sectional survey of doctors in North India

Emergency contraceptive pills (ECPs) are extremely safe and do not interfere with implantation. Yet many surveyed physicians in India did not know that there are no contraindications to using ECPs, and many had negative attitudes about ECP users. Most were against having ECPs available over-the-counter and wanted to impose age restrictions. Efforts are needed to address such misconceptions that might lead to limiting ECP availability.

ME Khan, Anvita Dixit, Isha Bhatnagar, Martha Brady
http://dx.doi.org/10.9745/GHSP-D-13-00139

Evaluation of community-based interventions to improve TB case detection in a rural district of Tanzania

Enlisting traditional healers and pharmacists to improve TB detection contributed 38% to 70% of new smear-positive case notifications per quarter in a rural district of Tanzania.

Charlotte Colvin, Jackson Muyubuso, Godwin Munuo, John Lyimo, Eyal Oren, Zahra Mkomwa, Mohammed Makame, Atuswege Mwangamale, Vishnu Mahamba, Lisa Mueller, D'Arcy Richardson
http://dx.doi.org/10.9745/GHSP-D-14-00026

Integrating family planning into postpartum care through modern quality improvement: experience from Afghanistan

Modern quality improvement approaches enabled hospital staff to analyze barriers and identify solutions for “how” to integrate family planning into postpartum care. Private spaces for postpartum family planning (PPFP) counseling, along with involving husbands and mothers-in-law in counseling, substantially increased the percentage of women receiving PPFP counseling and their preferred method before discharge. Self-reported pregnancy was also significantly lower up to 18 months post-discharge compared with women receiving routine services.

Youssef Tawfik, Mirwais Rahimzai, Malalah Ahmadzai, Phyllis Annie Clark, Evelyn Kamgang
http://dx.doi.org/10.9745/GHSP-D-13-00166

Systems approach to monitoring and evaluation guides scale up of the Standard Days Method of family planning in Rwanda

Scaling-up lessons included: (1) simplifying provider training and client materials; (2) ensuring core aspects of the intervention, for example, that the CycleBeads client tool was integrated into the supply chain system; (3) addressing provider-generated medical barriers; and (4) managing threats from changing political and policy environments. A focus on systems, the use of multiple M&E data sources, maintaining fidelity of the innovation, and ongoing environmental scans facilitated scale-up success.

Susan Igras, Irit Sinai, Marie Mukabatsinda, Fidele Ngabo, Victoria Jennings, Rebecka Lundgren
Glob Health Sci Pract. 2014;2(2):234-244
http://dx.doi.org/10.9745/GHSP-D-13-00165
FIELD ACTION REPORTS

Informed push distribution of contraceptives in Senegal reduces stockouts and improves quality of family planning services

Dedicated logisticians restocked contraceptives monthly at facilities to maintain defined minimum stock levels, freeing up clinic staff. High stockout rates were virtually eliminated. Also, quality and timely data on contraceptives distributed allowed for better program management.

Bocar Mamadou Daff, Cheikh Seck, Hassan Belkhayat, Perri Sutton

http://dx.doi.org/10.9745/GHSP-D-13-00171
Reduced mortality has been the predominant cause of the marked global population growth over the last 3/4 of a century. While improved child survival increases motivation to reduce fertility, it comes too little and too late to forestall substantial population growth. And, beyond motivation, couples need effective means to control their fertility. It is an inconvenient truth that reducing child mortality contributes considerably to the population growth destined to compromise the quality of life of many, particularly in sub-Saharan Africa. Vigorous child survival programming is of course imperative. Wide access to voluntary family planning can help mitigate that growth and provide many other benefits.

The 2014 Gates annual letter, “3 Myths That Block Progress for the Poor,” makes many valid points about development, and, commendably, it strongly supports family planning. However, in arguing against what it termed a “myth”—that saving lives leads to overpopulation—ironically, it succumbs to a common misunderstanding about reduced mortality and population growth.

THE CHILD SURVIVAL HYPOTHESIS

The letter’s basic proposition is: “When children survive in greater numbers, parents decide to have smaller families.” The inference is that reduced child mortality will somewhat automatically produce a corresponding and largely compensatory reduction in fertility levels, with little appreciable overall impact on population growth.

This concept, sometimes termed “the child survival hypothesis,” was discussed and researched considerably, particularly during the 1970s. It has some intuitive credence and demographic support, because often historically when death rates began to fall, declines in birth rates followed. However, such an association does not prove causality. Indeed, historically sometimes the 2 rates have declined fairly concurrently, and there are many examples where birth rates began to fall before death rates. Notably, the very intensive province-by-province “Decline of Fertility in Europe” analysis found that while there was some weak association between child mortality and fertility decline, fertility decline was also somewhat associated with industrialization, urbanization, literacy, and women’s employment. But the study’s overriding finding was that fertility declines spread rapidly “like an epidemic” through provinces that shared a cultural as well as spatial location, supporting strong ideational and normative explanations—that is, that people recognized that limiting family size was both feasible and acceptable to do.

Of course, the situation among modern developing countries varies and is different from that in Europe a century ago. For one thing, child mortality rates have typically declined much more rapidly in developing countries. And modern communications have fueled rising aspirations for many. But notably, substantial mortality declines in a number of countries, especially in Africa, have not yet been followed by appreciable declines in fertility. A prime example is Nigeria (Figure 1). Despite declines in infant mortality over many years, total fertility has persisted at about 6 children per woman.

In addition, for the child survival impetus to work, people must also perceive the decline in mortality and act on it. While the literature on that perception is limited, it suggests there is a major time lag before people do perceive such declines. Actually, in all likelihood, the major reason death and birth rates often fall over a similar time frame is due to general modernization changes in society—economic, educational, and social improvements, modern awareness, women’s empowerment, rising aspirations, and better access to services that lead to declines in both mortality and fertility levels. But most importantly, for fertility levels to decline, women and couples must have good
Means to control their fertility, in addition to motivation.

So yes, there is indeed something of a virtuous cycle in that lowered child mortality over time very likely does contribute to reduced fertility. But in and of itself, the effect is too little and too late.

WHAT HAS CAUSED MODERN POPULATION GROWTH?

Predominantly declines in mortality. For most of human history, global population growth was extremely slow, because mortality and fertility levels were in fairly close equilibrium. But recent times have taken us rapidly to 7 billion and counting. As demonstrated in the classic work of Thomas McKeown, The Modern Rise of Population, the only plausible explanation is declines in mortality. Consider, there are only 3 possible determinants of population change—fertility, migration, and mortality. Fertility may sometimes have increased marginally but, overall, certainly not appreciably; and migration is net zero for the planet, with mostly some out-migration for most developing countries. That leaves only mortality decrease as the primary explanation for the profound increase in population.

Moreover, reduced child mortality plays a huge role. Deaths to children under 5 typically account for at least half of all deaths in pre-transition societies, and child mortality declines have been dramatic. In addition, child survival contributes to population “momentum” because most of those surviving children will eventually have children themselves. Thus, not only does reducing mortality contribute to rapid population growth, it is the predominant cause, notwithstanding the partial virtuous cycle that reduced child mortality may partially help over time to reduce fertility levels.

Does Substantial Population Growth Matter?

As Malcolm Potts points out in this issue, estimates from the United Nations (UN) for the global population in 2100 range from 6.8 billion to 16.6 billion. Although these are very abstract numbers, the conclusion seems inescapable that the difference in the estimates would have major
impact on quality of life for the earth’s inhabitants. Indeed, the recent Royal Society report, “People and the Planet,” voiced major concern about current shortages of water, food, and fuel as well as environmental degradation, climate change, and urbanization.

Population growth appears destined to affect adversely the quality of life of people in the developing world, especially Africa. A key case in point is Nigeria, where, as previously mentioned, fertility levels remain quite high despite major decreases in mortality. The ominous implications are laid out in Figure 2. According to the UN medium projection (which even assumes considerable fertility decrease), Nigeria alone will be approaching a billion people in 2100, only slightly less than the United States and all of Europe combined.

Another even more extreme example is the environmentally fragile Sahelian country Niger. Partly because of very intensive health interventions, its infant mortality has declined to about 60/1,000 live births, but total fertility is even higher than in Nigeria, at 7.6 children per woman. Accordingly, its population is projected to increase well over 10-fold, from about 18 million today to over 200 million in 2100.

Because of decreasing child mortality and fairly stable fertility levels, in both Nigeria and Niger, their population growth rates have actually been increasing in recent years. While the future is hard to predict, surely it must be clear that such increases in population will likely impair the quality of life severely, particularly for those most in need in these countries.

It seems it has become less fashionable to express concern about population growth in recent years, partly because such concern is somehow associated with coercive practices. However, access to family planning is itself becoming better recognized as a human right. While we must condemn and steadfastly guard against misguided, and I would say rare, instances of coercion, neither should we ignore the benefits, including human rights benefits, to people and the planet that can come through voluntary family planning, including slower-paced population growth.
Reduced mortality leads to population growth

IMPLICATIONS OF THIS INCONVENIENT TRUTH FOR CHILD SURVIVAL AND FAMILY PLANNING PROGRAMMING

Like it or not, we face an inconvenient truth. Reducing child mortality does increase population growth, which will likely substantially impair the quality of life for those very people we wish to help. Does that mean we should curtail our child survival efforts? Not at all. We have an ethical imperative to reduce mortality, and it affirms our humanity. But in my view, it also reinforces the imperative to make a full menu of quality voluntary contraceptive services widely available, and as expeditiously as possible. Unmet need for family planning remains high in developing countries. And recent experience in Ethiopia and elsewhere demonstrates that quality family planning programming can be highly successful in advance of major socioeconomic development.

As Potts points out and as reinforced in the Gates annual letter, the great appeal of family planning is that it has so many benefits. Those include substantial health benefits for women and children, enhanced women’s empowerment, economic benefits for the family, the demographic dividend, reduced pressure on the environment, and the right to determine one’s own life destiny. Not just convenient, but a compelling opportunity. — James D Shelton, Editor-in-Chief

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**EDITORIAL**

Urban health: it’s time to get moving!

The global health community should mainstream urban health and implement urban health programs to address the triple health burden of communicable diseases, noncommunicable diseases, and injuries in low- and middle-income countries.

**INTRODUCTION**

Urbanization is irreversibly increasing around the world. In 2009, the level of urbanization around the world crossed the 50% mark. By 2050, the world’s population will exceed 9 billion and an estimated 67% will live in urban areas (Figure 1).

The United Nations Children’s Fund (UNICEF), the World Health Organization (WHO), the U.S. Agency for International Development (USAID), and others portray urbanization as an important priority (Box 1). However, there is no consolidated global vision, and major investments to address urban health issues, and/or the looming social and environmental threats that urbanization will exacerbate, are few and far between.

Between 2011 and 2030, the average annual urban growth rate in low- and middle-income countries is projected to be around 2%, translating to a doubling of the urban population in 35 years. Approximately 30% to 40% of urban dwellers in low- and middle-income countries live in slums; in Africa, an estimated 62% live in urban slums. (Figure 1, Box 1)

**FIGURE 1. Urban Population Growth by Region**

Data from the United Nations.  

**BOX 1. Urban Health Facts**

- The urban transition is here; by 2050, 6.3 billion people will live in urban areas.
- Virtually all of the world’s total population growth will be in urban areas of developing countries.
- Most growth is and will be in small and medium-sized cities.
- Megacities (cities with at least 10 million inhabitants) continue to grow.
- Urban slums predominate.
- The urban poor are underserved and underrepresented.
- Poor governance, inequity, social/economic stress, unemployment, and corruption can fuel political unrest across low- and middle-income countries.

Urban growth statistics are from the United Nations.
in slums. A great deal of the urban slum population is invisible and/or uncounted. Their need for water, fuel, power, waste removal, housing, education, health, and employment, and a myriad of other services will be staggering. We are not presently laying the foundations required to deal with the extraordinary physical, social, economic, and epidemiological trends that will characterize the cities of the future. Such neglect will likely adversely affect political stability, disease transmission, social norms, environmental health and safety, and the physical and mental well-being of billions of people.

The time has come to develop a global urban health vision and to commit significant resources to mitigate the adverse health impact of urban growth in low- and middle-income countries. Points of no return have already been passed.

THE URBAN CRUCIBLE

The urban environment in low- and middle-income countries represents a crucible in many respects. Varied elements of local ecologies and environments interact forming new cultural, social, demographic, epidemiological, economic, and political processes (Figure 2). Infectious diseases such as diarrhea, respiratory disease, vaccine-preventable diseases, HIV/AIDS, tuberculosis (TB), and vector-borne diseases will continue to persist and spread in urban environs. Additionally, noncommunicable diseases (NCDs) such as ischemic heart disease, stroke, chronic obstructive pulmonary disease, and diabetes will increase. Environmental and social conditions such as indoor/outdoor air pollution, obesity, depression and other mental health issues, vehicular injuries, gang culture, and gun violence will likely also increase, affecting all economic strata. Approximately 54% of disability-adjusted life years globally are due to NCDs, 35% from communicable diseases and maternal, neonatal, and nutritional disorders, and 11% from injuries. Thus, as global trends indicate, urban populations in low- and middle-income countries face a triple health burden, which will be exacerbated in the future.

THE URBAN OPPORTUNITY

Urbanization also presents new opportunities (Box 2). Population density and closer proximities of health infrastructure could facilitate service delivery by public and private institutions and nongovernmental organizations (NGOs). Mass media through print, radio, and even television have wide audience reach in urban centers. Decentralized authority in urban municipalities could foster pro-poor policies that maximize affordable preventive and curative care for underserved populations. Resources, both public and private, are often greater in the urban environment, and urban centers often enjoy political recognition and support. Furthermore,
the commercial sector has providers and products that can be better deployed. The Internet and the ubiquity of mobile phones enhance communication and the potential support for health promotion, disease prevention, and treatment. Perhaps most importantly, urban environs have a middle class and formal sector that support commerce, promote stability, and anticipate change for the better. These groups and cohorts may be early adopters to change.

**CASE STUDIES IN URBAN HEALTH**

Although few examples exist that describe remarkable urban health success stories, some notable examples presented below illustrate innovative approaches to urban health issues.

**India: National Urban Health Mission**

In May 2013, the Union Cabinet of India approved the National Urban Health Mission (NUMH), clearing the way for implementation of this hallmark program. The NUMH acknowledges the needs of the urban poor and makes commitments to urban infrastructure and human capacity development. It seeks to integrate existing national services in urban areas, promote equity for slum and other vulnerable populations, decentralize decision-making and implementation to municipalities, and include community organizations in planning. It will provide resources to support 1 urban primary health center per 60,000 people and 1 Auxiliary Nurse Midwife per 10,000 people. Performance-based incentives for public and private providers will aim to improve service delivery. Collaborative public-private health/sanitation/nutrition days will anchor community outreach and encourage service uptake. The Executive Summary for the NUHM Framework aptly describes the spirit of the Mission:

> The NUMH will systematically work towards meeting the regulatory, reformatory, and developmental public health priorities of urban local bodies. It will promote convergent and community action in partnership with all other urban area initiatives. Vector control, environmental health, water, sanitation, housing, all require a public health thrust. NUMH will provide resources that enable communitization of such processes. It will provide resources that strengthen the capacity of urban local bodies to meet public health challenges.

The Government of India recognizes that more than 775 cities represent a development imperative that cannot wait. Clearly, implementation will be challenging, but the NUHM represents a practical, political, and programming template for other countries.

**Curitiba, Brazil: Sustainable Urban Planning**

Curitiba is Brazil’s seventh largest city, with a population of about 1.8 million and a doubling time of approximately 39 years. Despite its size and rapid growth, it is perhaps the most sustainable city in the world.

Since 1965, Curitiba’s Master Plan has focused on a cohesive, sustainable urban development strategy that puts the quality of life for its residents at the forefront. A key strategic element of the Master Plan is “radial linear branching,” which governs the placement of new residents and industry along radial axes, expanding outward from the city. These axes are, in turn, served by public transportation, some with bus-only routes. Curitiba’s success is anchored in integrated urban services and an independent planning and implementing agency (the Urban Planning Institute of Curitiba) that sets the vision and coordinates investments. The vision focuses on people-centered efforts that are equitable, sustainable, and ecologically sound. This results in 30% lower use of fuel than other major Brazilian cities, a 45% rate of public transportation use, lower population density (even with an expanding population), cogent land use and zoning, and a network of strategically placed parks and lakes that comprise 20% of the urban landscape. The parks and lakes were designed to collect flood water, thus reducing flooding and minimizing risk and massive relocations. Residents have planted more than 1.5 million trees, and they recycle about 13% of solid wastes (compared with only 1% in São Paulo). Collectively, over time, these actions have increased property values and, consequently, tax revenues. The municipal budget is $600 million per year.

Curitiba has become a highly sustainable city, proving that applying a strategy with a people-first focus and continued, innovative planning can improve the quality of urban life for generations to come. Many lessons reside in the Curitiba example that can be applied elsewhere; the key requirements are sustained political leadership, a long-term vision, an appropriate...
budget, public commitment, and visible actions that serve the city and its environs (Box 3).

**Agra and Indore, India: Urban Health Resource Centre’s Community-Managed Slum Well-Being Program**

The Urban Health Resource Centre (UHRC) is a nonprofit organization in India that focuses on mobilizing slum populations, primarily through support for women’s health groups. In Agra, UHRC works in 60 slums and has organized 60 women’s groups; in Indore, they work with 90 groups. Every 10–15 groups are assembled into “federations.” The federations are registered with the government as a formal civil society whose aim is to disseminate health information, promote safe behavior, and effect positive change. The program has improved immunization rates and nutrition for children and has increased antenatal visits, facility deliveries, and breastfeeding levels. Although sustaining achievements is challenging, the UHRC model has helped to garner NGO support from the Government of India for its “communitization” efforts. A number of applicable lessons emerge from the UHRC model (Box 4).

**New York City: Bloomberg’s Health Legacy**

U.S. Mayor Michael Bloomberg endeavored to change the health profile of New York City in many ways. He has been praised as an innovator and criticized as a meddler. Either way, Bloomberg’s efforts fundamentally changed policy and public discourse regarding nutrition, physical activity, tobacco, and air pollution.

In 2006, the city required that any food served to customers contain less than 0.5 grams of trans fat per serving. In 2008, the city required all chain restaurants to label menus by disclosing caloric content on menu boards. In 2009, New York launched the National Salt Reduction Initiative (NSRI), a public-private partnership aimed at encouraging companies to reduce sodium content by 20% in overall sales within a given food category such as canned soup. The sugary drink portion limit rule (Portion Cap Rule) proscribed by the Board of Health sparked debate and disapproval locally and nationally. The rule neither bans nor limits the number of sweetened drinks, but limits the size of a drink that can be served by food-serving establishments to 16 ounces. It is mired in the courts, and prospects for approval are likely dim.

Efforts also focused on physical activity and transforming the built environment. New York added almost 400 miles of bicycle lanes, making the city bicycle friendly, and expanded pedestrian access to parks and green spaces. The “High

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**BOX 3. Lessons from Curitiba, Brazil**

- Continued political leadership and public commitment
- Creation of an independent planning and implementing agency
- Integrated traffic management, land use, and transportation to promote more pedestrian zones
- Special bus-only avenues with fixed/standard “social” fares that benefit low-income residents
- Flood management through the development of parks and lakes
- “Green Exchange” incentives for garbage disposal (residents get bus tickets or school supplies for dropping off trash at a neighborhood center)
- Recycling: “Garbage that’s not garbage program” supports weekly neighborhood collection of recyclable material.
- Open University provides training for residents in vocational skills, crafts, business, management, and environmental conservation.

**BOX 4. Lessons From Efforts in Agra and Indore, India**

- Promote viable linkages between NGOs and community-based organizations to complement public-sector services and enhance service uptake.
- Map slum facilities and target underserved slum populations.
- Link slum families with existing public- and private-sector services.
- Establish women’s groups, cluster coordination teams, and group federations; support these groups with a coordinating NGO.
- Register beneficiaries and unreached families.
- Provide continuous updates to exchange information and encourage continued service outreach.
Concrete interventions to address the triple burden of infectious and chronic diseases as well as injuries and trauma (built on an abandoned elevated rail line) attracts millions of users annually. New York’s tobacco control represents a historic effort to reduce smoking and exposure to secondhand smoke. The city’s smoke-free law banned smoking in all restaurants and bars, and cigarette taxes increased from US$0.08 to $1.50 per pack. The city also proposed raising the minimum age for buying tobacco and limits on marketing.16 Last but not least, the city reinforced an idling law that limits the idling of private vehicles to 3 minutes.

Although New York’s health reforms faced, and continue to face, strong challenges from numerous groups, they are applicable to low- and middle-income countries. Clearly, strong leadership is a key requirement to address the political, legal, and civil rights issues surrounding the implementation of urban public health laws.

WORDS TO ACTION

The above examples, albeit important and progressive, do not represent comprehensive approaches to urban health. Major bilateral and multilateral organizations, international NGOs, and foundations should link urban health with all of their major initiatives. HIV prevention and polio eradication efforts already understand the importance of urban areas to their long-term success. Similarly, maternal and child health, reproductive health, TB, malaria, chronic disease, injury, and all other health investments require direct action in urban areas, particularly in slums. Support to urban health efforts can be incorporated relatively easily through the reallocation of existing resources. Working smarter with existing resources should be considered.17

Policy makers must commit to a long-term action plan that addresses the triple burden of health issues faced by growing urban populations. A comprehensive global urban health strategy is in order; one similar to the global approach to HIV/AIDS, polio eradication, and malaria. The strategy should build on the urban experience, both positive and negative, from all regions of the globe and provide a clear vision and programmatic guidance. The strategy should include the following general elements:

- Use of resources among and between existing global health initiatives
- Expansion of public-private partnerships to capitalize on the existing infrastructure of commercial enterprises in urban areas
- Improved planning, implementation, and management capacity of urban municipalities
- Design and implementation of a set of urban health demonstration programs. These programs should include pillars of technical interventions, policy development, infrastructure support, planning, training, and emergency preparedness with various interventions within each pillar.

The world can ill-afford continued complacency, indecision, or neglect regarding urbanization and urban health. –Víctor K Barbiero, Associate Editor

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Strong leadership is key to ensuring innovative, and sometimes politically charged, urban public health laws.

By working smarter with existing resources, we can support positive urban health efforts.


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Getting family planning and population back on track

Malcolm Potts

COMMENTARY

After a generation of partial neglect, renewed attention is being paid to population and voluntary family planning. Realistic access to family planning is a prerequisite for women’s autonomy. For the individual, family, society, and our fragile planet, family planning has great power.

For policy makers and for practitioners, the reward and satisfaction of family planning is that it is an inextricable mixture of helping individuals achieve their reproductive goals while also maintaining an awareness of the multiple ways in which demography has determined our past and will inevitably shape our future. Voluntary family planning programs since the 1960s have helped 48% of the world’s population achieve replacement-level fertility or below. (Replacement-level fertility is the fertility rate at which each generation has only enough children to replace itself, and thus the population eventually stops growing. This is generally when the total fertility rate [TFR] is about 2.1 children per woman, although it can be at higher levels in countries with high mortality rates.)

Without this reduction in family size, the number of people living on less than US$1.00 a day would not have been halved, improvements in education would have been slower (such as was shown in Thailand), and there would not have been such a rapid decline in infant and maternal mortality. In many Asian countries, the rapid change in population structure from the introduction of voluntary family planning led to a ‘‘demographic dividend,’’ which helped lift millions of people out of poverty. The demographic dividend is the rapid economic growth that may result when a country transitions from high to low birth and death rates and the subsequent change in the age structure of the population—the smaller young dependent population with a larger working-age population translates into fewer people to support.

For a variety of reasons, which will be touched on shortly, following the 1994 United Nations (UN) International Conference on Population and Development (ICPD) in Cairo, family planning budgets fell. The fertility decline that had begun in some high-fertility countries, such as Kenya, stalled. The policy community paid less and less attention to population as a factor in development, in resilience to climate change and to the long-term sustainability of the global economy. The urgent need for new family planning initiatives, particularly in sub-Saharan Africa, was set aside. Today, there are approximately 424 million African children aged 14 or under. In 2050, Africa could have 770 million children, allowing a great deal of demographic momentum to build up. It is questionable whether some economies in sub-Saharan Africa will be able to benefit from the demographic dividend in the way that much of Asia did. These were costly mistakes that will help shape the remainder of the 21st century.

After providing an overview of global population projections and describing exactly what is at stake, this article reviews the evolution of the population and development debate and the resultant family planning policies from the 1960s to present day. In particular, it argues that while ICPD was a critical milestone in the history of population and development as well as in the history of women’s rights, it was also a turning point at which the focus was unfortunately taken off of voluntary family planning, interrupting an earlier decline in fertility.

BIG NUMBERS

Global population projections to 2100 from the UN Population Division present some profoundly different scenarios (Figure). The high and low population variants differ by half a child above or below the medium variant. Virtually all biologists and climatologists, along with an increasing number of sensible economists, would agree that a world with 6.8 billion people in the year 2100 (low-variant projection) would be more likely to be biologically sustainable, healthier, more educated, and less violent than one with 16.6 billion (high-variant projection).
Nearly all global population growth in the future will be in the less developed countries.\(^1\) Those countries can be divided further into 2 groups: countries such as Bangladesh and Kenya that have a reasonable chance of achieving replacement-level fertility in the foreseeable future, and those countries that still have a high birth rate. Since the UN first identified 25 least developed countries in 1971,\(^1\) only 1 country with a population of over 1 million (Botswana) has graduated to the “developing” country category\(^1\) (and the list included 48 countries as of June 2013). The least developed countries often have corrupt governments; the status of women is commonly abysmal in these countries; and rapid population growth in them is typically associated with a large number of poorly educated young men with few job opportunities—a recipe for violence and conflict.\(^1\) Currently, the least developed countries together have about 898 million people.\(^1\) In 2100, the medium UN population projection for these least developed countries is 2.9 billion, or as many as there were people in the whole world in 1960. The high estimate is 4.3 billion, or equivalent to the size of the world’s total population in 1980.\(^1\)

Each of the 3 projections in the Figure is possible. Which one the world follows will shape the world our children and grandchildren inherit and will play an immense role in determining global poverty, hunger, gender equality, and environmental sustainability outcomes. Thinking in terms of half a child may seem a bit laughable, but it emphasizes that the future well-being of the planet turns on a relatively small change in average family size. Considerations of population and family planning have been pushed off the policy agenda for many reasons, among which are religious and...
political conservatism, donor fatigue, and competition with funding for HIV/AIDS. Some economists assert that family planning programs are unnecessary because if couples want fewer children, the free market will solve their problems. Unfortunately, family planning is not a free market but one beset with biases and barriers that are not based on evidence. Population and family planning were regarded as too controversial to include as targets in the first round of the Millennium Development Goals, and they continue to be excluded from many discussions of climate change, conservation, and food security. For example, the 2013 annual Water for Food Conference, attended by more than 450 people from 24 counties and supported by the Bill & Melinda Gates Foundation, provided no space to discuss how family planning might alter the demand side for food.

Population and family planning also have been pushed off the agenda due to sheer enormity of the numbers. It demands an almost impossible intellectual and emotional effort to try and visualize what 16.6 billion means—counting 1 person per second would take 33 years to register just 1 billion people. In Paul Slovic’s powerful phrase, we are “numbed by numbers.” Slovic, an experimental psychologist, asked a sample of Americans how much money they would donate to help an individual hungry child in Africa. He identified such a child with a name, a photograph, and brief biography. The average donation offered was US$2.00. However, when Slovic told exactly the same story, but added that there were a million other hungry children, people donated less. When statistics were presented without a human face, people gave the least. “Grim statistics,” Slovic observes, “themselves paralyze us into inaction.”

Unless you are totally numbed by numbers, then the UN population projections are staggering predictions. Suddenly a half-child more or half-child less becomes of existential importance. Does voluntary family planning offer a proven way to ensure that half-child difference?

**MODELS OF FERTILITY DECLINE**

It has long been recognized that rapid population growth can hold back socioeconomic development, but policy makers remain divided on the weight to be given to family planning programs. For a long time, family planning policies have been split between those who hold that “Development is the best contraceptive,” and those who think that “Contraception is the best development.” These 2 polar opposites have deep roots.

When the U.S. Agency for International Development (USAID) first received support for international family planning in the 1960s, many demographers and economists were wedded to the standard “development is the best contraceptive” explanation of the demographic transition. Based on the history of Europe and North America, it was held that as deaths rates fell and as income and education improved, birth rates always fell. Couples, it was argued, made a rational decision to have fewer children. Socioeconomic change, it was asserted, was both necessary and sufficient for fertility decline: family size would fall “with great effectiveness” without the “assistance of modern contraceptive techniques.” The first family planning programs that USAID supported were dismissed as “quackery” and “wishful thinking.”

The alternative perspective was captured in a statement by Reimert Ravenholt, physician and epidemiologist and the first director of USAID’s population programs in the 1960s:

> It seems reasonable to believe that when millions of women throughout the world need only reproduce when they choose, then the many intense family and social problems generated by unplanned, unwanted and poorly cared for children will be greatly ameliorated and the now acute problems of too rapid population will be reduced to manageable proportions.

This pragmatic approach emphasized access to modern contraception and the need to remove the many non-evidence-based barriers to family planning. When contraception and abortion were illegal in the United States, it took 58 years (1842 to 1900) for the TFR to fall from 6 to 3.5 children per woman. When modern family planning was available in Thailand, a similar transition occurred in a mere 8 years (1969 to 1977). In Bangladesh, and to some extent in Brazil, Indonesia, and other countries, realistic access to family planning brought the birth rate down ahead of major socioeconomic improvements. The same thing has happened in Addis Ababa, Ethiopia, with a TFR of 1.5, which is unique among African capital cities. We associate the Islamic Republic of Iran with conservative ways, but once women had better access to family planning, the TFR actually fell more rapidly than in China—and without a one-child policy. Interestingly it needs to be recognized
that the TFR in China had fallen from 6.5 to 2.5 as the result of largely voluntary family planning, even before the one-child policy was introduced.

Although the standard model of the demographic transition has come under increasing academic criticism, it remains influential in many policy environments. Only last year, Jamison et al. wrote, “Families choose to have fewer children when they realize that the mortality environment has changed.” However, heterosexual couples have intercourse hundreds of times more frequently than is necessary to conceive even a large family. Therefore, the default position for couples is a large family. No woman can “choose” to have fewer children until she is given the means and information to separate sex from childbearing. In Niger, the “mortality environment” has changed dramatically (between 1990 and 2012, the infant mortality rate fell from 137/1,000 live births to 63/1,000), but the TFR remains at 7.6—the highest in the world.

Child marriage is a human rights abuse, mainly concentrated in the least developed countries. Rolling back the age of marriage is also a demographic imperative. Where child marriage is widespread, women will never be able to manage childbearing unless the age of the first birth is radically increased. Investing in girls and young women is a non-negotiable part of any strategy to slow population growth and to enable the least developed countries to move forward. Pilot studies in Northern Nigeria show it is possible to keep 70% to 80% of girls in secondary school in a region where only 4% of girls previously entered secondary school and none had completed their secondary education (personal communication with Daniel Perlman, Research Medical Anthropologist, University of California, Berkeley, Bixby Center for Population, Health & Sustainability, and Co-Director, Bixby/Fogarty International Center Population and Health Program, Nigeria, 2013). Bringing such programs to scale could require billions of dollars a year. Reinserting the population factor where it belongs in the family planning equation will give us the confidence and the evidence base to think big.

TRAGIC EPISODES OF COERCION

Paradoxically, if development really is the best contraceptive, then we have to ask: What will happen in a situation where rapid population growth is undermining socioeconomic progress? Indian Prime Minister Indira Gandhi faced this conundrum in the late 1970s. Under her leadership, in 1976 Dr. Karan Singh, then Minister for Health and Family Planning, released the following statement:

It is clear that simply to wait for education and economic development to bring about a drop in fertility is not a practical solution. The very increase in population makes economic development slow and more difficult of an achievement. The time factor is pressing and the population so formidable, that we have to get out of this vicious circle through direct assault upon this problem ... Where [an Indian] state legislature, in the exercise of its own powers, decides that the time is right and it is necessary to pass legislation for compulsory sterilization, it may do so.

The coercive family planning measures that Indira Gandhi introduced were among the unacceptable episodes of forceful family planning in our modern history. This step lost her the next election. It seems unlikely, however, that she would have gone out of her way to introduce unpopular policies if she had believed that development was the only way to lower the birth rate. What she did not understand was that if you respect women and remove the unjustified barriers to family planning then family size would fall, even without significant socioeconomic progress. Had she known that, then she might not have felt compelled to introduce coercive policies.

THE ICPD: REALITY AND MYTH

The Programme of Action adopted at the ICPD balanced a realistic concern for confronting rapid population growth with an eloquent statement of voluntary family planning as a human right:

Principle 4: Advancing gender equality and equity and the empowerment of women, and the elimination of all kinds of violence against women, and ensuring women’s ability to control their own fertility, are cornerstones of population and development-related programmes.

Principle 5: Population-related goals and policies are integral parts of cultural, economic and social development, the principle aim of which is to improve the quality of life of all people.

However, a different perspective was widely promoted after ICPD. Hodgson and Watkins describe how:

... a vision of fertility decline as a necessary consequence, not a cause, of large societal changes.
was to provide the frame that feminists would modify for later use at the 1994 Cairo conference.

Poignantly, such commentators were espousing the very paradigm that drove Gandhi to implement the most loathsome abuses in the history of family planning. Another group of advocates following the ICPD wanted to push population off the table in order to secure what they believed would be greater funding for the broader goals of women’s empowerment. The late Joan Dunlop, a powerful leader in the group, explained in an interview with author Michelle Goldberg:

What we wanted to do was, rather, simply [not]* throw the baby out with the bathwater; we wanted to redirect the money. We knew there were huge streams of money going into contraceptive development, and we wanted that money to go in a different direction.

The baby was indeed thrown out with the bath water. Dunlop’s desire to divert the “huge streams of money going into contraceptive development” was a classic case of being numbed by numbers. These “huge streams of money” that Joan Dunlop dreamed of diverting to the needs of women had never exceeded $15 million in any one year prior to ICPD. The goal of helping women needed a budget of billions of dollars.

The strategy to “move the money in a different direction” benefited from framing everything that happened in international family planning prior to ICPD as intrinsically coercive. Dunlop and others began a viral myth that is encapsulated in a book called Fatal Misconceptions by Matthew Connelly. Connelly engages in a systematic attempt to rewrite history to fit the ideology that all family planning programs are coercive. However, even Connelly was unable to verbally tar and feather Ravenholt, the charismatic advocate of voluntary family planning mentioned earlier.

Ravenholt’s office was virtually alone in its policy of refusing support for programs to create demand for contraception. He argued that supplying “unmet need” would be enough to solve the problem of population growth, or was at least worth trying before trying anything else. Many of his superiors and subordinates disagreed, and pressed Ravenholt for experiments with incentives.

Ravenholt continued to insist that incentives were not only unnecessary but also inappropriate.

**GETTING BACK ON TRACK**

We live in a complex, interconnected world facing unique problems that, if not tackled, could cause great pain, or even threaten a collapse of civilization as we know it. Can we create a world that lives within ecologically sustainable limits? Can we avoid ever-growing inequities between the least developed countries and the rest of the world? Can we create a more stable, less violent world? Family planning is only one factor in answering these existential questions, but family planning is a prerequisite for any solution.

The Family Planning 2020 (FP2020) partnership, with the goal of reaching 120 million additional women with voluntary access to family planning within the next 6 years, is an important step toward a more balanced and evidence-based approach to family planning and population after a generation of relative inactivity. Family planning saves maternal and infant lives. It has reduced maternal deaths by 40% in the past 20 years. A child conceived within 6 months of a prior birth is 60% more likely to die than a child whose conception was spaced by 2 years. Family planning can trigger economic development, and it can assist in both mitigation of and adaptation to climate change. Family planning is an investment that pays for itself in reduced health and educational costs, yet budgets are not commensurate to its impact. Slowing birth rates through voluntary family planning can preempt conflict and political instability. Family planning is listening to what women want, not telling them what to do. An estimated 47,000 deaths from unsafe abortion occur each year—evidence written in blood that millions of women want fewer children but do not have realistic access to modern contraception.

In 1969, I was invited to deliver the Tenth Darwin Lecture in London. I ended by saying:

Some writers are asking, “What is beyond family planning?” They are talking about incentives where previously they spoke of motivation. Reports of transistor radios are becoming tales of compulsory sterilization or hormones in the drinking water. I think this trend is dangerous and unnecessary. The ideal of voluntary parenthood is an exceptionally important freedom to preserve. I fear it is threatened.

* Author Goldberg recognizes a typo in her published text.
with erosion because we are failing to make a free choice of contraceptive methods available.

Forty-five years later, I still believe this to be true. I also suggest that there is an urgent need to reunite a concern for individual freedom with an emphasis on the need and opportunity to slow rapid population growth in a human rights context.

It is time for those advocating improvements in the status of women to link arms with those deeply worried about a world that is exceeding the capacity of the biosphere to sustain human activity. The investments that need to be made, and the policies that need to be put in place, are identical for both groups: meet the unmet need for family planning and advance girls’ education. Doing so will start the world population on a trajectory of 6.8 billion people by 2100. A world of 11 or 17 billion (Figure) could well find it impossible to make the transition to a biologically sustainable economy.

Voluntary family planning is founded on the core belief that every woman has the right to decide how to use her own body. It is the freedom that separates a slave from a free person. Making family planning readily accessible is the first step in breaking the shackles of reproductive slavery. It is also the first step in saving civilization from destroying itself. For the individual, the family, society, and our fragile planet, it is imperative to get voluntary family planning and a commitment to slowing rapid population growth back on the same track.

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Local markets for global health technologies: lessons learned from advancing 6 new products

Dipika Mathur Matthias, a Catharine H Taylor, b Debjeet Sen, c Mutsumi Metzler a

Key components to support local institutional and consumer markets are: supply chain, finance, clinical use, and consumer use. Key lessons learned: (1) Build supply and demand simultaneously. (2) Support a lead organization to drive the introduction process. (3) Plan for scale up from the start. (4) Profitability for the private sector is an absolute.

INTRODUCTION

Global procurement mechanisms are a major potent force in successful global health programming. Such mechanisms purchase key technologies such as vaccines, antiretroviral drugs, and contraceptives for distribution across many countries. However, many more critical technologies, particularly those affecting maternal and newborn health, require advancement of local markets for ultimate sustainability and public health impact. Unfortunately, many of these markets suffer from a basic dysfunction: the lack of sufficient market incentive to stimulate production and distribution as well as complicated local supply chains and delivery systems to reach those most in need.

In this article, we present 6 case studies of technologies recently introduced into developing-country markets (Oxytocin in Uniject, careHPV, Helping Babies Breathe, Woman’s Condom, Safe Water, and Ultra Rice). We use a market introduction framework as an organizing structure to highlight key elements that may have contributed to varying degrees of success and, when lacking, to certain challenges in these markets. Through these examples, we hope to contribute to the global discussion on best practices for creating healthy markets as the global health community works together to accelerate access to lifesaving technologies.

MARKET TYPES: GLOBAL, INSTITUTIONAL, AND CONSUMER

To cultivate the market for a given commodity, it is important to first understand key characteristics of that market. Although the boundaries between different market classifications are somewhat permeable, there are generally 3 types of markets for global health technologies:

- Globally coordinated markets, where technologies such as vaccines are procured and financed through centralized channels. Typically, in these types of markets a small number of buyers, such as the GAVI Alliance (formerly the Global Alliance for Vaccines and Immunization), the United Nations Children’s Fund (UNICEF), and the Global Fund to Fight AIDS, Tuberculosis and Malaria, purchase large volumes of product through pooled procurement at low prices, which are then distributed through relatively well-organized channels.

- Local institutional markets, in which national institutions, such as a ministry of health, purchase technologies such as drugs used for obstetric care, whether through their own resources or from donor grants or loans. These markets require strong facility inputs, such as skilled health workers, complex clinical protocols to ensure proper use of commodities, robust logistics systems to ensure commodities and equipment remain continuously available at health facilities, and local health budgets.

- Consumer markets, in which a large number of disaggregated consumers buy health goods, such as oral rehydration salts or water filters, for their own use. Although the value proposition may be clearer and the products easier to use than those in institutional markets, these products require purchase by consumers, who often do not consider health-related purchases a high priority. These markets also require significant investments in distribution and marketing by private-sector companies that naturally prefer to serve consumers...
with higher incomes due to the potential for greater profit margins and more consistent demand.

The crucial role of the latter two, or “local,” markets is amply demonstrated by the work of the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC), which is leading global efforts to improve access to 13 potentially lifesaving commodities essential to maternal and neonatal health (Table). The Commission has developed key recommendations to address the most critical bottlenecks facing product introduction, from innovation and global market-shaping to local delivery and demand generation.

Compared with global procurement, both institutional and consumer markets have less defined advocacy and policy pathways and often suffer from lack of donor funding to continue purchasing the product beyond initial introduction pilots, as they do not have large-scale, committed funding mechanisms behind them. Manufacturers are often left with insufficient demand to continue supply, while buyers have limited experience with and understanding of the value of the technology and, hence, have weak motivation to purchase.

Beyond the lack of financing, there are several additional reasons that these markets have not been effectively established. The framework we offer attempts to capture the broad range of elements required for effective introduction of global health products into local institutional and consumer markets.

## MARKET INTRODUCTION FRAMEWORK

A broad search of the published literature revealed that few market introduction frameworks for global health technologies exist. Most players involved in shaping global health markets rely on informal, unpublished frameworks that generally describe the market problems (such as high price), identify specific causes (such as risk for manufacturers), and then focus on interventions to address the root cause (such as enhancing demand through advanced purchase). These approaches tend to focus on the traditional market levers of price, volume, information, and quality. They are useful analytical frameworks that can help us identify which market interventions might address the problem most effectively.

However, by defining the market introduction sphere more broadly, we are better able to consider the larger range of causes for success or failure in these markets, and consequently, a broader range of potential interventions. This thinking has been captured in some excellent frameworks addressing the diffusion of health innovations. For example, Atun et al. point out the need to clearly delineate the problem, the willingness of major stakeholders to support adoption, and the readiness of health systems infrastructure. Free also considers a wide range of factors, such as appropriate design of the technology and engagement of gatekeepers.

Our market introduction framework builds on this critical systems-wide thinking; it is a modified version of a framework initially developed by Hozumi et al., through interviews with stakeholders with scale-up experience and

### TABLE. Market Classification for UNCoLSC Technologies

<table>
<thead>
<tr>
<th>Technology</th>
<th>Globally Coordinated Markets</th>
<th>Local Institutional Markets</th>
<th>Consumer Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maternal Health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytocin</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Magnesium sulfate</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Newborn Health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antenatal corticosteroids</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injectable antibiotics</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Neonatal resuscitation</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorhexidine</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td><strong>Family Planning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female condoms</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Implants</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency contraception</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Child Health</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral rehydration salts</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Zinc</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

Abbreviation: UNCoLSC, UN Commission on Life-Saving Commodities for Women and Children.
By defining the market introduction sphere more broadly, we are better able to consider the larger range of causes for success or failure in these markets.

The introduction phase is often where global health technologies destined for local markets falter.

Through retrospective evaluations of global health interventions advanced by PATH, this empirically driven framework serves as more of a “how-to” guide than an analytical framework. It focuses on critical market design factors related to the introduction of global health products, assuming that external elements, such as a strong leader and relevance of the product to the global health context, are already in place. (Often, even relevant products with strong champions still fail to reach market.)

Developing, deploying, and scaling up global health technologies is a multistep, iterative process taking many years, starting with research/design and development/validation, through regulatory approval, introduction, and scale up. This framework elaborates only on the introduction phase of this typical value chain for technologies.

Introduction, particularly for institutional and consumer markets, has several elements that must come together to ensure both the availability of the commodity and its effective use. In fact, the introduction phase is often where global health technologies destined for local markets falter. This phase can be broken down into its essential components of both supply and demand, as illustrated by the 4 pathways in the Figure: (1) supply chain, (2) finance, (3) clinical use, and (4) consumer use. The supply chain and finance pathways are relevant to both institutional and consumer markets, while clinical use pertains only to institutional markets and consumer use only to consumer markets. These critical pathways tend to run in parallel.

1. Supply Chain Pathway

Within the introduction phase, the supply chain pathway in both institutional and consumer markets focuses on conventional supply-chain development. For technologies that are capital-intensive or where quality manufacturing cannot be established locally, a centralized, global manufacturer may be the most effective commercialization strategy. However, as quality improves, technologies have increasingly been licensed to regional or local manufacturers, and appropriate manufacturing equipment needs to be purchased. A formal transfer of the technology is then conducted and manufacturing is validated. Also, distribution channels to appropriate clinical facilities, retail stores, and other outlets need to be established.

2. Finance Pathway

The finance pathway focuses on enhancing demand through appropriate financing for the buyers of these technologies. For institutional

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**FIGURE.** Framework for Introducing Global Health Technologies Into Local Markets

<table>
<thead>
<tr>
<th>Local Institutional Markets</th>
<th>Consumer Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Use (Demand)</strong></td>
<td></td>
</tr>
<tr>
<td>• Generate evidence of operational feasibility within clinics</td>
<td></td>
</tr>
<tr>
<td>• Develop clinical policy</td>
<td></td>
</tr>
<tr>
<td>• Build capacity of health care workers to use technology</td>
<td></td>
</tr>
<tr>
<td>• Establish supervisory and enforcement systems</td>
<td></td>
</tr>
<tr>
<td><strong>Finance (Demand)</strong></td>
<td></td>
</tr>
<tr>
<td>• Pursue advocacy</td>
<td></td>
</tr>
<tr>
<td>• For institutional buyers, consider tiered pricing</td>
<td></td>
</tr>
<tr>
<td>• Develop finance mechanisms</td>
<td></td>
</tr>
<tr>
<td>• Establish user/buyer incentive</td>
<td></td>
</tr>
<tr>
<td><strong>Supply Chain (Supply)</strong></td>
<td></td>
</tr>
<tr>
<td>• Assess incentives/profitability for private sector</td>
<td></td>
</tr>
<tr>
<td>• Establish manufacturing globally, regionally, or locally, as appropriate</td>
<td></td>
</tr>
<tr>
<td>• Enable distribution</td>
<td></td>
</tr>
<tr>
<td><strong>Consumer Use (Demand)</strong></td>
<td></td>
</tr>
<tr>
<td>• Influence changes in health behaviors</td>
<td></td>
</tr>
<tr>
<td>• Encourage the purchase of health-related commodities</td>
<td></td>
</tr>
</tbody>
</table>

*Introduction Success = Early Signs of Market Penetration, Sustainability, and Health Impact*
Local markets for global health technologies

markets, advocacy is often required to ensure appropriate institutional financing mechanisms, whether through government or private facilities, to support ongoing clinical use of the technology. This requires cultivating multiple champions in the ministries of health and finance to advocate the necessary budget allocations. Tiered pricing strategies, vouchers, and full subsidies may need to be considered by institutional buyers who pass a portion of their costs to distributors, health facilities, or consumers. Consumer products may also require financing, sometimes in the form of low-cost loans, particularly for more costly durable goods such as water filtration systems; low-income consumers often cannot pay the full cost upfront. These financing mechanisms can be provided through microfinance institutions and other businesses focused on consumer finance. Sometimes incentives, such as longer payback periods, are needed for consumers to take advantage of these financing mechanisms.

3. Clinical Use Pathway

A third and very important introduction pathway, particularly for institutional markets, is creating demand among providers and institutions by developing the clinical capacity to use the technology within health facilities. This is a rigorous undertaking in itself; it entails generating operational evidence on use of the technology in clinic settings, developing formal clinical policy to guide how the technology would be used appropriately within a clinical protocol, training to ensure that health workers understand the revised clinical guidelines, and establishing enforcement mechanisms, such as supervisory systems, to ensure sustained use. Lack of movement down this pathway has significantly slowed the adoption of many new global health technologies.

4. Consumer Use Pathway

The demand side for consumer markets usually requires social marketing to influence consumer purchase of products sold through retail channels, which may or may not be partially subsidized. Traditional behavior-change techniques also are used to encourage uptake of consumer products distributed through public and private-sector channels. For instance, village leaders may discuss healthy behaviors with mothers groups; in doing so, they may encourage the use of health products for their family, such as oral rehydration salts to treat diarrhea or soap to prevent infection.

These introduction activities, if carefully orchestrated and pursued in parallel, provide the basis for successful market introduction of global health products. As noted in the Figure, introduction success is achieved through early signs of market penetration, sustainability through public, private, and nongovernmental partners, and, ultimately, health impact in target markets. More significant penetration of these outcomes would indicate achievement of scale. We use this introduction framework in a retrospective analysis of 6 technologies—3 from institutional markets and 3 from consumer markets—each with varying degrees of success and failure. This framework can also serve as a guide for new market introduction efforts.

CASE STUDIES FROM INSTITUTIONAL MARKETS

Oxytocin in Uniject® Injection System: Supply Chain and Financing Hinder Market Introduction

Oxytocin in Uniject is an example of an introduction pathway complicated by high costs, leading to difficulty in establishing the supply chain with manufacturers and distribution partners, and, consequently, a financing pathway as well. Thus, the market for Oxytocin in Uniject has not yet been established.

There is a strong public health case for this technology. Hemorrhage is the leading cause of maternal death in low-income countries, responsible for an estimated one-third of such deaths annually, and postpartum hemorrhage accounts for the majority of obstetric hemorrhage cases. For prevention of postpartum hemorrhage, oxytocin (10 IU) is the drug of choice, recommended by the World Health Organization (WHO). Oxytocin is temperature-sensitive and needs to be injected intramuscularly. Its use has generally been restricted to medically trained staff in health facilities. Oxytocin in Uniject was developed to simplify oxytocin administration through a single-use, prefilled device that delivers the correct dose. In deliveries attended by auxiliary health workers, Oxytocin in Uniject provides a feasible alternative for delivery of prophylactic oxytocin.

There is good-quality clinical and operational evidence to support clinical policy permitting use of Oxytocin in Uniject by auxiliary health workers and outside facilities, including effectiveness and feasibility studies. The product attributes

*Uniject is a trademark of BD.
have been tested to ensure that they meet the need at both the community and higher levels of health service. A recent trial in Ghana demonstrated the feasibility at the community level of home delivery for prevention and early treatment. Thus, the clinical use pathway has largely been followed, even though in some countries, medical associations have objected to policies that would allow for task shifting of oxytocin administration to community health care workers. However, the greatest challenge for Oxytocin in Uniject has been in reaching sustainable levels of supply and demand-side financing to catalyze the market.

Cost has been the root problem. Current pricing is more than US$1 per unit, which far exceeds the approximately $0.25 cost of a needle, syringe, and ampoule of oxytocin. To date, buyers are unwilling to pay the premium for oxytocin in a prefilled Uniject device. Furthermore, it is not a needed product at higher levels of the health system, as facilities are well-stocked with needles, syringes, and ampoules of oxytocin. A study in Argentina, however, has demonstrated higher compliance with Oxytocin in Uniject than with conventional administration.

One of the reasons for the higher cost of Oxytocin in Uniject is that it requires pharmaceutical manufacturers to invest significant upfront capital to procure and commission specialized filling and packaging equipment. Donor funding to defray these costs has not been available to the various manufacturers of oxytocin. Additionally, as with any drug in a new form of primary packaging, the pharmaceutical producer would need to apply for and obtain drug regulatory approval in each country where the product would be sold—a long and expensive process that creates further disincentive to supply. This is especially true for those drug and vaccine manufacturers that are in highly competitive generic markets, such as oxytocin, as the investment may not shift in market share of their product.

We have collaborated with a number of pharmaceutical producers over the past decade to try to establish a sustainable supply of Oxytocin in Uniject. Three producers went as far as producing pilot batches and undertaking the costly stability studies. Due to the lack of clear demand at a price that would be commercially attractive, 2 producers dropped the project before completing development and regulatory approval. One producer stated it had cost close to US$100,000 to conduct the stability studies to WHO’s prequalification standards. If that producer could theoretically earn a $0.20 per-dose profit above the manufacturing cost, the company would have to sell 500,000 doses just to recoup the cost of the stability study, which is only one component of the total investment needed to produce and sell Oxytocin in Uniject. The one producer that took Oxytocin in Uniject to market in a number of Latin American countries has not achieved sustainable sales in private-sector channels, and also, as discussed, the institutional markets have not developed. It is not clear whether that producer will keep Oxytocin in Uniject in its product line.

Lack of movement down the finance pathway, also due to price, has further contributed to the difficulty of establishing a sustainable market for the product. Various groups have modeled the cost-effectiveness of Oxytocin in Uniject and have found that its value proposition remains very sensitive to the final price of the product. The current high price has made it difficult to advocate the product’s cost-effectiveness, leading to the lack of financial commitment from institutional buyers.

Lessons Learned
Regardless of the potential public health benefit and apparent elegance of the approach, an innovation must be extremely affordable relative to the alternatives for institutional uptake to occur. Simply put, we now understand the
difficulty of putting an inexpensive product such as oxytocin into a relatively expensive injection device such as Unject.

Additionally, we have learned that, in the absence of a concerted demand-side intervention, market mechanisms are unlikely to produce sufficient demand to yield significant economies of scale. We had expected the unit price to drop over time as manufacturers achieved economies of scale through high-volume production. We also expected sales in private markets at higher prices to cross-subsidize lower-priced sales in public-sector markets. Neither scenario has materialized.

We have also learned to moderate our expectations of how much drug and vaccine manufacturers in highly competitive generic product markets will invest in regulatory and market introduction of new delivery mechanisms for their products, even with support from the global health community, and especially if demand is unclear.

Finally, we learned that, if pricing does not fall within the target range for institutional buyers as development, manufacturing, and introduction progress, the public health community must consider withdrawing further support sooner in order to redirect energy and resources toward more marketable endeavors that may consequently have more impact. Without market penetration, it follows that sustainability and health impact have yet to be realized from this product.

careHPV*: Lack of Operational Evidence on Clinical Use Slows Pace of Adoption

Despite a clear supply pathway and good evidence of its effectiveness, use of careHPV remains limited. The careHPV test is an example of how lack of movement down the clinical use pathway, starting with the need for operational evidence of use within facilities, has slowed the pace of adoption.

The careHPV test is a screening test that detects the presence of human papillomavirus (HPV), the primary cause of cervical cancer, through cervical or vaginal samples. It was specifically designed for use in developing countries through collaboration between its manufacturer and PATH. Clinical studies, involving more than 20,000 women in 3 countries, have established that careHPV is almost twice as accurate as existing screening methods, such as the Pap Smear and Visual Inspection by Acid (VIA), when used as a primary screening method.\(^3\)\(^,\)\(^4\) Although the cost per test for careHPV is higher than for other screening methods, its lower rate of false negatives make it a strong public health tool, considering the high morbidity and mortality if cervical cancer goes undetected. The lower rate of false positives also avoids unnecessary costs associated with follow up. Finally, since careHPV can be used with vaginal samples, it can help avoid a pelvic exam, assuming clinical guidelines are in place for self-sampling. However, no country has yet adopted such a practice.

Stakeholder interviews revealed that, in general, clinicians in developing countries are not clear about which screening-to-treatment strategies to use for patients with HPV, since use of HPV tests as the primary screening method is new to both developed and developing countries. WHO guidelines were finally released in 2013, stating that practitioners can go directly from screening with careHPV to treatment in low-resource settings, without the need for cytology followed by a diagnostic test such as colposcopy.\(^15\) It will take time and effort for these guidelines to be mainstreamed into clinical practice.

In addition, policy makers in developing countries are uncertain about how to design the implementation program most appropriate for their local situation as well as about the implications of that approach for their human and financial resources. For instance, since careHPV requires processing at a lab, it is unclear how many lab facilities should be enabled within a given district’s unique size and capacities in order to maximize both cost efficiencies and appropriate coverage.

**Lessons Learned**

One key lesson learned from the careHPV experience is the clear need for operational studies to answer many of these questions, so that appropriate clinical guidelines can be established. This evidence is especially important in the absence of model clinical policies from the developed world that can be followed. In addition, these studies may need to be pursued in several countries to test feasibility in different clinical environments. Simultaneously, financial mechanisms for purchase by ministries of health need to be identified and developed to create a viable and sustainable market. However, since the financial mechanisms may not be established before the evidence is generated and clinical use policies are modified, additional funding from

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\(^*\)careHPV is a trademark of QIAGEN.
the global health donor community will be required. There is simply insufficient market incentive for the private sector to invest in the operational studies and advocacy required for enabling this market. Without these elements in place, the pace of adoption for careHPV will continue to be slow. Again, due to the lack of market penetration at this point, neither sustainability nor health impact has yet been achieved.

Helping Babies Breathe: Well-Coordinated Supply Chain, Financing, and Clinical Capacity Pathways Provide a Model for Success

The Helping Babies Breathe (HBB) initiative exemplifies the successful introduction of medical equipment into local institutional markets through well-coordinated supply chain, financing, and clinical use pathways. HBB’s success is attributable to the U.S. Agency for International Development’s (USAID) strong Global Development Alliances (GDAs) model, as well as to the commitment of Laerdal, the key equipment supplier and a founding member of HBB, to saving the lives of newborns in low-resource countries. As such, HBB took the role of a “backbone organization” to orchestrate the various actors and activities along the various introduction pathways.

As a GDA funded by USAID, HBB now includes 20 partners from the private and public sectors. In 2010, HBB began offering evidence-based training and high-quality, affordable neonatal resuscitation equipment to birth attendants in developing countries. As of November 2013, 60 countries had implemented the HBB curriculum, of which 18 have national plans coordinated by governments. In the 60 countries, approximately 130,000 health care providers were trained. In addition, HBB supplied 120,000 bag-and-mask resuscitation devices, 150,000 suction bulbs, and 50,000 simulators on a not-for-profit basis, and donated another 4,500 HBB training kits.

Laerdal supplies high-quality resuscitation equipment at reasonable cost to HBB partners that support the program. Laerdal has also donated simulators and other equipment to enhance use and spark further demand. Additionally, HBB’s master training programs, a critical element of the clinical use pathway, provides health care personnel with important operational experience with resuscitation equipment. In selected developing countries, Laerdal also offers grants to support implementation of the training program as well as guidelines on purchasing and maintaining equipment. The training not only increases competencies of birth attendants but also meets their latent need for higher-quality resuscitation equipment. This is important groundwork for creating sustainable, institutional demand from within public-sector facilities.

Lessons Learned

Clearly, HBB is a model to follow. HBB has stimulated the supply side of the market through affordable equipment and the demand side through training and implementation grants. In turn, this has created a viable market, maintaining engagement of the many partners and stakeholders involved. While HBB still needs to shift from being mostly donor-driven to country-driven, the initiative’s effective coordination role and the demand it has helped to establish by normalizing use of these products in clinic settings bodes well for adoption and scale up of this program by public health institutions in developing countries. It is likely that the role of the market coordinator is an underused mechanism in the uptake of global health products. This example demonstrates clear market penetration, with sustainability now emerging as HBB training guidelines are adopted by various ministries of health and incorporated into global health projects related to newborn resuscitation. Significant health impact is likely to follow.

CASE STUDIES FROM CONSUMER MARKETS

Woman’s Condom: Lack of Coordination Between Supply and Demand Limit Market Penetration

The Woman’s Condom exemplifies the challenge of trying to establish a sustainable supply and distribution chain for a new product when it is not coordinated with an equally well-resourced, demand-generation effort.

The Woman’s Condom is a new female condom whose design and early-stage validation was funded initially by USAID to expand contraceptive options for women in developing countries. PATH and its research partners employed a user-centered design process to develop a product that has proved to be highly acceptable. User acceptability has been a key barrier to use of other female condom products.

Female condoms are primarily a consumer product, in which the decision to purchase and use the product lies with the end user. However,
during the first 20 years of introduction, female condom purchasers largely have been bilateral and multilateral institutions, such as USAID, the United Nations Population Fund (UNFPA), and ministries of health, that distribute condoms through government-sponsored programs at free or highly subsidized rates. Although this is a legitimate strategy for introducing a new product class in the absence of robust funding to support demand generation, it has not allowed female condoms to become established as a consumer class product. Manufacturers have focused more attention on sales to institutional buyers, and while new female condom products, such as the Woman’s Condom, are helping to enlarge and differentiate the class, consumers are still conditioned to receiving the product for free.

The absence of sustained demand generation is not the only issue. Female condoms are more costly than male condoms, which further reduces demand from both institutional and consumer buyers. For instance, in 2009, donors purchased 71 male condoms for every 1 female condom.

To address these issues, PATH and its manufacturing partner, Dahua Medical Apparatus Company of Shanghai, China, have established a partnership to build a sustainable supply chain for the Woman’s Condom, which leverages both public-sector and commercial retail channels. The market penetration strategy is to first generate revenue from private-sector sales to help cover Dahua’s costs, thus allowing the company to offer more affordable pricing to low-resources settings served by the public sector in the longer term.

The Woman’s Condom has received South Africa Bureau of Standards certification marking (2013), Shanghai Food and Drug Administration approval (2011), and CE (Conformité Européenne, or European Conformity) marking (2010), which allow for distribution and marketing in private-sector retail channels in South Africa, China, and Europe, respectively. Early introduction efforts in China and South Africa are underway but have already faced challenges. One significant challenge is finding in-country distribution partners willing to invest in the extensive marketing and sales required to generate demand for an unfamiliar product. The cross-subsidy model requires sufficient sales in the commercial sector to cover the costs not recouped through lower prices offered to the public sector. However, due to the investment involved, the revenue from commercial sales is difficult to generate. In China, for example, public-sector sales have exceeded commercial sales,

forcing Dahua to sell the product below costs at this time. This situation further reduces Dahua’s ability and incentive to invest in the marketing necessary to cultivate private-sector markets.

Lessons Learned

A key lesson is the need to pursue aggressive demand-generation efforts simultaneously while establishing supply and distribution chains in order to create strong incentives for actors along the supply chain to engage. Several demand-side elements have been built into the project, including market research with women in China and South Africa, market tests to target consumer markets, and advocacy with the governments in both countries to create a supportive policy environment for female condoms more generally. However, the investment and scale of the demand generation effort has likely been underappreciated. In fact, no real social marketing campaign has yet been launched in either country. Due to the inherent risks involved for manufacturers and distributors, a more significant investment by the donor community may be warranted in order to catalyze this market. Similar to other examples, without market penetration, sustainability and health impact have yet to be achieved with this product.

Safe Water: Coordinated Supply, Financing, and Consumer Demand Demonstrate Viability of Market

Our Safe Water Project has experimented with several pilot strategies for developing the retail market to sell household water filters to con-
The most successful strategies have involved tight coordination between supply, availability of financing, and consumer demand generation efforts for enhancing the perceived value of the product.

A pilot study in Madhya Pradesh, India, offered consumers free water filters, manufactured by PATH’s commercial partner, Hindustan Unilever Limited (HUL), in an effort to draw them into the market. Although 44% of these consumers later took a loan for 2 replacement cartridges from our microfinance partner, Spandana Sphoorty Financial Limited, 35% of consumers reported gifting or selling the water filter. For those who used the product, current and consistent use dropped to 19.1% after 6 months, and then eventually to zero at 10 months. Since the water filter was a “giveaway,” neither the salespeople nor consumers appreciated its value. Therefore, salespeople did not have an incentive to make a strong sales pitch.

In contrast, in Tamil Nadu (Erode), India, the same water filter was offered to consumers without a subsidy. After 10 months, 21% of consumers reported currently using the filters, suggesting that the strategy succeeded in attracting consumers who valued the product and decided to try it based on their perception of its merits.

The strongest results were observed in Cambodia, where a water filter (Super Tunsai) manufactured by Hydrologic Social Enterprise was paired with a loan scheme offered by the microfinance institution VisionFund. The original Tunsai water filter was not perceived as desirable because of its very basic design and large subsidies to support its use. We worked with Hydrologic to redesign the original Tunsai filter to make it more appealing to customers—both from an aesthetic and functional point of view. The redesigned Super Tunsai filter was then marketed as a desirable product targeting consumers’ aspirations toward attaining middle-class status. In spite of the fact that the Super Tunsai cost twice as much as the original Tunsai filter, customers were willing to take full loans from VisionFund to purchase the product. After 10 months, 39% of consumers reported currently using the filter.

Lessons Learned
Pricing at full retail value is preferable to subsidies, as it attracts more committed consumers and avoids undermining the value of the product, as demonstrated in the Tamil Nadu pilot. We have observed an even stronger effect in Cambodia when this strategy was complemented with social marketing around desirability and affordable replacement cartridge costs. In fact, Hydrologic’s replacement cartridges are approximately US$5–$10 per year compared with $25 for the HUL filter used in India. Hydrologic and VisionFund are now scaling up their winning strategy to 11 provinces in Cambodia. Additionally, PATH is using the best practices from its water filter pilots to launch new programs, including a plan to make latrines available in Cambodia through similar schemes, as well as cook stoves, solar lamps, and insecticide-treated bed nets in other markets. The Cambodia pilot, in particular, has demonstrated reasonable market penetration, while signs of sustainability and health impact are emerging.

Ultra Rice Fortification Technology:
Sustainability Plans for Both Supply and Demand Drive Scale Up
Efforts to introduce Ultra Rice in Brazil show how creating pillars of sustainability on both the supply and demand sides of the market can enable replication and scale up by local organizations. While PATH’s Ultra Rice technology has a 15-year history of fits and starts, the approach in Brazil has created the knowledge and understanding of how to achieve sustainability before

Ultra Rice is a registered U.S. trademark of Bon Dente International, Inc.
the end of each country-specific funding stream under the umbrella project.

The Ultra Rice technology is a formulation and method for creating reconstituted rice grains packed with micronutrients such as iron, thiamin, zinc, and folic acid. When blended with conventional rice, typically at a 1:100 ratio, the resulting fortified rice can provide up to 50% of the recommended daily intake of a range of micronutrients. This helps bridge dietary gaps in micronutrient intake, especially among populations for whom rice constitutes a large portion of their caloric intake.

In Brazil, the market introduction process for fortified rice started by transferring the technology to local companies, including Urbano Agroindustrial, one of the nation’s largest rice millers, and Adorella Alimentos, a medium-sized pasta manufacturer. These companies continue to produce fortified rice kernels, which will not only be incorporated into their own fortified rice products but, as an obligation under PATH’s license, also be sold to other millers in order to create a competitive market. Additionally, we have directly licensed the Ultra Rice technology to a preeminent agribusiness university, the Federal University of Viçosa, giving that institution both the right and the obligation to license the technology to additional manufacturers in the future as the market grows. Establishing a small subset of current suppliers as well as an engine for further growth bodes well for supply-side sustainability.

On the demand side, instead of marketing the product primarily to lower-income market segments, which suffer disproportionately from the consequences of micronutrient malnutrition, we are targeting the widest possible range of consumers. In order to establish consumer confidence, the social marketing campaign is built around a quality seal on the packaged rice, conveying aspiration for the product. The Federal University of Viçosa and the national rice millers association, Abiarroz, verify the quality of the fortified grains and homogeneity of their blend into traditional rice. This process is open to all rice brands, including those typically purchased by consumers with lower incomes. While millers of both higher- and medium-price rice brands have led the way, lower-priced brands are likely to move through the verification process in due course, thus leveling the playing field with respect to fortified rice quality. This marketing strategy avoids any stigma that might develop if only the lower-cost brands were fortified and has already reached hundreds of thousands of consumers in the first 6 months since the launch of fortified rice in commercial retail markets.

Additionally, to further enhance demand, we have produced marketing materials for our partners and have negotiated rights to use cartoon characters owned by Turma da Monica (a local “Disney equivalent”), which are well-recognized by Brazilians. Prior to the end of the project, we plan to have these rights transferred to Abiarroz, so that the cartoon characters continue to be used as ambassadors to the product in order to stimulate demand. Also, we have enlisted a number of well-known and highly respected supporters, ranging from noted journalists to well-recognized health experts, who have now established micronutrient malnutrition as one of their social causes.

Lessons Learned

Although not all elements of this market penetration strategy can be replicated across rice markets in Africa and Asia, we have learned the value of closely coordinating the various introduction pathways as well as building sustainability into the product introduction plans from the outset. Donor-supported projects that are designed to stimulate global health markets are most successful when engines of further growth for both supply and demand are established well before project funding expires. In other words, planning for sustainability should commence at the start of the project, not after the pilot project.
has launched and tested the product. In Brazil, planning for sustainability required identifying the array of local organizations that can take ownership of the product and laying out the market development process well before PATH and partners exit. This example demonstrates early signs of significant market penetration and sustainability, although health impact in the target market may be achieved at a slower pace as fortified rice gains further traction in the Brazilian market.

**SUMMARY**

While the global health community has decades of experience bringing technologies, such as vaccines, bed nets, antiretroviral therapies, and malaria drugs, to scale through global procurement mechanisms, we are only now reflecting more systematically on our experience in developing local institutional and consumer markets, especially in light of UNCoLSC’s focus on these types of commodities. Global procurement markets require complex coordination among WHO, the GAVI Alliance, UNICEF, and other multilateral institutions to organize purchase and distribution at scale; however, the global health community wrestles even more with local market introduction. The lack of incentives on both demand and supply sides of the market creates natural dysfunction, but our accumulated experience can serve as guideposts as we navigate these challenges.

Among the salient lessons learned from these 6 case studies is the need to design more effective projects (Box). Sometimes, our failure to scale is a failure of design; we either do not recognize all the critical supply and demand elements that need to be pursued or assume other players in the market ecosystem will take them on. One critical design consideration is the need to **build supply and demand simultaneously**, not only to avoid a fatal imbalance, but also to ensure that all relevant demand-side pathways are included in the technology introduction plan, as captured in our framework.

Local market introduction of global health products can also benefit from a **lead organization**. Too often in the public health arena, each player, whether a nongovernmental organization (NGO), government, or private-sector firm, supports only a few elements of the required market-development activity, such as generating evidence of operational feasibility or pursuing advocacy for policy change. These small steps are vital elements on the critical path toward scale. Generally, however, no one organization takes on the important role of driving the market introduction process forward—often a necessity in these largely dysfunctional markets. The lack of such a lead is a natural consequence of the piecemeal nature of donor funding and the niche competencies that NGOs have developed to win grants. Few general contractors exist in global health markets. Consequently, we often have ample evidence of potential impact, several interested manufacturers, and strong data to support advocacy, but, despite all this, many of these markets have failed to flourish. A lead organization provides the natural base from which to plan and execute activities along all 4 of the introduction pathways captured in our framework.

Market orchestration also requires a **strong vision and intention to reach scale**—a goal that needs to be built into the project design from its inception and that is embodied within the set of supply and demand-side pathways captured in the framework. Projects driving toward sustainability within their life span create stronger and faster impact. The project nature of donor funding is a cumbersome mechanism for developing local markets. We need to develop stronger models that more closely mirror the required process for reaching scale, such as longer grant periods, flexibility to adjust funding levels to changing market needs, and more holistic project designs.

Finally, but most importantly, we need to pay stronger attention to the **incentives for profitability** of the private sector, which will continue to play an increasingly important role in public health techs.

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**BOX. Lessons Learned From Introducing Global Technologies Into Local Markets**

- **Build** supply and demand simultaneously.
- Consider the need for one organization to lead, oversee, and coordinate the entire market introduction activity.
- From the start, have a strong vision and intention to reach full scale through bold, holistic project concepts.
- Pay strong attention to the incentives and profitability of the private sector involved.

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**Local markets for global health technologies**

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health. This is a key element of the supply-side pathway described in the framework. For new technologies, the private sector is often faced with a cost structure that requires pricing above status quo alternatives and uncertain demand due to such issues as the lack of clear distribution channels, clinical policies, and value proposition for the buyer. This most often leads to significant risk and, consequently, an underinvestment in market development by the private sector. While the global health community has developed some effective risk-reduction strategies for products entering global procurement markets, such as advanced market commitments for vaccine development, expedited regulatory pathways for orphan drugs, and graduated copays for vaccine purchases by ministries of health, we need to develop similar, enabling innovations for those products entering local markets. We also need to better analyze the upfront risks to assess whether there would be natural incentives to both supply and adoption of the technology once the risks are sufficiently reduced through an infusion of grant funding. Effective market introduction is paramount and the only way to achieve sustainability.

CONCLUSION

Our experience underscores the widespread understanding that there is no universally applicable market introduction strategy for products of global health importance. The framework introduced in this article is a starting point, reflecting the general elements of market introduction that may be emphasized differently for each unique product, market, and cultural context. We hope that others continue to build upon the framework with additional insights gained from their experiences. Such empirically-driven frameworks may help minimize our missteps in design, which can be costly and time-consuming and can stymie our collective effort to create health impact in the most vulnerable groups. As a global health community, we need to continue sharing our rich experiences in developing markets for global health products to ensure that global initiatives, such as UNCoLSC, with so many important products destined for local institutional and consumer markets, maximize their potential to save lives.

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Are pregnant women prioritized for bed nets? An assessment using survey data from 10 African countries

Emily Ricotta, a Hannah Koenker, a Albert Kilian, b Matthew Lynch a

Women of reproductive age are generally more likely to sleep under an insecticide-treated net (ITN) than other household members. Universal coverage increases ITN use by all family members, including pregnant women. However, BCC efforts are needed to achieve desired levels of bed net use, which is especially important for pregnant women.

ABSTRACT

Background: Malaria in pregnancy is a major public health concern, contributing to roughly 11% of neonatal deaths and to 25% of all maternal deaths in some parts of the world. The World Health Organization has recommended priority interventions for malaria during pregnancy, including use of insecticide-treated nets (ITNs), but net distribution has shifted recently to a universal coverage paradigm rather than one targeting vulnerable populations.

Methods: To determine whether and to what extent pregnant women are prioritized within the household for ITN use, we assessed national survey data from 2009–2013 in 10 African countries. Proportion of pregnant women who slept under an ITN the previous night and 95% confidence intervals were calculated and compared between countries. Within-country logistic regression examined whether pregnancy was significantly associated with ITN use the previous night compared with other risk groups, and the predicted probability of net use for each risk group was calculated holding other covariates constant.

Results: A median 58% of households reported owning at least 1 ITN. On average, across all 10 countries, 35% of pregnant women in households with at least 1 ITN used a net. Households with universal coverage (at least 1 ITN per 2 people) had higher levels of net use among all family members; for example, 79% of pregnant women, on average, used a net in such households. In all countries, the predicted probability of ITN use by pregnant women was significantly higher than the probability of net use by most other household members except non-pregnant women of reproductive age.

Conclusion: These findings suggest that both pregnant women and non-pregnant women of reproductive age are being prioritized within the household for net use. However, behavior change communication strategies are needed to achieve ITN use goals for pregnant women.

INTRODUCTION

Malaria in pregnancy is a major public health concern, contributing to high rates of maternal and newborn morbidity and mortality. More than 30 million pregnant women reside in malaria-endemic areas of Africa, where Plasmodium falciparum infection in pregnancy is associated with low neonatal birth weight and where the infection contributes to roughly 11% of neonatal deaths. One of the most serious and potentially deadly consequences of malaria during pregnancy is maternal anemia, which presents even in women with asymptomatic malaria infection and in those with undetectable infection by blood smear due to mass sequestration in the placenta. In some parts of the world, malaria infection during pregnancy contributes directly to 25% of all maternal deaths.

Because of the significant impact of this disease on pregnant women and newborns, in 2000, multiple African countries south of the Sahara pledged to fight malaria in pregnancy with insecticide-treated nets (ITNs), intermittent preventive treatment of malaria in pregnancy (IPTp), and improved case management.
Three years later, the World Health Organization released “A Strategic Framework for Malaria Prevention and Control During Pregnancy in the African Region” to develop a standardized method for preventing and controlling malaria during pregnancy. By 2007, 39 African countries had incorporated part, or all, of this framework into their national malaria control plans. However, the extent to which these new strategies have been deployed or have reduced maternal malaria is uncertain.

According to an analysis by Stenberg and colleagues (2013), scaling up ITN coverage and IPTp and ensuring availability of appropriate malaria treatment could prevent 153 million episodes of malaria by 2035, saving US$5 billion in drug costs alone and US$280 million in outpatient visits. Additionally, studies have shown that targeting pregnant women and infants during ITN distribution campaigns is an effective method of reducing all-cause post-neonatal mortality.

Timing of ITN use during pregnancy is important. While the effects of malaria infection in the first trimester are largely unknown, risk of miscarriage seems to increase compared with women who become infected later in pregnancy, especially among women who develop clinical malaria. The highest rates of infection, severe disease, and fetal impairment occur in the second and third trimesters, but IPTp cannot be given to pregnant women in the first trimester due to potential teratogenicity and possible fetal death. These factors make it important for women to attend antenatal care (ANC) to obtain an ITN early during pregnancy.

Since 2009, there has been a move away from prioritizing vulnerable populations (such as children under 5 and pregnant women) during net distribution to a universal coverage paradigm. These campaigns strive to provide every household with 1 net per 2 people, or 1 net per sleeping space, regardless of household composition (that is, number of pregnant women and children). This strategy allows countries to rapidly attain high levels of net coverage throughout a region and includes households that do not have a pregnant woman or young children; however, in order to maintain protection across the population, there needs to be additional, focused distribution targeting pregnant women and children to ensure ITN coverage.

### TABLE 1. Characteristics of Surveys Included in the Analysis and Key Indicators Related to Malaria in Pregnancy

<table>
<thead>
<tr>
<th>Country</th>
<th>Survey Type</th>
<th>Year of Survey</th>
<th>No. of Households Sampled</th>
<th>Pregnant Women % (95% CI)</th>
<th>Household ITN Ownership % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liberia</td>
<td>MIS</td>
<td>2011</td>
<td>4,162</td>
<td>9.0 (8.1–10.0)</td>
<td>55.1 (54.3–55.8) 9.4 (8.9–9.8)</td>
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<tr>
<td>Madagascar</td>
<td>MIS</td>
<td>2013</td>
<td>8,574</td>
<td>7.4 (6.8–8.0)</td>
<td>62.4 (61.9–62.9) 19.5 (19.1–19.9)</td>
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<tr>
<td>Malawi</td>
<td>DHS</td>
<td>2010</td>
<td>24,825</td>
<td>9.3 (9.0–9.7)</td>
<td>60.4 (60.2–60.7) 14.7 (14.5–14.9)</td>
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<tr>
<td>Mozambique</td>
<td>DHS</td>
<td>2011</td>
<td>13,919</td>
<td>10.2 (9.7–10.7)</td>
<td>53.6 (53.2–54.0) 16.6 (16.3–16.9)</td>
</tr>
<tr>
<td>Nigeria</td>
<td>MIS</td>
<td>2010</td>
<td>5,895</td>
<td>10.8 (10.1–11.6)</td>
<td>48.8 (48.2–49.3) 9.8 (9.5–10.2)</td>
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<td>Rwanda</td>
<td>DHS</td>
<td>2010</td>
<td>12,540</td>
<td>6.8 (6.4–7.3)</td>
<td>85.8 (85.5–86.1) 32.8 (32.4–33.2)</td>
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<td>Senegal</td>
<td>DHS</td>
<td>2010</td>
<td>7,902</td>
<td>8.4 (8.0–8.9)</td>
<td>75.5 (75.2–75.8) 14.3 (14.1–14.6)</td>
</tr>
<tr>
<td>Tanzania</td>
<td>THMIS</td>
<td>2011</td>
<td>10,040</td>
<td>9.3 (8.8–9.8)</td>
<td>92.0 (91.8–92.2) 41.2 (40.8–41.6)</td>
</tr>
<tr>
<td>Uganda</td>
<td>MIS</td>
<td>2009</td>
<td>9,033</td>
<td>9.8 (9.0–10.8)</td>
<td>51.2 (50.5–51.9) 12.0 (11.6–12.4)</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>DHS</td>
<td>2010</td>
<td>9,756</td>
<td>7.8 (7.3–8.4)</td>
<td>30.4 (29.9–30.8) 9.2 (9.0–9.5)</td>
</tr>
</tbody>
</table>

Abbreviations: DHS, Demographic and Health Survey; ITN, insecticide-treated net; MIS, Malaria Indicator Survey; THMIS, Tanzania HIV/AIDS and Malaria Indicator Survey.

a At least 1 ITN per household.

b At least 1 ITN per 2 people.
at critical fetal and infant growth stages.\textsuperscript{16} Within the context of universal coverage campaigns, it is unclear whether pregnant women continue to be prioritized for ITN use, in terms of nets allocated at the national level that are specifically targeted for ANC distribution as well as net allocation within the household.

In this article, we focus on assessing available survey data from 10 countries in Africa to determine whether and to what extent pregnant women are prioritized within the household for ITN use. By applying the newly recommended indicators of access to an ITN within the household to this group, it is possible to see more precisely where pregnant women are using nets.\textsuperscript{17} These data provide a better understanding of net use behavior, differentiating between those who do not use a net because they do not have access to one versus those who have access to a net and do not use one for behavioral reasons.

**METHODS**

We analyzed recent Demographic and Health Surveys (DHS) and Malaria Indicator Surveys (MIS) collected in 2009 or later from 10 African countries (Table 1). Criteria for selection of the datasets included availability of data on individual ITN use and whether there were any pregnant women on the day of the survey within the household. The most recent publicly available dataset from each country was chosen; 9 of 10 datasets were from 2010–2013, to reflect recent scale up of coverage of long-lasting insecticidal nets (LLINs). All datasets were obtained with permission from MEASURE DHS.

Analyses were completed using R: A Language and Environment for Statistical Computing, version 3.0.2 (R Foundation for Statistical Computing, Vienna, Austria), and Stata Statistical Software: Release 13 (StataCorp LP, College Station, TX). Proportion of pregnant women who slept under an ITN the previous night and 95% confidence intervals were calculated and compared between countries. We used within-country logistic regression to examine whether pregnancy was significantly associated with ITN use the previous night when compared with other risk groups, including children under 5, children 5–14 years old, non-pregnant women of reproductive age (WRA), men ages 15–49 years, and adults over 49 years old. This analysis was restricted to those households that reported owning at least 1 ITN (referred to here as partial household coverage).

**TABLE 2. ITN Use Among Pregnant Women, Non-Pregnant Women of Reproductive Age, and Other\textsuperscript{a} Household Members, by ITN Household Coverage**

<table>
<thead>
<tr>
<th>Country and Risk Group</th>
<th>Partial Coverage Households\textsuperscript{b} % (95% CI)</th>
<th>Universal Coverage Households\textsuperscript{c} % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liberia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>38.9 (32.7, 45.5)</td>
<td>86.2 (67.4, 95.5)</td>
</tr>
<tr>
<td>WRA</td>
<td>36.2 (34.3, 38.1)</td>
<td>79.5 (74.3, 83.8)</td>
</tr>
<tr>
<td>Other</td>
<td>25.5 (24.8, 26.2)</td>
<td>74.9 (72.5, 77.2)</td>
</tr>
<tr>
<td>Madagascar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>40.6 (36.1, 45.3)</td>
<td>91.1 (85.3, 94.9)</td>
</tr>
<tr>
<td>WRA</td>
<td>41.0 (39.8, 42.3)</td>
<td>87.6 (85.9, 89.0)</td>
</tr>
<tr>
<td>Other</td>
<td>36.9 (36.3, 37.5)</td>
<td>85.8 (84.8, 86.7)</td>
</tr>
<tr>
<td>Malawi</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>28.2 (26.2, 30.4)</td>
<td>72.7 (68.2, 76.7)</td>
</tr>
<tr>
<td>WRA</td>
<td>28.5 (27.8, 29.2)</td>
<td>71.1 (69.6, 72.5)</td>
</tr>
<tr>
<td>Other</td>
<td>20.5 (20.2, 20.8)</td>
<td>65.8 (64.9, 66.6)</td>
</tr>
<tr>
<td>Mozambique</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>22.6 (20.2, 25.3)</td>
<td>68.9 (63.6, 73.8)</td>
</tr>
<tr>
<td>WRA</td>
<td>22.8 (22.0, 23.6)</td>
<td>68.8 (66.8, 70.7)</td>
</tr>
<tr>
<td>Other</td>
<td>18.4 (18.1, 18.8)</td>
<td>64.2 (63.1, 65.2)</td>
</tr>
<tr>
<td>Nigeria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>26.6 (23.1, 30.4)</td>
<td>81.2 (71.7, 88.2)</td>
</tr>
<tr>
<td>WRA</td>
<td>23.0 (21.9, 24.2)</td>
<td>69.8 (66.0, 73.2)</td>
</tr>
<tr>
<td>Other</td>
<td>17.8 (17.3, 18.3)</td>
<td>69.4 (67.4, 71.3)</td>
</tr>
<tr>
<td>Rwanda</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>60.0 (55.3, 64.5)</td>
<td>86.8 (83.1, 89.9)</td>
</tr>
<tr>
<td>WRA</td>
<td>58.2 (56.9, 59.4)</td>
<td>83.3 (82.0, 84.5)</td>
</tr>
<tr>
<td>Other</td>
<td>43.3 (42.7, 43.8)</td>
<td>76.1 (75.4, 76.8)</td>
</tr>
<tr>
<td>Senegal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>37.2 (34.4, 40.1)</td>
<td>73.7 (67.4, 79.2)</td>
</tr>
<tr>
<td>WRA</td>
<td>33.8 (33.0, 34.6)</td>
<td>72.6 (70.7, 74.6)</td>
</tr>
<tr>
<td>Other</td>
<td>28.5 (28.1, 28.9)</td>
<td>65.1 (64.1, 66.1)</td>
</tr>
</tbody>
</table>

\textsuperscript{a} Households that reported owning at least 1 ITN

\textsuperscript{b} Partial household coverage

\textsuperscript{c} Universal household coverage
Covariates were selected for each country using a priori research and included the categorical risk group variable, residence (urban/rural), administrative divisions, month the survey was conducted, and wealth quintiles. Wealth was based on household assets and obtained by principle component analysis.

Additional indicators used for analysis were developed by the Roll Back Malaria (RBM) Monitoring and Evaluation Reference Group, which included the “proportion of households with at least 1 ITN for every 2 people” to act as a measure for sufficient nets within the household so that every member could have used a net (referred to as universal household coverage).

The outcome variable was individual ITN use the prior night (yes/no), and P values < .05 were considered significant. Following regression, the predicted probability of net use for each risk group was calculated, holding other covariates constant at their observed value.

### RESULTS

The number of households surveyed ranged from 5,895 (Nigeria) to 24,825 (Malawi). The median proportion of those surveyed who were pregnant was 9%, ranging from 7% (Madagascar and Rwanda) to 11% (Nigeria) (Table 1).

#### Household ITN Ownership

The median proportion of households reporting ownership of at least 1 ITN was 58%. This proportion varied widely by country, from 30% in Zimbabwe to 92% in Tanzania (Table 1). Universal net coverage (at least 1 ITN per 2 people) was lower, ranging from 9% in Liberia and Zimbabwe to 33% in Rwanda.

#### ITN Use by Pregnant Women

Proportion of net use by pregnant women varied widely by country. Among households with partial net coverage, the proportion ranged from 5.5% in Zimbabwe to 60% in Rwanda. Households with universal net coverage had higher net use; the proportion of net use by pregnant women in these households ranged from 9% in Liberia to 91% in Madagascar and Uganda (Table 2). Mean proportion of net use by pregnant women across all countries in households with at least 1 ITN was 35%, compared with 79% among households with universal net coverage.

#### ITN Use by Pregnant Women Versus Other Household Members

Net use was generally higher among pregnant women and non-pregnant WRA than among other household members. There was no significant difference in use between pregnant women and WRA in any country, regardless of whether the household had sufficient nets for the entire family. In households with at least 1 ITN, a significantly higher proportion of pregnant women than “other” household members (comprising children through age 14, men ages 15–49, and adults over age 49) used a net in 8 of the 10 countries included in the analysis (Liberia, Malawi, Mozambique, Nigeria, Rwanda, Senegal, Tanzania, and Uganda). In households with universal coverage, a significantly higher proportion of pregnant women than other household members used nets in Malawi, Rwanda, Senegal, Tanzania, and Uganda (Table 2).

In all countries, the predicted probability of ITN use by pregnant women was significantly higher than the probability of ITN use by children.

### TABLE 2 (continued).

<table>
<thead>
<tr>
<th>Country and Risk Group</th>
<th>Partial Coverage Households&lt;sup&gt;b&lt;/sup&gt; % (95% CI)</th>
<th>Universal Coverage Households&lt;sup&gt;c&lt;/sup&gt; % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tanzania</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>56.5 (52.4, 60.5)</td>
<td>84.9 (81.2, 88.0)</td>
</tr>
<tr>
<td>WRA</td>
<td>55.6 (54.3, 56.8)</td>
<td>83.9 (82.7, 85.0)</td>
</tr>
<tr>
<td>Other</td>
<td>50.8 (50.2, 51.4)</td>
<td>77.5 (76.9, 78.2)</td>
</tr>
<tr>
<td>Uganda</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>32.8 (27.4, 38.8)</td>
<td>90.7 (77.0, 97.0)</td>
</tr>
<tr>
<td>WRA</td>
<td>27.2 (25.4, 29.1)</td>
<td>82.4 (78.2, 85.9)</td>
</tr>
<tr>
<td>Other</td>
<td>17.4 (16.8, 18.1)</td>
<td>74.0 (72.0, 76.0)</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant</td>
<td>5.5 (3.9, 7.6)</td>
<td>52.6 (41.0, 63.9)</td>
</tr>
<tr>
<td>WRA</td>
<td>6.5 (6.0, 7.1)</td>
<td>46.7 (43.3, 50.1)</td>
</tr>
<tr>
<td>Other</td>
<td>4.9 (4.6, 5.1)</td>
<td>39.9 (38.2, 41.8)</td>
</tr>
</tbody>
</table>

Abbreviations: ITN, insecticide-treated net; WRA, (non-pregnant) women of reproductive age.
<sup>a</sup> “Other” category comprises children through age 14, men ages 15–49, and adults over age 49.
<sup>b</sup> At least 1 ITN per household.
<sup>c</sup> At least 1 ITN per 2 people.
ages 5–14, men ages 15–49, and individuals over 49 after controlling for other household variables. See, for example, Figure 1, showing data from Liberia. (For data from other countries, see Supplemental Figures 1–5). Pregnant women were also more likely to use an ITN than children under 5 in all but 4 countries (Nigeria, Senegal, Tanzania, and Zimbabwe). See Figure 2 for sample data from Senegal and Supplemental Figures 6–8 for data from Nigeria, Tanzania, and Zimbabwe. In all countries, ITN use by pregnant women was not significantly different than for non-pregnant WRA when controlling for other household variables.

**DISCUSSION**

In this study, we compared ITN use by pregnant women in households with and without universal net coverage (that is, 1 net per 2 people) to determine whether lack of household access to ITNs was the main reason for non-use of nets by pregnant women. The results of this study demonstrate that across the 10 study countries, pregnant women as well as non-pregnant women of reproductive age were more likely to have used an ITN the night before the survey than other household members. In addition, an even higher proportion of pregnant women who lived in a household with universal coverage than pregnant women in households without universal coverage used nets. This suggests that both non-pregnant women of reproductive age and pregnant women are being prioritized within the household and that non-use is indeed more related to lack of access to an ITN rather than due to a behavioral issue.

Greater access to nets, however, does not always translate into greater use by pregnant women; behavior change communication (BCC) is still needed to ensure prioritization of and use by pregnant women. In some countries that recently had a net distribution campaign (such as in Madagascar and Tanzania, which had major distributions between 2009–2010 and 2010–2011, respectively), households were more likely to report higher net ownership, thus reducing the use:access gap. But these countries were not always the most likely to prioritize pregnant women, and some countries with low universal net coverage rates are more likely to prioritize pregnant women for net use. For example, in Nigeria only 9.8% of households reported having universal coverage, yet pregnancy was a significant predictor of net use when compared with children ages 5–14, men ages 15–49, and individuals over 49. This demonstrates that pregnant women were prioritized at the net distribution level, the household-allocation level (which also includes prioritization of non-pregnant women of reproductive age), or both. In early 2009, Nigeria embarked on a universal coverage campaign to distribute LLINs and spread messaging about malaria prevention, including in ANC clinics. Such BCC messages promoting ITN use for pregnant women have been part of national communication strategies since 2003, and it appears that households and communities have internalized them.

This study is not the first to note prioritization of ITN use by pregnant women in recent years. Lack of access to bed nets is an important barrier to use of nets by pregnant women.
years. Data from as early as 2004 demonstrate that children and women of reproductive age were more likely to use ITNs, especially in households with more nets per person, in African countries including Tanzania and Zambia. Additionally, these nets were in better condition than those used by older children and adults. In contrast, data from 15 national surveys between 2003–2006 showed that pregnant women had less access to ITNs than other household members and were not prioritized within the household.

The upward trend has led to an overall increase in net use by pregnant women, which can be attributed to increased intra-household net access as well as prioritization of all women of reproductive age by those household members responsible for net use and allocation decisions. In some countries evaluated in this study, net use by pregnant women has exceeded RBM’s 2010 goal of 80% use in households that report universal coverage. However, in households owning less than 1 net per 2 people, no countries met this goal.

Insufficient access to nets for pregnant women can be due to many factors, including local- and national-level stockouts of ITNs at ANC clinics, delays in ANC attendance, and insufficient provider training. These problems call for additional monitoring and evaluation of the supply chain and accountability both nationally and locally as well as improving ANC distribution systems to ensure consistent access to nets by pregnant women.

**Limitations**

One limitation of this study is that in some countries net ownership and use was so high that the difference in net use between pregnant and non-pregnant household members was too small to detect. In Tanzania, over 90% of households reported having at least 1 bed net, and 41% of households had at least 1 net for 2 people (Table 1). However, the difference in net use between pregnant and non-pregnant individuals was only 1%–2%. Although this could reflect lack of prioritization, it is more likely due to a long-standing targeted distribution program through ANC services, a recent universal coverage campaign, high net use, and a small sample size of pregnant women. Another limitation of this study is that net use was not stratified geographically within each country. It is known that net use varies regionally, but there were not enough data in this study to evaluate these differences.

**CONCLUSION**

Lack of access to bed nets appears to be the more important factor for non-use of ITNs by pregnant women in the 10 African countries analyzed in this study, rather than behavioral issues. However, it would be premature to assume that increasing net access alone would solve the problem completely, particularly since shortages and gaps in coverage are inevitable at national and local levels. Strategies such as behavior change communication to promote prioritization of pregnant women at both national program and household levels are necessary to achieve the coverage goals set by RBM for pregnant women.
Such strategies can increase pregnant women’s access to ITNs, further strengthen the culture of net use in countries in general, and continue to encourage net use specifically by pregnant women at all stages of pregnancy.

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Competing Interests: None declared.

REFERENCES


The quality–coverage gap in antenatal care: toward better measurement of effective coverage

Stephen Hodgins, a Alexis D’Agostino b

The proportion of pregnant women receiving 4 or more antenatal care (ANC) visits has no necessary relationship with the actual content of those visits. We propose a simple alternative to measure program performance that aggregates key services that are common across countries and measured in Demographic and Health Surveys, such as blood pressure measurement, tetanus toxoid vaccination, first ANC visit before 4 months gestation, urine testing, counseling about pregnancy danger signs, and iron–folate supplementation.

ABSTRACT

Background: The proportion of pregnant women receiving 4 or more antenatal care visits (ANC 4+) is used prominently as a global benchmark indicator to track maternal health program performance. This has contributed to an inappropriate focus on the number of contacts rather than on the content and process of care. This paper presents analysis of specific elements of care received among women reporting 4 or more ANC visits.

Methods: We conducted secondary analysis using Demographic and Health Survey data from 41 countries to determine coverage for specific elements of antenatal care. The analysis was conducted for: (1) women who delivered during the 2 years preceding the survey and who reported receiving 4 or more ANC visits, and (2) all women who delivered during the preceding 2 years. The specific ANC services that we assessed were: blood pressure measurement, tetanus toxoid vaccination, first ANC visit at less than 4 months gestation, urine testing, counseling about danger signs, HIV counseling and testing, iron–folate supplementation (≥ 90 days), and at least 2 doses of sulfadoxine/pyramethamine for malaria prevention. The difference between expected (100%) and actual coverage (the quality–coverage gap) was calculated for each service across the 41 surveys.

Results: Coverage for specific elements of care among women reporting 4 or more ANC visits was generally low for most of the specific elements assessed. Blood pressure and tetanus toxoid performed best, with median quality–coverage gaps of 5% and 18%, respectively. The greatest gaps were for iron–folate supplementation (72%) and malaria prevention (86%). Coverage for specific interventions was generally much lower among all pregnant women (reflecting population effective coverage) than among only those who had received ANC 4+ visits. Although ANC 4+ and average coverage across the elements of care correlated relatively well (Pearson $r^2 = 0.56$), most countries had lower average coverage for the content of care than for ANC 4+ (among all pregnant women).

Conclusion: We argue for the adoption of a summary indicator that better reflects the content of antenatal care than does the current ANC 4+ indicator. We propose, as an alternative, the simple average of a set of ANC content indicators available through surveys and routine health information systems.

INTRODUCTION

The proportion of pregnant women receiving 4 or more antenatal care visits (ANC 4+) has pride of place as a global benchmark indicator, standing in as a proxy for adequacy of antenatal care (ANC). It has been used as an indicator both for Millennium Development Goal 5 (improve maternal health) and for the United Nations Secretary General’s Commission for Information and Accountability for Women’s and Children’s Health.

In the late 1990s, José Villar led a multicountry study, under the auspices of the World Health Organization (WHO), comparing a more goal-oriented, abbreviated, 4-visit schedule with conventional ANC. Conventional ANC comprised about 12 visits (one visit each month during the first 6 months of pregnancy, once...
every 2–3 weeks for the next 2 months, and once a week thereafter until delivery). On most measures, there were no differences in maternal or perinatal outcomes. These findings have been the basis for adoption of the ANC 4+ indicator as a marker of receipt of adequate antenatal care.

Since that time, along with skilled birth attendance, ANC 4+ has been the most frequently used summary measure of maternal health program performance. This has had the unfortunate consequence of drawing the attention of program managers away from the content and process of care and toward mere contact. But content and process of care matter. As Bhutta and colleagues have documented in their comprehensive review, there is significant scope for improving health outcomes, even with a simple package of antenatal interventions that can be delivered by health auxiliaries consisting of:

- Tetanus toxoid
- Intermittent presumptive/preventive treatment of malaria
- Iron–folate and calcium supplementation
- Deworming
- Detection and treatment of preeclampsia, syphilis, and asymptomatic bacteriuria
- Counseling about essential newborn care practices (immediate and exclusive breastfeeding, clean delivery, and thermal protection) and care-seeking for institutional delivery and danger signs

Clearly, it is not mere contact that results in better outcomes; it is the actual substance of care delivered. Using data from the Demographic and Health Surveys (DHS), this paper explores the extent to which the ANC 4+ indicator tells us anything useful about the substance of care and proposes an alternative indicator to measure program performance.

**METHODS**

Recent DHS data from 41 countries were analyzed, retaining information on pregnancies during the preceding 2 years for which the mother reported receiving 4 or more ANC visits. From these data, we determined the proportion of survey respondents who reported receipt of 8 specific clinical preventive services:

- Blood pressure measurement
- Full protection against tetanus
- First antenatal visit at less than 4 months gestation
- Urine testing
- Counseling about danger signs
- HIV counseling and testing
- Iron–folate supplementation for at least 90 days
- At least 2 doses of sulfadoxine/pyrimethamine (SP) for presumptive/preventive malaria treatment

Surveys retained for this analysis had to have values for at least 5 of these interventions of interest. Among the surveys retained, the main distinction in which data were included was the presence or absence of HIV- and malaria-related indicators. A “quality–coverage gap” was calculated for each of these services—across the 41 surveys—as the difference between expected (100%) and actual coverage.

We also present additional DHS analysis on coverage for this set of services using, as the denominator, all women having a birth in the 2 years preceding the survey (regardless of the number of ANC visits received). For each country survey, a simple mean was calculated across the set of retained antenatal indicators listed above as well as the proportion of women who reported receiving all the interventions.

The country surveys were conducted by MEASURE DHS, a project of the Bureau for Global Health at the U.S. Agency for International Development (USAID). All the datasets are available online at www.dhsprogram.com. Analysis was done using Stata 12.1. In line with DHS practice, women not providing a response or answering “do not know” to questions on services received were retained in the denominators for calculation of the indicators (that is, it was assumed that they did not receive those services).

Results from each country were calculated using the weighting and sampling information and procedures specified in the DHS datasets and documentation.

**RESULTS**

**Quality of Care Among Those Receiving 4+ Visits**

The analysis presented in Table 1 can be considered as characterizing the quality of care received, among women who reported receiving 4 or more ANC visits. Colombia, the Dominican
TABLE 1. Receipt of Specific Services Among Pregnant Women With 4+ ANC Visitsa (%)  

<table>
<thead>
<tr>
<th>Survey</th>
<th>ANC4+</th>
<th>ANC&lt;4mo</th>
<th>IFA90+</th>
<th>TT2+</th>
<th>DSs</th>
<th>BP</th>
<th>Ur</th>
<th>HIV</th>
<th>SP2+</th>
<th>AVG</th>
</tr>
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<tr>
<td>Colombia 2010</td>
<td>87</td>
<td>82</td>
<td>62</td>
<td>83</td>
<td>100</td>
<td>98</td>
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<td>Dominican Rep 2007</td>
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<td>84</td>
<td>66</td>
<td>92</td>
<td>70</td>
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<td>97</td>
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<td>85</td>
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<td>Nepal 2011</td>
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<td>78</td>
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<td>87</td>
<td>94</td>
<td>72</td>
<td></td>
<td></td>
<td>83</td>
</tr>
<tr>
<td>Maldives 2009</td>
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<td>Honduras 2005–06</td>
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<td>75</td>
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<td>97</td>
<td>79</td>
<td>78</td>
<td></td>
<td>78</td>
</tr>
<tr>
<td>Rwanda 2010</td>
<td>36</td>
<td>73</td>
<td></td>
<td>74</td>
<td>88</td>
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<td>89</td>
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<td>Philippines 2008</td>
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Republic, and Nepal performed well; average coverage across the indicators measured in those surveys was 83%–85% (a quality–coverage gap of 15%–17%). Although Nepal performed as well as the other 2 countries with regard to average coverage, a considerably smaller proportion of pregnant women in Nepal reported 4+ visits (53% versus 87% in Colombia and 96% in the Dominican Republic). Timor-Leste, Indonesia, and Lesotho were the median performers across the 41 countries, with average coverage across indicators of 58% (average quality–coverage gap of 42%). The poorest performing countries were the Democratic Republic of Congo and Burundi, with an average coverage across indicators of 32% and 36% (quality–coverage gaps of 68% and 64%, respectively).

As seen in the Figure, with the exception of blood pressure measurement, there were marked quality–coverage gaps for each of these elements of care for most countries, ranging from 18% to 86%. The greatest gap was for 2 commodity-dependent functions—iron–folate supplementation (72%) and presumptive/preventive treatment for malaria with SP (86%). (HIV testing and tetanus toxoid are also commodity-dependent, but supply is commonly managed under separate, vertical systems; iron–folate and SP provision normally does not benefit from such special logistical arrangements.)

**Effective Coverage at Population Level**

Whereas Table 1 presented intervention-specific coverage among those reporting 4 or more ANC visits (that is, those who are supposedly “covered” with respect to ANC services), Table 2 presents data calculated for all women delivering over the previous 2 years as the denominator, reflecting effective coverage at the population level. Specifically, mean coverage across all the antenatal indicators offers an alternative summary measure that could be considered for antenatal program performance.

The tables (Table 1, reflecting ANC quality, and Table 2, reflecting population effective coverage) show somewhat similar rankings. For example, the top 7 performers are the same on these 2 measures. Most countries were
underperformers—in the sense that average population effective coverage for actual content was lower than for ANC 4+. For only 8 of the 41 countries was average coverage higher than the proportion of women reporting 4 or more visits (Table 2). (This is reflected in the generally large quality–coverage gaps for individual interventions.)

Four of the 10 highest-performing countries, with respect to average coverage across the specific elements of care, also had ANC 4+ values greater than 85% (Dominican Republic, Maldives, Colombia, and Peru) (Table 2). On the other hand, 2 of these 10 countries had comparatively low ANC 4+ values: Rwanda (36%) and Nepal (53%). Very low average coverage was generally associated with low ANC 4+. However, there were several cases of relatively low coverage on specific antenatal content in countries with relatively high ANC 4+ (for example, Congo Brazzaville, with average coverage of 38% and ANC 4+ of 72%; Indonesia, with average coverage of 52% and ANC 4+ of 81%; and Namibia, with average coverage of 53% and ANC 4+ of 70%).

Correlation Between Number of Visits and Care Received

Certainly, in general, the more ANC visits one has, the higher the likelihood of receiving specific elements of care. So, not surprisingly, ANC 4+ and mean coverage across the 8 elements of care correlate relatively well (Pearson $r^2=0.56$). In other words, 56% of the variance in mean coverage is accounted for by the value of ANC 4+. The number of visits does matter, in the sense that each visit provides an opportunity for provision of needed care. Fewer visits means fewer opportunities.

Mean number of visits correlates similarly well ($r^2=0.53$), and has the advantage that its use as an indicator would not (inappropriately) signal that any particular number of visits is automatically sufficient. Regardless of degree of association, whether with ANC 4+ or mean number of visits, as is evident in the data presented here, there is no necessary relationship with reliable delivery of the content of care.

Receipt of the Full Set of Interventions

Among all pregnancies during the 2 years preceding the survey, the proportion of women who reported receiving all 8 services (or fewer, if a particular indicator was not included in the survey) was zero in over one-third of the surveys (15 of 41) (Table 2). In only 4 countries was the proportion 20% or higher (Dominican Republic, Maldives, Colombia, and Nepal). In Honduras and the Philippines, the proportion was 10%; in Rwanda and Haiti, 8%; and in Peru, 7%. In none of the other countries was it above 5%.

DISCUSSION

As this analysis demonstrates, there are large quality–coverage gaps for most of the antenatal
### TABLE 2. Receipt of Specific Services Among All Pregnancies (\%)  

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interventions assessed. Such gaps mean ineffective care, and ineffective care means missed opportunities to achieve better outcomes. Focusing on mere contact rather than on the content of care means that we have taken our eye off what really matters.

ANC 1 (any ANC) and ANC visit within the first 4 months of gestation are programmatically useful indicators (although not sufficient, in themselves, as summary measures of program performance); they point to how adequately services are reaching intended beneficiaries. The same cannot be said for ANC 4+. This indicator has been used as an overall proxy for delivery of a package of needed antenatal care. As demonstrated by the analysis here, it serves this role poorly. For most elements of care, there were marked quality–coverage gaps. And high ANC 4+ coverage can be completely compatible with a large quality–coverage gap (for example, see Congo Brazzaville, Indonesia, Namibia, and Swaziland, in Table 1). Furthermore, its widespread use as the single benchmark indicator for antenatal care has the very unwelcome effect of directing the attention of clinicians and program managers toward optimizing the number of antenatal visits rather than ensuring delivery of the important substance of that care. This effect is exacerbated when attendance at 4 ANC visits is incentivized under conditional cash transfer programs, or when it serves as part of the basis for performance-based financing schemes.

Furthermore, continued use of this indicator reinforces the impression that an abbreviated schedule of antenatal visits is adequate. Recent analysis found higher risk of fetal death with the abbreviated ANC schedule of visits.

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<td>31</td>
<td>0</td>
</tr>
<tr>
<td>Burundi 2010</td>
<td>33</td>
<td>19</td>
<td>3</td>
<td>87</td>
<td>35</td>
<td>44</td>
<td>9</td>
<td>40</td>
<td>0</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>Nigeria 2008</td>
<td>44</td>
<td>16</td>
<td>12</td>
<td>48</td>
<td>38</td>
<td>53</td>
<td>46</td>
<td>15</td>
<td>6</td>
<td>29</td>
<td>0</td>
</tr>
<tr>
<td>Mali 2006</td>
<td>36</td>
<td>30</td>
<td>12</td>
<td>57</td>
<td>21</td>
<td>64</td>
<td>31</td>
<td>6</td>
<td>11</td>
<td>29</td>
<td>0</td>
</tr>
<tr>
<td>Dem Rep Congo 2007</td>
<td>47</td>
<td>18</td>
<td>1</td>
<td>37</td>
<td>33</td>
<td>62</td>
<td>42</td>
<td>6</td>
<td>7</td>
<td>26</td>
<td>0</td>
</tr>
<tr>
<td>Pakistan 2006–07</td>
<td>29</td>
<td>31</td>
<td>12</td>
<td>60</td>
<td>17</td>
<td>52</td>
<td>32</td>
<td>0</td>
<td>0</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Ethiopia 2011</td>
<td>17</td>
<td>10</td>
<td>49</td>
<td>9</td>
<td>31</td>
<td>17</td>
<td>16</td>
<td>22</td>
<td>1</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Niger 2006</td>
<td>15</td>
<td>13</td>
<td>7</td>
<td>23</td>
<td>12</td>
<td>41</td>
<td>18</td>
<td>1</td>
<td>0</td>
<td>14</td>
<td>0</td>
</tr>
</tbody>
</table>

Mean: 57 40 21 69 49 78 55 43 20 50

Abbreviations: ANC4+, 4 or more antenatal care visits; ANC<4mo, first antenatal care visit before 4 months gestation; BP, blood pressure; DSs, counseled on pregnancy danger signs; HIV, HIV counseling and testing; IFA, iron–folic acid supplementation for 90+ days; SP2+, at least 2 doses of sulfadoxine/pyramethamine for malaria prevention; TT2+, protected against tetanus; Ur, urine specimen taken.

AVG: Average coverage across the 8 interventions (or fewer, if specific intervention(s) not included in the survey). Country data are presented in order, from highest average coverage to lowest.

Self-reported receipt of services among all women delivering during the 2 years preceding the survey.

Recent analysis found higher risk of fetal death with the abbreviated ANC schedule of visits.
An increased number of routine visits may detect asymptomatic conditions such as preeclampsia, fetal growth restriction or reduced fetal movements earlier, allowing more timely intervention. The importance of the content and quality of routine antenatal care should not be lost to policy makers when decisions about numbers of visits with the available resources are being made.

It is time to drop the use of ANC 4+. It does not reliably tell us how adequate ANC services are, and relying on it encourages program managers and clinicians to focus on mere contact rather than on the content of care. Furthermore, as we have noted, 4 visits are not enough.

**Alternative Indicators to Measure ANC Program Performance**

ANC 4+ has been retained, to date, as the key global benchmark indicator for antenatal care not because there are passionate defenders of its validity but because there is a perception that there is no readily available alternative. But there is.

In principle, an attractive option would be the proportion of women who report receiving the full set of specific elements of care measured. This can be readily determined from survey data. Kyei and colleagues have done such analysis based on data from the 2007 Zambia DHS, using an overlapping, but not identical, set of ANC-related indicators to those used here.* In their study, “good-quality ANC” was defined as attending at least 4 ANC visits with a skilled provider and receiving at least 8 of the 10 antenatal interventions used in their analysis; “moderate-quality ANC” required 4 visits and 5–7 of the 10 antenatal interventions. In this paper, similar analysis found that in about one-third of the surveys (15 of 41), the proportion of women receiving all 8 services (or fewer, if a particular indicator was not included in the survey) was zero. So the utility of this specific measure is constrained by its lack of discriminating power. A further limitation is that, unlike a simple average across indicators—which can be easily calculated from corresponding indicators already tracked by routine health information systems—a measure of receipt of a full set of services at the level of the individual woman could, for the foreseeable future, only be feasible in periodic population surveys and special studies.

So we propose adopting, as a summary measure of antenatal program performance at the population level, the simple average of a set of available indicators for receipt of specific services (such as presented in this paper). For use at the global level, to ensure strict comparability, it may be necessary to restrict this composite indicator to content elements that are common across all countries. This would imply retaining HIV- and malaria-related interventions in the summary measure only for within-country use, in settings where this is warranted by local epidemiology and public health priorities. We propose that the same approach be used for periodic population surveys and for ongoing monitoring using routine health information systems.

Certainly, the specific components of an average measure merit further debate and discussion. There may be other interventions tracked by health management information systems and measured by DHS or other periodic surveys that could be included (for example, those in the analysis done by Kyei and colleagues). Likewise, average total number of ANC visits could be included in the summary average measure.

Such an average coverage measure would reflect much better how well the needs of the population are actually being met, with regard to the substance of antenatal care, than does the ANC 4+ indicator.

This brings us to an important issue of terminology. Shengelia and colleagues have provided a formal description of “effective coverage,” which comprises individual-level need, utilization, and quality. Bryce and colleagues have criticized this concept as unnecessarily complex and not readily measurable.

In the global health sphere, use of the term “coverage” is relatively unproblematic, as it is normally used to refer to delivery of specific technical interventions. However, in global maternal health discourse, “coverage” commonly refers to mere contact (notably ANC 4+ and skilled birth attendance), and these measures are used as proxies for adequate delivery of needed care to a population.

For maternal health, a shift toward use of indicators of overall program performance that take account of the actual substance of care provided is certainly called for. For that purpose,
we would endorse use of indicators that track “effective coverage,” as the term is used by Kyei and colleagues—the proportion of the population who need a service that receive it with sufficient quality [for it] to be effective.” In the case of antenatal care, using a more appropriate summary metric for overall program performance, as proposed here, would help effect a much-needed shift in focus, putting the content back into contact.

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Peer Reviewed

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Preferences for a potential longer-acting injectable contraceptive: perspectives from women, providers, and policy makers in Kenya and Rwanda

Elizabeth E Tolley, Kevin McKenna, Caroline Mackenzie, Fidele Ngabo, Emmanuel Munyambanza, Jennet Arcara, Kate H Rademacher, Anja Lendvay

High effectiveness, predictable return to fertility, and a single, prepackaged, disposable delivery system ranked high. Side effects were generally acceptable to women if they did not last long or disrupt daily activities. Cost was considered important for providers but not so much for most potential users.

ABSTRACT

Background: Between 1995 and 2005, injectable use doubled worldwide. However, discontinuation rates remain high, partly because of side effects but also because of missed appointments for reinjection. A longer-acting injectable (LAI) may improve compliance by reducing the required number of reinjection visits, thereby reducing unintentional discontinuation. This study examined acceptability of LAI characteristics comprising the target product profile (TPP).

Methods: In 2012, we conducted qualitative case studies in Kenya and Rwanda, consisting of 19 focus group discussions (FGDs) with 177 current, previous, or never users of injectables and 46 in-depth interviews (IDIs) with providers, program implementers, and policy makers. FGDs and IDIs assessed current injectable experiences; attitudes toward potential LAI products; and perceptions of TPP attributes, including ranking preferences for the most and least important characteristics. In addition, we obtained completed electronic surveys from 28 international family planning opinion leaders about the perceived need for an LAI, important product characteristics, and challenges to LAI development or introduction.

Results: Many FGD participants and interviewees spontaneously expressed strong interest in an LAI, but there was some variation in TPP preferences. The majority of participants ranked effectiveness as the most important TPP attribute. Providers were generally more concerned about side effects than potential users; some potential users suggested that side effects were related less to the product than to their own body chemistry and that side effects were acceptable as long as they did not last a long time or disrupt daily activities. Women and providers, especially in Kenya, preferred a method with a predictable return to fertility. Some participants associated amenorrhea with delayed or reduced fertility. Most women and providers preferred delivery of the LAI in a single, prepackaged, disposable injection system to facilitate injections by providers and to reduce the risk of pain or discomfort for women. While providers and policy makers ranked cost as one of the most important issues, it was among the least important issues for most potential users. Many Kenyan, but few Rwandan, participants appeared willing to pay for an LAI, with some presuming cost savings from reduced menstruation and fewer clinic visits.

Conclusions: Some TPP preferences for an LAI have implications for product development decisions about formulation, delivery mechanism, or presentation, while others point to the need for tailored communication and counseling approaches to ensure acceptability and adherence within clinical trials and beyond.
product administered through a single intramuscular injection in the upper arm or buttocks that lasts for 3 months. Other injectable contraceptives include 1-month combined hormonal products and a 2-month progesterone product. Additionally, as many as 183 contraceptive users currently rely on injectable contraceptives. Dramatic increases in injectable uptake have occurred in several African countries, including Kenya and Rwanda. However, injectable discontinuation is high, due in part to women experiencing menstrual and weight changes or other side effects. Additionally, as many as 40% of injectable users unintentionally discontinue due to missed appointments for reinjection. Injectable users who are late for a reinjection are often asked to return to the clinic during their next menses, increasing the likelihood of pregnancy before the next injection.

A longer-acting injectable (LAI) lasting for at least 6 months could prove to be a valuable addition to the method mix by decreasing the number of visits required of clients per year, thereby improving compliance and increasing effectiveness during typical use of the method. With funding from the Bill & Melinda Gates Foundation, FHI 360 is spearheading efforts to develop an LAI that would provide protection for a minimum of 6 months. Approaches under consideration include: (a) increasing the dosage of an existing injectable formulation, (b) altering the administration or injection site, or (c) identifying drug delivery systems that could prolong the release of the drug.

This research aimed to inform the development process of an LAI by providing a more in-depth understanding of the perspectives of potential users, providers, and opinion leaders on the target product profile (TPP), which identifies desired and minimally acceptable product characteristics related to such aspects as effectiveness and side effect profile. The results are intended to help inform the selection of potential product formulations for early proof-of-concept testing as well as for later product development efforts. Another paper is planned to present and discuss how TPP characteristics may affect health systems and introduction decisions more broadly. Such decisions will influence women’s access to an LAI by affecting the method’s affordability, availability, and ease of adoption; further affecting how well potential users can adhere to and sustain use of the new method.

**METHODS**

Between June and September 2012, we conducted qualitative case studies in Kenya and Rwanda, 2 countries with high levels of injectable contraceptive use but different service delivery environments. In each country, we recruited providers, including nurses, counselors, and community health workers (CHWs) as well as potential users from private- and public-sector clinics in the capital city and several peri-urban or rural areas.

Research assistants approached women in clinic waiting rooms to inform them about the study. The research assistants screened interested women to ensure they were 18–50 years old, and they provided women with an informational voucher to attend a focus group discussion (FGD) with current and previous injectable users or with women who had never used injectables.

Policy makers represented the Ministry of Health, public sector, and private sector/nongovernmental organizations (NGOs).

In total, we conducted 19 FGDS with 177 women (Table 1) as well as in-depth interviews (IDIs) with 27 service providers (15 in Kenya and 12 in Rwanda) and 19 policy makers and program implementers (12 in Kenya and 7 in Rwanda). FGDS were conducted in the local language by trained female interviewers following a topic guide to explore potential users’ DMPA-related knowledge and experiences; to discuss new LAI approaches; and to explore LAI characteristics identified in the TPP. IDIs were conducted by male or female interviewers in English, French, or the local language, following a similar guide.

During the FGDS and IDIs, interviewers used illustrations depicting each TPP characteristic to facilitate discussion. At the end of each FGD or IDI, the interviewers presented the illustrations to the participants again and asked them to prioritize the 3 most important and 3 least important product characteristics in the development of a new LAI. FGD participants had to reach consensus. (In 2 FGDS, participants split into 2 groups and provided 2 separate rankings.)

FGDS and IDIs were audio-recorded, translated into French or English, and transcribed. The documents were then uploaded into NVivo 9, and the information was coded and analyzed thematically. We wrote detailed memos describing subthemes related to each main code, including each of the TPP characteristics. We
also created Excel matrices to examine variations in subthemes by country and participant type.

In addition to the IDIs and FGDs, we distributed an electronic survey to 95 individuals from international funding agencies, foundations, NGOs, and universities who were identified as international family planning opinion leaders by peers. Organizations included the International Planned Parenthood Federation, the United Nations Population Fund, the World Health Organization, the U.S. Agency for International Development, Abt Associates, the Population Council, Management Sciences for Health, Marie Stopes International, and others. We received 28 responses. The opinion leaders were asked open-ended questions about whether they perceived a need for an LAI; what characteristics would be important; and what challenges might exist related to LAI development and introduction. Responses were organized into a matrix by topic.

The study was approved by FHI 360’s Protection of Human Subjects Committee and

### TABLE 1. Composition of Focus Group Discussions Among Potential Users of a Longer-Acting Injectable, by Country

<table>
<thead>
<tr>
<th>FGD Number</th>
<th>Location</th>
<th>Facility Type</th>
<th>Experience With Injectable Use</th>
<th>No. of Participants</th>
<th>Mean Age (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kenya</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Urban</td>
<td>Public health center</td>
<td>Current and past users</td>
<td>10</td>
<td>28.1 (21–38)</td>
</tr>
<tr>
<td>2</td>
<td>Urban</td>
<td>Public health center</td>
<td>Never users</td>
<td>8</td>
<td>36.7 (18–45)</td>
</tr>
<tr>
<td>3</td>
<td>Peri-urban</td>
<td>Public hospital</td>
<td>Current and past users</td>
<td>11</td>
<td>27.7 (21–37)</td>
</tr>
<tr>
<td>4</td>
<td>Peri-urban</td>
<td>Public health center</td>
<td>Current and past users</td>
<td>8</td>
<td>25.2 (20–32)</td>
</tr>
<tr>
<td>5</td>
<td>Urban</td>
<td>NGO health center</td>
<td>Current and past users</td>
<td>10</td>
<td>31.0 (23–40)</td>
</tr>
<tr>
<td>6</td>
<td>Urban</td>
<td>NGO health center</td>
<td>Current and past users</td>
<td>8</td>
<td>29.4 (25–37)</td>
</tr>
<tr>
<td>7</td>
<td>Urban</td>
<td>NGO health center</td>
<td>Never users</td>
<td>9</td>
<td>30.3 (23–36)</td>
</tr>
<tr>
<td>8</td>
<td>Peri-urban</td>
<td>Public health center</td>
<td>Current and past users</td>
<td>10</td>
<td>29.9 (22–40)</td>
</tr>
<tr>
<td>9</td>
<td>Peri-urban</td>
<td>Public health center</td>
<td>Current and past users</td>
<td>11</td>
<td>29.4 (25–38)</td>
</tr>
<tr>
<td>10</td>
<td>Peri-urban</td>
<td>Public hospital</td>
<td>Never users</td>
<td>8</td>
<td>31.6 (20–42)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td>93</td>
<td></td>
</tr>
</tbody>
</table>

| **Rwanda** |          |               |                               |                     |                  |
| 1          | Rural    | Public CBD     | Current, past, and never users | 10                  | 32.4 (24–50)    |
| 2          | Rural    | Public health center | Current and past users | 7                   | 30.7 (26–39)    |
| 3          | Peri-urban | Public health center          | Never users | 13                  | 28.0 (20–39)    |
| 4          | Urban    | Public hospital          | Never and past users | 11                  | 28.4 (21–37)    |
| 5          | Rural    | Public CBD     | Current users                 | 8                   | 37.7 (28–44)    |
| 6          | Rural    | Public health center | Current and past users | 9                   | 31.3 (21–40)    |
| 7          | Rural    | Public CBD | Current and past users          | 9                   | 34.8 (21–44)    |
| 8          | Urban    | Public hospital | Current users              | 7                   | 28.6 (22–35)    |
| 9          | Urban    | NGO health center | Current, past, and never users | 10                  | 31.9 (25–44)    |
| **Total**  |          |               |                               | 84                  |                  |

Abbreviation: CBD, community-based distribution.
by the Institutional Review Boards in Kenya and Rwanda.

RESULTS

The conceptual framework in Figure 1 provides an overview of the themes we analyzed and their relationship to LAI acceptability. Many women and providers/policy makers spontaneously expressed strong interest in an LAI. In general, we found that women’s interest in an LAI was informed by specific TPP product characteristics that influenced how well the product fit their fertility desires. However, for providers, policy makers, and international opinion leaders, interest in an LAI was informed by its contribution, relative to other temporary or long-acting contraceptive methods, to a country’s method mix.

In addition, participants’ attitudes toward specific product attributes were often framed in terms of their experiences with using or providing other available contraceptive options. These experiences were influenced by individual, sociocultural, and health systems contexts that led to some interesting variations in attitudes and preferences by participant type (providers versus potential users) and by country.

Figure 2 presents the most and least important product attributes of a new LAI ranked by the participants, while Table 2 shows the 3 most and 3 least endorsed attributes by country and participant type. (Rankings of providers and policy makers were counted individually while rankings of women were counted per focus group.) The majority of participants ranked effectiveness as one of the most important

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**FIGURE 1.** Conceptual Framework: Factors Influencing Acceptability of, Access to, and Use of a Potential Longer-Acting Injectable

Abbreviations: BF, breastfeeding; CBD, community-based distribution; LAI, longer-acting injectable; TPP, target product profile.
characteristics of a new injectable. However, there was less agreement on many other characteristics. In this paper, we describe in detail participants’ perspectives on several TPP characteristics with high, low, or variable consensus across participant groups. For each selected characteristic and TPP description, we first describe how past contraceptive experiences shape participants’ assessment of its importance and then transition to how the characteristic affects hypothetical LAI acceptability. We also indicate when such perspectives diverge between potential users and providers or by country, and how they compare to responses from the international opinion leaders.

**Effectiveness:** 99% Effective in Preventing Pregnancy When Used Correctly

Being at least 99% effective was ranked as the most important LAI characteristic by most participant groups from the 2 country case studies, but mentioned by only 7 of 28 international opinion leaders as a critical characteristic, probably because they assumed high effectiveness was a given. As one opinion leader noted, “Safety and efficacy are of course a no-brainer.”

Despite strong endorsement from Kenyan and Rwandan participants, their understanding of “effectiveness” was often based less on a quantitative understanding of rate and more on subjective experiences with other contraceptive methods. About a dozen potential users and providers incorrectly suggested that “all other contraceptive methods are 100% effective,” so an LAI should also be 100% effective. Similarly, a Kenyan provider said:

> I have never heard [of] any person who has ever used Depo and still conceived when the method was used correctly.

In contrast, twice as many women believed that no method was completely effective. A
<table>
<thead>
<tr>
<th>Attributes</th>
<th>Most Important</th>
<th></th>
<th>Most Important</th>
<th></th>
<th>Least Important</th>
<th></th>
<th>Least Important</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Potential Users</td>
<td>Providers</td>
<td>Policy Makers</td>
<td>Potential Users</td>
<td>Providers</td>
<td>Policy Makers</td>
<td>Potential Users</td>
<td>Providers</td>
</tr>
<tr>
<td>99% effective</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Safe for BF and new mothers</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Immediate return to fertility</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage without refrigeration</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepackaged, single dose, disposable</td>
<td>3</td>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost around US$4/year</td>
<td></td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Side effects no worse than current methods</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suitable for all women</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-month duration with 1-month window</td>
<td></td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can be administered in arm</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can be provided by CBD</td>
<td></td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: BF, breastfeeding; CBD, community-based distribution.

a In Kenya, rankings are among 10 groups of potential users, 15 providers, and 12 policy makers. In Rwanda, rankings are among 9 groups of potential users, 12 providers, and 7 policy makers.
Kenyan woman who had never used injectables acknowledged:

It’s okay [if the method is 98% or 99% effective] because there are no methods that are 100% [effective].

A handful of past and never users set minimum effectiveness as low as 45%–50%, before other FGD participants clarified the meaning of effectiveness rates.

**DMPA and Other Contraceptive Experiences:** More generally, women and providers thought of an LAI as extending the period of protection of the existing DMPA injectable, making it even easier and more convenient to use. In both countries, potential users and providers frequently contrasted the reliability of the 3-month injectable to women’s experiences using oral contraceptive pills. For example, a young Rwandan injectable user explained:

Usually, what’s good about the 3-month injectable is that you are at ease for 3 months. It’s only important not to forget the date to go back [to the clinic]. It’s not like with pills that you can forget to take.

Despite a widespread perception that current injectable contraception was highly effective, some women in almost all Kenyan FGDs and half of Rwandan FGDs also described instances of their own or another’s unplanned pregnancy while using injectables. Such instances were usually attributed to returning late for a re-injection. However, in 7 FGDs in Kenya, participants attributed contraceptive failure to the possibility of being administered a “fake” or an expired drug. This concern led one Kenyan contraceptive user to choose pills:

… because I’m assured of not getting pregnant when I’m on the pills, unlike the injection where some people are injected with water instead of the drug.

**Effectiveness and LAI Approaches:** Potential users and providers had little problem imagining how to achieve a highly effective LAI based on increasing the dose of an existing hormone. However, some participants wondered how other approaches to achieving an LAI might work. For example, a subcutaneous injection was viewed by some as likely to be less effective. One Kenyan woman from a non-injectable user group wondered:

How is the drug going to move? … Because when you are injected, they usually target a vein that is going to transport the medicine all over. So if it is under the skin, where are they aiming it? [I would prefer it to be injected] deep in the muscles, so I am sure it is going to reach the veins and the medicine will be transported all over.

Such views emerged strongly in 2 Kenyan FGDs of non-users as well as in 1 FGD of current or past injectable users. Another Kenyan woman indicated:

Okay for less pain, I would prefer under the skin, but to be sure it will work, I would go for the deeper one.

In Rwanda, at least a few participants in FGDs of current, past, or never users also suggested that an intramuscular injection might be more effective than a subcutaneous one. However, slightly more Rwandan potential users had a clear preference for subcutaneous injections, which they believed would be less painful.

**Side Effects: No Worse Than Currently Available Hormonal Methods/Injectables**

Providers, potential users, and opinion leaders had different perspectives on the relative importance for a new LAI to minimize side effects. Among all Kenyan focus groups as well as among providers in both countries, ensuring that LAI side effects are no worse than currently available methods was among the 3 most endorsed characteristics. In contrast, it was ranked as a least important characteristic among potential users in Rwanda.

When opinion leaders were asked about important considerations for an LAI, the most frequent response, reported by 21 of 27 opinion leaders, was side effects. Some opinion leaders stated that the side effects associated with an LAI should be no worse than those associated with DMPA, while others expressed the hope that an LAI would have a better side effect profile than currently available injectables.

**DMPA Experiences:** Providers and potential user groups associated a number of side effects with current injectable use, including increased menstrual bleeding and amenorrhea, decreased libido, weight changes, headaches, and dizziness. Certain side effects—especially heavier or prolonged bleeding and decreased libido—could disrupt marital relations and/or work patterns, making them less tolerated than other side effects. The possibility of discreet contraceptive

Minimizing side effects was more important for potential users in Kenya than in Rwanda.
use was cited by several Kenyan policy makers and at least a dozen women in each country as an important reason to use the injectable.

In Rwanda, a 38-year-old injectable user with 4 children described her symptoms:

_I am using the 3-month injectable but I bleed and don’t dry out. Currently, I have some serious problems with my husband because I am turning him away; we’re not really on good terms. Sometimes he asks me to stop; he also asks me why I am using it._

A community health worker in Rwanda suggested:

_Prolonged or heavy bleeding and also decreased sexual desire [weigh most on clients]. What is not very worrisome [for women] is amenorrhea. But weight gain is also a problem for women because the way they change shape is really noticeable and rapid. And then having no desire for your husband even though he is the one who brought you from your parents’ home is also a problem. And this bleeding that happens unexpectedly and lasts for weeks also becomes bothersome._

Women in both countries believed that certain side effects were interconnected. For example, in 3 of 9 Rwandan FGDs and 7 of 10 Kenyan FGDs, some women associated amenorrhea with the possibility of swelling, weight gain, abscesses, infertility, or cancer. A Kenyan injectable user said:

_When in my second year of using the injection, I completely stopped getting my periods. My stomach started to swell, and it reached a time instead of the period, I was very wet in my vagina and my sexual desire diminished._

On the other hand, not all side effects were viewed negatively. Several women in Rwanda and one in Kenya appreciated weight gain due to injectable use. Several dozen participants, including 6 Kenyan providers/program managers and potential users from both countries, associated amenorrhea with time and cost savings. One rural injectable user in Rwanda explained:

_The first advantage [of the injectable] is that you don’t see your period and so you don’t spend money buying Kotex or soap to wash your sanitary napkins. You have that money for other things._

Women indicated that most contraceptive methods had side effects. Indeed, women’s descriptions of side effects related to pills, injectables, and implants—and sometimes even intrauterine devices (IUDs)—were similar. They also indicated that side effects were frequently transitory. For many women, side effects were problematic only if they lasted a long time or were so severe that they disrupted women’s normal routines. In such cases, they might assume that the contraceptive method being used did not suit their bodies, leading them to discontinue or switch methods.

**Side Effects and LAI Approaches:** A common concern about a potential LAI, particularly among women who had already experienced side effects with DMPA, was that it might double the intensity of side effects. In several FGDs and IDIs, participants suggested that developing a nonhormonal LAI would be preferable, although some equated such nonhormonal approaches to the IUD, which was also considered to cause side effects for many women. A current implant user from Rwanda reported:

_Even the 3-month one [injectable] caused me serious bleeding and an excess of hormones above those already in my body. In my opinion, they should try to lower the quantity of hormones or just simply [make] a product without any hormones—and many would choose this method. Because when others see the effect that [the 3-month injectable] had on me, or on someone else who had the same problems I did, they are afraid to run the same risk._

Others believed that women’s experiences with injectable contraception were variable and related to their body’s own chemistry. Consequently, if a woman did not experience side effects from a current hormonal method, she would be unlikely to experience them with a longer-acting one, as expressed by one Rwandan injectable user:

_You see, if the injectable was given every 6 months instead of every 3 … that would be very good for me. I also think there wouldn’t be any side effects, because we don’t have any with the 3-month injectable we are using._

**Return to Fertility: Similar to Women Who Have Stopped Using Nonhormonal Methods**

In general, potential users were more concerned than providers about return to fertility, and this characteristic was of more concern in Kenya than in Rwanda. In considering an LAI, women preferred an immediate return to fertility, but a longer time frame could be acceptable if it were predictable.
preferred a product that provided an immediate return to fertility; however, a longer period of time—even as long as 18 months—could be acceptable, particularly if the time period were predictable. International opinion leaders generally agreed that return to fertility within a reasonable and predictable time frame was an important priority. One respondent stated:

*Return to fertility could be problematic if it extended far beyond what we already have with the 3-month injection.*

Another respondent noted that if an LAI were associated with a substantially longer return to fertility than DMPA, it “would be a major issue for women.” (Women who stop using DMPA become pregnant, on average, 10 months after their last DMPA injection.16)

**DMPA Experiences:** Many potential users and providers in both countries recounted stories about long delays in the return to fertility after injectable discontinuation. And, in more than half of Kenyan FGDs and one-third of Rwandan FGDs, some women believed that injectable contraception could lead to infertility. Delays were most commonly attributed to injectable-induced changes in menstruation—either heavy bleeding or amenorrhea—and frequently reflected fundamental misunderstandings about human anatomy and contraception. For example, a Rwandan woman associated heavy bleeding with fertility delays:

*I know about a woman who was using the 3-month injectable and she was bleeding a lot, but later, when she wanted to have another baby and stopped using it, she waited a long time without getting pregnant—for at least 5 years. When she went to the doctor, she was told she would no longer be able to have children because the bleeding carried away her eggs—that little remained for her to conceive.*

A Rwandan provider suggested that long periods of amenorrhea could lead to delays:

*We can’t say this to our clients, but our doctor here always tells us to counsel women to do a sonogram at least once a year, because they continue to use the 3-month injectable for a long time without knowing if the uterus has atrophied. And when the time comes to want to get pregnant, she doesn’t conceive because the uterus has atrophied ... she begins to worry.*

Most Kenyan providers agreed that delays in the return to fertility were a concern for women, but even more so for partners. And while few providers suggested that there might be a connection between injectable use and infertility, delays in the return to fertility made some reluctant to counsel nulliparous women about injectable use. As one Kenyan provider reported:

*The injectable cannot make one sterile—not unless you had [just] one good ovum ... we tell them not to start using family planning when one has not given birth, because a woman can start using family planning and they don’t have ova to conceive. You know, she will blame family planning and yet she is the one with the problem, or maybe that is the way she has been created. So, it is good to start using family planning when one has a child ... That is why it is referred to as family planning.*

Nevertheless, some women—and even some providers and policy makers—believed that other contraceptive methods were likely to induce even longer delays in the return to fertility, suggesting that return to fertility was somehow directly related to a method’s duration of protection. In Kenya, a policy maker reflected:

*Mmm ... I guess probably it’s sometimes explained [from the perspective of] a provider in terms of a continuum ... With the oral contraceptive pill it’s immediate; with the injectable it’ll take a period from you know, 1–3 months, or even up to 6 months with the implant ... and so, I think that depending on how it is explained to the client, [it] may be a cause of anxiety.*

**Return to Fertility and LAI Approaches:** Acceptability of a longer return to fertility for an LAI seemed to depend on women’s—and men’s—fertility desires. If couples were looking for longer protection, they would not care about the long return to fertility. Furthermore, if the delay in return to fertility were predictable, many suggested that a longer return to fertility might be perceived as a benefit. A Rwandan provider said:

*If this method had a return to fertility after 18 months for everyone, all women would use it because [if she wants to get pregnant in 4 years] ... she’ll use the method for 1½ years and she’ll wait another 1½ years even though she’s [already] stopped the method. I assure you it’s like this. Even those who use implants or the IUD will remove them to use this injectable. Even me, my wife doesn’t use the injectable but if it’s like this, I will be interested in this long-acting injectable.*
Some, but not all, participants conflated the long contraceptive “tail” (the period in which the drug stops having an acceptable level of effectiveness but has not been fully eliminated from the body) with an extended period of effectiveness. Thus, some providers in both Kenya and Rwanda reasoned that:

Alternatively, you can calculate the time that you want to get pregnant and stop like a year before the time you wish to get pregnant. If you wanted to get pregnant after 3 years, you could use the new method for 2 years and stop, then you will get pregnant after 1 year, which will add up to 3 years.

Reacting to a similar argument in her discussion group, one Rwandan woman exclaimed:

I was thinking about what my colleague just said. When she just said that she’d stop the injectable when her child is 4 years old, is she sure that this injectable will be 100% [effective], so that when she stops, she’ll spend 18 months without getting pregnant? Why do you put it in that kind of logic? With the injectable we normally use, you can stop and fall pregnant right away. Why don’t you think it could be the same thing, remembering that it [fertility] also depends on each one’s body?

Finally, several providers suggested that it would be very useful to identify a way to reverse the effect of the drug, so that women whose fertility intentions changed would be able to get pregnant more quickly. In Kenya, a provider proposed:

If there could be a way one would get an injection or drug to reverse back the medication any time they want a baby, instead of waiting for the whole period the drug would last, then that would be fine, like for instance the way one gets rid of pills and conceives almost immediately, or getting rid of [an] IUD.

A handful of potential users from different Kenyan FGDs also raised the possibility of manufacturing an antidote. As described by one non-injectable user:

So they have to go and look for this miti ni dawa [herbal treatment] so that they can go and wash their stomach … That is a traditional drink … herbs … that you take so that it can go and wash … those chemicals which is there.

### Delivery System: Single-Dose, Prepackaged, Disposable Injection System

Potential LAI approaches under consideration could result in changes to product presentation. For example, while the TPP aims for a single injection, increasing the dose of an existing formulation might require co-administration of 2 doses, whereas changes in the drug delivery system could require a 2-vial system.

For women in about one-third of the FGDs—mostly in Rwanda—characteristics of product presentation were important to consider for a new LAI. Providers were more divided on whether such characteristics were important. A few women in FGDs from more rural community-based distribution (CBD) programs felt 2 injections were not problematic, but most women and providers strongly preferred an LAI to be in a single, prepackaged injection. Kenyan providers worried about client acceptability, especially with regard to pain or discomfort. In both countries, a few women and providers added that providers were not always well-trained, so 2 injections could lead to even more swelling and pain. For example, a Kenyan provider commented:

Considering that human beings fear pain, it [2 shots] would minimize the number of clients and so you can be sure that most women would lose interest in the injectable.

Similarly, a Rwandan injectable client from a private NGO clinic said:

It’s best to have 1 injection instead of 2 because some people swell at the site of injection. For example, me, after an injection I have pain for about a week. So, it would be preferable to swell at 1 site rather than 2 sites.

For some Rwandan women, receiving 2 shots instead of 1 also increased the perception that one was receiving a very high dose of hormones. A woman from a public hospital setting in Kigali spoke for her fellow participants when she said:

Why have we all said, “No?” It’s because we are worrying about the consequences. I told you that I had an injection and I bled from the 1st to the 30th. And I imagine that the hormones will be double the quantity; I won’t be able to continue [like that] for 6 months. In that case, if you were using sanitary napkins, you would have to look for Pampers. … Instead of giving you 2 injections at
the same time, I wish that they could mix the 2 medicines and give them in a single injection.

Providers and potential users in both countries were also concerned about the idea of having to mix medicines before giving an injection. Concerns related to improper mixing, and consequently a reduction in safety or effectiveness. Participants raised the same kinds of concerns if multiple injections were given from a single vial. For example, one injectable user in Rwanda worried that the medicines from the 2 different injections might not “meet” (within her body) causing her some concern about the effectiveness of the LAI. Others described having more confidence in a product that was already premixed and packaged; it would be possible to check the expiry date as well. A potential user from Rwanda explained:

I think it would be a good thing if the longer-acting injectable is put in a single dose, because it would prevent people from having to first mix it before giving it, or from not drawing out all of the medicine from the vial. The provider will spend less time with the client, because he is not going to have to prepare. It will also prevent him from giving an incomplete dose to the clients.

Finally, current or past injectable users in 2 of the Rwandan FGDs, as well as a dozen providers from Kenya and Rwanda, preferred that a new LAI be delivered through disposable needles to “protect users from infections.”

Cost: US$4 or Less Per Year in a Public-Sector Program

Cost was one of the most important considerations for international opinion leaders, policy makers, and providers, but one of the least important considerations for most potential users. For the opinion leaders, affordability was the second most common response (14 of 28) to an open-ended question about which characteristics would be most important for a new LAI. One opinion leader stated:

Cost of the final product may be a challenge. It should be less than the cost of 2 DMPA 3-month injections we currently use.

Another respondent said that a key issue is:

Price … [An LAI] needs to compete. I’d say a unit price at less than [US]$4 per year.

The reasons for women’s low concern about cost were varied. Women in some Kenyan FGDs were already paying for contraception and consequently appeared willing to pay US$4, or approximately 350 shillings, per year for an LAI. For example, women already paid 20–100 shillings (US$0.24–$1.18) per cycle of pills, and some IUD or implant users reported paying 1,500–3,500 shillings. And, although injectables were free through the public sector, Kenyan women who obtained their method through a private-sector clinic or were compelled to buy their injectable at a chemist or drug shop because of stockouts, reported paying 150–300 shillings per injection. Clinics catering to higher-income segments might charge even more, according to several Kenyan policy makers and program implementers.

In Rwanda, a few women who received their injectable at a private or NGO facility reported paying 700–1,000 francs (US$1.16–$1.66) for a 3-month injectable, and several women suggested that the 2-month injectable cost 1,500 francs per dose, or 9,000 francs per year. Nevertheless, most women reported that they would not pay US$4 (approximately 2,400 francs) for an LAI, given that all other methods could be obtained for free. Women in the more rural FGDs were especially clear about the difficulty of paying. For example, one woman said:

It will be used by women with money. I’m not saying it is not going to be used, but we have a lot of poor people. There are some who may not even have 100 Rwandan francs a month. Others might have that, but they have a family. You know, child care may cost 5,000 or 6,000 francs a month.

On the other hand, women in several FGDs per country suggested that injectables can lead to cost savings, especially due to reduced bleeding and therefore less need to purchase hygiene products. Several also suggested that fewer trips to the clinic for an LAI would save money. Policy makers and providers also added that there could be systems savings due to lower client load.

DISCUSSION

This research identified strong support for the development of a longer-acting injectable contraceptive method for multiple reasons. An LAI would build on the existing popularity and high use of injectables; reduce the travel time and number of clinic visits needed for users; and increase convenience.
Some of the findings about desired attributes have immediate implications for LAI development activities. For example, there was little disagreement that a new LAI should be **highly effective**. The actual level of effectiveness needed to generate demand may vary somewhat, but potential users and providers thought the LAI would be acceptable as long as the method is perceived to be as effective as current injectable formulations. Additionally, potential users and providers expressed strong preferences for a product that was delivered in a **single injection** rather than 2 injections, was **prepackaged**, and could be **disposed** after one use. A prepackaged, single use, disposable LAI was associated with less pain for injectable users, higher levels of product safety and efficacy, and greater efficiency for providers.

Other TPP-related information indicates the need for more tailored communication and counseling approaches to ensure acceptability and adherence within clinical trials and beyond. For example, while almost all participants agreed that an LAI with **few or no side effects** and a **rapid return to fertility** was desirable, they were also quick to recognize that most contraceptive methods had side effects. Some side effects—especially heavier bleeding or loss of libido—were viewed as less acceptable than others. If LAI use were associated with lengthy periods of such side effects, it would offset one of the important perceived benefits of injectable use—that of discretion or privacy—by drawing attention to contraceptive use and potential disapproval from non-supported partners. Other side effects, such as amenorrhea, appeared tolerable or even appreciated, as long as users and their providers had correct information about them. Similarly, although different lengths of return to fertility might affect the types of women most likely to use an LAI, many participants anticipated that an 18-month return to fertility could be acceptable, if women were properly counseled about it.

The study did identify widespread misunderstanding about contraception, in general, and injectables specifically, among both providers and users. In particular, misperceptions about the effect of menstrual side effects on fertility, as well as variation in and reasons for injectable-related return to fertility should be addressed for existing injectables and new LAI methods.

Finally, this assessment of TPP characteristics revealed some interesting country-level differences, serving as a reminder that product demand is likely to depend on the specific context. In Rwanda, the potential for an LAI to last 6 months was a welcome alternative to shorter-acting methods such as condoms, pills, and 3-month injectables, particularly in more rural areas where contraceptive resupply could be difficult. In Kenya, where women appeared to access a wide variety of contraceptive options at a range of costs through a more diverse set of public, private, and/or NGO clinics, cost and the potential for service provision through community-based workers were less important, while concerns about ensuring the quality and control of LAI delivery were greater.

**Limitations**

The study has several limitations. We tried to reduce selection bias by approaching potential participants directly, rather than having clinic staff identify and recruit them. Nevertheless, because participants were drawn from health facilities, our findings may not represent the opinions of women who do not access family planning services through clinics or who do not use contraception at all. The study’s qualitative design and small sample size prevent us from making recommendations about the composition of specific characteristics that would optimize demand. However, the in-depth discussions about TPP characteristics from a range of stakeholders including policy makers, program managers, providers, and potential LAI users offer evidence of widespread support for the introduction of an LAI, as well as guidance about product characteristics that may be most or least important to target. Further quantitative research would be needed to determine the extent to which themes identified in this study can be generalized.

**CONCLUSION**

This study provides evidence of strong acceptability for an LAI. Furthermore, it provides some guidance related to product characteristics that should be prioritized in the development process, while also serving as a reminder that eventual demand will be influenced by policy and service delivery decisions that affect potential users’ knowledge about, access to, and correct use of the method.

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Rising cesarean deliveries among apparently low-risk mothers at university teaching hospitals in Jordan: analysis of population survey data, 2002–2012

Rami Al Rifai

ABSTRACT

Background: Cesarean delivery conducted without medical indication places mothers and infants at risk for adverse outcomes. This study assessed changes in trends of, and factors associated with, cesarean deliveries in Jordan, from 2002 to 2012.

Methods: Data for ever-married women ages 15–49 years from the 2002, 2007, and 2012 Jordan Population and Family Health Surveys were used. Analyses were restricted to mothers who responded to a question regarding the hospital-based mode of delivery for their last birth occurring within the 5 years preceding each survey (2002, N=3,450; 2007, N=6,307; 2012, N=6,365). Normal birth weight infants and singleton births were used as markers for births that were potentially low risk for cesarean delivery, because low/high birth weight and multiple births are among the main obstetric variables that have been documented to increase risk of cesareans. Weighted descriptive and multivariate analyses were conducted using 4 logistic regression models: (1) among all mothers; and among mothers stratified (2) by place of delivery; (3) by birth weight of infants; and (4) by singleton vs. multiple births.

Results: The cesarean delivery rate increased significantly over time, from 18.2% in 2002, to 20.1% in 2007, to 30.3% in 2012. Place of delivery, birth weight, and birth multiplicity were significantly associated with cesarean delivery after adjusting for confounding factors. Between 2002 and 2012, the rate increased by 99% in public hospitals vs. 70% in private hospitals; by 93% among normal birth weight infants vs. 73% among low/high birth weight infants; and by 92% among singleton births vs. 29% among multiple births. The changes were significant across all categories except among multiple births. Further stratification revealed that the cesarean delivery rate was 2.29 times higher in university teaching hospitals (UTHs) than in private hospitals (P<.001), and 2.31 times higher than in government hospitals (P<.001). Moreover, in UTHs, the rate was higher among normal birth weight infants (adjusted OR=2.15) and singleton births (adjusted OR=2.39).

Conclusion: The rising cesarean delivery rate among births that may have been at low risk for cesarean delivery, particularly in UTHs, indicates that many cesarean deliveries may increasingly be performed without any medical indication. More vigilant monitoring of data from routine health information systems is needed to reduce unnecessary cesarean deliveries in apparently low-risk groups.

INTRODUCTION

Worldwide, cesarean delivery is one of the most common surgeries performed in modern obstetrics. The surgery is intended to save the lives of mothers and newborns, as in cases of dystocia, breech presentation, multiple births, anticipated low/high birth weight, and fetal distress. But cesarean deliveries conducted without any medical indication place mothers and infants at risk for unfavorable outcomes. For example, compared with vaginal delivery, cesarean delivery is associated with increased risk of blood transfusion, hysterectomy, maternal and child death, uterine rupture, placenta accreta, and placenta previa in a subsequent pregnancy. In addition, cesarean deliveries cost more and require longer hospitalization than vaginal deliveries.
The World Health Organization (WHO) considers a population-based rate of cesarean deliveries over 15% unreasonable.10 A recent study found that half of 137 countries have exceeded this recommended threshold.11 A global survey conducted by WHO in 24 countries over 25 years showed that about 26% of all health facility-based deliveries were cesarean, and in 23 countries, rates of cesarean delivery without medical indication ranged between 0.01% and 2%.5 In Jordan, the last study examining trends in cesarean delivery rates using population-based data revealed a consistent increase in the rate.12

Jordan has one of the most modern health care infrastructures in the Middle East. The health system consists of 3 major sectors—public, private, and donors—that cover primary, secondary, and tertiary health care services. The public sector consists of health facilities governed by the Ministry of Health (MOH), Royal Medical Services (RMS), and University Teaching Hospitals (UTHs).13 Only tertiary health care facilities (hospitals) have the capacity to perform major surgical procedures such as cesarean deliveries.

According to the Jordan Population and Family Health Survey (JPFHS), almost all women (99%) in the country receive antenatal care (ANC) from a skilled provider, most commonly from a doctor (96%). Nearly all women (91%) have an ANC visit before their fourth month of pregnancy, and 78% of women make 7 or more ANC visits throughout their pregnancy.14 Virtually all births (99%) occur in a health facility; 3 births of every 4 are delivered by a doctor, and 1 birth of every 4, by a nurse or midwife.14 The maternal mortality ratio increased from 53 maternal deaths per 100,000 live births in 2008 to 63/100,000 in 2010, while the neonatal mortality rate persisted at rate of 12 deaths/1,000 live births between 2009 and 2013.15,16

The objectives of this study were to examine trends in, and factors associated with, cesarean deliveries in Jordan, from 2002 to 2012, using data from nationally representative surveys of ever-married women ages 15–49 years.

METHODS

Data Source and Sampling

This study used nationally representative data from the 2002, 2007, and 2012 JPFHS, which is part of the worldwide Demographic and Health Surveys (DHS) program.14

In total, 28,234 ever-married women ages 15–49 years participated in the 3 JPFHS survey rounds (Figure). Women who did not report giving birth over the prior 5 years or who reported that they delivered their last birth at home or abroad were excluded, resulting in a final sample of 16,774 women, or a weighted sample of 16,122 women (3,450 from the 2002 survey; 6,307 from 2007; and 6,365 from 2012).

Measurements

Outcome Variable

The outcome of interest was hospital-based mode of delivery for the last birth; cesarean delivery was reported as a binary response (yes/no).

Sociodemographic Variables

The analysis included information about different sociodemographic characteristics that may be associated with cesarean delivery:

- Woman’s age reported in 5 groups (15–19, 20–24, 25–29, and ≥ 30 years)
- Place of residence (urban/rural)
- Geographic region (central, north, or south)
- Mother’s and partner’s education level (no education, primary, secondary, or higher education)
- Employment status (mothers with any income-producing profession were reported as employed)
- Place of delivery (public hospitals governed by the MOH, RMS, or UTHs, or private hospitals)
- Wealth index constructed using data on household assets and categorized into quintiles (poorest, poorer, middle, richer, and richest)14,17

Obstetric Variables

- Mother’s age at first birth was reported in 4 groups: 12–18, 19–24, 25–30, or > 30 years.
- Parity was reported in 3 groups: 1, 2, or 3 or more children.
- Since low or high birth weight and multiple births are among the main obstetric variables documented in the literature to increase risk of cesarean delivery,12,18,19 these 2 variables were used in this analysis as markers for births that were potentially at low risk for cesarean delivery (while recognizing that this may not always be the case). Women who delivered either singleton or normal birth weight infants (2,500 to 3,999 grams) were categorized as low risk for cesarean delivery while women who delivered either multiple or low/high birth weight infants were categorized as high risk for cesarean delivery.

Global Health: Science and Practice 2014 | Volume 2 | Number 2

196
weight infants (< 2,500 grams or ≥ 4,000 grams) were categorized as high risk.¹²

Statistical Analysis

Frequencies and percentages for each measured characteristic by year of survey were recorded. Rates of cesarean delivery for the last birth born within the 5 years prior to the survey were compared between the 2002, 2007, and 2012 surveys, and the potential difference in the cesarean rate for each measured variable was evaluated for each survey, separately, by using chi-square tests.

To document trends in the cesarean rate over a period of 10 years, the first survey conducted in 2002 was set as a reference in 4 binary logistic regression models, which estimated odds ratios (ORs) and adjusted odds ratios (aORs) as well as 95% confidence intervals (CIs) for significance testing. The first model was run among all mothers together and the other 3 models were run for mothers stratified by: (1) place of delivery (public or private), (2) birth weights, and (3) birth multiplicity (singleton vs. multiple births).

To assess whether place of delivery was associated with changes in trends of cesarean deliveries, all subjects were further stratified according to birth weights and birth multiplicity in public and private hospitals, separately, as well as by type of public hospital (government hospitals vs. UTHs) for those who reported delivering in a public hospital. In order to control for potential confounding effects, even when there was no association with cesarean delivery, all covariates under analysis (sociodemographic and obstetric) were entered simultaneously in the multivariate logistic regression models.

Logistic regression models were also used to assess the association between measured covariates with cesarean delivery and to investigate the independent association of the year of the survey on cesarean delivery after merging the 3 datasets. P value for the trend was assessed for each model by entering the year of the survey as a continuous variable.²⁰ All analyses were conducted using SPSS version 18.0. The level of statistical significance for all analysis was set at α=.05.

RESULTS

Descriptive Profile of the Mothers

Overall, 57.4% of mothers in the 3 datasets combined were ≥ 30 years old. The majority lived in urban areas and had secondary or higher education. In 2002, 10.1% of the mothers were employed compared with 15.5% in 2012 (Table 1).

FIGURE. Sample Selection (Unweighted Numbers)

Approximately two-thirds (65.1%) of deliveries were in public hospitals with no significant changes in that percentage over the study period. The percentage of women belonging to poor (“poorest” and “poorer”) households declined by 8.5 percentage points between 2002 and 2012, with a corresponding 5.2 percentage point increase in those belonging to rich households (“richer” and “richest”).

First birth occurred at age 19–24 years among 58.5% of mothers, and most had 1 or 2 children. From 2002 to 2012, there was no significant change in the percentage of mothers reporting low/high birth weight infants or multiple births.

Trends in the Cesarean Delivery Rate

The cesarean delivery rate increased over time, from 18.2% in 2002 to 30.3% in 2012 (Table 2). Between 2007 and 2012, the rate increased by 10.2 percentage points compared with an increase of only 1.9 percentage points from 2002 to 2007.

Age, mother’s education, and place of delivery persisted as significant factors in the cesarean delivery rate during each survey round (P < .05 for all analyses).

The cesarean delivery rate in Jordan increased from 18% in 2002 to 30% in 2012.
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<td>974 (15.4)</td>
<td>854 (13.4)</td>
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<td>1669 (26.2)</td>
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<tr>
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<td>555 (8.8)</td>
<td>609 (9.6)</td>
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<td>661 (10.4)</td>
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<td>1645 (25.8)</td>
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within each indicator for each year) (Table 2). The rate generally increased over time for all categories within these indicators, thus displaying similar trends ($P > .05$ for the trend over years for these indicators). The largest increases over time were observed among mothers aged 25–29 years and $\geq 30$ years and among mothers with primary education.

Mother’s employment, parity, and age at first birth were also all significant factors in the cesarean delivery rate during each survey round, and the increases over time were also significant. In each category, the largest increases were among employed mothers (17.5 percentage point increase between 2002 and 2012), mothers with 3 or more children (23 percentage point increase), and mothers whose age at first birth was over 30 years (23 percentage point increase).

Wealth was a significant factor in the cesarean delivery rate in the 2007 and 2012 survey years. Mothers in the poor wealth categories (“poorest” and “poorer”) generally had lower cesarean delivery rates than those in the rich categories (“richer” and “richest”), but the largest increase in cesarean deliveries over time was among mothers belonging to middle-income households (15.2 percentage point increase).

During the study period, the increase in the cesarean delivery rate among the normal birth weight group was the same as that of the low/high birth weight group (about a 12 percentage point increase), but the rate increased more

### TABLE 1 (continued).

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<tr>
<th>Characteristics</th>
<th>2002 (N=3,450)</th>
<th>2007 (N=6,307)</th>
<th>2012 (N=6,365)</th>
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<td>Richer</td>
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<td>3661 (58.1)</td>
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<td>2254 (35.7)</td>
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All data are reported as No. [%].
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<tr>
<th>Characteristics</th>
<th>2002</th>
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<th>2012</th>
<th>Percentage Point Difference&lt;sup&gt;a&lt;/sup&gt;</th>
<th>P Value for Trend&lt;sup&gt;b&lt;/sup&gt;</th>
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<td>40.1</td>
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<td>Place of Delivery</td>
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<td>Public sector</td>
<td>16.8</td>
<td>19.0</td>
<td>29.4</td>
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among singleton than among multiple births (12.2 percentage points vs. 5.7 percentage points, respectively; P < .001) (Table 2).

### Trends in the Cesarean Delivery Rate Stratified by Place of Delivery, Birth Weight, and Birth Multiplicity

Place of delivery, birth weight, and birth multiplicity were significantly associated with cesarean delivery in the crude analysis and retained their statistical significance after adjustment for all covariates (Table 3). Multivariate models from the 3 combined datasets showed that the cesarean delivery rate increased significantly over time, by 13% between 2002 and 2007, and by 90% between 2002 and 2012 (P < .001).

Between 2002 and 2012, stratification showed that the cesarean delivery rate increased by 93% among normal birth weight infants vs. 73% among low/high birth weight infants. Over the past decade, the cesarean delivery rate in Jordan increased by 93% among normal birth weight infants vs. 73% among low/high birth weight infants.

---

TABLE 2 (continued).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>2002</th>
<th>2007</th>
<th>2012</th>
<th>Percentage Point Difference&lt;sup&gt;a&lt;/sup&gt;</th>
<th>P Value for Trend&lt;sup&gt;b&lt;/sup&gt;</th>
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<td>17.1</td>
<td>25.4</td>
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<td>33.3</td>
<td>15.2</td>
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<td>.01</td>
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</tbody>
</table>

<sup>a</sup> Percentage point difference between 2002 and 2012.
<sup>b</sup> P value for the trend was obtained from logistic regression models by using outcome and explanatory variables as continuous variables and including interaction terms between survey year and each tested explanatory variable for the years 2002 and 2012.
### TABLE 3. Bivariate and Multivariate Logistic Regression Analysis on Trends in the Cesarean Delivery Rate, Among All Mothers and Stratified by Place of Delivery, Birth Weight, and Birth Multiplicity According to Year of Survey

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<th>aOR (95% CI)</th>
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<td>1.13 (1.01–1.26)*</td>
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<td>1929 (30.3)</td>
<td>1.95 (1.76–2.16)***</td>
<td>1.90 (1.71–2.11)***</td>
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<tr>
<td><strong>By Place of Delivery</strong></td>
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<tr>
<td><strong>Public Sector</strong></td>
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<td>2007</td>
<td>768 (19.0)</td>
<td>1.16 (1.01–1.33)*</td>
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<tr>
<td>2012</td>
<td>1242 (29.4)</td>
<td>2.05 (1.80–2.34)***</td>
<td>1.99 (1.74–2.28)***</td>
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<td>1.80 (1.53–2.12)***</td>
<td>1.70 (1.43–2.02)***</td>
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<tr>
<td><strong>By Birth Weight</strong></td>
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<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2007</td>
<td>890 (18.1)</td>
<td>1.13 (0.99–1.28)</td>
<td>1.11 (0.98–1.26)</td>
</tr>
<tr>
<td>2012</td>
<td>1395 (28.4)</td>
<td>2.03 (1.80–2.29)***</td>
<td>1.93 (1.71–2.19)***</td>
</tr>
<tr>
<td><strong>Low/High</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>201 (24.2)</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2007</td>
<td>377 (27.1)</td>
<td>1.17 (0.96–1.42)</td>
<td>1.13 (0.93–1.39)</td>
</tr>
<tr>
<td>2012</td>
<td>534 (36.6)</td>
<td>1.81 (1.50–2.20)***</td>
<td>1.73 (1.42–2.10)***</td>
</tr>
<tr>
<td><strong>By Birth Multiplicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Singleton Birth</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>582 (17.3)</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2007</td>
<td>1194 (19.3)</td>
<td>1.15 (1.03–1.28)*</td>
<td>1.14 (1.02–1.27)*</td>
</tr>
<tr>
<td>2012</td>
<td>1838 (29.5)</td>
<td>2.01 (1.81–2.23)***</td>
<td>1.92 (1.72–2.13)***</td>
</tr>
<tr>
<td><strong>Multiple Birth</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>48 (60.0)</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2007</td>
<td>73 (589.3)</td>
<td>0.99 (0.55–1.75)</td>
<td>0.98 (0.49–1.95)</td>
</tr>
<tr>
<td>2012</td>
<td>92 (65.7)</td>
<td>1.28 (0.72–2.26)</td>
<td>1.29 (0.64–2.58)</td>
</tr>
</tbody>
</table>

Abbreviations: aOR, adjusted odds ratio (for all covariates under analysis); CI, confidence interval; OR, odds ratio.

*P value for the trend was obtained by entering the survey year as a continuous variable.

*P < .05; *** P < .001.
delivery rate increased significantly by 92% among singleton births ($P < .001$), whereas it increased by only 29% among multiple births ($P = .43$).

Table 4 shows trends in cesarean deliveries among all subjects stratified by birth weight and birth multiplicity according to place of delivery. The cesarean delivery rate for mothers of normal birth weight babies in public hospitals was 2.06 times higher in 2012 than in 2002, and in private hospitals, 1.71 times higher. Similarly, the cesarean delivery rate for singleton births in public hospitals was 2.0 times higher in 2012 than in 2002, and in private hospitals, 1.76 times higher. Mothers who delivered multiple births in public hospitals were 3 times more likely to undergo cesarean delivery in 2012 than in 2002. In contrast, in private hospitals, the rate declined by 92% over time (aOR = 0.08; $P = .03$).

Between 2002 and 2012, the cesarean delivery rate rose sharply in UTHs by 22.4 percentage points compared with increases of 11.4 and 11.9 percentage points in private and government hospitals, respectively (Table 5). Overall, the cesarean delivery rate in UTHs was 2.29 times higher than in private hospitals ($P < .001$).

### Table 4. Multivariate Logistic Regression Analysis on Trends in the Cesarean Delivery Rate by Place of Delivery, Stratified by Birth Weight and Birth Multiplicity According to Year of Survey

<table>
<thead>
<tr>
<th></th>
<th>Public Hospitals (N=10,496)</th>
<th>Private Hospitals (N=5,627)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%) aOR (95% CI)</td>
<td>No. (%) aOR (95% CI)</td>
<td></td>
</tr>
<tr>
<td><strong>By Birth Weight</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>247 (14.8) 1.00</td>
<td>181 (19.1) 1.00</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>525 (17.0) 1.17 (0.99–1.39)</td>
<td>365 (19.9) 1.00 (0.82–1.23)</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>877 (27.4) 2.06 (1.76–2.42)***</td>
<td>519 (30.4) 1.71 (1.41–2.09)***</td>
<td></td>
</tr>
<tr>
<td>Low/High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>128 (22.9) 1.00</td>
<td>73 (26.7) 1.00</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>242 (25.3) 1.12 (0.87–1.45)</td>
<td>135 (31.0) 1.22 (0.85–1.75)</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>366 (35.6) 1.87 (1.46–2.38)***</td>
<td>168 (39.1) 1.66 (1.16–2.38)**</td>
<td></td>
</tr>
<tr>
<td><strong>By Birth Multiplicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singleton Birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>347 (16.0) 1.00</td>
<td>234 (19.6) 1.00</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>718 (18.2) 1.15 (0.99–1.33)</td>
<td>476 (21.3) 1.08 (0.90–1.29)</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>1171 (28.3) 2.00 (1.74–2.29)***</td>
<td>667 (31.8) 1.76 (1.47–2.09)***</td>
<td></td>
</tr>
<tr>
<td>Multiple Birth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>28 (50.9) 1.00</td>
<td>20 (80.0) 1.00</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>49 (60.5) 1.85 (0.78–4.35)</td>
<td>23 (56.1) 0.32 (0.05–2.09)</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>72 (72.0) 3.05 (1.27–7.33)</td>
<td>20 (50.0) 0.08 (0.01–0.78)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: aOR, adjusted odds ratio (for all covariates under analysis); CI, confidence interval.

$P$ value for the trend was obtained by entering the survey year as a continuous variable.

* $P < .05$; ** $P < .01$; *** $P < .001$. 

The cesarean delivery rate in university teaching hospitals was more than 2 times higher than in private or government hospitals.
**TABLE 5.** Multivariate Logistic Regression Analysis on Cesarean Delivery Rate Among Mothers Delivering in Public Hospitals by Year of Survey, Stratified by Birth Weight and Birth Multiplicity According to Type of Public Hospital

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2007</th>
<th>2012</th>
<th>All Years Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>aOR (95% CI)</td>
<td>%</td>
<td>aOR (95% CI)</td>
</tr>
<tr>
<td><strong>All Mothers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>20.8</td>
<td>1.00</td>
<td>22.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Government (public)</td>
<td>16.6</td>
<td>0.86 (0.69–1.07)</td>
<td>18.1</td>
<td>0.87 (0.75–1.02)</td>
</tr>
<tr>
<td>UTH (public)</td>
<td>26.7</td>
<td>1.08 (0.57–2.05)</td>
<td>50.0</td>
<td>4.24 (2.85–6.29)***</td>
</tr>
<tr>
<td><strong>Mothers Delivering in Public Hospitals (N=10,494)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>16.6</td>
<td>1.00</td>
<td>18.1</td>
<td>1.00</td>
</tr>
<tr>
<td>UTH</td>
<td>26.7</td>
<td>1.19 (0.63–2.27)</td>
<td>50.0</td>
<td>4.20 (2.80–6.28)***</td>
</tr>
<tr>
<td><strong>Mothers Delivering in Public Hospitals By Birth Weight</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal Birth Weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>14.5</td>
<td>1.00</td>
<td>16.2</td>
<td>1.00</td>
</tr>
<tr>
<td>UTH</td>
<td>23.9</td>
<td>1.18 (0.55–2.55)</td>
<td>44.1</td>
<td>3.44 (2.22–5.33)***</td>
</tr>
<tr>
<td>Low/High Birth Weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>22.5</td>
<td>1.00</td>
<td>24.2</td>
<td>1.00</td>
</tr>
<tr>
<td>UTH</td>
<td>35.7</td>
<td>1.24 (0.35–4.41)</td>
<td>83.3</td>
<td>27.50 (6.54–115.5)***</td>
</tr>
<tr>
<td><strong>Mothers Delivering in Public Hospitals By Birth Multiplicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singleton Birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>15.7</td>
<td>1.00</td>
<td>17.2</td>
<td>1.00</td>
</tr>
<tr>
<td>UTH</td>
<td>29.6</td>
<td>1.73 (0.91–3.29)</td>
<td>48.7</td>
<td>4.06 (2.70–6.08)***</td>
</tr>
<tr>
<td>Multiple Birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>57.1</td>
<td>1.00</td>
<td>59.5</td>
<td>1.00</td>
</tr>
<tr>
<td>UTH</td>
<td>0.0</td>
<td>NA</td>
<td>100.0</td>
<td>NA</td>
</tr>
</tbody>
</table>

Abbreviations: aOR, adjusted odds ratio (for all covariates under analysis); CI, confidence interval; NA, not applicable; UTH, university teaching hospital.

*Government hospitals include hospitals run by the Ministry of Health or the Royal Medical Services.

*P < .05; **P < .01; ***P < .001.
and 2.31 times higher than in government hospitals ($P<.001$). Moreover, the odds of performing cesarean deliveries for low-risk groups—mothers of normal birth weight babies (aOR=2.15, 95% CI=1.65–2.80) and singletons (aOR=2.39, 95% CI=1.88–3.02)—was higher in UTHs than in governmental hospitals, whereas there was no significant difference in the cesarean delivery rate for multiple births between these hospital types.

Table 6 shows logistic regression analysis on the cesarean delivery rate after combining the 3 datasets. Employed mothers were significantly more likely than unemployed mothers to undergo cesarean delivery (aOR=1.34, 95% CI=1.19–1.51; $P<.001$). The odds of undergoing cesarean delivery increased linearly and significantly with increasing wealth and mother’s age at first birth. Mothers with only 1 child had higher likelihood of cesarean delivery compared with those with 2 or ≥3 children. Low/high birth weight infants also were more likely to have undergone cesareans. However, the strongest predictor that was associated with cesarean delivery was multiple births (aOR=5.60, 95% CI=4.20–7.09; $P<.001$).

**DISCUSSION**

This study shows that in Jordan the cesarean delivery rate has increased steadily over the past decade by two-thirds, from 18% in 2002 to 30% in 2012, and was double the maximum population-based rate of 15% recommended by WHO. In Jordan, 99% of deliveries occur in hospitals; thus, the cesarean delivery rates reported in the JPHFS (on which this study is based) reflect population-level rates since virtually all deliveries occur in facilities.

A similar study analyzing nationally representative population survey data from Jordan between 1990 and 2002 reported that the cesarean delivery rate was 8.5% in 1990 and 12.9% in 1997. In the current study, the 2012 cesarean delivery rate of 30.3% is 3.6 times higher than the 1990 rate of 8.5%. This increase is in line with consistent global increases in the cesarean delivery rate. Some of the increase may be justified, for example, due to better access to maternal health services and delayed age at marriage resulting in advanced age at birth, which may be associated with adverse pregnancy outcomes. However, the sizeable increases suggest that many cesarean deliveries might occur without any, or on questionable, medical indications.

Globally there has been an increase in demand for elective cesarean delivery. An estimated 4% to 18% of all cesarean deliveries worldwide are requested by mothers. In this study, from 2002 to 2012, the cesarean delivery rate in births that were likely low risk increased significantly over time after controlling for potentially confounding factors—among normal birth weight infants by 93% and among singletons by 92%.

After combining all 3 datasets and adjusting for all variables under analysis, the findings revealed that, on average, mothers who were employed had higher odds of cesarean delivery than unemployed mothers, and the cesarean delivery rate increased linearly with increasing wealth—both indicators of better economic status. This is consistent with findings from a study in Nepal. Mothers with higher economic status have a better chance of affording the expense of such a surgical procedure.

Cesarean deliveries increased among both public and private hospitals in Jordan but more substantially in public hospitals, and particularly at UTHs. The high rate of cesareans in UTHs was associated with higher cesarean delivery rates among apparently low-risk groups (singletons, normal birth weight infants) than among high-risk groups (multiples, low/high birth weight infants). Researchers have expected cesarean deliveries to increase particularly among the private sector in Jordan over time and have speculated that the gap between public- and private-sector cesarean delivery rates may be growing. However, in this study, the gap narrowed from a 4.0 percentage point difference ($P=.004$) in 2002 to 2.8 percentage points ($P=.02$) in 2012 (Table 2). The overall trend in cesarean deliveries between public and private hospitals from 2002 to 2012 was not significant ($P=.53$). This new finding differs from what was previously reported in Jordan.

In Jordan, there are 2 UTHs: the UTH of the University of Jordan and the King Abdullah University Hospital (KAUH) of the Jordan University of Science and Technology. A number of factors could potentially explain the higher rate of cesarean deliveries in UTHs in Jordan. First, the KAUH, which is the largest UTH, opened to the public in November 2002 and dramatically increased access to advanced medical procedures, including cesarean deliveries, for a large segment of the Jordanian population, specifically for those living in rural areas. In addition, the government initiated a health reform agenda in 2005, which...
<table>
<thead>
<tr>
<th>TABLE 6. Logistic Regression Analysis on Cesarean Delivery Rate by Background Characteristics, Among All Mothers From All Survey Datasets (2002–2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OR (95% CI)</strong> &amp; <strong>aOR (95% CI)</strong></td>
</tr>
<tr>
<td>Age, y</td>
</tr>
<tr>
<td>15–19</td>
</tr>
<tr>
<td>20–24</td>
</tr>
<tr>
<td>25–29</td>
</tr>
<tr>
<td>≥ 30</td>
</tr>
<tr>
<td>Place of Residence</td>
</tr>
<tr>
<td>Urban</td>
</tr>
<tr>
<td>Rural</td>
</tr>
<tr>
<td>Geographic Region</td>
</tr>
<tr>
<td>Central</td>
</tr>
<tr>
<td>North</td>
</tr>
<tr>
<td>South</td>
</tr>
<tr>
<td>Mother’s Education</td>
</tr>
<tr>
<td>No education</td>
</tr>
<tr>
<td>Primary</td>
</tr>
<tr>
<td>Secondary</td>
</tr>
<tr>
<td>Higher</td>
</tr>
<tr>
<td>Husband’s Education</td>
</tr>
<tr>
<td>No education</td>
</tr>
<tr>
<td>Primary</td>
</tr>
<tr>
<td>Secondary</td>
</tr>
<tr>
<td>Higher</td>
</tr>
<tr>
<td>Employment</td>
</tr>
<tr>
<td>Unemployed</td>
</tr>
<tr>
<td>Employed</td>
</tr>
<tr>
<td>Place of Delivery</td>
</tr>
<tr>
<td>Public sector</td>
</tr>
<tr>
<td>Private sector</td>
</tr>
</tbody>
</table>
include improving health insurance coverage, that could have increased access to government hospitals. Finally, gynecology and obstetrics residents at UTHs may be more inclined to perform cesarean deliveries for the sake of practicing the surgical procedure, potentially increasing the rate of elective cesareans.

This study used data from population-based surveys that are usually conducted every 5 years. Collecting and monitoring such data in routine health information systems (RHIS) on a more regular basis (for example, annually or semiannually) could help policy makers and health professionals develop and enforce strategies to control the increase in the cesarean delivery rate, particularly cesarean deliveries without any medical indication.

A number of clinical, psychosocial, and structural strategies have been used to reduce the likelihood of cesarean deliveries, even among those who may have a medical indication. For example, a systematic review demonstrated that external cephalic version (a procedure used to turn the fetus from a breech or transverse position into a vertex, or head-down, position before labor begins) and vaginal birth after a previous cesarean were effective at reducing cesarean delivery rates. In addition, one-on-one trained support during labor has been shown to reduce cesarean delivery rates.

Initiatives to raise awareness among the public and among health professionals about the adverse maternal outcomes associated with

### TABLE 6 (continued).

<table>
<thead>
<tr>
<th></th>
<th>OR (95% CI)</th>
<th>aOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wealth Index</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poorest</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Poorer</td>
<td>0.94 (0.84–1.05)</td>
<td>0.94 (0.84–1.06)</td>
</tr>
<tr>
<td>Middle</td>
<td>1.20 (1.07–1.34)***</td>
<td>1.27 (1.13–1.43)***</td>
</tr>
<tr>
<td>Richer</td>
<td>1.30 (1.16–1.45)***</td>
<td>1.32 (1.16–1.51)***</td>
</tr>
<tr>
<td>Richest</td>
<td>1.47 (1.30–1.65)***</td>
<td>1.39 (1.20–1.62)***</td>
</tr>
<tr>
<td><strong>Parity in Last 5 years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td>0.86 (0.79–0.93)***</td>
<td>0.81 (0.75–0.88)***</td>
</tr>
<tr>
<td>≥3</td>
<td>1.04 (0.90–1.18)</td>
<td>0.82 (0.70–0.95)*</td>
</tr>
<tr>
<td><strong>Age at First Birth, y</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12–18</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>19–24</td>
<td>1.10 (0.98–1.22)</td>
<td>1.14 (1.02–1.28)*</td>
</tr>
<tr>
<td>25–30</td>
<td>1.72 (1.52–1.94)***</td>
<td>1.75 (1.52–2.01)***</td>
</tr>
<tr>
<td>&gt; 30</td>
<td>4.69 (3.93–5.61)***</td>
<td>4.58 (3.77–5.55)***</td>
</tr>
<tr>
<td><strong>Birth Weight, g</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal (2500–3999)</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Low/High (&lt; 2500 or ≥ 4000)</td>
<td>1.55 (1.43–1.68)***</td>
<td>1.53 (1.40–1.66)***</td>
</tr>
<tr>
<td><strong>Birth Multiplicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singleton birth</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Multiple birth</td>
<td>5.47 (4.38–6.82)***</td>
<td>5.60 (4.20–7.09)***</td>
</tr>
</tbody>
</table>

Abbreviations: aOR, adjusted odds ratio (for all covariates under analysis); CI, confidence interval; OR, odds ratio. *P < .05; **P < .01; ***P < .001.
cesarean deliveries and advantages of vaginal delivery are also urgently needed to halt the steady increase in the cesarean delivery rate. Health professionals should give mothers full information about risks associated with cesarean delivery. Other interventions, such as midwifery training and education and establishment of birthing centers, could also help encourage mothers to deliver vaginally.

 strengths and limitations
This study has 3 major strengths. First, analysis was based on data collected from nationally representative samples by accredited and reliable official entities using comparable sampling procedure and inclusion criteria. Second, the probability of recall bias is low since women who had a cesarean delivery would not easily forget the mode of delivery given its surgical nature, particularly for the last birth. A recent study showed that DHS data on cesarean deliveries are sufficiently reliable for national and global monitoring purposes.

Third, stratification according to the type of hospital provided more insights about the substantial contribution of UTHs to the rising cesarean delivery rate in Jordan.

Limitations include that samples were collected through a cross-sectional design that limits the causality pathway with regard to the drivers of increased cesarean delivery rates and that the data did not include information about whether the cesarean deliveries were performed under medical indications or based solely on maternal demand. Instead, this study used only surrogate markers of what could potentially have been births at low or high risk of medically necessary cesarean delivery.

CONCLUSION
The cesarean delivery rate increased in Jordan from 2002 to 2012; the last survey in 2012 showed that the rate was double the maximum threshold recommended by WHO. The cesarean rate was higher among apparently low-risk mothers, and was particularly higher at UTHs than in private or government hospitals, which suggests that many cesarean deliveries may have been performed without medical indications. Delayed maternal age at first birth, low/high birth weights, multiple births, employment of mothers, and greater wealth were the main predictors of cesarean delivery in Jordan. More vigilant monitoring is needed to reduce unnecessary cesarean deliveries in what appear to be low-risk mothers, and in those delivering at UTHs in particular.

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REFERENCES


Peer Reviewed

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Medical barriers to emergency contraception: a cross-sectional survey of doctors in North India

ME Khan, Anvita Dixit, Isha Bhatnagar, Martha Brady

Emergency contraceptive pills (ECPs) are extremely safe and do not interfere with implantation. Yet many surveyed physicians in India did not know that there are no contraindications to using ECPs, and many had negative attitudes about ECP users. Most were against having ECPs available over-the-counter and wanted to impose age restrictions. Efforts are needed to address such misconceptions that might lead to limiting ECP availability.

ABSTRACT

Background: Some medical doctors in India have publicly expressed opposition to making emergency contraceptive pills (ECPs) easily accessible, even though ECPs are included in the method mix of the Ministry of Health and Family Welfare program and as an over-the-counter (OTC) product. Such opposition affects access to ECPs by influencing policy, procurement, and distribution, besides stigmatizing the ECP user. This study was conducted to assess ECP knowledge, attitudes, and practices of doctors in North India.

Methods: A cross-sectional survey of 83 doctors who provide ECPs, randomly selected from 3 cities in the state of Uttar Pradesh, was conducted in 2011. The quantitative data were complemented by 19 in-depth interviews with purposively selected senior gynecologists and other opinion leaders.

Results: All surveyed physicians cited the correct dose and regimen for ECPs. However, the large majority of those surveyed believed that ECPs work by preventing implantation. (The best evidence currently indicates that ECPs do not work by preventing implantation.) Most doctors also believed incorrectly that ECPs have several contraindications and side effects. They also had strong reservations against OTC provision of ECPs by pharmacists and community health workers (CHWs) and negative attitudes toward ECP users, which serve as serious medical barriers to mainstreaming use of ECPs.

Conclusion: Physicians and their professional associations exert a strong influence on the operationalization of national contraceptive policies. Evidence-based advocacy and educational campaigns targeting doctors are needed to address and resolve their reservations about ECPs, particularly about its provision as an OTC product and its distribution by CHWs. Partnerships with medical associations can help reduce doctors’ negative attitudes and create a conducive environment for influencing clinical practices. Such changes are needed to increase the availability and use of ECPs as part of a package of a full range of contraceptive method options to prevent unwanted pregnancy among the most vulnerable populations.

INTRODUCTION

Despite a long history of family planning programs in India, about 25% of pregnancies and births in the country are unplanned. In addition, there is continuing high unmet need for family planning, estimated at 21%, which contributes to short birth intervals and high numbers of abortions (6.7 million annually). These abortions are often illegal, unsafe, and performed under unhygienic conditions. All these factors lead to high maternal mortality (212 per 100,000 live births) and morbidity.

Emergency contraceptive pills (ECPs) give women a chance to prevent unwanted pregnancy if used within 5 days of unprotected sex or contraceptive failure. The primary mechanism of action is by preventing ovulation (Table 1). ECPs do not affect an established pregnancy, and there are no data supporting interference with implantation of a fertilized egg.
ECPs have no medical contraindications and no known serious medical complications.6

In 2002, the Ministry of Health and Family Welfare (MoHFW) introduced ECPs in the family welfare program. Despite opposition from some medical doctors, moral activists, and parents’ associations, in 2005, the method was introduced as an over-the-counter (OTC) drug.

Even with these supportive programmatic changes, evidence shows that awareness and use of ECPs is extremely low. National Demographic and Health Survey data show that less than 1% of married women (0.5% in rural areas and 0.8% in urban areas) have ever used ECPs, and less than one-third of unmarried women know about ECPs.

However, according to a supply audit by AC Nielsen ORG-MARG Research Ltd., a market research company in India, use of ECPs in large metro cities has become substantial. For example, in 2010, 15.2 million ECPs were sold in India, of which 10.4 million, or 68%, were sold in urban areas where only 28% of the country’s population lives. In comparison, 4.8 million ECPs, or 32%, were sold in rural areas where 72% of the country’s population lives. The largest 15 metropolitan cities, where 22% of the urban population lives, accounted for 3.7 million pills (36% of urban sales), indicating that even in urban areas, access to and use of ECPs are skewed toward large metropolitan cities.

Some of the main barriers to mainstreaming use of ECPs come from reservations among physicians and professional associations, who oppose ECPs as an OTC drug. Statements made in national newspapers reflect physicians’ strong reservations against easy ECP access and OTC sales. However, these opinions are based on inadequate knowledge and misconceptions about side effects and the mechanism of action of ECPs.7–10 For example, an article published in a national newspaper with high circulation in India stated:

… the brazen abuse of the OTC emergency drug is triggering severe side-effects, and sometimes even failing to prevent pregnancy, forcing girls to suffer the agony of successive abortions.11

Similarly, a well-read popular magazine, India Today, quoted a leading gynecologist saying:

… cases of herpes, HIV and hepatitis have increased over the past few years because people are increasingly replacing the condom with the emergency pill.12

Another gynecologist said:

### Table 1. Facts About Levonorgestrel-Based Emergency Contraception

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Fact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose and regimen</td>
<td>1.5 mg taken at one time, within 120 hours of unprotected sex, is the best approach.</td>
</tr>
<tr>
<td>Mechanism of action</td>
<td>Preventing/delaying/disrupting ovulation.</td>
</tr>
<tr>
<td></td>
<td>Possibly thickening cervical mucus.</td>
</tr>
<tr>
<td></td>
<td><strong>Does not prevent implantation based on best evidence.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Does not disrupt established pregnancy.</strong></td>
</tr>
<tr>
<td>Effectiveness</td>
<td>52%–94% reduction in what risk of pregnancy would have been; better if taken sooner after unprotected sex.</td>
</tr>
<tr>
<td>Medical eligibility</td>
<td>Should not be taken if the woman has a confirmed pregnancy (because no need to take), although best evidence indicates it would not harm fetus.</td>
</tr>
<tr>
<td></td>
<td>Otherwise, no medical restrictions, including age.</td>
</tr>
<tr>
<td>Side effects</td>
<td>Minimal and not harmful (for example, possible mild nausea, menstrual changes).</td>
</tr>
<tr>
<td>Repeat use</td>
<td>Regular repeat use not recommended because of relatively poor effectiveness over time and possible side effects such as menstrual irregularity. However, repeat use poses no known health risks.</td>
</tr>
</tbody>
</table>

Adapted from the World Health Organization.5

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Emergency contraceptive pills work primarily by preventing ovulation. Emergency contraceptive pills have been available over-the-counter in India since 2005, but awareness and use of the method remain low.
With the influence of Western culture and values, young people view casual sex as a normal activity, making the pill a powerful tool in a woman’s hands.\textsuperscript{12}

Such publicly expressed attitudes create medical barriers—provider practices derived partly from a medical rationale but that result in a scientifically unjustifiable barrier or denial of contraception.\textsuperscript{13} Providers at public and private facilities, particularly self-identified “moral police” and activists, contribute to further corrupting the opinions of the community. Some doctors, however, do believe that access to and use of ECPs will reduce the abortion rate.\textsuperscript{14}

Some physicians also oppose provision and distribution of ECPs by paramedics or community health workers (CHWs). However, studies show that CHWs can easily provide quality ECP services.\textsuperscript{10} In India, ASHAs (accredited social health activists), a CHW cadre paid based on performance of certain activities, have become an integral part of the health delivery system. There are currently 900,000 ASHAs throughout the country. Under a new scheme, ASHAs are the depot holder of condoms, oral contraceptive pills, and ECPs.\textsuperscript{15} Studies, however, show that ECP awareness among ASHAs is low (15%).\textsuperscript{16} In addition, government facilities have inadequate supplies of ECPs and frequent stock-outs, and, in a few cases, some facilities report never having received any ECP supply.\textsuperscript{16,17}

Medical barriers to ECPs, especially as an OTC product, have been reported globally. Often those opposing OTC sales lack knowledge about the mechanism of action and have a misunderstanding that ECPs induce abortion, or they fear that ECPs may be used for regular contraception and misused by adolescents.\textsuperscript{16–20} Parents also fear that wide availability of ECPs will increase promiscuous, premarital, and irresponsible sex as well as increase the risk of acquiring sexually transmitted infections (STIs).\textsuperscript{18–22}

This article explores the perceptions and attitudes of medical doctors in India about ECPs and how those might contribute to medical barriers and reduced access.

METHODS

In 2011, we interviewed 83 medical doctors (63 gynecologists and 20 general practitioners or other specialists) who provide ECP information or services using a pretested structured questionnaire.

A list of doctors prepared by the Urban Health Initiative, a family planning initiative funded by the Bill and Melinda Gates Foundation, was used as the sampling frame to select participants. Doctors were randomly selected from 3 large cities in Uttar Pradesh (UP)—Agra, Aligarh, and Lucknow. The state of UP is the largest and most populous state (with 199 million residents) in India, with one of the highest maternal mortality rates, low contraceptive use, and high rates of unmet family planning need and unintended pregnancy.

To complement the quantitative survey data, 19 key opinion leaders were interviewed in depth. Of these, 8 are well-regarded, influential, senior gynecologists.

RESULTS

Profile of the Doctors

Almost all the doctors interviewed were Hindu (99%) and female (98%), aged between 24 and 66 years (mean = 43.3, standard deviation = 8.4). The majority (78%) was from the private sector. On average, they had been working for 16 years, and 66% had a Doctor of Medicine degree. Most (68%) had received training in family planning, and 43% had received some orientation or training on ECPs.

Knowledge of Mechanism of Action and Contraindications

Most of the doctors (96%) believed that ECPs work by preventing implantation (Table 2). The
latest literature indicates that ECPs do not prevent implantation in any way and that they do not cause any harm to a fertilized egg. However, at the time of this study, the 20th edition of Contraceptive Technology, published in 2011, reported the mechanism of action as disrupting or delaying ovulation or preventing implantation of a fertilized egg.

Although only one doctor reported the mechanism as inducing abortion, after direct probing on whether ECPs could induce abortion, 10% replied positively. This indicates that the mechanism of action of ECPs is still not clear to many doctors, even senior gynecologists. Reinforcing these observations, a senior gynecologist working in public hospital said:

*It is a long-acting progestosterone. It hinders in the implantation; it makes the endometrium hostile for the fertilized ovum.*

Yet another gynecologist working in a large private hospital said:

*ECP doesn’t allow implantation of the zygote. I do not think people have any confusion regarding this.*

All doctors had correct knowledge about the number of ECPs that need to be taken, at what interval (in the case of the combined 2-pill regimen), and the number of hours within which ECPs must be taken after unprotected sex to be effective in preventing pregnancy. Most doctors (88%) believed that ECPs are safe, with some side effects.

However, there was confusion around contraindications; many believed that use of ECPs could be harmful if taken by pregnant women (59%), by patients with heart disease (37%) or liver disease (46%), or by women who are breastfeeding (27%). Only 3 doctors correctly answered that there are no contraindications to ECPs, and only 16% were aware of the national guidelines on ECPs.

**Attitudes About ECP Provision**

Even though 88% of doctors believed that ECPs are safe, two-thirds of the doctors were against providing ECPs as an OTC drug (Table 2).

The Head of the Obstetrics and Gynecology Department of a renowned medical college said:

*I personally feel that it should not be sold as an OTC drug. Though it reduced unwanted pregnancy, misuse is increasing. I feel that publicity of ECPs and its availability as an OTC product is not good.*

Women come to us only when complications arise due to repeat use; [they] never come for counseling or advice before use. The main reason for such misuse is the lack of knowledge and awareness among the public regarding its appropriate use.

A chief medical superintendent at a district hospital, expressing his reservations of making ECPs available OTC, said:

*The central government needs to ensure that ECPs are prescribed only at hospitals by the doctors. Neither the abortion pills nor the ECPs should be OTC, because girls are misusing them.*

More than half of the doctors also had reservations about easy access to ECPs, through paramedics or CHWs, and 42% opposed providing the method prophylactically (Table 2). Many respondents were concerned that paramedics and CHWs would potentially “misuse” (50%) the method and that they would have poor

**TABLE 2. Knowledge and Attitudes About ECPs Among Surveyed Doctors in North India (N=83)**

<table>
<thead>
<tr>
<th>Knowledge and Attitudes</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge of Mechanism of Action</strong></td>
<td></td>
</tr>
<tr>
<td>Inhibits ovulation</td>
<td>23</td>
</tr>
<tr>
<td>Prevents implantation</td>
<td>96</td>
</tr>
<tr>
<td>Induces abortion</td>
<td>1</td>
</tr>
<tr>
<td><strong>Attitudes About Expanding Access</strong></td>
<td></td>
</tr>
<tr>
<td>Oppose OTC provision</td>
<td>67</td>
</tr>
<tr>
<td>Oppose provision by CHWs</td>
<td>53</td>
</tr>
<tr>
<td>Oppose provision as prophylactic</td>
<td>42</td>
</tr>
<tr>
<td>Recommend age restriction</td>
<td>84</td>
</tr>
<tr>
<td><strong>Women Using ECPs Are More Likely To</strong>:</td>
<td></td>
</tr>
<tr>
<td>Engage in premarital sex</td>
<td>53</td>
</tr>
<tr>
<td>Engage in promiscuity/have more sex partners</td>
<td>75</td>
</tr>
<tr>
<td>Participate in risky sex behavior</td>
<td>18</td>
</tr>
<tr>
<td>Not use other family planning methods</td>
<td>33</td>
</tr>
<tr>
<td>Have sexually transmitted infections</td>
<td>26</td>
</tr>
</tbody>
</table>

**Abbreviations:** CHWs, community health workers; ECPs, emergency contraceptive pills; OTC, over-the-counter.

a Multiple responses were possible.

b Correct response.

All surveyed doctors knew the correct dose and regimen for emergency contraceptive pills, but there was confusion around contraindications.
knowledge about ECPs (32%). A senior doctor said:

None of the ANMs [auxiliary nurse-midwives] or CHWs have got any training on ECPs; they learnt by practice and by working with us. Even doctors have not been trained. Then how will anyone know about the exact or the appropriate use of ECPs?

Most of the doctors (84%) wanted a minimum age restriction for obtaining ECPs. The age restriction ranged from 16–25 years, with the majority (54%) in favor of 18–22 years. Most (95%) did not think programs to increase ECP accessibility were necessary because they believed ECPs were already easily available from shops. However, shop audit reports from AC Nielsen ORG-MARG Research Ltd., which provides some of the most authentic data on pharmaceutical industries, show very limited ECP stocks in rural areas, probably reflecting the general lack of knowledge about ECPs among people, and thus the very low uptake.\(^2,28\)

### Attitudes About ECP Users

Survey respondents generally had negative moral judgments about ECP users, which probably also negatively impacts access to ECPs. For example, 53% of respondents thought that women using ECPs are more likely to have premarital sex, and 75% thought they would have more sex partners (Table 2).

These attitudes were also reflected in the in-depth interviews. For example, a gynecologist from a private clinic expressed:

*...I do feel that the easy availability of ECPs has increased the sexual contacts among young girls. There is a lot of misuse of ECPs by the current generation.*

### Perceptions of When to Use ECPs

In India, societal norms prohibit people from openly condoning use of ECPs by adolescents. However, almost two-thirds of the doctors thought that it was appropriate for women having infrequent sex to use ECPs as a family planning method, potentially reflecting their openness to mainstreaming ECPs (Table 3).

Interestingly, more than three-fourths of the doctors thought that being married was an important criterion for appropriate use of ECPs, which might be more of a reflection of social norms than bias among the doctors. A senior gynecologist explained:

*I think unmarried girls who are exploring their sexuality and having infrequent sex with their boyfriends can use it.*

Most doctors felt that women under 29 years of age (68%) and married women (68%) were currently the main ECP users while only 21% of the doctors believed that unmarried young women used ECPs.

Two-thirds of the doctors interviewed believed there were no barriers in accessing or using ECPs. However, about 5% felt that there could be low demand for ECPs because of lack of information. A gynecologist from a public health facility reported:

*...demand for ECPs is also very low. One year back, I received a box of ECPs. Some of them are still in stock. Soon all of them will expire. People who live in the vicinity of the clinic are poor and are not educated. They do not know much about the method.*

### Repeat Use and Perceptions of Side Effects

There was substantial confusion about the definition of repeat use and about its possible adverse consequences. The initial reaction of 78% of the doctors interviewed was that ECPs should not be used more than once in one menstrual cycle because it is not a regular method of family planning: *“It is an emergency pill.”*

<table>
<thead>
<tr>
<th>TABLE 3. Attitudes of Surveyed Doctors About Appropriate Use of ECPs (N=83)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Situation/ Characteristic of User</strong></td>
</tr>
<tr>
<td>Married woman</td>
</tr>
<tr>
<td>Infrequent/ unpredictable sex</td>
</tr>
<tr>
<td>Contraceptive failure</td>
</tr>
<tr>
<td>Unprotected sex</td>
</tr>
<tr>
<td>Rape or sexual coercion</td>
</tr>
<tr>
<td>Living in refugee/ conflict settings</td>
</tr>
<tr>
<td>Multiple responses were possible.</td>
</tr>
</tbody>
</table>
A senior gynecologist from a public hospital said:

If a woman is taking ECPs several times, it means she is using it as a regular contraceptive. She needs to understand its harmful effect … ECPs are for [a] real emergency.

This is in line with national guidelines. Only 15 doctors (18%) felt that ECPs could be used more than once within the same menstrual cycle. Of these, 8 doctors suggested ECPs could be used up to 2 times, while the remaining 7 felt that it could be used more than 2 times, depending on the need.

Doctors’ perceptions of the possible side effects of repeat use varied, from menstrual disturbance/irregular bleeding, including excessive bleeding during menstruation (85%), to vomiting/nausea (20%) and weakness (12%). About 24% held the misperception that ECPs could cause ectopic pregnancy and infertility.

During in-depth interviews, many senior gynecologists expressed concerns regarding a high failure rate and possibility of ectopic pregnancy:

My colleagues have concerns about repeat use of ECPs. They question it because of [the] misconception of the increased chance of ectopic pregnancy and extent of failure rate. We do not have answers to such questions.

A substantial proportion (27%) of the 63 surveyed gynecologists reported that in the last month they were presented with 1 to 3 cases of pregnancy due to ECP failure. Based on their personal experiences, 40% of the gynecologists reported that there is an increase in patients with menstrual problems after using ECPs.

A senior gynecologist from a private hospital said:

There should be a rider on [the] ECP pack that the client should follow up with a gynecologist within 15 days of taking it, and then we can counsel women on the failure rates. Often the user has a little bleeding and confuses it as a normal period. But actually they have missed their period and when they come to us, they come with an advanced pregnancy.

Perceptions of Reduction in Abortions

Most gynecologists felt that there is little or no evidence to suggest that the abortion-seeking practice among young and unmarried girls had changed as a result of having ECPs available. In contrast, 5 gynecologists (8%) said that they were experiencing an increase in the number of induced abortions due to failure of ECPs. However, during in-depth interviews, 3 gynecologists reported that the frequency of very young girls seeking abortion had decreased. In the words of a senior gynecologist from Lucknow:

… the number of young girls who used to come to me for abortion has declined. In my own clinic, 2–3 young girls used to come every month. Now it is rare.

Recommendations for Mainstreaming ECPs

Two-thirds of the doctors surveyed recommended educational campaigns to disseminate information about ECPs and its correct use; they felt that public knowledge is negligible except among the educated urban class. A senior gynecologist from a public health hospital explained:

[Initially] ECP was being advertised as something very attractive to use. But it is not like that. The way we create awareness, educate, and counsel the public and the providers is very important. It should be done in such a way that it is something that should be used only in accidents or emergency. It should not be advertised as a contraceptive method and people should know it is much less effective if used frequently as a regular method.

The 2 main modes of communication that were recommended included advertising (100%), using mass and mid-media, and raising awareness through CHWs and other providers (67%), including doctors. A few (6%) felt that there was no need for any such initiatives, as they would lead to misuse.

On the topic of affordability, about one-third of the doctors did not feel a need to reduce costs or to increase free distribution of ECPs at public clinics. A gynecologist suggested:

Getting ECPs is not a problem as it is an OTC drug. You can go to an unknown chemist to buy ECPs, if you want privacy. Even the cost [ranging from Rs. 40 to Rs. 100] is not much.

DISCUSSION

This study shows that many physicians in North India lack up-to-date information on the mechanism of action of ECPs. But this may be because the study was carried out at the end of
2011, while information on mechanism of action was revised and updated in 2012. Some doctors have the misconception that the mechanism of action of ECPs could lead to abortions. Many of them also have misconceptions about contraindications.

Doctors’ biases reported in earlier literature were confirmed by this study.¹⁸ A majority of doctors oppose ECPs as a prophylactic and as an OTC drug. They also strongly believe that there should be an age restriction on the provision of ECPs, due to their experience with failure and side effects. Further, they believe that “easy” availability of ECPs would promote premarital sex and promiscuity, replace regular family planning methods, and increase chances of acquiring STIs through “irresponsible” sexual behavior. Similar opinions and concerns were expressed at 2 national consultations on emergency contraception organized by the Population Council and held in Delhi and Mumbai, which were attended by more than 100 national and international representatives, including from the Indian Medical Association (IMA), the Federation of Obstetric and Gynaecological Societies of India (FOGSI), the MoHFW, researchers, and ECP manufacturers.

Although ECPs are not recommended for use as a regular contraceptive because overall effectiveness is reduced over time, repeat use poses no known health risks.⁵ Furthermore, there is no research to limit the number of times that ECPs can be used within a menstrual cycle.⁶ Many gynecologists, however, expressed a fear of repeat use of ECPs and thought that more patients were coming to them with pregnancy due to repeat use of ECPs. Although failure of ECPs might be related to its repeated use, it could also be a factor of the interval between unprotected sex and ECP use or to the stage of the menstrual cycle when ECPs are taken. Educational campaigns for both providers and users are needed to address recommendations on repeat use of ECPs.

A few of the interviewed gynecologists feel that abortions have decreased since ECPs have become available. However, studies suggest there is no public health impact on abortion rates of ECP use.²⁹,³⁰ This gap in knowledge among doctors in India needs to be addressed. At the same time, the perception of reduced numbers of abortions, while it cannot be generalized or attributed to ECP use, should be explored further, for example, through a prospective study to assess whether easy access to ECPs will decrease unwanted pregnancies and the need for abortion.

In general, negative attitudes of physicians toward ECPs constitute significant medical barriers to mainstreaming the method into national programs as physicians are important opinion leaders. As doctors and their professional associations exert strong influence on policymaking, misconceptions and provider biases could be serious constraints or could delay decisions that could make ECP access easier at an affordable price.

To overcome these obstacles, evidence-based advocacy to address doctors’ reservations and a sustained educational campaign to disseminate correct information about ECPs to all stakeholders, including opinion leaders, providers, and the community at large, are needed. Support and positive advocacy by medical associations such as the IMA and FOGSI could be effective in reducing providers’ biases and medical barriers. Interventions that could potentially reduce medical barriers among doctors include lectures on ECPs in the final year of medical students’ training and half-day ECP orientation as part of on-the-job training. These activities could be done at very low cost and completed within 4 to 6 months.

Our recent efforts with FOGSI helped to increase discussions about ECPs. Information about ECPs, including benefits and mechanism of action, has been disseminated to each chapter of the association, and at least one session on ECPs is being organized at the annual conference. Efforts are required to make this a regular practice, for example, through continual dissemination of accurate information about ECPs such as through the FOGSI newsletter and journal. The key idea is to make the environment conducive for correct knowledge about ECPs, the role of the method in the national Family Welfare Program, and to make the method easily available and accessible to all.

One recent positive step in the direction toward increasing knowledge and reducing negative attitudes is the withdrawal of the government ban on ECP advertisement, so that ECP manufacturers can also play a supportive role in addressing the barriers and negative attitudes toward ECP use. To conclude, the study suggests an urgent need for advocacy among doctors and other stakeholders to make ECPs available to reduce unintended pregnancy.
Limitations
There are a few limitations to the study. First, it had a small sample size and was concentrated largely in one state, although it is one of the largest states in India and one with high unmet need. Second, the study was carried out in 2011, but updated guidelines on mechanism of action of ECPs were published in 2012, so we are unable to say confidently whether the doctors had correct knowledge about this critical piece of information.

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Enlisting traditional healers and pharmacists to improve TB detection contributed 38% to 70% of new smear-positive case notifications per quarter in a rural district of Tanzania.

ABSTRACT
In Tanzania, people with tuberculosis (TB) commonly self-medicate or visit traditional healers before seeking formal medical care. Between 2009 and 2011, we piloted a community-based project in Kisarawe District to improve TB case notification. The project trained 15 traditional healers and 15 pharmacists to identify and refer individuals with TB symptoms to diagnostic facilities. In addition, the project trained 2 community members to collect and fix sputum from symptomatic individuals onto slides, which they then delivered by bicycle to the nearest diagnostic facility. To determine effectiveness, we analyzed routine case detection data and referrals from traditional healers and pharmacists and conducted a cross-sectional survey of recently diagnosed smear-positive TB patients (N=150) to understand their treatment-seeking behavior. From 2009 to 2011, smear-positive TB case notification increased by 68% in Kisarawe District, from 28/100,000 to 47/100,000, even while TB case notification nationally stayed the same (at approximately 14/100,000). The traditional healers and pharmacists referred 434 people with presumptive TB to diagnostic facilities, 419 of whom (97%) went to the facilities; of those who went to facilities for testing, 104 people (25%) were diagnosed with TB. The percentage of new TB case notifications that were referred through the network ranged from 38% to 70% per reporting quarter. Sputum fixers collected and delivered specimens from 178 individuals, 17 of whom (10%) were diagnosed with TB. Almost 60% of surveyed smear-positive TB patients first visited a pharmacist or traditional healer before seeking care at a diagnostic facility. These results prompted scale up of community interventions to 9 more districts in 2011 and to another 26 districts in 2013. Establishing referral networks that bring TB information and services closer to community members can contribute to improved TB case notification.

INTRODUCTION
In 2006, the World Health Organization (WHO) and the Stop TB Partnership launched the “Stop TB Strategy” and published “The Global Plan to Stop TB, 2006–2015.” Both are key strategy documents aimed at broadening the scope of tuberculosis (TB) program implementation to include efforts needed to achieve global TB targets, which include the Millennium Development Goal of halting and reversing the incidence of TB by 2015. In 2012, an estimated 8.6 million people around the world developed TB, and 1.3 million people died from the disease.

Recognizing that the TB prevention, care, and treatment strategies used up to the time the strategy documents were published would not be sufficient to reach the 2015 target, the WHO strategy included empowering people with TB and affected communities as a central component, with the aim of supporting comprehensive, community-based responses. Community participation in disease prevention, diagnosis, care, and treatment has been recognized as a critical element in recent documents and initiatives. The WHO “Global Tuberculosis Report 2013” noted that Tanzania has reached a treatment success rate of
Community-based approaches have been recognized as critical to preventing and treating TB. 88% among smear-positive cases and a smear-positive case detection rate of 79%. Despite these laudable accomplishments, TB and TB/HIV co-infection continue to pose a substantial burden on the health system in Tanzania and remain a significant cause of morbidity and mortality: almost 40% of all TB patients with known HIV status are co-infected with HIV. Similar to other high-burden countries for TB, Tanzania’s National Tuberculosis and Leprosy Programme (NTLP) is investing in training, new diagnostic technologies, implementation of TB/HIV collaborative activities, infection prevention and control, community-based approaches, and other activities to improve case detection and to build on their accomplishments in treatment success.

Despite the emphasis placed on community-based approaches globally and within the NTLP strategy, there are few published data on the effectiveness of these interventions on TB outcomes. With support from the U.S. Agency for International Development (USAID) and in collaboration with the NTLP, PATH designed and implemented a package of innovative community-based activities to improve TB case notification in Kisarawe District in Pwani Region. From 2009 to 2011, PATH’s district TB/HIV coordinator worked with local officials to implement, monitor, and evaluate the interventions and to collect data on key outputs and outcomes associated with improved case notification, with the goal of identifying effective and feasible models to scale up throughout Tanzania.

The unique efforts undertaken in Kisarawe District provided an opportunity for Tanzania to play a significant role in informing the global TB community about which interventions may yield gains in case detection and how to monitor and evaluate such community-based approaches.

**INTERVENTION DESCRIPTION**

The interventions were piloted and evaluated in Kisarawe District, located in Pwani Region in the Coastal Zone, between 2009 and 2011. Kisarawe is a predominantly rural area, with a population of about 100,000, bordering metropolitan Dar es Salaam. Although recent district-level data are not available, a 2004 health profile for the Coastal Zone estimated that communicable diseases account for 44% of the total burden of disease, including malaria, TB, and HIV/AIDS.

In 2009, the baseline smear-positive case notification rate was 31/100,000, and the TB/HIV co-infection rate among TB cases with known HIV status was 34%.

Efforts to improve TB case notification through community-based approaches included:

- **Sensitizing regional and district TB coordinators, community leaders, and community-based organizations** on the importance of community-based interventions to support the local TB program. Local PATH staff met with stakeholders, including the Council Health Management Team, to obtain their support for improving TB diagnosis and treatment services in general and for the new interventions specifically. Additionally, the PATH team consulted with Community’s Own Resource Persons (CORPs) and a community-based organization, MKUKI, formed by former TB patients, to request their support and participation in implementing the interventions.

- **Training pharmacists and traditional healers** to identify and refer individuals with TB symptoms for follow up and further evaluation in public-sector DOTS (Directly Observed Therapy Short-Course) diagnostic facilities. As in other settings, it was assumed that many people with TB symptoms seek care first from a pharmacist or traditional healer before going to a public-sector DOTS facility. To address potential diagnostic delays, PATH introduced a formal referral network between willing pharmacists and traditional healers and the DOTS diagnostic centers. In July 2009, 15 pharmacists and 15 traditional healers received 2-day training on basic information about TB and DOTS-based diagnosis and treatment, proper screening of symptomatic individuals, and how to use referral slips and registers to track referrals to DOTS. The participants also received a directory of DOTS facilities in Kisarawe to facilitate referral of symptomatic individuals.

- **Training, deployment, and supervision of 2 sputum fixers**—community members who collected sputum from symptomatic individuals at remote facilities that did not have smear microscopy; prepared and “fixed” slides; and then delivered them by bicycle to the nearest DOTS diagnostic facility and assisted in reporting results back to the facility where the individual first presented. This reduced the travel burden on symptomatic individuals and increased access to
smear microscopy. The sputum fixers worked sporadically throughout 2009 and 2010.

- **Training 8 current TB patients** to develop a series of informational materials with and for community members based on “TB Photovoice,” a methodology that combines photography with grassroots social action to increase awareness about TB at the community level and provides insight into the day-to-day life of people living with TB. (For further information, see www.tbphotovoice.org.)

This package of community-based interventions was expected to increase the number of symptomatic individuals seeking care in the public-sector DOTS program and to reduce barriers to diagnostic services, which in turn would lead to an increased number of smear-positive TB cases notified and treated in Kisarawe District, as compared with the pre-intervention period. During the implementation period, the PATH TB/HIV district coordinator supervised the interventions and provided ongoing feedback to the pharmacists, traditional healers, sputum fixers, and the TB patients involved with the photography project.

**EVALUATION METHODOLOGY**

No single data source can address the question of whether a specific intervention or package of interventions results in measurable improvement in TB case notification. Thus, we used a triangulation approach to analyze multiple sources of data that uniquely contribute to our understanding of the effectiveness of community-based approaches.

First, we analyzed routine case notification data from 2009 through 2011 to compare trends prior to implementation, during the start-up phase, and after the interventions were in place for 1 year to assess whether the overall trend in case notification improved over time.

Second, we reviewed programmatic data to determine how well the interventions were performing over time, examining qualitative and quantitative outputs with short- and medium-term outcomes related to case notification. For example, we designed a series of tools for pharmacists and traditional healers to document referrals of symptomatic individuals to DOTS clinics and followed referrals to determine how many were eventually diagnosed with TB in order to estimate the contribution of these activities to overall case notification. We compared programmatic outcomes, such as the number of TB cases diagnosed after referral, to the routine case notification data to determine the contribution of the referral mechanism by quarter.

Finally, we conducted a cross-sectional survey of recently diagnosed smear-positive TB patients (N=150), using a pretested questionnaire, from October 2010 through March 2011 in Kisarawe District to measure exposure to specific interventions and to assess health-seeking behavior after developing TB symptoms. Approximately half of the interviews took place at the Kisarawe District Hospital, where TB diagnostic procedures take place and treatment is initiated.

These data were entered into SPSS and simple analysis was performed to identify key characteristics of the patients; their knowledge, attitudes, and behavior related to health-seeking for TB symptoms; and their reported
experiences with accessing TB diagnostic services. The study received ethical clearance from the PATH Research Ethics Committee based in Seattle, Washington, USA, and from the National Institute for Medical Research in Tanzania.

RESULTS

Analysis of Routine Case Detection Data

From 2009 to 2010, during the pre-intervention and launch period, there was no change in the smear-positive case notification rate (28/100,000). After a full year of implementation (2011), the smear-positive case notification rate increased by 68% to 47/100,000 (Figure 1). The smear-negative case notification rate dropped initially before climbing back to the same level at the start of the intervention.

At the national level, the overall smear-positive case notification rate did not increase during the intervention period (14.3/100,000 in the first quarter of 2009 and 14.1/100,000 during the same reference period in 2011) (Figure 1). Trends for smear-negative and all pulmonary TB cases were similar to the direction observed for smear-positive cases.

Analysis of Programmatic Data

After pharmacists and traditional healers received training, we followed up with supportive supervision, including ongoing analysis of referrals made by these providers and received at the DOTS facilities. From January 2010 through March 2011, the 30 pharmacists/traditional healers referred 434 individuals with presumptive TB to DOTS facilities, and 419 individuals (97%) arrived at DOTS facilities for further diagnostic testing (Figure 2). Among those who arrived for testing, 104 individuals (25%) were diagnosed with TB (all forms) and started treatment. Among the 30 providers involved in this network, there were clear outliers in terms of their willingness to refer people with symptoms—some pharmacists and traditional healers consistently used the screening tools and referred people who met the criteria for referral each quarter, while others made almost no referrals and did not actively participate in the network.

It is notable that males and females are equally represented in the TB cases that were diagnosed and started treatment after referral, although more females than males were identified and referred by the pharmacists and traditional healers.

These data were compared with routine case notification over selected quarters to determine the contribution of the network to overall case notification in Kisarawe. Although we began supervision at the end of 2009, we did not have complete data for assessing the contribution of the intervention to case detection for a full quarter of operation until the first quarter of 2010. The percentage of new TB cases notified that were referred through the network ranged from 38% (in the second quarter of 2010) to 70% (in the first quarter of 2010) (Figure 3).

Routine output data on the activities of sputum fixers as well as on the photography...
project were also reviewed to document their potential contribution to case notification. From October 2010 to September 2011, the sputum fixers collected, fixed slides for, and delivered specimens from 178 symptomatic individuals; of these, 17 individuals (10%) were diagnosed with TB and started on treatment.

The resulting photographs and stories from the photography project were used to create educational materials for use in DOTS clinics, private pharmacies, schools, markets, district headquarters, wards, village offices, and in public places throughout the district. Additionally, community leaders used them to educate the community about TB and TB/HIV co-infection.

Survey of New Smear-Positive TB Patients
All smear-positive TB patients registered for treatment during the survey period were interviewed (N=150). Two-thirds of the participants were male, and one-third were female. Median age of the respondents was 38 years old, and almost half of respondents were 35–44 years old.

In terms of health-seeking behavior upon developing TB symptoms, almost 60% first visited a pharmacist or traditional healer before seeking care at a public-sector DOTS facility. Additionally, almost half of the respondents visited the DOTS center on the recommendation of a family or household member.

More than two-thirds (70%) of the surveyed smear-positive TB patients mentioned the presence of a CORPs in their village and that CORPs members often led community meetings. The majority (85%) reported that TB was mentioned at the monthly community meetings that they attended. More than 90% also reported seeing information about TB through print media, which are often prominently displayed in the DOTS facilities.

DISCUSSION
This evaluation of community-based interventions aimed at improving TB case notification in Kisarawe District in Tanzania yielded valuable insights about the potential outcomes of such interventions as well as about the inherent challenges that could compromise optimal program implementation and effectiveness. After 2 years of implementation, the case notification rate for smear-positive TB increased by 68%, and the referral network contributed between 38% and 70% of these notifications.

The survey of new smear-positive TB patients confirmed the importance of pharmacists and traditional healers in the care-seeking pathway of symptomatic individuals, as well as the potential of family and community members such as the CORPs to influence behavior. It also demonstrated the importance of community leaders in educating the public about TB, given the high percentage of survey participants who...
recalled CORPs’ discussion of TB at community meetings. In terms of operationalizing the interventions, the sensitization of district officials and stakeholders was critical for gaining support to conduct the community-based interventions. These findings confirm that NTLP should continue pursuing opportunities to integrate or further exploit the role of traditional healers/pharmacists and community members in the health system. In fact, the positive results of the pilot project prompted scale up to 9 more districts in 2011 and to another 26 districts in 2013.

At the same time, the evaluation revealed the limitations of community-based approaches in the context of larger health system and other challenges. For example, the initial decrease in smear-negative TB case notifications as the interventions were starting up was likely due to a stockout of X-ray film at Kisarawe Hospital early in 2010, which compromised the ability of the local TB program to confirm and notify smear-negative cases.

Additionally, there are a number of unanswered questions related to “uneven” results, such as the wide variation in the percentage of new TB cases referred through the pharmacist and traditional healer network, which ranged from 38% to 70% per quarter. This could have been due to a real difference in the number of symptomatic people during the first quarter of 2010 (for example, an outbreak of respiratory illness that caused chronic cough but was not TB) or due to changes in referral practice over time. Still, these data show that at the lowest contribution level, almost 40% of TB cases diagnosed during the quarter were referred through the network.

Given variability in the willingness of pharmacists and traditional healers to screen and refer, further investigation of their motivation is needed to effectively expand this intervention. It is worth exploring the performance of the “best” providers in terms of their referral practices and yield of TB cases in order to better understand why they are willing to participate in the intervention and what elements of the model could be refined for improved results. For example, is there a need for additional training or supervision? Are there incentives that might be effective in ensuring participation of the providers? Why were some pharmacists and traditional healers not supportive of the network? Are there certain provider characteristics that may result in better performance? An exploration of these questions may provide valuable insights to inform scale up of the intervention and to ensure that investments are spent wisely on providers who will likely contribute to case detection.

Finally, it is difficult to establish the benefit of training and deploying sputum fixers at the community level to assist with specimen transport to the district laboratory. Although fruitful in terms of supporting TB diagnosis and treatment in remote areas, this intervention was difficult to implement and to supervise. There was no funding to service the bicycles, and the rough geographical terrain limited their use, particularly during the rainy season.

**Limitations**

Although this evaluation yielded valuable information about the role of community-based interventions to improve TB diagnosis and treatment, the study design and implementation context have some limitations. First, it was difficult to measure exposure to some interventions in the survey of new smear-positive TB patients. For example, direct measurement of exposure to the informational materials was not captured because they were not specifically “branded” and because there are a number of TB and TB/HIV information, education, and communication materials in use. Second, the intensity of the interventions varied (30 non-DOTS providers trained in referral vs. only
2 sputum fixers), so it is difficult to judge the relative yield of each component without more equal intensity. However, the benefits of including pharmacists and traditional healers in the intervention are clear, given the importance of these providers as a first step along the pathway to TB care and the high rates of referral among some of those trained by the project. Third, due to funding limitations, there was no control district for which we could conduct a similar analysis to compare the different contexts. Future evaluations should include a control arm (to the extent possible) for a more rigorous assessment of the specific interventions. Finally, we do not know how many of the individuals with TB cases notified via referral would have sought care at a DOTS facility in the absence of the referral network, nor do we know whether the referral network decreased the time period between becoming symptomatic and visiting a DOTS diagnostic facility, both issues that should be studied further.

CONCLUSION

Community-based interventions, such as the establishment of referral networks and other activities that bring TB information and services closer to those with symptoms, can contribute to improved TB case notification. This pilot provides a model for evaluation of community-based approaches to TB case notification that can be applied to similar efforts worldwide. Future research needs include cost-effectiveness analysis to determine the best combination of community-based activities in a given setting.

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REFERENCES


Integrating family planning into postpartum care through modern quality improvement: experience from Afghanistan

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Modern quality improvement approaches enabled hospital staff to analyze barriers and identify solutions for “how” to integrate family planning into postpartum care. Private spaces for postpartum family planning (PPFP) counseling, along with involving husbands and mothers-in-law in counseling, substantially increased the percentage of women receiving PPFP counseling and their preferred method before discharge. Self-reported pregnancy was also significantly lower up to 18 months post-discharge compared with women receiving routine services.

ABSTRACT

To address low contraceptive use in Afghanistan, we supported 2 large public maternity hospitals and 3 private hospitals in Kabul to use modern quality improvement (QI) methods to integrate family planning into postpartum care. In 2012, QI teams comprising hospital staff applied root cause analysis to identify barriers to integrated postpartum family planning (PPFP) services and to develop solutions for how to integrate services. Changes made to service provision to address identified barriers included creating a private counseling space near the postpartum ward, providing PPFP counseling training and job aids to staff, and involving husbands and mothers-in-law in counseling in person or via mobile phones. After 10 months, the proportion of postpartum women who received family planning counseling before discharge in the 5 hospitals increased from 36% to 55%, and the proportion of women who received family planning counseling with their husbands rose from 18% to 90%. In addition, the proportion of postpartum women who agreed to use family planning and left the hospital with their preferred method increased from 12% to 95%. Follow-up telephone surveys with a random sample of women who had received PPFP services in the 2 public hospitals and a control group of postpartum women who had received routine hospital services found significant differences in the proportion of women with self-reported pregnancies: 3% vs. 15%, respectively, 6 months after discharge; 6% vs. 22% at 12 months; and 14% vs. 35% at 18 months (P < .001). Applying QI methods helped providers recognize and overcome barriers to integration of family planning and postpartum services by testing changes they deemed feasible.

INTRODUCTION

Afghanistan has one of the highest maternal mortality rates in the world at 327 deaths per 100,000 live births. Neonatal mortality is also high at 40 deaths per 1,000 live births, and only 20% of married women use modern contraceptive methods.

Multiple factors contribute to such poor health indicators, including poor health infrastructure, inadequate access to skilled service providers, insufficient access to emergency obstetric and newborn care services, and poor quality of health care.

The value of integrating health services has been recognized universally. Integrating services eliminates missed opportunities for efficiently reaching vulnerable populations with essential preventive and curative services. However, an important challenge in limited-resource settings lies in identifying “how” to integrate services in the face of resource constraints and an overburdened health work force.

The World Health Organization (WHO) defines quality of health care as the:
proper performance (according to standards) of interventions that are known to be safe, that are afford-able by the society in question, and that have the ability to produce an impact on mortality, morbidity, disability, and malnutrition.\textsuperscript{2,3}

Building on WHO’s definition of quality health care, quality improvement (QI) has been defined as:

- a cyclical process of measuring a performance gap; understanding the causes of the gap; testing, planning, and implementing interventions to close the gap; studying the effects of the interventions; and planning additional corrective actions in response.\textsuperscript{4}

The main implication of this definition is that strategies for QI are not “fixed.” On the contrary, QI is a continuous and dynamic process that measures and responds to the results of interventions.

The traditional approach to improving health care quality has been to apply evidence-based guidelines; conduct training; introduce job aids, materials, and equipment; improve supervision; and instill regulation, such as licensing and accreditation. But the new paradigm provided by modern QI, which is derived from 20 years of experience, is based on the understanding that a system is designed to produce the results it produces; in order to obtain better results, the system must change.\textsuperscript{5}

Hence, the emphasis is on analyzing the systems and processes of delivering services and testing changes to obtain better results. This requires thorough analysis of existing procedures and the service delivery workflow to identify areas of potential problems or delays—areas in which change can result in improvement. Resolution of unclear, redundant, or incomplete processes within a broader context is more practical and palatable than placing blame on individuals or on the lack of resources.

The modern paradigm for QI also puts the emphasis squarely on the client in contrast to the traditional medical model that emphasizes the disease. A client-centered perspective draws attention to his/her needs and expectations and frames them within his/her community—not within a health facility. Teamwork is another basic tenet of modern QI. Team members bring valuable insights, not only in identifying and prioritizing problems but also in developing innovative solutions.\textsuperscript{5}

The last decade has seen further adaptation of established QI methods to apply evidence-based standards for rapid change and large-scale impact: collaborative improvement. Collaborative improvement is a collective improvement activity that unites the efforts of a number of teams to work together to rapidly achieve significant improvements in processes, quality, and efficiency of a specific area of care, with intention of spreading these methods to other sites. Collaborative improvement uses structured, shared learning among participating teams to promote rapid dissemination of successful practices.\textsuperscript{6}

This article describes the value of applying modern QI methods to improve service quality and to facilitate the integration of health services in a resource-constrained setting. It discusses how applying such methods can help health care providers analyze the existing service delivery pattern, recognize barriers to integration, and test changes to achieve the desired service integration.

**QUALITY IMPROVEMENT PROCESS**

In 2012, we applied modern collaborative QI methods to facilitate the integration of family planning and postpartum care services in 5 high-volume delivery hospitals in Kabul, Afghanistan.

Two of the hospitals were large public hospitals (Malalai and Isteqlal), and 3 were private hospitals (Afghan, Mihi, and Shinozada). The 5 hospitals combined register approximately 47,000 deliveries annually.

To start the QI process, we first provided an orientation to the leadership and management staff of the hospitals and came to agreement with them on the program’s aim and methods. The concepts of modern QI and the implementation steps were explained to the staff.

Accordingly, the hospitals’ leadership selected a QI team for each hospital to implement the program. QI teams were comprised of physicians, nurses, and midwives working in the maternity wards with involvement of selected staff working in the family planning units. These QI teams received training on QI concepts and data collection and analysis. They were the leading implementers of the QI process and for measuring its results.

QI teams applied root cause analysis, a method of listing the main direct causes for not providing family planning counseling and services to postpartum women in their respective maternity wards and of identifying the reasons
for such causes. Hospital staff involved in postpartum care, including doctors, nurses, and midwives, grouped the main root causes of not offering family planning counseling routinely within postpartum care services into the following categories:

- Job expectations
- Skills and knowledge
- Logistics
- Service delivery environment
- Tools
- Culture

Under each category, staff wrote down the most important/direct cause. The outcome of the analysis contributed to directing the participants to the main areas where interventions were likely to result in the desired quality improvement. Subsequently, the teams suggested changes to the process of providing services to make family planning counseling and service provision an integral part of services offered to postpartum women before leaving the hospital.

To capture the most innovative and effective suggestions, the teams applied the process of brainstorming, in which each team member gets a chance to suggest interventions/changes to the process of service provision that, from his/her point of view, can contribute most to achieving the desired integration of family planning counseling and services within postpartum care. All suggestions were written on a flip chart. After all QI team members provided their suggestions, the teams discussed the potential benefit and feasibility of each suggestion and selected a group of interventions, or a “change package,” that was expected to yield the desired results and that was within the capacity of the hospital to implement.

In addition, the QI teams conducted brief and efficient assessments of the family planning counseling capacity of the service providers working at the maternity ward and the availability of family planning methods and services at their respective hospitals.

The QI teams received training on developing and measuring indicators to monitor the effect of the implemented change package, including how to construct “time series charts” to track the changes in the selected indicators over time.

Representatives of the QI teams from the 5 hospitals also met every 3 months to share the changes implemented in their respective hospitals, compare results obtained in each hospital, and discuss challenges for integration and their responses to addressing those challenges.

**DATA COLLECTION**

Common indicators that were measured in all participating hospitals and graphed on time series charts to measure the impact of the adopted changes on service integration included the following:

- % of postpartum women who received family planning counseling in the maternity ward before discharge
- % of postpartum women who received family planning counseling with their husbands before discharge
- % of postpartum women who agreed to use a modern contraceptive method
- % of postpartum women who left the hospital with their preferred contraceptive method
- % of compliance with postpartum family planning (PPFP) counseling standards

In addition, we conducted a longitudinal study in Isteqlal and Malalai hospitals in order to measure the outcomes of the PPFP collaborative improvement project. We randomly selected 643 women who received PPFP counseling and 681 women from the same 2 hospitals who received routine hospital postpartum care (that is, they did not receive systematic PPFP counseling), to form intervention and control groups, respectively.

Female family planning counselors from the hospital called these women at 3, 6, 12, and 18 months post-discharge to gather data on the return of menstruation and whether the women thought they were pregnant at the time of the call (that is, self-reported suspected or confirmed pregnancy). If the women reported that they were not pregnant, the interviewers asked whether they were using a contraceptive method and, if so, which method. The family planning counselors also used the opportunity of the follow-up calls to answer questions from women in the intervention group about contraceptive methods and to repeat key family planning messages. (Calls to women in the control group did not include such family planning messages.)

The project team compiled and analyzed the data using Excel to perform frequency distribution and tabulation, and compared the results of
intervention and control groups at 3, 6, 12, and 18 months of follow up.

RESULTS

Root Cause Analysis of Barriers to Integration

The most important barriers to providing family planning services at the postpartum ward, based on root cause analysis (Figure 1), included:

- Lack of private space for counseling at the postpartum ward
- Inability of some postpartum clients to decide on using contraception without consulting their husbands or mothers-in-law
- Limited family planning counseling skills of postpartum ward nurses and midwives
- Insufficient access to a variety of contraceptive methods at the postpartum ward

In addition, the assessment of the availability of family planning services present at the hospitals revealed that Malalai and Isteqlal hospitals (large public hospitals) have a partnership with the Afghan Family Planning Guidance Association (AFGA), a nonprofit organization specialized in providing family planning services. Due to this partnership, the 2 public hospitals had adequate family planning services with access to different contraceptive methods, including barrier methods, hormonal contraception, and intrauterine devices (IUDs). However, the smaller private hospitals (Afghan, Mihdi, and Shinozada) had limited family planning services, offering mainly barrier methods and some hormonal contraceptives.

Change Package of Interventions to Improve Integration

The QI teams introduced innovative changes to address these barriers, including creating a private space for providing family planning counseling near the postpartum ward, providing family planning counseling training to selected postpartum ward staff, providing staff with job aids, and involving husbands or mothers-in-law in the counseling session, if needed, sometimes via mobile phones for those unable to attend in person.

Creating private counseling spaces was particularly important since this made it possible for husbands, who were previously not allowed on maternity wards, to join their wives in the newly formed private counseling spaces.
husbands—who were previously not allowed into the maternity wards—to join their wives for the counseling session. The 2 public hospitals assumed responsibility for building a free-standing counseling room near the postpartum ward and forged links between the postpartum ward and AFGA to provide PPFP services. After receiving PPFP counseling, women in these hospitals who chose a method, such as the IUD, were referred to the AFGA unit located on the hospital grounds near the postpartum ward and the private counseling room.

The 3 private hospitals created a private family planning counseling space by repurposing unused rooms close to the postpartum ward. Postpartum women who chose a method not available at the private hospital were referred to family planning providers outside the hospital.

**Effects on PPFP Counseling and Use**

Using the time series charts, the QI teams tracked substantial increases in the percentage of postpartum women who received family planning counseling before leaving the hospital, from 36% in January 2012 before the new interventions had been implemented to 55% by November 2012 (among all 5 hospitals combined). In addition, the proportion of women who received family planning counseling with their husbands, either in person or by mobile phone, increased in the 5 hospitals, from 18% in January 2012 to 90% by November 2012.

There was also noteworthy improvement in the proportion of postpartum women who received family planning counseling and left the hospital with their preferred contraceptive method (Figure 2). At baseline, only 12% of postpartum women who received family planning counseling obtained their preferred method. Once systematic PPFP counseling was introduced with women and their husbands, the percentage increased to 36%, and when mothers-in-law were added, to 55%. By the end of the project in June 2013, 95% of postpartum women receiving family planning counseling at the hospital left the hospital with their preferred method.

Among the 580 postpartum women in Isteqlal and Malalai public hospitals who received family planning counseling and decided to use family planning, most chose condoms (42%) or the Lactational Amenorrhea Method (20%). At least 10% chose oral contraceptive pills, hormonal injectables, or IUDs (Figure 3). Postpartum women in the intervention group at Isteqlal and Malalai public hospitals were significantly less likely than women in the control groups to be pregnant at 6, 12, and 18 months post-discharge (Table). At 18 months, 14% of women receiving systematic PPFP counseling reported they were pregnant compared with 35% of women receiving routine hospital care in the control group.

**DISCUSSION**

**Solutions for Integrating Family Planning Into Postpartum Care**

This study provides valuable insights on the specific challenges of integrating family planning into postpartum care in Afghanistan. Involving husbands in the family planning counseling process posed a special challenge, highlighting the gender aspects of service integration. In Afghanistan, typically men are not allowed in the labor ward, delivery room, or postpartum ward, which posed a particularly difficult challenge. QI approaches inject a culture of creativity that allows involved staff to “think outside the box” to test innovations that they otherwise would not be allowed to try. In this instance, a private counseling room was created by the hospital itself, and husbands were invited, personally or by mobile telephone, to participate in the counseling session.

The inability of the maternity staff to provide a wide range of family planning services,
particularly long-acting methods such as IUDs, posed another important challenge. Providing such clinical contraceptive methods is more difficult than providing certain resupply methods, such as condoms, on postpartum wards. Again, thinking outside the box, the staff realized that long-acting methods were available in the family planning unit of the same hospital, and that improving the link between the maternity ward and the family planning unit could result in expanding contraceptive options for postpartum women. When the postpartum ward was not able to satisfy a particular family planning need, the link created with AFGA maximized family planning options for postpartum women.

Often, health programs focus on advocating the integration of services, emphasizing the potential health, programmatic, and financial benefits of integration. However, the question of “how” to overcome barriers to service integration is usually not addressed adequately. Health care providers generally appreciate the value of integration. Modern QI offers practical approaches to help providers understand the barriers to integrating services in their own context and to guide them in identifying and testing interventions to overcome such barriers.

**Applying Modern QI: Lessons Learned**

This study provides evidence that clinical providers in limited-resource settings are capable of absorbing concepts of modern QI and applying them, with some technical support, to integrate services. QI teams in the selected hospitals received orientation on QI and on tools for improving links between maternity wards and family planning units of the hospitals improved contraceptive options for postpartum women.
analyzing health services processes, such as patient flow analysis and root cause analysis. In addition, the teams received training in data collection, monitoring, and use.

The involvement of hospital leadership in the QI process was essential to gain support for the improvement intervention and to enable the QI teams to apply changes to the current system and test their impact. The service providers involved in the QI process reported that the approach was easy to grasp and could be used to improve other health services. They felt encouraged and empowered when they were able to measure their own results and see an improvement in the quality and volume of services provided. In addition, the process augmented the sense of teamwork and cooperation between different staff categories because it required involvement of doctors, nurses, and midwives working together.

The results show the value of QI approaches in helping health care providers to functionally integrate services, such as integrating family planning into postpartum care services. The study adds to the growing body of evidence that modern QI methods can achieve significant improvements in quality of care, even in underdeveloped health systems such as in Afghanistan. The same approach of developing staff capacity to analyze their own system, identify challenges for integration, and select and test changes to achieve integration has potential for application to integrating a wide range of services.

Our experience of applying modern QI approaches at the hospital level in Kabul provides several lessons for Afghanistan and beyond. First, involving and gaining the support of the institutions’ leadership is essential. To apply QI effectively, staff members need a non-threatening environment where they feel free to contribute their ideas openly in order to expose problems and suggest solutions. Such an enabling environment can be established only through the support of the institution’s leadership.

Table 1. Self-Reported Pregnancy (Suspected or Confirmed) Among Intervention and Control Groups, Isteqlal and Malalai Public Hospitals, Kabul, Afghanistan

<table>
<thead>
<tr>
<th>Duration Since Delivery</th>
<th>Intervention Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Selected Sample</td>
<td>Sample Successfully Contacted</td>
</tr>
<tr>
<td>3 months</td>
<td>643</td>
<td>303</td>
</tr>
<tr>
<td>6 months</td>
<td>303</td>
<td>217</td>
</tr>
<tr>
<td>12 months</td>
<td>217</td>
<td>207</td>
</tr>
<tr>
<td>18 months</td>
<td>207</td>
<td>149</td>
</tr>
</tbody>
</table>

Intervention group comprised postpartum women in the 2 public hospitals who received systematic postpartum family planning counseling; control group consisted of women from the same hospitals who received routine postpartum care. Difference between intervention and control groups is statistically significant (*P* < .001) at 6, 12, and 18 months follow up.
Second, service providers and other staff who are intimately involved in the services must be involved in the QI process. Such individuals tend to have first-hand knowledge of the barriers to quality service and hence are able to come up with creative and practical solutions to overcome the identified barriers.

Third, the QI process should be kept simple enough so that service providers own it. Simplifying the process increases the likelihood that service providers can establish and measure indicators to monitor the progress of the QI project. It also helps ensure that they can use results from monitoring activities to take corrective actions to improve the QI process and the services delivery outcome.

Limitations
The methodology used to track women after their hospital stay resulted in a potentially biased sample and in smaller sample sizes over time. The initial sample at 3 months post-discharge was randomly derived, but for each subsequent follow-up period, the sampling frame consisted only of women who had been successfully contacted during the previous follow-up period. In addition, since follow up was conducted over the telephone, the sample may have been biased in favor of more socioeconomically privileged women who had access to telephones. However, almost 90% of women originally sampled in both groups had access to a mobile telephone number. Finally, the self-reported nature of current pregnancy status could also have been biased. However, these sources of potential bias could be expected to affect the control and intervention groups equally.

CONCLUSION
Integration of health services requires more than simply emphasizing the importance of integration; providing simple approaches and tools to guide health staff to address “how” they can integrate services helps to ensure success. In addition, engaging providers in analyzing their own care processes can stimulate innovative problem-solving and creative solutions. Modern quality improvement approaches have an important role in empowering service providers to identify barriers to health services integration, analyze the causes of the barriers, and test interventions to overcome them.

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Competing Interests: None declared.

REFERENCES
Systems approach to monitoring and evaluation guides scale up of the Standard Days Method of family planning in Rwanda

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Scaling-up lessons included: (1) simplifying provider training and client materials; (2) ensuring core aspects of the intervention, for example, that the CycleBeads client tool was integrated into the supply chain system; (3) addressing provider-generated medical barriers; and (4) managing threats from changing political and policy environments. A focus on systems, the use of multiple M&E data sources, maintaining fidelity of the innovation, and ongoing environmental scans facilitated scale-up success.

ABSTRACT
There is no guarantee that a successful pilot program introducing a reproductive health innovation can also be expanded successfully to the national or regional level, because the scaling-up process is complex and multilayered. This article describes how a successful pilot program to integrate the Standard Days Method (SDM) of family planning into existing Ministry of Health services was scaled up nationally in Rwanda. Much of the success of the scale-up effort was due to systematic use of monitoring and evaluation (M&E) data from several sources to make midcourse corrections. Four lessons learned illustrate this crucially important approach. First, ongoing M&E data showed that provider training protocols and client materials that worked in the pilot phase did not work at scale; therefore, we simplified these materials to support integration into the national program. Second, triangulation of ongoing monitoring data with national health facility and population-based surveys revealed serious problems in supply chain mechanisms that affected SDM (and the accompanying CycleBeads client tool) availability and use; new procedures for ordering supplies and monitoring stockouts were instituted at the facility level. Third, supervision reports and special studies revealed that providers were imposing unnecessary medical barriers to SDM use; refresher training and revised supervision protocols improved provider practices. Finally, informal environmental scans, stakeholder interviews, and key events timelines identified shifting political and health policy environments that influenced scale-up outcomes; ongoing advocacy efforts are addressing these issues. The SDM scale-up experience in Rwanda confirms the importance of monitoring and evaluating programmatic efforts continuously, using a variety of data sources, to improve program outcomes.

BACKGROUND
Rwanda is the most densely populated country in Africa and one of the poorest countries in the world.1 Following the devastating 1994 genocide, the country made intensive efforts to improve its social, economic, and health conditions. But almost 2 decades later, the health system still faces many challenges, including meeting people’s reproductive health needs. In 2005, the total fertility rate was more than 6 children per woman, and almost 40% of women of reproductive age had an unmet need for modern contraceptive methods.2

In an effort to help women meet their contraceptive needs and achieve healthy timing and spacing of pregnancies, the Rwanda Ministry of Health (MOH) joined in partnership with the Institute for Reproductive Health (IRH) at Georgetown University, as well as with other private and faith-based health groups, to expand access to the Standard Days Method (SDM) throughout the country.

SDM is a fertility awareness-based method of family planning based on a woman’s menstrual cycle (Box). Because SDM is a low-cost fertility awareness-based
Box. What is the Standard Days Method?

The Standard Days Method (SDM) is a simple, fertility awareness-based method of family planning developed and tested by Georgetown University’s Institute for Reproductive Health. Based on reproductive physiology, SDM identifies the days in the menstrual cycle (days 8–19) when a woman can get pregnant if she has unprotected sex. CycleBeads, a color-coded string of beads, helps women track the days of their cycles when they are most likely to get pregnant. The method works best for women with cycles that usually range 26–32 days. Over half of women meet this criterion.

If the woman does not want to get pregnant, she and her partner avoid unprotected sex on days 8 through 19 of her cycle. An efficacy study found a failure rate for SDM of 5 per 100 woman-years when used correctly. The failure rate during typical use is 12 per 100 woman-years. SDM has been introduced and assessed in different facility and community-based service delivery settings for over 12 years. The U.S. Agency for International Development and the World Health Organization have globally recognized the method as a modern, evidence-based contraceptive practice, and it is currently offered in more than 30 countries.

The Standard Days Method is an inexpensive, fertility awareness-based method with no side effects, and it does not require follow-up visits or resupplies.

It takes time to integrate new contraceptive methods into routine M&E systems, so additional data sources are often needed to monitor scale up.

Method with no side effects, was acceptable to faith-based groups, and does not require follow-up visits or resupplies, it filled a special niche in the Rwandan family planning program.

The method had been integrated successfully into both clinical and community-based government services in pilot programs. Scaling up the pilot program to the entire country, however, was a complex task. International family planning research shows that unless a new method is introduced in a systematic and strategic way, results are not likely to be positive or sustainable. For scale up to be successful, understanding the changing environmental contexts in expanded geographic areas—which may differ in significant ways from the pilot sites—is critical, and the concerns of many key stakeholders must be addressed. Partner organizations are essential to expand access and to leverage technical and financial resources, but they often have different project and funding durations from the scale-up program.

Developing workforce capacity to offer the new family planning method as part of routine service delivery is at the heart of scaling up, but it takes multiple family planning actors to make this happen, each with varying roles, abilities, and resources to apply to the scale-up process. New methods must be included in supply chain systems, and it can take several years before changes become operationalized in periphery services. Budget allocations for a new method require advocacy and evidence to reassure policy makers during scale up that the program investment is worthwhile. New methods are not yet well-integrated into routine monitoring and evaluation (M&E) systems in the early stage of scale up, so additional information sources are required to monitor the pace of expansion and integrity of the innovation. Thus, the process of wide-scale integration of the new method within a complex health system cannot be controlled or monitored to the same extent as more localized introduction efforts during the pilot stage.

To inform our scale-up process, we adopted the principles of the World Health Organization (WHO)/ExpandNet conceptual framework for sustainable scale up, the corollary Nine-Step Guide to develop a strategic scale-up plan, and related guidance by Simmons and Shiffman, who summarize the characteristics of a good scaling-up strategy, based on diffusion of innovation theory and other literature on scaling up health practices. Such characteristics comprise:

- An intervention that can be adapted to fit into the existing health system
- A participatory approach that includes local and central stakeholders and policy makers
- Reliance on systematic use of evidence for decision-making
- An ongoing focus on sustainability

After providing a brief introduction about the outcomes of the pilot phase as well as goals and outcomes of national scale up, this article provides lessons learned about how to successfully scale up health interventions. These lessons demonstrate the importance of ongoing monitoring and evaluation efforts for making midcourse corrections that support successful scale up.
SDM INTRODUCTION AND SCALE UP IN RWANDA

Pilot Phase Demonstrates Demand for SDM
In 2002, we introduced SDM in Rwanda through a pilot program in 7 public health facilities, 5 clinics run by faith-based organizations, and 1 nongovernmental organization site. In 2004, we introduced SDM in 15 more facilities (Figure).

The pilot program generated substantial demand for SDM: service statistics showed that 23% of new method users chose SDM. Interviews and focus groups confirmed that the method was easy to offer by providers, was a viable choice for many couples, and was often adopted by women who had never before used a modern method. Offering SDM also had an additive effect on contraceptive prevalence rates, making it an attractive option for the Rwandan national family planning program.

Scale-Up Challenges and Goals
Between 2005 and 2007, the country revitalized family planning efforts, and the MOH took this opportunity to integrate SDM into the new family planning policies, norms, training curricula, and management information and logistics systems.

Within this favorable policy environment, geographic expansion of SDM services continued in 2007 under a 6-year, dedicated scale-up program. Considerable progress had been made already in both horizontal scale up (geographic expansion) and vertical scale up (institutionalization, such as, inclusion in norms, training, supervision, procurement, and reporting systems). But much work remained:

• The program had to expand to the many districts where SDM was not yet available and build the capacity of national and local organizations to offer the method without outside technical assistance.
• SDM had to be integrated into preservice training—a key element of sustainability.
• The revised family planning policies had to be operationalized so that CycleBeads, a tool to help women track their fertile and infertile days, and related instructional materials would be included in supply chains, and so that SDM would become part of routine service statistics.
• Even though there was top-level approval, scale up required advocacy to create support among policy makers and service providers at different levels for adding a new family planning method.
• Scale up also relied on mass media and community-level promotion to ensure...
potential clients knew of the new method option, its unique attributes compared with other methods, and where to find facilities that offered it.

The Rwanda MOH continued its close involvement with SDM scale up throughout the country via the Maternal and Child Health Task Force and its subsidiary Family Planning Technical Committee, made up of key family planning actors including MOH, donors, and international and national nongovernmental and faith-based organizations. End-of-project goals identified by partners and key stakeholders included:

1. Availability of SDM in 95% of public and private health facilities that offer family planning and in all community-based family planning services
2. Institutionalization of SDM into family planning support systems

To manage the complex set of actions required, the partners developed a strategic plan to achieve these goals over 6 years, which encompassed strategic planning and coordination of organizational roles, phased-in implementation of activities, M&E, and midcourse corrections throughout the process.

Scale-Up Outcomes
The dedicated scale-up effort using a systems lens led to near-nationwide availability of SDM by the end of the scale-up period. In fact, by the end of the scale-up project, 717 service delivery points included SDM in the method mix, surpassing the benchmark of 690, and more than 7,000 individuals had been trained to counsel clients on how to use SDM (Table 1). According to endline survey results, awareness of the method among women and men was on the same level as other, more established methods, and 7.4% of women using family planning chose to use SDM. Most women using SDM at the time of the survey were satisfied with the method (97.5%) and planned to continue using it (87.4%).

LESSONS LEARNED FROM MONITORING AND EVALUATING THE SCALE-UP PROCESS
Because scale up is a non-linear process that occurs within complex systems with engagement of multiple organizations and health system actors, strategic use of data from multiple sources throughout the scale-up process provides timely information to allow program corrections and to support the policy process. To provide useful information, our M&E efforts had to cut across multiple levels, sources, and phases (Table 2). Lessons learned about our scale-up process follow, demonstrating the importance of collecting and using data to make midcourse corrections that supported successful scale up.

Lesson Learned 1. Expect to simplify elements of the intervention—even if they worked in the pilot phase—to function at scale and to ensure sustained integration into existing systems.
Results of provider supervision and client follow-up visits revealed that providers and clients at the scale-up sites found the training protocols and client materials from the pilot phase too difficult to use. We realized that the SDM intervention needed to be simplified further to support its integration into the national family planning program, since we could not provide the same concentrated attention to the larger number of facilities and community settings as we did to the smaller number of pilot sites.

We then field-tested the resulting simplified user instructions, translated into Kinyarwanda (the native language in Rwanda), to ensure that providers counseled accurately and that clients received correct information using the modified instructions. Client materials were modified a
second time in preparation for including SDM in social marketing within private-sector pharmacies and clinics.

**Lesson Learned 2. Maintain integrity of core aspects of the innovation package.**

M&E efforts also exposed the importance of defining the intervention “package” clearly—in terms of ensuring both successful scale up and accurate assessments of availability of the package. Although some components of pilot projects must be adapted as mentioned under the first lesson learned, critical aspects of the intervention must remain intact for scale up. According to the partners’ definition, the core SDM package included CycleBeads (offered in a small plastic bag with instructions and a multi-year calendar), training curricula and in-service training materials for health care providers and supervisors, and awareness-raising materials and activities that focused on both men and women.

Assessment of data from multiple sources, including ongoing program monitoring data as well as national health facility and population-based surveys, revealed seemingly incompatible data findings about SDM availability in facilities and use among women. As it turned out, the national surveys used a different definition of the full SDM package, which made a substantial difference in SDM availability and use.

Specifically, according to the preliminary Rwandan Service Provision Assessment (SPA) issued in 2008,15 75% of facilities that offered family planning reported offering SDM—25% more than our scale-up monitoring data had indicated. However, interim Demographic and Health Survey (DHS)16 data found that while 64% of women had heard of SDM, only 0.3% of women said they were using it (Table 3). So although most facilities were seemingly offering SDM and most women had heard of the method, very few women were actually using it.

During the pilot phase, once women had become aware of SDM, there was sizable demand for it; 23% of new family planning users had chosen SDM during the pilot phase. Although method uptake is expected to be somewhat lower in scale-up sites than in pilot sites, and DHS included sites where SDM had not yet been introduced, the extremely low 0.3% user figure coupled with the seemingly high percentage of facilities offering the method signaled that something was wrong.

The SPA final report revealed that while 75% of facilities reported that SDM was available, CycleBeads were observed in only 12% of facilities—in reality, rendering the method unavailable.

### Table 1. First-Year and End-of-Project Outcomes Compared With Benchmarks

<table>
<thead>
<tr>
<th></th>
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<th></th>
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<tbody>
<tr>
<td></td>
<td>No.</td>
<td>% of Benchmark</td>
<td>No.</td>
</tr>
<tr>
<td>Service delivery points that include SDM in the method mix</td>
<td>356</td>
<td>51.2</td>
<td>717</td>
</tr>
<tr>
<td>Individuals trained to counsel clients on how to use SDM</td>
<td>1,679</td>
<td>31.0</td>
<td>7,472</td>
</tr>
<tr>
<td>Organizations that have capacity to undertake SDM activities</td>
<td>5</td>
<td>50.0</td>
<td>7</td>
</tr>
<tr>
<td>Essential or key policies, norms, guidelines, and protocols in which SDM is included</td>
<td>2</td>
<td>50.0</td>
<td>3.5</td>
</tr>
<tr>
<td>Public or private training organizations that include SDM in their preservice training and/or continuing education</td>
<td>5</td>
<td>100.0</td>
<td>5</td>
</tr>
<tr>
<td>Public or private training organizations that include SDM in their in-service training</td>
<td>4</td>
<td>40.0</td>
<td>7</td>
</tr>
<tr>
<td>Information, education, and communication activities, materials, and mass media that include SDM</td>
<td>7</td>
<td>58.3</td>
<td>12</td>
</tr>
</tbody>
</table>

Abbreviation: SDM, Standard Days Method. 

a Includes SDM pilot activity in the country starting in 2002.
in most facilities per the program’s definition. In the SPA report, SDM method provision was probably defined as having trained providers at the facility and/or having the method listed in the facility service statistics, without considering actual availability of CycleBeads and other package components.

In 2008, the MOH and the Maternal and Child Health Task Force acted on this evidence by tasking the DELIVER Project (a USAID-funded project supporting contraceptive supply systems) to address CycleBeads stockouts at facility levels. The DELIVER Project reviewed the mechanism used by health facilities to order contraceptive supplies (including CycleBeads), instituted a new procedure for requesting urgent supplies, and trained health centers and district pharmacists on contraceptive resupply, particularly for new, underused methods. The scale-up resource team became more vigilant in monitoring stockouts in collaboration with DELIVER Project staff.

About 1 year later, we conducted a facility assessment, in part to determine whether mid-course corrections to the supply chain had resolved the issue with stockouts. The results were encouraging: 90% of facilities offered SDM and only 8% experienced stockouts of CycleBeads in the 3 months preceding the survey (Table 4).

### TABLE 2. Monitoring and Evaluation Data Collection by Scale-Up Indicator

<table>
<thead>
<tr>
<th>Indicator</th>
<th>M&amp;E Method(^a)</th>
<th>Type of Data</th>
<th>Main Purpose</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Awareness and use of SDM</td>
<td>Household survey</td>
<td>Quantitative</td>
<td>Evaluation</td>
<td>Endline</td>
</tr>
<tr>
<td>• Availability of quality services</td>
<td>Service statistics</td>
<td>Quantitative</td>
<td>Monitoring</td>
<td>Monthly</td>
</tr>
<tr>
<td>• Provider competency</td>
<td>“Most Significant Change” story collection</td>
<td>Qualitative</td>
<td>Evaluation</td>
<td>Year 4</td>
</tr>
<tr>
<td></td>
<td>Provider supervision and client follow-up reporting</td>
<td>Quantitative</td>
<td>Monitoring</td>
<td>Ongoing</td>
</tr>
<tr>
<td></td>
<td>Simulated clients study</td>
<td>Quantitative</td>
<td>Evaluation</td>
<td>Baseline and endline</td>
</tr>
<tr>
<td><strong>Outputs</strong></td>
<td>Facility/service delivery point survey</td>
<td>Mixed</td>
<td>Evaluation</td>
<td>Baseline</td>
</tr>
<tr>
<td>• Providers trained</td>
<td>Stakeholder interviews</td>
<td>Qualitative</td>
<td>Evaluation</td>
<td>Baseline and endline</td>
</tr>
<tr>
<td>• Clinics offering SDM</td>
<td>Benchmark reporting</td>
<td>Quantitative</td>
<td>Monitoring</td>
<td>Semiannually</td>
</tr>
<tr>
<td>• Demand-oriented Information, Education and Communication (IEC)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Supportive partners/stakeholders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Systems integration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td>Staff assessments of data on scale-up status</td>
<td>Qualitative</td>
<td>Monitoring</td>
<td>Annually</td>
</tr>
<tr>
<td>• Scale-up strategy</td>
<td>Organizational capacity assessments</td>
<td>Qualitative</td>
<td>Evaluation</td>
<td>Ongoing</td>
</tr>
<tr>
<td>• Dissemination and advocacy</td>
<td>Environmental scanning, including key events timeline reporting</td>
<td>Qualitative</td>
<td>Monitoring</td>
<td>Ongoing</td>
</tr>
<tr>
<td>• Organizational capacity-building process</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Resource mobilization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Environmental influences</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: M&E, monitoring and evaluation; SDM, Standard Days Method.
\(^a\) Classification based on method’s main M&E contribution, although there is overlap; for example, stakeholder interviews also assessed environmental influences, and resource mobilization was documented as part of benchmarking.
Lesson Learned 3. Track and address provider performance to avoid unnecessary medical barriers and ensure fidelity of new method protocols at scale.

A family planning innovation can also lose fidelity during scale up from provider bias and medical barriers. Integration of a new method in a service delivery system requires that providers not only are trained to offer the method but also appreciate its added value, since the providers must adjust their services to include the new method in their program.

During the SDM pilot program, it became clear that many providers doubted whether a fertility-awareness method could be effective. Perhaps in an effort to increase efficacy, some providers applied eligibility criteria that were neither part of the SDM service delivery protocol nor of evidence-based practice, which made the method less accessible. Specifically, some providers required women to monitor their cycle length for several months prior to initiating SDM; to be menstruating at the time they begin using the method; or to have their partner present during the counseling session.

Supervisors corrected such practices during the pilot phase, but this was not feasible during scale up. Early in the scale-up process, MOH district supervision reports provided observational and anecdotal evidence of alterations in the SDM service-delivery protocol. But to document and better define the existence of barriers to SDM adoption in routine service settings, we conducted a special simulated client study in conjunction with the 2009 facility assessment (mentioned under the second lesson learned). The simulated client study was conducted in facilities where providers were not interviewed for the facility assessment.

Simulated clients were women trained to play the role of clients seeking family planning services. They used specially designed client profile scripts that included contraceptive history, partner relationship, and method preference. After each clinic visit, the simulated clients completed a checklist about their experience that included more than 80 objective yes/no indicators regarding what should be included in quality counseling in general, and in counseling on SDM in particular. Items included eligibility screening for using the method, mechanisms of action, use of CycleBeads, correct condom use (for those who wished to use condoms on their fertile

### TABLE 3. Contraceptive Availability in Facilities Offering Family Planning and Knowledge and Use Among Married Women of Reproductive Age

<table>
<thead>
<tr>
<th>Method</th>
<th>Contraceptive Availability in Facilities&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Contraceptive Knowledge and Use&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Offer Method</td>
<td>% Method Available on Day of Survey</td>
</tr>
<tr>
<td>Standard Days Method</td>
<td>75</td>
<td>12</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>6</td>
<td>77.0</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>4</td>
<td>89.1</td>
</tr>
<tr>
<td>Pills</td>
<td>93</td>
<td>91.3</td>
</tr>
<tr>
<td>Intrauterine devices</td>
<td>20</td>
<td>51</td>
</tr>
<tr>
<td>Injectables</td>
<td>93</td>
<td>51</td>
</tr>
<tr>
<td>Implants</td>
<td>49</td>
<td>44</td>
</tr>
<tr>
<td>Male condoms</td>
<td>91</td>
<td>91.3</td>
</tr>
<tr>
<td>Female condoms</td>
<td>35</td>
<td>57</td>
</tr>
<tr>
<td>Emergency contraceptive pills</td>
<td>16</td>
<td>22</td>
</tr>
</tbody>
</table>

<sup>a</sup> Source: Rwanda Service Provision Assessment, 2008, Tables A-5.1 and A-5.2.<sup>15</sup>

<sup>b</sup> Source: Rwanda Interim Demographic and Health Survey, 2008, Tables 5.1, 5.3.1, and 5.4.<sup>16</sup>
days), couple communication about the fertile days, and follow up if there were any problems. This methodology had been validated in a number of previous studies. To respect principles of informed consent in research, providers in 28 selected facilities from the random sample of facilities participating in the facility assessment consented to be visited by a simulated client sometime over the next year, without knowing the specific date of the visit.

The facility assessment found that 94% of facilities had providers trained to offer SDM, and 94% had CycleBeads in stock. However, the simulated client study showed clearly that providers were creating unnecessary medical barriers to SDM use, thus diminishing method integrity and availability. For example, 21% of simulated clients were not offered SDM despite having the appropriate profile for the method (Table 4). One client who received SDM counseling did not receive CycleBeads at the time of her visit; the provider told her to return when her period started. Others who were given information but not counseling about SDM were also told to return when they got their period or to return with their partner so he could be present for the counseling. Moreover, one provider told a client that she did not offer SDM to her clients because she did not trust the method.

The MOH’s Maternal and Child Health Task Force and the Family Planning Technical Committee addressed these issues through refresher training and revised supervision protocols in the remaining years of the scale-up process. MOH supervisors worked with providers to become comfortable with offering the new method, including addressing questions of method effectiveness and reducing medical barriers. A small internal study conducted in 2011 evaluated the effectiveness of the focused supervision approach and found significant improvement. This improvement was confirmed by later supervision visits around the time of the endline evaluation for the scale-up project.

**Lesson Learned 4:** Regularly scan, identify, and address changing environmental influences on scale up.

Since scale-up processes operate within the complex systems in which family planning services are embedded, it is critical to scan environmental factors that may be influencing scale up, such as changes in national leadership or a family planning trend that becomes apparent only through repeated discourse. A cross-country analysis of factors influencing scale up of SDM in Rwanda and 4 other countries

| TABLE 4. Results From the Rwanda SDM Scale-Up Facility Assessment and Simulated Client Study, April 2009 |
| Facility Audit (N=118 facilities) % | |
| Facilities in which the program manager said that SDM was offered | 89.9 |
| Facilities with health providers trained to offer SDM | 94.1 |
| Facilities in which CycleBeads were available on day of audit | 94.0 |
| Facilities experiencing stockouts of SDM in the 3 months prior to the audit | 7.6 |
| Provider Interviews (N=155 providers) % | |
| Trained providers that demonstrated correct knowledge of SDM (on 4 key indicators) | 78.0–97.2 |
| Trained providers who offered SDM to at least 1 client in the 3 months preceding the interview | 90.8 |
| Simulated Clients (N=28 simulated client visits) % | |
| Received SDM counseling during the visit | 78.6 |
| Received CycleBeads during the visit | 75.0 |
| Correctly screened for cycle regularity | 81.8 |

Abbreviation: SDM, Standard Days Method.
Democratic Republic of Congo, Guatemala, India [State of Jharkhand], and Mali) revealed the importance of the political and health policy environments; such factors are not typically identifiable via routine monitoring systems because they are often unexpected, imprecise, and come from a host of sources. Therefore, we collected data on environmental factors through other methods including:

- Informal environmental scans to obtain information on social, economic, political, and policy changes but in relatively unstructured ways
- Interviews with staff and scale-up partners to explore their knowledge of the political and policy environments within and external to the national family planning program; this became a regular source of data collection
- Key events timeline, updated semiannually, to track important changes and stakeholder interviews
- FP stakeholder interviews gathered perceptions of forces and factors that might affect scale up from politically connected experts

Assessments from these data sources confirmed that SDM scale up benefited from the Rwandan government’s vision of family planning as a crucial national development tool. However, they also revealed the existence of counterforces. In particular, government policy discourse during the scale-up period focused heavily on long-acting and permanent methods which tended to divert attention from SDM. Also, data from environmental scans picked up changes in health financing policies during the second year of scale up. The MOH began promulgating a health-sector performance-based financing (PBF) system about the same time that scale up of SDM was progressing. The system provided incentives for well-performing health centers based on the quantity and quality of specific services they delivered, and while SDM was added to the system in 2009, it was dropped in 2010. Essentially, providers had financial incentives to offer other modern methods but not SDM, thus challenging sustainability of the method.

In response to these environmental obstacles, we positioned SDM among policy makers and influential technical stakeholders as a contraceptive option with unique attributes that filled an important niche in family planning programs. It is a long-acting method since clients can and do continue to use the method for years, it helps to involve male partners, and it increases women’s empowerment through basic understanding of their fertility. In addition, we began one-on-one advocacy efforts with individuals who were influential within the PBF Unit and technical arms of the MOH to provide sound rationales for including SDM in the PBF system. As the 6-year scale-up period ended, this critical issue for sustainability was still unresolved. However, champions had been identified to press the issue further on policy and technical grounds, and it appeared on the way to resolution.

**CONCLUSION**

SDM scale up is continuing in Rwanda, as it is in other countries, and the Maternal and Child Health Task Force and other family planning actors are organized to ensure sustainability of method integration.

M&E from multiple sources, including routine monitoring data and impact evaluations as well as special studies and national surveys, played a critical role in scale up by providing timely information for evidence-based decision-making and midcourse corrections to address a number of implementation issues. We learned several important lessons about facilitating nationwide expansion of a new service into an existing FP program and related integration of the service into existing FP support systems. Likewise, as we monitored the
process of scale up we learned several important lessons about designing effective M&E systems that recognize complex environments.

First, it is important to apply a systems lens to monitoring and evaluating the scale-up process and for maintaining a focus on sustained availability of quality services over time. We needed data to inform progress in all subsystems relevant to scale up, such as logistics, policies, demand creation, and provider training. This required multiple sources of data as no individual source of data could accurately reveal all the facets of the situation.

Second, data collected for evaluation purposes do play an important role in monitoring for midcourse corrections during scale up. It is important to not conflate impact evaluation with periodic evaluation, which provides timely information throughout a scale-up process. Secondary data sources such as the SPA were very useful in this case, given limitations of funding for primary M&E data collection.

Finally, environmental scanning facilitates the ability of the resource team to address political issues related to scale up in a systematic manner. Timely and accurate information about stakeholder opinions, political events, upcoming policy changes, and resource allocations will increase the effectiveness of resource teams to support the scale-up process.

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FIELD ACTION REPORT

Informed push distribution of contraceptives in Senegal reduces stockouts and improves quality of family planning services

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Dedicated logisticians restocked contraceptives monthly at facilities to maintain defined minimum stock levels, freeing up clinic staff. High stockout rates were virtually eliminated. Also, quality and timely data on contraceptives distributed allowed for better program management.

ABSTRACT

Contraceptive use in Senegal is among the lowest in the world and has barely increased over the past 5 years, from 10% of married women in 2005 to 12% in 2011. Contraceptive stockouts in public facilities, where 85% of women access family planning services, are common. In 2011, we conducted a supply chain study of 33 public-sector facilities in Pikine and Guediawaye districts of the Dakar region to understand the magnitude and root causes of stockouts. The study included stock audits, surveys with 156 consumers, and interviews with facility staff, managers, and other stakeholders. At the facility level, stockouts of injectables and implants occurred, on average, 43% and 83% of the year, respectively. At least 60% of stockouts occurred despite stock availability at the national level. Data from interviews revealed that the current “pull-based” distribution system was complex and inefficient. In order to reduce stockout rates to the commercial-sector standard of 2% or less, the Government of Senegal and the Senegal Urban Reproductive Health Initiative developed the informed push distribution model (IPM) and pilot-tested it in Pikine district between February 2012 and July 2012. IPM brings the source of supply (a delivery truck loaded with supplies) closer to the source of demand (clients in health facilities) and streamlines the steps in between. With a professional logistician managing stock and deliveries, the health facilities no longer need to place and pick up orders. Stockouts of contraceptive pills, injectables, implants, and intrauterine devices (IUDs) were completely eliminated at the 14 public health facilities in Pikine over the 6-month pilot phase. The government expanded IPM to all 140 public facilities in the Dakar region, and 6 months later stockout rates throughout the region dropped to less than 2%. National coverage of the IPM is expected by July 2015.

CONTEXT

Family planning use in Senegal is among the lowest in the world and has barely increased over the past 5 years, from 10% among married women in 2005 to 12% in 2011. 1 This low modern contraceptive prevalence rate (MCPR) is an important limiting factor for the country to achieve Millennium Development Goal 5 (improve maternal health), given a current maternal mortality ratio of 392 per 100,000 live births. 1

Unmet need for family planning is high, estimated at 29%. 1 In other words, nearly 1 currently married woman of every 3 wants to delay her next birth or stop childbearing entirely but is not using contraception. In the Dakar region, where almost one-quarter of the country’s population lives, unmet need is even higher, at 32%, despite a higher MCPR of 21%. Recognizing the critical importance of addressing unmet need for family planning, the Government of Senegal set an ambitious goal to increase MCPR among married women from 12% to 27% between 2011 and 2015,
The public-sector distribution system is a pull-based system that requires health facilities to replenish supplies using limited cash on hand, which would result in approximately 350,000 additional family planning users.

In support of this goal, the Bill and Melinda Gates Foundation is providing funding to IntraHealth International to implement the Urban Reproductive Health Initiative (URHI) in Senegal, a collaboration with government and nongovernmental partners to demonstrate that improving the quality of integrated maternal and reproductive health services and expanding the role of the private sector in providing family planning can significantly increase contraceptive use. URHI is testing innovative approaches to improve quality of and expand access to family planning information, supplies, and services, with a goal of achieving a 20 percentage point increase in modern contraceptive uptake in urban areas of Senegal.

Early on in the project, it became apparent that contraceptive stockouts in public facilities (where 85% of women access family planning services) severely limited URHI’s ability to test service delivery and demand creation interventions. More critically, anecdotal evidence indicated that women who sought family planning services at health facilities were frequently denied their preferred contraceptive method due to stockouts.

This article reviews results of a supply chain study to understand the magnitude and root causes of stockouts. It also provides an overview of a new distribution system pilot-tested in 1 district of Dakar and the effects of that system on stockout rates and overall management practices.

METHODS

We conducted a study between July 2011 and December 2011 of the in-country supply chain serving public-sector facilities in the adjacent districts of Pikine and Guediawaye in the Dakar region. At the time of the study, Pikine had a total population of approximately 375,000, served in the public sector by 3 obstetricians/gynecologists and 39 midwives across 1 health center and 13 health posts. Guediawaye had a total population of approximately 333,000, served in the public sector by 3 obstetricians/gynecologists and 35 midwives across 1 health center and 18 health posts.

The study included contraceptive stock audits over a 6-month period and a review of the previous 12 months of stock data at these 33 public-sector health facilities as well as at the district, regional, and national warehouses. In addition, we surveyed 156 consumers and interviewed facility staff, health system managers, government leaders, and donors.

A contraceptive stockout was defined as zero units available for sale at the facility on a day when the facility was open. To derive an annual percentage rate of stockouts, the number of days that a product was stocked out at a facility over a 1-year period was divided by 261 days of operation for that facility.

RESULTS

According to facility audits, stockouts of injectable contraceptives occurred, on average, 43% of the year. For this method, which requires 4 injections per year for effective contraceptive protection, a 43% stockout rate poses a significant barrier to continuous and sustained use. For contraceptive implants, the stockout rate was almost twice as high, at 83% of the year.

Through interviews with women currently using contraceptives, 84% reported that they had experienced a stockout of their preferred method in the past year. Among women experiencing a stockout, 55% switched methods (often to a less effective method), and 45% either discontinued use or went to the private sector and paid 3 to 9 times the price they would have paid at the public-sector facility.

Based on the warehouse and facility audits, we estimated that at least 60% of stockouts occurred despite stock availability at the national level, indicating that the in-country distribution system was not designed well or functioning effectively. Interviews and field observations revealed the following key issues:

- The public-sector distribution system is a highly complex “pull-based” system, involving an excessive number of steps and relying on about 900 midwives at service delivery points (SDPs) to accurately forecast, track, and order contraceptives. There are several problems with relying on midwives to manage stocks: the midwives lacked training on and ownership of the process, and more importantly, they lacked time because they were busy providing reproductive, maternal, and child health services.

- The pull-based system requires health facilities to replenish supplies using their own cash on hand, that is, working capital.
practice, most facilities have limited working capital, and so they are compelled to prioritize commodities that generate higher margins for the facility. Contraceptives generate relatively low margins, and so they are not a high priority, resulting in either limited or no replenishment of the facility’s contraceptive stock.

- Facilities are responsible for picking up supplies from warehouses at their own expense, and frequently health care providers must take time away from providing services to perform this task.
- Many facilities maintain poor inventory records, thus providing little visibility into contraceptive method preference and consumption. The lack of accurate and timely data limits the country’s ability to monitor and manage the performance of the family planning program.

KEY MEASURES FOR IMPROVEMENT

With clear evidence and data on the magnitude of stockouts and the associated impact on individual and population health indicators, the government became highly motivated to reduce stockout rates to the commercial-sector standard of 2% or less. In addition, reliable data on product consumption across methods and facilities were critical to monitor the performance of the supply chain and to understand service delivery patterns.

STRATEGY FOR CHANGE

To achieve our goal of an aggressive reduction in stockouts, we analyzed commercial-sector solutions and applications of those solutions in public health systems. The “Delivery Team Topping Up” system in Zimbabwe, a successful example of a widely practiced vendor-managed inventory model, provided a foundation on which to build a model adapted to Senegal’s environment and needs.

URHI and the Government of Senegal developed the “informed push distribution model” (IPM) and tested it in Pikine district over a 6-month pilot phase from February 2012 to July 2012. IPM brings the source of supply (a delivery truck loaded with supplies) closer to the source of demand (clients in health facilities) and streamlines the steps in between. With a professional logistician managing stock and deliveries, the health facilities no longer need to place orders and spend time picking up products (Figure 1).

Key features of the IPM include:

- Initial stock of contraceptives is provided at no cost to each facility.
- Dedicated logistics restock facilities on a monthly basis to maintain a minimum level of stock that is defined by the logisticiant around 2 months of estimated supply needs.
- Facilities pay only for the quantity of products that were sold and keep the margin.


A private logistician delivers contraceptives and collects data at a health post in Pikine, Senegal.
Logisticians collect data on product consumption at the time of delivery and report that data to the district medical chief within 72 hours.

Logisticians are paid according to fixed-fee contracts that clearly define requirements and penalties based on stockout rates and data availability. During the pilot study, logistician contracts were funded and managed by the URHI program.

Contraceptive sales revenue covers the cost of the logistician contracts.

**EFFECTS OF CHANGE**

The effects of IPM implementation in Pikine were immediate and sustained. Stockouts of contraceptive pills, injectables, implants, and intrauterine devices (IUDs) were completely eliminated at all 14 public health facilities in the district over the course of the 6-month pilot phase. In the month before IPM was implemented, injectables and pills were stocked out in 57% of facilities, implants were stocked out in 86% of facilities, and IUDs in 14% (Figure 2). During the same pilot period, in the neighboring district of Guediawaye where IPM was not implemented, stockouts of these products persisted, on average, at 23% of facilities.

Based on this dramatic impact on stockouts, the government decided to expand IPM to all 140 public facilities in the Dakar region; 6 months later, stockout rates throughout the region dropped to less than 2% according to facility and delivery records.

Importantly, district and regional health managers now have access to timely and accurate monthly contraceptive consumption data from each participating SDP, as required by the

**FIGURE 1. Informed Push Model Streamlines Deliveries and Eliminates Orders Between Service Delivery Points (SDPs) and the Regional Warehouse**

*Informed push distribution of contraceptives in Senegal www.ghspjournal.org*
logistician contracts, which enables the managers to quickly identify and address performance issues. For example, the Pikine district health management team identified a clinic that consistently consumed fewer implants than neighboring clinics. During a follow-up visit, the team learned that the midwife responsible for providing implants was uncomfortable with the procedure and unmotivated to learn it since she was nearing retirement. The management team responded by prioritizing this site to receive a newly graduated midwife; once placed, implant consumption increased to a level similar to that recorded in neighboring clinics.

In another example of performance management enabled by the IPM data, the district noticed a significant decline in implant consumption across facilities in a single month. The management team quickly learned that there was a shortage of the local anesthetic used for the implant procedure, which triggered an emergency order at the national level.

In Pikine, after 1 full year of implementing the informed push model (the 6-month pilot plus the following 6 months during expansion to the entire Dakar region) and maintaining stock of the full range of contraceptive methods, coupled with demand creation interventions and service delivery improvement measures, the average monthly consumption of pills increased by 127%, injectables by 121%, implants by 2,081%, and IUDs by 68%. These increases translate to an estimated growth in MCPR of approximately 11 percentage points in 1 year in Pikine, an unprecedented rate of growth in Senegal (Figure 3).

When all methods are available at a facility, health care providers are more comfortable counseling women on the full range of options, and the woman has the opportunity to select the method she prefers without the influence of stockouts. In fact, since stockouts have been eliminated in Pikine, the method mix has evolved with a greater proportion of women selecting long-acting methods (Figure 4). In addition, other positive changes resulted from IPM implementation. First, health care workers spend more time providing care to patients.

### Abbreviation: IUDs, intrauterine devices.
FIGURE 3. Average Monthly Consumption of Contraceptives in Pikine District, Dakar, Senegal, Before and 1 Year After IPM Implementation

- **Implants**: Jan-Feb 2012 (16), Aug-Oct 2012 (175), Jan-Mar 2013 (349), +2,081%
- **IUDs**: Jan-Feb 2012 (34), Aug-Oct 2012 (54), Jan-Mar 2013 (57), +68%
- **Injectables**: Jan-Feb 2012 (992), Aug-Oct 2012 (1,642), Jan-Mar 2013 (2,190), +121%
- **Pills**: Jan-Feb 2012 (1,544), Aug-Oct 2012 (2,746), Jan-Mar 2013 (3,503), +127%

Estimated annual growth in MCPR: ~11 percentage points

Abbreviations: IPM, informed push model; MCPR, modern contraceptive prevalence rate.

FIGURE 4. Method Mixa Before and 1 Year After IPM Implementation, Pikine District, Dakar, Senegal

- **January-February 2012**
  - IUDs and Implants 9%
  - Injectables 59%
  - Pills 32%

- **January-March 2013**
  - IUDs and Implants 24%
  - Injectables 48%
  - Pills 28%

Abbreviations: IPM, informed push model; IUDs, intrauterine devices.
a Excluding condoms.
workers have more time to provide care to patients because they do not have to manage stocks and logistics. Second, the regional and district health managers who experienced the impact of IPM for contraceptive products are advocating to use this distribution system for additional products. One example of where this has worked is in the region of Saint Louis, where 2 mobile warehouses were in place to deliver vaccines. The IPM was adapted to use the mobile warehouses for contraceptive distribution and data collection, and subsequently the regional managers insisted that HIV, malaria, tuberculosis, and essential medicines were also delivered via the mobile warehouses. This adapted version of IPM requires additional study to determine its cost-effectiveness relative to the contraceptive-only model implemented in Pikine.

**NEXT STEPS**

In 2012, the Ministry of Health developed and launched a national family planning plan. Given the positive IPM results from Pikine, one of the key pillars of the plan is national expansion of the IPM. By July 2014, the plan calls for scaling up IPM throughout the 6 regions that comprise more than 65% of the population, and to national coverage by July 2015 (Figure 5).

To support rapid national expansion, the Bill and Melinda Gates Foundation and Merck for Mothers are providing funding to IntraHealth International to support the Government of Senegal to establish standard operating procedures; issue and manage contracts with private logisticians; provide training to those engaged in the system; and support data use and performance management. The IPM is currently designed to maintain preexisting financial flows to the extent possible while introducing payment of contracts with private logisticians. As the model expands into regions that are less densely populated, and with more difficult road conditions, modifications to the model are expected to enable delivery optimization. According to an agreed-upon schedule through mid-2016, these functions will be funded and overseen by the government in a phased manner.

To ensure financial sustainability of the IPM, the government is evaluating different scenarios, and IPM design will remain flexible to respond to the most cost-effective and politically viable option. At present, the government is committed to advancing implementation of the IPM for family planning products, and there is interest in conducting an in-depth product segmentation analysis to guide the potential inclusion of other

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**FIGURE 5. National IPM Scale-Up Plan, Senegal**

<table>
<thead>
<tr>
<th>Date</th>
<th>Geographic Coverage</th>
<th>Population Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb 2012</td>
<td>Pilot in 2 districts</td>
<td>8%</td>
</tr>
<tr>
<td>Jun 2012</td>
<td>Expansion to Regions of Dakar and Saint-Louis</td>
<td>28%</td>
</tr>
<tr>
<td>Dec 2012</td>
<td>Extension to Regions of Thies &amp; Kaolack</td>
<td>47%</td>
</tr>
<tr>
<td>Apr 2013</td>
<td>Coverage of 6 regions of Senegal</td>
<td>65%</td>
</tr>
<tr>
<td>Jul 2014</td>
<td>Full national coverage</td>
<td>100%</td>
</tr>
</tbody>
</table>

Abbreviation: IPM, informed push model.

Senegal plans to scale up the informed push model nationally by 2015.
health products. Preliminary analysis suggests that the annual sales revenue from contraceptives when volumes reach the level required to support a national MCPR of 25% to 30% will be about US$1,050,000. At a national scale in the contraceptive-only scenario, the operating cost of the IPM was estimated at about $500,000, approximately 11% of national annual spending on contraceptives. While further study to refine the cost estimates is needed, a number of strategies to maintain funding for the IPM at national scale are under consideration, for example, using revenue from contraceptive and other product sales, including a government budget line item for product distribution, and collaborating with other donors and multilateral programs supporting product distribution.

Today, the public health system in Senegal is served by 7 unique supply chains, one for each of the 7 different product groups. Each vertical supply chain is funded through a unique agreement between a donor, the Ministry of Health, and the National Pharmacy, resulting in a wide range of operating procedures, personnel trainings, supervisory structures, data collection tools, and reporting requirements. The net effect is a distribution system that is uncoordinated and inefficient, resulting in stockouts across all product groups. With the political will and donor flexibility to better coordinate and manage this multiplicity as a segmented system, cost savings across Ministry of Health programs could be significant. Further analysis of costs associated with the current public-sector distribution channels across product categories is recommended, along with a comparative analysis of the cost per unit of product delivered through alternative distribution models.

CONCLUSION

This pilot study of the informed push distribution model demonstrated feasibility as an appropriate and effective solution to contraceptive stockouts in Senegal, generating timely and accurate data on contraceptive consumption by facility. Access to and use of this data is transforming public health management practices in general, fostering a culture of data-driven performance improvement throughout the system. Achievement of Senegal’s goals for family planning depend on the successful implementation of all priority interventions in the national plan, including demand generation, improved provider capacity, and an expanded network of SDPs: the IPM ensures availability of the products and data that underlie such success.

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