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

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EDITORIALS

Effective LARC Providers: Moving Beyond Training (Republication)

Effective and productive providers are the key to successful provision of long-acting reversible contraceptives (LARCs). But LARCs demand more of providers than short-acting resupply methods. In addition to sound training, key elements to developing highly productive providers of LARCs include a thorough understanding of the service delivery system context; selecting providers with the most potential, especially from mid-level cadres; strong mentoring and supportive supervision; and attention to the supply chain and to demand-side support.

James D Shelton, Anne E Burke
http://dx.doi.org/10.9745/GHSP-D-16-00258

VIEWPOINTS

Moving Medicine, Moving Minds: Helping Developing Countries Overcome Barriers to Outsourcing Health Commodity Distribution to Boost Supply Chain Performance and Strengthen Health Systems

Senegal and other developing countries are improving access to health commodities by outsourcing supply chain logistics to private providers. To achieve broader, lasting reform, we must support further adoption of the outsourced model; assist country-led cost-benefit analyses; and help governments build capacity to manage contracts and overcome other barriers.

Priya Agrawal, Iain Barton, Roberto Dal Bianco, Dana Hovig, David Sarley, Prashant Yadav
http://dx.doi.org/10.9745/GHSP-D-16-00130

COMMENTARIES

Accessible Contraceptive Implant Removal Services: An Essential Element of Quality Service Delivery and Scale-Up

Use of contraceptive implants has surged in recent years, yet emerging data show a deficit of service delivery capacity and coverage for implant removals. The number of projected removals needed in the 69 FP2020 focus countries in 2018 (4.9–5.8 million) is more than twice that estimated for 2015 (2.2 million). We must proactively plan and execute high-quality implant removal services in order to fulfill the exceptional promise of implants in meeting client needs and advancing toward FP2020 goals.

Megan Christofield, Maryjane Lacoste
http://dx.doi.org/10.9745/GHSP-D-16-00096
Using Qualitative Methods to Validate and Contextualize Quantitative Findings: A Case Study of Research on Sexual Behavior and Gender-Based Violence Among Young Swazi Women

Nesting qualitative data collection methods within quantitative studies improves results by assessing validity and providing depth and context. Using data from 3 sources from Swaziland, we triangulate qualitative and quantitative findings to highlight how different methodologies produce discrepant data regarding risky sexual behaviors among young women. We found that women reported similar numbers of lifetime sex partners in all sources, but the proportion reporting multiple and concurrent partnerships was several times higher in qualitative interviews. In addition, qualitative data can provide deeper understanding of how participants, such as those experiencing gender-based violence, understood the experiences behind the quantitative statistics.

Allison Ruark, Rebecca Fielding-Miller
http://dx.doi.org/10.9745/GHSP-D-16-00062

Vouchers: A Hot Ticket for Reaching the Poor and Other Special Groups With Voluntary Family Planning Services

Vouchers can be a highly effective tool to increase access to and use of family planning and reproductive health services, especially for special populations including the poor, youth, and postpartum women. Voucher programs need to include social and behavior change communication with clients and quality assurance for providers, whether in the private or public sector. In the longer term, voucher programs can strengthen health systems capacity and provide a pathway to strategic purchasing such as insurance or contracting.

Elaine P Menotti, Marguerite Farrell
http://dx.doi.org/10.9745/GHSP-D-16-00084

SUCCESSFUL IMPLEMENTATION OF A MULTICOUNTRY CLINICAL SURVEILLANCE AND DATA COLLECTION SYSTEM FOR EBOLA VIRUS DISEASE IN WEST AFRICA: FINDINGS AND LESSONS LEARNED

Despite resource and logistical constraints, International Medical Corps cared for thousands at 5 Ebola treatment units in Liberia and Sierra Leone between 2014 and 2015 while collecting hundreds of data points on each patient. To facilitate data collection and global reporting in future humanitarian responses, standardized data forms and databases, with clear definitions of clinical and epidemiological variables, should be developed and adopted by the international community.

Reshma Roshania, Michaela Mallow, Nelson Dunbar, David Mansary, Pranav Shetty, Taralyn Lyon, Kacey Pham, Matthew Abad, Erin Shedd, Anh-Minh A Tran, Sarah Cundy, Adam C Levine
http://dx.doi.org/10.9745/GHSP-D-16-00186
Safety and Acceptability of Community-Based Distribution of Injectable Contraceptives: A Pilot Project in Mozambique

Trained community health workers, including traditional birth attendants (TBAs), safely and effectively administered injectables in northern Mozambique; two-thirds of the women choosing injectables had never used contraception before. Including TBAs in the Ministry of Health’s recent task sharing strategy can improve rural women’s access to injectables and help meet women’s demand for contraception.

Ana Jacinto, Mahomed Riaz Mobaracaly, Momade Bay Ustab, Cassimo Bique, Cassandra Blazer, Karen Weidert, Ndola Prata
http://dx.doi.org/10.9745/GHSP-D-16-00133

Scheduled Follow-Up Referrals and Simple Prevention Kits Including Counseling to Improve Post-Discharge Outcomes Among Children in Uganda: A Proof-of-Concept Study

Post-hospital discharge is a vulnerable time for recurrent illness and death among children. An intervention package consisting of (1) referrals for scheduled follow-up visits, (2) discharge counseling, and (3) simple prevention items such as soap and oral rehydration salts resulted in much higher health seeking and hospital readmissions compared with historical controls.

Matthew O Wiens, Elias Kumbakumba, Charles P Larson, Peter P Moschovis, Celestine Barigye, Jerome Kabakyenga, Andrew Ndamiira, Lacey English, Niranjan Kissoon, Guohai Zhou, J Mark Anserminoa
http://dx.doi.org/10.9745/GHSP-D-16-00069

Intensive Group Learning and On-Site Services to Improve Sexual and Reproductive Health Among Young Adults in Liberia: A Randomized Evaluation of HealthyActions

Combining intensive group learning and provision of on-site reproductive health services through an existing alternative basic education program increased use of contraception and HIV testing and counseling among young out-of-school Liberians.

Rebecca Firestone, Reid Moorsmith, Simon James, Marilyn Urey, Rena Greifinger, Danielle Lloyd, Lisa Hartenberger-Toby, Jewel Gausman, Musa Sanoeg
http://dx.doi.org/10.9745/GHSP-D-16-00074

A Randomized Controlled Trial of a Trauma-Informed Support, Skills, and Psychoeducation Intervention for Survivors of Torture and Related Trauma in Kurdistan, Northern Iraq

Providing survivors of torture, imprisonment, and/or military attacks with a counseling program that includes support, skills and psychoeducation by well-trained and supervised community mental health workers can result in moderate yet meaningful improvements in depression and dysfunction.

Judith Bass, Sarah McVor Murray, Thikra Ahmed Mohammed, Mary Bunn, William Gorman, Ahmed Mohammed Amin Ahmed, Laura Murray, Paul Bollt
http://dx.doi.org/10.9745/GHSP-D-16-00017
Progress in Harmonizing Tiered HIV Laboratory Systems: Challenges and Opportunities in 8 African Countries

Countries have had mixed results in adhering to laboratory instrument procurement lists, with some limiting instrument brand expansion and others experiencing substantial growth in instrument counts and brand diversity. Important challenges to advancing laboratory harmonization strategies include:

1. Lack of adherence to procurement policies
2. Lack of an effective coordinating body
3. Misalignment of laboratory policies, treatment guidelines, and minimum service packages

Jason Williams, Farouk Umaru, Dianna Edgil, Joel Kuritsky
http://dx.doi.org/10.9745/GHSP-D-16-00004

REVIEWS

Postabortion Care: 20 Years of Strong Evidence on Emergency Treatment, Family Planning, and Other Programming Components

Twenty years of postabortion care (PAC) studies yield strong evidence that:

- Misoprostol and vacuum aspiration are comparable in safety and effectiveness for treating incomplete abortion.
- Misoprostol, which can be provided by trained nurses and midwives, shows substantial promise for extending PAC services to secondary hospitals and primary health posts.
- Postabortion family planning uptake generally increases rapidly—and unintended pregnancies and repeat abortions can decline as a result—when a range of free contraceptives, including long-acting methods, are offered at the point of treatment; male involvement in counseling—always with the woman’s concurrence—can increase family planning uptake and support.

Douglas Huber, Carolyn Curtis, Laili Irani, Sara Pappa, Lauren Arrington
http://dx.doi.org/10.9745/GHSP-D-16-00052

FIELD ACTION REPORTS

Improving the Quality of Postabortion Care Services in Togo Increased Uptake of Contraception

The quality improvement approach applied at 5 facilities over about 1 year increased family planning counseling to postabortion clients from 31% to 91%. Of those counseled provision of a contraceptive method before discharge increased from 37% to 60%. Oral contraceptives remained the most popular method, but use of injectables and implants increased. The country-driven approach, which tended to use existing resources and minimal external support, has potential for sustainability and scale-up in Togo and application elsewhere.

Stembile Mugore, Ntapi Tchiguiri K Kassouta, Boniface Sebikali, Laurel Lundstrom, Abdulmumin Saad
http://dx.doi.org/10.9745/GHSP-D-16-00212
Short Reports

Use of the World Health Organization’s Medical Eligibility Criteria for Contraceptive Use Guidance in sub-Saharan African Countries: A Cross-Sectional Study

The revised 2015 World Health Organization guidance expanded the recommended contraceptive options available to breastfeeding women during the early postpartum period to include progestogen-only pills and implants, but a substantial number of surveyed country representatives indicated that as yet their national policies did not allow such women to use these methods at that time. Countries may benefit from support to incorporate MEC guidance into national service delivery guidelines.

Melissa J Chen, Mary E Gaffield, James Kiarie

http://dx.doi.org/10.9745/GHSP-D-16-00216
Effective LARC Providers: Moving Beyond Training (Republication)

James D Shelton, Anne E Burke

Effective and productive providers are the key to successful provision of long-acting reversible contraceptives (LARCs). But LARCs demand more of providers than short-acting resupply methods. In addition to sound training, key elements to developing highly productive providers of LARCs include a thorough understanding of the service delivery system context; selecting providers with the most potential, especially from mid-level cadres; strong mentoring and supportive supervision; and attention to the supply chain and to demand-side support.

Note: This is a republication of an editorial first published in GHSP, Volume 4, Supplement 2, “Long-Acting Reversible Contraception Crucial to Meeting Unmet Need Goals by 2020: Key Papers From the 2016 International Conference on Family Planning.”

The special issue of GHSP, focused on long-acting reversible contraceptives (LARCs) based on papers presented at the 2016 International Conference on Family Planning, provides testimony to the remarkable rise in the popularity of implants and intrauterine devices (IUDs), as well as some limited evidence on permanent methods. As these articles report, we see substantial uptake of LARCs in a wide variety of situations when they are provided in a quality fashion, including provision of a wide choice of methods. These situations include:

- Public and private sectors
- Postpartum
- Postabortion
- Difficult crisis-affected settings
- Peri-urban slums
- With vouchers for those particularly in need
- Via a range of provider cadres.

Moreover, these articles provide insights specifically into the acceptability and provision of IUDs, which have long been recognized as underutilized.

WHAT IS NEEDED FOR GOOD LARC PROVISION?

For any health service to be successful, going beyond the technology or basic intervention alone is crucial. This lesson is particularly important for LARCs and permanent methods, which are more complicated to provide than short-acting methods. It is essential to address the local context, systems, and infrastructure through which LARCs are provided. Key situational issues include physical resources, staffing, organization of work, and cultural context.

Providers are central to the success of any health program. The global health field tends to focus on training to assure providers’ capabilities. But training alone is not enough. Drawing largely on articles in this issue, we offer observations on some program elements that are necessary to help providers be highly productive in LARC programming.

Selecting Providers With the Most Potential

Inserting and removing LARCs requires particular skills and more effort than providing many other family planning services, such as pills or injectables. Thus, providers of LARCs must be not only technically competent but also motivated to provide the service again and again. So, one selection criterion is whether a provider is likely to be able to provide LARCs often enough to keep her or his skills and have confidence in them. And that calls for selecting staff who are already motivated to provide, and even be champions for, family planning in general. Also, many nonphysician providers may find satisfaction from “task sharing”—being able to provide a service that was previously reserved for physicians—and so may be enthusiastic about providing LARCs. Providers such as midwives and qualified nurses often suit this role. In addition, it appears crucial to select providers who are likely to remain in their...
Mentoring and Supervising
It is telling that many of the articles in this special issue that describe full programming efforts emphasize ongoing support to providers, variously referred to as mentoring, supportive supervision, or coaching (Samuel, White, Gueye, Muthamia, Pleah). A common strategy is to begin by recruiting, training, and deploying a core cadre of mentors, who then train and mentor other providers. Good mentoring greatly benefits any service, providing technical support, accountability, and motivation. But it is especially productive for a potentially challenging intervention such as provision of LARCs, which calls for a higher level of skill, commitment, and motivation, and for which skills are easily lost if not practiced. Good mentoring also provides broader support for provision of all family planning methods, including counseling and practical problem solving.

Assuring the Supply Chain
A provider without the proper commodities cannot provide the service. And a disrupted supply chain undermines confidence in the entire service. Thus, several of the articles in this issue focus on building and maintaining a reliable supply chain. In addition to the contraceptives themselves, LARC provision requires equipment and supplies such as gloves, antiseptics, and local anesthetics. While external donors may supply the implants and IUDs, especially at the beginning of a project, disposable supplies cannot be overlooked or assumed. A reliable source of ongoing supply is crucial to sustain continuous services, particularly once programs leave the shelter of donor funding.

Supporting the Demand Side
Several of the articles emphasize demand promotion activities, especially outreach to the community, including religious leaders, and some mass media communication. Promotion of IUDs, in particular, benefits from such activities. Misperceptions about IUDs persist among both providers and the general public, as documented by Twesigye and colleagues. Addressing such misperceptions is essential. In addition, the use of vouchers can increase demand and service seeking among clients particularly in need, as reported by Boddam-Whetham and colleagues and Bajracharya and colleagues.

CONTRAST WITH A LESS SUCCESSFUL PROJECT
The project in Bangladesh reported by Rahman et al. resulted in some appreciable increase in use but less than in comparison districts, which had no such intensive intervention. The project included substantial training, with some focus on the supply chain and demand-side support. However, it appears the intervention was operating in a much more challenging system context than that in the comparison districts. For example, there were substantially more provider vacancies and fewer clients were contacted by community health workers in the program districts than in the comparison districts. The high vacancy rate of providers speaks to the possible importance of a stronger selection process from the outset. Notably, an appreciable ongoing mentoring or supportive supervision activity was absent. Would the Bangladesh project have been more successful had it included stronger provider selection and mentoring components? Yes, we believe so.

CONCLUSION
In the context of availability of a wide range of other methods, provision of LARCs can be the linchpin in the effort to attain FP2020 goals to meet the contraceptive needs of millions of people. The global health community must make the necessary investment to foster the skills and motivation of LARC providers and give them sufficient system support to facilitate program success.

Competing Interests: None declared.

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Global Health: Science and Practice 2016 | Volume 4 | Number 3

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Moving Medicine, Moving Minds: Helping Developing Countries Overcome Barriers to Outsourcing Health Commodity Distribution to Boost Supply Chain Performance and Strengthen Health Systems

Priya Agrawal,a Iain Barton,b Roberto Dal Bianco,a Dana Hovig,c David Sarley,c Prashant Yadavd

Senegal and other developing countries are improving access to health commodities by outsourcing supply chain logistics to private providers. To achieve broader, lasting reform, we must support further adoption of the outsourced model; assist country-led cost-benefit analyses; and help governments build capacity to manage contracts and overcome other barriers.

INTRODUCTION

Until recently, women in Senegal who went to their local public health clinics seeking a means to prevent pregnancy had about a 3 or 4 in 5 chance of leaving empty-handed.1 Implants, pills, injectables, and other contraceptives, while promoted as part of Senegal’s commitment to improving maternal health and access to family planning, were routinely out of stock. The problem, all too common in developing nations, was improper supply chain management, specifically inventory management and delivery. To address this, the government of Senegal embarked on a major overhaul of its supply chain for 9 different contraceptives (with 2 more added later). Within 6 months, stock-outs ceased almost entirely.1,2

Key in the success of Senegal’s reform was the government’s strong commitment to, and effective implementation of, hiring private third-party logistics providers (3PLs) to manage orders and handle deliveries from district warehouses to local health facilities, with clear benefits for service levels and costs. One analysis compared cost and service through the use of private operators versus those of government employees performing the same activity in a different region of the country. The analysis found that outsourcing decreased the proportion of facilities experiencing stock-outs from over 80% to less than 2%3 while reducing distribution costs by 36% annually.4

These gains were achieved during a 3-year program supported by MSD for Mothers (known as Merck for Mothers in the United States and Canada), The Bill & Melinda Gates Foundation, IntraHealth International, and other partners. During the program, other components developed by the private sector were implemented, including an innovative inventory management system and new methods of data tracking to support mobile warehousing. These made stock replenishment more responsive to real consumption. Contracted workers are able to accurately track and verify consumption and stock levels and plan and customize shipments; regular data uploads allow them to quickly address potential issues.

Qualitative analysis and cost comparisons between regions being served by 3PLs and the one region that was not served by 3PLs helped garner support within the government for the outsourced model. In summer 2016, the new system began transitioning from donor-supported partners to government control under Senegal’s National Supply Pharmacy (PNA), a process that is expected to take several months. At the launch of the handover process in August, the Director of the PNA pledged to continue contracting with private operators for last-mile deliveries to all 1,400 of the country’s service delivery points, and to expand the system to cover approximately 100 products by the end of 2017. Senegal’s Minister of Health and Social Action has endorsed the outsourced model as a way to help ensure access to essential medicines and health commodities for all citizens. This political support is both encouraging and necessary, as long-term success will depend on the government’s ability to institutionalize the approach.
A handful of other developing countries are also pursuing outsourcing and reaping the benefits. In the Western Cape Province of South Africa, for example, the storage, handling, and transportation of vaccines has markedly improved in the hands of a 3PL while costs have also been lowered.4 Kenya outsources the transport of medical supplies to all its health care facilities, having determined that managing a fleet of trucks was neither a core competency of government nor an effective use of government resources.5 In Nigeria, direct deliveries from an outsourced provider have increased the availability of vaccines in Kano and Lagos,6 and, despite constraints from the economic downturn and weaknesses in management capacity, the direct delivery model is gradually being expanded nationally. In Mozambique and Zimbabwe, direct deliveries of a range of products have increased stock availability, enhancing system performance.7,8 In other places, however, such as Togo, similar programs have not been as successful. The success of direct-delivery programs managed by the private sector ultimately depends on strong government commitment; clear roles and accountability mechanisms; a robust technical design; and effective multi-stakeholder collaboration.

We urge other developing nations—in Africa and elsewhere where public-sector supply chains have been underperforming for years—to look to these countries’ experiences as examples of what can be achieved and reminders of the issues that will need to be addressed (Table).

THE ADVANTAGES

When deciding whether to outsource, there are many benefits to consider. For example:

- Outsourcing improves performance through competition. It brings market forces into play, with competitive bidding and performance-based incentives. To stay competitive, 3PLs invest to acquire the technical expertise and capital assets they need to provide top service while keeping prices in line. Top performers earn contracts. If they fail to perform, another company gets the job. Poor performance by public-sector personnel is more difficult to rectify.

- Private operators are highly incentivized to comply with the strict storage requirements governing health commodities. Those who fail to do so risk termination of their contracts. (For these incentives to work, of course, governments must be willing to hold those service providers accountable.)

- Private 3PLs are better-equipped to manage growth. Government agencies typically lack the flexibility and capacity to scale quickly to address seasonal issues or outbreaks, due to rigid budgets and bureaucratic hiring processes.

- 3PLs typically add stronger information and data management systems, enabling greater stock management and resource efficiency. (Data, and data visibility, are central to supply chain performance.)

For all these reasons and more, outsourcing is standard practice across Canada, Europe, and the United States, and in the rest of the developed world. In fact, no country in the Organisation for Economic Co-operation and Development (OECD) has a government-run public health supply chain.10-12 The U.S. Centers for Disease Control, for example, has achieved significant cost efficiencies outsourcing storage and distribution for its multibillion dollar Vaccines for Children program;13 the UK National Health Service, which outsources procurement, storage, and distribution to DHL, has projected a savings of a billion pounds over 10 years.14,15

Developing countries stand to benefit from outsourcing in two other critical ways. First, with private contractors handling deliveries and other on-the-ground logistics, doctors, nurses, and other clinical staff can concentrate on their primary responsibility and core competency: patient care. In a government-run system, it is the medical personnel, already in short supply across the developing world, who are often saddled with part-time supply chain duty, filling out inventory forms, traveling to storage sheds to collect stock, and performing other tasks for which they were not originally trained. When outsourced, skilled 3PL workers make the deliveries and perform the inventory control. This task shifting is a key benefit of Senegal’s outsourced distribution model. It has allowed government employees to be redeployed to new clinical support and management positions, not downsized, as is often feared.

Second, government spending through outsourcing stimulates the local economy by creating business opportunities for local entrepreneurs that in turn create new private-sector jobs. In Senegal, local operator Cabit SA has doubled its
TABLE. Outsourcing Supply Chain Logistics in Low- and Middle-Income Countries: The Advantages, the Hurdles, and Some Recommendations on How to Move Forward

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Hurdles</th>
<th>Recommendations</th>
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<tr>
<td>Outsourcing saves money: Using private operators to distribute medicines and other health commodities can reduce costs by as much as one-third or more.a</td>
<td>There is general reluctance by in-country leadership to give up government ownership of delivery systems and infrastructure.</td>
<td>Evaluate what lies within government’s core competency, and what lies outside of it. Through oversight and enforcement of strict service-level agreements, governments can maintain control over their supply chains even while outsourcing the logistics; government still owns and manages the process, even when non-government drives the trucks.</td>
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<td>Built-in performance incentives: Logistics operators are motivated to provide effective, efficient service and prevent stock-outs in order to win and keep their contracts.</td>
<td>There is insufficient capacity and expertise within governments to write and effectively manage contracts with private operators.</td>
<td>Assist governments with building effective contract management and enforcement teams.</td>
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<td>Medical staff at service delivery points are no longer responsible for restocking inventory and can focus on patient care; new jobs are created in the local private sector as local companies hire more employees and otherwise invest in their own growth to secure government contracts.</td>
<td>Outsourcing the logistics of health commodity distribution could threaten to eliminate some public-sector jobs.</td>
<td>Governments may need help restructuring their human resources and retraining and reassigning employees for oversight and supervisory roles; local private operators may need training and other support.</td>
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<td>In a government-run distribution system, employee working hours and staffing levels are fixed; private operators can be more flexible, so government pays only for what it needs and uses.</td>
<td>In some markets, it can be difficult to find private-sector operators trained and equipped to use state-of-the-art approaches to inventory management and to comply with strict requirements regarding storage and transport of medicines.</td>
<td>Private-sector donors or businesses, acting as fourth-party providers, can assist in the professional development of local private-sector operators.</td>
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<td>Contracting with multiple operators can help spread risk, so that the failure of one is far less likely to bring a whole system down.</td>
<td>Concerns exist about long-term financing and sustainability of the new health distribution system given the temporary nature of donor support.</td>
<td>Private-sector expertise can help with the necessary costing analysis, but top-level, in-country leadership must take ownership over the process—and the solutions.</td>
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Outsourcing in Senegal reduced distribution costs by an estimated 36%, and outsourcing the distribution of vaccines in South Africa yielded significant savings, from 28% of the vaccine cost to 6%.

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staff from 30 to 60 since being contracted by IntraHealth International to handle logistics. In Malawi, contraceptives and some essential medicines (including antimalarial drugs) are distributed by Cargo Management Logistics (CML), a local private company that has grown from 46 to 112 employees in the 4 years since taking on this work. In Nigeria, Imperial Health Sciences manages warehousing services and deliveries by 7 locally owned and financed transport companies, which together employ more than 270 people to deliver products to 5,000 points of care.

THE CHALLENGES

Given all the upside, why has outsourcing failed to catch on in the developing world? Here, we provide a few explanations. First, outsourcing requires a sharp break with an old tradition of moving medicine through government-owned centralized stores. This colonial practice was later reinforced when Ghana gained independence and tried to emulate the supply chain model used in the former Soviet Union. The Soviets owned and operated the medicine supply chain, so Ghana
and many other countries in Africa did the same. However, this model has long proved inefficient and fragile, hobbled by weak performance incentives and the inability to flex capacity as needed. By the 1990s, the model was already struggling across Africa and it buckled when the HIV crisis hit. Subsequent efforts, with international assistance, to sustain this model have done little to alter the fundamental structure, which continues to prove incapable of handling the ever-widening scale and diversity of products required to meet patient needs.

Second, many developing nations lack the mechanisms and capacities for contract management and oversight. And it can be difficult to find local private operators capable of handling health product distribution. In some countries, private logistics operators may only serve urban areas, For example, Beale et al.\textsuperscript{16} and VillageReach\textsuperscript{17} highlight the lack of transport providers in rural Mozambique. Private companies require long-term contracts to invest in transport capacity in an underserved region where they do not currently serve a market. Yet governments are hesitant to make long-term contracts as for many this is not yet a proven model. For transporters, especially smaller local players, the timeliness of government payment is also critical for their cash flow.

Third, concerns that outsourcing threatens public health sector jobs can dampen political support. Nobody wants the prospect of laying people off, particularly in countries where the public sector is the primary source of stable employment.

In addition, while outsourcing can reduce product diversion and pilferage, a robust, transparent, and rigid tender process for the outsourced contract award is a prerequisite for its success.

Finally, there is the question of sustainability. Donor-funded programs are often the way that outsourcing is introduced and tested in a country. Yet it is often the pattern that such efforts prove initially successful, only to revert to insourcing when the program transitions back to government. Kenya, for example, reverted back to insourcing some of its distribution activities when an outsourcing project supported by the U.S. Agency for International Development (USAID) ended. Concerns about long-term financing—and the temporary nature of donor support—have made many country leaders reluctant to take the necessary steps toward change, even as they readily acknowledge a pressing need for it. The benefits of outsourcing and direct delivery are based on the combination of technical design (who manages inventory control, information flow), source of financing (donor financed vs. domestic financing), and commitment from political leaders or heads of public agencies. The benefits can start declining when one of these ingredients is missing or becomes diluted over time.

**THE WAY FORWARD**

To overcome these barriers, we need to support country leaders as they determine which segments of their supply chains are best suited for outsourcing, and as they seek to identify what truly lies within the core competency of government

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Employees of Cabit, a 3PL hired to handle last-mile distribution of contraceptives and other health commodities, record consumption and delivery data in a stock room of a health center in the Fatick region of Senegal.
and what lies outside it. They will need support to adequately assess risks, costs, and potential savings, as well as their own abilities to manage contracts with outsourced partners. And they may need help restructuring internal human resources for new supervisory roles within the new system. The 2015 Gavi study, “Outsourcing the Distribution Component of Vaccine and Medicine Supply Chains,” carried out by Transaid,18 offers a useful framework for these strategic discussions.

For those governments considering a move toward outsourcing their supply chains and to all supporting partners and stakeholders—public and private—we recommend the following:

- Conduct an in-depth, cost-risk-benefit analysis of the existing government-run, insourced distribution system. Have an honest discussion about what changes are feasible and who is going to pay for it. The private sector knows how to do the kind of granular costing analysis that is required, and does it well.
- Top-level country leadership should drive the process from the beginning, so that government—including the finance ministry—takes ownership of both the analysis and the solutions.
- Take full account of the many hidden costs of a government-run distribution system, such as asset depreciation and staff time spent away from their clinic post. If not exposed, these hidden costs can make an outsourced model, in which costs are more explicit, seem expensive by comparison. Spending more may make sense if it means dramatically improved product availability on shelves.
- Make clear the return on investment.
- Procure 3PL services through a competitive process to keep costs in line.
- Consider having a commercial or NGO partner serve as a fourth-party provider (4PL) to manage subcontracts with several 3PLs—which Mozambique, Nigeria, Senegal, and Zimbabwe all have done. A 4PL adds value by streamlining the government’s role in the nitty-gritty logistics and in performance management, by creating a single point of engagement. The 4PL can find, train, and manage all local transport partners, and it has the incentive to make sure they do well. (In Senegal, IntraHealth International, acting as a 4PL, provided training for Cabit SA and other 3PL employees on the new inventory management techniques adopted as part of Senegal’s newly revamped distribution system.) Engaging a 4PL represents an additional cost layer, however, and can be a disincentive to outsourcing unless the benefits are clearly understood.
- Build a transition plan from the start to ensure sustainability after donors pull out. The main challenges facing Senegal during its transition will be managing the higher costs and greater data collection and demand planning requirements posed by a tenfold increase in the number of 3PL-distributed products.
- Explore how existing government staff might be retrained and reassigned to new roles in contract management and oversight. In an outsourced system, government is still in control of the public supply chain, so it is government that must enforce service-level agreements and ensure that performance targets are achieved. Look at pharmacists and others who have been pulled away from their field to work the supply chain and allow them instead to return to what they originally studied.
- Develop sufficient government capacity for contract management and other mechanisms for effective private-sector engagement. Rigorous government oversight is essential to secure compliance, prevent corruption, and ensure that drugs are not misused or mishandled. Contracts will also need to include the proper incentives to ensure that 3PLs distribute to rural and remote areas, not just the major towns and other densely populated regions. (USAID’s experience through its DELIVER Project highlights the importance of building a strong contract management team,19 and VillageReach’s experience in Mozambique highlights similar challenges.8) Key performance indicators—the ability of outsourced partners to manage costs, quality of service, responsiveness, etc.—must be carefully designed and monitored. Strong contract language by itself is not enough; overseers must be willing and able to enforce the terms and conditions.
- Select individuals with prior private-sector logistics and supply chain experience to serve as top-level supply chain managers. Those with a commercial background are more likely to make the bold (and sometimes politically unpopular) decisions necessary to implement
change. Progress in Kenya has been widely attributed to the fact that an executive with rich private-sector experience was brought in to run the Kenya Medical Supplies Authority (KEMSA). Under his leadership, KEMSA has become less bureaucratic, more independent, and more competitive and a good model for other countries looking to outsource and otherwise streamline their operations.

- Engage the public in the debate over supply chain reform, by communicating what’s at stake for consumers—in other words, how a well-functioning supply chain helps protect, improve, and save lives. One way to do this is to present performance metrics in terms that are relevant and relatable to patients. Are the medicines and other supplies available when they need them? Are they affordable and accessible? How far do patients have to travel to get to them? Activists and civil society can play an important catalytic role by shining a spotlight on poor performance and advocating for more reliable access.

Supply chains will have to be even stronger, more efficient, and more effective in the future to enable governments to meet the needs of their citizens.

Global stakeholders should build a stronger evidence base for where, when, and how outsourcing works in a long-term, sustainable way in developing country health systems. This will create a global public good in terms of knowledge of what any country starting to consider outsourcing should watch out for, and how to remedy failures and create the right prerequisites for success. Before embarking on such projects, global agencies must also pay close attention to the complex political economy surrounding such projects that is present in many low- and middle-income countries. They must develop a clear path to more effectively communicate its benefits and risk mitigation approaches and bring on board government stakeholders who will strongly advocate for this.

**CONCLUSION**

Demands on in-country supply chains will only intensify going forward. The sheer volume of drugs and other products flowing into the public health pipeline increases year after year, as new treatment options become available and governing bodies establish more ambitious health targets. The newly adopted Sustainable Development Goals call for universal access to reproductive health care. The new “90-90-90” targets from the Joint United Nations Programme on HIV/AIDS (UNAIDS)—by 2020, 90% of people living with HIV will know their HIV status, 90% of people diagnosed with HIV will receive sustained antiretroviral therapy, and 90% of people receiving antiretroviral therapy will have viral suppression—will essentially double the number of patients who will require treatment over the next 5 years. The need to ensure continuous access to maternal and child health commodities, as well as the rising prevalence of hypertension, diabetes, and other non-communicable diseases in developing countries, will add further strain. Supply chains will have to be even stronger, more efficient, and more effective to enable governments to meet the needs of their citizens. The recent Ebola outbreak is a stark reminder that supply chains must be agile and responsive—and a reminder of the tragic consequences when they are not.

We believe that to get public health supply chains—and patient access—to where they need to be, private-sector outsourcing needs to be part of the equation. Health ministries can and should learn from the Senegal experience, and from the successful efforts of other countries to outsource parts of their supply chains. We believe that many of the obstacles are surmountable and that in most cases, with the proper conditions and support, outsourcing can improve health commodity availability and help strengthen health systems.

The women of Senegal are already benefitting from their country’s supply chain overhaul in family planning. Since the reform, a young wife trying to space her pregnancies to avoid complications, the mother of 6 children who is in no condition to have a seventh, and all the other women who require contraceptives, have been able to depend on the availability of contraceptive products in a way that was unheard of just a few
years ago. This is what a top-performing supply chain can do, and it is what every person, everywhere, deserves.

Acknowledgments: We thank Mark Allen, Maryanne Buechner, Jeffrey Jacobs (Merck & Co., Inc., Kenilworth, NJ, USA), and Adam Williams (Robin Martin, New York, NY, USA) for their editorial support in preparing this article.

Competing Interests: Dr. Agrawal reports that she is an employee of Merck & Co., Inc., Kenilworth, NJ, USA, and may hold stock or stock options in the company. Dr. Barton reports that he is an executive of a logistics company that provides outsourced services to governments, donors, and pharmaceutical companies; he also serves on the advisory board of Merck for Mothers.

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Peer Reviewed

Received: 2016 Apr 21; Accepted: 2016 Aug 26


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Use of contraceptive implants has surged in recent years, yet emerging data show a deficit of service delivery capacity and coverage for implant removals. The number of projected removals needed in the 69 FP2020 focus countries in 2018 (4.9–5.8 million) is more than twice that estimated for 2015 (2.2 million). We must proactively plan and execute high-quality implant removal services in order to fulfill the exceptional promise of implants in meeting client needs and advancing toward FP2020 goals.

Renewed investment in scaling up contraceptive implants has resulted in a dramatic increase in their use since 2012. The surge is due in part to the reduction in price and increases in donor investments made through the Implants Access Program (a collaboration between public and private organizations to make implants accessible to women in the world’s poorest countries) and ministerial prioritization and support to facilities and providers, as well as user preference. Among the 69 Family Planning 2020 (FP2020) focus countries, prevalence of injectables and implants is growing faster than all other contraceptive methods; in Ethiopia, Kenya, Malawi, Senegal, and Zimbabwe, the percentage of women ages 15–49 using implants is growing by over 1 percentage point per year. Implants are reaching more women than ever before, including those who have traditionally been underserved. Implants also now have the potential to meet the needs of postpartum women who are breastfeeding immediately after birth as a result of the World Health Organization’s recent decision to allow their use among this important population, which is reflected in the fifth edition of the Medical Eligibility Criteria for Contraceptive Use. Recently, implant manufacturers Merck and Bayer announced plans to sustain their current reduced implant pricing for an additional 5 years, through 2023, creating price parity for all the currently available implant products and further paving the road for potential continued scale-up.

However, emerging data show that service delivery capacity for implant removals has not kept pace with that for insertion. For example, in Kenya, among Ministry of Health facilities offering family planning services in 2015, 86% provided contraceptive implants while only 67% provided removals. Clients who access removal at private-sector (and some public-sector) facilities can encounter user fees, and those who receive their method from a mobile outreach campaign or a community health worker are at times without clear or accurate, up-to-date information on how and where to seek follow-up services and removal. While there is a paucity of evidence regarding access to removal in the peer-reviewed literature, ministries and program managers increasingly cite reports of clients’ failed attempts in obtaining the removal procedure.

With the rapid expansion of implants services, the family planning community—donors, implementers, ministries, advocates, and health care providers—has reached a critical point at which it needs to assure the availability of convenient, quality removal services for
clients who want removal for any reason throughout the use of their implant, including those discontinuing contraceptive use, switching to another method, or removing the implant to have a subsequent implant inserted. The family planning community has a responsibility to support method continuation as well as access to quality removal when desired—commensurate to the attention paid to the method’s initiation—such that clients’ reproductive intentions can be realized.9 We need more data visibility into implant removals and adoptable approaches to expanding access to removal services—and it is imperative that we act urgently.

WHY THE FOCUSED ATTENTION ON REMOVALS?

Implant removal is an essential component of contraceptive implant scale-up, critical to offering high-quality services and continuity of care for family planning. Inadequate removal services leave some clients on contraception when they would prefer not to be, whether the intention is to conceive or discontinue the method for other reasons. This inability to access removal within a reasonable time frame consistent with access to other services compromises clients’ rights and choice. As the literature on rights-based family planning has made clear, ensuring access to implant removal helps fulfill the aim of voluntary family planning such that it extends into the method’s discontinuation as well.10,11 For example, the FP2020 “Rights and Empowerment Principles for Family Planning,” within the tenet of availability, states clearly, “Health care facilities, trained providers and contraceptive methods are available to ensure that individuals can exercise full choice from a full range of contraceptive methods. ... Availability of services includes follow-up and removal services for implants and IUDs.”11

There is precedent for serious concern about lack of quality removal services. The learning generated from the global scale-up effort of Norplant implants (beginning in the early 1990s) blames the method’s low uptake, in part, on inadequate access to and quality of removals.12-15 Furthermore, issues of access to quality removal services had repercussions; Frost and Reich noted that “for several reasons, removal problems became major barriers to Norplant access in some countries, with negative implications for the product’s reputation, appropriate use, and customer satisfaction.”12 And while the advent of 1- and 2-rod implant technologies (compared with Norplant’s 6 rods) has made the removal procedure much easier,7 it has not freed the method from technical difficulties.16

The sheer volume of anticipated removals in the coming years should give us pause. This unprecedented growth in the availability of implants will result in an equal growth in the need for implant removals in the near future because currently available implants have a 3-to-5-year lifespan. Using publically available data from RHInterchange,2 which has contraceptive procurement data from major donors and international organizations for more than 140 countries, we modeled the approximate timeline and magnitude of this upcoming removal burden (Figure). The bars in the Figure show procurement of implants by year, over the past 10 years, in the 69 FP2020 focus countries. We calculated the lines projecting number of implants due for removal by disaggregating procurement data by implant product, adding a 12-month period from receipt in-country to insertion in a client, and then assuming that once inserted, each product was used for its couple-years of protection (CYP) unit—2.5 years for Implanon, 3.2 years for Sino-implant (II), and 3.8 years for Jadelle.17 For example, a shipment of Jadelle that arrived in a country in July 2008 was modeled for removal in April 2013. A second scenario is also presented in the Figure to account for the possible shift of Implanon’s qualified effectiveness from 3 years to 5 years (represented as 3.8 CYP in the model). This was applied beginning with clients who had an Implanon implant inserted in 2014, with the assumption that current users will be notified that they may keep their implant inserted longer than 3 years. Although the model uses procurement data as a proxy for use, it echoes the previously acknowledged trend of increasing growth in use of implants and conveys overall that with either scenario we will experience a growing number of removals in years to come, as current implant users age out of their implants or remove for other reasons. According to this model, the number of estimated removals needed in 2015 (2.2 million) was less than half the number projected for 2018 by either scenario (4.9 million for the first scenario, 5.8 million for the second scenario)—a worrisome figure if removal issues have already begun to emerge.

Of note, the model’s limitations include: (1) use of procurement data as a proxy for use, (2) the assumption that all implants are used for
their CYP unit to calculate the removal projection, (3) use of the general estimate of 12 months to represent the time between the implant shipment’s arrival in country and the product’s insertion into a client, and (4) the exclusion of direct procurement by governments and some other third-party procurement (for example, Indonesia’s procurement) from RHInterchange procurement numbers.

PROMISING EFFORTS

Access to implant removal has not been neglected entirely. In addition to the presence of removal guidance and training within national guidelines and curricula (and the global implants learning resource package18), many programs are addressing implant removal proactively within their independent settings. For example, with USAID funding, Marie Stopes International (MSI) – Tanzania partnered with the Ministry of Health and Social Welfare to build capacity of public-sector providers to provide voluntary long-acting reversible contraceptive services, including removal of implants and intrauterine devices (IUDs). They supported these facility-based providers by including them in a 3-week tour with an MSI mobile outreach team where they received on-the-job training with many opportunities for insertion and removal practice due to the high client load.19 And in Ethiopia, where health extension workers (HEWs) provide implants, helping the nation achieve great gains in the modern contraceptive prevalence rate, the Federal Ministry of Health and Pathfinder International (under the USAID-funded Integrated Family Health Program) developed a


* Scenario 1 assumes that each implant is used for its current CYP unit—2.5 years for Implanon, 3.2 years for Sino-implant (II), and 3.8 years for Jadelle. Scenario 2 accounts for the possible shift in the approved length of effectiveness for Implanon, from 3 years to 5 years, which would change its CYP unit to 3.8 CYP.

Source of data: RHInterchange.2
coordinated strategy to expand access to implant removal through strong referral and support mechanisms—Ethiopia’s task-shifting policy allows HEWs to insert but not remove implants. When HEWs identify clients in need of implant removal, they notify the linked health center, which responds by sending a skilled service provider to the community level to provide the service. In this way, clients who receive their implant from a HEW are equally supported to get the implant removed when desired. Furthermore, research is underway in Nigeria to assess the capability of community health extension workers to insert and remove implants, an assessment that has the potential to inform other community provision models. Cost solutions are also being tested, including the use of vouchers that capture the insertion, follow-up care, and removal fees within 1 voucher so that the user fee is only levied upon uptake.

At a global level in 2015, several partners, including UNFPA and CHAI, developed a standardized consumables kit for contraceptive implant services. The kit includes supplies for insertion and removal, offering an easily procurable option for places where supply planning has been an issue. With Bill & Melinda Gates Foundation funding, the Performance Monitoring and Accountability 2020 (PMA2020) project and FHI 360 developed a series of implant removal access questions for piloting in PMA2020 surveys in Ethiopia and Kenya. In part, the questions aim to collect information on why and to what extent clients attempt to have their implant removed but fail to do so. Recently published data from this effort show that 4% of current implant users in Kenya and 7.2% in Ethiopia have attempted but failed to have their implant removed.

Coordinated and systematic efforts to highlight and implement best practices in expanding access to implant removal services could greatly benefit situations in which implant removals have not received commensurate attention or are only now emerging as a problem area. At the global level, the Implants Access Program Operations Group partnered with Jhpiego to support 2 technical consultations on implant removals. In late 2015, the group initiated the Implant Removal Task Force to bring together implementing partners and donors to identify existing best practices and call attention to research and programming gaps for future action. The task force also aims to bring awareness and ensure adequate attention to the issue of implant removal. While only in its infancy, the task force has already shared lessons learned and identified a learning agenda. In addition, in each of the task force’s 4 subgroups (capacity building and service delivery; data and monitoring; research; and difficult removals), action plans have been developed and new tools, approaches, and analyses are in development to meet the needs of ministries, providers, partners, and donors. As this task force matures, it expects to deliver clear evidence and best practices and offer tangible solutions to those who need them. As a starting point, the task force has developed a short list of requirements of quality, client-centered implant removal services (Box).

**WHAT WE CAN DO NOW**

Now is the right time to tackle this issue. In this period of rapid scale-up of contraceptive implants, the opportunities for advocacy and action surround us. Whether in the development of costed implementation plans, in updates to health management information systems, in the actions associated with national FP2020 commitments, or in so many other efforts, each offers the opportunity to address preparedness for, and delivery of, implant removals when desired.

First and foremost, more data are needed. The great success in implant scale-up has been measured almost exclusively by its uptake, yet monitoring removal is one way to support accountability in providing the full range of an implant service (an area where donors could add pressure by requiring reporting on revisits and discontinuation). To better assess the extent to which this full range of service—including follow-up and removal—has been scaled, programs can employ both traditional tactics, such as including follow-up and removal indicators in facility registers and survey instruments, and new ways, such as innovative monitoring of client access through technology solutions (which could potentially also capture incidence of difficult removals and indicators of quality). Although an increasing number of countries track implant uptake through DHIS 2 and other health management information systems, few routinely track removals; yet systematic capture of data on removals is integral to developing plans and scaling up access to this essential service. So too, we need to better understand reasons for method switching and discontinuation.

Altogether, these data could offer ministries and program managers visibility into the performance of their family planning programs, which will
help them align volumes of insertions with volumes of removals, and could reflect the quality of care within their programs. With this in mind, the data and monitoring subgroup of the Implant Removals Task Force is developing an adaptable tool to assist countries in identifying and addressing implant removal trends and issues. Additionally, where possible globally managed surveys, such as those conducted by PMA2020 and the Demographic and Health Surveys, should incorporate questions on capacity to provide removal services, number of implant removals, their timing of removal in relation to the 3-to-5-year life-of-use, the reasons for removal, and whether the client elected to use another implant or any other method after removal of an implant.

Ultimately all inserted implants will need to be removed, and thus the ability to offer quality removal services on demand is of inevitable importance. This readiness rests on our ability to:

1. **Ensure clients are well-informed.** Not only should women be counseled at the time of insertion on when, where, and how to access follow-up care and removal, but programs should also explore how to make sure this information is available on an ongoing basis and clients are aware when it is time to have the implant removed. Community mobilization, including use of community health workers, as well as social and behavior change communication efforts may be effective here.

2. **Support providers to maintain competence and confidence in the removal procedure.** We must find ways to overcome the barriers to providers’ ability to perform implant removals, through traditional and non-traditional approaches. Currently, opportunities for clinical practice are limited because demand for removals at training events is relatively low or nonexistent during this phase of introduction or rapid scale-up. This means few providers get the chance to practice in the supportive learning environment of a training. Those who do leave training competent may face low client load upon return to their facility, which leaves them with few opportunities to maintain their skill. These factors may also affect the quality of the removal and capacity to identify and manage difficult removals. Reviewing training plans (including plans for client mobilization) and expanding session times on removal practice is a starting point while additional solutions are explored.

3. **Plan ways to include implant provision (insertion, follow-up, and removal) within the total health system.** At a planning level, strategies, budgets, and costed implementation plans should accommodate the equipment and consumables, human resources, and trainings required to ensure availability of removal services, including ensuring that services are free for the poor or that any fees levied are affordable. While it may not be feasible for every level of the health system or provider offering implants to provide removals, planning will be needed to establish removal services through a referral system or other approaches. Additionally, service delivery approaches that expand access to implants should include contingencies for access to removal services. For example, task shifting

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**BOX. What Would Quality Implant Removal Services Look Like?**

- Supplies for implant removal are available at the point of service.
- Provider is competent and confident.
- Systems are in place for managing difficult removals.
- Counseling, side-effect management, and resupply and switching are offered.
- Client knows when and where to go for removal.
- Service is available when client wants it, within a reasonable distance.
- Service is affordable (or free).
- Removal data are collected and monitored.


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and mobile outreach have helped implants meet demand for family planning and penetrate farther into rural and other underserved communities, but these programs must think ahead when expanding access through means that do not guarantee continuous and universal access to a competent provider for follow-up and removal. An optimal approach to expanding access to implant removals likely involves a total market approach that leverages private and NGO partners and uses their comparative advantages to ensure that the needs of all segments of the population are met and that available resources are maximized so the poor and vulnerable are not left out.

The current scale-up of implants is the result of coordinated efforts on the part of many groups and individuals, including providers, seeking to sustain the expanded choice of methods presented by implants. To prevent the ongoing scale-up from being undermined, further investment and efforts to measure and expand access to implant removals are needed, and the timing is right. We also call on advocates to aid in focusing efforts and refining our “asks” at the global, national, and subnational levels, such that change can be achieved thoughtfully and efficiently.

The Implant Removal Task Force is poised to play an important role in collecting and disseminating knowledge on this topic; we encourage all parties engaged in contraceptive implants provision to look carefully at all aspects of providing quality removal services—the client, the provider, and the system—and take swift action to ensure the availability of quality implant removal services.

Acknowledgments: Critical contributions and review were provided by the following individuals (in alphabetical order): Elaine Charurat (Jhpiego), Lila Cruikshank (Global Impact Advisors), Ricky Lu (Jhpiego), Patricia MacDonald (USAID), Julia McDowell (CHAi), Elaine Menotti (USAID), Sandra Novo (UNFPA), and Renee Van de Weerdt (UNFPA). Additional support was provided by Lindsay Breithaupt (Jhpiego) and Elizabeth Thompson (Jhpiego).

Competing Interests: None declared.

REFERENCES
Using Qualitative Methods to Validate and Contextualize Quantitative Findings: A Case Study of Research on Sexual Behavior and Gender-Based Violence Among Young Swazi Women

Allison Ruark, a* Rebecca Fielding-Millerb*

Nesting qualitative data collection methods within quantitative studies improves results by assessing validity and providing depth and context. Using data from 3 sources from Swaziland, we triangulate qualitative and quantitative findings to highlight how different methodologies produce discrepant data regarding risky sexual behaviors among young women. We found that women reported similar numbers of lifetime sex partners in all sources, but the proportion reporting multiple and concurrent partnerships was several times higher in qualitative interviews. In addition, qualitative data can provide deeper understanding of how participants, such as those experiencing gender-based violence, understood the experiences behind the quantitative statistics.

Dr. Allison Ruark and Dr. Rebecca Fielding-Miller contributed equally to the writing of this article.

INTRODUCTION

Most modern public health researchers in the behavioral and social sciences situate their research within a post-positivist framework, either explicitly or implicitly.1,2 Researchers working within a post-positivist framework assume that while objective “truths” of human behavior and experience exist, measuring and defining these realities is at best an approximate science. A physician or clinical researcher can measure blood pressure or CD4 count using precisely calibrated instruments and feel confident in the accuracy of the measurements, but quantifying aspects of human health and well-being is not so simple.

Social scientists and public health practitioners face multiple challenges in determining how best to measure social phenomena and various behaviors relevant to public health and how to define precisely what to measure. Efforts to conceptualize and assess important constructs such as self-efficacy, stigma, social norms, sexual identity, violence, and sexual behavior have generated a great deal of research and debate.3-7 From a post-positivist point of view, these phenomena are subjective by their very nature, making them impossible to precisely define and measure, especially in a way that is meaningful across all contexts.

In this commentary, we consider the challenges of collecting and interpreting data on sexual behavior and gender-based violence (GBV). We present a case study that illustrates challenges and potential solutions to maximize data validity and describe these behaviors and experiences as closely as possible. The comparisons and concepts come from our experience conducting 2 separate research studies in Swaziland in 2013–2014, both of which characterized sexual behavior among Swazi women in their 20s and 30s. We did not set out to collect comparable data, but we noticed that our research studies (1 qualitative and 1 quantitative using audio computer-assisted self-interviewing [ACASI]) produced very different findings about sexual behavior in research populations that seemed to be quite similar. Our data also differed markedly from the latest Swaziland Demographic and Health Survey (DHS).8 These observations led to further consideration of how different data collection methodologies and various sources of bias may influence the story that participants tell in a research interview, and how closely our research findings reflect the “true” nature of behaviors in our study populations. We believe that frank
Measuring and defining human behavior and experience is at best an approximate science.

Frank consideration of the strengths and weaknesses of data collection methodologies is critical to maximizing the validity of collected data and the value of research.

Using qualitative methods to collect data on sensitive topics, such as sexual history or violence, can provide critical insight and context, resulting in better interventions.

In qualitative research, the researcher is the instrument used to collect data, and therefore rapport between the researcher and participant is a critical aspect.

consideration of the strengths and weaknesses of data collection methodologies is critical to maximizing the validity of collected data and the value of research.

COLLECTION OF BEHAVIORAL DATA

The collection of behavioral data in public health research rests on 2 assumptions. First, that research participants have life experiences and engage in behaviors that influence their health risks and outcomes. Second, that data collected through behavioral research can measure the “true” nature of these experiences and behaviors with enough accuracy to be useful to interventions designed to mitigate health risks.

The challenge of behavioral research is to minimize the degree of error and bias, which is inevitable in all research studies, but especially in studies that use self-reported behaviors on sensitive topics.

Collecting data through self-report is often necessary for sensitive topics such as sexual history, experience or perpetration of violence, or other phenomena for which observation is problematic or impossible. Self-reported data on sensitive topics are subject to a number of well-recognized potential biases, including social desirability bias, item response bias, reporting bias, and recall bias. People may report their sexual behavior inconsistently over time, and self-reports of sexual behavior have been found to be inconsistent with biological data and reports of sexual partners. Many types of bias derive from the data collection activity itself and are influenced by the methodology used and the skill and identity of the data collector.

There are many reasons why research participants may choose to represent their stories in research settings in a certain way. The interview is a “situated, social activity” in which the person being interviewed “produces, reproduces, and articulates” an identity, largely in response to rapport with and perceptions of the interviewer, and in response to “situational, cognitive, social, and psychological factors.” While there is likely no research methodology that can consistently deliver data that perfectly represent reality, there are many good reasons to strive to improve the validity of the data we collect. For example, using qualitative data collection methods to understand sexual risks and experiences of sexual violence in a population can result in better interventions.

Comparing the Validity of Different Methods of Collecting Data on Sexual Behavior and Gender-Based Violence

Various studies provide evidence that study interviewers can influence participants’ reports of sexual behavior or experiences of violence. In South Africa, respondents reported more conservative sexual behavior (fewer lifetime sexual partners and more condom use) to older interviewers, and men were especially likely to report fewer lifetime sexual partners to male interviewers. In Uganda, women were more likely to report sexual activity and willingness to use condoms to male interviewers compared with female interviewers. In Malawi, adolescent girls were more likely to report having had sex when asked by a nurse before testing for sexually transmitted infections, compared with face-to-face interviews or ACASI.

In qualitative research, the researcher is the instrument used to collect data, and rapport between the researcher and participant is a critical aspect of data collection. ACASI has frequently been employed to increase confidentiality and data validity in research on sexual behavior. ACASI has generally been found to yield higher reports of some sensitive sexual behaviors, but not others, compared with face-to-face interviews, differing in some cases by respondent gender. Two 2010 reviews yielded somewhat different conclusions. Langhaug and colleagues concluded that there was “strong evidence” that computer-assisted interviewing increased reports of sensitive sexual behaviors in developing countries. Phillips and colleagues conducted a meta-analysis of data from low- and middle-income countries (LMICs). They concluded that compared with face-to-face interviews, other methods did not consistently yield higher reports of ever having sex, non-condom use, or number of sexual partners, but did produce higher reports of forced sex.

We identified few studies that compared the validity of various methodologies for collecting self-reported data on GBV experiences.Interviewer training and skill is likely an important factor, and without specific training on the nature of GBV and sexual assault, even highly trained research assistants may struggle with how to categorize a particular event. Evaluations from the United States and Canada suggest that ACASI may capture more reports of intimate partner violence than face-to-face interviews, and that many women prefer disclosing these experiences to a computer rather than to another person.
However, very little evidence exists on the relative validity of using ACASI to measure self-reports of violence in LMICs. In low-income communities in Bangladesh, India, young married women reported significantly fewer experiences of domestic violence via ACASI than they did in face-to-face interviews. In these contexts, face-to-face interviews may have had higher disclosure because of their perceived cathartic value, or because of the potential of being connected to services in otherwise low-resource settings.

Qualitative methods can increase opportunities for building trust between an interviewer and a participant and contain the flexibility to enable the participant to co-construct the interview and introduce new topics of inquiry. These attributes of qualitative research may produce data that are richer, more nuanced, and more valid than data collected through quantitative means. Studies of individual sexual behavior and sexual violence typically use in-depth interviews (IDIs) rather than focus group discussions (FGDs). The privacy and confidentiality of IDIs encourages participants to share their personal opinions on sensitive topics, whereas FGDs are more likely to capture data on community norms, or what FGD participants believe is socially acceptable to say in front of others.

Survivors of violence may construct their experiences in a variety of ways depending on their cultural context, current life circumstances, and the interview scenario itself, and therefore GBV studies may particularly benefit from a qualitative approach that allows space for nuance and flexibility. Survivors may be reluctant to discuss experiences of violence out of shame, particularly with survey interviewers with whom they have little rapport. Survivors may not recall their experiences, or they may reconstruct what occurred in a way that distances them from stigmatized identities (such as that of a rape or sexual assault victim). A qualitative exploration in South Africa found that women who described non-consensual, coerced, or violent sexual experiences with intimate partners would frequently describe these experiences as disappointing, emotionally hurtful, or traumatic, but rarely categorized them as rape and often attributed them to men’s “natural” sexual drives and entitlement.

The Importance of Using Mixed Methods in Research on Sexual Behavior

It is not uncommon for large research trials to use qualitative data to contextualize quantitative findings about sexual behavior. While the value of combining quantitative and qualitative methods in research of violence has been recognized, few studies using such a mixed-method approach in LMIC contexts were found in the literature. Schatz and Williams note that many researchers have called for mixed-methods research on topics related to gender, and issue a specific call for qualitative studies to validate and contextualize DHS data on gender inequality. Qualitative research can inform the development of structured, quantitative questionnaires, establish which words or phrases are locally understood to refer to acts of violence such as rape or coerced sex, or aid researchers in navigating complex cultural minefields as they ask sensitive questions about sex and violence. Qualitative methods also provide context. For example, a study of GBV in the Democratic Republic of the Congo used FGDs with women who had suffered violence to further explore topics addressed in a quantitative survey. The open-ended nature of the FGDs enabled women to voice concerns and priorities that had not been addressed in the quantitative survey instrument, resulting in suggestions for further research.

Despite the frequency with which qualitative and quantitative methods are used in the same project, we identified only 1 study that used qualitative data to validate quantitative sexual behavior data. In Malawi, a qualitative study nested within a larger quantitative project found that more young women and men reported having ever had sex in IDIs compared with face-to-face surveys; 39% of young women and 17% of men gave discrepant answers in the 2 interview modalities. In an analysis of the IDIs, Poulin concluded that they allowed for “flexibility and reciprocal exchange” that did not exist in the surveys, thus producing trust between the interviewer and participant and resulting in more accurate reporting. Repeated IDIs may be especially effective in increasing rapport, and may also be useful for collecting longitudinal data on the experiences of participants over time.

**CASE STUDY COMPARING DATA ON SEXUAL BEHAVIOR AND GBV FROM DIFFERENT SOURCES**

In this case study, we compare data from 3 sources: the Swaziland DHS 2006–2007; a quantitative ACASI survey of young women’s sexual histories that included questions on GBV; and...
a qualitative interview-based study of young women’s sexual partnerships that also elicited data about GBV. We provide this case study as a practical example for public health researchers and practitioners who wish to integrate qualitative methods into a quantitative study. We believe this approach can lead to better research and outcomes.

Swaziland Demographic and Health Survey

The 2006–2007 Swaziland DHS was a large, nationally representative survey carried out by the Swaziland Central Statistics Office in partnership with Macro International and the first and only DHS to be conducted in Swaziland.8 Trained Swazi data collectors administered face-to-face interviews with participants from all 4 regions of Swaziland between July 2006 and February 2007. The DHS report does not mention any effort to match interviewers to respondents by age or gender. The Woman’s Questionnaire took an average of 2 hours to complete and included questions about demographic characteristics and attitudes and behaviors related to fertility and health, including a sexual partner history extending to the 3 most recent sexual partners. Nearly 5,000 women ages 15 to 49 were included in the DHS (a 94% response rate). In this case study we present weighted data for 2,767 women ages 20 to 39 who reported ever having sex to increase comparability to other data presented. We had no role in collecting these data, but the first author (AR) extracted age-specific data from datasets made available at www.dhsprogram.com.

Audio Computer-Assisted Self-Interview Survey

Between February and June 2014, the second author (RFM) conducted a quantitative survey with 406 pregnant women ages 18 to 42 accessing antenatal care in 1 rural and 1 urban public health clinic.47,48 In this case study, we present a sub-sample of 340 women ages 20 to 39 who reported ever having sex to increase comparability to other data presented. We had no role in collecting these data, but the first author (AR) extracted age-specific data from datasets made available at www.dhsprogram.com.

Qualitative Interviews

From June 2013 to September 2014, the first author (AR) carried out a qualitative ethnographic study of the transitions and trajectories of young Swazi adults’ sexual partnerships.51,52 Data presented here are from repeated in-depth life-course interviews with 14 Swazi women between the ages of 20 and 39. Participants were recruited from a central location in Mbabane, the capital of Swaziland, and were purposively sampled to provide variation in education level, marital and relationship status, and place of residence (urban, peri-urban, and rural). Interviews were carried out in siSwati or in a mixture of English and siSwati by trained Swazi interviewers who were themselves young women in their 20s and 30s.

Each woman was interviewed 3 to 5 times, with the total average interview time per woman being over 3 hours and the average time between first and last interview being 9 months. Interviews were semi-structured and addressed family backgrounds and sexual partnership history, with emphasis given to the chronology and overlap of sexual partnerships. Each woman was encouraged to tell the story of each of her sexual
partnerships in as much detail as she was willing to divulge. Further details about the methodology of this study are provided elsewhere. The SEC and the Institutional Review Board of the Miriam Hospital (Providence, RI, USA) approved this study.

**USING QUALITATIVE DATA FOR TRIANGULATION: SEXUAL BEHAVIOR**

In Figure 1, Figure 2, and Figure 3, we present sexual history data derived from the 3 sources described. Triangulating research findings from different sources provides a validity check to all data sources. We noted that women reported similar numbers of lifetime sexual partners in all surveys, with a very similar proportion of participants reporting 1 or 2 lifetime sexual partners in ACASI and DHS data, and only a small minority in all 3 surveys reporting 5 or more lifetime sexual partners. The proportion of women reporting multiple and concurrent sexual partnerships in qualitative interviews was several times that observed in the quantitative surveys, however. A substantial minority of women reported only 1 lifetime sexual partner in both ACASI and DHS data, but no participants in the qualitative interviews did so. The proportion of women who reported 2 or more sexual partners in the past 12 months among qualitative interview participants was an order of magnitude greater than the proportion reporting multiple partners among ACASI and DHS participants. Similarly, participants in the qualitative interviews were several times more likely to report having concurrent partners in the past 12 months than were participants in the ACASI survey.

We do not argue that these data are directly comparable, and we have intentionally presented them visually rather than numerically so as not to invite statistical comparison. Calculating the magnitude and significance of differences between data from these discrepant sources would be epistemologically and statistically inappropriate. These data were drawn from different populations at different points over a decade, and with somewhat different inclusion criteria. By definition, all women participating in the ACASI study had reported at least 1 sexual partner in the preceding 12 months. The ACASI and qualitative studies also used convenience samples while the DHS data attempted to create a nationally representative sample.

**FIGURE 1.** Number of Sexual Partners, Lifetime

![Bar chart showing the number of sexual partners reported by women across different data sources: Qualitative (n = 14), ACASI (n = 310), and DHS (n = 2676).](chart.png)

Abbreviations: ACASI, audio computer-assisted self-interviewing; DHS, Demographic and Health Survey.
FIGURE 2. Number of Sexual Partners, Past 12 Months

Abbreviations: ACASI, audio computer-assisted self-interviewing; DHS, Demographic and Health Survey.

FIGURE 3. Concurrent Sexual Partners, Past 12 Months

Abbreviation: ACASI, audio computer-assisted self-interviewing.
All data describe young, sexually experienced women between the ages of 20 and 39 in Swaziland. We believe the observed differences between the 3 sources are striking and strongly suggest that qualitative methods may produce higher reports of sensitive sexual behaviors than do standard quantitative surveys. We assume that Swazi women will be highly unlikely to over-report socially stigmatized behaviors (such as multiple and concurrent sexual partnerships), and therefore that data showing higher levels of socially stigmatized behaviors are more accurate.

The qualitative methods may have produced higher reports of multiple and concurrent sexual partners for 2 reasons. First, an in-depth interview enables a conversation between an interviewer and a participant that elicits a detailed story rather than isolated points of data, reducing the possibility of misunderstanding.21 The longitudinal and iterative nature of the research allowed interviewers to probe and confirm information over multiple interviews (in some cases gently challenging reports that seemed inconsistent or lacking in credibility), and to detect circumstances of risk (such as concurrent sexual partners) that may not have emerged in a once-off interview. Second, repeated interviews and the prolonged nature of the relationship between interviewer and participant created trust and rapport, which we believe increased participants’ willingness to reveal sensitive information. In many cases, additional interviews increased frankness and disclosure as interviewers built rapport with participants over time, resulting in reporting of additional sexual partners.

**USING QUALITATIVE DATA FOR CONTEXTUALIZATION**

In the qualitative and ACASI studies, we asked women how they would describe their first sexual experience. The qualitative study focused on participants’ own interpretation of their experience, whereas the ACASI study asked them to select one of multiple preexisting options: “I wanted to,” “I was persuaded,” “I was tricked,” “I was forced,” or “I was raped.” A comparison of results is shown in Figure 4, with each bubble plotted on the vertical axis according to the proportion of women who reported each outcome, and with the size of each bubble representative of the absolute number of women. For the qualitative data, a brief quote is presented for each woman who reported coerced or forced first sex. While we deliberately present these as a diagram to discourage direct statistical comparisons that would be inconsistent with the nature of the data, we do note that just over one-third of women in both samples described their first sexual experience as forced or coerced. This suggests that a well-implemented ACASI survey can produce similar levels of disclosure as same-gender, face-to-face interviews with strong rapport—the suggested best practice for collecting data on violence against women.17,53

In addition to this validity check of the quantitative ACASI data, triangulating survey findings with qualitative data provides a deeper understanding of how participants understood the experiences behind the statistics, and how their understanding may have shifted over time. Just less than half of ACASI respondents reported acquiescing to sex after a partner “persuaded” or “begged” them (Figure 4). However, from the ACASI survey alone we do not know precisely how women may have experienced an encounter that they later labeled as “persuasion.” Restrictive cultural norms may lead participants to select the “persuaded” option to describe a fully consensual and enthusiastic encounter if they feel it is culturally unacceptable for women to express strong sexual desire.54 Conversely, women who reported being “persuaded” by a partner could also be revising traumatic events because they feel shame admitting to experiences of sexual violence. In the qualitative data, some women recast violent or coercive events into acts of love or desire, such as this account of a woman’s first sexual partner:

*He used to overpower me, to be honest. We didn’t have sex because we were in love … He took advantage of me and I could see that he wanted to have sex with me and I refused. He said that I couldn’t refuse now and he carried on … I got used to him even though I was scared of him … He saw that so he tried to bring me closer by apologizing and the relationship was okay from there.*

While this participant might choose the category “I was persuaded,” given limited response options in a quantitative survey about her first sexual encounter, her account suggests the difficulty of subsuming complex experiences into a single descriptor or category. We suggest there is a need for nested qualitative research to build context and “thick” description55—rich,
contextualized description of human behavior—
into larger observational and survey-style studies
on subjects such as GBV.

RECOMMENDATIONS

Based on a comparison of multiple data sources
from Swaziland, we suggest that qualitative meth-
ods have an important role to play in research
studies, including surveillance, observational, and
experimental studies. Formative qualitative work
before and during a quantitative survey may
identify potentially unclear questions and language,
improving the quality of the survey questions and
final interpretation of the data. We also recom-

We recommend nesting qualitative data collection
within quantitative studies of sensitive topics
such as sexual behavior and GBV.

Validation

For topics that may benefit from better rapport
between an interviewer and participant, and the
opportunity to probe or revisit topics over the course
of an interview, we recommend systematically
sampling participants from the quantitative survey
and inviting them to participate in a qualitative
interview on the same topic. Although qualitative
research is not traditionally used to generate
statistics, data from a systematically sampled,
representative subsample could provide a useful vali-
dation check on the larger quantitative project.

FIGURE 4. Experiences of Young Swazi Women During First Sex, Qualitative Research Findings Compared With Quantitative ACASI Study Findings

Abbreviation: ACASI, audio computer-assisted self-interviewing.

Each quote is plotted on the vertical axis according to the proportion of women who reported each outcome. For the qualitative data, 5 of 14 women reported coerced or forced first sex, and a single quote represents an individual woman’s account. The size of each bubble represents the absolute number of women reporting each outcome.

We recommend nesting qualitative data collection within quantitative studies of sensitive topics such as sexual behavior and GBV.

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Contextualization
For sensitive or ambiguous topics, in addition to rigorous qualitative formative work to build valid survey instruments, we recommend purposively sampling a subsection of participants who have participated in the quantitative data collection process, or from a similar population, to better understand the context and potential shifting meanings within a survey item. Both the methodology and underlying philosophy of qualitative research provide the flexibility to understand and report the sometimes ambiguous data that result as participants construct and reconstruct traumatic or sensitive experiences. The goal in this case is not to compare and contrast qualitative and quantitative findings, but rather to continue with qualitative investigation until the qualitative data have provided as rich, nuanced, and complete an understanding of the quantitative data as possible.

Rigor
The process of designing a qualitative study, or conducting qualitative interviews or focus groups, requires specific skill sets and explicit training. Acquiring credible, dependable, and confirmable qualitative data to complement quantitative data requires careful thought and an understanding of why and how a given qualitative method (i.e., IDIs, FGDs, observation) is best suited to the question. It is also critically important to select interviewers whose age, gender, social background, and life experiences enable them to create the right kind of rapport with interview participants. Qualitative interviewers require training specific to qualitative approaches and methods to help them build rapport with a participant, feel confident deviating from interview guides when appropriate, and probe deeply to draw out participant stories.

LIMITATIONS OF QUALITATIVE AND QUANTITATIVE METHODS
Despite the importance of qualitative methods, particularly IDIs, we note that they are not appropriate for all research objectives nor are they the panacea for all data quality issues. Qualitative methods are not intended to produce generalizable statistical inferences, and they are time and energy intensive, making qualitative studies with large numbers of participants impractical. The iterative nature of data collection and analysis is also inherently dependent on the researcher-as-instrument, requiring intense and specific training to assure data quality. As we discuss in this commentary, quantitative methods also have substantial weaknesses; they lack the flexibility and iterative approach of qualitative research and cannot detect or correct for the distance between what a participant reports and the “truth.” Mixed-method approaches have the potential to enable qualitative and quantitative methods to work together in complementary and synergistic ways, resulting in higher-quality research.

CONCLUSION
In this commentary, we present a case study comparing 3 sources of data on sexual behavior and GBV experiences of young women in Swaziland. We highlight discrepant findings not for the purpose of statistical comparison, but as a means of discussing the importance of data collection methodology and the unique strengths of qualitative methods in providing validation and contextualization for quantitative data. The higher frequency of multiple and concurrent sexual partnerships and the rich description of GBV provided in the qualitative study suggest that qualitative methods may more closely approach the “truth” of certain behaviors and experiences. Our objective in this commentary is not to offer definitive answers regarding sexual behavior and GBV among young women in Swaziland, but to raise questions—and offer suggestions—about how research might better capture sensitive behaviors and experiences. We argue that qualitative methods are critical and underused in validating and contextualizing data collected through quantitative methods.

Acknowledgments: We thank the Swazi women who participated in our research and contributed their experiences and insights. We also thank Nonhlanhla Mazibuka, Lunga Dlamini, Mphumi Ncongwane, and Cynthia Vilakati for their assistance. Dr. Ruark acknowledges support from National Institute on Drug Abuse (NIDA) grant T32DA13911 and from the New Paradigm Fund. Dr. Fielding-Miller was supported financially and materially by a US Fulbright Grant, the USAID-funded Swaziland Health Community Capacity Collaborative, and the Center for AIDS Research at Emory University (P30AI050409). Support in preparing this manuscript was provided by NIDA grants T32DA023356 and R21DA039782.

Competing Interests: None declared.

REFERENCES
Using Qualitative Methods to Improve Quantitative Findings


Vouchers: A Hot Ticket for Reaching the Poor and Other Special Groups With Voluntary Family Planning Services

Elaine P Menotti, a Marguerite Farrell a

Vouchers can be a highly effective tool to increase access to and use of family planning and reproductive health services, especially for special populations including the poor, youth, and postpartum women. Voucher programs need to include social and behavior change communication with clients and quality assurance for providers, whether in the private or public sector. In the longer term, voucher programs can strengthen health systems capacity and provide a pathway to strategic purchasing such as insurance or contracting.

WHAT ARE VOUCHERS?

Vouchers are a form of results-based financing that have been used in many sectors, including the health sector, in low-, middle-, and high-income countries. Vouchers work as both financing mechanisms to ensure equity and programmatic tools to reduce barriers to access and increase use of critical health services. They are paper or electronic tickets that are distributed or sold to segments of the population who exchange them for health services at accredited facilities. To be accredited, a provider or outlet is generally reviewed against certain facility requirements and quality standards. When accompanied by social and behavior change activities and quality assurance approaches, including training, monitoring, supportive supervision, and site improvements, voucher programs can increase uptake of health services and improve service quality. A voucher program can also prepare a health system for strategic purchasing (e.g., insurance and contracting), engage the private sector, and protect the poor and other special groups. In the last decade, many countries in Asia and Africa have introduced medium- and large-scale voucher programs. We have an opportunity to learn from their experiences.

HOW DO VOUCHERS WORK?

Once established, a voucher program involves a series of transactions between key players. Key transactions include the following, as illustrated by the numbered arrows in Figure 1:

1. A government or donor provides funding to the voucher management agency to establish and run systems and processes; identify and accredit providers and outlets to participate in the program; and provide training on voucher components and requirements to key players including providers and voucher distributors. In addition, the voucher management agency is engaged in monitoring and oversight of voucher distribution and service delivery on an ongoing basis.

2. The voucher management agency provides vouchers to trained distributors, such as NGOs and community health workers.

3. Voucher distributors counsel prospective clients and, if appropriate, give or sell vouchers (for a nominal amount) to a defined segment of the population, for example, the poor, youth, and pregnant or postpartum women.

4. Clients visit preapproved, quality-assured health care providers for products or services covered by the voucher program.

5. Providers give clients products or services free of charge in exchange for a voucher.

6. Providers then submit their claims to the voucher management agency for processing and reimbursement of services, according to a defined verification process.

7. The voucher management agency reimburses providers after verifying service provision.

8. The voucher management agency monitors, reviews, and examines data and submits reports to the donor/governance structure.

Some voucher programs also use an external verification body as an additional layer of monitoring outside of the role of the voucher management agency.
This external verification body conducts audits at regular intervals to ensure vouchers are being used appropriately and provider claims are accurate.

The objective of a voucher program is to address key barriers to accessing and using health services, especially among vulnerable populations. It should have the resources to operate at a medium to large level of scale, given the substantial systems investments required to set it up and operate. As outlined in Figure 2, the key design features of a voucher system cover 4 main areas:

- **Foundational** elements include the source of funding, generally donor or loan funds but could also be the government; program objectives and time frame; and the governance structure, often an advisory board comprised of government, donors, and other stakeholders.
- **Management** begins with identifying a capable voucher management agency (government, donor, or other).
NGO, or commercial entity) that establishes systems and processes for selection and accreditation of health care facilities; provider quality assurance; designing, printing (if using paper vouchers), and delivering vouchers to distributors; claims processing and reimbursement; mitigation and control of fraud; and ongoing monitoring and reporting to the donor/governance structure. Alternatively, these functions could be executed by multiple agencies to leverage existing local capacity. Management of the voucher system may include external verification to ensure transparency and fraud mitigation. This is particularly common when the voucher management agency participates in service provision and implementation, for example, when social franchise organizations (typically NGOs) serve as the voucher management agency while using their franchised health clinic networks and existing contracts with health care providers to deliver services in voucher programs.

- **Provider** factors include determining the type, level, location, and sector (public, private for-profit, private not-for-profit, or a mix of these) of health care facility to include; recruiting, accrediting, and retaining qualified providers to participate in the voucher program; and identifying and establishing service packages and pricing. The design of the voucher program should incorporate ongoing quality assurance inputs and support to providers so that the services covered by the program achieve quality standards and revenue from vouchers can be reinvested into quality improvements.

- **Client** factors include identifying key segments of the population and their need for services, how much to charge for a voucher (always below the market rate) or whether to distribute the vouchers for free, how to distribute vouchers, which services to include, how to promote the services and the program to the intended population to generate demand, and how to deliver services. Vouchers may focus on a single health area, such as family planning, but could include multiple services in that area such as counseling, method provision, a follow-up visit, and method removal (as relevant). Alternatively, vouchers can include a package of services such as antenatal care, institutional delivery, postpartum services, child health, and family planning.

**THE ADVANTAGES OF A WELL-IMPLEMENTED VOUCHER PROGRAM**

Voucher programs for family planning services have been implemented successfully in a range of settings where financial, information, and other barriers impede access to and use of modern contraceptives. For example, Box 1 illustrates how a voucher program in Uganda increased uptake of family planning services, particularly of voluntary long-acting reversible contraceptives. For example, Box 1 illustrates how a voucher program in Uganda increased uptake of family planning services, particularly of voluntary long-acting reversible contraceptives. Box 2 highlights two examples of voucher programs that provided family planning and reproductive health services for youth. A review of available literature and implementation experience shows that vouchers can be an effective programmatic tool as well as a financing mechanism for family planning and reproductive health. Key benefits and comparative advantage of voucher programs are summarized in the Table and outlined in more detail below.

- **Target health care subsidies toward the poor and other special groups.** Vouchers,
BOX 1. Voucher Program in Uganda Increases Access to and Use of Long-Acting Reversible Contraceptives

From 2011 to 2014, Marie Stopes Uganda implemented a voucher program in private franchised clinics to provide family planning services to more than 325,000 clients; 66% were not using a contraceptive method before the program and nearly 80% had no education or only primary education (a proxy indicator for low income).9

The voucher program offered all methods of contraceptives; however, the majority (94.9%) chose long-acting reversible contraceptives, which have limited availability in the public sector and may be too expensive for some clients. Estimates show that the voucher program increased modern contraceptive prevalence by nearly 1.5 percentage points. It is clear that reducing financial and other access barriers successfully increased uptake of family planning services.

BOX 2. Spotlight on Voucher Programs for Youth

In Madagascar, a voucher program implemented between July 2013 and December 2014 provided family planning and reproductive health services for more than 43,000 youth who faced financial and other barriers in accessing a full range of services; 78% chose an implant or intrauterine device, and just over half received screening or treatment for sexually transmitted infections.10

In Nicaragua, a youth voucher program running from September 2000 to July 2001 that provided a total of 28,771 vouchers, found that youth participating in the program were 3 times more likely to use family planning and reproductive health services, 2 times more likely to use modern contraception, and 2.5 times more likely to report condom use at last sexual contact compared with youth not participating in the program.11 Researchers also found that providers participating in the Nicaragua voucher program had better knowledge, improved practices, and some attitudinal changes in support of provision of family planning and reproductive health services to youth compared with providers not involved in the program.12

<table>
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<th>TABLE. Key Advantages and Challenges of Voucher Programs</th>
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<td><strong>Advantages</strong></td>
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<tr>
<td>Reduce financial and other client barriers to accessing health services.</td>
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<td>Allow governments and donors to target subsidies for populations in need, such as poor, youth, and pregnant or postpartum women.</td>
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<tr>
<td>Allow resources to be directed toward key or high-impact health interventions and can stimulate demand for health services and behaviors.</td>
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<tr>
<td>Create a network of quality-assured health care providers, which can enhance access to services in the short term, and a platform for strategic purchasing in medium to longer term.</td>
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<tr>
<td>Voucher revenue can flow directly to health care providers, which the providers can then reinvest in facilities and services to further improve them.</td>
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Voucher programs help to protect vulnerable groups, increase uptake of health services, improve service quality, engage the private sector, and strengthen health systems.

The private sector serves an especially important role where public-sector quality may be weak, where people already seek private care, and where use of preventive services is limited.

- Promote demand for and use of family planning and reproductive health services while enhancing client choice. Voucher programs can be a promotional tool to expand access to and choice of health care services. Programs can and should accompany voucher distribution with social and behavior change communication efforts to promote demand for and improve knowledge of the key health behaviors and services. Promotion of the voucher program helps raise client awareness of what services are offered and where, particularly if they are new or underused services; without promotion efforts, clients may not be aware of and use the voucher. In one voucher program area, only 25% of women from the communities had heard of the family planning voucher, versus 82% who had heard of the safe motherhood voucher; corresponding family planning service uptake was lower than for safe motherhood. Researchers suggest that low uptake may have been due in part to the absence of adequate communication with clients and communities about the family planning voucher program. Vouchers can particularly address access barriers for clinical services, such as long-acting and reversible contraceptives and permanent methods, in areas where poor women are less likely to use them, by reducing out-of-pocket costs for clients and ensuring providers get reimbursed for these methods that are relatively costlier to provide than short-acting methods. Often, providers are motivated to participate in a voucher program as it gives them an opportunity to gain new skills, offer new services to clients, and make their clinic more of a “one-stop shop” for clients. Because vouchers subsidize the poor’s purchasing power, this can facilitate the poor’s access to the private sector without spending money out of pocket, thereby reducing inequities in access to health services including family planning.

- Engage and leverage the existing health system to maximize service delivery. Voucher programs can be designed to fit the existing health system and mix of providers, although most programs engage both private- and some public-sector providers to ensure maximum reach and to leverage capacity. Engaging the private sector in voucher provision is particularly important in contexts where quality may be weak in the public sector, where people seek health care in the private sector, and use of preventive services is limited. Increasing the provider mix in a network also extends the reach of social protection and creates more provider choice for clients. In addition, voucher programs can establish a network of health care providers from fractionalized separate entities that were not linked before, but are now accredited voucher service providers. A voucher program in Yemen, implemented by an NGO, kept primary health services, including family planning, running in public clinics or offered the choice of private clinics when the government was unable to flow resources due to active conflict. A successful voucher program implemented by private franchised clinics in Pakistan expanded access to family planning services, as none of the providers offered these services before participating in the voucher program. Providers often like participating in a voucher program because they can increase the number of clients served and attract new clients while offering a range of services, potentially making clinics more profitable.

- Assure and improve the quality of family planning and reproductive health care. Implicit in a voucher program is that participating health care facilities must be accredited and/or provide services according to established quality standards. Programmatic inputs are often required to get a facility accredited and enrolled in the voucher program and fully functional within the system to process
Vouchers and Family Planning Services

Vouchers were introduced to build social health programs or insurance. In Cambodia, providers could then provide services for government facilities participating in the voucher program, thereby driving competition and encouraging providers to make quality improvements, such as privacy, cleanliness, and the addition of other services. In Kenya, postnatal clients at facilities participating in the voucher program received more comprehensive counseling on fertility, healthy birth spacing, and available contraceptive methods than postnatal clients at comparable non-participating facilities. In the longer term, vouchers can institutionalize performance in a clinical setting by focusing attention on quality services rendered, and for public-sector clinics this can improve productivity and efficiency.

- **Provide a pathway for health care providers to participate in insurance.** Most voucher programs are financed by donors or loan funds, but these could eventually be financed by governments with domestic resources. Vouchers can be a precursor to health insurance capability in the health sector and to increase government’s familiarity with purchasing services from the private sector. Successfully contracting with the private sector in a voucher program resulted in a government plan for how to scale up the program nationally. Voucher programs that work with social franchise clinics can network fractionalized private providers with a third-party intermediary organization (usually an NGO) that addresses quality inputs, simplifies reimbursement, and lends itself to future financial transaction flows from governments to multiple private providers.

### THE CHALLENGES OF IMPLEMENTING VOUCHER PROGRAMS

The potential for voucher programs are substantial, but challenges in their implementation do exist. As with most complex interventions, implementers must focus on the specifics and get immersed in the details to ensure a well-implemented program. With experience, the design and function of the voucher system improves and implementation becomes easier. Vouchers can work in a range of contexts, but program implementation should be iterative and dynamic, with monitoring and regular opportunities to adjust designs, service packages, pricing, methods of means testing to identify populations in need, and voucher distribution approaches to ensure optimal functioning and to reach the defined client population. The following questions are important to consider:

- **Programs require substantial administration and oversight—do the benefits outweigh the challenges?** Voucher programs are somewhat complex to set up and manage, and they require ongoing oversight and management inputs. Because of this, voucher programs should be implemented at a medium to large scale to maximize investment in these systems. Costs are high at the early stages of setting up systems, but they should decrease over time as systems are established and expertise is strengthened. Using local organizations to manage voucher programs can organize health care facilities, including a fractionalized private sector, into a quality-assured network, which could then provide services for government health programs or insurance.
Costs may be higher at the early stages of setting up voucher systems but should decrease over time as systems are established and expertise is strengthened.

Single-service family planning vouchers have been successful, but most voucher programs offer a package of integrated services.

such as in India’s Below Poverty Line card or Cambodia’s Health Equity Fund.1,5

- How can public-private partnerships be encouraged? The majority of voucher programs to date have been designed to facilitate contracting of health services through the private sector, including social franchise clinics,1 to leverage private-sector reach, expand provider choice, and improve quality service provision. Voucher programs can, however, function as a type of public–private partnership, with specific roles and functions carried out by the government and private sector. For example, in India a formal public–private partnership approach to the Sambhav voucher program was considered a success.5 In many countries, public-sector health care services are mandated as free, so governments may face difficulty in making the rationale to include public-sector services in a voucher program. Without concerted efforts to address operational challenges, governments may not have the infrastructure, staff, or systems in place to adequately implement, oversee, and manage all aspects of a voucher program to function optimally.25 However, even if public-sector health care provision and facilities are not included, governments can play important roles in oversight, planning, and priority setting with the longer-term view of transitioning a voucher program to government financing, contracting, or insurance. While vouchers should not compete with other social protection mechanisms, such as social health insurance, they should be positioned as complementary and a partnership opportunity to stimulate uptake of health services and incentivize high-quality service provision. Vouchers can also fill a gap when family planning methods or services are not covered, or only partially covered, by insurance packages.

- How does voucher programming influence service provision as a whole? While vouchers may play an important role in ensuring access to and delivery of key health services to populations in need, it is not clear how vouchers affect service provision as a whole or how they affect services not covered by vouchers or clients without vouchers.25 Voucher programs provide facility-level support (e.g., improving infection prevention measures; ensuring adequate clean water/sanitation facilities; installing adequate client privacy measures; training on clinical standards and guidelines; ensuring availability of high-quality commodities, instruments, and consumables; providing job aids, counseling guides, and client informational materials) to ensure that providers have sufficient quality standards to participate in the program, which may have spillover effects on improving the quality of other health services (e.g., infection prevention or client-centered care). In addition, revenue from voucher programming may enable health care facilities to hire staff or purchase supplies and equipment to add or improve services, potentially improving specific services, the client experience, or health care provision overall. However, it is also possible to increase uptake of services but not see any improvements in outcomes or service quality, as shown by researchers examining maternal health demand-side financing programming, including vouchers.31 For family planning, this may not be the case, as any use of services can improve overall health outcomes, such as maternal and infant mortality reduction, but it is important to provide high-quality services and continuity of care with vouchers. In addition to quality assurance inputs and training of providers, a family planning voucher program in Uganda aimed for continuity of care by offering a single voucher that included 4 services with separate, reimbursable barcodes: family planning counseling, method provision, a follow-up visit to address any side effects, and a removal visit (for long-acting and reversible contraceptives).8

- Should family planning be integrated into a multi-service, integrated voucher program or have its own voucher? In Uganda, single-service family planning voucher programs have operated with success, including alongside other types of health vouchers.9,13,14,21 Most voucher programs, however, offer integrated services, such as a program in India that included a package of antenatal, institutional delivery, postpartum, and family planning services.1 In Zimbabwe, a voucher program for youth initially included only family planning services, but later added screening and treatment for sexually transmitted infections after receiving feedback from clients who were interested in and needed more services (personal communication with Anna Mackay,
Deputy Director, Support for International Family Planning Organizations [SIFPO-MSI] Project, Feb. 2016). It is unclear exactly the best way to include family planning services in a bundled package so that the family planning services are still promoted and provided. Experience from two different voucher programs in different areas of Pakistan suggests that a separate family planning visit may yield more uptake.32,33 In one of these programs, 79% of voucher clients visited clinics for family planning services when the services were offered through a separate postnatal care visit. In comparison, 62% of clients in the second program visited clinics for family planning as part of a package of postnatal care services.

• **How can we prepare providers to handle an increase in demand for services?** A key design feature of voucher programs to ensure success is the appropriate selection and retention of qualified health care providers. Retaining qualified providers is particularly important for programs that provide resource-intensive quality monitoring and supervision. Voucher programs may stimulate rapid uptake of services, and if providers are not prepared (e.g., with adequate staff, commodities, and supplies; sufficient operating hours; efficient management of services) the increased service volume may have negative consequences on provider job satisfaction.22 The increased demand for services may also result in providers not being able to provide comprehensive or client-centered care due to time constraints. The possibility of overload may be more acute in public-sector health care facilities, which may have less ability to hire staff, extend hours, or use the reimbursement revenue to make changes, unless the program is designed to address these challenges.25 Private-sector clinics may have more autonomy over the revenue to direct it toward quality improvements, whereas public-sector clinics may not have the autonomy to organize service provision or direct access to resources flowing into the facility.1

**NEXT STEPS**

When implemented at a medium to large scale, voucher programs can achieve results, including reducing barriers to access and improving uptake of key health services to meet the health needs of the poor, vulnerable, and other special populations, in part because of their aim and perhaps ability to facilitate change at both client and provider levels. Voucher programs may also get populations familiar with using key preventive and essential primary health care services and thus may change behavior at a social normative level, another way of ensuring sustainability.

As we work to reaching the Family Planning 2020 (FP2020) goals by addressing gaps in access to family planning, vouchers offer an opportunity to target donor and government resources to those who most need family planning services and products. Those with the highest unmet need may not seek family planning services without subsidies or support and are therefore vulnerable to unintended pregnancy and adverse maternal health outcomes. As we look to improve access to family planning for 120 million more women and girls, we should focus donor and government resources on ensuring that the poor and other special groups can achieve their reproductive intentions.

While universal health coverage may be a vision for the future, there is less discussion in the literature on which short- or medium-term steps we need to take to get there. Vouchers could serve as an intermediate step for public financing to begin to target subsidies to address inequitable rates of maternal, child, and infant mortality among the poor, versus traditional supply-oriented health financing that faces challenges in reaching the poor and underserved.3,4,16 Voucher programs may strengthen capacity and readiness in the health system for implementing universal health coverage that prioritizes the health needs of the poor, engages the private sector, and has a service package that does not leave out key primary health interventions and preventative care, such as family planning. In Cambodia, a voucher program became better aligned with the government’s Health Equity Fund, a safety net program for the poor,1 and even helped to identify new beneficiaries. However, such experiences of transitioning voucher programs into larger health insurance programs are limited.

The community of practice on health voucher implementation in developing countries is growing and has experiences to share, as many voucher programs must undergo midcourse corrections and adoptions to function optimally. We need partner organizations to document their experiences and share their results, and conduct research to address these challenges.25 Private-sector clinics may have more autonomy over the revenue to direct it toward quality improvements, whereas public-sector clinics may not have the autonomy to organize service provision or direct access to resources flowing into the facility.1

**Vouchers can support the aims of FP2020—addressing gaps in family planning access by targeting resources to those who want voluntary family planning services but who may not otherwise seek services without a subsidy or support.**

**We need partner organizations to document their experiences with vouchers, share their results, and demonstrate impact through research when possible.**
when possible to further demonstrate impact and contribute to the body of knowledge to address common challenges and issues in implementation. We have more to learn about voucher programs, and we encourage the implementation and research communities to collaborate to shed light on the following areas:

1. Understand key differences in voucher programs that are implemented by public-sector, private-sector, or mixed public- and private-sector health care facilities, and ways to maximize performance, particularly how best to strengthen implementation and quality in public-sector voucher programs.

2. Gain efficiencies in voucher program operations including:
   - Best practices for provider reimbursement
   - Opportunities for leveraging mobile health technology (e.g., electronic vouchers, provider reimbursement using mobile money, applications for tablets or mobile phones to facilitate provider supervision and oversight techniques)
   - Optimal strategies to target voucher subsidies toward the populations that can most benefit from them while minimizing fraud
   - Strengthened monitoring of programs with aligned key outcomes of interest

3. Document more experiences of medium- to large-scale voucher programs that provide information on performance (e.g., client uptake, new or lapsed family planning clients, poverty status of voucher clients, and observed and reported quality) and cost.

4. Test and document the transition of a donor-funded voucher program to government financing.

Acknowledgments: The views expressed in this article are those of the authors and do not necessarily reflect the views of the U.S. Agency for International Development or the U.S. Government.

Competing Interests: None declared.

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Peer Reviewed

Received: 2016 Mar 22; Accepted: 2016 Jun 8; First Published Online: 2016 Sep 26


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Successful Implementation of a Multicountry Clinical Surveillance and Data Collection System for Ebola Virus Disease in West Africa: Findings and Lessons Learned

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Despite resource and logistical constraints, International Medical Corps cared for thousands at 5 Ebola treatment units in Liberia and Sierra Leone between 2014 and 2015 while collecting hundreds of data points on each patient. To facilitate data collection and global reporting in future humanitarian responses, standardized data forms and databases, with clear definitions of clinical and epidemiological variables, should be developed and adopted by the international community.

ABSTRACT

Background: The 2014 outbreak of Ebola virus disease (EVD) in West Africa was the largest ever recorded. Starting in September 2014, International Medical Corps (IMC) managed 5 Ebola treatment units (ETUs) in Liberia and Sierra Leone, which cumulatively cared for about 2,500 patients. We conducted a retrospective cohort study of patient data collected at the 5 ETUs over 1 year of operations.

Methods: To collect clinical and epidemiological data from the patient care areas, each chart was either manually copied across the fence between the high-risk zone and low-risk zone, imaged across the fence, or imaged in the high-risk zone. Each ETU’s data were entered into a separate electronic database, and these were later combined into a single relational database. Lot quality assurance sampling was used to ensure data quality, with reentry of data with high error rates from imaged records.

Results: The IMC database contains records on 2,768 patient presentations, including 2,351 patient admissions with full follow-up data. Of the patients admitted, 470 (20.0%) tested positive for EVD, with an overall case fatality ratio (CFR) of 57.0% for EVD-positive patients and 8.1% for EVD-negative patients. Although more men were admitted than women (53.4% vs. 46.6%), a larger proportion of women were diagnosed EVD positive (25.6% vs. 15.2%). Diarrhea, red eyes, contact with an ill person, and funeral attendance were significantly more common in patients with EVD than in those with other diagnoses. Among EVD-positive patients, age was a significant predictor of mortality: the highest CFRs were among children under 5 (89.1%) and adults over 55 (71.4%).

Discussion: While several prior reports have documented the experiences of individual ETUs, this study is the first to present data from multiple ETUs across 2 countries run by the same organization with similar clinical protocols. Our experience demonstrates that even in austere settings under difficult conditions, it is possible for humanitarian organizations to collect high-quality clinical and epidemiologic data during a major infectious disease outbreak.

INTRODUCTION

The outbreak of Ebola virus disease (EVD) in West Africa that began in 2014 is the largest since the Ebola virus was first discovered in 1976. Nearly
30,000 people were infected and almost 12,000 died in the hardest-hit countries: Liberia, Sierra Leone, and Guinea.1–3 The World Health Organization (WHO) formally declared the Ebola epidemic in West Africa a public health emergency of international concern on August 8, 2014.4 Days later, International Medical Corps (IMC), which had already begun its own assessment, launched its initial response to the outbreak.

Starting in September 2014, IMC opened and managed 5 Ebola treatment units (ETUs) in Liberia and Sierra Leone. These 5 ETUs cumulatively cared for more than 2,500 patients. IMC used a comprehensive approach to EVD prevention and management, which included direct health care within ETUs; water, sanitation, and hygiene interventions; psychosocial support; support for infection, prevention, and screening in local health facilities; and social and behavior change elements within affected and at-risk communities.

From the 5 ETUs in Liberia and Sierra Leone, IMC amassed more than 25,000 pages of clinical, epidemiological, psychosocial, and operational data over the course of the epidemic. IMC established an Ebola Research Team in March 2015 with the goal of collecting, aggregating, cleaning, quality checking, and analyzing this data to better inform the scientific and humanitarian response to future epidemics.

Several prior reports have documented the experiences of individual ETUs in Sierra Leone and Guinea. However, no prior studies have presented data from multiple ETUs across multiple countries run by the same organization with similar clinical protocols.5–9 In addition, prior published studies have focused on demographic and outcome data for patients with EVD, and have not presented a comprehensive picture of the details involved in both providing and documenting clinical care for patients with EVD in resource-limited settings.

This study presents IMC’s EVD case management operations across Liberia and Sierra Leone, including numbers and trends of patient admissions to our ETUs; key demographic information and outcomes among admitted patients; and geographical and longitudinal displays of patient admissions, EVD positivity, and mortality. In addition, we provide detailed information, within this article and the supplemental appendices, on the clinical care provided to patients and the methods of data collection within our ETUs.

**METHODS**

**Study Design**

This retrospective cohort study includes patient data collected at 5 ETUs operated by IMC in Liberia and Sierra Leone between September 15, 2014, and September 15, 2015, as part of IMC’s comprehensive response to the West African EVD epidemic. Ethical approval for this study and exemption from informed consent was provided by the Sierra Leone Ethics and Scientific Review Committee, the University of Liberia–Pacific Institute for Research and Evaluation Institutional Review Board, and the Lifespan Rhode Island Hospital Institutional Review Board.

**Program Setting**

In cooperation with local health ministries, IMC operated 5 ETUs in Sierra Leone and Liberia between September 15, 2014, and December 31, 2015. The first 2 ETUs to open, in September and November 2014, were located in Bong County and Margibi County, respectively, in Liberia, where the epidemic first peaked in the summer and fall of 2014. As the epidemic began to peak in neighboring Sierra Leone, 2 additional ETUs were established there: in Lunsar, Port Loko District, and in Makeni, Bombali District. In April 2015, IMC assumed management of a fifth ETU in Kambia, Kambia District, Sierra Leone.

**Patient Triage Procedures**

Individuals experiencing symptoms consistent with EVD arrived at IMC’s 5 ETUs in 3 ways: transported in an IMC ambulance, transported in a government or private ambulance, or via their own means of transportation (private car, taxi, or walking). The Liberia ETUs received all patients from the ETUs’ catchment areas. In Sierra Leone, however, there were multiple agencies operating in the ETUs’ districts, and the government-run District Ebola Response Center determined where patients were sent.

A minority of patients, tested in the community or at government-managed holding centers before arriving at the ETU, presented with laboratory-confirmed EVD. Most patients, however, presented to the ETU with 1 or more symptoms consistent with EVD but without laboratory confirmation. Upon arrival, all patients without a previously confirmed test for EVD were brought through triage. In triage, patients were screened by trained ETU clinical staff to ensure that they
Patients arriving at an ETU who met the case definition for Ebola virus disease were admitted, while those who did not were referred elsewhere for care.

All patients at IMC ETUs were treated according to standard treatment protocols adapted to the needs of the host country.

Patients were cared for by trained hygienists, nurses, physician assistants, physicians, or psychosocial support staff.

All staff entering the high-risk patient care areas were required to wear full personal protective equipment.

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All staff entering the high-risk patient care areas were required to wear full personal protective equipment.

met the clinical case definition for EVD. IMC created guidelines for this process (see supplementary material) based on WHO and Médecins Sans Frontières (MSF) guidelines and in consultation with local health authorities.10-13 Patients who met the case definition were admitted to the ETU, while those who did not were referred to another operating public or private health care facility, when available, for necessary care.

After triage at the ETU, patients without previously confirmed EVD but who met the case definition were brought to the ward for either suspect or probable disease. There they had a blood sample drawn for initial EVD testing within 24 hours. Patients with an initial negative test result who had had symptoms for fewer than 3 days were held for repeated testing until 72 hours had passed since the onset of their symptoms. Patients with a second negative test result after having symptoms for more than 3 days were considered EVD-negative (EVD-) and were discharged home from the suspect or probable ward or were transferred to another health care facility for further care as soon as logistically possible. Patients with a positive test result were considered EVD-positive (EVD+) and were moved to the ETU’s confirmed ward for further management, as were patients who presented to the ETU with laboratory-confirmed EVD.

Laboratory Testing
For both the Bong and Margibi ETUs, laboratory diagnosis of EVD was performed at the United States Naval Medical Research Center (NMRC) Mobile Laboratory in Bong County, Liberia. Diagnosis was confirmed with the 1-step quantitative Ebola Zaire real-time reverse transcriptase–polymerase chain reaction (RT-PCR) (TaqMan) assay (NMRC, Frederick, MD). Briefly, Qiagen Buffer AVL and ethanol-inactivated blood samples were extracted with QIAamp Viral RNA Mini Kit. Extracted ribonucleic acid was tested for 2 EVD gene targets (Zaire ebolavirus [EBOV] locus and minor groove binding locus), using the Applied Biosystems StepOnePlus instrument. A sample was confirmed to be positive for EVD if both targets were detected, but was considered indeterminate if only 1 target was detected. An indeterminate result led to retesting of the patient.

In Sierra Leone, the Public Health England (PHE) laboratories in Port Loko and Bombali districts performed EVD testing for patients admitted to the Lunsar and Makeni ETUs, while the Nigerian laboratory in Kambia District (supported by the European Union Mobile Laboratory Consortium) provided RT-PCR testing for patients admitted to the Kambia ETU. The processes were similar to those used by the NMRC laboratory, except that the PHE and Nigerian laboratories tested only a single EVD gene target (EBOV locus) as opposed to 2 targets. In addition, the PHE laboratories switched from using the commercially available Altona real-time RT-PCR assay to using the in-house Trombley assay in February 2015.14-16

The PHE and Nigerian laboratories in Sierra Leone performed malaria tests in addition to EVD tests. However, no other laboratory diagnostics were consistently available for any of the 5 ETUs.

Clinical Management
All IMC ETU patients were treated according to standard treatment protocols that were based on guidelines developed by WHO and MSF during prior outbreaks and adapted by IMC, in consultation with local Ministry of Health officials, to the needs and resources of Liberia and Sierra Leone.12,13 Briefly, the standard clinical protocol included empiric antimalarial treatment; broad-spectrum antibiotics; oral rehydration solution (ORS); medications to prevent gastritis; vitamins and nutritional supplementation; and symptomatic treatment for fever, pain, nausea, and delirium. Those who presented with or developed moderate to severe dehydration or inability to drink sufficient ORS independently were treated with boluses of crystalloid solution. The standard clinical and psychosocial procedures manual provided with the supplementary materials includes detailed information on all treatments provided.

Throughout their inpatient course, patients were cared for by trained hygienists, nurses, physician assistants, physicians, or psychosocial support staff. In general, patients were rounded on 1 to 2 times per day by a physician or physician assistant, who documented clinical signs and prescribed treatments, and 3 to 6 times per day by either a nurse, who provided treatment, or a hygienist, who disinfected the environment to prevent spread of the disease in the wards. Because the suspect, probable, and confirmed wards were all located in the high-risk zone of the ETU, all staff entering this area were required to wear full personal protective equipment (PPE).
including scrubs, boots, Tyvek or Tychem suits, masks, hoods, goggles, aprons, and double latex gloves. This limited clinician rounds to 1 to 2 hours at a time due to the heat stress caused by the PPE. The limited rounds meant that all clinical care had to be provided within those periods of rounding, and that for the majority of the day, patients in the wards were unsupervised by clinical staff. At times, however, patients were supported by fellow ETU patients or by EVD survivors who served as caregivers for the very sick.

**Clinical Documentation and Data Collection**

In consultation with local and national ministries of health, WHO, and other international organizations, IMC developed forms to capture demographic, clinical, and psychosocial support data on patients admitted to our ETUs. Examples of these forms, which varied slightly by ETU, are provided as supplementary materials. Triage, laboratory, and discharge forms captured information on patient demographics, presenting symptoms, laboratory test results, and final outcomes and were kept in patient files in the low-risk (nonclinical) area of the ETU. Patient rounding and treatment forms, which were filled out in the high-risk zone of the ETU at the patient’s bedside, included data on patient vital signs and symptoms and on treatments given. Psychosocial support forms included data on mental health symptoms and family and caregiver support, and were filled out once patients were well enough to receive psychosocial support in either the low- or high-risk zone. The data forms were designed to track information on all patients admitted into our ETUs at each critical juncture in their stay from admission through discharge and community follow-up. Forms were also specifically designed with a system of check boxes to minimize the time clinicians spent charting while wearing full PPE.

Because all forms in the high-risk zone were considered contaminated, various methods were used to transfer data out of the ETU. In some cases, the information was read across the fence between the high- and low-risk zones after rounds were completed each day. In these cases, data was read by one staff member, copied onto an identical chart by another staff member, and then placed in the patient’s file in the low-risk zone. In other cases, charts from the high-risk zone were either imaged from across the fence between high- and low-risk zones or imaged inside the high-risk zone using a waterproof camera. The camera was then decontaminated by soaking in a chlorine solution for 30 minutes before being transferred to the low-risk zone, where the images were downloaded onto a laptop computer. All patient files were eventually scanned into PDF, JPEG, or TIFF format within the low-risk zone of each ETU. All data were collected as part of routine clinical care and for epidemiologic purposes.

Patient data, from paper forms or scanned images, were entered into separate electronic databases at each ETU by local data officers and were later combined into a unified database. The combined database was relational in structure and included 10 separate tables encompassing patient demographic, triage, rounding, treatment, laboratory, psychosocial support, outcome, and follow-up data.

At the conclusion of IMC’s ETU program, scanned images of patients’ paper records were stored in IMC’s secure network drive, and the hard copies were transferred to the Ministry of Health in each country. Camera images from high-risk zones in Liberia were stored in this same IMC network drive. Laboratory data, including EVD RT-PCR cycle thresholds, as well as malaria test results from Sierra Leone, were obtained from the NMRC, PHE, and Nigerian laboratories and linked to patient data in IMC’s unified database.
Data Quality Audit and Reentry

In November 2015, we used lot quality assurance sampling (LQAS), a random sampling methodology, to assess the quality of the data entered from original patient charts into the ETU-specific databases.17,18 A random sample of 19 patient ID numbers from 2 substrata, EVD+ and EVD-, were selected from each ETU (except Margibi, where 19 total patient ID numbers were randomly selected because only 5 EVD+ patients were admitted) for this data quality audit.

Due to a high number of discrepancies found among triage, rounding, and treatment patient charts and data entered in the unified database, we reentered data using scanned files of original patient charts. Triage data were reentered for all admitted patients; daily rounding and treatment data were reentered only for EVD+ patients, to prioritize limited resources. We took the following steps to ensure minimal errors during data reentry: (1) using data validation settings in Excel reentry documents, (2) using a codebook to ensure that patient data from various types of patient charts were standardized, (3) conducting additional audits by data entry research assistants, and (4) discussing data entry concerns with the principal investigator.

Once reentry was complete, we conducted another data quality audit using LQAS. From each ETU, we selected 19 patient IDs from 2 substrata, EVD+ and EVD- (except in Margibi). We then compared data on scans of EVD+ and EVD- triage, EVD+ rounding, and EVD+ treatment in patient charts with data in the unified database. Each discrepancy was recorded as an error. The number of errors per patient chart was divided by the total number of data points for the specific patient, which depended on the patient’s length of stay. The total percentage of errors was then calculated. With the results from this audit, we concluded that approximately 99% of the data in IMC’s unified database were consistent with information from scans of patient charts. Table 1 summarizes the results of the LQAS.

Data Analysis

The primary outcome variables of interest for patients admitted to the ETUs were final diagnosis (confirmed Ebola, probable Ebola, or other), disposition (survived, deceased, or transferred), and length of stay in the ETU. Length of stay was calculated as the number of days from date of admission to date of discharge, inclusive of the date of admission. Other variables of interest included demographic variables such as country of origin, sex, and age. Age was categorized based on WHO identification of infants under 1 and children under 5 as particularly vulnerable and then into 10-year blocks. We analyzed ETU admission trends by categorizing the date of admission into epidemiological weeks consistent with WHO usage (Monday through Sunday). Clinical variables at triage, including fever, were self- or family-reported and categorized as yes (1) or no (0).

We used geographic information system (GIS) software to visualize the geographic distribution of total admitted patients and total EVD+ patients by subregion (e.g., chiefdom or district in which a patient’s home village was located).
located). The maps generated for this analysis display the sum of records per subregion. For the map of total confirmed cases, a defined interval classification method with an interval size of 15 was used to display the number of confirmed Ebola diagnoses across the subregions included in the EVD data set; the map of total patients uses a modified natural breaks (Jenks) classification method. More information about the GIS methods used is provided as supplementary material.

Basic descriptive statistics were calculated for the primary outcome variables as well as for demographic, clinical, epidemiologic, geographic, and time-dependent variables. We used chisquare analysis to compare clinical and epidemiologic variables present on the patient’s arrival against the patient’s final diagnosis. We conducted bivariate logistic regression analyses to examine differences in outcomes by age, sex, and country of origin, presenting odds ratios (ORs) with 95% confidence intervals (CIs). To assess differences in length of stay by subgroup, we conducted independent samples t tests and 1-way analysis of variance (ANOVA) tests, as appropriate. Statistical significance was established at .05. Data analyses were conducted in R version 3.2.1 and ArcGIS for Desktop 10.3.1.

RESULTS

The full IMC data set contained information on 2,768 total patients presenting to our 5 ETUs. To ensure full follow-up data was available, we excluded from the analysis 88 patients whose data were either missing the date of triage or who were triaged outside the selected 1-year time period. Patients who were declared dead on arrival (n = 24) and those who were not admitted because they did not meet the predefined case definition (n = 260) were also excluded from analysis. Finally, 45 patients with missing data on EVD outcomes (final diagnosis and/or disposition) were also excluded, leaving 2,351 separate patient admissions for analysis (Figure 1).

Longitudinal and Geographic Data

Figure 2 shows total patient admissions by ETU by epidemiologic week between September 15, 2014, and September 15, 2015. Overall, 1,524 (64.8%) patients were admitted to the 3 ETUs in Sierra Leone, and 827 (45.2%) were admitted to the 2 ETUs in Liberia. Figure 3 shows the distribution of patients’ geographic origin by both total patient admissions (Figure 3A) and confirmed EVD+ patient admissions (Figure 3B). The supplemental figures in the GIS supplementary material provide additional information on the proportions of EVD+ and deceased patients by geographic origin as well as on the numbers of patients EVD+ by the location where they first became ill.

Demographic Data

Of the 2,351 patient admissions analyzed, 53.4% were men and 46.6% were women. The median age was 30 years (interquartile range: 18, 43). Almost 10% of admitted patients were under age 5, and 11% were 55 years or older, while nearly 25% were 25 to 34 years old (Table 2).

Clinical and Epidemiologic Data

Table 3 lists the clinical symptoms and epidemiologic characteristics of patients admitted to the 5 ETUs for triage, stratified by their final diagnosis. Clinical symptoms, including fever, were self- or family-reported and endorsed. While fever (75.3%, P = .11), weakness (71.9%, P = .76), and loss of appetite (68.4%, P = .20) were the most common symptoms in patients with EVD, they were equally common in patients without EVD. Among clinical symptoms, only diarrhea (54.0%, P < .001) and red eyes (27.5%, P < .001); a variable that included both conjunctivitis and conjunctival hemorrhage) were more common in patients with EVD than in those with other diagnoses. Abdominal pain (54.0% vs. 43.5%, P < .001), shortness of breath (30.9% vs. 23.5%, P = .002), and non-ocular bleeding (11.3% vs. 5.5%, P < .001) were actually more common at triage among patients without EVD than those with EVD.

Among epidemiologic variables, any contact with a sick person (82.1% vs. 21.5%, P < .001) and attendance at a funeral (39.7% vs. 8.8%, P < .001) were far more common among patients with EVD. Eating bush meat and working in health care were both uncommon at triage and were not associated with a final EVD diagnosis, while recent travel was somewhat more likely in patients without EVD.

Outcome Data

Among all patients admitted for triage, 470 (20%) tested positive for EVD, including 14 patients

At triage, diarrhea and red eyes were more common among patients diagnosed with EVD than those without. Abdominal pain, shortness of breath, and non-ocular bleeding were more common among patients without EVD.

20% of the patients admitted to IMC ETUs for triage tested positive for EVD.
with probable EVD who died before laboratory testing. Of these 470 patients, 197 recovered to discharge, 5 were transferred to other facilities (final outcome unknown), and 268 died. The overall case fatality ratio (CFR) was 57%. Among EVD- patients, 156 of 1,881 admissions also died during their stay in the ETU, for an overall CFR of 8.1%. Figure 4 shows the total number of patients admitted per week across all 5 ETUs, by diagnosis and outcome.

Average length of stay was 4.7 (standard deviation [SD] = 3.9) days for all admitted patients, although this differed greatly based on diagnosis and outcome (Table 4). The average length of stay for EVD+ patients who recovered was 14.7 (SD = 5.5) days; the average for EVD+ patients who died was 5.6 (SD = 3.2) days (P < .001). For EVD- patients, average length of stay was 3.6 (SD = 1.6) days for those who survived and 2.3 (SD = 1.4) days for those who died (P < .001).
Outcome by Age, Sex, and Location

Figure 5A and Figure 5B show the proportion of patients diagnosed with EVD by age and by sex. Although a higher absolute number of patients admitted to the 5 ETUs were men (53.4% vs. 46.6%; see Table 2), a much larger proportion of women admitted were actually diagnosed with EVD (25.6% vs. 15.2%, \( p < .001 \)). Figure 5C and Figure 5D show outcomes for EVD+ patients (i.e., deceased or recovered) by age and sex.

Table 5 summarizes the CFR among EVD+ patients by age, sex, and location. As shown in Figure 5 and Table 5, EVD+ patients ages 15 to 24 had the lowest CFR (38.0%), while the youngest and oldest patients had the highest CFRs (89.1% for patients under 5; 71.4% for patients over 55). As compared with patients aged 15 to 24, children under 5 had a mortality odds ratio of 12.8 (95% CI, 4.8 to 41.3; \( p < .001 \)), while patients over 55 had a mortality odds ratio of 4.0 (95% CI, 1.9 to 8.7; \( p < .001 \)). No significant differences were found among EVD+ patients in the odds of death based on sex (OR = 1.0; 95% CI, 0.7 to 1.4; \( p = .09 \)) or country of origin (OR = 0.8; 95% CI, 0.5 to 1.1; \( p = .15 \)).

DISCUSSION

With nearly 30,000 cases of EVD, the 2014 outbreak in West Africa dwarfed all prior epidemics of viral hemorrhagic fever.\(^1\) At its height, this Ebola epidemic completely overwhelmed the limited response capacity of the 3 most-affected countries and led to an untold number of secondary deaths due to breakdowns in the local health care and public health systems.\(^19,20\) However, as horrific as this epidemic has been for the people of West Africa, it likely could have been far More men than women were admitted to IMC ETUs. However, a greater proportion of the women admitted were diagnosed with EVD. Among patients with EVD, those ages 15 to 24 had the lowest case fatality rate; the youngest and oldest patients had the highest case fatality rates.
worse had the international community failed entirely to respond. Recent mathematical modeling from Sierra Leone suggests that the introduction of treatment beds for patients with EVD between June 2014 and February 2015 averted an estimated 56,600 cases, while opening ETUs just 1 month earlier could have averted an additional 12,500 cases.21

IMC, in collaboration with local ministries of health, contributed to the 2014 Ebola response in West Africa by opening 5 ETUs to manage suspected and confirmed Ebola cases. IMC trained health workers in infection prevention and control, EVD clinical management, and ETU operations and worked in communities to build awareness around Ebola response activities. While the efforts of IMC and other humanitarian organizations to provide direct medical care to patients and limit the spread of the epidemic has been well recorded by the lay media, another critical activity IMC engaged in has gone almost completely unnoticed: Staff at IMC ETUs collected clinical and epidemiologic data in the most austere and difficult of circumstances.22,23

When IMC first launched its Ebola response in Liberia in September of 2014, very little was known about optimal prevention, treatment, or management strategies for a large-scale EVD outbreak. Despite more than 2 dozen prior outbreaks over the past 4 decades, little empirical evidence existed to guide response operations at the start of this outbreak.22 While recent reports have documented the experiences of individual ETUs in Guinea and Sierra Leone, no prior studies have presented data from multiple ETUs across multiple countries run by the same organization with similar clinical protocols.5-9 The lack of empirical evidence made it difficult to develop standardized clinical protocols for patient care. More importantly, the lack of evidence made it nearly impossible to prioritize our limited available resources for those who might benefit the most, especially early in the response.

As a result of the data collected by our teams in Liberia and Sierra Leone, we know far more about this disease now than when we began our 2014 response. We now have a better understanding of the demographics of patients affected, the expected length of stay in an ETU based on patient diagnosis and outcome, and the expected mortality, for patients both with and without EVD, in a resource-limited environment. We found, for instance, that although fewer women will visit an ETU, a larger proportion of them will have EVD. Where prior publications generally stratified patients into 2 age groupings (young vs. old), we chose to look at patients in 10-year blocks to get a more granular understanding of the effect of age on diagnosis of EVD and patient mortality. This more granular presentation...
of age revealed some interesting nuances, such as highlighting the age groups with the lowest CFR (15–24 years) and the highest mortality (children under 5 and adults over 55). Our data confirmed that high-risk epidemiological factors for contracting EVD include contact with a sick person and attendance at a funeral, but found that eating bush meat was not a significant risk factor for EVD, and that recent travel was more likely in patients without EVD.

In addition, prior analyses of our data set have helped us to develop better tools for EVD screening. We have planned further analyses of our data set as well, which we expect will continue to help us learn about the natural history of this disease and the best ways to diagnose and manage it in resource-limited settings. Our experience in West Africa, however, also taught us important lessons about the many challenges to collecting high-quality data during an epidemic, and the various ways in which these challenges can be overcome.

### Major Challenges to Data Collection and Lessons Learned

#### Lack of Data Standardization

One of the greatest challenges in building our data was the lack of standardization in the data collected across different countries and different ETUs. Despite being managed by the same organization, the various ETUs collected different types of clinical and epidemiologic data in somewhat different formats, and in some cases the types of data collected changed over time. This was due to a variety of factors, including the

---

**TABLE 2. Outcomes Among All Admitted Patients by EVD Status, Sex, Age, and Location, Liberia and Sierra Leone, September 15, 2014, to September 15, 2015**

<table>
<thead>
<tr>
<th>EVD + Recovered</th>
<th>EVD + Deceased&lt;sup&gt;a&lt;/sup&gt;</th>
<th>EVD + Transferred</th>
<th>EVD + Total</th>
<th>EVD- Discharged</th>
<th>EVD- Deceased</th>
<th>EVD- Total</th>
<th>All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>197 (8.4)</td>
<td>268 (11.4)</td>
<td>5 (0.2)</td>
<td>470 (20.0)</td>
<td>1,725 (73.4)</td>
<td>156 (6.6)</td>
<td>1,881 (80)</td>
</tr>
<tr>
<td>Sex&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>76 (6.1)</td>
<td>107(8.5)</td>
<td>3(0.2)</td>
<td>190(15.2)</td>
<td>959 (76.6)</td>
<td>97 (7.7)</td>
<td>1,062 (84.8)</td>
</tr>
<tr>
<td>Women</td>
<td>118 (10.8)</td>
<td>159 (14.6)</td>
<td>2(0.2)</td>
<td>279 (25.6)</td>
<td>754 (69.1)</td>
<td>58 (5.3)</td>
<td>812 (74.4)</td>
</tr>
<tr>
<td>Age, years&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 to &lt; 1</td>
<td>1 (1.9)</td>
<td>13 (24.5)</td>
<td>0 (0.0)</td>
<td>14 (26.4)</td>
<td>36 (67.9)</td>
<td>3 (5.7)</td>
<td>39 (73.6)</td>
</tr>
<tr>
<td>1 to 4</td>
<td>4 (2.4)</td>
<td>28 (16.5)</td>
<td>0 (0.0)</td>
<td>32 (18.8)</td>
<td>127 (74.7)</td>
<td>11 (6.5)</td>
<td>138 (81.2)</td>
</tr>
<tr>
<td>5 to 14</td>
<td>36 (15.5)</td>
<td>29 (12.4)</td>
<td>1 (0.4)</td>
<td>66 (28.3)</td>
<td>158 (67.8)</td>
<td>9 (3.9)</td>
<td>167 (71.7)</td>
</tr>
<tr>
<td>15 to 24</td>
<td>44 (10.8)</td>
<td>27 (6.7)</td>
<td>1 (0.2)</td>
<td>72 (17.7)</td>
<td>312 (76.8)</td>
<td>22 (5.4)</td>
<td>334 (82.3)</td>
</tr>
<tr>
<td>25 to 34</td>
<td>45 (8.1)</td>
<td>42 (7.6)</td>
<td>2 (0.4)</td>
<td>89 (16.1)</td>
<td>434 (78.5)</td>
<td>30 (5.4)</td>
<td>464 (83.9)</td>
</tr>
<tr>
<td>35 to 44</td>
<td>33 (8.8)</td>
<td>53 (14.2)</td>
<td>1 (0.3)</td>
<td>87 (23.3)</td>
<td>260 (69.5)</td>
<td>27 (7.2)</td>
<td>287 (76.7)</td>
</tr>
<tr>
<td>45 to 54</td>
<td>17 (5.8)</td>
<td>36 (12.3)</td>
<td>0 (0.0)</td>
<td>53 (18.1)</td>
<td>214 (73.0)</td>
<td>26 (8.9)</td>
<td>240 (81.9)</td>
</tr>
<tr>
<td>≥ 55</td>
<td>16 (6.2)</td>
<td>40 (15.5)</td>
<td>0 (0.0)</td>
<td>56 (21.7)</td>
<td>175 (67.8)</td>
<td>27 (10.5)</td>
<td>202 (78.3)</td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>114 (7.5)</td>
<td>173 (11.4)</td>
<td>5 (0.3)</td>
<td>292 (19.2)</td>
<td>1,122 (73.6)</td>
<td>110 (7.2)</td>
<td>1,232 (80.8)</td>
</tr>
<tr>
<td>Liberia</td>
<td>83 (10.0)</td>
<td>95 (11.5)</td>
<td>0 (0.0)</td>
<td>178 (21.5)</td>
<td>603 (72.9)</td>
<td>46 (5.6)</td>
<td>649 (78.5)</td>
</tr>
</tbody>
</table>

Abbreviation: EVD, Ebola virus disease.

All data reported as No. (%).

<sup>a</sup> Patients with suspected EVD (n = 14) included in EVD+ deceased.

<sup>b</sup> Missing values not included.
need to comply with local guidelines and use government-approved triage forms; the emergent nature of the epidemic and the lack of time to agree upon and disseminate standardized data collection forms; and the lack of prior empiric evidence on which data elements were most important to collect in the context of EVD.

Some variables, such as eating bush meat or recent travel, were collected in only 1 of the 2 countries. In some cases, subtle differences between the types of clinical variables collected made it difficult to compare data. For example, we had to group “red injected eyes,” “conjunctivitis,” and “hemorrhagic eyes” into a single variable (“red eyes”) for analysis. In the future, standardized data forms with clear, consensus-based definitions of clinical and epidemiologic

| TABLE 3. Chi-Square Analysis of Symptoms Reported at Triage by Patients With and Without EVD, Liberia and Sierra Leone, September 15, 2014, to September 15, 2014 |
|---------------------------------|-----------------|-----------------|-----------------|
| **Clinical symptom**            | **EVD+ Patients, No (%)** | **EVD- Patients, No (%)** | **P Value** |
| Fever                           | 353 (75.3)       | 1,481 (78.7)    | .11           |
| Asthenia (weakness)             | 337 (71.9)       | 1,338 (71.1)    | .76           |
| Loss of appetite                | 321 (68.4)       | 1,228 (65.3)    | .20           |
| Headache                        | 273 (58.2)       | 1,109 (59.0)    | .77           |
| Myalgia or arthralgia (muscle or joint pain) | 273 (58.2)       | 1,093 (58.1)    | .97           |
| Nausea or vomiting              | 225 (58.0)       | 947 (60.4)      | .38           |
| Diarrhea                        | 235 (54.0)       | 662 (37.4)      | < .001        |
| Abdominal pain                  | 204 (43.5)       | 1,016 (54.0)    | < .001        |
| Red eyesa                       | 129 (27.5)       | 189 (10.1)      | < .001        |
| Sore throat or difficulty swallowing | 112 (23.9)       | 440 (23.4)      | .82           |
| Dyspnea (shortness of breath)   | 110 (23.5)       | 581 (30.9)      | .002          |
| Hiccups                         | 57 (12.2)        | 246 (13.1)      | .59           |
| Jaundice                        | 24 (5.1)         | 108 (5.7)       | .60           |
| Bleeding, non-ocular            | 26 (5.5)         | 212 (11.3)      | < .001        |
| **Epidemiologic variable**      |                  |                 |               |
| Had contact with someone ill    | 340 (82.1)       | 367 (21.5)      | < .001        |
| Attended funeral                | 144 (39.7)       | 146 (8.8)       | < .001        |
| Had recent travel outside of home district | 18 (11.7)        | 122 (20.0)      | .02           |
| Worked in health sector         | 9 (4.2)          | 62 (6.5)        | .20           |
| Had contact with bush meat      | 0 (0.0)          | 13 (2.5)        | .06           |

Abbreviation: EVD, Ebola virus disease.

a Includes red injected eyes, conjunctivitis, and hemorrhagic eyes.
Variables should be developed and adopted in advance by the international community to support data collection during outbreaks of viral hemorrhagic fever and other diseases of epidemic potential. Such standardized forms will allow for more consistent and comparable data. Furthermore, clinical staff working with these clinical variables should receive training to ensure that knowledge of these variables is properly used in the field. Evidence collected during this epidemic by our organization and others on the symptoms, signs, and tests that are most predictive of EVD diagnosis and outcomes will likely be helpful in developing these new tools; in the end it will require substantial coordination by the international humanitarian community and local governments to put these tools into practice.

**Logistical Constraints**

The severe logistical constraints related to collecting data in the setting of a highly contagious and virulent disease such as Ebola cannot be overemphasized. Aside from the initial triage data, which we collected by asking patients or family members questions from across a barrier fence at a distance of 2 meters, all of the daily symptom data and treatment information had to be collected at the patient’s bedside in the ETU’s high-risk zone. The providers collecting the data were dressed in full PPE, which limited both their movements and the time they could spend at the bedside. Clinical data forms thus had to be simple to fill out; it was easiest to use mostly check boxes or circles. Moreover, the paper forms that the data was collected on could themselves easily become contaminated with highly infectious body fluids, making each form a biohazard that could not safely be removed from the high-risk zone. Because clinicians washed their (gloved) hands with chlorine in between each patient, but did not dry their hands, the paper forms also became degraded by chlorine over time. Extraction of the data from these contaminated and

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**FIGURE 4.** Final Diagnosis and Outcome of Admitted Patients by Epidemiological Week, Liberia and Sierra Leone, September 15, 2014, to September 15, 2015 (N=2,351)

<table>
<thead>
<tr>
<th>Year and Epidemiological Week</th>
<th>Number of Admissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.38</td>
<td>14.46</td>
</tr>
<tr>
<td>EVD+ Recovered</td>
<td>EVD+ Deceased</td>
</tr>
</tbody>
</table>

Abbreviation: EVD, Ebola virus disease.
In the future, additional solutions for collecting data in high-risk zones safely and efficiently should be considered, such as the use of electronic medical records.

Degraded forms required either the laborious and error-prone process of reading the data over the fence between risk zones and copying it onto new forms after each set of rounds, attempting to image the forms from across the fence, or sending in additional personnel in full PPE for the sole purpose of imaging the forms with a submersible camera that could be decontaminated and removed from the high-risk zone. While each of these methods were used at different ETUs, no method was ideal.

In the future, other solutions could be considered for more efficient means of collecting data. Electronic medical records, accessed through handheld tablets kept in the high-risk zone of the ETU, might offer an easier way to collect data.

Electronic data could then be transmitted via Wi-Fi to a computer located outside of the high-risk zone. Yet while ideal from a data collection standpoint, this method would present challenges in very resource-limited settings: it would be necessary to get the tablets prepositioned and configured before the start of an outbreak, and they would need a working Wi-Fi network. Another option would be a dual system, using paper charts that could be scanned and downloaded onto a laptop within the high-risk zone after each set of rounds, and then electronically transmitted via Wi-Fi when available or even via a simple Ethernet cable to another computer in the low-risk zone.

### Table 4. Average Length of Stay (in Days) in ETU by EVD Status, Outcome, Sex, Age, and Location, Liberia and Sierra Leone, September 15, 2014, to September 15, 2015

<table>
<thead>
<tr>
<th></th>
<th>EVD +</th>
<th>EVD -</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recovered</td>
<td>Deceased</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>ALOS</td>
</tr>
<tr>
<td>All patients</td>
<td>197</td>
<td>14.7</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>77</td>
<td>13.6</td>
</tr>
<tr>
<td>Women</td>
<td>118</td>
<td>15.4</td>
</tr>
<tr>
<td>Age, years *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 to &lt; 1</td>
<td>1</td>
<td>18.0</td>
</tr>
<tr>
<td>1 to 4</td>
<td>4</td>
<td>23.0</td>
</tr>
<tr>
<td>5 to 14</td>
<td>36</td>
<td>15.4</td>
</tr>
<tr>
<td>15 to 24</td>
<td>44</td>
<td>14.4</td>
</tr>
<tr>
<td>25 to 34</td>
<td>44</td>
<td>13.5</td>
</tr>
<tr>
<td>35 to 44</td>
<td>33</td>
<td>15.0</td>
</tr>
<tr>
<td>45 to 54</td>
<td>17</td>
<td>13.4</td>
</tr>
<tr>
<td>≥ 55</td>
<td>16</td>
<td>15.3</td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>113</td>
<td>14.6</td>
</tr>
<tr>
<td>Liberia</td>
<td>83</td>
<td>14.9</td>
</tr>
</tbody>
</table>

Abbreviations: ALOS, average length of stay; ETU, Ebola treatment unit; EVD, Ebola virus disease.

* EVD + patients who were transferred (n = 5) not included.

b Patients with suspected EVD (n = 14) included in EVD + deceased.

c Missing values not included.
**Data Entry Constraints**

The final challenge involved entering data from paper charts or scanned images into an electronic format that could be analyzed. While local data officers entered data into electronic databases in real time at each of the 5 ETUs, the data entry methods and quality control varied by ETU and over time depending on the severity of the epidemic (meaning more patients and more data to enter) and availability of staff. This led to slight differences in the way variables were coded and the formats in which they were coded. Just as the data forms used varied from ETU to ETU, the database software also varied, with some ETUs using Microsoft Access and others using Microsoft Excel. This led to substantial challenges and a great deal of extra work to combine the different data sets. Moreover, our initial quality assurance check demonstrated unacceptably high error rates in some of the data, and it had to be reentered from scanned images of the patient charts. Although we were eventually able to ensure a low error rate of about 1% for our data set overall, much time and effort could have been saved through closer oversight and real-time quality assurance assessments in the field. In addition, just as standardized data forms would have helped, a standardized database with data entry controls (such as preset ranges for certain...
variables and drop-down lists for other variables, with limited ability to enter free-form text), coupled perhaps with a standardized training for data entry officers, would have simplified the process greatly and led to less data errors in the field.

**CONCLUSION**

Despite the challenges faced, IMC was able to collect roughly 25,000 pages of clinical and epidemiologic data on more than 2,500 patients in the midst of the largest epidemic of viral hemorrhagic fever to date. This data is already helping to improve our operational guidelines and preparedness for the next major outbreak and could help a national Ministry of Health launch a response to a future Ebola outbreak. Hopefully the lessons learned from this experience can also lead to higher-quality and better-coordinated data collection in future epidemics, leading in turn to an improved overall humanitarian response.

**Acknowledgments:** We would like to thank the governments of Liberia, Sierra Leone, and Guinea for contributing to IMC’s humanitarian response. We would also like to thank all of our generous institutional, corporate, foundation, and individual donors, who placed their confidence and trust in IMC and made our work during the Ebola epidemic possible. We thank the United States Naval Medical Research Center, Public Health England, the European Union Mobile Laboratory Consortium, and the Nigerian laboratory in Kambia District for providing laboratory data to our ETUs. We acknowledge the support of members of our Research Review Committee and other technical teams who contributed to this research, including Rabih Torbay, Amin Canavan, Dennis Waltz, Daniel Rodman, Yoav Rappaport, Samuel Grindley, Syed Hassan, Erin Shedd, Ryan Burbach, Saikrishna Madhireddy, Benedict Adajogah, Melody Xie, Madezda Sekulacar, Inka Weissbecker, Sean Casey, Farrah Zughni, Natalie Sarles, and August Felix. Finally, we also wish to thank medical directors Vanessa Wolffman and Kassahun Gebrehiwot; monitoring and evaluation staff including Annie Abbate, Razia Laghari, Allison Stewart, Alex Tran, Matthew Siakoy, David Mansaray, Lamin Bangura, Sorie Sesay, and Joseph Fangzwa; and all other data collection officers at our ETUs.

**Competing Interests:** None declared.

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**TABLE 5. Case Fatality Ratios Among Patients With EVD by Gender, Age, and Location, September 15, 2014, to September 15, 2014**

<table>
<thead>
<tr>
<th></th>
<th>EVD + Recovered, No. (%)</th>
<th>EVD + Deceased,(^a) No. (%)</th>
<th>Total,(^b) No. (%)</th>
<th>EVD Fatality, OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>197 (42.4)</td>
<td>268 (57.6)</td>
<td>465 (100)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex(^c)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>78 (41.7)</td>
<td>109 (58.3)</td>
<td>187 (40.3)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Women</td>
<td>118 (42.6)</td>
<td>159 (57.4)</td>
<td>277 (59.7)</td>
<td>1.0 (0.7, 1.4)</td>
<td>.09</td>
</tr>
<tr>
<td>Age, years(^c)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 to &lt;1</td>
<td>1 (7.1)</td>
<td>13 (92.9)</td>
<td>14 (3.1)</td>
<td>18.3 (3.3, 463.5)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>1 to 4</td>
<td>4 (12.5)</td>
<td>28 (87.5)</td>
<td>32 (7.0)</td>
<td>10.8 (3.7, 40.8)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>5 to 14</td>
<td>36 (55.4)</td>
<td>29 (44.6)</td>
<td>65 (14.0)</td>
<td>1.3 (0.7, 2.6)</td>
<td>.49</td>
</tr>
<tr>
<td>15 to 24</td>
<td>44 (62.0)</td>
<td>27 (38.0)</td>
<td>71 (15.3)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>25 to 34</td>
<td>45 (51.7)</td>
<td>42 (48.3)</td>
<td>87 (18.8)</td>
<td>1.5 (0.8, 2.9)</td>
<td>.20</td>
</tr>
<tr>
<td>35 to 44</td>
<td>33 (38.4)</td>
<td>53 (61.6)</td>
<td>86 (18.5)</td>
<td>2.6 (1.4, 5.0)</td>
<td>.004</td>
</tr>
<tr>
<td>45 to 54</td>
<td>17 (32.1)</td>
<td>36 (67.9)</td>
<td>53 (11.4)</td>
<td>3.4 (1.6, 7.4)</td>
<td>.001</td>
</tr>
<tr>
<td>≥ 55</td>
<td>16 (28.6)</td>
<td>40 (71.4)</td>
<td>56 (12.1)</td>
<td>4.0 (1.9, 8.7)</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Country</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>114 (39.7)</td>
<td>173 (60.3)</td>
<td>287 (61.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Liberia</td>
<td>83 (46.6)</td>
<td>95 (53.4)</td>
<td>178 (38.3)</td>
<td>0.8 (0.5, 1.1)</td>
<td>.15</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; EVD, Ebola virus disease; OR, odds ratio.
\(^a\) Patients with suspected EVD (n = 14) included in EVD + deceased.
\(^b\) EVD + patients who were transferred (n = 5) not included.
\(^c\) Missing values not included.
REFERENCES


Peer Reviewed

Received: 2016 Jun 3; Accepted: 2016 Aug 23

Safety and Acceptability of Community-Based Distribution of Injectable Contraceptives: A Pilot Project in Mozambique

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Trained community health workers, including traditional birth attendants (TBAs), safely and effectively administered injectables in northern Mozambique; two-thirds of the women choosing injectables had never used contraception before. Including TBAs in the Ministry of Health’s recent task sharing strategy can improve rural women’s access to injectables and help meet women’s demand for contraception.

ABSTRACT
Mozambique has witnessed a climbing total fertility rate in the last 20 years. Nearly one-third of married women have an unmet need for family planning, but the supply of family planning services is not meeting the demand. This study aimed to explore the safety and effectiveness of training 2 cadres of community health workers—traditional birth attendants (TBAs) and agentes polivalentes elementares (APEs) (polyvalent elementary health workers)—to administer the injectable contraceptive depot-medroxyprogesterone acetate (DMPA), and to provide evidence to policy makers on the feasibility of expanding community-based distribution of DMPA in areas where TBAs and APEs are present. A total of 1,432 women enrolled in the study between February 2014 and April 2015. The majority (63% to 66%) of women in the study started using contraception for the first time during the study period, and most women (over 66%) did not report side effects at the 3-month and 6-month follow-up visits. Very few (less than 0.5%) experienced morbidities at the injection site on the arm. Satisfaction with the performance of TBAs and APEs was high and improved over the study period. Overall, the project showed a high continuation rate (81.1%) after 3 injections, with TBA clients having significantly higher continuation rates than APE clients after 3 months and after 6 months. Clients’ reported willingness to pay for DMPA (64%) highlights the latent demand for modern contraceptives. Given Mozambique’s largely rural population and critical health care workforce shortage, community-based provision of family planning in general and of injectable contraceptives in particular, which has been shown to be safe, effective, and acceptable, is of crucial importance. This study demonstrates that community-based distribution of injectable contraceptives can provide access to family planning to a large group of women that previously had little or no access.

INTRODUCTION
Mozambique has witnessed a climbing total fertility rate in the last 20 years despite declining fertility rates in the East African region. For example, the fertility rate increased from 5.2 in 1997 to 5.9 at the time of the most recent Demographic and Health Survey (DHS) in 2011. Just over 11% of women in union and 30% of unmarried women were using modern contraception in 2011, although knowledge of at least one contraceptive method was universal. Modern contraceptive use appears to be strongly correlated with higher wealth and education, as well as urban residence. For instance, 3% of women in the lowest wealth quintile were currently using modern family planning methods at the time of the survey, compared with 30% in the highest quintile, and only 5% of women with no education were using modern contraception compared with 31% of those who had reached the secondary level or more. Only 7% of women in rural areas were using modern contraception compared with 21% of women in urban areas. Furthermore, nearly one-third of married women in Mozambique have an unmet need for family planning. The supply and distribution of family planning services and
contraceptives did not meet demand, as 40.1% of women surveyed expressed a desire for any method of contraception, with only 29% of demand met. The preferred method for future contraceptive use—according to DHS data from 2003 when this indicator was last measured—was injectable contraceptives, for more than 42% of women of reproductive age. However, only 4.3% of all women were using injectable contraceptives in 2011, suggesting an unmet need.

Access to contraception itself increases use. In Mozambique, rural women find themselves cut off from access to family planning services due to a shortage of health facilities. In 2011, 77% of family planning services were delivered through the public health system. Family planning services and counseling are typically provided through health facilities, and skilled providers are historically the gatekeepers of those services. Evidence from the past decade, however, shows that community health workers (CHWs) are making key advances to increase access to injectables in other sub-Saharan African countries. Although implants recently surpassed injectables as the fastest-growing method of contraception in sub-Saharan Africa, injectables are still the most commonly used method among married women in the region; the ease of use and convenience of access at the community level is likely a contributing factor.

Community-based distribution (CBD) of injectables by trusted CHWs may be an effective approach to increasing family planning use in rural Mozambique quickly, given the success of CHWs in countries with similar barriers to access. The Mozambique Ministry of Health (MOH) approved the revitalization of the national CHW program in 2010 in recognition of the critical importance of CHWs to expand access to basic primary health care services to communities. Some CHWs, called *agentes polivalentes elementares* (APEs) (polyvalent elementary health workers), focus on improving the health of the community primarily through health promotion and prevention activities. They serve as a linkage between communities and health facilities, and they provide community case management for HIV/AIDS, maternal care, nutrition, and acute illness among children (diarrhea, malaria, and respiratory infections). Historically, APEs have not provided family planning services, although some APEs provided contraceptives informally. In 2016, APEs will offer a new package of services that includes provision of pills, condoms, and injectables. In December 2013, the MOH trained 2,270 APEs on this new family planning package.

Mozambique’s Family Planning Strategy 2010–2014 was released at the same time the APE program restarted. The MOH recognized the need for community involvement and participation to improve universal access to family planning services and committed to improving access through CHWs. The strategy also addressed the potential role of traditional birth attendants (TBAs) in the provision of family planning counseling and select methods. This was an important inclusion because TBAs often live in poor, rural areas that are far from health facilities, and they have direct access to women during labor, delivery, and the postpartum period. They may be uniquely suited to providing injectables in communities. They can serve as a bridge to the formal health system and effectively convey information to women in culturally appropriate ways.

Very few studies have assessed TBAs as family planning providers in sub-Saharan Africa, and these studies showed mixed results. A pilot study conducted in Senegal, however, successfully included *matrones*, or trained TBAs, to distribute injectables.

Although policy makers are supportive of CBD in Mozambique, there is limited country-specific experience on best practices, so stakeholders have called for operations research in Mozambique. In response to the call for more research, we conducted this study to determine whether APEs and TBAs could safely and effectively administer the injectable contraceptive depot-medroxyprogesterone acetate (DMPA), with high client acceptability, among women in 2 rural districts.

**INTERVENTION AND SETTING**

From February 2014 to April 2015, Pathfinder International implemented a pilot study on the distribution of DMPA by both APEs and TBAs—in partnership with the Mozambican Society of Obstetricians and Gynecologists and the Bixby Center for Population, Health, and Sustainability. The study was conducted in 2 districts in northern Mozambique, Chiure and Montepuez, which are located in the Cabo Delgado Province, where in 2011, only 2.9% of married women were using contraceptives, with just 0.8% using injectable contraceptives. The intervention was designed so that TBAs served clients in Montepuez and APEs served clients in Chiure.

In 2003, the preferred method for future contraceptive use was injectable contraceptives. In 2011, however, only 4.3% of women were using this method, suggesting an unmet need.

Access to contraception itself will increase use. In Mozambique, however, rural women lack access to contraception due to a shortage of health facilities. Evidence from other countries shows that community health workers may help bridge this gap.
Selection, Training, and Supervision of Community Health Workers

All 25 APEs that had worked in the Chiure district since 2009 were selected to participate in the study. Only 8 of the 25 APEs were women. The predominance of male APEs in this study reflects the APE program in general, which is 71% male. This gender imbalance is likely a result of the government requirement that APEs should have completed at least grade 7 to participate in the program. APEs in Mozambique receive general training on health care prevention. Their roles and responsibilities in the communities they serve include health promotion, provision of vitamin A, deworming, malaria testing and administration of malaria medication, and antenatal care sensitization. APEs are not officially part of the MOH, although they receive a stipend of 1,200 meticais (US$19) per month from the government as compensation for their participation in the program. External partners provide all funding for the program including the stipend.

The 34 TBAs who participated in the study were registered with the MOH and worked collaboratively with the health facilities in the Montepuez district. All 34 TBAs were women. TBAs participate in a nationally recognized training program that includes hygienic management and infection control; recognition of danger signs for referral, postpartum, and umbilical cord care; and mobilizing communities to use general preventive health care services. The TBAs were not paid for their participation in the study and in general do not receive any formal compensation for the work they perform in the community. However, they do receive informal monetary and in-kind contributions from women in exchange for their services. All participating TBAs were literate, which was necessary for study recordkeeping.

Both APEs and TBAs received standardized training before the study began. Five physicians conducted a 10-day training composed of 3 stages. Stage 1 included classroom training on topics such as family planning methods and counseling, study protocol, recruitment and screening requirements, injection administration, infection prevention, and reporting procedures. APEs and TBAs were trained on how to counsel women on all family planning methods to promote informed choice. However, because the providers (APEs and TBAs) would administer only injectables, the clinical aspects of the training focused on determining clients’ eligibility for DMPA and administering the injection.

The providers also distributed condoms and received training on promoting dual protection against both unintended pregnancy and sexually transmitted infections (STIs) including HIV.

After completing the classroom training, providers enrolled in stage 2, a practicum on injection administration. All providers practiced giving injections until they felt confident. They were considered qualified to administer injections after passing a test in which they provided an injection to a volunteer.

Stage 3 of the training involved a 1-week practicum at a health facility in their catchment area. During the practicum, providers were responsible for administering informed consent to clients; completing medical screening for DMPA; enrolling participants and assigning a client number; completing the enrollment questionnaire; providing contraceptive counseling, and administering DMPA with a plan for reinjection. This was done at the health facility under supervision of the physicians leading the training and nurses in the facilities before the study began.

There were 3 levels of supervision provided during the study implementation:

1. In the first level of supervision, 18 trained nurses (1 per facility in the catchment area) oversaw data collection and clinical supervision. Nurse supervisors were responsible for confirming completion of the enrollment questionnaire filled out by the study providers and for addressing any clinical issues that arose during the course of the study.

2. The province coordination team provided a second level of supervision on a monthly basis to ensure that nurse supervisors performed their responsibilities as detailed in the study protocol, including timely administration of the 3-month and 6-month follow-up questionnaires to clients.

3. The study investigators provided a third level of supervision on a quarterly basis by reviewing all components of the project including data entry and management.

METHODS

The study was a prospective non-randomized community intervention trial designed to assess the safety, acceptability, and effectiveness of the provision of DMPA by APEs and TBAs as well as continuation outcomes among clients of both providers. The study design was based on earlier
successful pilot studies in Ethiopia and Uganda. By building upon these study designs, we hoped to provide a mechanism for standardizing data across countries. In the case of clinical research, standardization has been shown to increase data quality, improve data integration and reusability, and enable facilitation of data exchange with partners.

Safety, acceptability, effectiveness, and continuation rates were the outcomes of interest. We compared these outcome rates among clients who received DMPA from APEs and clients who received DMPA from TBAs. We based the sample size of 1,000 women on the need to test for non-inferiority of the services provided by the 2 types of providers. We assumed a continuation rate of 65% after first injection among APE clients and a continuation rate of at least 55% among TBA clients (for a maximum difference of 10% between groups) as being equivalent. We also assumed a loss to follow-up of 20%, a design effect of 2.0, and similar recruitment rates in all districts.

All women of reproductive age in the community were made aware of the project through existing community meetings led by CHWs and enabled facilitation of data exchange with partners.

We entered the data in Epi Info (version 7.1.4.0) and conducted the analysis with Stata (version 13). The results presented in this article include information generated through frequency and cross-tabulations. We assessed differences in responses between the APE clients and TBA clients using chi-square tests for association among categorical variables and t tests for independent samples to determine differences between the client group means. Discontinuation and continuation rates overall and by provider were estimated over time from the first injection to the second injection and from the first injection to the third injection. We estimated continuation, discontinuation, and lost-to-follow-up rates using data from the questionnaires at 3 months and 6 months. Women who reported receiving their second and third injections represent continuation at 3 months and at 6 months, respectively. Discontinuation during this same period was estimated if a woman reported in her 3-month and 6-month questionnaire that she did not receive her second or third injection. Lost to follow-up was estimated for women who completed the enrollment questionnaire, but for whom both the 3- and 6-month questionnaires were absent.

Ethical approval for this project was granted by the Committee for Protection of Human Subjects at the University of California, Berkeley (CPHS # 2012-06-4460) and from the Mozambique Ministry of Health Comite de bioetica para a saúde (IRB00002657, Ref: 197/CNBS/13).

RESULTS

A total of 1,432 eligible women enrolled in the study between February and November 2014. TBAs recruited 782 women and APEs recruited 649 women for the study. The summary of enrollment and follow-up data is illustrated in Figure 1. At the 3-month follow-up visit, 1,242 women participated in the questionnaire; 48 women refused to respond to the questionnaire, resulting in a response rate of 96%. At the 6-month visit, 1,264 women responded to the questionnaire, with a response rate of 98.6%; this included 22 women who refused the 3-month questionnaire, and were therefore assumed lost to follow-up. These 22 women were asked about their second injection; if they received it, they were added to the continuation rates.

Table 1 outlines demographic and other key indicators for the 1,432 women who enrolled in the study. Clients of APEs and TBAs were statistically

The 1,432 women who enrolled in the study had a high response rate to questionnaires given at the 3-month visit and the 6-month visit—96% and 98.6%, respectively.
similar on most variables. Although most clients in both groups reported no education, clients of APEs had significantly less education than clients of TBAs.

Table 2 describes the rates of discontinuation and loss to follow-up by group–APE clients and TBA clients. Discontinuation rates were estimated for 2 time frames: (1) between enrollment and the second injection; and (2) between enrollment and the third injection. Overall, the continuation rate was high (81.1%) in both groups after 3 injections, with TBA clients having significantly higher continuation rates both at 3 months and at 6 months. Loss-to-follow-up rates were 13.8% for the entire project period between enrollment and the third injection at 6 months; however, APE clients had 20.8% loss to follow-up compared with 7.8% among TBA clients. For APE clients, the most common reason given for discontinuation at 3 months (50.6%) and 6 months (53.6%) was that the woman was planning to get her injection but had not yet reached the provider to receive it. Both TBAs and APEs provided injections at their own home, their client’s home, or another place in the community as determined by the provider and client. TBA clients were more likely to state “other reasons” without explaining why they missed injections at both 3 months and at 6 months (data not shown).

The majority of women enrolled in the study had never used a contraceptive method before (63% of TBA clients and 66% of APE clients). Approximately 30% of all clients reported previous use of DMPA. Figure 2 provides details on previous types of methods used.

More than 60% of both APE and TBA clients reported duration of effectiveness as the reason why they preferred DMPA. About 29% of TBA clients and 20% of APE clients reported that they chose to use DMPA because their husbands permitted this method. Additionally, nearly 10% of TBA clients reported that they chose DMPA for the convenience, and 24.2% of APE clients liked DMPA because there were “fewer side effects” (data not shown).

APE clients reported receiving more counseling on side effects and STIs including HIV than TBA clients.
The majority of women were satisfied with both the method and their provider. Among TBA and APE clients, 74.7% and 88.2%, respectively, were satisfied with DMPA at 3 months. At 6 months, 90.1% of TBA clients and 89.2% of APE clients reported satisfaction with the method (data not shown). At 3 months, 73.7% of TBA clients and 89.1% of APE clients reported satisfaction with their provider. At 6 months, reported client satisfaction with the provider improved to 89.8% among TBA clients and 94.1% among APE clients (data not shown).

Overall, 64% of women in the study reported that they were willing to pay for DMPA, but TBA clients were much more willing to pay than APE clients (data not shown). For women in both client groups, the mean amount they were willing to pay was about 34 meticais (US$0.93). At the 3-month visit, the mean amount that women were willing to pay was about 39 meticais (US$1.07) and 5 meticais (US$0.13) among TBA clients and APE clients, respectively. At the 6-month visit, women were willing to pay 40 meticais ($1.10) and 7 meticais ($0.19), respectively (data not shown).

**DISCUSSION**

Although CBD of injectable contraceptives is no longer a novel idea in sub-Saharan Africa, the process of translating community-based health care policies into effective programs is not always straightforward. For example, policy makers in Mozambique were supportive of CBD, but there was limited country-specific experience and no country-level data to support the policy. Consequently, this study generated evidence to support CBD of DMPA in northern Mozambique and

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### TABLE 1. Background Characteristics of Enrolled Women, by Provider (N = 1,431)

<table>
<thead>
<tr>
<th></th>
<th>TBA Clients (n = 782)</th>
<th>APE Clients (n = 649)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at enrollment, years, mean (SD)</td>
<td>29.3 (6.9)</td>
<td>29.9 (7.6)</td>
</tr>
<tr>
<td>No. of living children, mean (SD)</td>
<td>4.2 (2.1)</td>
<td>4.8 (2.6)</td>
</tr>
<tr>
<td>Marital status, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/living together</td>
<td>655 (83.8)</td>
<td>539 (83.1)</td>
</tr>
<tr>
<td>Single, never married</td>
<td>52 (6.7)</td>
<td>52 (8.0)</td>
</tr>
<tr>
<td>Divorced/separated/widowed</td>
<td>64 (8.2)</td>
<td>40 (6.2)</td>
</tr>
<tr>
<td>Education, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>488 (62.4)</td>
<td>472 (72.7)*</td>
</tr>
<tr>
<td>Only read and write</td>
<td>38 (4.9)</td>
<td>49 (7.6)</td>
</tr>
<tr>
<td>Primary</td>
<td>246 (31.5)</td>
<td>177 (18.0)*</td>
</tr>
<tr>
<td>Secondary or higher</td>
<td>6 (0.8)</td>
<td>6 (0.9)</td>
</tr>
<tr>
<td>Husband supportive of using DMPA, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>614 (78.5)</td>
<td>526 (81.1)</td>
</tr>
<tr>
<td>No</td>
<td>47 (6.0)</td>
<td>46 (7.1)</td>
</tr>
<tr>
<td>Husband not aware</td>
<td>28 (3.6)</td>
<td>16 (2.5)</td>
</tr>
<tr>
<td>Not married/does not know</td>
<td>70 (9.0)</td>
<td>48 (7.4)</td>
</tr>
</tbody>
</table>

Abbreviations: APE, agente polivalente elementare [polyvalent elementary health worker]; DMPA, depot-medroxyprogesterone acetate; SD, standard deviation; TBA, traditional birth attendant.

Note: Percentages include missing, not shown. One client of the total recruited was missing provider information. * P<0.05 for comparison of TBA vs. APE.
### TABLE 2. Discontinuation and Loss to Follow-Up, by Provider (N=1,432)

<table>
<thead>
<tr>
<th></th>
<th>Second Injection</th>
<th>Third Injection</th>
<th>Total After 3 Injections</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TBA Clients</td>
<td>APE Clients</td>
<td>TBA Clients</td>
</tr>
<tr>
<td>Received injection, No. (%)</td>
<td>627 (80.2)</td>
<td>442 (68.1)*</td>
<td>716 (91.6)</td>
</tr>
<tr>
<td>Discontinued, No. (%) (did not receive injection)</td>
<td>11 (1.4)</td>
<td>89 (13.7)*</td>
<td>5 (0.006)</td>
</tr>
<tr>
<td>Lost to follow-up, No. (%) (includes missing data)</td>
<td>144 (18.4)</td>
<td>118 (18.2)</td>
<td>61 (7.8)</td>
</tr>
<tr>
<td>Total number of clients at enrollment</td>
<td>782</td>
<td>649</td>
<td>782</td>
</tr>
</tbody>
</table>

Abbreviations: APE, agente polivalente elementare (polyvalent elementary health worker); TBA, traditional birth attendant.

Note: Percentages include missing, not shown. One client of the total recruited was missing provider information.

* P<.05 for comparison of TBA vs. APE.

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### FIGURE 2. Previous Use of Contraception Among Study Population, by Provider Type (N=1,432)

Abbreviations: APE, agente polivalente elementare (polyvalent elementary health worker); DMPA, depot-medroxyprogesterone acetate; IUD, intrauterine device; TBA, traditional birth attendant.
found that provision of injectable contraceptives by APEs and TBAs was feasible, safe, effective, and acceptable among women. Very few morbidities at the injection site and no deaths were reported. The study demonstrated that APEs and TBAs can improve contraceptive access and use in rural Mozambican communities; in fact, the majority of women in the study started using contraception for the first time during the study period, and satisfaction with community-based providers was high and improved over the entire study period.

Continuation rates in both clients groups were high overall and similar to rates found in other pilot studies on CBD of DMPA in Kenya and Ethiopia. Interestingly, TBA clients had significantly higher continuation rates than APE clients. This difference could indicate a gender barrier in the program because the majority of APEs were men and all TBAs were women; however, we believe it suggests that TBAs have a critical role in linking women to reproductive health services at the community level. For example, TBAs are involved in initiation rituals that take place before women become sexually active in Cabo Delgado, the province included in this study, and TBAs are also considered advisors for sexual and reproductive health in many rural communities in Mozambique. The high continuation rates among TBA clients might indicate that TBAs can conduct more rigorous client follow-up compared with APEs, or it may be that women interact with their TBAs more regularly.

Women may also place more trust in their TBAs, or have higher satisfaction with TBAs as a family planning provider. Nearly 17% of births in the country in the 5 years preceding the most recent 2011 DHS were assisted by a TBA, which is up from 11% in 2003. This suggests that women and TBAs have an important relationship in Mozambique.

This study confirms previous findings that TBAs are uniquely poised to address critical gaps in postpartum contraceptive uptake. This is an important finding given that postpartum women are among those with the greatest unmet need for family planning and often do not receive family planning services. In fact, a previous analysis of DHS data from 27 low- and middle-income countries found that although 95% of postpartum women wanted to avoid a pregnancy within the next 2 years, only 30% were using contraception. Our study generated pivotal evidence to support the inclusion of TBAs in delivery of injectable

![Figure 3. Percentage of Women Counseled on Side Effects and STIs Including HIV at Follow-Up Visits, by Provider (N=1,432)](image-url)

Abbreviations: APE, agente polivalente elementare (polyvalent elementary health worker); STI, sexually transmitted infection; TBA, traditional birth attendant.
contraceptives. However, future research is needed to understand the important linkage between TBAs as family planning providers and high contraceptive continuation rates among their clients. Future qualitative research into women’s gender preference among providers may also illuminate some of the differences between continuation results of APEs and TBAs.

In addition to recognizing the advantages of including TBAs in family planning, it is important to address the challenges surrounding limited STI counseling related to TBA provision of services. TBAs provided substantially less STI counseling (36%) than APEs (70%) did at the 3-month follow-up visit, and only slightly improved at 6 months (45%). TBAs were also less likely to offer condoms in addition to DMPA for dual protection. Considering their lower education levels compared with APEs, and relative inexperience with trainings, TBAs may require additional support to provide these services consistently and adequately. Findings from a recent systematic review found a moderate increased risk of HIV among women using DMPA in the general population. With an HIV prevalence of 11.1% in Mozambique, HIV counseling and dual protection should be prioritized in future trainings, and TBAs should receive regular refreshers that emphasize the importance of these issues.

APE clients reported receiving more STI counseling than TBA clients; however, the low rates of reported side effects among all clients may indicate the quality of TBAs’ counseling on side effects, and may also have influenced continuation rates. Typical side effects associated with DMPA use were reported at lower rates (10% at 3 months) in this study than in similar studies in Ethiopia and Uganda, where approximately

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**FIGURE 4.** Reported Side Effects Following Second and Third Injections of DMPA, by Provider (N=1432)

<table>
<thead>
<tr>
<th>6 month</th>
<th>APE</th>
<th>TBA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amenorrhea</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>Spotting</td>
<td>20%</td>
<td>15%</td>
</tr>
<tr>
<td>Heavy bleeding</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>Irregular bleeding</td>
<td>20%</td>
<td>15%</td>
</tr>
<tr>
<td>None</td>
<td>55%</td>
<td>70%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3 month</th>
<th>APE</th>
<th>TBA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amenorrhea</td>
<td>5%</td>
<td>10%</td>
</tr>
<tr>
<td>Spotting</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>Heavy bleeding</td>
<td>20%</td>
<td>15%</td>
</tr>
<tr>
<td>Irregular bleeding</td>
<td>25%</td>
<td>20%</td>
</tr>
<tr>
<td>None</td>
<td>55%</td>
<td>70%</td>
</tr>
</tbody>
</table>

Abbreviations: APE, agente polivalente elementare (polyvalent elementary health worker); DMPA, depot-medroxyprogesterone acetate; TBA, traditional birth attendant.
20% to 30% of women reported side effects.\textsuperscript{7,9} It is difficult to draw conclusions without additional research into the quality of services and perceptions of clients. Results of research on side effects and continuation have been mixed and both individual characteristics of the users and service delivery factors have been shown to affect both reporting of side effects and continuation.\textsuperscript{31} Nonetheless, several studies have found that both providers’ attitudes and the information they provide may influence a woman’s perception of bleeding.\textsuperscript{31-33}

Women’s overall willingness to pay for DMPA (64%) is also noteworthy and highlights the demand for injectable contraceptives among Mozambican women as well as an opportunity for scaling up CBD in Mozambique. Although donors contribute more than 50% of the country’s total budget for health, with the United Nations Population Fund (UNFPA) and the U.S. Agency for International Development (USAID) purchasing Mozambique’s contraceptive supplies,\textsuperscript{18} this may not always be the case. Cost recovery approaches for contraceptive delivery may therefore be necessary in the future, even though they are not currently in place in the public sector. TBA clients were more willing to pay for injectable contraceptives than APE clients, which may be related to women’s expectations. Trained TBAs have reported informal compensation, both in-kind and monetary, for births that they have attended,\textsuperscript{28} whereas APE services are paid for by the government and free to the client. Consequently, TBA family planning clients might be more comfortable with family planning user fees.

**Limitations**

In this study, 197 women (14%) were lost to follow-up, and therefore it cannot be determined whether these women discontinued use of DMPA. Additionally, verification of DMPA injection was completed at the 3- and 6-month follow-up visits. Even among women who were not lost to follow-up, the response rate was not 100%. Women who refused to respond to the questionnaire were not captured in the continuation and discontinuation rates, with the exception of the 22 women who refused the 3-month questionnaire but accepted the 6-month questionnaire (Figure 1). The lost to follow-up total does include women who were interviewed, but did not have recorded data about whether they received DMPA. The number of women without data was small (9 women for the 3-month questionnaire and 1 woman for the 6-month questionnaire).

**CONCLUSION**

Given Mozambique’s largely rural population and critical health care workforce shortage, a reliance on safe, effective, and acceptable community-based family planning provision is of crucial importance. Evidence-based strategies should guide programmatic implementation. In the case of Mozambique, 2 strategies could be adopted based on evidence generated through this study: (1) TBAs should be included as community-based distributors of family planning services; and (2) public-sector programs should include client fees based on willingness to pay and/or allow for revitalization of private-sector distribution of contraceptives in rural areas. This study demonstrated that CBD of injectables can provide access to a large group of women that previously had little to none, considering the tremendous proportion of women using contraception for the first time during this study. More importantly, it also highlighted the central role that TBAs can play in a context similar to rural Mozambique. In regions where the fertility rate is high, births are too closely spaced, and women face innumerable obstacles in reaching health facilities, TBAs can provide family planning services that promote healthy timing of pregnancies with high continuation rates. To meet the contraceptive desires of vulnerable women, policy makers and program staff should consider CBD of injectables, especially models where TBAs are trained and trusted to provide safe and acceptable ongoing care.

**Acknowledgments:** We wish to express our gratitude to USAID/Washington for providing the financial support to conduct this study and those at the USAID Mission in Mozambique for their guidance and technical oversight during the development of this pilot study. We also wish to acknowledge the Provincial Health Directorate and Provincial Medical Chief Officer of Cabo Delgado.

**Competing Interests:** None declared.


20. Global Health: Science and Practice 2016 | Volume 4 | Number 3


23. Tolley E, Loza S, Kafali L, Cummings S. The impact of menstrual side effects on contraceptive discontinuation: findings from a

Peer Reviewed

Received: 2016 Apr 28; Accepted: 2016 Jul 5; First Published Online: 2016 Sep 20


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Scheduled Follow-Up Referrals and Simple Prevention Kits Including Counseling to Improve Post-Discharge Outcomes Among Children in Uganda: A Proof-of-Concept Study

Matthew O Wiens,¹ Elias Kumbakumba,¹ Charles P Larson,² Peter P Moschovis,³ Celestine Barigye,⁴ Jerome Kabakyenga,⁵ Andrew Ndamira,⁵ Lacey English,⁶ Niranjan Kissoon,¹ Guohai Zhou,¹ J Mark Ansermino⁷

Post-hospital discharge is a vulnerable time for recurrent illness and death among children. An intervention package consisting of (1) referrals for scheduled follow-up visits, (2) discharge counseling, and (3) simple prevention items such as soap and oral rehydration salts resulted in much higher health seeking and hospital readmissions compared with historical controls.

ABSTRACT

Background: Recurrent illness following hospital discharge is a major contributor to childhood mortality in resource-poor countries. Yet post-discharge care is largely ignored by health care workers and policy makers due to a lack of resources to identify children with recurrent illness and a lack of cohesive systems to provide care. The purpose of this proof-of-concept study was to evaluate the effectiveness of a bundle of interventions at discharge to improve health outcomes during the vulnerable post-discharge period.

Methods: The study was conducted between December 2014 and April 2015. Eligible children were between ages 6 months and 5 years who were admitted with a suspected or proven infectious disease to one of two hospitals in Mbarara, Uganda. A bundle of interventions was provided at the time of discharge. This bundle included post-discharge referrals for follow-up visits and a discharge kit. The post-discharge referral was to ensure follow-up with a nearby health care provider on days 2, 7, and 14 following discharge. The discharge kit included brief educational counseling along with simple preventive items as incentives (soap, a mosquito net, and oral rehydration salts) to reinforce the education. The primary study outcome was the number of post-discharge referral visits completed. Secondary study outcomes included satisfaction with the intervention, rates of readmission after 60 days, and post-discharge mortality rates. In addition, outcomes were compared with a historical control group, enrolled using the same inclusion criteria and outcome-ascertainment methods.

Results: During the study, 216 children were admitted, of whom 14 died during hospitalization. Of the 202 children discharged, 85% completed at least 1 of the 3 follow-up referral visits, with 48% completing all 3 visits. Within 60 days after discharge, 22 children were readmitted at least once and 5 children (2.5%) died. Twelve (43%) readmissions occurred during a scheduled follow-up visit. Compared with prospectively enrolled historical controls, the post-discharge referral for follow-up increased the odds of readmission (odds ratio [OR], 1.92; 95% confidence interval [CI], 1.14 to 3.23) and care sought after discharge (OR, 14.61; 95% CI, 9.41 to 22.67). Overall satisfaction with the bundle of interventions was high, with most caregivers strongly agreeing that the discharge kit and post-discharge referrals improved their ability to care for their child.

Conclusions: Interventions initiated at the time of discharge have the potential to profoundly affect the landscape of care during illness recovery and lead to significantly improved outcomes among children under 5 years of age.

BACKGROUND

In resource-poor countries, in-hospital death rates for children hospitalized for a serious infection are similar to death rates in the weeks after they return home.¹
Health care workers, policy makers, and caregivers are often unaware of the high vulnerability during this post-discharge period and are poorly equipped to identify, triage, and provide definitive care for the children. An effective strategy is therefore required to address recurrent illness following hospital discharge in order to reduce overall childhood mortality.

This study builds on an earlier observational study in Uganda conducted between 2012 and 2014, in which we observed children who had been admitted to the hospital with proven or suspected infections, for the purpose of developing prediction models for post-discharge mortality. The predictive models included up to 5 variables, easily collected at admission, that identified children at high risk of mortality during the critical post-discharge period. These models can help direct resources to the most vulnerable children, but any interventions must be evaluated to determine their impact on morbidity and mortality before implementing at scale.

The objective of this proof-of-concept study was to determine the effectiveness of a discharge package—consisting of a discharge kit (including educational counseling and simple preventive items as incentives) and a post-discharge referral for scheduled follow-up visits—in improving families’ health-seeking behavior from a qualified provider, and ultimately in improving mortality during the post-discharge period.

**METHODS**

**Design**

This proof-of-concept study builds upon an earlier observational study in Uganda in 2012–2014, which had the primary objective to derive models to predict post-discharge mortality. The current study described in this article was conducted between December 2014 and April 2015 and represents the interventional continuation of the observational study. This study included an intervention aimed at improving outcomes following hospital discharge, whereas the earlier study was purely observational. The earlier study did not implement any systematic post-discharge policy. All children received routine care during enrollment and the post-discharge period. It is common practice to discharge children with instructions to return to a health center or hospital in the event of recurrence or worsening of illness.

**Population**

This study was conducted at 2 sites—the Mbarara Regional Referral Hospital and the Holy Innocents Children’s Hospital, both in Mbarara, Uganda. The Mbarara Regional Referral Hospital is a public hospital funded by the Uganda Ministry of Health and is associated with the Mbarara University of Science and Technology Faculty of Medicine. The pediatric ward admits approximately 5,000 patients per year. Holy Innocents Children’s Hospital is a Catholic children’s hospital offering subsidized fee-for-service outpatient and inpatient care in Mbarara and admits approximately 2,500 patients annually. These study sites were chosen to reflect the relatively high proportion and use of both private and public hospitals in Uganda, and to improve external validity by comparing 2 types of institutions.

The earlier observational study was approved by the institutional review boards at the University of British Columbia (Vancouver, Canada) and the Mbarara University of Science and Technology (Mbarara, Uganda), the details of which have been published. This proof-of-concept study was separately reviewed and approved by the institutional review boards at the University of British Columbia (Vancouver, Canada) and the Mbarara University of Science and Technology (Mbarara, Uganda). The study was funded by Grand Challenges Canada.

**Eligibility**

Using the same criteria as the observational study, children who were eligible to enroll in the proof-of-concept study were between the ages of 6 months and 5 years, and were admitted to the hospital with a proven or suspected infection. Subjects already enrolled in the study were not eligible to enroll again for subsequent admissions, nor were subjects residing outside of the official catchment area of the hospital (10 surrounding districts).

**Study Procedure**

The proof-of-concept study used the same research nurses, field officers, and all equipment as in the earlier observational study. Following enrollment, a research nurse obtained and recorded clinical signs and symptoms as described in the observational study. The clinical care provided during the study was in accordance with local and national guidelines and reflected the in-hospital procedures used in the observational study (with the exception of the intervention itself). This was done to ensure a high degree of consistency when comparing the 2 cohorts.
Interventions at Discharge

During enrollment in the study, children received routine care according to the Uganda National Guidelines until the point of discharge. At discharge, the children received a bundle of interventions. The bundle consisted of (1) post-discharge referral for follow-up visits organized by the research nurse at the time of discharge, and (2) a discharge kit consisting of counseling and simple preventive items to reinforce the counseling.

During the discharge counseling, the research nurse provided the child’s caregiver with a paper referral form for follow-up with either a community health worker or at a nearby health center on days 2, 7, and 14 following discharge. These days were chosen as the highest-risk times during the early post-discharge period. Before this study, we collected information on community health workers and health centers in the catchment area (10 districts) at the parish level. Caregivers could choose either a community health worker or a health center for the child’s follow-up visits, based on preference and proximity to their home. For caregivers who chose a follow-up visit at a health center, nurses provided a list of health centers (private and public) from which the caregivers could choose. The referral form was then addressed to either the health center or the community health worker, and caregivers received relevant information as written instructions.

The caregivers also received a discharge kit, which included brief educational counseling paired with simple preventive items as incentives to reinforce the education. The educational counseling consisted of a storyboard-style, laminated card written in the local language (supplementary material). Using this card, the nurse explained the child’s vulnerability during the discharge period and discussed 3 main themes of action: (1) prevention through hygiene and other health behaviors (e.g., mosquito net use), (2) recognition of signs of early illness recurrence, and (3) prompt care sought at a health center or from a community health worker. In our earlier research, these themes featured prominently in the children who died following discharge. Caregivers received the card along with 3 preventive items meant to reinforce the education (a mosquito net, 1 kg of soap, and 5 sachets of oral rehydration salts). The value of these household incentives was approximately US$6.50. The time it took hospital staff to give the bundle of interventions was less than 30 minutes.

Approximately 60 days after discharge, field officers visited all subjects at their homes to determine vital status and assess whether care had been sought at a health center or from a community health worker. Field officers also administered a short survey to caregivers of the children to solicit feedback on the discharge intervention and the post-discharge referral for follow-up. Field officers were trained, prior to the earlier observational study, in patient tracking and administering questionnaires, and they had some health-related training. The procedures used to ascertain outcomes were the same in both the observational study and this study.

Study data were collected electronically using tablet computers and managed using the Research Electronic Data Capture (REDCap) tool hosted at the Child and Family Research Institute in Vancouver, Canada. REDCap is a secure, web-based application designed to support data capture for research studies.

Analysis

Outcomes

The primary study outcome was the proportion of children who successfully completed at least 1 post-discharge referral for a follow-up visit at a health center or with a community health worker. Secondary study outcomes included caregiver satisfaction with the interventions (the discharge kit and post-discharge referral) and comparisons in post-discharge mortality, readmission, and care sought between this study and the earlier observational study.

Statistical Analysis

We performed descriptive analyses of the primary outcome and of caregiver satisfaction. Using logistic regression, we also performed comparative analyses between the earlier observational study and this study. In this analysis, the outcomes of readmission and post-discharge health seeking were adjusted for both site of enrollment and the post-discharge mortality risk score. The post-discharge mortality risk score is a 5-item composite score including mid-upper arm circumference, oxygen saturation, time since most recent hospitalization, HIV status, and coma score. We also conducted a secondary univariate logistic regression analysis examining factors associated with completing post-discharge referrals. For the secondary analysis, a sample of 200 children would provide 80% power to detect a 10% absolute
difference in health seeking compared with the historical cohort, at an alpha of .05. All analyses were conducted in SAS 9.4 (Cary, North Carolina, USA).

RESULTS
A total of 216 children were enrolled in the study. An additional 93 children were screened but excluded from the study, mostly because they presented with a non-infectious illness (Figure). The median age was 16.1 months (IQR 10.2–29.1), and the sample was nearly evenly split between boys and girls (107 children, or 49.5%, were boys) (Table 1). Forty-two children (20%) were referred for the initial hospital admission, mostly from health centers. Fifty-three (24.7%), 59 (27.4%), and 56 (26.2%) children were underweight, stunted, or wasted (defined as height-for-age z score less than -2). One hundred and four (48%) were diagnosed with pneumonia, while 45 (20%) were diagnosed with malaria and 17 (8%) with diarrhea. The rate of in-hospital mortality was 6.5%.

Post-Discharge Referrals
The number of children who survived to discharge was 202 (93.5%). Of these, 170 (84%) completed at least 1 scheduled post-discharge follow-up visit, 143 (71%) completed 2 follow-up visits, and 96 (48%) completed all 3 follow-up visits. Among those children who did not complete all 3 follow-up visits, the 3 most commonly reported reasons for non-completion were (1) health system factors, such as a closed health center; (2) family factors, such as lack of transportation or high cost; and (3) the child’s family did not consider the visit important (Table 2). For the first post-discharge follow-up visit, 115 (68%)...
### TABLE 1. Baseline Characteristics of Study Subjects (N=216)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%)</td>
<td>107 (49.5)</td>
</tr>
<tr>
<td>Age, months, median (IQR)</td>
<td>16.1 (10.2, 29.1)</td>
</tr>
<tr>
<td>Prior care sought for illness, No. (%)</td>
<td>160 (74.1)</td>
</tr>
<tr>
<td>Referred for the initial hospital admission</td>
<td></td>
</tr>
<tr>
<td>Referral source: hospital</td>
<td>3 (7.0)</td>
</tr>
<tr>
<td>Referral source: health center</td>
<td>33 (78.6)</td>
</tr>
<tr>
<td>Referral source: untrained health worker</td>
<td>6 (14.3)</td>
</tr>
<tr>
<td>MUAC &lt;115 mm, No. (%)</td>
<td>14 (6.5)</td>
</tr>
<tr>
<td>MUAC 115–125 mm, No. (%)</td>
<td>21 (9.7)</td>
</tr>
<tr>
<td>Underweight (WAZ &lt; -2), No. (%)</td>
<td>53 (24.7)</td>
</tr>
<tr>
<td>Severely underweight (WAZ &lt; -3), No. (%)</td>
<td>24 (11.2)</td>
</tr>
<tr>
<td>Wasted (WHZ &lt; -2), No. (%)</td>
<td>56 (26.2)</td>
</tr>
<tr>
<td>Severely wasted (WHZ &lt; -3), No. (%)</td>
<td>28 (13.1)</td>
</tr>
<tr>
<td>Stunted (HAZ &lt; -2), No. (%)</td>
<td>59 (27.4)</td>
</tr>
<tr>
<td>Severely stunted (HAZ &lt; -3), No. (%)</td>
<td>31 (14.4)</td>
</tr>
<tr>
<td>HIV positive, No. (%)</td>
<td>15 (7.0)</td>
</tr>
<tr>
<td>Maternal education, No. (%)</td>
<td></td>
</tr>
<tr>
<td>No school</td>
<td>18 (8.3)</td>
</tr>
<tr>
<td>Less than primary 3</td>
<td>17 (7.9)</td>
</tr>
<tr>
<td>Primary 4 to primary 7</td>
<td>91 (42.1)</td>
</tr>
<tr>
<td>Secondary 1 to secondary 6</td>
<td>60 (27.8)</td>
</tr>
<tr>
<td>Post-secondary</td>
<td>30 (13.9)</td>
</tr>
<tr>
<td>Discharge diagnosis, No. (%)</td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>43 (19.9)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>104 (48.2)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>17 (7.9)</td>
</tr>
<tr>
<td>Discharged against medical advice, No. (%)</td>
<td>17 (8.0)</td>
</tr>
<tr>
<td>In-hospital mortality, No. (%)</td>
<td>14 (6.5)</td>
</tr>
<tr>
<td>Referred to higher level of care, No. (%)</td>
<td>4 (1.9)</td>
</tr>
</tbody>
</table>

Abbreviations: HAZ, height-for-age z score; IQR, interquartile range; MUAC, mid-upper arm circumference; WAZ, weight-for-age z score; WHZ, weight-for-height z score.
were completed at a local health center and 56 (33%) were completed by a local community health worker. For the second and third visits, the same provider was used in 84% and 80% of cases, respectively. Among the total referral visits (N=407), 12 (2.9%) resulted in admission, 9 (2.2%) resulted in referral to a higher level of care, and 127 (31.2%) resulted in an outpatient-based intervention. Further details of the breakdown of these outcomes according to first, second, and third visit

**TABLE 2. Post-Discharge Referral Completions and Outcomes Among Discharged Children**

<table>
<thead>
<tr>
<th>Referral program completions (N=202)</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1 visit</td>
<td>170 (84)</td>
</tr>
<tr>
<td>At least 2 visits</td>
<td>143 (71)</td>
</tr>
<tr>
<td>All 3 visits</td>
<td>96 (48)</td>
</tr>
</tbody>
</table>

Outcome for visit 1 (n=171)

| No intervention                     | 111 (65) |
| Outpatient-based intervention        | 54 (32)  |
| Admission                            | 2 (1)    |
| Referral to higher level of care     | 4 (2)    |

Outcome for visit 2 (n=141)

| No intervention                     | 88 (62)  |
| Outpatient-based treatment           | 42 (30)  |
| Admission                            | 8 (6)    |
| Referral to higher level of care     | 3 (2)    |

Outcome for visit 3 (n=95)

| No intervention                     | 60 (63)  |
| Outpatient-based treatment           | 31 (33)  |
| Admission                            | 2 (2)    |
| Referral to higher level of care     | 2 (2)    |

Reasons for missed referral visits (n=104)

<table>
<thead>
<tr>
<th>Reason</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child not sick/visit not considered important</td>
<td>22 (22)</td>
</tr>
<tr>
<td>Child away</td>
<td>12 (12)</td>
</tr>
<tr>
<td>Child admitted</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Child died</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Forgot to go</td>
<td>15 (15)</td>
</tr>
<tr>
<td>Visit not possible (health system factorsa)</td>
<td>16 (16)</td>
</tr>
<tr>
<td>Visit not possible (family factorsb)</td>
<td>23 (23)</td>
</tr>
</tbody>
</table>

a Examples of health system factors include closed health center and unavailable community health worker.
b Examples of family factors include cost barriers, no transportation available, and husband denied permission.
are detailed in Table 2. Outpatient interventions were defined as disease-specific treatments. While general health advice was commonly provided, this was not considered an outpatient intervention. Outpatient interventions were accepted in 121 (95%) cases.

There were no statistically significant findings in the secondary analysis of predictors of follow-up, although trends toward increased referral compliance were noted among those children with increasing mid-upper arm circumference or weight-for-age z score, who had used a mosquito net consistently, and who had a length of stay of less than 5 days during the initial admission. Age, sex, household crowding, sibling deaths, and age of the child’s mother were not associated with follow-up success (Table 3).

**Post-Discharge Readmission and Mortality**
During the 60-day post-discharge period, a total of 22 (11%) children were readmitted at least once, for a total of 28 admissions (Table 4). Of those children who were readmitted, 12 were admitted through a scheduled referral visit, and the remaining 10 through self-referral. During the post-discharge period, 5 children died (2.5%); 4 died at home and 1 during a readmission. The child who died in the hospital was seen twice at referral follow-up visits. The 4 who died at home were not seen at follow-up visits or any occasion; no care was sought from any health care provider before death.

**Satisfaction With the Interventions**
Approximately 60 days after discharge, field officers administered a short survey with 5 questions for caregivers to solicit feedback on the bundle of interventions (Table 5). Overall, more than 75% of caregivers strongly agreed that the education provided at discharge improved their ability to care for their child during the post-discharge period; 65% of caregivers strongly agreed that the simple preventive items provided were helpful in caring for their child. Among those who completed at least 1 referral (n = 170), 62% found that the referrals were very helpful in caring for their child and 75% found that the referrals were neither difficult nor inconvenient. Overall, 75% were very satisfied with the interventions. When asked what else could have been done to help with their child, the responses varied. However, 3 responses occurred often, with 82 (41%) respondents stating they wished the program had provided transportation for the post-discharge referrals, 47 (23%) stating they wished the program provided either food in the hospital or following discharge, and 41 (20%) stating they wished the

| TABLE 3. Analysis of Factors Associated With Post-Discharge Referral Completion (N = 202) |
|------------------------------------------|-----------------|-------------------|
| **Variable**                | **OR (95% CI)** | **P Value**  |
| Sex (female)                | 1.03 (0.48, 2.21) | .93              |
| Age (for each month increase) | 1.00 (0.97, 1.02) | .77              |
| Referral at initial admission | 0.85 (0.32, 2.60) | .74              |
| MUAC (for each 1 mm increase) | 1.01 (1.00, 1.04) | .10              |
| WAZ (for each 1 SD increase) | 1.20 (0.96, 1.50) | .11              |
| HIV positive                | 2.52 (0.32, 19.96) | .38              |
| Crowding (for each additional household member) | 1.09 (0.90, 1.31) | .38              |
| Sibling death               | 1.03 (0.39, 2.72) | .95              |
| Maternal age (for each 1-year increase) | 1.01 (0.94, 1.08) | .81              |
| Mosquito net use (always vs. no/sometimes) | 2.00 (0.90, 4.47) | .09              |
| Length of stay > 5 days     | 0.53 (0.24, 1.19) | .12              |

**Abbreviations:** CI, confidence interval; MUAC, mid-upper arm circumference; OR, odds ratio; SD, standard deviation; WAZ, weight-for-age z score.

**Within 60 days after discharge, 11% of children were readmitted.**

**75% of caregivers were very satisfied with the interventions.**

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educational component was administered at the time of admission.

**Comparing the Two Cohorts**

In the earlier observational study, 1,307 children were enrolled using the same enrollment criteria as this study. Of these, 65 died during hospitalization (5%), resulting in 1,242 live discharges (Table 6). During the first 60 days of follow-up, 41 (3.3%) children died, 72 (5.8%) were readmitted, and 383 (30.8%) sought care with a community health worker, health center, or hospital. During the current study that included a bundle of interventions, the rates of mortality, readmission, and health seeking were 2.5%, 10.9%, and 87.6%, respectively. We found a non-significant 25% lower odds of death at 60 days (odds ratio [OR], 0.75; 95% confidence interval [CI], 0.29 to 1.92), a nearly twofold higher adjusted odds of readmission (OR, 1.97; 95% CI, 1.14 to 3.23), and a 14-fold higher adjusted odds of seeking post-discharge care (OR, 14.61; 95% CI, 9.41 to 22.67).

The absolute increase in care seeking post-discharge increased from approximately 30% in the earlier observational study (with no intervention) to nearly 90% in the current study (with the intervention to promote health-seeking behavior post-discharge). This indicates that less than 2 children would need to receive this intervention in order for 1 additional child to receive in-person follow-up care who otherwise would not have received follow-up care after discharge. The characteristics of these 2 samples were similar. However, the earlier observational cohort had a higher proportion of patients with severe malnutrition. The interventional cohort had a substantially higher proportion of pneumonia and lower proportion of malaria (and thus a lower mean oxygen saturation). The proportion of children with HIV and of those with an abnormal Blantyre Coma Scale score was slightly higher in the interventional cohort (Table 7). When applying our previously derived post-discharge mortality prediction model, we found a 25% lower odds of death at 60 days, a nearly 2-fold higher adjusted odds of readmission, and a 14-fold higher adjusted odds of seeking post-discharge care.

**DISCUSSION**

This proof-of-concept study evaluated the effectiveness of using a discharge bundle, consisting of a

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**TABLE 4. Post-Discharge Mortality and Readmission Details (N = 202)**

<table>
<thead>
<tr>
<th></th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality within 60 days post-discharge</td>
<td>5 (2.5)</td>
</tr>
<tr>
<td>Location of death</td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>3 (60.0)</td>
</tr>
<tr>
<td>Home of a relative or friend</td>
<td>1 (20.0)</td>
</tr>
<tr>
<td>Hospital</td>
<td>1 (20.0)</td>
</tr>
<tr>
<td>60-day post-discharge readmission</td>
<td></td>
</tr>
<tr>
<td>Once</td>
<td>16 (72.7)</td>
</tr>
<tr>
<td>Twice</td>
<td>4 (18.2)</td>
</tr>
<tr>
<td>Three times</td>
<td>2 (9.1)</td>
</tr>
<tr>
<td>Source of readmission (n = 28)</td>
<td></td>
</tr>
<tr>
<td>Self-referral</td>
<td>16 (57.1)</td>
</tr>
<tr>
<td>Scheduled post-discharge referral</td>
<td>12 (42.8)</td>
</tr>
</tbody>
</table>
discharge kit (education and preventive items as incentives) and post-discharge referrals for follow-up visits, in a hospital environment in southwestern Uganda to improve health-seeking behavior and post-discharge mortality. Results showed that this intervention was both feasible and effective. After administering this intervention to the caregivers of some 200 children, we found that 89% of children successfully achieved at least 1 post-discharge follow-up visit, with nearly 50% completing all 3 follow-up visits. The observed falling compliance in referral completion, however, and the fact that 40% of missed visits were due to circumstances that appeared to be beyond the control of the caregiver, suggest that 2 visits may be more practical in bringing this type of intervention to scale.

Post-discharge care was community focused, with referrals being directed to community health

Two, instead of three, follow-up visits post-discharge may be more practical in bringing this type of intervention to scale.

<table>
<thead>
<tr>
<th>TABLE 5. Caregiver Satisfaction With Interventions(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. (%)</strong></td>
</tr>
<tr>
<td>Did the education provided at discharge improve your ability to take care of your child? (n = 191)</td>
</tr>
<tr>
<td>Yes, strongly</td>
</tr>
<tr>
<td>Yes, somewhat</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Were the soap, oral rehydration salts, and mosquito net helpful in better caring for your child after discharge? (n = 189)</td>
</tr>
<tr>
<td>Yes, strongly</td>
</tr>
<tr>
<td>Yes, somewhat</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Did you feel that the referrals were helpful in caring for your child after discharge? (n = 170)</td>
</tr>
<tr>
<td>Yes, very helpful</td>
</tr>
<tr>
<td>Yes, somewhat helpful</td>
</tr>
<tr>
<td>Not sure</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Did you find the referrals difficult/inconvenient? (n = 170)</td>
</tr>
<tr>
<td>Yes, very difficult/inconvenient</td>
</tr>
<tr>
<td>Yes, somewhat difficult/inconvenient</td>
</tr>
<tr>
<td>Not sure</td>
</tr>
<tr>
<td>No, not difficult/inconvenient</td>
</tr>
<tr>
<td>Overall satisfaction with discharge kit and post-discharge referral (n = 195)</td>
</tr>
<tr>
<td>Very satisfied</td>
</tr>
<tr>
<td>Somewhat satisfied</td>
</tr>
<tr>
<td>Not satisfied</td>
</tr>
</tbody>
</table>

\(^a\) Sample size for the satisfaction indicators are slightly different, reflecting that not all children discharged (such as most who were discharged against medical advice) received the counseling and incentives, and not all caregivers participated in the satisfaction survey.
### TABLE 6. Comparison of Outcomes Between Earlier Observational Cohort (N = 1,242) and Current Intervention Cohort (N = 202)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Earlier Observational Cohort, No. (%)</th>
<th>Current Intervention Cohort, No. (%)</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readmission</td>
<td>72 (5.8)</td>
<td>22 (10.9)</td>
<td>1.97&lt;sup&gt;b&lt;/sup&gt; (1.14, 3.23)</td>
</tr>
<tr>
<td>Any visit</td>
<td>383 (30.8)</td>
<td>177&lt;sup&gt;a&lt;/sup&gt; (87.6)</td>
<td>14.61&lt;sup&gt;b&lt;/sup&gt; (9.41, 22.67)</td>
</tr>
<tr>
<td>Death</td>
<td>41 (3.3)</td>
<td>5 (2.5)</td>
<td>0.75 (0.29, 1.92)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval; OR, odds ratio.

<sup>a</sup> Also includes non-referral visit; therefore, the number in this table is higher than the 170 indicated in Table 2.

<sup>b</sup> Adjusted for site of enrollment and post-discharge mortality risk score.

### TABLE 7. Characteristics of Discharged Subjects, Comparison Between Earlier Observational Cohort (N = 1,242) and Current Intervention Cohort (N = 202)

<table>
<thead>
<tr>
<th></th>
<th>Earlier Observational Cohort</th>
<th>Current Intervention Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%)</td>
<td>682 (54.9)</td>
<td>103 (51.0)</td>
</tr>
<tr>
<td>Age, months, median (IQR)</td>
<td>18.1 (10.8, 34.6)</td>
<td>16.2 (10.0, 29.0)</td>
</tr>
<tr>
<td>MUAC &lt;115 mm, No. (%)</td>
<td>96 (7.7)</td>
<td>12 (5.9)</td>
</tr>
<tr>
<td>MUAC 115–125 mm, No. (%)</td>
<td>87 (7.0)</td>
<td>19 (9.4)</td>
</tr>
<tr>
<td>Severely underweight (WAZ &lt; -3), No. (%)</td>
<td>188 (15.1)</td>
<td>20 (10.0)</td>
</tr>
<tr>
<td>Severely wasted (WHZ &lt; -3), No. (%)</td>
<td>232 (18.7)</td>
<td>24 (11.9)</td>
</tr>
<tr>
<td>Severely stunted (HAZ &lt; -3), No. (%)</td>
<td>187 (15.0)</td>
<td>28 (13.9)</td>
</tr>
<tr>
<td>Mean SpO2 at admission</td>
<td>94.0 (90.0, 96.0)</td>
<td>91.0 (85.5, 97.0)</td>
</tr>
<tr>
<td>Percent with abnormal BCS score (&lt; 5)</td>
<td>133 (10.7)</td>
<td>31 (15.4)</td>
</tr>
<tr>
<td>HIV positive, No. (%)</td>
<td>58 (4.7)</td>
<td>14 (7.0)</td>
</tr>
<tr>
<td>Maternal education, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than primary 3</td>
<td>250 (20.1)</td>
<td>29 (14.4)</td>
</tr>
<tr>
<td>Primary 4 to primary 7</td>
<td>630 (50.7)</td>
<td>85 (42.1)</td>
</tr>
<tr>
<td>Secondary 1 to secondary 6</td>
<td>269 (21.6)</td>
<td>58 (28.7)</td>
</tr>
<tr>
<td>Post-secondary</td>
<td>93 (7.5)</td>
<td>30 (14.9)</td>
</tr>
<tr>
<td>Discharge diagnosis, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>418 (33.6)</td>
<td>39 (19.3)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>390 (31.4)</td>
<td>98 (48.5)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>96 (7.7)</td>
<td>17 (7.4)</td>
</tr>
<tr>
<td>Discharged against medical advice, No. (%)</td>
<td>120 (9.6)</td>
<td>17 (8.4)</td>
</tr>
</tbody>
</table>

Abbreviations: BCS, Blantyre Coma Scale; HAZ, height-for-age z score; IQR, interquartile range; MUAC, mid-upper arm circumference; WAZ, weight-for-age z score; WHZ, weight-for-height z score.
Post-discharge mortality is a neglected but important issue in the field of pediatric global health. Prior research has shown that, in some areas, mortality after discharge exceeds mortality in the hospital. Improved post-discharge mortality is an important contributor to overall childhood mortality; however, policy and practice have not recognized its importance, and a systematic approach to post-discharge care is lacking in most resource-poor countries. While resources such as the Integrated Management of Childhood Illness strategy and the Emergency Triage Assessment and Treatment guidelines provide standardized approaches to the acute phase of infectious illness, no resources or guidelines currently exist to provide recommendations during the vulnerable recovery phase.

Although post-discharge care should be an important component in the care of all discharged children, limited resources and an already strained health system are likely to be major barriers in its implementation. The current context among hospitals in Uganda and elsewhere is that the limited post-discharge care that does occur focuses primarily on the ongoing treatment of specific diseases such as HIV and tuberculosis. We are not aware of any hospitals in resource-poor settings that have adopted general discharge policies. In addition to a lack of robust policies for post-discharge care, the larger issue is the availability of resources, which is a major limitation to the scalability of effective post-discharge care. At the community level, the capacity to complete follow-up visits is sufficient and does appear to exist in most areas, but the hospital resources to assess children for risk and to implement the referral process are likely to be insufficient. We propose the establishment of discharge nurses to oversee this role, as has been suggested for improving post-stroke outcomes in sub-Saharan Africa. Further, engagement with other key stakeholders (e.g., ministries of health, hospital administrations, and community health worker training programs) is critical in the development of a scalable intervention.

The identification of the most vulnerable children presents an important strategy to improve the cost-effectiveness of post-discharge care, as limited resources can be used to target high-risk children. Our group recently derived a clinical prediction tool that uses 5 easily collected variables to identify such children. This tool has been incorporated into a mobile application to enable frontline health workers to rapidly identify vulnerable children before discharge. The administration of the discharge bundle evaluated in this study could be an inexpensive and effective strategy to improve care following discharge, as it is well recognized that caregivers could benefit from additional education surrounding illness recognition and health seeking.

Prior research has shown that a significant proportion of child deaths occur outside of health facilities. Our study found that 4 out of 5 children who died after discharge were outside of the health system, reflecting similar findings from our work during the observational study. Critical to addressing post-discharge care, therefore, is improved community-level care during the vulnerable post-discharge period, which was an important focus of our work.

Limitations
This proof-of-concept study is subject to several important limitations. First, the small sample size limits the ability of this study to make robust comparisons with the earlier observational study. Although comparisons of study outcomes such as health seeking and readmission provide some insight into the potential value of a post-discharge intervention, a primary study outcome based on mortality is preferable and will be a primary component of future research. The results of this study, however, serve an important role in guiding...
the design and sample size calculations for subsequent research, as does the feedback provided by the participants in the study. A further limitation of this study, and similar studies, is that the incorporation of post-discharge follow-up in a research context may not be easily replicated in a non-research context. The discharge education given to caregivers, highlighting the vulnerability of their children during the post-discharge period, likely played an important role in motivating them to sacrifice time and money to complete the follow-up referral visits. Follow-up interventions, therefore, must be strongly linked to education at the time of discharge. A final limitation of this study is the relatively narrow age range (6 months to 5 years) of children. The reason this age range was chosen was based on design considerations for the earlier observational study, which we used to develop the prediction model. Our research group is currently working toward the expansion of these prediction models to eventually include both younger (<6 months) and older (>5 years) children. Finally, because this intervention consisted of a bundle of interventions, it is impossible to identify which components were critical in the results that were observed. The simple preventive items that complemented the education (a mosquito net, soap, and oral rehydration salt) were relatively expensive (approximately US$6.50) and may impact scalability. However, it is unlikely that these particular incentives are required in order to observe these benefits. The mosquito net was the most expensive item in the bundle (about US$5.75); it could easily be replaced with a less expensive item that complements the education while still providing value to the caregiver, and could serve as a means to reinforce the instructions provided by the discharge nurse.

CONCLUSION

In conclusion, we found that a simple bundle of interventions at discharge, including brief educational counseling and a post-discharge referral, can improve post-discharge care and outcomes among children discharged from the hospital. New research is currently being planned to establish the benefit of a bundle of interventions at discharge to improve post-discharge mortality and will explore bringing such interventions to scale in Uganda.

Acknowledgments: This study was funded by Grand Challenges Canada. Dr. Wiens is supported by a fellowship from Mitacs Canada. Dr. Moschovis is supported by the National Institutes of Health (5-F32-HL124951) and the Thrasher Research Fund. We gratefully acknowledge the contributions of Annet Twinomuguni, Justine Kamazima, Clare Komugisha, Solome Kabugyenzi, Brenda Kembabazi, Alexander Mutungi, and Hassan Bandaikwera. Without their dedication, this study could not have been completed.

Competing Interests: None declared.

REFERENCES

Combining intensive group learning and provision of on-site reproductive health services through an existing alternative basic education program increased use of contraception and HIV testing and counseling among young out-of-school Liberians.

ABSTRACT

Introduction: Young Liberians, particularly undereducated young adults, face substantial sexual and reproductive health (SRH) challenges, with low uptake of contraceptive methods, high rates of unintended pregnancy, and low levels of knowledge about HIV status. The purpose of this study was to assess the impact of a 6-day intensive group learning intervention combined with on-site SRH services (called HealthyActions) among out-of-school young adults, implemented through an existing alternative education program, on uptake of contraception and HIV testing and counseling (HTC).

Methods: The intervention was implemented among young women and men ages 15–35 who were enrolled in alternative basic education learning sites in 5 counties of Liberia. We conducted a randomized evaluation to assess program impact. Baseline data were collected in January–March 2014, and endline data in June–July 2014. Key outcomes of condom use, contraceptive use, and HTC were estimated with difference-in-difference models using fixed effects. All analyses were conducted in Stata 13.

Results: We assessed outcomes for 1,157 learners at baseline and 1,052 learners at endline, across 29 treatment and 26 control sites. After adjusting for potential confounders, learners in the HealthyActions intervention group were 12% less likely to report never using a condom over the last month compared with the control group (P = .02). Female learners who received HealthyActions were 13% more likely to use any form of modern contraception compared with learners in control sites (P < .001), with the greatest increase in the use of contraceptive implants. Learners in HealthyActions sites were 45% more likely to have received HTC (P < .001).

Conclusion: Providing intensive group learning in a supportive environment coupled with on-site health services improved SRH outcomes among participating learners. The focus of HealthyActions on participatory learning for low-literacy populations presents an adaptable solution for health programming across Liberia and the region.

INTRODUCTION

Even before the recent Ebola crisis, Liberia has faced intersecting health and development challenges. Fourteen years of conflict disrupted preexisting social structures, resulting in young people being forced to take on adult responsibilities without experiencing healthy developmental milestones. Liberians value education highly as the path to better employment, and
particularly appreciate the positive impact that educating girls can have on families and communities. However, due to war, poverty, and family disruption, many young people in Liberia were forced to drop out of school and never participated in community leadership structures. In a sense, they were caught between youth and adulthood.

As a result, in Liberia the government’s definition of youth—15–35 years—is unique to a post-conflict environment. This broad definition speaks to delayed social and cognitive development across generations, warranting creative solutions to reach young people and provide access to much-needed services.

Liberia’s legacy of conflict, orphanhood, lack of social cohesion, and school drop-out, combined with early sexual debut, place young Liberians at increased risk of negative sexual and reproductive health (SRH) outcomes. According to Liberia’s 2013 Demographic and Health Survey, the median age at first sex among women 25–49 is 16.2 years. Nearly one-quarter (24%) of women ages 25–49 had sexual intercourse by age 15; about three-quarters (78%) by age 18; and over 90% by age 20. Among men ages 25–49, the median age at first sex is slightly older at 18.3 years. By age 20, 75% of men have had sex. By age 24, nearly 80% of women have begun childbearing. Only 25% of sexually active girls and young women (ages 15–29) use a modern contraceptive method, and about 30% have an unmet need for contraception. Overall, HIV prevalence is low in Liberia at 1.9% for adults 15–49. Among women, peak prevalence (3.6%) occurs in the 25–29 age group; among men, prevalence is highest (3.6%) among those 40–44. While nearly all Liberians have heard of HIV/AIDS and the majority know where to get tested, only 37% of 15–24-year-old women and 11% of 15–24-year-old men have ever been tested and have received their results.

Low education levels exacerbate this situation; in 2013, 33% of women 15–49 and 13% of men 15–49 reported they had never been to school. Primary school gross enrollment is only 52%, and nearly a third of all students enrolled in school drop out in the first grade. Low rates of school enrollment and poor quality of teaching result in few Liberians gaining actionable knowledge and skills.

Youth in Liberia face several barriers that limit their access to formal health services. To begin, the armed conflict led to an overall collapse of the health care system characterized by the flight of health workers, looting, and destruction of health facilities and the desecration of roads. Even where health services do exist, young people often face additional barriers. As in many countries in the world, young people in Liberia face financial barriers in accessing services, unfriendly providers (particularly if they are seeking SRH services and are unmarried), and lack of privacy and confidentiality. Unequal gender norms mean that young women are less likely than young men to receive an education and make autonomous decisions. Social acceptance of intimate partner violence reflects a culture of male dominance. Intergenerational and transactional sex is widespread across wealth quintiles. Many young women engage in transactional relationships to secure school fees, clothing, and other commodities.

Young people in Liberia transition into adulthood in an environment in which there is pervasive distrust of all institutions connected with the government, which includes the health system. This may be in large part due to the fact that quality of life has increased minimally since the end of the conflict in 2003, despite donor money and support from the United Nations. Many communities lack social cohesion, and in some cases, young people are actively marginalized from existing organizational structures within their communities. The lack of formal training opportunities and/or education, along with limited supportive family structure, prevent many young people from becoming actively involved in their communities. The inability to rationalize appropriately within a group and/or to socialize normally during their formative years creates enormous barriers for young people to conform to conventional social norms. Further, there are widely respected taboos around discussing sex and sexuality, particularly for young women. Yet young women face greater pressure to have sex earlier, due to their desirableness to older men and the fact that the exchange system of young women’s sexuality for material goods has become normalized. These normalizations, however, have not relieved the health system actors of their judgment about young people, and young women in particular.

Supportive family, school, and peer environments are often associated with improved health outcomes among young people. Connectedness

Liberia’s legacy of conflict combined with early sexual debut places young Liberians at increased risk of negative sexual and reproductive health outcomes.
to schools, community, and family can have a protective effect on SRH outcomes, such as age of sexual debut, number of sexual partners, and contraceptive use. Programs that aim to strengthen social ties through participation in basic education can promote positive engagement in learning, socialization, and recreation while also improving access to SRH information and promoting healthy behavior.

Uptake of SRH services is strongest when interventions designed to bolster demand for services are linked directly to supply, and where there is community and social support; for example, an evaluation of a program implemented in Ghana and Nigeria that provided both contraceptives within a school setting and referrals for other SRH services as part of a comprehensive SRH program targeting youth, showed improved contraceptive uptake among participants. Educational settings, whether formal or informal, can provide ample opportunities for improving access to SRH information and services for young people. Information and services are brought to learners, rather than learners needing to seek them out. Additionally, learners can access services at the same time as one another, reducing the stigma associated with seeking contraceptive and HIV services. In Liberia, reaching young adults with reproductive health information and services through an existing platform could help overcome barriers to accessing services and ensure that they receive high-quality, youth-friendly services while also establishing relationships with local health service providers.

Evidence of effective SRH strategies remains limited in West Africa, despite the efforts of the Ouagadougou Partnership to expand access to family planning. We aimed to assess whether an intervention package consisting of intensive group learning and provision of on-site SRH services could increase use of modern contraception and HIV testing and counseling (HTC) services among out-of-school young adults in Liberia. We hypothesized that participation in an alternative basic education project where this program, called HealthyActions, was implemented would be associated with greater use of modern contraception among women, greater condom use among young women and men, and greater use of HTC services by women and men, compared with participation in an alternative basic education project where HealthyActions was not implemented.

METHODS

Intervention

HealthyActions was structured as a 6-day intensive “burst” of participatory and action-oriented SRH education activities packaged with on-site health services, designed to be easily integrated into an alternative basic educational setting; in this case, the U.S. Agency for International Development (USAID) Advancing Youth Project, an alternative basic education project implemented by the Education Development Center (EDC). The USAID Advancing Youth Project, which began in October 2011 and will end in June 2017, provides basic literacy and numeracy skills, social and leadership development, and livelihoods training for out-of-school Liberian youth ages 15–35 who have no or marginal literacy skills. The first round of HealthyActions implementation took place from August 2012 to July 2013 in Nimba and Montserrado counties as a pilot to gain feedback on the curriculum and approach. The second round of larger-scale implementation took place from November 2013 to May 2014 in Bong, Grand Bassa, Lofa, Montserrado, and Nimba counties.

Over three-quarters of Advancing Youth learners are women, most of whom have never been to school before. The median age is 29. Most learners report that they are living with a partner or spouse and that they have an average of 3 children. Only about 5% are adolescents under the age of 18; these adolescents take the same classes as older learners and are integrated into all activities including youth clubs and skills training. The main difference between older and younger participants in the program is their experience of war; however, both groups have issues with identity formation and positive role models, and poverty puts learners at risk for transactional sex and other risky behaviors.

The USAID Advancing Youth Project works through the Liberian Ministry of Education, using government schools and teachers, with the classes scheduled in the evening to make learning accessible to young people who have left the formal school system. In the Advancing Youth Project’s approach to alternative basic education, Level 1 is for students who have never been to school at all or have dropped out in grade 1 or 2. Level 2 is roughly equivalent to grades 3 and 4, and level 3 to grades 5 and 6. Students are placed in the appropriate level based on the results of a short literacy and math test at intake.
HealthyActions was implemented through a partnership between Population Services International (PSI) Liberia and EDC, and was originally funded in partnership between the 2 organizations; 50% from EDC via the Advancing Youth Project and 50% from a PSI innovation fund. The Advancing Youth Project’s life-skills module has been one of the most popular among learners because of its relevance and applicability; however, teachers are often uncomfortable addressing SRH topics with learners. HealthyActions provided the opportunity to bring in expert trainers to reinforce learning and to link learners directly to health services. Since the majority of learners are young women who never attended or dropped out of school due to pregnancy, topics related to contraception and parent and partner communication are of extreme interest.

HealthyActions was conceived as a package of educational and empowering SRH activities that would motivate learners to use health services, which were brought to them to try on-site. The program consisted of 15 hours of classroom-based modules delivered over the course of 5 sequential days, focused on building knowledge and improving attitudes and skills related to SRH. The package then culminated in a community-based celebration on the 6th and final day of the program, during which HealthyActions participants and their families and communities were invited for a day of music, food, and health services. The celebrations were held on-site, with government health workers providing contraceptive counseling and services, HTC, and referrals to local clinics for HealthyActions participants and other community members. At sites where classrooms were available, health care providers used the classrooms as private and confidential spaces to provide services. At sites where private indoor space was limited, tables and curtains were used to create private and clean areas for service delivery. Participants who required clinical follow-up (e.g., for a positive HIV test, insertion of an intrauterine device [IUD], continued injections) were provided with referrals to the nearest government health facility.

The HealthyActions curriculum was designed through an iterative and youth-centered process that included (1) insight gathering with learners; (2) curriculum development; (3) pilot testing with learners; and (4) adaptation and implementation. Additionally, PSI looked to USAID’s recently released Youth in Development Policy to ensure the program design aligned with the U.S. Government’s key priorities for youth initiatives. In line with the policy, HealthyActions:

- Used an assets-based approach that focused on building internal assets (e.g., self-esteem, communication and assertiveness skills, gender transformative attitudes) as well as external assets (e.g., access to education and social cohesion)
- Involved communities by engaging learners, their parents, and their community members in health service delivery and promotion on community celebration days
- Created opportunities for youth participation particularly through insight gathering, piloting the curriculum, and peer education opportunities
- Worked cross-sectorally by integrating SRH education and services within formalized (albeit nontraditional) education programming

To begin, PSI conducted an analysis of published and gray literature with a particular eye toward any discourse on Liberian youth’s assets and behavioral drivers. Results were used to support the design of a focus group discussion guide that was fielded through 2 group discussions with USAID Advancing Youth Project learners to glean insights about their knowledge, attitudes, and perceptions of SRH. Key insights from those discussions—such as misconceptions about the safety and efficacy of certain contraceptive methods, harmful gender norms, and negative attitudes toward condom use—were used to design curriculum content. Other insights related to young people’s hopes, aspirations, and curiosity were used to design curriculum delivery approaches.

The curriculum was grounded in the information, motivation, behavioral skills, and resources (IMBR) model, a health behavior theory often used in peer-based learning contexts that places equal emphasis on teaching young people knowledge and skills while also increasing access to products and services. Adult learning approaches were incorporated that included games and trivia to build knowledge; values exercises to address attitudes and norms; and role-play and small group discussions to drive critical thinking, self-esteem, and skill-building. Many of the curriculum’s activities drew on existing resources developed by international organizations, adapted for the Liberian context.

On Day 1, learners were introduced to the program and to one another, and they set group
norms, took a pretest, and learned about “Healthy Competition”—a competitive element to the program. On that first day, the class was split into 2 teams. Every day thereafter, there was at least one competitive exercise whereby teams competed for points. At the end of the week, the team with the most points won a small prize, presented at the community celebration day. The competition provided a fun and engaging way to keep learners motivated and to improve teamwork.

Day 2 focused on puberty, sex, and reproductive health. Activities included body mapping exercises, true/false trivia games, role-playing exercises to practice talking about sex (with parents, health care workers, sexual partners, and their own children), and values exploration exercises to explore feelings about sexuality.

Day 3 focused on HIV/AIDS and included a game of tag to explain how HIV works in the body, true/false trivia, small group discussions about HIV stigma, and creating songs and dances to promote HTC.

Day 4 focused on contraception and pregnancy. Activities included a trivia game to learn about the available contraceptive methods, condom demonstration and practice, storyboard discussions about early pregnancy and community norms surrounding pregnancy outside of marriage, and values exploration surrounding use of contraception.

Day 5 focused on communication skills and taking action. Activities included a storyboard discussion on gender and power, small group discussions about coerced vs. voluntary sex, defining and practicing assertiveness skills, and a game to understand the negative effects of alcohol and drugs on decision making. Each day ended with a call to action (such as getting an HIV test or talking to a health care provider about contraception) and a condom demonstration, including practice putting condoms on models.

Day 6 was a clinic celebration day to mark the end of the curriculum and to introduce on-site health services to HealthyActions participants and members of the community. The aim in linking health service provision in a “burst” with the curriculum was to enable participants to act quickly on what they had learned and share their learning with family and community members to create further motivation for health service utilization, thus building trust in government health services.

The curriculum was pilot tested with a group of 15 learners during a weeklong facilitator training so that adaptations could be made to fit the needs of participants and facilitators. The curriculum was originally developed for 15-24-year-olds—the age range defined by the United Nations as “youth.” However, during pilot testing we learned that the likely age range of participants would skew older and that many would already be parenting. Although the Advancing Youth Project is open to younger participants, it tends to draw older participants who were denied schooling and now see that they need literacy and numeracy skills in order to better support themselves and their families, and to gain respect in the community. However, levels of SRH knowledge remain very low, regardless of age. We therefore added content to the curriculum that included positive parenting and parent-child communication about SRH.

Skilled facilitators, called County Health Leads, were trained to deliver the curriculum. County Health Leads were PSI employees, trained as health educators, and chosen for their ability to communicate well with young adults in a fun, nonhierarchical, and yet still authoritative fashion. County Health Leads worked in pairs of one man and one woman. They were not teachers from the Advancing Youth Program—who were uncomfortable with and lacked knowledge to provide in-depth information about SRH—but rather knowledgeable outsiders brought into the program to engage topics that “insiders” usually cannot broach. County Health Leads visited a different USAID Advancing Youth Project site each week, in pairs, to implement the curriculum.

During the course of the HealthyActions week, the County Health Leads elected, with their permission, 2 learners to serve as Peer Health Educators. The learners were selected based on their demonstrated leadership and grasp of the curriculum, as well as eagerness to remain involved with the project after the 6-day intervention. Peer Health Educators volunteered to sustain the teachings of the program among their peer learners and other community members. Following HealthyActions, they received a formal 3-day training from the County Health Leads and PSI staff on delivery of the HealthyActions curriculum. However, because of low literacy levels, PSI and EDC first created 8 recordings that could be played through basic mobile phones. The recordings, produced in the style of popular Liberian radio shows and in Liberian English, feature a host who guides the Peer Health Educator through a facilitation of that recording’s lesson. For instance, the host says, “My friend [referring
to the Peer Health Educator, please ask the group what they have heard about the oral contraceptive pill.” After a 2-minute pause, the host provides a brief explanation of the oral contraceptive pill. A sample recording can be found on PSI’s website.  Peer Health Educators convened small gatherings within their communities to listen to and discuss the recorded lessons on the phones. Peer Health Educators also provided vouchers for family planning referrals to locally accessible clinics. Peer Health Educators used FrontlineSMS to send text messages to PSI and EDC on the number of participants, disaggregated by gender, in their meetings and the number of vouchers distributed.

HealthyActions was implemented twice between 2012 and 2014. The first round of implementation took place from August 2012 to July 2013 in Nimba and Montserrado counties as a pilot to gain feedback on the curriculum and approach. The second round of larger-scale implementation took place from November 2013 to May 2014 in Bong, Grand Bassa, Lofa, Montserrado, and Nimba counties. This second round included the Peer Health Educator component of the program. The evaluation for the program was undertaken during the second round of implementation.

**Evaluation Design**

We used the Consolidated Standards of Reporting Trials (CONSORT) statement to structure reporting of this evaluation. A randomized design was used to evaluate the intervention during the second phase of HealthyActions. Eligible USAID Advancing Youth Project learning sites were identified as clusters to be randomized. Learning sites were randomly assigned to receive HealthyActions during the evaluation period or to serve as control sites. Learning sites were not eligible to participate if they were private education institutions and/or had participated in the first phase of HealthyActions. Out of 150 sites assessed for eligibility, 34 sites were assigned to the treatment group and 26 sites to the control group using a lottery process executed by PSI/Liberia research staff (Figure). Sample size was calculated using G*Power software version 3.1.6. The following parameters were used: difference between 2 independent means statistical test, a priori type of power analysis, one-tailed, .005 probability of Type I error, 95% power, 1:1 allocation ratio. Resulting sample size was 1,144, rounded to 1,200.

The total number of eligible sites was stratified by county, and sites were sampled proportionate to the number of eligible sites per county. Site names were written on paper and stacked in separate piles. One county at a time, site names were placed in a box. Names of sites were selected from the box, with the first draw for treatment sites, the second for control sites, etc. One member of the research team selected treatment sites; another selected control sites; and a third held the box. Blinding of sites and participants to intervention status was not possible. The University of Liberia Institutional Review Board provided ethical approval for this study.

**Data Collection**

Baseline data collection occurred in January–March 2014 and was conducted on a rolling basis across all 60 selected sites. Teams of data collectors and quality control supervisors were assigned by county, due to transportation challenges. At intervention sites, baseline data were collected on day 2 of the HealthyActions week, while at control sites baseline data were collected during standard USAID Advancing Youth Project sessions. Eligible study participants—current USAID Advancing Youth Project learners between the ages of 15–35—were randomly sampled from the group of learners available on the day that the data collection team visited a selected learning site. After informing all learners about the purpose and objectives of the evaluation, a minimum of 20 eligible learners per site were selected by asking learners to pull blocks out of a bucket. The number of blocks in the bucket corresponded to the number of learners at the site that day, with blocks coded for selection to participate in the evaluation. Learners could not see into the bucket when they selected a block. Identities of selected participants were cross-checked against a site roster after sampling.

After ensuring informed consent, trained female data collectors administered a 20–25 minute questionnaire on sociodemographic characteristics, parent-child and partner communication, gender norms, sexual history, contraception knowledge and use, HIV knowledge and testing experience, and, for female respondents, pregnancy history. The questionnaire was developed using Liberian English terms when possible, and data collectors were trained to administer the questionnaire consistently. Respondents above
the age of 18 were administered a verbal consent script, and enumerators recorded their consent to participate via tablet. A paper consent form was administered to eligible respondents under the age of 18, with the minor’s informed assent, and consent provided by the learning site administrator in lieu of a parent. Data were collected electronically using SurveyToGo on Android tablets. Questionnaire administration occurred away from other learners, typically in an empty classroom.

Endline data collection occurred after all intervention sites completed HealthyActions and during standard USAID Advancing Youth Project sessions at both intervention and control sites in June–July 2014. Because of expected difficulties in contacting learners sampled at baseline and confirming their identities, the survey was administered to a newly selected sample of USAID Advancing Youth Project learners using the same sampling techniques as at baseline.

For this analysis, we removed cases from 5 learning sites (4 sites assigned to the control group received the intervention; 1 site was not included in the initial sampling frame). The final analytical sample included 55 sites.
Measures
Outcome measures used for this analysis were as follows:

Among women:
1. Contraceptive use (modern or traditional methods)\textsuperscript{32}
2. Condom use with regular partners and with casual partners (never; intermittently, including sometimes or most of the time; or always)
3. HIV knowledge
4. Ever been tested for HIV and know the result
5. Intention to seek HIV counseling and testing in the next year

Treatment was defined as assignment to a learning site where HealthyActions was implemented. Other measures assessed included sociodemographic factors of age, gender, daily income (no income; 1-100 Liberian dollars [LRD]; 100–500 LRD; 600–1,000 LRD; or > 1,000 LRD, where 85 LRD = US$1), alternative basic education learning level (1, 2, or 3), number of living children, and marital status (single/never married, married/living together, divorced, or widowed). We also assessed women’s reproductive history including number of pregnancies and live births, currently pregnant or breastfeeding, and reproductive intentions.

Statistical Analysis
Descriptive statistics were calculated at baseline and endline. Balance between treatment and control was assessed at baseline using chi-square tests and t tests to assess quality of randomization. For all outcomes, a difference-in-difference logistic regression model with fixed effects was used to assess the effect of HealthyActions participation on observed changes in the outcomes of interest. The general model was specified as:

\[
Y = \alpha + \beta_1 \text{treatment} + \beta_2 \text{time} + \beta_3 \text{covariates} + \beta_4 \text{time} \times \text{treatment}
\]

This model adjusted for both observed and unobserved differences between treatment and control at baseline to minimize possibility of confounding. The interaction term between treatment (coded 0 = control site and 1 = treatment site) and time (coded 0 = baseline and 1 = endline) served as the intervention effect. Other key demographic variables (learning level [1, 2, or 3], income, marital status, age, number of children) were included in the model to account for differences between the samples at endline. Interactions with age and gender were tested for all outcomes. Standard errors were clustered at the learning-site level to account for clustering due to randomization. All analyses were conducted using Stata 13.

RESULTS
At baseline, a total of 1,255 learners were recruited to participate in the evaluation across 34 intervention sites and 26 control sites (Figure). At endline, 1,142 learners were recruited across the same number of learning sites. For this analysis, we assessed outcomes for 1,157 learners at baseline and 1,052 learners at endline in 55 learning sites. HealthyActions treatment and control groups shared similar demographic profiles at baseline and endline, indicating that randomization produced a balanced sample (Table 1). At baseline and endline, the sample consisted primarily of women with an average age of 28 years. The majority of respondents had a very low level of education (corresponding to Alternative Basic Education level 1), were married or living with a partner, and had children. At baseline, there were no statistically significant differences between the treatment and control groups on any demographic variables. At endline, the control group had slightly more women than the treatment group, and the control group was slightly more educated and had a slightly higher average income.

We saw modest improvements in condom use with a regular sexual partner after taking part in HealthyActions (Table 2). No statistically significant differences by age (15–24 vs. 25–35) or gender were found. After adjusting for potential confounders, individuals in the treatment sites were 12% less likely to report never using a condom with a regular partner over the last month when compared with the control group (\(P = .02\)). Positive changes in condom use were also noted among learners reporting that they use condoms always or intermittently, although these findings were not statistically significant. Frequency of condom use was slightly higher among learners reporting condom use with a casual partner, but at endline only 38% of those in the control group reported always using a condom with their casual partners compared with 44% of
those in the treatment group. None of these changes was statistically significant.

Among women who were not pregnant or breastfeeding at the time of the survey, substantial increases were seen in use of contraception for those in the treatment group (Table 3). Young women participating in HealthyActions were 13% more likely to report using a modern contraceptive method than women in the control group ($P = .01$). Increases in modern contraceptive use were greatest among unmarried women (33.7 percentage points; $P = .002$), and among adolescents ages 15–19 we saw a 13 percentage point increase ($P = .005$). Specifically, participation in HealthyActions was associated with an 8 percentage point increase in the probability of using oral contraceptives ($P = .06$) and a 9 percentage point increase in the probability of using implants ($P = .007$), and there were no differential effects by age. In all groups before and after the intervention, injectables and pills remained the first and second most popular methods, respectively. Among the poorest women, at endline those in the treatment group were 31% ($P = .009$) more

| TABLE 1. Demographic Profile of Sampled Learners at Baseline (January–March 2014) and Endline (June–July 2014), Selected Counties of Liberia |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                 | Baseline (N = 1,157) | Endline (N = 1,052) |
|                 | Control (n = 518) | Treatment (n = 639) | Control (n = 503) | Treatment (n = 549) |
| Female, No. (%) | 368 (71.04) | 466 (72.93) | .48 | 327 (65.01) | 400 (72.86) | .01 |
| Age, years, mean (SD) | 28.41 (5.93) | 28.09 (5.81) | .35 | 28.03 (5.86) | 28.86 (6.24) | .41 |
| No. of children, mean (SD) | 2.91 (2.08) | 2.83 (2.16) | .55 | 2.73 (2.17) | 2.79 (1.93) | .65 |
| No. of children, No. (%) | 65 (12.55) | 77 (12.05) | .80 | 75 (14.91) | 86 (15.66) | .73 |
| Marital status, No. (%) | | | | | |
| Single/never married | 187 (36.10) | 241 (37.72) | .70 | 167 (33.2) | 180 (32.79) | .08 |
| Married/living together | 313 (60.42) | 379 (59.31) | | 320 (63.62) | 340 (61.93) | |
| Divorced | 14 (2.70) | 12 (1.88) | | 6 (1.19) | 20 (3.64) | |
| Widowed | 4 (0.77) | 7 (1.10) | | 10 (1.99) | 9 (1.64) | |
| Educational level, mean (SD) | 1.72 (0.82) | 1.65 (0.73) | .12 | 1.78 (0.81) | 1.60 (0.75) | <.01 |
| ABE level 1, No. (%) | 268 (51.74) | 324 (50.70) | .12 | 232 (46.12) | 306 (55.74) | |
| ABE level 2, No. (%) | 127 (24.52) | 216 (33.80) | | 148 (29.42) | 156 (28.42) | |
| ABE level 3, No. (%) | 123 (23.75) | 99 (15.49) | | 123 (24.45) | 87 (15.85) | |
| Income, No. (%) | | | | | |
| 0 | 74 (14.29) | 127 (19.87) | .10 | 98 (19.48) | 137 (24.95) | .08 |
| LRD 1–100 | 80 (15.44) | 83 (12.99) | | 52 (10.34) | 70 (12.75) | |
| LRD 100–500 | 234 (45.17) | 257 (40.22) | | 210 (41.75) | 237 (43.17) | |
| LRD 600–1,000 | 68 (13.13) | 77 (12.05) | | 79 (15.71) | 57 (10.38) | |
| More than LRD 1,000 | 58 (11.20) | 94 (14.71) | | 61 (12.13) | 47 (8.56) | |
| Don’t know/no answer | 4 (0.77) | 1 (0.16) | | 3 (0.60) | 1 (0.18) | |

Abbreviations: ABE, alternative basic education; LRD, Liberian dollars; SD, standard deviation.
likely to report using an implant than those in the control group.

Substantial improvements were seen in HIV counseling and testing after participating in HealthyActions (Table 4). At endline, 42% of individuals in the control group reported having been tested for HIV compared with 88% in the treatment group. After adjusting for baseline probability and other potential confounders, participation in HealthyActions resulted in a 45% increase in the probability that an individual had ever been tested for HIV and knew the result ($P < .001$). There was no differential effect of the intervention for HIV testing among men versus women, nor by age. Intention to test was high in both groups at baseline; however, learners in treatment sites had a 6% higher probability than those in the control sites to report planning to get an HIV test in the upcoming year ($P < .001$).

Benefits of participating in HealthyActions were concentrated among youth under the age of 19 in HealthyActions sites were 32% more likely to know where to get an HIV test than their counterparts in the control sites ($P < .001$). A 3-way interaction term between assessment period, intervention exposure, and age was also found to be highly significant ($P = .02$), indicating that the intervention had a positive, differential effect on adolescents 15–19 years old compared with the general population of learners in the study. Girls under the age of 19 also showed increased knowledge of where to obtain an HIV test as a result of HealthyActions: adolescent girls in HealthyActions sites were 40% ($P < .001$) more likely to report knowing where to obtain an HIV test than their counterparts in control sites; in comparison, adolescent boys were 26% ($P = .02$) more likely to know where to obtain a test than their counterparts in control sites. A 4-way interaction term was also tested between assessment period, intervention exposure, age, and gender, which was also found to be statistically significant ($P = .01$), indicating that HealthyActions had a stronger effect among girls than boys.

**TABLE 2.** Self-Reported Condom Use With Regular and Casual Partners Among Sampled Learners at Baseline (January–March 2014) and Endline (June–July 2014), Selected Counties of Liberia

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th></th>
<th>Control</th>
<th>Treatment</th>
<th>$P$ Value</th>
<th></th>
<th>Endline</th>
<th></th>
<th>Control</th>
<th>Treatment</th>
<th>$P$ Value</th>
<th></th>
<th>Average Marginal Effects (95% CI)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>With regular partner</td>
<td></td>
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<tr>
<td>Sample size</td>
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</tr>
<tr>
<td>Never</td>
<td>356 (64.33)</td>
<td>427 (67.45)</td>
<td>312 (63.78)</td>
<td>304 (62.30)</td>
<td>-0.12 (-0.22, -0.02)</td>
<td>0.02</td>
<td></td>
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<tr>
<td>Intermittently</td>
<td>102 (28.65)</td>
<td>114 (26.70)</td>
<td>94 (30.13)</td>
<td>113 (37.17)</td>
<td>0.08 (-0.02, 0.17)</td>
<td>0.13</td>
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</tr>
<tr>
<td>Always</td>
<td>25 (7.02)</td>
<td>25 (5.85)</td>
<td>19 (6.09)</td>
<td>32 (10.53)</td>
<td>0.04 (-0.01, 0.09)</td>
<td>0.10</td>
<td></td>
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<tr>
<td>With casual partner</td>
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</tr>
<tr>
<td>Never</td>
<td>89 (38.20)</td>
<td>121 (46.28)</td>
<td>80 (31.25)</td>
<td>84 (28.57)</td>
<td>-0.05 (-0.18, 0.07)</td>
<td>0.41</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermittently</td>
<td>33 (37.08)</td>
<td>31 (25.62)</td>
<td>24 (30.00)</td>
<td>22 (26.19)</td>
<td>-0.4 (-0.16, 0.08)</td>
<td>0.48</td>
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<td></td>
</tr>
<tr>
<td>Always</td>
<td>20 (22.47)</td>
<td>33 (27.27)</td>
<td>30 (37.50)</td>
<td>37 (44.05)</td>
<td>0.10 (-0.07, 0.28)</td>
<td>0.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Don’t know</td>
<td>2 (2.25)</td>
<td>1 (0.83)</td>
<td>1 (1.25)</td>
<td>1 (1.19)</td>
<td>–</td>
<td>–</td>
<td></td>
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</tbody>
</table>

Abbreviation: CI, confidence interval.
Data reported as No. (%) except when otherwise noted.
### TABLE 3. Current Contraceptive Use Among Non-Pregnant, Non-Breastfeeding Women at Baseline (January–March 2014) and Endline (June–July 2014), Selected Counties of Liberia

<table>
<thead>
<tr>
<th>Method</th>
<th>Baseline (N = 546)</th>
<th>Control (n = 232)</th>
<th>Treatment (n = 314)</th>
<th>P Value</th>
<th>Endline (N = 470)</th>
<th>Control (n = 215)</th>
<th>Treatment (n = 255)</th>
<th>P Value</th>
<th>Average Marginal Effects (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short-acting methods</strong></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Injectable</td>
<td></td>
<td>56 (24.14)</td>
<td>76 (24.20)</td>
<td>.99</td>
<td>65 (30.23)</td>
<td>62 (24.31)</td>
<td>.15</td>
<td>-0.05 (-0.13, 0.04)</td>
<td>0.27</td>
<td></td>
</tr>
<tr>
<td>Male condom</td>
<td></td>
<td>19 (8.19)</td>
<td>29 (9.24)</td>
<td>.67</td>
<td>18 (8.37)</td>
<td>28 (10.98)</td>
<td>.34</td>
<td>0.03 (-0.0, 0.93)</td>
<td>.37</td>
<td></td>
</tr>
<tr>
<td>Pill</td>
<td></td>
<td>53 (22.84)</td>
<td>53 (16.88)</td>
<td>.08</td>
<td>33 (15.35)</td>
<td>60 (23.53)</td>
<td>.03</td>
<td>0.08 (0.00, 0.17)</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>Female condom</td>
<td>1 (0.43)</td>
<td>0 (0.00)</td>
<td>.24</td>
<td></td>
<td>0 (0.00)</td>
<td>1 (0.39)</td>
<td>.21</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Long-acting methods</strong></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Implant</td>
<td>9 (3.88)</td>
<td>17 (5.41)</td>
<td>.41</td>
<td></td>
<td>16 (7.44)</td>
<td>39 (15.29)</td>
<td>.01</td>
<td>0.09 (0.03, 0.16)</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td>Female sterilization</td>
<td>1 (0.43)</td>
<td>1 (0.32)</td>
<td>.83</td>
<td></td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>&gt;.99</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>&gt;.99</td>
<td></td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>&gt;.99</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>IUD</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>&gt;.99</td>
<td></td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>&gt;.99</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any long-acting or permanent method</td>
<td>10 (4.31)</td>
<td>18 (5.73)</td>
<td>.63</td>
<td></td>
<td>16 (7.44)</td>
<td>39 (15.29)</td>
<td>.01</td>
<td>0.10 (0.05, 0.16)</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td>Any modern method</td>
<td>123 (53.02)</td>
<td>159 (50.64)</td>
<td>.58</td>
<td></td>
<td>119 (55.35)</td>
<td>170 (66.67)</td>
<td>.01</td>
<td>0.13 (0.04, 0.22)</td>
<td>&lt;.01</td>
<td></td>
</tr>
<tr>
<td><strong>Traditional methods</strong></td>
<td></td>
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</tr>
<tr>
<td>Rhythm</td>
<td>4 (1.72)</td>
<td>4 (1.27)</td>
<td>.67</td>
<td></td>
<td>8 (3.72)</td>
<td>7 (2.75)</td>
<td>.55</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other traditional</td>
<td>4 (1.72)</td>
<td>0 (0.00)</td>
<td>.02</td>
<td></td>
<td>1 (0.47)</td>
<td>3 (1.18)</td>
<td>.40</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; IUD, intrauterine device.
Data reported as No. (%) except when otherwise noted.
a Estimations for some methods could not be calculated because of the small number of users in the sample.
Combining intensive group learning with provision of on-site health services increased use of contraception and HIV testing and counseling services among Liberian youth.

TABLE 4. HIV Knowledge, Attitudes, and Testing Behaviors Among Sampled Learners at Baseline (January–March 2014) and Endline (June–July 2014), Selected Counties of Liberia

<table>
<thead>
<tr>
<th></th>
<th>Baseline (N = 1,157)</th>
<th>Baseline (N = 1,157)</th>
<th>Control (n = 518)</th>
<th>Treatment (n = 639)</th>
<th>Control (n = 503)</th>
<th>Treatment (n = 549)</th>
<th>Average Marginal Effects (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you heard of HIV or AIDS?</td>
<td>510 (98.46)</td>
<td>510 (98.46)</td>
<td>498 (97.94)</td>
<td>547 (99.4)</td>
<td>503 (99.01)</td>
<td>549 (99.64)</td>
<td>0.000 (0.001, 0.02)</td>
</tr>
<tr>
<td>Do you know where to access HIV testing services?</td>
<td>429 (78.44)</td>
<td>429 (78.44)</td>
<td>397 (76.97)</td>
<td>494 (89.86)</td>
<td>397 (79.01)</td>
<td>494 (89.98)</td>
<td>0.000 (0.001, 0.02)</td>
</tr>
<tr>
<td>Have you ever been tested for HIV and received the result?</td>
<td>237 (42.75)</td>
<td>237 (42.75)</td>
<td>211 (41.59)</td>
<td>482 (87.80)</td>
<td>211 (41.59)</td>
<td>482 (87.80)</td>
<td>0.000 (0.001, 0.02)</td>
</tr>
<tr>
<td>Do you intend to get an HIV test within the next year?</td>
<td>474 (91.51)</td>
<td>474 (91.51)</td>
<td>457 (90.65)</td>
<td>560 (87.64)</td>
<td>457 (90.65)</td>
<td>560 (87.64)</td>
<td>0.000 (0.001, 0.02)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.
Data reported as No. (%) except when otherwise noted.
*P < 0.05; **P < 0.01.

DISCUSSION

We sought to assess the effectiveness of an intensive sexual and reproductive health intervention embedded in an alternative basic education program for Liberian out-of-school young adults. Combining intensive group learning with provision of on-site health services increased use of contraception and HTC in this setting. The HealthyActions group setting, educational components, and on-site access to services were designed, implemented and tested as a package; thus, we cannot tease out whether some components had greater impact than others nor whether some components could have been removed. We hypothesized that the components interacted with each other to achieve impact, but this could be formally tested in future research.

Increases in use of contraceptive implants observed among the HealthyActions sites are likely related to the program’s emphasis on providing information and counseling to young women about long-acting reversible contraceptive methods as well as improving access to the products themselves. Implants are generally used less frequently than other methods in Liberia: 11% of currently married women in Liberia use injectable contraception and 2% use implants, while 22% of sexually active unmarried women use injectables and 4% use implants. We suspect that contraceptive implants were less familiar to HealthyActions learners. Many young women likely did not have sufficient information about implants from other sources, so supportive information about the method, provided in the context of informed choice, and with ready access to services, was an attractive offer. Further, contraceptive stock-outs are often widespread in Liberia, limiting access to the full range of methods. Easy access to a long-acting method likely helped to motivate women to choose implants. We suspect that assurances that the commodities would be available increased women’s confidence in and willingness to use the services provided on clinic celebration day. Counseling on removal of implants was also provided.

Despite the substantial increase in use of implants, HealthyActions did not appear to have an impact on use of long-acting or permanent methods overall. Increase in the use of implants corresponded with a decline in use of injectables among HealthyActions participants, although the decline was not statistically significant. It was not possible in this study to measure method switching, but it is possible that the availability of
implants along with comprehensive information about all contraceptive methods contributed to a small substitution effect by which young women using injectables switched to implants. As implants provide a longer-term solution for women who want to avoid a pregnancy than do injectables, this finding is still consistent with program goals and the value of informed choice.

Continuation rates may ultimately improve among these women given that implants do not require resupply, which would also be a positive result of the study, although it is not possible to assess continuation with the data available. Longer-term follow-up would need to be conducted to assess whether continuation rates improved after HealthyActions, which was beyond the scope of this study.

The large proportion of HealthyActions learners who were tested for HIV is indicative of the existing barriers to accessing HTC in Liberia. The national average for HIV testing is 23% and 45% for men and women, respectively, whereas 88% of respondents in HealthyActions learning sites had been tested for HIV at endline and knew their results. The HealthyActions curriculum delivered factual information and sought to discredit myths and misconceptions about HIV in addition to supporting confidentiality of services. Due to the interconnectedness of many Liberian communities, protocols around confidentiality are not always respected. Many young Liberians don’t access health services, particularly those for HIV, for fear of being gossip about by staff and older patients. HealthyActions may have also succeeded in forging a connection between learners and their local clinics or hospitals. Despite Liberia’s low HIV prevalence, HealthyActions’ large effect on use of HIV testing and counseling services holds promise for replication in other settings with higher HIV prevalence.

Condom use was featured throughout the HealthyActions curriculum, including activities that highlighted (1) the dual protective benefits of condoms (to prevent HIV and other sexually transmitted infections [STIs] as well as unintended pregnancy); (2) how to negotiate condom use particularly by young women; and (3) condom demonstrations and practice with models. There are a few possible explanations to account for the changes in condom use with regular partners that we observed. Trends were suggestive of improvements in intermittent or consistent use of condoms with regular partners. The decline in reporting never using condoms with a regular partner was statistically significant, but increases in use were not. Respondents may have struggled with distinctions between regular and casual partners given that regular partners are often loosely defined in a Liberian context, and regular may not equate with monogamous. According to the 2013 Liberian Demographic and Health Survey, 7% of women reported 3.4 sexual partners in the past year, and 18% of men reported 8 partners. HealthyActions did not touch on potential risks of concurrent partnerships, but the program encouraged consistent condom use and supported development of skills in partner communication and condom negotiation. An intervention of longer duration may be needed to address condom use with Liberian young adults.

Further, additional research is needed to gain insight into sexual partner types and processes of partner formation in Liberia, including the influence of economic factors. Available evidence suggests that these processes are complex. We implemented HealthyActions within a specifically targeted environment of learning sites providing alternative basic education. The selection of this setting was deliberate in order to leverage a group setting that facilitated the formation of trusted peer networks. However, descriptive statistics of sampled learners were generally comparable to the rural Liberian population. HealthyActions’ approach may have broader applicability to other settings where young adults, particularly those outside the formal school system, gather in Liberia or in similar settings, such as women’s associations, farmer groups, or trade associations. However, some specific subgroups of out-of-school youth, such as male ex-combatants, may need different intervention strategies.

As implemented in this setting, HealthyActions was designed as a short, intensive intervention to test the approach. However, the implementation model could be readily adapted to increase its scalability. HealthyActions could be delivered over the course of several weeks—with one activity per week for instance—rather than in 5 consecutive days. The curriculum could also be delivered as one intensive burst, with follow-up “booster” sessions every few months to sustain the messages. Additional studies could be used to measure the effectiveness of the short-term, intensive “burst” of education versus a longer-term, lower dosage program. Linkage to service delivery could also be adapted. In this setting, linking motivations and skills built into the curriculum to use of readily accessible services was important to...
Intensive Group Learning and On-Site Services to Improve SRH

enhance participants’ and community members’ trust in the health system. In other settings, delivery of the curriculum could be timed to coincide with regularly scheduled mobile health units, or the curriculum could provide vouchers or referrals to static health clinics, in either the public or private sector. Again in this setting, clinic celebration days included provision of contraception and HTC services. Antenatal and/or postnatal care could potentially be added. The components of the program promote ready adaptation and investigation to determine what a “lighter touch” yet still effective implementation model might be.

Our findings contribute to filling a gap in evidence for how to reach the large population of out-of-school youth and young adults in sub-Saharan Africa, who are otherwise engaged in a group learning setting, with comprehensive SRH information and services. A market-based intervention in Nigeria found similar increases in contraceptive use, but no change in condom use among sexually active youth. 34 Community-based and structural interventions can contribute to attitudinal changes around sexual risk and partnership formation, and there is some evidence of reductions in risk of STIs. 35 However, these interventions have tended to focus on STIs/HIV, without necessarily combining access to contraceptive services. Youth-friendly services can successfully provide HTC but are challenged to retain youth in follow-up care, a limitation of HealthyActions as well. 36 However, we have not been able to locate programs that show comparable increases in levels of HIV testing uptake among African youth.

Limitations

This study had several limitations. Because HealthyActions was designed as a package that combined a “burst” of learning with rapid provision of services, we cannot assess the relative effects of the components. However, the learning component was designed to motivate use of services, and thus attempting to tease out effects attributable to each component may not have been appropriate. Further, we were not able to assess any potentially beneficial “spill-over” of HealthyActions in uptake of services by community members, since only Advancing Youth learners were sampled. We initially intended to recruit and follow a sample of learners in intervention and control sites over time to control for individual preferences. However, we determined that tracking individuals over time would not be feasible due to challenges in ensuring that unique identifiers would remain unique. We therefore recruited cross-sectional samples at baseline and endline, using the same sampling procedure to ensure comparability. It is possible that our design was under-powered, since initial sampling plans did not fully account for clustering of learning sites. However, substantial effect sizes and narrow confidence intervals, even accounting for clustering of standard errors during analysis, suggest that we did have sufficient statistical power.

Due to the rolling nature of data collection, intervention sites received differing recall periods following implementation of HealthyActions, which may have attenuated estimates. Recall of some outcomes, such as condom use, may have been subject to social desirability bias.

The timing of endline data collection coincided with harvest season, rainy season, and the timing of tribal bush schools. As data collection took place during the early evening hours, the onset of the harvest season meant that some learners were needed on the farms until after dark. This was problematic because some learners would not be able to attend class until much later than usual and missed the sampling process. In an effort to address this issue, a small number of sites were resampled after those working on the farms arrived. In many parts of rural Liberia, participation in tribal bush schools marks the transition from childhood to adulthood. Often, the young people participating in the bush schools will be away for weeks at a time; this happened to coincide with endline data collection at one site, and the site was therefore resampled.

Training health service providers in youth-friendly services was outside the scope of this project, and therefore we could not guarantee that the health services we brought on the community celebration day would be aligned with standards for youth-friendly health services. 37 PSI had since undertaken a training program for health care providers in the private sector in Monrovia to offer youth-friendly health services, particularly with adolescents and younger, unmarried youth in mind, and this program ran concurrently to the second round of HealthyActions. Funds were originally allocated for scale-up of youth-friendly health services; however, they were redirected to Ebola efforts. The County Health Leads did meet with the government health care providers before the program to prepare them for the community celebration day and confirm their participation.
and mitigate against the risk of unfriendliness during the intervention.

**CONCLUSION**

Despite a range of obstacles to progress for Liberia’s young people, the desire for opportunities for learning and growth is ever-present. *HealthyActions* brought together key components of established social ties, intensive learning, and convenient SRH services, presenting a new opportunity for many people in need. Based on our findings, this comprehensive package targeted to young adults appears to have produced substantial results; expanding access resulted in increased uptake of both modern contraceptives, particularly implants, and HIV counseling and testing.

The concentration of positive family planning results among youth under 19 and the success in increasing uptake of contraceptive implants suggests that the *HealthyActions* model is successfully affecting the portion of the target audience that is most difficult to reach and that stands to gain the most from using contraception. *HealthyActions* targets youth who are unlikely to be reached by traditional health outreach efforts, and holds promise to enact substantial behavior change over a short period of time. In a context where SRH knowledge and youth-friendly services are nearly nonexistent, getting the conversation started and making services available were the highest priorities of the program. Follow-on funding was sought and is considered to be crucial to institutionalizing the program and sustaining longer-term behavior change. In Liberia, this became challenging due to staff turnover and the need to respond to the Ebola epidemic. However, the program’s focus on sexual and reproductive health integration within an established learning environment, particularly among low-literacy populations, presents an adaptable solution for health programming across the country and the region.

_Acknowledgments:_ Support for *HealthyActions*, including this evaluation, was made possible by internal Population Services International (PSI) and Education Development Center (EDC) resources as well as by the generous support of the American people through the United States Agency for International Development, USAID/Liberia Cooperative Agreement No. 669-A-11-00001 to Education Development Center. Manuscript preparation was made possible under the terms of USAID Cooperative Agreement No. AID-OAA-A-10-00030 to Population Services International, Inc.; 2009. Co-published by Associates for Global Change. Available from: http://pdf.usaid.gov/pdf_docs/Pnadq258.pdf

Competing Interests: None declared.

**REFERENCES**


A Randomized Controlled Trial of a Trauma-Informed Support, Skills, and Psychoeducation Intervention for Survivors of Torture and Related Trauma in Kurdistan, Northern Iraq

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Providing survivors of torture, imprisonment, and/or military attacks with a counseling program that includes support, skills and psychoeducation by well-trained and supervised community mental health workers can result in moderate yet meaningful improvements in depression and dysfunction.

ABSTRACT
Supportive counseling type interventions are frequently provided to meet the mental health needs of populations in emergency and post-conflicts contexts, but it has seldom been rigorously evaluated. Existing evaluations from low- and middle-income countries provide mixed evidence of effectiveness. While Iraqi Kurdistan experienced relative stability following the fall of Saddam Hussein’s government, the population in the northern Dohuk region has continued to experience periodic violence due to conflicts with neighboring Turkey as well as more recent ISIS-associated violence. We evaluated the impact of a trauma-informed support, skills, and psychoeducation intervention provided by community mental health workers (CMHWs) on depressive symptoms and dysfunction (primary outcomes) as well as post-traumatic stress, traumatic grief, and anxiety symptoms (secondary outcomes). Between June 2009 and June 2010, 295 adults were screened; 209 (71%) met eligibility criteria (trauma exposure and a symptom severity score indicating significant distress and functional impairment, among others) and consented to participate. Of these, 159 were randomized to supportive counseling while 50 were randomized to a waitlist control condition. Comparing average symptom severity scores post-treatment among those in the intervention group with those in the waitlist control group, the supportive counseling program had statistically and clinically significant impacts on the primary outcomes of depression (Cohen’s d, 0.57; \( P = .02 \)) and dysfunction (Cohen’s d, 0.53; \( P = .03 \)) and significant but smaller impacts on anxiety. Although studies by the same research team of psychotherapeutic interventions in other parts of Kurdistan and in southern Iraq found larger effects, this study adds to the global research literature on mental health and psychosocial support and shows that a well-trained and supervised program of trauma-informed support, skills, and psychoeducation that emphasizes the therapeutic relationship can also be effective.

INTRODUCTION
Traumatic events, including torture, put people at increased risk for a range of mental health problems.1 Physical torture has been shown to be a robust predictor of mental distress in prisoners of war and other conflict-affected or displaced populations years, and even decades, after torture occurred.1–3 To address these problems, the most frequent type of mental health intervention provided in emergency or post-conflict contexts has been basic supportive counseling from trained community workers.4 This is consistent with the Guidelines on Mental Health and Psychosocial Support in Emergency Settings, from the Inter-Agency Standing Committee (IASC), which recommends that basic supportive counseling components be provided by community health workers to support psychosocial well-being.5
The content and activities provided in interventions labeled as basic counseling vary widely. Commonly used strategies for trauma-affected adult populations include problem solving, conflict resolution, psychoeducation (information provided to the participant about their condition), relaxation, and sharing of traumatic experiences, as well as teaching skills in coping, stress management, and basic communication. While the literature suggests that evidence-based treatments, such as Cognitive Behavioral Therapy, are effective for mental health problems in conflict and post-conflict settings (see, for example, Weiss et al. 2016), it is possible that some of the commonly seen depression and anxiety symptoms in such settings may be made more severe due to environmental stress, and these symptoms may be amenable to a more generally supportive counseling approach.

These types of basic supportive counseling programs, as opposed to more structured and manualized psychotherapies (i.e., therapies that follow a series of prescribed goals and techniques to ensure uniformity across therapists), have seldom been rigorously evaluated and existing evaluations from low- and middle-income countries provide mixed evidence of effectiveness for survivors of torture and related traumas. For example, a group problem-solving counseling program delivered in conflict-affected areas of Aceh, Indonesia, showed an effect on improving daily functioning in men and coping in both men and women, but showed no effect on depression or anxiety symptoms. In a study among torture survivors in Nepal, a multidisciplinary counseling program similarly improved functioning and decreased participants’ somatic symptoms, but did not reduce mental health symptoms. In a trial in Uganda, the vast majority of Sudanese refugees were found to still meet criteria for post-traumatic stress disorder (PTSD) following a 4-session supportive counseling program that included problem solving, conflict resolution, and psychoeducation components.

In contrast, in a treatment trial of former Palestinian political prisoners, participants in an individual counseling program that contained trauma-specific elements, such as desensitization, stress inoculation, coping skills, and emotion regulation, and that addressed broader social problems saw small but significantly greater improvements in traumatic stress symptoms than waitlist controls. Female survivors of conflict and associated sexual violence in Liberia participating in a supportive counseling program that included sharing of past traumatic experiences, conflict resolution, and stress management experienced small mean declines in trauma symptoms, while those enrolled in basic skill-building activities and waitlist controls experienced small mean increases in trauma symptoms over the study period.

The population in Iraqi Kurdistan has experienced significant trauma in the past several decades. In the late 1980s, the regime of then-Iraqi President Saddam Hussein conducted a violent campaign in Iraqi Kurdistan, known as the Anfal, that included genocide, chemical weapon attacks, and torture. Within Kurdistan’s northernmost governorate, Dohuk, hundreds of villages were razed leading up to and during the Anfal in the name of “Arabization.” While Kurdistan experienced relative stability following the fall of Saddam Hussein’s government, conflict between Kurdish groups and neighboring Turkey continued to produce periodic violence in the Dohuk border region. Recently, the brutal advance of ISIS (the Islamic State of Iraq and Syria) has made Dohuk a major site of refuge for displaced Iraqis and refugees.

Even prior to the current ISIS conflict, the population in the Dohuk region of Iraqi Kurdistan has had little access to community-based mental health services for trauma. As part of a larger study to evaluate mental health services for torture and trauma survivors throughout Iraqi Kurdistan, in 2010 we evaluated a counseling program that is based on psychotherapies that are designed for trauma-affected populations and includes specific skills and psychoeducation components to improve the participants’ symptoms of depression, anxiety and trauma, and dysfunction. The intervention was provided by community mental health workers (CMHWs) at Ministry of Health clinics in the Dohuk governorate of Kurdistan, Northern Iraq. The study aimed to assess the impact of the intervention on primary outcomes of depressive symptoms and dysfunction, and secondary outcomes of post-traumatic stress, traumatic grief, and anxiety symptoms. Based on a preliminary qualitative study conducted with a similar population, depressive symptoms were identified as the most important mental health problem affecting this population, with anxiety, traumatic stress, and traumatic grief as secondary outcomes. Heartland Alliance International (HAI), an international NGO based in the United States with offices and programs in Iraq, developed this intervention as part of a broader program of integrating...
mental health into the health care system in Iraqi Kurdistan.

INTERVENTION DESCRIPTION

Program Development
From 2005 to 2007, HAI implemented an integrated mental health program into the primary health care system in Iraqi Kurdistan, including a comprehensive mental health curriculum for the paraprofessional level, CMHWs. CMHWs were recruited through a joint selection process by the Department of Health in the Dohuk governorate, the Health Staff Association of Kurdistan (a non-governmental professional group of health staff), and staff of HAI including a study coauthor (AA). The main selection criteria were clinical staff from the local primary clinics who had time and expressed an interest in gaining skills in mental health and psychosocial support and had experience working in rural areas with people who had experienced torture and trauma. The goal was to identify 1 male and 1 female health staff to be trained as CMHWs, although the lack of female staff in the health centers in Dohuk meant that there were more male CMHWs. These staff, who would become the CMHWs, included pharmacists, nurses, and physician assistants, and were permanent employees of the Ministry of Health. None of the CMHWs had any formal mental health training prior to the HAI project.

At the time of the program, there were limited mental health services in the country and those that did exist were concentrated in the major urban areas, with a focus on medication treatment. The HAI program’s first step was establishing a CMHW role within the health centers and providing them with foundational knowledge to deliver care and support. At the time of the current study in 2009, HAI had trained approximately 50 CMHWs in Kurdistan region.

Training Curriculum
The basic skills curriculum was developed as a 2-week training program that emphasized a social work model of helping and support. It included information on mental health and illness and the skills necessary to provide psychosocial support to individuals, with a particular focus on depression, anxiety, and post-traumatic stress. The curriculum emphasized basic knowledge and skills of a helping professional including the therapeutic relationship, compassionate care, maintaining confidentiality, active listening, empathy, and problem solving, as well as core tasks such as medication management, providing psychoeducation, working in the community, and advocacy. In addition to practice evidence derived from working with survivors of torture in the United States, trauma theory and conceptual frameworks considered important for contexts with historical and ongoing political violence were integrated throughout the curriculum. This included a phase-based orientation to work with survivors of trauma that emphasized the importance of the therapeutic relationship and clinical principles of safety and stability when working with survivors of trauma.

The curriculum used a multisystem or person-in-environment approach to understanding problems resulting from violence and trauma exposure and a strengths-based orientation to working with clients. All HAI training included a train-the-trainer manual and a participant workbook. The basic training, together with a series of advanced trainings, in total took place over the course of 2 years and included 30 days (240 hours) of in-person training and monthly field supervision.

The curriculum development team consisted of U.S.-based adult learning experts and mental health technical staff as well as Iraqi program staff with diverse expertise in curriculum development, trauma-focused mental health practice and Iraqi culture and society. The project used an iterative, participatory action model for curriculum development, which took several months to complete and included (1) identifying learning needs in collaboration with Iraqi staff and CMHWs; (2) gathering information via interviews with Iraqi staff and CMHWs to map curriculum content; (3) drafting the curriculum; (4) testing the curriculum during pilot train-the-trainer sessions; (5) gathering post-pilot evaluative information to revise training materials; (6) implementing the revised training with CMHWs; and (7) ongoing evaluation and further refinement. This process resulted in locally informed training materials and allowed for ongoing quality improvement. U.S.-educated, licensed clinical social workers with expertise working cross-culturally and with torture survivor communities facilitated the train-the-trainer program, while the HAI program staff in Iraq, mainly physicians, facilitated the CMHW trainings.

Adaptation for the Trial
In preparation for this trial, the original basic skills curriculum was adapted into a...
time-limited trauma-informed support, skills, and psychoeducation intervention so that it could be compared with 2 other trauma-focused manualized interventions that were selected for study. This intervention was designed to include 6–12 sessions for each client depending on particular client needs and to include techniques and skills analogous to what is done at the beginning of phase-oriented treatment for trauma with significant emphasis on the importance of the therapeutic relationship.

This process of adaptation for the study was led by the HAI clinical director (BG), a clinical psychologist with extensive expertise in torture rehabilitation. Together with the Kurdish study psychiatrist in Dohuk (TM), who acted as the clinical supervisor throughout the study, they conducted a refresher training for the 11 CMHWs who were part of the evaluation study in the Dohuk region. This training presented a much-shortened version of the original HAI program that was specific to survivors of torture and imprisonment. CMHWs were presented with an array of 9 techniques to use in counseling clients; for each technique, the CMHWs were taught 4 to 6 activities (Table 1). These activities were to be used according to the individual needs of each client. The refresher training also emphasized core clinical skills of empathic reflection, building trust, emotional expression and regulation, and the conveying of hope and meaning.

CMHWs were trained to organize interactions with clients into (1) a preparatory first session that set the stage for the development of a trusting relationship and engaged the client in the work; (2) a series of 4 to 10 “response” sessions in which difficulties related to the principal concerns of PTSD, depression, anxiety, traumatic grief, and impaired functioning were assessed and strategies were taught to address them; and (3) a concluding session that focused on exploring progress made in treatment, consolidation of work and skills learned, and planning for the future. The counseling process was expected to require 6–12 sessions depending on the presenting problems and progress of the client. For counseling to be considered completed, 3 criteria must have been met:

- The participant attended at least 6 sessions.
- The participant expressed no longer feeling the need to attend counseling.
- The CMHW agreed the participant no longer required counseling as evaluated by a review of whether the participant was no longer experiencing many symptoms.

Standards of professional practice were incorporated into the original training as well as into the refresher training prior to trial initiation. These included the need for completing accurate treatment monitoring records, having regular supervision meetings, adherence to ethical standards (e.g., do no harm, maintain professional relations and boundaries), and reporting problems to the supervisor. The CMHWs were advised to monitor their own feelings in the counseling process, follow effective self-care strategies, make use of professional consultation and other support, and maintain a working balance between their clinical experience and their personal lives. These advisements were made to try to avoid CMHWs developing secondary trauma, becoming overly involved in or distanced from the client’s torture experience (enmeshment or detachment), or otherwise burning out.

Supervision and Monitoring
Fidelity to the treatment model was promoted by monthly on-site group supervision by a psychiatrist (TM) as well as weekly check-ins via mobile phone. If CMHWs had questions during the week, they could contact TM directly via phone. To monitor adherence to the counseling protocol during the on-site meetings, TM reviewed clinical notes, which included how the CMHW responded to the client’s needs and checklists of the different activities the CMHW could have provided. The client monitoring form also included a brief checklist of common mental health symptoms that was used to review client progress and help the CMHW and supervisor decide, together with the client, when treatment would be completed.

METHODS
The study sample from Dohuk governorate was originally planned to be part of a larger trial evaluating 3 different mental health interventions (including the one described in this article) across 3 different regions of Kurdistan, Iraq. The study sample size was calculated for all 3 intervention groups and control participants combined. However, prior to initiating the trials, it became clear that there were substantial...
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<tr>
<th>Techniques</th>
<th>Activities</th>
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<tr>
<td>Psychoeducation</td>
<td>Give clients, families, or communities information on psychological problems. Reduce stigma about problems and treatment. Teach how thoughts, behaviors, and feelings can influence each other positively. Explain how talk therapy can help.</td>
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<tr>
<td>Treatment planning</td>
<td>Make arrangements with the client to begin treatment (e.g., confidentiality). Agree on how to continue treatment (e.g., weekly sessions, involving family if needed). Explain the way treatment will end. Describe follow-up assistance if needed after sessions end.</td>
</tr>
<tr>
<td>Empowerment</td>
<td>Help clients develop skills and use positive actions and attitudes. Start with small changes and help them focus on better parts of life, not only problems. Grow from a view of themselves as dependent to better able to care for themselves. Reduce feelings of helplessness by being more active and involved with family and community.</td>
</tr>
<tr>
<td>Motivation</td>
<td>Encourage clients to come to treatment regularly and make recommended changes in their behavior and thinking. Normalize their problems. Emphasize the progress they are making. Use the treatment relationship for emotional support with empathic listening and reflective techniques.</td>
</tr>
<tr>
<td>Crisis management</td>
<td>Assess for suicide or self-injury. Use safety plan if needed. Be more directive if needed. Involve family or other resources if needed. Get more consultation and supervision if needed. Change the balance between strengths and supports vs. stresses to manage the crisis.</td>
</tr>
<tr>
<td>Medication management</td>
<td>Explain how drug therapy can combine with talk therapy to help reduce negative feelings and improve sleep and other problems. Advise against the use of alcohol or illegal drugs, which can worsen problems. Consult with the physician about a combined therapy plan. Monitor for side effects and encourage daily use for later improvement.</td>
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<tr>
<td>Strength building</td>
<td>Identify the skills clients already have. Remind them how they have solved problems before. Find new ways to feel better, like talking about what is inside. Express concern for the negative parts of the client’s life but focus more on the positive (e.g., love of God or their children). Emphasize client’s ways of taking care of themselves (e.g., time with friends).</td>
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population-based differences across the regions, with the population in the Dohuk governorate speaking a different Kurdish dialect, tending toward greater religiosity and political conservativeness, and experiencing different types of trauma exposure given proximity to the Turkish border compared with the other study governorates. We thus made the decision to separate the trials into one trial focusing on 2 of the interventions in the Erbil and Sulaimaniyah governorates and one trial in Dohuk concentrating only on the supportive counseling program.

**Study Design**

This randomized controlled trial was conducted through the primary health clinics staffed by the study CMHWs. Potential trial participants were identified through referral by doctors in the clinics and by referrals from former prisoner organizations. All adults (ages 18 or older) referred to the CMHWs were administered the study instrument as part of the standard intake process for the HAI mental health services. This screening interview also served as the baseline assessment for eligible participants. Trial eligibility criteria comprised:

- Being 18 years or older
- Residing in the Dohuk governorate
- Reporting experiences of torture
- Presenting with significant depressive symptoms
- Not being currently psychotic or actively suicidal
- Being mentally competent to give consent

Experiencing torture was defined as personally experiencing or witnessing physical torture, imprisonment, and/or military attacks. Significant depression was defined as reporting a total score of at least 20 on the 20-symptom, adapted Hopkins Symptom Checklist (HSCL) depression scale and meeting both of the following specific criteria necessary for a DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, 4th edition) diagnosis of a major depressive episode: crying or feeling depressed most or all of the time in the last 2 weeks, and loss of interest in sex or loss of interest in things generally (as evidenced by being unable to enjoy festivals and celebrations most or all of the time) in the last 2 weeks.

If eligible, CMHWs read the study consent form that explained if a person agreed to participate they would be randomly assigned to receive the counseling service beginning immediately or to wait approximately 3 to 5 months before receiving treatment. Persons who did not meet criteria or refused to be in the study were still able to receive services provided by the CMHW but were not included in the trial. Supervisors reviewed all completed assessments and contacted all eligible

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### Table 1 (continued).

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<th>Techniques</th>
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<tr>
<td>Stress reduction</td>
<td>Assess and encourage client's interests in positive activities (e.g., praying, exercising). Teach relaxation techniques like deep breathing and focusing inside. Practice relaxation regularly in counseling and have clients use it at home daily. Help clients use relaxation techniques any time they are upset, worried, or cannot sleep.</td>
</tr>
<tr>
<td>Advocacy</td>
<td>Identify resources in the family or community that can be used for additional client support. Help the client get additional needed services (e.g., medical or legal assistance). Promote human rights with equal protection, respect, and benefits for everyone. Try to end domestic abuse or child abuse and gender-based violence. Connect with other government offices, community programs, and NGOs to increase public awareness about mental health problems and find solutions.</td>
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**Abbreviations:** CMHW, community mental health worker; HAI, Heartland Alliance International.
clients who declined to join the study to confirm their refusal to participate.

Random allocation of participants to intervention or waitlist control was done at the participant level. Study CMHWs were provided with a set of prenumbered consent forms with the designation of intervention or waitlist control status on a piece of paper that was folded and stapled to the back. ID numbers were randomly allocated to study condition by study author (JB) using Stata’s randomization function with a ratio of 3 intervention participants to 1 waitlist control participant, based on the original study design that included all of Kurdistan.

The study was approved by the Johns Hopkins Bloomberg School of Public Health Internal Review Board and by the Ethical Committee of the College of Medicine at the University of Sulaimani in Kurdistan, Northern Iraq.

**Mental Health and Functioning Assessments**

A mental health assessment instrument was developed based on initial qualitative data collected in 2008 in the Suleimaniyah governorate of Kurdistan with women and men who had been subjected to torture and/or prison during Saddam Hussein’s regime. Symptoms of mental distress described by study respondents included feeling sad and depressed, ruminating on the past, loneliness, being withdrawn, fear, anger, anxiety, insomnia, remembering past traumatic events, and avoiding reminders of the past. Based on these results, we selected the following mental health measures to be adapted for the trial:

- The Hopkins Symptom Checklist-25 (HSCL-25) for symptoms of depression and anxiety
- The Harvard Trauma Questionnaire (HTQ) for symptoms of post-traumatic stress
- The Inventory of Traumatic Grief for symptoms of traumatic grief

We adapted and validated these instruments for the local context using methods described elsewhere. The adaptation process included adding 22 locally relevant symptoms identified during the previous qualitative study, including 19 that described features of depression, anxiety, trauma, or traumatic grief but were not already represented on these measures. Of these items, 5 were added to the depression measure, 7 to the post-traumatic stress measure, 1 to the traumatic grief measure, and 3 to the assessment but not a particular symptom scale. In total, we included 70 items in the full mental health instrument (see Bolton et al., 2014 for a list of all mental health symptom items). For all items, participants rated how frequently they experienced each symptom in the prior 2 weeks using an ordinal scale of 0 (never) to 3 (always).

Functionality was defined based on a series of tasks and activities, identified during a prior qualitative study, regularly done by adults in Dohuk to take care of themselves and their families, and to participate in their community. We developed separate measures for men and women. Respondents were asked to report how much difficulty they had completing each task and activity. Dysfunction for each activity was rated on a Likert scale ranging from 0 (no more difficulty than most other men/women of the same age) to 4 (frequently unable).

We conducted a brief validation study of the mental health and measure of dysfunction, which is described elsewhere in detail. Briefly, Cronbach’s alpha scores for mental health and dysfunction scales ranged from 0.73 to 0.93, indicating adequate to good internal reliability. Pearson correlation coefficients for combined inter-rater/test-retest reliability (repeat by different interviewer) ranged between 0.73 and 0.86. Intraclass correlation coefficients (ICC) similarly ranged from 0.80 to 0.87.

We compared mean scores for the mental health measures between individuals identified as having each syndrome with those identified as not having the syndromes to evaluate whether our measures could adequately discriminate between them. Discriminant validity was identified for all mental health syndromes in men but only for PTSD in women. Because of the generally good performance of the symptom and dysfunction scales on other tests of validity and reliability for both sexes, we suspected that the poor validity among women was due to testing methods in which we relied on husbands to report the existence of problems among their wives, which may have resulted in misidentification due to husbands being less skilled at assessing the occurrence of these problems among their wives. We therefore concluded that the symptom measures were likely adequate for use among both men and women in this population.

**Waitlist Control Condition**

CMHWs contacted waitlist control participants monthly, usually by telephone, for a brief check if they were experiencing substantially greater distress.
or had become a danger to themselves or others. Control participants were also instructed to contact the CMWHs at any time during the study if their symptoms worsened for assessment and referral if necessary, including transportation to a psychiatrist or the Trauma Rehabilitation and Training Center in Suleimaniyah.

**Post-Intervention Assessment**

We aimed to readminister the study instrument within 1 month of completing counseling for the intervention participants and the equivalent (between 3 to 5 months after baseline) for the waitlist controls. The majority (82%, \( n = 154 \)) of the follow-up interviews were implemented by CMHWs who were blinded to the participant’s treatment status, whereas 18% (\( n = 34 \)) were implemented by CMHWs or study supervisors who were unblinded. This latter group included persons who dropped out of the trial but were subsequently located by a member of the research team who confirmed that they did not want to continue or be seen again. Rather than risk losing them to follow-up, the research supervisors and staff (instead of CMHWs) did these follow-up interviews despite the lack of blinding. Analyses were done with and without the 34 participants who were assessed unblinded to evaluate the impact of the unblinded subjects.

Trial recruitment ran from June 2009 through June 2010. Due to logistic challenges and difficulty keeping track of study participants (i.e., many often turned off their phones or left the area for work), the average time between baseline and follow-up assessments was 6.4 months for waitlist control participants (range, 3.1 to 10.7) and 5.9 months for intervention participants (range, 2.8 to 13.1). Although this difference was not statistically significant we did control for length of time between assessments in the analyses.

**Sample Size**

We calculated the sample size required to detect a 20% greater reduction in depression symptom scores among intervention participants compared with controls, with 80% power and an alpha of 0.05. The choice of 20% represents our estimate of a likely meaningful change. This yielded a sample size of 85 per arm. Estimating a dropout rate of 25%, we increased the recruitment target to 106 in each arm. The 106 participants in the waitlist control condition were to be spread across the 3 intervention programs (i.e., about 26 per treatment program) in the original study design, but because of the decision to evaluate the Dohuk study separately from the other 2 interventions, we continued to enroll participants using the same allocation ratio until our control group reached 50 participants to increase our statistical power. A post-hoc power analysis comparing mean outcomes at follow-up with unequal sample sizes at alpha of 0.05 resulted in 52% power for the depression symptoms outcome and 88% for the dysfunction outcome.

**Statistical Analysis**

For each study participant, average baseline and follow-up syndrome-specific and dysfunction scale scores were generated. Our main intent-to-treat analyses used multilevel models with a robust variance estimator and 2 random effects: participant and CMHW. Assessment of treatment effects was based on comparing differences by study arm in the change in average syndrome-specific and dysfunction scale scores from baseline to follow-up (interaction of 2 fixed effects: study arm and time). We controlled for age, sex, marital status (currently married vs. not married), and employment status (any current work vs. not working) based on theory and literature indicating these factors may be potential confounders. We also included variables that differed between treatment and control at baseline or predicted change in outcome as covariates: number of children, disability (yes or no), and length of time between assessments.

Multiple imputation by chained equations was used to account for item-level missingness in scales for any participant as well as missing post-assessment scale scores, employment status, disability status, and length between assessments for those lost to follow-up. Marital status, years of education completed, and number of children were carried forward for those lost to follow-up. Multiple imputation was also used to estimate missing scale scores for 2 participants whose baseline questionnaires were lost. For these 2 participants, demographic information was carried back from follow-up. All analyses were conducted using Stata version 12.0.

**RESULTS**

**Participant Flow Including Losses and Exclusions**

A total of 295 adults living in the Dohuk governorate seeking services from a study CMHW were screened for eligibility. CMHWs found
82 participants to be ineligible, and 4 others refused participation (Figure). A total of 209 men and women were randomized to either the intervention (n=159) or a waitlist control condition (n=50). Of the 159 allocated to the counseling intervention, 5 never initiated counseling. Of these 5, 3 dropped out of the trial stating they desired financial assistance, 1 was assigned to a CMHW who quit due to increased administrative responsibilities in the hospital, and 1 failed to initiate counseling for an unknown reason but remained under follow-up.

During the course of the trial, 7 (14.0%) individuals were lost to follow-up in the control arm, and 10 (6.3%) individuals who initiated therapy were lost to follow-up in the intervention arm. In total, 188 individuals completed follow-up (90.0%). Individuals lost to follow-up were significantly more likely to be female \( (P= .04) \), self-employed \( (P= .07) \), and unmarried \( (P= .04) \).

### Treatment Completion and Content

Among those who initiated treatment \( (n=154) \), the rate of completion was 95.5% \( (n=147) \). (Some participants completed treatment by definition but did not complete a follow-up assessment.) The mean number of sessions attended was 11.29 (range, 7 to 12) among completers and 1.86 (range, 0 to 3) among non-completers who initiated treatment. Neither treatment completion nor mean number of sessions attended differed significantly by participant sex. Among those who initiated treatment, a higher average baseline depression scale score \( (P= .04) \) and higher average baseline post-traumatic stress symptoms \( (P= .03) \) were both related to treatment completion. There was also variation across CMHWs in treatment completion among their clients \( (P= .01) \); however, all but 3 CMHWs had greater than 90% completion rates among their clients who initiated treatment.

Based on CMHW monitoring forms and supervisory reports, the activities most commonly used by CMHWs included relaxation and psychoeducation on mental health symptoms, treatment, and prognosis. If a client was comfortable with their family having knowledge of their problems, CMHWs visited their families to provide psychoeducation. In 5 instances, CMHWs helped clients find employment. The study intervention emphasized the importance of social support, and CMHWs commonly encouraged clients to engage in social activities (e.g., going to coffee, shopping, or on a picnic) and even accompanied them in some cases.

### Baseline Characteristics

Table 2 presents the demographic characteristics of the supportive counseling and waitlist control participants. The average study sample age was 40 years and ranged from 18 to 82. About a third of the sample was female, and about 20% self-reported disability. The majority of the sample was married, approximately half reported being unemployed, and more than 40% reported no education. Demographic characteristics of the participants across the 2 arms were comparable with no differences reaching statistical significance.

### Trial Effects

Estimates of treatment effects across the primary outcomes of depression and dysfunction are presented in Table 3. The intervention had a statistically significant and moderate-sized effect on depression symptoms (Cohen’s d, 0.57; \( P= .02 \)) and dysfunction (Cohen’s d, 0.53; \( P= .03 \)). Although the intervention also appeared to decrease symptoms of the secondary outcomes (post-traumatic stress, traumatic grief, and anxiety), these effects were small. Of the secondary outcomes, the effect was statistically significant for anxiety (Cohen’s d, 0.41; \( P= .01 \)) and marginally significant for post-traumatic stress (Cohen’s d, 0.35; \( P= .07 \)) and traumatic grief (Cohen’s d, 0.26; \( P= .08 \)).

Analyses conducted removing the 34 participants who were assessed unblinded to their treatment status resulted in smaller effect sizes across outcomes (-0.04 to -0.05 difference in Cohen’s d) but did not meaningfully change results. Analyses conducted removing the 34 participants who were assessed unblinded to their treatment status resulted in smaller effect sizes for depression (Cohen’s d, 0.45; \( P= .12 \)), dysfunction (Cohen’s d, 0.47; \( P= .08 \)), and anxiety (Cohen’s d, 0.36; \( P= .06 \)) and larger effect sizes for trauma (Cohen’s d, 0.43; \( P= .11 \)) and traumatic grief (Cohen’s d, 0.28; \( P= .11 \)).

### DISCUSSION

We assessed the impact of a trauma-informed support, skills, and psychoeducation intervention on depression symptoms and dysfunction scores among survivors of torture and related traumatic experiences living in the Dohuk governorate of Kurdistan. We found moderate effect sizes for the
study intervention on the primary outcomes, which is consistent with the 16 studies of mental health treatments for survivors of torture and trauma that reported effect sizes included in the review by McFarlane and Kaplan. Treatment effects on the secondary outcomes of post-traumatic stress, anxiety, and traumatic grief were smaller, with the study intervention having the greatest impact on anxiety and the smallest impact on traumatic grief.

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These findings are consistent with what we would expect to see from a trauma-informed approach that emphasizes building a sense of internal safety and regulation by coping with and managing reactions to symptoms. In a progressive treatment model, this type of work is characterized as setting the stage for later, more in-depth narrative work that focuses on addressing underlying trauma experiences and associated PTSD symptoms, which the HAI intervention did not include.8,29,30

Similar to other randomized controlled trials of psychological interventions in low- and middle-income countries,7,8,26 we observed average symptom improvement among the control sample. Study eligibility was based in part on having severe enough symptoms to warrant a mental health intervention. Given that mental health symptoms and accompanying dysfunction can vary over time, average improvement over time may be due to regression to a population mean. Improvement may also be a result of participants experiencing some relief in symptoms because an interviewer is taking the time to ask them about their problems. It is also possible that control participants accessed other supportive services in the community unrelated to the clinical services offered. Regardless, a study without a control sample would have likely overestimated the intervention effectiveness.

Given the nature of the intervention and the context of historical and ongoing trauma exposure, the reductions in depression symptoms and improvements in functioning seem particularly notable. While depression manifests in culturally distinct ways, a core feature typically includes negative beliefs about oneself and one’s life. It seems plausible that building skills in symptom identification, stress reduction, and emotion

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**TABLE 2.** Baseline Characteristics of Intent-to-Treat Sample, Dohuk Governorate, Kurdistan, June 2009–June 2010 (N = 207)

<table>
<thead>
<tr>
<th></th>
<th>Counseling Intervention (n = 157)a</th>
<th>Waitlist Control (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>40.30 (15.3)</td>
<td>40.76 (12.82)</td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>54 (34%)</td>
<td>15 (30%)</td>
</tr>
<tr>
<td>No. of children, mean (SD)</td>
<td>4.80 (4.09)</td>
<td>4.86 (3.91)</td>
</tr>
<tr>
<td>Disabled, No. (%)</td>
<td>32 (20%)</td>
<td>9 (18%)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married, No. (%)</td>
<td>116 (74%)</td>
<td>43 (86%)</td>
</tr>
<tr>
<td>Single/divorced/widowed, No. (%)</td>
<td>41 (26%)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not working, No. (%)</td>
<td>87 (55%)</td>
<td>26 (52%)</td>
</tr>
<tr>
<td>Regular work, No. (%)</td>
<td>27 (17%)</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>Self-employed, No. (%)</td>
<td>23 (15%)</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>Irregular work, No. (%)</td>
<td>20 (13%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None, No. (%)</td>
<td>68 (43%)</td>
<td>24 (48%)</td>
</tr>
<tr>
<td>Primary, No. (%)</td>
<td>53 (34%)</td>
<td>14 (28%)</td>
</tr>
<tr>
<td>Secondary, No. (%)</td>
<td>29 (18%)</td>
<td>11 (22%)</td>
</tr>
<tr>
<td>Bachelors/institutional degree or certificate, No. (%)</td>
<td>7 (4%)</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

Abbreviation: SD, standard deviation.

a 159 were allocated to the counseling intervention, but 2 participants’ paperwork at baseline was lost.
regulation resulted in a greater sense of self-efficacy for participants and reductions in depression symptoms. The HAI intervention also emphasized the centrality of the therapeutic alliance in trauma-informed work, one that is characterized by compassion, positive regard, and fostering a sense of hope. Although not specific to the Iraqi context, a strong client-provider relationship is emphasized as a core therapeutic factor across many different treatment approaches and has been found to be an important element in predicting positive client outcomes. While there is good conceptual rationale for these ideas, future studies looking at these particular intervention

<table>
<thead>
<tr>
<th>TABLE 3. Adjusted Treatment Effects on Primary and Secondary Study Outcomes, a Dohuk Governorate, Kurdistan, June 2009–June 2010 (N = 209)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Counseling Intervention (n = 159)</strong></td>
</tr>
<tr>
<td><strong>Score (95% CI)</strong></td>
</tr>
<tr>
<td><strong>Primary Outcomes</strong></td>
</tr>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>Baseline</td>
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<tr>
<td>Follow-up</td>
</tr>
<tr>
<td>Pre-post change</td>
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<tr>
<td>Functional impairment</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Follow-up</td>
</tr>
<tr>
<td>Pre-post change</td>
</tr>
<tr>
<td><strong>Secondary Outcomes</strong></td>
</tr>
<tr>
<td>Post-traumatic stress</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Follow-up</td>
</tr>
<tr>
<td>Pre-post change</td>
</tr>
<tr>
<td>Anxiety</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Follow-up</td>
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<tr>
<td>Pre-post change</td>
</tr>
<tr>
<td>Traumatic grief</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Follow-up</td>
</tr>
<tr>
<td>Pre-post change</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval. a Model-estimated differences after adjusting for age, sex, employment status, time between assessments, number of children, and marital status in all models. All models include multiple imputation by chained equations for missing data and for missing outcomes due to loss to follow-up. Robust standard error estimators are used to account for clustering by counselor. b Measured using Cohen's d statistic and pooled baseline variances.
A strong client-provider relationship has been found to be an important element in predicting positive client outcomes.

Elements—self-efficacy, therapeutic alliance—and client outcomes are needed to test these hypotheses.

The results of this study are particularly relevant as many organizations working in humanitarian contexts are moving forward with the development and implementation of what are commonly referred to as “low-intensity interventions,” i.e., interventions delivered and/or supported by community-based providers without formal mental health training and provided with limited support by formal health care institutions. These interventions fit within the larger WHO model for global mental health services—i.e., the Mental Health Gap Action Programme (mGAP).36 Like the HAI intervention evaluated in this study, these low-intensity interventions tend to base on the techniques used in cognitive behavioral therapy (CBT) that support relieving distress and improving daily functioning.37 For example, the World Health Organization (WHO) has developed such an intervention, Problem Management Plus (PM+), that, similar to the HAI program, is aimed at treating a wide range of presentations of distress. The PM+ intervention integrates problem-solving and behavioral techniques in a program that can be implemented by community providers with ongoing supervision.38 Ongoing trials of these low-intensity supportive counseling programs will be important to understand their effectiveness in reducing the burden of mental health problems among trauma-affected populations.

Our choice to use depression symptoms as criteria for entry into this trial was based on our previous qualitative study that found that depression-like symptoms were described most frequently in discussions of mental distress with survivors of torture in Kurdistan.39 This is in contrast to other mental health intervention studies for torture survivors that have generally included only those suffering from PTSD-related symptoms.35 The choice to use depression symptoms for screening was to identify those survivors who expressed a high degree of distress with respect to a group of symptoms that were clearly important locally (depression).

While depression symptoms were the main entry criteria, the study intervention was originally designed to assist survivors with a wide range of mental and psychosocial issues. Therefore, our finding of small to moderate effects across multiple mental health outcomes suggests that the intervention produced a wide-ranging, although limited, effect on these specific outcomes. The moderate reduction in dysfunction may reflect the cumulative impact of reduction in the symptoms we measured as well as impacts on other problems that we did not assess. The moderate impacts, while significant, do not approach the effect sizes seen when evidence-based psychotherapy interventions have been implemented for the same outcomes with similar populations in Iraq.2,32 suggesting that for organizations that want to specifically target common mental disorders, evidence-based treatment can have more impact for similar levels of training and supervision resources.

Limitations
Several limitations must be acknowledged. As part of the informed consent process, the waitlist control group was informed that they would be offered treatment regardless of their scores on the follow-up interview to reduce the possibility that they might try to report severe symptoms. It is still possible, however, that controls may have seen an incentive to report more distress at follow-up than intervention participants. In addition, as controls did not meet with CMHWs routinely, we are uncertain as to how much of the intervention’s impact was due to counseling content as opposed to the act of meeting weekly with CMHWs. We also did not explore the cultural understanding of what counseling might mean in this community and how the experience of counseling may differ based on participant sex or other cultural factors. Another limitation is that the participants were chosen on the basis of significant levels of depressive symptoms. The HAI program was originally designed to be a referral program for clients with a wider range of presenting problems, so the results may not represent the typical target population for this program. Our use of unblinded assessors for approximately 15% of the post-intervention assessments resulted in our interviewing a larger proportion of the study participants but did introduce some bias into our findings; while the general conclusions were not affected, the significance of the findings were somewhat affected. However, it is not clear if the variation in significance was due to unblinding or due to the change in sample size when the unblinded sample was excluded. Finally, we also are unable to assess if the effects seen following counseling were sustained, due to a lack of long-term follow-up.

Conclusion
The study intervention was developed as a trauma-informed treatment approach that could...
be provided by CMHWs for torture and trauma survivors living in rural areas of Northern Iraq. This intervention was well defined, based on extensive practice experience with torture survivors and trauma-affected communities, and the CMHWs were provided with training on the content of the program as well as when and how to implement the different activities and therapeutic skills. The intervention was adapted by a clinician with experience providing trauma-focused care and the CMHWs received regular clinical supervision from a local psychiatrist. The results suggest that this type of well-supervised, trauma-informed intervention can provide moderate improvement for depression and anxiety symptoms and functional impairments in torture- and trauma-affected communities. The current WHO model—Mental Health Gap Action Programme (mhGAP)—requires that moderate to severe cases of mental health problems be treated via referral to specialist services. Under such a model, supportive services that have a moderate effect and are widely accessible at the community level, such as the one studied here, can play an important role as the first line of treatment for less severe cases. However, it is not clear at this time how good access to specialist services in low- and middle-income countries is to be achieved, leaving community-level services as the only accessible option. Service providers will need to decide whether this type of supportive intervention is sufficient for communities with a high burden of moderate to severe cases of common mental disorders, or whether more effective community-based interventions will also be needed.

Acknowledgments: This study was solely funded by the USAID Victims of Torture Fund (VOT) under grant #101978. USAID/VOT was not involved in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript. We particularly thank USAID/VOT for their commitment to evidence-based programming as the basis for effective services. Dr. Murray was supported in part by an NIMH Training grant for Global Mental Health [T32MH103210]. We also wish to thank Heartland Alliance, the Kurdistan Ministry of Health, and the Dohuk Mental Health Center for their essential role in the training and implementation of the intervention.

Competing Interests: None declared.

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Peer Reviewed

Received: 2016 Jan 28; Accepted: 2016 May 27; First Published Online: 2016 Sep 8

Progress in Harmonizing Tiered HIV Laboratory Systems: Challenges and Opportunities in 8 African Countries

Jason Williams, a Farouk Umaru, b Dianna Edgil, c Joel Kuritsky c

Countries have had mixed results in adhering to laboratory instrument procurement lists, with some limiting instrument brand expansion and others experiencing substantial growth in instrument counts and brand diversity. Important challenges to advancing laboratory harmonization strategies include:

1. Lack of adherence to procurement policies
2. Lack of an effective coordinating body
3. Misalignment of laboratory policies, treatment guidelines, and minimum service packages

ABSTRACT

In 2014, the Joint United Nations Programme on HIV/AIDS released its 90-90-90 targets, which make laboratory diagnostics a cornerstone for measuring efforts toward the epidemic control of HIV. A data-driven laboratory harmonization and standardization approach is one way to create efficiencies and ensure optimal laboratory procurements. Following the 2008 “Maputo Declaration on Strengthening of Laboratory Systems”—a call for government leadership in harmonizing tiered laboratory networks and standardizing testing services—several national ministries of health requested that the United States Government and in-country partners help implement the recommendations by facilitating laboratory harmonization and standardization workshops, with a primary focus on improving HIV laboratory service delivery. Between 2007 and 2015, harmonization and standardization workshops were held in 8 African countries. This article reviews progress in the harmonization of laboratory systems in these 8 countries. We examined agreed-upon instrument lists established at the workshops and compared them against instrument data from laboratory quantification exercises over time. We used this measure as an indicator of adherence to national procurement policies. We found high levels of diversity across laboratories’ diagnostic instruments, equipment, and services. This diversity contributes to different levels of compliance with expected service delivery standards. We believe the following challenges to be the most important to address: (1) lack of adherence to procurement policies, (2) absence or limited influence of a coordinating body to fully implement harmonization proposals, and (3) misalignment of laboratory policies with minimum packages of care and with national HIV care and treatment guidelines. Overall, the effort to implement the recommendations from the Maputo Declaration has had mixed success and is a work in progress. Program managers should continue efforts to advance the principles outlined in the Maputo Declaration. Quantification exercises are an important method of identifying instrument diversity, and provide an opportunity to measure efforts toward standardization.

INTRODUCTION

In 2014, the Joint United Nations Programme on HIV/AIDS (UNAIDS) released targets of testing 90% of people living with HIV/AIDS, placing 90% of those with HIV/AIDS on antiretroviral therapy, and ensuring that 90% of those on antiretroviral therapy are virally suppressed. These 90-90-90 targets made laboratory diagnostics a cornerstone for national efforts toward the epidemic control of HIV. A data-driven laboratory harmonization and standardization approach is one way to create efficiencies and ensure optimal laboratory procurements.

In 2008, a consensus meeting on clinical laboratory testing, harmonization, and standardization was held in Maputo, Mozambique. Representatives of governments,
multilateral agencies, development partners, professional associations, and academic institutions sought to address overarching laboratory challenges that had limited the scale-up of services for tuberculosis, malaria, and HIV diagnosis and care. The meeting was organized by the World Health Organization | Regional Office for Africa (WHO-AFRO) and the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), with the support of the World Bank, The Global Fund to Fight AIDS, Tuberculosis and Malaria, the Bill & Melinda Gates Foundation, the Clinton Health Access Initiative (CHAI), and the Partnership for Supply Chain Management (PFSCM). The outcome of this meeting was the “Maputo Declaration on Strengthening of Laboratory Systems”: a call to governments to take leadership in harmonizing tiered laboratory networks and standardizing testing services.

Those attending the meeting—120 experts and policy makers from 33 countries, including representatives from 28 sub-Saharan African countries—were invited to reach a consensus on technical and operational guidance for strategic planning for responsive laboratory development. Participants recognized a need to address the challenges limiting the uptake of diagnostic services in resource-limited settings. These challenges included lack of or insufficient leadership and advocacy, human resources, national laboratory policies, strategic and financial planning, physical infrastructure, supply chain management, and quality management systems.

To address these issues, participants recommended that countries adopt a tiered laboratory system strategy within a harmonized network. A tiered laboratory system features stratified levels of laboratories (national, central/regional, provincial, district, and health center) based upon agreed testing services, with each level offering increased technical testing complexity and capacity (Figure 1). This tiered laboratory scheme is critical to strengthening public health laboratory services and informing effective national laboratory policy.
In addition to the call for government leadership in the Maputo Declaration, the meeting resulted in technical and operational recommendations to guide the harmonization and standardization of clinical laboratory testing in developing countries. Key recommendations from group breakout sessions included the following:

- Prioritize laboratory system coordination by developing national laboratory policies, establishing departments of laboratory systems within ministries of health, and calling upon donors and partners to support national governments in this effort.
- Define and establish the minimum test offerings required at each level of an integrated, tiered laboratory network, as well as the associated diagnostic instruments, equipment, and human resources required to provide such services.
- Prioritize supply chain systems and maintenance and service contracts for laboratory-based equipment at all levels of the laboratory network.

Following the 2014 Ebola outbreak in Western Africa, a follow-on harmonization meeting was held in Freetown, Sierra Leone, in October 2015. This meeting extended the call for international and local laboratory partners to increase capacity and further emphasized the need to develop tiered laboratory networks. The Freetown meeting brought together the African Society for Laboratory Medicine, WHO-AFRO, and ministry of health officials from more than 20 countries in Africa. The meeting resulted in the “Freetown Declaration on Developing Resilient Laboratory Networks for the Global Health Security Agenda in Africa,” which announced the need to effectively integrate tiered laboratory networks into disease surveillance and public health institutes. The declaration also emphasized the need to regularly measure progress with a standardized scorecard. The recent Ebola outbreak clearly demonstrates the critical need to reduce vulnerabilities in health care facilities and the laboratory system interface.

**ESTABLISHING A STRATEGY FOR LABORATORY HARMONIZATION AND STANDARDIZATION**

From 2008 to 2015, expenditures for laboratory instruments and commodities have increased substantially among all countries, with the aim of addressing access to critical HIV-related laboratory services. PEPFAR, The Global Fund, CHAI, and others have led efforts to expand coverage of diagnostic instrumentation as part of the global response to the HIV epidemic. Between 2007 and 2016, the United States Agency for International Development’s (USAID’s) primary PEPFAR procurement mechanism was PFSCM’s Supply Chain Management System. USAID’s financial contribution through this mechanism toward instrument procurements and laboratory commodity requirements increased from US$33,759,096 (2008) to $82,152,562 (2015) following the Maputo Declaration, for a total contribution of $511,475,320 across 43 countries. Countries have introduced hundreds of diagnostic instruments to reach patients within their laboratory networks, as well as at the health center level with the introduction of point-of-care (POC) instrumentation.

Now 8 years after Maputo, we review in this article how this financial and technical support has enhanced efforts to implement harmonization strategies as part of scale-up efforts. The terms “harmonization” and “standardization” are often used interchangeably among laboratory practitioners and policy makers. Here we define “laboratory harmonization” as a process of coordinating host country governments and stakeholders in the procurement and placement of laboratory products within a defined tiered laboratory network. This process is informed through consultation with key stakeholders, such as physicians, program leads, laboratory professionals, and procurement officers to develop technical policies. We define “standardization” as the process of implementing and adhering to the established technical policies.

Harmonization and standardization efforts offer considerable benefits. In South Africa, an integrated and standardized tiered service delivery model for CD4 (cluster of differentiation 4) testing could improve turnaround times by ensuring appropriate placement and integration of POC technologies within the conventional tiered laboratory structure. These efforts demonstrated a reduction of R125 million (US$8.8 million) in HIV/AIDS program costs annually. Harmonization and standardization also offer the following broader benefits to laboratory service delivery:

- Establishing minimum diagnostic test offerings and standardized testing methods within the tiered health network.

**The 2008 Maputo Declaration recommended prioritizing coordination of national laboratory systems.**

**Laboratory harmonization is the process of coordinating governments and stakeholders in a defined tiered laboratory network.**

**Standardization is the process of implementing and adhering to established technical policies.**
Laboratory harmonization and standardization offer many benefits, including reduced costs and improved turnaround times. We sought to measure progress in harmonization and standardization over time in 8 countries by analyzing annual HIV laboratory quantification data.

- Reducing variation in laboratory products across different facilities, thereby improving commodity logistic systems, standardized quality control practices, and quality assurances.
- Simplifying the identification and quantification of laboratory-based products.
- Training laboratory staff more efficiently.
- Improving coordination in laboratory instrument procurement, maintenance, and placement practices.

Over the past 9 years, PFSCM’s Supply Chain Management System, a project funded by PEPFAR and administered by USAID, facilitated laboratory harmonization and standardization workshops in 7 African countries at the request of the respective ministries of health. The USAID DELIVER PROJECT and U.S. Centers for Disease Control and Prevention (CDC) with PEPFAR provided direct assistance for an eighth workshop. These workshops were held in a mix of PEPFAR-supported sub-Saharan African countries (Eastern [3], Western [2], and Southern [3] African countries). In general, requests for workshops were initiated to address HIV supply chain challenges (e.g., quantification, procurement, commodity diversity, and logistics) as well as suboptimal instrument placement and high levels of instrument diversity related to increasing numbers of donated instruments for rapid scale-up of HIV programs.  

Each harmonization and standardization workshop had these overall objectives:

1. Arrive at consensus on the methodology for harmonization and standardization.
2. Establish national minimum test offerings and methodologies to be employed at each laboratory tier for each test.
3. Derive an evidence-based list of harmonized diagnostic instruments to support the required laboratory services.
4. Establish the minimum ancillary equipment requirements at each tier.
5. Define the staffing complement required at each tier to support the recommended laboratory services.
6. Determine a strategic implementation plan, with defined roles and responsibilities.

A technical consultation document released following the 2008 Maputo meeting was used as a reference standard to initiate workshops. This document details a notional list of tiered test offerings, diagnostic instruments, and ancillary equipment, as well as human resource templates, that countries can use as a starting point to guide their laboratory harmonization efforts. These lists were generalized to better serve multicountry planning efforts, with detailed recommendations relevant to workshop participants.

We view facilitation of harmonization and standardization workshops as a 2-step process. Phase 1, at the start, is for policy stakeholders, implementers, clinicians, and key program, procurement, and laboratory staff to define what testing services are required within the health system and at what tier of the laboratory system they should be offered (Figure 2).

In Phase 2, laboratory experts establish the appropriate diagnostic methods to be used for testing services at each tier. The experts then develop a proposed harmonized list of diagnostic instruments by tier, the necessary ancillary equipment, and the staffing required for the defined testing menu. These lists are then translated into a national harmonization and standardization policy for implementation. The instrument harmonization approach is informed by existing coverage of diagnostic instruments and the degree of instrument diversity. Standardized instrument lists should not be limited to one particular brand, but should include several brands to disperse risk across diagnostic specialties and eliminate the potential for monopolization.

**METHODOLOGY FOR REVIEWING PROGRESS IN HARMONIZATION AND STANDARDIZATION**

Past evaluations associated with implementation of the Maputo Declaration have been limited. A review of previous work on laboratory harmonization implementation focused on selection of the most appropriate tests and equipment types within the clinical cascade, as well as on how tiered networks are defined. Other evaluations have reviewed published reports, interviewed donors, and assessed coordination efforts, with implementation of national laboratory plans found to be inconsistent and frequently problematic. Past evaluations have not targeted instrument brand diversity as a measure of adherence to standardized procurement policies.

Recognizing these limitations, we sought to measure implementation progress over time in the 8 countries in which harmonization and
standardization workshops were held. We did this by analyzing available annual HIV laboratory quantification data. These data include instrument types and brands as a component of commodity forecasting over time. We organized standardized data import templates from ForLab (http://www.forlabtool.com), which is a multi-method laboratory forecasting tool, developed in partnership with USAID and CHAI. Laboratory instrument data were extracted by country for multiple forecasting periods. These data would help measure adherence to instrument procurement practices against established harmonization and standardization instrument policies in the countries where we held workshops.

All quantification data used in this comparison were collected through site visits, implementing partner data collection efforts, national equipment inventory lists, and commodity distribution data from national logistics systems. The final instrumentation network was validated in coordination with each country’s national laboratory leadership, as well as by PEPFAR implementing partners and U.S. Government missions (USAID and CDC), before we initiated the national forecasting exercises within ForLab.
We performed additional validation at the conclusion of each national laboratory quantification exercise for commodity budgeting and procurement purposes. Additionally, we assessed initial harmonization and standardization proposals for potential instrument reductions by comparing existing diagnostic instrument variety against proposals that were developed at the time of each harmonization and standardization workshop (where data were available). When our harmonization workshops were held, attendees identified recurring challenges to implementing harmonization proposals. These challenges were reviewed to identify obstacles to address as part of implementing harmonization and standardization efforts.

The intent of this analysis is (1) to illustrate the efforts made to conduct harmonization and standardization workshops to influence laboratory development; (2) to determine how well these countries have done; and (3) to describe what potential underlying challenges must be overcome to advance laboratory harmonization and standardization efforts.

**FINDINGS**

**Instrument Counts and Increased Capacity**

Figure 3 provides a summary of recent instrument counts by country. These numbers were extracted from national HIV laboratory forecasting exercises conducted in 2014 and 2015. Figure 4 represents the percentage growth by diagnostic area over time in the 3 countries where consecutive data points were available (Country B, Country E, and Country F). These 3 countries have had marked increases in instrument counts: Country B has increased CD4 instrumentation by 155% (from 288 to 447) since 2012 by introducing the Becton Dickinson FACSPresto in 2015 to replace aged FACSCounts machines and to expand CD4 testing to lower-level health facilities. From 2011 to 2014, Country E’s chemistry and hematology coverage increased more than 450% (from 124 to 567, chemistry, and from 111 to 502, hematology) due to program scale-up. And Country F reached an 820% growth in CD4 instrumentation (from 81 to 664) since 2009, primarily due to national deployment of
Alere Pima CD4 testing machines as a POC solution to address CD4 sample referral challenges.

**Instrument Brand Diversity**

The highest levels of instrument diversity, in manufacturer brand or unique diagnostic instrumentation types, were found in chemistry and hematology (Figure 5). Chemistry and hematology instruments are used in general care and clinical patient management services, but also play a key role in monitoring those on lifesaving HIV treatment. It should be noted that CD4 monitoring and molecular diagnostic instrumentation are predominantly procured through donor mechanisms. These procurements are influenced by the WHO prequalification process for introducing new diagnostic technology and therefore appear more harmonized due to fewer choices of approved brands.14,15

As with CD4 testing instrumentation, glucometers and hemoglobinometers (POC devices) contribute to high instrument counts, but unlike CD4 instrumentation, these devices also contribute to high levels of instrument diversity, with ministries, donors, implementing partners, and other stakeholders procuring many brands. High brand diversity further adds to higher levels of unique commodity types. For example, a CD4 test run on a FACSCount requires a minimum of 6 different items: CD4 reagents, a control kit, clean solution, rinse solution, FACSFlow sheath fluid, and thermal paper. Thus, if a country has 5 different types of CD4 instruments, more than 30 different commodities may be required for CD4 testing alone.

Many countries are using multiple open systems (e.g., systems in which reagents and consumables are nonproprietary) for chemistry instrumentation, which helps reduce commodity variation by allowing for sharing of reagents and general consumables, but it introduces challenges in training and variation with instrument maintenance. Hematology is a closed system market.

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Abbreviations: EID, early infant diagnosis; PCR, polymerase chain reaction; VL, viral load.
(e.g., the systems require proprietary reagents), and these systems require many commodity types to keep instruments operational.

**Proposed Reductions in Instrument Diversity**

Following HIV harmonization and standardization workshops, participants proposed substantial reductions in instrument diversity, ranging from a 17% reduction in Country D’s existing CD4 instruments to a high of 88% for Country H’s chemistry testing instruments (Table). As mentioned earlier and demonstrated in Figure 6 and Figure 7, chemistry and hematology account for the most diagnostic instrument diversity, hence have the largest potential for instrument reduction. Potential reduction for both CD4 instrumentation and polymerase chain reaction–based molecular instrumentation is between 1 and 2 from an absolute count perspective.

**Efforts to Implement Harmonization and Standardization**

We compared the earlier adopters of the Maputo Declaration—Country B (2012), Country C (2007), Country F (2009), and Country G (2007)—and found notable differences between countries in implementation and adherence to harmonization strategies (Figure 7).

Country B and Country G have been successful at limiting instrument brand expansion. Country B’s success is partly due to PEPFAR, which has historically provided funding for and coordinated closely with partners and the ministry of health around procuring laboratory instrumentation with the goal of complying with standardized instrument lists. Country G has succeeded by limiting commodity availability and supporting procurement and distribution of commodities only for approved instrumentation. Both of these countries have improved national laboratory forecasting efforts, which are now led by national quantification committees and have directly influenced commodity availability and improved laboratory logistic system proficiency due to reduced commodity counts. For example, as part of its harmonization efforts, Country G designed an initial laboratory logistics system in 2007 that reduced commodity types from more than 400 down to 185 HIV-specific products. Once the national logistics system was established and institutionalized, the commodity profile was later expanded to include a full array of diagnostic products (more than 380), further
### TABLE. Proposed Instrument Reductions by Instrument Type

<table>
<thead>
<tr>
<th>Country</th>
<th>CD4</th>
<th>Chemistry</th>
<th>Hematology</th>
<th>Molecular</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country A</td>
<td>-50%</td>
<td>-82%</td>
<td>-56%</td>
<td>-33%</td>
</tr>
<tr>
<td>Country B</td>
<td>0%</td>
<td>-22%</td>
<td>-33%</td>
<td>0%</td>
</tr>
<tr>
<td>Country C</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Country D</td>
<td>-17%</td>
<td>-55%</td>
<td>-71%</td>
<td>-50%</td>
</tr>
<tr>
<td>Country E</td>
<td>0%</td>
<td>-76%</td>
<td>-67%</td>
<td>0%</td>
</tr>
<tr>
<td>Country F</td>
<td>0%</td>
<td>-20%</td>
<td>-75%</td>
<td>0%</td>
</tr>
<tr>
<td>Country G</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Country H</td>
<td>0%</td>
<td>-88%</td>
<td>-80%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Note: Percentage reduction cannot be calculated for Country C and Country G due to lack of data on instrument diversity in these countries before harmonization efforts began.

### FIGURE 6. Comparison of Current and Proposed Instrument Diversity in 6 African Countries With Harmonization Proposals

![Comparison of Current and Proposed Instrument Diversity in 6 African Countries With Harmonization Proposals](image-url)
expanding the breadth of services offered and improving the overall planning and procurement practices associated with laboratory service delivery overall, not just HIV-related services.16,17

Conversely, Country C and Country F appear to have had less success in implementing an approach that would reduce instrument diversity, and instead have experienced substantial growth in brand diversity. Country F has seen marked increases in chemistry and hematology instrument diversity, much of which was driven by POC technology, with molecular instrumentation being the only diagnostic area that has remained constant. As stated earlier, in many countries the coordination efforts associated with implementing national laboratory plans and adherence to harmonization and standardization policies have been inconsistent and frequently problematic.13,18 We believe that this may play an important role in the ability of Country C and Country F to achieve leveled or decreasing brand diversity.

Another 4 of the evaluated countries—Country A, Country D, Country E, and Country H—have developed harmonization and standardization proposals only within the last 3 years, so it is difficult at this point to determine how well these countries will succeed at advancing their procurement practices to better align to their proposed strategies.

**Common Challenges and Critical Success Factors to Advancing Harmonization**

Throughout the harmonization and standardization efforts facilitated by PFSCM’s Supply Chain Management System, in-country program leads, stakeholders, and workshop participants expressed recurring challenges in advancing harmonization strategies. Overall, 10 recurring challenges were identified across countries: the structure of and lack of adherence to existing procurement policies, misalignment of service delivery policies and guidelines, lack of defined laboratory tiers, lack of an effective coordinating body responsible for laboratory harmonization, and issues with equipment maintenance, data availability, managing

### FIGURE 7. Shifts in Instrument Diversity in 4 African Countries Following Their Harmonization Proposals

![Bar chart showing shifts in instrument diversity in 4 African countries](https://via.placeholder.com/150)

Note: Country C has 75 additional instruments for chemistry and 55 additional instruments for hematology that are not included in the bar chart.

**National laboratory quantification committees can directly influence commodity availability and improve laboratory logistic systems.**

Across countries, 10 recurring challenges to laboratory harmonization have been identified.
frequent shifts in technology, human resources, competing priorities, and political agendas. To advance the harmonization and standardization agenda at a national level, we believe that 3 of the challenges identified by participants are the most important to address: (1) lack of adherence to procurement policies (i.e., instrument diversity), (2) lack of an effective coordinating body, and (3) misalignment of laboratory policies, treatment guidelines, and minimum services.

**Lack of Adherence to Procurement Policies**
There are high levels of instrument diversity in laboratory diagnostic instruments, equipment, and services across health facilities. The lack of coordination in the procurement and deployment of laboratory equipment contributes to different levels of compliance with service delivery standards across facilities that provide similar levels of care.

Compounding this challenge, procurement agents and national governments may see reducing instrument diversity as reducing competitiveness. They may assume that limiting the number of types of diagnostic instruments will lead to sole and single sourcing of instruments and reagents, creating monopolies and restricting competition, which contradicts most country-level procurement regulations.

If harmonization and standardization policies were static, this argument could hold true, but policies must be dynamic and based on instrument and vendor performance. In addition, over time, systems and clinical demands shift, technology advances, and existing instruments age and become obsolete. Countries thus must update standardized instrument lists to align service delivery expectations and ensure that laboratories can provide the necessary services with instruments that perform well, with reliable vendor support. Monitoring instrument and vendor performance should be continuous. These performance measures have traditionally been linked to commodity logistics systems, which are based on procurement lead times and instrument repair response times that inform replenishment of reagents. Historically, these systems have had challenges, but with meaningful technical support and investment from PEPFAR, commodity logistics systems are improving. Harmonization and standardization policy reviews should occur at a minimum of every 2 years, and should use annual laboratory quantification and logistics data to measure progress and general instrument and vendor performance, but also to assess the potential for introducing new technology.

**Lack of an Effective Coordinating Body**
Many countries do have a national laboratory directorate or coordinating body responsible for guiding laboratory development, but they are unable to prioritize laboratory harmonization and move the harmonization agenda from proposal to actual policy. This may be due to national priorities or political agendas, with laboratory technical working groups operating without a formal mandate or authority. Formalizing laboratory technical working groups with specific terms of reference, authority, and accountability would support advocacy efforts and help finalize harmonization and standardization proposals, as well as guide implementation.

Additionally, technical working groups should be charged with monitoring instrument procurement and placement, as well as laboratory technology development. This will ensure that ministries of health define processes for evaluating new technologies before they are deployed. The working groups should also guide ministries in developing policy for laboratory network development and other national laboratory interests. Once policy is finalized by the technical working groups, it is critical to ensure stakeholder adherence to standardization of procurement practice, as well as instrument placement.

**Misalignment of Laboratory Policies, Treatment Guidelines, and Minimum Services**
In many countries, laboratory policies, minimum packages of care, and national HIV/AIDS care and treatment guidelines are not aligned at the time of harmonization and standardization workshops. Laboratory and treatment policies and guidelines may have been updated with differing frequencies and without coordination between laboratory staff and clinicians. Many laboratories may have been providing tests that were outdated or not aligned with the minimum care needs by tier, or tests that were not clearly defined within existing laboratory policy and/or strategy documents.

For example, the harmonization and standardization effort in Country A began with a review of the country’s laboratory strategic plan, the essential health service package, the integrated health service plan, and the HIV/AIDS care and treatment guidelines. In Country E, a policy review was initiated with the country’s norms and standards for medical laboratories, the laboratory
strategic plan, and the HIV/AIDS prevention and treatment guidelines. When long-standing strategic plans cover many years and HIV treatment guidelines are more dynamic, these documents can quickly diverge in regard to priorities, implementation planning, and overall expectations associated with laboratory service delivery.

Additionally, budget growth and scale-up efforts for laboratory, program, and clinical needs increasingly diverge, further widening the gap between clinical needs and laboratory service capacity.

In most cases, the harmonization and standardization workshops were the first time clinicians and program staff had met in a large forum to discuss laboratory service delivery challenges, to define minimum test offerings by tier, and to advance a coordinated and aligned way forward.

To address these challenges, it is important to ensure that when treatment guidelines or minimum packages of care are updated, laboratory personnel have the opportunity to inform decision makers of existing laboratory capacity and scalability. Laboratory, clinician, and program staff should be engaged frequently to ensure that the laboratory network evolves to meet clinical and program needs. Laboratory investigations should be fully integrated into clinical and preventive protocols and programs, with the rational use of essential tests relevant to the level and type of facility.

As consumers of laboratory tests, clinicians should help laboratory programs determine test offerings for each laboratory tier based on the established national health care package, clinical importance, cost, suitability to the environment, and level of expertise of the service provider and end users.

**Limitations**

We recognize several limitations to the analysis described here. Our current analysis targets HIV-related diagnostics only. This choice was due to the high quality of HIV laboratory data that was available. It should be noted that all harmonization and standardization workshops included all diagnostic services and were not limited to just HIV diagnostics.

The primary measure of harmonization and standardization in this article was limited to instrument brand diversity, as a way to measure compliance to procurement from a national standardized instrument list. Other evaluations have sought to focus on appropriateness of tests and equipment types within the clinical cascade, as well as on how tiered networks are defined and implemented.12,13 Ideally, a combination of measures associated with testing availability within the laboratory network, instrument brands, and potential placement of instruments within the tiered laboratory network would provide a more complete picture of harmonization and standardization success. This could even provide opportunities to identify optimization strategies that build upon laboratory standardization efforts. Additional research could provide greater understanding of which components of harmonization efforts have achieved success and which are works in progress or more challenging to implement more broadly.

Implementing a harmonization and standardization policy and demonstrating alignment to a standardized instrument list can take many years. Half of the countries included in this analysis had completed harmonization workshops before 2013, the other half completed their workshops more recently. A follow-up evaluation in a few years could identify additional challenges not considered here, or could demonstrate further compliance and success.

**CONCLUSION**

The Maputo Declaration and, more recently, the Freetown Declaration, called on national governments to prioritize laboratory system development and emphasized the need to foster national ownership; more importantly, participants at these two meetings urged donors and partners to commit to working in close coordination to support efforts to strengthen sustainable public health laboratory systems.

Although the list of tiered test offerings and diagnostic instruments included in the Maputo Declaration11 is now dated, the founding principles and primary objectives are still relevant today, as illustrated by the 2015 Freetown Declaration. New technologies are emerging to address diagnostic and patient-monitoring challenges, along with additional levels of complexity in laboratory networks due to the introduction of POC technology and associated decentralization of laboratory services. A strategic harmonization and standardization framework is critical to ensure a coordinated and sustainable laboratory development agenda.

Overall, harmonization and standardization efforts have been implemented with mixed success,
with some countries only recently implementing measures to introduce harmonization policies. Effectively implementing a harmonization and standardization policy and demonstrating alignment to a standardized instrument list can take many years. For example, the rate of replacing existing equipment with approved instruments depends on instrument life span. Using harmonization and standardization principles as programs scale up, with new instruments purchased for replacements and network expansion at new sites, will limit growth in instrument and brand diversity. Leveraging scorecards, as recommended by the Freetown Declaration, may be another way to advance these efforts.

Since the inception of the global response to the HIV epidemic, procurements of HIV-related diagnostic instruments have increased markedly. A data-driven laboratory harmonization and standardization approach is one way to ensure optimal use of laboratory-based instrument diagnostics and to create efficiencies in product procurement, placement, training, and use. This will be increasingly important to efforts to achieve UNAIDS’ 90-90-90 targets.1

However, less has been done to regulate procurement and reduce instrument diversity within chemistry and hematology, where critical safety monitoring tests for antiretroviral therapy are performed, or to provide highly needed general health and screening diagnostics. As a result, chemistry and hematology now represent the highest levels of instrument diversity within laboratory networks.

A high level of instrument diversity has a great impact on laboratory commodity forecasting, supply chain systems, equipment maintenance, and quality laboratory service delivery. Although many years have passed since the Maputo meeting in 2008, the 2015 Freetown Declaration illustrates the continued need to improve adherence to harmonization and standardization practices. Improved coordination is required, as well as the development, implementation, and—more importantly—monitoring and updating of laboratory harmonization and standardization policies over time. Developing a tiered laboratory network, procuring from standardized instrument lists, as well as ensuring the alignment of laboratory policies, minimum packages of care, and national care and treatment guidelines, are all critical to achieving the benefits of harmonization and standardization.

As donor contributions and priorities shift in response to viral load scale-up as part of the 90-90-90 effort among HIV practitioners, there is potential for less support and focus on chemistry and hematology instrumentation, as well as on other diagnostic specialties. Support for HIV programs has historically included procurement of chemistry- and hematology-related commodities and instruments, with the assumption that local governments will assume responsibility for these lower-cost tests moving forward. It is therefore critical to improve efforts to ensure that national ministries of health can expand and sustain not only their existing HIV-related laboratory services but also the general public health laboratory services, to serve broader health and surveillance needs. It is important for program managers, supply chain activity managers, and others to work with their colleagues to understand the capacity, use, and placement of instrument-based diagnostics. There is still a need to reduce excess numbers of products, improve use, decrease costs, and increase efficiency.

Important gains have already been achieved within national laboratory networks, but there is still a need to ensure that countries are able to provide continued quality laboratory services in an efficient and sustainable manner. The Maputo and Freetown Declarations provide a detailed strategic approach that is critical to ensure a coordinated and sustainable laboratory development agenda to address the broader health security agenda in Africa.

Acknowledgments: The content in this manuscript are those of the authors and do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

Competing Interests: None declared.

REFERENCES


Postabortion Care: 20 Years of Strong Evidence on Emergency Treatment, Family Planning, and Other Programming Components

Douglas Huber,a Carolyn Curtis,b Laili Irani,c Sara Pappa,d Lauren Arrington,e

Twenty years of postabortion care (PAC) studies yield strong evidence that:
- Misoprostol and vacuum aspiration are comparable in safety and effectiveness for treating incomplete abortion.
- Misoprostol, which can be provided by trained nurses and midwives, shows substantial promise for extending PAC services to secondary hospitals and primary health posts.
- Postabortion family planning uptake generally increases rapidly—and unintended pregnancies and repeat abortions can decline as a result—when a range of free contraceptives, including long-acting methods, are offered at the point of treatment; male involvement in counseling—always with the woman’s concurrence—can increase family planning uptake and support.

ABSTRACT

Worldwide, 75 million women need postabortion care (PAC) services each year following safe or unsafe induced abortions and miscarriages. We reviewed more than 550 studies on PAC published between 1994 and 2013 in the peer-reviewed and gray literature, covering emergency treatment, postabortion family planning, organization of services, and related topics that impact practices and health outcomes, particularly in the Global South. In this article, we present findings from studies with strong evidence that have major implications for programs and practice. For example, vacuum aspiration reduced morbidity, costs, and time in comparison to sharp curettage. Misoprostol 400 mcg sublingually or 600 mcg orally achieved 89% to 99% complete evacuation rates within 2 weeks in multiple studies and was comparable in effectiveness, safety, and acceptability to manual vacuum aspiration. Misoprostol was safely introduced in several PAC programs through mid-level providers, extending services to secondary hospitals and primary health centers. In multiple studies, postabortion family planning uptake before discharge increased by 30–70 percentage points within 1–3 years of strengthening postabortion family planning services; in some cases, increases up to 60 percentage points in 4 months were achieved. Immediate postabortion contraceptive acceptance increased on average from 32% before the interventions to 69% post-intervention. Several studies found that women receiving immediate postabortion intrauterine devices and implants had fewer unintended pregnancies and repeat abortions than those who were offered delayed insertions. Postabortion family planning is endorsed by the professional organizations of obstetricians/gynecologists, midwives, and nurses as a standard of practice; major donors agree, and governments should be encouraged to provide universal access to postabortion family planning. Important program recommendations include offering all postabortion women family planning counseling and services before leaving the facility, especially because fertility returns rapidly (within 2 to 3 weeks); postabortion family planning services can be quickly replicated to multiple sites with high acceptance rates. Voluntary family planning uptake by method should always be monitored to document program and provider performance. In addition, vacuum aspiration and misoprostol should replace sharp curettage to treat incomplete abortion for women who meet eligibility criteria.

INTRODUCTION

Worldwide, 210 million women become pregnant annually; 135 million will have a live birth, and 75 million, or one-third, will have a spontaneous or induced abortion and need postabortion care (PAC).
Of the 75 million abortions, 31 million are spontaneous (miscarriages) and 44 million are induced; half of the induced abortions are unsafe, performed by persons lacking the necessary skills or in an environment not in conformity with minimal medical standards.1

Since 1994, the United States Agency for International Development (USAID) has supported implementation of PAC programs in more than 40 countries to address complications related to miscarriage and incomplete abortion.2 PAC may be a unique service delivery model that is both curative and preventative—curative in treating incomplete abortion and the symptoms of hemorrhage and sepsis; preventative in providing family planning services to address unmet need for contraception and reduce unintended pregnancies and repeat abortions. The 3 components of USAID’s PAC model are2:

1. Emergency treatment
2. Family planning counseling and service delivery, and where financial and human resources exist, evaluation and treatment of sexually transmitted infections (STIs) as well as HIV counseling and/or referral for testing
3. Community empowerment through community awareness and mobilization

PAC is an integral part of maternity care, and all components of PAC services are essential, as stated at the 1994 International Conference on Population and Development. All 3 components have been included in USAID programs since 1994.2,3

In 2007, USAID published the first global PAC research compendium, “What Works, A Policy and Program Guide to the Evidence on Postabortion Care,” which reviewed the PAC literature from 1994 through 2003.4 This article summarizes the major findings on PAC interventions with strong evidence, described in the forthcoming second edition of USAID’s global PAC research compendium. The second edition builds on the first edition by including more detailed findings that address the cycle of repeated unintended pregnancy and abortion.4,6

METHODS AND SCOPE

The first and second editions of the USAID PAC research compendium reviewed in detail more than 550 articles and reports published between 1994 and 2013, representing 20 years of PAC research. We searched Scopus, MEDLINE, and POPLINE for relevant PAC interventions that had been evaluated, using several search words relevant to PAC, such as postabortion care, postabortion contraception, incomplete abortion, abortion complications, dilation and curettage, misoprostol, and manual vacuum aspiration. If the article title indicated there might be an intervention that could be replicated, we reviewed the full-text article to determine if there was sufficient information to be included in the “What Works” compendium and that the intervention took place in low- or middle-income countries in Asia, Africa, Latin America, or the post-Soviet states.4,3

Key interventions that had taken place only in high-income countries (namely Australia, Japan, Europe, or the United States) were included only if we determined that the interventions could be relevant for low-resource country contexts but had not yet been initiated in developing countries.

We also reviewed unpublished reports (gray literature) from key websites to supplement the studies published in peer-reviewed publications because of the limited amount of published literature on PAC. The websites reviewed comprised United Nations (UN) agencies, the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO), the Cochrane Collaboration, the Open Source Initiative (OSI), the International Center for Research on Women (ICRW), Futures Group, Population Services International (PSI), the Population Council, the International Council of Women (ICW), the World Bank, Family Health International (FHI) (renamed FHI 360 in 2011), Gynuity Health Projects, Ipas, and the Guttmacher Institute. Biomedical information was included insofar as it was relevant to programmatic considerations. The articles and reports included in our review covered the 3 components of the USAID PAC model as well as a fourth component that addressed policy, programs, and health systems in postabortion care. We adapted the Gray scale (Table 1) with its 5 levels to assess the strength of research evidence for each article or report cited in the compendium.4,7 Strong evidence was drawn primarily from the first 4 levels that included randomized controlled trials, well-designed trials with or without randomization, and some well-designed nonexperimental studies from more than one center or research group. Evidence was considered “strong” if it had support of at least 2 Gray I, II, or IIa studies and/or 5 Gray IIIb, IV, or V studies.2

Studies with strong evidence for postabortion care are highlighted in this article and critical areas
TABLE 1. Gray Scale of Strength of Evidence

<table>
<thead>
<tr>
<th>Strength of Evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Strong evidence from at least one systematic review of multiple well-designed, randomized controlled trials.</td>
</tr>
<tr>
<td>II</td>
<td>Strong evidence from at least one properly designed, randomized controlled trial of appropriate size.</td>
</tr>
<tr>
<td>IIIa</td>
<td>Evidence from well-designed trials/studies without randomization that include a control group (e.g., quasi-experimental, matched case-control studies, pre-post with control group).</td>
</tr>
<tr>
<td>IIIb</td>
<td>Evidence from well-designed trials/studies without randomization that do not include a control group (e.g., single group pre-post, cohort, time series/interrupted time series).</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence from well-designed, nonexperimental studies from more than one center or research group.</td>
</tr>
<tr>
<td>V</td>
<td>Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees.</td>
</tr>
</tbody>
</table>

Note: Gray includes 5 levels of evidence. For the “What Works” compendiums, level III was subdivided to differentiate between studies and evaluations whose design included control groups (IIIa) and those that did not (IIIb).

Electric and manual vacuum aspiration are safe, effective, and preferable to sharp curettage for uterine evacuation.

for future research are identified. Preference was given to studies from the Global South, but where evidence was scant from the South, studies from the Global North were included. Both editions of the compendium include a full description of the evidence statements along with complete references. In this article, we summarize the strong evidence we consider most applicable for extending PAC services, increasing access to family planning, improving cost-efficiency, and enhancing client satisfaction.

**FINDINGS**

Recent PAC studies (2004–2013) reinforce most of the strong evidence statements from the 2007 PAC research compendium; specifically, those related to access to services, quality of care, community awareness of PAC, and postabortion family planning. Recent research also highlights the continuing challenges of providing complete PAC services, including family planning, counseling, and client information. Treatment options for incomplete abortion, task shifting, and decentralizing services are rapidly evolving and well documented.

In this section, we summarize key findings on the 4 main components covered in the scope of our literature review: (1) emergency treatment of incomplete abortion, (2) postabortion family planning counseling, including STI/HIV evaluation, (3) community empowerment, and (4) health systems and policies.

**Emergency Treatment of Incomplete Abortion**

**Surgical Treatment**

Vacuum aspiration, either electric vacuum aspiration (EVA) or manual vacuum aspiration (MVA), is safer and less painful than sharp curettage, which is usually performed with general anesthesia in an operating theater. Many of the resources we reviewed focused on MVA. Main findings included:

- Women treated by vacuum aspiration (electric or manual) for incomplete abortion had shorter procedures and significantly less blood loss than those treated by sharp curettage. Pain is generally less than with sharp curettage.
- The use of general anesthesia with sharp curettage is associated with increased risk of blood loss, cervical injury, uterine perforation, and subsequent abdominal hemorrhage.
- Verbal support (“verbacaine”) to provide reassurance and diversion during the MVA procedure and/or paracervical block were generally inadequate for pain management with MVA.
- Sedation with analgesics plus emotional...
Postabortion Care: 20 Years of Evidence

Global Health: Science and Practice 2016 | Volume 4 | Number 3

Midwives. Trained nurses and midwives should be provided by trained nurses and midwives. It should be an available option for women needing post-abortion care.

Paracervical block with local anesthesia for incomplete abortion with an open cervix provided no discernible benefit over placebo in studies of MVA procedures. Costs can be substantially reduced by introducing MVA to replace sharp curettage when accompanied by changes in protocols for admission, place of procedure (often a simple procedure room), and an improved service delivery model that gives priority to PAC clients. Direct costs are reduced by avoiding use of the operating theater, general anesthesia, blood transfusions, and prolonged hospital stays.

Prophylactic antibiotics to prevent postoperative infection have not shown effectiveness in the relatively underpowered studies from the Global South. One large study of induced abortion in the United States showed a reduction in postoperative infections for vacuum aspiration and medical induced abortion using doxycycline 100 mcg twice daily for 7 days. However, infections were rare with or without prophylactic antibiotics.

Successful evacuation rates with misoprostol ranged 89%-99% at 1-2 weeks post-treatment.

The past decade has seen major advances in medical evacuation using misoprostol for treatment of incomplete abortion. Misoprostol is rapidly gaining acceptance as a safe, effective treatment for incomplete abortion in primary and secondary outpatient settings and can be provided by trained nurses and midwives. It should be an available option for women needing post-abortion care.

Evidence from at least 16 studies of misoprostol points to an optimal dose and route of administration of 400 mcg sublingually or 600 mcg orally; both are equally effective for treating uncomplicated first-trimester incomplete abortion, either spontaneous or induced. No advantage was seen with higher or multiple doses, or when given by other routes of administration.

Study criteria for misoprostol treatment typically included first-trimester incomplete abortion without complications and an open cervix. Other selection criteria in clinical trials usually included women residing within one hour’s travel distance of a hospital. Back-up surgical evacuation and ultrasound were available on site or by ready referral to another regional or tertiary hospital.

Table 2 summarizes findings from 8 high-quality studies conducted in the Global South between 2005 and 2012 in tertiary and district hospitals. Successful evacuation rates ranged between 89% and 99% at 1 to 2 weeks post-treatment without recourse to surgical intervention. A follow-up was usually scheduled at 1 week. If evacuation was not complete, the woman was offered the option of waiting a second week or having an immediate surgical evacuation, usually by MVA. If not complete at 2 weeks, a surgical evacuation was performed.

Success rates were lower in studies with shorter time frames for judging completion and more frequent follow-up visits. For example, one study scheduled the first follow-up visit at day 2; if evacuation was not complete, women could opt to return at day 7, but not later. Success rates were lower and also different between the 2 study sites, 44% vs. 85%, suggesting major provider and institutional variations. The authors of the study acknowledged that providers’ lack of confidence in using misoprostol may partly explain the large differences between sites.

Surgical evacuation is still needed for the 2% to 8% of women with incomplete evacuation following misoprostol; women presenting with complications (e.g., sepsis, heavy bleeding); women with advanced gestational age; and women who prefer surgical management. Most studies specified that participants live within the facility’s geographic catchment area or within one hour of travel time, and that ultrasound be available by referral. Ultrasound was seldom needed; current misoprostol training curricula note that ultrasound is not required to diagnose complete evacuation, although in selected circumstances it may assist in the evaluation.

None of the 8 misoprostol studies in Table 2 documented postabortion contraception uptake, a critical component of postabortion care.

Recent programmatic expansions in Senegal document favorable client and clinical outcomes when misoprostol is given at lower-level health facilities farther from hospitals. Thirteen studies in 9 countries included nurse-midwives as providers. Major findings with misoprostol for PAC are as follows:

- Success rates were comparable with MVA in most studies using doses of 400 mcg sublingually or 600 mcg orally with optional follow-up extended to 2 weeks (Table 2). Surgical evacuation is still needed for the 2% to 8% of women with incomplete evacuation following misoprostol; women presenting with complications (e.g., sepsis, heavy bleeding); women with advanced gestational age; and women who prefer surgical management. Most studies specified that participants live within the facility’s geographic catchment area or within one hour of travel time, and that ultrasound be available by referral. Ultrasound was seldom needed; current misoprostol training curricula note that ultrasound is not required to diagnose complete evacuation, although in selected circumstances it may assist in the evaluation.

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### TABLE 2. Effectiveness and Satisfaction With Treatment for Incomplete Abortion, Misoprostol Compared With Surgical Evacuation, 10 Countries, 2005–2012

<table>
<thead>
<tr>
<th>Article</th>
<th>Country (Sample Size)</th>
<th>Study Design: Misoprostol/Surgical Comparison Group</th>
<th>Effectiveness: % With Complete Evacuation</th>
<th>% Client Satisfaction With Procedure</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blandine 201217</td>
<td>Burkina Faso (N=99)</td>
<td>400 mcg misoprostol sublingually/ referral for surgical</td>
<td>M: 98%</td>
<td>M: 99%</td>
<td>PAC with misoprostol introduced to 2 district hospitals with no previous PAC service. All eligible women chose misoprostol over optional referral for MVA.</td>
</tr>
<tr>
<td>Dao 200718</td>
<td>Burkina Faso (N=447)</td>
<td>600 mcg misoprostol orally/ MVA</td>
<td>M: 94% S: 99%</td>
<td>M: 97% S: 98%</td>
<td>2 teaching hospitals.</td>
</tr>
<tr>
<td>Weeks 200514</td>
<td>Uganda (N=317)</td>
<td>600 mcg misoprostol orally/ MVA</td>
<td>M: 96% S: 92%</td>
<td>M: 94% S: 95%</td>
<td>Misoprostol was associated with less pain and fewer complications but increased bleeding. All received antibiotics after treatment.</td>
</tr>
<tr>
<td>Taylor 201119</td>
<td>Ghana (N=230)</td>
<td>600 mcg misoprostol orally/ MVA</td>
<td>M: 98% S: 99%</td>
<td>M: 94% S: 89%</td>
<td>44% were very satisfied with misoprostol vs. 8% with MVA; 95% of those treated with misoprostol would choose it again vs. 36% treated with MVA.</td>
</tr>
<tr>
<td>Shwekerela 200720</td>
<td>Tanzania (N=150)</td>
<td>600 mcg misoprostol orally/ MVA</td>
<td>M: 99% S: 100%</td>
<td>M: 99% S: 100%</td>
<td>75% were very satisfied with misoprostol vs.55% with MVA; more side effects were associated with misoprostol; greater pain with MVA.</td>
</tr>
<tr>
<td>Bique 200721</td>
<td>Mozambique (N=270)</td>
<td>600 mcg misoprostol orally/ MVA</td>
<td>M: 91% S: 100%</td>
<td>M: 96% S: 100%</td>
<td>87% were very satisfied with misoprostol vs. 37% with MVA; trained midwife provided MVA with only verbal anesthesia; tertiary hospital site.</td>
</tr>
<tr>
<td>Montesinos 201122</td>
<td>Ecuador (N=242)</td>
<td>600 mcg misoprostol orally/ MVA</td>
<td>M: 94%</td>
<td>M: 96% S: 97%</td>
<td>47% were very satisfied with misoprostol vs. 40% with MVA; ultrasound use decreased threefold for misoprostol and MVA in 1 year.</td>
</tr>
<tr>
<td>Shochet 201223</td>
<td>Senegal (N=199)</td>
<td>400 mcg misoprostol sublingually/ standard surgical care (MVA or D&amp;C)</td>
<td>Senegal M: 93% S: 100%</td>
<td>Overall in the 5 countries M: 99% S: 98%</td>
<td>Antibiotics given with the surgical option; success rates much higher with misoprostol after first month from introduction. Ultrasound not needed on site. Nurses and midwives had prominent roles in care in Burkina Faso, Niger, and Senegal.</td>
</tr>
</tbody>
</table>

Abbreviations: D&C, dilation and curettage; M, misoprostol; MVA, manual vacuum aspiration; PAC, postabortion care; S, surgical.
evacuation (usually MVA) was available on site or by referral if the woman requested and for those who did not meet the criteria for misoprostol.

- Complications were low and comparable to MVA. Most studies reported less pain with misoprostol than with MVA.\textsuperscript{14,20} Bleeding was slightly increased, compared with MVA, though not of clinical significance.\textsuperscript{14} Client acceptability was high, with substantially more women reporting they were “very satisfied” compared with MVA. Misoprostol recipients were also more likely to recommend it to a friend (Table 2).

- High client satisfaction and complete evacuation rates were also achieved when misoprostol was expanded to secondary and district hospitals and health posts that had no previous capability to treat incomplete abortion.\textsuperscript{17,23,25,28,29}

- Pain management with ibuprofen, 800 mg to 1000 mg, was generally adequate and clearly superior to paracetamol (acetaminophen).\textsuperscript{35-37}

- Routine ultrasound was not necessary to diagnose incomplete abortion or confirm complete uterine evacuation when misoprostol was used at less than 12 weeks gestation; clinical judgment was adequate for the large majority of cases.\textsuperscript{14,17,20}

- Two studies noted that ultrasound available through referral was helpful for establishing ectopic pregnancy, determining gestational age, and confirming complete evacuation for a few cases.\textsuperscript{17} Typically ≥90% of women in Burkina Faso and Senegal were managed entirely at the primary point of care without referral for ultrasound.\textsuperscript{14,17,20} However, these studies contained few sites.

- Mid-level clinicians can correctly diagnose and treat incomplete abortion with misoprostol and accurately determine complete evacuation.\textsuperscript{23,25,28} Expanding the scope of practice for mid-level providers for counseling and provision of misoprostol was found to be safe, effective, and acceptable.\textsuperscript{17,18,21}

### Postabortion Family Planning Counseling and Services

Although emergency treatment for incomplete abortion often receives greater attention than postabortion family planning, the family planning component to reduce preventable child and maternal deaths in both the postpartum and postabortion periods is a growing focus for maternal, neonatal, and child health programs.\textsuperscript{1,38} Many PAC clients were not using a modern contraceptive method at the time of conception. When providing family planning counseling and services, it is necessary to understand the reproductive intentions of the woman and her partner. Expanding the method mix, including long-acting reversible contraceptives (LARCs) and permanent methods, allows the woman to choose what she wants and what works best for her. Women need adequate counseling and choice of methods to make informed voluntary decisions about family planning.

The Family Planning High Impact Practices brief on postabortion care summarized the results of 15 studies to strengthen postabortion family planning in 14 countries.\textsuperscript{39} Postabortion family planning uptake before discharge rose by 30–70 percentage points within 1 to 3 years in several studies, sometimes increasing by as much as 60 percentage points in 4 months.\textsuperscript{4,39} The interventions providing postabortion family planning counseling and services at the same time and location as treatment rapidly increased immediate postabortion contraceptive acceptance. They found an average 37 percentage point increase of women receiving a method before discharge, from 32% before the intervention (range, 1% to 65%) to 69% post-intervention (range, 25% to 98%).\textsuperscript{39} Other post-intervention studies reported even greater family planning uptake.\textsuperscript{40} Counseling and family planning uptake continued to increase in one Peru study over 3 years after support for the intervention stopped, a demonstration of sustainability.\textsuperscript{41} One study in Zimbabwe comparing a postabortion family planning intervention at one hospital with a control hospital with no special intervention reported significantly greater family planning uptake in the intervention hospital, as well as significantly fewer unintended pregnancies and repeat abortions; the study enrolled 982 women in total, 527 of whom were followed for 12 months.\textsuperscript{42}

Multiple studies (published between 1998 and 2010) from 9 countries show that training providers in family planning counseling, service delivery, and MVA increases family planning uptake.\textsuperscript{39,41,43-46} Other factors contributing to success were continuing education in family planning counseling skills, provider job aids, and client education materials.\textsuperscript{47,48} Placing commodities at the point of treatment such as in a
After women gave permission for including their husbands in counseling, family planning use increased. Counseling covered follow-up care, rapid return to fertility, and family planning methods. Men also provided physical, emotional, and material support for PAC clients during recovery. Husbands who were counseled were 60% more likely to provide a high level of support for family planning use; 30% were also more likely to provide a high level of emotional support.50-53

Providing all contraceptive methods free to PAC clients greatly contributed to the increased uptake of postabortion family planning prior to discharge from the facility.42,46,48,49,54 This is a key consideration for governments, ministries of health, and policy makers. Many women are not able to pay for contraceptives at the time of treatment.

Delaying the next pregnancy for at least 6 months after miscarriage or abortion reduces the incidence of preterm delivery, low birth weight, premature rupture of membranes, and maternal anemia.55 Therefore, it is particularly important to stress the need for spacing after spontaneous abortion when women may desire another pregnancy soon. Advising every woman to delay her next pregnancy also removes the potential stigma that accepting family planning implies her abortion was induced.

Insertion of an intrauterine device (IUD) immediately after a first-trimester abortion yielded few expulsions and carried no increased risk of perforation or infection. There was only a minimal increase in expulsion rates over delayed insertion.56,57 With misoprostol treatment, the IUD is usually inserted at the 1-week follow-up visit provided that uterine evacuation is complete.57 Delayed insertion may increase the likelihood of failing to return for the planned IUD insertion, thus placing women at higher risk of unintended pregnancy.58

Several studies found that women receiving immediate postabortion LARCs had fewer subsequent unintended pregnancies and repeat abortions than those who were offered delayed insertions (3 to 6 weeks post-procedure).56,59,60

**HIV Testing and STI Prevention**

Women with HIV who are symptomatic are at an increased risk for spontaneous abortion.61-65 Few studies have been done in this area of PAC and HIV, although some show promising results. For example, in Tanzania offering HIV testing to 706 women as part of PAC services resulted in 58% of the women accepting HIV testing; 14% of these women had HIV. HIV testing in conjunction with PAC was found to be acceptable and relevant in this high-risk setting.66

We did not find documentation that PAC services routinely included counseling on STI and HIV risk factors and provided condoms for prevention. One study identified this as an unmet need.67 No studies were found that documented both diagnosis and treatment for STIs and HIV in relation to PAC.

**Other Counseling Concerns**

Women who have undergone induced or spontaneous abortion may require special counseling considerations. Increased risk of spontaneous abortion is associated with several common conditions, including malaria, HIV/AIDS, STIs, gender-based violence, smoking, excess alcohol use, exposure to pesticides, and previous spontaneous abortion.68-75 Approximately one-third of women seeking abortion have been victims of abuse sometime during their lifetime.73,76 Significant anxiety is experienced by 40% to 45% of women before an induced abortion. Distress is reduced after the procedure, although about one-fourth may report anxiety and depression from 1 month to 2 years after the event. The long-term psychological outcomes are similar between women who have had an induced abortion and those who have given birth.5,77,78 The short-term emotional reactions to miscarriage appear to be as large or larger than those to induced abortion.5,6 Most psychological outcome studies, however, have been conducted in developed countries, so it is difficult to apply the findings to low-resource settings. Some of women’s counseling needs may be amenable to community education and intervention as part of community health worker (CHW) activities. However, studies are not yet available to document interventions and effectiveness.

A substantial percentage (40%) of PAC clients are under the age of 25, yet they account for almost half of the deaths from unsafe abortion.79 Factors contributing to maternal deaths in young PAC clients include not seeking PAC services soon enough due to late recognition of complications, delay due to stigma in the community, lack of funds for transport and services, and delay due to provider bias and attitude to young clients.80,81 Skilled counseling is especially important for younger women whose first interaction with the health system may be for postabortion care.1
Community Awareness, Mobilization, and Empowerment

The Community Action Cycle—a participatory problem-solving approach involving community diagnosis, planning, implementation, participatory evaluation, and scale-up—can increase awareness of PAC services, especially through training of CHWs to provide postabortion family planning counseling and services, including referral to facilities. In Kenya, CHWs were instrumental in rapidly increasing access to essential PAC services by providing contraceptives to 63% of users and referring 90% of PAC clients to health facilities. The Community Action Cycle also helped educate communities on recognition of danger signs during pregnancy, such as bleeding, to encourage health-seeking behavior for PAC. However, major gaps remain in knowledge of linkages between community mobilization and PAC services.

Policy, Programs, and Systems

Wide Replication of PAC Including Essential Organization of Services

In several countrywide PAC programs, postabortion family planning is emerging as a strong program component. Nepal was one of the first countries to widely replicate PAC programming and document valuable lessons learned during the expansion phase. The lessons are especially relevant as the challenges are similar throughout most PAC programs. In 1995, Nepal first initiated PAC services at the Maternity Hospital in Kathmandu. It then expanded services to 78 sites in 50 districts mainly in public-sector health facilities. The program focused on (1) replacing sharp curettage with MVA by establishing PAC training centers at the district level using group-based and on-the-job training, and (2) training staff nurses and senior auxiliary nurse-midwives as primary providers, thereby expanding access to primary health centers and linking PAC with family planning services. Key achievements included training more than 170 providers in PAC and starting 46 new PAC service sites in primary health centers with task shifting for most of PAC services from doctors to nurses. This resulted in the increase of MVA use from 47% to 74% and family planning uptake of 81% (a high percentage compared with most programs although baseline data were not available), with injectables being the most popular method.

In Nepal, technical support service centers were crucial for institutionalizing comprehensive PAC services. Resistance by doctors and hospital management to nurses providing MVA was partly overcome through formal and informal orientations for doctors. Structured on-the-job training was cost-effective for maintaining PAC skills and strengthening services. PAC program data were difficult to collect as they were not included in the Ministry of Health and Population’s regular health management information system. Challenges included the frequent transfer of trained PAC service providers; unavailability of family planning services to women having sharp curettage procedures; insufficient caseload at some sites to support group-based training; and irregular supply and replacement of MVA equipment.

Guatemala expanded its PAC program to 22 of the 33 public district hospitals. The 22 district hospitals increased postabortion family planning counseling from 31% to 78% over 18 months; postabortion family planning acceptance before discharge rose from 20% to 49%; and vacuum aspiration increased from 38% to 68.

Tanzania achieved high performance when initiating PAC with MVA, expanding from 11 to 229 sites between 2005 and 2010. In 2010, the PAC program served 9,563 PAC clients, with 84% of women being counseled on family planning and 82% accepting a method. Senegal also rapidly expanded services in 23 of 56 districts, covering 60% of the population by 2006. Formal PAC training was given to 523 providers from 323 health facilities. Health centers with adequate space, materials, and equipment increased from 29% to 95% between 2003 and 2006, and facilities with reorganized services capable of providing 24/7 PAC services rose from 55% to 84.

In replicating PAC services, Rwanda engaged lower-level health facilities to provide PAC, including misoprostol, and increased use of family planning services. Before the pilot program, only 2 of 50 health centers were providing PAC services; all other health centers referred PAC clients to hospitals. Within a year, 91% of PAC clients were treated at health centers and only 9% were referred to hospitals. Overall, misoprostol was used to treat 83% of PAC clients, and 59% of women were discharged with a contraceptive method. A system of data collection and monitoring was implemented to inform the scale-up, providing a good example of the
inclusion of family planning uptake in the health management information system. Wide replication of PAC in multiple sites is a strong step toward sustainable and scaled-up services. These are not as well documented in the literature.

**Task Shifting**

An expanded scope of practice for mid-level providers was assessed in a number of studies providing PAC service delivery. These studies confirm the safety, effectiveness, and acceptability of trained nurses and midwives as providers of MVA, affirming their ability to accurately determine complete evacuation.

**Costs**

Twelve studies compared costs for PAC services using MVA versus sharp curettage. There was strong evidence that using MVA for PAC instead of sharp curettage along with changes in protocols and an improved service delivery model can significantly reduce costs of care in most cases. In-patient hospital and personnel costs were the main drivers of cost for PAC service delivery. Interventions to reduce costs included:

- Changes in protocol to the standard use of MVA with local anesthesia if the uterus was smaller than 12 weeks’ size
- Providing PAC as an ambulatory outpatient procedure
- Provider training on information and counseling (on health status, uterine evacuation procedure, postabortion contraception, and care after leaving the hospital)
- Refresher training and supportive supervision

A number of cost studies document the high cost of treating abortion complications, the value of expanding PAC services with a robust family planning component, and the substantial savings that could be achieved by preventing unintended pregnancies and abortion through improved contraceptive services. Immediate postabortion insertion of an IUD after surgical evacuation offers special promise of cost-efficient, high contraceptive continuation with a very effective method.

One study also made the case that greater use of misoprostol for PAC could free surgical resources to be used for more complicated cases. Good costing studies on use of misoprostol compared with surgical evacuation are lacking; this is a major area for further research and documentation.

**PAC PROGRAM AND PRACTICE RECOMMENDATIONS**

The implications for practice flow from PAC research documenting practices that impact health outcomes and that are practical and cost-efficient to implement. These include emergency treatment of incomplete abortion and postabortion family planning.

**Emergency Treatment of Incomplete Abortion**

Medical (misoprostol) and surgical management (electric or manual vacuum aspiration) have been proven to offer safer options over sharp curettage for treatment of incomplete abortion. In countries where both misoprostol and vacuum aspiration are authorized, women should be informed of appropriate treatment options. Programs should ensure that both are available, staff are trained, and communities are informed, including CHWs. New protocols and training curricula for vacuum aspiration and medical evacuation, for example, from USAID and Ipas, incorporate the findings of recent research and will facilitate revised practices. These are important instruments for ensuring quality and competence of providers and programs.

**Postabortion Family Planning**

The voluntary informed choice of whether to use contraception must always be solely that of the woman. Asking the woman about her reproductive intentions and providing counseling for all methods (short-acting methods, LARCs, and permanent methods) will promote informed and voluntary choice for her; her health and that of her next pregnancy will benefit. Several studies have found an urgent need to improve content and quality of client counseling. The most important recommendations emerging from PAC studies are to offer all women family planning counseling and services before they leave the facility regardless of the method of uterine evacuation, and to complement counseling with written instructions on:

1. Her chosen contraceptive method—including how to use the method, what to expect, and how to resupply.
2. The rapid return of fertility after the abortion (within 2 to 3 weeks)
3. The signs and symptoms of postabortion complications (e.g., heavy bleeding, fever, increasing pain) that would need medical attention

These actions are endorsed by a joint consensus statement by the professional organizations of obstetricians/gynecologists, midwives, and nurses along with major donors.\textsuperscript{1}

The International Confederation of Midwives (ICM) recently included PAC and postabortion family planning as basic skills in their “Essential Competencies for Basic Midwifery Practices”.\textsuperscript{99} Postabortion family planning should likewise be incorporated into emergency obstetrical care (EmOC) indicators for managing incomplete abortion.\textsuperscript{100}

Health management information systems need to universally report postabortion contraceptive services as an essential measure of program and provider performance. Documentation should include the percentage of postabortion clients receiving contraceptives by method before leaving the facility and at return visits.

Documentation of method-specific uptake in the postabortion period needs a special focus when using misoprostol. Many of the misoprostol studies failed to report on this key component of PAC. LARCs deserve special emphasis, given that postabortion IUD insertion must be delayed until complete evacuation after misoprostol.

**POLICY, ADVOCACY, AND FUTURE RESEARCH**

Among the many topics for future research, two especially stand out. Cost studies are needed to better assess the potential benefits of misoprostol in comparison with both vacuum aspiration and sharp curettage, especially given that sharp curettage is still widely used. Better evaluation is needed on the effects of misoprostol on expanding the scope of practice for nurses and midwives, frequency of surgical procedures, use of lower-level facilities, and community engagement.

For women wanting to use the IUD postabortion, there may be benefits to offering immediate postabortion insertion with vacuum aspiration as an alternative to delayed insertion with misoprostol and the lost-to-follow-up that inherently occurs—an opportunity for research.

Advocacy for universal access to postabortion family planning is supported by health professional organizations, major donors, and maternal health networks.\textsuperscript{1} In parallel, this alliance strongly advocates universal access to postpartum family planning.\textsuperscript{36} Together these advocacy and policy positions create a foundation for universal access to family planning in the postpartum and post-abortion periods, with major implications for policy, practice, and training, both in-service and preservice.

**REFERENCES**


Peer Reviewed

Received: 2016 Feb 18; Accepted: 2016 May 24; First Published Online: 2016 Aug 25


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Improving the Quality of Postabortion Care Services in Togo Increased Uptake of Contraception

Stembile Mugore,¹ Ntapi Tchiguiri K Kassouta,² Boniface Sebikali,³ Laurel Lundstrom,⁴ Abdulmumin Saade⁵

The quality improvement approach applied at 5 facilities over about 1 year increased family planning counseling to postabortion clients from 31% to 91%. Of those counseled provision of a contraceptive method before discharge increased from 37% to 60%. Oral contraceptives remained the most popular method, but use of injectables and implants increased. The country-driven approach, which tended to use existing resources and minimal external support, has potential for sustainability and scale-up in Togo and application elsewhere.

See also article by Huber.

ABSTRACT

High-quality postabortion care (PAC) services that include family planning counseling and a full range of contraceptives at point of treatment for abortion complications have great potential to break the cycle of repeat unintended pregnancies and demand for abortions. We describe the first application of a systematic approach to quality improvement of PAC services in a West African country. This approach—IntraHealth International’s Optimizing Performance and Quality (OPQ) approach—was applied at 5 health care facilities in Togo starting in November 2014. A baseline assessment identified the following needs: reorganizing services to ensure that contraceptives are provided at point of treatment for abortion complications, before PAC clients are discharged; improving provider competencies in family planning services, including in providing long-acting reversible contraceptive implants and intrauterine devices; ensuring that contraceptive methods are available to all PAC clients free of charge; standardizing PAC registers and enhancing data collection and reporting systems; enhancing internal supervision systems at facilities and teamwork among PAC providers; and engaging PAC providers in community talks. Solutions devised and applied at the facilities during OPQ resulted in significant increases in contraceptive counseling and uptake among PAC clients: During the 5-month baseline period, 31% of PAC clients were counseled, while during the 13-month intervention period, 91% were counseled. Of all PAC clients counseled during the baseline period, 37% accepted a contraceptive, compared with 60% of those counseled during the intervention period. Oral contraceptive pills remained the most popular method during both periods, yet uptake of implants increased significantly during the intervention period—from 4% to 27% of those accepting contraceptives. This result demonstrates that the solutions applied maintained method choice while expanding access to underused long-acting reversible contraceptives. OPQ shows great potential for sustainability and scale in Togo and for application in similar contexts where the health system struggles to offer safe, high-quality, accessible PAC services.

INTRODUCTION

Countries in francophone West Africa have long struggled to offer women and girls safe, effective, and accessible reproductive health services, including the complete package of postabortion care (PAC) services. That package includes emergency treatment for abortion complications, family planning counseling and contraceptive methods, treatment and referral for sexually transmitted infections including HIV, and community awareness and mobilization to increase demand and acceptance of PAC services.¹ In a region where just 17% of married women of reproductive age are using any form of contraception,² more than 25% of pregnancies are unintended,³ and unsafe abortion services are all
It is widely acknowledged that availability and consistent, correct use of contraceptives to avoid pregnancy would curb maternal deaths—in part by minimizing the use of unsafe abortion services.

OPQ is a cyclical process for analyzing the performance of health workers, organizations, and systems and setting up interventions to build on strengths and successes.

Postabortion Care Services in Togo and Contraceptive Uptake

too common, not offering the complete package of PAC services places women and girls at undue risk of maternal death and morbidities.

In Africa in 2014, at least 9% (16,000) of maternal deaths were due to unsafe abortion. The last examination of regional statistics, in 2008, estimated that unsafe abortions account for approximately 12% of all maternal deaths in West Africa. It is widely acknowledged that availability and consistent, correct use of contraceptives to avoid pregnancy would curb maternal deaths—in part by minimizing the use of unsafe abortion services. An analysis of data from 172 countries found that in 1 year, family planning prevented an estimated 272,000 maternal deaths, achieving a 40% reduction in women dying of pregnancy-related causes. High-quality PAC services avert repeat unplanned pregnancies and the cycle of repeat abortions; they do this by providing counseling and a broad range of contraceptive services at the time and location of emergency treatment of abortion complications, and before the patient is discharged from the facility. Women who do not use contraception after an abortion are at risk of pregnancy almost immediately.

To generate evidence that would inform improvements to PAC services in West Africa, the Evidence to Action (E2A) project, funded by the United States Agency for International Development (USAID), assessed PAC services in Burkina Faso, Guinea, Senegal, and Togo from 2012 to 2013. Since 2008, the 4 countries had been participating in the Virtual Fostering Change Program to scale up best practices that would improve PAC services. The assessment’s findings were presented in 2013 at a regional meeting on PAC for francophone West African countries. Using recommendations from the assessment, country teams devised road maps for strengthening PAC services.

Since 2014, E2A, under the leadership of Togo’s Division of Family Health, has worked with the Togo country team to increase access to family planning services during PAC. This work has included expanding method choice to include long-acting reversible contraception—namely, implants and intrauterine devices (IUDs)—through a systematic approach to quality improvement at 5 health care facilities. This is the first time this systematic approach, IntraHealth International’s Optimizing Performance and Quality (OPQ) approach, has been applied and documented to improve access to high-quality PAC services in a West African country. The purpose of this article is to describe the quality improvement approach undertaken in Togo and to evaluate its effectiveness in improving contraceptive counseling and use at the health care facilities.

METHODS

Site Selection

The Division of Family Health within Togo’s Ministry of Health and E2A selected 5 health care facilities appropriate for applying quality improvement solutions. Selection was based on criteria that included the location of the facility, to ensure a balance in the Maritime and Plateaux regions; a substantial client load for PAC; the facility’s role as a referral site for PAC; and availability of a broad range of contraceptive methods and providers trained to offer PAC and family planning services. Two of the 5 facilities were part of E2A’s earlier assessment of PAC services in Togo.

Baseline Assessment

E2A and the Division of Family Health conducted a baseline assessment that included site visits and a review of the 5 facilities’ organization of services, clinical records, data use and reporting, supervision systems, referral systems, equipment and supply systems, cost of services to clients, and provider competencies. The baseline assessment identified shortcomings to be addressed through the quality improvement processes (Table). These shortcomings were shared with providers, used to inform action plans for improving the services, and reassessed by E2A and supervisors during on-site supportive supervision visits.

Intervention

Selecting a Quality Improvement Approach

The Division of Family Health selected IntraHealth International’s OPQ approach and tools for adaptation to the Togo health system. OPQ is a cyclical process for analyzing the performance of health workers, organizations, and systems and setting up solutions to build on strengths and successes. It fosters teamwork and ownership; applies a problem-solving process to address performance gaps; and develops skills in stakeholder engagement and leadership, connecting providers at facilities with support from national, regional, and district supervisors. The Togo health system has limited capacity in both number and skills of supervisors, and the Division of Family
# Access to and Quality of PAC Services in Togo: Baseline Assessment Findings, Quality Improvement Solutions, and Results of Applying the Solutions

<table>
<thead>
<tr>
<th>Baseline Findings</th>
<th>Quality Improvement Solutions</th>
<th>Results</th>
</tr>
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</table>
| **Organization of services hindered access and quality:**  
- Separation of treatment for abortion complications (in maternity ward), FP counseling (in postnatal ward), and provision of contraceptive methods (in FP unit located in the maternal and newborn health clinic), and no formal referral system from maternity ward to FP unit.  
- Clients had to purchase contraceptives from the facility pharmacy, open 8 a.m. to 5 p.m. on weekdays only, and return to the maternity or FP unit for contraceptive administration or instructions on how to use the method.  
- Clients had to wait for services if delivery room was full, which put clients treated for septic abortion at risk of infection. | **Facility-based quality improvement teams were oriented** on elements of successful PAC during OPQ training and supported, during on-site supervision, to reorganize services to ensure privacy during treatment and counseling, improve infection prevention practices, and ensure availability of contraceptives at point of treatment.  
**Facility managers were sensitized** to the importance of postabortion FP services, which mobilized their support for creating a separate space/room for PAC treatment and FP services to be used 24 hours per day, 7 days per week. | **All 5 clinics provide a full range of contraceptive options at point of treatment for abortion complications.**  
**At 3 health facilities, services were reorganized to provide FP counseling and methods around the clock at point of treatment for abortion complications, either in a separate room for PAC or in the delivery room, which is also used for emergency obstetric care.**  
**At 2 health facilities, due to lack of space, the FP providers who provide treatment and counseling also provide contraceptives in the units to which they are allocated** |
| **Very limited FP counseling was offered to postabortion clients, although a range of contraceptives were available at the facilities:**  
- At 3 facilities, no PAC clients were counseled or offered contraceptive methods.  
- At 2 facilities, counseling was largely reserved for the few clients who had a self-induced abortion, and contraceptive choice was limited to pills. | **Providers were trained to improve PAC competencies, establishing counseling for all PAC clients on the full range of contraceptives by addressing provider bias; stigma, particularly toward young unmarried clients; need for FP services regardless of whether abortion was induced or spontaneous; rights-based care; and eligibility criteria for contraceptives following emergency treatment of abortion complications.** | **Mix of contraceptive methods expanded to include injectables, implants, and IUDs.**  
**Significant increases in counseling and contraceptive uptake among all PAC clients.** |
| **Few providers were trained to offer long-acting implants or IUDs:**  
- Those trained had not had a refresher training for more than 5 years in either administration of long-acting methods or emergency treatment for abortion complications. | **Providers received competency-based trainings and follow-up support on MVA for treatment of abortion complications and provision of contraceptives, with a focus on updating contraceptive technology competencies to address barriers to contraceptive methods, counseling skills, and provision of IUDs and implants.** | **Improved provider competencies for MVA, implants, and IUDs.**  
**Significant increase in percentage of PAC clients choosing implants.** |
| **Four out of 5 health facilities did not have IUD kits readily available.**  
- Instead, providers assembled kits from other instruments in the theater and maternity ward. | **The national quality improvement team was mobilized to address procurement and logistics and conduct regular supportive supervision at facilities to monitor and procure stocks.** | **All facilities now have IUD kits.** |
### TABLE (continued).

<table>
<thead>
<tr>
<th>Baseline Findings</th>
<th>Quality Improvement Solutions</th>
<th>Results</th>
</tr>
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</table>
| Costs for services varied by location.  
* Treatment for abortion complications cost US $25–$30, including purchasing supplies; the range of costs of contraceptives were US$0.25–0.50 for 3 cycles of oral pills, US$0.25–$1.50 for injectables, and US$4–$6 for implants and IUDs.  
* High costs prohibited access to more expensive contraceptives. | * Discussions were held with facility managers and policy makers on cost of services.  
* At 4 facilities, a decision was made to offer free contraceptives to PAC clients by using contraceptive stocks from mobile units, which were already offered for free. (At 1 facility, clients still pay for contraceptives, which continues to impede access.)  
* The extent to which costs were a barrier to access and influenced method choice (e.g., clients opting for less expensive contraceptives) was documented in order to influence policy on free contraceptives for clients. | * Significant increase in uptake of contraceptive methods among PAC clients. |
| Health information systems were neither standardized nor effective:  
* PAC registers were not standardized.  
* Data quality was generally poor—with multiple data entry points where PAC clients received services, and clients who were referred to the FP unit for contraceptives or who returned for their 7-day check-ups were not tracked.  
* Data were not being used for decision making. | * PAC registers were standardized by adapting the register from the PAC Global Resource Center for use in Togo.  
* Providers were oriented to complete the registers during on-site supportive supervision.  
* Registers were reviewed for accuracy and consistency.  
* Monthly data were submitted to leadership—including facility managers and the Division of Family Health.  
* Continuous support for data collection and analysis was offered to providers, and progress was analyzed against the desired performance detailed in facility action plans. | * Facilities use a standardized PAC register that tracks PAC services, including family planning counseling and uptake of contraceptives by method.  
* There is a marked improvement in completeness of registers and quality of data.  
* Data are routinely analyzed and used to monitor progress toward set performance objectives and to update performance and quality improvement plans. |
| No links existed between facility-based providers and community health workers:  
* Facility-based providers were not involved in community efforts to create awareness of the dangers of unsafe abortion, importance of seeking services for bleeding during pregnancy, and merits of obtaining contraceptives during the postabortion period. | * Providers from all 5 facilities conduct talks, in communities, antenatal, postnatal, and child health clinics, focusing on the dangers of unsafe abortion and generating demand for FP services.  
* National quality improvement teams are charged with strengthening community–facility links. | * Links between communities and facilities are improved. |

Abbreviations: FP, family planning; IUD, intrauterine device; MVA, manual vacuum aspiration; OPC, Optimizing Performance and Quality; PAC, postabortion care.
Health selected OPQ because it can be implemented and guided by an internal team at a health care facility. The 5 facilities selected for the study had already appointed the in-charges from the maternity ward and family planning unit as internal supervisors charged with overseeing PAC services.

The Division of Family Health also formed a national quality improvement team to support the 5 health care facilities. The division national quality improvement team then developed a plan to improve access to quality family planning services during PAC, primarily by fostering teamwork and ownership of quality improvement solutions, strengthening provider competencies, addressing policy barriers, and improving how services are organized, supported, monitored, and analyzed.

Adapting the OPQ Methodology

To establish quality improvement measures at the 5 health care facilities, the OPQ methodology was adapted for PAC. Facilities were asked to assess their current performance (based on elements of successful postabortion family planning services as defined by a High Impact Practices in Family Planning brief13); define desired performance (based on the capacity of the service delivery system); identify performance gaps; and work on solutions to address the performance gaps using best practices for strengthening service delivery. Findings from the baseline assessment were integrated into OPQ to identify performance gaps, develop quality and performance objectives, and define standards against which the facilities could measure their performance.

Establishing a National Quality Improvement Team

The national quality improvement team included focal point persons for PAC, reproductive health, and maternal health. The team was trained to use OPQ tools and was tasked with documenting the quality improvement process, providing on-site and remote support to facility-based quality improvement teams, providing policies and guidelines on family planning and PAC, facilitating provider trainings, and creating links between community-based and facility-based services.

Establishing Facility-Based Quality Improvement Teams

The Division of Family Health’s plan required the in-charges of each facility’s family planning unit and maternity ward, as well as the district supervisors for family planning and reproductive health, to work together in facility-based quality improvement teams. The facility team provided leadership in conducting performance assessments, defining desired performance, identifying gaps, and implementing and monitoring quality improvement activities. The team was also tasked with obtaining resources from facility or district or regional managers to support implementation of quality improvement activities.

Training the Quality Improvement Teams, Phase I

The Division of Family Health, national and the facility-based quality improvement teams received a 4-day training on OPQ in November 2014. Facility teams defined their desired performance benchmarks and identified performance gaps, including their root causes. During participatory work, the teams used service data from the baseline assessment; elements of successful postabortion family planning services; and the “Ten Elements of Family Planning Success.”14 Using OPQ tools to explore factors that influence performance, the facility-based teams developed action plans that included solutions to close gaps and reach desired performance.

Training the PAC Service Providers, Phase II

The quality improvement action plans emphasized the need for more providers trained to provide both PAC and family planning, including long-acting contraceptive implants and IUDs. During a second training, in February–March 2015, 14 nurses and midwives from the 5 participating facilities attended a 2-week PAC training and contraceptive technology update that emphasized competency-based skills for providing implants and IUDs.
The training also addressed issues such as provider bias regarding clients, including youth; the need to provide counseling and family planning methods regardless of whether the abortion was induced or spontaneous; rights-based care; eligibility criteria for family planning methods following emergency treatment of abortion complications; and recordkeeping and data use. After guided live practice to meet required practicum objectives, in June–July 2015 the trainers conducted competency-based assessments on counseling, insertion of IUDs and implants, and manual vacuum aspiration (MVA) with 14 trained providers. These assessments resulted in certification of all participants.

**Supporting the Facility-Based Quality Improvement Teams**

In March and July 2015, the national quality improvement team and E2A offered on-site and virtual support to facility-based teams to address performance issues and barriers to implementation. Progress was assessed through observation of service delivery practices, review of registers, and interviews with providers. After each on-site support session, the national team debriefed facility managers and Division of Family Health leadership, providing feedback and soliciting needed support and resources (e.g., adequate supply of registers and contraceptives, cost waivers for PAC clients). The facility-based teams periodically updated regional and district health management teams on progress at the 5 facilities, advocating further support to improve PAC services. In August 2015, the facility-based quality improvement teams met to share preliminary results and further address performance challenges through peer-to-peer support.

**Data Collection and Analysis**

We adapted the postabortion register from the PAC Global Resources Guide (http://postabortion-care.org) for use in Togo. The 5 health care facilities used the standardized register to track client indicators, including age, type of abortion complication, and method of treatment, as well as whether client was counseled, a family planning method offered and accepted, and other reproductive health services provided. To measure progress over time, monthly data were compiled and submitted to facility managers and the Division of Family Health. The facility managers and head of the Division of Family Health provided feedback and support to each facility team using information from both quantitative and qualitative monitoring. During on-site monitoring and support visits, the national quality improvement team reviewed the PAC and family planning registers for accuracy and consistency, and data were collected on the referral of clients from the maternity ward to the family planning unit or, in rare cases, to mobile units for contraceptive services. The E2A technical advisors also observed services provided, supported data collection and analysis, and analyzed progress against desired performance detailed in the facilities’ action plans. The next section describes the results of the monitoring. We plan a further evaluation to inform development of scale-up plans.

**RESULTS**

**Primary Outcomes: Increased Counseling and Contraceptive Uptake**

Since November 2014, when quality improvement processes were first initiated at the 5 health care facilities, the proportion of PAC clients who were counseled on family planning and received a contraceptive steadily increased. Overall, 91% (749/823) of women who presented for PAC services during the intervention period were counseled, and of those counseled, 60% (448/749) received a contraceptive. During the baseline period, 31% (59/190) of PAC clients were counseled, and 37% (22/59) of those received a contraceptive method (Figure 1).

Over time, the facilities expanded the contraceptive methods that PAC clients could access to include implants, IUDs, injectables, oral contraceptives, pills, and condoms. Before the intervention, 81% of the PAC clients who accepted contraceptives chose oral pills, while 4% chose implants and 4% chose IUDs. The provider trainings resulted in increased client uptake of all methods, although oral pills (32%) remained the most popular method, followed by implants (27%). Only 1 facility had IUD kits readily assembled; at that facility, from November 2014 to November 2015, 9% of clients accepting contraceptives had IUDs inserted, slightly more than double the percentage (4%) during the baseline period (Figure 2).

**Other Positive Outcomes**

**Fostering Teamwork and Ownership**

Teamwork among the maternity and family planning service providers led to the removal of major
barriers to offering clients contraceptives at point of treatment for abortion complications, as well as increased client access to family planning. One of the facility managers remarked:

*I like that the maternity and family planning midwives are working together and addressing their own service delivery challenges. They come with suggestions to solve problems and not just present problems.*

**Strengthening Provider Competencies**

Having providers at all 5 facilities certified in PAC, including provision of long-acting clinical contraceptive implants and IUDs, has increased access to family planning services.

**Improving Messages to Clients**

All 5 facilities now organize talks an average of 2 to 3 times per week on PAC and healthy timing and spacing of pregnancy. These talks are directed to antenatal, postnatal, and immunization clients, including at the community level. PAC and family planning providers conduct the talks, which focus on the dangers of unsafe abortion and generating demand for family planning services.

**Improving Service Organization**

At each of the 5 health care facilities, services were reorganized so that clients could access family planning services at 3 different service delivery points: (1) point of treatment for abortion complications, (2) in the family planning unit, and (3) in a mobile unit. The majority of clients

### FIGURE 1. Percentage of PAC Clients Who Received Counseling and Percentage of Those Counseled Who Accepted a Contraceptive Method, Pre-Intervention (5 Months’ Duration) and Post-Intervention (13 Months’ Duration), 2014–2015

<table>
<thead>
<tr>
<th></th>
<th>Total Counseled</th>
<th>Total Accepted Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(N=190)</td>
<td>31%</td>
<td>37%</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(N=823)</td>
<td>91%</td>
<td>60%</td>
</tr>
<tr>
<td>Pre-Intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(N=59)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post-Intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(N=749)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: PAC, postabortion care.

Note: The pre-intervention data include data from only 2 facilities that were offering contraceptive methods at the time, whereas the post-intervention data include data from all 5 facilities that began offering postabortion family planning services after the Optimizing Performance and Quality training.
received their contraceptive methods at point of treatment, with the family planning unit the next most common delivery point. Only on rare occasions did clients receive contraceptives from mobile units.

**Point of treatment:** In 3 facilities, contraceptives are now available 24 hours per day, 7 days per week at point of treatment, either in a separate room for PAC or in the delivery room. The quality improvement teams identified a room for PAC service provision and advocated for approval and support to equip these rooms to manage PAC clients and other obstetric emergencies. One of the providers stated that “for us in our facility, maternity and family planning services are one, we no longer see them as separate.”

**Family planning unit:** In 2 facilities, due to lack of space, the providers who treat abortion complications in the maternity ward take clients to the family planning unit for counseling and contraceptives. Because the family planning unit operates only on weekdays, from 8 a.m. to 5 p.m., clients admitted for abortion complications on weekday nights are treated and then discharged the next morning so that they can access contraceptive methods before they go. On the weekends, a small stock of contraceptives is kept in the maternity ward for PAC clients.

**Mobile unit:** Mobile units in Togo provide free contraceptives, and 4 of the facilities operate a mobile unit once per month at the facility’s maternal and child health clinic, or at the regional or district health office near the facility. At these 4 facilities, clients are occasionally referred to the mobile unit for long-acting IUDs and implants. However, the main contribution of the mobile

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**FIGURE 2.** Percentage of Counseled PAC Clients Who Accepted a Contraceptive Method by Type of Method, Pre-Intervention (5 Months’ Duration) and Post-Intervention (13 Months’ Duration), 2014–2015

<table>
<thead>
<tr>
<th>Type of Contraception</th>
<th>Pre-Intervention (N=22)</th>
<th>Post-Intervention (N=443)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCPs</td>
<td>81%</td>
<td>32%</td>
</tr>
<tr>
<td>Injectables</td>
<td>25%</td>
<td>4%</td>
</tr>
<tr>
<td>Implants</td>
<td>27%</td>
<td>4%</td>
</tr>
<tr>
<td>IUDs</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Condoms</td>
<td>0%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Abbreviations: IUD, intrauterine device; OCPs, oral contraceptive pills; PAC, postabortion care.
units to the quality improvement solution is in transferring contraceptive stocks to these 4 facilities so that their PAC clients can receive contraceptives for free.

**Improving Recordkeeping and Data Use**

Standardized PAC registers in all facilities, with a trained person in charge of recordkeeping, has improved data collection and quality. Data collection now includes recording clients who receive contraceptive methods during 7-day check-ups. When a client is referred to the family planning unit for contraceptives, the family planning providers record whether the client has been referred from PAC services, and the PAC providers update the PAC registers with the contraceptive method provided to the client. A review of monthly service data showed that over 90% of the PAC and family planning registers had complete information on each client, and monthly data summaries were consistent with the registers. However, use of the data at district, regional, and national levels is limited.

**Challenges Remaining**

**Strengthening Supportive Supervision at Facilities and by District Supervisors**

Although the Division of Family Health provided leadership and guidance throughout the quality improvement processes, the division’s capacity to support health care facilities is limited. Continuing challenges include a shortage of staff with supportive supervision skills and their tendency to work in silos—for example, the PAC focal point person does not always involve the focal point persons for family planning and reproductive health.

**Addressing Cost of Contraceptives**

In the 4 facilities that offer mobile family planning services, district managers decided to use contraceptives from the mobile units during PAC services so that they could be provided for free. In the remaining facility participating in the intervention, clients pay for contraceptives, and cost was found to impede some clients’ acceptance and choice of methods.

**Addressing Policies That Inhibit Access to Services**

During this intervention, 4 of the health care facilities intentionally chose to use the contraceptives provided by their mobile units to show that more clients will use contraceptives when they are available for free. Discussions about how the government can ensure free contraceptives at health care facilities are ongoing. A positive outcome in terms of standards and guidelines is that the Division of Family Health adopted the training materials used for the intervention as Togo’s national PAC training curriculum.

**DISCUSSION**

PAC clients are an underserved, vulnerable group of women. Country ownership of quality improvement and a country-led OPQ approach had a positive effect on these women’s access to family planning counseling and choice of contraceptive methods. Our results show that applying an evidence-based, participatory approach to quality improvement has the potential to increase the accessibility and quality of services in a short time. The improvements to service delivery, which were largely driven by managers and providers at the 5 health care facilities and tended to use existing resources, required minimal external support. The feasibility of these improvements encouraged government commitment. Involving both national government and regional and district health officials from the beginning ensured their buy-in and investment in improving the quality of services and honoring PAC clients’ right to high-quality family planning services, including a full range of contraceptive methods. This approach could be adapted and applied in similar contexts, particularly in other West African countries, where PAC programs face similar challenges.

The facilities’ quality improvement solutions led to an expanded mix of contraceptive methods offered to PAC clients and to significant increases in contraceptive uptake. However, clients’ most commonly chosen method—oral contraceptive pills—remained the same during the baseline and intervention periods. This may be due to the fact that when midwives have a heavy workload and the family planning unit is not operating, oral contraceptive pills are the easiest method to provide. Togo’s Ministry of Health is considering a task-sharing strategy that would enable delivery assistants to provide implants. This is a strategy that implementing partners who support PAC and family planning in Togo should monitor closely to determine whether it makes a significant difference in which contraceptives women choose.

Many abortion clients are young people. Despite this fact, many service providers remain...
Many service providers remain averse to encouraging young people to space or delay pregnancy, particularly if a young client has just experienced her first pregnancy. E2A is currently in the process of adding a youth-friendly PAC component to Togo’s national training curriculum. The revised curriculum will address provider bias and stigma to improve young people’s access to quality, client-focused PAC services that offer the full contraceptive method mix, including long-acting contraceptive implants and IUDs. The Government of Togo will need to remain focused on ensuring that young people have access to family planning services during PAC in order to honor their reproductive rights and choices and to truly have an impact on the health of women and girls in the country. During this study’s baseline assessment, stock-outs of contraceptive methods were not identified as an issue that needed to be addressed through the quality improvement solutions. However, 4 of the 5 facilities had limited capacity to offer full method choice because they did not have IUD kits readily assembled. Additionally, only 2 facilities had functional MVA kits. To manage incomplete abortion, providers who did not have an MVA kit used manual digital removal of retained products from conception or referred clients to doctors for dilation and curettage. After training additional providers in the 5 facilities and equipping each facility with, on average, 5 MVA kits provided by Ipas, MVA became more common than manual digital removal. To ensure quality care going forward, it will be essential for all facilities that offer PAC to have the necessary equipment and commodities available at time of service.

CONCLUSION

The quality improvement approach described in this article involved national stakeholders, regional and district health officials, and health facility managers. It was found to enable joint problem solving, and has given Togo’s public health system the impetus to sustain and scale up high-quality PAC services. The Division of Family Health has expressed a commitment to continue supporting the quality improvement teams and is now looking at how to apply lessons learned to scale up OPQ to other health care facilities and institutionalize the approach and relevant tools in routine supervision. Due to limited capacity, the Division of Family Health will require continued support from willing partners and bilateral projects to scale up OPQ for PAC and to apply OPQ to improve the quality of family planning services. It is also likely that the package of solutions will need to be simplified, given the division’s limited skills in training providers and supervisors on OPQ and providing on-site support. The division is also challenged by resource limitations, a shortage of midwives, and inadequate infrastructure and equipment for reorganization of services. Thus, sustaining the positive changes realized through OPQ and expanding the solutions to additional health care facilities in Togo will require continued ownership, support, and political will, through efforts including the following:

- Building the capacity of PAC providers, including in application of OPQ
- Providing on-site supportive supervision, especially as staff turn over from their current roles
- Training new quality improvement teams as staff move or retire
- Addressing both the cost of PAC services, including contraceptives, and commodity security through shifts in policy

Acknowledgments: This article and the work it describes was made possible through support provided by the Office of Population and Reproductive Health, Bureau for Global Health, U.S. Agency for International Development, under the terms of Award No. AID-OAA-A-11-00024. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

Competing Interests: None declared.

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Peer Reviewed

Received: 2016 Jun 27; Accepted: 2016 Aug 19


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Use of the World Health Organization’s Medical Eligibility Criteria for Contraceptive Use Guidance in sub-Saharan African Countries: A Cross-Sectional Study

Melissa J Chen, a Mary E Gaffield, b James Kiarie b

The revised 2015 World Health Organization guidance expanded the recommended contraceptive options available to breastfeeding women during the early postpartum period to include progestogen-only pills and implants, but a substantial number of surveyed country representatives indicated that as yet their national policies did not allow such women to use these methods at that time. Countries may benefit from support to incorporate MEC guidance into national service delivery guidelines.

ABSTRACT
Given recent updates to the postpartum contraception recommendations in the fifth edition of the Medical Eligibility Criteria for Contraceptive Use (MEC), published by the World Health Organization (WHO), the purpose of this qualitative study was to assess the extent to which national family planning policies in sub-Saharan African countries are in agreement with the WHO MEC, particularly with regard to postpartum contraceptive use. WHO headquarters sent questionnaires to country-level focal points to complete with their Ministry of Health counterparts. Between February and May 2016, 23 of 32 (72%) surveys were completed. All respondents reported that their countries had used the MEC document in the past, with most reporting that they had used the guidance as a reference (n = 20, 87%), for training purposes (n = 19, 83%), to change clinical practices (n = 17, 74%), and to develop national policies (n = 16, 70%). While many respondents (16, 70%) indicated their countries already include immediate postpartum intrauterine device insertion among breastfeeding women in their family planning policies, few reported currently allowing use of progestogen-only pills (n = 8, 35%) or implants (n = 8, 35%) during the immediate postpartum period (i.e., less than 48 hours after delivery) for breastfeeding women. A higher percentage of respondents indicated their countries allowed breastfeeding women the option of progestogen-only pills (n = 16, 70%) and implants (n = 13, 57%) between 48 hours and 6 weeks postpartum. Findings from this baseline assessment suggest that many countries may benefit from training and policy formulation support to adapt both new WHO MEC updates as well as existing recommendations from previous MEC revisions into national family planning guidelines.

INTRODUCTION

High unmet need for postpartum contraception exists globally despite renewed focus on postpartum family planning. Lactating women experience contraceptive effects while breastfeeding; however, this protection remains only when the woman is exclusively breastfeeding, amenorrheic, and within 6 months postpartum. Up to 62% of all women who gave birth in the last year have an unmet need for contraception—that is, they do not want to become pregnant within the next 2 years but are not using contraception—according to survey data from 57 countries. The highest rates are among women who live in West and Central Africa (75%) and East and Southern Africa (65%). A greater understanding of the barriers to postpartum contraception is needed to address these health care gaps.

The World Health Organization (WHO) published the first edition of the Medical Eligibility Criteria for Contraceptive Use (MEC) in 1996 to provide evidence-based guidance on which clients can safely use various contraceptive methods. WHO has updated this guidance periodically based on the latest scientific evidence.
and is currently in its fifth edition (published in 2015). The goal of the guidance is to improve the quality of family planning care and expand access to contraceptive use worldwide. In the guidance document, an eligibility category from 1 to 4 is assigned to a health condition or characteristic to indicate the degree of restriction for use of a particular method in the presence of that specific health condition or characteristic (Table). The target audience of the MEC includes policy makers and family planning program managers, and the intention is for the MEC document to serve as a reference for each individual country’s adaptation into national service delivery guidelines and policies.

In this article, we focus on the recent MEC changes related to contraceptive eligibility for postpartum women, which include:

1. A change from WHO MEC category 3 (use of the method not usually recommended unless other more appropriate methods are not available or not acceptable) to category 2 (generally use the method) for use of progestogen-only pills (POPs) and implants among breastfeeding women who are less than 6 weeks postpartum
2. A change from category 3 to category 2 for use of the levonorgestrel-releasing intrauterine device (IUD) among breastfeeding women who are less than 48 hours postpartum
3. Additional risk stratification for venous thromboembolism for use of combined hormonal contraceptives (CHCs) among non-breastfeeding women based on time since delivery: those who are less than 21 days postpartum (category 4, method not to be used) and those who are 21 days postpartum or more (category 3)

### TABLE. World Health Organization Medical Eligibility Criteria for Contraceptive Use Categories for Contraceptive Eligibility

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A condition for which there is no restriction for the use of the contraceptive method</td>
<td>Use method in any circumstances</td>
</tr>
<tr>
<td>2</td>
<td>A condition where the advantages of using the method generally outweigh the theoretical or proven risks</td>
<td>Generally use the method</td>
</tr>
<tr>
<td>3</td>
<td>A condition where the theoretical or proven risks usually outweigh the advantages of using the method</td>
<td>Use of method not usually recommended unless other more appropriate methods are not available or not acceptable</td>
</tr>
<tr>
<td>4</td>
<td>A condition which represents an unacceptable health risk if the contraceptive method is used</td>
<td>Method not to be used</td>
</tr>
</tbody>
</table>

The updated 2015 WHO Medical Eligibility Criteria expanded the contraceptive options for postpartum women, including breastfeeding mothers, to encompass POPs, implants, and the levonorgestrel-releasing IUD.
In early 2016, we conducted a qualitative study to assess the extent to which national family planning policies in sub-Saharan Africa are in agreement with the 2015 WHO MEC. In this article, we focus particularly on the agreement between the national policies and the MEC regarding the use of various contraceptive methods during the postpartum period and focus specifically on African countries because of the particularly high unmet need among postpartum women identified in surveys.

METHODS

Between February and May 2016, WHO headquarters sent baseline evaluation questionnaires (either in English or French, depending on the country) to 32 focal points in WHO country offices within sub-Saharan Africa (see supplementary material for English version of the questionnaire). The surveys asked about the countries’ family planning policies in terms of which contraceptive methods can be provided to women who are (1) postpartum and breastfeeding, (2) younger than 20 years old, (3) nulliparous, or (4) living with HIV infection and taking antiretroviral therapy. In addition, the questionnaire included items regarding emergency contraception policies and risky sexual behavior. The country-level focal points were asked to complete the survey in conjunction with their national Ministry of Health counterparts to increase accuracy of reporting.

We made 3 e-mail requests to complete the surveys over a period of 12 weeks. The WHO Ethics Review Committee considered this quality assessment study, with data reported in the aggregate and not by individual country, exempt from full review.

RESULTS

Of the 32 country-level focal points, 23 completed the survey (72% response rate). Responding countries are listed in the Box. While most respondents (n = 19, 83%) reported that their countries have used the MEC document more than 2 times in the past, 4 (17%) respondents reported that their countries used the MEC document only 1 to 2 times. The government has the responsibility of distributing family planning guidance in most countries (n = 14, 61%); in other cases, WHO country offices or NGOs perform distribution. Respondents indicated that the MEC is primarily used in their respective countries as a reference (n = 20, 87%), for training purposes (n = 19, 83%), to change clinical practices (n = 17, 74%), and to develop national policies (n = 16, 70%).

With regard to the immediate postpartum period (i.e., less than 48 hours after delivery), 16 (70%) countries include IUD insertion as a contraceptive option. In contrast, few countries currently incorporate POPs (n = 8, 35%) or implants (n = 8, 35%) in their guidelines as methods eligible for breastfeeding women during the immediate postpartum period.

Among breastfeeding women who are between 48 hours and 6 weeks postpartum, respondents indicated that POP use among breastfeeding women between 48 hours and 6 weeks postpartum women identified in surveys.

70% of respondents indicated their countries allowed POP use among breastfeeding women between 48 hours and 6 weeks postpartum and 57% allowed implant use.

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Among breastfeeding women who are between 48 hours and 6 weeks postpartum, respondents indicated that POP and implant use are included in the national policies of 16 (70%) and 13 (57%) of their countries, respectively. Ten (44%) respondents indicated their countries also allow depot medroxyprogesterone (DMPA) and norethindrone enanthate (NET-EN) injections for breastfeeding

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women who are less than 6 weeks postpartum, which has a category 3 classification in the MEC.

Among breastfeeding women who are greater than 6 weeks postpartum, 6 (26%) countries allow CHC use. The MEC classifies breastfeeding women who are between 6 weeks and 6 months postpartum as category 3 for use of CHCs, whereas breastfeeding women who are 6 months or more postpartum are classified as category 2. All other methods (i.e., POPs, DMPA, NET-EN, implants, and the IUD) are included in national policies, as recommended in the MEC.

DISCUSSION

This qualitative assessment reveals that there is a need to improve awareness in sub-Saharan African countries that POPs and implants can be used during the first 6 weeks postpartum to expand contraceptive options for breastfeeding women. Evidence suggests that early initiation of POPs or implants does not adversely affect breastfeeding performance, maternal health, or infant growth parameters; review of this evidence resulted in the change from category 3 to category 2 in the updated WHO MEC guidance.4

In addition, while many sub-Saharan African countries include immediate postpartum IUD insertion in national family planning guidelines, our findings indicate that this practice has not been universally adopted by all countries despite the introduction of this recommendation in the fourth (2009) edition of the WHO MEC.6 Although the priority for WHO and implementing partners is to support countries in adapting the most recent WHO MEC updates into national family planning guidelines, some countries may also benefit from technical review of current policies to incorporate existing recommendations from previous WHO MEC revisions.

Our findings also revealed that some country guidelines are more lenient than the WHO MEC recommendations for certain methods and conditions. For example, the WHO MEC recommendations remain unchanged for DMPA and NET-EN use among breastfeeding women who are less than 6 weeks postpartum (category 3) due to theoretical concern of neonatal exposure to steroid hormones. However, almost half of the survey respondents reported the inclusion of DMPA or NET-EN as a contraceptive option for this group of women in their national guidelines. It is possible that individual countries consider the benefits of contraceptive access outweigh the potential harm, thus leading to this difference in national policies from WHO guidance. Similarly, some countries reported allowing use of CHCs among breastfeeding women after 6 weeks postpartum, whereas the WHO MEC recommends allowing use of the method among this group of women after 6 months postpartum. These countries may consider that access to CHCs outweighs the potential risks of shortened breastfeeding duration due to decreased milk supply with estrogen exposure. Family planning guidelines in other countries, such as the United States7 and United Kingdom,8 are also more lenient on these issues, allowing for earlier use of DMPA and NET-EN injectables as well as CHCs among breastfeeding women. These differences reinforce WHO’s intention that the MEC guidance serve as a framework for each country to adapt in accordance with local needs, values, preferences, and resources.

More than 50 national programs across the world have adopted the WHO MEC guidance.9 In addition to updating and distributing the MEC recommendations, WHO and implementing partners can provide technical assistance to countries who request training in the MEC guidance. Findings from this study provide an initial assessment of areas for further education among country policy makers, program managers, and service providers. Many factors contribute to contraception initiation and continuation, especially in the postpartum setting, but having comprehensive, up-to-date, and evidence-based policies is the first step for countries to improve access to postpartum contraception and reduce unmet need for their citizens.

Limitations

This study was based on a self-reported survey of national policies, and not an independent review of the policies, which may lead to reporting bias. In addition, the country-level focal points were instructed to complete the survey in conjunction with their Ministry of Health counterparts; however, some surveys were completed either by the Ministry of Health personnel or WHO country-level focal points and not by both parties together, potentially affecting the accuracy of the responses. Despite follow-up requests from WHO headquarters, 9 (28%) country-level focal points did not complete the survey. A non-response bias may be present if some countries did not respond to the survey because attention is being shifted away from family planning services. Additionally, the survey was available in French and English, and previous MEC.
and only one of two invited Lusophone (Portuguese-speaking) countries participated.

**CONCLUSION**

This qualitative assessment revealed a need to support country policy makers on incorporating the updated WHO MEC recommendations into national guidelines, particularly with regard to expanding the contraceptive options available to breastfeeding women during the early postpartum period. Future assessments can explore reasons for the discrepancies between MEC guidelines and national family planning policies to guide efforts in training and policy formation.

**Acknowledgments:** The authors express gratitude to the World Health Organization’s Intercountry Support Team leaders and the individual country focal points for their assistance in providing reproductive health policy data.

**Competing Interests:** None declared.

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