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Cover caption: A nurse discusses CycleBeads and other family planning methods with a client at Nyamata Hospital in Rwanda. © 2018/Bobby Neptune

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Alexander W. Peters, Lina Roa, Emile Rwamasirabo, Emmanuel Ameh, Mpoki M. Ulisubisya, Lubna Samad, Emmanuel M. Makasa, John G. Meara

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<https://doi.org/10.9745/GHSP-D-19-00314>

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Meghna Nandi, Jillian Moore, Marcela Colom, Andrea del Rosario Garcia Quezada, Anita Chary, Kirsten Austad

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Julie Hubbard, Khumbo Phiri, Corrina Moucheraud, Kaitlyn McBride, Ashley Bardon, Kelvin Balakasi, Eric Lungu, Kathryn Dovel, Gift Kakwesa, Risa M. Hoffman

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Daniel Kahn, Kara-Lee Pool, Linna Phiri, Florence Chibwana, Kristin Schwab, Levison Longwe, Ben Allan Banda, Khumbo Gama, Mayamiko Chimombo, Chifundo Chipungu, Jonathan Grotts, Alan Schooley, Risa M. Hoffman

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Dale A. Barnhart, Donna Spiegelman, Corwin M. Zigler, Nabihah Kara, Megan Marx Delaney, Tapan Kalita, Pinki Maji, Lisa R. Hirschhorn, Katherine E. A. Semrau

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Jillian Pintye, Zoe Rogers, John Kinuthia, Kenneth K. Mugwanya, Felix Abuna, Harison Lagat, Joseph Sila, Valarie Kemunto, Jared M. Baeten, Grace John-Stewart, Jennifer A. Unger, for the PrYA Program Team

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Annabel Erulkar, Girmay Medhin, Eva Weissman, Gisele Kabore, Julien Ouedraogo

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<https://doi.org/10.9745/GHSP-D-19-00132>

Unmet Need for Family Planning and Experience of Unintended Pregnancy Among Female Sex Workers in Urban Cameroon: Results From a National Cross-Sectional Study

Female sex workers (FSWs) in Cameroon have unmet need for effective contraception, and experience of unintended pregnancy and pregnancy termination is common. Reducing barriers to accessing high-quality, voluntary family planning services in FSW-focused community services is a key strategy to promote client-centered care, promote informed choice, reduce unintended pregnancies, and improve quality of life for FSWs.

Anna L. Bowring, Sheree Schwartz, Carrie Lyons, Amrita Rao, Oluwasolape Olawore, Iliassou Mfochive Njindam, Jimmy Nzau, Ghislaine Foud, Guy H. Fako, Gnilane Turpin, Daniel Levitt, Sandra Georges, Ubald Tamoufe, Serge C. Billong, Oudou Njoya, Anne-Cécile Zoung-Kanyi, Stefan Baral

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Sruthi Mahadevan, Elena T. Broaddus-Shea

Glob Health Sci Pract. 2020;8(1):100–113

<https://doi.org/10.9745/GHSP-D-19-00340>

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Pilot introductions of the Standard Days Method (SDM) of family planning demonstrated its potential to meet unmet contraceptive needs in key populations, strengthen male involvement, and increase overall contraceptive uptake. Few countries had implemented national scale-up due to barriers, such as competing resource priorities and uneven stakeholder engagement. Demand-side user barriers, including insufficient fertility awareness knowledge, were also constraints. Policy makers should determine the SDM's added value to the contraceptive method mix and identify potential barriers to its implementation.

Julianne Weis, Mario Festin

Glob Health Sci Pract. 2020;8(1):114–124
<https://doi.org/10.9745/GHSP-D-19-00287>

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Patience A. Afulani, Laura Buback, Brienne McNally, Selemani Mbuyita, Mary Mwanyika-Sando, Emily Peca

Glob Health Sci Pract. 2020;8(1):125–135
<https://doi.org/10.9745/GHSP-D-19-00323>

COMMENTARY

National Surgical, Obstetric, and Anesthesia Plans Supporting the Vision of Universal Health Coverage

Alexander W. Peters,^{a,b,c} Lina Roa,^{b,c,d} Emile Rwamasirabo,^e Emmanuel Ameh,^f Mpoki M. Ulisubisya,^g Lubna Samad,^h Emmanuel M. Makasa,^{i,j} John G. Meara^{b,c}

Developing a national surgical, obstetric, and anesthesia plan is an important first step for countries to strengthen their surgical systems and improve surgical care. Barriers to successful implementation of these plans include data collection, scalability, and financing, yet surgical system strengthening efforts are gaining momentum in achieving universal access to emergency and essential surgical care.

■ BACKGROUND

In 2018, 40 years after the Declaration of Alma-Ata, the global community renewed its commitment to universal health coverage (UHC) and reemphasized the importance of primary health care in health systems strengthening (HSS) in the Declaration of Astana.^{1,2} If we are to achieve UHC, several important synergistic health services must be considered beyond only primary health care. In particular, access to surgical, anesthesia, and obstetric services is essential to enhancing physical, mental, and social well-being.

Despite calls for surgery and health for all from World Health Organization (WHO) leaders as far back as 1980,³ surgical, obstetric, and anesthesia (SOA) care has often been deemed too expensive and complex to deliver at scale⁴ and has, until recently, remained largely neglected in global surgery policy.⁵ To address this gap, a surge of research, advocacy, policy, and implementation efforts to expand access to these services have been taking root in several low- and middle-income countries.

In 2015, the *Lancet* Commission on Global Surgery published a report that approximately 70% of the world still lacked access to safe, affordable emergency and essential SOA care when needed—a shortfall disproportionately affecting those living in low- and middle-income countries. The Commission proposed 6 indicators to measure surgical systems (Table 1).^{4,6–8}

In the same year, the World Health Assembly passed a resolution (WHA 68.15) that declared emergency and essential surgical and anesthesia care as essential components of UHC,⁹ and the World Bank Group described 44 cost-effective surgical interventions in *Disease Control Priorities*.¹⁰ SOA care has become increasingly viewed as integral to achieving the United Nations Sustainable Development Goals,¹¹ and global leaders have begun to call for greater investments in surgical care.¹²

This article reviews the health policy roadmaps that 5 countries have developed since WHA 68.15 as they strive to include equitable access to SOA care in their health programs.

■ NATIONAL SURGICAL, OBSTETRICS, AND ANESTHESIA PLAN FRAMEWORK

Since 2015, several countries in Africa and Asia have begun to integrate national surgical, obstetric, and anesthesia plans (NSOAPs) into their country's national health strategic plans. These innovative, context-specific NSOAPs are meant to fit within the country's broader HSS initiatives. Their ultimate goal is to guide countries or regions to identify and close gaps as they move toward achieving, by 2030, the core surgical benchmarks necessary to deliver UHC and fulfill their commitments to WHA 68.15.

The NSOAP development process is founded on 6 core domains adapted from the World Health Organization (WHO) HSS Building Blocks.¹³ The process

^a Department of Surgery, Weill Cornell Medical College, New York, NY, USA.

^b Program in Global Surgery and Social Change, Department of Global Health and Social Medicine, Harvard Medical School, Boston, MA, USA.

^c Department of Plastic and Oral Surgery, Boston Children's Hospital, Boston, MA, USA.

^d Department of Obstetrics and Gynecology, University of Alberta, Edmonton, Alberta, Canada.

^e Department of Surgery, King Faisal Hospital, Kigali, Rwanda.

^f Department of Surgery, National Hospital, Abuja, Nigeria.

^g Ministry of Health Community Development Gender Elderly and Children, Dar es Salaam, Tanzania.

^h Center for Essential Surgical and Acute Care, Indus Health Network, Karachi, Pakistan.

ⁱ Public Service Management Division Cabinet Office, Office of the President, Lusaka, Zambia.

^j Wits Centre of Surgical Care for Primary Health & Sustainable Development, School of Medicine, Faculty of Health Sciences, University of Witwatersrand, Johannesburg, South Africa.

Correspondence to Alexander Peters (awp9003@nyp.org).

TABLE 1. *Lancet* Commission on Global Surgery Core Key Performance Indicators for Monitoring Surgical Systems

Indicator	<i>Lancet</i> Commission on Global Surgery Definition	<i>Lancet</i> Commission on Global Surgery Target by 2030	Included in the World Bank Group's World Development Indicators	Included in the World Bank Group's 2018 Atlas of Sustainable Development Goals	Included in the World Health Organization's Core 100 Indicators
Access to timely essential surgery	Proportion of the population that can access a facility within 2 hours that can do cesarean delivery, laparotomy, and open fracture repairs	A minimum of 80% coverage of essential surgical and anesthesia services per country	-	-	Yes
Specialist surgical workforce density	Number of specialist surgical, anesthetic, and obstetric physicians working, per 100,000 population	100% of countries with at least 20 surgical, anesthetic, and obstetric physicians per 100,000 population	Yes	Yes	Yes
Number of surgical procedures performed	Procedures done in an operating theatre, per 100,000 population per year	80% of countries by 2020 and 100% of countries by 2030 tracking surgical volume; a minimum of 5,000 procedures per 100,000 population	Yes	-	Yes
Perioperative mortality rate	All-cause death rate before discharge in patients who have undergone a procedure in an operating theater, divided by the total number of procedures	80% of countries by 2020 and 100% of countries by 2030 tracking perioperative mortality; in 2020, assess global data and set national targets for 2030	-	-	Yes
Protection against impoverishing expenditure for surgical care	Proportion of households protected against impoverishment from direct out-of-pocket payments for surgical and anesthesia care	100% protection against impoverishment from out-of-pocket payments for surgical and anesthesia care	Yes	-	Yes
Protection against catastrophic expenditure for surgical care	Proportion of households protected against catastrophic expenditure from direct out-of-pocket payments for surgical and anesthesia care	100% protection against catastrophic expenditure from out-of-pocket payments for surgical and anesthesia care	Yes	-	Yes

replaces access to essential medicines with surgical infrastructure and places the medicines required for surgical care (e.g., anesthetic agents) within care delivery itself (Figure 1).¹⁴ These design parallels have allowed NSOAP development processes to complement other HSS initiatives and fit within broader WHO policy frameworks.

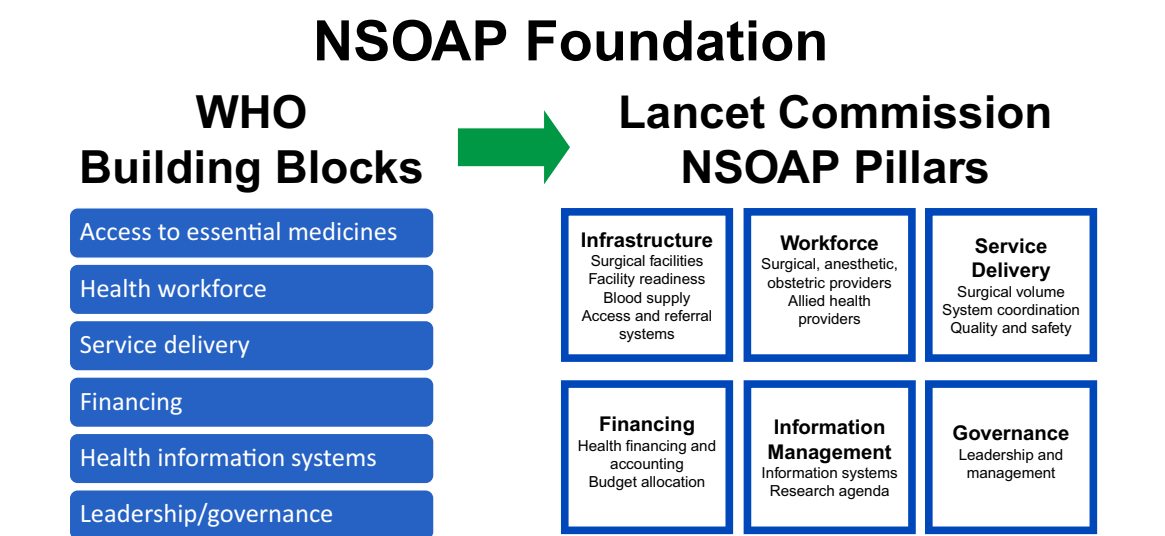
To facilitate adoption, the development process follows a flexible 8-step theoretical framework (Figure 2) to drive health policy reforms that will improve access to surgical care while engaging all key stakeholders.¹⁵⁻¹⁷ This framework begins from within or by obtaining support from the ministry of health and follows specific steps that allow for baseline assessments, stakeholder engagement, policy formulation, monitoring and evaluation, costing, governance, and implementation.¹⁵ In Tanzania,

where NSOAP implementation is underway, the planning process took approximately 17 months (Figure 3). The core output of the NSOAP framework is a context-specific, baselined, costed, consensus plan with clear monitoring, evaluation, and governance for investing in and implementing surgical scale-up in any province, country, or region.

■ NOTABLE NSOAP DEVELOPMENT PROCESSES

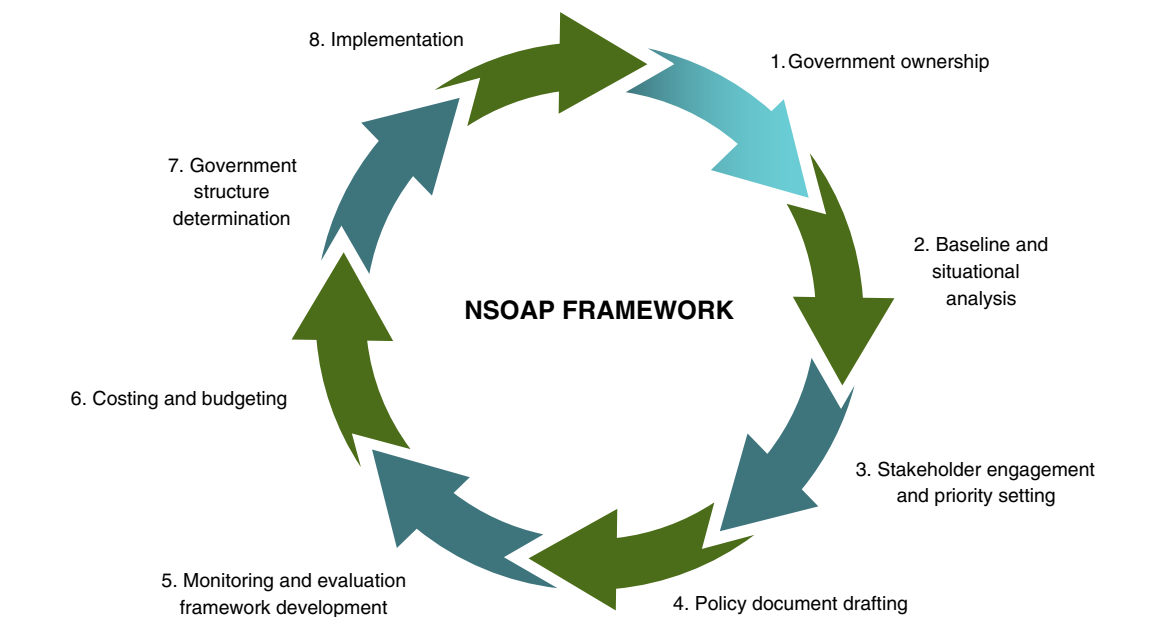
Around the world, countries have started developing NSOAPs to sustainably expand access to SOA care. We describe 5 examples with which the authors have been closely involved and that demonstrate country-led processes that have

FIGURE 1. Adapting WHO Building Blocks for NSOAPs¹⁴



Abbreviations: NSOAP, National Surgical, Obstetric, and Anesthesia Plan; WHO, World Health Organization.

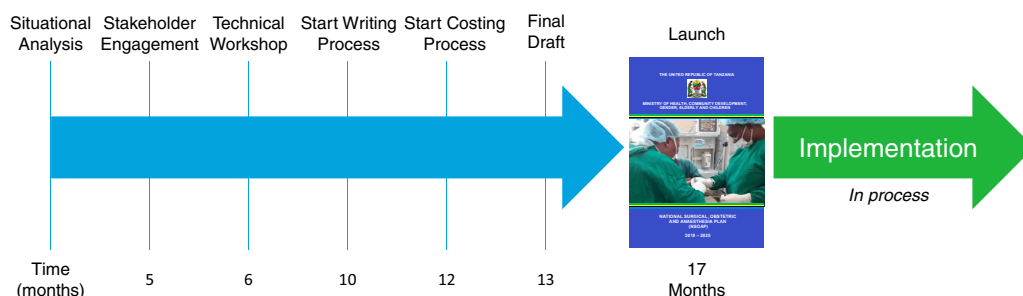
FIGURE 2. NSOAP Creation Theoretical Framework (Adapted^{11–13})



Abbreviation: NSOAP, National Surgical, Obstetric, and Anesthesia Plan.

focused on addressing health system gaps, integrating surgical policies into broader national policies, and including and consulting all relevant stakeholders in the planning process. However, it

must be noted that this list is not exhaustive. Important country and regional-level efforts are taking place worldwide, including in Ethiopia, Madagascar, and Vietnam.

FIGURE 3. Tanzania NSOAP Development Process Timeline

Abbreviation: NSOAP, National Surgical, Obstetric, and Anesthesia Plan.

Zambia

The Republic of Zambia has led efforts to expand access to surgical care, sponsoring and chairing the diplomatic negotiations that culminated in the adoption of WHA68.15 in 2015 as well the follow-up Resolution WHA70(22) in 2017 that requires WHO member states to report on their progress of WHA68.15 every 2 years.¹⁸

The Zambian Ministry of Health brought together many different surgical system stakeholders to adopt the NSOAP. Two prior nationwide assessments, the emergency obstetrics and newborn care survey, and the emergency and essential surgical care capacity survey provided the baseline from which the Zambian NSOAP was structured. The fully costed Zambian NSOAP (2017–2021)¹⁹ that was launched at the World Health Assembly in Geneva in 2016 marked the first NSOAP modeled on the *Lancet* Commission's theoretical framework and the first country to affirm its political commitment to WHA 68.15.¹⁸ The NSOAP has since been fully integrated into the Zambian National Health Strategic Plan 2017–2021,²⁰ which is a key part of Zambia's broader National Development Plan.²¹ Through this integrated process, the Republic of Zambia served as a model for incorporating NSOAP implementation within a country's broader sustainable development agenda. Furthermore, Zambia has also sponsored and chaired the adoption of regional resolutions aimed at closing the gaps in SOA care at the East Central and Southern African Health Community in 2017 and the Southern African Development Community (SADC) Health Ministers Conferences in Windhoek in 2018²² and Dar es Salaam in 2019.²³

Tanzania

The Tanzanian NSOAP development process, completed in 2018, sought to include a wide range

of stakeholders at every step of policy dialogue and creation.²⁴ Stakeholders were engaged in 4 key phases, and over 200 diverse stakeholders were interviewed through a situational analysis to better understand local challenges to providing quality surgical care. To accomplish this, the NSOAP development team visited health facilities at each level of care delivery and interviewed frontline providers, training institutions, blood banks, health insurers, government officials and private practitioners. This allowed them to obtain a comprehensive picture of the gaps in surgical care that could inform their priority setting.²⁵ During the priority-setting phase, more than 70 stakeholders were engaged in policy dialogue to establish priority areas of the plan based on the situation analysis and their on-the-ground experiences. The plan was then drafted, costed, and ultimately adopted and signed by the Tanzanian Ministry of Health in 2018.

As a result of this bottom-up approach, the Tanzanian NSOAP reflects the challenges facing all actors in the surgical ecosystem, including frontline providers who will ultimately implement the plan, ensuring their buy-in and ownership from the beginning.

Pakistan

The NSOAP theoretical framework provides a flexibility that can also be applied in a decentralized, context-specific manner. In Pakistan, due to its large population, the federal government regulates and coordinates the overall strategic approach to health care provision. However, priority setting, policy, and service implementation is devolved to provincial governments. The forthcoming Pakistani *National Vision for Surgical Care 2025*, a context-specific NSOAP development process begun in November 2018, will establish a guiding

Through the NSOAP process, the Republic of Zambia served as a model of strong national ownership, advocacy, leadership, and coordination.

Based on the results of a situational analysis involving key stakeholders, the Tanzanian NSOAP reflects the challenges facing all actors in the surgical ecosystem.

vision for surgery that aligns with Pakistan’s federal-level *National Health Vision 2016–2025* (Figure 4). Pakistan’s NSOAP aims specifically to include children’s surgery to more effectively serve the one-third of its’ population under the age of 15.²⁶ It also provides a roadmap for each individual provincial government to identify local barriers to surgical care, develop individually tailored provincial SOAPs, and implement context-specific changes within their provincial health networks.²⁷ This unique approach specifically tailored to the Pakistani context provides a model for other countries with regional health authorities to adapt the NSOAP framework to their particular governance structures.

Rwanda

In 2017, the Rwandan Ministry of Health, together with Rwandan professional societies and international academic collaborators, embarked on a systematic baseline assessment of surgical care across the country. In a simultaneous effort to bolster surgical research capacity, this assessment was led by active Rwandan surgical residents in all of Rwanda’s 42 district hospitals using modified WHO assessment tools to measure facility and health system preparedness for emergency and essential surgery services. Using the *Lancet* Commission’s

framework, data were organized and analyzed around the 6 surgical indicators and consequently 5 intervention domains were established. Surgical workforce (e.g., surgeons, anesthetists, obstetricians, nurses, etc.) was identified as the largest barrier to providing essential surgical care in Rwanda and became the main focus of the NSOAP development process.²⁸

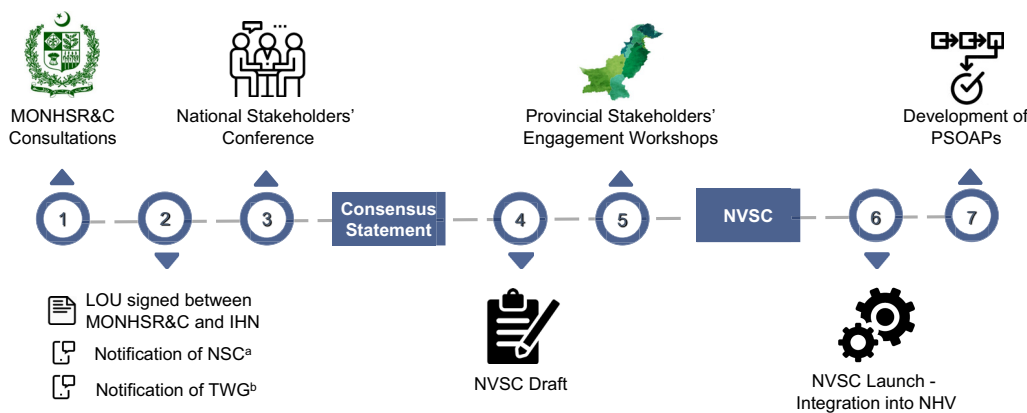
Consensus on targets, strategies, activities, and financing was reached through 3 intensive workshops that brought together public and private stakeholders from every level. The Rwanda NSOAP was launched in December 2018, and then integrated into the Health Sector Strategic Plan 2018–2019 in January 2019.²⁸ Since this launch, NSOAP monitoring tools have been embedded into Rwanda’s health management information systems, and a steering committee has been designated to meet on a quarterly basis to monitor progress of surgical care across Rwanda.

In Rwanda, surgical workforce—identified as the largest barrier to providing essential surgical care—became the focus of the NSOAP process.

Nigeria

In 2017, Nigeria embarked on a national surgical, obstetric, anesthesia, and nursing plan (NSOANP) process that was driven first by the national surgical and anesthesia societies and then ultimately taken up by the Federal Ministry of Health. This stepwise engagement ensured provider buy-in

FIGURE 4. Roadmap for Pakistan’s Surgical Care Strengthening, From National Vision to Provincial Plans



Abbreviations: IHN, Indus Health Network; LOU, letter of understanding; MONHSR&C, Ministry of National Health Services, Regulation, and Coordination; NHV, National Health Vision; NSC, National Steering Committee; NVSC, National Vision for Surgical Care; PSOAP, Provincial, Surgical, Obstetric, and Anesthesia Plan; TWG, technical working group.

^a Consisting of representatives from international and national public and private stakeholders to oversee and coordinate the process of being the decision maker.

^b Consisting of international and national partners to conduct research, provide technical support throughout the process, and draft documents.

Nigeria prioritized children's surgery and nursing care in its NSOAP.

from the beginning and will likely be central to the success of forthcoming NSOANP implementation. In Nigeria, the federal government creates health care policies and priorities through the Federal Ministry of Health. However, implementation of these policies is done both centrally through federally owned tertiary health institutions and the primary health care development agency as well as at the state level through separate local health authorities.

Strategic Priorities for Surgical Care (StraPS), Nigeria's NSOANP, created prioritized surgical system targets and an implementation roadmap that includes monitoring, evaluation, and feedback for central and state governments to follow. StraPS is unique for several reasons. In Nigeria, children under 15 years old constitute 43% of the population of 199 million. StraPS included children's surgery in a surgical plan for the first time and addressed the surgical needs of this unique demographic. In addition, StraPS specifically included nursing care, which forms an inseparable component of surgical quality and safety, to ensure that nursing is captured in surgical training and workforce development programs.

Similar to other surgical plans, StraPS was structured to be integrated into Nigeria's existing National Strategic Health Development Plan 2018–2022 rather than exist as a standalone vertically implemented health policy.²⁹

■ CURRENT CHALLENGES TO NSOAP PROGRESS

Developing an NSOAP is an important first step toward surgical system strengthening as it formalizes a country's intention to improve surgical care and charts a roadmap for addressing real gaps in the health system as ascertained through baseline assessments. Nonetheless, having a plan for surgical system reform does not guarantee that implementation of the plan or meaningful change will occur. Despite the early successes of NSOAP development, implementation and scalability still face several barriers. Overcoming the barriers to implementation in each country will take engagement and collaboration from a diverse group of national and international stakeholders.

Financing for Implementation

The World Bank Group urged that access to essential surgery should be financed early on in any nation's path to UHC.¹⁰ To do this, ministries of health and finance should be involved from the earliest stages of NSOAP development to best advocate for NSOAP financing among competing

priorities in health system budgeting. An important step toward guaranteeing a budget line for NSOAP implementation within a ministry of health's broader budget is by integrating an NSOAP into a country's national health strategic plan, as several countries have done. NSOAP advocates can combine data on the current state of a country's surgical system with cost-effectiveness analyses and estimates of the potential macroeconomic benefits of investing in surgical care to gain early political support for including surgical care in HSS. Clear economic incentives exist for those financing HSS to consider including investments in surgical scale-up; the *Lancet* Commission reported that investments in surgical scale-up across low- and middle-income countries totaling approximately \$350 billion could avert gross domestic product losses of US\$12 trillion.⁴

In Tanzania, where the NSOAP development process was completed in 2018 (Figure 3), the total cost of implementation is estimated at US\$600 million by 2025, or US\$1.7 per capita per year.²⁴ As health budgeting and spending varies in each of the 5 countries described in this article (Table 2),³⁰ no single funding source is expected to back this goal. NSOAP leaders should engage both domestic and international sources of financing early on. Organizations such as the United States Agency for International Development, the Bill & Melinda Gates Foundation, and the World Bank's Global Financing Facility may have new opportunities to align their existing programmatic priorities around maternal and child health, especially those regarding obstetric care, and around neglected tropical diseases with overlapping NSOAP priorities, such as blood banking and infection control.^{31–33}

In Zambia, where NSOAP implementation has been slow, a new strategy has focused on finding entry points into existing health programs so that financial resources can be synergistically leveraged. Implementation is now poised to start with a small pilot program to generate evidence that demonstrates the impact and cost-effectiveness of surgical services with the intention of applying lessons learned toward broader Zambian surgical system scale-up.

Scalability and Regionalization

Further adoption and implementation of NSOAPs needs to be considered both within countries and in geographic regions to see broad improvements in surgical care globally. Programmatic implementation of NSOAPs as new health policies could be advanced through pilot programs within

Ministries of health and finance should be involved from the earliest stages of NSOAP development to best advocate for financing among competing health system budgeting priorities.

TABLE 2. Overview of Health Spending, by Country, 2016³⁰

	Health Spending per Capita, USD ^a	Health Spending per GDP, %	Government Health Spending per Total Health Spending, %	Out-of-Pocket Spending per Total Health Spending, %	Development Assistance for Health per Total Health Spending, %
Nigeria	71.0	2.4	14.5	75.2	8.6
Pakistan	41.0	2.7	26.2	62.7	8.3
Rwanda	44.0	5.0	37.0	8.1	43.6
Tanzania	41.0	4.0	34.3	22.8	41.6
Zambia	64.0	3.2	38.1	12.3	44.0

Abbreviations: GDP, gross domestic product; USD, United States dollar.

^aIn 2018 purchasing power parity US dollars.

subnational states or provinces to evaluate their impact on HSS and health outcomes before nationwide scale-up of SOA services. Furthermore, despite an increasing number of countries developing and beginning to implement surgical health policies, integration of these policies into their broader national health strategic plans remains a challenge in some cases.

To facilitate scale-up among SADC nations, regional-level cooperation has been shown to provide support and guidance for countries newly embarking on the NSOAP development process. Across the SADC nations, health ministers reaffirmed their commitment to WHA 68.15 in 2018;²² in 2019, they agreed to support the acceleration and completion of NSOAPs by formulating a regional SOA strategy together with a regional monitoring and accountability framework.²³

Similarly, 14 nations across the South Pacific came together to measure the 6 *Lancet* Commission surgical key performance indicators (Table 1) in collaboration with Australia and New Zealand.³⁴ Exemplifying the impactful role that professional association of high-income countries can have when aligned with regional priorities, the Royal Australasian College of Surgeons has supported the broader region with data collection, workforce training, and overall surgical scale-up. In 2019, at the Pacific Health Ministers Meeting in French Polynesia, 22 ministers of health or their designates from Pacific Island Countries & Territories committed to developing NSOAPs as a tool for strengthening surgical care in the region.

Such regionalization also creates an opportunity for WHO regional offices to better engage with member states that are committed to strengthening surgical care. For example, at the

72nd World Health Assembly in 2019, Dr. Takeshi Kasai, WHO Regional Director for the Western Pacific, committed to incorporating surgical systems strengthening into its regional health strategy. These regional and country-level offices can provide technical support to policymakers and catalyze financing for NSOAP development within the context of existing national health plans and broader regional priorities. They can also coordinate surgical care improvements within existing programs that are already working on emergency care, maternal and child health, noncommunicable diseases, and other overlapping health priorities. As the global momentum for UHC grows, regional offices can ensure that essential SOA care is included in UHC planning.

Data Collection

Systematic and sustainable data collection remains an essential component of the NSOAP development process. Adequate baselining and needs assessments must guide health sector prioritization, and ongoing data collection will allow for effective monitoring and evaluation of surgical system strengthening. Despite these advantages, data collection around SOA care remains limited.

To improve data collection efforts, ministries of health must support robust monitoring and evaluation plans to promote accountability around health financing and measure the impact of health reforms. To facilitate data reporting to projects like the World Bank's World Development Indicators, surgical questions must be integrated into widely used data collection mechanisms (e.g., Demographic and Health Surveys); such efforts are already underway in Zambia.

To improve data collection efforts, ministries of health must support robust monitoring and evaluation plans to promote accountability around health financing and measure the impact of health reforms.

Furthermore, academic collaborations and international professional societies have played an essential role in building research capacity, data collection, and analysis.^{34–38} The international nature of medical professional societies has provided them with a unique opportunities to work with several stakeholders to support surgical system strengthening efforts. For example, the World Federation of Societies of Anesthesiology has mapped and tracked the global anesthesia workforce and has led training and advocacy initiatives to increase the skilled anesthesia workforce. They also developed International Standards for Safe Practice of Anesthesia³⁹ as well as an Anesthesia Facility Assessment tool.⁴⁰ The International Federation of Gynecology and Obstetrics has led capacity building, training, and guideline development efforts for fistula surgery, management of postpartum hemorrhage, and cesarean hysterectomy and also collaborates closely with the International Congress of Midwives. As nurses and midwives provide a significant amount of surgical-related care, their inclusion in NSOAP development is paramount.

THE WAY FORWARD

Given that 5 billion people lack access to surgical care,⁴ NSOAPs that promote equitable access to safe surgical, obstetric, nursing and anesthesia services can play a critical step for improving access to essential health services worldwide. NSOAP development will complement national health plans and be an important step toward achieving UHC and the Sustainable Development Goals.^{15,41}

Surgical system strengthening efforts continue to gain momentum with dedicated international forums,¹² broad adoption at WHO's Emergency and Essential Surgical Care Programme,^{42,43} and stakeholder engagement meetings for surgical care in Africa, Asia, and Latin America all occurring more frequently.⁴⁴ Embarking on the NSOAP development process is only a first step toward improving access to surgery. Widespread implementation and financing of surgical care will take time. These important first steps are inching us closer to universal access to emergency and essential surgical care—and UHC—for all.

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COMMENTARY

Insights Into Provider Bias in Family Planning from a Novel Shared Decision Making Based Counseling Initiative in Rural, Indigenous Guatemala

Meghna Nandi,^{a,b} Jillian Moore,^{b,c} Marcela Colom,^{b,c} Andrea del Rosario Garcia Quezada,^b Anita Chary,^{b,d} Kirsten Austad^{b,e}

Race, ethnicity, and indigenous status should be considered as potential drivers of provider bias in family planning services globally. Efforts to confront provider bias in family planning counseling should include concrete strategies that promote provider recognition of biases and longitudinal curriculums that allow for sustained feedback and self-reflection.

➔ See related article in *Solo and Festin*.

➔ Resumen en español al final del artículo.

■ INTRODUCTION

An article by Solo and Festin¹ discusses the importance of addressing provider bias in family planning services. We agree that provider bias in family planning services is a widespread problem that restricts clients' autonomy and empowerment and applaud the authors for directing a spotlight on this important issue.

Our goals in writing this response are 2-fold. First, drawing from our experiences providing family planning services to primarily indigenous Maya women in rural Guatemala, we would like to expand Solo and Festin's discussion on bias against specific groups to include race and ethnicity. In this article, we understand race is defined as a social group based on perceived skin color or other physical qualities and ethnicity is defined as a social group based on common cultural or national traditions.²

Solo and Festin's article highlights sources of client-based bias, including age, parity, and marital status, as well as biases against specific socially marginalized groups, emphasizing youth, women who have HIV, women seeking abortion, those with disabilities, and

men seeking permanent contraception. However, race and ethnicity are not singled out as a specific source of bias in their article. In our family planning work, ethnic minority patients report judgment, bias, and coercion in their reproductive health care experiences. We hope to use our professional observations and the current literature on racial and ethnic biases in health care to build on Solo and Festin's article by including race and ethnicity as factors that merit recognition in this larger discussion of provider bias in family planning.

Second, we would like to complement Solo and Festin's discussion about how to address provider bias of all types by sharing specific strategies we have used in our work. After years of providing family planning services in rural Guatemala, we have seen how training that does not directly confront bias has limited power to promote quality counseling rooted in client autonomy and choice. Here, we hope to share insight from our own on-the-ground efforts to eliminate provider bias in our family planning program.

■ OUR CONTEXT

We have been involved in women's health programs at the nongovernmental organization (NGO) Wuqu' Kawoq | Maya Health Alliance, which was founded to address a lack of culturally and linguistically appropriate health and social services for indigenous people in Guatemala. Nearly half of Guatemalans are of indigenous Maya descent³ and have sociocultural practices, such as speaking indigenous languages and wearing traditional clothing, that distinguish them from those of European or mixed ancestry. Although Guatemala has recently been reclassified from a lower- to a middle-income country, most Maya citizens live on less than US\$1 per day. Limited access to quality health care due

^a Warren Alpert Medical School, Brown University, Providence, RI, USA.

^b Wuqu' Kawoq | Maya Health Alliance, Bethel, VT, USA.

^c Department of Family and Community Medicine, University of New Mexico, Albuquerque, NM, USA.

^d Department of Emergency Medicine, Massachusetts General Hospital, Boston, MA, USA.

^e Department of Family Medicine, Boston University School of Medicine, Boston Medical Center, Boston, MA, USA.

Correspondence to Kirsten Austad (kirsten.austad@bmc.org).

to language barriers, cultural differences, and widespread discrimination⁴ perpetuates these inequalities. The Guatemalan constitution guarantees free health care to all its citizens, but the public health system is underfunded and has been unable to provide adequate care to rural indigenous areas of the country.^{5,6}

Indigenous women in rural areas have a higher unmet need for modern contraception than their nonindigenous counterparts (43.4% vs. 26.7% according to most recent estimates).^{3,7–9} The public sector is the largest source of family planning services in Guatemala and offers women a range of methods for free including female surgical sterilization, oral contraceptive pills, condoms, copper intrauterine devices, injectables, and implants.^{3,10} The quality of family planning services is questionable. Public clinics have frequent shortages of contraceptive methods.¹⁰ In our clients' experiences, long-acting reversible contraceptive (LARC) method placement and removal were not offered daily but rather were provided through intermittent missions coordinated by health centers. Strikingly, the majority of public sector providers are not indigenous and do not speak local Mayan languages,⁶ even though the public sector is often the most affordable and geographically accessible health care option for rural indigenous communities. Nearly all visits are conducted in Spanish,³ which further increases barriers to care for monolingual speakers^{5,6,11} and may contribute to disparities in reproductive health care utilization and contraceptive use between indigenous and nonindigenous women.⁹

A number of NGOs have attempted to fill in these gaps in family planning services. NGOs provide women with the same methods available in the public sector for a nominal cost, often determined by her capacity to pay, or free of charge (as in the case of Wuqu' Kawoq).^{10,12,13} Asociación Pro-bienestar de la Familia, affiliated with the International Planned Parenthood Fund, is the largest NGO providing these services and one of the largest family planning providers nationally with approximately 25 health centers spanning the country.^{10,12} Although private hospitals, clinics, and pharmacies also offer contraceptive services, their fees are prohibitive for most Maya women.^{3,10}

■ PROVIDER BIAS BASED ON RACE AND ETHNICITY

Higher unmet need for contraception among indigenous Guatemalans is likely multifactorial.

Structural inequalities faced by Maya women, including poverty, rural isolation, and language barriers, are well-documented and are at least partly to blame for reproductive health disparities.¹¹ Provider bias based on age and parity—among those highlighted by Solo and Festin—may also play a role as Maya women begin childbearing earlier and have larger family sizes than the general Guatemalan population. In addition, our experiences as health care providers suggest discrimination based on race/ethnicity as an important contributing factor.

There is sound empirical evidence of racial and ethnic biases among providers generally in health care broadly^{14–16} and specifically in family planning care. Most studies to date have been conducted in the United States. For example, a 2008 study found that black women were more likely to report having felt pressured by a provider to use a particular contraceptive method than white women.¹⁷ Similarly, a national patient survey found that minority women in the United States were more likely to be counseled on birth control including sterilization.¹⁸

Other research has sought to directly measure providers' racial and ethnic bias, either explicitly through self-report of conscious attitudes or implicitly. For example, 2 studies presented providers with clinical scenarios involving patients identical apart from race and found that health care providers were more likely to recommend LARCs or sterilization to minority patients than to white patients.^{19,20} Implicit bias in medical providers has also been assessed using the implicit association test, which is supported by strong psychometric evidence. The implicit association test serves as a proxy for attitudes that people are unwilling or unable to report because these perceptions are unconscious and are a predictor of discriminatory behavior.²¹ Multiple systematic reviews have confirmed that implicit racial bias exists among health care professionals at the same rates as the general population, though to our knowledge none has focused explicitly on family planning providers. It is worth highlighting that racial and ethnic bias is more likely to manifest in areas like family planning in which decisions depend strongly on patient preference and thus demand personalized counseling. One study in the field of genetic counseling, similarly directed by patient preference, found that higher pro-white implicit bias was associated with less individualized counseling of minority patients.²²

Racial and ethnic bias in family planning deserves special attention for multiple reasons.

We hope to share insight from our own on-the-ground efforts to eliminate provider bias in our family planning program.

Racial and ethnic bias is more likely to manifest in areas like family planning in which decisions depend strongly on patient preference and demand personalized counseling.

Racial and ethnic bias remains largely invisible, leading to the dangerous and false conclusion that “racism” has been erased from medicine.

First and foremost, race and ethnic groups are not biologic entities but instead social constructs. Despite abundant scientific inquiry regarding a biologic basis for race, compelling evidence is lacking. As such, there is no evidence to support offering disparate contraceptive recommendations by race. Compare this to other biases such as parity, where biologic differences such as the increased risk for obstetric complications in grand multiparity could justify making unique recommendations based on this characteristic.

Second, racial and ethnic bias is more likely than other forms of bias to manifest implicitly. In many medical contexts it is not socially acceptable to express overtly racist views. However, implicit bias is not manifested through reported beliefs, but rather is detected by methods revealing subconscious beliefs, like the implicit association test, and through subtle behaviors, like poor communication. Well-intentioned providers may find it difficult to accept evidence that their behaviors contribute to racial and ethnic disparities in care, especially when this conflicts with their explicit beliefs and morals. Because it is implicit, racial and ethnic bias remains largely invisible, leading to the dangerous and false conclusion that “racism” has been erased from medicine.

Third, the strength of the evidence demonstrating bias is more substantial for race and ethnicity than any other category covered in Solo and Festin’s review. In fact, a recent systematic review of implicit bias included 42 studies, 27 of which examined race and ethnicity as compared to only 14 for gender and 11 for age.²³

Fourth, the most egregious examples of bias in family planning—forced or coerced sterilization—is most commonly linked to race and ethnicity. In contrast, nearly all examples of bias provided by Solo and Festin are related to withholding contraception from women who desire it or limiting their range of choices. Those of us who are family planning providers in the United States are acutely aware of our not-so-distant history of forced sterilization against women of color, including thousands of American Indian women.^{24,25} Similarly, across the world, sterilization without informed consent has been documented well into modern day.²⁶

■ RACIAL AND ETHNIC BIAS IN LOW-RESOURCE SETTINGS

Stories from the patients we care for support the existence of ethnoracial bias in public sector family planning services in Guatemala as well. One

indigenous client described to us how she had hoped to have more children, but the doctors at the public hospital “would not permit it” and badgered her in to signing the consent form for tubal ligation because she had already had 2 cesarean deliveries. Another indigenous woman reported how during her last birth, she was asked repeatedly by the nonindigenous doctors why she would not agree to surgical sterilization and interrogated about how much land and money she had to support her children. When our NGO started offering contraceptive implants, there was high uptake among indigenous women even in villages where women could also access them with no cost in public health centers. Many of these women reported that because they were repeatedly told in public health centers that they had “too many children” they feared the doctor would refuse to remove the implant if they were unsatisfied or desired pregnancy. One woman stated “they do not value our children because we are dark-skinned.” In other instances, women have expressed uncertainty about whether or not they were left sterile following their last cesarean delivery at the public hospital. Indeed, an ethnographic study of maternal health in a rural Guatemalan community documents women forcibly undergoing tubal ligations after cesarean delivery without giving consent.²⁷

Our patients’ anecdotal experiences of perceived discrimination are supported by empiric evidence. Numerous qualitative studies have documented the discrimination indigenous Guatemalans face in public health facilities that actively deters them from seeking care.^{11,27–29} Similar experiences are shared by the other 370 million indigenous people worldwide.^{30–35} Multiple studies have identified implicit bias among health care providers favoring white over indigenous ethnicities.^{30–32,35} One study also found an association between ethnic bias and clinical recommendations and beliefs about patient compliance.³⁵ A study from New Zealand found that indigenous patients were more likely to be started on a riskier form of dialysis treatment than their nonindigenous counterparts, even when controlling for socioeconomic factors and clinical comorbidities.³³ In a qualitative study, health care providers in Canada also described discrimination toward indigenous patients affecting clinical practice.³⁴

However, there is a relative paucity of research examining racial and ethnic biases of family planning health workers in low-resource settings. One study interviewed 108 family planning providers in public clinics in rural areas of Guatemala.³⁶ More than half reported that indigenous patients

Patients’ anecdotal experiences of perceived discrimination are supported by empiric evidence.

lacked the ability to understand information they provided and could not make their own decisions about contraception. Additionally, some expressed overtly derogatory views including that indigenous women were dirty. Many reported withholding counseling on certain methods as a result of their indigenous patients' inability to properly use it. In contrast, a randomized control trial in Peru found no significant difference between the quality of family planning counseling provided to indigenous and nonindigenous ethnic profiles. However, the study had significant methodological limitations; the authors acknowledged that by using the same standardized patient to alternate ethnic profiles, they explored a relatively small range of ethnoracial characteristics.³⁷ To our knowledge, no studies conducted in low-resource settings have examined family planning providers' implicit bias according to race or ethnicity. However, given the ubiquity of implicit racial and ethnic bias in health care,^{14,38} it would be surprising if Guatemalan family planning providers were immune to the cognitive trap that has befallen the thousands of physicians studied to date.

As such, further research is needed to document the extent of racial and ethnic bias in contraceptive care in low-resource settings. Initiatives to develop empiric evidence must accompany the growing conversation about widespread disrespectful and abusive reproductive health care globally.³⁹ These efforts are especially important among indigenous people and those living in extreme poverty, who are among the most vulnerable.^{40–43} Indeed, given the strong negative correlation between indigeneity and both economic status and literacy in the national language, separating out the role of each individually will pose a significant methodologic challenge.

■ FINDING SOLUTIONS

Fortunately, there are a number of promising strategies to overcome racial and ethnic bias in health care delivery. Literature from the field of social-cognitive psychology suggest that providers can confront implicit racial bias once they are made aware of those biases through concrete activities and tests that elucidate unconscious biases and stereotypes.^{44–46} One study tested a package of interventions aimed at breaking racially prejudicial thought patterns using 5 cognitive exercises (Table) and showed a significant reduction in implicit bias.⁴⁶ As Solo and Festin highlighted in their review, it is important to support providers in self-reflection rather than blame them.

Another method to confront racial and ethnic bias involves increasing providers' individualized interactions with members of other groups, for instance with colleagues of different racial or ethnic backgrounds,⁴⁵ lending support to efforts to diversify health care provider workforces. It is important to acknowledge that individuals can hold bias against members of their own social groups, whether that bias is based on race and ethnicity or other client characteristics.

In addition to these person-level interventions, it is vital to recognize that the sources of racial and ethnic biases are deeply rooted in historical power structures and sociocultural forces that will likely require larger social movements to fully dismantle. Nonetheless, our organizational experiences and the current evidence on how to overcome biases leaves us optimistic that the global family planning community can successfully reduce its influence on clients' contraceptive choices.

Our organization offers family planning by training local nurses fluent in the indigenous languages spoken in the communities where they work. To expand our reach, we have developed an innovative partnership with the microfinance organization Friendship Bridge, which specializes in economic empowerment of primarily rural indigenous women in Guatemala, to provide a package of preventive health services, including a full range of family planning methods, to their clients. When we began to offer comprehensive contraceptive counseling and methods in 2014, we realized that family planning visits were often guided by providers' biases rather than by client preferences. For example, we witnessed our nurses encouraging women to initiate long-acting reversible contraception because they had "too many children."

■ SHARED DECISION MAKING

Our first step in confronting provider bias was to select a counseling approach to combat all types of provider bias. We implemented a shared decision making approach to contraception counseling, which prioritizes autonomy, control, and personal experiences in counseling by first clarifying a woman's unique preferences and guiding her to the "best fit" method (or no method at all). This model is well suited to combat provider bias of all types; indeed, a definition for provider bias quoted by Solo and Festin directly references "... failing to ascertain and respect the client's preference."⁴⁷ Moreover, shared decision making has been shown to improve patient satisfaction and increase continuation of chosen method, though

Initiatives to develop empiric evidence must accompany the growing conversation about widespread disrespectful and abusive reproductive health care globally.

Our first step in confronting provider bias was to select a counseling approach to combat all types of provider bias.

TABLE. Habit-Breaking Exercises Shown To Decrease Implicit Bias Based on Race and Ethnicity^a

Cognitive Strategy	Description
Stereotype replacement	Recognize your own responses that are based on stereotypes and teach yourself to have a different response
Counter-stereotypic imaging	Think of specific examples that do not fit with the racial and ethnic stereotypes you have been taught
Individuation	Overcome responses based on stereotypes by thinking about the person's individual qualities
Perspective taking	Imagine yourself in the place of the person from a racial or ethnic minority
Increasing opportunities for contact	Seek out chances to interact with members of other racial and ethnic groups

^a Adapted from Devine et al.⁴⁶

Counseling tools cannot achieve high-quality counseling using shared decision making without adequately unpacking provider bias.

it is only supported by rigorous evidence from high-resource contexts.^{48,49} We have had to consider our local cultural context to thoughtfully adapt this approach for the communities in which we work. Our efforts include working closely with Guatemalan providers (including some of the authors of this article) to create training materials that integrate realistic cases and vignettes based on actual, local client visits and use feedback from community nurses to improve and finalize training and counseling materials.

The tenets of shared decision making may help providers become aware of their own biases. First, Solo and Festin discuss how emphasizing a client's right to make decisions could help make providers aware of their own biases. Similarly, the shared decision making approach encourages client-centered counseling in which the locus of control to make a final decision stands with the client. Second, Solo and Festin highlight that the negative impact of bias can in part stem from assumptions providers make based on bias as opposed to focusing on the individual client needs. Along these lines, shared decision making recognizes that each client is unique and encourages providers to personalize counseling by asking each client about her preferences rather than making assumptions. Finally, Solo and Festin discuss how the hierarchical medical model can further exacerbate bias. Shared decision making moderates this hierarchy by establishing client and provider as a team, in which the provider may be an expert on family planning methods, but the client is the expert on her personal situation and unique life circumstances.

Although a shared decision making approach has the potential to ameliorate bias in family planning, to effectively use shared decision making, providers must first confront their biases. A provider cannot successfully engage in this type of counseling if their biases prevent them from

recognizing the validity of clients' preferences and desires. For example, consider the method-based bias held by many providers that the most efficacious methods—LARCs—are best. If providers are not aware of this bias or not able to move past this bias, they may have a hard time hearing, accepting, and responding to clients' other desires, such as using a method over which she has complete control. For these providers, it can be very difficult to offer clients other methods more aligned with the clients' personal preferences.

Two counseling tools widely available in low-resource settings have incorporated aspects of shared decision making. The World Health Organization's decision making tool⁵⁰ and the Population Council's toolkit⁵¹ promote better provider-client interaction through decision algorithms that tailor counseling to each woman's individual circumstances. Each tool is accompanied by a core 1-day training curriculum to improve provider counseling skills, but these trainings dedicate little time to uncovering and addressing provider bias. However, similar to the other strategies reviewed by Solo and Festin, these existing shared decision making tools lack strong supporting evidence. Although both appear to improve the content of counseling—at least in the short-term—they have shown little to no impact on client use of contraception and lack rigorous evaluation of patient-centered outcomes, such as perception of respectful care.^{52–56} One possible explanation for these disappointing results is that counseling tools cannot truly achieve high-quality counseling using shared decision making without adequately unpacking provider bias.

Learning from these prior efforts, we have developed trainings on family planning counseling that specifically address provider bias before introducing shared decision making techniques and continue to reinforce the theme throughout the longitudinal curriculum. Although taking time to discuss overarching values and principles around

Shared decision making establishes the client and provider as a team: the provider as an expert in family planning methods and the client as an expert on her personal situation and life circumstances.

BOX. Helpful Strategies To Increase Awareness of Provider Bias in Family Planning and Encourage Shared Decision Making

Include training activities in which providers must identify their own preferences and make complex decisions in real-life scenarios outside of health care.

- For example, we ask nurses to choose a vacation destination and present information on a variety of factors, including cost, travel, time, and risk of crime, that impact this decision.
- These activities bring awareness to method-related biases by drawing parallels and reinforce the concept that there is rarely a single, best approach because each person has a unique context that will impact what is best for her.

Create realistic client case-based activities related to family planning, akin to an applied values clarification exercise.

- For example, we write cases to directly engage specific client-based biases including age, parity, and socioeconomic status.
- These activities bring awareness to client-based biases by eliciting providers' reactions to cases and helping providers to empathize with why clients may make decisions with which providers themselves do not agree.

Encourage health care provider group reflection on actual family planning visits that frontline workers have identified as being "difficult" for them.

- For example, we strive to recognize provider bias without judgment or blame to normalize this experience.
- These reflections encourage providers to explore which biases made those visits challenging.

Develop a longitudinal curriculum that includes not only follow-up trainings but also direct observation in the field.

- In our experience, classroom trainings alone are not enough to effectively confront provider bias.
- Direct observation of actual patient encounters reinforces recognition of biases and provides real-time feedback on counseling skills.

necessary step in ensuring client autonomy and satisfaction in this work in global health. We hope that our commentary encourages recognition of race and ethnicity as an important source of bias in family planning and that insights from our work may stimulate ideas for how to confront provider bias in other family planning programs.

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client autonomy and nonjudgment can be important, we found that focusing on concrete examples has been more useful in encouraging awareness of personal biases. Lastly, we reinforce these themes through a rights-based framework, including training on reproductive aspects of Guatemalan human rights laws. We describe several strategies that we have found especially helpful (Box).

To date we have trained 20 providers in our curriculum. We would like to emphasize that while our approach is strongly based in theory, we are still in the early stages of implementation. Although we do not have enough longitudinal data to rigorously assess our program's impact on nurses' attitudes, patients' perception of provider bias, or clinical outcomes at this time, we hope to share our findings soon.

CONCLUSION

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En español

Perspectivas del prejuicio de los proveedores de servicios de salud en la planificación familiar desde una nueva iniciativa de consejería basada en toma de decisiones compartidas en comunidades indígenas rurales de Guatemala

La raza, etnia, y el ser indígena deben considerarse como factores que contribuyen al prejuicio de los proveedores de servicios de planificación familiar a nivel mundial. Los esfuerzos para enfrentar el sesgo en la consejería de planificación familiar deben incluir estrategias concretas que promuevan el reconocimiento de los prejuicios, así como currículos longitudinales que permitan una retroalimentación sostenida y auto-reflexión.

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ORIGINAL ARTICLE

A Qualitative Assessment of Provider and Client Experiences With 3- and 6-Month Dispensing Intervals of Antiretroviral Therapy in Malawi

Julie Hubbard,^{a,b} Khumbo Phiri,^b Corrina Moucheraud,^c Kaitlyn McBride,^c Ashley Bardon,^d Kelvin Balakasi,^b Eric Lungu,^b Kathryn Dovel,^a Gift Kakwesa,^b Risa M. Hoffman^a

Clients with HIV on antiretroviral therapy (ART) perceived the 6-month ART dispensing interval as highly acceptable due to reduced transport costs and increased time for income-generating activities. Providers reported benefits in reduced clinic workload and improved ability to see clients who need more support. Before implementing this dispensing interval on a large scale, countries should conduct further research on how to encourage client health-seeking behaviors for health problems, ensure women have access to family planning services outside of ART clinic visits, and encourage providers to use best practices for counseling messages.

ABSTRACT

Introduction: Multimonth dispensing (MMD) of antiretroviral therapy (ART) is a differentiated model of care that can help overcome health system challenges and reduce the burden of HIV care on clients. Although 3-month dispensing has been the standard of care, interest has increased in extending refill intervals to 6 months. We explored client and provider experiences with MMD in Malawi as part of a cluster randomized trial evaluating 3- versus 6-month ART dispensing.

Methods: Semi-structured in-depth interviews were conducted with 17 ART providers and 62 stable, adult clients with HIV on ART. Clients and providers were evenly divided by arm and were eligible for an interview if they had been participating in the study for 1 year (clients) or 6 months (providers). Questions focused on perceived challenges and benefits of the 3- or 6-month amount of ART dispensing. Interviews were transcribed, and data were coded and analyzed using constant comparison.

Results: Both clients and providers reported that the larger medication supply had benefits. Clients reported decreased costs due to less frequent travel to the clinic and increased time for income-generating activities. Clients in the 6-month dispensing arm reported a greater sense of personal freedom and normalcy. Providers felt that the 6-month dispensing interval reduced their workload. They also expressed concern about clients' challenges with ART storage at home, but clients reported no storage problems. Although providers mentioned the potential risk of clients sharing the larger medication supply with family or friends, clients emphasized the value of ART and reported only rare, short-term sharing, mostly with their spouses. Providers mentioned clients' lack of motivation to seek care for illnesses that might occur between refill appointments.

Conclusions: The 6-month ART dispensing arm was particularly beneficial to clients for decreased costs, increased time for income generation, and a greater sense of normalcy. Providers' concerns about storage, sharing, and return visits to the facility did not emerge in client interviews. Further data are needed on the feasibility of implementing a large-scale program with 6-month dispensing.

INTRODUCTION

A growing body of research has identified a number of health systems and service delivery barriers to antiretroviral therapy (ART) adherence and retention

in care among people living with HIV,^{1,2} particularly in high-prevalence low- and middle-income countries.³ Common challenges to delivering ART in resource-limited settings include overburdened clinical staff and facility congestion, resulting in constrained abilities to offer quality care.^{4,5} Although ART is provided free-of-charge in many low- and middle-income countries, the need for lifelong medication imposes burdens on clients, including the time and cost of frequent refill visits.^{3,6}

Malawi has been heavily impacted by the HIV epidemic with a current prevalence of 9.4% and 740,000 adults currently on ART.⁷ Routine HIV care for clients who are

^a University of California Los Angeles, David Geffen School of Medicine, Division of Infectious Diseases, Los Angeles, CA, USA.

^b Partners in Hope Medical Center, Lilongwe, Malawi.

^c University of California Los Angeles, Fielding School of Public Health, Department of Health Policy and Management, Los Angeles, CA, USA.

^d University of Washington, School of Public Health, Department of Epidemiology, Seattle, WA, USA.

Correspondence to Julie Hubbard (juliannehubbard@outlook.com).

stable is delivered using an integrated model in which all services (i.e., clinical evaluation and dispensing of ART and any other medications) occur in a single visit at a single location. Visits are not required outside of the routine ART visit unless the client has a change in clinical status that warrants closer follow-up.

In Malawi, clients on ART who are stable typically receive a 3-month supply of ART per visit, with additional exceptions to allow longer dispensing intervals for individuals with special circumstances (e.g., military service or traveling abroad). All individuals who have HIV in Malawi receive cotrimoxazole prophylaxis with ART, and a subset of people who live in high-burden tuberculosis districts also receive isoniazid preventive therapy.

Differentiated models of care (DMOC) may improve clients' adherence to ART and engagement in care by relieving their time- and cost-related barriers and may improve the capacity of health facilities and providers to care for clients who have been newly diagnosed or who require more support.^{1,3} Examples of ART DMOCs that have been implemented in sub-Saharan Africa include community-based ART groups, adherence clubs, fast-track refills, mobile clinics, and multi-month dispensing (MMD).^{8–10}

The MMD model increases the quantity of ART received at one time and subsequently reduces the frequency of client facility visits.¹¹ Guided by the U.S. President's Emergency Plan for AIDS Relief, longer dispensing intervals (up to 6 months of ART) are being implemented across Africa^{1,7,12–14}; however, large-scale implementation experience with this model of care is lacking. Provider and client experiences with MMD have yet to be documented. As DMOCs, such as MMD, aim to affect all levels of the HIV service delivery cascade, understanding the experiences of both clients and providers is critical for examining the feasibility and acceptability of MMD and its potential for successful scale-up.

Varying Intervals of ART to Improve Outcomes for HIV (INTERVAL) is an ongoing cluster randomized controlled trial in Malawi and Zambia that is evaluating MMD for clients with HIV who are stable, a widely promoted DMOC.¹⁴ INTERVAL compares 3- and 6-month ART dispensing on the outcomes of retention, virologic suppression, and cost-effectiveness. The trial has been fully enrolled, and outcome data are currently being collected for the 1-year end point.

We performed a substudy to assess the experiences of providers and clients in Malawi

comparing the 3- and 6-month dispensing arms. Our objective was to understand clients' and providers' perceived benefits and barriers of 3-month versus 6-month dispensing, with particular focus on areas of agreement and disagreement between providers' and clients' perceptions.

METHOD

Setting

The INTERVAL trial was conducted between May 10, 2017, and April 30, 2018, and included 15 health facilities in Malawi: 5 facilities randomized to 3-month dispensing, 5 facilities to 6-month, and 5 facilities to “standard of care” in which study interference was minimal and providers selected the amount of ART to dispense based on their clinical assessment and patient preferences. For this qualitative substudy, we included all 3- and 6-month health facilities from the INTERVAL trial (N=10). We did not include the standard-of-care facilities because they largely approximated 3-month sites. Health facilities were predominantly government and mission hospitals (80%) in the central and southern regions, and 60% of the study facilities had ART cohorts of more than 1,500 clients. INTERVAL health facilities were chosen based on their ability to enroll clients and to support MMD because of time and funding constraints; thus, they were generally larger than the average ART clinic in Malawi.

Clients in the INTERVAL trial received either 3 or 6 months of all medications to avoid the need for any additional refill visits during the year.

Study Design

From June to August 2018, we conducted semi-structured in-depth interviews with a random subset of 62 enrolled INTERVAL clients from the 10 selected health facilities. Clients were eligible for in-depth interviews if they met INTERVAL trial eligibility as a stable ART client (see [Box](#)), were in either the 3- or 6-month study arm, and gave consent at baseline to be contacted for an interview at the end of the first year after enrollment. The 62 clients were stratified by study arm (32 from the 3-month arm, 30 from the 6-month arm) and gender to ensure equal representation. A total of 17 health care providers were randomly selected from the 10 chosen health facilities to be interviewed. Providers were eligible to participate in the study if they were clinical officers or nurses who directly prescribed ART at the selected study

BOX. INTERVAL Trial Client Eligibility Criteria for Malawi

Clients with HIV were eligible for the INTERVAL trial in Malawi if met the following inclusion criteria:

- 18 years of age or older
- On ART 6 months or longer
- On first-line ART regimen as defined by country-specific guidelines (efavirenz/lamivudine/tenofovir)
- No drug toxicity/tolerability issues within the prior 6 months
- Not without medication for >1 month during the last 6 months
- No active opportunistic infection suspected (including tuberculosis) and not treated for an opportunistic infection in the last 30 days
- Viral load <1000 copies/mL within the last 6 months
- If female, not pregnant or breastfeeding

Abbreviations: ART, antiretroviral therapy; INTERVAL, Varying Intervals of ART to Improve Outcomes for HIV

sites and had worked in the ART clinic at least once a week, on average, for a minimum of 6 months during the first year of study implementation. The study was approved by the Malawi National Health Sciences Research Committee and the Institutional Review Board at the University of California Los Angeles.

Interview Guide Development

Interview guides were developed using McLeroy et al.'s socioecological model¹⁵ to elucidate relevant factors operating at the individual, interpersonal, community, and organizational levels. Clients were asked about the challenges and benefits of the amount of ART dispensed, including carrying, storing, sharing, and selling ART. Providers were asked how the dispensing interval at their site impacted workload and clinic efficiency. They were also asked about clients' satisfaction with the ART dispensing interval and whether clients reported any challenges with carrying, storing, and/or sharing ART. Both client and provider interview guides included probes to draw out information about additional non-ART facility visits (e.g., illness or family planning) during the year and the "ideal" ART dispensing interval. The interview guides were piloted with 10 clients and 2 providers before data collection began to ensure comprehensibility; they were refined based on feedback. Full interview guides are provided in the [Supplement](#).

Data Collection

In-depth interviews were independently conducted in private locations at the health facilities and ranged in duration from 20–60 minutes. Seven research staff members conducted

interviews in the local language (Chichewa). All interviews were audio recorded after obtaining written consent from clients and providers. Clients were compensated for their transportation costs with a stipend of Malawi Kwacha 2,000 (approximately US\$2.50).

Data Analysis

Audio recordings were transcribed and translated to English. A preliminary codebook was developed for both interview types based on the socioecological model framework. Four investigators, 2 for client interviews (JH and CM) and 2 for provider interviews (KP and KM), piloted the codebook by independently reading and coding a randomly-selected subset of transcripts (8 clients and 6 providers). Through an iterative consultative process, each pair of investigators revised their respective codebook and repeated this process until there was high interrater reliability. All transcripts were coded in Atlas.ti version 8.3 using constant comparison, and coding disagreements were resolved by consensus. Analysis focused on agreement and disagreement between the 3- and 6-month arms and between clients and providers.

RESULTS

The 62 clients interviewed (32 from the 3-month arm, 30 from the 6-month arm) were evenly divided by gender and had a median age of 41.5 years. The majority had disclosed their HIV status to their partner. Key differences in clients by study arm were in secondary educational attainment (31% in the 3-month arm versus 57% in the 6-month arm) and formal employment (25% in the 3-month arm versus 53% in the 6-month arm) ([Table 1](#)). The median number

TABLE 1. Demographic Characteristics of Clients With HIV on ART Participating in In-Depth Interviews in 10 Health Facilities in Malawi (N=62)

	INTERVAL Trial Arm	
	Clients Receiving 3 Months of ART (n=32)	Clients Receiving 6 Months of ART (n=30)
Gender, No. (%)		
Female	16 (50)	16 (53)
Male	16 (50)	14 (47)
Age, years, median (IQR)	40 (35–47)	43 (37–50)
Marital status, No. (%)		
Married	25 (78)	26 (87)
Unmarried	7 (22)	4 (13)
Disclosure of HIV status to primary sexual partner, No. (%)		
Yes	26 (81)	26 (87)
No	1 (3)	0 (0)
No primary sexual partner	5 (16)	4 (13.3)
Household size, median (IQR)	5 (4–6)	5 (3–7)
Number of children, median (IQR)	2 (1–3)	1 (1–3)
Employment, No. (%)		
Formal employment	8 (25)	16 (53)
Informal employment	18 (56)	12 (40)
Not working	6 (19)	2 (7)
Education, No. (%)		
No education	3 (9)	2 (7)
Primary	19 (59)	11 (37)
Secondary or higher	10 (31)	17 (57)

Abbreviations: ART, antiretroviral therapy; INTERVAL, Varying Intervals of ART to Improve Outcomes for HIV; IQR, interquartile range.

of ART pills dispensed to clients was 90 (interquartile range [IQR] 87–92) in the 3-month arm and 179 (IQR 175–182) in the 6-month arm, indicating a high level of adherence to the randomized dispensing strategy. One client in the 6-month arm met the national clinical criterion for treatment default (out of care for >60 days) during the study follow-up period of 1 year.

We interviewed 17 ART providers (8 from the 3-month arm and 9 from the 6-month arm); of these, 9 were women. The providers had a median age of 35 years and nearly all had been dispensing ART for 4 or more years. The majority of providers were nurses (n=14), and the remaining providers were clinical officers (n=3).

Sharing and Selling of ART

When asked about sharing or selling ART, the vast majority of clients in both arms reported that they did not share ART (97%) and cited the importance of maintaining their own drug supply.

How will I share? If the person wants drugs, he/she should go to the hospital to do that. We don't share (ART) with each other like panado [acetaminophen]—this is not panado. —Female, 44 years old, 6-month arm

Clients cited several reasons they did not share or sell ART: (1) they think that the drugs are precious because they are lifesaving, (2) they get different ART medications, (3) they have been

The majority of clients reported that they did not share or sell ART.

Half of the providers in both 3- and 6-month arms expressed concerns about clients' ability to store a larger supply of ART, but clients reported no challenges.

instructed by health workers not to share, and (4) they will run out of pills sooner and may have problems at refill appointments.

If I sell a bottle it means I have wasted 1 month. So, when I go to the hospital, what lie will I tell the doctor? ... I can't sell a bottle of drugs because it will mean that I'm selling my life. —Female, 37 years old, 6-month arm

Several clients said that when someone had asked them for medicines, they did not share or sell pills, but they helped in other ways such as escorting the individual to the health facility or gifting them with other items like money or flour.

She came to me and said, "I'm too shy to go to the hospital. Share your drugs. If people see me receiving the drugs, they will laugh at me." I told her, "You are saying that they will laugh at you, but everyone keeps his/her own life. Let's go to the hospital. I will escort you. If you think it's far, I will also use my transport money." —Female, 30 years old, 6-month arm

In contrast, providers in both the 3- and 6-month arms raised concerns about pill sharing, primarily among couples. Commonly cited scenarios included sharing 1 bottle between 2 partners, sharing when a partner runs out of their medication, and sharing when a partner is unable to return to the ART clinic for a refill due to work or family reasons.

[It's] very common [sharing of medication]. You find someone has missed their appointment date. When you ask them, they tell you, "Yes, but there is never a day that I have missed without taking drugs." When you ask how, you will hear them say, "I was taking my wife's drugs." —Clinical Officer, 3-month arm

Less common among the providers were concerns of sharing ART with friends and in the broader community, although a few examples were provided in both arms.

A client said, "I forgot mine [ARVs]." And the other said, "You shouldn't forget," as she took them [ARVs] from her wrapper. Seeing this, you know that these people are sharing drugs. —Nurse, 3-month arm

Clients and providers were unable to provide examples of selling ART. Both clients and providers questioned the benefit of selling when asked because ART is freely available. Clients in the 6-month arm did not report added pressure or desire to share or sell ART despite having an increased supply of medication.

I have never heard [of selling], but I can say it would be difficult for a person to buy something that can be

acquired easily [for free]. —Clinical Officer, 3-month arm

Both providers and clients had heard rumors of alternative uses of ART, such as mixing it with beer and spirits to improve taste and potency and/or feeding ART to livestock to help growth, but no one reported any personal or direct experience with these uses of ART.

What people say is that they want the beer to be sour and that people should get drunk fast [if ART is added]. I don't have the proof that people do that. —Male, 46 years old, 6-month arm

Storage of ART

Approximately half of the providers in both arms expressed concerns about clients' ability to store an increased supply of ART. Although providers gave limited specific examples, one provider remembered a client who had reported his ART was destroyed because it was stored close to where he built his fire in his home.

Today, a patient showed me drugs that have completely melted. That person was given 3 months' supply. When I asked, he said, "Where I store my drugs, I also make fire." So, when I give him 6 months' supply, if the 3 months' supply has melted, what will happen to the other? —Clinical Officer, 3-month arm

When we asked clients about storage, none reported challenges with storing the 3- or 6-month supply. In both arms, clients frequently mentioned that protecting ART from damage (e.g., water or sun exposure) and keeping medication out of children's reach were considerations with medication storage. Additionally, clients reported that disclosing their HIV status to their household members facilitated storage of ART because they did not need to hide their supply at home and they could depend on others to assist in keeping them safe.

My husband also receives the drugs, so I don't hide [them]. My husband is also aware of the amount of drugs I have. —Female, 54 years old, 6-month arm

Drugs are dangerous to children. Children can't recognize them. They can get them [the drugs] and eat [them], and this can cause an accident. So, it's like hiding them [the drugs] and taking care of them [the children] at the same time. —Female, 36 years old, 6-month arm

All clients were asked if they had lost or misplaced their ART or if it had been stolen during the study. Only 1 client in the 3-month arm said

they had lost their ART supply. When asked about keeping ART safe, clients strongly voiced that they protected their ART because it was lifesaving.

No, I have never lost any. I take care of them because it's my whole life. —Female, 53 years old, 3-month arm

HIV Status Disclosure and Stigma

The majority of clients on ART in both arms reported having disclosed their HIV status to their primary sexual partner (96% in the 3-month arm and 100% in the 6-month arm). Providers did not discuss stigma and disclosure challenges in general or related to 3- versus 6-month dispensing. No clients in either arm reported unwanted partner disclosure related to ART supply. However, for some clients, carrying ART from the health facility was associated with a fear of unwanted disclosure to community members. Clients in both 3- and 6-month arms reported instances of being mocked for carrying ART bottles, particularly when they carried their medicines in plastic bags.

One day, they [community members] saw me carrying the bottles. They said a lot of bad things like, "Look at him, he is coming from the hospital carrying [ART], he is a fool, he is about to die." —Male, 44 years old, 3-month arm

Clients in the 6-month arm reported that although carrying the increased drug supply was not a burden, they changed their routine to accommodate it by adopting sturdier and more private bags like backpacks and cloth bags. Providers also noted that clients in the 6-month arm had changed their carrying methods.

When they changed me to 6 bottles, it was difficult to put 3 bottles in 1 pocket and the other 3 bottles in another pocket. That is why I thought of taking a bag to carry the medicine. —Male, 47 years old, 6-month arm

Benefits of Multimonth Dispensing

Clients in the 6-month arm reported several benefits of having less frequent visits to the health facility: (1) decreased direct costs in transportation; (2) decreased indirect costs in lost wages; (3) less time spent traveling to the health facility, particularly if they lived far away; and (4) less time waiting.

Clients reported that the 6-month dispensing interval was very helpful in alleviating these constraints.

I'm able to work for our daily needs and have time to rest and find food for the day. I see it as a good thing compared with back then [when receiving standard of

care] when you had to cancel plans so that you can go to the hospital to get drugs. —Female, 38 years old, 6-month arm

Clients in both arms mentioned feeling a greater sense of freedom and normalcy with fewer ART facility visits; this benefit was particularly evident among those in the 6-month arm. Examples of this freedom included being able to avoid unwanted HIV status disclosure due to fewer facility visits and having the freedom to prioritize personal and work endeavors.

I forget that I am a patient. I don't often have concerns that today or tomorrow I should go and get drugs. When I notice how much time I have, I do my work without any problems. When the appointment date is due, I come here. —Male, 39 years old, 6-month arm

I can tell the difference between the time that I was getting 3 bottles because now I come here fewer times. Since I am working, it is not good to be excusing yourself, and sometimes they [employers] don't respond positively, saying, "You are fond of excuses." I think it is very helpful to be getting 6 bottles. —Female, 39 years old, 6-month arm

Providers in the 6-month arm reported that longer ART dispensing periods also helped the health facility by alleviating clinic congestion resulting from large numbers of stable clients needing refills. Providers in the 3-month arm spoke about how 6-month dispensing would be beneficial for their workload.

But to me the option that can reduce my workload is the option of 6-months dispensing. And tell the patient that please if they have any problems, they can come and meet me. —Nurse, 3-month arm

Additional Facility Visits

Seventy-two percent of clients reported visiting a health facility during the study period for intercurrent illnesses including cough, headache, and skin rashes (77% in the 3-month arm and 66% in the 6-month arm). Only 2 of the 31 female respondents (both in the 3-month arm) reported returning to the ART facility for family planning during the year.

When asked about return visits, a subset of providers associated the 6-month dispensing strategy with poor client health-seeking behavior between appointments.

Those who are having a problem are forced to stay home until the [refill] date comes; that's what I have observed. Maybe they have developed a cough, and they are a TB

Clients in both study arms mentioned feeling a greater sense of freedom and normalcy with fewer ART facility visits.

Compared to the 3-month arm, a lower percentage of clients in the 6-month arm reported visiting a health facility for intercurrent illnesses.

[tuberculosis] suspect, but they don't come until they reach their appointment date. —Nurse, 6-month arm

Ideal ART Supply

Both clients and providers were asked about the ideal ART dispensing interval. Although providers raised concerns about clients' delayed health-seeking behaviors, nearly all providers chose a 6-month interval. They cited reasons including reduced congestion of clinics, reduced provider workload, and improved ability to care for clients who are newly initiated and unstable/ill. They also reiterated the benefits for clients such as reduced burden of accessing the clinic frequently.

Clients' ideal ART dispense interval ranged from 4 to 12 months, with approximately half choosing either 6 months (n=17) or 12 months (n=16). The reasons provided related to the benefits of decreased clinic visits that bring increased freedom and financial savings.

Six bottles would be much better. [Six-month dispensing] would help doctors have enough time to rest. Not only that, it would ease our mobility challenges and give us enough time to rest. —Female, 35 years old, 3-month arm

I would be happy if they gave 6 months', even a year [supply]. It would do me a lot of good. When your

appointment date is due, you plan and raise transport money. But maybe the day comes, and you don't have transport [money]. I farm during rainy season, and it's hard to stop and go out and look for transport money. You can even go into debt just so you can go to the hospital and get drugs. —Female, 38 years old, 6-month arm

A summary of areas of client and provider similarities and differences is provided in [Table 2](#).

DISCUSSION

In this qualitative substudy of the INTERVAL trial, long dispensing intervals were highly acceptable to clients and providers, with an ideal dispensing duration of 6 to 12 months. These findings are both valuable and timely in addressing potential implementation concerns of the acceptability of 6-month dispensing as a DMOC. Decreased clinic visits emerged as the strongest benefit of extended refill intervals for both clients and providers. This finding echoes that of other studies that have found that minimizing refill visits is highly attractive to both clients and providers.¹⁶ For clients, the 6-month dispensing interval provided time and financial savings related to a less frequent visit schedule. This finding aligns with many other studies that identify health-seeking costs—long wait times, expensive transport, and lost wages—as major barriers

TABLE 2. Comparison of Providers' and Clients' Perceived Challenges and Benefits of 6-Month ART Dispensing Interval, 10 Health Facilities in Malawi

Socioecological Model Theme	Client	Provider
Individual		
Sharing ART	Only 1 client reported sharing; all others did not share	Considered a common problem, particularly sharing among partners
Storage of ART	No reported challenges	Perception that clients have challenges storing increased ART supply
Communal		
Unwanted HIV status disclosure to community	Reported minimal challenges with easy adaptation strategies to avoid unwanted disclosure	Did not report challenges with pill carrying but perceived adaptive behaviors (i.e., using different bags)
Selling ART	No reports of personal experience with selling	No concern about selling
Organizational		
Visits for ART refills	Reduced number of visits Reduced cost Increased time and ability to attend to family and work demands	Reduced clients' costs and time Reduced providers' workload and clinic congestion Improved ability to see newly initiated/unwell clients
Visits for acute health needs	Reported returning for acute illnesses frequently	Perceived delays in clients' health-seeking behaviors

to successful ART adherence.^{3,17–19} Additionally, several clients in the 6-month arm noted that reduced clinic visits improved their ability to keep their HIV status private to the community and contributed to feelings of normalcy because they were spending less time seeking health services.

Benefits of decreased clinic visits also extended to the health system level. Providers reported decreased workload and improved ability to see clients who are unstable. Findings from other DMOCs, including fast-track refills and community-based ART groups, also show improved operational efficiency at the clinic level by reducing patient overcrowding and staff workload.^{5,10–12}

None of the clients in the 3-month arm reported benefits associated with this interval that suggested it was superior to 6-month dispensing. There were no obvious trends in our analysis to suggest that women had outlying barriers related to 3- and/or 6-month dispensing when compared to men.

Although clients and providers agreed about the acceptability of MMD, they disagreed about certain aspects. Providers perceived challenges and voiced concerns around clients' ability to handle the larger ART supply. Providers reported that sharing ART was common, but clients denied sharing and provided examples of alternative methods of support (i.e., transport, accompaniment) for those needing ART. Studies evaluating MMD have not reported instances of clients sharing ART due to the extended supply. However, sharing has been documented with other prescription medications, including antibiotics and antihypertensives.²⁰ It is possible that clients underreported sharing due to social desirability bias because ART providers strongly discourage it.

Medication storage was another provider concern that was not borne out in the client interviews. High rates of HIV disclosure (98%) facilitated ART storage among clients in our study. Findings may be different in a population with lower rates of disclosure. If 6-month dispensing is taken to scale, providers should review proper medication storage guidelines with clients and should suggest ways to ease burdens related to carrying and storing an increased drug supply.

Clients in both the 3- and 6-month arms mentioned that the value of ART was a reason they did not sell or share ART. The 6-month interval did not incentivize selling or sharing. Although the literature indicates that financial stress can influence ART adherence due to lack of money for transport to clinic or inability to step away from income-generating activities for refill visits,^{2,18,21} there is

scarce published evidence of selling ART for economic improvement. As clients and providers mentioned, there is a limited market for selling ART because medications are provided for free in most settings. It is possible that individuals underreported selling, but research staff were trained to emphasize confidentiality of responses and to build rapport to facilitate an honest discussion.

Finally, although most (72%) clients reported utilizing health services for intercurrent illnesses between their longer-duration ART refill visits, providers perceived 6-month dispensing to be associated with delayed presentation of acute illnesses. A study evaluating the impact of spaced clinic appointments for clients with HIV (6 months versus 1 month) found that 30% were removed from 6-month dispensing due to having unstable medical conditions such as decreased CD4 counts, ART regimen changes, pregnancy, nonadherence, and drug toxicity.²² If 6-month dispensing is taken to scale, clients should be counseled about coming to the ART clinic without delay for any new health issues. Providers should receive appropriate training about when to shift clients to shorter intervals due to poor adherence/virologic failure, side effects, after regimen changes, or during pregnancy.

Although we did not ask clients specifically about family planning visits at other types of facilities nor about community- or pharmacy-based family planning services, we found low reported utilization of family planning services at the ART clinic aside from refill visits. Thus, family planning service use may have been underreported (all women of reproductive age in the 6-month arm were counseled on the importance of regular family planning visits upon study enrollment). Future program implementation and research should focus on improved access to family planning under 6-month dispensing and/or other DMOCs that reduce clients' interactions with health care providers.

Limitations

Our study has several limitations. Clients were recruited for interviews if they could be reached by phone; this potentially resulted in selection bias based on socioeconomic status. Because the INTERVAL study is an unblinded clinical trial, both clients' and providers' responses may be subject to social desirability bias. We did not specifically ask providers how they adjusted their counseling with clients in the 6-month dispense interval arm. All but 1 of the 62 randomly selected clients were retained in care based on their randomly assigned ART dispense interval. Clients

Providers reported that longer dispensing intervals decreased workload and improved their ability to see clients who are unstable.

who did not stay on their assigned dispensing interval, defaulted from care, or were taken off of their interval for clinical reasons were not represented. Similarly, providers interviewed for the study may not necessarily reflect the views of all health care workers at the study sites.

CONCLUSION

Both clients and providers perceived 6-month ART dispensing as highly feasible and acceptable, citing benefits such as reduced cost of transport for clients, increased time for income-generating activities for clients, and improved clinic efficiency for providers. Further research is needed on encouraging client health-seeking behaviors for acute illnesses and use of family planning services for clients on 6-month dispensing intervals. If 6-month dispensing is scaled in high-burden HIV settings, ongoing evaluation should be performed to include both client and provider perspectives on the benefits and challenges of this DMOC.

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ORIGINAL ARTICLE

Diagnostic Utility and Impact on Clinical Decision Making of Focused Assessment With Sonography for HIV-Associated Tuberculosis in Malawi: A Prospective Cohort Study

Daniel Kahn,^a Kara-Lee Pool,^b Linna Phiri,^c Florence Chibwana,^c Kristin Schwab,^d Levison Longwe,^c Ben Allan Banda,^c Khumbo Gama,^c Mayamiko Chimombo,^c Chifundo Chipungu,^c Jonathan Grotts,^e Alan Schooley,^c Risa M. Hoffman^f

Among patients with HIV and with probable/confirmed TB, using the focused assessment with sonography for HIV-associated TB (FASH) protocol led to a 5-fold increase in the clinician's decision to initiate TB treatment on that day. FASH is a supplementary tool that can help clinicians diagnose patients with HIV-associated TB at the point-of-care and reduce delays in their treatment, particularly when access to other diagnostics is limited or unavailable.

ABSTRACT

Background: The focused assessment with sonography for HIV-associated tuberculosis (TB) (FASH) ultrasound protocol has been increasingly used to help clinicians diagnose TB. We sought to quantify the diagnostic utility of FASH for TB among individuals with HIV in Malawi.

Methods: Between March 2016 and August 2017, 210 adults with HIV who had 2 or more signs and symptoms that were concerning for TB (fever, cough, night sweats, weight loss) were enrolled from a public HIV clinic in Lilongwe, Malawi. The treating clinicians conducted a history, physical exam, FASH protocol, and additional TB evaluation (laboratory diagnostics and chest radiography) on all participants. The clinician made a final treatment decision based on all available information. At the 6-month follow-up visit, we categorized participants based on clinical outcomes and diagnostic tests as having probable/confirmed TB or unlikely TB; association of FASH with probable/confirmed TB was calculated using Fisher's exact tests. The impact of FASH on empiric TB treatment was determined by asking the clinicians prospectively about whether they would start treatment at 2 time points in the baseline visit: (1) after the initial history and physical exam; and (2) after history, physical exam, and FASH protocol.

Results: A total of 181 participants underwent final analysis, of whom 56 were categorized as probable/confirmed TB and 125 were categorized as unlikely TB. The FASH protocol was positive in 71% (40/56) of participants with probable/confirmed TB compared to 24% (30/125) of participants with unlikely TB (odds ratio=7.9, 95% confidence interval=3.9,16.1; $P<.001$). Among those classified as confirmed/probable TB, FASH increased the likelihood of empiric TB treatment before obtaining any other diagnostic studies from 9% (5/56) to 46% (26/56) at the point-of-care. For those classified as unlikely TB, FASH increased the likelihood of empiric treatment from 2% to 4%.

Conclusion: In the setting of HIV coinfection in Malawi, FASH can be a helpful tool that augments the clinician's ability to make a timely diagnosis of TB.

INTRODUCTION

The risk of developing active tuberculosis (TB) is 20–37 times higher in people living with HIV than in people who do not have HIV.¹ This risk is compounded by difficulty in diagnosing TB in individuals who have HIV, as they more commonly present with atypical radiographic findings, smear-negative TB, and disseminated extrapulmonary manifestations.² As a result, individuals with HIV and TB have a higher mortality rate, likely due to diagnostic uncertainty that leads to delays in therapy.³ Gold standard diagnostics, such as TB

^a Department of Internal Medicine, David Geffen School of Medicine, University of California at Los Angeles, Los Angeles, CA, USA.

^b Department of Radiology, David Geffen School of Medicine, University of California at Los Angeles, Los Angeles, CA, USA.

^c Partners in Hope, Lilongwe, Malawi.

^d Department of Medicine, Division of Pulmonology, David Geffen School of Medicine, University of California at Los Angeles, Los Angeles, CA, USA.

^e Department of Medicine Statistics Core, David Geffen School of Medicine, University of California at Los Angeles, Los Angeles, CA, USA.

^f Department of Medicine, Division of Infectious Disease, David Geffen School of Medicine, University of California at Los Angeles, Los Angeles, CA, USA.

Correspondence to Daniel Kahn (DaKahn@mednet.ucla.edu).

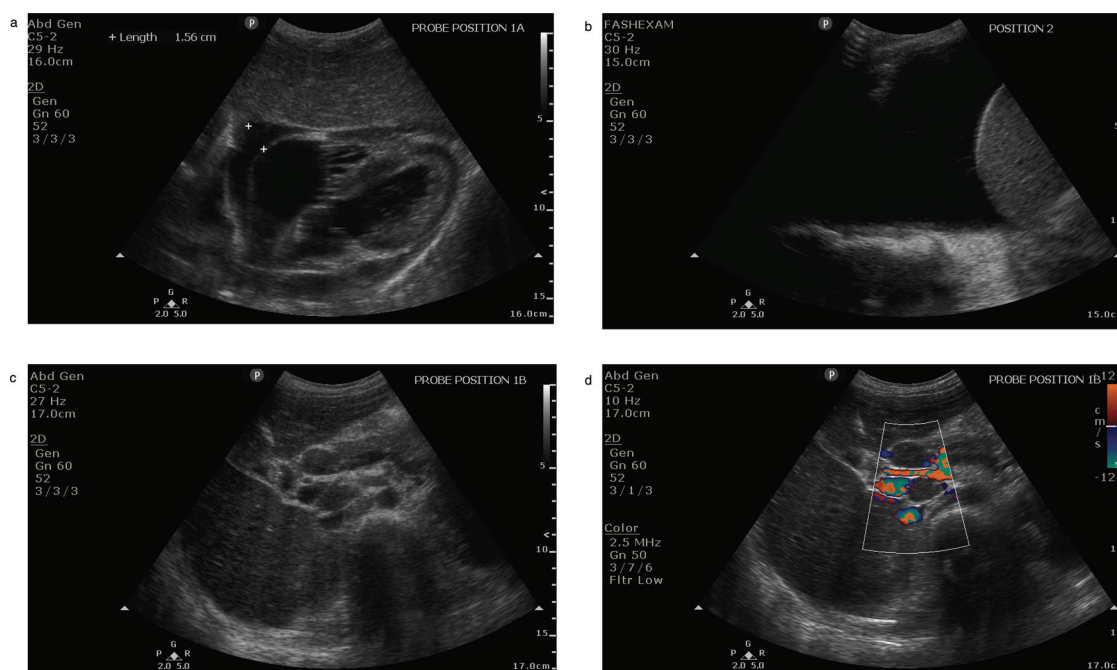
culture, are often unavailable in regions with the highest burden of TB and HIV. Even when these diagnostics are available, the results can take up to 6 weeks to return, causing delays in diagnosis and treatment. A recent autopsy study investigating patients with HIV who died in an inpatient ward in South Africa found that TB was implicated in two-thirds of those deaths and one-third of those cases were not diagnosed and treated at the time of death.⁴

To reduce TB morbidity and mortality, decrease transmissibility, and gain control of the epidemic, improved point-of-care diagnostics in resource-limited settings are needed. Ultrasound is one such diagnostic modality. Point-of-care ultrasound (POCUS) provides the clinician with immediate feedback to make informed decisions that can avoid delays in treatment. One POCUS protocol, focused assessment with sonography for HIV-associated TB (FASH), has been developed to improve the diagnosis of extrapulmonary TB in patients with HIV by evaluating for pericardial fluid, pleural fluid, ascites, abdominal lymphadenopathy, and hepatic

and splenic hypoechoic focal lesions.⁵ These sonographic findings of HIV-associated extrapulmonary TB have been described in various settings and populations.^{6–13} The FASH protocol has been shown to detect TB that would be missed based on other available diagnostics.^{14,15} In many resource-limited settings, POCUS is more available than regular radiology services (due to availability of low-cost, small, rechargeable ultrasound devices) and point-of-care lab diagnostics, which require equipment, a regular electricity source, a supply chain for reagents, and trained technicians. FASH can be taught to midlevel health workers and has been successfully implemented in resource-limited settings.^{5,16–19} It is increasingly plausible that rural facilities could rely only on history, physical exam, and FASH to make an initial assessment of TB.

Despite the reported benefits of using FASH for TB diagnosis, uncertainty remains about its sensitivity, specificity, and predictive value in settings like Malawi where exams are often performed by midlevel providers. It is also unclear how best to incorporate FASH into the TB diagnostic algorithm. We

The FASH protocol has been shown to detect TB that would be missed based on other available diagnostics.



Images of Findings From Focused Assessment With Sonography of HIV-Associated Tuberculosis Protocol in Participants With Signs and Symptoms of Tuberculosis

(a) Anechoic fluid surrounding the heart consistent with a moderate pericardial effusion. (b) Anechoic area superior (left) to the diaphragm and liver consistent with a large right pleural effusion. (c) Isoechoic nodules consistent with peri-portal and para-aortic lymphadenopathy. (d) Color Doppler further differentiates vasculature from lymph nodes.

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sought to quantify the predictive value of the FASH protocol for TB and to assess the impact on clinical decision making at the point-of-care in Malawi.

METHOD

Setting

We performed a prospective cohort study at Partners in Hope Medical Center in Lilongwe, Malawi, a facility that delivers free HIV care and includes an antiretroviral therapy clinic serving approximately 5,500 clients. Staff at the medical center have the following diagnostic tests available to them when evaluating clients who present with signs and symptoms of TB: complete blood count, CD4 cell count, viral load, acid fast bacteria stains, Xpert MTB/RIF to detect *Mycobacterium tuberculosis* (MTB) and resistance to the anti-TB drug rifampicin (RIF), urine lipoarabinomannan assay (LAM), and chest radiography. In 2015, the medical center acquired an ultrasound machine, and clinicians were trained in the FASH protocol. Information about this training has been previously published.^{17,18}

Population

Between March 2016 and August 2017, we enrolled 210 adults with HIV who were 18 years of age or older who presented to Partners in Hope Medical Center for care and answered “yes” to having 2 or more of the following TB symptoms: fever, cough, night sweats, weight loss. We used convenience sampling to enroll participants. If an individual met criteria based on the routine TB screening questions, and the study and clinical staff were available to perform screening, consent, and study procedures, then the participant was screened and enrolled, if eligible. Participants were eligible regardless of antiretroviral therapy status. Individuals were excluded if they were already receiving TB treatment or were pregnant.

Written informed consent was obtained from all participants, and the study was approved by the Malawi National Health Sciences Research Committee and the University of California at Los Angeles (UCLA) Institutional Review Board.

Study Procedures

After enrollment, the treating clinician (1 of 5 clinical officers or 1 medical doctor) conducted a history and physical exam and documented on a paper study form whether they would empirically treat for TB based on the history and physical exam findings. The treating clinician

then conducted the FASH protocol, which included assessment for pericardial, pleural, and ascitic fluid; abdominal lymphadenopathy; and focal liver and splenic lesions using a Philips ClearVue 650 with a C5-2 abdominal transducer (2–5 MHz). FASH was defined as positive if any single component was positive, with the exception of trace pericardial effusions (defined as pericardial effusion <0.5 cm), which are considered clinically insignificant. After completing the FASH, the same clinician documented whether they would treat for TB based on the FASH results (before conducting any labs or other studies) to mimic scenarios that may commonly occur in settings throughout Malawi that could have access to POCUS but not point-of-care labs or chest radiography.

After FASH was completed, all participants were then evaluated with sputum microscopy, sputum Xpert MTB/RIF assay, urine LAM, complete blood count, CD4 cell count, viral load, and chest radiography. Sputum and tissue cultures were not obtained as they were not readily available in Malawi.

At the end of the clinical visit, based on all available data, the treating clinician made final management decisions, including whether to treat for TB. Participants were asked to return for study follow-up visits at 2 weeks, 3 months, and 6 months after enrollment. At each follow-up visit, a study nurse evaluated the participant for ongoing TB symptoms, took vital signs and weight, and reviewed the medical record for any new diagnostic results related to TB. Long-term management of TB treatment was performed by Partners in Hope clinicians per the standard of care in Malawi.

FASH Quality Assurance

Still images of each FASH protocol component were shared with a UCLA radiologist using an encrypted file-sharing program. This radiologist read all images within 72 hours. Discrepancies between the clinical officer and expert radiologist review were immediately communicated to the clinical team such that patient management could be adjusted as needed. Detailed methods on FASH quality assurance have been previously published.¹⁸

Definitions for Analysis

After the 6-month follow-up visit, we categorized each participant into 1 of 3 diagnostic groups based on likelihood of TB: (1) confirmed TB, defined by any 1 positive microbiologic test (sputum acid fast bacteria microscopy, Xpert MTB/RIF assay, or urine LAM); (2) probable TB, defined as a

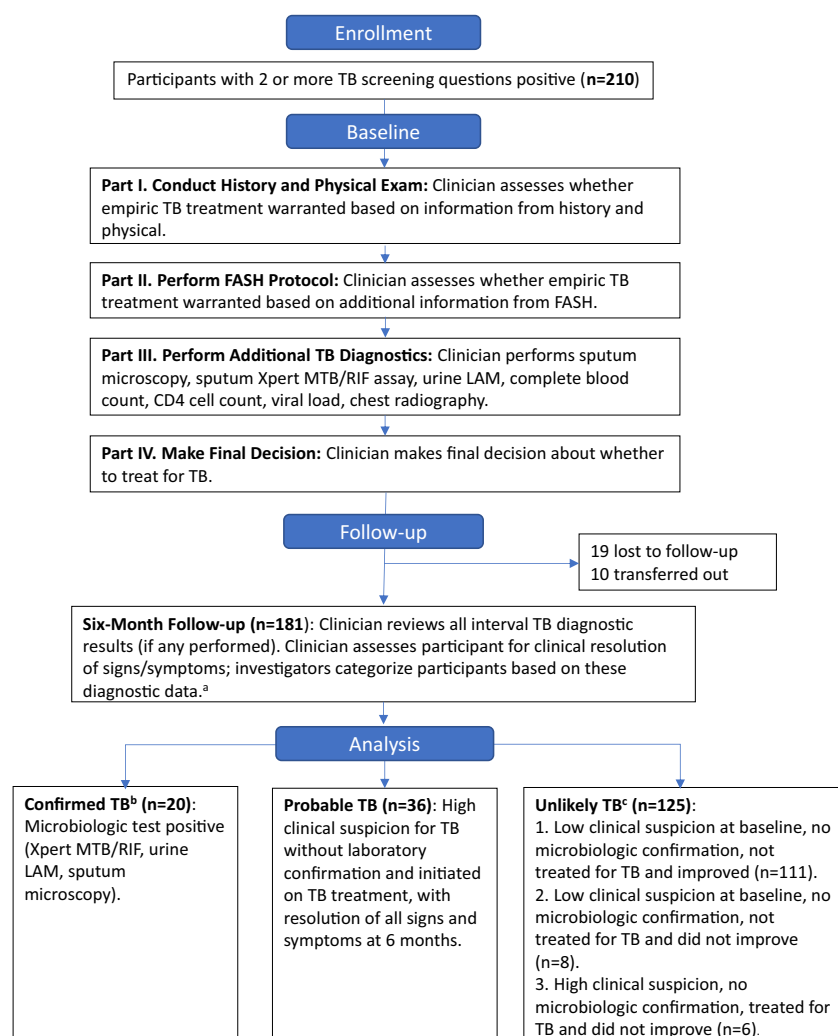
clinical diagnosis of TB without laboratory confirmation and initiated on TB treatment, with resolution of all signs and symptoms at 6 months; or (3) unlikely TB, defined as no positive laboratory finding for TB and was either treated for TB and did not improve by 6 months or was not treated for TB (Figure 1).

There were no significant differences between the baseline characteristics of confirmed and probable TB groups (Supplementary Table 1);

therefore, these diagnostic categories were combined into 1 group for analyses and are referred to throughout as probable/confirmed TB.

Individuals who died during the study without laboratory confirmation of TB were categorized as unlikely TB whether they were treated for TB or not based on the above definition. Participants who transferred out or were lost to follow-up were excluded from the analysis as they could not be assigned a TB category.

FIGURE 1. Participant Enrollment in a Prospective Cohort Study Assessing Diagnostic Utility of FASH at an Urban Medical Center, Lilongwe, Malawi, and Clinicians' Stepwise Diagnostic Evaluation and Decision Making



Abbreviations: FASH, focused assessment with sonography for HIV-associated tuberculosis; LAM, lipoarabinomannan; MTB, *Mycobacterium tuberculosis*; RIF, rifampicin; TB, tuberculosis.

^aFinal categorization made by study investigators based on 6-month data and definitions above.

^bIncludes 2 deaths.

^cIncludes 12 deaths: 7 in Subgroup 2 and 5 in Subgroup 3.

Statistics

Summary statistics were performed for all baseline demographic and clinical data. We compared characteristics of participants in each diagnostic category using Wilcoxon Rank Sum tests for continuous data and Fisher's exact tests for discrete data. FASH data and associations with TB were summarized using odds ratios (OR), sensitivity, specificity, positive predictive value and negative predictive value, and positive likelihood ratio and negative likelihood ratio with 95% confidence interval (CI). A *P* value below .05 was considered statistically significant, and all tests were 2-sided. Statistical analysis was done using the R Language and Environment for Statistical Computing (R Core Team, 2019, Vienna, Austria).

RESULTS

Baseline Characteristics

Of the 210 participants enrolled, 19 were lost to follow-up and 10 transferred out; these 29 participants were excluded from the analysis. The 14 participants who died during the study were included in the final analysis, including 2 participants with confirmed TB, and categorized accordingly, and 12 without laboratory confirmation and were categorized as unlikely TB. Of the 181 participants included in the final analysis, we classified 56 as probable/confirmed TB (20 microbiologically confirmed and 36 probable) and 125 as unlikely TB. Compared to the unlikely TB group, those with probable/confirmed TB were more likely to have never taken antiretroviral therapy and to have had a lower CD4 count and lower body mass index (Table 1).

The most common positive confirmatory tests were urine LAM (13), sputum Xpert MTB/RIF (9), and sputum microscopy (7). Twenty-eight percent (50/181) of participants had an abnormal chest radiography, including 64% (36/56) of participants in the probable/confirmed TB group and 11% (14/125) of participants in the unlikely TB group. Of those who had an abnormal chest radiography, 18% (9/50) had a positive sputum (either by microscopy or Xpert).

Comparison of Baseline FASH Findings

Seventy-one percent (40/56) of participants with probable/confirmed TB were found to have a positive FASH, compared to 24% (30/125) of participants in the unlikely TB group (OR=7.9, 95% CI=3.9,16.1; *P*<.001). Pericardial effusions (≥0.5 cm) were the most common sonographic

finding in those with probable/confirmed TB but were also seen in the unlikely TB group (43% versus 10% respectively, *P*<.001). In the group of participants who had a positive FASH protocol but were not treated for TB, the majority had small pericardial effusions as the only FASH finding. In the probable/confirmed TB group, abdominal lymphadenopathy and pleural effusions were seen in 24% and 14% of patients, respectively, and were rarely seen in the unlikely TB group at 2% and 1%, respectively (*P*<.001). Ascites was also seen more frequently with probable/confirmed TB compared to unlikely TB (16% versus 4% respectively, *P*=.01). Hepatic and splenic lesions were uncommon in both groups (Table 2). In a sensitivity analysis comparing only those with confirmed TB (probable TB excluded) to those with unlikely TB, all associations above remained significant except for ascites (Supplementary Table 2). In a sensitivity analysis recategorizing participants who died without microbiologic confirmation from unlikely TB to probable TB, the association of FASH with probable/confirmed TB was strengthened (Supplementary Table 3).

Predictive Value of the FASH Protocol

Individual FASH findings were highly specific for probable/confirmed TB (≥90%), but not sensitive (range 2%–43%). Abdominal lymphadenopathy, followed by pleural and pericardial effusions, had the highest positive predictive value and positive likelihood ratio for probable/confirmed TB (Table 3). A positive FASH, defined as any single finding of the protocol being positive, raised the sensitivity to 71% while lowering the specificity to 76%.

Impact of FASH on Clinical Decision Making

Clinicians reported that the FASH protocol aided clinical decision making in 76% of encounters. Based on history and physical exam alone, clinicians reported that they would empirically treat 9% (5/56) of participants who were ultimately classified into the probable/confirmed TB group. After the FASH protocol was completed and before any further diagnostic tests were conducted, clinicians reported they would empirically treat 46% (26/56) of these same participants. Of the 36 participants with probable TB (clinically diagnosed and treated, with complete resolution of symptoms), FASH provided sonographic evidence of TB in 75% (27/36) of participants. For those individuals classified as unlikely TB, clinicians reported they would treat 2% (3/125) of

Clinicians reported that the FASH protocol aided clinical decision making in 76% of encounters.

TABLE 1. Baseline Demographic and Clinical Characteristics of Participants at an Urban Medical Center, Lilongwe, Malawi, Stratified by TB Category (N=181)

	Unlikely TB (n=125)	Probable/Confirmed TB (n=56)	P Value
Age, years, median (IQR)^a	40.0 (34.0–45.0)	39.0 (33.0–43.0)	.51
Gender			.42
Male, No. (%)	56.0 (44.8)	29.0 (51.7)	
Female, No. (%)	69.0 (55.2)	27.0 (48.2)	
Baseline CD4 Count (cells/mm³), median (IQR)^b	256.0 (80.0–484.0)	117.0 (29.0–176.0)	<.001
Viral Load (copies/ml)^c			.21
<1,000, No. (%)	80.0 (64.0)	28.0 (50.0)	
1,000–50,000, No. (%)	14.0 (11.2)	11.0 (19.6)	
>50,000, No. (%)	22.0 (17.6)	9.0 (16.0)	
Baseline ART Regimen^d			.001
TDF/3TC/EFV, No. (%)	70.0 (56.0)	20.0 (35.7)	
Other NNRTI-based regimen, No. (%)	17.0 (13.6)	2.0 (3.6)	
Protease inhibitor-based regimen, No. (%)	12.0 (9.6)	3.0 (5.4)	
No ART, No. (%)	25.0 (20.0)	26.0 (46.4)	
Previous TB,^e No. (%)	32.0 (25.6)	12.0 (21.4)	.58
TB Sign/Symptom^f			
Fever, No. (%)	83.0 (66.4)	42.0 (75.0)	.30
Cough, No. (%)	108.0 (86.4)	51.0 (91.1)	.47
Night sweats, No. (%)	77.0 (61.6)	37.0 (66.1)	.62
Weight loss, No. (%)	98.0 (78.4)	50.0 (89.3)	.10
BMI, median (IQR)	19.2 (17.5–22.9)	18.6 (16.7–19.8)	.01

Abbreviations: ART, antiretroviral therapy; BMI, body mass index; IQR, interquartile range; NNRTI, non-nucleoside reverse transcriptase inhibitor; TB, tuberculosis; TDF/3TC/EFV, tenofovir disoproxil fumarate/lamivudine/efavirenz.

^aMissing in 5 individuals.

^bMissing in 4 individuals.

^cMissing in 17 individuals.

^dMissing in 6 individuals.

^eBased on participant self report.

^fParticipants could have 2 or more signs/symptoms based on screening questions at study entry.

participants after the history and physical exam and 4% (5/125) after the FASH protocol and before any further diagnostic tests were conducted (Figure 2).

DISCUSSION

Our data show the diagnostic utility of the FASH protocol in Malawi and support the recently published 2018 Malawi TB guidelines that recommend the use of FASH to improve the diagnosis of TB in individuals coinfecting with HIV.²⁰ Our

data are consistent with prior studies from other settings that demonstrate that the FASH protocol is predictive of TB.^{5,8,9,14,15,21,22} A recent study from Malawi noted that the majority (61%) of TB diagnoses could not be confirmed microbiologically,²³ leaving the clinician with a challenging decision: initiate the unconfirmed individual on prolonged and potentially toxic medications, or defer therapy, risking morbidity and mortality from untreated TB. Delays in TB diagnosis in individuals who have HIV result in high morbidity and mortality, so any intervention that can reduce

TABLE 2. Baseline FASH Findings in Participants at an Urban Medical Center, Lilongwe, Malawi, Stratified by TB Category (N=181)

	Overall, No. (%) (N=181)	Unlikely TB, No. (%) n=125	Probable/Confirmed TB, No. (%) n=56	P Value
Pericardial effusion ^a	36 (19.9)	12 (9.6)	24 (42.9)	<.001
Pleural effusion	9 (5.0)	1 (0.8)	8 (14.3)	<.001
Ascites	14 (7.7)	5 (4.0)	9 (16.1)	.01
Abdominal lymphadenopathy	15 (8.3)	2 (1.6)	13 (23.2)	<.001
Liver lesions	4 (2.2)	3 (2.4)	1 (1.8)	>.99
Splenic lesions	5 (2.8)	2 (1.6)	3 (5.4)	.17
FASH positive ^b	70 (38.7)	30 (24.0) ^c	40 (71.4)	<.001
FASH negative	111 (61.3)	95 (76.0)	16 (28.6)	<.001

Abbreviations: FASH, focused assessment with sonography for HIV-associated tuberculosis; TB, tuberculosis.

^a Trace pericardial effusions were excluded from the analysis due to unclear clinical significance.

^b Any single finding of the protocol is positive.

^c Positive FASH for unlikely TB subgroups: (1) low clinical suspicion with improvement=19/111; (2) low clinical suspicion without improvement=5/8; (3) High clinical suspicion, treated, without improvement=6/6.

TABLE 3. Associations of FASH Findings With Probable/Confirmed TB in Participants at an Urban Medical Center, Lilongwe, Malawi (N=56)

Variable	OR (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	PLR (95% CI)	NLR (95% CI)
Pericardial effusion ^a	7.06 (3.18, 15.66)	0.43 (0.30, 0.57)	0.90 (0.84, 0.95)	0.67 (0.49, 0.81)	0.78 (0.70, 0.84)	4.30 (2.32, 7.97)	0.63 (0.50, 0.80)
Pleural effusion	8.91 (2.35, 33.82)	0.18 (0.09, 0.30)	0.98 (0.93, 1.00)	0.77 (0.46, 0.95)	0.73 (0.65, 0.79)	9.00 (2.58, 31.45)	0.84 (0.74, 0.95)
Ascites	4.60 (1.47, 14.44)	0.16 (0.08, 0.28)	0.96 (0.91, 0.99)	0.64 (0.35, 0.87)	0.72 (0.64, 0.79)	4.00 (1.40, 11.39)	0.88 (0.78, 0.99)
Abdominal lymphadenopathy	13.35 (3.66, 48.71)	0.25 (0.14, 0.38)	0.98 (0.93, 1.00)	0.82 (0.57, 0.96)	0.74 (0.67, 0.81)	12.50 (3.74, 41.80)	0.77 (0.66, 0.90)
Hepatic lesions	0.74 (0.08, 7.27)	0.02 (0.00, 0.10)	0.98 (0.93, 1.00)	0.25 (0.01, 0.81)	0.69 (0.62, 0.76)	1.00 (0.11, 9.40)	1.00 (0.96, 1.05)
Splenic lesions	3.48 (0.57, 21.43)	0.05 (0.01, 0.15)	0.98 (0.94, 1.00)	0.60 (0.15, 0.95)	0.70 (0.63, 0.77)	2.50 (0.43, 14.55)	0.97 (0.91, 1.04)
FASH positive	7.92 (3.89, 16.12)	0.71 (0.58, 0.83)	0.76 (0.68, 0.83)	0.57 (0.45, 0.69)	0.86 (0.78, 0.92)	2.96 (2.08, 4.21)	0.38 (0.25, 0.58)

Abbreviations: CI, confidence interval; FASH, focused assessment with sonography for HIV-associated tuberculosis; NLR, negative likelihood ratio; NPV, negative predictive value; OR, odds ratio; PLR, positive likelihood ratio; PPV, positive predictive value; TB, tuberculosis.

^a Trace pericardial effusions were excluded from the analysis due to unclear clinical significance.

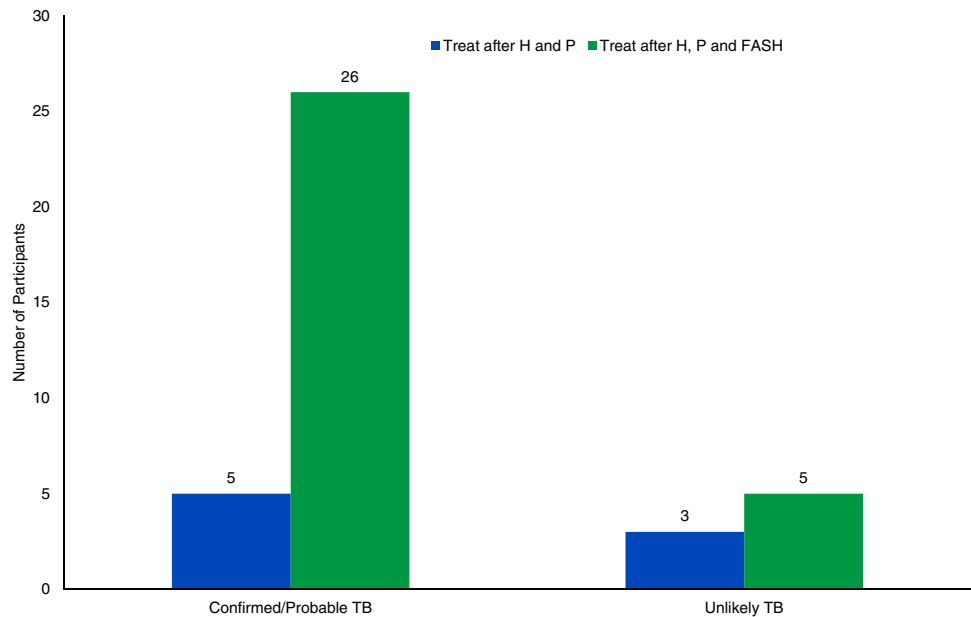
Our study is unique in assessing clinicians' suspicion of TB both after completing a history and physical exam and after completing the FASH protocol.

time to TB treatment has the potential to have a significant impact on clinical outcomes.²⁴

Our study is unique in that we assessed clinicians' suspicion of TB at 2 time points: (1) after completion of the history and physical exam, and (2) after completion of the FASH protocol, but before any other diagnostic tests were performed, allowing for a real-time assessment of how FASH influenced the decision making of clinicians in settings where chest radiography and lab

diagnostics may not be available. This is relevant because in many rural settings in Malawi, traditional radiography and lab diagnostics remain limited while POCUS equipment is becoming increasingly available. Therefore, FASH could help clinicians decide to start empiric TB treatment while awaiting test results and/or referring to facilities for further diagnostic testing. In our study, when the history and physical exam were less consistent with TB, the FASH protocol did not

FIGURE 2. Comparison of Clinicians' Decision to Empirically Treat TB in Participants at 2 Time Points at an Urban Medical Center, Lilongwe, Malawi, by TB Category^a



Abbreviations: FASH, focused assessment with sonography for HIV-associated tuberculosis; H, history; P, physical exam; TB, tuberculosis.

^aTB categories determined by study authors after 6-month follow-up.

increase the clinician's clinical concern for TB, therefore FASH did not contribute to overtreatment. Among those with probable/confirmed TB, FASH led to a 5-fold increase in the clinician's decision to initiate treatment on that day.

When performing the FASH protocol, if a patient has certain findings, such as abdominal lymphadenopathy, pleural effusions, and splenic lesions, the odds of the patient having TB are high. These findings should warrant strong consideration for empiric treatment.^{8,22} A recent study evaluating FASH in participants with culture proven HIV-associated TB demonstrated that FASH is more specific than sensitive, and specificity continues to increase with incrementally positive FASH findings.¹² Conversely, FASH should not be used to exclude a diagnosis of TB given its low sensitivity. It is important to consider other etiologies that may lead to positive FASH findings, such as Kaposi sarcoma, lymphoma, and non-TB mycobacteria. It is also possible that untreated HIV can be associated with findings, such as abdominal lymphadenopathy, without any other contributory coinfection. However, prior studies demonstrate that lymphadenopathy ≥ 1.0 – 1.5 cm is characteristic of TB with HIV.^{7,11,12} It is also

important to note that the cause of positive FASH findings differ in individuals who do not have HIV or in environments with low TB prevalence.⁸

Contrary to prior studies, we had very few participants with splenic lesions, which have been shown to be common and significantly associated with TB.^{8–11,22,25,26} This is likely secondary to a higher degree of difficulty in acquiring this image and increased sensitivity when using the high frequency linear probe in place of the abdominal curvilinear probe, which was not used in our study.²⁷ As FASH training expands across Malawi and similar resource-limited settings, ample time should be dedicated to training on how to obtain splenic images.

Limitations

Our study has several limitations. First, it is possible that participants in the unlikely or probable TB categories were misclassified due to the lack of microbiological or histological confirmation. This is a common limitation for TB studies in low-resource areas and represents the reality faced by clinicians. This study took a conservative approach and required a high burden of evidence to classify a

Among those with probable/confirmed TB, FASH led to a 5-fold increase in the clinician's decision to initiate treatment on that day.

participant as probable TB. We chose to classify deaths without TB diagnostic confirmation as unlikely TB to avoid the possibility of biasing the results in favor of the FASH protocol. However, many of these individuals presented late, had positive FASH findings, and may have died from TB. We performed a sensitivity analysis recategorizing those who died as probable TB, and our results were strengthened. Second, given our small sample size, we did not exclude participants with pulmonary TB from the sample nor stratify by pulmonary versus extrapulmonary TB. In settings where pulmonary TB can be confirmed at the point-of-care by sputum microscopy and chest radiography, FASH would not be required as an adjunctive tool. Lastly, performing ultrasound has a high degree of interoperator variability. Our study had strong support from an expert radiologist from UCLA who provided continuous and real-time quality assurance. This type of support may not be available for many programs. Expansion of teleradiology to support the implementation of FASH should be considered within resource-limited settings.^{18,28}

CONCLUSION

The FASH protocol is an adjunctive diagnostic tool that is predictive of TB in individuals with HIV and can augment clinicians' ability to diagnose TB at the point-of-care and reduce delays in treatment, particularly in settings with limited lab diagnostic capacity. The FASH protocol also plays an important role for clinicians who remain concerned for TB coinfection in individuals with an initial negative work-up but ongoing high clinical suspicion. Efforts to evaluate real-world implementation of FASH across a variety of settings will be important for understanding how to best scale this strategy in a range of resource-limited settings.

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ORIGINAL ARTICLE

Coaching Intensity, Adherence to Essential Birth Practices, and Health Outcomes in the BetterBirth Trial in Uttar Pradesh, India

Dale A. Barnhart,^a Donna Spiegelman,^{a,b} Corwin M. Zigler,^{c,d} Nabihah Kara,^e Megan Marx Delaney,^{a,e} Tapan Kalita,^{f,g} Pinki Maji,^f Lisa R. Hirschhorn,^h Katherine E. A. Semrau^{e,i,j}

Frequent coaching was associated with increased adherence to evidence-based essential birth practices among birth attendants but not with improved maternal and perinatal health outcomes in the BetterBirth Trial, which assessed the impact of a complex intervention to implement the World Health Organization's Safe Childbirth Checklist. To promote sustainable behavior change, future coaching-based interventions may need to explore cost-effective, feasible mechanisms for providing more frequent coaching delivered with high coverage among health care workers for longer durations.

ABSTRACT

Background: Coaching can improve the quality of care in primary-level birth facilities and promote birth attendant adherence to essential birth practices (EBPs) that reduce maternal and perinatal mortality. The intensity of coaching needed to promote and sustain behavior change is unknown. We investigated the relationship between coaching intensity, EBP adherence, and maternal and perinatal health outcomes using data from the BetterBirth Trial, which assessed the impact of a complex, coaching-based implementation of the World Health Organization's Safe Childbirth Checklist in Uttar Pradesh, India.

Methods: For each birth, we defined multiple coaching intensity metrics, including coaching frequency (coaching visits per month), cumulative coaching (total coaching visits accrued during the intervention), and scheduling adherence (coaching delivered as scheduled). We considered coaching delivered at both facility and birth attendant levels. We assessed the association between coaching intensity and birth attendant adherence to 18 EBPs and with maternal and perinatal health outcomes using regression models.

Results: Coaching frequency was associated with modestly increased EBP adherence. Delivering 6 coaching visits per month to facilities was associated with adherence to 1.3 additional EBPs (95% confidence interval [CI]=0.6, 1.9). High-frequency coaching delivered with high coverage among birth attendants was associated with greater improvements: providing 70% of birth attendants at a facility with at least 1 visit per month was associated with adherence to 2.0 additional EBPs (95% CI=1.0, 2.9). Neither cumulative coaching nor scheduling adherence was associated with EBP adherence. Coaching was generally not associated with health outcomes, possibly due to the small magnitude of association between coaching and EBP adherence.

Conclusions: Frequent coaching may promote behavior change, especially if delivered with high coverage among birth attendants. However, the effects of coaching were modest and did not persist over time, suggesting that future coaching-based interventions should explore providing frequent coaching for longer periods.

INTRODUCTION

Rates of maternal and neonatal mortality in low- and middle-income countries can be more than 10 times higher than in high-income countries.^{1,2} Despite global increases in facility-based deliveries, progress in reducing the rates of these preventable deaths has been slower than expected due to poor quality of care in health facilities and poor adherence to evidence-based practices among birth attendants.^{3–7} Improving the quality of care at birth facilities has the potential to avert 531,000 stillbirths, 1.3 million newborn deaths, and 112,000 maternal deaths each year.⁸ However, evidence-based

^a Harvard T.H. Chan School of Public Health, Boston, MA, USA.

^b Center for Methods in Implementation and Prevention Science and Department of Biostatistics, Yale School of Public Health, New Haven, CT, USA.

^c University of Texas, Austin, TX, USA.

^d Dell Medical School, Austin, TX, USA.

^e Ariadne Labs, Boston, MA, USA.

^f Population Services International, Lucknow, Uttar Pradesh, India.

^g Access Health International, Hyderabad, Telangana, India.

^h Northwestern University Feinberg School of Medicine, Chicago, IL, USA.

ⁱ Brigham and Women's Hospital, Boston, MA, USA.

^j Harvard Medical School, Boston, MA, USA.

Correspondence to Dale Barnhart (dale_barnhart@hms.harvard.edu).

strategies for improving the quality of care in birth facilities are lacking. Providing training alone can increase knowledge of evidence-based practices but does not necessarily translate into meaningful improvements in quality of care.^{9,10} Consequently, additional strategies are needed to improve the quality of intrapartum and postpartum care.

Coaching is one strategy to promote birth attendant behavior change. The coaching process helps individuals use their existing skills, resources, and training to improve their performance and achieve personalized goals.^{11,12} Typically, coaching focuses on individual behavior change, but it can also be directed toward addressing systemic problems. Unlike traditional supervision, which is a hierarchical process where a leader is accountable for the activities of a group or individual,¹³ or mentoring, which is focused more broadly on professional and personal development, coaching is individual-focused, task-oriented, and performance-driven.¹⁴ To improve performance, coaches use multiple approaches, including modeling desired behaviors, providing supportive supervision, providing auditing and feedback, and promoting problem solving.¹⁵ These strategies are effective at improving quality of care in low- and middle-income countries across a variety of clinical areas,^{16,17} including Integrated Management of Childhood Illness,^{18,19} drug management and prescription practices,^{20,21} primary care,²² malaria case management,²³ voluntary male circumcision,²⁴ and reproductive health.^{25,26}

Although some studies have reported associations between increased intensity of coaching-related activities and improved quality of care,^{21–23} the optimal coaching intensity needed to promote and sustain behavior change is unknown. Coaching intensity can be quantified across multiple domains, including frequency (e.g., 2 coaching visits per week); duration (e.g., 6 weeks of coaching); and cumulative dose, which reflects both the frequency and the duration of the intervention (e.g., 2 sessions per week for 6 weeks equals 12 cumulative visits).²⁷

Once the desired coaching regimen has been determined, coaching fidelity can also be described in terms of scheduling adherence or the extent to which the coaching regimen is delivered in accordance with the intended schedule.²⁸ Additional dimensions of coaching intensity exist (Box), and fidelity could also be described in terms of these other domains. Understanding which domains of coaching intensity are most strongly associated with quality of care improvements can identify coaching regimens that are optimized to promote behavior change and, ultimately, to improve health outcomes.

One coaching-based intervention designed to improve the quality of care provided to mothers and newborns during facility-based childbirth is the BetterBirth Program. Although this intervention did not reduce maternal morbidity or maternal and perinatal mortality in a recent matched-pair, cluster-randomized trial conducted in Uttar Pradesh, India, it increased birth attendant adherence to 18 essential birth practices (EBPs) believed by experts to prevent or successfully manage complications during facility-based deliveries from an average of 7.9 in the control arm to an average of 11.1 in the intervention arm.²⁹

In this article, we used data from the intervention arm of the BetterBirth Trial to assess the relationship between coaching frequency, cumulative coaching, and scheduling adherence with birth attendant adherence to EBPs and maternal and perinatal health outcomes. By investigating multiple dimensions of coaching intensity, we aimed to provide insights into the optimal coaching regimen for future coaching-based interventions.

METHODS

Intervention

The BetterBirth Program was designed to promote the use of the World Health Organization's Safe Childbirth Checklist (SCC), a 28-item tool intended

By investigating dimensions of coaching intensity, we aimed to provide insights into the optimal coaching regimen for future interventions.

BOX. Coaching Intensity Domains

Coaching Form^a: coaching delivery method, including the coach's identity and experience level (e.g., peer coaching, expert coaching) and the strategies the coach used to generate behavior change (e.g., role playing, motivational support)

Coaching Quality^a: coach's ability to correctly and consistently use coaching strategies to generate behavior change

Coaching Frequency: number of coaching sessions delivered over a specific duration of time (e.g., 2 coaching visits per week)

Coaching Duration^a: time period during which coaching is delivered (e.g., 6 weeks of coaching)

Cumulative Coaching: accrual of exposure to coaching over time that is determined by both coaching frequency and coaching duration (e.g., 2 sessions per week for 6 weeks equals 12 cumulative visits)

^aCoaching intensity domain not covered in this analysis.

to assist birth attendants in performing EBPs. To ensure EBPs are completed in time to avoid potential complications, these items are organized into 4 “pause points”: (1) on admission, (2) just before pushing, (3) within 1 hour after birth, and (4) before discharge. When using the checklist, birth attendants can either first read the item and then complete the task or first provide care and then review the checklist to confirm that all tasks for that pause point have been completed.³⁰ Coaching was recommended as a core component of SCC implementation packages since the checklist’s initial development³¹ and was a major feature of the BetterBirth Program’s multicomponent implementation package.

The BetterBirth Program used an engage-launch-support model, which has been previously described in detail.^{32–34} Briefly, district- and facility-level leadership were introduced to the BetterBirth program and engaged to identify priority areas for improvement related to the SCC. Each facility held an educational and motivational launch event to train birth attendants on using the SCC. Finally, ongoing coaching and data feedback were used to support behavior change.

Birth attendants, who were primarily auxiliary nurse midwives or general nurses in the labor and delivery wards, received peer-to-peer coaching from study staff who were nurses with training in childbirth and at least 2 years of experience in delivery. These coaching relationships were designed to be collaborative and were not designed to replace the existing traditional supervision structure. In practice, coaches’ training, age, and years of experience were similar to that of the nurse birth attendants, who comprised approximately 78% of the birth attendant population. However, about 16% of the birth attendant population were auxiliary nurse midwives, who were older and had fewer years of formal training but more years of experience, and approximately 7% were lady medical officers, who were trained as physicians.³⁵

Coaches’ clinical skills were assessed via interviews during the recruitment process. Coaches received 5–7 days of skills-based training, which emphasized coaching skills, including relationship building; verbal and nonverbal interpersonal communication; handling difficult persons or situations; observation, listening, and speaking skills; and prioritizing and setting goals with frontline health workers. The training program for coaches also included a physician-led review of government guidelines around skilled birth attendants.

Coaching followed an “opportunity-ability-motivations-supplies” framework adapted from

previous behavior change models.^{33,36,37} In this framework, coaches motivated birth attendant behavior change using techniques such as storytelling and positive acknowledgment to emphasize the importance of adopting EBPs to meet national guidelines and save lives. They also observed deliveries, collected data, and provided real-time feedback on current adherence to EBPs; identified existing opportunity-, ability-, motivation-, or supply-related barriers to EBP adherence; and engaged in group problem solving to address these barriers. For example, if birth attendants were unable to complete EBPs because supplies or medications were missing, coaches would classify the issue as a supply-related barrier and advocate with administrators or pharmacists to obtain the supply. Other examples of how coaches addressed specific barriers can be found elsewhere.^{33,38} As part of the study design, coaches did not directly provide additional technical training or coach on clinical quality but did advocate with facility leaders (lady medical officers or medical officers in-charge) for additional training opportunities or engage in role playing to address ability-related barriers.

Birth attendant coaching was scheduled to occur twice per week during the first through fourth months of the intervention, once per week during the fifth and sixth months of the intervention, once every 2 weeks during the seventh month, and once per month in the eighth month for a total of 43 visits per health facility. Coaching visits were intended to last for the entire duration of a daytime shift (8 am to 5 pm). Additional details on the content of coaching sessions, perceptions around the credibility of the peer-coaching program, and the quality of the relationships between coaches and birth attendants have been published elsewhere.³⁴ The same coaching schedule was planned for all facilities, regardless of delivery load or birth attendant staff size.

A parallel peer-to-peer coaching also occurred at the facility leadership level with facility leadership being coached by other physicians or public health professionals to help improve their abilities to provide leadership and supervision. In this manner, coaching was intended to support rather than substitute for existing supervision structures. Facility leadership coaching followed a similar, but less intensive, schedule for a total of 23 visits. To promote long-term sustainability, each site also designated a childbirth quality coordinator who was a well-respected facility-based staff member but not necessarily a supervisor or manager and was intended to serve as a long-term, facility-

based coach and project champion. In practice, this role was often filled by a head nurse, medical officer in-charge, or pharmacist. This champion was intended to continue the practice of peer-coaching and not replace existing supervision practices.

Trial Design and Study Setting

This implementation package was evaluated in a matched-pair, cluster-randomized trial that enrolled 120 primary-level health facilities in Uttar Pradesh, India, a region with high maternal (258/100,000 live births) and neonatal (49/1,000 live births) mortality.³⁹

All facilities enrolled in the BetterBirth Trial were required to conduct at least 1,000 deliveries per year, have at least 3 birth attendants trained at the level of auxiliary nurse midwife or higher, have no concurrent quality improvement or research programs, and have district and facility leadership who were willing to participate. Forty-six facilities were primary health centers, 56 were community health centers, and 18 were first referral units.²⁹ Primary-level facilities should have had the capacity to provide basic emergency obstetric and newborn care but often lacked the necessary resources to do so.⁴⁰ District hospitals were not included in this study. Eligible facilities were matched on baseline characteristics and randomized within pairs to receive either the coaching-based intervention or the current standard of care. Roll-out of the intervention was staggered across 5 geographically-defined research hubs centered in the urban areas of Agra, Gorakhpur, Lucknow, Meerut, and Varanasi. Full details on study procedures, including sample size calculations, can be found elsewhere.⁴¹

Data Collection

At each facility, registers were used to document the admission date for each woman in labor and any instances of facility-based mortality and morbidity. Data on 7-day health outcomes were obtained using a call center, which contacted mothers and their families between 8 and 42 days postpartum, followed by home visits if neither the woman nor a family member was reached by phone after 22 days postpartum.⁴²

In a convenience sample of births occurring in 30 facilities (15 intervention, 15 control) located in the Lucknow hub, which is in central Uttar Pradesh, additional direct observations of deliveries were conducted to collect data on birth attendant EBP adherence. Trained independent nurses

observed and recorded EBP adherence using standardized data collection tools. Visits from independent data collectors occurred in addition to the coaching visits, which occurred in all intervention facilities. Unlike coaches, who used the opportunity-motivation-supplies framework to improve birth attendant performance, study nurses who served as independent observers did not serve as coaches and did not intervene in clinical care. Data collection on EBP adherence occurred during 3 of the 4 pause points: on admission to facility, just before pushing, and within 1 hour after birth. However, practical considerations related to the timing and duration of labor prevented all births from being continuously observed from admission through discharge. Consequently, not all EBPs were observed for each birth. For intervention facilities, nurse coaches recorded the date of each coaching visit as well as the unique ID code for each birth attendant who was coached during that visit.

Outcomes

We considered 2 types of outcomes: birth attendant EBP adherence and maternal and perinatal health outcomes. EBP adherence was measured as the number of EBPs that a birth attendant successfully completed of the 18 practices that the World Health Organization recommends as essential for all mothers and newborns (Table 1).^{29,30} Previous research has suggested that this EBPs adherence metric is associated with reduced risk of perinatal mortality in this setting.⁴³

Mother-baby dyads were included as a birth in our EBP analysis if they occurred at 1 of the 15 intervention facilities where EBP adherence data were collected, occurred after the start of coaching at that facility, and were directly observed during admission to facility, just before pushing, and within 1 hour after birth such that adherence to all 18 practices was recorded. Our analysis was conducted exclusively among intervention sites to focus on likely effects of birth attendant coaching without potential confounding from other components of the complex intervention.

As in the main trial, our primary health outcome was a composite outcome of events occurring within 7 days after delivery that included severe maternal morbidity, defined as self-reported complications including seizures, loss of consciousness for more than 1 hour, fever with foul-smelling vaginal discharge, hemorrhage, or stroke; maternal mortality; or perinatal mortality, defined as still-birth or death within the first 7 days of life. A

TABLE 1. Eighteen Essential Birth Practices From the World Health Organization Safe Childbirth Checklist^a

At Admission	Before Pushing	After Birth	Any Time
Partograph started	Hand hygiene	Oxytocin administered within 1 minute	Maternal temperature taken
Birth companion present	Clean towel available	Birth companion present	Maternal blood pressure taken
	Clean blade available	Baby weighed	
	Cord tie available	Baby temperature taken	
	Mucus extractor available	Skin-to-skin warming initiated	
	Neonatal bag available	Skin-to-skin warming maintained for 1 hour	
	Clean pads available	Breastfeeding initiated	

^a Independent observers assessed the birth attendant's adherence to essential birth practices but not their technical skill or quality in performing the practice.

secondary composite health outcome consisting of only 7-day maternal or perinatal mortality was also considered.²⁹

Mother-baby dyads were included as a birth in the health outcomes analysis if they occurred in an intervention facility after the start of coaching, if mothers consented to follow-up, and if data on 7-day outcomes were obtained. As in the main trial, dyads were included in the 7-day outcome analysis even if they were transferred to a higher-level facility before delivery. Because the timing of direct observations of birth attendant adherence to EBPs (that occurred 0–8 and 13–17 months after the start of coaching) differed somewhat from the timing of call center activities (that continued from 0–13 months after the start of coaching), the EBP adherence sample is not a subset of the health outcomes sample. However, some births appear in both samples.

Coaching Intensity

For each birth, we calculated metrics that reflected multiple domains of coaching intensity, including coaching frequency, cumulative coaching, and scheduling adherence. These metrics were based on the dates of the peer-to-peer birth attendant coaching visits that had occurred at a given facility before each birth. For coaching frequency, we assigned each birth a coaching intensity equal to the number of coaching visits occurring at that facility in the 30 days before the admission date (visits in the past month).

Because we hypothesized that the impact of coaching on birth-related outcomes would be stronger when we considered the intensity of coaching provided to the birth attendants who conducted the deliveries rather than to the facility as a whole, we also created coaching frequency

metrics that reflected coaching delivered at the birth attendant level. In this study, it was not possible to identify which birth attendant conducted a specific delivery, so we created coaching metrics that reflected the delivery of coaching among all birth attendants working at a single facility. These metrics included the average number of visits in the past month among birth attendants, the percentage of birth attendants receiving at least 1 visit in the past month, and the standard deviation of coaching visits in the past month among birth attendants. We hypothesized that facilities would experience more benefits from coaching if birth attendants had, on average, a greater number of visits in the past month, higher coaching coverage (percentage of birth attendants receiving at least 1 visit in past month), and a more equal distribution of coaching visits among birth attendants (lower standard deviation in visits among birth attendants in the past month).

All metrics reflecting coaching delivered at the birth attendant level were calculated under the assumption that the birth attendants listed in the coaching database reflected a complete list of birth attendants employed by the facility over the course of the intervention. These metrics did not consider staff turnover, which was assumed to be minimal over the intervention period. We also explored coaching frequency metrics calculated over a 1-week, rather than a 1-month, time horizon. However, since these 2 time windows produced similar results, we have presented only the results for the 1-month time horizon. Results for the 1-week time horizon can be found in the [Supplemental Tables](#).

For cumulative coaching, we assigned each birth a coaching intensity equal to the total number of coaching visits accrued at the facility

between the start of program and the admission date (total visits). As with coaching frequency, we believed that (a) coaching delivered at the birth attendant level would have a greater impact on birth attendant behavior change and health outcomes than coaching delivered at the facility level and (b) facilities with higher coverage of coaching at the birth attendant level would experience greater benefits from coaching. Therefore, for each birth we also calculated the mean number of visits accrued among birth attendants between the start of the program and the admission date and the standard deviation of coaching visits among birth attendants.

Scheduling adherence was defined according to the prescribed frontline coaching schedule of attaining at least 2 visits per week during the first 4 months of the intervention, at least 1 visit per week during the fifth and sixth months, at least 1 visit every 2 weeks during the seventh month, and at least 1 visit per month during the eighth month. Current scheduling nonadherence was a binary variable reflecting whether the date of admission occurred on a day when the facility had deviated from this schedule. Cumulative scheduling nonadherence reflected the total number of nonadherent days accrued between the start of program and the date of admission. For example, if a facility had been 3 days late for its first coaching visit and 4 days late for its second coaching visit, then subsequent births would receive a cumulative scheduling nonadherence value of 7.

Statistical Methods

Because the BetterBirth Program prescribed high-frequency coaching early in the intervention and gradually reduced the frequency of coaching over time, there were strong correlations among coaching frequency metrics, cumulative coaching metrics, and time since the start of the intervention. We reported the mean and standard deviation for each coaching metric and explored correlations between coaching metrics graphically and using Spearman correlation coefficients. To assess associations between each metric of coaching intensity and the outcomes of interest, we used generalized linear models and accounted for clustering at the facility level by estimating standard errors using the empirical variance with an exchangeable working covariance structure.⁴⁴

For EBP adherence, we estimated the change in the number of EBPs that birth attendants adhered to associated with each coaching intensity metric using an identity link and a normal

distribution. For binary health outcomes, we estimated the risk ratios associated with each coaching intensity metric using a log link and a binomial distribution.⁴⁵ Because coaching metrics had very different ranges (e.g., total coaching ranged from 1 to 47 and percentage of birth attendants receiving at least 10 visits ranged from 0% to 100%), we reported effect sizes associated with increasing each of the coaching metrics from their 25th percentile to their 75th percentile, or by 1 interquartile range. These percentiles were calculated in the health outcomes dataset. Where relevant, we also reported effect sizes for a 1-unit increase.

For all models, we used robust score tests to assess the statistical significance of model parameters.⁴⁶ Our primary models adjusted for facility-level covariates, including research hub location; being located in a high-priority district, a designation used by the Indian government to identify districts with a high overall burden of mortality; distance to district hospital in kilometers; and number of skilled birth attendants at that facility. At the birth level, models also adjusted for whether or not the birth occurred on the same day as a coaching visit. We fit models for each coaching metric separately and also used stepwise regression to assess whether multiple coaching metrics should be included in the same model based on an $\alpha \leq .05$ criterion for model entry and exit.

Because the effects of behavior change interventions often fade over time,⁴⁷ a phenomenon that could render time since start of the intervention to act as a confounder that biases results against cumulative coaching metrics and in favor of coaching frequency metrics, in a secondary set of models we additionally adjusted for months since the start of the intervention. We tested for potential nonlinear relationships between months since the start of the intervention and our outcomes of interest using restricted cubic splines⁴⁸ selected using a publicly available SAS macro.⁴⁹

Finally, we assessed whether the association between coaching intensity metrics and EBP adherence or health outcomes changed over the course of the intervention by adding an interaction between each coaching metric and months since the start of the intervention to our models. Because of the strong collinearities between coaching metrics and months since the start of the intervention, several models produced statistically significant interaction terms that were not interpretable. To ensure interpretability, we reported results for these interaction models only if both the time-by-coaching interaction term and the overall effect of coaching

For each birth, we calculated the mean number of visits accrued among birth attendants between the start of the program and the admission date and the standard deviation of coaching visits among birth attendants.

based on the joint null hypothesis that both the main effect of coaching and its interaction term were zero, were statistically significant at the $\alpha=.05$ level.

RESULTS

Study Population

Data on EBP adherence at intervention facilities were collected for 3,283 births. We excluded 262 births that occurred before the start of the coaching intervention and 938 that were not observed for all 3 pause points for a final sample of 2,083 births (Figure 1a). Health outcomes data at intervention facilities were collected among 83,166 births. We excluded 6 deliveries referred from another facility, 436 deliveries that occurred after a study facility's obstetric services moved to a new location, 5 women admitted for abortion, 352 births that occurred before the start of coaching, 1,868 births for which patients did not consent to follow-up, and 265 births that were lost to follow-up for a final sample of 80,234 births (Figure 1b). An additional 457 births lacked complete data on maternal morbidities and were excluded from analyses of the primary composite outcome. The EBP adherence and health outcome samples overlapped by 1,100 births and shared many similarities (Table 2). However, facilities in the EBP adherence sample came exclusively from

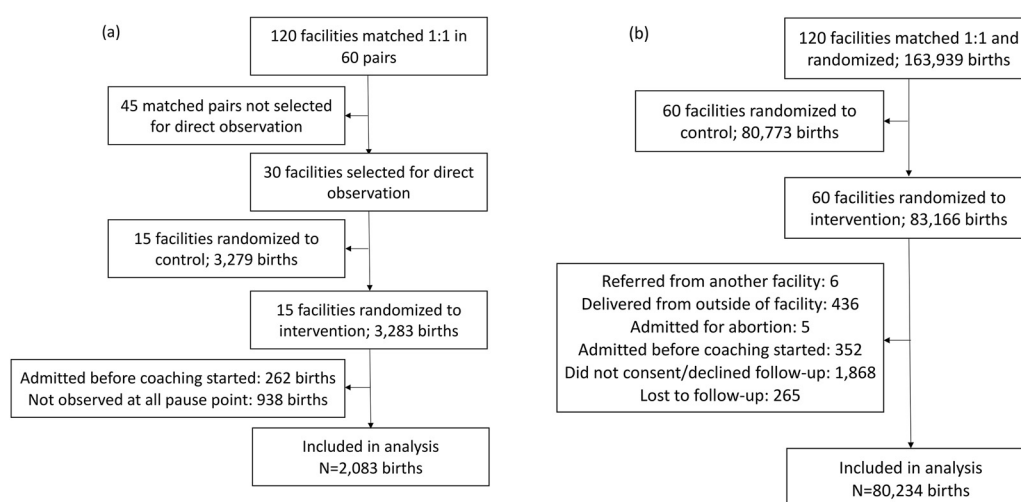
the Lucknow hub, located in the center of the state, and were more likely to be in a high-priority district. Due to differences in the timing of data collection in the 2 samples, births in the EBP adherence sample were less likely to have occurred on a coaching day.

Coaching Intensity

Fidelity to the coaching schedule was very high. By the end of the intervention, of the 60 facilities, 53 (88%) of facilities reached the target of 43 total coaching visits, 6 (10%) reached 42 visits, and 1 (2%) facility reached 37 visits. However, fidelity at the facility level did not necessarily translate into delivery of high-coverage coaching among birth attendants. Although birth attendants received, on average, 10 coaching visits by the end of the intervention, 34% received fewer than 5 visits. Figure 2 shows the changes in coaching metrics over time as well as the global mean and standard deviation for each coaching metric. As would be expected based on the prescribed coaching schedule, cumulative coaching metrics increased with months since the start of the intervention, but coaching frequency metrics decreased over time. By design, cumulative coaching measures were positively associated with time since intervention ($p=0.36$ to 0.87) and with each other ($p=0.30$ to 0.86) while coaching frequency metrics were negatively associated with

Fidelity at the facility level to the coaching schedule did not always translate into delivery of high-coverage coaching among birth attendants.

FIGURE 1. Study Populations from the BetterBirth Trial for Analysis on (a) Essential Birth Practice Adherence and (b) Health Outcomes,^a Uttar Pradesh, India



^aSample includes 436 births that were excluded from main the randomized controlled trial analysis due to being involved in baseline collection.

TABLE 2. Descriptive Statistics for the EBP Adherence and Health Outcomes Study Populations

	EBP Adherence Sample	Health Outcomes Sample
Facility-level variables	N=15	N=60
Research hub, No. (%)		
Agra	–	9 (15.0)
Gorakhpur	–	11 (18.3)
Lucknow	15 (100.0)	19 (31.7)
Meerut	–	7 (11.7)
Varanasi	–	14 (23.3)
High priority district, No. (%)	7 (46.7)	7 (11.7)
Distance to district hospital (km), mean (SD)	29.5 (12.0)	29.5 (14.0)
Number of skilled birth attendants, mean (SD)	4.5 (1.1)	4.4 (1.2)
Annual delivery load, mean (SD)	1,795 (468.0)	1,599 (435.0)
Birth-level variables	N=2,083	N=80,234
Birth occurred on coaching day, No. (%)	107 (5.1)	7,533 (9.4)
Months since intervention started at facility, mean (SD)	8.5 (5.8)	6.7 (2.8)
EBP adherence (of 18 practices), mean (SD)	12.1 (2.4)	–
Primary composite, ^a No. (%)	–	12,062 (15.0)
Secondary composite, No. (%)	–	3,907 (4.9)

Abbreviations: EBP, essential birth practices; SD, standard deviation.

^a 457 births are missing data on maternal morbidity, and therefore, are missing data on the primary composite outcome.

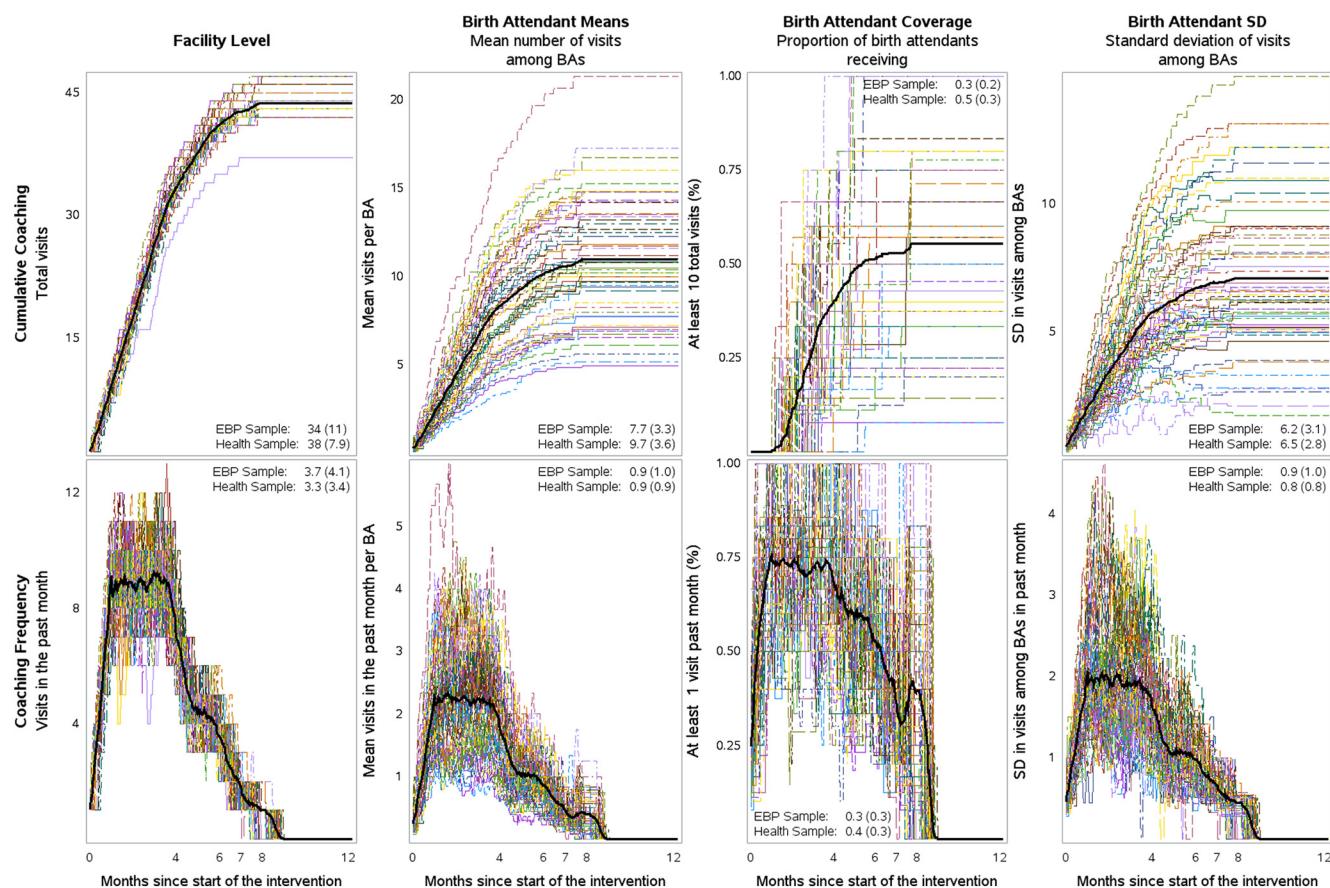
time since intervention ($\rho=-0.82$ to -0.97) and positively associated with each other ($\rho=0.79$ to 0.98) ([Supplemental Materials Table 5](#)).

EBP Adherence

In our primary model, all 4 coaching frequency metrics were significantly associated with increased EBP adherence ([Table 3](#)). On average, providing a facility with 6 coaching visits per month was associated with birth attendants adhering to an additional 1.3 EBPs (95% CI=0.6, 1.9). The association between EBP adherence and coaching frequency was larger in magnitude and if coaching was delivered with high coverage among birth attendants: providing 70% of birth attendants with at least 1 visit per month was associated with adherence to 2.0 additional EBPs (95% CI=1.0, 2.9), and providing all BAs at a facility with at least 1 visit per month was associated with adherence to 2.8 additional EBPs (95% CI=1.4, 4.2). However, no cumulative coaching or scheduling adherence metrics were significantly associated with EBP adherence. The stepwise selection procedure did not

identify a model that included multiple coaching metrics.

When we included months since the start of the intervention in our model, we did not detect any nonlinear effects of time. After adjusting for time since the start of the intervention, mean visits in the past month per birth attendant and percentage of birth attendants who received at least 1 visit in the past month, 2 coaching frequency metrics that both assessed coaching delivered at the birth attendant level, remained significantly and positively associated with increased EBP adherence. Also, cumulative coaching metrics became nonsignificantly associated with increased EBP adherence. When we included an interaction term between coaching intensity metrics and time since the start of the intervention, the effect of coaching was found to vary over time for only 1 coaching metric, mean coaching visits per birth attendant (test for interaction: $P<.01$; test for overall significance of coaching: $P=.04$; [Supplemental Materials Tables 2 and 3](#) show results from additional models). This cumulative coaching measure was associated with

FIGURE 2. Coaching Intensity Over Time^a

^aEach colored line reflects the coaching intensity at a given facility over time with the bolded black line reflecting the average coaching intensity across all facilities. Each panel provides the mean and (standard deviation) for the exposure in the EBP adherence and health outcome samples. Abbreviations: BA, birth attendant; SD, standard deviation.

increased EBP adherence during the early months of the intervention when coaching occurred very frequently, but the positive association did not persist after coaching visits ceased (Figure 3). There was no evidence that the association between coaching frequency metrics and EBP adherence were modified by months since the start of the intervention.

Health Outcomes

In general, coaching was not associated with health outcomes (Table 4). In our primary model, nonadherence to the coaching schedule was associated with an increased risk of the primary composite outcome, which reflected maternal morbidity, maternal mortality, and perinatal mortality, but

this result was attenuated after adjusting for months since the start of the intervention. After adjusting for months since the start of the intervention, we also observed a significant association between average visits per birth attendant and increased risk of the primary composite outcome (relative risk [RR]=1.10, 95% CI=1.03, 1.18). However, because this model also estimated an implausibly strong 18% reduction in the risk of mortality or morbidity over the course of a year (RR=0.82, 95% CI=0.71, 0.95), this association likely reflects strong correlations between time and coaching rather than a true adverse effect of coaching. Our stepwise selection procedure did not identify a model that included multiple coaching metrics, and no significant interactions were detected.

TABLE 3. Association Between Coaching Intensity and EBP Adherence Among BAs During Births in 15 Health Facilities, Uttar Pradesh, India (N=2,083 Births)

Coaching Domain	Units in IQR Increase	Model 1 ^a			Model 2 ^b		
		Change in Practices Adhered to Associated With 1-Unit Increase (95% CI)	Change in Practices Adhered to Associated With IQR Increase (95% CI)	P Value	Change in Practices Adhered to Associated With 1-Unit Increase (95% CI)	Change in Practices Adhered to Associated With IQR Increase (95% CI)	P Value
Coaching frequency							
Visits in the past month	6.0	0.2 (0.1, 0.3)	1.3 (0.6, 1.9)	<.01	0.2 (−0.0, 0.4)	1.0 (−0.1, 2.2)	.10
Mean visits in the past month per BA	1.3	1.0 (0.6, 1.4)	1.2 (0.7, 1.8)	<.01	0.9 (0.2, 1.6)	1.2 (0.3, 2.1)	.01
BAs receiving ≥1 visit in past month, %	70	2.8 (1.4, 4.2)	2.0 (1.0, 2.9)	.01	3.4 (1.0, 5.8)	2.4 (0.7, 4.0)	.03
Standard deviation in visits among BAs past month	1.3	0.9 (0.5, 1.4)	1.2 (0.6, 1.8)	.01	0.7 (0.0, 1.5)	1.0 (−0.0, 1.9)	.08
Cumulative coaching							
Total visits	8.0	−0.0 (−0.1, 0.0)	−0.4 (−0.8, 0.1)	.09	0.1 (0.0, 0.1)	0.6 (0.3, 0.9)	.07
Mean visits per BA	5.3	−0.2 (−0.4, 0.0)	−1.0 (−2.1, 0.1)	.09	0.2 (0.0, 0.4)	1.0 (0.0, 2.0)	.21
BAs receiving ≥10 visits, %	40	−3.0 (−5.9, −0.1)	−1.2 (−2.4, 0.0)	.12	0.3 (−3.5, 4.1)	0.1 (−1.4, 1.6)	.89
Standard deviation in visits among BAs	3.5	−0.2 (−0.4, 0.1)	−0.6 (−1.5, 0.2)	.12	0.3 (0.0, 0.5)	0.9 (0.2, 1.7)	.08
Scheduling adherence							
Current scheduling nonadherence	NA ^c	0.3 (−0.7, 1.3)	–	.55	−0.5 (−1.3, 0.4)	–	.27
Cumulative scheduling nonadherence	12	−0.0 (−0.1, 0.0)	−0.5 (−1.0, 0.1)	.08	0.1 (0.0, 0.1)	0.8 (0.0, 1.6)	.11

Abbreviations: BA, birth attendant; CI, confidence interval; EBP, essential birth practice; IQR, interquartile range; NA, not applicable.

Effects are reported for a 1-unit increase and for increasing each continuous coaching metric from its 25th percentile to its 75th percentile, that is, by 1 IQR. Results are from a generalized linear model with an identity link. Standard errors are estimated using the empirical variance with an exchangeable working covariance structure to account for clustering at the facility level.

^a Adjusted for whether the facility was in a high-priority district, distance to district hospital, facility staff size, facility delivery load, and whether birth occurred on the same day as a coaching visit.

^b Adjusted for everything in Model 1 plus months since start of the intervention.

^c Because current scheduling nonadherence is a binary outcome, we report the effect for nonadherence vs. no adherent, rather than for a 1 IQR increase.

DISCUSSION

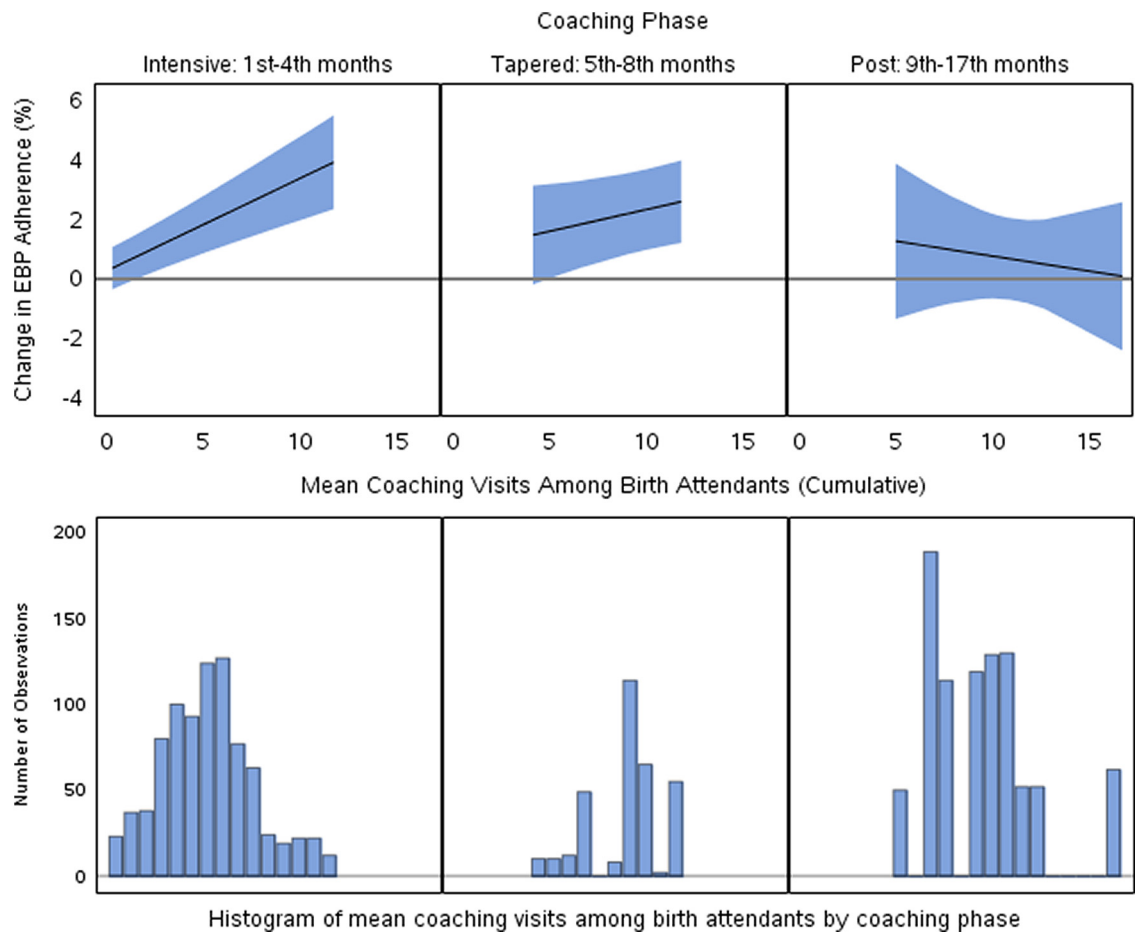
Our analysis suggests that in the BetterBirth Trial, coaching frequency was associated with modestly increased EBP adherence. Associations between coaching frequency and EBP adherence tended to be stronger when considering coaching delivered at the birth attendant level rather than the facility level. In contrast, cumulative coaching was generally not associated with EBP adherence. However, when we adjusted for time since the start of the intervention, cumulative coaching metrics became

nonsignificantly positively associated with increased EBP adherence. When we allowed the effect of coaching to change over time since the start of the intervention, one cumulative coaching metric, mean visits per birth attendant, was significantly associated with increased EBP adherence during the early months of the intervention.

Because the BetterBirth coaching schedule induced strong correlations between coaching metrics, it is difficult to isolate the independent effects of coaching frequency from cumulative

Associations between coaching frequency and EBP adherence were stronger when we assessed coaching delivered at the birth attendant level rather than the facility level.

FIGURE 3. Effect Modification of the Association Between Mean Coaching Visits Among Birth Attendants (Cumulative) and EBP Adherence Over Months of the Intervention (N=2,083)^a



Abbreviation: EBP, essential birth practice.
^aEffect sizes for coaching phases plotted at 2, 6, 12 months since the start of the intervention. Test for interaction: $P<.01$. Overall test for all coaching terms: $P=.04$.

Health outcomes were generally not associated with coaching.

coaching. Despite this limitation, our analyses suggest that high-frequency, high-coverage coaching can modestly increase birth attendant adherence to EBPs. However, the positive effects of coaching diminished over time. Since the gains in EBP adherence were not sustained after frequency tapered, future interventions seeking to promote sustained improvements in EBP adherence may consider providing high-frequency, high-coverage coaching over a longer period of time. Future researchers may also consider identifying feasible and cost-effective mechanisms for delivering this sort of high-intensity coaching as well as mechanisms for improving the sustainability of

the intervention through enhanced facility-level engagement.

The main trial reported greater EBP adherence in the intervention arm (11.1 of 18.0 EBPs, 95% CI=10.4,11.8) compared to the control arm (7.9 of 18.0 EBPs, 95% CI=7.4, 8.4) 12 months into the intervention but no significant changes in health outcomes.²⁹ Similarly, in the present analysis, health outcomes were generally not associated with coaching. As has been previously noted, this may reflect the fact that adherence to EBPs is an inadequate surrogate outcome for maternal and neonatal health.⁵⁰ Alternatively, this lack of association may reflect the fact that the

TABLE 4. Risk Ratios for the Association Between Coaching and Health Outcomes^a Among BAs During Births in Health Facilities, Uttar Pradesh, India

Coaching Domain	Units in Increase	Primary Composite Maternal Morbidity or Maternal or Infant Mortality (n/N=12,062/79,777)				Secondary Composite Maternal or Infant Mortality (n/N=3,907/80,234)			
		Model 1 ^b		Model 2 ^c		Model 1 ^b		Model 2 ^c	
		RR (95% CI)	P Value	RR (95% CI)	P Value	RR (95% CI)	P Value	RR (95% CI)	P Value
Coaching frequency									
Visits in past month	6.0	1.03 (0.99, 1.07)	.14	1.03 (0.94, 1.13)	.49	0.98 (0.92, 1.05)	.61	1.01 (0.88, 1.15)	.91
Mean visits in past month per BA	1.3	1.03 (1.00, 1.06)	.10	1.02 (0.97, 1.08)	.36	0.98 (0.93, 1.04)	.54	0.99 (0.92, 1.07)	.84
BAs receiving ≥1 visit in past month, %	0.7	1.05 (1.00, 1.10)	.05	1.06 (0.98, 1.15)	.15	1.00 (0.92, 1.09)	.99	1.07 (0.93, 1.22)	.36
Standard deviation in visits among BAs in past month	1.3	1.02 (0.98, 1.05)	.30	0.99 (0.94, 1.05)	.82	1.00 (0.95, 1.06)	.98	1.06 (0.99, 1.14)	.11
Cumulative coaching									
Total visits	8.0	0.99 (0.97, 1.02)	.50	1.02 (0.98, 1.05)	.42	1.01 (0.97, 1.05)	.59	1.00 (0.94, 1.06)	.93
Mean visits per BA	5.3	1.01 (0.96, 1.07)	.70	1.10 (1.03, 1.18)	.03	1.07 (0.98, 1.18)	.18	1.10 (0.98, 1.25)	.16
BAs receiving ≥10 visits, %	0.4	1.00 (0.96, 1.05)	.87	1.04 (0.99, 1.09)	.14	1.04 (0.96, 1.13)	.32	1.04 (0.94, 1.15)	.42
Standard deviation in visits among BAs	3.5	1.00 (0.95, 1.06)	.89	1.04 (0.98, 1.11)	.25	1.04 (0.96, 1.13)	.34	1.04 (0.96, 1.14)	.37
Scheduling adherence									
Current scheduling nonadherence ^d	1	1.06 (1.01, 1.12)	.04	1.05 (1.00, 1.11)	.08	0.97 (0.86, 1.09)	.58	0.98 (0.87, 1.10)	.69
Cumulative scheduling nonadherence	12	1.00 (0.96, 1.05)	.85	1.06 (0.99, 1.13)	0.10	1.03 (0.98, 1.09)	.23	1.05 (0.99, 1.12)	.12

Abbreviations: BA, birth attendant; CI, confidence interval; RR, risk ratio.

^a Effects are reported for increasing each continuous coaching metric from its 25th percentile to its 75th percentile, that is, 1 interquartile range. Results are from a generalized linear model with a log link and binomial distribution. Standard errors are estimated using the empirical variance with an exchangeable working covariance structure.

^b Adjusted for hub name, whether the facility was in a high-priority district, distance to district hospital, facility staff size, facility delivery load, whether birth occurred on the same day as a coaching visit.

^c Adjusted for everything in Model 1 plus months since start of the intervention.

^d Because current scheduling nonadherence is a binary outcome, we report the effect for infidelity vs. no infidelity, rather than for a 1 interquartile range increase.

magnitude of the association between coaching and total EBP completion was relatively modest. This small absolute change in EBP adherence may not have produced sufficient improvements in the quality of care to impact health outcomes. We did observe an increased probability of experiencing maternal morbidity, maternal mortality, or perinatal mortality on days when sites had deviated from the intervention's prescribed coaching schedule.

Because coaching was not associated with improved health outcomes in any other models, this association likely does not reflect direct benefits of coaching. Instead, it may suggest that sites that were unable to adhere to the coaching schedule were also experiencing other structural issues, such as poor leadership, understaffing, or inaccessibility, that placed mothers and infants at risk of harm.

This is the first article that simultaneously investigated multiple domains of coaching intensity on care worker behavior change.

Previous articles have reported dose-response relationships between coaching intensity and health worker behavior change,^{21–23} but to our knowledge, this is the first article that simultaneously investigated multiple domains of coaching intensity. Consequently, there was relatively little precedent for defining coaching intensity metrics. Although we initially expected greater variation in coaching among birth attendants to reflect poor coaching coverage and be associated with worse outcomes, greater standard deviations in visits among birth attendants in the past month was significantly associated with improved EBP adherence. This unexpected association could be explained if coaches were strategically providing additional coaching to specific birth attendants, such as the facility's designated childbirth quality coordinator. Alternatively, this metric may have been too strongly correlated with the remaining coaching frequency metrics ($\rho=0.79$ to 0.98) to serve as an independent metric of coaching disparities among birth attendants. Similarly, although cumulative scheduling nonadherence and cumulative standard deviation in visits among birth attendants were hypothesized to have adverse effects, both metrics were highly correlated with and produced results similar to cumulative coaching metrics hypothesized to be beneficial. In coaching-based interventions, deviations from the coaching schedule and disparities in the delivery of coaching to individual health care workers will gradually accrue over time as new opportunities for scheduling conflicts arise. Consequently, in many settings, we would expect cumulative scheduling nonadherence and standard deviation-based coaching metrics to exhibit problematic correlations with other cumulative coaching metrics that complicate their interpretation and may not be appropriate choices of coaching intensity metrics for future studies.

Our finding that frequent coaching was associated with modest improvements in EBP adherence is similar to previous reports. A recent meta-analysis found that strategies commonly used to improve health care worker performance including supervision, training, and group problem solving, are associated with improving health care worker performance by 1.0, 6.4, and 13.6 percentage points, respectively.¹⁷ We found that, using the BetterBirth model of coaching, providing intervention facilities with 6 coaching visits per month was associated with adherence to 1.3 additional EBPs, or a 7.2 percentage-point increase on our 18.0-point EBP adherence scale. Although the magnitude of the association between coaching

and EBP adherence was relatively small, providing high-frequency, high-coverage coaching may be able to make a greater difference. Our results suggest that if all birth attendants at a facility were provided with at least 1 coaching visit per month, EBP adherence could increase by 2.8 practices, or 15.0 percentage points. Our results are similar to findings related to low-dose, high-frequency (LDHF) training, which combines brief onsite trainings with short, frequent practice sessions and has produced positive behavior change among birth attendants and improved maternal and child health outcomes.^{51,52} Although LDHF models emphasize the acquisition of new skills through training and practice rather than coaching health care providers to better use their preexisting training, both the LDHF model and our results suggest that frequent contact with health care workers may be necessary to improve quality of care and sustain the improvements.

In this study, all facilities were primary-level health facilities located in Uttar Pradesh, and all coaching was provided by external peer coaches according to the opportunity-ability-motivations-supplies framework.³³ Consequently, we do not know the extent to which the relationships observed in this analysis can be generalized to other settings or to other forms of coaching. Contextual factors, including staffing levels, facility infrastructure, and the interactions between coaching activities and traditional supervision processes may modify the effectiveness of coaching.

Other programs that have used coaching as a Safe Childbirth Checklist implementation strategy have reported extremely variable EBP adherence at end line (range=32%–93%).^{29,53–60} In general, these interventions have not specified behavior change models nor provided full details on the frequency or duration of coaching delivered. Consequently, it is difficult to determine the extent to which observed differences in the effectiveness of these interventions result from contextual differences between study settings, differences in facilities' readiness to change, or differences in their coaching intensity. Furthermore, some of these studies relied primarily on internal coaches recruited from within intervention facilities.^{53,60} Although the intensity of external coaching interventions can be evaluated using dates of coaching visits, this approach would not apply to internal coaches who are embedded within the intervention facilities and may therefore engage in coaching for variable amounts of time each day. Alternative approaches of assessing coaching intensity, such as time-motion studies, may be more appropriate for evaluating the intensity of internal coaching

strategies.⁶¹ Future research is needed to compare both the effectiveness and the sustainability of internal and external coaching in this setting.

Our data provide several practical insights for those seeking to implement or study future coaching-based interventions. First, even high fidelity to a facility-centric coaching schedule will not necessarily ensure that individual health care workers receive adequate coaching coverage. In our study, the unequal distribution of coaching among birth attendants likely reflect preferential behavior on the part of the coaches, dynamics related to the timing of shifts in birth facilities or are the result of staff turnover. Interventionists should specify and monitor coaching delivered at both the facility and the health care worker levels to identify whether these processes are taking place.

Second, our study suggests that high-frequency coaching can improve health worker adherence to EBPs, but maintaining high-frequency coaching is a resource-intensive intervention. Future interventionists may wish to explore cost-effective methods for maintaining high-frequency coaching over longer periods of time, such as recruiting internal coaches, coaching more consistently on health systems at a facility-level, or combining in-person coaching visits with remote coaching methods.

Third, identifying optimal coaching regimens requires designing interventions that have uncorrelated variation in coaching frequency and cumulative coaching. This could be achieved, for example, by conducting a 3-armed trial with 1 control arm, 1 arm receiving evenly spaced coaching visits over a set duration of time, and a third arm receiving the same total number of coaching visits delivered over the same duration of time but following a tapered schedule similar to that of the BetterBirth Program's.

Finally, statistically significant improvements in quality of care indicators such as EBP adherence do not necessarily translate into meaningful improvements in health outcomes. In general, changes in quality of care indicators will be more likely to predict improvements in health outcomes if researchers choose quality of care indicators that are a valid surrogate for the primary health outcomes of interest, have been empirically demonstrated to have a causal relationship with the health outcome, if the magnitude of the change is clinically meaningful on the absolute scale (e.g., EBP adherence increased by 20 percentage points from 60% to 80%) rather than on the relative scale (e.g., EBP adherence doubled from 5% to

10%), and if the quality of care indicators reflect most or all major determinants of the primary health outcome.⁶² We recommend that future researchers consider whether the quality of care improvements observed in their study are large enough to plausibly generate meaningful improvements in the health outcomes. If not, some combination of more frequent coaching, additional implementation strategies, and identifying and addressing systemic barriers may be needed to further improve the quality of care and ultimately achieve the desired health impact.

Limitations

Our analysis has several limitations. As discussed above, the BetterBirth Program's coaching schedule created strong correlations among coaching intensity metrics, which complicated the interpretation of some findings. Second, this analysis focused on 2 domains of coaching intensity, coaching frequency and cumulative coaching, but was unable to assess other domains, including coaching quality, which was unmeasured, or coaching form, which did not vary across sites. Therefore, we cannot comment on which aspects of coaching are most effective, and it is possible that alternative coaching models, such as those that coach on clinical quality rather than on adherence to certain tasks, may be more effective than the model used here. We also did not capture information on the duration or timing of individual coaching visits.

Third, although we sought to minimize bias by adjusting for facility-level characteristics, residual confounding is possible if unmeasured facility or birth attendant characteristics that were associated with the outcomes also impacted coaches' behavior. For example, reports suggest that, to minimize travel time, coaches would provide difficult-to-reach facilities with visits on back-to-back days. If less accessible facilities experienced worse outcomes, we would expect this practice to bias our results against coaching frequency metrics. Coaches may have also been more likely to provide coaching to the facilities or birth attendants who were most motivated and receptive to their help and less likely to provide coaching to relatively junior nurses, who often staff evening, night, and weekend shifts. We would expect both of these processes to bias our results in favor of coaching.

Fourth, assessment of EBP adherence outcomes was based on directly-observed sessions that took place during daylight hours and may not reflect adherence at night or when birth

Although high-frequency coaching can improve health worker adherence to EBPs, it is a resource-intensive intervention.

attendants were not observed. Finally, because we were unable to link individual birth attendants to individual births in our dataset, we assessed the effectiveness of coaching delivered at the birth attendant level using facility-level aggregated metrics that did not consider staff turnover within the health facility. We would expect this measurement error to result in an underestimation of the direct benefits of providing coaching to individual birth attendants.

CONCLUSIONS

Frequent coaching was associated with increased adherence to essential birth practices among birth attendants in the BetterBirth Trial. The effect size was greater for coaching delivered at the birth attendant level compared to coaching delivered at the facility level. Cumulative coaching metrics were not associated with essential birth practice adherence, suggesting that the short-term effects of high-frequency coaching may not translate into sustained effects of cumulative coaching over time. Future coaching-based interventions seeking to promote sustainable change may need to consider identifying sustainable, cost-effective models for providing more frequent, high-coverage coaching for longer periods. Coaching was generally not associated with health outcomes, suggesting that additional coaching and other implementation strategies may be needed to achieve the desired health impact.

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Availability of data and material: Data from this study are available at the Harvard Dataverse repository at Barnhart DA, Spiegelman D, Zigler CM, et al. Coaching intensity, adherence to essential birth practices, and health outcomes in the BetterBirth Trial. Harvard Dataverse, V2. <https://doi.org/10.7910/DVN/ONRYVC>.

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ORIGINAL ARTICLE

Two-Way Short Message Service (SMS) Communication May Increase Pre-Exposure Prophylaxis Continuation and Adherence Among Pregnant and Postpartum Women in Kenya

Jillian Pintye,^{a,b} Zoe Rogers,^a John Kinuthia,^{a,c} Kenneth K. Mugwanya,^a Felix Abuna,^c Harison Lagat,^c Joseph Sila,^c Valarie Kemunto,^c Jared M. Baeten,^{a,d,e} Grace John-Stewart,^{a,c,d,f} Jennifer A. Unger,^{a,g} for the PrYA Program Team

We evaluated a 2-way short messaging service (SMS) communication platform to improve continuation of pre-exposure prophylaxis (PrEP) for HIV prevention among Kenyan pregnant and postpartum women who initiated PrEP within routine maternal child health and family planning clinics. SMS increased support for PrEP, provided opportunities for dialogue beyond the clinic, and enabled women to ask and receive answers in real-time, which facilitated continued PrEP use.

ABSTRACT

Introduction: We evaluated a 2-way short message service (SMS) communication platform to improve continuation of pre-exposure prophylaxis (PrEP) for HIV prevention among Kenyan women who initiated PrEP within routine maternal child health (MCH) and family planning clinics.

Methods: We adapted an existing SMS platform (Mobile WACH [mWACH]) to send PrEP-tailored, theory-based SMS and allow clients to communicate with a remote nurse. Women who did not have HIV and who were initiating PrEP at 2 MCH/family planning clinics in Kisumu County, Kenya, from February to October 2018, were offered enrollment into the mWACH-PrEP program; SMS communication was free. We evaluated acceptability, satisfaction, and implementation metrics. In a pre/postevaluation, we compared PrEP continuation at 1-month postinitiation among women who initiated PrEP in the period before (n=166) versus after mWACH-PrEP implementation, adjusting for baseline differences.

Results: Of the 334 women who were screened for enrollment into the mWACH-PrEP program; 193 (58%) were eligible and of those, 190 (98%) accepted enrollment. Reasons for ineligibility (n=141) included no phone access (29%) and shared SIM cards (25%). Median age was 25 years (interquartile range=22–30), and 91% were MCH clients. Compared to women who initiated PrEP in the month before mWACH-PrEP implementation, women who enrolled in mWACH-PrEP were more likely to return for their first PrEP follow-up visit (40% vs. 53%; adjusted risk ratio [aRR]=1.26; 95% confidence interval [CI]= 1.06, 1.50; P=.008) and more likely to continue PrEP (22% vs. 43%; aRR=1.75; 95% CI=1.21, 2.55; P=.003). Among those who returned, 99% reported successful receipt of SMS through the mWACH-PrEP system and 94% reported that mWACH-PrEP helped them understand PrEP better. Concerns about PrEP use, how it works, and side effects accounted for the majority (80%) of issues raised by participants using SMS.

Conclusions: Two-way SMS expanded support for PrEP and opportunities for dialogue beyond the clinic and enabled women to ask and receive answers in real time regarding PrEP, which facilitated its continued use.

^aDepartment of Global Health, University of Washington, Seattle, Washington, USA.

^bDepartment of Biobehavioral Nursing and Health Informatics, University of Washington, Seattle, WA, USA.

^cDepartment of Obstetrics/Gynecology, Kenyatta National Hospital, Nairobi, Kenya.

^dDepartment of Epidemiology, University of Washington, Seattle, Washington, USA.

^eDepartment of Medicine, University of Washington, Seattle, Washington, USA.

^fDepartment of Pediatrics, University of Washington, Seattle, Washington, USA.

^gDepartment of Obstetrics/Gynecology, University of Washington, Seattle, Washington, USA.

Correspondence to: Jillian Pintye (jpintye@uw.edu).

INTRODUCTION

Young women in sub-Saharan Africa have one of the highest HIV incidence rates globally.¹ This high HIV incidence persists during pregnancy and breastfeeding,² and there is evidence that HIV acquisition risk increases by more than 2-fold during pregnancy and the postpartum period.³ Pregnant women who become acutely infected with HIV account for an estimated 26% of all vertical HIV transmissions.^{4,5} To prevent HIV acquisition during pregnancy and reach elimination of vertical

transmission, the World Health Organization recommends offering oral tenofovir-based pre-exposure prophylaxis (PrEP) to pregnant women who do not have HIV in high-burden settings.⁶

Data from Kenya estimated that HIV incidence among pregnant and postpartum women is 2.31/100 person-years.⁷ Programmatic PrEP delivery to pregnant and postpartum women in maternal child health (MCH) clinics is ongoing in Kenya,^{8,9} and other countries are planning PrEP implementation within MCH settings.

Although a majority of pregnant and postpartum women with HIV risk factors accepted PrEP when offered within routine MCH settings in Kenya,⁹ more than 50% discontinued PrEP within 30 days of initiation. Mobile health (mHealth) tools can be used to educate clients, provide reminders for visits and medications, improve communication between health care workers and clients, and improve self-efficacy, all potentially leading to better medication adherence outcomes.^{10–13} Studies are ongoing to enhance PrEP continuation and adherence using mHealth approaches in diverse populations including men who have sex with men, transgender women, and adolescent girls who are not pregnant.^{14–17} To date, no PrEP adherence intervention studies have targeted pregnant or postpartum women who have unique considerations for PrEP use. Qualitative studies have found that pregnant women who use PrEP are highly motivated to protect their infants from HIV, though some have concerns about whether PrEP affects their infant,¹⁸ and postpartum women have challenges remembering to take PrEP pills during the complex transition to motherhood.¹⁸ Therefore, mHealth strategies tailored to pregnant and postpartum women who use PrEP are needed.

To support PrEP continuation and adherence among pregnant and postpartum women, we adapted the mobile communication platform, Mobile WACH [mWACH]—named for the University of Washington’s Global Center for Integrated Health of Women, Adolescents, and Children—^{19–21} using 2-way short message service (SMS) between participants and remote nurses. We conducted a mixed-methods evaluation within a programmatic PrEP delivery setting to assess implementation metrics and evaluate PrEP continuation and adherence outcomes among women PrEP initiators enrolled in the SMS program.

METHODS

Program and Setting

The PrEP Implementation for Young Women and Adolescents (PrIYA) Program was a 2-year

implementation project in Kisumu County, Kenya, a region where adult HIV prevalence is 19.9% (up to 28% among pregnant women).^{22–24} The program was designed to reach adolescents and young women at high risk for HIV acquisition through integrated delivery of PrEP within routine MCH and family planning systems.⁹ Conducted in collaboration with the Kisumu County Department of Health and Sanitation and the National AIDS and STI Control Programme, PrIYA was first implemented in 16 facilities (11 public, 4 faith-based, and 1 private) followed by a PrEP mentorship program in 20 additional sites. The 16 highest volume (based on monthly number of new antenatal care ANC clients) facilities in Kisumu County were selected to be in the PrIYA Program. The current evaluation focuses on the implementation of a 2-way SMS intervention among a subset of participants in the PrIYA Program. The SMS intervention was conducted at 2 public-sector sites purposively selected based on the highest monthly enrollment of new PrEP clients.

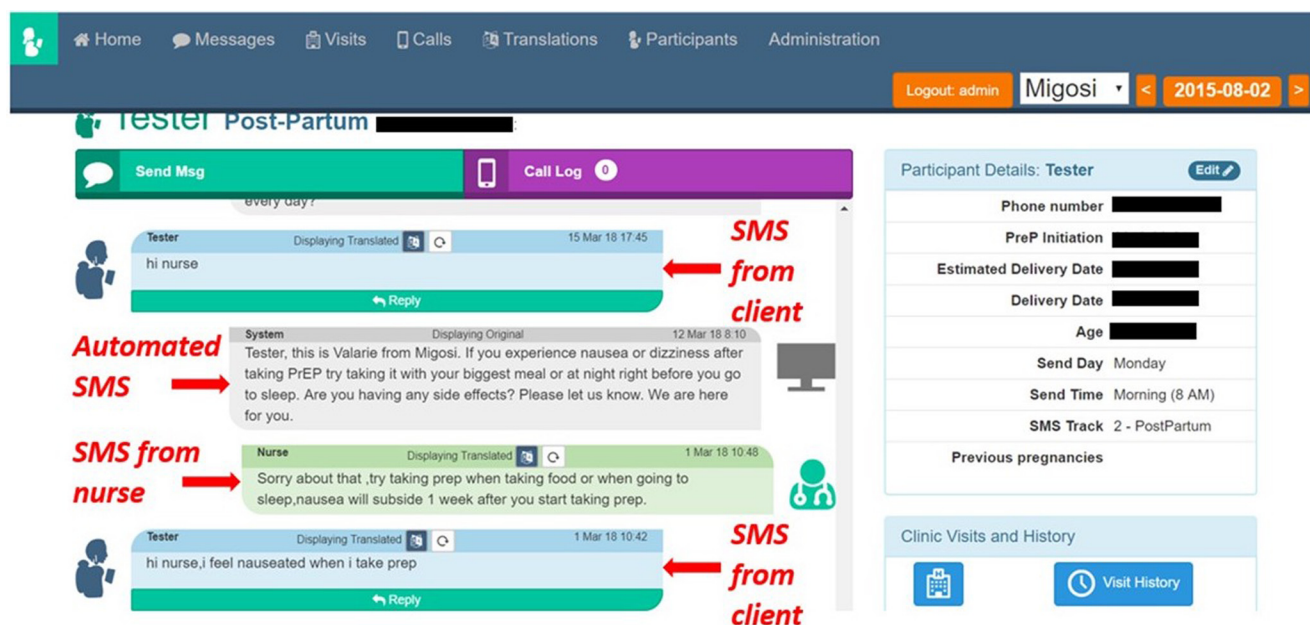
In the PrIYA Program, 40 program-supported nurses were trained on PrEP delivery per national guidelines as previously described.²⁵ Briefly, nurses screened women who did not have HIV for behavioral risk factors, including male partner HIV status and willingness to consider PrEP. Behavioral risk factors were assessed using a standardized risk assessment tool.⁸ Women who wanted to initiate PrEP and were medically eligible received same-day PrEP and were scheduled for a 1-month follow-up visit.⁹

mWACH-PrEP Program Evaluation Design

This mixed-methods evaluation of the SMS communication program for supporting PrEP adherence and continuation had 3 primary aims: (1) describe implementation metrics (e.g., eligibility, acceptability, satisfaction, and utilization); (2) compare frequency of PrEP continuation and self-reported adherence before and after the introduction of the SMS program; and (3) identify issues and concerns among new PrEP initiators by qualitatively analyzing transcripts of SMS conversations.

mWACH-PrEP Program Development

Our team previously developed mWACH, a user-friendly bidirectional interactive SMS platform, that enables efficient communication between women attending MCH clinics and nurses.¹⁹ The mWACH platform sends timed preprogrammed SMS messages that clients can respond to and



Interface of mWACH-PrEP System With Mock Data
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allows clients to send messages with questions or concerns. A trained nurse-counselor receives and responds to messages from women, providing a mechanism for women to interact with nurses in real-time and an opportunity for medication adherence support.⁹ mWACH has been shown to be feasible, acceptable, and effective in improving MCH outcomes.^{20,21}

We adapted the mWACH platform to send weekly PrEP-tailored, theory-based SMS and to allow MCH and family planning clients who initiate PrEP to communicate with a nurse about their individual needs. SMS messages incorporated behavioral theory-informed counseling framed in the informational-motivational-behavioral skills model, specifically tailored to women receiving PrEP in the context of MCH/family planning services (Box). The intervention was field-tested by PrIYA nurses with more than 6 months of experience delivering PrEP to MCH and family planning clients before implementation. During field-testing, we elicited feedback from PrEP providers on the utility, frequency, and content of SMS messages to refine the tool. The final message bank was translated and back translated from English to Kiswahili and Dhuluo (a prevalent local language in western Kenya). PrIYA nurses were trained on using the mWACH-PrEP system and responding to SMS messages from clients based on behavioral counseling principles including

informational-motivational-behavioral skills, motivational interviewing, and positive reinforcement. We also developed and tested quality assurance/quality control systems that reviewed

BOX. Example SMS From Automated Message Bank and Behavioral Theory Adapted for PrEP

Motivational Interviewing (e.g., goal-oriented action plans)
{name}, this is {nurse} from {clinic}. It can be difficult to take medications every day especially if you are trying to be discrete. Many people ask a friend to help remind them, set a timer on their phone, or take it with a meal. You can also put it in a different container you can carry with you in private. How do you remember to take your medication? Do you have any challenges taking it every day?

Theory of Planned Behavior (e.g., perceived behavioral control)
{name}, this is {nurse} from {clinic}. Side effects from PrEP affect each person differently. Most side effects lessen after the first few weeks of use, once the body is used to the medication. Please let us know if you are having any side effects. We can help you manage them or know if it is okay to continue.

Health Belief Model (e.g., perceived barriers)
{name}, this is {nurse} from {clinic}. You are doing a great job taking care of yourself. PrEP is very effective at preventing you from getting HIV if you take it every day. It also helps prevent HIV infection to your baby if you are pregnant. If you miss too many doses it may not work. Are you having any challenges taking the medication?

Social-Cognitive Theory (e.g., positive reinforcement)
Good job coming in for your visit! You will receive weekly SMS to help support taking your medication. Please SMS back and tell us any questions or concerns you have. Please tell us if you need assistance with your prevention medication. If you have any challenges or stop PrEP, please let us know.

and discussed responses to SMS with medical and research teams in Kenya and Seattle to ensure consistency and accuracy of nurses' responses to women.

Program Procedures

From February to October 2018, we approached women on the same day they initiated PrEP at the 2 selected MCH/family planning clinics and offered them participation in the mWACH-PrEP program. Women were eligible if they initiated PrEP that day, had a functioning cellphone in-hand that they did not share with anyone, and had an active SIM card on the Safaricom network (Kenya's largest network provider). Reasons for ineligibility were captured. We did not exclude women who expressed confidentiality concerns related to their PrEP use or content of the SMS. All women were free to decline enrollment and welcome to stop receiving SMS at anytime.

Women registered into the mWACH-PrEP platform indicated their preferences for message delivery including a preferred name for messaging, language (English, Kiswahili, or Dholuo), and day of the week and time for SMS delivery. All automated push messages included participant nickname, clinic, and nurse name, an educational message or actionable advice targeting PrEP adherence and continuation and/or MCH/family planning topics, and a question related to the content. SMS topics included adherence encouragement, PrEP efficacy and safety, self-efficacy for prevention of HIV, support for potential PrEP side effects, behavioral skills (tips for remembering PrEP medications), and visit reminders. During enrollment, the program nurse explained that replies to the automated SMS questions were voluntary, though women were encouraged to reply. Women were also encouraged to send SMS with their concerns or questions whenever they arose. The program nurse was available to answer SMS during normal business hours on weekdays. All messaging was free of charge to the participant using a reverse billed short code. SMS were sent from enrollment until December 2018. Participants could voluntarily and autonomously exit the program by texting "STOP," which would end all platform communication.

Data Management and Analysis

All SMS communication was conducted through our custom web application designed for 3-way communication between the automated push system, program staff, and participants. SMS data

were downloaded biweekly by program data managers to track SMS outages and data on implementation activity (e.g., new enrollments, successful automated SMS delivery, participant responses, voluntary exits). When a participant sent an unprompted question or sent a reply to an automated message that was not in English, program nurses translated the SMS into English within the system daily to ensure interpretation consistency and allow for quality assurance/quality control. We defined utilization using 2 metrics: responding to automated push messages and sending an unprompted question or concern using SMS.

Program nurses administered questionnaires to women enrolled in mWACH-PrEP at routine 1-month PrEP follow-up visits to assess satisfaction using a series of items on a 5-point Likert scale (e.g., I would recommend the SMS program to other women who use PrEP; strongly agree, agree, neutral, disagree, strongly disagree). Closed-ended items assessed self-reported utilization experiences with the platform (e.g., I took action based on the nurse's advice; yes/no). We also abstracted PrEP indicators from the Kenya Ministry of Health client encounter form that included data on attendance of a PrEP follow-up visit, self-reported adherence (number of missed PrEP doses in the past month), and PrEP refills. We defined PrEP continuation as confirmed dispensation of a PrEP refill at an attended follow-up visit. PrEP discontinuation was defined as no PrEP refill or no attendance at a follow-up visit. Data from PrEP follow-up visits were abstracted for all women who initiated PrEP in the month before implementation of the mWACH-PrEP program and from all women who were screened for mWACH-PrEP enrollment.

We used descriptive statistics to summarize acceptability, satisfaction, and utilization indicators. We used Chi-squared tests for proportions and Kruskal-Wallis tests for continuous measures to compare baseline demographic and behavioral characteristics of women who were eligible and enrolled in the mWACH-PrEP program with (1) women who initiated PrEP in the month before implementation of mWACH-PrEP and (2) women who were screened for enrollment but were ineligible/declined. We compared PrEP continuation and self-reported adherence among women who enrolled in mWACH-PrEP with women in the other 2 groups using Chi-squared tests and multivariate Poisson regression models with robust error variance, an approach used when the outcome prevalence is not rare (e.g., >10%).^{26,27} Final multivariate Poisson models were adjusted for age and marital status because

these characteristics were significantly different between women who enrolled in the mWACH-PrEP program and those who initiated PrEP before mWACH-PrEP implementation. All statistical analyses were performed by using StataSE 15.0 (StataCorp, College Station, TX). Statistical comparisons were 2-sided and were considered significant at the $P < .05$ level.

Qualitative Analysis

At the completion of the mWACH-PrEP program, transcripts of SMS conversations were analyzed using a modified constant comparative approach. Our primary goal was to identify issues raised by women who initiated PrEP through unprompted questions or concerns sent to nurses using the mWACH-PrEP system. We developed an initial codebook based on a review of a subset of transcripts and input from nurses who responded to participants' messages, and the codebook was iteratively refined. SMS transcripts were transferred into Microsoft Excel for data management. All transcripts were coded by 2 research team members (ZR and JP), and coding disagreements were resolved through discussion. Key issues raised by women who enrolled in mWACH-PrEP were identified by reading transcripts to identify similarities

and differences across conversations, and codes were subsequently organized within thematic categories to identify trends. We also selected representative quotations pertaining to each main category.

Human Subjects Considerations

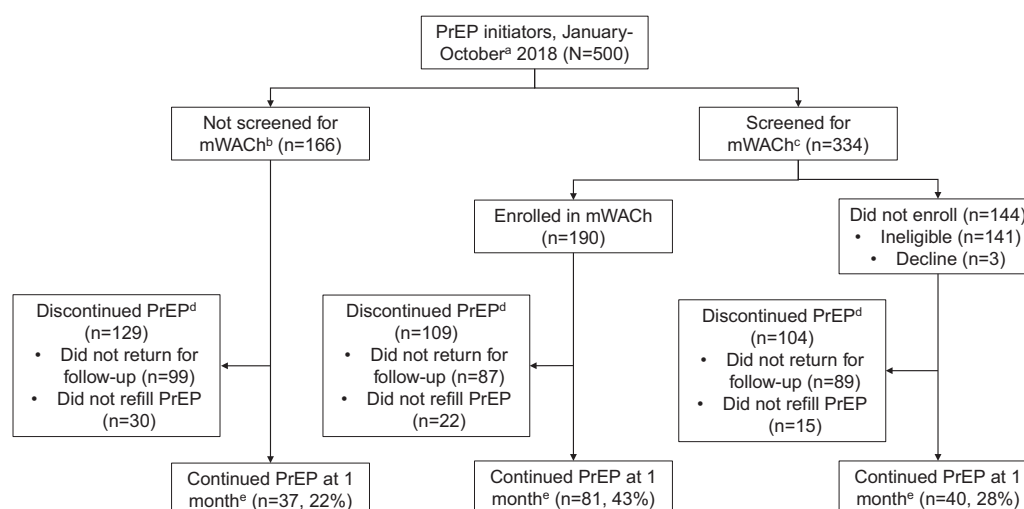
Protocols were reviewed and approved by the Kenyatta National Hospital-University of Nairobi Ethics Research Committee and University of Washington Human Subjects Review Committee. In addition, approval was obtained from the Kisumu County Department of Health and administrators in respective health facilities. Women provided informed consent for all activities.

RESULTS

Overall, 334 women were screened for participation in the mWACH-PrEP program (Figure 1); 193 (58%) were eligible and 190 (98%) of eligible women enrolled. Reasons for ineligibility ($n=141$) included not having a phone (28%) or Safaricom SIM card (15%) in the clinic that day, sharing SIM cards (24%), using a network other than Safaricom (15%), having a broken phone (12%) or other phone issues (3%). Among the 3 (2%) women who declined, 2 feared intimate partner

Our primary qualitative analysis goal was to identify issues that women who initiated PrEP raised through unprompted messages.

FIGURE 1. Enrollment of Women in mWACH Program at PrEP Initiation Visits, Kusumu County, Kenya



Abbreviations: mWACH, Mobile WACH; PrEP, pre-exposure prophylaxis.

^a From 2 sites that participated in the mWACH-PrEP program.

^b PrEP initiators who were not screened for mWACH-PrEP initiated PrEP in January 2018 before mWACH-PrEP implementation, which began in February 2018.

^c PrEP initiators who were screened for mWACH-PrEP initiated PrEP between February and October 2018.

^d PrEP discontinuation was defined as either not returning for a follow-up visit or not refilling a PrEP prescription at a follow-up visit.

^e PrEP continuation was defined as attending a follow-up visit and refilling a PrEP prescription.

violence and 1 felt the program was unnecessary because she did not anticipate adherence issues. Among women who enrolled in the mWACH-PrEP, 48% were 24 years old or younger, 91% were MCH clients, and 9% were family planning

clients; 89% were married (Table 1). Almost half (47%) of women who enrolled reported having a male partner who did not have HIV, 10% had a known partner with HIV, and 44% had a male partner who did not know his HIV status. Among

TABLE 1. Characteristics of Women Screened for mWACH-PrEP and Women Who Initiated PrEP Before mWACH-PrEP,^{a,b} by Enrollment, Kusumu County, Kenya

	Screened for mWACH			Initiated PrEP Before mWACH (n=166)	
	Enrolled (n=190)	Ineligible or Declined ^a (n=144)	P Value ^b		P Value ^c
Age, years, median (IQR)	25 (22–30)	23 (20–27)	<.001	24 (21–28)	.006
Age category, No. (%)					
<18 years	3 (1.6%)	9 (6.3%)	.04	11 (6.6%)	.06
18–24 years	89 (46.8%)	80 (55.6%)		77 (46.4%)	
25–29 years	46 (24.2%)	28 (19.4%)		47 (28.3%)	
30–34 years	38 (20.0%)	18 (12.5%)		22 (13.3%)	
≥35 years	14 (7.4%)	9 (6.3%)		9 (5.4%)	
Client recruitment clinic, No. (%)					
Antenatal care	78 (41.1%)	63 (43.8%)	.84	80 (48.2%)	.19
Postnatal care	95 (50.0%)	70 (48.6%)		78 (47.0%)	
Family planning	17 (9.0%)	11 (7.6%)		8 (4.8%)	
Married, No. (%)	171 (90.0%)	125 (86.8%)	.36	134 (81.2%)	.02
Male partner HIV status, No. (%)					
HIV-negative	89 (46.8%)	55 (38.2%)	.04	75 (45.5%)	.81
HIV-positive	19 (10.0%)	8 (5.6%)		14 (8.5%)	
Unknown	823 (43.2%)	81 (56.3%)		76 (46.1%)	
Gestational age, years, median (IQR)	25 (20–28)	26.5 (20–32.5)	.25	24.5 (20–32)	.51
First antenatal care visit, No. (%)	24 (34.3%)	16 (27.6%)	.42	38 (52.1%)	.03
Behavioral risk factors (last 6 months), No. (%)					
Had sex without a condom	187 (98.4%)	144 (100.0%)	.13	164 (98.8%)	.77
Exchanged sex for money or other favors	0 (0.0%)	2 (1.4%)	.10	1 (0.6%)	.28
Diagnosed with or treated for a sexually transmitted infection	1 (0.5%)	2 (1.4%)	.41	0 (0.0%)	.35
Forced to have sex against will	5 (2.6%)	4 (2.8%)	.93	8 (4.8%)	.27
Experienced intimate partner violence	4 (2.1%)	3 (2.1%)	.99	8 (4.8%)	.16

Abbreviations: mWACH, Mobile WACH; PrEP, pre-exposure prophylaxis.

^a Overall, 3 women were eligible for mWACH-PrEP and declined participation; 141 women were ineligible.

^b Chi-squared tests for proportions or Kruskal-Wallis tests for continuous measures, comparing women who were eligible and enrolled with women who were ineligible/declined among those screened for mWACH-PrEP.

^c Chi-squared tests for proportions or Kruskal-Wallis tests for continuous measures, comparing women who were eligible and enrolled with women who initiated PrEP in the month before mWACH-PrEP implementation.

pregnant women who enrolled ($n=73$), the median gestational age was 25 weeks (interquartile range [IQR]=20–28).

Women who were eligible and enrolled were slightly older than women who were ineligible or declined enrollment (median age 25 years old and 23 years, respectively; $P<.001$). Compared to women who initiated PrEP in the period before mWACH-PrEP, eligible and enrolled women were also slightly older (median age 24 years old and 25 years, respectively; $P=.006$), more frequently married (81% and 90%, respectively; $P=.02$), and more frequently attending first ANC visits, if pregnant (33% and 52%, respectively; $P=.03$). There were no other differences in demographic and behavioral characteristics between women who were eligible and enrolled and women who were either ineligible/declined or who initiated PrEP before mWACH-PrEP (Table 1).

Acceptability and Satisfaction

Overall, 100 of 190 (53%) women who enrolled returned for a follow-up visit at a median of 29 days (IQR=28–40) since PrEP initiation. Almost all (99%) reported successful receipt of SMS messages through the mWACH-PrEP system. Among the 99 women who received messages, 72 (73%) women reported consulting by SMS with the nurse and, of those, 47 (66%) reported continuing PrEP because of the nurse's advice (Supplemental Tables). Most women (94%) reported that the SMS helped them understand PrEP better and 89% reported that the SMS helped them adhere to PrEP. Almost all (95%) would recommend mWACH-PrEP to other women who use PrEP, and 95% would also use the program again, if offered (Supplemental Tables).

PrEP Continuation and Adherence

Among the 166 women who initiated PrEP in the month before mWACH-PrEP implementation, 67 (40%) attended a PrEP follow-up visit compared to 101 (53%) of women who enrolled in mWACH-PrEP (adjusted risk ratio [aRR]=1.26; 95% confidence interval [CI]=1.06, 1.50; $P=.008$). Compared to women who initiated PrEP in the month before mWACH-PrEP implementation, women who enrolled in mWACH-PrEP were almost twice as likely to continue PrEP after adjustment for age and marital status (22% vs. 43%; aRR=1.75; 95% CI=1.21, 2.55; $P=.003$). Among women who returned for follow-up, 74 (73%) of women who enrolled in mWACH-PrEP self-reported high PrEP adherence (<1 missed pill/

week) compared to 37 (55%) of women who initiated PrEP before mWACH-PrEP (aRR=1.35; 95% CI=1.28, 1.41; $P<.001$). Compared to women in a contemporaneous cohort who were ineligible or declined enrollment, women enrolled in mWACH-PrEP were also more likely to return for a follow-up visit (38% vs. 52%, respectively; $P=.02$) and continue PrEP (28% vs. 43%; $P=.005$); among those who attended follow-up visits, self-reported high adherence was similar across those contemporaneous groups (67% vs. 73%, respectively $P=.42$).

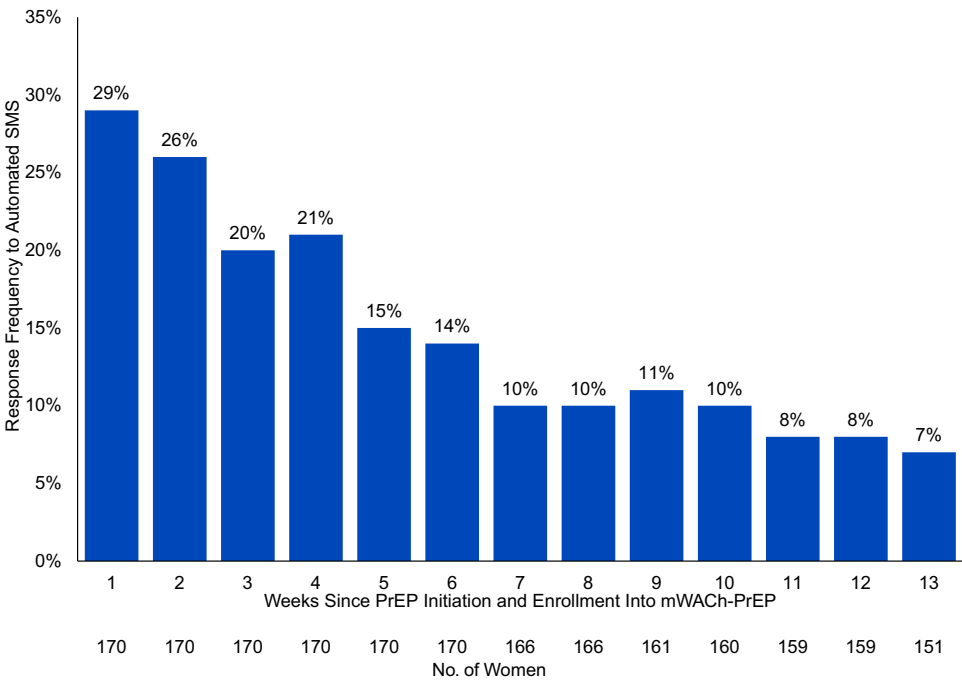
Participant Utilization of mWACH-PrEP

Full transcripts from SMS conversations were available and analyzed for 170 of the 190 (89%) women who enrolled in the mWACH-PrEP program. Among 170 women with analyzed transcripts, 97 (57%) ever responded to the automated messages. Median duration of enrollment in the mHealth program was 24 weeks (IQR=17–31). Frequency of responding to automated messages was highest at week 1 (29%) and substantially lower by week 6 (14%) (Figure 2a). The median time to response cessation was 6 weeks (IQR=1–13) among women who ever responded.

Overall, 74 of the 170 (44%) participants ever sent unprompted questions or concerns to the nurse using SMS during follow-up, and a total of 183 unprompted SMS were received and answered by nurses. The median number of unprompted questions/concerns sent per client was 2 (IQR=1–3). Seven major topics were raised by participants in their SMS queries (Figure 2b). PrEP continuation and discontinuation was the most frequently raised topic overall (27%). These messages included queries about how long one must continue PrEP use, if stopping and restarting PrEP is possible, and self-reporting PrEP discontinuation among participants who did not return for follow-up visits (Table 2). Side effects (24%) were the next most frequent topic of unprompted questions/concerns. These messages included requests for advice on dealing with side effects, confirmation of whether symptoms experienced (e.g., nausea, vomiting, weakness) were normal with PrEP use, and clarification of whether and when symptoms would eventually subside. Participants also raised issues about the logistics of PrEP use (16%), including where/how to get refills and what to do if doses were missed. Participants also sought clarifications about PrEP (13%) including how PrEP works, how it is different from drugs used to treat HIV, and whether men could also

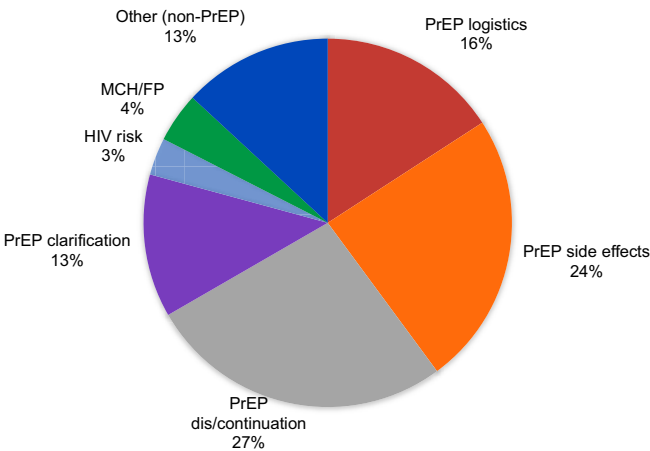
Most women reported that the SMS helped them understand PrEP better and helped them adhere to PrEP.

FIGURE 2a. Women’s Response Frequency to Automated SMS Over Time Since PrEP Initiation and Enrollment in mWACH-PrEP Program, Kusumu County, Kenya^a



Abbreviations: mWACH, Mobile WACH; PrEP, pre-exposure prophylaxis; SMS, short message service.
^a Full SMS transcripts were available and analyzed for 170/190 (90%) of women who enrolled into mWACH-PrEP.

FIGURE 2b. Frequency Distribution of Unprompted Question and Concern Topics Sent by Women Who Initiated PrEP to Remote Nurses Using the mWACH-PrEP Platform, Kusumu County, Kenya (N=183)^a



Abbreviations: mWACH, Mobile WACH; PrEP, pre-exposure prophylaxis; SMS, short message service.
^a Overall, 170 participants who initiated PrEP were enrolled in the mWACH-PrEP program had full transcripts available for analysis and 74 (44%) ever sent an unprompted question to a remote nurse during follow-up. Remote nurses received and responded to 183 unprompted questions in total from 74 women.

TABLE 2. Representative Quotations Pertaining to Each Main Topic of Questions or Concerns and Corresponding Responses, mWACH-PrEP Platform^a

Topic	Unprompted Question or Concern Sent by Participants by SMS	Nurse's Response to Participant (Time to Response From SMS Receipt)
PrEP dis/continuation	Thanks, nurse, for the concern. Just want to know the duration of taking PrEP? Because in my case, we are a discordant couple.	Hello {Name}. It is important that you continue taking PrEP until your partner's viral load is suppressed. You can incorporate condoms during sexual intercourse to protect you further. We encourage that you freely share health information related to your partners care. (14 hours; participant sent SMS in the evening, nurse responded the next morning)
	Hi, I separated with my husband because of mistrust. He felt ill and was taken to the hospital, where he tested HIV-negative and malaria-positive. Should I continue using this drug? I am not a sex worker.	Hello {Name}. You can continue taking your medication. But should you desire to discontinue, please come back to our clinic for further advice. I would also like to tell you that PrEP is not ONLY used by sex workers, but also those who feel they are at risk of becoming infected. (3 hours)
	Hi {Nurse's name}. If I'm abstaining from sex and I also stay alone, should I continue to use this drug?	Hello {Name}. If you feel you are no longer at risk of being infected, you may stop PrEP. However, you should continue taking the drug 1 pill daily for 28 days from the last risk period. (1 hour)
Side effects	After taking it (PrEP), and I vomit once a day.	Nausea and vomiting is common in pregnancy and could also be a side effect of PrEP. Minor side effects like nausea and vomiting are manageable. Avoiding fatty food, eating smaller meals, and limiting spicy foods may help. PrEP minor side effects subside after a short period of time. (20 minutes)
PrEP clarification	Hey, is it true that PrEP is a type of ARV? They say it is given to HIV+ and HIV- individuals.	Hello {Name}. PrEP is classified as one of the antiretroviral medications used to protect someone from HIV/AIDS. PrEP medication is given to different people depending on the substantial risks involved. Discordant couples, unknown HIV status of your sexual partner, and individuals with multiple sexual partners are some of the people at risk who could be eligible to use PrEP. (2 hours)
	Does PrEP prevent someone from conceiving?	Morning {Name}. PrEP does not prevent someone from conceiving. It is safe for pregnancy as well. It can have side effects like headache, nausea, and vomiting that subsidize with time. (1 hour)
	I abide by what you people told me at the clinic, but some information I was told elsewhere is different. I heard it is not good to use this medication (PrEP) until I know my partner's status. Another issue is that PrEP is an antiretroviral medication. Can I get HIV/AIDS if I use PrEP medication for long periods?	Hello, {Name}. PrEP medication helps to prevent HIV/AIDS acquisition. Not knowing your partners status is one of the risks that may lead to an individual acquiring HIV/AIDS. It is important to know your partner's status because it helps to reduce the risk of HIV acquisition. In case you want to stop PrEP, it is advisable to come back to the clinic for discontinuation. (2 hours)
PrEP logistics	Hello, Nurse. I would like to ask if it is good to take my medications before taking my meals?	Hello, {Name}. It is good to take the medications after meals to avoid side effects such as nausea and vomiting. (10 minutes)
	Is it a must that I should take it (PrEP) at bedtime?	Hello, it is not a must to take at bedtime. PrEP can be taken one tablet daily either in the morning, afternoon or evening. It is also advisable to be strict on the time you take the medication. In case you decide its morning hours, then every day you should take it in the morning. (19 hours; participant sent SMS in the evening, nurse responded the next morning)

Continued

TABLE 2. Continued

Topic	Unprompted Question or Concern Sent by Participants by SMS	Nurse's Response to Participant (Time to Response From SMS Receipt)
	In case I forget to take PrEP medication today and then I remember the next day, can I take the medicine then?	Hello, at that point in time when you remember to take medication, you should swallow 1 tablet. It is not advisable to swallow 2 tablets at once because you forgot taking the medication the previous day. You can set an alarm on your phone to act as a reminder when to take the medication. (20 hours; participant sent SMS in the evening, nurse responded the next morning)
HIV risk	I am inquiring if I have 2 partners, 1 has HIV and the other one is HIV-negative. If it happens that I have sex with the negative partner, can he get HIV because the other one is positive?	How are you, {Name}. You can't transmit HIV to him because you are negative and you are on PrEP taking them faithfully. Again, if your positive partner is taking antiretrovirals as prescribed, he can't transmit HIV to you.However, you should also use condoms when you are meeting your negative partner because you don't know if he is having multiple partners. (4 hours)
MCH/family planning	Hello, I have been using Depo Provera for a long time until I stopped because of excess bleeding. . .I haven't experienced any of these side effects since I stopped using the injection. My monthly periods have resumed normally, 5 days, with 3 heavy days and lighter 2 days. Which method of family planning can I use without side effects?	Hello, I would kindly advise you to find time and come to the hospital so that we can talk more on the other methods of family planning, so that you can be able to decide and choose one of the family planning methods that you would want to use. (2 hours)
	Now is when the baby is breastfeeding too much because she had mouth rash, she was not feeding.	Hello {Name}. Breastfeeding is important for the baby because it helps in growth and development. Did you bring the child for review at the clinic regarding the oral thrush? When the baby has lesions in the mouth it can affect how the baby breastfeeds and feeding orally. (16 hours; participant sent SMS in the evening, nurse responded the next morning)
Other (not related to PrEP)	I have a problem when having sex with my husband with a condom. I experience bloating and abdominal pain. What can I do please? Should I stop having sex?	Hi {Name}. You can stop having sex, but I would like you to see a doctor for further management and instructions. (23 hours; participant sent SMS on the weekend, nurse responded on Monday)

^a Some quotations have been modified from their original short message form to increase language clarity.

This is the first evaluation of an mHealth intervention for PrEP adherence targeting pregnant and postpartum women.

take PrEP. The remaining 20% of unprompted questions and concerns sent by participants and answered by nurses were not PrEP-related. These messages included concerns regarding HIV risk (3%), queries regarding MCH or family planning issues in general (4%), and other topics like allergic reactions to other medications or relationship concerns (13%).

DISCUSSION

In this mixed-methods evaluation of an mHealth tool within a programmatic PrEP delivery setting, we found very high acceptance (98%) among the subset of women who met inclusion criteria, an almost 2-fold greater early PrEP continuation, and higher self-reported adherence among women who were enrolled in mWACH-PrEP than those

who initiated PrEP before mWACH-PrEP implementation. We also found high satisfaction with the mWACH-PrEP system and high utilization. Almost half (44%) of the women who enrolled had unprompted questions or concerns addressed using SMS, most of which were PrEP-related. To our knowledge, this is the first evaluation of an mHealth intervention for PrEP adherence targeting pregnant and postpartum women, and this communication platform addressed topics very specific to pregnancy and the postpartum period. As PrEP delivery within routine MCH/family planning settings expands, mHealth strategies tailored to pregnant and postpartum women may improve PrEP continuation and adherence in this unique population.

We previously reported that PrEP counseling before initiation in the PriYA program lasted

approximately 18 minutes per client.²⁵ Women who initiated PrEP received this standardized counseling from nurses who were experienced with PrEP delivery, yet clarifications and concerns about the PrEP use and how PrEP works accounted for more than half (56%) of all unprompted issues raised by the participants. This indicated that many women who initiated PrEP left the clinic with concerns about PrEP use or that PrEP concerns may have arisen after they left the clinic that would otherwise go unaddressed without access to a remote nurse. Additionally, nearly one-quarter (24%) of issues raised by participants pertained to side effects. Pregnancy may amplify side effects associated with early PrEP use (e.g., nausea, vomiting, gastrointestinal alterations), and experiencing side effects is a leading cause of PrEP discontinuation in this population.²⁸ mHealth applications have successfully facilitated monitoring and mitigation of medication side effects for other health conditions in low- and middle-income countries.^{29,30} Promoting self-management of PrEP side effects and empowering women by filling PrEP knowledge gaps could be a mechanism by which the mWACH-PrEP platform improved PrEP continuation in this study. We found diminished response to automated messages after 1 month, which suggests that a time-limited mHealth intervention may be sufficient to address concerns and support onboarding to sustained PrEP use.

Ongoing studies are testing mHealth tools that address various stages of the PrEP care continuum in diverse populations, including using mHealth to increase uptake^{31,32} and enhance adherence.^{14–17} We focused on early PrEP continuation and adherence among women who initiate PrEP within MCH/family planning because we previously found a steep drop-off in PrEP continuation and suboptimal PrEP adherence in this population. The mWACH platform was initially designed to address maternal and infant health concerns among pregnant and postpartum women.¹⁹ The adapted mWACH-PrEP system focused on PrEP use. Thus, our evaluation assessed short-term PrEP-specific outcomes and did not measure other MCH-related outcomes. Additionally, in this evaluation we did not assess provider time or other costs associated with implementation. Future studies should incorporate information beyond early PrEP outcomes, including impact on maternal/infant health and provider time and costs, to determine whether mWACH-PrEP is a cost-effective strategy within routine MCH/family planning systems delivering PrEP.

Although we found high acceptability in our evaluation, 42% of screened women were ineligible due to cell phone-related issues. The most frequent reason for ineligibility was not having a cell phone in the clinic; this was required to confirm registration was successful. Future iterations of the mWACH-PrEP platform could incorporate off-site registration options for clients to complete self-registration at a later time. Additionally, not having a SIM card compatible with the mWACH system was another major reason for ineligibility. We partnered with Safaricom for mWACH-PrEP as this is the largest network provider in Kenya. Inclusion of other network providers within the platform, which is feasible at a modest additional cost, would increase accessibility and reach.

Limitations

Our evaluation has limitations. We did not collect information on mWACH-PrEP eligibility criteria (e.g., phone availability) during the period before mWACH-PrEP implementation. Therefore, our pre/postevaluation design produced less rigorous results than a randomized trial, and we may have unmeasured differences between our comparison groups that could influence effect size. However, this nonrandomized evaluation provides insight into how mHealth interventions work in a real-world context. Within a program setting, we found nearly a 2-fold increase in PrEP continuation among women who enrolled in the mWACH-PrEP compared to both women who initiated PrEP before mWACH-PrEP implementation and a concurrent cohort of women who were ineligible/declined.

We intentionally restricted our comparison group to only January 2018, the month immediately preceding mWACH-PrEP implementation. Several events during the period before January 2018 were beyond control of the program and limited the program's ability to consistently provide PrEP in a representative population. A national nurses strike in Kenya from June through November 2017 halted service delivery in public-sector facilities,³³ and the response in Kisumu to the presidential election of August 2017 also impacted the health sector.³⁴ January 2018 was the most comparable month in terms of PrEP provision and stability of service delivery within health facilities in Kisumu.

We did not offer incentives or reimbursement for enrollment into mWACH-PrEP and did not conduct any procedures beyond routine clinical care and satisfaction surveys, including intensive

follow-up procedures or contact tracing. Additionally, we offered mWACH-PrEP enrollment to all PrEP initiators, regardless of partner HIV status or other behavioral HIV risk factors. Therefore, our results may be more representative of what could be expected if mWACH-PrEP were to be programmatically rolled out than a randomized trial or an approach targeted to only women who self-disclose high behavioral HIV risk.

We relied on routinely collected data to measure PrEP continuation and self-reported adherence without an objective biomarker for PrEP exposure, which could have introduced reporting bias or misclassification. Studies comparing self-reported PrEP adherence to objective drug levels among men who have sex with men, transgender women, and individuals in HIV-serodiscordant couples in real-world settings have found reasonably high concordance.^{35–37} Future evaluations among pregnant and postpartum women in African settings could incorporate biomarkers of PrEP exposure to confirm self-reported adherence. We only included women who newly initiated PrEP. Future evaluations could assess whether the mWACH-PrEP program improves adherence among women with a poor adherence history. Additionally, our satisfaction data are limited to women who returned for a follow-up visit and may not be representative of all women enrolled in the mWACH-PrEP program.

CONCLUSION

In summary, we found very high acceptance of the mWACH-PrEP program among pregnant and postpartum women and improved early PrEP continuation and adherence among those enrolled compared to women who initiated PrEP before the mWACH-PrEP program. mWACH-PrEP extended the reach of the clinic and enabled clients to promptly address concerns about PrEP which, in turn, appeared to help them continue and/or adhere to PrEP. Women found a short period of SMS support helpful. It is plausible that this system could be readily scalable and cost-effective, potentially improving outcomes and offsetting costs from unused or misused medicines.

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ORIGINAL ARTICLE

Designing and Evaluating Scalable Child Marriage Prevention Programs in Burkina Faso and Tanzania: A Quasi-Experiment and Costing Study

Annabel Erulkar,^a Girmay Medhin,^b Eva Weissman,^c Gisele Kabore,^d Julien Ouedraogo^e

Minimal, low-cost approaches can be effective in delaying child marriage and increasing school attendance. Program managers should consider the cost, quality, and coverage of interventions, especially because child marriage persists in the most hard-to-reach, rural areas of many countries.

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

ABSTRACT

Background: A significant number of girls are married as children, which negatively impacts their health, education, and development. Given the sheer numbers of girls at risk of child marriage globally, the challenge to eliminate the practice is daunting. Programs to prevent child marriage are typically small-scale and overlook the costs and scalability of the intervention.

Implementation: This study tested and costed different approaches to preventing child marriage in rural Burkina Faso and Tanzania. The approaches tested were community dialogue, provision of school supplies, provision of a livestock asset, a model including all components, and a control arm. A quasi-experimental design was employed with surveys undertaken at baseline and after 2 years of intervention. We examined the prevalence of child marriage and school attendance controlling for background characteristics and stratified by age group. Programmatic costs were collected prospectively.

Results: Among those in the community dialogue arm in Burkina Faso, girls aged 15 to 17 years had two-thirds less risk (risk ratio [RR]=0.33; 95% confidence interval [CI]=0.19, 0.60) of being married and girls aged 12 to 14 years had a greater chance of being in school (RR=1.18; 95% CI=1.07, 1.29) compared to the control site. In Tanzania, girls aged 12 to 14 years residing in the multicomponent arm had two-thirds less risk of being married (RR=0.33; 95% CI=0.11, 0.99), and girls 15 to 17 in the conditional asset location had half the risk (RR=0.52; 95% CI=0.30, 0.91). All the interventions tested in Tanzania were associated with increased risk of girls 12 to 14 years old being in school, and the educational promotion arm was also associated with a 30% increased risk of girls aged 15 to 17 years attending school (RR=1.3; 95% CI=1.01, 1.67). Costs per beneficiary ranged from US\$9 to US\$117.

Conclusion: The study demonstrates that minimal, low-cost approaches can be effective in delaying child marriage and increasing school attendance. However, community dialogues need to be designed to ensure sufficient quality and intensity of messaging. Program managers should pay attention to the cost, quality, and coverage of interventions, especially considering that child marriage persists in the most hard-to-reach rural areas of many countries.

INTRODUCTION

Child marriage has powerful negative implications for a young woman's health and well-being as it frequently marks the beginning of sexual activity and early

childbearing, as well as an end to educational pursuits.¹ Globally, child marriage is a widespread problem, especially in the developing world. Currently, 650 million women and girls were married before they turned 18 years old, with 12 million underage girls married each year.^{2,3} If efforts to prevent child marriage are not intensified, United Nations Children's Fund (UNICEF) estimates that 150 million more girls will be married by 2030.⁴ Girls affected by the practice are largely from the poorest families in the poorest and most remote rural places. In sub-Saharan Africa—where 38% of the child

^a Population Council, Addis Ababa, Ethiopia.

^b Addis Ababa University, Addis Ababa, Ethiopia.

^c Columbia University, New York, NY, USA.

^d Pathfinder International, Ouagadougou, Burkina Faso.

^e Christian Children's Fund of Canada, Ouagadougou, Burkina Faso.

Correspondence to Annabel Erulkar (aerulkar@popcouncil.org).

marriages are found—countries where significant proportions of girls marry before they are 18 years old are Niger (76%), Central African Republic (68%), Chad (67%), Burkina Faso (52%), Mali (52%) and South Sudan (52%).³

Existing evidence on interventions suggests that child marriage is not an intractable practice and that dedicated programs can have positive impacts on the practice. Several meta-analyses and evaluations of individual programs have examined what works in delaying child marriage. In 2012, Lee-Rife et al undertook a systematic review of evaluated child marriage interventions in developing countries. Among the 23 evaluated programs, only 4 focused on preventing child marriage as the primary objective and only 5 studies were undertaken in sub-Saharan Africa. Although evidence was limited, the review found that the most effective approaches in delaying child marriage were those that offered incentives and those that are directed at girls, providing them knowledge, skills, and opportunity to expand their social networks.⁵ More recent reviews explored both published and gray literature evaluations of child marriage prevention. These reviews found most of the successful programs included a conditional cash transfer or other provisions to allay the cost of schooling such as provision of school supplies, findings that essentially support those of the earlier review.^{6,7} Another review of rigorously evaluated projects found that empowerment approaches (approaches that give girls information, skills, and social support) were the most effective in reducing child marriage. In contrast to previous reviews, this review found economic approaches such as conditional cash/asset transfers to be of limited effectiveness.⁸

Given the sheer numbers of girls at risk of child marriage globally, the challenge to accelerate elimination of the practice is daunting. Pilot programs to prevent or reduce child marriage, whether evaluated or not, typically overlook the costs and scalability of the intervention design.⁸ Child marriage takes place on a massive scale, and responses must also be at-scale. However, most child marriage prevention programs remain at a small scale, led by nongovernmental organizations (NGOs) and reach fewer than 50,000 girls.^{9–11} The benefits of addressing child marriage are significant; the World Bank estimates that eradicating child marriage by 2030 will result in global benefits of over US\$600 billion dollars.¹² Child marriage largely occurs in the poorest countries with the greatest

resource constraints. Therefore, is it incumbent upon program managers and researchers to not only ask what interventions work in preventing child marriage but also what package of interventions can reach the most girls at the least cost and still be effective in preventing the practice? For example, interventions such as the Zomba scheme in Malawi offered households a conditional cash transfer of between US\$4 to US\$10 per month and girls between US\$1 to US\$5 dollars per month.¹³ Although the scheme was found to be effective, it is unclear if such interventions can be scaled up in poor countries, given the cost of the intervention when offered to large numbers of families and girls.

Berhane Hewan

In Ethiopia, *Berhane Hewan* (Amharic for “Light for Eve”) was one of the early child marriage prevention programs to include a rigorous, quasi-experimental evaluation. The program was a multicomponent package that included (1) community conversations to address social norms related to child marriage; (2) provision of school supplies to encourage school enrollment and thereby protect girls from marriage; (3) a conditional asset transfer, promising girls and their families a goat if they remain unmarried and in school; and (4) girls’ groups led by adult women mentors that were mainly attended by married girls. After 2 years of intervention, girls aged 10 to 14 years in the Berhane Hewan site were one-tenth as likely to be married and 3 times more likely to be in school compared to girls residing in the control area.¹⁴

Given the success of Berhane Hewan in delaying marriage age, it was anticipated that government and NGO partners would scale up the approach to other locations in Ethiopia where child marriage was prevalent. However, in-country partners questioned the feasibility of scaling up the project given the complexity of its multicomponent design and wanted more information about the costs associated with scaling up the program over larger populations.¹⁵

As a result, a second generation of research was designed related to child marriage prevention. We sought to examine if streamlined, low-cost interventions could be effective in delaying marriage in sub-Saharan Africa, and at what cost? In this phase, we adapted the interventions used in the original Berhane Hewan project but implemented them separately in different geographical areas, with the intention to isolate the specific

This study tested and costed streamlined interventions to delay the age at marriage in Burkina Faso and Tanzania.

impact of streamlined interventions. During this research phase, costing data were collected for all interventions, and the program was expanded beyond Ethiopia to include the Cascades province of Burkina Faso and the Tabora region of Tanzania.

In this article, we present implementation, impact results, and costing data for child marriage prevention schemes in Burkina Faso and Tanzania only. Although we included research sites in the Amhara region of Ethiopia, where the Berhane Hewan project had been tested, we had to eliminate the control site because it became a resettlement area for people from other parts of the country. As a result, the population in this area was frequently unfamiliar with each other, making it significantly different from the other intervention sites. Marriage arrangements in Ethiopia are rooted in family ties and the desire to strengthen bonds between families who are essentially known to each other and/or neighbors. The control site included a resettled population, many of whom were strangers to each other or from different religions, inherent differences that could not be captured in the survey. As such, the marriage market in this area was compromised and rates of marriage were extremely low and uncharacteristic of the region.

■ STUDY LOCATIONS

Burkina Faso is a francophone West African country where the prevalence of child marriage is the eighth highest in the world (52% married by age 18 years).³ Polygamous unions are common, and age differences between married girls and their husbands can be significant: on average 10.9 years among ever-married women aged 20 to 24 years.¹⁶ The Cascades Region is 1 of 13 administrative regions in Burkina Faso and borders Cote d'Ivoire and Mali. With a population of nearly 525,000, the region is largely agricultural and has cotton as a major economic activity. According to the 2010 Demographic and Health Survey (DHS) for Burkina Faso, 58% of girls aged 20 to 24 years in the Cascades region were married by their 18th birthday and 10% were married by age 15 years. Among women aged 20 to 24 years in the Cascades region, 64% have never been to school and only 15% have attained a secondary level education.¹⁶

The Tabora region is located in the central-western part of Tanzania and has a population of more than 2.2 million. The largely agricultural region has tobacco production as a major economic activity. Based on the 2010 Tanzania DHS, 63% of Tabora girls are married by age 18 years and

16% are married by age 15 years. Among girls aged 20 to 24 years, 42% have never been to school and only 9% have reached the secondary level.¹⁷

■ PROGRAM DESCRIPTION

This study tested and costed streamlined interventions to delay the age at marriage in Burkina Faso and Tanzania. Local NGO partners implemented different child marriage prevention strategies derived from the Berhane Hewan program in Ethiopia in different geographical areas of the project regions. In each country, 4 approaches were implemented: (1) addressing community attitudes related to child marriage through community dialogue (2) providing unmarried girls aged 12 to 17 years with school materials, (3) offering a conditional asset transfer in the form of a goat, both conditioned on the 12-to-17-year-old girl remaining unmarried and in school for the duration of the pilot period (27–28 months), and (4) offering all components: community dialogue, school supplies and a conditional asset transfer. A fifth area served as a control where no intervention took place.

The interventions were similar between regions but not identical. In each of the countries, modest modifications and adaptations were made by local implementing partners based on experiences and preferences as well as local circumstances, and so as not to impose approaches that might not be appropriate to the context (Table 1). Interventions were implemented for 28 months in Tanzania and 27 months in Burkina Faso.

Addressing Community Attitudes Through Community Dialogue

Approaches to community dialogue differed in Burkina Faso and Tanzania with the approach in Burkina Faso being more systematic. In Burkina Faso, community facilitators were recruited from project communities and trained for 5 days using a facilitation manual. The manual contained information on facilitation techniques and on child marriage and girls' education. After training, facilitators mobilized community discussion groups composed of roughly 30 members containing a cross-section of the community: adult men, adult women, adolescent men, and adolescent women. Groups were taken through a 16-week curriculum that included both educational and action-oriented sessions. Education sessions provided information on the negative impact of early marriage and the value of girls' education. The action-oriented sessions provided a space for group members to devise

TABLE 1. Overview of Child Marriage Prevention Program Interventions, by Model, Burkina Faso and Tanzania

	Burkina Faso	Tanzania
Community dialogue	<ul style="list-style-type: none"> Facilitators recruited from communities and trained for five days. Facilitators mobilize a cross-section of the community in groups of 30. Groups attend 16 sessions. Sessions include information on child marriage and girls' education and devising and implementing solutions. 	<ul style="list-style-type: none"> Community and religious leaders recruited and trained for two days. Leaders deliver messages on child marriage and girls' education through routine community meetings such as religious services and community meetings.
School supplies and clubs	<ul style="list-style-type: none"> Mentors go house-to-house to identify unmarried girls aged 12–17. Parents and girls register to receive school supplies in public ceremony Ceremonies used to educate public on importance of girls' education and eliminating child marriage. Girls given school supplies once per year at the beginning of the school year. Supplies were notebooks, pens, pencils, mathematical sets and US\$3.50 subsidy of school fees. 	<ul style="list-style-type: none"> Mentors go house-to-house to identify unmarried girls aged 12–17. Parents and girls register to receive school supplies in public ceremony Ceremonies used to educate public on importance of girls' education and eliminating child marriage. Girls given school supplies or school uniform once per year at the beginning of the school year. Supplies were notebooks, pens, pencils, mathematical sets or a school uniform. In-school girls' clubs formed including life skills and tutoring.
Conditional asset transfer	<ul style="list-style-type: none"> Mentors go house-to-house to identify unmarried girls aged 12–17. Parents and girls register to receive conditional asset (goat) in public ceremony Goats awarded after two years if girls remained unmarried and in school. Ceremonies used to educate public on importance of girls' education and eliminating child marriage. 	<ul style="list-style-type: none"> Mentors go house-to-house to identify unmarried girls aged 12–17. Parents and girls register to receive conditional asset (goat) in public ceremony Goats awarded after two years if girls remained unmarried and in school. Ceremonies used to educate public on importance of girls' education and eliminating child marriage.
Comprehensive model (all components)	<ul style="list-style-type: none"> All interventions above 	<ul style="list-style-type: none"> All interventions above
Control	No intervention	No intervention

home-grown solutions to child marriage and develop strategies to address it. Strategies could include house-to-house campaigns or systems of punishments or rewards for community members. Following the completion of the 4-month period, groups could have continued to meet on their own, if they desired. However, facilitators moved to additional areas to form new discussion groups. By the end of the program, 495 individual community members had taken part in the dialogues in Burkina Faso.

In the Tanzania community dialogue locations, community and religious leaders received 2 days of training on the benefits of delaying marriage and promoting girls' education. Leaders were trained on how to facilitate discussions and deliver messages and were asked to pass messages

in their villages or places of worship. In contrast to the approach in Burkina Faso, the community dialogues in Tanzania did not include sustained and systematic contact with community groups but rather ad hoc contact with community members who attended routine community or religious meetings. Leaders in Tanzania did not record the number of community members who received their messages.

Promoting Schooling Through Provision of School Supplies and School Clubs

Both in-school and out-of-school girls aged 12 to 17 years who were unmarried were eligible for the provision of school supplies, with out-of-school girls encouraged to return to school or join nonformal

education. In school promotion locations, community-based mentors who were recruited and trained by the project identified eligible girls by going house-to-house. Once identified, project staff explained the scheme to girls and parents/guardians in the household and invited them to register for the scheme at a central location (mainly the local school) on a designated day. These explanations of the scheme were scripted so that information provided about the school promotion scheme was complete and uniform across households. On the day of registration and at the designated location, both the registering girl and her parent/guardian would sign the registration form in the presence of other community members and local leadership and take school materials with them with the agreement that the girl would remain unmarried and in-school for the duration of the pilot. Once it was confirmed that girls were attending school and remained unmarried, they were given her subsequent allocation of supplies in public ceremonies acknowledging their achievements by local leadership and school officials. These public ceremonies were also used as occasions to educate the community on the value of educating girls and keeping them unmarried.

Girls were given supplies once per year at the beginning of the school year, but the support differed by country. In Burkina Faso, registered girls received school supplies (notebooks, pens, pencils, and a mathematical set). In addition, they received a subsidy for school fees equivalent to US\$3.50. In Tanzania, girls were given the choice of receiving a school uniform or school supplies. Tanzanian girls could attend Smart Girls' Clubs, which were after-school clubs that included life skills, reproductive health information, and tutoring. In all, 1,055 girls registered for the schooling program in Burkina Faso and 1,617 registered in Tanzania.

Conditional Asset Transfer

Girls were recruited for the conditional asset transfer through community-based mentors going house-to-house to identify unmarried girls aged 12 to 17 years. Girls and their parents/guardians were sensitized on the scheme through a scripted narrative and asked to come to a central registration site on a specified day, if they wanted to enroll. In both countries, families and girls were awarded a goat at the end of the pilot period if the registered girls remained unmarried and in-school throughout the intervention period. In Tanzania, a pregnant goat was preferred because project

partners perceived that such an asset would be further incentivizing to project communities. At the end of the pilot period, girls who remained unmarried and in school were awarded their livestock in a public ceremony with all the community members and local officials. As with the school material ceremonies, these occasions were used to educate the community on the value of girls' education. Seven hundred and thirty-two girls registered in Burkina Faso compared to 805 in Tanzania.

Comprehensive, Multicomponent Model Site

In both countries, 1 location included all the project interventions: community dialogue, school promotion, and conditional asset transfer. All interventions we tested were designed to change social norms related to child marriage in different ways. The community dialogues directly addressed attitudes and beliefs related to child marriage and the status and value of girls. In addition, promotion of schooling and provision of conditional asset transfers were all implemented through public events under the auspices of local community leadership. These events raised the visibility and status of girls in the community and included messages from local leaders emphasizing the value delaying marriage and girls' education.

METHODS

Research Design

This was a quasi-experimental study design with cross-sectional baseline and end line surveys undertaken among girls aged 12 to 17 years. These surveys were used to measure population-level prevalence of child marriage and school attendance associated with the different interventions, using the control to measure changes that would have taken place without the interventions. Separate, cross-sectional baseline and end line surveys were undertaken before the interventions were established and after 27 to 28 months of intervention implementation.

The sample size was calculated to detect a 10-percentage point change in the prevalence of child marriage and adjusted for nonresponse and design effect. In each country, 2,500 girls aged 12 to 17 years were sampled, 500 per intervention area, at each round of survey. In each study commune (Burkina Faso) and ward (Tanzania), we randomly selected 17 enumeration areas from the existing national sampling frame. Each selected enumeration area underwent a household

listing to establish a sampling frame. All members of the household were listed. Using the random number function in SPSS, we selected 30 girls aged 12 to 17 years per enumeration area. Only 1 respondent was interviewed per household. Where there was more than 1 eligible respondent per household, we used a Kish grid to select just 1 respondent.

Female interviewers were recruited from the project regions, ensuring that they were familiar with local languages and customs. At each survey round, interviewers received a 5-day training that included review of the questionnaire, review of ethical procedures, and practice interviews between interviewers and with girls recruited from outside the study areas.

Interviewers approached sampled respondents for a one-on-one interview. Similar to the DHS, interviewers made up to 3 visits to the household to locate and interview the sampled respondent. There was no replacement if the sampled respondent could not be located or refused to participate. Informed consent for the interviews was obtained from the parent or guardian of the sampled adolescent, and informed assent was obtained from the girl. If a girl was married, we considered her as an emancipated minor who could provide her own consent.

The questionnaire used in the study was a structured instrument covering areas such as demographic characteristics and living conditions, education, families and parent-child relationships, livelihoods, attitudes toward marriage and the experience of marriage, sexual experience, family planning, maternal and child health, and HIV and AIDS. A separate, abbreviated questionnaire was administered to younger respondents aged 12 to 14 years. This questionnaire omitted especially sensitive or potentially upsetting questions such as those related to violence or sexual coercion. The questionnaires were the same across countries at baseline and end line, except for country-specific modifications such as response codes for ethnic groups or religion. However, at end line, an additional section was added at the end to measure exposure to the interventions. The study received ethical clearance from the host institution's review board as well as local review boards in each of the study countries.

Measures

The main outcome indicators measuring the impact of interventions was the percentage of girls who had ever been married and the percentage of

girls in school in the current or previous year. Marriage was measured by asking the question, "Have you ever been married or lived with a person as married?" and a follow-up confirmatory question, "Have you ever been married but later divorced?" Girls who answered yes to either of these questions were coded as having been married and were asked a series of follow-up questions related to their husband and the timing and nature of their marriage.

To indicate whether girls had attended school in the last year, we asked respondents if they had ever been to school, if they were currently in school, and, if not, the age at which they left school. We used these 3 variables as well as the respondent's current age to construct a dichotomous variable reflecting school attendance in the previous year. We considered not only girls who were currently in school but also those who recently dropped out from school. This was because school supplies were only provided once per year at the beginning of the school year. Our field reports suggested that some girls in the 2 project countries dropped out of school in the second year of implementation after receiving their supplies because they knew no further supplies were forthcoming.

Multivariate models controlled for age, ethnicity, household assets as a reflection of socioeconomic status, and religion. Household socioeconomic status of respondents was measured based on ownership of a list of assets derived from DHS surveys. Each of these assets were given weights varying from 1 to 5, with the larger weight indicating greater value of the asset. Hence, car/truck was given a weight of 5; motorcycle/scooter was given a weight of 4; television, refrigerator, bicycle, and animal drawcart were given weights of 3; clock or watch, radio, telephone, mobile phone, and solar panel were given weights of 2; and table, chair, bed, and mattress were given a weight of 1. In each country, a weighted asset score was calculated after which respondents were scored as low-, middle-, or high-economic status. For religion, a dichotomous variable was created in both countries to reflect if the respondent was a Muslim or another religion.

Exposure and participation in the interventions were measured by asking respondents 2 separate questions. First, they were asked if they had heard of a project in their area offering community dialogues, school supplies, or a goat. In Tanzania, we also asked if girls had heard about a program offering girls' clubs in school. The second question asked if they had participated in the program including community dialogues, school supplies, or

a goat. Those who had heard of and reported participation were coded as having participated in the project. Because the community dialogue arm included interventions that were targeted to both girls and the community at-large, respondents who had either heard of or participated in community dialogue were coded as having been exposed to the project. As the intervention was targeted to the community and not necessarily intended for the girl, it was assumed that those who had heard of the community dialogue had family and community members exposed to its messages. To measure exposure to the comprehensive model, we considered only residents of the study cell who had been exposed to all 3 project components as having been exposed to the comprehensive model. Follow-up questions were asked to assess levels of exposure to the interventions such as how many times they received school materials and how many community meetings they attended.

Analysis

The analysis of the demographic characteristics was based on the unweighted sample. All other analyses were adjusted for the number of eligible females in the household to compensate for unequal probabilities of selection. Weighted numbers were reported. Exposure to the interventions is reported for each of the respective project sites at end line. In each of the countries, 1 study area was assigned to each model tested, due to logistical constraints. We undertook tests of equivalence using a confidence interval approach to understand the comparability of the study cells in each country.^{18,19} Through this approach, we assessed if intervention sites were within $\pm 20\%$ of the control site on various background measures. Sites with estimates that fell within $\pm 20\%$ of the control site estimate were considered to be equivalent in terms of that characteristic. We highlighted areas in which experimental sites were either equivalent or nonequivalent to the control site and controlled for all characteristics in the multivariate models. Additional analysis demonstrated that the conditional asset transfer site in Burkina Faso was significantly different from the control site, even after controlling for background factors. Thus, the conditional asset arm was eliminated from the analysis of results from Burkina Faso.

To estimate the impact of the interventions, we use Poisson regression to model risk ratios (RR) of having been married and having attended school in the last year, controlling for age, religion,

ethnicity and low-, middle- or high-socioeconomic status. We stratified analysis by younger (aged 12 to 14 years) versus older (aged 15 to 17 years) adolescents. This stratification was done because the Berhane Hewan study demonstrated that interventions may operate differently among younger versus older adolescents, reflecting the divergent experiences and circumstances of older versus younger adolescents. At the same time, our sample was not powered to account for stratification. Separate models are presented for each intervention site, with reference to the control site, presenting RRs and 95% confidence intervals (CI) for residence in the intervention sites versus the control site, at end line. In addition, we did not assess the child marriage outcome for girls aged 12 to 14 years in Burkina Faso because there were too few cases of marriage among this age group at both baseline and end line.

Management Information Systems

Management information systems in each country tracked information on girls' participation in each of the study arms. When registering, basic demographic information about each girl was entered into the database including age, school attendance, and highest year of education attained. Girls participating in the community sensitization arm were not registered as this approach targeted the community at-large. Management information systems data were entered in each country in an Epi-data file and converted to SPSS for analysis.

Costing Study

At the beginning of the study, a Microsoft Excel spreadsheet was developed by a costing expert to enable systematic compilation of all project costs. Cost categories included staff time, office expenditures, training and meeting costs, travel expenditure, and purchase of commodities. Costs associated with evaluation were not included. Cost data were updated in the spreadsheet on a monthly basis by project staff and our in-country partners. On a yearly basis, costing data were validated by the costing expert.

At the end of the intervention, total costs were calculated by country and model. Using data from the management information system on the number of girls served per model, we calculated the cost per girl served, per year. Because the community dialogue did not include only girls, we estimated the population reached using population estimates and the percentage of girls at end line

hearing about or participating in community dialogue.

■ RESULTS

Sample Characteristics

Table 2 shows the demographic characteristics of girls interviewed at baseline in the 2 countries, by study cell. Only 47% of Burkinabe girls and 57% of Tanzanian girls were in school at the time of baseline. Religious composition varied considerably between countries. The study population in Burkina Faso was predominantly Muslim (85%). There was a greater religious mix in Tanzania with about half (55%) being Muslim, 37% Christian and 8% another religion. At baseline, 18% of Burkinabe girls had ever been married compared to 8% of Tanzanian girls. Characteristics of girls varied between study cells in many cases. Where characteristics were not comparable, these variables were adjusted for in regression models.

Table 3 shows the percentage of girls at end line who were exposed or took part in the interventions in each study arm, by country. Overall, interventions achieved better coverage in Tanzania than in Burkina Faso. Exposure to the interventions varied considerably between countries. In Burkina Faso, the 2 interventions that achieved the most coverage were conditional asset transfer (54% of girls enrolled), followed by community dialogue/sensitization (48% of girls either participating or hearing of meetings). Schooling promotion received the most coverage in Tanzania (91%) followed by community sensitization (89%). The comprehensive model with multiple components achieved among the lowest coverage (20% in Burkina Faso and 52% in Tanzania).

Child Marriage

We modelled the RRs at end line associated with being married in each of the study communities in Burkina Faso and Tanzania, with reference to the control site. In Burkina Faso, we did not examine the impact on marriage age among younger girls aged 12 to 14 years, as too few girls were married at both baseline (12 married girls) and end line (5 married girls). As previously mentioned, the conditional asset transfer arm was removed from analysis because of incomparability of that site, even after controlling for background factors. In Burkina Faso, girls aged 15 to 17 years who were enrolled in the community dialogue arm

were one-third as likely to be married as those in the control site (RR=0.33; 95% CI=0.19, 0.60) (Table 4).

In Tanzania, girls 12 to 14 residing in the comprehensive site had two-thirds less risk of being married compared to girls in the control site (RR=0.33; 95% CI=0.11, 0.99). Tanzanian girls 15 to 17 residing in the conditional asset transfer site had roughly half the risk of being married compared to girls in the control site (RR=0.52; 95% CI=0.30, 0.91).

We re-analyzed data to model RRs among Burkinabe and Tanzanian girls who reported that they had been exposed to the intervention at end line, with reference to the control site. Although selectivity issues undoubtedly impact upon results, the results of these analyses are consistent with the findings presented above (analysis not shown). In Burkina Faso, girls exposed or aware of the community dialogue had three-quarters less risk of being married (RR=0.27) compared to girls in the control site. Tanzanian girls aged 15 to 17 years residing in the conditional asset transfer arm and the comprehensive model had 90% less risk of being married compared to those in the control. This analysis demonstrates similar results among the exposed compared to the intention-to-treat analysis design, giving us confidence in the findings from our earlier analysis.

School Attendance in the Current or Last Year

We examined differences in the risk of girls attending school in the current and previous years. We included attendance during the current year and previous year because school material was provided only once per year. We received information from staff in the field that some participants left school after receiving the second tranche of school supplies, knowing that additional supplies would not be provided in the next year. Table 5 shows the risk ratios and 95% CI for Burkinabe and Tanzanian girls attending school during the current and previous year, with reference to girls in the control site.

Burkinabe girls aged 12 to 14 years residing in the community dialogue site had a greater chance of being in school (RR=1.2; 95% CI=1.07, 1.29) compared to their counterparts in the control. This finding is consistent with the fact that girls in this site were also less at risk for child marriage, which supports the effectiveness of this intervention in Burkina Faso. In Tanzania, all the interventions tested were associated with increased risk of girls aged 12 to 14 years being in school. The

TABLE 2. Demographic Characteristics of Girls Aged 12 to 17 Years Surveyed at Baseline, by Country and Model^a

Burkina Faso	Total, % (N=2421)	Control, % (n=504)	Community dialogue, % (n=321)	Education promotion, % (n=509)	Asset transfer, % (n=488)	Comprehensive model, % (n=599)
School Status						
In school	47.2	50.1	59.1 ^b	50.8	33.0 ^b	47.1
Out of school	52.8	49.9	40.9 ^b	49.2	67.0 ^b	59.9
Religion						
Christian	4.2	4.8	6.5 ^b	3.7	3.3	3.5
Muslim	84.6	91.2	61.7 ^b	92.7	87.5	82.1
Other ¹	11.2	4.0	31.8 ^b	3.6	9.2	14.4
Ethnicity (% Senoufo)	67.9	62.6	65.4	36.1 ^b	89.1 ^b	83.1 ^b
Marital status						
Never married	82.2	84.1	88.2 ^b	80.7 ^b	66.9 ^b	90.9 ^b
Ever married	17.8	15.9	11.8 ^b	19.3 ^b	33.1 ^b	9.1 ^b
Asset based SES						
Low	36.1	51.8	28.7 ^b	43.9 ^b	12.5 ^b	39.5 ^b
Middle	36.9	29.4	38.9 ^b	36.2 ^b	36.1 ^b	43.5 ^b
High	27.0	18.8	32.4 ^b	19.9 ^b	51.4 ^b	17.0 ^b
Tanzania	Total (N=2133)	Control (n=414)	Community sensitization^b (n=398)	Education promotion^b (n=483)	Asset transfer^b (n=408)	Comprehensive model^b (n=430)
School status						
In school	56.7	47.8	63.0	53.1	59.3	60.8
Out of school	43.3	52.2	37.0	46.9	40.7	39.2
Religion						
Christian	36.7	58.4	30.1	30.2	39.6	26.5
Muslim	55.3	17.9	64.1	64.6	57.0	71.2
Other ^c	8.0	23.7	5.8	5.2	3.4	2.3
Ethnicity (% Mnamezi)	54.3	31.9	59.5	59.0	59.9	60.7
Marital status						
Never married	91.9	88.4	91.7	93.4	91.8	93.7
Ever married	8.1	11.6	8.3	6.6	8.2	6.3
Asset-based socioeconomic status						
Low	44.1	54.6	39.7	42.4	39.0	44.9
Middle	28.8	23.2	30.7	31.9	27.2	30.5
High	27.1	22.2	29.6	25.7	33.8	24.6

^a Unweighted data.^b Measures not equivalent using confidence interval tests of equivalence.^c No religion or other/traditional religion.

TABLE 3. Girls Aged 12 to 17 Years Exposed to the Child Marriage Prevention Interventions, at End Line, by Study Arm and Country^a

	Burkina Faso, % (N=2,655)	Tanzania, % (N=2,324)
Community dialogue/sensitization	47.9	89.4
School promotion: school materials	30.6	90.7
School promotion: 'Smart Girl Clubs' (Tanzania only)	-	50.7
Conditional asset transfer	53.9	52.0
Comprehensive model	20.2	52.3

^aWeighted data and weighted numbers presented.**TABLE 4.** Risk Association of Intervention for Burkinabe and Tanzanian Girls Having Ever Been Married at End Line, With Reference to the Control Group, by Study Arm and Age Group^a

	Aged 12 to 14 Years, RR ^b (95% CI)	Aged 15 to 17 Years, RR ^b (95% CI)
Burkina Faso		
Community dialogue	—	0.33 (0.19, 0.60) ^e
Education promotion: school materials and fees	—	0.99 (0.66, 1.49)
Comprehensive model	—	0.77 (0.52, 1.15)
Tanzania		
Community sensitization	1.13 (0.48, 2.68)	0.74 (0.43, 1.27)
Education promotion: school materials and girls' clubs	0.70 (0.30, 1.65)	0.99 (0.64, 1.53)
Conditional asset transfer	0.41 (0.15, 1.15)	0.52 (0.30, 0.91) ^c
Comprehensive model	0.33 (0.11, 0.99) ^c	0.59 (0.34, 1.01)

Abbreviations: CI, confidence interval; RR, risk ratio.

^aWeighted data.^bAdjusted for age, religion, ethnicity, and socioeconomic status.^c $P < .05$.^e $P < .001$.

educational promotion arm was also associated with a 30% increased risk of being in-school among girls aged 15 to 17 years (RR=1.3; 95% CI=1.01, 1.67).

Cost Analysis

Table 6 shows the cost per participating girl per year for the different intervention models. It should be noted that this is not cost-effectiveness but rather the cost to the program to implement the activities and support girls through various approaches. In both countries, community dialogue

and school promotion cost roughly the same: from US\$9 to US\$12 per community member served for community dialogue and from US\$13 to US\$18 per girl served with school supplies. That the community sensitization was much less expensive in Tanzania compared to Burkina Faso probably reflects the less intensive and ad hoc nature of the intervention. In Tanzania, community leaders were trained to deliver messages but were not followed-up nor asked to report on the number of type of messages passed. In contrast, community dialogue in Burkina Faso involved intensive and systematic activities using paid

TABLE 5. Risk Association for Burkinabe and Tanzanian Girls Being in School in the Current and Previous Years at End Line, by Age Group^a

	Age 12 to 14, RR ^b (95% CI)	Age 15 to 17, RR (95% CI)
Burkina Faso		
Community dialogue	1.18 (1.07, 1.29) ^c	1.06 (0.94, 1.19)
Education promotion: school materials and fees	0.99 (0.89, 1.09)	0.92 (0.80, 1.05)
Comprehensive model	1.07 (0.96, 1.18)	1.03 (0.91, 1.15)
Tanzania		
Community sensitization	1.17 (1.04, 1.32) ^c	0.92 (0.68, 1.23)
Education promotion: school materials and girls' clubs	1.21 (1.08, 1.35) ^c	1.30 (1.01, 1.67) ^d
Conditional asset transfer	1.34 (1.20, 1.48) ^e	1.29 (1.00, 1.68)
Comprehensive model	1.28 (1.15, 1.43) ^e	1.00 (0.76, 1.32)

^a Weighted data.^b Adjusted for age, religion, ethnicity, and socioeconomic status.^c $P < .01$.^d $P < .05$.^e $P < .001$.**TABLE 6.** Cost per Girl/Person Served per Year, by Model and Country

	Burkina Faso (US\$)	Tanzania (US\$)
Community sensitization/dialogue	12	9
School supplies and fees	13	–
Girls' clubs	–	18
Conditional asset transfer	33	107
Comprehensive model	60	117

facilitators to take community members through 4 months of structured discussions. The conditional asset transfer and the comprehensive models were the most costly to implement. In particular, provision of livestock and the comprehensive model was expensive in Tanzania, over US\$100 per girl served. In Tanzania, the purchase, transport, and storage of goats added to the cost of implementation. In addition, program managers purchased more expensive pregnant goats, rather than the less expensive younger goats procured in Burkina Faso.

DISCUSSION

Lessons Learned

Child marriage is considerably more common in rural areas compared to urban areas. Sites for this

study were all rural and difficult to access. As such, the cost to deliver interventions in these rural areas was undoubtedly higher than similar efforts in urban areas. The coverage or reach of interventions varied. A much lower proportion of girls was exposed to the comprehensive model in both countries, likely reflecting the increased difficulty in implementing complex, multicomponent programs, exacerbated by the fact that interventions are being implemented in remote rural areas, where households are dispersed, isolated, or inaccessible. Although it had been expected that the comprehensive model would be more effective than simpler or single-component models in bringing about improved outcomes, the difficulty in implementing multicomponent programs in remote areas may have undermined the

effectiveness of the intensive program model. Therefore, program implementers should closely monitor the coverage and quality of child marriage interventions. Specifically, they should weigh the trade-offs between more comprehensive program design that may be difficult to implement at scale in remote areas against simpler models that can more easily achieve coverage and scale and maintain quality.

Child marriage is commonly perceived as an intractable traditional practice. Many practitioners assume that complex and cost-intensive interventions are needed to achieve a tipping point. Our study results suggest that streamlined minimal approaches can be effective in delaying child marriage and encouraging school attendance. Community dialogue was effective in Burkina Faso, both in delaying child marriage and in increasing school attendance; however, the approach did not bring about measurable change in Tanzania. Community dialogue in Burkina Faso was systematically implemented using dedicated, paid facilitators who implemented a set curriculum among representatives of the community recruited for the dialogues. The approach in Tanzania was less rigorous and used existing community leaders to pass messages during routine community meetings. The ad hoc nature of the approach in Tanzania probably weakened the quality and intensity of messaging, as well as, possibly, cultural differences or differential receptivity to messages. This suggests that efforts to promote social norm change need to be implemented in a rigorous and systematic manner and not simply delegated to community members or religious leaders without rigorous training and follow-up.

Finally, this is one of the few studies on child marriage prevention to include rigorous costing data. The study demonstrated that streamlined interventions can be effective to both delay marriage and contain costs, thus maximizing the likelihood for scale-up to large numbers of at-risk girls. Community dialogues in Burkina Faso cost only US\$12 per person reached per year; schooling promotion in Tanzania cost only US\$18 per girl supported per year. However, the cost of providing goats as a conditional asset transfer ranged from US\$33 per girl served in Burkina Faso to US\$107 per girl in Tanzania. The higher cost of purchasing pregnant goats in Tanzania compared with purchasing less expensive younger goats in Burkina Faso coupled with the delivery cost to remote areas of Tabora region drove up the cost of the conditional asset transfer in Tanzania. The

high unit cost in Tanzania underscores the fact that decisions about programs and purchases should take cost into careful consideration to avoid excessive costs that undermine the chances of scalability. In addition, programmers should carefully consider the choice of economic incentives. A more recent program in Ethiopia eliminated livestock and introduced solar-powered lanterns as incentives to delay child marriage.²⁰ Not only were the lanterns less expensive than livestock and easier to deliver, but they were used by recipients both to light homes and study in the evening and to generate income by charging cell phones for a small fee.

Child marriage affects a large number of developing country girls, mainly in the poorest, most remote, and hard-to-reach locations. Programs designed to reach the greatest number of girls possible will require a greater number of impact evaluations coupled with costing studies. This study demonstrated that cost-contained interventions are feasible and can be effective in preventing child marriage. However, interventions need to take into account the quality and coverage of interventions, especially considering the difficulty of implementation in remote areas, where child marriage tends to persist.

Limitations

The study had a number of limitations. Due to logistical and budgetary constraints, only 1 location was used to test and compare each model implemented. Including multiple sites per model tested would have likely increased comparability between sites and our confidence in the study results. Unfortunately, the control site in Ethiopia was found not to be comparable to the experimental sites, which weakened our ability to detect changes associated with interventions. In addition, the conditional asset transfer site in Burkina Faso was not comparable to the control site, even after controlling for background factors. As such, we could not assess the effectiveness of this approach. Lastly, based on past experience, it was necessary to stratify the analysis by age group. At the same time, the sample was not necessarily powered to accommodate this subgroup analysis.

CONCLUSION

This study demonstrates that minimal, low-cost approaches can be effective in delaying child marriage and increasing school attendance. However, community dialogues need to be designed to ensure sufficient quality and intensity of messaging.

Our study results suggest that streamlined minimal approaches can be effective in delaying child marriage and encouraging school attendance.

This is one of the few studies on child marriage prevention to include rigorous costing data.

Program managers should consider the cost, quality, and coverage of interventions, especially because child marriage persists in the most hard-to-reach, rural areas of many countries.

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En français

Conception et évaluation des programmes de prévention des mariages des enfants prêts pour une mise à échelle au Burkina Faso et en Tanzanie: Une étude quasi-expérimentale et de calculs des coûts

Des approches minimales et peu coûteuses peuvent être efficaces pour retarder le mariage des enfants et augmenter la fréquentation scolaire. Les questionnaires de programmes doivent tenir compte du coût, de la qualité et de la couverture des interventions, notamment parce que le mariage des enfants persiste dans les zones rurales les plus difficiles d'accès de nombreux pays.

RÉSUMÉ

Contexte: Un grand nombre de filles sont mariées lorsqu'elles sont enfants, ce qui a un impact négatif sur leur santé, leur éducation et leur développement. Étant donné le nombre de filles qui risquent d'être mariées dans le monde, le défi pour éliminer cette pratique est immense. Les

programmes visant à prévenir le mariage des enfants sont généralement de petite envergure et négligent les coûts et l'extensibilité de l'intervention.

Mise en œuvre: Cette étude a testé et chiffré différentes approches de prévention du mariage des enfants dans les zones rurales du Burkina Faso et de la Tanzanie. Les approches testées étaient le dialogue communautaire, l'allocation de fournitures scolaires, la fourniture de matériel d'élevage, un modèle incluant toutes les composantes et un bras de contrôle. Un modèle quasi-expérimental a été utilisé avec des enquêtes entreprises au départ et après deux ans d'intervention. Nous avons examiné l'évolution de la prévalence des mariages d'enfants et de la fréquentation scolaire, en contrôlant les caractéristiques du contexte et en les stratifiant par groupe d'âge. Les coûts du programme ont été recueillis de manière prospective.

Résultats: Parmi les participants au dialogue communautaire au Burkina Faso, les filles âgées de 15 à 17 ans avaient deux tiers de risque en moins (rapport de risque [RR]=0,33; intervalle de confiance [IC] de 95%=0,19, 0,60) d'être mariées et les filles âgées de 12 à 14 ans avaient une plus grande chance d'être scolarisées (RR=1,18; IC de 95%=1,07, 1,29) par rapport au site témoin. En Tanzanie, les filles âgées de 12 à 14 ans résidant dans le site à composantes multiples avaient deux tiers de risque en moins d'être mariées (RR=0,33; 95% IC=0,11, 0,99), et les filles de 15 à 17 ans dans le site à actifs conditionnels avaient la moitié du risque (RR=0,52; 95% IC=0,30, 0,91). Toutes les interventions testées en Tanzanie étaient associées à un risque accru de scolarisation des filles de 12 à 14 ans, et le volet promotion de l'éducation était également associé à un risque accru de 30% de scolarisation des filles de 15 à 17 ans (RR=1,3; 95% IC=1,01, 1,67). Les coûts par bénéficiaire allaient de 9 à 117 dollars américains.

Conclusion: L'étude démontre que des approches minimales et peu coûteuses peuvent être efficaces pour retarder le mariage des enfants et augmenter la fréquentation scolaire. Toutefois, les dialogues communautaires doivent être conçus de manière à garantir une qualité et une intensité suffisantes des messages. Les responsables de programmes doivent prêter attention au coût, à la qualité et à la couverture des interventions, surtout si l'on considère que le mariage des enfants persiste dans les zones rurales les plus difficiles à atteindre de nombreux pays.

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ORIGINAL ARTICLE

Unmet Need for Family Planning and Experience of Unintended Pregnancy Among Female Sex Workers in Urban Cameroon: Results From a National Cross-Sectional Study

Anna L. Bowring,^{a,b} Sheree Schwartz,^a Carrie Lyons,^a Amrita Rao,^a Oluwasolape Olawore,^a Iliassou Mfochive Njindam,^{a,c} Jimmy Nzau,^d Ghislaine Fouda,^e Guy H. Fako,^c Gnilane Turpin,^a Daniel Levitt,^f Sandra Georges,^e Ubald Tamoufe,^{c,g} Serge C. Billong,^h Oudou Njoya,^h Anne-Cécile Zoung-Kanyi,^{h,i} Stefan Baral^a

Female sex workers (FSWs) in Cameroon have unmet need for effective contraception, and experience of unintended pregnancy and pregnancy termination is common. Reducing barriers to accessing high-quality, voluntary family planning services in FSW-focused community services is a key strategy to promote client-centered care, promote informed choice, reduce unintended pregnancies, and improve quality of life for FSWs.

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

ABSTRACT

Background: Female sex workers (FSWs) in Cameroon commonly have unmet need for contraception posing a high risk of unintended pregnancy. Unintended pregnancy leads to a range of outcomes, and due to legal restrictions, FSWs often seek unsafe abortions. Aside from the high burden of HIV, little is known about the broader sexual and reproductive health of FSWs in Cameroon.

Methods: From December 2015 to October 2016, we recruited FSWs aged ≥ 18 years through respondent-driven sampling across 5 Cameroonian cities. Cross-sectional data were collected through a behavioral questionnaire. Modified-robust Poisson regression was used to approximate adjusted prevalence ratios (aPR) for TOP and current use of effective nonbarrier contraception.

Results: Among 2,255 FSWs (median age 28 years), 57.6% reported history of unintended pregnancy and 40.0% reported prior TOP. In multivariable analysis, TOP history was associated with current nonbarrier contraceptive use (aPR=1.23, 95% confidence interval [CI]=1.07, 1.42); ever using emergency contraception (aPR=1.34, 95% CI=1.17, 1.55); >60 clients in the past month (aPR=1.29, 95% CI=1.07, 1.54) compared to ≤ 30 ; inconsistent condom use with clients (aPR=1.17, 95% CI=1.00, 1.37); ever experiencing physical violence (aPR=1.24, 95% CI=1.09, 1.42); and older age. Most (76.5%) women used male condoms for contraception, but only 33.2% reported consistent condom use with all partners. Overall, 26.4% of women reported currently using a nonbarrier contraceptive method, and 6.2% reported using a long-acting method. Previous TOP (aPR=1.41, 95% CI=1.16, 1.72) and ever using emergency contraception (aPR=2.70, 95% CI=2.23, 3.26) were associated with higher nonbarrier contraceptive use. Recent receipt of HIV information (aPR=0.72, 95% CI=0.59, 0.89) and membership in an FSW community-based organization (aPR=0.73, 95% CI=0.57, 0.92) were associated with lower use nonbarrier contraceptive use.

Conclusions: Experience of unintended pregnancies and TOP is common among FSWs in Cameroon. Given the low use of nonbarrier contraceptive methods and inconsistent condom use, FSWs are at risk of repeat unintended pregnancies. Improved integration of client-centered, voluntary family planning within community-led HIV services may better support the sexual and reproductive health and human rights of FSWs consistent with the United Nations Declaration of Human Rights.

^a Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA.

^b Burnet Institute, Melbourne, Australia.

^c Metabiota, Yaounde, Cameroon.

^d CARE SRHR Global Team, Atlanta, GA, USA.

^e CARE Cameroon, Yaounde, Cameroon.

^f CARE USA, New York, NY, USA.

^g Johns Hopkins Cameroon Program, Yaounde, Cameroon.

^h Faculty of Medicine and Biomedical Sciences, University of Yaoundé I, Yaounde, Cameroon.

ⁱ Division of Operations Research, Ministry of Health, Yaounde, Cameroon.

Correspondence to Anna Bowring (abowrin1@jhu.edu).

BACKGROUND

Female sex workers (FSWs) have a disproportionate burden of HIV infection and experience systematic barriers to accessing existing HIV prevention and treatment services.¹ Based on 9 studies conducted during 2011–2016, HIV prevalence among women who sell sex ranged from 11% to 24% across western and central

Africa and was more than 60% across southern Africa.² Specific guidelines for HIV interventions among FSWs have shaped programs targeting HIV prevention, testing, and treatment. However, less attention has been given to FSWs' other comprehensive sexual and reproductive health services, including voluntary family planning.

FSWs may consider pregnancy prevention a more influential motivator for condom use than HIV prevention.³ Previous work has demonstrated that unintended pregnancy is a high-priority issue for FSWs, with unintended pregnancy incidence of 27 per 100 person-years among FSWs in low- and middle-income settings without presence of a sexual and reproductive health intervention.⁴ One potential outcome of unintended pregnancy is termination. Among FSWs, experience of termination of pregnancy (TOP) is widespread in global estimates and often higher than national estimates among all women.⁵ In many countries where FSWs are most affected by unintended pregnancy, abortion policy is generally restrictive,⁶ which can lead to women seeking unsafe abortions. Across sub-Saharan Africa specifically, it is estimated that unsafe abortions contribute to at least 10% of maternal deaths.^{6–8} In addition, unintended pregnancy leading to live births can have financial implications that may perpetuate vulnerability and HIV risks related to sex work.^{9,10}

Male and female condoms remain important means of preventing unintended pregnancy and HIV and STIs among FSWs in 2019.¹¹ However, extensive social and structural factors affect both condom use and condom failure among FSWs.^{12–15} These factors include punitive laws and policies, local policing practices, economic insecurity, intersecting stigmas, physical and sexual violence, and drug and alcohol use during sex work.¹⁶ Even in settings with high levels of consistent condom use with paying partners, condom use between FSWs and their nonpaying or emotional partners is low due to interpersonal barriers to condom use.^{17,18} Previous studies have demonstrated associations between having regular, emotional partners and unintended pregnancy or abortion.^{19,20}

In light of the reduced effectiveness of condoms with typical use as opposed to perfect use,^{21,22} especially in the context of violence,¹⁶ and differences in condom use with clients and nonpaying partners, dual-method contraceptive use—condoms combined with an effective non-barrier method—for both HIV/STI and pregnancy prevention is recommended for key cisgender women populations.²³ However, widespread

studies have shown that FSWs across several low- and middle-income countries have significant unmet need for effective contraception and voluntary family planning services.^{5,24} The current use of modern nonbarrier methods among FSWs is estimated to be below 40% in numerous settings across sub-Saharan Africa,^{25–27} and FSWs report most often using injectables or oral contraceptive pills.^{14,26,28,29} Although these are both effective methods with perfect use,²¹ they are user-dependent, are prone to misuse due to delays in renewal or well-documented issues with daily adherence, respectively,²⁸ and often have high discontinuation of use due to side effects and barriers to accessing family planning services.^{30–32} Long-acting reversible contraceptives (LARCs), which include intrauterine devices (IUDs) and implants, are globally recommended for reducing unintended pregnancy due to high effectiveness, continuation rates, and higher tolerability compared to other nonbarrier methods,³¹ but availability and utilization of LARCs remain low among FSWs in much of sub-Saharan Africa.^{4,33}

Women in Cameroon most commonly use short-acting and user-dependent contraceptive methods. In 2015, among a household survey of women in urban Yaoundé using any contraceptive method, only 8% were using LARCs and an additional 5% reported using an oral contraceptive pill.³⁴ Perceived efficacy and easy accessibility were the 2 main considerations for contraceptive choice, and only half of women were aware of LARCs. In Cameroon, LARCs are intended to be available through hospitals and selected clinics that provide family planning and reproductive health services.^{34,35} However, a recent evaluation indicates that stock-outs prevail, with 70%–80% of facilities reporting stock-outs of each offered LARC method on the day of assessment.³⁶ The unmet need for contraception results in high numbers of unintended pregnancies.³⁶

Cameroon's abortion policy has been described as restrictive: legally permitted only in cases of rape, incest, or to preserve a woman's physical or mental health, and even then, it can be difficult to obtain legal standing for abortion.³⁷ Nonetheless, experiences of abortion are common, with estimates ranging from 20%–35% prevalence among women.^{38–40} Due to legal and regulatory restrictions, abortions are often unsafe. Notably, unsafe abortions have been demonstrated to account for one-quarter of registered maternal deaths in Cameroon.^{41,42} Although generalizable data are limited, abortions have been reported in both home and clinical settings and are most commonly

provided by nurses, general practitioners, a friend, or through self-induction. The most commonly reported procedures are dilatation and curettage, manual vacuum aspiration, or misoprostal.⁴³ There is no standard practice for postabortion care in Cameroon, but it may include further manual vacuum aspiration, sharp curettage, or misoprostal depending on resource availability.^{37,44} It is not clear whether postabortion care services routinely include family planning counseling and methods.³⁷

As of 2016, more than 1 in 4 sex workers in Cameroon are estimated to be living with HIV¹² compared to around 1 in 20 among all women aged 15–64 years.⁴⁵ Sex work is illegal in Cameroon, and arrests as well as police violence, raids, and extortion have been commonly reported.^{46,47} Earlier work has demonstrated that physical and sexual violence as well as depression are prevalent among FSWs in Cameroon and associated with condom nonuse, being offered more money for condomless sex, and condom failure.^{46,48} These circumstances may similarly affect risk of unintended pregnancy. However, there are limited studies evaluating unintended pregnancy, pregnancy outcomes, or related consequences with the majority of studies focused on HIV risks. In response, these analyses aim to fill a gap in knowledge of reproductive health among FSWs in Cameroon by characterizing the prevalence of unintended pregnancy, TOP, and contraceptive use.

These analyses aim to fill a gap in knowledge of reproductive health among FSWs in Cameroon.

METHODS

Study Overview and Population

This is a secondary analysis of data collected through a cross-sectional respondent-driven sampling (RDS) study in 5 cities of Cameroon: Bamenda, Bertoua, Douala, Kribi, and Yaoundé. These represent the 2 largest cities and cities with high absolute and relative population of sex workers.⁴⁹ This study was conducted from December 2015 to October 2016 as a baseline assessment to inform service provision models for the Continuum of prevention, care, and treatment of HIV/AIDS with Most at-risk Populations (CHAMP) program, implemented by an alliance of community-based organizations (CBOs) and led by the nongovernmental organization CARE.

Women were eligible to participate if they were assigned the female sex at birth, reported sex work as their principal source of income in the previous year, were 18 years or older, spoke French or English, and had resided in the city of recruitment for at least 3 months before recruitment.

Study Recruitment and Procedures

Methods have been reported in more detail previously.^{12,50} Briefly, 6 FSWs were purposively selected as “seeds” based on their peer networks. Seeds and subsequent participants were provided with referral coupons to recruit up to 3 other FSWs from their social network for participation. Sampling continued until recruitment across cities reached the desired sample size (Bamenda: 340, Bertoua: 301, Douala: 460, Kribi: 578, Yaoundé: 571). Sample size calculations were based on the estimated HIV prevalence by region and included a design effect of 2, alpha of 0.01, and were intended to measure HIV prevalence with a precision of $\pm 3\%$.

Trained interviewers assessed participant eligibility, obtained informed verbal consent, and administered a 45–60-minute questionnaire on individual, community, network, and structural-level HIV risks; sexual and reproductive health; and service engagement. Questionnaires and biological data were linked by a confidential unique identifying code, and data were nonidentifiable. Women diagnosed with HIV were supported for linkage to treatment; others were linked to community-based HIV prevention and support services. All participants were reimbursed 2,000 FCFA (US\$4) and received an additional 1,000 FCFA (US\$2) for each successful recruit.

Ethical approval and administrative clearance were obtained from the Cameroonian National Research Ethics Committee (reference 2015/05/591/CE/CNERSH/SP and 2016/06/782/CE/CNERSH/SP) and Ministry of Public Health (reference 631 2315), respectively.

Outcomes

The 2 primary outcomes of interest were lifetime experience of TOP and current use of a nonbarrier contraceptive. Given the complexity of measuring unintended pregnancy and bias associated with retrospective reporting of pregnancy intentions,⁵¹ TOPs was used as an indirect measure of unintended pregnancy as well as an indicator of potential risk to women’s health due to unsafe TOP.⁸ Respondents were asked the number of lifetime pregnancies experienced followed by whether they had ever experienced the following outcomes: live birth, stillbirth, miscarriage, or voluntary termination. Participants were also asked to select all methods currently being used to prevent pregnancy. Nonbarrier contraceptive use considered current use of an oral contraceptive pill, IUD, injectable method, implant, or female

sterilization. Secondary outcomes considered were unintended pregnancy, defined as ever having a self-reported an unplanned or unwanted pregnancy and LARC use. Unintended pregnancy was defined as a pregnancy that was unplanned or unwanted. LARC use included current use of a contraceptive implant or IUD.

Covariates of Interest

The association of multiple covariates with TOP and nonbarrier contraception were considered. Covariates related to service access included previous HIV testing, receipt of information on HIV in the previous 6 months, and member of a CBO working with FSWs.

HIV status was categorized as HIV-negative, HIV-positive previously diagnosed, HIV-positive newly diagnosed, and indeterminate based on serological testing and self-reported HIV status.

Covariates related to other contraceptive use and sexual behavior included ever using emergency contraception, number of clients in the past month, condom use with clients, condom use with regular nonpaying partners, number of regular nonpaying partners in the past year, number of times experienced condom failure in the past year, and whether engaged in sex work during last pregnancy. Consistency of condom use was assessed among participants reporting at least 1 of given partner type on an average week and was assessed separately for regular and casual paying and nonpaying partners. Condom use was defined as consistent if they always reported using condoms during vaginal and anal sex with the given partner type and inconsistent if they reported using condoms less than always. In regression analysis, categorization of condom use with clients (regular and casual nonpaying partners combined) also included not having vaginal or anal sex with clients. In addition, future pregnancy intentions were considered, defined as intending to have children in the future (yes, no, does not know).

Covariates related to structural determinants of health included ever experiencing physical violence or assault, ever being forced to have sex, and experience of health-related stigma. Health-related stigma included reporting any of the following in relation to involvement in sex work: ever being afraid of seeking health services, avoidance of health services, mistreatment in a health center, heard health providers gossip, denied health services, or forced to have an HIV test.

Analytical Approach

Data were combined from 5 independent study sites. Primary outcomes are presented as both crude and RDS-adjusted proportions, the latter were calculated by study site and averaged to estimate overall RDS-adjusted proportion.

On account of primary outcomes being common, modified Poisson regression with robust variance was used to approximate prevalence ratios (PR) for each primary outcome.^{52,53} Models were corrected for RDS-weighting and clustering by seed. Firstly, bivariate associations were assessed for variables with theoretical association to the given outcomes. A multivariable model was developed for each primary outcome with variables with a *P* value < .1 in bivariate association. Any regular nonpaying sex partner(s) in the past year and consistent condom use with clients were included *a priori* in both models, and age group was included *a priori* when modelling associations with history of TOP. To prevent collinearity between HIV testing history and previous HIV diagnosis, only HIV status was considered in multivariable models.

Site-specific RDS sampling weights were computed using the Gile's SS estimator, which generates weight by estimating the probability of being included in the study using self-reported network size, using RDS Analyst (version 0.42, Los Angeles, CA). All other analyses were conducted using Stata version 14 (StataCorp, College Station, TX). Unless indicated, missing data were omitted from analyses.

RESULTS

In total, 2,255 FSWs were recruited, age range 18–70 years (median age 28 years, interquartile range [IQR] 23–36) (Table 1). The median age of first sex in exchange for money or goods was 22 years (IQR 12–50). The majority of women (77.0%, 1,735/2,254) were never married but reported at least 1 regular nonpaying partner in the previous year (72.8%, 1,638/2,252).

Reproductive Experience

Overall, 91.5% (2,058/2,250) of women reported ever being pregnant, and 57.6% (1,294/2,248) of women reported ever having an unintended pregnancy (Table 2). Most women (83.9%, 1,892/2,255) reported having living biological children.

Among women with any pregnancy experience, 93.1% (1,915/2,058) had any live births, and 32.3% (657/2,035) of women reported any births since beginning to sell sex. At last pregnancy

TABLE 1. Sociodemographic Characteristics of Female Sex Workers in 5 Cities, Cameroon

	N ^a	n(%)
Age group, years		
18-24	2,255	724 (32.1)
25-34	2,255	890 (39.5)
35+	2,255	641 (28.4)
Education level		
Primary school or less	2,254	702 (31.1)
Any secondary education or higher	2,254	1,552 (68.9)
Monthly income ^b		
<50 000 XAF	2,247	663 (29.5)
≥50,000 XAF	2,247	1,584 (70.5)
Age first sold sex for money or goods, years		
<18	2,234	297 (13.3)
18-24	2,234	1,038 (46.5)
25+	2,234	899 (40.2)
Number of clients in past month		
0-10	2,255	681 (30.2)
11-30	2,255	518 (23.0)
31-50	2,255	238 (10.6)
51+	2,255	723 (32.1)
Unknown	2,255	95 (4.2)
Marital status		
Never married	2,254	1,735 (77.0)
Married	2,254	22 (1.0)
Stable partner	2,254	233 (10.3)
Separated/divorced/widowed	2,254	264 (11.7)
Number of regular nonpaying partners in past year		
None	2,252	614 (27.3)
One	2,252	1,222 (54.3)
2+	2,252	416 (18.5)

^a Minor changes in denominator due to missing data.

^b Income through formal and informal work with a threshold of 50,000 XAF (~US\$90) per month based on national minimum wage (36,270 XAF/month).

34.2% (650/1,903) of women concurrently engaged in sex work.

Overall, 64.4% (1,452/2,255) women intended to become pregnant in the future. The most common contraceptive methods reported being currently used were male condoms (76.5%), female condoms (30.9%), and the rhythm method (22.7%); more than 1 response was permissible.

Based on lifetime recall, 15.8% (355/2,255) of women reported ever using emergency contraception. Among these women, the median times of emergency contraception use was 7 (IQR 2-34).

TOP Experience

Among all women, 40.0% (902/2,250) reported a TOP (RDS-adj 39.8%, [35.1%, 44.7%]) (Table 3).

TABLE 2. Reproductive Experience and Contraceptive Use of Female Sex Workers in 5 Cities, Cameroon

	N	n (%)
Number of lifetime pregnancies		
0	2,250	192 (8.5)
1–2	2,250	800 (35.6)
3–4	2,250	634 (28.2)
5+	2,250	624 (27.7)
Ever had an unintended pregnancy	2,248	1,294 (57.6)
Number of living biological children		
0	2,255	363 (16.1)
1	2,255	624 (27.7)
2	2,255	587 (26.0)
3+	2,255	681 (30.2)
Among FSWs ever pregnant:		
Any live births	2,058	1,915 (93.1)
Any still births	2,058	164 (8.0)
Any miscarriage	2,058	447 (21.7)
Any termination of pregnancy	2,058	902 (43.8)
Sought antenatal care at last pregnancy	2,057	1,712 (83.2)
Among FSWs with any live births (N=1915)		
FSW age at first birth		
<18 years	1,891	1,286 (68.0)
18+ years	1,891	605 (32.0)
Births while FSW		
0	1,892	1,235 (65.3)
1	1,892	405 (21.4)
2+	1,892	252 (13.3)
Engaged in sex work during last pregnancy	1,903	650 (34.2)
Time to return to sex work during last pregnancy		
0–3 months	634	311 (49.0)
4–6 months	634	143 (22.6)
7–9 months	634	66 (10.4)
10–12 months	634	78 (12.3)
>1 year	634	36 (5.7)
Future pregnancy intentions		
No	2,255	761 (33.7)
Yes	2,255	1452 (64.4)
Don't know	2,255	42 (1.9)

Continued

TABLE 2. Continued

	N	n (%)
Consistent condom use ^a :		
With clients	2,237	1734 (77.5)
With regular nonpaying partners	1,565	306 (19.6)
With all partners ^b	2,251	747 (33.2)
Current contraceptive use ^c :		
Male condom	2,255	1,724 (76.5)
Female condom	2,255	697 (30.9)
Oral contraceptive pill	2,255	284 (12.6)
Injectable	2,255	205 (9.1)
Intrauterine device	2,255	52 (2.3)
Implant	2,255	93 (4.1)
Diaphragm	2,255	2 (0.1)
Rhythm method	2,255	511 (22.7)
Withdrawal method	2,255	224 (9.9)
Female sterilization	2,255	32 (1.4)
Other ^d	2,255	62 (2.7)
Ever used emergency contraception	2,255	355 (15.8)

Abbreviations: FSW, female sex worker.

^a Reported among individuals reporting at least 1 of given partner type in an average week and refers to condom use during vaginal and anal sex.

^b Includes regular and casual paying partners and regular and casual nonpaying partners.

^c Respondents could select more than one contraceptive and percentages do not add up to 100.

^d Includes drinking whisky (n=22), traditional medicine (n=8), salted water (n=7), paracetamol/aspirin/quinine (n=5), menopause (n=5), Nescafé (n=3).

TOP was higher among women living with HIV (44.3%, 243/548) than those who were not living with HIV (38.8%, 658/1,695, $P=.027$).

In multivariable analyses, variables associated with higher prevalence of lifetime TOP were: older age, aged 25–34 years (aPR=1.46, 95% confidence interval [CI]=1.19, 1.79) or ≥35 years (aPR=1.70, 95% CI=1.35, 2.13) compared to aged 18–24 years; residing in Douala (aPR=1.21, 95% CI=1.04, 1.42) or Bamenda (aPR=1.26, 95% CI=1.04, 1.53) compared to Yaoundé; currently using a nonbarrier contraceptive (aPR=1.23, 95% CI=1.07, 1.42); ever using emergency contraception (aPR 1.34, 95% CI=1.17, 1.55); >60 clients in the past month (aPR 1.29, 95% CI=1.07, 1.54) compared to 30 or less; reporting inconsistent condom use with clients (aPR=1.17, 95% CI=1.00, 1.37); and ever experiencing physical violence or assault (aPR=1.24, 95% CI=1.09, 1.42) (Table 4).

Condom Use

Overall, 77.5% (1,734/2,237) of women reported consistent condom use with clients. In addition to paying clients, FSWs reported nonpaying regular (72.7%, 1,638/2,252) and casual (22.6%, 509/2,252) partners in the previous year. Considering all sex partners, 33.2% (747/2,251) of women reported consistent condom use (Table 2).

In the past year, 36.7% (806/2,198) of participants reported experiencing condom failure 1–4 times and a further 23.5% (516/2,198) 5 or more times.

Nonbarrier Contraceptive Use

Overall, 6.2% (140/2,255) women reported currently using any LARC, and 26.4% (596/2,255 RDS-adj 27.1% [22.9%, 31.7%]) reported

TABLE 3. Crude and RDS-Adjusted Prevalence of TOP and Current Nonbarrier Contraceptive Method Use by Study Site and Overall

	Lifetime Experience of TOP					Current Use of a Nonbarrier Contraceptive Method				
	Crude			RDS-Adjusted		Crude			RDS-Adjusted	
	N	n	%	%	(95% CI)	N	n	%	%	(95% CI)
Yaoundé	573	219	38.2	38.6	(34.4, 42.9)	574	153	26.7	27.3	(23.5, 31.5)
Douala	457	233	51.0	50.6	(45.7, 55.5)	457	91	19.9	18.6	(15.2, 22.6)
Bertoua	300	81	27.0	26.8	(22.0, 32.2)	304	89	29.3	30.1	(25.0, 35.7)
Bamenda	341	169	49.6	48.5	(42.9, 54.2)	341	117	34.3	34.2	(29.0, 39.8)
Kribi	579	200	34.5	34.5	(30.7, 38.5)	579	146	25.2	25.3	(21.9, 29.0)
Overall	2,250	902	40.1	39.8	(35.1, 44.7)	2,255	596	26.4	27.1	(22.9, 31.7)

Abbreviations: CI, confidence interval; RDS, respondent-driven sampling; TOP, termination of pregnancy.

currently using any nonbarrier contraceptive method (Table 3). Nonbarrier contraception was trending higher among women not living with HIV (27.6%, 469/1,698) compared to women living with HIV (22.9%, 126/550, $P=.072$). Approximately half (51.2%, 1,152/2,251) of women reported either nonbarrier contraceptive use or consistent condom use with all partners.

In multivariable analyses, variables associated with higher use of nonbarrier contraception were: previous TOP (aPR=1.41, 95% CI=1.16, 1.72) and ever using emergency contraception (aPR=2.70, 95% CI=2.23, 3.26). Variables associated with lower use of nonbarrier contraception were: receipt of HIV information in the previous 6 months (aPR=0.72, 95% CI=0.59, 0.89) and membership in an FSW-CBO (aPR=0.73, 95% CI=0.57, 0.92) (Table 5).

Experience of Violence

Overall, 24.8% (559/2,251) of participants had experienced physical violence, and 32.6% (735/2,253) had ever been forced to have sex. Physical violence was most commonly perpetrated by clients (67.6%, 378/559), a uniformed officer (25.4%; 142/559), a boyfriend or husband (17.4%, 97/559), or another FSW (22.2%, 124/559). Sexual violence was most commonly perpetrated by clients (33.3%, 245/735), a stranger (29.3%, 215/735), or a boyfriend or husband (17.0%, 125/735).

DISCUSSION

FSWs across 5 cities in Cameroon experienced a high burden of unintended pregnancy and TOP.

Given the history of inconsistent or no condom use, nonbarrier contraceptive use is highly indicated to prevent unintended pregnancies and associated health consequences, but coverage among FSWs was low. These results remind us that the health needs of FSWs in Cameroon extend beyond HIV and underscore the importance of removing structural barriers as integral to optimizing coverage of health care services. The evidence suggests that community-based and FSW-focused services in Cameroon do not currently meet these broader needs. Comprehensive services, including access to client-centered, voluntary family planning counseling and services, are needed to effectively address FSWs' fertility and reproductive health needs.⁵⁴

Compared to other studies of FSWs, experience of TOP was similar or higher than observed across Southern Africa.^{29,55} TOP estimates among FSWs were twice as high as those reported among young women in urban areas or women seen in antenatal care (ANC) in other Cameroon-based studies.^{38,40} TOP performed in unsafe settings, even if supported by a health care worker, may lack appropriate counseling and information and miss opportunities to prevent future unintended pregnancy.^{6,8,56} Although this information was not collected here, among women with history of TOP in Cameroon, less than one-third reported currently using a non-barrier contraceptive and nearly one-quarter reported inconsistent condom use with clients. Subsequently, these women are likely at risk of future unintended pregnancies.

Findings from this study suggest that high burden of targeted violence in the context of criminalization experienced by FSWs may increase

Although FSWs have a history of unintended pregnancy and termination of pregnancy coupled with inconsistent condom use, nonbarrier contraceptive use remains low.

High burden of targeted violence experienced by FSWs may increase vulnerability to TOP.

TABLE 4. Associations with Experience of TOP Among FSWs in Univariate and Multivariable Poisson Regression Corrected for RDS-Weighting and Clustering by Seed, Cameroon

	N	TOP		Unadjusted Analysis			Adjusted Analysis		
		n	%	PR	95% CI	P Value	aPR	95% CI	P Value
Site									
Yaounde	573	219	38.2	REF			REF		
Douala	457	233	51.0	1.31	(1.13, 1.52)	<.001	1.21	(1.04, 1.42)	.01
Bertoua	300	81	27.0	0.70	(0.56, 0.87)	.001	0.87	(0.69, 1.10)	.26
Bamenda	341	169	49.6	1.26	(1.07, 1.48)	.005	1.26	(1.04, 1.53)	.02
Kribi	579	200	34.5	0.89	(0.76, 1.05)	.17	1.04	(0.88, 1.23)	.66
Age group, years									
18–24	722	203	28.1	REF			REF		
25–34	889	388	43.6	1.58	(1.29, 1.93)	<.001	1.46	(1.19, 1.79)	<.001
35+	639	311	48.7	1.73	(1.42, 2.12)	<.001	1.70	(1.35, 2.13)	<.001
Education level									
Primary school or less	700	272	38.9	REF					
Any secondary education or higher	1,549	630	40.7	1.01	(0.88, 1.17)	.86			
Previously tested for HIV ^a									
No	223	49	22.0	REF					
Yes	2024	851	42.0	1.92	(1.32, 2.79)	.001			
HIV status									
Negative	1,695	658	38.8	REF			REF		
Positive, previously diagnosed	290	148	51.0	1.31	(1.16, 1.49)	<.001	1.13	(0.96, 1.34)	.13
Positive, newly diagnosed	258	95	36.8	0.95	(0.80, 1.13)	.54	0.88	(0.71, 1.10)	.27
Indeterminate	7	1	14.3	0.37	(0.06, 2.26)	.28	1.82	(0.77, 4.30)	.17
Received any information on HIV in past 6 months									
No	755	268	35.5	REF			REF		
Yes	1,495	634	42.4	1.21	(1.04, 1.41)	.01	1.13	(0.96, 1.31)	.13
Uses nonbarrier contraceptive									
No	1,655	619	37.4	REF			REF		
Yes	595	283	47.6	1.29	(1.12, 1.48)	<.001	1.23	(1.07, 1.42)	.003
Ever used emergency contraception									
No	1,892	705	37.3	REF			REF		
Yes	354	196	55.4	1.36	(1.18, 1.57)	<.001	1.34	(1.17, 1.55)	<.001
Engaged in sex work during last pregnancy									
No	1,253	549	43.8	REF					
Yes	650	268	41.2	0.90	(0.77, 1.05)	.19			
Intend to have children in the future									
No	759	335	44.1	1.16	(1.02, 1.33)	.03	REF		
Yes	1,449	547	37.8	REF			1.01	(0.87, 1.18)	.86

Continued

TABLE 4. Continued

	N	TOP		Unadjusted Analysis			Adjusted Analysis		
		n	%	PR	95% CI	P Value	aPR	95% CI	P Value
Does not know	42	20	47.6	1.00	(0.55, 1.81)	.99	0.93	(0.54, 1.59)	.79
Number of clients in past month									
0–30	1195	450	37.7	REF			REF		
31–60	346	138	39.9	1.10	(0.91, 1.34)	.32	1.12	(0.91, 1.38)	.27
>60	615	289	47.0	1.27	(1.09, 1.48)	.002	1.29	(1.07, 1.54)	.006
Unknown	94	25	26.6	0.88	(0.53, 1.45)	.61	1.01	(0.57, 1.78)	.98
Condom use during vaginal/anal sex with clients									
Consistent	1745	688	39.4	REF			REF		
Inconsistent	502	213	42.4	1.09	(0.92, 1.28)	.33	1.17	(1.00, 1.37)	.04
Any regular sex partner(s) in past year									
No	611	232	38.0	REF			REF		
Yes	1,636	669	40.9	1.14	(0.97, 1.33)	.11	1.15	(0.99, 1.34)	.07
Condom failure in the past year									
Never	875	322	36.8	REF					
1–4 times	803	337	42.0	1.07	(0.92, 1.25)	.40			
5+ times	515	226	43.9	0.98	(0.82, 1.16)	.79			
Ever experienced physical violence or assault									
No	1688	626	37.1	REF			REF		
Yes	558	276	49.5	1.27	(1.11, 1.46)	.001	1.24	(1.09, 1.42)	.001
Ever forced to have sex									
No	1515	576	38.0	REF					
Yes	733	325	44.3	1.09	(0.94, 1.25)	.25			

Abbreviations: aPR, adjusted prevalence ratio; CI, confidence interval; FSW, female sex worker; PR, prevalence ratio; RDS, respondent-driven sampling; TOP, termination of pregnancy.

^a Excluded from adjusted analyses due to collinearity with HIV status.

vulnerability to TOP.¹⁶ Links between violence and unintended pregnancy have also been reported in other settings,⁵⁷ and associations between violence and HIV acquisition among FSWs are well-described.^{14,16,58} The relationships between violence and unintended pregnancy are likely similarly multifaceted.^{58,59} Violence and condom failure are commonly related,^{15,46} and past year condom failure was exceptionally common among this group of FSWs. In addition, it is possible that unintended pregnancy may itself trigger intimate partner violence.⁶⁰ Given that physical violence is not factored into the conditions for legal abortion, FSWs experiencing physical violence leading to or arising from

unintended pregnancy may perceive a lack of support to safely consider their options. Including access to emergency contraception and HIV postexposure prophylaxis as part of services for violence prevention and response could prevent unintended pregnancy and HIV acquisition resulting from sexual or physical violence. Programs that encourage social cohesion may help strengthen existing networks for violence coping and prevention mechanisms among FSWs.^{16,61} Uniformed officers have been common perpetrators of violence in this and other settings,¹⁶ suggesting the utility of training these officers in the public health outcomes of punitive enforcement as well as legal advocacy to overcome policy-level

TABLE 5. Associations with Nonbarrier Contraceptive Method Use Among FSWs in Univariate and Multivariable Poisson Regression Corrected for RDS-Weighting and Clustering by Seed, Cameroon

	N	Uses Nonbarrier Contraceptive Method		Unadjusted Analysis			Adjusted Analysis		
		n	%	PR	95% CI	P Value	aPR	95% CI	P Value
Site									
Yaounde	574	153	26.7	REF			REF		
Douala	457	91	19.9	0.68	(0.53, 0.87)	.002	0.84	(0.67, 1.07)	.16
Bertoua	304	89	29.3	1.10	(0.88, 1.39)	.41	1.21	(0.96, 1.53)	.10
Bamenda	341	117	34.3	1.25	(1.01, 1.55)	.04	1.15	(0.91, 1.44)	.24
Kribi	579	146	25.2	0.93	(0.76, 1.13)	.46	1.03	(0.84, 1.27)	.78
Age group (years)									
18–24	724	169	23.3	REF					
25–34	890	275	30.9	1.11	(0.87, 1.43)	.40			
35+	641	152	23.7	0.85	(0.64, 1.13)	.27			
Education level									
Primary school or less	702	175	24.9	REF			REF		
Any secondary education or higher	1,552	420	27.1	1.39	(1.10, 1.76)	.005	1.21	(0.97, 1.50)	.09
HIV status									
Negative	1,698	469	27.6	REF			REF		
Positive, previously diagnosed	290	66	22.8	0.65	(0.47, 0.90)	.009	0.85	(0.62, 1.18)	.33
Positive, newly diagnosed	260	60	23.1	0.85	(0.61, 1.20)	.35	0.95	(0.69, 1.29)	.73
Indeterminate	7	1	14.3	0.13	(0.01, 1.47)	.10	0.11	(0.01, 1.11)	.06
Previously tested for HIV ^a									
No	223	35	15.7	REF					
Yes	2,029	561	27.7	1.87	(1.14, 3.07)	.01			
Received any information on HIV in past 6 months									
No	756	222	29.4	REF			REF		
Yes	1,499	374	25.0	0.70	(0.56, 0.86)	.001	0.72	(0.59, 0.89)	.002
FSW-CBO member									
No	1,650	474	28.7	REF			REF		
Yes	604	122	20.2	0.58	(0.46, 0.73)	<.001	0.73	(0.57, 0.92)	.01
Ever terminated a pregnancy									
No	1,348	312	23.1	REF			REF		
Yes	902	283	31.4	1.44	(1.17, 1.77)	<.001	1.41	(1.16, 1.72)	.001
Ever used emergency contraception									
No	1,896	406	21.4	REF			REF		
Yes	355	189	53.2	2.95	(2.45, 3.56)	<.001	2.70	(2.23, 3.26)	<.001

Continued

TABLE 5. Continued

	N	Uses Nonbarrier Contraceptive Method		Unadjusted Analysis			Adjusted Analysis		
		n	%	PR	95% CI	P Value	aPR	95% CI	P Value
Intend to have children in the future									
Yes	1,452	345	23.8	REF					
No	761	238	31.3	1.00	(0.81, 1.25)	.99			
Does not know	42	13	31.0	0.63	(0.25, 1.60)	.33			
Number of clients in past month									
0–30	1199	343	28.6	REF					
31+	961	231	24.0	0.98	(0.80, 1.21)	.88			
Unknown	95	22	23.2	0.70	(0.36, 1.37)	.30			
Condom use during sex with clients									
Consistent/NA	1,749	434	24.8	REF			REF		
Inconsistent	503	162	32.2	1.23	(0.95, 1.59)	.11	1.00	(0.77, 1.29)	.98
Regular sex partner(s) in past year									
None	614	152	24.8	REF			REF		
Any	1,638	442	27.0	1.17	(0.93, 1.47)	.19	1.13	(0.91, 1.40)	.28
Any health-related stigma									
No	2,015	518	25.7	REF			REF		
Yes	237	78	32.9	1.49	(1.13, 1.96)	.004	1.29	(0.98, 1.69)	.07

Abbreviations: aPR, adjusted prevalence ratio; CBO, community-based organization; CI, confidence interval; FSW, female sex worker; NA, not applicable; PR, prevalence ratio; RDS, respondent-driven sampling; TOP, termination of pregnancy.

^aExcluded from adjusted analyses due to collinearity with HIV status.

structural determinants in promoting greater protection and access to health and justice for FSWs.^{47,61}

Unintended pregnancy is largely preventable through effective nonbarrier contraceptives or consistent and correct condom use. FSWs in Cameroon were generally reliant on condoms for contraception, with limited use of nonbarrier methods and even lower use of more effective LARCs. This finding is consistent with the low use of LARCs in general across Cameroon,³⁴ which despite government commitment⁶² has not expanded at the same rate as observed in countries across eastern and southern Africa.⁶³ We also identified differences in contraceptive access within Cameroon, with relatively higher access in Bamenda despite regional sociopolitical unrest. A similar finding has been previously reported in relation to ANC services in Cameroon and may be due to long-standing investment and resource

mobilization in the region where Bamenda is located.⁶⁴

Despite the reliance on condoms, most women did not report consistent condom use, particularly with nonpaying partners. There is substantial evidence from Cameroon and further abroad that pervasive structural factors, such as violence, stigmatization, price premiums for condomless sex, legal status, and policing, as well as social considerations, undermine FSWs' agency to negotiate condom use consistently.^{46,48,65} Although current fertility intentions were not known, half of women were susceptible to pregnancy due to inadequate contraceptive use. Access to contraceptive choice and counseling is an essential part of sexual and reproductive health services.⁵⁴ Expanding access to nonbarrier contraceptives and emergency contraception can reduce the risk of unintended pregnancy and related health, social, and economic consequences and provide women greater

Interventions targeting the social and structural influences on condom use are needed to promote the comprehensive protection of dual-method use for HIV and STI prevention.

Expanding community-based, FSW-led services to include integrated family planning, STI, and HIV service delivery may be an effective strategy to reduce unintended pregnancies among FSWs.

control over the timing and number of their children.⁶⁶

Supplementary interventions targeting the social and structural influences on condom use are still needed to promote the comprehensive protection of dual-method use for HIV and STI prevention.^{11,16} Alternative user-controlled interventions for HIV prevention such as through pre-exposure prophylaxis may also benefit FSWs.^{11,66} Programs implementing single-purpose interventions such as contraception, pre-exposure prophylaxis, and antiretroviral therapy to FSWs can benefit from maintaining a comprehensive view of sexual and reproductive health. For example, proactively considering existing contraceptive mix and accessibility as pre-exposure prophylaxis is scaled up can maximize opportunities to prevent unintended pregnancies and counter potential changes in condom negotiation power or resource allocation.^{66,67} In addition to meeting the broader needs of FSWs, STI education, screening, prevention, and treatment programs can help prevent the potential STI-related risks associated with IUD use in the context of voluntary family planning services.⁶⁸

With the exception of HIV testing, indicators of HIV service access—in particular FSW-oriented community services—were associated with substantially lower coverage of nonbarrier contraceptives. In comparison, membership in an FSW-oriented CBO was associated with higher recent HIV testing (data not shown). In Cameroon, most community-based facilities serving FSWs currently offer services fairly focused on HIV prevention, testing, and treatment support, with family planning often limited to counseling.⁶⁹ Although these services appear to be an effective way to deliver HIV testing to FSWs,⁷⁰ they may miss opportunities for contraceptive provision. Requiring women to access multiple service points to meet their sexual and reproductive health needs may further disincentivize contraceptive use and act as a structural barrier.⁷¹ This may be particularly relevant given there are already well-characterized barriers affecting FSWs' access to family planning through public clinics.^{72,73} Further qualitative research to assess personal considerations, barriers, and facilitators of voluntary contraceptive use among FSWs in Cameroon, including emergency contraception, could better inform local family planning delivery strategies and integration of services adapted to the needs and preferences of FSWs. Elsewhere, it has been demonstrated that FSW-led mobilization for HIV services through community drop-in centers has been associated with

reductions in HIV incidence among FSWs in Tanzania.⁷⁰ Expanding this community empowerment model for integrated family planning, STI, and HIV service delivery may represent an effective strategy to reduce unintended pregnancies and be responsive to critical health care needs.

Although there is growing evidence that integrated HIV and family planning delivery in a single location facilitates contraceptive uptake,^{71,74,75} there are several considerations for implementation within existing community-based HIV services. There is empirical evidence that providing multiple contraceptive options improves uptake.⁷⁶ Elsewhere, making longer-acting methods readily available to FSWs at a drop-in center alongside counseling on methods suited to a woman's needs and current fertility intentions significantly increased demand and uptake of effective contraceptives.⁷⁵ However, the predominance of lower cadres of health care workers and peer outreach workers who often staff community-led FSW services may limit the number of staff with specific training and skills for contraception administration, especially when considering voluntary LARCs.^{77,78} Physical space with adequate privacy and space for an examination table required for LARC administration may also be limited in drop-in centers.⁷⁸ Within the setting of community-based services, means to improve contraception availability and coverage may include task-sharing⁷⁹ and collaborations with services already providing family planning or ANC to offer periodic clinics with outside staff within the community-based settings. Active, facilitated referrals may reduce the number of women falling through the service gap⁸⁰ but may still pose barriers to some women. Lastly, not all FSWs in Cameroon are regularly accessing HIV testing¹² and the majority were not associated with an FSW-focused CBO at the time of study. A single model of HIV and family planning integration is unlikely to reach all women, and considering alternative points of service access for multi-pronged, bidirectional approaches to integration and family planning service delivery may optimize coverage.^{81,82}

As for many working cisgender women, FSWs are often mothers with ongoing fertility desires.⁸³ Consequently, they would benefit from family planning services that are adaptive to changes in fertility intentions and contraceptive needs, including services for safer conception and

pregnancy. Given pregnancy experience, including a sizeable proportion of pregnancies occurring after women began sex work, FSWs may benefit from greater links between FSW-oriented services and ANC. Approximately one-third of FSWs engaged in sex work during their last pregnancy, with potential for ongoing acquisition risks and resulting vertical transmission, especially if HIV is newly acquired in this period and missed by traditional approaches for preventing vertical transmission.⁸⁴ Although the majority of women had sought ANC at last pregnancy, it has been documented that FSWs as well as young, unmarried women commonly face stigma in ANC services and subsequently may avoid disclosure, thus limiting access to appropriate services.^{85–87} In our case, we identified associations between health care-related stigma and current use of nonbarrier contraception. Strengthening bidirectional collaborations between FSW-oriented services and ANC may foster more equitable access to quality and respectful family planning and ANC services for FSWs, including women living with HIV.

Limitations

These findings are subject to several limitations. Indicators related to sexual and reproductive health were asked as part of a broader survey on HIV risk and vulnerability. There was limited space to comprehensively explore domains related to unintended pregnancy and TOP experiences. Because we did not assess current pregnancy intentions, we could not determine the current unmet need for contraception. Pregnancy outcomes were assessed based on lifetime experience rather than specific to each pregnancy, and contraception was assessed in a different timeframe based on current use. TOP was used as an indirect measure of unintended pregnancy due to biases associated with direct, retrospective measurement of unintended pregnancy.⁵¹ Some discrepancy is expected given that not all unintended pregnancies will result in TOP and TOP may also occur after planned pregnancies. With the exception of HIV status, all indicators were based on self-report and may be subject to social desirability and recall biases. However, despite social desirability biases, reported history of termination was high and reported use of current contraception low. Importantly, data collected were cross-sectional and causality cannot be inferred. Lastly, findings are based on FSWs recruited from 5 urban cities; access to contraception and TOP likely differs among women residing in rural areas, and findings cannot be generalized.

CONCLUSION

In conclusion, experience with unintended pregnancy is common among FSWs in Cameroon, and women seeking TOP likely face risks associated with unsafe abortion given the restrictive legal environment. The ultimate direct and indirect impacts of TOP on health and mortality cannot be ascertained from these cross-sectional data, and longitudinal follow-up of women is needed to understand sexual and reproductive health outcomes that transcend HIV. The structural drivers of excess violence among FSWs remain a critical barrier to upholding the sexual and reproductive health and human rights of FSWs consistent with the United Nations Declaration of Human Rights. Reliance on condoms alone for preventing both HIV and pregnancy are failing the health needs of FSWs in Cameroon. Although the potential preventive impact of condoms has been substantial and continued promotion is critical, improved access to high-quality family planning counseling and a wider range of contraceptives, including nonbarrier and particularly long-acting contraceptives, is also necessary to improve client-centered care, promote informed choice, and reduce unintended pregnancies. Ultimately, mitigating structural and facility-level barriers to the coverage of high-quality, voluntary family planning services and method choice in FSW-focused community services represents a key strategy to overcome current barriers to access and move towards optimizing sexual and reproductive health outcomes among FSWs.

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En français:

Besoins non satisfaits en planning familial et cas de grossesses non désirées chez les travailleuses du sexe en zone urbaine au Cameroun: Résultats d'une étude nationale transversale

Les travailleuses du sexe (TS) au Cameroun ont des besoins insatisfaits en contraception efficace, et les cas de grossesses non désirées et d'interruptions de grossesse sont fréquents. La réduction des barrières à l'accès aux services de qualité de planning familial volontaire dans les services communautaires dédiés aux TS est une stratégie majeure dans la promotion des soins centrés sur le client, du choix éclairé, de la réduction des grossesses non désirées et l'amélioration de la qualité de vie des TS.

RÉSUMÉ

Contexte: Les besoins en contraception des travailleuses du sexe (TS) au Cameroun sont généralement non satisfaits, ce qui représente un risque élevé de grossesses non désirées. Les grossesses non désirées entraînent une série de résultats et, en raison de restrictions légales, les FSW recherchent souvent des avortements dangereux. Hormis la charge élevée du VIH, très peu d'informations relatives à la vie sexuelle et reproductive des TS au Cameroun sont connues.

Méthodes: De décembre 2015 à octobre 2016, des TS âgées de plus de 18 ans ont été recrutées dans 5 villes du Cameroun à l'aide d'un échantillonnage fondé sur les répondants. Des données transversales ont été recueillies à l'aide d'un questionnaire comportemental et du dépistage biologique du VIH/syphilis. Une approche modifiée et fiable de la régression de Poisson a été utilisée pour parvenir à une approximation des taux de prévalence ajustés (TPa) des IVG et l'utilisation en cours de contraceptifs non barrières efficaces.

Résultats: Des 2 255 TS (âge médian, 28 ans), 57,6% ont rapporté une grossesse non désirée et 40% une IVG antérieure. Au cours de l'analyse multi-variables, les antécédents d'IVG ont été associés à l'utilisation de méthodes contraceptives non barrières (TPa=1,23, 95% intervalle de confiance [IC]=1,07, 1,42); l'utilisation systématique de la contraception d'urgence (TPa=1,34, 95% IC=1,17, 1,55); >60 clients au cours du mois précédent (TPa=1,29, 95% IC=1,07, 1,54) contre £30; l'utilisation non systématique du préservatif avec les clients (TPa=1,17, 95% IC=1,00, 1,37); la violence physique (TPa=1,24, 95% IC=1,09, 1,42); et l'âge avancé. La majorité des femmes (76,5%) utilise le préservatif masculin comme contraception, mais seules 33,2% ont déclaré une utilisation constante du préservatif avec tous les partenaires. Au total, 26,4% des femmes ont déclaré qu'elles utilisent actuellement une méthode contraceptive non barrières, et 6,2% ont déclaré qu'elles utilisent une méthode contraceptive à longue durée d'action. Les antécédents d'IVG (TPa=1,41, 95% IC=1,16, 1,72) et l'utilisation systématique de la contraception d'urgence (TPa=2,70, 95% IC=2,23, 3,26) ont été associés à l'utilisation élevée de méthodes contraceptives dites non barrières. L'obtention récente d'informations sur le VIH (TPa=0,72, 95% IC=0,59, 0,89) et l'adhésion à une organisation à base communautaire pour les TS (TPa=0,73, 95% IC=0,57, 0,92) ont été associées à la faible utilisation des méthodes contraceptives non barrières.

Conclusion: Les cas de grossesse non désirées et d'IVG sont fréquents chez les TS au Cameroun. Au vu de la faible utilisation des méthodes contraceptives non barrières et la non utilisation systématique du préservatif, les TS présentent un risque de contracter des grossesses non désirées de manière répétée. Une meilleure intégration des services de planning familial volontaire axés sur le client au sein des services communautaires du VIH permettrait de mieux appuyer la santé sexuelle et reproductive et les droits de l'homme des TS conformément à la Déclaration des droits de l'homme des Nations Unies.

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ORIGINAL ARTICLE

How Should Home-Based Maternal and Child Health Records Be Implemented? A Global Framework Analysis

Sruthi Mahadevan,^a Elena T. Broaddus-Shea^b

Our assessment of home-based record use in low- and middle-income countries indicated that the implementation process consists of 8 interdependent components involving policy makers, funders, and end users—health care workers, pregnant women, and the parents/caregivers of children. Successful implementation can result in improved maternal and child health outcomes and more efficient use of government and donor investments.

ABSTRACT

Background: A home-based record (HBR) is a health document kept by the patient or their caregivers, rather than by the health care facility. HBRs are used in 163 countries, but they have not been implemented universally or consistently. Effective implementation maximizes both health impacts and cost-effectiveness. We sought to examine this research-to-practice gap and delineate the facilitators and barriers to the effective implementation and use of maternal and child health HBRs especially in low- and middle-income countries (LMICs).

Methods: Using a framework analysis approach, we created a framework of implementation categories in advance using subject expert inputs. We collected information through 2 streams. First, we screened 69 gray literature documents, of which 18 were included for analysis. Second, we conducted semi-structured interviews with 12 key informants, each of whom had extensive experience with HBR implementation. We abstracted the relevant data from the documents and interviews into an analytic matrix. The matrix was based on the initial framework and adjusted according to emergent categories from the data.

Results: We identified 8 contributors to successful HBR implementation. These include establishing high-level support from the government and ensuring clear communication between all ministries and nongovernmental organizations involved. Choice of appropriate contents within the record was noted as important for alignment with the health system and for end user acceptance, as were the design, its physical durability, and timely redesigns. Logistical considerations, such as covering costs sustainably and arranging printing and distribution, could be potential bottlenecks. Finally, end users' engagement with HBRs depended on how the record was initially introduced to them and how its importance was reinforced over time by those in leadership positions.

Conclusions: This framework analysis is the first study to take a more comprehensive and broad approach to the HBR implementation process in LMICs. The findings provide guidance for policy makers, donors, and health care practitioners regarding best implementation practice and effective HBR use, as well as where further research is required.

INTRODUCTION

A home-based record (HBR) is a physical or electronic health document that a patient or caregiver keeps, rather than a health facility.¹ HBRs are used by pregnant women and parents/caregivers of children as an instant access to their own or their child's health information, by health care workers and volunteers to triangulate patient information and to prompt health education conversations, and by public health administrators as

a data management tool to help plan and evaluate services.²

HBRs were initially introduced in immunization programs but have since become widely used throughout maternal, neonatal, and child health (MNCH) programs.³ They can take many forms including antenatal care records, vaccination-only cards, vaccination-plus cards or booklets, child health books, and combined maternal and child health books.^{1–4} They are designed to record health parameters such as developmental milestones, vaccinations received, or antenatal appointments attended. Some HBRs also contain health education messages, for example, about immediate and exclusive breastfeeding or managing minor childhood illnesses.^{3,5} Throughout this article, we use the term

^a University College London Medical School; Royal Free London NHS Foundation Trust, London, UK.

^b Department of Family Medicine, University of Colorado Anschutz Medical Campus, Aurora, CO, USA.

Correspondence to Sruthi Mahadevan (sruthi.mahadevan.12@ucl.ac.uk).

HBR to encapsulate the diversity of different record types.

This study was part of the evidence synthesis for the World Health Organization (WHO) recommendations on HBRs for MNCH³ alongside a quantitative systematic review and meta-analysis of peer-reviewed literature⁶ and a qualitative review of peer-reviewed literature.⁷ The guidelines, published in September 2018, recommend HBRs as a tool to improve MNCH outcomes.³ Studies summarized within the quantitative review and meta-analysis found that HBRs had statistically significant effects on improving antenatal care attendance and supportive household environments; however, the evidence base is small and of low to very low certainty.^{6,8} Further effects, also of low certainty, were seen for child health including immunization completion, infant feeding, growth and development monitoring, and reducing risks of cognitive delay.⁶ Even though the effects seen on individual end users in each study were small, the WHO deemed that HBRs in MNCH still have the potential to create significant large-scale impact since the population of end users is so vast.³ Future research is needed to further explore impacts on each health outcome and potential undesirable effects since no harms were identified from the available evidence, but there was a paucity of evidence on many of the outcomes studied.^{3,6}

Despite less quantitative data on MNCH outcomes, there were significant data from the qualitative and quantitative studies, as well as from the respondents in this study, that emphasized that women, caregivers, and health care workers value HBRs.^{3,6,7} There is evidence that they can improve patient-provider communication, continuity of care,^{7,9} and increase women's feelings of control and empowerment.^{7,10} Including and empowering women and children by encouraging them and their caregivers to be health literate and actively participate in their own care is a key step toward achieving universal health coverage.¹¹

Unfortunately, despite being underpinned by research, many evidence-based interventions never gain traction in routine practice or they only do so after many years.¹² HBRs can be found in at least 163 countries; however, population coverage varies wildly between these countries and even between regions within countries.¹³ For example, in Bangladesh, Ethiopia, Indonesia, Nigeria, and Pakistan—countries with some of the world's highest birth rates—less than 50% of eligible mothers and children owned HBRs.¹³ Even where HBRs were available, they were not always used fully or as they were intended.¹⁴

Implementation science has proved that focusing on and optimizing the implementation of health tools and services improves equity of coverage and improves quality and efficiency.^{12,15} By optimizing implementation of HBRs, we can potentially increase ownership and equity of coverage and improve engagement with the HBR content. By doing so, we can also maximize value from limited resources and maximize overall public health impact.

It is difficult to recommend strategies to improve HBR implementation without first identifying the blockages along the implementation pipeline that have resulted in this research-to-practice gap. Existing literature has examined selected aspects of implementation, some slightly more than others, namely design of the HBR^{2,16–20} and promotion of end user engagement.^{21–24} However, substantial operational challenges still remain even in these areas and require further research.^{14,25} The majority of existing literature studied HBRs in high-income countries.^{3,6,7} This study sought to identify a broad understanding of the HBR implementation process in low- and middle-income countries (LMICs) and the possible facilitators and barriers to each implementation component. What are the causes of ineffective implementation, and why do they persist? Conversely, how do we build successful HBR programs?

METHODS

Framework analysis is a qualitative thematic analysis approach that involves an ongoing and dynamic interplay between textual data collection, analysis, and theory development. A matrix of structured summarized data is created and categorized by key themes to identify similarities and differences both between and within the data from each data source.²⁶ Therefore, it is suited to the dual data sources used for this study: semi-structured interviews and written documents that have been prescreened for relevance. The sampling of data sources was designed to capture the diversity of responses around each key theme and was not intended to proportionately represent HBRs according to the prevalence of each different HBR type.²⁶

Framework Development

The WHO's HBR Working Group comprised a small group of HBR experts who worked for the past few years assisting national-level ministries and nongovernmental organizations to effectively redesign their HBRs. These subject experts created an initial framework of expected implementation

Optimizing implementation of HBRs can potentially increase ownership and equity of coverage and improve engagement with the HBR content.

components that consisted of 15 categories. We used the initial framework to develop our interview guide. During each interview, we also delved further into any emerging themes and explicitly asked respondents whether they felt any other implementation components deserved discussion. After analyzing the collected data, we iteratively revised the framework to remove less relevant themes or subsume them under broader categories and to include new themes and categories emerging from the data. The initial and revised frameworks are included in a [Supplement](#).

Data Collection

Data used in this analysis consisted of semi-structured key informant interviews and relevant gray literature documents.

Key Informant Interviews

We contacted 25 individuals with experience in HBR implementation in LMICs. Of these,

13 replied and indicated willingness to be interviewed. Due to adverse weather events in 1 respondent's country, we conducted 12 interviews using phone or Skype. Key informants included individuals with associations to the Japan International Cooperation Agency (n=2), John Snow, Inc. (n=5), United Nations Relief and Works Agency for Palestine Refugees in the Near East (n=1), and United Nations Population Fund (n=4). They had diverse professional expertise including a mix of international (n=6) and in-country (n=6) work, a combination of frontline service provision and management perspectives, and a variety of MNCH specializations ([Table 1](#)).

Each interview was conducted by 2 members of the research team using an interview guide based on the initial analytic framework categories. Detailed notes were taken on respondents' answers, interviews were recorded with permission, and recordings were referenced for clarification or further detail as needed. Interviews lasted approximately 45 minutes. Afterward, notes

TABLE 1. Characteristics of Key Informants Who Were Interviewed About HBR Implementation (N=12)

Number	Job Level	Qualifications	HBR Type Familiar With	Countries Familiar With
R1	International	Maternal and Child Health Program Expert	Multiple focus	Afghanistan, Angola, Burundi, Cambodia, Cameroon, China, Gabon, Ghana, India, Indonesia, Kenya, Lao PDR, Micronesia, Myanmar, Palestine, Philippines, Rwanda, Senegal, Tajikistan, Thailand, Vietnam, Timor Leste, Uganda
R2	International	Maternal and Child Health Program Expert	Multiple focus	Gaza, Jordan, Lebanon, Syria, West Bank
R3	Country	Maternal and Child Health Program Expert	Multiple focus	Madagascar
R4	Country	Maternal and Child Health Services Expert	Single focus	Bangladesh (current), India, Rwanda, Somalia, Sierra Leone
R5	Country	Maternal and Child Health Program Expert	Single focus	Nepal
R6	International	Maternal and Child Health Program Expert	Multiple focus	Ghana, Jordan, Lebanon, Palestine, Syria
R7	Country	Midwifery Specialist	Multiple focus	Pakistan
R8	Country	Midwifery Specialist	Multiple focus	Zambia
R9	Country	Midwifery Specialist	Multiple focus	Ethiopia (current), Malawi
R10	International	Senior Immunization Technical Officer	Single and multiple focus	Benin, Cameroon, Democratic Republic of the Congo, Ghana, India, Kenya, Madagascar, Nepal, Nigeria, Tanzania, Zimbabwe
R11	International	Maternal and Child Health Program Expert	Single and multiple focus	Ethiopia, Ghana, Liberia, Madagascar
R12	International	Immunization Program Expert	Single and multiple focus	Bangladesh, Ethiopia, Madagascar

Abbreviation: HBR, home-based record.

were compiled and sent to the respondent to review for accuracy. Interviews were conducted until it was determined that saturation had been reached on the key topics of interest (i.e., little new information emerged with each interview).

Document Review

All interview participants and other staff from organizations involved in HBR implementation were asked to provide relevant program documents, workshop reports, and other gray literature that provided insight and information on the HBR implementation process. Documents were also obtained from the WHO's HBR Working Group. Screening criteria were drafted to include or exclude documents based on relevance to HBR implementation in MNCH. We included documents that addressed at least 1 HBR implementation component, the barriers or facilitators to implementation components, or context-specific aspects of HBR implementation—each with justification of their importance in terms of empirical outcomes or stakeholder perspectives. We excluded documents if they studied the impact that HBRs have on MNCH outcomes but did not address implementation or if they made implementation recommendations without any justification. In total 69 documents were screened. We conducted all screening individually, following initial double-screening of 20 documents that indicated consistency in application of the screening criteria. In total, 18 documents were included in the analysis: technical briefs or reports (n=5) and presentations (n=8), case study (n=1), blog post (n=1), working paper (n=1), newspaper article (n=1), and project proposal (n=1). All documents described implementation in LMICs—a detailed breakdown of the characteristics of all the gray literature documents is in [Table 2](#).

Data Analysis

As data collection progressed, we took notes on and discussed emerging themes, trends, and other impressions and revised the analytic framework accordingly. Once the majority of data collection was complete, we began extracting information from documents and interviews and summarizing the information into a matrix. Each row in the matrix represented a data source, and each column represented a topic or theme from the revised analytic framework. We both first charted the data from the same 3 sources to check consistency on the interpretation of framework categories, the rest of the documents and interview notes were

charted individually. After completing data abstraction, we identified a refined list of 8 key implementation components that best captured the emerging themes.

RESULTS

We identified 8 main components of the implementation process ([Figure](#)). All the components of the implementation process are spokes of the wheel of a successful HBR program. We present the components as a logical way for readers to follow the process, not by importance or true chronological linearity. In practice, these can take place concurrently or nonsequentially.

1. Establishing High-Level Support

The government can push something that they really want to prioritize. —Key Informant 4

Many respondents and documents noted that when a government did not take HBRs seriously, it gave less substantial and sustainable support (in terms of time, human resources, and budget prioritization) to the HBR program compared to settings with more committed governments.

Many respondents highlighted that to achieve high-level support, strong advocacy is required to educate government stakeholders, particularly health ministry officials, and donor and coordinating agencies about the benefits of an HBR program and what is required to implement it. It was noted that currently this advocacy came largely from external agencies specializing in HBRs, though it could have also been from responsible officials within the ministries of health.

Respondents identified robust evidence about HBRs to be a prerequisite for successful and credible advocacy. Although this seemed to exist in a few country contexts, most respondents were frustrated by a paucity of data on HBRs. A common suggestion was for a question on HBR ownership and usage to be included in national Demographic and Health Surveys alongside existing questions on immunization.

2. Coordinating Partners

Each partner wants their own activity to be highest priority for the HBR. —Key Informant 3

In some respondents' countries, fragmentation and a lack of coordination of the HBR program resulted in the concurrent rollout of multiple records with overlapping content. This was found to inconvenience and confuse families and health care workers alike.

Respondents noted that strong advocacy is required to educate government stakeholders and donor and coordinating agencies about the HBR program benefits and implementation requirements.

TABLE 2. Document Characteristics of Gray Literature Included in Framework Analysis of HBR Implementation

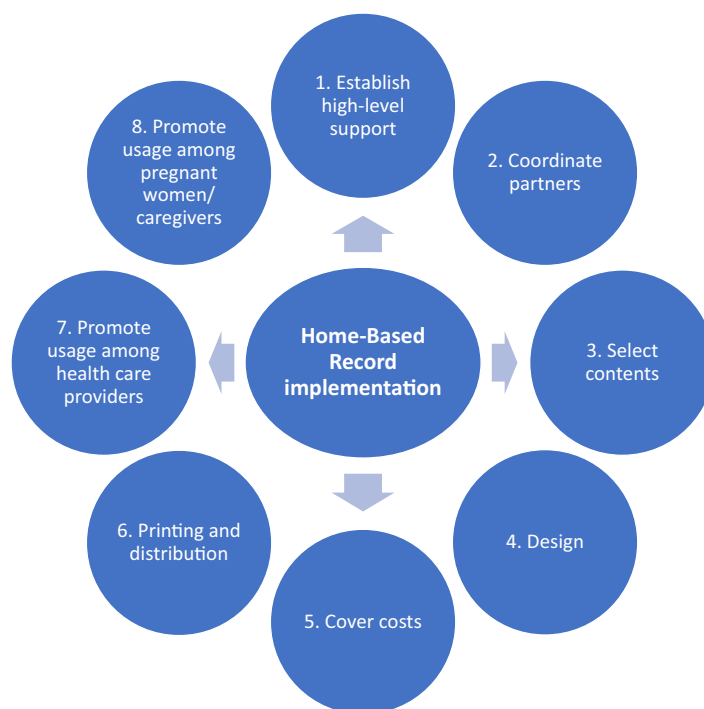
ID	Document Title	Source	HBR Type Addressed	Countries Addressed
D1	Omar MA, Sugushita T. <i>Kenya: What Mothers Have MCH Booklet?</i> Tokyo, Japan: Japan International Cooperation Agency; 2016.	JICA	Multiple focus	Kenya
D2	JSI. <i>Home-Based Record Redesigns That Worked: Lessons from Madagascar & Ethiopia</i> . Rosslyn, VA: John Snow, Inc; 2017.	JSI	Multiple focus	Madagascar and Ethiopia
D3	Basic Support for Institutionalizing Child Survival Project (BASICS II). <i>Madagascar Case Study: Improving Family Health Using an Integrated Community-Based Approach</i> . Arlington, VA: USAID; 2004.	JSI	Multiple focus	Madagascar
D4	John Snow, Inc (JSI). <i>Country Experiences With Home-Based Records (HBR): Survey Conducted by JSI and the Gates Foundation Jan - Apr 2016</i> . Presentation at the Home-Based Records Revitalisation Workshop; February 21–24, 2017; Kampala, Uganda.	JSI, Bill & Melinda Gates Foundation	Single and multiple focus	24 different countries in Africa and Asia
D5	Aiga H. <i>Self-Monitoring Child Nutrition Status Through MCH Handbook</i> . Tokyo, Japan: Japan International Cooperation Agency, 2013.	JICA	Multiple focus	Vietnam
D6	Rapp A, Hasman A, Radka R. <i>Home-Based Records Revitalisation Workshop: Workshop Report</i> . WHO, Bill & Melinda Gates Foundation/Claro; 2016.	Bill & Melinda Gates Foundation, UNICEF, Claro	Single and multiple focus	Afghanistan, India, Nepal, Pakistan
D7	Rane M. Blog Post. www.mrane.com . <i>Redesigning the Immunization Card for an Indian Context</i> . 2016.	Indian Institute of Technology Bombay	Single focus	India
D8	WHO/UNICEF/Bill and Melinda Gates Foundation. <i>Preparation Work Questionnaire Cameroon</i> . Presentation at the Home-Based Records Revitalisation Workshop; February 21–24, 2017; Kampala, Uganda.	WHO, UNICEF, Bill & Melinda Gates Foundation	Multiple focus	Cameroon
D9	Ministry of Health, Federal Democratic Republic of Ethiopia. <i>Home-Based Record Revitalization Workshop-Ethiopia</i> . Presentation at the Home-Based Records Revitalisation Workshop; February 21–24, 2017; Kampala, Uganda.	Ethiopia Ministry of Health	Single focus	Ethiopia
D10	WHO, UNICEF, Bill and Melinda Gates Foundation. <i>Home-Based Records Revitalisation Workshop: Preparation Work Questionnaire Liberia</i> . Presentation at the Home-Based Records Revitalisation Workshop; February 21–24, 2017; Kampala, Uganda.	WHO, UNICEF, Bill & Melinda Gates Foundation	Single focus	Liberia

Continued

TABLE 2. Continued

ID	Document Title	Source	HBR Type Addressed	Countries Addressed
D11	Anyar B/WHO Regional Office for Africa. <i>Home-Based Records Context in the African Region</i> . Presentation at the Home-Based Records Revitalisation Workshop; February 21–24, 2017; Kampala, Uganda.	WHO, Regional Office for Africa	Single and multiple focus	Regional Office for Africa countries
D12	Gazi R, Khatun J, Ashraf A, ul-Alam M, Kabir H. <i>Assessment of Retention, Perceived Usefulness, and Use of Family Health Card in the Bangladesh Health and Population Sector Programme</i> . Dhaka, Bangladesh: ICDDR,B: Centre for Health and Population Research; 2003.	ICDDR,B	Multiple focus	Bangladesh
D13	Kanda A. <i>Child Health Handbook Put in App for Refugees in Jordan</i> . The Asahi Shimbun. Asia and Japan Watch - Japan News Section. April 3, 2017.	Japanese National Newspaper	Multiple focus	Jordan
D14	Hagiwara A. <i>Development of New Combined Maternal and Child Health Record Book in Ghana: Background, Achievement and Way Forwards</i> . Tokyo, Japan: Japan International Cooperation Agency; 2017.	JICA	Multiple focus	Ghana
D15	Hagiwara A. <i>What is Maternal and Child Health (MCH) Handbook? Introduction of MCH Handbook to Ghana</i> . Tokyo, Japan: Japan International Cooperation Agency; 2017.	JICA	Multiple focus	Ghana
D16	Aboagye P, Hodgson A, Ogasawara Y, Hagiwara A. <i>Progress of Development of MCH Record Book in Ghana</i> . Poster presented at 10th International Conference on the MCH Handbook; November 23–25, 2016; Tokyo, Japan.	Ghana Health Service, JICA	Multiple focus	Ghana
D17	Hagiwara A/Japan International Cooperation Agency. <i>MCH Handbook for Refugees</i> . Presentation at the Home-Based Records Revitalisation Workshop; February 21–24, 2017; Kampala, Uganda.	JICA	Multiple focus	Gaza, Jordan, Lebanon, Syria, West Bank
D18	Service de la vaccination, Ministère de la santé et du planning familial. <i>Enquête sur la couverture vaccinale</i> . Antananarivo: Ministère de la santé et du planning familial, Repoblikan'i Madagasikara (Republic of Madagascar); 2008.	Madagascar Ministry of Health	Single focus	Madagascar

Abbreviation: HBR, home-based record; JICA, Japan International Cooperation Agency; JSI, John Snow, Inc.; UNICEF, United Nations Children's Fund; WHO, World Health Organization.

FIGURE. Eight Components of a Successful Home-Based Record Program Implementation Process

Multiple sources noted that all partners involved in implementing the HBR program needed to frankly discuss their individual priorities at the start of the whole process to ensure they were on the same page and committed to creating harmonious HBR content rather than competing with each other. In the experience of the key respondents, partners could include committees for nutrition, MNCH, immunization, malaria, and breastfeeding, among others, within ministries of health and donor organizations.

Many documents and respondents specified that the overall responsibility for coordinating partners should lie with the ministries of health rather than nongovernmental organizations or donors. They explained that ministries of health usually know their population and health needs better than external groups and having this responsibility helped empower them. It also encouraged the government to eventually assimilate the program into their own budget. This institutionalized the HBR program and gave it greater long-term stability than relying upon donors each year. However, respondents noted that government leadership was difficult to ensure, especially in poorer ministries in which donors exerted more

control or within governments in which corruption or lack of knowledge about HBR programs resulted in inaction.

3. Selecting HBR Contents

If it is not being used, be ruthless and take it out. Otherwise, you undervalue the importance of the records. —Key Informant 10

Sections of the HBR that did not get used at the ground level were noted to not only have been a waste of money but also have been a discouragement to parents and health care workers from using the HBRs altogether. To prevent this, documents and key informants alike noted that contents should have been created and selected appropriately for the local demographics and burdens of disease and for the local health system's available services and staff (for example, the record should not have included sections for recording results of tests that were not available in that country or region).

International and ministry-level respondents with policy experience in multiple countries indicated that the HBRs had the dual purposes of recording health parameters and communicating

Contents should have been created and selected appropriately for the local demographics and burdens of disease and for the local health system's available services and staff.

health education messages. However, many respondents with experience in service provision and planning at local levels viewed them only as recordkeeping tools, admitting that any health education content was often overlooked. They suggested emphasizing this dual purpose to health care workers when introducing them to the HBR and training them to use the HBR as a starting point for health education conversations.

Most respondents and a document noted the conflict between choosing single-focus or multiple-focus HBRs. Single-focus HBRs contain content relevant to 1 health topic or 1 population group, for example, vaccination cards for children or antenatal care notes held by pregnant woman.

Multiple-focus HBRs contain content about more than 1 health topic and also have chronologically ordered content that can cover a prolonged period of time. The United Kingdom's National Health Service paper-based child health record—commonly known as the “Red Book”—is a multiple-focus HBR given to a child's caregivers at birth and used for various purposes throughout childhood. It contains vaccination records, growth charts, records of illness, and health education messages. Japan's Maternal and Child Health Handbook, which has also been implemented in many LMICs, contains similar content but also contains antenatal records. The handbook is given to the mother during pregnancy, then after birth, the same handbook is used for the child. In favor of multiple-focus HBRs, some respondents stated that it was simply more convenient for women/caregivers to have a single comprehensive document and that fragmentation into many smaller records had a greater chance of loss. Some respondents with experience of the Maternal and Child Health Handbook also argued that child health HBRs with an antenatal component encouraged mothers/caregivers to be more involved in their child's care. Arguments against multiple-focus HBRs centered upon delays associated with the involvement of multiple partners in creating the different content areas and the increased cost associated with them, which may make them unfeasible in certain settings.

4. Designing HBRs

The problem is that most records are designed top-down. —Key Informant 9

Interviewees unanimously agreed that the design process should involve community and end user input. They noted that incorporating health care workers' feedback during the design process

ensured that the HBR layout aligned with their workflow, making it more likely to be used. In addition, incorporating feedback from the communities that will use the HBR was noted to be vital in ensuring that records were mindful of local cultural sensibilities. Pretesting was consistently mentioned as a vital step in the process to obtain this feedback from end users.

Respondents explained that it was important for regional languages to be represented on HBRs, not just the official or national language/s. Many sources noted the importance of adapting HBRs for low-literacy populations by using pictorials and rigorously testing these to ensure they conveyed the desired message. The role of health care workers in explaining the HBR to a woman or caregiver was also noted to be more significant in low-literacy contexts.

Both respondents and documents indicated that physical durability of the HBR hugely affected its use. A respondent with experience in Nepal noted that their child health cards easily disintegrated in the rain and were so flimsy that they were used as children's drawing paper instead. They piloted a simple plastic cover for the record that increased durability and retention significantly.

Keeping the HBR up-to-date with new best practices and health service changes was noted as vital. Designs and redesigns were found to be most effective when set on a defined timetable, such as biannually. Respondents explained that mandatory HBR redesigns tended to be led by immunization groups when new vaccines entered the national vaccination schedule. One respondent with international experience noted that involving multiple nonimmunization health sectors (whose content is less timebound) could lead to delays, emphasizing the need for partner coordination not only for initial planning stages but for redesigns as well.

5. Covering Costs

A lot of money goes toward design, but when the government asks for funding for training and supervision, suddenly, there is no money left. —Key Informant 11

International-level respondents and documents described how costs varied with the size of the record, number of topics covered, color versus black-and-white printing, and the system of distribution. However, accurate estimates were not available.

It was reported that costs of HBR programs in LMICs tended to be covered primarily by donors, particularly during early stages of implementation

Using pictorials for low-literacy populations and creating HBRs in regional languages or dialects were noted as vital for reaching and engaging end users.

A commonly cited barrier to effective HBR programs was that health care workers did not always know or care enough about using the records.

for design, initial printing cycles, and capacity building. Respondents and documents explained that this was often problematic and led to a lack of dependable funding. For example, costs could be covered ad hoc when donors had money to spare at the end of a financial year or only the initial design and the first round of printing would be covered, which caused stock-outs and left the local system struggling to continue the program.

Suggestions for improvement included obtaining long-term donor funding agreements (including contributions from every partner that had inserted their content into the record) each time a batch of HBRs was planned and ensuring the agreement covered all downstream activities, not just design and initial printing. Many sources preferred early planning for a gradual transition to government funding, and they noted that this planning was made easier when the government/Ministry of Health was empowered from the start to lead the process. A few sources mentioned charging women and caregivers for the HBR or covering costs through advertisement space on the record, however, these did not appear to be common practices.

6. Printing and Distribution

Medicines and vaccines have very strong logistics management systems, but HBRs are not currently subject to the same rigor or quality control. —Key Informant 10

Multiple sources found printing and distribution to be where the most roadblocks occurred. Respondents spoke of how funding often was given for the design and printing of HBRs but not for distribution. They noted that this was a barrier to sustainable HBR programs and a major cause of stock-outs.

A solution proposed by some sources was to integrate HBRs into existing health system supply and distribution chains just like vaccines, medicines, and other essential health commodities. However, they cautioned that in many settings, these existing chains also required strengthening. Respondents explained that efficient printing and distribution required planning ahead and accurately estimating the demand for HBRs. This planning was usually performed yearly by district health management teams using population and birth data, which were incomplete in some settings. One respondent noted that rural and remote regions and those with large transient populations (e.g., refugees) posed particular challenges both in terms of estimating numbers and in terms of HBRs and other services practically reaching them.

Efficient printing and distribution required planning ahead and accurately estimating the demand for HBRs.

7. Promoting Use of HBRs Among Health Care Providers

There's an assumption that training health care providers at the national level on how to use the records will be enough to get them to use them. That doesn't work in reality. Providers need on-site mentoring and coaching to use the records to habituate them. —Key Informant 4

A commonly cited barrier to effective HBR programs was that health care workers did not always know or care enough about using the records. Two respondents explained that an underlying reason for lack of motivation to engage with the HBRs was a lack of understanding of their value. HBRs were created primarily to record health data, but some HBRs also function to promote health education. Many respondents and documents alike praised these dual-purpose HBRs. However, we learned that in reality, they were rarely used as a deliberate starting point for conversations between health care workers and women or caregivers. Sources explained that health care workers were often unaware of the educational purpose and its importance. They also suggested that these issues could be due to time-restricted consultations and a sense that completing HBRs was double the work because most health care workers had to complete their own facility-based records as well.

For a more successful HBR program, sources explained that initial training on using the HBR must be given at the local level to all health care workers in both the public and private sectors who deal with HBRs. Centralized training for only senior health care workers was deemed insufficient. They also explained that initial training for health care workers was paramount, but ongoing refresher training, which was often neglected, was equally important. Refresher training was especially useful for community health workers who tended to have less formal education but who were vital in engaging rural or disenfranchised women/caregivers with the HBR. One suggestion for legitimizing HBRs was to mandate HBR training as part of preservice professional training and as a prerequisite for professional body accreditation. Another suggestion was to reward health care workers who complete the most HBRs in practice.

8. Promoting Use of HBRs Among Pregnant Women and Parents/Caregivers of Children

Women like records. They make them feel important, like they are taking care of themselves, and like the

provider will take more notice of them if they bring them.—Key Informant 4

Respondents stated several factors that they believed affected HBR use and retention by pregnant women and children's caregivers. Education was noted to improve understanding of the purpose of the records, and urban living was noted to be associated with lower rates of HBR loss due to shorter travel distances over less difficult terrain. Having a clear and consistent policy for replacement of lost or damaged records was also noted to be important.

Many documents and nearly all respondents spoke about the importance of patients/caregivers being introduced carefully to the HBR when they received it for the first time, with an explanation of its value and the necessity of bringing it to every health visit. Respondents reported that in some countries, HBR-documented proof of vaccination completion was required for school entry, and in others, HBRs were used to officially register a child's birth. These measures were thought to increase the legitimacy and value of the HBR. Involving health professionals, such as community health workers and midwives, and nonhealth-sector stakeholders, such as religious and community leaders, in HBR pretesting and promotion was also viewed as important for gaining the acceptance of end users and making HBRs more relevant to them.

■ DISCUSSION

This framework analysis formed the final study in a WHO-commissioned series to inform the 2018 WHO recommendations on HBRs in MNCH.³ Our findings indicated 8 key components that played a crucial role in determining successful implementation of HBRs. These were relevant to those involved with HBRs at all levels: ministry and policy, program, and end user.

We hope that the findings will help health care workers, pregnant women, and parents/caregivers of children use HBRs more effectively, provide key program stakeholders with a rough blueprint of the implementation process to be adapted for individual regional contexts when beginning and/or strengthening implementation, and help health care providers and planning groups identify and develop solutions for roadblocks in their own HBR programs.

Our findings build on the existing body of literature on HBR implementation. Studies found that mandating HBR ownership for all children in Indonesia²⁷ or requiring proof of immunization

for school entry in Australia²⁸ both led to increased HBR ownership and retention. Conversely, when the government's agenda priorities for HBRs were not articulated into clear policies or incentives, various providers interpreted these priorities differently, resulting in a lack of consistent progress.²⁹

Our respondents suggested including questions about HBRs in Demographic and Health Surveys and censuses to build credible advocacy for high-level support. However, analysis showed that a question on HBR ownership has been already included in the Demographic and Health Surveys for the majority of countries.¹³ Perhaps to garner more high-level support, the Demographic and Health Surveys should include more specific questions to qualify patterns of HBR use or should adapt the way the data are harnessed to turn it into constructive action and advocacy.

The need for coordination of partners came up often in our data. Unfortunately, no research currently exists specifically on how to coordinate donors, nongovernmental organizations, and ministry departments within a country who are all working on the same HBR program, but it was recognized as necessary to prevent fragmentation of HBRs and services.³⁰ However, there is evidence that at the regional level, there has been coordination between LMICs to visualize and prototype improvements in their HBRs while focusing on their country-specific contexts.³¹ This may remain difficult to operationalize due to crowded agendas, limited resources, and the priorities of donor organizations.³¹

Many HBR content areas were not used by end users and not referred to by health care providers during consultations.¹⁴ In multiple-focus child health or maternal and child health books, the patient demographics and vaccination sections were the most consistently completed sections, and other sections including the growth monitoring charts were often neglected.³² As our respondents alluded, having unused content sections could undermine the value of the rest of the HBR as perceived by both health care workers and women or caregivers. The extra resources used in creating these unused sections may have been unjustifiable and unnecessary costs.¹⁴ Reasons for unused content must be explored, and when similar HBR formats are being implemented in multiple countries, the content should be adapted to be country- and region-specific.³³

There was insufficient evidence to recommend one form of HBR over others, and no studies that directly compared the implementation of a multiple-focus HBR to a single-focus HBR. Multiple-focus

When patients/caregivers receive the HBR for the first time, they should be given an explanation of its value and of the necessity of bringing it to every health visit.

HBRs, for example, maternal and child health handbooks, were widely recognized to be more expensive to print.^{5,33} A theoretical argument suggested that this was more cost-effective overall than printing multiple single-focus records;^{33,34} however, formal economic evaluation is required. The choice of single-focus or multiple-focus HBR is likely to be context-specific, so more local research in LMICs is required to delineate these context-specific determinants.^{3,25}

A number of existing studies have affirmed the importance of the design of the HBR.^{16–19} In addition, in 2015, the WHO published a guide for designing, using, and promoting HBRs in immunization programs.² All these sources advocate for plastic covers for physical durability, simple uncluttered layout, large print size, nontechnical language, attractive colors and shading, and clear photos or illustrations. Incorporating these changes when redesigning immunization cards contributed to improving childhood immunization adherence in studies in both urban and rural Pakistan.^{18,19}

Our sources echoed existing studies advocating that HBRs should be created in regional languages. For example, the Road to Health card in South Africa was printed in English, Afrikaans, and Xhosa,²¹ and the Patient Passport in the USA had better impact when there was a concurrent Spanish version.³⁵ An informal review conducted by Brown showed that the health messages in HBRs were often poorly aligned to national literacy levels.²⁵ Studies agreed that clear pictorials were needed for women and caregivers with low-literacy levels, but even these could sometimes be difficult to decipher, and they often required additional support from health care workers or relatives to access the HBR content.^{20,36,37} This could pose concerns regarding equity in accessing the HBR content and needs to be explored further.

There was a substantial theoretical case for the long-term health system cost savings associated with an effective HBR program.³⁸ Regarding current funding of HBR programs, a survey of immunization records in 135 countries showed that the majority of HBR financing was shared between the health ministry and development partners or other partnership combinations.⁵ There was greater involvement of development partners in low-income countries and those in the GAVI alliance.⁵ Relying solely on single-source funding arrangements seemed to be more associated with HBR stock-outs, as with very complex multi-source funding arrangements.³⁹ More research on the funding arrangements of all types of HBR

programs—building on existing research on vaccination cards—is vital to be able to better forecast demand and help build sustainable funding streams for each component of the implementation process.

As our data showed, the systems for estimating demand and printing HBRs accordingly were often poorly planned and maintained. In data from WHO and UNICEF's Joint Reporting Form on Immunization, 48 of 194 countries reported at least 1 national level HBR stock-out during a 3-year period. Several of these countries had multiple stock-outs. In addition, the supply chains were often poorly monitored: 75 countries did not have any information about HBR stock-outs in at least 1 of the 3 years.³⁹

Even when an adequate number of HBRs are printed, they must reach the appropriate end users, including those who are remote or disenfranchised. In a study of slum communities in Kampala, Uganda, delivering in a health facility was found to be the strongest determinant of receiving an HBR. However, the majority of births in Uganda occurred outside formal health facilities.⁴⁰ This raises the challenge of how to extend HBR distribution chains and to incorporate HBRs into existing health system strengthening programs.

There was evidence to suggest that health care workers in low-income settings valued HBRs, and especially integrated multi-focus HBRs, for the information provided, convenience, and long-term value.⁷ This was especially true in settings where facility-based record systems were incomplete or incorrect. In addition, studies indicated that HBRs that incorporated not only the data recording function but also the additional health education function provided a common talking point for patients and health care workers, enhancing patient-provider communication.⁷ In contrast, our sources felt that in some settings, enhanced communication was an ideal rather than a reality due to various barriers preventing health care workers from realizing the value of HBRs. For example, health care workers did not use or promote HBRs well when the contents did not match their workflow. Therefore, they must be involved in the content selection and design process.²¹

There was evidence that overall, women and caregivers valued HBRs for recording information, increasing their knowledge about their or their child's health care, and increasing their sense of empowerment during interactions with health professionals to enable shared decision making.⁷ However, this value was not necessarily automatic

or inherent. Studies across multiple countries agreed with our respondents that the health care worker's initial explanation and request to see the HBR at every health visit determined the owner's perception of their HBR's value and their subsequent engagement with it. Retention of the record plummeted when the record was not explained clearly.^{22–24,32}

Strengths of this study include a broad and comprehensive approach to exploring HBR implementation; this meant that we were able to develop a more complete picture of the implementation process, not simply 1 or 2 factors. Our key respondents had a breadth of experience: across continents, across different health and development sectors, and involving both policy- and ground-level implementation. They had experience predominantly in LMICs. In contrast, the majority of existing HBR literature was from high-income countries. Finally, in this framework analysis, we reached saturation on the major themes (i.e., minimal additional information emerged from subsequent interviews), and there was strong consistency between interview respondents and gray literature documents.

Further research is required on the perspectives and motivations of health care workers who deal with HBRs and on how HBRs can be effectively integrated with existing facility-based health information systems. Research is also required on the differences between implementing single-focus and multiple-focus HBRs, including whether their unique characteristics make them suited to different contexts or populations. Accurate costings of the full implementation process are needed, including for downstream activities such as printing and distribution, to enable health ministries and donors to make informed and sustainable planning decisions.

The implementation components that we have identified come from experiences of successes and failures in HBR programs. Some of the strategies suggested are mirrored in the existing literature, but some are new and require further research on how they can best be operationalized. There are multiple interlinkages between our 8 implementation components. For example, high-level support and partner coordination is required to secure long-term funding, which determines the potential for designs and redesigns, printing, distribution, and initial as well as refresher training for health care providers. Meanwhile, the content areas chosen and the design of the HBR affect how it is valued and used by health care providers and pregnant women/caregivers.

We can assume that if all the 8 components are optimized, an HBR program will be more successful. However, more operational research is required to confirm this, to understand how much each individual factor contributes, and to explore how they interact with each other in different country contexts.

Limitations

This study had several limitations. We had a small number of respondents (n=12). Some of our 12 respondents had hands-on, frontline experience with HBRs, but we were directed toward these country-level respondents by international-level respondents at donor organizations. Secondly, although key respondents talked about their experience with failures in HBR programs, the gray literature rarely covered this because, unfortunately, donor-published reports were seldom willing to publicize failures.

In addition, a few subthemes did not reach saturation since they were only addressed briefly or by only 1 or 2 sources. These subthemes included electronic HBRs and the use of HBRs in vulnerable populations such as refugees. One respondent with experience in refugee settings described meeting a mother who had arrived after an arduous journey to the country of asylum with very few essential and valuable items, one of which was her infant's HBR. The WHO recommendations on HBRs note that transient and vulnerable populations in particular stand to benefit from records that they can carry with them.³ Meanwhile, electronic records have been well studied in the literature, though almost exclusively in high-income countries. Implementation barriers included lack of universal high-speed internet access, concerns about data confidentiality, complexity of software, and difficulties integrating electronic HBRs with facility records.^{41–45} The implementation of electronic records in LMICs that have just started to pilot electronic HBRs and are rapidly growing in technological capabilities deserves attention in future research.

CONCLUSION

Home-based records are a remarkably diverse group of tools that can be complex to implement and coordinate. They already exist worldwide, albeit with inconsistent coverage, but have been neglected when it comes to research, quality improvement, and funding. Our findings provide a more comprehensive overview of the implementation process for HBR programs. The hope for the related WHO guidelines² is that policy makers,

This study used a broad and comprehensive approach to develop a more complete picture of the HBR implementation process.

donors, and the end users of HBRs (frontline health care providers, pregnant women, and the families of children) will all be able to better harness the benefits of HBRs for improved MNCH outcomes, increased participation and shared decision making, and better coordination and continuity of care.

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REVIEW

Implementation and Scale-Up of the Standard Days Method of Family Planning: A Landscape Analysis

Julianne Weis,^a Mario Festin^b

Pilot introductions of the Standard Days Method (SDM) of family planning demonstrated its potential to meet unmet contraceptive needs in key populations, strengthen male involvement, and increase overall contraceptive uptake. Few countries had implemented national scale-up due to barriers, such as competing resource priorities and uneven stakeholder engagement. Demand-side user barriers, including insufficient fertility awareness knowledge, were also constraints. Policy makers should determine the SDM's added value to the contraceptive method mix and identify potential barriers to its implementation.

ABSTRACT

The Standard Days Method (SDM), a modern fertility awareness-based family planning method, has been introduced in 30 countries since its development in 2001. It is still unclear to what extent the SDM was mainstreamed within the family planning method mix, particularly in low- and middle-income country (LMIC) settings, where the SDM had been introduced by donors and implementing partners. This review of implementation science publications on the SDM in LMICs first looked at community pilot studies of the SDM to determine the acceptability of the method; correct use and efficacy rates; demographics of users; and changes to contraceptive prevalence rates and family planning behaviors, especially among men and couples. Then, we examined the status of the SDM in the 16 countries that had attempted to scale up the method within national family planning protocols, training, and service delivery. At the community level, evidence demonstrated a high level of acceptability of the method; efficacy rates comparable to the initial clinical trials; diversity in demographic characteristics of users, including first-time or recently discontinued users of family planning; increased male engagement in family planning; and improved couple's communication. Nationally, few countries had scaled up the SDM due to uneven stakeholder engagement, lackluster political will, and competing resource priorities. Results of this review could help policy makers determine the added value of the SDM in the contraceptive method mix and identify potential barriers to its implementation moving forward.

INTRODUCTION

The Standard Days Method (SDM) is a fertility awareness-based family planning method that identifies a 12-day fertile window during which women with regular menstrual cycles (26–32 days long) should abstain from sex or use a barrier method to prevent pregnancy. SDM is limited to women with regular menstrual cycles of 26–32 days, which applies to an estimated 50%–60% of women of reproductive age, though contraindications, including recent pregnancy and breastfeeding, can also affect cycle regularity and eligibility for the method.¹

First developed and tested in 2001 by the Institute for Reproductive Health (IRH), the SDM was introduced with “CycleBeads,” a string of different colored beads that each represent 1 day in the menstrual cycle, as a visual tracking tool to facilitate correct use of the method. Brown beads indicate nonfertile days, and white beads

indicate fertile days when the user should abstain from sex or use a barrier method. The user moves a small rubber ring along the CycleBeads string each day to track their fertility. In 2012, the free iCycleBeads app was introduced and piloted as a digital version of the CycleBeads for download on a mobile device.

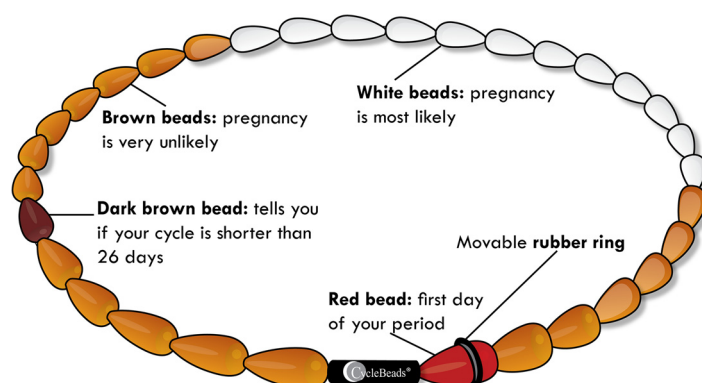
The SDM is 95% effective in perfect use and 88% effective in typical use.² Classified as a modern method of family planning by the World Health Organization, U.S. Centers for Disease Control and Prevention, and other international health organizations, the SDM has been introduced in 30 countries globally in an effort to expand contraceptive method choice.

Although the SDM was introduced largely in pilot programs by nongovernmental organizations (NGOs) and donor agencies that supported ministries of health (MOHs), it remains unclear to what extent the SDM was implemented or scaled up at the national level within health systems. Reported use of the SDM captured in Demographic and Health Surveys remained less than 1% across countries where it was introduced. Reported

^aUnited States Agency for International Development, Washington, DC, USA.

^bWorld Health Organization, Geneva, Switzerland.

Correspondence to Julianne Weis (jweis@usaid.gov).



CycleBeads have colored beads that each correspond to 1 menstrual cycle day. © 2019/Institute for Reproductive Health

knowledge of the SDM also varied considerably in Demographic and Health Surveys, from less than 1% in India to 82% in Rwanda, with a median of 26% (STATcompiler, ICF International, 2012, Washington, DC).

This landscape analysis of implementation studies of the SDM intended to answer the following key questions:

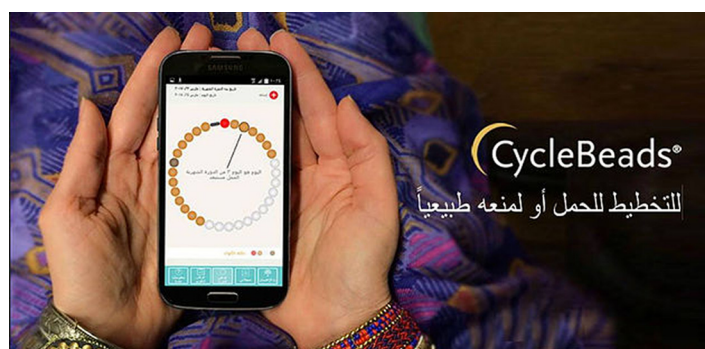
- What happened when the SDM was first introduced in low- and middle-income country (LMIC) settings?
- Was the SDM an effective and feasible method of family planning for users?
- What was the status of the SDM implementation and scale-up at national levels in LMICs?

This analysis focused on SDM implementation in low-resource settings and user-based outcomes, including users' approval of the method,

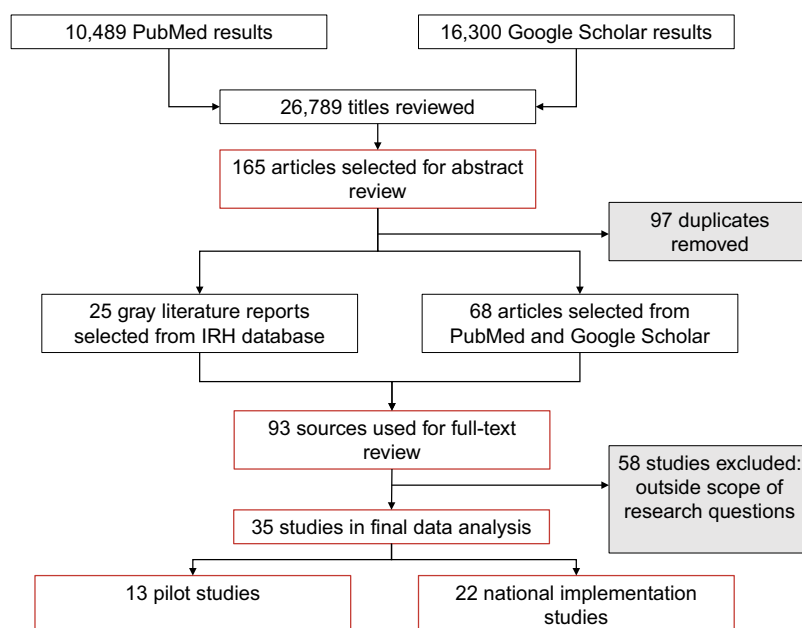
continuation rates, and efficacy, as well as the impact of attempts to institutionalize the SDM within the family planning method mix at the national level. This landscaping review examined implementation science of the SDM specifically in LMIC settings from a user perspective and complemented other reviews on method efficacy.³ This analysis helped examine the barriers and enablers to the SDM's introduction at both community and national levels and could help inform broader policy on fertility awareness-based methods in LMICs moving forward.

DATA AND METHODS

To complete the landscape analysis, we completed database searches in both PubMed and Google Scholar using the search terms "Standard Days Method + family planning + implementation." We limited the search results to publications from



The iCycleBeads mobile device app in Arabic. © 2019/Cycle Technologies

FIGURE. Methodology of Landscape Analysis Review of SDM Studies

Abbreviations: IRH, Institute for Reproductive Health; SDM, Standard Days Method.

2000 to 2019 because of the SDM's recent development as a fertility awareness-based method.

PubMed recovered 10,489 results, and Google Scholar found 16,300 results. After scrutinizing the titles of all 26,789 results, 165 studies were included for further screening of abstracts. All 165 studies addressed some aspect of the SDM of family planning, whereas the other search results were unrelated to the SDM specifically. Of these, 97 studies were duplicates in both PubMed and Google Scholar search results; therefore, 58 studies were selected for further review from Google Scholar and 10 from PubMed (Figure).

In addition to conducting database searches, we searched for gray literature reports on the IRH website. Because of IRH's long history in developing and implementing the SDM, we understood that their program materials had significant evidence on the status of the SDM in LMICs, especially in terms of nationalization and scale-up. This search yielded an additional 25 gray literature reports, including annual reports, project briefs, and evaluation materials.

We completed a full-text analysis of the 93 sources identified in both database and IRH searches. In completing this analysis, we excluded 58 studies that did not provide answers to our initial research questions on user-based outcomes of

the SDM implementation and status in national family planning systems in LMICs. Ten studies were excluded because they did not explicitly study the SDM but merely mentioned the SDM in conjunction with other family planning methods. We excluded 12 studies that provided general commentary on the SDM as an addition to the family planning method mix but did not provide new evidence of the SDM's implementation. Five studies were excluded because they were efficacy studies of the SDM, so they relied on only 1 data point (pregnancy rate) in a clinical trial setting. We were interested in examining other outcomes of the SDM and its feasibility as a method when implemented in more routine family planning practice. Sixteen studies were excluded because they were not conducted in an LMIC setting. We excluded 9 studies on the social marketing and provider-side issues of the SDM implementation because these were outside the scope of our research questions. Studies that examined provider-based outcomes, including training, feasibility of counseling, and marketing methodologies, warrant a separate rigorous analysis and review. Lastly, 6 studies were excluded because they did not provide sufficient data on user-based outcomes of the SDM implementation. These studies did not study the SDM explicitly (included user numbers along a

range of other family planning methods introduced in a family planning project) and/or included only 1 data point (e.g., pregnancy rate) and included nothing about correct use, satisfaction with method, or other user-based outcomes. Many of the studies that were excluded from full data analysis informed the discussion section of our review.

Using these exclusion criteria, 35 studies were included for final, in-depth analysis. We separated these studies into those that presented evidence from a pilot introduction of the SDM in an LMIC community (13) and those that examined results of national scale-up efforts of the SDM (22). In terms of study methodologies, all 13 pilot studies followed study cohorts for a period of 6–18 months, collecting user data at multiple points. None of the studies used a control or comparison group. The 22 national scale-up reports were cross-sectional implementation studies.

For pilot studies, our analysis focused on the following factors: (1) number of participants in study, (2) demographics of participants, (3) reasons for discontinuation of method, (4) approval of method, (5) number of participants who would recommend method, (6) ability to understand and use the method correctly, (7) previous experience with family planning, (8) intent to continue using the SDM, (9) reasons for using the SDM, (10) change to modern contraceptive prevalence rate (mCPR), (11) number of pregnancies, and (12) other outcomes of the SDM introduction.

For scale-up studies, our analysis used the following factors: (1) lead organizations in scale-up efforts, (2) whether the SDM was included in provider training, (3) if CycleBeads were in national procurement, (4) if the SDM was included in health management information systems or other national measurements and national family planning protocols, (5) number of service delivery points with the SDM, (6) number of service providers trained in the SDM, and (7) number of registered SDM users.

■ RESULTS

Pilot Introductions of the SDM

A total of 13 pilot studies to introduce the SDM were conducted in 10 countries: Albania, Benin, Burkina Faso, the Democratic Republic of the Congo (DRC), El Salvador, Ethiopia, Guatemala, India, Rwanda, and Turkey. Apart from Ethiopia, Guatemala, and Turkey, the remaining 7 pilot introductions and studies of the SDM were conducted by IRH with U.S. Agency for International Development funding. Although

study methodologies varied slightly, each of these pilot studies involved first training health workers of various cadres including community health workers, health agents, nurses, midwives, and physicians to teach the SDM to new users with the assistance of CycleBeads, job aids, and visual brochures. Health workers were trained to counsel potential SDM users on the menstrual cycle, including the period start date and fertile window, and how to move the rubber ring along the different colored CycleBeads to track their cycle. On days 8–19, indicated by the white beads, users were taught to either abstain from sex or use a barrier method during intercourse. Users were taught the SDM in both home and clinic settings, and the SDM was often introduced with a range of other contraceptive methods and in routine family planning outreach and clinic settings. To accept the SDM, users were to report having regular cycles of 26–32 days. Those who accepted the SDM were offered the chance to participate in a study ranging from 6–18 months to follow their progress and experience using the method. In each study, recruitment of study participants was part of a program to introduce the SDM through family planning service delivery at home or in the clinic. Participation was wholly optional, and participants could have left the study at any time. Users did not have to participate in the studies to receive family planning services.

The pilot studies had sample sizes ranging from 76 to 767 users with a total of 2,906 users (Table 1). There was a wide range of study discontinuation rates, from 1%–45%, with a median of 30% discontinued method use within a 3–18 month period. The majority of users who discontinued use did so within the first 3–6 months. The primary reasons for method discontinuation were menstrual cycle lengths outside the range for SDM eligibility (419 users, 14%), unintended pregnancy (403 users, 14%), dissatisfaction with the method (125 users, 4%), and desire to become pregnant (107 users, 3%). Other reasons included unspecified personal reasons and switching to a different contraceptive method. The high numbers of users who discontinued because they had menstrual cycle lengths outside the range of eligibility demonstrated that many women may agree to use the SDM without having proper knowledge of their own history of cycle irregularity. This lack of knowledge could have been due to insufficient instruction by the health care provider or lack of previous tracking from the user, indicating a need for initial body literacy and fertility awareness

TABLE 1. Quantitative Results of Landscape Analysis of Pilot Studies in 10 Countries on the Standard Days Method of Family Planning

Study	Country	Participants, N	Discontinuation, N	Pregnancies, N	Approval, %	Would Recommend, %	Correct Use at 6 Months, %	Previous FP Use, %
Ram and Doracaj, 2007 ⁷	Albania	76	30	5		91	85	43 ^a
Capo-Chichi and Anastasi, 2005 ⁸	Benin	219	33	21	90	90	95	45 ^a ; 39 ^b ; 20 ^c ; 7 ^d
Bicaba et al., 2005 ⁹	Burkina Faso	79	20	2	90	90	95	22 ^a
IRH, 2008 ¹¹	Democratic Republic of the Congo	88	4	4	99	—	84	15 ^a
IRH, 2005 ¹⁴	El Salvador	143	43	17	—	—	90	62 ^e
Bekele, 2012 ¹⁰	Ethiopia	184	36	2	—	—	91	20 ^a
Burkhardt et al., 2000 ¹³	Guatemala	301	63	32	100	100 ^f	95	88 ^a
Dosajh, Ghosh, Lundgren, 2005 ¹⁵	India	230	82	20	99 ^{f,h} ; 70 ^{g,h}	98 ^{c,i} ; 77 ^{d,i}	87	74 ^{f,k} ; 66 ^{m,p} ; 1 ^{n,o,p}
IRH, 2006 ¹⁶	India	482 ^a ; 285 ^r	130 ^a ; 68 ^r	77 ^a ; 20 ^r	—	—	97	45 ^{a,p} ; 28 ^{a,q}
Johri, Panwar, Lundgren, 2005 ¹²	India	482	225	73	90 ^s	90 ^f ; 70 ^g	98	59 ^r ; 41 ^c ; <3 ^p
Blair et al., 2007 ¹⁸	Rwanda	121	30	16	—	—	99 ^f ; 88 ^g	96 ^a
Kalaca et al., 2005 ⁶	Turkey	132	53	4	—	—	—	—
Kursun, Cali, Sakarya, 2014 ⁵	Turkey	84	34	8	63 ^{f,s} ; 67 ^{g,s}	—	—	12 ⁿ

Abbreviations: FP, family planning; IRH, Institute for Reproductive Health.

^aNever used modern method.^bPeriodic abstinence.^cCondoms.^dWithdrawal.^eNot using modern family planning method in previous 2 months.^fWomen.^gMen.^hConsider it a useful method.ⁱOf those who completed 1 year of use.^jWho hit 12 cycles.^kHad used some method in past, primarily condoms.^mCondoms.ⁿWithdrawal.^oIntrauterine device.^pUsing method in previous 2 months.^qRural.^rUrban.^sSatisfied with method.^tFirst-time family planning users.

instruction before introducing the SDM as a family planning method.

Overall, the pregnancy rates among SDM users in the community studies ranged between 10% and 18% in each study population, which varied from the initial efficacy study that reported a 12% typical use pregnancy rate.² This failure rate was calculated as percentage of users who experienced an unintended pregnancy while using the method over the study period, between 6 and 18 months dependent on the study. The different failure rates reported in the SDM pilot studies may indicate variability in the quality of the method's introduction, counseling, and screening of potential users. One study collated data from 1,646 users in 6 studies from various countries and reported a pregnancy rate of 14%, a figure closer to the rate

found in the clinical trial.⁴ The majority of pregnancies occurred within the first 3 months of method use, which indicated users' failure to understand the method correctly, users' actual ineligibility for the method due to misunderstood patterns of irregular cycles, or husbands'/sexual partners' lack of cooperation to comply with the required abstinence/use of a barrier method on fertile days. This also indicated that the SDM had unique demand-side challenges as a family planning method, including a solid grounding in body literacy and fertility awareness and ability to communicate and negotiate sexual activity with a partner.

The trend in pregnancy rates matched results on correct use of the SDM among study participants. In most pilot studies, users were asked at multiple intervals to describe the mechanism of

the SDM use, including how to identify the start of a menstrual cycle and manage fertile days. Answers to these questions improved over time. After 6 months of use, between 85%–99% of respondents correctly described the SDM, including which were the fertile days and how to correctly use CycleBeads, compared to 65%–75% in the initial surveys. This demonstrates how familiarity and comfort with the SDM, similar to other family planning methods, improved with time and use. Among users who continued the SDM beyond an initial 3 cycles, approval rates were very high, between 90%–100% saying they enjoyed the method and would recommend it to others. However, this approval figure was likely biased possibly from a courtesy bias dependent on the relation between study subject and data collector. In addition, these figures often did not include those users who discontinued the method in the initial months.

The demographics of users varied across study populations. Two studies found higher education levels among the SDM users compared to other family planning methods and the general population: in Turkey^{5,6} and in Albania, 49% of the SDM users had a high school degree, compared with 35% of users of other modern family planning methods.⁷ Four studies showed that the number of SDM users with a secondary education was higher than the general population: in Benin, 53% of SDM users had a secondary education⁸; in Burkina Faso, 64%⁹; in Ethiopia, 29%¹⁰; and in the DRC, 49%.¹¹ More research is needed to understand why the method appealed to women with higher levels of education, but perhaps these women were better able to negotiate sex with partners, had more regular menstrual cycles due to better nutritional intake, or had more cognitive resources necessary to track the cycle.

Three studies measured the implementation of the SDM specifically in underserved, lower- educated populations. The majority of users in these studies had lower schooling levels or had never attended school. In rural Jharkhand State, India, 59% of SDM users had no schooling,¹² in Guatemala, 32% of the SDM users were illiterate,¹³ and in El Salvador, 80% of the SDM users lived in rural areas and had less than a primary education.¹⁴

Both pregnancy rates and rates of correct use were similar between the higher-educated and lower-educated groups across all studies. Other demographic indicators, including parity, wealth, and place of residence, varied considerably and showed the wide range of users who were attracted to the SDM as a family planning method.

A consistent finding across the studies was reason for uptake of the SDM. The majority of users cited no side effects or health effects as the primary reason for choosing the method, while others cited low cost, no need for health visits, convenience, or existing familiarity with periodic abstinence as a family planning method. Measurement of previous use of modern methods of contraception varied across studies. For those that asked about ever use of modern family planning, between 15%–96% of SDM users said this was the first time they were using a modern method of family planning. Other studies asked about contraceptive use in the 2 months before SDM uptake, and answers varied between 21%–62% of users stating they were not using contraception in the immediate past. Common methods used recently included withdrawal, condoms, rhythm, and periodic abstinence.

Only 3 studies measured change to overall mCPR in target communities after the introduction of the SDM. In El Salvador, the mCPR increased from 45% to 58%, with 4% of new contraceptive users using the SDM.¹⁴ Three other studies from separate communities in India had similar results, with mCPR increasing 7%–8% overall, with 1% of women using the SDM.^{12,15,16}

Lastly, many users in the community studies cited improved couple's communication, increased male involvement in family planning, and more consistent condom use as additional benefits of using the SDM. A study from Bihar, India, demonstrated that "couple-based fertility awareness education is effective in increasing demand for contraception and improving knowledge of fertility overall."¹⁷ In the pilot studies that asked about changes to male involvement and couple's communication after the SDM introduction, nearly all participants reported an improvement in joint decision making and male involvement.^{8–11,15,18}

National Scale-Up of the SDM

Sixteen countries had conducted some level of national standardization and institutionalization effort for the SDM (Table 2). National scale-up efforts took place largely from 2001–2013 as part of the U.S. Agency for International Development-funded AWARENESS Project, of which IRH was the prime implementing partner. Each of the 22 national scale-up studies included in this review were published by IRH; no studies by other organizations were found in the database searches. Nationalization efforts involved incorporating the SDM in health worker training materials, adding CycleBeads in national commodity procurement, including the

The majority of users chose SDM because it has no side effects or health effects.

Many users cited improved couple's communication and increased male involvement in family planning among the added benefits of using the SDM.

TABLE 2. Status of Scale-Up of the Standard Days Method of Family Planning in 16 Implementation Countries

Country	SDM in Training	SDM in National Measurements	SDM in National Protocols	Service Delivery Points With SDM, N	Service Providers Trained in SDM, N	Registered SDM Users, N
Benin	Yes	Yes	Yes	150	Not recorded	10,500
Bolivia	Yes	No	Yes	277	2,100	14,000
Burkina Faso	Yes	Yes	Yes	57	287	5,000
DRC	Yes	Yes	Yes	749	600	Not recorded
Ecuador	Yes	Yes	Yes	11	Not recorded	Not recorded
Guatemala	Yes	Yes	Yes	305	2,200	13,000
Haiti	No	No	No	20	141	700
Honduras	Yes	Yes	Yes	183	950	2,211
India, Jharkhand State	Yes	Yes	Yes	1,900	15,000	Not recorded
Madagascar	Yes	Yes	Yes	218	427	1,210
Mali	Yes	Yes	Yes	Not recorded	14,200	2,000
Nicaragua	No	No	Yes	336	1,308	343
Peru	Yes	Yes	Yes	348	725	7,862
Philippines	Yes	Yes	Yes	125	489	8,000
Rwanda	Yes	Yes	Yes	717	7,000	6000
Senegal	No	No	No	58	1,219	Not recorded

Abbreviations: SDM, Standard Days Method.

SDM in national health information measurement services, and integrating the SDM into national family planning protocols and policies. In studies examining the results of scale-up efforts, IRH also tracked the number of service delivery points providing the SDM, number of registered SDM users, and number of service providers trained in the SDM.

Although IRH led the process for institutionalization of the SDM in all 16 countries, local civil society groups helped lead efforts in Latin American countries, including Bolivia,¹⁹ Ecuador,²⁰ Guatemala,^{21,22} Honduras,²³ Nicaragua,²⁴ and Peru.^{25,26} International NGOs had more involvement in other countries, including Benin,²⁷ Burkina Faso,²⁸ the DRC,^{22,29} Haiti,³⁰ Madagascar,³¹ Mali,^{22,32,33} the Philippines,³⁴ Rwanda,^{22,26,35,36} and Senegal.³⁷ Local faith-based organizations had an active role in Burkina Faso (Catholic Diocese), the DRC (Catholic Relief Services), and Senegal (ChildFund). IRH also led efforts on the SDM integration with the Jharkhand State MOH in India.^{26,38,39}

The extent of the SDM scale-up varied considerably across the different country contexts. Some countries, including Bolivia, Haiti, Nicaragua, and Senegal, did not complete the full national scale-up

because of lack of interest or capacity of both local MOHs and civil society partners. In Senegal, efforts were limited to only 2 years of pilot activities in training and initial service provision with the NGO, Tostan, but the MOH chose not to continue programming for the SDM after the pilot. The situation in Haiti was similar; although the government supported a 2-year pilot introduction, they did not continue supporting the method in national protocols, reporting mechanisms, or training manuals beyond the initial pilot. Reasons for discontinuing support of the SDM were limited capacity and resources at the level of the MOH, competing priorities in family planning/reproductive health, and limited political will within the MOH.

In Latin America, the SDM was first introduced in key target areas with low modern contraception uptake and high numbers of users of traditional family planning methods. Bolivia and Nicaragua limited the SDM to these targeted populations with high demand for the method, and Ecuador, Guatemala, Honduras, and Peru continued to expand the method. All of the Latin countries had included the SDM in national health worker training, measurements, and protocols and policies. Decisions to take the SDM beyond

Some countries discontinued support of the SDM because of limited capacity and resources at the level of the MOH, competing priorities, and limited political will.

initial pilots were made based on both the capacity and the will of local partners and country MOHs.

Aside from Senegal, every other African country included in scale-up efforts had the SDM included in national training, measurements, and family planning protocols. The SDM had the greatest institutional reach in the DRC. IRH partnered with 26 local organizations in the DRC and included considerable investment in social marketing for the method through Population Services International and Catholic Relief Services. The role of faith-based providers in the DRC was critical to expanded uptake of the method, and the national MOH also recognized both the local demand for and added value of the method.

A study in Rwanda demonstrated that 87% of trained community health workers correctly screened clients for eligibility to use the SDM based on cycle lengths/history and 92% accurately explained how to use CycleBeads. Further, 89% of clients reported knowledge of all key steps in the SDM after being counseled by the community health worker.⁴⁰ There was some evidence that improved job aids could have overcome clinical providers' oversight of community health worker SDM provision and counseling,⁴⁰ while task shifting or sharing were important and effective tools to disseminate the SDM.

IRH used an approach in Madagascar that was similar to efforts in the DRC, forging partnerships with faith-based organizations to promote the SDM nationally. The MOH in Mali recognized the demand for natural methods in the country and had consistent MOH advocates for the method who promoted family planning programming. Mali's MOH also encouraged the strategy of task shifting in SDM provision, training 13,000 community health workers in SDM teaching and promotion in areas with low uptake and accessibility to other modern methods of family planning.

Due to the decentralized nature of health policy and service provision in India, IRH partnered directly with the of Jharkhand State MOH in promoting the SDM, concentrating first on half of the state's districts with the greatest need for family planning services. Jharkhand included the SDM in state training, measurement, and family planning policies, and within 11 years, 6% of registered family planning users in Jharkhand were using the SDM, and half of the state population had heard of the SDM as a method of family planning.³⁹

No country managed to include CycleBeads in national commodity procurements as it was

considered an unconventional medical commodity and supplied by only 1 U.S.-based company. Supplies of CycleBeads were purchased through international NGOs, faith-based organizations, or donor bilateral funding and were then distributed within private and public sector clinics. The lack of national procurement of CycleBeads limited the continued implementation of the SDM and remained the most common barrier to national institutionalization of the method. The free digital versions of CycleBeads, in the form of mobile device apps, may help countries overcome this barrier in the future.

■ DISCUSSION

This analysis showed various enablers and barriers to the SDM's community-level introduction and national-level scale-up. Pilot introductions were largely successful in generating demand for and correct use of the SDM, especially among new users of family planning. At the national level, the scale-up of the SDM were predicated on strong levels of government cooperation and broad-based coalitions of partners and advocates for the method. As in the cases of Bolivia, Haiti, Nicaragua, and Senegal, even after a successful pilot introduction of the SDM, without sufficient levels of advocacy and cooperation from national actors, the SDM will not be scaled up beyond the pilot intervention sites. Other countries with a more robust institutionalization of the SDM, including Burkina Faso and the DRC, had both strong levels of support from national stakeholders and an active coalition of partners invested in its implementation.

The low percentage of SDM acceptors in comparison to other contraceptive methods may have been a barrier to stakeholders' investment in national implementation of the method. Although community pilots demonstrated a level of demand for the SDM across numerous demographic indicators, in those studies that measured the percentage of SDM users within the broader contraceptive method mix, the percentage of family planning acceptors who chose the SDM did not move beyond 1%–5%. Worldwide, about 4% of all couples of reproductive age have used fertility awareness-based methods.⁴¹

Results from this analysis demonstrated that demand for the SDM was especially pronounced in communities already practicing fertility awareness-based methods of family planning, including less effective methods like periodic abstinence and withdrawal. High acceptance rates in Burkina Faso, the DRC, and among Mayan communities in

No country managed to include CycleBeads in national commodity procurements.

Including the SDM in family planning programming had potential to improve couple's empowerment in reproductive decision making, sexual negotiation, and consistent condom use.

Guatemala were all due to existing traditions of periodic abstinence and demonstrated the potential to improve the efficacy of these methods in teaching the SDM. The higher demand for the SDM in certain populations may have been a reason that national governments chose a more limited implementation of the SDM among targeted groups, rather than a national, system-wide scale-up.

Results also demonstrated other community benefits to the SDM introduction, including improved couple's communication, dispelled myths on modern contraception, and strengthened family planning use more broadly. For many couples, the introduction of the SDM was the first opportunity to discuss family planning jointly and involve men in decision making on both sexual activity and contraceptive use.

To achieve these results, pilot introductions of the SDM relied on direct training of frontline health workers and often employed an aspect of social marketing in the community to encourage conversations and improve knowledge of family planning overall. The importance of high-quality health worker training was especially evident when examining both the results on discontinuation of the SDM as a family planning method and failure rate in the initial 3 months of use. Although the majority of discontinuation occurred in the first 3 months of method use, either due to irregular cycles or unintended pregnancy, discontinuation rates varied considerably across study locations, likely demonstrating variants in teaching the method and appropriately screening eligible users. It also underscored the need for accompanying social and behavior change communication programming, particularly around body literacy and fertility awareness, to ensure both health care providers and clients understand the cycle requirements for eligibility and to better prevent unintended pregnancies in the initial months of use.

Although there was skepticism that teaching the SDM was overly complicated and cumbersome for service providers, evidence from studies in this analysis demonstrated the opposite. There was evidence that various cadres of health workers, including at the community level, had the capacity to adequately screen potential users for method eligibility. If properly trained, followed with supportive supervision, and equipped with job aids and guidelines, multiple levels of health providers taught the SDM effectively, which allowed users to understand the mechanisms of use quickly, and correct use improved over time. However, health workers were known to underutilize evidence-based practice guidelines.⁴² Guidelines developed,

especially at the national level, were often not widely disseminated, and both in-service training and supportive supervision of health workers remained costly investments for governments with resource constraints.⁴³

The SDM was never more popular than other family planning methods, but there was still a demand for the method and other clear benefits to its introduction to improve client satisfaction and prevent unintended pregnancy. Those most attracted to the method were often first-time or discontinued users of modern family planning methods, and there was potential to improve contraceptive use within these populations by introducing the SDM. Further, inclusion of the SDM in family planning programming had potential to improve couple's empowerment in reproductive decision making, sexual negotiation, and consistent condom use.

Moving the SDM away from donor-supported pilots required both method champions at the national MOH level and buy-in from health care providers within the clinic and community. This proved challenging as some family planning/reproductive health commentators argued against promoting the SDM in family planning programming, stating that there wasn't sufficient evidence on the efficacy of the SDM to merit its promotion as a modern method of family planning.⁴⁴ This debate and skepticism of the method affected the level of investment in the SDM among family planning donors and implementing partners and buy-in at the national and community level in LMICs. Even within the countries targeted for national scale-up by IRH, barriers to its continued implementation remained. Some of the access barriers related to procurement may have been overcome given the development of the iCycleBeads app.

Limitations

In reviewing the published literature available to complete this landscape review, 2 main limitations on the data arose: the preponderance of gray literature and high level of influence of IRH on the SDM research. The majority of literature on the implementation of the SDM were not peer reviewed, gray literature reports from foreign assistance programs. These reports were also all published by IRH. Researchers at IRH had also published 5 of the 9 peer-reviewed articles included in the study; the 4 others were published by non-IRH-affiliated researchers in Ethiopia,¹⁰ Guatemala,¹³ and Turkey.^{5,6} Even within external

If properly trained, health providers taught the SDM effectively, and correct use improved over time.

database searches, the high imprint of IRH on published material on the SDM was noteworthy. This demonstrated not only a limited investment in the SDM's implementation in LMICs outside of IRH but also a potential for bias in published literature, given IRH's initial development in the method and interest in its proliferation.

CONCLUSION

Pilot introductions of the SDM demonstrated that the method was acceptable, especially to users of other fertility awareness-based methods of family planning or those concerned about side effects of hormonal contraception. Many SDM acceptors were first-time users of modern family planning. Other community benefits of the SDM's introduction included improved couple's communication, male involvement in family planning, and increased contraceptive uptake overall. Both discontinuation and method failure rates varied across study sites, highlighting the importance of high-quality health worker training in teaching the method and screening potential users. Tendency to experience unintended pregnancies in the first 3 months of use also demonstrated a need for more demand-side interventions to teach fertility awareness and body literacy when introducing the method to users.

At the national level, multiple barriers to the SDM's implementation and scale-up remained. Although the SDM had been piloted in over 30 countries worldwide, 16 countries had undergone rigorous scale-up processes to mainstream the SDM within the broader family planning method mix. Twelve of those countries had included the SDM in national family planning protocols, measurement tools, and health worker training, but no country managed to get CycleBeads into national procurement.

National implementation of the SDM was predicated on strong local political will and a broad-based coalition of local advocacy partners coordinating the method's implementation. There was little evidence of national scale-up of the SDM beyond the 16 countries included in this study. Although pilot studies demonstrated the potential for the SDM to match unmet contraceptive needs in key populations, strengthen male involvement, and increase overall family planning uptake, both demand-side and institutional barriers to include the SDM in the family planning method mix persisted.

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REVIEW

A Rapid Review of Available Evidence to Inform Indicators for Routine Monitoring and Evaluation of Respectful Maternity Care

Patience A. Afulani,^a Laura Buback,^a Brienne McNally,^a Selemani Mbuyita,^b Mary Mwanyika-Sando,^c Emily Peca^d

We present a set of indicators that could be used to measure the effects of programs on RMC. Integrating these indicators into programs to improve quality of care and other health system outcomes will facilitate routine monitoring and accountability around experience of care.

ABSTRACT

Background: Some opportunities to routinely capture and improve respectful maternity care (RMC) during facility-based childbirth include quality improvement (QI) initiatives, community-based monitoring efforts through community score cards (CSC), and performance-based financing (PBF) initiatives. But there is limited guidance on which types of RMC indicators are best suited for inclusion in these initiatives. We sought to provide practical evidence-based recommendations on indicators that may be used for routine measurement of RMC in programs.

Methods: We used a rapid review approach, which included (1) reviewing existing documents and publications to extract RMC indicators and identify which have or can be used in facility-based QI, CSCs, and PBF schemes; (2) surveying RMC and maternal health experts to rank indicators, and (3) analyzing survey data to select the most recommended indicators.

Results: We identified 49 indicators spanning several domains of RMC and mistreatment including dignified/nondignified care, verbal and physical abuse, privacy/confidentiality, autonomy/loss of autonomy, supportive care/lack thereof, communication, stigma, discrimination, trust, facility environment/culture, responsiveness, and nonevidence-based care. Based on the analysis of the survey data, we recommend 33 indicators (between 2 and 6 indicators for each RMC domain) that may be suited for incorporation in both facility-based QI and CSC-related monitoring efforts.

Conclusion: Integrating RMC indicators into QI and CSC initiatives, as well as in other maternal and neonatal health programs, could help improve RMC at the facility and community level. More research is needed into whether RMC can be integrated into PBF initiatives. Integration of RMC indicators into programs to improve quality of care and other health system outcomes will facilitate routine monitoring and accountability around experience of care. Measurement and improvement of women's experiences will increase maternal health service utilization and improve quality of care as a means of reducing maternal and neonatal morbidity and mortality.

BACKGROUND

Documentation of neglectful, disrespectful, and abusive care in health facilities globally has elevated respectful maternity care (RMC) to the forefront of global discussions on the quality of maternity care. Such mistreatment during pregnancy and childbirth care is a violation of human rights. In addition, it deters childbirth in health facilities and may have more direct effects on maternal and neonatal outcomes.^{1,2}

Because addressing disrespect and abuse (D&A) is important to reducing maternal mortality and morbidity, the World Health Organization (WHO) issued a statement calling for greater action, dialogue, research, and advocacy on RMC.³ According to the WHO, RMC refers to care organized for and provided to all women in a manner that maintains their dignity, privacy, and confidentiality; ensures freedom from harm and mistreatment; and enables informed choice and continuous support during labor and childbirth.⁴

Early qualitative research on D&A during childbirth in countries such as Ethiopia, Kenya, Mozambique, and Tanzania exposed concerning degrees of D&A,⁵ which precipitated stakeholder demand for taking action to improve women's childbirth experiences. Consequently,

^aInstitute for Global Health Sciences, University of California San Francisco, San Francisco, CA, USA.

^bIndependent consultant.

^cAfrica Academy for Public Health, Dar es Salaam, Tanzania.

^dUniversity Research Co., LLC, Chevy Chase, MD, USA.

Correspondence to Patience Afulani (patience.afulani@ucsf.edu).

there has been much effort to quantitatively measure and describe instances of negative experiences (D&A or mistreatment) as well as positive experiences of maternity care (respectful care), acknowledging that one is not the converse of the other. Much of this work has focused on intrapartum care, although there is emerging evidence that D&A also occurs along the reproductive, maternal, newborn, and child health continuum.^{6–9}

Most quantitative studies have investigated D&A based on the categories proposed by Bowser and Hill: physical abuse, nonconsented care, non-confidential care, nondignified care, discrimination, abandonment of care, and detention in facilities.¹⁰ Some have also applied the typologies of mistreatment proposed by Bohren et al (2015) that include these third-order themes: physical, sexual, and verbal abuse; stigma and discrimination; failure to meet professional standards of care; poor rapport between women and providers; and health system conditions and constraints.⁵ However, translation of these concepts into data collection tools has not been consistent. In a review of 5 studies in Ethiopia, Kenya, Nigeria, and Tanzania by Sando et al (2017), the prevalence of D&A ranged from 15% to 98%.¹¹ These wide-ranging results in similar contexts highlighted varying methodologies along with various sources of systematic errors related to operational definitions and measurement of the categories, selection of sites and participants, as well as mode, timing, and setting of data collection.¹¹

Simultaneously, there has been an increase in work toward development of validated tools that capture women's childbirth experiences. In a systematic review conducted by Nilver et al (review completed in January 2016), they identified 36 instruments developed for measuring various aspects of women's childbirth experiences. Only 7 of the instruments, none of which had been validated in a low- or middle-income country (LMIC), had good psychometric properties.¹² However, since the review, 2 scales have been developed for measuring women's childbirth experiences in LMICs, both with good psychometric properties—high validity and reliability. These include the RMC perception scale validated in Ethiopia¹³ and the person-centered maternity care scale validated in Ghana, India, and Kenya.^{14–16} In addition, 2 additional scales have been validated in Canada for measuring respect and autonomy in high-resource settings.^{17,18} These scales include items that extend the work on women's experiences beyond measuring D&A to measuring various positive aspects of women's childbirth experiences. The questions in

these scales, as well as questions in various prior questionnaires for surveys and birth observations on women's experiences, provide useful indicators for evaluating interventions to improve women's childbirth experiences.

Further, WHO's Network for Improving Quality of Care is working with 10 pilot countries to incorporate a modest set of common quality of care indicators for routine monitoring of maternal and newborn care. The Network's monitoring framework includes a flexible set of indicators for each WHO quality of care domain, including the 3 experience of care domains. The small set of common measures includes a mix of health outcome, processes of clinical care, infrastructure/input indicators, and 3 initial RMC indicators, namely: proportion of women who receive predischARGE counseling, experience verbal or physical abuse, and who are able to have a companion of choice.¹⁹ Other process and outcome indicators related to RMC are detailed in the WHO standards for quality of maternal and neonatal health care.²⁰ Although these are positive steps, how to incorporate indicators and support sustained measurement of women's experiences of care from their perspective remains a challenge.

There is an opportunity to translate the lessons learned from the early and largely well-funded research studies on RMC into feasible and sustainable routine indicators of experiences of care. Opportunities to routinely capture experience of care include facility-based quality improvement (QI) initiatives, community-based monitoring efforts through accountability mechanisms such as community score cards (CSC), as well as performance-based financing (PBF) initiatives. QI interventions vary in form but generally consist of a structured approach to measure and improve quality of care on a continuous basis. Their objective is to improve quality based on the findings of routine quality assessments, which could be through surveys, observations, or other methods.^{21–23} CSCs and similar approaches like citizen report cards have a similar aim of continuous improvement but through accountability mechanisms led by the community.²⁴ They seek input from users on experience of care, often using participatory methods such as community meetings or consultations to get feedback from both users and providers to guide improvement efforts.^{25–27} PBF, on the other hand, is generally a mechanism to measure and incentivize providers' and facilities' performance: facilities and providers earn incentives based on achievement of specific performance criteria.^{21,28,29}

For this review, we wanted to consider widely used approaches and platforms with potential to generate routine data for accountability on RMC in lower-resource settings. QI or assurance approaches have been used in LMICs for more than 30 years and are a major source of investment by major donors such as the United States Agency for International Development (USAID). The modern paradigm of improving health care quality has been characterized as quality management with a “focus on the client, systems and processes, teamwork, and the use of data.”³⁰ There are examples of QI as a tool to advance RMC with the potential to learn more about how to sustain and institutionalize these opportunities to use data on experiences of care for QI.^{31,32}

CARE’s CSC social accountability approach (and other similar models) can contribute to improvements in service availability, access, utilization, and quality.³³ CSCs allow for systematic collection of feedback (or data) to improve public services and have been used to inform dimensions of quality such as user-centered indicators like providing respectful care, listening to patients, and respecting privacy.^{24,33}

PBF programs have become a popular development approach for improving quality of care. A recent review identified 32 programs in 28 LMICs, which collectively produced a total of 68 quality measurement tools.²⁸ Maternal and child health was often a focus and granting of rewards were based on measuring performance. Although the incentives were largely tied to aspects of structural quality versus process and outcome measures, there is potential to include RMC measures (now conceptualized as important aspects of quality) within these schemes.

Given more recent efforts and potential to advance RMC through PBF, QI, and CSC, these platforms were chosen as a starting point for investigation into identifying D&A/RMC indicators for monitoring, accountability, and improvement. This review addresses the dilemma of deciding which D&A/RMC indicators may be best suited for routine monitoring. Integrating such indicators into existing operational schemes for QI may provide stakeholders with a solution to the ongoing challenge of routine RMC improvement.

The objective of this rapid review was to provide practical evidence-based recommendations on indicators that are best suited for more routine measurement of RMC and D&A, using QI, CSCs, and PBF initiatives as example platforms. This article is not endorsing or promoting the aforementioned (or any other) approaches to addressing

D&A/RMC. Instead, we are recommending indicators that can be integrated into existing platforms.

The review was originally motivated by the authors’ engagement in the Global Respectful Maternity Care Council³⁴ and inspired by the USAID-funded Health Evaluation and Applied Research Development (HEARD) project’s³⁵ activities in East Africa, during which national decision makers posed the question: “what indicators should we use for monitoring performance on RMC?” The answer is not simple, and the work required to best answer the question can easily result in the general status quo: exclusion of RMC indicators from routine measurement. Therefore, to advance the thinking around which indicators are most suitable, this article presents available existing indicators to inform selection and testing of indicators in LMIC contexts and can serve as a useful starting point for future consultations to support decision making.

METHODOLOGY

Guided by the goal of this project, which was to provide timely evidence to make recommendations for the inclusion of RMC indicators for routine monitoring, we used a rapid review approach. Rapid review has been defined as “a type of knowledge synthesis in which systematic review processes are accelerated and methods are streamlined to complete the review more quickly than is the case for typical systematic reviews.”³⁶ Systematic reviews take at least a year to complete, but rapid reviews take an average of 5–12 weeks to complete. Therefore, they are able to provide evidence within a shorter time frame to inform health policy, programming, and systems decisions.^{36,37}

The rapid review had 3 phases. We first started with a review of handpicked existing documents to identify indicators that have been used to measure RMC or D&A/mistreatment. These initial documents included the RMC indicator compendium by the RMC measurement workgroup of USAID’s Maternal and Child Health Integrated Program and the WHO standards for improving quality of maternal and newborn care in health facilities, which includes standards related to RMC.^{20,38,39} We also reviewed all the quantitative studies in the mixed-methods systematic review by Bohren et al that are also described by Sando et al in an article on methods used in prevalence studies for D&A.^{5,11,40–45} In addition, we included 2 articles describing the validation of scales for measuring women’s experiences in LMIC settings.^{13,14}

We present available existing indicators to inform selection and testing of indicators in LMIC contexts.

Integrating RMC indicators for routine monitoring into existing QI operational schemes may provide stakeholders with a solution to the challenge of routine RMC improvement.

From these documents and publications, we identified indicators of RMC and D&A/mistreatment and extracted them into a Microsoft Excel spreadsheet by: domain, indicator, source of indicator, specific questions asked or observation instructions, type of indicators (observed or self-reporting), how the indicator was used (e.g., exit survey, facility-based routine data collection, etc.), where the indicator was used (country and population), if it was validated, and full citations of documents/papers in which the indicator was referenced. We then updated the spreadsheet by searching on the Internet for additional publications on RMC and D&A. We reviewed the RMC council resources page and searched on PubMed using the key words “respectful maternity care,” “mistreatment,” “disrespect and abuse,” and “person-centered maternity care” published between 2015 and the time of the review (October 2017). We focused on indicators that could be measured quantitatively. In total, we reviewed 35 articles on D&A and RMC.

The second phase of the rapid review identified RMC/D&A indicators that had been used in CSCs using the keywords “maternal health,” “obstetrics,” “respectful maternal care,” “labor and delivery,” and “community score cards” in PubMed and Google Scholar searches. Five articles were identified from this review, and the indicators from these documents were extracted into the spreadsheet. Since few indicators had actually been used in the CSCs, we also included RMC indicators mentioned as potentially useful in CSCs. In addition, we reviewed 11 handpicked articles to identify RMC indicators that could be used for PBF. We then updated the indicator spreadsheet to identify which could potentially be used in CSCs and PBF schemes. All papers reviewed are shown in [Supplement 1](#).

Finally, for the third phase of the rapid review, we developed a questionnaire with the list of indicators to survey the RMC and other maternal and child health experts. We asked respondents to select which of the indicators they would recommend for use in QI, CSCs, and PBF initiatives, whether they had used any of the indicators in their work, if they have been involved in developing measures for any of the indicators, if they had any concerns about any of the indicators, and if there were any indicators that they were aware of that were not included in the list provided. In addition, we collected demographic data on participants including gender, age, years of work experience in maternal and child health, continents and countries where they currently worked, type of organization in which they

worked, main area of work, and whether or not they had been involved in PBF or CSC projects. The survey was in English and self-administered online. It was conducted using the RedCap application⁴⁶ and distributed to the RMC council and Health Information and Publications Network listservs, as well as distributed directly to individuals involved in RMC measurement.

After conducting the survey, we analyzed the data and ranked the indicators based on their frequency of selection. We then grouped the indicators by the top 3 selected for each RMC domain for QI, CSC, PBF. The domains were based on classifications used in the various studies reviewed, which included a combination of domains from various prior frameworks including Bowser and Hill’s classification, the typologies of mistreatment, and WHO’s quality of care framework. We organized the domains to ensure they captured all domains previously used but avoided as much overlap as possible (recognizing that most RMC domains are not mutually exclusive). Next, we reviewed each of the top 3 indicators in each domain to assess their importance, feasibility of measurement, if they included or were missing key indicators, and if there were any particular concerns raised about them. We reviewed the qualitative data from the responses to the open-ended questions for additional feedback on the indicators from the survey to guide this process.

■ RESULTS

From the rapid review we identified 49 indicators spanning several domains of RMC and mistreatment including dignified/nondignified care, verbal and physical abuse, privacy/confidentiality, autonomy/loss of autonomy, supportive care/lack thereof, communication, stigma, discrimination, trust, facility environment/culture, responsiveness, and nonevidence-based care. These indicators had been used as part of questionnaires and self-reported in exit interviews or in community surveys or as part of checklists for direct observations during labor and delivery and broader facility assessments. The full set of indicators extracted from the review are shown in [Supplement 1](#) with details on their sources and if they had been used in QI, CSC, or PBF initiatives.

Thirty-seven people responded to the survey (34 female). Respondents worked in various regions around the world: 16 in East Africa; 6 each in West Africa, Southern Africa, Asia, and North America; 5 in Europe; and 4 in South America. Eighteen worked in academic institutions, 12 in

government institutions, 10 in nonprofit institutions, and 2 in for-profit institutions. Most (25) were engaged in research, with between 3 and 8 in other activities such as teaching, clinical practice, program management and implementation, advocacy, and other related fields. Thirty respondents had never been involved in CSC or PBF initiatives. The indicators in the survey (Supplement 2) are ranked by how frequently the respondents selected them for QI, CSC, and PBF.

Almost all the indicators (about 46 of the 49 indicators) were selected by more than half of respondents for QI and CSC. However, only 12 of the indicators were selected by more than half of the respondents for PBF. In addition, there was concern among some respondents that it was premature to recommend specific indicators for PBF programs without testing them and also that RMC-related behaviors should be normative and not rewarded. Thus, we decided to present only indicators for QI and CSC as more work needs to be done to be able to recommend RMC indicators for PBF. This process led to a set of 33 indicators for QI and CSC, which includes between 2 and 6 indicators for each RMC domain that could be used for both facility-based QI and CSC initiatives (Table). All of the indicators except women's perception of wait time and trust could be obtained from both surveys and direct observations.^{13,14,39–45}

■ DISCUSSION

We have shared a set of indicators spanning various domains of RMC that might be used to measure program impacts on RMC. Although the initial focus of the review was for QI and CSC initiatives, these indicators can be used in other programs to improve women's experiences including for routine monitoring of RMC indicators in comprehensive maternal and neonatal programs or as part of other programmatic approaches to reduce mistreatment and improve RMC. The recommended indicators are a useful pool to draw from. However, selection of indicators for any setting should be preceded by a local review process by local experts and key stakeholders at the appropriate level (e.g., unit and facility leaders, community leaders, national policy and planning officials, bureaus of statistics, health management and information system designers, and managers, depending on the level of the initiative).

The goal of this process was to create a parsimonious list of measures that are core to RMC or respectful care more generally that could be feasibly measured. Thus, the list is neither exhaustive

nor meant to be prescriptive. For users who prefer a more extensive list of indicators, Supplement 1 is a useful reference. Also, this process focused on identifying the indicators that have been or could be used rather than how to measure them. The indicators in the Table include some that have been used as part of validated scales that have undergone psychometric analysis and others that have been used in surveys and observations without a formal validation process. For those that are part of validated scales, the scales could serve as important measurement tools to collect data on the indicators. For those that are not part of validated tools, they could still be measured as stand-alone questions in surveys or observations, with careful attention to wording of survey questions and observation prompts.

So, how do decision makers arrive at how many indicators and which ones? How the indicators are selected and used depends on local policy and program goals. Key questions to consider are: what are the prioritized aspects of respectful care in the context; whose perspectives do you want to measure and what are the feasible method(s) by which to measure these perspectives; and how can these indicators fit into existing data collection systems? These questions address implementation science goals of engaging stakeholders and marshalling the best evidence in support of decision makers with the goal of improving implementation outcomes such as acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability of efforts related to RMC.^{47,48} Applicability of the indicators may differ for locally driven compared to globally driven programs, and these need to be considered in the selection of indicators.

Other considerations include whether programs are interested in capturing more than discrete instances of D&A. To assess women's experiences more broadly on a continuous scale, we recommend using validated scales such as the person-centered maternity care^{14–16} and RMC perception scales.¹³ These scales can be used to generate experience of care scores that rate women's experiences of care from their perspective. Other programs might be interested in just the proportion of women who experienced certain aspects of care based on their intervention elements or targeted priority areas. For example, the proportion of women who were allowed a companion during labor and/or delivery, the proportion allowed to choose their birth position, the proportion verbally or physically abused, and proportion who experienced discrimination. Such

Decision makers can choose the indicators to include based on local policy and program goals.

These indicators can be used for QI and CSC initiatives and in other programs to improve women's experiences.

Table. Potential Respectful Maternity Care Indicators for Quality Improvement and Community Score Cards, by Domain

	Potential Information Source	
	Community-Based/ Exit Surveys With Women	Facility Assessments/ Observations
Dignified care		
1. Women treated with respect (subject to women's/local interpretation)	X ^a	X
2. Providers introduce themselves to women	X	X
3. Women treated in a friendly manner (subject to women's/local interpretation)	X	X
4. Women called by name	X	X
Privacy and confidentiality		
5. Physical privacy ensured (e.g., examined behind screens or curtains and other physical visual barriers)	X	X
6. Auditory privacy ensured (Private patient health information not heard by others)	X	X
7. Patient records and medical files are kept confidential (not accessible to people not involved in care provision)	X	X
No abuse		
8. No verbal abuse (insults, intimidation, shouting, scolding, threatening)	X	X
9. No physical abuse (slapping, hitting, pushing, pinching, restraining, or otherwise beating the patient)	X	X
10. No episiotomy given or sutured without anesthesia	X	X
Autonomy		
11. Providers explain to women what to expect and any medications administered, or procedures performed	X	X
12. Women give informed consent prior to procedures and examinations	X	X
13. Women and family involved in care (e.g., decision making on treatment and procedures)	X	X
14. Women allowed to assume position of choice during labor and delivery	X	X
Communication		
15. Women encouraged to and able to ask questions	X	X
16. Providers speaks to women in a language and at a language-level that they understand	X	X
Supportive care		
17. Women allowed to have choice of companion during labor and delivery	X	X
18. Not denying women care (e.g., refusing care for any reason)	X	X
19. Not abandoning women during labor and delivery (e.g., not responding to woman's call for help)	X	X
20. Providers ask about emotional feelings and concerns of women	X	X
21. Women trust staff (subject to women's interpretation)	X	—
Facility environment		
22. Cleanliness of facility	X	X
23. Facility is perceived safe	X	X
24. Facility not overcrowded/woman has own bed	X	X
25. Facility has electricity	X	X
26. Facility has water	X	X

Continued

Table. Continued

	Potential Information Source	
	Community-Based/ Exit Surveys With Women	Facility Assessments/ Observations
27. Enough providers		
Responsiveness		
28. Perception of wait time	X	—
29. Actual wait times	X	X
30. Payment/equity/cost		
31. No discrimination or poor treatment based on ethnicity, race, economic status, HIV status, birth outcomes, age, number of children	X	X
32. Not requesting bribes or informal payments	X	X
33. Women not detained at facilities due to lack of payment	X	X
34. Health care services affordable for all	X	X

^aX denotes that it can be obtained from relevant potential data source.

Supplement 1 has full list of sources for each indicator.

needs could be met by including specific individual items in surveys or observation checklists. The scales could also be used to obtain such individual percentages as well as scores in both prevalence studies and program evaluation.^{16,49}

Respectful care is a complex and multidimensional construct that is not well-captured by a single satisfaction measure in which responses are often inflated and lack sufficient specificity to be actionable.^{7,50,51} Also, just because a woman was not verbally or physically abused does not mean she was treated with dignity and respect. Additionally, experiences of respect may be intermixed with disrespect. For example, a woman could have been allowed a birth companion and still have received very little information or consent related to her care. Further, we want to avoid the idea that the implementation of one (albeit important) action, like hanging curtains for privacy, means respectful care was achieved. Therefore, we suggest a careful consideration of the domains of mistreatment and respectful care and generally recommend multiple indicators for a more holistic approach to assessing client experiences. Each domain in Table includes 2–6 indicators, and we recommend selecting at least 1 to 2 indicators from each domain based on program goals.

Irrespective of which indicator is selected, careful attention is needed for using it in a particular context. The person-centered maternity care scale items capture most (but not all) of the indicators and includes items in all domains except

payment/equity/cost.¹⁶ Therefore, it is a useful resource for measuring the indicators in QI, CSC, or other types of RMC interventions.⁴⁹ For the indicators not included in the scale, reviewing how those indicators have been used in prior studies and then testing in the setting will ensure questions are relevant, understandable, and measure what is intended.

Each program will also need to decide the most feasible and useful way to obtain information in their setting. The recommended indicators can be integrated into exit interviews with women, community-based surveys, as well as facility assessments/observations. However, each method has its limitations. Exit surveys are the most easily conducted but also have the highest bias from social desirability (i.e., women responding based on what they think is acceptable to say rather than based on what they actually experienced). For example, women may not want to report negative experiences when interviewed at the facility due to fear of retaliation. Observations may be the most objective, but they are also the most labor and time intensive, and observers' reports may not necessarily reflect women's experiences. Community surveys may be the best approach for CSCs since they likely will involve community participation or better still may be community led. Community participation in the overall project will facilitate entry into the community for data collection. The most cost-effective approach will depend on existing data collection

Respectful care is a complex construct that is not well-captured by a single satisfaction measure in which responses are often inflated and lack sufficient specificity to be actionable.

mechanisms in the particular setting. Where there is no existing data collection mechanism to integrate RMC indicators, facility-based exit surveys of women who have recently given birth might be the least expensive approach. However, the limitations of the approach selected must always be kept in mind.

In each case, quality training of all data collectors is essential, regardless of previous QI or CSC experience, due to the complex, sensitive, and subjective nature of many RMC indicators. Other key considerations will be related to sampling and timing of interviews or observations. In addition, integrating these indicators in routine health systems is challenging due to their need of extra workforce to collect the data and thus the need to advocate with policy makers to integrate them into health information systems.

Although this review focused on quantitative indicators, it is important to recognize the important role of qualitative data for more nuanced understanding of women's experiences of care. A mix of quantitative and qualitative methods of data collection and analysis are most optimal for understanding and monitoring women's experiences of childbirth care to inform program implementation. The development of local expertise in mixed methods will help support routine monitoring of quantitative indicators as well as the periodic application of qualitative methods (e.g., in-depth interviews or focus groups on a quarterly/semi-annual basis).

Limitations and Strengths

A potential limitation of this process was that we used a rapid review approach, which is less rigorous than a systematic review. However, rapid reviews are useful for synthesizing information in a more timely manner. In addition, given that the team involved in this work had prior experience in measurement and there were recent documents and reviews of RMC indicators, a rapid review was an efficient approach to promptly recommend RMC indicators. Rapid reviews are specifically useful for new and emerging research topics, as well as for assessing the amount of information available, which applies to a project for assessing the applicability of RMC indicators in other initiatives. The expert review component complemented the rapid review to increase the robustness of the recommended indicators. Expert reviews are often used in the user experience domain of the technology industry for new products to provide fast, practical input based on the usability of

a potential product. The principle is that experts know the domain very well, in this case RMC and maternal and newborn health, so they can provide recommendations for usability and feasibility.

Another limitation was the fact that we focused on only indicators for QI, CSCs, and PBF initiatives and were not able to recommend indicators for PBF. There is potential to include RMC indicators in PBF initiatives, but this requires further research. Additionally, we focused on indicators mostly used in the intrapartum period, even though RMC is important beyond the intrapartum period. For example, a growing body of research has highlighted that women also have poor experiences during prenatal care.^{6–9} Thus, there is a need for indicators to track women's experiences along the reproductive, maternal, newborn, and child health continuum. Some of the indicators recommended have been used to measure women's experiences during prenatal care,⁹ but more work is needed in this area. Furthermore, we did not include indicators that capture the provider experience and structural/systems-level drivers of mistreatment. These are important but require more work to make evidence-based recommendations.

The indicators each have their own limitations, depending on the implementation, context, and method of data collection. Some indicators are more objective (relatively), such as whether a provider introduces himself, if physical privacy is observed, or if there is verbal or physical abuse. However, some indicators such as being treated with respect and involving women in care, or trust, are more subjective and context-specific—whether self-reported or externally observed. Although factors related to respectful care such as infrastructure (e.g., supplies, infrastructure) are easiest to capture, real system improvements will only be informed through the inclusion of self-report from the client and provider perspectives. Social desirability and recall bias are limitations where indicators are self-reported, and the extent varies depending on place and timing of interviews. Observations may be more objective but subject to Hawthorne effect—providers may perform better than normal when being observed—and not directly capture women's experiences. The Hawthorne effect has not been a big issue so far in some studies as providers may not identify their behavior as mistreatment.^{31,52,53} But as provider awareness of RMC increases, it may become a bigger issue during observations. However, we will continue to grapple with these issues in any work involving assessing people's experiences

and decisions will have to be made carefully to balance relevance, accuracy, and feasibility.

Since we completed the review, there have been other quantitative studies measuring RMC. We did not attempt to systematically update our indicators. However, most of these studies measure mistreatment based on previously used indicators that were captured in the review. A key addition to the literature are the WHO tools for measuring how women are treated during facility-based childbirth that focus on measuring mistreatment through community surveys and labor observations.⁵⁴ However, the focus is on measuring existing indicators, most of which are captured in our original list. Notwithstanding, we note that the recommended indicators are intended to be comprehensive and representative of key domains of RMC but not exhaustive. Thus, we recommend these indicators as a guide and starting point for a consultative process to identify relevant RMC indicators for programs.

CONCLUSIONS

Although this review was initially motivated by our collaborative activities in East Africa and burgeoning efforts to use QI and CSC to advance RMC, the indicators could be used more globally by program implementers with objectives to measure and improve client experiences of care. Early implementers of these indicators are encouraged to document their experiences and lessons learned, particularly as they relate to the incorporation of indicators into routine monitoring and evaluation systems. Methodological work on RMC measurement is growing, and additional indicators may evolve from this process. QI and CSC initiatives are just 2 ways of improving RMC at the facility and community level through accountability mechanisms. Additionally, the opportunity for integration of RMC in PBF initiatives needs further exploration and research. There may also be other quality and performance improvement efforts that can adopt RMC indicators.

We hope that feasible, sustainable efforts to institutionalize monitoring and evaluation of D&A/RMC by local institutions emerge from this analysis—supported by continued partnership among all actors involved in these endeavors. Higher-level advocacy is needed for policies to assure RMC across all levels of the health system, and community-level interventions are needed to empower women and the community at large on their rights and knowledge of RMC. Such interventions will facilitate global efforts to

increase maternal health service utilization and improve quality of care as a means of reducing maternal and neonatal morbidity and mortality.

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