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Aisha Dasgupta, Michelle Weinberger, Ben Bellows, Win Brown

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Brian J Morris, John N Krieger, Jeffrey D Klausner

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Excellent Family Planning Progress in Nigeria Reported by PMA2020

- **Modern method contraceptive prevalence among married women in Nigeria has jumped to 16.0% in 2016 compared with <10% in 2013.**
- **Notable increases were observed in the South as well as in some Northern states that had strong programming.**
- **Most of the increase was in the uptake of highly effective implants and injectables.**
- **But substantial unmet need for family planning remains, especially among the poorest quintile.**
- **Implants and IUDs are not offered in many facilities and stock-outs are common, suggesting further progress is achievable with improved program effort.**

Glob Health Sci Pract. 2017;5(1):28–32
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- **More than 58,000 free vouchers distributed to young people, of which 74% were redeemed.**
- **79% chose long-acting reversible contraceptives (LARCs) and 51% received STI counseling.**

Client profile data snapshot:
- **69% had never previously used contraception and 96% were 20 or younger.**

Eva Burke, Judy Gold, Lalaina Razafinirinasoa, Anna Mackay

Glob Health Sci Pract. 2017;5(1):33–43
https://doi.org/10.9745/GHSP-D-16-00321

Community Health Workers as Social Marketers of Injectable Contraceptives: A Case Study from Ethiopia

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Karen Weidert, Amanuel Gessessew, Suzanne Bell, Hagos Godefay, Ndola Prata

Glob Health Sci Pract. 2017;5(1):44–56
https://doi.org/10.9745/GHSP-D-16-00344

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Miriam Cremer, Proma Paul, Katie Bergman, Michael Haas, Mauricio Maza, Albert Zevallos, Miguel Ossandon, Jillian D Garai, Jennifer L Winkler

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Sarah D Rominski, Emmanuel SK Morhe, Ernest Maya, Abukar Manu, Vanessa K Dalton

Glob Health Sci Pract. 2017;5(1):65–74
https://doi.org/10.9745/GHSP-D-16-00281

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Benjamin Nieto-Andrade, Eva Fidel, Rebecca Simmons, Dana Sievers, Anya Fedorova, Suzanne Bell, Karen Weidert, Ndola Prata

Glob Health Sci Pract. 2017;5(1):75–89
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Jessica Gergen, Erik Josephson, Martha Coe, Samantha Ski, Supriya Madhavan, Sebastian Bauhoff

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Anne Fitzpatrick, Katherine Tumlinson

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Judith McFarlane, Rozina Karmaliani, Hussain Maqbool Ahmed Khuwaja, Saleema Gulzar, Rozina Somani, Tazeen Saeed Ali, Yasmeen H Somani, Shireen Shehzad Bhamani, Ryan D Krone, Rene M Paulson, Atta Muhammad, Rachel Jewkes

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The MediCapt mobile app has promise for clinicians to capture medical and forensic evidence of sexual violence and securely transmit the data to legal authorities for potential use in prosecution. We believe this application broadens the traditional scope of mHealth to collecting evidence, and thus name it mJustice.

Ranit Mishori, Michael Anastario, Karen Naimer, Sucharita Varanasi, Hope Ferdowsian, Dori Abel, Kevin Chugh

Glob Health Sci Pract. 2017;5(1):138–151
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RAHI–SATHI Indo-U.S. Collaboration: The Evolution of a Trainee-Led Twinning Model in Global Health Into a Multidisciplinary Collaborative Program

RAHI–SATHI presents an innovative twinning model of global health academic partnership, resulting in a number of successful research activities, that features trainees or students as the driving force, complemented by strategic institutional support from both sides of the partnership. Others can promote similar student-led initiatives by: (1) accepting an expanded role for trainees in global health programs, (2) creating structured research and program opportunities for trainees, (3) developing a network of faculty and trainees interested in global health, (4) sharing extramural global health funding opportunities with faculty and trainees, and (5) offering seed funding.

Apurv Soni, Nisha Fahey, Abraham Jaffe, Shyamsundar Raithatha, Nitin Raithatha, Anusha Prabhakaran, Tiffany A Moore Simas, Nancy Byatt, Jagdish Vankar, Michael Chin, Ajay G Phatak, Shirish Srivastava, David D McManus, Eileen O'Keefe, Harshil Patel, Niket Patel, Dharti Patel, Michaela Tracey, Jasmine A Khubchandani, Haley Newman, Allison Earon, Hannah Rosenfield, Anna Handorf, Brittany Novak, John Bostrom, Anindita Deb, Soaham Desai, Dipen Patel, Archana Nimbalkar, Kandarp Talati, Milagros Rosal, Patricia McQuilkin, Himanshu Pandya, Heena P Santry, Sunil Thanvi, Utpala Kharod, Melissa Fischer, Jeroan Allison, Somashekhar M Nimbalkar

Glob Health Sci Pract. 2017;5(1):152–163
https://doi.org/10.9745/GHSP-D-16-00190

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The American Mock World Health Organization (AMWHO) provides a platform for students to apply their knowledge of global health policy through simulations of the World Health Assembly (WHA). This model engages and empowers future global leaders in health policy while sharpening their skills in diplomacy, public speaking, and conflict resolution. The major theme for the AMWHO 2015 was Universal Health Coverage, reflecting what the WHA had discussed in preceding months.

Mia Lei, Neha Acharya, Edith Kwok Man Lee, Emma Catherine Holcomb, Veronica Kapoor

Glob Health Sci Pract. 2017;5(1):164–174
http://dx.doi.org/10.9745/GHSP-D-16-00138

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EDITORIAL

Can We Expect Results-Based Financing to Improve Quality of Care?

Performance-based incentives as currently employed appear poorly adapted for improving quality of clinical processes. They mainly measure structural items that, while easier to measure, are remote from actual clinical quality, and they could even perversely lead to heightened attention to those factors at the expense of clinical quality.

See related article by Gergen.

Results-based financing (RBF) schemes in health care are premised on the notion that "paying for results" rather than for inputs is more likely to improve performance. But getting from that attractive hypothesis to program efforts that improve quality of care and outcomes at population scale—in the real world—is far from simple.

The article by Gergen[1] in this issue of GHSP offers an overview of a set of RBF schemes, mainly funded under the World Bank's Health Results Innovation Trust Fund (HRITF). Under this funding, performance-based incentives are paid to health workers and health facilities, with the intention of improving quality of health services for women and children. As of late 2016, this major funding program, supported primarily by the governments of Norway and the United Kingdom, has provided close to US$400 million in grants and more than US$2 billion in associated loans to RBF programs in 29 countries.[2]

STRUCTURE VS. PROCESS VS. OUTCOME

Incentives, as used in these schemes, get health worker attention but may not direct attention where it's most needed. As the Gergen paper acknowledges, in these financing schemes quality is operationalized largely in terms of *structure*, rather than *processes* or *outcomes* of care (using the language of the Donabedian model[3]). Among the 54 most common indicators tracked by the checklists used in the schemes Gergen et al. review, the large majority relate to what they describe as "structural quality." The 4 most frequently used are:

- Latrines/toilets present and in good working order
- Performance or activity reports submitted on time
- Financial and accounting documents available and well kept
- Fencing around the building existent and well kept

Important though such indicators may be, it's not at all clear that in the aggregate they constitute an adequate account of the causal factors that can be expected to drive improved *clinical processes* and *outcomes*. Indeed, in the Donabedian model, it is the additive effect of inputs and care processes that yield improved health outcomes. Using terms from the Institute of Medicine's conceptualization of health care quality, the focus needs to be on ensuring that *actual clinical care* provided to every client is safe, effective, patient-centered, timely, efficient, and equitable.[4]

To be sure, among the RBF performance indicators presented by Gergen et al., a few attempt to get at what care is actually provided and there is frequent discussion among RBF proponents about how to incorporate more quality of care process measures into financial incentive schemes in low-resource settings.

But, as described by Gergen et al., the data used for verification in the schemes they review are largely limited to information abstracted from routine registers and patient records; very little is based on direct observation or client exit interviews. In most instances, review of routine documents as described in the Gergen article will be inadequate to assess clinical quality or appropriateness of care (e.g., "Integrated Management of Childhood Illness [IMCI] protocol is applied correctly").

WHAT'S IMPORTANT MAY NOT BE READILY MEASURABLE; WHAT'S MEASURABLE MAY NOT BE IMPORTANT

We can assume that those developing performance measures for these funding schemes would have very much liked to have more and better measures of actual

Unlike tracking of service volume, clinical quality of care tends to be difficult to measure.

quality of care. Unlike tracking of service volume, however, clinical quality of care tends to be difficult to measure. This challenge is particularly acute in low-resource settings where primary patient data are often absent (e.g., lack of standardized patient records, stock-outs of registers) and routine health information systems often include few quality of care clinical process and health outcome measures. Concomitantly trying to measure quality of care while building health information systems capable of measuring quality is a common challenge faced by programs implementing quality improvement and financial incentive schemes alike.

But if we are seeking to incentivize based on measures of performance, unless we use measures that closely approximate what we're most interested in influencing, we risk misdirecting effort toward factors that are less likely to contribute to improvements on meaningful endpoints and away from potentially more important unmeasured factors.

THE FULL SET OF CONDITIONS REQUIRED FOR IMPROVED OUTCOMES

Moving back a step on the causal chain from the process of clinical care, we have a set of conditions that need to be met if appropriate, quality care is to be provided for every client every time. This has been referred to as "implementation strength."[5] One simple way to think about the immediate proximal set of such factors is to remember the acronym ACME; for a specific service to be delivered such that it produces its desired benefit, systems need to be functional such that health workers are:

In order to provide quality care, health workers need to be available, capable, motivated, and enabled.

- **A**vailable to those needing the service
- **C**apable, i.e., have the knowledge and skills required for that particular service
- **M**otivated to provide the service
- **E**nabled, i.e., have the necessary infrastructure, equipment, drugs, and other supplies

Not all of this will be easily measurable, but any scheme aiming to bring about improved individual- and population-level health outcomes must seriously come to grips with the conditions that need to be satisfied to achieve such improvements.

PERFORMANCE: THE REAL THING OR ONLY THE APPEARANCE?

For RBF schemes to be effective, those designing and delivering them need to be clear-eyed about what behaviors they are actually incentivizing. Like measurement of quality, rigorous, independent verification can be difficult and costly. But without such verification, it is not possible to know whether these schemes are, in fact, contributing to improved quality of care. In the absence of clear evidence for the effect of financial incentives on improved quality of care and health outcomes in low-resource settings,[6] it is more important than ever to pursue rigorous assessments of the effect and costs of implementing such schemes.

Incentive schemes risk rewarding the mere appearance of improved performance. It is not clear that implementation of these schemes has been accompanied by adequate safeguards against complicity, for example, between those in the health facility being incentivized and their peer-reviewers.

WHAT'S MISSING FROM THIS PICTURE?

On finishing the Gergen article, the reader may be left wondering:

- Why should one believe that incentivizing primarily structural factors will necessarily lead to improvement in clinical processes or outcomes?
- Even if there were an impact on quality or outcomes, to what extent would it prove feasible to replicate and sustain such results at scale?
- Implemented at scale, strong data validation mechanisms (like the rigorous impact evaluations done when these schemes were first piloted[7]) would be difficult to sustain. In the absence of such strong validation, won't there be a tendency to try to game the system since maintaining the appearance of good performance will often be easier than producing the real thing?
- For improving quality, what is more likely to be effective: (1) data use within the health facility for directing problem solving, or (2) documenting and reporting data to submit elsewhere, serving as a basis for an incentive calculation? Or both? How compatible are these 2 approaches to improving performance?
- How consistent are performance-based incentives, as used in these schemes, with known best practices in the quality improvement field?[8]

In fairness, RBF schemes are typically not just about quality improvement; they are concerned

with program performance more broadly defined. But surely we are kidding ourselves if we think that measuring and incentivizing performance operationalized mainly in terms of "structural" factors will take us very far toward improved clinical care and health outcomes. –*Global Health: Science and Practice*

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EDITORIAL

Winners of the Consortium of Universities for Global Health–Global Health: Science and Practice Annual Student Manuscript Contest

James D Shelton,[a] Pierre Buekens,[b] Elizabeth Grant[c]

The 2 inaugural winners of the CUGH–GHSP Annual Student Manuscript Contest describe (1) the American Mock World Health Organization model for engaging students in global health policy and diplomacy, and (2) a successful Indo-U.S. twinning model of global health academic partnership led by students.

See related articles by Lei and by Soni.

This issue marks the inauguration of publication of the first 2 winning articles from the Consortium of Universities for Global Health (CUGH)–Global Health: Science and Practice (GHSP) Annual Student Manuscript Contest. Each year at the CUGH annual meeting, we intend to select the best manuscripts from among student papers submitted for this competition. Manuscripts are judged by members of CUGH's Research Committee and one or more GHSP editors. Winning manuscripts are announced at the annual meeting and, assuming they undergo the further appropriate peer review, published in a subsequent GHSP issue.

The 2 winning articles in this issue are:

- Lei et al. American Mock World Health Organization: An Innovative Model for Student Engagement in Global Health Policy[1]
- Soni et al. RAHI–SATHI Indo-U.S. Collaboration: The Evolution of a Trainee-Led Twinning Model in Global Health Into a Multidisciplinary Collaborative Program[2]

The articles are especially notable for 2 reasons. First, they provide a healthy amount of rich process description, in keeping with GHSP's strong interest in documenting not only results but also how interventions are carried out. Thus, readers can better understand how implementation might be adapted for other situations. Second, both articles reflect a high level of student initiative and leadership in carrying out the activities described in the papers.

One of the major strengths of CUGH as reflected in its annual meeting is the strong engagement of students; students are actively engaged in poster sessions, presentations, and satellite sessions. Accordingly, we see the Annual Student Manuscript Contest as an excellent opportunity to collaborate with CUGH to help advance the future generation of global health technical excellence and leadership.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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COMMENTARY

"New Users" Are Confusing Our Counting: Reaching Consensus on How to Measure "Additional Users" of Family Planning

Aisha Dasgupta,[a,b] Michelle Weinberger,[c] Ben Bellows,[d] Win Brown[e]

FP2020's overarching goal is framed around the new metric of "additional users." This measure inherently captures population-level change but has been conflated with other ambiguous metrics, such as "new users." Therefore, we propose a standard set of terms to provide more consistent measurement. Although commonly used service-level metrics cannot be directly compared to the population-level metric of additional users, we describe 2 modeling approaches that can allow service-level data to inform estimates of additional users.

INTRODUCTION

In July 2012, the London Summit on Family Planning reenergized the reproductive health field by establishing a new commitment to bring modern contraception to women and girls with an unmet need for family planning—those who say they do not want a child soon or at all but are not currently using contraception. At that time, it was estimated that 222 million women in the developing world had an unmet need for modern contraception.[1] Most of these women were concentrated in the world's 69 poorest countries.[2] The family planning community committed at the Summit to enabling an *additional* 120 million women in these 69 countries to use modern contraception by 2020.[2–4] The community felt that designating a single number would help rally the community and push forward a renewed focus on family planning.[3]

Nearly 5 years later, the widely recognized "120 by 20" goal supported by the Family Planning 2020 (FP2020) global partnership can be credited for galvanizing renewed commitment to family planning. However, the new metric of "additional users"—an aggregate metric that estimates how many more modern contraceptive users there are now compared with the estimated 2012 baseline number—has created confusion about the definition and meaning of several other related family planning metrics, including "new users," "acceptors," "first-time users," and "adopters." It has also raised the question of how service-level metrics collected by programs can be linked to the aggregate concept of "additional users" to assess progress of individual programs toward population changes in contraceptive use at the country level. In this article, which follows from a panel discussion among the 4 coauthors held during the 2016 International Conference on Family Planning, we outline several of the metrics currently used to measure family planning program progress and propose a preferred set of service-level metrics to inform contributions to the FP2020 aggregate-level goal of reaching "additional users." We also describe 2 approaches—Track20's Family Planning Estimation Tool (FPET) and Marie Stopes International's Impact 2 model—for bridging the gap between service-level measures available in programs' routine service statistics and the aggregate metric of additional users. Finally, we draw attention to the need for more robust data collection systems that allow for the collection of harmonized routine longitudinal metrics rather than focusing solely on visit-based service statistics or cross-sectional household surveys.

ALIGNING INDICATORS: WHY IT MATTERS

Metrics, especially when used by donors and governments to set goals and measure performance, can drive how family planning programs are designed and implemented. Using the right metrics ensures that program growth translates into additional impact, gives credit for ensuring current family planning clients have continued access to services, and links programmatic increases in

[a] Marie Stopes International, London, UK.
[b] United Nations Population Division, New York, NY, USA.
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contraceptive use with expanded national coverage, not just attracting clients from other providers.

Not all current data management systems enable effective monitoring of family planning program performance. A key dimension to the success of any family planning program that is not fully captured with service statistics, for example, is the effective, voluntary use of a preferred contraceptive method by each program beneficiary over time. Reasons for method-specific discontinuation rates are critical to understanding this longitudinal perspective but this information is often not captured with service statistics. Researchers have instead created models that use available service statistics to estimate program performance.

Several types of indicators are collected to measure family planning program performance, and in particular contraceptive use. Some of these indicators, such as "commodities distributed" and "first-time users," are collected through routine client-level service statistics or client exit interviews, whereas others, such as "users" and "additional users," are estimated in models or collected from population-level surveys. To ensure clarity of terminology used throughout this article, we summarize these definitions in the Box.[5]

THE AGGREGATE MEASURE OF "ADDITIONAL USERS" BASED ON HOUSEHOLD SURVEYS AND MODEL-BASED ESTIMATES

"Additional users" is inherently an *aggregate* metric indicating how many more modern contraceptive users there are across the 69 poorest countries now compared with the estimated 2012 baseline number of modern contraceptive users in the same countries. Each year, the FP2020 Secretariat publishes its annual progress report showing progress toward the "120 by 20" goal—FP2020's first core indicator.[6,7] The additional user results are shown at the country level as well as summed across all 69 countries. At the country level, the number of additional users is calculated using 2 variables, the estimated modern contraceptive prevalence rate (mCPR) and the estimated number of women of reproductive age (WRA), at 2 time periods, currently and the 2012 baseline, as follows:

$$\textit{Additional users} = (WRA_{YYYY} \times mCPR_{YYYY}) - (WRA_{2012} \times mCPR_{2012})$$

Where YYYY = the current time period of interest

The estimate of current mCPR (FP2020's second Core Indicator) is a model-based estimate, informed by nationally representative household surveys, such as the Demographic and Health Surveys (DHS), Multiple Indicator Cluster Surveys (MICS), and Performance Monitoring and Accountability 2020 (PMA2020) surveys, as well as service statistics (in select countries) and historic regional and global patterns of change.

For FP2020, the goal of reaching 120 million additional users can only be achieved if family planning programs (1) continue to sustain services to more than 270 million women,[8] the number already using modern contraceptives in the world's 69 poorest countries when the FP2020 initiative began in 2012, and (2) further grow the number of users beyond this base. Thus, priority must be placed both on reaching non-users and on ensuring women who are currently using contraceptives have continued access to high-quality services to minimize discontinuation due to dissatisfaction.[9]

To date, national and global-level understanding of progress in family planning has typically been informed by household surveys, including DHS, MICS, and PMA2020, as well as other national and cross-national survey programs (such as the Contraceptive Prevalence Surveys, Reproductive Health Surveys, and World Fertility Surveys). Such surveys are invaluable in providing a cross-sectional insight into contraceptive use, typically from questions such as "Are you currently doing something or using any method to delay or avoid getting pregnant?" However, surveys have limited ability to capture the dynamic longitudinal nature of contraceptive use, including first-time use, discontinuation, switching of methods, resumption of use, and so on. An exception is the calendar section of the DHS questionnaire, which captures a woman's retrospective self-reported contraceptive status (and method), pregnancies, births, breastfeeding status, and method terminations every calendar month for the 5 years prior to interview. Although these data do not suffer from problems of loss to follow-up, the calendar data are vulnerable to selection bias as only women surviving to interview can report, and there are likely to also be memory recall issues. Besides DHS's calendar method, there are some recent examples of electronic client information systems[10] and a handful of specialist studies[11,12] that have captured method switching or discontinuation, but overall conventional measurement

BOX. Key Terms Used to Talk About Women Using Contraception

Commonly Collected Routine Service Statistics Data

- **Client visits:** The number of times clients interacted with a provider for contraceptive services. In most cases, the same client is counted multiple times because the client comes for multiple visits (e.g., 4 injections over a year). Most health management information systems (HMISs) count client visits.
- **Clients served:** The number of clients who received contraceptive services in a given time period, often 1 year. This is often counted using a client-based HMIS and thus is not very common as few systems have the means to track a uniquely identified client across multiple visits (usually requires an electronic-based system).
- **Commodities distributed/services provided:** The number of contraceptive commodities distributed or services provided to clients (e.g., number of pill cycles, number of IUDs, number of male sterilization services). In some cases, this may be captured at the client level (e.g., counted when products or services are provided to clients), while in other cases they might be counted further back in the supply chain (e.g., counted when products are distributed to a clinic). These counts are often aggregated into the couple-years of protection (CYPs) measure.

Family Planning Client Characteristics Data Captured Routinely or via Client Surveys

- **First-time user:** A person who starts using modern contraception for the first time in her life.
- **Lapsed user:** A person who has used modern contraception at any time in the past, but is not currently using a modern method.
- **Adopter:** A client who was not using a modern contraceptive method at the time of her visit, which includes first-time users and lapsed users. The definition of "time of her visit" can vary, for example, today, last month, or last 3 months.
- **Provider-continuer:** A client who, at the time of her visit, was already using a modern contraceptive method that she received from the same service provider (or same network) and comes back for another family planning service (e.g., for resupply of the same method or to switch methods). The definition of "time of her visit" can vary, for example, today, last month, or last 3 months.
- **Provider-changer:** A client who, at the time of her visit, was already using modern contraception and comes for another family planning service, but who had previously received her family planning from a different provider. The definition of "time of her visit" can vary, for example, today, last month, or last 3 months.

Note: The 3 terms adopter, provider-continuer, and provide-changer are mutually exclusive groups: all clients served fall into only 1 of these 3 categories. Collectively, these 3 terms are often referred to as the "client-use profile."

Population-Level Data (not directly captured in routine data)

- **User:** A person who is currently using contraception, regardless of when the method was received. This is not directly comparable with the number of clients served in a year, because it includes women still using long-acting or permanent methods received previously (e.g., a woman who had an IUD inserted in 2012 may still be an IUD user in 2015). This can be estimated through population-based surveys, such as Demographic and Health Surveys, Multiple Indicator Cluster Surveys, or Performance Monitoring and Accountability 2020 surveys, or through modeled estimates of the contraceptive prevalence rate and the number of women of reproductive age (e.g., Track20's Family Planning Estimation Tool and United Nations Population Division estimates) or modeling from service provision data (e.g., Marie Stopes International's Impact 2 model). Note that "currently using" can be interpreted differently by women asked about current use in survey questionnaires.
- **Additional users:** The net number of current contraception users above a specified baseline; in the case of FP2020, the baseline is the number of current contraception users in 2012 in the world's 69 poorest countries. Note that this concept does not apply to an individual but rather to an aggregate population.

Terms We Suggest Dropping

- ***New user:*** *A term that has multiple definitions including first-time user, new to the provider (e.g., provider-changer), new to the method (e.g., switching methods), not recently using a method (e.g., lapsed user), and even additional user.*
- ***Acceptor:*** *A term that has multiple definitions including first-time user, new to the provider (e.g., provider-changer), new to the method (e.g., switching methods), not recently using a method (e.g., lapsed user), using a method after an abortion or birth, and even additional user.*

Because of the ambiguity with the terms "new user" and "acceptor" and because the concepts are adequately captured in other clearer terms, we suggest the family planning community drops these 2 terms from our list of terminology.

approaches to contraceptive use are unable to capture this type of detail.

LINKING INDIVIDUAL CLIENT AND VISIT DATA FROM ROUTINE SERVICE STATISTICS WITH THE AGGREGATE MEASURE OF "ADDITIONAL USERS"

Performance monitoring of program outputs and trends in family planning services occurs below the aggregate national and global levels, and presents different measurement challenges. Examples include government monitoring of provision of family planning services through the public sector or a private service delivery organization monitoring provision throughout its delivery network. In either case, program monitoring generally relies on routine data from an HMIS. These data originate from registers kept at family planning service delivery points, in which key programmatic elements are recorded on a daily basis, such as date of visit, age and gender of the client, type of family planning service provided, and so on. Yes, information available from HMIS and other routine systems are notoriously compromised by data quality issues, but they are valuable for indicating basic details of service delivery.

At the same time, programs are increasingly interested in understanding how program-level outputs contribute to population-level changes in contraceptive use in the country. More specifically, they want to know whether their services are contributing to an increase in the number of additional users nationally. To answer this question, one must connect outputs measured at an individual level (e.g., clients served) to an aggregate change in contraceptive use nationally (e.g., additional users). As an attempt to bridge this gap, some programs capture information on recipients of services. The most commonly collected client attributes are "adopters" and "first-time users." These metrics have their merits and can inform aspects of increasing access to contraception. However, they are not comparable with each other and are not the same as population-level "additional users."

To build a bridge between service and population-level measures, we first need to select the most appropriate service-level metrics that can help inform a program's contribution to population-level contraceptive use. We then need a way to account for both uptake and discontinuation of contraception as women move in and out of contraceptive use throughout their lifespan.

Service-Level Metrics: What Do They Tell Us?

At the individual level, a "first-time user" is a woman who initiates contraception having had no previous experience with contraceptive use. A client can be a first-time user only once during her lifetime. In contrast, an "adopter" is someone who starts using family planning who was not currently using modern contraception at the time of her visit, but may have used modern contraception in the past. Thus, a woman could be an adopter several times during her life if she stops and starts using contraception. As adopters include both first-time users and lapsed users, in the context of program-level monitoring, the number of first-time users will always be lower than the number of adopters.

When assessing a program's contribution to increasing contraceptive use nationally, adopters is a more useful metric and preferred over first-time users, since it is a more inclusive measure of adding women into current contraceptive use. Ideally family planning providers or organizations would capture a full suite of indicators including both adopters and first-time users. In reality, they often have to choose a handful of indicators from a longer list to make routine data collection manageable for service providers; hence, the need to prioritize which indicators to include. It is important to note, however, that capturing the number of adopters is not sufficient alone to estimate how national levels of contraceptive use are changing, as will be discussed below.

The terms "new user" and "acceptor" have been frequently used and misused in multiple contexts to refer to a first-time user, an adopter, and even an additional user. In recent years, "new user" has often been used incorrectly to refer to measuring contributions toward FP2020's goal of 120 million additional users. Not only is the "new user" term ambiguous and confusing—"New" to contraception or "new" to the provider? "New" as differentiated from the 2012 baseline of modern method users?—these measures of "new" do not adequately capture important concepts associated with measuring additional users. We suggest, in the interest of clarity, to drop the terms "new user" and "acceptor" from the family planning metrics language and replace them with the clearly defined term of first-time user, adopter, or additional user, as appropriate.

Service-Level Versus Population-Level Measures: Why They Are Not Directly Comparable

Maintaining the 2012 baseline number of modern contraceptive users in the world's 69 poorest countries does not mean that the same 270 million women will continue to use contraception year after year. Women will move in and out of contraceptive use over time, as their needs and situations change. There are many reasons a woman might discontinue use of contraception, such as ageing out of her reproductive years, mortality, method-related reasons when still in need (including health concerns or side effects, partner disapproval, cost, or access challenges), method failure, or no longer needing contraception due to not being sexually active, wanting to get pregnant, partner separation/dissolution, or menopause.[13,14] Population-level estimates of contraceptive use at different points in time capture the fact that there is both uptake and discontinuation of contraception.

However, tracking indicators that are captured at the service level (e.g., number of adopters) focuses on one side of the equation (gains) without measuring the other side (losses), and so does not allow us to see the full dynamic of continuation, discontinuation, and net change. One has to account for levels of continuation and discontinuation to know how many of the adopters are "replacing" women who moved out of current use and how many are "adding" to total current use. Without seeing the full equation, it is not possible to know the extent to which the number of adopters are offsetting declines due to women dropping out from the baseline (Figure 1). In fact, in an extreme case it is possible that despite reaching a large number of adopters, total contraceptive use nationally could stay the same, or even decline. Therefore, program-level data that capture information about individual clients served or client visits are not a direct measure of changes in population-level contraceptive use. Further complicating this issue is that most HMISs are visit-based rather than client-based. Since some methods require clients to make multiple visits over 1 year of use (e.g., injections) while other methods require only 1 visit over several years (e.g., implants), visit numbers must be adjusted to the approximate number of "users." In some instances, data that refer to individual visits are labeled and interpreted as individual users or clients, creating further confusion.

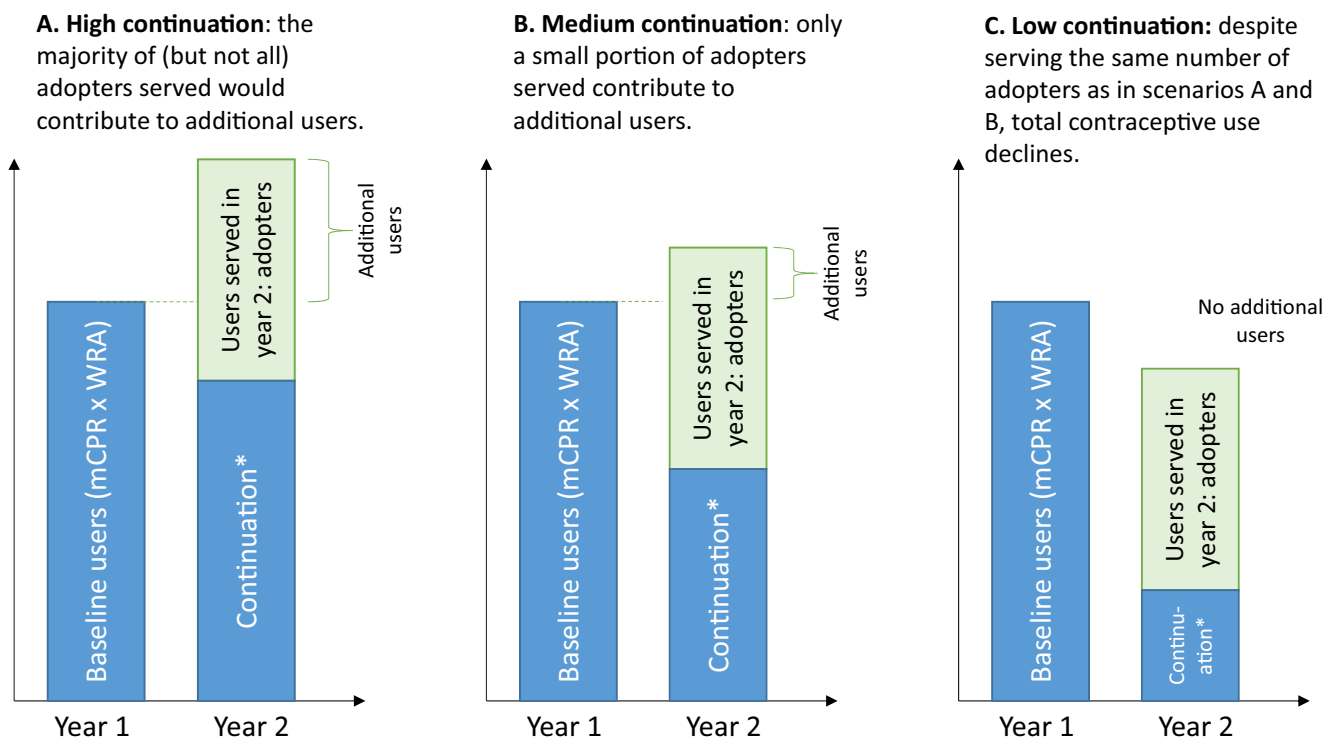
Tools and Models Can Bridge the Gap Between Service and Population Measures

When available, client-level data can be used to inform national level changes in mCPR and estimate contributions by particular organizations to national-level changes using existing tools and models, namely, FPET and the Impact 2 model.

FPET combines survey data and service statistics to inform trends in mCPR growth: Track20's FPET,[15] adapted from a model used by the United Nations Population Division,[16] generates statistical estimates of mCPR that are informed by survey data as well as regional and global patterns of change. FPET has been modified to allow service statistics (either client visits by method or commodities distributed to clients by method) from government HMISs to inform the trajectory of mCPR growth after the latest survey. These service statistics are converted into an Estimated Modern Use (EMU). This value is not directly comparable with the mCPR (due to limitations and biases within routine data); however, the shape of the trend is used to inform the progress of mCPR growth. For example, in Figure 2 service statistics are seen to be trending well with surveys for a number of years and can now be used to inform annual progress after the 2013–2014 DHS survey. This allows service statistics to inform projections of mCPR (and therefore of additional users) indirectly, circumventing the issues discussed above that do not allow HMIS data to be directly extrapolated to estimates of national-level mCPR changes.

Impact 2 model uses service statistics and client-use profile data to estimate contributions to additional users: The Impact 2 model, developed by Marie Stopes International, allows organizations to estimate their contribution to national-level additional users, based on program-level and other input data.[17,18] First, the number of services provided is converted into the number of estimated users in a given country (accounting for long-acting and permanent method continuation, mortality, and short-acting methods needed for a year of coverage). Next, client-use profile data (the proportion that are adopters, provider-continuers, and provider-changers; see the Box) are used to allocate users to 1 of 3 categories: (1) any growth in users that came from provider-changers are discounted ("substitution effect");[19] (2) the previous year's baseline must be maintained with provider-continuers and adopters; and (3) only the remaining adopters are allowed to contribute to further growth. This approach uses the client-use profile information

FIGURE 1. Contribution of Adopters to Additional Users Depending on High, Medium, and Low Continuation Scenarios



*In this graphic, continuation includes both LAPM users still protected by a method received in a previous year and users who come back for resupply of their method. A portion of this continuation would be picked up in the year 2 service statistics as client revisits or services/commodities provided to clients, depending on levels of LAPM use in the country.

Abbreviations: LAPM, long-acting and permanent methods; mCPR, modern contraceptive prevalence rate; WRA, women of reproductive age.

to model how the organizations' increases in users are likely changing national contraceptive use levels. Rather than directly counting increases in users or relying wholly on program-level indicators such as first-time users or adopters, the model accounts for the full dynamics of continuation, discontinuation, and substitution between providers in order to estimate contribution to population-level change (Figure 3). This approach is comparable with FP2020's concept of additional users.

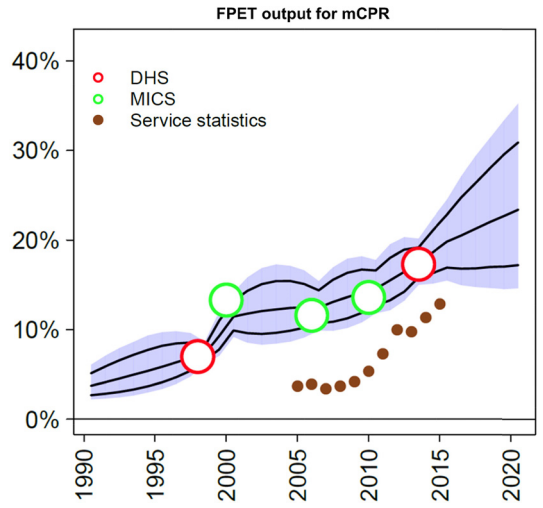
For more information about FPET and the Impact 2 model, see the supplement.

FINAL REFLECTIONS

We call on government ministries, service providers, and donors to align how they define and track their contributions to FP2020, so that across the sector we are all aiming for the same goal and measuring the same concept. Doing so will strengthen the field's ability to respond to important measurement challenges as we transition from the FP2020 goals to those of universal access to reproductive health and the 2030 Sustainable Development Goals that follow.

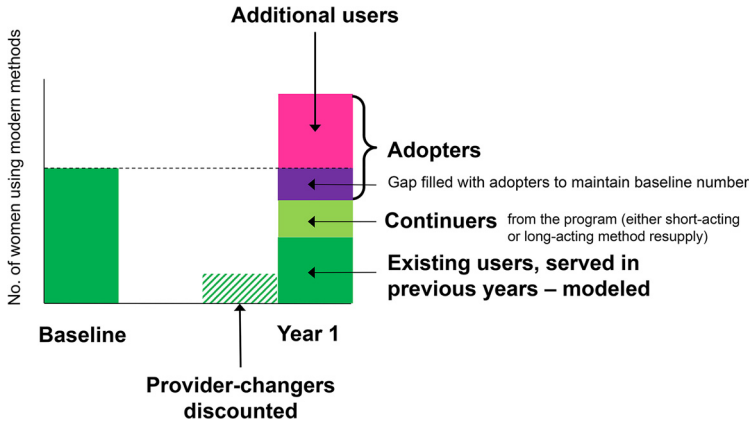
There is much focus on the goal of ensuring that an additional 120 million women use contraception by 2020. What has been less visible from this goal is the 270 million women in the world's poorest 69 countries who were estimated to be already using contraception in 2012.[8] This number of users will need to be maintained before any progress can be made toward reaching the additional 120 million women. Maintaining this base takes work; those who rely on short-acting methods

FIGURE 2. Using Service Statistics in FPET to Inform Trends in mCPR Growth



Abbreviations: DHS, Demographic and Health Surveys; FPET, Family Planning Estimation Tool; MICS, Multiple Indicator Cluster Surveys; mCPR, modern contraceptive prevalence rate.

FIGURE 3. How Contribution to Additional Users Are Modeled in Impact 2



Source: Adapted from Weinberger, Fry, and Hopkins (2015).[18]

will need continual resupply and those using long-acting methods may need their methods replaced. In addition, some women will drop out of contraceptive use, either because they will age beyond their reproductive years or discontinue either due to method-related problems or because they no longer have a need for contraception. Therefore, there will always be a need to reach adopters as part of the efforts to sustain existing contraceptive use in any given population. Only when looking at the complete picture can we see to what degree our efforts are resulting in actual increases in modern contraceptive users at the national and global levels.

Service-level outputs (services provided, client visits, and CYPs) play an important role in monitoring family planning programs, and thus their tracking should not be undervalued. As HMISs improve with technological advances in electronic data collection and analysis, enabling more robust collection of longitudinal metrics that track individual clients' first-time use, discontinuation, method switching, resumption of use, and so on, even more value can be obtained from routine tracking. However, due to the limitations described in this article, these program-level measures will never be directly comparable with population-level changes in contraceptive use such as additional users.

Finding ways to bridge the gap between program and population measures is important. Using validated models allows implementing organizations, governments, and donors to translate service statistics into meaningful estimates of national-level changes in continued contraceptive use. For example, from experience in the social franchising space, the Metrics Working Group has defined the metric of choice for measuring "additionality" in contraceptive use to be the "contribution to additional users as modeled by the Impact 2 model."[20] The group recognized the importance of not only measuring the scale of family planning provider networks (through metrics such as CYPs) but also going the next step to understand how the provider network is contributing to national-level changes in contraceptive use.

We have outlined how national-level estimates of additional users can be informed by routine data and how individual organizations can estimate their contribution to additional users. Therefore, we call on donor agencies, governments, implementing organizations, and other partners to:

- Focus on "additional users" as an indication of sustained growth in contraceptive use at the national level

- Drop "new users" and "acceptors" from the family planning measurement agenda as these ambiguous terms create confusion
- Focus on capturing data on "adopters" as the preferable client characteristic to better understand who is being reached by family planning programs and to inform modeled estimates of additional users
- Use output measures such as client visits, services provided, and CYPs not only to inform program monitoring but also to inform modeled estimates of additional users and to better understand the link between the service and population levels

Collectively, these steps will ensure that across the family planning sector we are using a standardized and comparable terminology and approach to define and measure progress. More importantly, they will ensure that growth is measured in a way that takes into account both growth beyond a baseline level of use and provision of services to women who were not previously protected by contraceptives. If the additionality metric is widely adopted, programs will be able to immediately see their contributions to the global goal of enabling women to access modern contraception.

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COMMENTARY

CDC's Male Circumcision Recommendations Represent a Key Public Health Measure

Brian J Morris,[a] John N Krieger,[b] Jeffrey D Klausner[c]

Frisch and Earp, opponents of male circumcision, have criticized draft recommendations from the CDC that advocate counseling men and parents of newborn boys in the United States about the benefits and risks of male circumcision. We provide a rebuttal to Frisch and Earp's criticisms and contend that the recommendations are entirely appropriate and merit consideration for policy development.

INTRODUCTION

After an extensive evaluation of the scientific evidence, the United States Centers for Disease Control and Prevention (CDC) released draft policy recommendations in December 2014 affirming male circumcision (MC) as an important public health measure.[1–3] The CDC's summary[1] (Box 1) was accompanied by a 61-page literature review.[2] The CDC supported the 2012 American Academy of Pediatrics (AAP) infant MC policy[4,5] (Box 2) and recommended that providers: (1) give parents of newborn boys comprehensive counseling about the benefits and risks of MC; (2) inform all uncircumcised adolescent and adult males who engage in heterosexual sex about the significant, but partial, efficacy of MC in reducing the risk of acquiring HIV and some sexually transmitted infections (STIs) through heterosexual sex, as well as about the potential harms of MC; and (3) inform men who have sex with men (MSM) that while it is biologically plausible that MC could benefit MSM during insertive sex, MC has not been proven to reduce the risk of acquiring HIV or other STIs during anal sex.[3]

The CDC has a mandate to use the best available evidence to inform the public on interventions for disease prevention. In the case of early infant MC, there are few public health interventions in which the scientific evidence in favor is now so compelling. Despite this, opponents of MC do not accept the CDC's position. Two prominent opponents, Frisch and Earp, published arguments that led them to conclude that "from a scientific and medical perspective, current evidence suggests that circumcision is not an appropriate public health measure for developed countries such as the United States."[6]

BOX 1. U.S. Centers for Disease Control and Prevention's Summary of Its Draft Male Circumcision Recommendations[1]

These recommendations are intended to assist health care providers in the United States who are counseling men and parents of male infants, children and adolescents in decision-making about male circumcision. Such decision-making is made in the context of not only health considerations, but also other social, cultural, ethical, and religious factors. Although data have been accumulating about infant male circumcision for many years, clinical trials conducted between 2005–2010 have demonstrated safety and significant efficacy of voluntary adult male circumcision performed by clinicians for reducing the risk of acquisition of human immunodeficiency virus (HIV) by a male during penile-vaginal sex ("heterosexual sex"). Three randomized clinical trials showed that adult male circumcision reduced HIV infection risk by 50–60% over time. These trials also found that adult circumcision reduced the risk of men acquiring two common sexually transmitted infections (STIs), herpes simplex virus type-2 (HSV–2) and types of human papilloma virus (HPV) that can cause penile and other anogenital cancers, by 30%. Since the release of these trial data, various organizations have updated their recommendations about adult male and infant male circumcision.

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BOX 2. Conclusions of the 2012 Circumcision Policy Statement by the American Academy of Pediatrics Task Force on Circumcision[3]

Systematic evaluation of English-language peer-reviewed literature from 1995 through 2010 indicates that preventive health benefits of elective circumcision of male newborns outweigh the risks of the procedure. Benefits include significant reductions in the risk of urinary tract infection in the first year of life and, subsequently, in the risk of heterosexual acquisition of HIV and the transmission of other sexually transmitted infections.

The procedure is well tolerated when performed by trained professionals under sterile conditions with appropriate pain management. Complications are infrequent; most are minor, and severe complications are rare. Male circumcision performed during the newborn period has considerably lower complication rates than when performed later in life.

Although health benefits are not great enough to recommend routine circumcision for all male newborns, the benefits of circumcision are sufficient to justify access to this procedure for families choosing it and to warrant third-party payment for circumcision of male newborns. It is important that clinicians routinely inform parents of the health benefits and risks of male newborn circumcision in an unbiased and accurate manner.

Parents ultimately should decide whether circumcision is in in the best interests of their male child. They will need to weigh medical information in the context of their own religious, ethical, and cultural beliefs and practices. The medical benefits alone may not outweigh these other considerations for individual families.

Findings from the systematic evaluation are available in the accompanying technical report. The American College of Obstetricians and Gynecologists has endorsed this statement.

Here, we critically assess the evidence used by Frisch and Earp to support their thesis and respond to their main criticisms (summarized in Box 3).

BENEFITS VERSUS RISKS

Male circumcision confers immediate and lifelong protection against numerous medical conditions.

MC confers immediate and lifelong protection against numerous medical conditions (Box 4).[1,2,4,5,7–9] For example, MC protects against a number of STIs including HIV, and it partially protects against oncogenic types of human papillomavirus (HPV)[10–15] that together with phimosis, balanitis, and smegma are major risk factors for penile cancer,[10,16–18] as shown in meta-analyses that found 12-, 4-, and 3-fold statistically significant higher risks of penile cancer for phimosis, balanitis, and smegma, respectively.[16] Infancy is the ideal time for MC and there are cogent reasons why it should not be delayed until the boy or man can make up his own mind[19] (Table).

The benefits gained from male circumcision far exceed risks.

Disputing the value of MC's protection against STIs, Frisch and Earp argue that less invasive STI prevention strategies should instead be promoted, such as encouraging safe sex practices. But we argue that public health messages normally include *all* effective measures for protection against disease, and in the case of STIs, MC complements current safe sex messages. The effectiveness of each approach should, moreover, be considered in real-world settings.

Frisch and Earp also contend that many STIs can be treated effectively if they do occur. We dispute that logic and instead argue that prevention is preferable to treatment, especially for viruses for which there is no cure (e.g., HIV, herpes simplex virus [HSV], and HPV). And for bacterial STIs and urinary tract infection (UTI), antibiotic-resistant strains mean that infections that were once easily treatable can now be life threatening.[22–25]

The benefits of medical procedures should always, of course, be weighed with the potential risks. Frisch and Earp question whether the potential benefits of MC are "worth" the risk, pointing to potential risks of surgical accidents and supposed adverse psychological or sexual effects. The risk of major surgical mishaps with MC, however, is extremely low and the benefits gained from MC far exceed risks.[2,5,8,9] Furthermore, there is no long-term adverse effect of infant MC on psychological[26,27] or sexual[28–33] outcomes. Systematic reviews have found no adverse effect of MC on sexual function,[28,29,33] sensitivity, or satisfaction.[29] A meta-analysis of all common male sexual dysfunctions found none were related to MC status.[28] Furthermore, the third British National Survey of Sexual Attitudes and Lifestyles (Natsal-3), a large national probability survey, which used a new, comprehensive, validated measure of sexual function, the Natsal-SF, presented findings for 6,293 men and 8,869 women aged 16–74 years, broadly representative of the British population.

BOX 3. Criticisms of the U.S. Centers for Disease Control and Prevention's Draft Male Circumcision Recommendations and Responses

In a recently published article, Frisch and Earp[6] oppose the 2014 draft MC recommendations from the U.S. Centers for Disease Control and Prevention (CDC),[3] referring to what they believe are "numerous scientific and conceptual shortcomings." Here, we quote these 7 criticisms by Frisch and Earp and provide our response to each criticism.

1. *Failure to provide a thorough description of the normal anatomy and functions of the penile structure being removed at circumcision (i.e., the foreskin)*
   Response: There seems to be no need for the CDC to provide a thorough description of the anatomy and functions of the foreskin.
2. *Failure to consider the intrinsic value to some men of having an unmodified genital organ*
   Response: While some men may believe there is "an intrinsic value to having an unmodified genital organ," those men should be made aware of the risks posed by their foreskin.
3. *Undue reliance on findings from sub-Saharan Africa concerning circumcision of adult males (as opposed to infants or children)*
   Response: The evidence shows the CDC is correct in concluding that findings from sub-Saharan Africa concerning circumcision of adult males for protection against heterosexually-acquired HIV and certain other STIs also apply to men in the United States. The findings also apply to boys when they grow up. Moreover, the cumulative lifetime benefit is greatest if circumcision is performed early in infancy since early infant circumcision is simpler, more convenient, and carries lower risk than when performed later, and circumcision confers immediate protection against urinary tract infections, phimosis, balanitis, and, when older, specific STIs and genital cancers. MC also protects the female partners, as confirmed in randomized controlled trials.
4. *Uncritical reliance on a prima facie implausible benefit-risk analysis performed by a self-described circumcision advocate*
   Response: The benefit-risk analysis used by the CDC is based on the best current evidence relevant to the United States, and the results are plausible.
5. *Reliance on misreported statistics to downplay the problem of pain in the youngest of boys*
   Response: While procedural pain can occur during circumcision, the evidence cited by the CDC indicates that, with use of local anesthetic, pain is negligible in the first week of a boy's life. Frisch and Earp misconstrue pain statistics to overplay the issue of pain.
6. *Reliance on incomplete register data to assess the frequency of short-term post-operative complications associated with circumcision, leading to a likely underestimation of their true frequency*
   Response: By selective citation and misrepresentation of findings, Frisch and Earp overstate the frequency of short-term postoperative complications associated with MC while ignoring data from large high-quality studies such as those published recently by CDC researchers.
7. *Serious underestimation of the late-occurring harms of circumcision presenting months to years after the operation (most notably meatal stenosis).*
   Response: Frisch and Earp selectively cite small, outdated, weak studies, often involving traditional circumcisers, and misrepresent data while ignoring large, high-quality studies. As a result, they overestimate the frequency of meatal stenosis occurring years after the MC procedure.

The survey concluded that MC is not associated with men's overall sexual function.[31] In addition, a recent survey of 1,000 adults by an Internet-based market research firm that is a member of the British Polling Council found 29% of *un*circumcised men wished they had been circumcised, compared with only 10% of circumcised men who wished they had not been circumcised (margin of error ±4%).[34] A randomized controlled trial (RCT) of uncircumcised men in Kenya found sexual pleasure increased in most men after MC.[35] It is possible some circumcised men may be unhappy due to exposure to misleading propaganda that dominates the Internet.

A risk-benefit analysis[8] cited by the CDC[2] found that benefits of infant MC exceed risks by

BOX 4. Medical Conditions That Male Circumcision Protects Against Over the Lifetime

- Urinary tract infection
- Penile inflammation, for example, balanitis, balanoposthitis, lichen sclerosus
- Candidiasis
- Phimosis and paraphimosis
- Inferior hygiene
- Sexually transmitted infections including high-risk human papillomavirus (HPV), genital herpes simplex virus (HSV), trichomoniasis, mycoplasma, syphilis, chancroid, and HIV
- Physical injuries to the foreskin, including coital injuries
- Cancers of the penis, prostate, and cervix

Sources: CDC technical review[2] and draft policy recommendations,[3] AAP review[5] and infant MC policy statement,[4] risk-benefit analyses by Morris et al.[7–9]

TABLE. Why Infant Male Circumcision Is Preferable to Male Circumcision at a Later Age

Infant Male Circumcision	Male Circumcision of Older Boys and Men
Simple	More complex
Quick (a few minutes)	Takes half an hour or more
Low cost	Expensive (often unaffordable)
Low risk (adverse events 0.4%)[20]	Moderate risk (adverse events 4%–8%)[20]
Bleeding is minimal	Bleeding more common, requiring cautery or other interventions
No need for sutures	Sutures or tissue glue needed
Convenient (baby mostly sleeps)	Inconvenient (time off school or work required)
Local anesthesia for those <2 months of age[21]	General anesthesia for those >2 months to 9 years of age; local anesthesia for men, although general anesthesia sometimes preferred by surgeon
Healing is fast (2 weeks)[21]	Healing takes 6 weeks or more
Cosmetic outcome usually good	Stitch marks may be seen
No long-term memory of procedure	Fear of undergoing an operation
	Abstinence from sexual intercourse for the 6-week healing period

over 100:1. A letter[36] questioning this risk-benefit analysis that Frisch and Earp cite contained misunderstandings, as pointed out in the response to the letter.[37] A large study by CDC researchers found frequency of adverse events for newborn MC was 0.4%.[20] These data are robust and withstand Frisch and Earp's non-evidence-based speculation to the contrary. Frisch and Earp refer to analysis conducted by the Canadian Paediatric Society (CPS) that tabulated risks and benefits of newborn MC, concluding the risk-benefit ratio was "closely balanced."[38] But risk figures in the CPS analysis were exaggerated because they were drawn from a global study that included data from

traditional (non-medical) MCs[39] and outlier studies while ignoring a more recent study by CDC researchers of 1.4 million (mostly newborn) MCs.[20] In addition, multiple benefits (phimosis, balanitis, balanoposthitis, prostate cancer, some STIs, candidiasis, and lifetime prevalence of urinary tract infections) were omitted, and the actual risk-benefit ratio was not determined. (See critique[40] for further details.)

In addition to potential risks from the surgical procedure, Frisch and Earp point to other potential negative consequences of MC, namely, "the loss of healthy, functional tissue" (i.e., the foreskin). But they fail to acknowledge that the healthy foreskin of an uncircumcised male remains vulnerable to adverse medical conditions, infections, and genital cancers. We draw attention to a Danish study by Sneppen and Thorup that found "significant morbidity related to foreskin problems in a predominantly uncircumcised population."[41] It pointed out that the reason most Danish boys might go through infancy, childhood, and adolescence without being circumcised reflects "the strict foreskin-preserving culture of Denmark."[41] "More than 5% . . . were admitted to the pediatric surgical department with foreskin-related problems [mainly phimosis] and at least 1.66% of the boys needed surgical procedures in [*sic*] general anesthesia."[41] Of these, 24% initially received a circumcision and another 5% received circumcision after alternative treatment failed. Moreover, foreskin-preserving preputioplasty had to be repeated in 5.5% of cases (repeat surgery for MC was lower, at 2%), further exposing the boy to surgical risks.

Foreskin problems continue into adulthood, as does MC for medical and cosmetic reasons. Since some men might not seek medical attention, especially for sexual or genital conditions, foreskin problems will always be more common than evident in case studies such as the one by Sneppen and Thorup. Infant MC would prevent later foreskin problems and obviate the need for later MC which is more costly and risky.[19] Risk-benefit analyses calculated that half of uncircumcised males will, over their lifetimes, suffer from an adverse medical condition attributable to their foreskin.[8,42] One such condition among uncircumcised men is lichen sclerosus (a condition that creates patchy, white skin that is thinner than normal, most often affecting the genital area).[43] This had a prevalence of 0.37% in the Danish study.[41] Lichen sclerosus is difficult to treat, and treatment has a low success rate.[43] Frisch and Earp go into a lengthy argument that another condition, meatal stenosis (a subcategory of urethral stricture disease), is one of the most common complications after MC, citing numerous studies. But most of the studies they cite to support their claim are small, quite old, comprised of MC performed by non-medical personnel, lack a control group of uncircumcised males, and either include no statistical analyses or include *P* values that were not statistically significant. Furthermore, meatal stenosis is seen in *uncircumcised* males as well. In the Danish study, risk of developing meatal stenosis in uncircumcised boys before 18 years of age was 0.17%.[41] Prevalence was 0.01% in a large U.S.[20] study of infants and a U.K.[44] study of boys aged 0–15 years, although follow-up in each study was only 6 months. Among the lichen sclerosus patients in the Danish study, 37.5% developed meatal stenosis.[40]

The uncircumcised foreskin remains vulnerable to adverse medical conditions, infections, and genital cancers.

Finally, Frisch and Simonsen reported that circumcised boys may be at increased risk for autism spectrum disorder (ASD) due to MC-related pain.[45] Their conclusion was based on their finding of ASD prevalence of 6.3% in circumcised and 1.5% in uncircumcised Danish boys. That report has been criticized.[41,46,47] Sneppen and Thorup, in particular, found ASD prevalence was 7.2% in *uncircumcised* Danish boys and suggested Frisch's study suffered from confounding.[41]

DOES AN "INTACT SEXUAL ORGAN" HAVE ANY VALUE?

Frisch and Earp criticize (without *scientific* evidence) the CDC's draft recommendations for not discussing the "protective and sexual functions" of the foreskin. A study by Frisch claiming sexual dysfunctions in circumcised men[48] was one-sided and suffered from confounding and statistical flaws.[29,49] In this Danish study, MC of the mostly (89%) Lutheran or non-religious Danish men surveyed was likely for medical conditions that often affect sexual function, either directly or from a preexisting psychological aversion that develops because the condition causes difficulties with intercourse.[29,49,50] Participation bias, small sample sizes for cases among the 5% who were circumcised, and failure to correct for multiple testing were also noted.[29,49] Confounding and statistical flaws were also noted for a study of penile sensitivity by Sorrells et al.[51] That study was severely criticized for a multitude of reasons, including failure to correct for multiple testing that, if performed, would have rendered the age-adjusted *P* value of .014 non-significant; mode of recruitment; large discrepancies in

subject numbers between the methods and results sections; and failure to compare comparable sites on the penis of circumcised and uncircumcised men (which when performed by the critics were shown to be not statistically significant).[29,52] A recent Canadian study concluded that "if sexual function is related to circumcision status, this relationship is not likely the result of decreased penile sensitivity stemming from neonatal circumcision."[32] It has also been found that sensory nerve endings (Meissner's corpuscles) in the foreskin are lower in density and smaller in size than those in other glabrous (hairless) epithelia of the body.[53]

Male circumcision could reduce heterosexual HIV risk by about 21% in African-Americans and 12% in Hispanics.

Sensitivity to vibration (not tested by either Bossio et al.[32] or Sorrells et al.[51]) correlates with sexual response and is similar in uncircumcised and circumcised men.[30] Studies of histological correlates of sexual sensation concluded that the glans, not the foreskin, is involved in sexual sensation.[30,54] C-fibers (activated by thermal stimuli and punctate pain) may be involved in erotic sensation and sexual arousal.[55] Similar unmyelinated free nerve endings predominate in the glans, not the foreskin.[30]

Thus, speculation and outdated opinion pieces claiming special properties of the foreskin, such as in penile function and masturbation, should be viewed with skepticism. Perhaps sensitivity of the foreskin to fine touch (which activates Aβ, large diameter, myelinated nerve fibers) might have served as an "early warning system" in our naked upright forebears from the intrusion of biting insects and parasites while protecting the glans.[56]

The area of the outer and inner foreskin combined spans a wide range: 7–100 cm^2 (n=965)[57] and 18–68 cm^2 (n=8),[58] respectively. In discussing vestigial structures, Charles Darwin stated, "An organ, when rendered useless, may well be variable, for its variations cannot be checked by natural selection."[59] The variability in foreskin size is consistent with the foreskin being a vestigial structure. Larger foreskins place uncircumcised men at increased risk for HIV infection.[56]

SCIENTIFIC INFERENCE FROM AFRICAN TRIALS

Arguments by MC opponents disputing the validity of the large African RCTs showing that MC provides substantial protection against heterosexually-acquired HIV infection have been exposed as fallacious.[60–72] Frisch and Earp instead question the CDC for applying the African trial findings to the United States. Although the proportion of HIV infections acquired heterosexually in the United States is far less than in sub-Saharan Africa, in some U.S. localities heterosexually-acquired HIV incidence is high. Furthermore, 2014 CDC figures show 24% of new HIV infections in the United States involved heterosexual contact.[73] It was estimated that if all boys in the 2011 annual U.S. male birth cohort were circumcised, 5,530 HIV infections would be prevented over their lifetime.[74] Lifetime risk of HIV diagnosis in heterosexual males in the United States is currently 1 in 524.[75] The increase in HIV infections in African-Americans, in particular, has been faster than in all other groups.[76] Modeling by the CDC found MC could reduce heterosexual HIV risk by approximately 21% in African-Americans and by approximately 12% in Hispanics, and costs would be saved in each group.[77] Actual MC-related risk reduction in heterosexual African-American men with known HIV exposure was 51%.[78]

Comparison of HIV and MC prevalence in high-income countries also suggest MC has a protective effect, providing further support to the applicability of the African MC trials to the United States and other high-income countries. For example, HIV prevalence in the mostly uncircumcised populations of France and the Netherlands was much higher than in Israel where almost all men are circumcised, despite all other risk factors being comparable.[79] In Australia, where MC is less common than in the United States and Israel, the number of HIV infections related to heterosexual contact has increased by 28% over the past decade, representing 25% of new diagnoses in 2013, 29% being in Australian-born patients.[80] In Canada, where infant MC prevalence has, like in Australia, declined in recent decades, 9.5% of new HIV infections involve men infected heterosexually.[81]

As well as substantial protection against HIV, data from the African RCTs reinforced the ability of MC to protect against several other STIs in heterosexual males,[10,11,13,16,71,82–90] as well as their female sex partners[10,91–95] and among MSM who are insertive-only.[96–100] With regard to MSM in particular, a Cochrane analysis of MC and HIV prevalence among MSM found results were statistically significant among 3,465 men in 7 studies reporting an insertive role (odds ratio, 0.27; 95% confidence interval, 0.17 to 0.44; I^2=0%), but were not significant among 1,792 men in 3 studies reporting a receptive role (odds ratio, 1.20; 95% confidence interval, 0.63 to 2.29; I^2 = 0%)."[1,80] MC also reduces the risk of potentially fatal penile, prostate, and cervical

cancer.[10,16–18,101–104] Partial protection against prostate cancer incidence was seen in U.S.[101] and Canadian[103] studies and in a meta-analysis of all studies,[104] the protective effect being strongest (36%[101] and 60%[103]) in North American men of African heritage.

EUROPEAN EXPERIENCE

It is misleading to compare HIV prevalence in the United States, where MC is common, with a similar or slightly lower prevalence in Europe, where MC is uncommon, and conclude that MC does not make a difference, as Frish and Earp do. Unlike Africa, most HIV infections in the United States and Europe occur in MSM. HIV subtype B arrived in Haiti from Africa between 1961 and 1970, reaching the United States in the mid-1970s after Haiti became a popular destination for sex tourism.[105] The United States thus had a "head-start" on Europe and the rest of the developed world.

COSTS

Because Frisch and Earp dispute the low prevalence of adverse events with MC, they disagree with the conclusions from a cost-benefit study by authors from the Johns Hopkins University.[74] This study found that if infant MC prevalence in the United States decreased from the current 80% prevalence[106] to the levels of 10% typical in Europe, the additional direct medical costs in infancy and later for treatment of UTIs and STIs would exceed US$4.4 billion over 10 annual birth cohorts, after accounting for the cost of the MC procedure and treatment of MC complications.[74] If early infant MC rates decreased to 10%, lifetime prevalence of infant UTIs would increase by 211.8%, high- and low-risk human HPV by 29.1%, HSV-2 by 19.8%, and HIV by 12.2%.[74] Among females, lifetime prevalence of bacterial vaginosis would increase by 51.2%, trichomoniasis by 51.2%, high-risk HPV by 18.3%, and low-risk HPV by 12.9%.[74]

Frisch and Earp also take issue with the CDC's modeling findings[77] that MC in the United States was cost-saving for HIV prevention among black and Hispanic males but not necessarily among, what Frisch and Earp refer to as, "the majority population of white males." The CDC found that "for all males, circumcision resulted in undiscounted lifetime HIV-related health care savings of $2,070 per male and discounted lifetime HIV-related health care savings of $427."[77] As pointed out in the CDC study, the lack of cost-effectiveness for white males may be because white males in the United States already have a high prevalence of MC, a low lifetime risk of HIV, and a low risk of acquiring HIV through heterosexual sex compared with black and Hispanic males. We also contend that if other factors were considered in the model, including medical conditions associated with lack of MC, infections and genital cancers in both sexes, and indirect costs, MC would likely be cost-saving among U.S. whites as well. For example, in the absence of MC in the United States, there would be 24%–40% more prostate cancer cases and US$0.8–1.1 billion extra in costs for treatment and terminal care per year.[107] Annual cost-savings for genital cancer prevention by a shift from the current rate of 10%–20% for infant MC in Australia to 80% was calculated as $1–2 million for direct medical costs, unadjusted for inflation.[108]

The U.S. state of Florida provides an illustrative case study of the cost-savings benefits of MC. In 2003, the state withdrew Medicaid health insurance coverage for infant MC. That resulted in a 6-fold increase in medical costs for publicly funded MCs for medical indications, because later MCs are substantially more expensive than early infant MCs.[109] In response, Florida restored Medicaid coverage in 2014.

Thus, in contrast to the assertions by Frisch and Earp, the cost-savings estimated by the CDC[77] and Johns Hopkins researchers[74] appear conservative. Moreover, cost-savings from infant MC apply to whites, blacks, and Hispanics.

PROCEDURAL AND POST-OPERATIVE PAIN IN INFANTS

Claims of long-term psychological, emotional, and sexual impediments from infant MC "pain" are anecdotal.[110,111] In contrast, in a longitudinal study of New Zealand boys circumcised in 1977, MC had no adverse effect on breastfeeding outcomes or cognitive ability later in childhood.[26] In another follow-up study, of Swedish boys after MC, the boys showed no adverse psychological effect of MC.[112]

There are many painful experiences encountered by the child before, during, and after birth.[113] MC, *if performed without anesthetic*, is one of these. Cortisol levels, heart rate, and respiration have registered an increase during and shortly after infant MC.[114,115] Adequate anesthesia is essential for pain management during MC at any age. Most MC procedures can be performed under

local anesthesia. General anesthesia involves risks, is usually unnecessary, and is falling out of favor. The AAP[5] and CDC[2] recommend local anesthesia for infant MC.

Frisch and Earp take issue with a study the CDC cited related to the issue of pain associated with the MC procedure, arguing that the figures cited from the study were inaccurate. The study objectively scored pain experienced by newborns when undergoing MC and concluded that "painless circumcision [by Gomco clamp] is possible in almost all newborns if it is performed during the first week of life."[116] It is regrettable that there were indeed some errors in the figures reported in the study—in the abstract of the article, 6.5% of infants 1 week old or younger were reported to have pain scores of 2 or greater, whereas the source table in the main body of the article reports the figure of 6.7% and the raw data indicate the figure should actually be 7.1%. However, the error is trivial, resulting in a minor difference of up to 0.6 percentage points and thus does not negate the study's overall conclusion.

In the 3 large RCTs of adult male circumcision conducted in sub-Saharan Africa, less than 1% of men reported severe pain with the procedure.

In addition, Frisch and Earp highlight that infants may also experience pain from administration of the anesthesia itself before the MC. Pain does occur during injection of local anesthetics, but it can be reduced by prior application of readily available topical anesthetic creams containing lidocaine and prilocaine (EMLA, or the more potent LMX4). In a clinical trial, application of EMLA cream 2 hours prior to Plastibell MC resulted in near absence of evidence of pain during and for 4 hours after infant MC, by which time nerves at the ablation site would have died, meaning a pain-free MC.[117] Furthermore, we contend that any pain associated with injection of local anesthetic is no greater than pain incurred with injection of a vaccine.

While infants may experience pain from administration of a local anesthetic before circumcision, the pain can be reduced by prior application of topical anesthetic creams.

A small telephone survey, misconstrued by Frisch and Earp, actually found parents' (subjective) perception of level of discomfort among infants circumcised at 4–167 days of age (mean, 41.7 days) was mild in 84% of cases, moderate in 11%, and severe in only 5%.[118] The average discomfort score for MC was less than for other simple ambulatory pediatric procedures evaluated in the study. Similarly, Frisch and Earp summarize results of another telephone survey[119] by stating that "71% of parents reported varying degrees of circumcision-related pain in their infants . . . up to six weeks after surgery." When analyzing the study's results in detail, however, one finds that only about 2% of parents whose sons were circumcised using a Gomco clamp reported "more than acceptable pain" (1.5%) or "much more pain" (0.9%). In comparison, 29% reported "no pain," 15% reported "minimal pain," and 53% reported "acceptable pain." For Plastibell MC, these figures were 32% (no pain), 11% (minimal pain), 50% (acceptable pain), 3.2% (more than acceptable pain), and 3.8% (much more pain).[119]

Men circumcised as adults are well placed to communicate MC-related pain. In the 3 large RCTs of adult MC conducted in sub-Saharan Africa, only 0.8%,[120] 0.3%,[121] and 0.2%[122] of men reported severe pain.

COMPLICATION RATES AFTER CIRCUMCISION

Frisch and Earp speculate about adverse MC-related events after discharge from hospital and over the long-term. They considered meatal stenosis to be "particularly worrying," but misconstrue data on its prevalence, which, as noted earlier in this article, we argue will not affect "between 5% and 20% of boys undergoing nontherapeutic circumcision." A recent study by Frisch and Simonsen found meatal stenosis incidence in Denmark to be very much lower than those figures and higher in uncircumcised than in circumcised elderly men,[123] possibly contributed by lichen sclerosus. A critical evaluation of the literature suggests prevalence is in the order of 0.01%–1%, with a similarly low frequency among both circumcised and uncircumcised boys.[13,20,44,124]

Frisch and Earp also point to findings of retrospective case study that 4.7% of cases operated on in the pediatric surgery department of the MassGeneral Hospital for Children between 2003 and 2007 were for late complications related to newborn MC.[125] Since that hospital serves the wider Boston area and receives cases following MC elsewhere, the sample is not representative. Besides vaccination, newborn MC is the most common pediatric procedure among males in the United States. Frisch and Earp concede that the "total number of circumcisions [that these figures relate to are] unknown." In contrast, a recent study of 95,046 elective MCs from 2004 to 2013 in ambulatory surgery centers of 43 U.S. tertiary care pediatric hospitals found only 0.1% underwent a second ambulatory procedure within the first 7 days, being higher for older boys than for infants.[126]

OTHER MC POLICY STATEMENTS

The draft CDC recommendations advocate informing parents of newborn boys and adolescent and adult men about the benefits and risks of MC,[3] and the accompanying technical report[2] refers to an analysis that finds the benefits of MC exceed the risks.[8] The AAP policy also concluded that benefits of MC exceed the risks. Policy statements from Australian, British, and Dutch medical bodies, however, are more conservative or even negative about MC. Frisch and Earp point to these differences as a "lack of international agreement with the U.S. view,"[6] but they fail to mention that none of these other bodies go to the level of claiming that MC detracts from sexual pleasure or function, oppose MC in high-HIV prevalence countries, or recommend that MC should be legislated against in their own countries. One negative policy, by the Royal Australasian College of Physicians, even maintains a relatively balanced view on MC, stating that[127]:

1. It is reasonable for parents to weigh the benefits and risks of circumcision.
2. To make the decision whether or not to circumcise their sons, the medical attendant is obliged to provide accurate, unbiased, and up-to-date information on the risks and benefits of the procedure.
3. Parental choice should be respected.
4. The operation should be undertaken in a safe, child-friendly environment by an appropriately trained competent practitioner, capable of dealing with the complications and using appropriate analgesia.

And while the CPS (Canada) newborn MC position statement[38] does not recommend routine MC of every newborn male, it does acknowledge that "there may be a benefit for some boys in high-risk populations and circumstances where the procedure could be considered for disease reduction or treatment."

The policy statements by the CDC and AAP have raised the bar. Policy statements on MC by medical bodies should follow their lead and rely on a thorough evaluation of the medical evidence to support their conclusions.

CONCLUSION

We find major shortcomings in the criticisms by Frisch and Earp of the CDC's draft MC recommendations. In summary, the current scientific evidence shows that MC provides protection against numerous adverse medical conditions and infections, and the benefits of the procedure, including cost-savings over the long-term, greatly exceed risks, with benefits found in both poor and wealthy countries such as the United States. In addition, MC has no adverse effect on sexual function, sensitivity, or pleasure, nor is there reliable evidence for any long-term adverse psychological effect of MC. Furthermore, complication rates following the procedure are low, especially following early infant MC. Finally, pain that may be associated with the procedure during the first week of life can be negligible when local anesthesia is used.

Criticisms of the AAP and CDC policies by MC opponents have been consistently exposed as flawed (AAP policy[42,128–131]; CDC policy[132,133]). Convincing arguments have been made that it would be unethical to withhold information about the risks and benefits of MC from parents of boys.[130–132,134,135] as recommended by the AAP and CDC. Curiously, those who condemn parent-approved infant MC are not as quick to condemn procedures that provide no medical benefit to children (e.g., cosmetic orthodontia, correction of harelip, surgery for tongue-tie, treatment of dwarfism by growth hormone injections, and surgery for removal of supernumerary digits).[135] Why then do some regard MC as controversial?[135] Article 24(1) of the United Nations Convention on the Rights of the Child states, "States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health" and "shall strive to ensure that no child is deprived of his or her right of access to health care services."[136] Therefore, we assert that the CDC's draft MC recommendations do nothing more than advocate appropriately the right of male infants, children, adolescents, and adults to access health care services with medical benefits—that is, MC—and that adoption of the draft CDC recommendations into formal policy should improve public health in the United States.

Convincing arguments have been made that it would be unethical to withhold information about the risks and benefits of male circumcision from parents of boys.

Adoption of the draft CDC recommendations into formal policy should improve public health in the United States.

Policy statements on male circumcision by medical bodies should rely on medical evidence.

Competing Interests: Dr. Morris reports that he is a member of the Circumcision Academy of Australia, a government registered incorporated association whose Constitution states that it is "a non-profit organization" whose objectives are to "educate health professionals and the general public about male circumcision, including but not limited to the benefits, the risks and methods of male circumcision" and "to promote ease of access and affordability of male circumcision in Australia." Dr. Krieger reports that he performs male circumcision in his clinical practice as a urologist, outside the submitted work. In addition, Dr. Krieger has a patent pending for a male circumcision device. Dr. Klausner has nothing to disclose.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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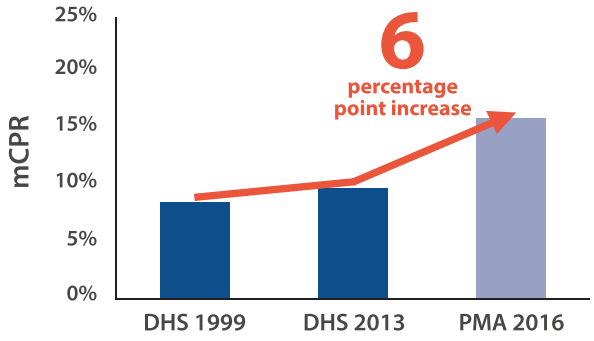
Global Health Data Pearls

Excellent Family Planning Progress in Nigeria Reported by PMA2020

- Modern method contraceptive prevalence among married women in Nigeria has jumped to 16.0% in 2016 compared with <10% in 2013.
- Notable increases were observed in the South as well as in some Northern states that had strong programming.
- Most of the increase was in the uptake of highly effective implants and injectables.
- But substantial unmet need for family planning remains, especially among the poorest quintile.
- Implants and IUDs are not offered in many facilities and stock-outs are common, suggesting further progress is achievable with improved program effort.

mCPR Among Married Women Increases

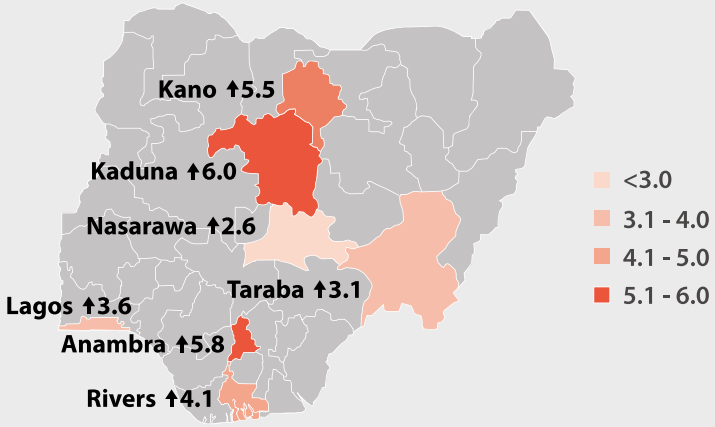


Since 1999, mCPR in Nigeria has been stagnant, hovering just under 10% among married women. But PMA2016 data suggest that in just 3 years—since the start of FP2020—mCPR has jumped by 6 percentage points.

Substantial Increases in mCPR Among Married Women in Most of the 7 Sampled States

Percentage Point Increase in mCPR (2013-2016)

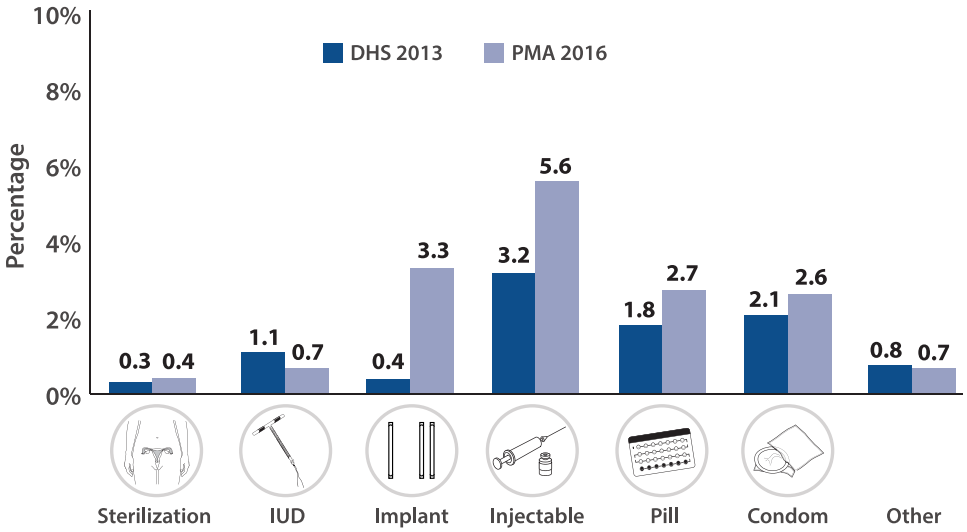
Substantial increases in mCPR generally occurred in the more developed South as well as in some Northern states with robust programmatic efforts, such as Kaduna.



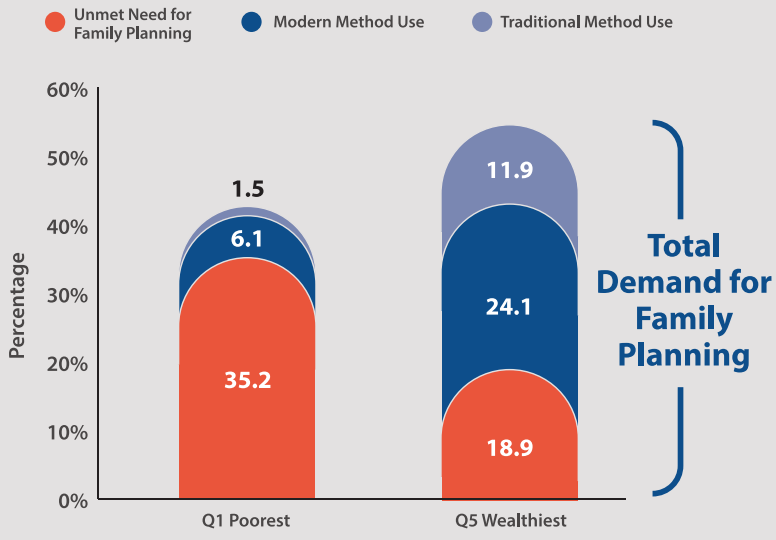
Kaduna and Lagos data are based on PMA2016 and PMA2014 survey differences. Data for the remaining states that did not conduct a PMA2014 survey are based on PMA2016 and DHS 2013 survey differences.

Increases Mainly in Implants and Injectables

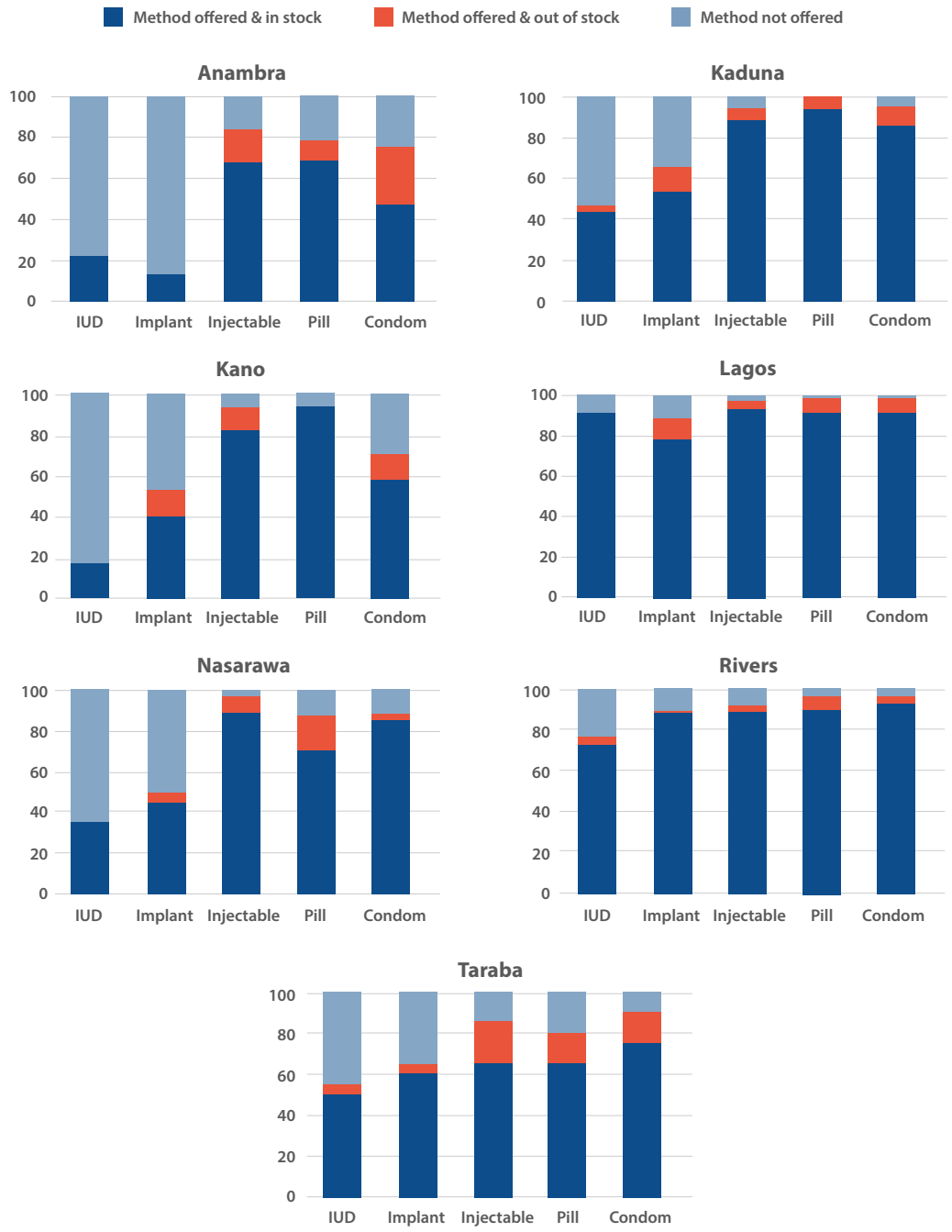
Changes in mCPR Among Married Women by Method



Major Unmet Need Remains, Especially Among the Poorest Quintile



Implants and IUDs Not Offered in Many Public Facilities That Offer Family Planning, Stock-Outs Common



About PMA2020

PMA2020 gathers nationally representative data on family planning and WASH annually at both the household and facility level in 10 FP2020 priority countries. By training a network of women from the selected communities to collect and transfer the survey data through smartphones, PMA2020 turns the data around rapidly and cost-effectively. The PMA2020 project is implemented by the Bill & Melinda Gates Institute for Population and Reproductive Health at the Johns Hopkins Bloomberg School of Public Health and funded by the Bill & Melinda Gates Foundation. For more information, visit www.pma2020.org.

About Global Health Data Pearls

In this issue of *Global Health: Science and Practice*, we are launching a new series to highlight emerging issues in global health data. For the first segment in this series, we are drawing on PMA2020 data from Nigeria.

PMA/Nigeria sample design

In 2014 and 2015, the PMA/Nigeria survey was conducted in 2 purposely selected states, Kaduna in the northwest and Lagos in the southwest. In 2016, the survey was expanded to 7 of the 36 states in the country to expand the geography for monitoring and to provide nationally representative estimates. In 5 of the 6 geopolitical zones, 1 state was selected using probability proportional to population size among all states within the zone. In the sixth zone, Lagos, the largest state in Nigeria, was selected. The sample size was calculated to estimate the mCPR with a 3% margin of error. In each sampled state, PMA2020 used a 2-stage cluster design, first selecting EAs using probability proportional to population size, then randomly selecting households in each selected EA. The final completed sample consisted of 10,131 households (97.1% response rate) and 11,054 women (97.9% response rate). Data collection was conducted between May 2016 and June 2016.

National-level estimates and comparability with DHS

To produce nationally representative data, estimates were adjusted for the probability that a given state would be selected among all states in its respective zone and for the population distribution across zones in the country. The additional stage of sampling at the state level is different from the 2-stage cluster sampling approach used at the national level in the DHS. Thus, considering the differences in arriving at national-level estimates, in addition to larger sampling errors with the PMA/Nigeria survey, some degree of care in comparing results from the 2 surveys is warranted.

Abbreviations

DHS, Demographic and Health Surveys; EA, enumeration area; FP2020, Family Planning 2020; mCPR, modern contraceptive prevalence rate; IUD, intrauterine device; PMA, Performance Monitoring and Accountability; WASH, water, sanitation, and hygiene.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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ORIGINAL ARTICLE

Youth Voucher Program in Madagascar Increases Access to Voluntary Family Planning and STI Services for Young People

Eva Burke,[a] Judy Gold,[b] Lalaina Razafinirinasoa,[c] Anna Mackay[d]

Program accomplishments during the first 18 months:

- **More than 58,000 free vouchers distributed to young people, of which 74% were redeemed.**
- **79% chose long-acting reversible contraceptives (LARCs) and 51% received STI counseling.**

Client profile data snapshot:

- **69% had never previously used contraception and 96% were 20 or younger.**

ABSTRACT

Background: Young people often express a preference for seeking family planning information and services from the private sector. However, in many Marie Stopes International (MSI) social franchise networks, the proportion of young clients, and particularly those under 20 years of age, remains low. Marie Stopes Madagascar (MSM) piloted a youth voucher program that joins a supply-side intervention—youth-friendly social franchisee training and quality monitoring—with a corresponding demand-side-component, free vouchers that reduce financial barriers to family planning access for young people.

Methods: Young people identified by MSM's community health educators (CHEs) received a free voucher redeemable at a BlueStar social franchisee for a package of voluntary family planning and sexually transmitted infection (STI) information and services. BlueStar social franchisees—private providers accredited by MSM—are reimbursed for the cost of providing these services. We reviewed service statistics data from the first 18 months of the youth voucher program, from July 2013 to December 2014, as well as client demographic profile data from July 2015.

Findings: Between July 2013 and December 2014, 58,417 vouchers were distributed to young people by CHEs through a range of community mobilization efforts, of which 43,352 (74%) were redeemed for family planning and STI services. Most clients (78.5%) chose a long-acting reversible contraceptive (LARC), and just over half (51%) of young people benefited from STI counseling as part of their voucher service. Most (78%) services were provided in the Analamanga region (the capital and its surroundings), which was expected given the population density in this region and the high concentration of BlueStar franchisees. The client profile data snapshot from July 2015 revealed that 69% of voucher clients had never previously used a contraceptive method, and 96% of clients were aged 20 or younger, suggesting that the voucher program is successfully reaching the intended target group.

Conclusion: MSM's youth voucher program has revealed a high demand for voluntary family planning services, especially among youth under 20 years old, and MSM has since integrated the youth voucher beyond the initial pilot locations. MSM's experience indicates that youth vouchers are a novel and effective means of increasing young people's access to voluntary family planning services in Madagascar, and this model could potentially be replicated or adapted in other contexts where young people are faced with barriers to accessing quality information and services.

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INTRODUCTION

Vouchers offer opportunities to reach specific groups of people with health services by removing financial barriers.[1,2] The services provided with vouchers are

typically highly specified—for example, family planning services—but generally allow the user to choose from a range of providers using a reimbursable token, often in paper form but sometimes digital.

The use of vouchers to support access to contraceptives can be traced back to Taiwan in the 1960s, where subsidized coupons were introduced to partially reimburse private-sector physicians for providing contraceptives under the national family planning program.[3] Although the approach was slow to expand to other countries, there has been increased experimentation with voucher programs since 2000, with at least 30 programs in developing countries identified in a 2011 review of the use of vouchers in sexual and reproductive health (SRH) programs.[4] Most voucher programs are used to engage the private sector, including NGOs, in subsidized service delivery to poorer women although a small number of programs have also experimented with using vouchers to increase access to public-sector facilities.

Voucher programs rarely target young people and/or adolescents exclusively. A recent systematic review of evaluations of family planning voucher programs identified only 2 studies of such programs: one in Vietnam focused on young people and another in Nicaragua focused on adolescents. No studies were identified on family planning voucher programs that focused on adolescents or young people in sub-Saharan Africa.[5]

Recent evaluations of family planning vouchers schemes have shown that vouchers have had a significant effect on voluntary contraceptive uptake in a range of settings.[6–8] Vouchers appear to be more effective among poorer women with high demand to use contraception but who are less likely to access family planning due to higher prices.[6]

Marie Stopes International (MSI), an NGO providing family planning and SRH services in 37 countries, has introduced voucher schemes in several of its country programs to provide SRH services to the poorest and hard-to-reach populations, resulting in thousands of women accessing quality services. The success of these programs to date has been attributed to multiple factors such as targeted awareness-raising interventions, complemented by quality assurance measures and robust controls for voucher management. In many cases, the programs have engaged their private-sector social franchisee networks to deliver the services.[9]

Madagascar Context

Madagascar is an island nation of 23 million inhabitants located off the east coast of Africa. Poverty levels are high; 92% of the population lives on less than US$2 per day.[10] Almost two-thirds (64%) of the population is under 25 years of age,[11] and there is a high rate of fertility among adolescents (163 births per 1,000 adolescents).[12] Rates of maternal mortality are also high, with an estimated 478 deaths per 100,000 live births, and 17% of female adolescent deaths are due to maternal causes.[12] The most recent Demographic and Health Survey (DHS) conducted in 2008–09 revealed that 17% of married women and 14% of unmarried, sexually active women aged 15–19 years were using a modern method of contraception, but 27% of married women of this age group expressed an unmet need for family planning.[13] Long-acting reversible contraceptives (LARCs) were used by less than 0.5% of 15–19-year-olds, and are not readily available through the public sector, limiting contraceptive choices to short-acting methods. The same survey found high rates of teenage childbearing; 32% of women aged 15–19 years already had children or were currently pregnant, and this was significantly higher for the poorest quintile where 51% had started childbearing.[13] Early marriage is common in Madagascar where 48% of girls are married before the age of 18.[14]

Marie Stopes Madagascar (MSM) has been operating in Madagascar since 1992 and is one of the largest non-state providers of voluntary family planning and SRH services. MSM delivers services to clients in all 22 regions of Madagascar through a network of 20 clinics; 200 MSI-trained midwives offering short-acting and voluntary LARC methods through mobile community visits; 22 mobile outreach teams; and 150 private and 140 public social franchisees. Social franchisees are existing, third-party private providers who are trained, accredited, and quality-monitored under MSI's social franchising brand, BlueStar (private sector) or CSBStar (public sector in Madagascar), to deliver a broad range of voluntary high-quality family planning services, including LARCs.

In 2012, MSM recognized that despite the high youth population of Madagascar and the high rates of early marriage, pregnancy, and unmet need for family planning, only 12% of BlueStar franchisee clients were aged 15–19 years. Cost is a key barrier for young people to access services, as documented by other MSI country programs,[15]

and the high levels of poverty in Madagascar indicated that cost should also be considered a key barrier for this age group.

Since 2011, MSM has been implementing a voucher program linked to the BlueStar franchise network whereby clients who are assessed as poor can purchase a voucher for Malagasy Ariary 200 (approximately US$0.06) and use the voucher to receive voluntary family planning counseling and services at a BlueStar facility for no additional fee.[16] This program, aimed at reducing financial barriers for poor clients and expanding method choice, uses SMS reporting of voucher claims and mobile money payments to franchisees.[17] In 2013, MSM began designing and developing a youth voucher program to improve youth's access to voluntary family planning services. This article describes the design of the youth voucher program and reviews service statistic data from the first 18 months of implementation.

METHODS

Voucher Program Design and Development

To design the youth voucher program in Madagascar, MSM drew on its own voucher program management experience and on lessons from other MSI country programs that have used vouchers to reach young people. Lessons learned from a youth voucher pilot program in MSI's Zimbabwe country platform in 2013, funded by the United States Agency for International Development (USAID), confirmed that the provision of vouchers to young people for family planning services was welcome by recipients for overcoming the cost barrier of paying out of pocket for health services.[18] Client and provider feedback on this pilot highlighted the need to expand the range of services available through the voucher to include services for sexually transmitted infections (STIs) and follow-up care for family planning services, e.g., removals or check-ups for voluntary LARC methods. As well as reducing cost barriers, voucher programs were considered a means to increase the range of voluntary contraceptive choices available, as well as the quality of services provided.

MSM was also aware that the overall use of mobile phones in Madagascar had increased dramatically, with an estimated 40% of the population owning a mobile phone,[19] or 46 mobile phones per 100 people.[20] A 2012 survey revealed that over half of MSM BlueStar clients owned mobile phones. MSM decided that mobile phones not only offered an opportunity to deliver vouchers electronically (i.e., eVouchers) to young people, but also that these could be seen as attractive and novel by MSM's target youth audience, increasing their appeal and thus distribution potential.

MSM adapted its existing voucher management software to incorporate the youth voucher component and trained community health educators (CHEs) and BlueStar franchisees on the new youth voucher. CHEs are contracted by MSM to provide quality counseling on comprehensive family planning and referral support at the community level to MSM BlueStar franchisees. They are based within or near the communities in which they work and distribute the poverty and youth vouchers to those eligible to receive them. To ensure that the needs of young people were appropriately addressed, MSM introduced youth-friendly training for the entire social franchise network of 150 BlueStar franchisees and for all CHEs. The training curriculum used by MSM, and delivered by MSM's Youth Medical Advisor, was adapted from the Ministry of Health's youth strategy and included a range of modules such as communication techniques, SRH of young people, and how to adapt service delivery to be youth-friendly.

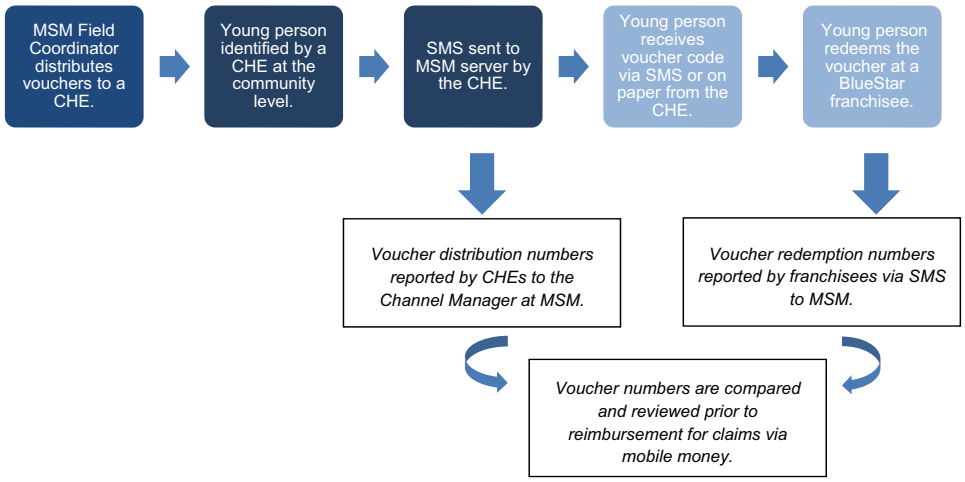
Marie Stopes Madagascar (MSM) began a youth voucher program in 2013 to improve youth's access to voluntary family planning and STI services at BlueStar franchisees.

MSM initially envisioned the youth voucher exclusively as an SMS-based mobile voucher. In parallel to commencing mobile voucher activities, MSM conducted a study to assess the acceptability of a mobile-based voucher program and to better understand how to reach young people who did not possess a mobile phone.[21] Results revealed that young people were receptive to receiving family planning information through mobile phones, with a desire for more information on the range of contraceptive methods and where to access them. However, the study also highlighted the need for an alternative strategy as only 20% of respondents under the age of 20 years possessed a mobile phone. In addition, remote parts of Madagascar have limited access to phone network coverage. To maximize the program's reach, MSM adapted its voucher distribution system to include a paper voucher component.

The youth voucher program was initially envisioned as an SMS-based mobile program, but paper vouchers were added to ensure access for youth without mobile phones or living in remote areas without mobile phone coverage.

The voucher program commenced in late 2013 in 6 regions with 27 CHEs and 24 BlueStar franchisees, and expanded in scope over time, reaching 10 regions with 56 CHEs and 80 BlueStar franchisees by late 2014. More details of the voucher program methodology can be found in a program report.[22]

FIGURE 1. Distribution Process During the Initial Phase of the MSM Youth Voucher Program (July 2013–December 2014)



Abbreviations: CHE, community health educator; MSM, Marie Stopes Madagascar.

Voucher Distribution

During the initial phase of the voucher program, when an eligible young person expressed interest in receiving a service from a provider in the BlueStar network, the CHE initially provided him or her with a voucher in one of two ways (Figure 1):

Youth voucher program services included family planning counseling, provision of short-acting and long-acting methods, and STI counseling.

1. If the young person had a mobile phone, the CHE would send an SMS to MSM to request an electronic voucher be sent to the young person's phone. This code formed the youth voucher, which the young person could then use to redeem for voluntary family planning and/or STI services at a participating BlueStar franchisee of his or her choice.
2. If the young person did not have a mobile phone or did not want an eVoucher sent, CHEs requested a voucher code (as described above) using their own mobile phone, and upon receipt, the CHEs wrote the code on a piece of paper for the young person to redeem for a free service.

Voucher Package of Services

MSM designed a package of services covered under the voucher to meet the needs of young people. When a young person presents at a BlueStar facility with a voucher, the franchisee provides information and counseling about the voluntary family planning and STI services available at the clinic. The young person then decides if he or she wants a service, and if so, which one(s). These services are then provided at no cost to the client. The services available under the youth voucher program are:

- Family planning counseling
- Provision of short-acting contraceptive methods (oral contraceptive pill, 3-month injectable, emergency contraception, condoms)
- Provision of LARCs (3-year implant, 10-year IUD)
- STI screening, counseling, and referral for treatment
- Removal of LARC method

A young person is able to obtain a combination of services under one voucher, for example a contraceptive method of choice and STI counseling and screening.

Voucher Awareness Creation

MSM launched the youth voucher program with a comprehensive awareness-creation strategy to engage young people. All of MSM's

CHEs—largely young women under the age of 25 years—distribute vouchers in their communities. Following a mapping exercise, CHEs identify eligible young people (male or female) aged 24 years or younger, with a focus on those under 20 years old, through their personal networks, concentrating mobilization efforts in areas where young people congregate, such as in and around schools and at youth associations and markets.

Community-based mobilization efforts by CHEs are complemented by other informational activities, such as concerts for young people where information on the vouchers is available, and community sensitization with influential community members such as parents, teachers, and community leaders. MSM also collaborates with organizations working with commercial sex workers in HIV prevention and support to refer young commercial sex workers for voluntary family planning and STI services using the voucher.

In addition, MSM introduced collaborative community mobilization efforts led by CHEs working together with BlueStar franchisees in their communities. The events take place either at or outside the franchisee facility. To increase service accessibility, some franchisees temporarily provide services outside their regular clinic, at sites within sensitized communities, following identification of sites with high potential youth demand for voucher services. If the site does not meet the necessary MSI clinical quality standards to provide services, the CHEs distribute the vouchers but young people are referred to the franchisee facility to redeem their voucher for a service(s).

This collaboration between the CHEs and franchisees to provide comprehensive information and voucher distribution coupled with same-place, same-time provision of services is appealing to young people, resulting in many young people redeeming their vouchers on the same day as the event.

Quality Assurance and Support for BlueStar Providers

As part of its social franchising service delivery channel, MSM conducts ongoing quality assurance monitoring and support for BlueStar franchisees. Regular visits conducted by the medical team help ensure adherence to MSI's global quality standards and identify support requirements. BlueStar franchisees are included in annual MSM internal and external clinical audits to evaluate the quality of client care and service provision by individual providers. Client experience, one key indicator of service quality, is monitored annually through client exit interviews and mystery client visits. These measures, together with youth-friendly training received by each BlueStar franchisee participating in the voucher program, support providers to consistently deliver high-quality services that meet the needs of young clients.

Ongoing quality assurance monitoring coupled with training in provision of youth-friendly services have supported providers to consistently deliver high-quality services that meet the needs of young clients.

Voucher Reimbursement to BlueStar Providers

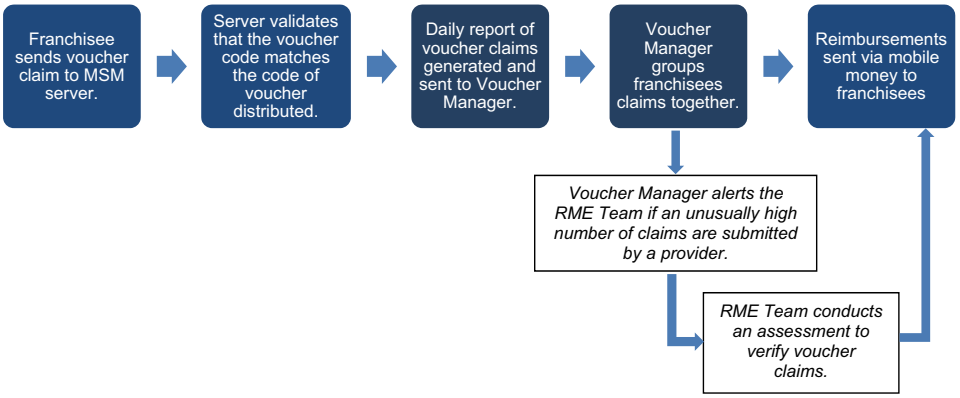
BlueStar providers deliver services free of charge to voucher-bearing young clients. Following service delivery, BlueStar providers submit claims for voucher services provided, and MSM reimburses providers for their costs. Following similar operating procedures for MSM's other, large-scale poverty voucher program, the franchisees send an SMS to MSM containing the required information, including the voucher code. MSM confirms that the SMS is from an approved mobile phone number and that the voucher code matches the database of voucher codes recorded as distributed by the CHE (Figure 2). This system allows MSM to reimburse providers promptly and identify operational issues through ongoing monitoring of real-time program data.

BlueStar franchisees submit reimbursement claims regularly, and payments are processed through online mobile money payment systems available in Madagascar, via the franchisees' mobile money network of choice. The amount reimbursed for each voucher varies depending on the type of service(s) provided (Table 1), as some services incur a higher commodity cost and take a longer timer to counsel on and provide, such as the provision of voluntary LARC methods. Set reimbursement rates for each service, or combination of services, are communicated to each participating franchisee prior to accreditation.

Monitoring and Verifying Claims

Monitoring visits by the MSM team provide the opportunity to cross-reference client data in daily registers with reimbursement claims made to MSM. The ongoing receipt of requests for voucher codes and claims for reimbursement permit real-time monitoring of the voucher program by MSM. Daily tracking of the number of voucher codes distributed by CHEs, the number of voucher codes redeemed, and the number of reimbursement claims enable MSM's

FIGURE 2. Marie Stopes Madagascar Youth Voucher Program Reimbursement and Verification Process



Abbreviation: RME, Research, Monitoring, and Evaluation.

TABLE 1. Marie Stopes Madagascar Reimbursement Rates to BlueStar Franchisees for Youth Voucher Services

Service	Reimbursement Rate (MGA)	Reimbursement Rate (USD)[a]
IUD insertion	9,500	$4.00
Implant insertion	7,500	$3.20
Removal and reinsertion of an IUD	12,000	$5.10
Removal and reinsertion of an implant	10,000	$4.20
Removal of long-acting method for a short-acting method	2,000	$0.80
Short-acting method	2,000	$0.80
IUD plus STI counseling	12,500	$5.30
Implant plus STI counseling	12,500	$5.30
Short-acting method plus STI counseling	5,000	$2.10

Abbreviations: IUD, intrauterine device; MGA, Malagasy Ariary; STI, sexually transmitted infection; USD, U.S. dollars.
[a] Using the average exchange rate from Oanda.com for the period July 2013–December 2014 (US$1=2359 MGA).

Voucher Manager to follow up immediately in the event of data inconsistencies, including contacting franchisees if he/she experiences problems processing vouchers or submitting claims. Such real-time monitoring and provision of support would not be possible without using a system of unique codes that allows for continual submission of data.

An alert system was developed to identify instances of unusually high volume of claims submitted by a BlueStar franchisee. The Voucher Manager receives a daily report of voucher claims

generated by providers. If the manager detects an unusually high number of claims submitted by a provider, the manager alerts the Research, Monitoring, and Evaluation (RME) team. In such instances, the RME team conducts a rapid voucher tracing assessment to check the validity of the claims by verifying client identities and reimbursed services (Figure 2). To ensure confidentiality, voucher clients provide their consent (or not) ahead of time to be contacted if their participation is required later for an assessment.

If services claimed by franchisees cannot be validated during the assessment process, MSM does not reimburse the franchisee. During the initial pilot phase of the youth voucher program, the assessment process was conducted on a monthly basis. We later shifted to conducting the process on a quarterly basis by selecting a random sample of franchisees for assessment. This mechanism highlights the importance of maintaining accurate client data records to ensure that claims can traced and validated.

Data Collection and Analysis

In this article, we present service statistic data collected during the initial phase of the youth voucher program, from July 2013 to December 2014. Data include the number of vouchers distributed by CHEs and redeemed by youth, location of redemption, and types of services redeemed. MSM did not routinely collect demographic data on voucher clients during the initial pilot period of the program. Following the shift to 2 separate voucher distribution systems (eVouchers and paper vouchers), MSM commenced data collection to better understand the profile of the young people being reached. In this article, we present client profile data of paper voucher clients from July 2015. Client profile data were collected using smartphones, uploaded to a Microsoft Excel database, and numbers and percentages were extracted to generate a snapshot of the voucher clients' profile.

RESULTS

During the initial phase of the youth voucher program, between July 2013 and December 2014, MSM distributed 58,417 vouchers, of which 43,352 were redeemed (74% redemption rate). As intended, most voucher redemptions (95%) occurred at BlueStar social franchisees, with only 4% redeemed at participating MSM outreach sites and 1% at MSM's Tulear region clinic.

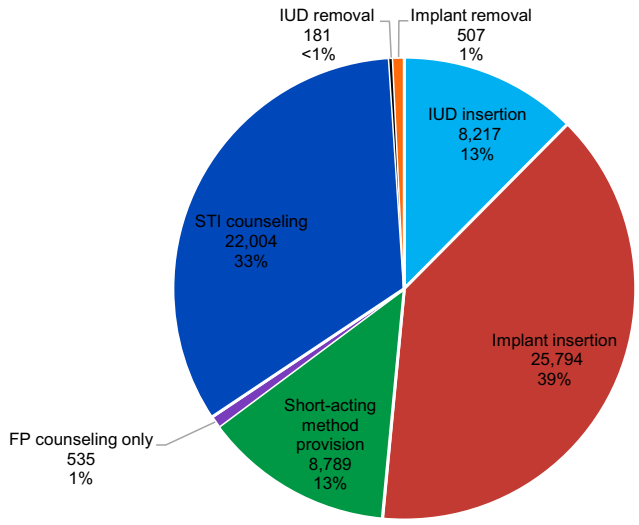
Voluntary LARCs were the most frequently chosen type of service (78.5%), with implants chosen 3 times as frequently as IUDs (Table 2). Some of these LARC services entailed removal of the IUD or implant, but in nearly all cases, the client had a new IUD or implant inserted. Short-acting methods were chosen by 20% of clients. About 1% of clients received family planning counseling only without provision of a method. Just over half of clients (51%) received STI counseling in addition to a contraceptive method. MSM reported that, in general, young people visited a service point seeking a voluntary family

TABLE 2. Vouchers Redeemed by Type of Service, Marie Stopes Madagascar Youth Voucher Program, July 2013–December 2014 (N=43,352 Vouchers Redeemed)

Service	No. (%)
Long-acting family planning services	
IUD only	2,818 (6.5)
Implant only	11,608 (26.8)
IUD plus STI counseling	5,220 (12.0)
Implant plus STI counseling	13,682 (31.6)
Removal only of an IUD	2 (0.005)
Removal only of an implant	3 (0.007)
Removal and reinsertion of an IUD	179 (0.4)
Removal and reinsertion of an implant	504 (1.2)
Total long-acting family planning services	**34,016 (78.5)**
Short-acting family planning services	
Short-acting method only	5,564 (12.8)
Short-acting method plus STI counseling	3,102 (7.2)
Removal of long-acting method for a short-acting method	123 (0.3)
Total short-acting family planning services	**8,789 (20.3)**
Other services	
Family planning counseling only	535 (1.2)
Referrals	12 (0.03)
Total other services	**547 (1.3)**
TOTAL	**43,352 (100.0)**

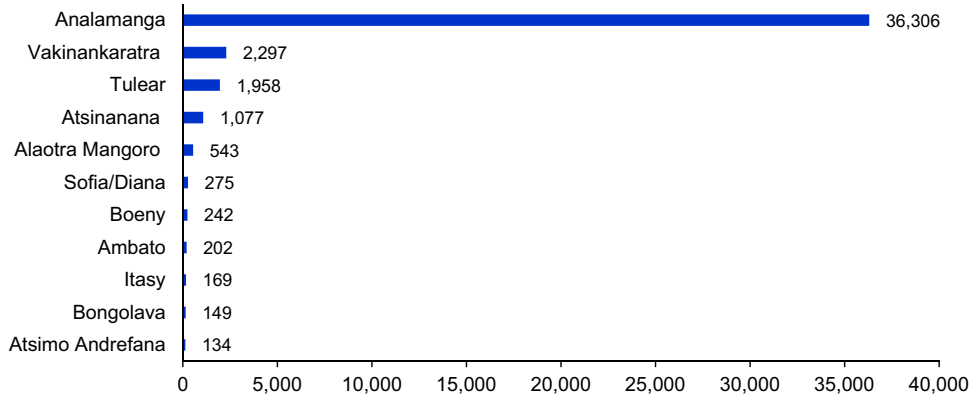
Abbreviations: IUD, intrauterine device; STI, sexually transmitted infection.

FIGURE 3. Services Redeemed by Young People With Vouchers, July 2013–December 2014 (N=66,027 Services)



Abbreviations: FP, family planning; IUD, intrauterine device; STI, sexually transmitted infection.

FIGURE 4. Number of Youth Vouchers Redeemed by Region, Marie Stopes Madagascar, July 2013–December 2014 (N=43,352 Vouchers Redeemed)



planning service. However, during history-taking, franchisee providers discovered that many young people were at risk of an STI (through the syndromic management approach), and subsequently many clients opted for STI counseling. BlueStar franchisees are reimbursed for the time taken to counsel a young person on STIs. As vouchers could be used to redeem one or a combination of services, Table 2 depicts these services separately (e.g., it separates "implant" from "implant plus STI counseling"). Figure 3 provides a more holistic picture of the volume of each type of service by grouping similar types of services. For example, all implant insertions are combined

together (whether the client received only an implant insertion or an implant insertion plus STI counseling). The denominator in Figure 4 is thus the 66,027 total services provided. In the first year and a half of operation, the youth voucher program provided 25,794 implants, 8,217 IUDs, and 8,789 short-acting methods. The largest share (39%) of services was for insertion of an implant, followed by STI counseling (33%).

Results by Region

Youth vouchers were initially introduced in 4 regions; Analamanga, Mangoro, Tulear, and Vakinankaratra. By the end of the pilot period in December 2014, the vouchers had been extended to 11 of Madagascar's 22 regions where BlueStar franchisees and a significant youth population were concentrated. The highest proportion of voucher distribution and redemptions were in the region of Analamanga, where the capital city of Antananarivo is located, with 80% of all vouchers distributed and 78% of all vouchers redeemed in this region (Figure 4). This was expected, as Analamanga is the most densely populated region in Madagascar and has the highest concentration of BlueStar franchisees.

Results by Demographic Characteristics

Table 3 provides a snapshot of characteristics of the 1,425 young people who used paper vouchers to receive a service in July 2015. Most (91%) of these youth voucher users were women, and the large majority (96%) were 20 years old or younger, suggesting that the voucher program is successfully reaching the intended target group. While the majority (53%) did not have any children, a significant proportion (46%) had one or more children. Over a third (39%) were married or cohabiting with a partner. Of the 1,425 young people, 69% had never previously used a contraceptive method.

TABLE 3. Paper Voucher Client Profile, Marie Stopes Madagascar, July 2015 (N=1,425)

Client Characteristic	No. (%)
Sex	
Female	1303 (91)
Male	122 (9)
Age, years	
<15	75 (5)
15–18	786 (55)
19–20	514 (36)
21–24	50 (4)
No. of living children	
0	757 (53)
1	502 (35)
2	148 (10)
3	14 (1)
5 or more	4 (0.3)
Marital status	
Married or cohabiting	553 (39)
Single or living alone	872 (61)
First-time family planning user	
Yes	987 (69)
No	438 (31)

DISCUSSION

The MSM voucher program enabled a significant number of young people in Madagascar to access a range of voluntary family planning and STI information and services, while increasing the capacity of BlueStar franchisees to provide high-quality services to this key group of people. The voucher program expanded young people's choice of contraceptive methods to include voluntary LARCs, which the public sector to date has not been able to fulfill. (See the Box for a story of a youth voucher client.)

More than 43,000 young people accessed services in the voucher program's first 18 months of operation. These impressive results demonstrate that need exists among young people for high-quality family planning information and a broad range of voluntary services. The success of the voucher program is likely due to a combination of factors: on the demand side, the provision of community-based information, education, and communication activities to young people and other community members and the removal of service fees; and on the supply side, the availability of a broad range of contraceptive methods and a quality provider of the client's choice with the willingness and capacity to serve young people. These complementary components of the voucher program led to a significant redemption of the

The MSM voucher program expanded young people's choice of contraceptive methods to include voluntary LARCs.

BOX. Marie Stopes Madagascar Youth Voucher Client Story

One of Marie Stopes Madagascar's (MSM's) youth voucher beneficiaries is a 17-year-old who has a 2-month-old baby. She has 8 siblings and left primary school when she was 9 years old because her mother could not afford to keep sending her. She is unemployed but her fiancé works at the bus station, earning between US $1.70 and $6.00 a day. Following a visit to Dr. Florence's BlueStar clinic for her baby's vaccinations, she met one of MSM's community health educators and learned about the voucher program for young people. Having never previously used a contraceptive method, she chose to redeem her voucher for an IUD. Without the voucher program, her only option to access family planning services would have been at a public health center, limiting her to only short-acting methods since long-acting methods are not widely available in the public sector.

vouchers, and could be a demonstration of young people feeling empowered to make informed choices about their SRH.[23] The voucher program also highlighted the high demand for voluntary LARCs among young people if they are made available to them; over 4 times as many voluntary LARCs were chosen by young people compared with short-acting methods when they were provided with a broad choice of methods.

The program demonstrated the ability of vouchers to leverage private provider networks to provide quality services to a large number of young people, and MSM has been impressed by the willingness, and increasing confidence, of private-sector providers to provide voluntary family planning and STI information and services to this group.

Lessons have been learned along the way, especially related to the absence of mobile phones among young people in poorer communities. The voucher distribution system was quickly adapted, and later refined, to provide a paper-based voucher to complement the eVoucher, enabling access for young people without mobile phones while ensuring robust voucher tracking and follow-up. CHEs now distribute only the paper voucher at the community level. Meanwhile, MSM's Call Centre—a free hotline where callers receive family planning information and referrals to service providers—provides an opportunity to reach young people with mobile phones who may not have been reached via community-based CHE activities to date. This two-pronged approach will undoubtedly increase access to voluntary family planning and STI services for young people in the future. The voucher system will continue to evolve over time, as MSM fine-tunes operations and responds to client feedback. Systems will be continuously reviewed to ensure that the distribution, redemption, and claims processes are robust and efficient. Quarterly assessments of a random selection of social franchisees is an example of how one of MSM's monitoring activities has evolved to enhance data accuracy and identify any necessary support requirements.

CONCLUSION

MSM's experience indicates that youth vouchers can be a novel and effective means of increasing access to voluntary family planning services for young people, and that the private sector can be an appropriate and acceptable delivery channel to deliver a broad range of voluntary contraceptive methods for young people. MSM's approach of using vouchers to increase awareness and support to improve supply has the potential to be replicated (with adaptation to context) and taken to scale in other countries where young people face barriers in accessing voluntary, quality information and services, thus increasing family planning access and choice for the growing youth cohort in developing countries.

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GLOBAL HEALTH: SCIENCE AND PRACTICE
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ORIGINAL ARTICLE

Community Health Workers as Social Marketers of Injectable Contraceptives: A Case Study from Ethiopia

Karen Weidert,[a] Amanuel Gessessew,[b] Suzanne Bell,[c] Hagos Godefay,[d] Ndola Prata[a]

Volunteer community health workers (CHWs) administered injectable contraceptives to women in the community for a small fee while providing counseling and referrals for other methods. Over nearly 3 years, more than 600 CHWs provided an estimated 15,410 injections. The model has the potential to improve sustainability of community-based distribution programs by incorporating social marketing principles to partially recover commodity costs and compensate CHWs.

ABSTRACT

Ethiopia has made notable progress in increasing awareness and knowledge of family planning and is considered a success story among funders and program planners. Yet unmet need among rural women (28.6%) is almost double that of urban women (15.5%), with a wide gap in total fertility rate depending on urban (2.6) or rural (5.5) residence. This study investigates the impact of a service delivery model that combines community-based distribution (CBD) of contraception with social marketing in Tigray, Ethiopia, to create a more sustainable approach to CBD. Between September 2011 and October 2013, 626 volunteer CHWs were recruited and trained to administer depot medroxyprogesterone acetate (DMPA) injections and provide counseling and referrals to the health post for other methods; the project implementation period ended in June 2014. The CHWs received a supply of DMPA injections in the form of a microloan from a drug revolving fund; the CHWs charged women a minimal fee (5 birr, or US$0.29), determined based on willingness-to-pay data, for each DMPA injection; and the CHWs returned part of the fee (3 birr) to the drug revolving fund while keeping the remaining portion (2 birr). The CHWs also promoted demand for family planning through door-to-door outreach and community meetings. Existing health extension workers (HEWs) provided regular supervision of the CHWs, supplemented by in-depth supervision visits from study coordinators. Baseline and endline representative surveys of women of reproductive age, as well as of participating CHWs, were conducted. In addition, DMPA provision data from the CHWs were collected. Between October 2011 and June 2014, the CHWs served in total 8,604 women and administered an estimated 15,410 DMPA injections, equivalent to providing 3,853 couple-years of protection. There was a 25% significant increase in contraceptive use among surveyed women, from 30.1% at baseline to 37.7% at endline, with DMPA use largely responsible for this increase. Changes in quality of family planning markers from baseline suggested services improved between baseline and endline: nearly 50% more women reported being told about side effects and what to do if they experience side effects, and 25% more women said they were told about other methods of contraception. The results from household surveys at baseline and endline suggest that CHWs in this model made a significant contribution to family planning in the region.

INTRODUCTION

Meeting the contraceptive needs of rural women in sub-Saharan Africa remains a challenge. Family planning services are predominantly offered through public health facilities, but access is limited by distance to facility, quality of services, availability and affordability of contraceptive methods, and medical or legal barriers.[1–4] There is strong evidence to support the hypothesis that a country's contraceptive prevalence is directly associated with measures of access to both individual methods and a balanced method mix.[1,5–7]

In 2011, injectable contraceptives were the most commonly used method among married women in sub-Saharan Africa,[8] and this trend has continued.[9] Using multivariate models, Skiles et al. examined the effect of access to contraceptive services on injectable use and demand for family planning in Malawi and found that

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the probability of injectable use among rural women with the most access, as measured by distance alone and distance combined with supply reliability, was 7–8 percentage points higher than among rural women with the least access.[7]

Community-based distribution (CBD) programs that rely on community health workers (CHWs) have been successful in increasing access to and use of injectable contraceptives, particularly in settings where unmet need is high, access is low, and geographic or social barriers to use of services exist.[7,10–14] A major strength of CBD programs is that they bring information, services, and supplies to women and men in the communities where they live and work. Integrating CHWs into health systems is considered a high-impact practice for family planning,[15] yet funding and sustaining such programs remain a challenge given the cost of training and supervising CHWs who are often dispersed across geographic regions.[16]

Ethiopia has made notable progress in increasing awareness and knowledge of family planning and is considered a success story among funders and program planners. Favorable political will, generous donor support, public-private partnerships, and the government's establishment of a Health Extension Worker (HEW) program have been identified as key factors in this success.[17] The Government of Ethiopia launched the HEW program in 2004[18] to deploy salaried health care providers to serve the primary health care needs of rural communities. The HEWs have a tenth grade education or more and receive training for 18 months. Two HEWs are based in each rural health post and provide some community outreach, such as vaccination campaigns.[19,20]

Starting in 2007, the government allowed HEWs to administer injectable contraceptives. This likely contributed to the doubling of injectable contraceptive use among women of reproductive age, from 6.8% in 2005 to 14.0% in 2011.[17] In 2009, the government began training HEWs in the insertion of contraceptive implants. Subsequently, implant use increased from 0.2% in 2005 to 3.4% in 2011.[17,21,22] Though HEWs have been an important addition to the public health sector, provision of family planning is just one of 16 basic health services they deliver to large, widespread populations, which may present limitations in family planning outreach efforts. Meanwhile, unmet need for family planning among rural women (28.6%) is almost double that of urban women (15.5%), with a wide gap in total fertility rate depending on urban (2.6) or rural (5.5) residence.[22]

Consequently, volunteer CHWs can still be a valuable resource for bridging outreach activities and health post services. They can support HEWs delivering family planning information and services, serving as extensions of the health posts for remote areas, which is important given the high percentage of the Ethiopian population living in rural areas (81%).[22] CHWs are also necessary given the multifaceted clinical roles HEWs have to assume due to health care worker shortages in the country. With declining fertility preferences and high unmet need for contraception, there is an opportunity to optimize CHWs and shift or share the task of family planning provision, including injectable contraceptives.

Community-based distribution programs have been successful in increasing access to and use of injectable contraceptives, but funding and sustainability of such programs remain a challenge.

Recognizing a continued need for community-based access to the injectable contraceptive depot medroxyprogesterone acetate (DMPA), the University of California at Berkeley Bixby Center for Population, Health and Sustainability, in conjunction with Mekelle University College of Health Sciences, the Women's Association of Tigray, and the Tigray Regional Health Bureau, developed a service delivery model that combined CBD with social marketing. This model grew from a desire to scale up a pilot study where CHWs were successfully trained to provide injectable contraceptives in Tigray, Ethiopia.[12] We incorporated private-sector strategies such as willingness-to-pay, social marketing, and a drug revolving fund, with the aim of creating a sustainable contraceptive service delivery model that used CHWs as rural social marketing agents to distribute DMPA. Long-term availability of DMPA, the supply and distribution of DMPA, and reduced CHW attrition were key factors in designing the model.

We tested a service delivery model that combined community-based distribution of injectable contraceptives with social marketing.

The purpose of this article is to illustrate the impact of the program model on reducing barriers to DMPA access in Tigray and increasing commodity security in rural communities. We draw on experiences from scaling up this model to describe lessons learned and factors that contributed to implementation of the program in Ethiopia, with hopes of informing family planning strategies and practical application in other settings.

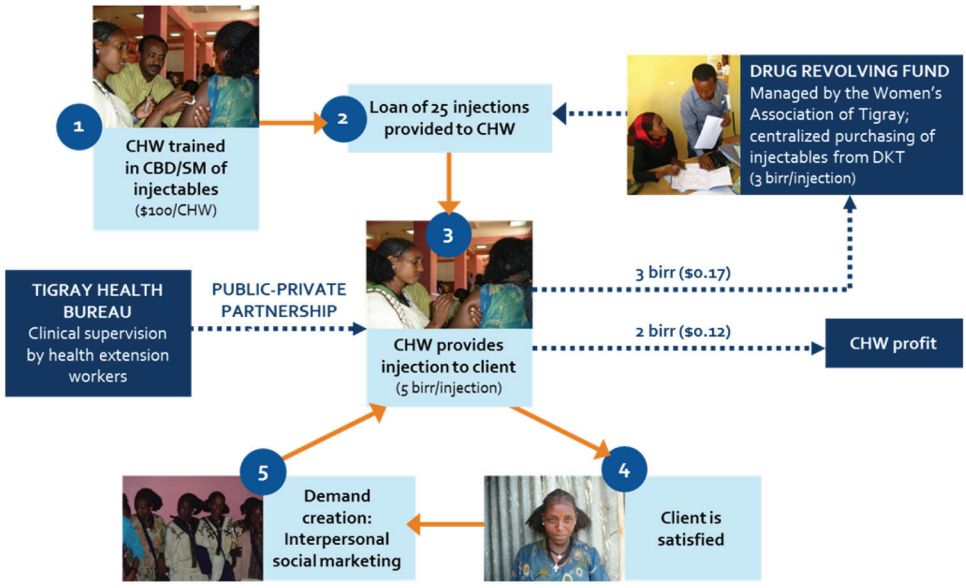
PROGRAM DESCRIPTION

Program Model

The Figure depicts the program model implemented in this study in the Central and Southern rural zones of Tigray, Ethiopia, between September 2011 and June 2014. First, 2 CHWs were selected and trained from each participating *kebele* (village) to administer injectable

In Ethiopia, unmet need for family planning among rural women is double that of urban women.

FIGURE. Program Model for Combining Community-Based Distribution and Social Marketing in Tigray, Ethiopia



Abbreviations: CBD, community-based distribution; CHW, community health worker; SM, social marketing.

CHWs used social marketing techniques, tailored to rural audiences, to promote demand for family planning.

contraceptives and provide counseling and referrals to the facility for other contraceptive methods. After the training, CHWs were provided with a supply of 25 DMPA injections in the form of a microloan from a drug revolving fund. The drug revolving fund credited CHWs 3 birr (US$0.17) for each dose of DMPA, which was the subsidized cost of 1 dose of DMPA purchased from DKT-Ethiopia, the social marketing agency. CHWs provided each DMPA injection to women for 5 birr (US$0.29). This amount was determined using willingness-to-pay data from the pilot study,[12] which was confirmed as acceptable during baseline data collection.[23] Of the 5 birr payment received for each injection administered, CHWs returned 3 birr to the drug revolving fund and kept the remaining 2 birr (US$0.12). CHWs also had discretion to provide injections for free to women who could not afford to pay and were not able to reach a facility for free injections; the CHWs were not held accountable for the cost of the drug in these instances. Funds returned to the system through sales of DMPA were managed by the Women's Association of Tigray and used to purchase additional DMPA from DKT-Ethiopia.

Of the 5 birr that CHWs charged women for each DMPA injection, the CHWs returned 3 birr to the drug revolving fund and kept the remaining 2 birr.

These doorstep services were intended to increase client satisfaction. Social marketing, an approach that integrates marketing concepts with other approaches such as subsidized products to influence behaviors that benefit individuals and communities for the greater social good, was used to create awareness of the product and generate demand for services (Box). In fact, CHWs were considered rural social marketers generating demand through both conventional social marketing techniques and methods tailored more to rural audiences. The injectable contraceptive product of DKT-Ethiopia used in this project is marketed under the brand name *Confidence*, which helped with visibility in the community. CHWs received a marketing poster for display in their homes, but their services were also promoted through door-to-door outreach, community meetings, and word-of-mouth among women. The rationale behind the program model and initial roll out is described in more detail by Prata et al.[25]

BOX. Social Marketing

Social marketing seeks to develop and integrate **marketing** concepts with other approaches to influence behaviors that benefit individuals and communities for the greater **social** good, such as anti-smoking campaigns and use of contraception for better maternal and child health. Unlike commercial marketing in which the primary aim is to reap financial benefits, the focus of social marketing is on the social good.

Social marketers must create competitive advantage by constantly adapting to and instigating change. Market changes are likely to be more successful if actions are guided by knowledge of the forces shaping market behaviors and insights that enable the development of sustainable competitive advantages.

In the family planning field, it became apparent that social marketing of contraceptives since the 1980s has not only increased awareness, acceptability, and use of modern contraceptives in developing countries but also overcome logistic problems in service delivery.[24] This strategy has the ability to reach large numbers of potential clients, and it markets contraceptives as common consumer products. Each contraceptive social marketing program is built around a theme tailored to meet specific cultural, social, and management requirements. The primary target populations are those who cannot afford regular commercial products and those who are not adequately reached by government programs.

Selection and Training of CHWs

CHWs, formerly called community-based reproductive health agents (CBRHAs) in Ethiopia, are volunteer community lay health care workers who have been mobilized to provide basic family planning education, services, and referrals in rural areas. The Women's Association of Tigray selected the CHWs for this program (2 per *kebele*), who came from the existing pool of CBRHAs in the region. Nurses and clinical officers from Mekelle University facilitated the training sessions under the supervision of program staff from the Bixby Center and Mekelle University. Each training session lasted 4 days, including ethical, clinical, and logistical components. Participating CHWs first practiced their injection techniques on oranges and learned how to dispose of the used needles following infection prevention procedures. After much practice, CHWs administered distilled water injections to each other until they were able to demonstrate proficiency. CHWs were trained in screening procedures using a checklist intended for use by clinical and nonclinical health care providers, including community-based distributors, which was developed by FHI 360.[26] They were also trained on procedures for reporting side effects and adverse events, as well as referring clients to facilities for other methods. Business components such as requesting payment, procurement of DMPA, and basic logistics to avoid stock-outs were also included in the training. CHWs were trained on how to counsel on all family planning methods but were trained to provide only DMPA. Upon completion of the training, CHWs were recognized by the Tigray Regional Health Bureau as qualified DMPA providers.

Clinical Supervision

The Tigray Regional Health Bureau was engaged as a partner in monitoring and evaluation to ensure supervision efforts during the study period were an extension of the public health system rather than a parallel system. The ultimate goal was to promote compliance with family planning practice standards and assure delivery of high-quality services that continued after the completion of the study.

Thus, 2 levels of supportive supervision were employed. The first level of supervision, as well as the most important, was conducted by the HEWs. At the time of program implementation, HEWs were already meeting with existing *kebele* CHWs to discuss other community health initiatives. The HEWs provided the most obvious link between our program CHWs and the public health system. HEWs collected data on service statistics and discussed any clinical issues with CHWs including referrals for long-acting methods such as implants. These data were reported to the maternal and child health (MCH) experts at district health offices on a monthly basis. MCH experts reported monthly data to research study coordinators.

Health extension workers (HEWs) from the Tigray Regional Health Bureau supervised the CHWs.

As a second level of supervision, MCH experts and research study coordinators scheduled frequent visits to CHWs to provide both supervision and to learn about the experiences of participating CHWs. CHWs that were effective as well as those

who were ineffective participants in the program were selected for these in-depth visits, as it was through such visits that research staff gained insights into enablers and barriers to success.

All levels of supervision were done once a month in person at minimum, followed in some cases by cell phone communication if needed.

Drug Revolving Fund

A drug revolving fund was included in the program model to promote geographical equity of access to DMPA. Procurement of DMPA occurred at the regional level with distribution to 18 satellite locations in each participating *woreda* (district). The Women's Association of Tigray provided financial supervision of the CHWs. As a civil society organization with a presence in each *woreda* and experience overseeing microloans, the Women's Association of Tigray was in a position to provide this supervision for the foreseeable future and ensure the timely resupply of commodities to the CHWs. At the same time, with a central office, the organization was able to manage the drug revolving fund and procure DMPA at a lower rate by purchasing on behalf of the region. DMPA was distributed to the local office located in each *woreda* center. A leader from the Women's Association of Tigray collected money from and reviewed the financial records of CHWs, replenished CHWs' stock, and managed *woreda*-level drug revolving fund supply and financial records. These leaders established bank accounts for deposits, and transfers were made to the regional office prior to procurement of additional DMPA.

Social Marketing in a Rural Setting

Social marketing is generally limited to urban settings where exposure to the mass media is high, private shops and pharmacies are common, and demand for contraception is strong.[25,27] However, recognizing that the foundation for social marketing existed in the rural setting, the program model incorporated social marketing into standard CBD. For one, the private sector is increasingly meeting the needs of poor populations. At the same time, existing community networks could be tapped through CHWs while retention could be improved with compensation from sales. Consequently, social marketing tactics were adapted for the rural context. For example, while the product was branded and CHWs were given marketing posters as is typical with social marketing, the CHWs also promoted their services through community meetings and door-to-door marketing.

METHODS

Study Design and Sampling

We used a pre- and post-intervention study design. A multistage, cluster random sampling design was used to conduct a representative survey of women of reproductive age (15–49) at baseline (September 2011) and endline (May 2014) in the Central Zone of Tigray, Ethiopia. The total final samples consisted of 1,490 women for the baseline survey[23] (99% response rate) and 1,501 women for the endline survey[28] (100% response rate). Participating CHWs were also surveyed at baseline and endline, with a 99% response rate (N=621) at baseline and a 74% response rate (N=466) at endline. The endline response rate reflects those CHWs who participated at a large program review meeting where the survey was implemented. Thus, 26% is not a true refusal rate but rather reflects the number of CHWs absent from the meeting. Additionally, 87% of trained CHWs (N=545) submitted programmatic DMPA provision data at endline.

Project Setting

Tigray is made up of 5 rural zones divided into 47 *woredas*. Each *woreda* is further divided into approximately 20–25 *kebeles*. Each *kebele* has a population size of approximately 5,000 people or 1,000 households. Two zones participated in the project: Central and Southern. The Central and Southern Zones are comprised of 10 and 8 *woredas*, respectively, with an estimated 239,626 and 197,215 women of reproductive age in each zone, respectively, based on projected population growth since the 2007 census.[29]

Incremental Implementation

The project was implemented between September 2011 and June 2014, with a total of 626 CHWs recruited and trained from 18 *woredas*. During the first 12 months, the project was implemented in just 3 districts with 139 CHWs to test the service delivery model and address any challenges before scaling up sixfold.[25] Starting in the second year of the project, scale-up was accelerated with 4 trainings of 100–150 CHWs each. The intervention was incrementally scaled up to all *woredas* in the Central and Southern Zones between October 2011 and October 2013.

Data Collection and Analysis

Programmatic data on the number of clients, number of injections provided, and money

collected were gathered from CHWs and supervisors, aiding the program team in determining the feasibility, cost, and sustainability of scaling up the intervention. A provider characteristics survey was completed by CHWs at the time of training and after implementation of the program to gather demographic data and capture information on their experience with the program.

Comparisons between the baseline and endline household survey data were used to measure the impact of the intervention. Student's *t* tests for comparison of 2 proportions were estimated for indicators comparing baseline and endline. Significance was established at *P* value of .05. The surveys captured demographic, fertility, and contraceptive use patterns among the target population to assess changes in family planning knowledge, access, use, and preferences. The surveys also included questions regarding knowledge, attitudes, and practices related to DMPA. Key indicators from baseline and endline reports were compared to determine changes over the course of the intervention. Human subjects approval was provided by the Center for Protection of Human Subjects (CPHS) at the University of California Berkeley (CPHS Protocol IDs 2011-07-3465 and 2014-02-5995).

All paper questionnaires from the provider characteristics surveys, as well as baseline and endline household surveys, were processed at the Bixby Center and entered into a database using Epi Info Version 3.5.3. A master file of programmatic data collected from CHWs at endline meetings was created by research staff. Research staff were able to verify data accuracy by reviewing the actual records of the CHWs, whereas the ongoing monthly data collection had limitations and concerns regarding accuracy and completeness. Additionally, due to differences in the Ethiopian and Gregorian calendar, programmatic data could not be accurately analyzed per month. All data analyses were conducted using Stata version 13.

RESULTS

Background Characteristics and Experience of CHWs

The CHWs (N=621) who completed the baseline questionnaire were, on average, 27.1 years old, and 60% were married or cohabiting. Almost all (98%) participating CHWs were women, and 67% identified farmer or housewife as their current occupation. Forty-two percent of participating CHWs had 5–9 years of education, while 41% completed secondary school or higher. The higher levels of education observed among program CHWs compared with the general population was a result of targeted recruitment of CHWs based on the characteristics we identified among successful CHWs in the first year of implementation, which included greater education. At the time of training, 26% of CHWs were currently providing family planning, with 5% stating they had ever provided a DMPA injection. Nearly all (93%) felt that providing DMPA injections would improve their services to the community; meanwhile, 96% and 87% of CHWs felt comfortable providing services to adolescents and unmarried women, respectively.

CHWs completed another survey at endline in June 2014 (N=466). Nearly 85% reported a leadership role in their community. While the CHWs largely identified having a leadership position in the Women's Development Army (61%), they also had positions in the Women's Association of Tigray (25%) and *kebele* government (7%); these categories were not mutually exclusive. On average, CHWs were 50 minutes walking distance from the nearest government health post and spent approximately 5 hours per week marketing DMPA. Many CHWs confirmed they had provided an injection to unmarried (58%) or adolescent women (63%). Most (75%) felt comfortable collecting payment for services. Meanwhile, most CHWs felt supported by project personnel (89%), HEWs (88%), and the Women's Association of Tigray (82%). Nearly all CHWs (95%) felt the community accepted the project, and 89% of married/cohabiting CHWs felt supported by their husband or partner.

Many CHWs confirmed they had provided a DMPA injection to unmarried or adolescent women.

Programmatic Results

Between May 2014 and June 2014, 87% of trained CHWs (N=545) participated in endline data collection meetings and submitted final programmatic data. The number of months of data collected corresponded with the gradual training approach used over the course of project implementation. Consequently, while CHWs trained from the first 3 *woredas* had 30 months of programmatic data, CHWs in the last training had only 8 months of programmatic data. On average, 16 months of programmatic data were collected from participating CHWs.

Between October 2011 and June 2014, the CHWs served a total of 8,604 women and administered an estimated 15,410 DMPA injections. This is equivalent to providing 3,853 couple-years of

Between October 2011 and June 2014, the CHWs administered an estimated 15,410 DMPA injections, equivalent to 3,853 couple-years of protection.

protection (CYP). A substantial percentage (19%) of CHW clients were new to family planning and 25% were new to DMPA specifically. The majority (87%) of the DMPA injections were paid for at the time of provision. The costs of delivering contraceptive services were collected in 3 *woredas* where the project was first implemented. A cost analysis conducted with these data found the programmatic cost per CYP to be US$17.91, which included direct, indirect, and operating costs. The direct cost per CYP was US$2.96.[30]

Changes Over Time at the Community Level

The baseline and endline survey captured demographic, fertility, and contraceptive use patterns among the target population. Table 1 presents the background characteristics of all women ages 15–49 who participated in the surveys. None of the characteristics presented differed with statistical significance. At both baseline and endline, the majority of the sample population was under the age of 30, most women were married or cohabiting, and approximately half of each sample had received no formal education. The average number of living children among women in the sample population was 3.6 at baseline and 3.5 at endline, and desired number of children was 4.1 and 4.5 at baseline and endline, respectively. Most survey participants responded that they did want a/another child at baseline (60%) and endline (66%), but the desire for more children gradually declined as the number of living children reported by the participants increased (data not shown).

Comparisons between baseline and endline showed substantial changes in contraceptive knowledge and prevalence, some of which is likely attributable to the program CHWs' activities. For example, between October 2013 and June 2014, women's knowledge of modern methods increased significantly ($P<.005$) for all methods except the rhythm method (Table 2). In addition, there was a 25% increase ($P<.001$) in contraceptive use among surveyed women, from 30.1% at baseline to 37.7% at endline, with DMPA use largely responsible for this increase ($P<.001$) (Table 3). The largest increase in DMPA use with statistical significance was found among women aged 15–24 ($P<.001$). Also, among all women of reproductive age, 8.3% preferred to receive contraception from a CHW at a baseline, whereas 31.1% ($P<.001$) preferred to receive contraception from a CHW at endline (Table 3).

Contraceptive use among surveyed women had increased significantly by 25% between baseline and endline, from about 30% to 38%.

At endline, one-quarter of women using DMPA indicated that they received DMPA from CHWs ($P<.001$) (Table 4). The percentages were even higher among younger women, with 35% of women aged 15–24 and 46% of women aged 25–34 stating that CHWs provided their most recent DMPA injection (data not shown). In addition, there was a substantial change in women who preferred to receive DMPA from CHWs between baseline and endline, from 2.7% to 34.1% ($P<.001$) (Table 4). Finally, changes in

TABLE 1. Background Characteristics Among All Women of Reproductive Age at Project Baseline (September 2011) and Endline (May 2014), Tigray, Ethiopia

	Baseline (N=1490)	Endline (N=1501)
Age		
15–19	19.3	18.5
20–24	17.1	20.7
25–29	17.9	17.2
30–34	15.7	14.5
35–39	13.4	13.3
40–44	8.3	7.9
45–49	7.5	7.9
Marital status		
Never married	13.6	12.5
Married/cohabiting	72.3	76.4
Divorced/widowed	13.9	10.9
Education		
No education	53.6	48.4
1–4 years	13.2	14.3
5–9 years	22.4	25.9
Secondary or greater	10.6	11.1
Number of children ever born, mean	3.9	4.0
Number of living children, mean	3.6	3.5
Desired number of children, mean	4.1	4.5

Data reported as percentages unless otherwise specified.

quality of family planning markers from baseline suggest services had improved: nearly 50% ($P<.001$) more women reported being told about side effects (from 46.8% to 68.7%) and what to do if they experience side effects (from 43.5% to 63.1%), and over 25% ($P<.001$) more women reported being told about other methods of contraception (from 65.4% to 82.9%) (Table 5).

TABLE 2. Changes in Knowledge of Contraceptive Methods Among Women of Reproductive From Project Baseline (September 2011) to Endline (May 2014), Tigray, Ethiopia

	Baseline (N=1490) %	Endline (N=1501) %	% Change	*P* Value
Female sterilization	21.0	33.8	61	<.001
Male sterilization	7.9	15.4	95	<.001
Pill	91.7	96.2	5	<.001
IUD	23.9	50.6	112	<.001
DMPA/injectables	96.1	97.9	2	<.01
Implants	69.8	88.6	27	<.001
Male condom	57.1	78.5	37	<.001
Female condom	16.5	26.3	59	<.001
LAM	30.1	34.2	14	<.05
Rhythm method	31.3	34.0	9	NS
Withdrawal	12.6	20.1	60	<.001
Emergency contraception	11.2	15.1	35	<.01

Abbreviations: DMPA, depot medroxyprogesterone acetate; IUD, intrauterine device; LAM, lactational amenorrhea method; NS, not significant.

DISCUSSION

Evidence suggests that CHW provision of contraceptives help to reduce barriers to family planning access due to CHWs' placement within the community. The important role CHWs play in changing norms and influencing traditional structures in rural Africa as respected community members should also not be overlooked when exploring the importance of contraceptive CBD programs.[31,32] CBD has been shown to effectively meet the growing demand for contraceptives but still remains one of the more expensive modes of service delivery in sub-Saharan Africa.[33] Additionally, lack of appropriate remuneration as balanced with responsibilities has implications for both motivation and the quality of work among CHWs.[34] Consequently, political will and financing, including incentives to CHWs, must be addressed to ensure sustainability and scalability of CBD programs.[16,32,35]

This study demonstrated a model for incorporating CBD with social marketing that offers an opportunity for expanding rural community access to DMPA injectables while recovering some program costs and compensating volunteer CHWs with proceeds from contraceptive sales. In addition, the model has the potential to increase quality of services by providing more women with information on a wide range of contraceptives, side effects, and what to do if they experience side effects. The willingness and ability of CHWs in this study to serve adolescents was a particularly important finding, given that unmarried and younger women in sub-Saharan Africa often face barriers to receiving family planning services, including barriers related to provider discrimination and unnecessary medical restrictions based on, for example, age or marital status.[36,37]

However, anecdotal evidence from CHWs collected during supportive supervision visits indicated that adolescent clients were less likely to pay for services than older clients, which is not surprising given that youth might have less access to cash in rural Tigray. The drug revolving fund was included in the program to enable services for all women, even those without means to pay or reach a health facility for free services. For the most part, CHWs referred women to health posts for services if they were unable to pay, but CHWs were given the discretion to provide free DMPA injections without them having to reimburse the drug revolving fund the cost of the injection. This drug revolving fund was set up to ensure continued DMPA stock in the community, but its long-term sustainability is dependent on women's response to paying for DMPA and the number of payment exemptions made.

Incorporating community-based distribution with social marketing offers an opportunity to expand rural access to DMPA injectables while recovering some program costs and compensating volunteer CHWs.

While the majority (87%) of injections were paid for over the 3-year implementation period, the continued desire and ability of women to seek out and pay for family planning is affected by socioeconomic factors. The women marketed through this intervention are predominantly rural farmers and therefore at risk for unpredictable economic shocks, leaving families to prioritize food and the health of existing children, rather than family planning commodities. Thus, the health and future outlook of the drug revolving fund is theoretically in danger if women are not able to pay the

TABLE 3. Changes in Key Family Planning Indicators Among Women of Reproductive Age From Project Baseline (September 2011) to Endline (May 2014), Tigray, Ethiopia

	Baseline No. (%)	Endline No. (%)	% Change	*P* Value
Unmet need	1077 (16.4)	179 (11.9)	−28	<.01
Currently using contraception	448 (30.1)	566 (37.7)	25	<.001
Currently using DMPA	307 (20.6)	408 (27.2)	32	<.001
By age group				
15–19	21 (7.3[a])	39 (14.1)	93	<.01
20–24	53 (21.3)	99 (31.8)	49	<.01
25–29	91 (34.1)	93 (36.1)	6	NS
30–34	61 (26.1)	77 (35.5)	36	<.05
35–39	48 (24.0)	59 (29.5)	23	NS
40–44	21 (17.1[a])	27 (22.7)	33	NS
40–49	7 (6.3[a])	14 (11.9[a])	88	NS
CHW as preferred source of contraception	124 (8.3)	467 (31.1)	275	<.001

Abbreviations: CHW, community health worker; DMPA, depot medroxyprogesterone acetate; NS, not significant.
[a] Estimate was based on less than 25 cases.

current price of the injection. The drug revolving fund would also be threatened if the price of a DMPA injection increased to an amount that it is no longer affordable to women. As noted, DKT-Ethiopia subsidized the DMPA product for the project (US$0.17 per unit); however, a 2012 analysis from the United Nations Population Fund (UNFPA) found the average cost of 1 injection globally was $0.86.[38] Thus, it is important to consider this price differential when thinking about the findings from this study.

The total number of injections (15,410) provided over the course of the 3-year period was not as high as might be expected with more than 600 CHWs participating in the project. This is partially due to the protracted scale-up of the model over a 2-year period, but it also indicative of the challenges associated with family planning service provision in rural areas. In addition to geographic isolation of small communities, the decision to adopt family planning and people's desired family size also influence demand for services. However, the growing preference among women to receive contraception from CHWs between baseline and endline does suggest the continued potential of this model and the importance of providing community-based access to family planning.

Data from the CHWs indicated that many clients who received their first and second injections from the HEWs received their third and fourth injections from CHWs. No unintended pregnancies from missing injections were reported by CHWs during the study period. A few CHWs did report that after receiving initial DMPA injections for a fee in the community from the CHWs, some women subsequently went to health posts for free reinjections. Unfortunately, we do not have data from health posts to verify if this was actually the case. However, a forthcoming and more detailed analysis of population-based data on continuation rates seem to indicate that women report getting the injections. Similarly, CHWs reported making many referrals to health posts for other contraceptive methods, largely implants; however, we cannot verify the referrals and subsequent method adoption with health post data.

While robust recruitment and training strategies increased engagement, commitment, and comprehension among CHWs, compensation remains an important factor to understand. The number of injections provided per CHW directly

TABLE 4. Changes in Most Recent Source of DMPA Among Women Who Have Ever Used DMPA From Project Baseline (September 2011) to Endline (May 2014), Tigray, Ethiopia

	Baseline (N=662) %	Endline (N=840) %	% Change	*P* Value
Most recent source of DMPA				
Government hospital	1.1[a]	0.5[a]	−56.4	.19
Government health center	59.8	37.9	−36.7	<.001
Government health post	37.8	30.5	−19.4	<.001
CBRHA	0.8[a]	25.5	3085.0	<.001
Other	0.6[a]	0.0[a]	NA	NA
Preferred source of DMPA				
Government hospital	1.8[a]	1.4[a]	−20.6	.54
Government health center	51.4	41.4	−19.4	<.001
Government health post	39.9	53.8	34.9	<.001
CBRHA	2.7[a]	34.1	1161.1	<.001
Other	9.7	0.1[a]	−98.8	<.001

Abbreviations: CBRHA, community-based reproductive health agent; DMPA, depot medroxyprogesterone acetate.
[a] Estimate was based on less than 25 cases.

TABLE 5. Changes in Quality of Family Planning Service Markers From Project Baseline (September 2011) to Endline (May 2014) as Reported by Women of Reproductive Age Who Are Currently Using Contraception, Tigray, Ethiopia

	Baseline (N=448) %	Endline (N=566) %	% Change	*P* Value
Told about side effects	46.8	68.7	46.9	<.001
Told what to do if they experience side effects	43.5	63.1	45.0	<.001
Told about other methods	65.4	82.9	26.7	<.001

impacts her compensation, which was a factor that influenced the program design. CHWs received 2 birr ($0.17) per paid injection, but there was not substantial evidence to determine the compensation that would motivate CHWs to continue providing DMPA beyond the project. There is actually a strong legacy of volunteerism for community health in Ethiopia,[39] and particularly in Tigray, which may have contributed to the low attrition of CHWs, even given small profit margins. Nonetheless, the importance of incentivizing CHWs to improve retention and performance has been well documented[16] and should be further explored with regards to this contraceptive service delivery model in Tigray.

It is also critical to understand this service delivery model within the larger context of family planning service delivery in Tigray. For example,

with a social marketing model, it is also important to determine the material contribution beyond injections, including increases in knowledge and change in community norms surrounding family planning. In the 2011 Ethiopia Demographic Health Survey, 23% of women and men of reproductive age in Tigray had never heard or seen a family planning message. Moreover, 64% of women of reproductive age who were not using contraception reported that they had never discussed family planning with a field worker or at a health facility.[22] By training health workers in the community to provide messages on the benefits of family planning, community beliefs are influenced and demand for family planning will likely grow over time as myths are dispelled and side effects understood.

Expanding on the existing health service delivery platform likely contributed to the success of the public-private partnership model.

Another underlying key to the success of this model was that it expanded upon the existing health service delivery platform in Tigray, essentially creating a public-private partnership between the health posts and CHWs. Linkages with the community were supported through this model by including the Women's Association of Tigray to both manage the drug revolving fund and provide financial supervision of the CHWs. The organization has a strong presence from the regional level down to each *kebele* in Tigray. This allowed for both centralized purchasing of DMPA, as well as localized management of microloans to CHWs. The model also improved community linkages with public health services through referrals and monitoring. HEWs supervised CHWs' clinical activities, which enabled project monitoring with minimal additional impact on the health system. Most CHWs were leaders in the Women's Development Army and therefore already met with HEWs on regular basis to share updates on their activities.

Finally, the program model expanded services of the public health system for a fee to women who were willing to pay for the convenience and privacy the CHWs provided. With monitoring systems already incorporated into the activities of the Tigray Regional Health Bureau, the program was able to continue after the 3-year funding period ended with minimum transition efforts.

Limitations

The Ethiopian calendar is substantially different than the Gregorian calendar. CHWs recorded data following the Ethiopian calendar, with the intention that the monitoring and evaluation program team would translate these data into a 12-month calendar. The transferring of data from CHWs to program staff was prone to error because of calendar issues combined with untimely submission of data due to remote location of many CHWs. Ultimately, we limited our results to total injections, which did not permit us to analyze trends and month-by-month breakdown between *kebeles* and CHWs—key information that could have helped inform future programming.

There were also resupply and data collection challenges related to the drug revolving fund. The Women's Association of Tigray was selected to manage the drug revolving fund given its experience in supporting programs that involved microloans at the community level. However, given the time demands and complexity of implementing a regional drug revolving fund with satellites in 18 *woredas*, the organization required more experience and logistical support than provided and the records on resupply and repayment were challenging to triangulate with records from CHWs. At the same time, with a nascent drug revolving fund, it is difficult at this time to draw real conclusions about its long-term sustainability and whether the CHWs have sufficient revenues to replenish the DMPA stocks. Consequently, further research on the drug revolving fund is necessary. Nonetheless, the results from household surveys at baseline and endline suggest that CHWs in this model made a significant contribution to family planning services in the region.

CONCLUSION

By addressing women's willingness-to-pay for contraception while incorporating social marketing and a drug revolving fund, this contraceptive service delivery model has potential to increase sustainability by training volunteer CHWs to become rural social marketing agents of DMPA injectables. This model can help accelerate contraceptive adoption, especially among rural women in sub-Saharan Africa. However, long-term sustainability of CBD should be addressed when designing programs, particularly the key challenges of managing attrition among CHWs and maintaining supply of contraceptives.

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ORIGINAL ARTICLE

A Non–Gas-Based Cryotherapy System for the Treatment of Cervical Intraepithelial Neoplasia: A Mixed-Methods Approach for Initial Development and Testing

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A non–gas-based treatment device for early cervical cancer treatment, adapted for use in low-resource settings to improve ease of use, portability, and durability, performed similarly to a standard gas-based cryotherapy device in small-scale testing. A large randomized clinical trial is currently underway for further assessment.

ABSTRACT

Background: Gas-based cryotherapy is the most widely used treatment strategy for cervical intraepithelial neoplasia (CIN) in low-resource settings, but reliance on gas presents challenges in low- and middle-income countries (LMICs). Our team adapted the original CryoPen Cryosurgical System, a cryotherapy device that does not require compressed gas and is powered by electricity, for use in LMICs.

Methods: A mixed-methods approach was used involving both qualitative and quantitative methods. First, we used a user-centered design approach to identify priority features of the adapted device. U.S.-based and global potential users of the adapted CryoPen participated in discussion groups and a card sorting activity to rank 7 features of the adapted CryoPen: cost, durability, efficacy and safety, maintenance, no need for electricity, patient throughput, and portability. Mean and median rankings, overall rankings, and summary rankings by discussion group were generated. In addition, results of several quantitative tests were analyzed including bench testing to determine tip temperature and heat extraction capabilities; a pathology review of CIN grade 3 cases (N=107) to determine target depth of necrosis needed to achieve high efficacy; and a pilot study (N=5) investigating depth of necrosis achieved with the adapted device to assess efficacy.

Results: Discussion groups revealed 4 priority themes for device development in addition to the need to ensure high efficacy and safety and low cost: improved portability, durability, ease of use, and potential for cure. Adaptions to the original CryoPen system included a single-core, single-tip model; rugged carrying case; custom circuit to allow car battery charging; and sterilization by high-level disinfection. In bench testing, there were no significant differences in tip temperature or heat extraction capability between the adapted CryoPen and the standard cryotherapy device. In 80% of the cases in the pilot study, the adapted CryoPen achieved the target depth of necrosis 3.5 mm established in the pathology review.

Conclusion: The LMIC-adapted CryoPen overcomes barriers to standard gas-based cryotherapy by eliminating dependency on gas, increasing portability, and ensuring consistent freeze temperatures. Further testing and evaluation of the adapted CryoPen will be pursued to assess scalability and potential impact of this device in decreasing the cervical cancer burden in LMICs.

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BACKGROUND

Cervical cancer continues to be a global public health problem, with the greatest disease burden in low- and middle-income countries (LMICs).[1] The number of women screened for cervical cancer has increased in many countries over the past decade.[2] However, screening must be linked with effective, affordable treatment in order to achieve a reduction in cervical cancer incidence and mortality.

Gas-based cryotherapy is the most widely used treatment for cervical neoplasia in low-resource settings, but challenges around procuring gas and transporting and refilling gas tanks exist.

Gas-based cryotherapy is the most widely used treatment strategy for cervical intraepithelial neoplasia (CIN) in low-resource settings. This ablative technique uses compressed carbon dioxide or nitrous oxide gas to freeze lesions, resulting in necrosis of cells. Although gas-based cryotherapy is safe, simple, and generally inexpensive, challenges include difficulties with procuring gas, transporting and refilling gas tanks, and providing treatment in high-volume settings.[3–5] A standard-size gas tank has the capacity to provide treatment for only 3 patients, while a large tank can treat more women but is difficult to transport from clinic to clinic.[6]

The CryoPen Cryosurgical System, which does not require compressed gas, was originally designed to treat dermatologic conditions and was later modified for gynecologic use.

Innovative new technologies offer treatment alternatives. For example, the CryoPen Cryosurgical System is a novel cryotherapy technology that does not require compressed gas and is powered by electricity. The CryoPen reaches extreme cold temperatures with use of a Stirling Cryocooler that chills the core to operational temperatures of −105°C. Between treatments, the core rests in the chilling well filled with an ounce of ethanol or grain alcohol, which facilitates heat transfer. The CryoPen was originally designed to treat dermatologic conditions and was modified for gynecologic use in 2011. It is currently approved by the U.S. Food and Drug Administration (FDA) for CIN grade 2 and more severe (CIN2+) diagnoses.

We adapted the CryoPen system for use in low-resource settings following a user-centered design approach to identify essential features.

The original CryoPen device, however, is not conducive for use in LMICs. Our team of clinicians and biomedical engineers collaborated to develop an LMIC-adapted CryoPen optimized for use in low-resource settings. To design the LMIC-adapted CryoPen prototype, we sought guidance on features that would meet the needs of clinicians interested in using this technology in LMICs. We followed a user-centered design approach to better understand current cryotherapy methods in LMICs, features that would be essential in an LMIC-adapted CryoPen, advantages and disadvantages of the initial prototype, and factors that may facilitate adoption of the adapted device.

To ensure that the LMIC-adapted CryoPen is non–inferior to standard cryotherapy devices, we performed in vitro studies using ballistic gelatin and the double-freeze approach recommended by the World Health Organization to determine the prototype's tip temperature and heat extraction capabilities.[7] A pilot study was performed using an exploratory single-freeze approach to compare the depth of necrosis achieved by the LMIC-adapted CryoPen and CO_2-based cryotherapy in healthy cervical tissue.

The purpose of this article is to describe the design approach and device adaptations of the LMIC-adapted CryoPen and to report initial clinical data.

MATERIALS AND METHODS

Qualitative Methods: Experiences With Cryotherapy and Device Perceptions

Using a convenience sample, we held 3 focus group discussion sessions with key stakeholders and potential users of the LMIC-adapted CryoPen. Verbal consent to participate was obtained prior to the discussions. None of the participants were compensated for their participation in any way.

During the first session, at CryoPen, Inc. headquarters in September 2014, 10 cervical cancer prevention stakeholders met to discuss the development of the LMIC-adapted CryoPen. Two additional discussion sessions were held in conjunction with the Global Academic Partnership (GAP) conference in Houston, Texas, in April 2015. Most of the stakeholders who participated in the September discussion session participated in the second session. From the larger group of GAP conference attendees, we identified participants who worked in cervical cancer prevention globally and invited them to join the third discussion session. This third group consisted of 22 potential users or key stakeholders from Brazil, China, Colombia, India, Mexico, South Africa, Thailand, and Zambia, as well as U.S. participants who have performed cryotherapy in Guatemala and Peru. The stakeholders were all experienced in cervical cancer prevention and included trainers or practitioners in visual inspection with acetic acid (VIA) and cryotherapy, a cryotherapist, a colposcopist, gynecologic oncologists, a pathologist, a radiologist, and a registry and cervical cancer prevention program planner.

During the second and third discussion sessions, the participants used a card sorting activity to rank 7 features of the LMIC-adapted CryoPen and then discussed the potential design trade-offs in various settings. Participants described their experiences with cryotherapy and shared feedback on the LMIC-adapted CryoPen prototype.

Digital recordings and field notes were reviewed using an iterative content analysis approach for qualitative analysis to identify emerging themes. Key quotes were transcribed to illustrate identified themes. We calculated a mean and median ranking for each feature included in the card sorting exercise and generated an overall

ranking for each feature as well as a summary ranking for each by discussion group.

The University of Pittsburgh Institutional Review Board (IRB) determined that the focus group discussions qualified as non–research.

Quantitative Methods: Device Testing

Bench Testing

Bench testing of the LMIC-adapted CryoPen and a standard cryotherapy device, the N_2O-based Wallach LL100 System, was performed in the Basic Health International laboratory in San Salvador, El Salvador. The office lab has the capacity to maintain consistent room temperature and humidity, which provided controlled testing between trials. No animals or hazardous materials were used in testing. An engineer who graduated from the ABET-accredited bioengineering program at Rice University conducted the bench tests.

For comparative studies of the tip temperature and heat extraction capabilities of the 2 devices, ballistic gelatin was used as the cervical tissue analogue. It is not a perfect surrogate, but the bias is the same for all devices that were tested. Ballistic gelatin, composed of gelatin powder and water, is FDA-cleared to test gynecologic ablation devices such as the Her Option Uterine Cryoblation Therapy System (PMA Number P000032). Standard procedure was followed for preparing ballistic gelatin samples for testing. The starting temperature of the gelatin samples was room temperature. A custom jig was designed to perform freezing tests on ballistic gelatin using the CryoPen Cryosurgical System (both standard and prototype LMIC-adapted models). Fifteen trials were conducted with each device using a double-freeze approach consisting of a 3-minute freeze, followed by a 5-minute thaw, and a second 3-minute freeze (3′–5′–3′), which is the recommended treatment approach per the most recent World Health Organization guidelines for cryotherapy.[7]

Heat extraction capabilities were measured in terms of mass of the freeze ball and the lateral freeze and depth of freeze dimensions. At the completion of the 3′–5′–3′ freeze cycle, the freeze ball was excised from the gelatin. Excess gelatin was removed from the freeze ball before the mass was recorded on a scale. After the freeze ball mass was recorded, the lateral freeze and depth of freeze dimensions were recorded using calipers. Fifteen tests of each set of data points were performed to ensure data collection replication. Copper-constantan thermocouples and an Omega Instruments Data Acquisition system were used to collect temperature data.[8]

Pathology Review to Determine Target Depth of Necrosis

We investigated the depth of CIN in order to determine target depth of necrosis required for high efficacy of the device. A study of the depth of CIN1–3 by Abdul-Karim showed a depth of necrosis of 3.5 mm is needed to treat 95% of CIN1–3 lesions and a depth of 4.8 mm is needed to treat 99% of all cases.[9] With our collaborators at the National Institute for Neoplastic Diseases (INEN) in Peru, our group analyzed 107 confirmed cases of CIN3 in cold knife cone biopsy specimens from an under-screened population. Two expert pathologists reviewed slides of previously confirmed cases of CIN3. INEN and Cleveland Clinic granted IRB approval.

Our clinical goal was to achieve a minimum depth of necrosis of 3.5 mm in at least 80% of cases in order to determine equivalence to standard cryotherapy treatment.

Depth of CIN3 ranged from 0.2 mm to 6.9 mm, with a mean of 2.0 mm. Overall, 85/107 (79.4%) had a depth <3.0 mm, 96/107 (89.7%) had a depth <3.5 mm, 100/107 (93.5%) had a depth <4.0 mm, and 100/107 (93.5%) had a depth <5.0 mm. Using these findings and Abdul-Karim's conclusion that a depth of 3.5 mm is needed to treat 95% of CIN2+ lesions, we determined that our clinical goal was to achieve a minimum depth of necrosis of 3.5 mm in at least 80% of cases. Since cryotherapy is approximately 80% effective in treating CIN, we set 80% as the goal in order to determine equivalence.

Pilot Study to Determine Depth of Necrosis Achieved With LMIC-Adapted CryoPen

A pilot study (N=5) was then conducted to determine if the LMIC-adapted CryoPen achieved a depth of necrosis of 3.5 mm in women with healthy cervical tissue. Women aged 21–64 years who presented at INEN for hysterectomy indicated by conditions unrelated to cervical precancer or cervical cancer were invited to participate. Women did not receive any financial incentive to participate. IRB approval for the pilot study was granted by both INEN and Cleveland Clinic.

Five women prescheduled for hysterectomy for reasons unrelated to cervical precancer or cancer were first treated with the adapted CryoPen to determine depth of necrosis achieved.

Five women were treated with a single 5-minute (5′) freeze application of the LMIC-adapted CryoPen; the straightforward 5′ freeze was chosen so that providers could become comfortable with the device. The participants then underwent their prescheduled hysterectomy 24 hours after treatment, and cervical tissue was processed to allow evaluation of depth of necrosis caused by ablation. The entire cervix obtained

from the hysterectomy procedures was detached from the uterus and cut at 3 and 9 o'clock positions to separate the anterior and posterior lips. Both pieces of tissue were fixed in formalin for 24 hours. Multiple serial sections of specimens were obtained from each of the cervical lips.

The pathologists evaluating the cervical specimens were blinded to which device was used to perform the ablative treatment. Microscopic evaluation of depth of necrosis was conducted by superimposing a micrometer in the 10x eyepiece. Multiple measurements were taken and only the deepest area of necrosis was recorded for this study. Determination of the deepest level of necrosis was based on the observation of destruction of the glandular epithelium in the gland crypts in the stroma or of the endothelium of the stromal blood vessels.

RESULTS

Qualitative Results

Experience With Cryotherapy

Providers in our group with experience in Colombia, Guatemala, Peru, Thailand, and Zambia described the context in which they use cryotherapy for precancerous cervical lesions. Cryotherapy is practiced broadly in Thailand and is provided either at a health center or through a mobile clinic. In Zambia, cryotherapy is performed at regional health facilities; although the mobile units maintained by the Ministry of Health could provide cryotherapy, this is not currently practiced. In Colombia, precancerous cervical lesions are primarily treated through excision techniques; cryotherapy is performed only in remote counties. Other providers in our group from Brazil, China, and India reported using only excisional techniques such as loop electrosurgical excision procedure (LEEP) and had limited experience with cryotherapy.

Device Perceptions

Card sorting participants ranked efficacy and safety highest in terms of desired features of an adapted CryoPen.

The card sorting activity facilitated the core conversation in which participants ranked the most important features (out of 7) for a new cryotherapy device designed for the low-resource settings in which they practice. The 7 features and their overall rankings are as follows:

Efficacy and safety (overall ranking 1): While there was some variation in the ranking of efficacy and safety, this feature was ranked highest overall. A participant from Zambia noted:

> *Efficacy and safety was the most important [feature] because whatever new device goes into the market, it has to be non–inferior to the current practice.*

Cost (overall ranking 2): Cost was ranked either very high or very low, but the summary ranking was second overall. Participants felt that the target price of US$4,000 for the new device was reasonable, especially given that this device would not require purchase of gas.

Durability and Maintenance (overall ranking 3): Durability and maintenance, 2 separate features, were discussed in interwoven language. Durability was considered a core issue for this setting. Participants defined durability in terms of simplicity and the concept that a device could not be broken. A participant from the United States who has practiced broadly in low-resource settings said:

> *I ranked durability first, and part of that is that I feel like every public hospital I've gone to in low- and middle-income countries, you can barely walk down the hall because there are all these donated instruments from the U.S. lining the halls that don't work, that are broken . . . You know, no one knows how to maintain them.*

Another participant who has practiced cryotherapy in Guatemala raised the need for simplicity of design:

> *. . . but as you've shown you have the [thermo]coupler, a microchip, a something, it sounds like there are a lot more things that could break there than your typical cryo unit and a nitrous tank . . . . 'cause the only thing that can go wrong with the [traditional] cryo gun is if you try to use it when the pressure is too high in the tank.*

Participants were supportive of simple inexpensive maintenance, but reiterated the importance of durability. Participants also acknowledged that routine maintenance has generally not been practiced with current cryotherapy equipment.

Portability (overall ranking 4): Portability was discussed in terms of the ability to bring a device to a remote setting. Participants felt that a truly portable device would open up the option of delivering cryotherapy in remote settings that are not currently being reached because of the logistical difficulties of transporting the gas tank needed for standard cryotherapy. A participant from Zambia noted:

> *If it is not portable then it can't get to the rural areas where you want to reach out.*

Patient throughput (overall ranking 5): Participants explained that the proposed target of each device being able to treat 15 patients per day was acceptable, and so they saw no need to prioritize this issue above others. One participant explained:

> *When we screen about 200–250 [patients], we only freeze about 15 a day, that is why it was at the bottom.*

No electricity (overall ranking 6): Many sites where cryotherapy will be practiced have electricity. Participants felt that the proposed approach of paying an additional cost for a modularized additional battery feature would adequately address the need to bring the device to remote areas that do not have electricity.

Integrating Feedback to Optimize the LMIC-Adapted CryoPen Cryosurgical System

The device prototype was modified based on the 4 priority areas that came out of the focus group discussions: (1) improved portability—essential for large mobile health services that many countries rely on to treat women living in remote areas, (2) better durability, which allows for decreased maintenance and costs, and increases capacity for rugged travel and use, (3) greater ease-of-use, which simplifies operation of the device and expands potential for use by trained providers, and (4) enhanced potential for cure, which ensures greater efficacy for the treatment of precancerous lesions.

The LMIC-adapted CryoPen Cryosurgical System has several design modifications that distinguish it from the original CryoPen (Figure 1). To increase efficacy of treatment, a single 19–20 mm conical tip was designed for the new model. Compared with the original model's tip, the new larger tip size ensures that the adapted device achieves greater coverage of precancerous lesions, and the anatomically correct tip shape allows for better contact with the cervix. The original CryoPen required a core swap mid-procedure, whereas the LMIC-adapted CryoPen has a single core that can be applied for a 3′–5′–3′ or a single 5′ procedure. A clear sheath, made of medical-grade polycarbonate, increases visibility and protects the vaginal walls. The sheath is inserted with the attached tip positioned against the cervix; the core is then inserted into the sheath, with a gap preventing contact between the sheath and core for insulation purposes.

To increase durability, the new model was built to handle irregular currents and to withstand physical damage in extreme conditions (ambient temperatures of −100°C to 40°C) and from drops up to 5 feet. In addition, the new model is easily maintainable. The device has a removable air filter, which can be removed, cleaned, and replaced on site. The protective sheath and attached tip are the only components in direct contact with human tissue and can be cleaned sufficiently with high-level disinfection (HLD) rather than requiring autoclave sterilization.

FIGURE 1. Standard CryoPen System Available in the United States (left) and the CryoPen System Adapted for Use in Low- and Middle-Income Countries (right)

The LMIC-adapted device is portable, weighing 20 lbs., and equipped with a handle. To address focus group participants' interest in a modularized approach to a battery feature, a custom circuit was designed to allow the LMIC-adapted CryoPen to run via car batteries for use in settings without another source of electricity.

The adapted CryoPen is portable and can run on car batteries in settings without another source of electricity.

Quantitative Results: Device Testing

Results of Bench Testing

The results of the 15 bench test trials showed that the LMIC-adapted CryoPen achieved equivalent depth of freeze, depth of lateral freeze, diameter of freeze, and mass of freeze ball compared with the Wallach LL100 (Table 1). The minimum tip temperatures reached by both devices and the average of the temperatures reached during the 2 freezes were also equivalent. There were no significant differences between devices in any

TABLE 1. Bench Testing Results Comparing Heat Extraction Capabilities and Tip Temperatures of Standard Cryotherapy (Wallach LL100) Versus LMIC-Adapted CryoPen

	Wallach LL100 (n=15) Mean (SD)	LMIC-Adapted CryoPen (n=15) Mean (SD)	*P* Value
Depth of freeze, mm	7.14 (1.00)	6.33 (1.21)	.06
Lateral depth of freeze, mm	7.86 (0.96)	7.93 (1.32)	.88
Diameter of freeze, mm	29.37 (2.09)	30.71 (3.61)	.23
Mass of freeze ball, g	7.71 (1.16)	8.27 (1.33)	.22
Average tip temperature in freeze cycle, °C	−51.84 (4.99)	−48.28 (6.37)	.10
Minimum (coldest) tip temperature, °C	−56.11 (4.19)	−55.08 (7.42)	.64

tip temperature or heat extraction capability measurements.

Depth of Necrosis Pilot Study

Bench trial tests showed the adapted CryoPen performed equivalently to the standard cryotherapy device, and the pilot test found depth of necrosis of at least 3.5 mm was achieved in 80% of the samples.

Average maximum depth of necrosis in the anterior lip was 4.12 mm (standard deviation [SD], 1.49 mm), and average maximum depth in the posterior lip was 4.08 mm (SD, 1.05 mm) (Table 2). A depth of necrosis of 3.5 mm was achieved in 80% of the samples (maximum depth of necrosis was ≥4.0 mm in 80% of cases).

DISCUSSION

Despite the continued need for secondary prevention of cervical cancer via treatment of precancerous lesions, there have been few efforts to develop treatment devices tailored to the specific challenges and needs of LMICs. In developing the LMIC-adapted CryoPen cryotherapy treatment device, each adaptation was made specifically to optimize utility in low-resource settings while maintaining high efficacy and safety. The user-centered design approach used in this study was an effective way to solicit input about important features to potential users and helped inform development of the CryoPen technology for LMIC settings.

The adapted CryoPen device overcomes barriers to standard gas-based cryotherapy by eliminating the need for gas and increasing mobility.

Participants were enthusiastic about the potential of a non–gas-based cryotherapy device. The LMIC-adapted CryoPen overcomes barriers to standard gas-based cryotherapy by eliminating dependency on gas, increasing mobility, and ensuring consistent freeze temperatures without blockages; the device can perform 3 procedures per hour when connected to an electrical source. Participants emphasized that durability and simplicity were important factors, highlighting the need for the new device to survive being moved frequently from one location to another in hot environments without requiring intensive maintenance. Product life, which remains unknown despite promising durability, was therefore also an outstanding concern. With these concerns in mind, the LMIC-adapted CryoPen was designed with intention to enhance 3 key features:

1. **Durability/Maintenance.** Features include the ability to handle irregular currents; withstand physical damage in extreme temperatures; tolerate drops from 5 feet; be cleaned by HLD; and be maintained easily with a removable air filter.
2. **Portability.** Features include a lightweight device; a carrying case with handle; and the ability to run on 2 car batteries in series when electricity is unavailable.
3. **Ease-of-use.** Features include a single-tip, single-core device; a clear sheath for increased visibility and safety; and a device amenable to one-handed operation.

Safety and efficacy were the most important features to participants, as introducing this technology to the current treatment paradigm will require non–inferiority to current practice. We ensured non–inferiority in safety and efficacy to the current standard, gas-based cryotherapy, by conducting bench testing of the LMIC-adapted

TABLE 2. Preliminary LMIC-Adapted CryoPen Depth of Necrosis with a Single 5-Minute Freeze

Sample	Maximum Anterior Depth of Necrosis (mm)	Maximum Posterior Depth of Necrosis (mm)
1	4.0	3.9
2	1.5	2.8
3	6.1	6.0
4	4.5	3.8
5	4.5	3.9
Mean	4.12	4.08

CryoPen and through a clinical trial pilot determining the depth of necrosis the device achieved in healthy cervical tissue. The average tip temperature of both freezes (−51.84°C) reached by the device is in a range theoretically capable of destroying cervical tissue.[10–12] The LMIC-adapted CryoPen achieved equivalent heat extraction capabilities, including depth of freeze, lateral depth of freeze, and mass of freeze ball, compared with the standard Wallach LL100. During the clinical trial pilot, the LMIC-adapted CryoPen achieved a depth of necrosis of at least 3.5 mm in 80% of cases, demonstrating the promising efficacy of the device. Given the consistent performance in bench testing, the freeze that performed less well in the clinical trial pilot may be attributable to the process of clinicians adjusting to the new technology in a clinical setting. The sample size of the pilot study was small. A large randomized clinical trial that will more fully investigate safety and efficacy issues is currently underway; the results of this trial will have greater precision than the pilot.

Despite the advantages presented by the LMIC-adapted CryoPen, there are several limitations associated with the device. The $4,000 cost, although within the range deemed reasonable by focus group participants, is more expensive than a gas-based system ($2,000). This is a significant investment for areas with limited funding. However, the initial capital cost of the device is mitigated by the elimination of ongoing gas expenses for clinics. Depending on frequency of use, the cost difference between the LMIC-adapted CryoPen and a gas-based system would be negligible within 6–18 months of use.

We recognize that costs are entailed by the device's electricity requirement, but we believe that even with this constraint the LMIC-adapted CryoPen will be more affordable than conventional cryotherapy. In cost-effectiveness analysis, a health economist will account for both sources of electricity that can be utilized by the device—alternating current supplied by an electrical grid and car batteries.

The LMIC-adapted CryoPen was designed to be simple and user-friendly, but there are steps that must be followed during use. These include filling the chilling well with ethanol; ensuring that the green indicator light is on before beginning treatment; and wiping condensation from the core before reinserting it into the holding well. These steps are simple, but they are unique to this device and essential for proper functioning. As with introducing any new device, proper training and repeated use will address these concerns. An instruction booklet and video are available for reference.

Although the device does not require N_2O or CO_2, ethanol is needed to prevent the core from freezing to the well in which it rests between procedures. Manufacturer-approved ethanol is relatively easy to find and inexpensive; if unavailable, ethanol can be substituted with grain alcohol such as Everclear. A small bottle can facilitate hundreds of treatments. It will nonetheless be important that procurement systems include ethanol for use with this device.

Further testing and evaluation of the LMIC-adapted CryoPen should be pursued to assess scalability and potential impact of this device. Despite introduction of the prophylactic human papillomavirus (HPV) vaccine, generations of unvaccinated women will still need to be screened and treated for cervical precancer. In the 3 decades it may take to implement primary prevention of cervical cancer by HPV vaccine globally, an estimated 20 million more women will be diagnosed with cervical cancer in LMICs.[13] If improvements in secondary prevention—including greater utility of treatment devices in low-resource areas—are not pursued, more than 250,000 women will continue to die annually from a preventable disease.

A randomized clinical trial is underway to more fully investigate safety and efficacy issues.

The initial capital cost of the adapted CryoPen is offset by eliminating the need for ongoing gas expenses.

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ORIGINAL ARTICLE

Comparing Women's Contraceptive Preferences With Their Choices in 5 Urban Family Planning Clinics in Ghana

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Women's method choice largely matched their stated desired duration of effectiveness but not their desires to avoid certain side effects. While most women reported they were counseled about side effects, many fewer reported being specifically counseled about common menstrual side effects with their chosen method, including side effects the women said would cause them to stop using the method.

ABSTRACT

Background: Concern about contraceptive side effects is a common reason reported by women for not using contraception or discontinuing use. We sought to characterize women's preferences related to method characteristics and side effects and to examine whether their adopted method was consistent with their stated preferences.

Methods: Between June 1, 2015, and August 31, 2015, we surveyed women attending 5 urban family planning clinics in Kumasi and Accra, Ghana, before and after their counseling sessions. All women attending these clinics were approached to gauge their interest and eligibility for inclusion. Before counseling, women were asked about desired method characteristics and bothersome and intolerable side effects. After counseling, women were asked about method adoption and the counseling received about side effects. We then used crosstabs to compare the side effects women were counseled to expect, as well as those they reported would be intolerable, with their adopted methods to determine consistency between women's preferences and choices.

Results: In total, 414 and 411 women completed the pre- and post-counseling surveys, respectively. The analysis sample consisted of 336 participants who adopted a method and were matched between the 2 surveys. The 3 most commonly chosen methods were the implant (n=135, 40.1%), injectables (n=109, 32.4%), and the intrauterine device (IUD) (n=52, 13.4%). The large majority (at least 87%) of method adopters chose a method that was well matched with their desired duration of effectiveness. Consistency between women's expressed intolerable side effects and their chosen methods was substantially lower: at least 70% of women choosing the implant, IUD, or injectables had stated they would stop using a method if they experienced those side effects that are in fact common with their respectively chosen methods. While 65.0% of those who adopted a method reported they were counseled to expect side effects, substantially less were counseled to expect the side effects common with use of their adopted method.

Conclusion: Women's choice of contraceptive methods generally matched their stated preferences related to desired duration of effectiveness but not to potential side effects, and most women reported they were not counseled to expect the side effects common with use of their chosen method. Providers need to address potential side effects during counseling both to ensure women choose methods that will be a good fit with their desires and to reassure them that commonly experienced side effects are not harmful.

INTRODUCTION

Although use of effective contraception is growing in many parts of the world, only about 17% of women of reproductive age in sub-Saharan Africa use a modern contraceptive.[1] Low levels of usage, however, do not indicate a lack of interest in family planning among women and their male partners; while fertility desires in many countries in sub-Saharan Africa are high, so too is the demand to both space and limit births, even among young women.[2]

Contraceptive use, as measured by the contraceptive prevalence rate (CPR), in Ghana has not changed significantly since a rapid increase from 12.9% in 1988 to 25.2% in 2003.[3] The most recent Ghana Demographic

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and Health Survey showed a CPR in 2014 of 26.7%. Although the National Population Policy has an explicit objective "to ensure accessibility to, and affordability of, family planning means and services for all couples and individuals to enable them regulate their fertility,"[4] the total fertility rate (TFR) in 2014 was 4.2 births per woman, a slight increase from the 2008 figure of 4.0 births per woman.[5] This is in contrast to the marked decline in the fertility rate observed between the mid-1980s and the 1990s.

Unmet need for contraception is the percentage of women of reproductive age who want to stop or postpone childbearing but who report that they are not using a method to prevent pregnancy,[6] and is used as an indicator of the gap between the demand for contraceptives and contraceptive use. Current unmet need for contraception is high in Ghana at about 30% of married women and 42% of sexually active unmarried women.[5] This suggests potential high interest and demand for family planning among women and their partners.

Bleeding changes are a key reason for discontinuation of contraceptive methods.

Encouraging new adopters of contraceptive methods is important, but so too is understanding consistency of use among existing users.[7] In 14 of 15 low-income countries, the majority of unplanned and unwanted births were the result of either contraceptive failure or discontinuation of a method for reasons other than a desire to get pregnant.[8] Women's expectations of and experiences with side effects may lead to satisfaction with their method and continuation with using it or dissatisfaction and discontinuation of their method.[9] Further, recent evidence suggests that the experience of side effects is increasingly a reason for why women have an unmet need for contraception.[10] In Ghana specifically, intolerance of side effects is often an underlying reason for method discontinuation[11,12] and is cited as the reason many women avoid initiating contraception.[13] In recent years, health concerns and the experience of or concerns about side effects are increasingly driving non-use of contraception by Ghanaian women; the percentage of women who mentioned these as their reason for non-use increased from 14% in 1988 to 43% in 2008.[14] This could, in part, be due to the heavy reliance on oral contraceptives and injectables,[5] methods for which women report high levels of displeasure with side effects.

This study aimed to characterize the extent women chose methods that matched their preferences for desired characteristics including side effects.

While there is a large body of evidence based on clinical trials detailing the possible physical symptoms and side effects that may be caused by using a particular contraceptive method, ranging from bleeding changes, headaches, breast tenderness, and weight change with hormonal methods to increased bleeding with the copper IUD,[15–17] how users feel about these side effects is inherently subjective. In many settings, including Ghana, side effects and health concerns or fears are conflated.[13] Further, Ghanaian women's unfavorable attitudes toward contraceptive methods, a key driver in use or non-use, originate from fears regarding the safety of these methods and intolerance of menstrual side effects, rather than from social or moral objections.[14] Menstrual disruption is often considered to be a clinically benign side effect and is therefore sometimes minimized or dismissed by health personnel.[18] However, many women have a low tolerance for menstrual changes, and thus side effects, and in particular bleeding changes, are a key reason for discontinuation of contraceptive methods.[19] Understanding individuals' expectations of and tolerance for side effects is an important part of counseling and a means to ensuring satisfaction with the chosen method, and ultimately to ensuring consistent use of contraceptive methods.

In this study of Ghanaian family planning adopters, we aimed to (1) describe method characteristics women find desirable and side effects women report would be untenable; (2) describe the side effects women were counseled to expect from the method they adopted; and (3) characterize to what extent women chose methods that matched their desires for acceptable vs. intolerable side effects and other method characteristics.

METHODS

Setting and Participant Recruitment

We conducted this cross-sectional study in urban family planning clinics of 2 teaching hospitals and 3 district hospitals in Kumasi and Accra, Ghana. Data were collected between June 1, 2015, and August 31, 2015. All women attending these clinics for family planning counseling and method choice were approached by a member of the study team and informed about the study to gauge their interest and eligibility for inclusion. Inclusion criteria consisted of being over the age of 18, intending to adopt a new method of family planning, and being able to converse in either English or Twi or Ga (the local languages). If the women met these inclusion criteria and agreed to participate, they were taken through a comprehensive verbal consent process. Consenting participants were interviewed both before and after their family planning counseling. This study used a convenience sample; all women who attended the clinic

for family planning during the study period were invited to participate. No sample size calculations were conducted prior to study initiation.

Survey Instrument

The survey was developed by the authors, an international study team with experience in family planning in Ghana. Questions were developed based on literature and expert opinion. The questionnaire was pretested for clarity and flow among women in the study clinics who met the inclusion criteria before the beginning of data collection. Revisions to the questionnaire were made based on this pilot testing. Questionnaire items included previous use of contraceptive methods and reasons for discontinuation, as well as what method of contraception women wanted to adopt, what method characteristics they desired, which side effects they would find bothersome, and which would be intolerable, causing them to discontinue the use of a contraceptive. After their counseling session, women were asked whether they were leaving with a method and, if they were, whether they were counseled to expect any side effects. If they had been counseled about side effects, they were asked what side effects they were counseled to expect. These answers were collected as free response and grouped. Multiple responses were maintained.

Survey Administration

Interviews were conducted both before and after women's family planning counseling session in a private room near the family planning clinics. Only the woman and the research assistant were in the room where the interview took place, and no identifying information was collected. Phone numbers were used to link the pre- and post-counseling surveys. All data were collected on a Google tablet computer using Qualtrics software and results could not be seen once the form was completed. Questionnaires were interview-administered by trained research assistants.

Data Analysis

To determine women's preferences, participants were asked 3 sets of questions. First, women were asked a variety of questions about method characteristics, such as, "I would prefer a method that I take every day." The answers were recorded on a 5-point Likert scale from strongly disagree to strongly agree. We then created a dichotomous variable to represent yes/no agreement to the statement by grouping "strongly agree" and "agree" to indicate agreement with the statement, and "neither agree nor disagree," "strongly disagree," and "disagree" to indicate disagreement.

In the second set of questions to determine preferences, questions about side effects, such as, "I would not like a method if it stopped me from bleeding," were asked also on a 5-point Likert scale. Similarly, "strongly agree" and "agree" were grouped, as were "neither agree nor disagree," "strongly disagree," and "disagree."

Finally, participants were asked whether the experience of a variety of side effects would be intolerable enough to cause them to stop using the method. The answers to these questions were collected as a dichotomous variable (yes/no) and included such statements as, "Increased bleeding would cause me to stop using the method."

In the post-counseling survey, participants were asked about the method they had adopted and also if they were counseled to expect side effects. Those who answered they were counseled to expect side effects were asked which side effects they were expecting. The side effects they were expecting, as well as those they reported as being so intolerable as to cause them to stop using the method, were compared with their adopted methods. Those who adopted methods that are known to cause such side effects were determined to have adopted a method that was not concordant with their preferences. For example, if a woman indicated decreased bleeding would be bothersome enough to cause her to stop using her method, but she adopted the injectable or the implant, she was determined to have adopted a method discordant with her preference. Women who reported they were counseled to expect side effects that are in fact shown in the literature to be caused by the method they adopted were determined to have been counseled appropriately to expect side effects common with the chosen method. For example, a woman who adopted an IUD and reported she was counseled to expect increased bleeding was determined to have been counseled to expect a side effect common with her chosen method. These comparisons were done using crosstabs in SPSS (Chicago, IL) version 22. Data are presented as descriptive statistics.

Ethical Review

All study materials and methods were reviewed and approved by the Ghana Health Service Ethical Review Committee and the University of Michigan Institutional Review Board.

RESULTS

Background Characteristics

A total of 414 women completed the pre-counseling survey, and 411 completed the post-counseling survey. Of the original 414 participants, 336 left with a method and were matched between the 2 surveys (183 in Kumasi and 153 in Accra). A total of 55 participants did not leave with a method and an additional 23 participants from the pre-counseling survey could not be matched with the post-counseling survey. Thus, our analytical sample consisted of the 336 participants who had complete records.

Participants were generally well distributed across sociodemographic variables; the mean age of the total sample of 414 women who completed the pre-counseling survey was 29.3 years (range, 18 to 51; standard deviation, 6.7), and 248 participants (59.9%) were married (Table 1). Of the 411 women who completed the post-counseling survey, 337 (82.0%) left their counseling appointment with a method (1 participant who left with a method was not matched to the pre-counseling survey and thus was not included in the analytical sample). The primary reasons women gave for not leaving with a method were needing to wait for a pregnancy test (n=17), the clinic not having the supplies/equipment/providers necessary (n=13), having high blood pressure (n=9), and needing to consult with the husband (n=5).

Almost half of the sample (n=200, 48.3%) had previously used some form of contraception, with the injectable being the most commonly used method (n=97, 48.5%), followed by the pill (n=53, 26.5%) (Table 1).

TABLE 1. Background Characteristics of Participants, Kumasi and Accra, Ghana (N=414)

	Value
Age, years, mean (SD)	29.3 (6.7)
Married	248 (59.9)
Highest education	
None	31 (7.5)
Primary	71 (17.1)
Junior secondary	146 (35.3)
Senior secondary	89 (21.5)
More than secondary	77 (18.6)
Previously used a method(s)[a]	200 (48.3)
Pill	53 (26.5)
IUD	12 (6.0)
Injectable	97 (48.5)
Implant	36 (18.0)
Male condom	20 (10.0)
Female condom	3 (1.5)

Abbreviations: IUD, intrauterine device; SD, standard deviation.
Data presented as "number (%)" unless otherwise specified.
[a] Respondents could select more than 1 method.

Women's Stated Preferences

The majority (n=310, 74.9%) of the full sample of participants agreed or strongly agreed that they would prefer a method that protects them for years (Figure 1a). A substantial number of women agreed or strongly agreed that they would prefer a method that they take every few months (n=175, 42.3%) or that lasts forever (n=88, 21.3%). Only 67 (16.2%) women agreed or strongly agreed they would prefer a method that they had to take every day. A majority (n=252, 60.9%) was not opposed to using a method that requires a visit to the facility to stop using it.

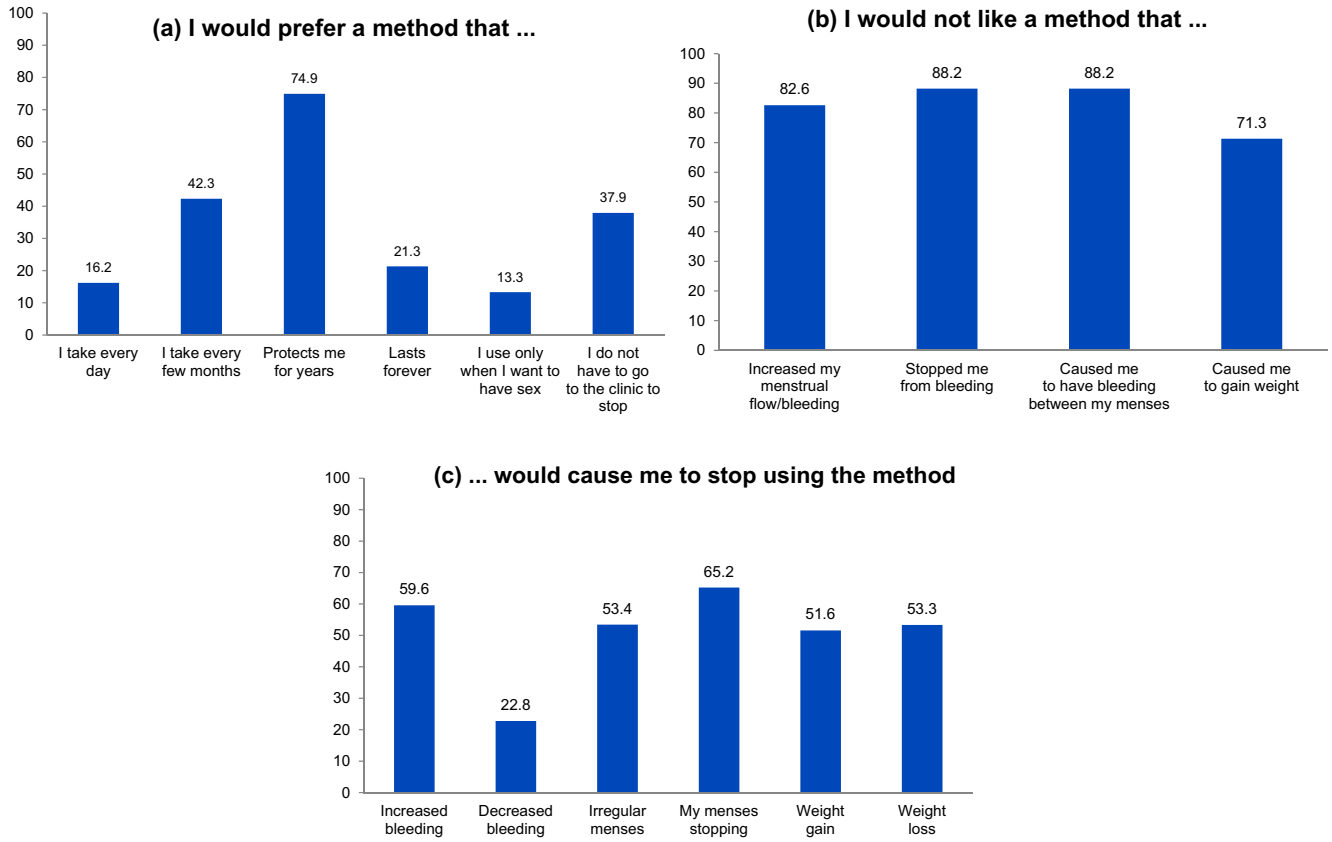
Most women in this study chose a long-acting reversible contraceptive.

Participants had generally unfavorable attitudes toward bleeding changes caused by contraceptives. For example, a majority reported that increased bleeding (n=246, 59.4%), irregular bleeding (n=219, 52.9%), and amenorrhea (n=268, 64.7%) would be intolerable enough for them to stop using the method (Figure 1c). Decreased bleeding seemed to be more tolerable to women as only 94 women (22.8%) reported it would be intolerable enough to stop using the method.

Women's Method Choices

The majority (n=187, 55.7%) of women who left with a method and were matched with the pre-counseling survey chose a long-acting reversible contraceptive (LARC); 52 women (15.5%) chose the IUD and 135 women chose the implant (40.2%) (Table 2). A substantial number (n=109, 32.4%) chose injectables. The remaining chose either sterilization (n=11, 3.3%) or short-acting methods (n=29, 8.6%).

FIGURE 1. Women's Stated Preferences About Contraceptive Method Characteristics and Side Effects, Kumasi and Accra, Ghana (N=414) (percentage who agreed or strongly agreed with the statements)



Counseling About Side Effects

Of the 336 participants who adopted a method of contraception, 218 (64.9%) reported they were counseled to expect side effects. Table 3 presents data on the percentage of women who reported being counseled to expect certain side effects by the method adopted; the side effects presented in the table are those side effects that are known to commonly occur with the method. Among the 52 women who adopted the IUD, only 16 (30.8%) reported they were counseled to expect an increase in bleeding (a commonly expected side effect with copper IUD use). Among the implant adopters, 28 (20.7%) reported they were counseled to expect irregular bleeding, while 14 (10.4%) and 37 (27.4%) reported they were counseled to expect decreased bleeding and no menses, respectively. For those using injectables, 46 (42.2%) reported they were counseled to expect their menses to stop.

Consistency Between Women's Method Choice and Stated Preferences

Figure 2 shows the concordance between women's method choice (for the 3 most popular methods—the IUD, the implant, and injectables) and their stated preferences at the pre-counseling survey with regard to desired duration of effectiveness and intolerable side effects (side effects that, if experienced, women stated they would stop using the method). The intolerable side effects included in the figure are those bleeding side effects that are commonly expected with use of that particular method; for example, increased bleeding for IUDs. Figure 2 also displays the proportion of method adopters who reported being

Most women reported they were counseled to expect side effects, but much fewer reported being counseled to expect the side effects that commonly occur with their chosen method.

TABLE 2. Women's Contraceptive Method Choices, Pre- and Post-Counseling, Kumasi and Accra, Ghana

Method	Preferred Method at Pre-Counseling (N=414)	Method Choice Post-Counseling (N=336)
Implant	172 (41.5)	135 (40.2)
Injectable	125 (30.2)	109 (32.4)
IUD	58 (14.0)	52 (15.5)
Pill	20 (4.8)	27 (8.0)
Female sterilization	17 (4.1)	11 (3.3)
Male condom	2 (0.5)	2 (0.6)
Don't know	20 (4.8)	NA

Abbreviation: IUD, intrauterine device.
All data are presented as "number (%)."

TABLE 3. Percentage of Women Who Reported Being Counseled to Expect Commonly Occurring Side Effects by Method Adopted

Method and Side Effect Counseled to Expect	No. (%)
Implant (N=135)	
Irregular bleeding	28 (20.7)
Decreased bleeding	14 (10.4)
No menses	37 (27.4)
Not counseled on any of these side effects	39 (28.9)
Injectables (N=109)	
Decreased bleeding	12 (11.0)
No menses	46 (42.2)
Weight gain	13 (11.9)
Not counseled on any of these side effects	34 (31.2)
IUD (N=52)	
Irregular bleeding	6 (11.5)
Increased bleeding	16 (30.8)
Not counseled on any of these side effects	26 (50.0)

Abbreviation: IUD, intrauterine device.

73% of IUD adopters stated in their pre-counseling survey that experiencing increased bleeding would cause them to stop using the method.

The large majority of women chose methods that lined up with their stated preferences for duration of effectiveness.

counseled to expect bleeding changes with their chosen method and the proportion reporting they were not counseled to expect bleeding changes.

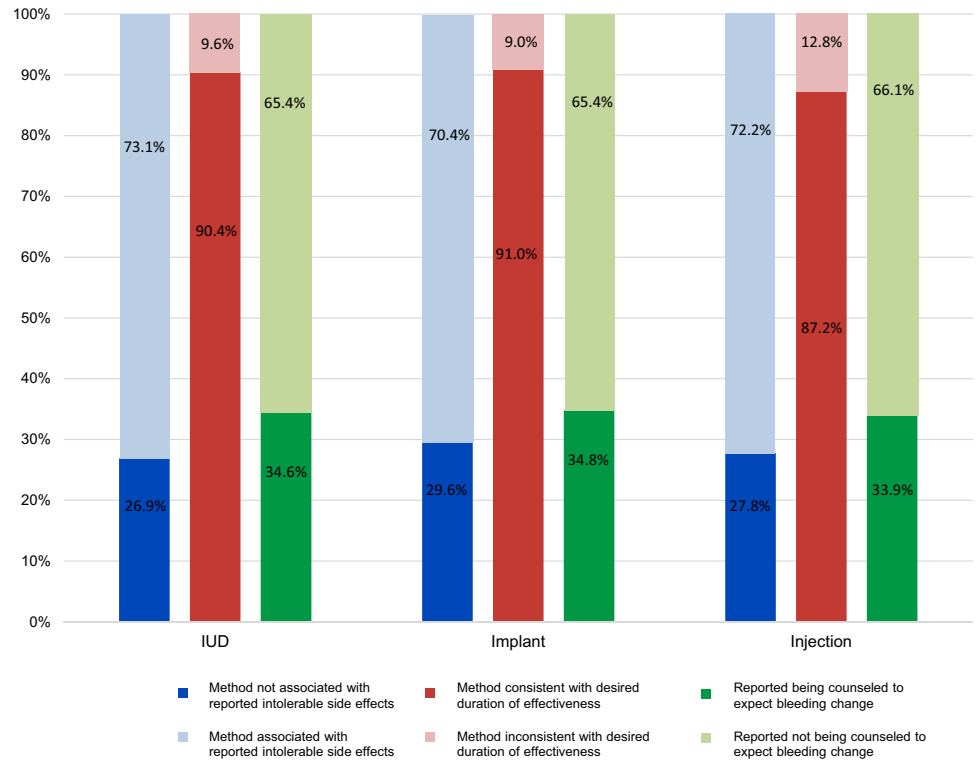
Among IUD adopters, 73.1% stated in their pre-counseling survey that experiencing increased bleeding would cause them to stop using the method, suggesting discordance with their chosen method because copper IUDs have been shown to increase bleeding among many users. Similarly, 70.4% of implant adopters stated at the pre-counseling survey that irregular, decreased, or no bleeding would cause them to stop using the method and 72.2% of injectable users stated that decreased or no bleeding would cause them to stop using the method, suggesting discordance since these are commonly experienced side effects with use of these methods. The majority (around 65%) of IUD, implant, and injectable adopters reported they were not counseled to expect bleeding changes. Bleeding changes are in fact expected to occur with all 3 of these methods.

There seemed to be greater concordance between women's choice of method and their stated desired duration of effectiveness: at least 87% of the adopters indicated a desired duration of effectiveness that lined up with the duration of effectiveness of their chosen method (a few months for injectables and years for LARCs).

DISCUSSION

This study, conducted in urban areas of Accra and Kumasi, Ghana, sought to characterize women's contraceptive preferences and to examine whether their adopted method was consistent with their stated preferences. We found that the vast majority of women attending family planning clinics had a method in mind before the family planning counseling session, and many had strong preferences for and against method-specific qualities or side effects. It seems that most women received the method that they had been planning to use, and most women adopted a method that appeared consistent with some of their stated preferences, most notably duration of effectiveness. However, the majority of women left the clinics with a method that is known to cause the side effects they had characterized as intolerable—ones that would cause them to stop using the method. Furthermore, most women reported they were not counseled to expect these commonly occurring side effects.

FIGURE 2. Consistency Between Women's Chosen Contraceptive Method and Their Stated Preferences for Duration of Effectiveness and Intolerable Side Effects, Along With Percentage of Women Counseled to Expect Bleeding Changes With Their Chosen Method



Improving access to and use of modern contraception is an important strategy to both reduce maternal mortality and assist women to meet their fertility goals. Side effects are a key reason both for not using contraception and for discontinuing use of contraceptives.[10,14] Women are diverse in preferences and providers need to guide them to the method that best suits their preferences. Our results show that while there is generally a good match with women's preferences regarding desired duration of effectiveness, many women are leaving with a method well known to cause a side effect they characterized as intolerable. It is not clear from these data if women were well informed about potential side effects; many did not report being educated on these side effects. Adopting a patient-centered model of care has been demonstrated to increase consistent contraceptive method use in high-resource settings,[20] and has been tested on a limited basis in low-resource settings.[21] More specifically, providers need to tailor information for women so that they know what side effects are common and not harmful and what things might cause temporary or longer-term discomfort, compared with potential (rare) complications to look for.

It appears that not all women in our study were provided with clear information about the side effects they should expect with the method they were given. Others too have reported that women are sometimes poorly informed about side effects,[2] and this could lead to dissatisfaction and discontinuation. A recent analysis of the 2008 Ghana Demographic and Health Survey showed that 71% of IUD adopters discontinued the use of this method, mainly due to side effects and health concerns.[22] Discussion of method side effects appears to not have changed much over the past decades. In 1995, Bongaarts and Bruce[23] found that fewer than 50% of new adopters were counseled about their method's side effects and about 35% of women had discussions about how

Many women in this study left with a method well known to cause a side effect they characterized as intolerable.

to manage these side effects should they arise.[23] More recently, in Niger in 2012, only 40% of women reported being informed of possible side effects of methods.[24] Some providers may be reluctant to discuss potential side effects for fear of the "nocebo" effect,[25] the phenomenon where women experience side effects after being told to expect them because of the power of suggestion. However, evidence suggests that the discussion of negative side effects is not detrimental to method adoption and may be beneficial to method adherence.[26–28] In fact, patients report that the reluctance of providers to discuss side effects makes them distrustful of counseling.[20]

The counseling session is an opportunity for providers to help align clients' desires and preferences with method characteristics.

Providers need training and support in good-quality counseling skills. The counseling session is an opportunity for providers to help align clients' desires and preferences with method characteristics so that clients receive a method that is likely to suit their needs, and thus one that they are more likely to continue using. Above all, it is the responsibility of providers to help women make an informed family planning choice by giving them information about the methods available to them, the characteristics of those methods, including side effects, and how to correctly use their chosen method. Given this information, some women may decide to sacrifice some of their preferences when those preferences do not align perfectly with available methods (for example, a woman who wants a long-acting method but finds menstrual changes bothersome may decide to use a long-acting method anyways because the other positive characteristics balance out the bleeding side effects). While supply-side barriers have long been determined to be factors limiting contraceptive uptake and continuation, demand-side barriers are increasingly being determined to be important as well.[14] Once a woman overcomes the many potential barriers to adopting a method, the provider can help ensure her satisfaction with the chosen method by reassuring her that side effects are common with use and not harmful, which may improve her adherence to and continued use of the method. If women do not have good family planning experiences, this may erode their trust of the health care provider or health center and influence members of their social network to avoid using contraceptive methods. Clearly, more research is needed to fully understand the patient-provider interaction in this particular study setting.

Beyond the individual patient-provider relationship, it is possible that mass media campaigns aimed at reducing misinformation and myths about common side effects could help women to be more tolerant of innocuous side effects. The ability of women to use family planning is, of course, a larger societal issue, and many societal and cultural barriers reduce demand for family planning.[29]

The most frequently cited side effect that women said would cause them to stop using the method was amenorrhea, followed by increased bleeding. This finding supports research conducted in the 1970s, which suggested that amenorrhea was unacceptable to many women,[30] although no African women were included in that study. In a qualitative study of women from a range of countries from the 1990s, women were "dismayed" by the possibility of a contraceptive method causing amenorrhea.[31] However, in more recent work, Glasier and colleagues[32] found that Nigerian women were generally willing to accept a method of contraception that induces amenorrhea, even though a majority said monthly bleeding was important to them. This could be indicative of a shift in the acceptability of a cessation in menses, although most women in our sample were not eager to adopt a method with such an effect. Education on the non-contraceptive health benefits of reduced blood loss associated with hormonal contraceptives, and reassurance that current global evidence-based guidance advises this is not harmful,[15,33] could make some clients adopt methods with such a side effect.

Limitations

This study is not without limitations. The relatively small sample size, as well as the fact that all study sites were located in urban areas, reduces the ability of these findings to be generalized. Further, these women were all seeking services at family planning clinics at district hospitals or tertiary care centers and thus might have been more interested in LARCs than women who seek contraceptive services from other locations. Qualitative investigation is important to develop clearer and deeper understanding of the concerns women have about contraceptives and what they expect from service providers. It is possible that counseling from the provider during the session changed women's perceptions toward side effects, and so their stated intolerance of a side effect before their visit changed post-counseling. These data would not capture a woman's change in preferences due to counseling. Finally, this cross-sectional survey does not allow us to determine to what

extent women's reported desires matched actual behaviors. A follow-up, longitudinal study is important to assess if women's experience with either expected or unexpected side effects impacts contraceptive adherence.

CONCLUSION

This study interviewed women before and after their contraceptive counseling session to determine to what extent women were receiving methods that matched their stated desires. Women had clear preferences regarding several contraceptive characteristics, including duration of effectiveness and side effects. It is important for providers to understand women's individual preferences and needs and how these preferences may interact with each other to guide women to make informed family planning choices. While women generally adopted methods that matched their stated desires related to duration of effectiveness, the adopted methods were less well matched to women's preferences regarding potential menstrual side effects. Future work could investigate whether the experience of side effects, both expected and unexpected, is associated with contraceptive adherence and continuation.

Competing Interests: None declared.

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ORIGINAL ARTICLE

Women's Limited Choice and Availability of Modern Contraception at Retail Outlets and Public-Sector Facilities in Luanda, Angola, 2012–2015

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Despite high rates of unintended pregnancy, access to a wide range of contraceptive methods, especially injectables and long-acting reversible contraceptives (LARCs), is severely limited in both public and private facilities. Knowledge of contraceptive choices is likewise limited, yet a substantial proportion of women are not using their preferred method among the methods they know of.

ABSTRACT

In Angola, many women want to use family planning but lack access to affordable and preferred methods. This article assesses the link between women's choice and availability of contraceptive methods in Luanda, Angola, drawing on data from 3 surveys: a 2012 survey among women ages 15–49 and 2 retail surveys conducted in 2014 and 2015 among outlets and facilities offering contraceptive methods. Descriptive statistics for women's contraceptive knowledge, use, and preferred methods were stratified by age group. We report the percentage of establishments offering different methods and brands of modern contraception, and the mean price, volume of units sold, and value (Angolan Kwanzas) for each brand. Data from the 2 retail surveys are compared to measure changes in availability over time. Results show that 51% of women reported having an unwanted pregnancy. Less than 40% of women knew about long-acting reversible contraceptives (LARCs). Overall, the method most commonly used was male condoms (32.1%), with a substantial proportion (17.3%) of women not using their preferred contraceptive. Trends in contraceptive use mirror availability: in 2015, condoms were available in 73.6% of outlets/facilities, while LARC methods were available in less than 10%. The availability of different methods also dropped significantly between 2014 and 2015—by up to 15 percentage points—with a subsequent price increase in many brands. To meet women's needs for contraception and make informed choice possible, Angola should reinforce demand creation and contraceptive supply in both the public and private sectors through behavior change programs aimed at both women and providers, improved quality of services, training of health personnel on method options and delivery, and improved supply chain distribution of contraceptives. This will allow women to find the methods and brands that best suit their needs, preferences, and ability to pay.

INTRODUCTION

Angola's slow recovery after almost 30 years of civil war has led to the country's unique demographic situation compared with other similarly developed sub-Saharan African nations.[1,2] Specifically, women in Angola were less likely to have children during wartime, particularly in areas where the impact was the most intense; the probability of having a child was only 39% in 1994 during the intense war period, compared with 52% in 1996 when fighting was at a stalemate.[3]

The temporary decline in childbearing during the war did not result, however, in a long-term reduction in fertility: in 2014, the total fertility rate was 5.7 births per woman, one of the highest rates in the world.[4] Geographic differences in fertility are stark, with women in rural areas having an average of 3 more children than women in urban areas.[5] Over time, the age-specific fertility rate among adolescents increased faster than that of older women. For example, from 2006 to 2011 the age-specific fertility rate among 15–19-year-olds increased from 151 to 188 births per 1,000 women, compared

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with an increase from 242 to 244 births per 1,000 women among 30–34-year-olds.[6] High fertility rates are often associated with high maternal and child mortality. In Angola, the infant mortality rate is 96 per 1,000 live births and the maternal mortality ratio is 460 per 100,000 live births.[7,8]

Not surprisingly, the contraceptive prevalence rate (CPR) is low (17.7% for modern and traditional methods; 12.8% for modern methods only), with significant differences by geography (27% of urban women use contraception vs. 7% of rural women) and income level (28.1% of women in the wealthiest quintile vs. 1.4% of women in the poorest).[5,8,9] Contraceptive use is also associated with education, marital status, and previous childbearing experience. A study in Luanda, the capital of Angola, found that sexually active women who are unmarried, less educated, and have never given birth are less likely to be users of any method of contraception.[10] More than half of women who were not using contraception at the time of the study reported feeling that contraception was inaccessible, underlying the importance of improving method availability and choice.[10]

Women's preferences for particular methods are based on a multitude of factors, including cost, ease of use, efficacy, side effects (both real and perceived), and partner relationships, among many others factors. Having a full range of family planning options is considered an important component of quality of care and informed choice, resulting in improved uptake of family planning.[11] Access to more methods increases the odds that a woman will use and continue to use contraception: for each additional method widely available in a country, the percentage of married women using contraception increases by an average of 3.3 percentage points.[12] At the same time, greater availability of contraceptive brands generates competition in the market, increasing chances of price reduction and improving women's access to contraceptives within the private sector.[13]

Angola's national family planning program began in the mid-1980s with the goal of improving maternal health by spacing pregnancies.[15] The program promised to offer free family planning services through state-run public clinics (maternity hospitals, health centers, and health posts), but implementation has been difficult due to the limited number of trained providers and inconsistent supply of contraceptive commodities.[2,15–17] When the public sector experiences stock-outs of short-acting methods, women might be directed to get contraceptives from the private sector, which is comprised of small local pharmacies (*boteco*), modern pharmacies (e.g., Mecofarma), and private clinics.[18,19] In the case of condoms, the private sector also includes non-traditional establishments such as local stores, markets, gas stations, and hotels.

Little is known about the availability of a range of contraceptive methods in Angola or the choices women make.

The public sector obtains contraceptives through donations from the United States Agency for International Development (USAID) or the United Nations Population Fund (UNFPA). Specific brands of oral contraceptive pills (Microgynon, Microlut), injectables (Depo-provera), and implants (Jadelle) are donated exclusively for the public sector for free. In 2015, the private sector generally obtained contraceptives from wholesalers (including Princefarma, Shalina, Farwell, and Ecofarma, among others) who import products mostly from Europe and Asia and, in some cases, from Angolan border countries.[20,21] The products in the private sector include a wide range of brands for condoms (Davigra, Kamasutra, Durex, among others), oral contraceptive pills (e.g., Yasmin, Diane35), and oral emergency contraceptives (Pilula S and Norlevo).[20,21]

Angola's family planning strategy currently centers on strengthening supply so that women can choose from a range of affordable products and services needed to space or limit pregnancies. Angola's National Health Development Plan is bolstering health systems to increase the proportion of facilities offering family planning and better distribute qualified providers.[22] UNFPA helped obtain more than 60% of the country's family planning commodities, and its program for 2015–2019 allocates US$12 million to strengthen the supply chain and integrate activities for family planning, maternal health, and prevention of sexually transmitted infections (STIs) including HIV.[9] In its 2014–2017 Country Development Cooperation Strategy, USAID will use a market-based approach to support the local commercial sector to supply a suite of contraceptive products to women at different income levels.[22]

Based on the existing literature, little is known about the availability of different contraceptive methods in Angola or the choices women make. This article helps to contribute to the discussion by presenting results from a population-based survey (2012) and two retail studies (2014 and 2015), all conducted in Luanda, Angola, to understand women's contraceptive choices and their link with contraceptive availability in the market.

MATERIALS AND METHODS

Data Sources

This analysis draws on data from 3 surveys conducted by Population Services International (PSI) to understand women's choices and availability of contraception.

Family Planning Survey 2012. The 2012 study, conducted in collaboration with the Bixby Center at the University of California Berkeley, surveyed women ages 15–49 in Luanda province between October and November 2012. The purpose of the survey was to assess contraceptive use and fertility preferences, as well as barriers to and drivers of contraceptive use. The questionnaire was based on a standard PSI questionnaire that explores the opportunity, ability, and motivational variables to use contraception, and it borrowed elements of the family planning section of the Angola Malaria Indicator Survey 2011 and of the Women's Questionnaire supplement to the Demographic and Health Surveys (DHS) 2008–2013.[6,23] A total sample of 1,545 women completed the survey through multistage random sampling. First, the sample size was distributed proportionally to the size of each municipality. Then a number of sampling points (churches, hospitals, gas stations, etc.) were randomly selected in each municipality from a list created for that purpose. The number of sampling points chosen per municipality varied according to its population size. Within each of these sampling points, a fixed number of households was selected. One woman within the age criteria was then randomly chosen and invited to participate. PSI hired a research marketing agency, SINFIC (*Sistemas de Informação Industriais e Consultoria*), to conduct the fieldwork.

Retail Survey 2014. PSI conducted an audit survey among retail stores and health facilities in Luanda province from June to September 2014 to learn about the availability of different contraceptive methods, the brands available for each method, the units sold, the price, and stock-out problems. SINFIC was also hired to conduct the fieldwork for this study. The survey included a census of all establishments selling or distributing at least 1 type of contraceptive in the entire province of Luanda (301 *bairros*), including pharmacies, drug dispensing units in public hospitals, supermarkets, grocery stores, kiosks, gas stations, bars/discos, and hotels. Of the 2,173 establishments identified, 1,833 completed the interview (84.3% response rate). Reasons for not participating were (1) establishment was closed during fieldwork, or (2) absence of manager or owner who could provide permission. Three visits were made to the establishment before desisting from the interview. Establishments participating in the study were similar to those not participating in terms of establishment type. Of the final sample, 2.8% of the establishments were from the public sector (96.1% drug dispensing units at public health centers and 3.9% NGOs), while 97.2% were private-sector outlets (76.6% *boteco*, 10.0% modern pharmacies, 6.7% pharmacies of private clinics, and 6.0% other type of outlet such as kiosks, local stores, street vendors, hotels, and gas stations).

Retail Survey 2015. This second round of the retail study also measured contraceptive availability, brand market share, and price. It used the same data collection instrument as in 2014, but unlike the first round, it selected only 50 neighborhoods (*bairros*) at random out of a total of 301 in the entire province. Within those selected neighborhoods, a census of all establishments was conducted. Based on the levels of contraceptive availability detected in 2014, sample sizes for outlets were calculated for each method provided, assuming a 95% confidence interval, 84.0% response rate, 80% power, 2-sided significance tests, and a design effect of 2. The number of completed interviews needed for each method (after discounting the 16.0% non-response rate), was (1) 344 establishments for condoms, (2) 501 establishments for injectable methods, (3) 769 establishments for oral contraceptive pills, and (4) 820 for emergency oral contraceptive pills. Details of the sampling formula can be found elsewhere.[24,25] Fieldwork was conducted by PSI/Angola. A total of 957 establishments were identified and invited to participate; 766 completed the interview (80.0% response rate). No notable differences were found in the type of establishments that participated in the study compared with those that did not. Of the 766 establishments included in this analysis, 3.5% were public-sector outlets (85.2% drug dispensing units at public health centers, 7.4% public maternities, and 7.4% NGOs), while 96.5% were private-sector outlets (62.0% *boteco*, 19.5% modern pharmacies, 3.5% pharmacies of private clinics, and 15.0% other type of outlet).

A 2012 population-based study in Luanda province assessed contraceptive use and fertility preferences as well as barriers to and drivers of contraceptive use.

Two audit surveys among retail stores and health facilities conducted in 2014 and 2015 measured contraceptive availability, brand market share, and price.

Data Analysis

Family Planning Survey 2012. Descriptive statistics are presented in this article, including: *sociodemographics* of the sample, *pregnancy intention* (measured by whether women wanted their last pregnancy at the time it happened, wanted it later,

or did not want more children at all), *contraceptive knowledge* (prompted), *contraceptive use* (the percentage of sexually active women using modern methods), as well as the *unmet need for preferred contraception* (defined as the percentage of sexually active, fecund women who are currently using contraception but report that their current method is not their preferred method). Main results are presented for the overall sample and by age group. Given that adolescent women generally face greater barriers in accessing reproductive health services, 2 age groups were created from the sample of young women: ages 15–19 and ages 20–24. Women aged 25 and older comprised the final age group.

Retail Surveys 2014 and 2015. Availability of contraceptive methods on the market was calculated for each year, defined as the percentage of establishments that reported selling or distributing different types of modern contraceptive methods. Independent sample *t* tests were produced to measure changes over time for the overall samples and for the private and public sector, separately.

For 2015, market share indicators were produced, defined as the proportion that each brand represents within its respective contraceptive category in terms of volume (number of units sold) and value (Angolan Kwanzas: AKZ), measured during the 30 days prior to the survey. No data were presented for 2014 given that the dominant contraceptive brands remained so in 2015. Availability of brands was also calculated based on proportion of outlets having specific brands within the outlets selling or distributing the corresponding contraceptive category.

Finally, mean price per brand was reported for each year with its 95% confidence intervals, in order to measure significant changes over time. This was calculated as the arithmetic average of price provided by establishments. This indicator is presented in local currency, rather than US dollars, to better reflect changes in prices and its impact on Angolan women: recent depreciation of AKZ with respect to US dollars could hide the real cost of contraceptives to consumers if US currency is used. The exchange rate as of October 30, 2014, was US$1 for 99AKZ.[26]

The majority of women knew about condoms, pills, and injectables, but less than half knew about IUDs or implants.

Although contraceptive prevalence was relatively high (59%) among survey respondents, most of it was due to the reported reliance on condoms.

Ethical Considerations

The family planning study conducted in 2012 received ethical approval from the Berkeley Center for Protection of Human Subjects (CPHS # 2011-08-3521) at the University of California Berkeley, and from the Ethical Committee at the Public Health Institute in Luanda, Angola. The retail study in 2014 was commissioned to an external agency (SINFIC) and followed its internal ethics processes, which consisted of providing ethics training to its interviewers to minimize any potential risk in breach of confidentiality and to assure justice, beneficence, and respect during the data collection process; interviewers also signed a pledge of confidentiality. The retail study in 2015, conducted by PSI/Angola, went through PSI's ethics committee, which deemed the study to be not human subjects' research as it was a survey about product availability. Interviewers still received training in human subjects to ensure compliance with ethics principles.

RESULTS

Women's Fertility Preferences and Contraceptive Use

Results from the 2012 Family Planning Survey show a relatively young female population (median age of 24 years), with more than half having completed high school (Table 1). Most of the women aged 20–24 reported being single (81.7%) and were sexually active (90.9%). Although half of them had already been pregnant, the majority (72.2%) either did not plan or did not want their last pregnancy. Younger women wanted fewer children: women aged 20–24 wanted an average of 3.7 children, while women 25 years and older desired 4.3 children.

Nearly all women knew about condoms (95.0%) and, to a lesser extent, oral contraceptive pills (79.7%) and injectable contraceptives (68.9%). In contrast, less than half of the respondents knew about long-acting reversible contraceptives (LARCs), which consist of intrauterine devices (IUDs) (39.6%) and implants (38.6%). Knowledge of LARCs was extremely low in the youngest age group (15–19): only 19.1% knew about IUDs and 18.2% knew about implants.

While the overall contraceptive prevalence rate was relatively high among the study participants (58.7%), most of it was due to the reported reliance on condoms, with little to no use of other methods, especially among the younger age groups. For example, 52.0% of women 15–19 years old reported using condoms as a family planning method, while only 3.2% reported using oral contraceptive pills and 2.0% injectable contraceptives. Almost no young respondents used implants (0.4%) or IUDs (0.0%). A similar pattern was observed in the 20–24 year age group.

TABLE 1. Demographic and Behavioral Characteristics of Women of Reproductive Age in Luanda, Angola, 2012

Variables	Age Groups			
	15–19 (N=451)	20–24 (N=361)	≥25 (N=729)	All (N=1545)
Sociodemographics				
Age, median	NA	NA	NA	24.0
Marital status				
Single	98.2	81.7	39.4	66.5
Married/cohabiting	1.8	18.3	56.0	31.3
Divorced/widowed	0.0	0.0	4.1	2.2
Education				
High school or less	55.3	28.8	45.3	44.4
More than high school	44.7	71.2	54.7	55.6
Sexual Behavior and Fertility Preferences				
Ever had sex	55.0	90.9	91.4	80.6
Ever been pregnant	11.5	49.9	90.4	57.9
Intention to get pregnant at last pregnancy[a]				
Wanted it at that moment	17.3	27.8	57.7	49.3
Wanted it later	53.8	56.1	28.1	35.2
Did not want more children	28.8	16.1	14.3	15.5
Ideal number of children, mean[b]	3.8	3.7	4.3	4.2
Knowledge of modern contraceptives				
Condoms	96.7	95.6	93.7	95.0
Oral contraceptive pills	68.9	84.2	87.4	79.7
Injectable	47.2	65.7	84.1	68.9
Female condoms	34.2	42.1	54.7	45.6
IUD	19.1	36.3	54.2	39.6
Implants	18.2	35.7	52.7	38.6
Female sterilization	14.6	26.6	39.4	29.1
Emergency oral contraceptive pills	10.3	21.6	32.8	23.5
Male sterilization	5.3	12.5	22.2	15.0
Contraceptive Use[c]				
Current prevalence of any modern contraception	58.5	64.9	55.9	58.7

Continued

TABLE 1. Continued

Variables	Age Groups 15–19 (N=451)	20–24 (N=361)	≥25 (N=729)	All (N=1545)
Current prevalence of:				
Condoms	52.0	46.0	17.7	32.1
Injectables	2.0	6.1	18.8	12.1
Oral contraceptive pills	3.2	11.0	14.1	11.1
Implants	0.4	1.5	2.6	1.9
IUD	0.0	0.0	1.4	0.7
Female sterilization	0.8	0.0	0.8	0.6
Female condoms	0.0	0.3	0.6	0.4
Male sterilization	0.0	0.0	0.0	0.0
Ever used emergency contraceptive pills[d]	1.1	6.4	5.8	4.5
Current contraceptive users not using their preferred method[e]	15.1	20.7	16.0	17.3
Preferred contraceptive method among women not using their preferred method[f]				
Injectables	13.6	25.0	31.0	25.6
Condom	31.8	22.7	8.6	17.6
Implants	13.6	4.6	27.6	16.8
Oral contraceptive pills	4.6	13.6	12.1	12.0
Rhythm method	4.6	0.0	1.7	1.6
Female condom	4.6	0.0	0.0	0.8
Female sterilization	0.0	0.0	1.7	0.8
None	13.6	20.5	0.0	9.6
Other	13.6	13.6	17.2	15.2

Abbreviation: IUD, intrauterine device.
All data are reported as percentages unless otherwise noted.
[a] Among women ever pregnant (N=52 among 15–19-year-olds; N=180 among 20–24-year-olds; N=659 among ≥25-year-olds; and N=891 among the entire sample of women).
[b] Among women who have given birth (N=25 among 15–19-year-olds; N=128 among 20–24-year-olds; N=608 among ≥25-year-olds; and N=764 among the entire sample of women).
[c] Among women who have had sex (N=248 among 15–19-year-olds; N=328 among 20–24-year-olds; N=666 among ≥25-year-olds; and N=1245 among the entire sample of women).
[d] The survey did not explicitly include emergency contraceptive pills as an option for current method but included a question on ever use of emergency contraceptive pills.
[e] Among fecund women who have had sex and who are currently using contraception (N=146 among 15–19-year-olds; N=213 among 20–24-year-olds; N=363 among ≥25-year-olds; and N=722 among the entire sample of women).
[f] N=22 among 15–19-year-olds; N=44 among 20–24-year-olds; N=58 among ≥25-year-olds; and N=125 among the entire sample of women.

There was some discrepancy between actual and preferred contraceptive method use: women were looking for a wider range of alternatives than what they actually had. Overall, 17.3% of women currently using contraception reported not using their preferred method. Of these women, the most commonly reported preferred method was injectable contraceptives (25.6%), followed by condoms (17.6%) and implants (16.8%).

In summary, results from the 2012 Family Planning Survey among women in Luanda illustrate a high percentage of unwanted pregnancy and a lack of knowledge about the full array of contraceptive methods, particularly LARCs, which is especially true among younger cohorts. There is a heavy reliance on condoms as a family planning method, and there is a substantial percentage of women who are not currently using their preferred contraceptive method.

Contraceptive Availability in Luanda

Data from the 2014 and 2015 Retail Surveys showed limited choice for contraceptive methods in Luanda, with a decline in availability over that period of time (Table 2). Although 85.9% of all outlets reported having at least 1 method of contraception in 2015, when the information was analyzed by method type, it was clear that women did not have many contraceptive options. In both years, the most widely available contraceptive method on the market was the male condom, present in 81.4% of the outlets visited in 2014 and in 73.6% of outlets visited in 2015 ($P<.001$). Following condoms, oral contraceptive pills and emergency contraceptives were the next most available methods; however, during the same period, their availability declined from 58.6% to 43.3% ($P<.001$) and from 42.4% to 34.4% ($P<.01$) of outlets, respectively. Availability of injectable contraceptives declined significantly by 6.0 percentage points to reach a level of 7.3% in 2015 ($P<.001$).

17% of women currently using contraceptive reported not using their preferred women.

When comparing the public and the private sectors, we observed a larger decrease in the availability of oral contraceptive pills in the public sector: while it declined 14.9 percentage points in the private sector (from 58.7% in 2014 to 43.8% in 2015; $P<.001$), it dropped 24.5 percentage points in the public sector (from 54.1% to 29.6%; $P<.05$). We did not observe a significant change in the availability of male condoms in the public sector, most likely due to the small number of public-sector facilities. Availability of the male condom in the private sector, however, dropped significantly by 7.3 percentage points. Overall, the male condom was more available in the private sector than in the public sector in both 2014 and 2015 (for example, 75.1% in the private sector versus 33.3% in the public sector in 2015).

Although 86% of all outlets reported having at least 1 contraceptive method in 2015, the most widely available method on the market was the condom.

TABLE 2. Availability of Contraceptive Methods by Sector, Luanda, Angola, 2014–2015

	Private Sector			Public Sector			Total		
Method	2014 (N=1782)	2015 (N=739)	Difference	2014 (N=51)	2015 (N=27)	Difference	2014 (N=1833)	2015 (N=766)	Difference
Any method[a]	97.6	86.9	−10.7***	84.3	59.3	−25.0*	97.2	85.9	−11.3***
Male condom	82.3	75.1	−7.3***	49.0	33.3	−15.7	81.4	73.6	−7.8***
Oral contraceptive pills[b]	58.7	43.8	−14.9***	54.1	29.6	−24.5*	58.6	43.3	−15.3***
Emergency contraceptive pills[b]	43.3	35.8	−7.5**	11.8	11.1	−0.7	42.4	34.4	−7.5**
Injectables[b]	13.1	6.6	−7.56.5***	19.6	18.5	−1.1	13.3	7.3	−6.0***

All data for 2014 and 2015 reported as percentages; the differences between 2014 and 2015 are percentage points.
*$P<.05$; ** $P<.01$; *** $P<.001$.
[a] Any method includes at least one of the following: condoms, oral contraceptive pills, emergency contraceptive pills, injectable methods, hormonal patches, spermicides, intrauterine devices (IUDs), mini-mola or Essure (a non-surgical permanent method for women), and Vasalgel (a long-acting gel similar to no-scalpel vasectomy but likely more reversible). Less than 5% of the outlets overall reported having hormonal patches, female condoms, spermicides, IUDs, vaginal rings, or implants. Only 0.1% reported providing mini-mola or Essure or Vasalgel.
[b] Gas stations, hotels, and bars were not included in the calculation of oral contraceptive pills, emergency contraceptive pills, or injectable availability, since those outlets mainly distribute or sell condoms.

TABLE 3. Brand Market Share by Type of Contraceptive Among Outlets Selling the Respective Contraceptive Method, Luanda, Angola, 2015

Contraceptive Method and Brand	% Outlets Offering the Brand	Units Sold Last Month[a]	% Units	Value (AKZ) Sold Last Month	% Value
Condoms (N=635 outlets)					
Sensual	51.8	17,716	22.8	1,295,650	25.6
Legal	37.3	17,092	22.0	845,000	16.7
Davigra	15.6	12,103	15.6	535,530	10.6
Boss Man	11.8	3,153	4.1	176,240	3.5
Kamasutra	9.6	2,193	2.8	6,300	0.1
Control	6.0	4,711	6.1	611,994	12.1
Durex	3.3	8,576	11.0	948,365	18.7
Generic	1.3	7,527	9.7	293,150	5.8
Other brands (+40)	<5.0 each	4,557	5.9	358,795	7.1
Total for condoms	NA	77,628	100.0	5,071,024	100.0
Oral contraceptive pills (N=357 outlets)					
Microgynon	76.6	2,885	66.0	1,058,303	40.6
Microlut	27.7	457	10.4	141,394	5.4
Yasmin	8.6	234	5.3	434,366	16.4
Diane 35	7.8	108	2.5	167,442	6.4
Other brands (+10)[b]	<5.0 each	690	15.8	802,642	31.2
Total for oral contraceptive pills	NA	4,374	100.0	2,604,147	100.0
Emergency contraceptive pills (N=255 outlets)					
Pilula S	45.4	1,064	38.4	656,100	22.7
Ella	24.3	595	21.5	554,200	19.1
IPL72	20.4	463	16.7	330,700	11.4
Norlevo	14.1	6	0.2	1,086,707	37.5
Other brands (7)[c]	<5.0 each	643	23.2	266,518	9.3
Total for emergency contraceptive pills	NA	2,771	100.0	2,894,225	100.0
Injectables (N=54 outlets)					
Depo-provera	83.3	260	97.7	21,700	94.1
Mesignya	1.9	n/a	n/a	n/a	n/a
Other brands	<1.0 each	6	2.3	1,360	5.9
Total for injectables	NA	266	100.0	23,060	100.0

Abbreviation: AKZ, Angolan Kwanzas.
[a] Units are individual condoms for condoms; cycles for oral contraceptive pills; packs for emergency contraceptive pills; and individual units for injectables.
[b] Other brands of oral contraceptive pills included Cezarette, Climen, Ella, Gynera, Marvelon, Minygesty, etc.
[c] Other brands of emergency contraceptive pills included CO-Pill, Plan Fam, Levo 72, etc.

A higher percentage of public-sector establishments distributed injectable contraceptives in both years (over 18.0%) compared with the private sector, which dropped from 13.1% in 2014 to 6.6% in 2015 ($P<.001$). All other methods (hormonal patch, female condoms, spermicides, IUDs, vaginal rings, and implants), which are mostly distributed in the public sector, were present in less than 5.0% of all establishments in both years.

Brand Market Share and Price

The number of brands on the market is also an indicator of the number of choices available to women in terms of quality and price. This section presents a landscape of the market share (volume and value) and price for the most available contraceptive methods in 2015. While condoms, oral contraceptives, and emergency contraceptive pills have multiple brands in the market, each brand individually only represents a small proportion of market. For example, Table 3 shows that only 4 condom brands have a strong individual presence in terms of sales: Sensual, with 22.8% of total volume of the market and 25.6% of the total value (AKZ), followed by Legal (22.0% volume and 16.7% value), Davigra (15.6% volume and 10.6% value), and Durex (11.0% volume and 18.7% value). Together these 4 brands represent

Of the more than 40 condom brands on the market in Luanda, only 4 of the brands have strong presence in terms of sales.

TABLE 4. Mean Price (Angolan Kwanzas)[a] for Main Brands of Contraceptives, Luanda, Angola, 2014–2015

Method and Brand [No. of outlets selling the method in 2014, 2015]	Mean Price per Unit[b] (95% CI)		% Change
	2014	2015	
Condoms			
Sensual [N=697; N=359]	69.5 (44.3, 72.7)	73.4 (71.2, 75.6)	+5.6%
Legal [N=529; N=237]	36.1 (33.2, 39.0)	46.8 (42.8, 50.8)	+29.8%^
Davigra [N=267; N=99]	59.5 (55.5, 63.5)	58.9 (45.0, 72.7)	−1.0%
Durex [N=57; N=21]	119.3 (90.8, 147.8)	200.9 (145.1, 256.8)	+68.4%
Boss Man [N=264; N=71]	54.1 (51.2, 57.0)	60.4 (55.7, 65.2)	+11.7%
Oral contraceptive pills			
Microgynon [N=840; N=261]	238.8 (231.7, 245.9)	498.5 (448.3, 548.8)	+108.8%^
Microlut [N=365; N=82]	278.8 (264.5, 293.2)	394.8 (346.0, 443.6)	+41.6%^
Yasmin [N=51; N=43]	705.5 (651.8, 759.3)	2300.2 (2017.5, 2583.0)	+226.0%^
Diane 35 [N=69; N=22]	1068.5 (952.9, 1184.0)	1830.7 (1200.3, 2461.1)	+71.3%^
Emergency contraceptive pills			
Pilula S [N=325; N=108]	453.4 (427.3, 479.5)	579.2 (536.0, 622.4)	+27.7%^
Ella [N=225; N=63]	699.3 (657.5, 741.1)	959.0 (659.5, 1258.6)	+37.1%^
IPL72 [N=113; N=46]	509.6 (456.0, 563.3)	700.5 (602.8, 798.2)	+37.5%^
Norlevo [N=109; N=30]	2026.9 (1814.3, 2239.4)	2950.9 (2502.3, 3399.6)	+45.6%[a]
Injectables			
Depo-provera [N=213; N=45]	351.0 (321.0, 281.1)	482.2 (323.0, 641.5)	+37.4%[a]

^ Indicates significant changes based on 95% confidence intervals not overlapping between 2014 and 2015.
[a] Prices reflect mostly the private sector. According to the National Health Care System, the public sector must offer health services and medicines for free. The exchange rate as of October 30, 2014, was 99 Angolan Kwanzas for US$1.[26]
[b] Units are individual condoms for condoms; cycles for oral contraceptive pills; packs for emergency contraceptive pills; and individual units for injectables.

over 70.0% of both measures of market share. Each of the more than 40 other condom brands available in the market is present in less than 5% of the outlets.

As seen in Table 4, the prices of Sensual and Legal condoms are among the lowest in the market: 73 and 46 AKZ per individual condom in 2015, respectively (about US$0.74 and $0.47, respectively, given an exchange rate of 99 AKZ for US$1).[26] Between 2014 and 2015, most of these major brands raised their product price to the final consumer, although by comparing the 95% confidence intervals around the mean values in both years, we observed that only in the case of Legal was the difference statistically significant: the confidence intervals each year do not overlap.

As with condoms, only 2 of more than 10 brands of oral contraceptive pills dominate the market in Luanda.

Only 2 oral contraceptive pill brands dominate the market: Microgynon was present in 76.6% of establishments selling or distributing oral contraceptive pills, followed by Microlut, which was present in 27.7% of establishments (Table 3). These 2 brands are both government/donor-procured and together represent 76.4% of units (monthly cycles) sold or distributed and 46.0% of the value sold in the market. On average, these 2 brands are the most accessible to the final consumer in terms of price: 499 AKZ and 395 AKZ, respectively, compared with other brands that ranged in price between 1831 AKZ and 2300 AKZ per cycle in 2015 (Table 4). All brands of oral contraceptive pills significantly increased their price to the consumer by more than 30% between 2014 and 2015, as judged by comparing the 95% confidence intervals around the mean value each year.

Most types of contraceptive methods are difficult to find in Luanda, with the exception of condoms and pills.

Similarly, out of 11 brands of emergency contraceptive pills, 3 non-government-procured brands dominate the market: Pilula S, Ella, and IPL72. These brands together represent 76.6% of units sold and 53.2% of the market value (Table 3). Like oral contraceptive pills, brands of emergency contraceptive pills significantly increased their price from 2014 to 2015 by at least 27% (Table 4).

Patterns of contraceptive use in Luanda mirror the levels of knowledge of each method.

In summary, data from the 2014 and 2015 Retail Surveys on contraceptives in Luanda show limited availability of contraceptives. With the exception of condoms and oral contraceptive pills, most other types of contraceptive methods are difficult to find. Even oral contraceptive pills and condoms are not found in all establishments, and their overall availability dropped significantly from 2014 to 2015, while significant increases in price to final consumer were observed in many brands. The private sector reported greater availability of condoms, oral contraceptive pills, and emergency contraceptives compared with the public sector, including brands of oral contraceptive pills that are government/donor-procured for the public sector. These brands should only be available in the public sector for free, yet they are present in the private sector offering the lowest prices.

DISCUSSION

The analysis of the Family Planning Survey 2012 and the Retail Surveys 2014/2015 suggests that limited knowledge and use of a range of contraceptive methods, and the limited availability of LARCs in particular, are interplaying factors shaping the contraceptive market landscape and women's choices in Luanda, Angola. Recognizing that there are other multiple factors affecting the contraceptive landscape in a country, this article focuses only on demand and supply. Our findings suggest that women's lower knowledge of LARC methods (including misconceptions around them) may explain their lower demand, while the limited presence of those methods in the market can also reinforce women's lower knowledge and use.

Limited Knowledge and Use of LARCs

The present analysis shows that there were important differences in knowledge of contraceptive methods among women of reproductive age. Specifically, more women knew about short-acting methods (such as condoms and oral contraceptive pills) than long-acting methods (IUDs and implants). Furthermore, knowledge of LARCs was lower among adolescents than older women, a result corroborated by other studies that have found that awareness of different contraceptive methods varies by age group.[27,28] Because limited knowledge of contraceptive methods can be a barrier to contraceptive use, women of reproductive age should have more scientific information about the different contraceptive methods available to them.[28]

Patterns of contraceptive use mirror the levels of knowledge of each method: male condoms was the most used contraceptive method across all age groups, followed at a distance by oral contraceptive pills and injectable contraceptives. Although the use of LARC methods was generally low across all age groups, an even smaller percentage of adolescents used LARCs compared with older women, a pattern found in other studies.[27,29] In 2015, a study conducted by Key Research in

Luanda showed that short-acting methods were the most widely used methods by women, with condoms as the most-used method (19.1%), followed by injectable methods (12.0%) and oral contraceptives (9.2%). LARC methods were barely used, particularly among young women.[29] This confirms qualitative findings where young women reported fears of becoming infertile if they used contraceptive methods other than condoms; they all considered that oral contraceptive pills, injections, and especially LARCs were only for women who already had children.[18] Given the high fertility rate in Angola, the use of LARCs by young women could make a positive impact in reducing not only the fertility rate but also the rates of unintended pregnancy, unsafe abortion, and maternal mortality.

Impact of Limited Availability of Contraceptives on Women's Choices

The present analysis also shows limited availability of contraceptive methods, with the private sector generally performing better than the public sector. Not surprisingly, in the Key Research study a larger proportion of women in Luanda reported obtaining their method from pharmacies, private hospitals, or local stores (64.8%), compared with public hospitals, health posts, and NGOs (34.2%).[29] The limited availability of contraceptives in the market appears to constrict women's choice of a contraceptive method.[30] In our study, almost one-fifth of women using contraception reported not using their preferred method. Among the most common reasons for non-use was the method being difficult to obtain or not being available where women receive family planning (data from the 2012 Family Planning Survey, not shown). The Retail Surveys 2014 and 2015 also show that, overall, condoms, oral contraceptives, and emergency contraceptives are more widely available than other types of contraceptives. Even within the public sector, where IUDs or implants are expected to be available, very few outlets reported having them in stock. This is likely a contributing factor explaining why condoms and oral contraceptive pills are the most widely used methods, while LARC methods are among the least known and used in Luanda.

In general, providers do not recommend LARC because of stock-out problems, lack of training, or beliefs that such methods are only for women who already have children.[21] This reinforces women's own beliefs that condoms are the best methods for childless women because other methods can cause infertility.[18]

Knowledge, use, and availability of the male condom has increased more sharply in sub-Saharan Africa than in other regions of the world, partly because it can be promoted as a dual protection method that can protect against both unwanted pregnancy and HIV.[30] In Angola, male condoms were promoted for many years more than any other contraceptive method and have been offered for free or sold in a wide range of outlets in Luanda.[31] Accordingly, the high availability of male condoms stimulates its greater use across all age groups.

Earlier research has shown that greater availability of different contraceptive methods is linked with higher contraceptive prevalence rates.[12] Ready access to a wide range of methods allows each subgroup of users to find the method that best fulfills their family planning needs.[30] Thus, it is important for a country to invest in different contraceptive methods in order to increase informed choice and satisfaction among users. Allowing brand competition also helps the market benefit women by increasing the chances of price reduction, and consequently improving women's access to contraceptive methods.

There is limited availability of a range of methods on the market, with the private sector generally performing better than the public sector.

Role of International Aid and of the Economic Crisis on Contraceptive Market Landscape

According to market data analyzed in this paper, the most available brands of condoms and oral contraceptives are those that have been supported by external donations. In the case of condoms, the brands Sensual and Legal were originally introduced in the Angolan market with support from USAID and DFID (United Kingdom Department for International Development).[32] After more than 10 years in Angola, these socially marketed, affordably priced brands are successfully competing, as indicated by their high market share in terms of both volume and value. In the case of oral contraceptives, the Microgynon and Microlut brands were introduced with support from USAID and UNFPA to be distributed for free in the public sector.[33] However, the retail surveys found these brands on sale in the private sector, contrary to their initial purpose. It is not clear how these brands leak into the private sector, but because they offer the lowest price to consumers and compete against commercial brands, there is little space in the market share for other commercial brands to grow: together these 2 brands represent 76.0% of the total volume of oral contraceptives.

The most available brands of condoms and pills are those that have been supported by donations by external donors.

The leakage also reflects a weak health system with a poor regulatory environment and limited human resources to monitor the supply chain operations and lack of standard operational procedures.[34]

Reductions in the proportion of outlets having different types of contraception translated into price increases for many brands.

Market data also show a significant reduction in the proportion of outlets having different types of contraception from 2014 to 2015. The decrease in availability translates into a price increase for many contraceptive brands and represents a step back in women's choices and affordability of different contraceptives, especially in a country where 56.4% of the employed population lives on less than US$2 per day (less than 200 AKZ).[35] The situation may persist in the current economic context, in which a substantial drop in oil prices (Angola's main income-generating product) has limited government's expenditure on health and the private sector's capacity to import products due to lack of international currency (US dollars).[36,37]

Market segmentation would allow the private sector to reach those population segments with some ability to pay for contraception, thereby reducing the burden on the public sector to provide free commodities broadly.

As Angola has shifted from having a low- to middle-income economy, the role of external donor agencies is changing from directly purchasing essential products to serving in a solely technical or advocacy role. As an example, between 2014 and 2015 UNFPA decreased the number of Microgynon and Microlut oral contraceptive pills donated from 349,189 to 285,730 cycles and the number of Jadelle implants from 85,000 to 0.[20] In this context, the Angolan government will have to increase its direct investment in contraceptive products and play a more active part in satisfying the need for family planning. In 2012, the government budget represented only 10% of the total amount spent on family planning, compared with 30% provided by UNFPA and 60% by USAID.[21] In its plans for fiscal year 2016, the Ministry of Health forecasted an investment covering 23.0% of the family planning budget, while UNFPA and USAID would provide the remaining 47.0% and 29.0%, respectively.[38] There is still a long way to go toward self-sufficiency, and Angola should continue to introduce strategies to ensure availability and fair competition of family planning products on the market, while encouraging demand for contraception.

Market Segmentation: Public and Private Sectors Working Together on Family Planning

In order to achieve universal coverage for family planning, it is important to have cooperation and coordination between the public and private sectors (including civil society, NGOs and donors). While the public sector can provide country leadership by setting regulations, taxes and fees, policies, and quality standards, as well as serving the lowest quintiles through public services, the private sector can reach population sectors that can afford to pay, thereby reducing the burden on the public sector to provide free commodities broadly.

Through market segmentation, the private sector can reach segments of the population with some economic power interested in using family planning, which are not usually the target of the public sector. Preventing leakage of "free" products from the public sector into the private sector (which are later sold at "unfair" prices) will assure that (a) such products actually reach women with limited resources, for whom they are intended, and (b) the private sector invests more to meet the demand of family planning for a segment that can actually pay for it. With an interest in growing its business, the private sector will guarantee the availability of products that represent a margin of profit for them, reducing the chances of stock-out.

There is the potential to expand and improve the family planning market in the private sector in Angola, yet this potential is not realized and is often overlooked. Thinking in the new Angolan context in which donors are reducing donation of products and are focusing mostly on technical assistance, it is important to consider how best to reinforce the private sector as a complementing component to the overall health system.

Limitations

There are some limitations in the present analysis that should be highlighted. First, the family planning survey and the retail studies were not conducted during the same year, preventing a direct comparison between contraceptive use and method availability. The 2-year difference raises the question of whether the context was the same when use and availability of contraceptive methods were analyzed. To mitigate this limitation, information on contraceptive use from an OMNIBUS Study conducted by Key Research in Luanda is incorporated in the discussion section. The study was conducted at the same time as the Retail Study 2015. Overall, it showed similar patterns as the Family Planning Study 2012: a relatively high reliance on male condoms and continued low prevalence of LARC methods, especially among young age groups

The small sample size of public-sector facilities in the retail studies also limits the comparative

analysis over time of contraceptive availability in public health facilities. Statistical tests are less likely to show significant differences where there actually is a difference. This limitation cannot be overcome; even when conducting a census of public-sector facilities in the province (as in the Retail Study 2014), the number of public facilities is still limited.

Finally, the required sample size for emergency contraceptive pills was not sufficiently large enough to measure a change of at least 10 percentage points over time, so analysis about statistically significant changes in the availability of this method should be made with caution. The data serve though to understand the tendency over time in the availability of this method, which follows the same tendency reported in this article for other methods.

CONCLUSIONS

National data show high levels of fertility in Angola: almost 6 children per women at the end of her reproductive life, with the adolescent fertility rate increasing over time.[4,6] Many Angolan women want to space or limit childbirth, but they have few real opportunities to do so. This paper shows that in Luanda province, the capital of Angola, half of women did not want their last pregnancy. On average, the ideal number of children reported in this paper (4.2) is lower than the actual number of children born to women at the end of their reproductive life in Luanda (5.5).[39]

Male condoms and oral contraceptive pills are the most available methods in Luanda and the most used methods across all age groups. In contrast, few women rely on implants or IUDs, at least in part because LARC methods are less available. Similar to other research in family planning, we can infer that the availability or unavailability of a contraceptive method influences its use (or nonuse). Besides availability, this article finds that other factors such as age and awareness of a contraceptive method were also linked to contraceptive choice and use.

In order to meet the latent demand for contraception, it is necessary not only to ensure the availability and affordability of contraceptives currently on the market, but also to expand the range of options for women and to guarantee women's real access to sexual and reproductive health products and services. To achieve that goal, it is important to take actions toward:

- Improving women's knowledge about all contraceptive methods, including their characteristics and potential side effects, as well as reducing current myths and misconceptions about use of contraception, allowing women to make informed choices
- Increasing the availability of different contraceptive methods in the private and public sector with an adequate segregation of the market; for instance, making generic or less expensive brands available in public sector, while selling more expensive brands in private pharmacies or drug shops
- Improving the efficiency of supply chain distribution to prevent stock-outs in the market, while simultaneously strengthening the regulatory health system, to avoid leakage from the public to the private sector, and helping women from low socioeconomic sectors to have real access to free contraception within the public sector
- Assuring a self-sustained market, where supply meets—and at the same time enhances—demand, with little dependence on donations from international organizations
- Improving family planning services by eliminating provider's own misconceptions (only women who already had children should use contraception due to risks of infertility); also through counseling and provision of all type of methods, including LARC methods
- Advocating the inclusion of all LARC methods on the national list of essential medicines, to ensure availability within the public and private sectors

Accordingly, public health policies need to (1) ensure provision of a much wider range of contraceptive methods; (2) improve the efficiency of the supply chain distribution (with adequate monitoring and evaluation); and (3) strengthen demand generation activities. These actions will have a greater impact if they are developed within a context of strong political will, social accountability, and significant and sustained human and financial resources devoted to improve family planning services for the benefit of all women and their partners.

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REVIEW

Quality of Care in Performance-Based Financing: How It Is Incorporated in 32 Programs Across 28 Countries

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Structural aspects of quality such as equipment and infrastructure were the most frequently measured, with some measurement of processes of clinical care. Further examination is warranted to assess whether variations in how quality of care is incorporated into performance-based financing programs lead to differential effects.

ABSTRACT

Objective: To describe how quality of care is incorporated into performance-based financing (PBF) programs, what quality indicators are being used, and how these indicators are measured and verified.

Methods: An exploratory scoping methodology was used to characterize the full range of quality components in 32 PBF programs, initiated between 2008 and 2015 in 28 low- and middle-income countries, totaling 68 quality tools and 8,490 quality indicators. The programs were identified through a review of the peer-reviewed and gray literature as well as through expert consultation with key donor representatives.

Findings: Most of the PBF programs were implemented in sub-Saharan Africa and most were funded primarily by the World Bank. On average, PBF quality tools contained 125 indicators predominately assessing maternal, newborn, and child health and facility management and infrastructure. Indicators were primarily measured via checklists (78%, or 6,656 of 8,490 indicators), which largely (over 90%) measured structural aspects of quality, such as equipment, beds, and infrastructure. Of the most common indicators across checklists, 74% measured structural aspects and 24% measured processes of clinical care. The quality portion of the payment formulas were in the form of bonuses (59%), penalties (27%), or both (hybrid) (14%). The median percentage (of a performance payment) allocated to health facilities was 60%, ranging from 10% to 100%, while the median percentage allocated to health care providers was 55%, ranging from 20% to 80%. Nearly all of the programs included in the analysis (91%, n=29) verified quality scores quarterly (every 3 months), typically by regional government teams.

Conclusion: PBF is a potentially appealing instrument to address shortfalls in quality of care by linking verified performance measurement with strategic incentives and could ultimately help meet policy priorities at the country and global levels, including the ambitious Sustainable Development Goals. The substantial variation and complexity in how PBF programs incorporate quality of care considerations suggests a need to further examine whether differences in design are associated with differential program impacts.

INTRODUCTION

Performance-based financing (PBF)—a mechanism by which health care providers or facilities earn incentives on the basis of achieving specific performance criteria—is emerging as an important tool to encourage providers and facilities to become more efficient and responsive to their clients.[1] Because PBF allows narrow targeting of health services and requires measurement and verification of progress, it is increasingly appealing to implementers and policy makers as a path to making progress toward the health-related Sustainable Development Goals (SDGs). In recent years, PBF programs have proliferated in many low- and middle-income countries (LMICs), often with technical and financial support from donors and international agencies.[2] For example, in 2015 the World Bank's Health Results Innovation Trust Fund supported 36 PBF programs on maternal and child health, associated with US$400 million in grants and US$2.2 billion in concessional loans.[3]

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In addition to paying providers and facilities for the quantity of services provided, PBF programs also often explicitly address quality of care in their payment formulas. Quality is included either directly, by paying for specific indicators, or indirectly, by modifying the overall bonus payment according to a broader measure of quality. There are several reasons to account for quality. First, providers may compromise quality when increasing the volume of services in response to the payment incentives.[2] Second, quality is increasingly recognized as a priority area in its own right. Third, to the extent that demand responds to quality, *increasing quality can also help achieve desired increases in service utilization*. Existing evidence indicates substantial gaps and variations in quality in many settings,[4–6] which has contributed to the inclusion of quality in the global development agenda. For example, one of the targets for SDG 3 (ensure healthy lives and promote well-being) is to achieve … access to quality essential health care services and … quality and affordable essential medicines and vaccines ….[7] PBF programs can potentially contribute to achieving these goals.

However, there is little systematic evidence on the design and implementation aspects of how existing PBF programs account for quality of care. While many studies focus on an individual PBF program's impact, there appears to be substantial heterogeneity in design and operational features of such programs,[2,8,9] reflecting the fact that PBF is comprised of a range of approaches rather than a uniform method. This variation has led to calls for better documentation of programs to better interpret impact estimates and provide practical guidance to policy makers.[8,9]

In this article, we review how 32 PBF programs in 28 countries integrate quality of care within the programs' designs. Drawing on PBF program documents, we describe existing practice for how quality enters into the PBF payment formula, what quality indicators are being used, and how these measures are verified. This allows us to provide a deeper review of program parameters, describe both commonalities and variations across programs, and identify areas for further research and program development.

METHODS

This study employed an exploratory scoping methodology to characterize the full range of quality components in PBF and potential gaps that require further research. For our purposes, we focus on the supply-side performance-based incentives that are targeted at individual health facilities, and the payments that are linked to outputs and possibly modified by quality indicators.[8]

In addition to paying for the quantity of services provided, performance-based financing (PBF) programs also often explicitly address quality of care in their payment formulas.

Identifying Programs

First, we compiled a list of known existing supply-side, health facility-based PBF programs in LMICs based on a document review of published analyses in both the peer-reviewed and gray literature. We also identified existing programs through expert consultation with a number of key donor representatives from the World Bank, Kreditanstalt Für Wiederaufbau (KfW), the U.S. Centers for Disease Control and Prevention (CDC), and the U.S. Agency for International Development (USAID). Each donor provided a list of their PBF programs and a key contact person for each, if available. We solicited programmatic information from implementers and donors primarily through email. Our research team collected and organized program manuals and accompanying tools used to measure quality performance for all facility levels (primary, secondary, and tertiary).

All programs identified were included if sufficient program information could be obtained (Figure 1). Programs were not excluded based on year of implementation, size, or phase (i.e., small-scale pilots to national implementations).

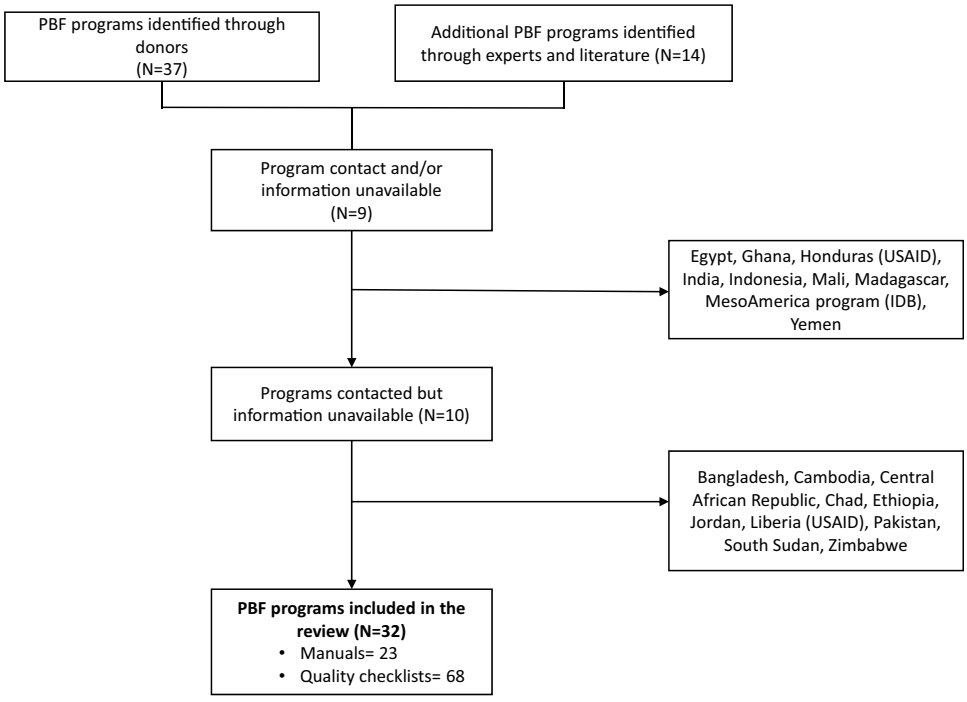
There is little systematic evidence on the design and implementation of how PBF programs account for quality of care.

Abstracting and Coding

We systematically reviewed each of the current (most recent) program manuals and entered information into a Microsoft Excel database that captured key quality of care program attributes, including PBF scheme (purchaser, regulator, provider), payment formula, quality assessment processes (e.g., checklists or direct observations), geographic coverage, funder, level of facility, targeted health services, and the verification process. If the information in the manual was unclear, we followed up with the implementer or donor to obtain clarification. For countries with multiple programs, we included all for which we had sufficient information.

We also collected quality checklists for all levels of care and entered the quality indicators contained in the checklists in a distinct database, including revised checklists for the same program. We copied indicators verbatim from the original checklist documents and pasted them into the database. We translated indicators in languages other than English, primarily French, and confirmed the translation with a proficient speaker.

FIGURE 1. Performance-Based Financing Program Selection Process



Abbreviations: IDB, Inter-American Development Bank; PBF, performance-based financing; USAID, U.S. Agency for International Development.

For the purposes of this study, we defined an indicator as any measure with an associated point value in a PBF quality checklist, i.e., an indicator that could affect PBF payments. Some checklists included criteria to fulfill an indicator that did not have an associated score, and these criteria were therefore not considered to be indicators. Because checklists varied in the maximum point value, we also transformed the point value into a weight that could be compared across checklists. The weight for each indicator was calculated as a percentage value of the entire checklist of its particular PBF scheme, so that the sum of all indicators' weights within an individual PBF checklist totaled to 100.

Data from the manuals and checklists were input by 3 researchers in multiple phases. Predetermined definitions were used to classify each programmatic component and indicator. After entering half of the indicators, a second researcher reviewed the database for consistency. Once all indicators were entered, the third researcher reviewed all entries. Difficult classifications were resolved through team discussions.

PBF payments typically use one of two approaches: carrot-and-stick (rewards and punishments) or carrot-and-carrot (bonus payment on top of the quantity payment).

Analysis

We primarily used Microsoft Excel pivot tables to compare basic characteristics across the PBF programs, including regional distribution, funding source, geographic coverage, and bonus recipient categories. Several specific analyses were conducted on the classification of payment types, verification and means of assessments, and service types.

Health facilities receiving PBF payments typically use one of two performance payment types. The first type is a "carrot-and-stick" approach that uses a combination of rewards and punishment to induce behavior change. The "carrot" refers to the quantity payment and the "stick" is a deflator associated with the quality performance, i.e., the bonus is reduced if the quality score is less than the maximum.[2] The second type of performance

payment is a carrot-and-carrot approach, consisting of a bonus payment for the quality performance that is added to the quantity payment.[2] This dichotomy indicates whether the program rewards or penalizes a health facility based on quality performance.

However, penalties and rewards can also be calculated using additional measures and in different ways. We therefore classified programs into 7 different payment types. The taxonomy for the type of payment used was developed by coding all programs on the basis of: (1) the relationships between quality and quantity, and (2) the presence of a threshold performance score. Each of the payment types are defined and visually displayed in Table 1. We retained the distinction between penalty and reward but further specified whether the payment's calculation was determined by quality performance thresholds.

Most PBF programs purchase services conditional on the verified quality of those services. Verification is the process by which the reported quantity of services provided and the quality scores are verified externally. Many programs verify performance at multiple levels of the health system; this assessment is concerned with the health facility performance. Counter-verification, or ex-post verification, is a supplemental verification process undertaken after the PBF payment has been distributed to assess that quality services were actually received by patients, typically through patient surveys and community assessments.

Programs also vary in their means of assessment and service types. We distinguished 7 means of assessment: checklists, register review, patient record review, direct observation, staff surveys, patient surveys, and exit interviews. We

TABLE 1. Performance-Based Financing Payment Typologies

Payment Type	Definitions	Relationship Between Quantity and Quality
Conditional deflator	Quality score deflates quantity payment continuously from 100% to minimum threshold. Below threshold, PBF payment is 0%. For example, in Kenya quantity payment can be any percentage between 100% and 50%, or 0%.	
Unconditional deflator	Quality score deflates quantity payment continuously from 100% to 0%.	
Conditional inflator (inflator, threshold)	Quality score dictates amount of quality bonus received contingent upon achievement of a minimum quality score (threshold) required to receive any of the bonus.	
Unconditional inflator	Quality bonus pool available; quality score dictates amount of quality bonus received.	
Hybrid	Quality score can act as both an inflator and deflator depending on the quality score thresholds.	
Quality only	Payment is provided only for quality; no quantity payment.	

Abbreviation: PBF, performance-based financing.

aggregated health service types into 10 categories guided by the International Classification of Diseases and the International Healthcare Accreditation classifications.

Limitations

Our analysis has several limitations. First, we obtained program information from a small set of donors. As a result, our analytic sample is skewed toward programs with involvement of these donors, and programs of a particular donor may share design commonalities across countries. Related, there is no database of PBF programs worldwide that could help us establish the relative size or representativeness of our sample. Second, we were unable to obtain complete information on all PBF programs identified, and those programs for which complete information could not be obtained were excluded from the analysis.

Recipients of the PBF incentive payments included the health facility, providers, or facility management and administrative staff.

RESULTS

Analytical Sample

We assessed the quality components of 32 PBF programs, which collectively used 68 quality tools and 8,490 indicators.

The final analytic sample includes 32 PBF programs initiated between 2008 and 2015 in 28 LMICs. Collectively, these interventions used 68 quality tools and 8,490 quality indicators. Comprehensive information (programmatic manual and a set of quality tools) was available for 23 PBF programs; for 9 programs we received only quality tools without manuals (Supplementary Table). Results on PBF program components are limited to those for which we received a manual. For 6 countries, we received multiple versions of revised checklists from different years. Three countries, the Democratic Republic of the Congo (DRC), Malawi, and Rwanda, had 2 concurrent PBF programs in distinct geographic regions and supported by different donors.

Primary Characteristics of the PBF Programs

The PBF programs included in this review were heavily concentrated in sub-Saharan Africa, and the World Bank was the primary donor for most.

The PBF programs included in the analysis were heavily concentrated in sub-Saharan Africa (n=21), followed by Europe and Central Asia (n=3), East Asia and the Pacific (n=2), South Asia (n=1), and Latin America and the Caribbean (n=1). The World Bank was the primary donor for 84% of the PBF programs (n=27), while a handful of programs were either partially or solely supported by other donors including USAID (n=5), the CDC (n=2), the Global Fund to Fight AIDS, Tuberculosis and Malaria (n=2), Gavi, the Vaccine Alliance (n=2), the United Nations Children's Program (UNICEF) (n=1) and KfW (n=1). A small set of the programs are cofinanced by country governments.

Table 2 summarizes the characteristics of the geographic coverage, funding sources, payment typologies, and incentive allocation formulas for each of the 23 programs with manuals. Program coverage was predominately subnational, with just 4 of the 23 programs achieving national coverage and significant variation in the geographic coverage for the remaining programs. For each PBF program, the incentive payments were disbursed according to allocation formulas to 3 potential facility-based recipient categories: (1) the health facility, for reinvestment in supplies, infrastructure, and related items; (2) providers, as bonuses or salary top-ups; and (3) in some cases, facility management and administrative staff, also as bonuses or salary top-ups. The median percentage allocated to health facilities was 60% and ranged from 10% in Armenia to 100% in Burundi. The median percentage allocated to health care providers was 55%, ranging from 0% in Lesotho to 80% in Burkina Faso. In Armenia, Benin, and the DRC (USAID), a portion (10% to 20%) of the total PBF payment was distributed to facility-based managerial or administrative teams. Typically, the payments were allocated to all facility-based workers or facility-based workers responsible for PBF indicators.

Payment Type

In over half of the programs (n=13), performance on the quality checklists inflated the payments received by health facilities for their quantitative outputs (the carrot-carrot approach). Six of the programs were inflators without thresholds, meaning that health facilities received a quality bonus if they received a score >0%. The other 7 programs were conditional inflators with threshold scores ranging from 50% to 70% on quality checklists. Facilities had to exceed this threshold in order to increase the quantity payment.

Deflators or penalties tended to be unconditional (4 programs), meaning that the quantity payment could be deflated from 100% to 0% depending on the quality score. One program used a conditional deflator approach in which the quantity payment could deflate from 100% to the minimum threshold of 50%, and then quantity payments could be discontinuously reduced to zero if the quality score was below the threshold. Otherwise put, a minimum quality score of

TABLE 2. Characteristics of Quality of Care Components in PBF Programs (N= 23)

Country (Year)[a]	Primary Donor	Coverage		Payment Type	Quality Performance Threshold (%)[b]	Quality Payment Proportion (%)[c]	Equity Bonus (%)	Allocation of PBF Payment (%)
		National or Subnational	Geographic					Health Facility / Health Care Providers / Facility Management
Afghanistan (2012)	World Bank, USAID	Subnational	10 provinces	Unconditional deflator				30 / 70
Armenia (2013)	World Bank	Subnational	360 PHC	Quality only				10 / 70 / 20
Benin (2014)	World Bank, GF, Gavi	National	34 health zones	Unconditional deflator			0%–35%	50 / 30 / 20
Burkina Faso (2013)	World Bank	Subnational	19 districts, 6 regions	Inflator, threshold	≥50%		0%–40%	20 / 80
Burundi (2010)	World Bank	National	18 provinces	Hybrid	≥70% 50%–70% ≤50%	+25% 0% -25%		100
Cameroon (2011)	World Bank	Subnational	4 districts	Unconditional inflator		30%	0%–30%	50 / 50
Democratic Republic of the Congo (2015)	World Bank, UNICEF, GF	Subnational	100 health zones	Inflator, threshold	≥50%	25% (HC) 40% (Hospital)		50 / 50
Democratic Republic of the Congo (2014)	USAID	Subnational	80 health zones	Unconditional inflator				30 / 60 / 10
Djibouti (2014)	World Bank	Subnational	2 regions	Hybrid	≥80% 60%–79.9% 50%–59.9% 40%–49.9% 30%–39.9% ≤30%	+30% +25% 0% -10% -20% -25%		70 / 30
Haiti (2014)	World Bank, USAID	Subnational		Unconditional inflator		+25%		30
Kenya (2013)	World Bank	Subnational	20 counties	Conditional deflator	≥70%			40 / 60
Kyrgyz Republic (2013)	World Bank	Subnational		NA[d]				
Lesotho (2013)	World Bank	Subnational	6 districts	Inflator, threshold	100% 90%–99% 80%–89% 70%–79% 60%–69% 50%–59% ≤50%	+25% +20% +15% +10% +5% +2% 0%	0%–30%	25 / 75
Malawi (2015)	USAID	Subnational	3 districts	Inflator, threshold	≥70%	+50% (x quantity)		100
Malawi (2015)	KfW, Norway	Subnational	4 districts	Unconditional inflator				30 / 70
Mozambique (2015)	CDC	Subnational	2 provinces	Inflator, threshold	≥60%	+80% (x quantity)	10%–30%	40 / 60
Nigeria (2014)	World Bank	Subnational	3 states	Inflator, threshold	≥50%	+25% (x quantity)		50 / 50
Rwanda (2012)	World Bank, CDC, USAID	National	5 provinces	Unconditional deflator				40 / 60

Continued

TABLE 2. Continued

Country (Year)[a]	Primary Donor	Coverage		Payment Type	Quality Performance Threshold (%)[b]	Quality Payment Proportion (%)[c]	Equity Bonus (%)	Allocation of PBF Payment (%)
		National or Subnational	Geographic					Health Facility / Health Care Providers / Facility Management
Senegal (2012)	World Bank	Subnational	3 districts	Unconditional deflator				25 / 75
Sierra Leone (2014)	World Bank	National	12 districts	Hybrid		+30% to -30%		40 / 60
Tajikistan (2015)	World Bank	Subnational	8 Rayons	Inflator, threshold	≥90% 85%–90% 80%–84.9% 75%–79.9% 70%–74.9% 65%–69.9% 60%–64.9% 55%–59.9% ≤55%	+150% of quantity payment +125% +100% +75% +50% +30% +20% +10% 0%		70 / 30
Tanzania (2015)	World Bank	Subnational	1 region	Unconditional inflator				75 / 25
Zambia (2010)	World Bank	Subnational	10 districts	Unconditional inflator				75 / 25

Abbreviations: CDC, U.S. Centers for Disease Control and Prevention; GF, Global Fund to Fight AIDS, Tuberculosis and Malaria; KfW, Kreditanstalt Für Wiederaufbau; PBF, performance-based financing; UNICEF, United Nations Children's Fund; PHC, primary health center; USAID, U.S. Agency of International Development.

[a] The table includes only the PBF programs for which we received manuals. The year denotes the version of the manual provided for this analysis.

[b] The Quality Performance Threshold (%) provides the performance threshold that health facilities must achieve in order to receive any quality bonus or incentive. For instance, in Burkina Faso, health facilities must score at least 50% on the quality checklist to receive a quality bonus. The amount of the bonus is quantity bonus amount ($) multiplied by quality score (50% or higher).

[c] The Quality Payment Proportion (%) column details the quality payment proportion if the program provides further stipulations to the quality payment calculation beyond the Quality Performance Thresholds reported in the previous column. For instance, in Djibouti, if a health facility scores above 80% on the quality checklist, it receives a quality bonus that is equal to 30% of its calculated quantity bonus. However, if a health facility scores 45% on the quality checklist, it loses 10% of its anticipated quantity bonus. The percentages provided in the Quality Payment Proportion column are the proportion of the quantity payment that is allocated due to the quality score. None of the information provided in this table differs by facility level (primary, secondary, tertiary) except for when denoted in the Quality Payment Proportion column.

[d] Information about the payment classification for Kyrgyz Republic was requested but the question remains unanswered.

50% was required to receive any PBF payment for the quarter. Three programs were hybrids, meaning that the quality score could serve as either a bonus or a penalty depending on the facility's quality score (range from +30% to −30%). The program in Armenia paid for performance solely based on quality checklists.

There were 5 programs that included what is called an "equity bonus" for certain health facilities that was calculated based on eligibility criteria ranging from 0% to 30% of the quantity payment. The allocation of the equity bonus was irrespective of the facility quantity or quality performance and was intended to ensure that incentives were sufficient for health facilities in rural or hard-to-reach areas with low population densities.

Countries with concurrent PBF programs (the DRC and Malawi) demonstrated variability in payment formulas. In the DRC, the USAID-funded project payment was based on achievement against the target, with a cap for each indicator. Quality payment was based on a quality assessment score alongside the quantity indicator score and was subject to its own target (i.e., quality score multiplied by the quality payment cap). By contrast, the program funded by the World Bank, UNICEF, and the Global Fund set the quality bonus at 25% of the quantity payment only after a

facility scored 50% or above. In general, using descriptive analysis, our study did not find a relationship between payment type and related programmatic functions, for instance, allocation of incentives (between providers and facilities).

Quality of Care Indicators

Table 3 lists the number of indicators per checklist for each of the different facility levels; only the most recent quality checklists per program are included (N=50). Across all checklists, the average number of indicators per checklist was 125 (range, 15 to 286), with an average of 146 indicators in secondary and tertiary facilities (N=19), 122 indicators for primary facilities (N=25), and 105 indicators that applied to all health facility levels (N=5). A more extensive analysis of these indicators can be found in a related paper.[10]

Health Facility Verification

Nearly all programs (91%, n=29) verified quality scores quarterly (every 3 months); the remaining 3 verified the scores biannually (Table 3). Verifiers were commonly regional government management teams, i.e., provincial, district, or health zone teams. In approximately half (8 of 15) of the programs with PBF programs at the tertiary and secondary level, the hospitals were verified using a peer-to-peer technique, in which a team of providers from one hospital verified another nearby hospital. The team composition and sampling of hospitals differed by program. All programs with complete information (n=23) included some type of counter verification, usually by an independent third party.

Means of Assessment

The means of assessment for quality indicators varied widely among PBF programs and between health facility levels (Table 3). On average, 78% of the indicators collected were measured via checklists (6,656 of 8,490) and largely (over 90%) measured structural aspects including equipment, beds, and infrastructure. Record and register reviews each accounted for 9%, which, given the settings of these programs, required the verifier to page through multiple register books or paper-based patient records. The other assessment mechanisms included direct observation (3%) and surveys, staff interviews, and exit interviews (each <1%).

Health Service Types

Figure 2 and Figure 3 show the percentage of indicators, in the most recent checklists, that measure specific types of health services; Figure 2 focuses on primary health facilities and Figure 3 on secondary and tertiary facilities. General trends were similar for primary and secondary/tertiary health facilities. Checklists emphasized maternal care and facility management, followed by newborn and child care and facility equipment.

Most of the quality checklist indicators emphasized maternal care and facility management.

On average, maternal, newborn, and child care indicators accounted for 34% of the weight of checklist points (of maximum number of points per checklist), varying between 37% for primary facilities and 28% for secondary/tertiary facilities. There was a 15% increase in the weight of points of inpatient and outpatient services from the primary facility level to the secondary/tertiary level. The increase was predominantly for structural attributes for inpatient services, such as surgical equipment and supplies.

On average, there were 125 indicators per checklist to assess quality of care in PBF programs.

Table 4 lists 54 of the most common PBF program indicators across 10 service delivery categories. A majority (76%) of the indicators measured structural (physical) aspects of the health facility environment, while 24% measured processes of care delivered by the health worker. Indicators categorized in facility management, infrastructure, and maternal, newborn, and child health were more common (shared) across all checklists, compared with the other service categories.

Nearly all PBF programs verified quality scores on a quarterly basis, usually by regional government management teams.

DISCUSSION

This study found that the quality components of PBF programs are implemented in many contexts and with high variability and complexity.[8,11] Generally, the functional components for measuring and paying for quality (measurement tools, verification, payment formula) are consistent across programs, but the design and implementation differ.

The quality indicators largely measured structural aspects such as equipment and infrastructure.

For the programs included in this study, the quality payment formulas are split between bonuses and penalties. Within the same country (the DRC and Malawi), multiple PBF programs employ different payment formulas and allocation divisions for health care providers and facilities. Approximately half of the programs allocate 60% or more of the PBF payment (including the quality and quantity payments) to health facilities for reinvestment, while the other half allocates more than 60% to health care providers or splits it evenly between providers and facilities.

The quality payment formulas for the PBF programs included in this study are split between bonuses and penalties.

TABLE 3. Verification Process and Means of Assessing Quality of Care in PBF Programs

Country (Year) Facility Level	No. of Indicators per Checklist[a]	Verification Process		Means of Assessment[b]						
		Frequency	Verifier	Checklists No. (%)	Patient Record Review No. (%)	Register Review No. (%)	Direct Observation No. (%)	Staff Survey No. (%)	Patient Survey No. (%)	Exit Interview No. (%)
Afghanistan (2012)										
Secondary & Tertiary	15	Quarterly	Regional govt. team	0 (0)	1 (7)	6 (40)	0 (0)	0 (0)	8 (53)	0 (0)
Armenia (2014)										
Primary & Secondary	28	Biannually	Regional govt. team	0 (0)	22 (79)	6 (21)	0 (0)	0 (0)	0 (0)	0 (0)
Benin (2014)										
Primary	215	Quarterly	Regional govt. team	172 (80)	19 (9)	22 (10)	0 (0)	2 (1)	0 (0)	0 (0)
Tertiary	240	Quarterly	Peer-to-peer	201 (84)	22 (9)	15 (6)	1 (<1)	1 (<1)	0 (0)	0 (0)
Burkina Faso (2011)										
Primary	143	Quarterly	NA	64 (45)	50 (35)	29 (20)	0 (0)	0 (0)	0 (0)	0 (0)
Tertiary	119			46 (39)	53 (45)	20 (17)	0 (0)	0 (0)	0 (0)	0 (0)
Burundi (2010)										
Primary	188	Quarterly	Regional govt. team & NGO (patient surveys)	153 (81)	27 (14)	8 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Tertiary	63	Quarterly	Peer-to-peer & NGO (patient surveys)	44 (70)	13 (21)	5 (8)	0 (0)	1 (1)	0 (0)	0 (0)
Cameroon (2012)										
Primary	165	Quarterly	Regional govt. team	141 (85)	14 (8)	10 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Tertiary	139		Peer-to-peer	112 (81)	4 (3)	22 (16)	0 (0)	0 (0)	0 (0)	0 (0)
Congo (2014)										
Primary	185	NA	NA	148 (80)	6 (4)	23 (16)	7 (5)	1 (0)	0 (0)	0 (0)
Tertiary	237			185 (78)	18 (10)	25 (14)	7 (4)	2 (0)	0 (0)	0 (0)
Democratic Republic of the Congo (2015)										
Primary	167	Quarterly	Regional govt. team	146 (87)	10 (6)	9 (5)	1 (0)	1 (0)	0 (0)	0 (0)
Tertiary	237	Quarterly	Regional govt. team & Peer-to-peer	187 (79)	25 (11)	17 (7)	7 (3)	1 (0)	0 (0)	0 (0)
Democratic Republic of the Congo (2012)										
Primary	143	Quarterly	Regional govt. team & PROSANI team	130 (91)	5 (4)	6 (4)	1 (<1)	1 (<1)	0 (0)	0 (0)
Tertiary	158			137 (87)	4 (2)	17 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Djibouti (2014)										
Primary	193	Quarterly	Regional govt. team	166 (86)	16 (8)	11 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Tertiary	163		Peer-to-peer	141 (87)	12 (7)	9 (6)	0 (0)	1 (0)	0 (0)	0 (0)

Continued

TABLE 3. Continued

Country (Year) Facility Level	No. of Indicators per Checklist[a]	Verification Process		Means of Assessment[b]						
		Frequency	Verifier	Checklists No. (%)	Patient Record Review No. (%)	Register Review No. (%)	Direct Observation No. (%)	Staff Survey No. (%)	Patient Survey No. (%)	Exit Interview No. (%)
Gambia, The (2015)										
Primary	240	NA	NA	195 (81)	6 (3)	33 (14)	0 (0)	1 (<1)	5 (2)	0 (0)
Tertiary	275			221 (80)	8 (3)	40 (15)	0 (0)	1 (<1)	5 (2)	0 (0)
Haiti (2013)										
Primary	147	Quarterly	NGO	131 (89)	4 (3)	11 (8)	0 (0)	1 (<1)	0 (0)	0 (0)
Ivory Coast (2014)										
Primary & Secondary	155	Quarterly	Regional govt. team	132 (85)	6 (4)	16 (10)	0 (0)	1 (<1)	0 (0)	0 (0)
Kenya (2015)										
Primary & Tertiary	85	Quarterly	Regional govt. team	78 (92)	1 (1)	6 (7)	0 (0)	0 (0)	0 (0)	0 (0)
Kyrgyz Republic (2012)										
Tertiary	49	Quarterly	Peer-to-peer	39 (80)	7 (14)	0 (0)	1 (2)	1 (2)	1 (2)	0 (0)
Laos (2014)										
Tertiary	176	NA	NA	147 (84)	25 (14)	4 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Lesotho (2014)										
Primary	135	Quarterly	Regional govt. team	102 (76)	10 (7)	19 (14)	2 (1)	1 (<1)	1 (<1)	0 (0)
Tertiary	221			161 (73)	19 (9)	40 (18)	1 (<1)	0 (0)	0 (0)	0 (0)
Liberia (2013)										
Tertiary	141	NA	NA	132 (94)	1 (<1)	8 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Malawi (2015) (KfW)										
Primary, Secondary	76	Quarterly	Regional govt. team	59 (78)	12 (16)	5 (7)	0 (0)	0 (0)	0 (0)	0 (0)
Malawi (2015) (USAID)										
Primary	193	Biannually	Regional govt. team	151 (78)	16 (8)	5 (3)	20 (10)	1 (<1)	0 (0)	0 (0)
Mozambique (2012)										
Primary & Tertiary	179	Biannually	Regional govt. team & managing NGO	97 (54)	0 (0)	4 (2)	78 (44)	0 (0)	0 (0)	0 (0)
Primary & Tertiary	81			48 (59)	29 (36)	0 (0)	3 (4)	0 (0)	0 (0)	0 (0)
Primary & Tertiary	26			15 (58)	7 (27)	4 (15)	0 (0)	0 (0)	0 (0)	0 (0)
Nigeria (2013)										
Primary	182	Quarterly	Regional govt. team	164 (90)	3 (2)	7 (4)	8 (4)	0 (0)	0 (0)	0 (0)
Tertiary	228	Peer-to-peer		189 (83)	21 (9)	10 (4)	7 (3)	1 (1)	0 (0)	0 (0)
Rwanda (2012)										
Primary	206	Quarterly		139 (67)	10 (5)	27 (13)	30 (15)	0 (0)	0 (0)	0 (0)

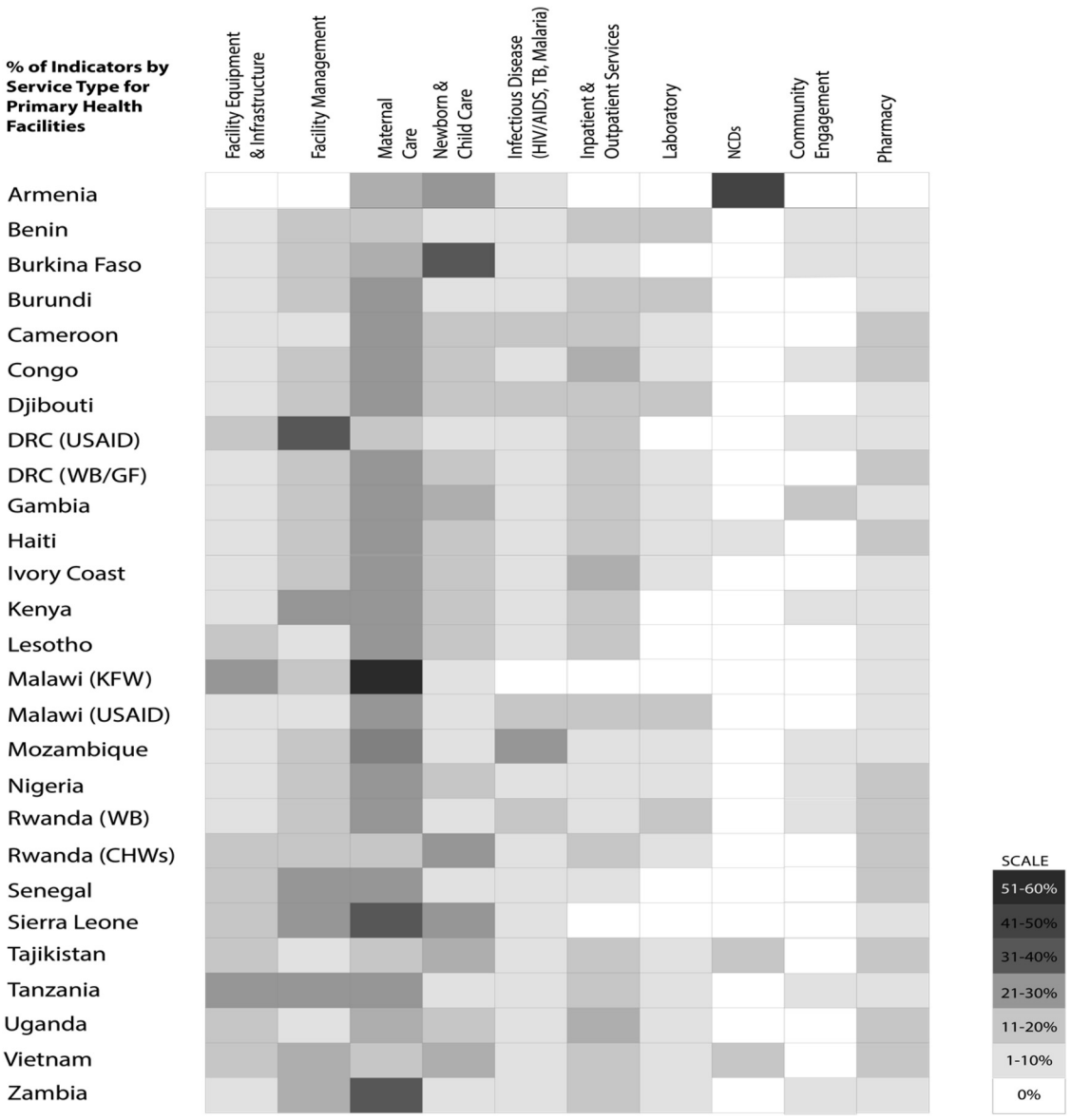
Continued

TABLE 3. Continued

Country (Year) Facility Level	No. of Indicators per Checklist[a]	Verification Process		Means of Assessment[b]						
		Frequency	Verifier	Checklists No. (%)	Patient Record Review No. (%)	Register Review No. (%)	Direct Observation No. (%)	Staff Survey No. (%)	Patient Survey No. (%)	Exit Interview No. (%)
			Regional govt. team & Facility management							
Rwanda (2009) (CHW)										
Primary	111	Quarterly	NA	76 (68)	28 (25)	3 (3)	4 (4)	0 (0)	0 (0)	0 (0)
Senegal (2015)										
Primary	72	Quarterly	National & regional govt. team	61 (85)	3 (4)	7 (10)	1 (1)	0 (0)	0 (0)	0 (0)
Tertiary	109			91 (83)	6 (6)	12 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Sierra Leone (2012)										
Primary	61	Quarterly		61 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Tertiary	17		Peer-to-peer	10 (59)	1 (6)	6 (35)	0 (0)	0 (0)	0 (0)	0 (0)
Tajikistan (2014)										
Primary	60	Quarterly	Regional govt. team	50 (83)	6 (10)	4 (7)	0 (0)	0 (0)	0 (0)	0 (0)
Primary (Rural HC)	93			72 (77)	17 (18)	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Tanzania (2015) (World Bank)										
Primary	64	Quarterly	Regional govt. team	41 (64)	6 (9)	10 (16)	0 (0)	0 (0)	7 (11)	0 (0)
Secondary	109			83 (76)	14 (13)	6 (6)	0 (0)	0 (0)	6 (6)	0 (0)
Tanzania (2015) (Danida)										
Primary	32	NA	NA	24 (75)	0 (0)	9 (28)	1 (3)	1 (3)	1 (3)	0 (0)
Secondary, Tertiary	44			35 (80)	4 (9)	5 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Uganda (2013)										
Primary	26	NA	NA	8 (31)	0 (0)	8 (31)	5 (19)	0 (0)	0 (0)	5 (19)
Vietnam (2014)										
Primary	71	NA	NA	48 (68)	10 (14)	7 (10)	0 (0)	5 (7)	1 (1)	0 (0)
Secondary	57			27 (47)	16 (28)	10 (18)	1 (2)	2 (3)	1 (2)	0 (0)
Zambia (2012)										
Primary	76	Quarterly	Regional govt. team	61 (80)	3 (4)	2 (3)	10 (13)	0 (0)	0 (0)	0 (0)
Avg. No. of Indicators: 125										
Total No. of Indicators Collected: 8,490										
Avg. per Assessment Method				6,656 (78)	731 (9)	771 (9)	248 (3)	34 (<1)	45 (<1)	5 (<1)

Abbreviations: CHW, community health worker; GF, Global Fund to Fight AIDS, Tuberculosis and Malaria; govt., government; HC, health center; KfW, Kreditanstalt Für Wiederaufbau; MoPH, Ministry of Public Health; PROSANI, XXX; USAID, U.S. Agency for International Development.
Note: Quarterly equates to a 3-month period of time.
[a] Only the most recent quality checklist per program were included in this analysis, amounting to a total of 50 checklists.
[b] Definitions for Means of Assessment: checklist, a verifier physically observes and assigns a point value; direct observation of a clinical consultation by the verifier; facility register, into which detailed patient contacts with the health facility are entered; patient record, in which consultation and treatment information is recorded by providers; patient survey, assessing the quality of care through a survey of patients; staff interview obtains information and knowledge from staff; exit interview, formal meeting with patient that is leaving the facility.

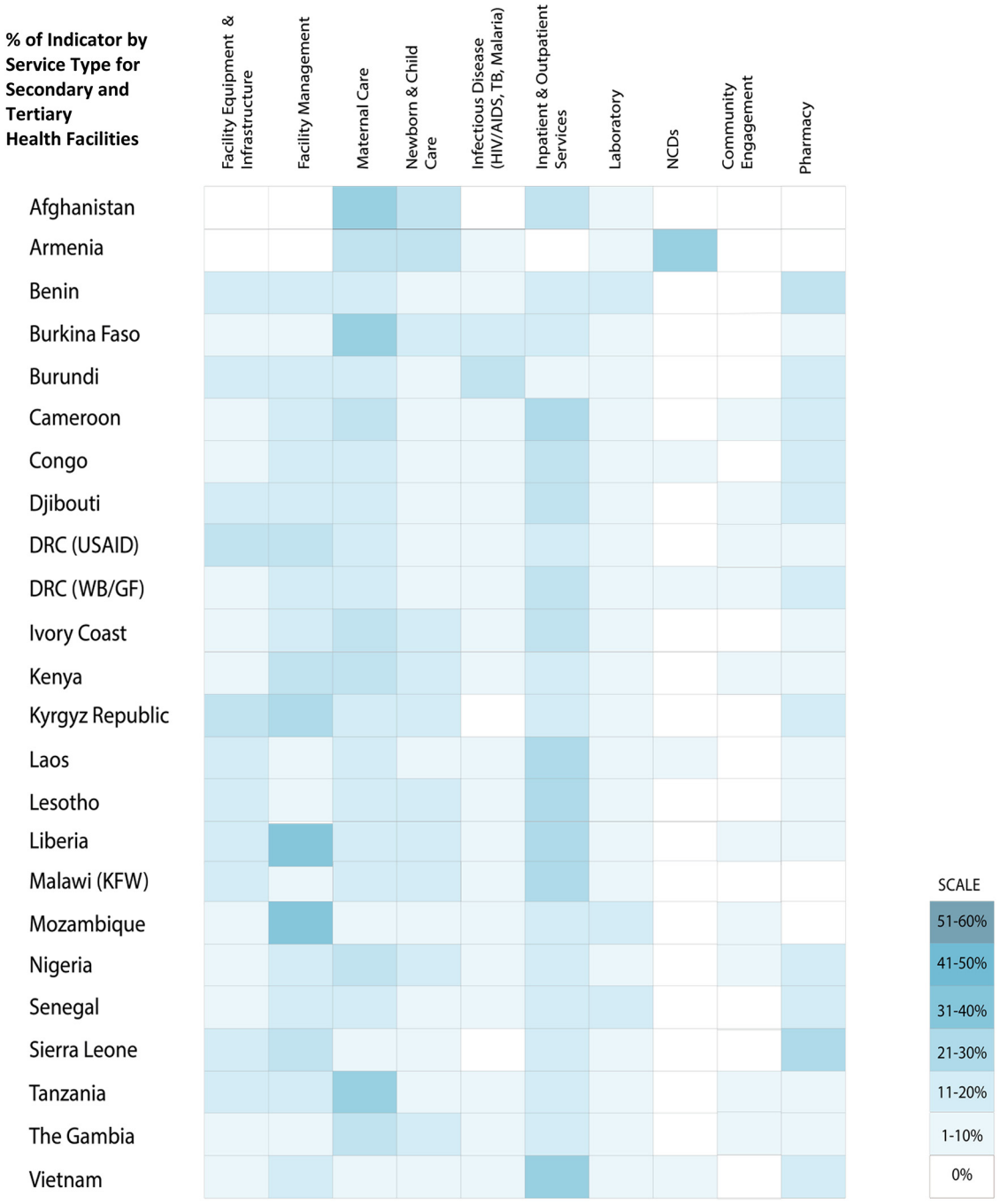
FIGURE 2. Distribution of PBF Quality Indicators by Service Type in Primary Health Facilities



Abbreviations: DRC, Democratic Republic of the Congo; GF, Global Fund to Fight AIDS, Tuberculosis and Malaria; KFW, Kreditanstalt Für Wiederaufbau; NCD, non-communicable diseases; PBF, performance-based financing; TB, tuberculosis; USAID, U.S. Agency for International Development; WB, World Bank.

Note: Classification of service types was guided by international standards into 10 categories to ease comparison. Inpatient and outpatient services were grouped together because the types of indicators and items being measured consisted of similar equipment and services.

FIGURE 3. Distribution of PBF Quality Indicators by Service Type in Secondary and Tertiary Health Facilities



Abbreviations: DRC, Democratic Republic of the Congo; GF, Global Fund to Fight AIDS, Tuberculosis and Malaria; KFW, Kreditanstalt Für Wiederaufbau; NCD, non-communicable diseases; PBF, performance-based financing; TB, tuberculosis; USAID, U.S. Agency for International Development; WB, World Bank.

Note: Classification of service types was guided by international standards into 10 categories to ease comparison. Inpatient and outpatient services were grouped together because the types of indicators and items being measured consisted of similar equipment and services.

TABLE 4. Common PBF Quality Indicators (N=54) by Service Type[a]

Common Indicators by Service Delivery Category	No. of Checklists (% of Total Checklists)[b]
Facility Equipment & Infrastructure	
Presence of latrines/toilets which are sufficient and well maintained (clean, good condition, etc.)	36 (53%)
Existence of well-kept fencing around health facility buildings	30 (44%)
A communication system (radio or telephone) is effective 24/7 between health facility and next referral center(s)	21 (31%)
Existence of the health map of the geographical area is available (and displayed)	20 (29%)
Plan detailing the maintenance activities to be performed	8 (12%)
Available general inventory of all furniture and equipment	8 (12%)
Availability of electricity 24/7 (electricity, generator or solar power)	8 (12%)
Facility Management	
Performance or activity reports submitted on time	32 (47%)
Financial and accounting documents (including for RBF) available and well kept (bank statements, receipts, invoices etc.)	31 (46%)
Waste is treated and disposed properly in accordance with regulations of health care waste management (e.g., waste pit, placental pit, incinerator)	27 (40%)
Meeting minutes or documentation available from management or governing committee meeting	24 (35%)
HMIS data analysis report for the quarter being assessed concerning priority problems	24 (35%)
Business plan exists and is up-to-date	20 (29%)
Maternal Care	
All deliveries are carried out by qualified personnel	27 (40%)
Presence of proper maternity equipment (sterile clamp, maternity beds, insecticide-treated bed net)	26 (38%)
Sufficient water with antiseptic soap and liquid antiseptic in delivery room [verbatim]	24 (35%)
Weighing scale available and calibrated at zero (weight for ANC alone)	23 (34%)
Delivery room is in good condition: (1) Walls are made of solid material, are not cracked, and are plastered and painted; (2) Cement floor is not cracked; (3) Ceiling is in good condition; (4) Windows have glass and curtains; (5) Doors are in working condition; [Variable] Light 24/7, clean	22 (32%)
Book of the ANC (for mom) available – at least 10 [verbatim]	21 (31%)
Privacy (door or curtain)	22 (32%)
Newborn & Child Care	
Vaccination (proper administration and registry)	27 (40%)
Baby weighing and height scale available and in working condition	26 (38%)
Under-5 services (EPI, growth monitoring, curative care, health promotion) are available every day (at least 5 days a week)	22 (32%)
IMCI care protocol is applied correctly	21 (30%)
Adequate supplies for child care (1% Tetracycline eye ointment; Vitamin K)	18 (26%)

Continued

TABLE 4. Continued

Common Indicators by Service Delivery Category	No. of Checklists (% of Total Checklists)[b]
Infectious Disease (e.g. HIV, Tuberculosis, Malaria)	
Malaria medication in stock (Co-artemeter, Sulfadoxine/pyrimethamine, Co-trimoxazol, Quinine)	15 (22%)
Tuberculosis treatment in stock (Rifampicin, Streptomycin, Ethambutol)	14 (21%)
Correct case management of simple (uncomplicated) malaria	14 (21%)
ARI protocol correctly applied for children <5 years	13 (19%)
Well-equipped HIV counseling room ensuring privacy	13 (19%)
Correct case management of severe (complicated) malaria	12 (18%)
Knowledge of tuberculosis danger signs and criteria for referral	12 (18%)
Laboratory	
Available and functional microscope	23 (34%)
Availability of parasites demonstrations (GE/FS, stools, sputum) (on laminated paper, in a color book, or posters)	20 (29%)
Lab results are correctly recorded in the lab register and conform with the results in the patient booklet or lab request slip	20 (29%)
Availability of a working centrifuge	18 (26%)
Waste disposal performed correctly—organic waste in a bin with lid, safety box for sharp objects available and destroyed according to waste disposal directives	18 (26%)
Non-Communicable Diseases (NCDs)	
Hypertension managed according to protocol	4 (6%)
Hypertension diagnosis correctly made	2 (3%)
Counseling materials (IEC) are available for hypertension	2 (3%)
Diabetes diagnosed correctly	2 (3%)
Diabetes protocol applied	2 (3%)
Proper screening for hypertension conducted	2 (3%)
Inpatient & Outpatient	
Consultation room offers physical privacy	24 (35%)
Presence of a triage system with numbered cards or tokens to follow a cue	23 (34%)
Lighting available in every room (outpatient consultation and inpatient)	21 (31%)
Materials exams available in the consultation room and functional (e.g., thermometer, stethoscope, otoscope, sterile gloves, weight, tongue depressor)	21 (31%)
Examination bed available	21 (31%)
Community Engagement*	
List and mapping of community health workers	3 (4%)

Continued

TABLE 4. Continued

Common Indicators by Service Delivery Category	No. of Checklists (% of Total Checklists)[b]
Pharmacy	
Drugs stored properly	25 (37%)
Stock of essential drugs (paracetamol, diazepam, glucose solution, oxytocin, etc.)	18 (26%)
Pharmacy compliant with: (1) Shelves, (2) ventilated, (3) protection against direct sunlight, (4) protection against theft	17 (25%)
Stock record cards are kept accurately	17 (25%)
No expired drugs or falsified labels	15 (22%)

Abbreviations: ANC, antenatal care; ARI, acute respiratory infection; EPI, Expanded Programme on Immunization; FS, Frottis Sanguin (for blood smear) GE, Goutte Epaisse (for blood smear); HMIS, health management information system; IEC, information, education, and communication; IMCI, Integrated Management of Childhood Illness; PBF, performance-based financing; RBF, results-based financing.
[a] Five most "common" (frequency of indicator across entire sample of checklists) indicators are listed for each service category. In the event of a tie, we included all indicators that shared the same frequency, with the exception of community engagement (see footnote c).
[b] Analysis based on 68 checklists (total sample).
[c] Only 1 common indicator (of 68) for community engagement was observed across 3 checklists. In 2 of the checklists, there were 15+ community engagement indicators. Due to the low "commonality" of these indicators and the inability to distinguish the 5 most common indicators, we have included only the top (most frequent) indicator for community engagement.

The justifications for the differences in allocation remains unexplained by donors and program designers. Moreover, it is difficult to discern what implications each payment type has on the quality of care provided and on provider behavior. PBF offers autonomy in quality investments through health facility managerial teams. However, determining the amount of a quality bonus requires knowledge of the quantity and quality score and the application of a complex formula. The implications for variable levels of fund allocation to facilities or staff and/or facility-level fiscal autonomy and strategic investment on quality dimensions, such as infrastructure and equipment, clinician competency, and patient satisfaction efforts, remains understudied.

Notably, the verification process is the most consistent across regions, with similar teams carrying out the verification on quarterly schedules. This is likely due to the availability of regional management teams already on the government payroll or the availability of donor-supported NGOs contracted to undertake the verification. This heavy reliance on regional management teams points to a common challenge faced by many countries—that is, the additional burden placed on these District Health Management Teams or equivalent regional teams to undertake regular verification of PBF facilities on an average of 125 indicators per facility. In addition, deploying district officials to conduct verifications could generate a conflict with their other roles, for example, to constructively monitor and support providers.[12] In the case of hospitals, peers may not be effective at verification—but in some contexts they may be some of the few experts qualified to assess quality. These issues point to the logistical and operational constraints in which PBF programs operate and also affirm the need for a well-articulated theory (or set of theories) of change for PBF.[13]

It is difficult to discern what implications different payment types have on the quality of care provided and on provider behavior.

Moreover, results from Table 3 point to a reliance on the checklist for assessment, limiting the utility of the PBF program to effect improvements in certain aspects of quality. Mixed modalities of assessment can address quality of care more holistically. For example, exit interviews and direct observation can inform the experience and provision of care while provider interviews can shed light on motivation. (Additional detail about indicator typology and measurement can be found in a related paper.[10]) Selection of assessment methods is likely informed by trade-offs between cost and quality of data. For instance, register and patient

Using mixed methods to assess quality in PBF programs could address quality of care more holistically but most programs relied on checklists.

record reviews may be less costly, but the quality data may vary. In Rwanda, patient record review, verified by qualified supervisors, were considered a valuable quality criterion, resulting in systemic improvements in data collection, monitoring, and supervision that contributed far more to the quality improvements than service delivery improvements.[14] Direct observations may yield good quality at relatively higher cost. One potential solution is to always conduct register reviews and supplement with direct observations for a random sample of facilities, hence maintaining this thorough measurement but at a lower overall cost. Moreover, the findings from Table 3 suggest that more cost-effective methods of assessment may need to be developed and/or employed such as clinical vignettes and tablet- or smartphone-based verification. Indeed, cost-effectiveness itself of different verification methods should be assessed to inform the selection of one method over another or a justification for using mixed methods.

Future research could model the various incentives that we've identified in the PBF programs included in this study to characterize which approaches may be most effective.

There is also consistency in quality assessment of service types. Figure 2 and Figure 3 demonstrate a clear preference for incentivizing maternal, newborn, and child health services and inpatient and outpatient services, suggesting a focus on burden of disease (mortality and morbidity). This could reflect homogeneity in policy priorities of the countries or donors, including the maternal, newborn, and child health focus of the Health Results Innovation Trust Fund of the World Bank, involved in these programs. Community engagement, non-communicable diseases, and pharmacy appear to have the fewest associated indicators, suggesting that these may be hardest to measure (community engagement), represent relatively low burden of disease or surveillance in the included countries (non-communicable diseases), or hardest to effect systemic improvements (supply chain in pharmacy) using PBF.

PBF is a potentially appealing instrument to address shortfalls in quality of care.

Our study also highlights the need for more systematic documentation. Theoretically, PBF should offer a wealth of data on quality of care given the length and frequency of measurement; however, this information remains hard to access by all actors. For policy makers and PBF practitioners, there is no comprehensive central repository for PBF program manuals and quality tools. The current structure of PBF manuals and quality checklists, long documents in PDF format, is not conducive to information sharing and aggregation, so the current state of practice has been unknown up to this point. Performance data from quality tools is inaccessible on a country or health facility level, with the notable exception of the PBF portal, which is an online platform that displays quantity and quality data at the facility level for select countries.[15] Although the portal is an important first step, sharing of health facility performance per quality indicator is required to better understand what types of quality measures are well suited for PBF. The growing PBF Community of Practice could be a good place to house both programmatic documentation and available performance data.[16]

While our findings shed light on the current and past state-of-practice of addressing quality in PBF, they raise further questions. The observed differences in payment formula and allocation, service types, and length of the tools call for further examination of why each program is unique and the justification for the differences, and most importantly whether differences in design are associated with differential program impacts. Future foundational research could model the various incentives we identified in real-life PBF programs, also to characterize which approaches may be most effective, at least in theory. Specific research gaps related to program operations include detailed performance data and the percentage of incentives paid based on quality, leading to the cost-benefit to management and providers for completing the quality tool and investing in quality improvement measures. There is also the black box of PBF costs; calculating time costs to facility staff and quality-specific costs, predominantly verification costs. These costs and benefits should be compared with those of other quality assessment methods that are already being used like supportive supervision, accreditation, and independent quality evaluations by NGOs.

CONCLUSIONS

PBF is a potentially appealing instrument to address shortfalls in quality of care and, ultimately, to help meet policy priorities at the country and global levels, including the ambitious goals set forth in the SDGs. As our review of 32 PBF programs highlights, there is substantial variation and complexity in how programs incorporate quality of care considerations. There are differences in how quality is incorporated in the payment formula, how many and what indicators are included in checklists, and how they are measured. While PBF programs should be aligned with local conditions and they need to primarily focus on executing payments, the heterogeneity and similarities between programs suggests scope for learning how these programs can more effectively

incentivize and support providers to address gaps in quality.[11] More research and policy effort is urgently needed to make the best use of PBF as a targeted supply-side intervention.

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METHODOLOGY

Strategies for Optimal Implementation of Simulated Clients for Measuring Quality of Care in Low- and Middle-Income Countries

Anne Fitzpatrick,[a] Katherine Tumlinson[b]

When properly implemented, use of simulated clients ("mystery clients") can provide insight into actual experiences of real clients and evaluate quality of care. Successful implementation calls for recruiting mystery clients who represent the facility's clientele, have strong recall of recent events, and are comfortable being undercover data collectors. Developing training protocols and checklists to standardize mystery client behavior and responses is also key.

ABSTRACT

The use of simulated clients or "mystery clients" is a data collection approach in which a study team member presents at a health care facility or outlet pretending to be a real customer, patient, or client. Following the visit, the shopper records her observations. The use of mystery clients can overcome challenges of obtaining accurate measures of health care quality and improve the validity of quality assessments, particularly in low- and middle-income countries. However, mystery client studies should be carefully designed and monitored to avoid problems inherent to this data collection approach. In this article, we discuss our experiences with the mystery client methodology in studies conducted in public- and private-sector health facilities in Kenya and in private-sector facilities in Uganda. We identify both the benefits and the challenges in using this methodology to guide other researchers interested in using this technique. Recruitment of appropriate mystery clients who accurately represent the facility's clientele, have strong recall of recent events, and are comfortable in their role as undercover data collectors are key to successful implementation of this methodology. Additionally, developing detailed training protocols can help ensure mystery clients behave identically and mimic real patrons accurately while short checklists can help ensure mystery client responses are standardized. Strict confidentiality and protocols to avoid unnecessary exams or procedures should also be stressed during training and monitored carefully throughout the study. Despite these challenges, researchers should consider mystery client designs to measure actual provider behavior and to supplement self-reported provider behavior. Data from mystery client studies can provide critical insight into the quality of service provision unavailable from other data collection methods. The unique information available from the mystery client approach far outweighs the cost.

INTRODUCTION

Accurate data collection is essential to evaluating potential problems in service delivery, particularly in low-and middle-income countries. Several methodological tools can be used to gather such information, such as facility-level surveys including provider interviews or the client exit interview. Another tool is the *simulated client* design. In this approach, a study team member or assistant pretends to be a real customer (mystery shopper) or client/patient (standardized patient) who seeks services or care according to standardized prearranged scripts. During the health care visit, the provider is unaware that the encounter is for research purposes. Following the session, the undercover data collector—henceforth referred to as the mystery client—then reports her observations to the study team.

The mystery client methodology has been used successfully in several studies to assess the quality of health care delivery and identify areas for quality improvement.[1–3] Mystery clients are considered to be a highly reliable and valid method for assessing provider communication skills and behavior.[4,5] Mystery clients have been used extensively in medical education to train and

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assess the competency of doctors.[6,7] This methodology has been used in evaluating provider behavior more generally since 1985,[8–10] but is currently used less frequently than other methods such as surveys.

Mystery clients allow insight into actual transactions and experiences of real customers or patients. By relying on data recalled by mystery clients, this method overcomes some key concerns with traditional structured interviews or direct observation methods.[11] For example, in direct observation, provider behavior is confounded by patient behavior. In contrast, mystery clients are trained to display standardized behavior, isolating how providers respond to observationally similar patrons. Similarly, directly observing providers may result in them changing their behavior toward what they believe will impress or please their observers, in a *Hawthorne effect*. In structured questionnaires of real patrons, there may be a desire for the respondent to be polite or positive toward the provider (*courtesy bias)* or they may simply make mistakes in recalling information (*recall bias)*.[12–14] In addition, patients and health care providers may not be eager to participate in surveys—patients may not feel well and providers may be in a rush to deliver medicines to the patient—resulting in *response bias* from refusal rates as high as 38%.[15] Finally, surveys of providers may instead reflect their best intentions or how they have been trained to deliver services rather than what they actually do in practice, a phenomenon called the "know-do gap."[16] However, mystery client studies may present special challenges as compared to survey or interview-based designs—particularly in low- and middle-income countries.

In this article, we discuss our experiences from studies conducted in Kenya and Uganda using mystery client designs and identify lessons learned to inform successful implementation of this approach to assess quality of care. In Kenya, within a sample of 19 urban public and private health facilities, mystery clients were employed to assess the validity of standard data collection tools used to measure the quality of family planning service delivery in large-scale demographic surveys[17]; this study revealed harmful provider practices not detected by the standard tools.[18] In Uganda, mystery clients purchased anti-malarial medicines at nearly 500 informal private-sector outlets to measure counterfeit drug rates; the study included both urban and rural areas.[15] We augment our experiences with findings and approaches from recent research from other mystery client studies.

APPROACH

Prior to the Visit: Ethical Approval

In general, the ethical issues involved will be study-specific. Using mystery clients may be classified as "deceptive research" depending on the design details, for example, if providers are not informed about the study and do not provide informed consent in advance. Therefore, institutional review boards (IRBs) should be consulted and approve all protocols and activities to ensure ethical concerns are addressed. Study team members must be aware that they are acting as observers and must keep all experiences and data strictly confidential both during and after study completion. Shoppers may sign non-disclosure agreements as a condition of employment to enforce the importance of confidentiality. There may also be special challenges in observing public health facilities due to long lines and possible political sensitivity around the evaluation of government facilities. For example, it may also be necessary to obtain ethical approval from the provincial- and district-level ministries of health. Consulting with these agencies may also help relevant stakeholders feel invested in and appreciate the results of the study. Such buy-in may also help prevent concerns of trespassing on government property.

To avoid discontent among respondents (i.e., health care providers), IRBs may require principal investigators (PIs) to disclose the study design in advance and gain consent of providers or facility supervisors without specifying the date of the visit ahead of time. Alternatively, IRBs may require debriefing providers after the transactions are completed. IRBs may also require that, if debriefed, providers maintain the right to have their data withdrawn because the information was collected by deception. If a sufficient number of providers withdraw as a result of forewarning or debriefing, then the generalizability of results may be in question—particularly if either low- or high-quality providers differentially withdraw.

In Uganda, the IRB agreed to waive both forewarning and debriefing requirements. This waiver was approved because (1) the societal benefits exceeded potential harms to providers due to a dearth of evidence on drug quality, and (2) the deception itself was minor and protocol sufficiently mimicked real-life interactions. Thus, potential harm to subjects was minimal. Signing informed consent before or after the study may also have provided identifying information, risking confidentiality if data were compromised. By contrast, in Kenya, the IRB required informed

In the simulated client approach, a study team member pretends to be a real client (or "mystery client") who seeks services according to standardized prearranged scripts.

The mystery client method overcomes some key concerns with traditional research methods, including the Hawthorne effect and courtesy, recall, and response biases.

Institutional review boards should be consulted and approve all mystery client protocols and activities to ensure ethical concerns are addressed.

Institutional review boards may require investigators to disclose the mystery client design in advance to providers or debrief providers afterward.

consent from all facility managers and also required that the identity of individual providers be kept strictly confidential to avoid negative consequences for those providers offering low-quality care.

In addition, while giving providers feedback on results could be beneficial to improving their service delivery, such feedback must be given in a confidential manner that does not in any way jeopardize their job security. In Uganda, it was deemed likely that providers would not believe their data were for research purposes only. Thus, informing providers post-facto that deception had occurred may have aroused more anger, fear, or anxiety from providers than simply not informing them at all. The potential harm from debriefing was exacerbated because providers were primarily informal-sector outlet vendors potentially in violation of legal regulations or engaged in illegal activities.

In the Kenya study, aggregate results for the district were presented to facility managers and local health officials for debriefing and identifying areas for quality improvement. However, the PI presented only data aggregated from all 19 facilities to avoid negative consequences for any particular low-performing providers or facilities.

Finally, PIs may consider whether to obtain informed consent from mystery clients themselves. Informed consent is necessary to publish characteristics of shoppers such as age, gender, or education. Although not required in the Kenya study, this information was requested for the Uganda study at a later date by manuscript reviewers to determine the generalizability of results.

Prior to the Visit: Training

Recruitment and training of appropriate study team members is essential. Although the PI may pose as the shopper himself or herself,[19] in our view this is undesirable because the PI may subconsciously change the nature of the interaction in line with preexisting hypotheses. Instead, hiring mystery clients with strong recall ability can help ensure accurate data collection. Recall ability can be assessed during hiring by memory tests. In addition, researchers may wish to consider an applicant's educational qualifications, or language abilities, as a practical matter. In Uganda, for example, it was deemed essential that the PI could directly communicate in English with the study team members. Therefore, all study team members were required to demonstrate English reading and writing ability to facilitate data collection.

Hiring mystery clients with strong recall ability, which can be assessed with memory tests, is important to ensuring accurate data collection.

As a result, the average educational levels of mystery clients exceeded those of the average drug shop clientele, potentially affecting the interpretation of results. In the Kenya study, which took place in central Kisumu, mystery clients had to be fluent in the local language of Dholuo to avoid suspicion on the part of local health care providers; as such, data collectors from Nairobi willing to reside for the duration of the study period in Kisumu were ineligible because they spoke Swahili, not Dholuo. PIs may additionally find it helpful to train and hire several more study team members than needed in the event of attrition or illness; this was necessary in the Uganda study but not in Kenya where data collection activities were completed within 2 weeks.

Similarly, accurate data collection also implies that providers are unaware the shopper is also a research team member. For example, if mystery clients are intended to represent a particular income or regional group, their language, dress, and even hairstyle must be standardized to match the target demographic's typical appearance. It also will be important to remove accessories that are correlated with wealth while conducting visits (e.g., wedding rings, watches, and cell phones, among others). This may be challenging; for example, standards of dress may differ between urban and rural areas. In situations where language or dialect varies substantially across areas, researchers may consider using multiple study teams or adjusting protocol to reflect differing norms. In the Uganda study, 2 different teams with different local language abilities were used. If using multiple teams is not possible, then the PIs should alternatively consider restricting to a more homogeneous geographic area. Finally, depending on the script content, shoppers may also need to appear outwardly healthy to ensure that the providers do not get confused about what ailment to treat.

These safeguards appear to have worked in our studies in Kenya and Uganda. In Uganda, during a separate survey conducted at the same outlets that mystery clients visited, providers reported that, on average, they suspected the mystery client only 3% of the time.[8] Although there may be concerns that shoppers may stand out more in rural areas, this rate did not statistically differ between urban and rural areas. In Kenya, in only 1 visit out of 134 did a mystery client report that the provider questioned her authenticity.

Adequate time for training study team members—including supervisors—is also important to ensure all shoppers follow protocols

exactly and consistently. In our studies, mystery clients received extensive training over 3 to 5 days on the study protocol, including the survey instrument, research objectives, outlet or facility locations, transportation logistics, dress code, confidentiality, and other study policies. Training should also emphasize that shoppers should not prompt providers in an effort to help them perform "better." Training periods may vary depending on the complexities of the intervention. While our studies used 24–40 training hours, one study reported 250 hours of training.[20]

Generally, mystery clients should feel comfortable in their role as an "undercover" data collector; toward this end, extensive time should be set aside during training for role play and practice using the data collection instrument. Role play activities conducted in front of all mystery clients can also help to ensure shopper behavior is standardized. If possible, create time to pilot test the data collection instrument and allow the mystery clients the opportunity to test out their new role in a location away from the study sites. In Uganda, pilot shopping rounds were both supervised and conducted independently, giving confidence to both shoppers and supervisors that shoppers were prepared for full-study data collection.

During this time, the trainer can also make sure that shoppers are interpreting and answering questions in the same way to ensure standardization and inter-rater reliability. In both Kenya and Uganda, a short checklist was used to help the mystery clients recall aspects of their visit and provide a standardized evaluation.[21] Questions should be as objective as possible to prevent speculation.

Finally, training must emphasize protocols that protect mystery clients from harm. For example, providers can sometimes recommend intramuscular injections even when not clinically indicated. Similarly, project leaders must ensure that less obvious risks, such as taking a temperature with an unsterilized thermometer, also do not occur. As part of their training, mystery clients need to be prepared with various culturally appropriate and plausible strategies and answers to avoid any procedure that could put them at risk. In addition to physical harm, emotional harm and stress can also be minimized by preparing answers for both expected and unexpected questions. In Kenya, all mystery clients were trained to use culturally appropriate excuses to avoid unwanted services such as injections, implantable contraception, or the intrauterine device; excuses included telling the provider they changed their mind or that they first needed to ask their husband, think about it, acquire sufficient funds, or compare with another facility. In Uganda, shoppers were prepared to answer questions ranging from details on the patient's illness to the shopper's personal background. Standardizing shopper answers also ensures that providers view each shopper identically, regardless of what occurs during the transaction. Conducting focus groups with real customers or patients, interviews with local experts, or receiving support from an anthropologist may help PIs anticipate expected questions and ensure realistic responses in line with cultural norms. In the Ugandan study, the exact language, translations, and excuses used were discussed and validated by the mystery clients during training. In extreme circumstances where risks cannot be sufficiently minimized or providers may not accept refusals to treat, the research design should be modified or a different methodology used. For example, in any study ascertaining the quality of service delivery around actual insertion of an intrauterine device or the implantation or injection of a contraceptive method, the mystery client methodology would not be appropriate.

Planning the Visit: Sampling Frame

Building a sampling frame can also be particularly challenging in low- and middle-income countries. Many health care outlets lack outward signage; official records may be incomplete; administrative boundaries uncertain. Developing a standardized protocol for building the sample frame of eligible outlets and creating the study plan is important to reduce bias and minimize unexpected events during fieldwork. If data are to be collected more than once from the same location, as is common in audit study designs, study team members may create maps of all study areas, along with a physical description of the outlets or buildings, to help them find the same outlets again. We followed this approach in Uganda. If ethical approvals allow, GPS coordinates can facilitate this process. In Uganda, we validated mapped location information by consulting with local key informants, such as village chiefs or motorcycle taxi drivers, to cross-reference geographic details. The location of health care facilities selected for the Kenya study were widely known to both the local population and the data collectors, who also resided in the area.

In mystery client studies in Kenya and Uganda, checklists were used to help the mystery clients recall aspects of their visit and provide standardized evaluations.

Planning the Visit: Pre-Study Visits

Even if a reliable sample frame already exists, visits to study sites prior to actual data collection are

essential for planning how clients approach a provider. Such visits can be conducted in advance by the PI when obtaining informed consent from the facility manager; for studies in which informed consent has been waived, a member of the study team can assess the location in advance of study implementation. Pre-study visits also establish a specific location to conduct the post-visit shopper debriefing with the supervisor, which ideally would occur immediately after each encounter to ensure accurate recall. Establishing a meeting point location also gives shoppers confidence that their supervisors are close by if any complications arise. If debriefing is done orally or with qualitative methods—which can capture additional interesting and important details of the transaction—then identifying quiet areas where confidential discussions can occur is of additional importance.

Clear protocols and rules need to be established if mystery clients are to conduct financial transactions.

During the Visit: Standardized Shopper Behavior

During the visit, all shopper behavior—from words spoken to shopper demeanor—should be completely standardized to be able to make comparisons across providers or visits. Ensuring data are collected according to guidelines over time requires ongoing effort and close monitoring. In both Kenya and Uganda, we reviewed protocol and common responses to questions during daily team meetings to ensure consistency over time and allow for a discussion of how shoppers were feeling. In our studies, supervisors conducted audits and additional checks to ensure that the correct facilities were visited, while being careful not to compromise the mystery client's covert status.

During the Visit: Collecting Data on Prices

Prices for services or products in developing countries are often not posted and receipts are uncommon. If the research design requires shoppers to make financial payments, then developing strategies to ensure shoppers honestly and correctly report prices is of utmost importance. One option is to trust study team members to honestly report the prices they paid and allow them to bargain for the best price in an effort to balance minimizing study costs with gaining insight to true client experiences. While common in studies of bargaining, this type of protocol could be expensive and may still lead to incorrect data if shoppers switch to cheaper treatments (without notifying the study team). Our approach in both Kenya and Uganda was to instead have multiple shoppers visit the same outlet or facility; this created the impression that the study team could cross-reference prices between shoppers, even though in Uganda, measuring price differences between shoppers at the same provider was the outcome of interest. Researchers considering this approach should ideally have visits conducted by different shoppers several hours (or even days) apart. Multiple visits to the same provider, facility, or outlet are typically feasible but may be difficult if the provider is frequently absent from work or if the facility or outlet has limited operating hours. On occasion, official hours of operation may differ from actual hours.

Similarly, clear protocols and rules need to be established if shoppers are to conduct financial transactions. In Uganda, we set a budget of 10,000 UGX (Ugandan shillings) per transaction. The bills used were in small denominations of used-looking money to minimize the likelihood that providers lacked adequate change to complete a transaction and ensure that the shopper remained inconspicuous. The money was placed in an envelope with the shop and transaction ID labeled on the outside. After the transaction, the shoppers returned the balance to the envelope and accounts reconciled with the price paid. If shoppers required additional funds for a purchase, they were required to return to supervisors. Shoppers were not allowed to use their own money under any circumstances. Separate funds and budgets were used for transportation expenditures. Similar procedures were observed in Kenya.

In addition, collecting data from real customers, or drug pricing data from vendors, may provide better data and allow for cross-referencing of price data. Additional data collection can also validate assumptions of the experimental design. In the Ugandan context, collecting additional data from real customers validated the assertion that mystery clients behaved similarly to real customers. Another mystery client study examined whether providers altered drug prices or quality if they perceived customers to be of different income levels. To validate provider impressions of shopper income levels, the researchers took daily photographs of shopper outfits that were then evaluated by real customers to test whether mystery clients' appearance reasonably represented socioeconomic status.[22]

Changing Study Protocols and Rules

Developing good communication is important to ensuring study team members perform as

directed. However, listening to concerns of shoppers implies possibly adapting protocol and rules accordingly. For example, during the pilot for the Uganda study, shoppers reported difficulty in understanding the debriefing instrument. As a result, prior to the full study, the debriefing checklist was shortened from 46 items to 18 items and reorganized. In another example, in Uganda it became clear that the bargaining protocol was difficult to enforce; shoppers were worried they were not getting a "good price" because the protocol limited them to 3 rounds of bargaining. Thus, the protocol was simplified and shoppers were allowed to act as they normally would in a bargaining situation with unlimited rounds of bargaining. In Kenya, mystery clients sometimes needed an additional day to collect data on providers with high rates of absenteeism. Other examples of modifications include altering the dress code in urban areas to reflect shopper concerns that their appearance did not reflect local norms.

CONCLUSION

In summary, the use of mystery clients offers a unique and critical opportunity to accurately measure the quality of service provision. When selecting mystery clients, it is important to choose people who will present realistically and have excellent recall. In addition, careful attention should be paid to strategies that allow mystery clients to feel comfortable in their role and to prevent unwanted exams or procedures. Researchers should appreciate details of data collection and listen to concerns of their team members. Despite these challenges, the unique information available from this type of methodology far outweighs the cost.

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METHODOLOGY

Preventing Peer Violence Against Children: Methods and Baseline Data of a Cluster Randomized Controlled Trial in Pakistan

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Peer violence was remarkably high at baseline. Among urban public school students, 94% of 6th-grade boys and 85% of girls reported being victimized by peers in the last 4 weeks. And 85% of boys and 66% of girls reported perpetrating such violence. Boys scored worse on a number of mental health measures. A cluster RCT is underway to evaluate a well-established school-based intervention using sports and games to reduce peer violence.

ABSTRACT

Background: Violence against and among children is a global public health problem that annually affects 50% of youth worldwide with major impacts on child development, education, and health including increased probability of major causes of morbidity and mortality in adulthood. It is also associated with the experience of and perpetration of later violence against women. The aim of this article is to describe the intervention, study design, methods, and baseline findings of a cluster randomized controlled trial underway in Pakistan to evaluate a school-based play intervention aiming to reduce peer violence and enhance mental health.

Methods: A cluster randomized controlled design is being conducted with boys and girls in grade 6 in 40 schools in Hyderabad, Pakistan, over a period of 2 years. The Multidimensional Peer-Victimization and Peer Perpetration Scales and the Children's Depression Inventory 2 (CDI 2) are being used to measure the primary outcomes while investigator-derived scales are being used to assess domestic violence within the family. Specifics of the intervention, field logistics, ethical, and fidelity management issues employed to test the program's impact on school age youth in a volatile and politically unstable country form this report.

Baseline Results: A total of 1,752 school-age youth were enrolled and interviewed at baseline. Over the preceding 4 weeks, 94% of the boys and 85% of the girls reported 1 or more occurrences of victimization, and 85% of the boys and 66% of the girls reported 1 or more acts of perpetration. Boys reported more depression compared with girls, as well as higher negative mood and self-esteem scores and more interpersonal and emotional problems.

Interpretation: Globally, prevalence of youth violence perpetration and victimization is high and associated with poor physical and emotional health. Applying a randomized controlled design to evaluate a peer violence prevention program built on a firm infrastructure and that is ready for scale-up and sustainability will make an important contribution to identifying evidence-informed interventions that can reduce youth victimization and perpetration.

Violence against children is a global public health problem, affecting 50% of youth worldwide each year.[1] It takes many different forms, of which violence among children (also known as peer violence or bullying) and violence by caregivers against children (including child sexual and physical abuse) are the most commonly described. Most research comes from high-income countries, but in recent years there has been an increasing focus on documenting and developing responses to the problem in a more global context, led in particular by Together For Girls, a public-private

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partnership of several U.S. Government agencies and 5 United Nations (UN) partners headed by the United Nations Children's Fund (UNICEF).[2]

Violence against children violates children's human rights and impacts their education, quality of life, and mental health and dramatically increases the probability of major causes of morbidity and mortality in adulthood.[3–5] Furthermore, violence experienced by children or perpetrated by children is associated with experience of and perpetration of later violence against women, as well as other adult violence, and impacts children's ability to reach their full social and economic potential in adulthood.[5] The 2030 Agenda for Sustainable Development[6] highlights the importance of securing youth safety for global development by requiring the prevention of all forms of violence against children, which is further endorsed by the UN report on violence prevention.[7]

This article describes the methods of an evaluation underway to assess the effectiveness of a peer violence prevention initiative.

Evidence demonstrates that drivers of violence against children are found at different levels of the socioecological model within the child, family, community/school, and society.[8] In the area of prevention of youth peer violence, which is the focus of this article, interventions have largely been school-based (with or without involvement of families) or skills/cognitive behavior modification-based, and some have included work on focal groups, such as bystander behavior.[9] The theoretical basis for school-wide interventions starts with the view that a school itself is an ecosystem. The logic for this ecological approach is particularly strong for most peer violence occurs when traveling to or from school or in the school. Within the school, behaviors and attitudes are influenced by psychological and social factors within or related to the child; attitudes, behaviors, and lessons within the peer environment and conveyed through the teachers and principal; and the broader school policy and social context that includes formal policies, management style, and attitudes toward the use of violence. A recent systematic review identified 17 published randomized controlled trials (RCTs) of interventions to prevent peer violence, all of which were conducted in Australia, Europe, or the United States.[9] In general, whole-school interventions have been shown to be more successful than focused interventions.

This article describes the methods of an evaluation that is being undertaken as part of the "What Works to Prevent Violence?" global program,[10] funded by the UK Department for International Development (DFID). The initiative seeks to learn what works to prevent violence against women and girls in low- and medium-resourced countries. The program held a competitive grant process that sought to identify ongoing violence prevention initiatives located in Africa, Asia, and the Middle East that were already being delivered at scale or had good potential for scale-up and sustainability but had never been rigorously evaluated. One such program selected, which forms the focus of this research, is "The Positive Child and Youth Development" program of the Right To Play[11] Pakistan office.

Right To Play is an international NGO that has worked with more than a million children in 20 countries using the transformative power of play to build essential life skills, enhance school retention, and prevent violence among children. Specific to violence prevention, the Right To Play objectives posit a change in social norms that contribute to violence against women and girls, especially attitudes that support gender inequities and subordination of girls and women. Additionally, the program aims to empower girls and boys to prevent interpersonal violence and simultaneously build the capacity of schools, teachers, education departments, and communities to reduce violence against women and girls. Right To Play is operating in many countries but has not previously been evaluated with an RCT.

Right To Play's Positive Child and Youth Development program in Pakistan includes games and activities from the manual *Red Ball Child Play* that focus on 4 areas of youth development, including physical, cognitive, social, and

Students in Pakistan engage in the Right To Play curriculum through games and activities twice weekly.

emotional components.[11] These structured activities, designed to help children and adolescents improve their confidence, resilience, and critical thinking, were developed by a team of experts including educationists, athletes, teacher-trainers, and psychologists. All the games were designed to meet specific learning outcomes for particular age groups of children, and then these games are compiled in the form of manuals. The games can be modified at the field level. For example, a game can be modified according to setting and environment to include a child with a disability.

These *Red Ball Child Play* and youth development activities are integrated into the school schedule through a 35–40-minute time period twice weekly. A monthly schedule for each game session is discussed within Right To Play's implementation team, the school head, and teachers. Depending on the need of the school or curriculum outcome, a game is selected and children are engaged in it by the Right To Play coach and/or teacher during these periods. For community-based programs, a mutually agreed upon timeslot is allocated to conduct these games at community settings. The Positive Child and Youth Development program has been delivered to more than 200,000 children in Pakistan.

This article outlines the methodology, issues, concerns, and essential processes of a cluster RCT to test impact on violence prevention outcomes of the Positive Youth and Child Development program that is being delivered to low-resourced children in public, urban school settings in Hyderabad, Sindh province, Pakistan.

METHODS

Study Purpose and Objectives

The primary objective of this RCT is to determine whether exposure to sport and play as practiced by Right To Play's intervention is effective in reducing experience and perpetration of violence among children and enhancing mental health among boys and girls in grade 6. The secondary objectives are to determine whether the exposure to the intervention is effective in improving school performance and attendance, reducing exposure to violence at home and corporal punishment at school, and changing gender attitudes, including attitudes toward violence, among boys and girls in grade 6.

Study Design

The study used a cluster RCT design with 2 arms. The intervention arm is receiving the full Positive Child and Youth Development program of Right To Play delivered over 2 years, beginning in January 2016 and ending in December 2017, while the control arm receives regular schooling.

Population and Setting

The study is set among 6th graders in 40 public schools in Hyderabad, Sindh province, Pakistan. We chose Sindh province for ease of access for the research team and because Right To Play has been active there for some years. Hyderabad is an accessible city (3 hours' drive from Karachi, Pakistan), large enough to give the requisite number of clusters for the study, and one in which Right To Play had not previously worked.

We selected the 6th grade for several reasons. Peak school-age perpetration and victimization occurs between the ages of 13 to 15 years.[12] Therefore, to prevent violence, an intervention is required during the pre-teenage years. In Pakistan, middle school includes grades 6–8, and so children recruited in 6th grade theoretically would be followed fairly easily for the 2 years of the trial, before leaving school completely or, if fortunate, entering a high school. Thus, we focused on initiating the intervention with 11–12-year-olds in the 6th grade and continuing through the 8th grade for maximum prevention impact. Public schools were selected to increase potential scale-up and integration of Right To Play's intervention, if proven effective, into the public, government-sponsored system of education in Pakistan.

Peak school-age perpetration and victimization occurs between the ages of 13 to 15 years, so interventions to prevent peer violence should start during the pre-teens.

Access to the schools for the research was given at 2 levels of educational administration: each individual school head Master or Mistress and the district-level administrator. We needed 40 fairly homogenous schools from which to randomize that met the criteria of having a play area where the program could be implemented and with school directors who were willing to participate and commit time during the school day, twice a week, to the intervention sessions. We identified 50 gender-specific schools that met all criteria and were willing to participate. We visited each school to assess willingness to participate, examine school facilities to assess a safe play area, and collect information on school attendance to ensure an adequate cluster sample size of youth from each school.

Inclusion criteria for schools were thus to be single-gender public secondary schools with an outside playground or indoor space in which games could be played, and to have 35 or more students in the grade-6 class who would give

consent to participate. To reduce contamination between arms, if there were more than 40 eligible schools we included only schools that were more than 1 kilometer away from the nearest other included school of that gender.

The inclusion criteria for children were that they be students in grade 6 in selected schools, obtain consent for the study from their parents, and agree to participate themselves. The youth needed to read the national language Urdu or provincial language Sindhi competently, so they could self-complete the questionnaire. Where schools had fewer than 50 children in a grade-6 class, we approached all grade-6 classes to be in the study and accepted children who gave consent. If there were more than 50 grade-6 children, we randomly selected a grade-6 section (or 2 grade-6 sections) at the school to get a number as close as possible to 35 to invite for the study. All the children in grade 6 receive the intervention, but not all are part of the research.

Power Analysis and Sample Size

The study assesses outcomes at 3 levels: peer victimization, peer perpetration, and child depression.

The study has 3 primary outcomes: the mean score on a scale measuring victimization of violence among children over the past 4 weeks; the mean score on a scale measuring perpetration of violence among children over the past 4 weeks; and the mean score on a scale measuring self-reported child depression over the past 2 weeks. All outcomes will be measured at 24 months post-baseline. We recognize that in the past primary outcomes have tended to be more narrowly defined as single measures, but there is a well-established precedent when evaluating interventions that seek to achieve multiple results that are equally important to select a small number of primary outcomes.[13–16]

A cluster RCT was required for intervention testing at the school level. A literature review revealed a small expected effect size of 0.2 difference between the mean scores of youth peer victimization and perpetration scores between intervention and control arm schools, following effective violence prevention interventions.[17] *A priori* power analysis was conducted to determine the minimum sample size and cluster sizes required to find significance with power set at 0.80, an alpha level of 0.05, and a small effect size of 0.20 (f).[18] Based on the analysis, it was determined that a minimum of 25 students per school and 20 schools per treatment and control groups were required to ensure adequate power for a hierarchical linear model.[19]

This sample and cluster size is adequate for binary and continuous dependent measures. Schools were randomly selected and then randomly assigned to either the treatment or control group. Since schools are segregated by gender, we needed 20 schools in the intervention group (10 boys' schools and 10 girls' schools) and 20 schools in the control group (10 boys' schools and 10 girls' schools). Student data were needed on a minimum of 1,000 students, 25 youths in each school, collected across 40 schools and measured yearly for 3 consecutive years to compose baseline, 12-month outcomes, and 24-month outcomes.

We learned about 20% to 30% of 12-year-old youth drop out from school, usually to marry, migrate, or join the labor force, and would therefore be unavailable to complete a 2-year study. Allowing for up to 40% attrition, we added a minimum cluster size of 35 youth per school for a minimum sample size of 1,400.

The Positive Child and Youth Development Program

The intervention is being delivered to all children in the selected schools, even though not all students are included in the research. This is in keeping with a whole-school approach and best practices with regard to school interventions.[9] Although the approach of using the transformative power of play has not been one that has been previously evaluated, the intervention could be classified as belonging to the family of interventions that seek to more generally build social and emotional capabilities in children (such as the Positive Action Program[20]), rather than focusing on addressing bullying per se and establishing bullying policies (an example of the latter being the KiVa programme[21]). Interventions within both of these categories, especially Positive Action and KiVa, have been shown to be effective, but they have not been rigorously evaluated in a setting akin to Pakistan.

Male and female coaches deliver the intervention. Criteria for coach selection include completion of an intermediate education, previous experience in working with children, a passion and willingness to participate in Right To Play's training, a positive attitude toward child protection, and living in relatively close proximity to the school where the coaches will work. The latter is advised due to scarcity and unpredictability of available public transportation. Coaches and project staff meet twice a month for discussion of

issues and challenges and further training if appropriate. Coaches are also trained to identify and mentor junior youth leaders in the schools.

The intervention for the youth follows the age-specific *Red Ball Child Play* manual. For the age group of the study participants, there are 103 learning games (activities) in the manual, which will be imparted over 2-years' time through 130 learning sessions. The sessions are organized into 5 thematic groups (known as balls) (Table 1). Red Mind Ball games are designed to enhance concentration skills among children and develop organizational skills, which help children to learn strategic thinking. Games in the Black Body Ball focus on physical development, while games with the Yellow Spirit Ball are designed to develop positive emotions, self-confidence, and hope, and to overcome negative emotions. Blue Peace Ball games are designed to promote positive emotions and control negative emotions to build healthier personalities of children. Finally, Green Health Ball games are designed to sensitize and educate children about well-being by providing knowledge and strategies to ensure good hygiene. The play-based learning activities are offered twice a week during 40-minute sessions by the coaches, who follow a curriculum of games and discussions. Each 40-minute session includes time for the students to participant in the play-based activity and then discuss to reflect, connect, and apply the content. For examples of games and discussion formats from the Blue Peace Ball and Yellow Spirit Ball, see the supplementary material.

The games are designed for play with fairly basic equipment. Further, most can be played in an indoor room, which is a requirement in some schools for girls and essential at some times of year due to heat. However, all the schools included in the study have some form of outside area in which the games can be played. This ranges in practice from a large interior courtyard to a relatively small walled space on the roof of a school. Initially the games are led by the trained coaches and later by junior leaders selected from among the children. Junior leaders are given leadership training, and they participate as assistants to the coaches, for example, by leading warm-up exercises. Sixty junior leaders (30 boys and 30 girls) were trained in accordance with Right To Play's Junior Leader Facilitation Toolkit.

Right To Play's intervention goes well beyond the *Red Ball Child Play* manual in its efforts to provide change through holistic engagement. There

TABLE 1. Development and Skill-Building Areas Addressed by the *Red Ball Child Play* Activities by "Ball" Thematic Groups

Ball Name	Symbol	Development Areas	Skill-Building Areas
Red Mind		Thinking and Intellectual Development	Awareness, Perception, Concentration, Memory, Insight, Understanding, Learning, Numeracy, Literacy, Knowledge, Strategy, Organization
Black Body		Physical Development	The Senses, Aerobic Capacity, Strength, Flexibility, Coordination, Development of Healthy Lungs, Bones, Muscles and Heart
Yellow Spirit		Feelings and Emotional Development	Self-Esteem, Optimism, Fear, Hope, Security, Humor, Coping Skills, Self-Expression, Expression of Positive and Negative Emotions
Blue Peace		Relationships and Social Development	Communication, Cooperation, Teamwork, Leadership, Empathy, Trust, Relationships With Peers, Family, and Community
Green Health		Development of a State of Well-Being	Dangers of Drugs and Infectious Diseases, Dealing With Aches, Pains, and Strains, Importance of Physical Activity, Hygiene, Diet, Sleep and Healthy Environment

The Right To Play intervention in Pakistan encouraged girls' engagement in sports by holding tournaments and community events.

The school-based intervention also engages parents and the community at large through tournaments, events, and other activities.

are also sports tournaments and thematic Play Days (for example, focused on the theme of "Stop Violence") held several times a year (each attended by about 400 people), and parents are invited to engage in these events. They serve to increase the visibility, in particular, of girls' engagement in sport. There is also selection of youth ambassadors (10 girls and 10 boys) for training on community sensitization and mobilization to prevent violence against women and girls. Youth ambassadors are the volunteer youth from the local communities who are passionate about bringing positive change in their communities and becoming active change-makers. They are provided with mentorship and leadership training by Right To Play in order to strengthen them in skills of leadership, gender equality, communication, action planning, team work, and the role of sport and play for youth development. After attending the training, these youth ambassadors go back to their communities, identify pressing challenges, and implement small-scale projects to tackle the ground-level issues, such as making safe areas for play.

In addition, Right To Play has a network of community groups and holds quarterly awareness sessions with them, including parents, on child rights, gender equality, and positive discipline. Further, there is training of teachers on Right To Play's foundational resources, positive disciplining, and gender and child protection in order to create a safer environment in and around schools. For example, midway through the first year of the intervention, 2 summer camps were held (1 camp for boys and 1 camp for girls) with the theme "Inclusion, Friendship, Equality, and Peace." Right To Play worked closely with the District Education Office who participated in the event alongside teachers, parents, and local community-based organizations. More than 200 children aged 11–14 years (50% girls) attended the camps.

The activities of Right To Play to which research participants will be exposed will continue on an ongoing basis between the start of grades 6 until the endline assessment. At that point, the intervention will then be delivered to control arm schools.

Logistics of Randomization

A public randomization of intervention and control schools was conducted to build trust and increase transparency of the research project. We invited all officials in the school district to the draw and gave them time to introduce themselves, their role, and name their school and location. We then followed the presentations with the public random draw. All schools signed an agreement of participation. Understanding all schools might desire the intervention, we offered 6 months of the intervention to all control schools following the final outcome measures. Further, we mitigated the disappointment of being a control arm school by offering control schools a water tank as an incentive. We chose this after consulting with school partners and parents and learning that all public schools in the area had a pressing need for potable water. Many schools did not have a water tank, resulting in dehydration among some youth who could not bring their own drinking water to school and the frequent need to dismiss school early due to lack of potable water.

Instruments

Instruments were selected following data analysis for the formative phase and in alignment with the primary outcomes of reducing youth perpetration and victimization and the secondary outcome of improving child mental health. Toward this end, we chose Multidimensional Peer-Victimization and Peer Perpetration Scales[22] and the Children's Depression Inventory 2 (CDI 2).[23] For food security, gender attitudes, and family life, investigator-initiated questionnaires were developed. Table 2 presents a description of all instruments used along with coefficient alpha. All instruments were forward-translated from English to Urdu and Sindhi. People who had not seen the English questionnaire and had not participated in the forward translation independently back-translated the instruments. Discrepancies were discussed

TABLE 2. Instruments to Measure Primary and Secondary Outcomes of the School-Based Positive Youth and Child Development Program, Hyderabad, Pakistan

Scale/Assessment	Characteristics	Alpha for Present Study
School Victimization and Perpetration		
Multidimensional Peer-Victimization Scale[22]	16-item measure with 4 subscales assessing physical and verbal victimization, social manipulation, and property attacks. Point values are assigned to responses: never=0; once=1; a few times=2; many times=3. Scale scores summed to a possible range of 0 to 48.	• Peer victimization overall=0.873 • Physical=0.673 • Verbal=0.642 • Social manipulate=0.696 • Property attacks=0.658
Peer Perpetration Scale[22]	16-item measure with 4 subscales assessing physical and verbal perpetration, social manipulation, and property attacks. Point values are assigned to responses: never=0; once=1; a few times=2; many times=3. Scale scores summed to a possible range of 0 to 48.	• Peer perpetration overall=0.890 • Physical=0.733 • Verbal=0.696 • Social manipulate=0.723 • Property attacks=0.716
Location and Impact of Victimization		
Peer Victimization Location and Perpetrator Characteristics Scale	6 items on frequency of victimization in locations, i.e., inside or outside of school. 3 items on characteristics of perpetrator, i.e., older or more powerful. Point values are assigned to responses: never=0; once=1; a few times=2; many times=3.	These items were not considered a subscale and alpha was not calculated.
Peer Victimization Impact	6 items on frequency of impact of peer victimization, i.e. feeling sick, not able to study. Point values are assigned to responses: never=0; once=1; a few times=2; many times=3. Scale scores summed to a possible range of 0 to 18 for impact of victimization.	Impact of victimization=0.603
Child Mental Health		
Children's Depression Inventory 2 (CDI 2) [23]	28-item self-report questionnaire to assess the severity of current or recent (last 2 weeks) depressive symptoms. Response options are rated on a 3-point scale as: 0=no symptom; 1=mild symptom; 2=definite symptom. Scale scores range from 0 to 56.	Alpha=0.725
Investigator-Derived Questions		
Corporal Punishment at School	6 items on the frequency (i.e., never, once, 2–3 times, or 4 or more times) the youth was punished by a teacher (i.e., slapped, hit or beaten, made to run, kneel or stand). Scale scores range from 0 to 24.	Alpha=0.758
Parent Fighting	3 items on frequency (i.e., never, once, 2–3 times, or 4 or more times) child witnessed parent fighting, including father violence against the mother, father violence against other adults, mother violence against other family members.	These items were not considered a subscale and alpha was not calculated.

Continued

TABLE 2. Continued

Scale/Assessment	Characteristics	Alpha for Present Study
Child Attitudes Toward Child Punishment	5 items that assess child agreement (i.e., strongly agree, agree, disagree, and strongly disagree) with events that deserve child punishment, such as disobeying parents and misbehaving at school. Scale scores range from 0 to 15.	Alpha=0.653
Child Attitudes Toward Gender Norms and Women's Participation	13 items that assesses child agreement (i.e., strongly agree, agree, disagree, and strongly disagree) with gender norms, such as girls going to school, wives obeying husbands, husbands' right to punish wives, and women's participation in social events and employment. Scale scores range from 0 to 39.	Alpha=0.738
Child Physical Punishment at Home	2 items to assess parental physical punishment frequency (i.e., never, once, 2–3 times, 4 or more times) and severity to the child at home.	Due to only 2 items, coefficient alpha was not determined.
Family Life	9 items that assess food security, parent literacy, and home assets, such as electricity and water.	Due to many of the items having a dissimilar metric and dichotomous responses, coefficient alpha was not determined.
Early Marriage	3 items that assess if the child has been promised in marriage and age of marriage of older siblings.	Due to only 2 items having a similar metric, coefficient alpha was not determined.
Child School Performance	7 items that assess academic performance (i.e., below average, average, above average), number of absences from school, and reasons for absences.	Alpha=0.642, for the 4 academic performance items that had a similar metric.

between the translators and resolved until language agreement was reached.

Procedures

Pilot Testing

Following review and approval by the Ethical Review Committee of Aga Khan University and the Ethics Committee of the Medical Research Council of South Africa, we collaborated with Right To Play organization to identify fairly demographically homogenous public schools for girls and boys, who were ages 11–12 years and in the 6th grade, who would be receptive to pilot testing the instruments. The schools also had to be in a school district geographically distant from the main study site to avoid any potential for contamination. Schools with receptive school directors and willing teachers were identified. Children in the segregated girls' and boys' schools were given parental consent forms, which when returned with parent consent enabled the researchers to obtain assent from the youth. Over 90% of the parents signed consent forms and all youth assented to the questionnaire.

The instruments were tested among 124 youth attending the 6th grade who were between ages 11 and 12. The instruments were intended to be self-administered using a paper-and-pencil version. Although the instruments were written to a 6th grade reading level, many children had difficulty reading the questionnaires. Consequently, the researchers read each question, resulting in a 2.5-hour administration period. The questionnaires were revised to reduce their length, and the interview protocol was revised so that questionnaires could be self-completed but with interviewer assistance by reading the questions aloud. This enabled the questionnaires to be completed within an hour.

Data Collection

Data were collected at baseline during November and December 2015 and will also be collected 12 months after baseline (midpoint) and 24 months after baseline (endline). Data collection for the

40 schools, with 1 facilitator who read each question to a group of 4 children, required a team of 40 data collectors, each of whom was bilingual in the national language of Urdu and the local district language of Sindhi.

Baseline data collection for the 40 schools was completed over a 60-day period, following receipt of parental informed consent and child assent. For the 40 schools, we sent home a total of 2,486 parental consent forms and received 1,858 affirmed parent consents for a return rate of 75%. Of the 1,858 forms signed and returned by the parents, 1,767 children assented for a rate of 95%. In general, more parents of girls consented than parents of boys (79% compared with 70%, respectively). A total of 1,752 youth questionnaires were completed and entered into an SPSS database.

Contact List for Retention

Integral to any longitudinal study is participant retention. To minimize attrition, a contact list was formed following a protocol for retaining abused women.[24] In addition to the home address, children were asked for parent and relative names and phone numbers so they could be contacted if they were not attending school at the time of the follow-up interviews. Participant contact details are kept under lock and key in the research office and have not been entered into a computer. Thus, there is no electronic way of connecting participant information and questionnaire responses.

Our protocol for tracking loss to follow-up is that if children are unavailable for the 12-month or 24-month follow-up interview, we will try to learn why. First, we will ask the teacher if the unavailable children are currently absent but normally present at school. If teachers respond that the children are usually present, we will make up to 3 return visits to the school to complete missing interviews. If we are unable to find the children after 3 visits, we will note the children as absent but still in school. If children are not in school, we will need to determine if the absence is due to marriage or wedding preparations, whether the children are now out of school or have transferred to another school, or whether there is another reason, such as loss of interest or refusal to attend school due to violence. To discover the reason, we will first ask the teacher and then ask the relatives or neighbors, named on the tracking form. If all strategies fail, we will visit the children's home to ask their parents.

Intervention Fidelity Monitoring

The primary responsibility for monitoring the fidelity of the intervention delivery rests with the intervention organization, Right To Play. To ensure fidelity, Right To Play monitors logs that record the dates a coach goes to a school, the game(s) played with grade 6 students, and the number of children from grade 6 participating in the intervention. This information is reported quarterly. The information is compared with the planned intervention delivery schedule and deviations flagged and sent to Right To Play for correction.

The research team is also conducting spot checks on the fidelity logs to ensure accuracy. Two research staff members are visiting each intervention school monthly on a randomly chosen day and independently collecting data on the work in the school over the previous month, including the number of days coaches came and the games played. To collect this information, research staff talk to a teacher and 3 randomly chosen grade-6 pupils.

Health and Personal Safety Protocols

Potable water and basic sanitation are major challenges in Pakistan. The geographic area of the 40 schools is located in an arid and very hot area, where temperatures of 49°C (120°F) are common. Clean drinking water and toilets are scarce at the public schools. Additionally, the journey from the University where the researchers work to the intervention schools is 3 hours each way with meager facilities for water and sanitation in transit, requiring the researchers to transport ample potable water, food, and emergency supplies for the 6-hour road journey and 6- to 8-hour work day at the schools. The 12- to 14-hour workday requires us to maintain close vigilance on hydration and fatigue level of all personnel.

For optimum safety, we follow the University safety protocol, which requires registering each trip with the University Department of Safety that assesses the level of terrorism daily and authorizes (or denies) each trip. It is not uncommon to plan and prepare for a data collection day only to be denied travel authorization, which requires cancellation with data collectors, schools, and community partners. Close adherence to health and safety was maintained throughout baseline data collection. We experienced no threats or known risks to personal safety and all staff remained hydrated.

Ethics

As mentioned previously, the Ethical Review Committee of Aga Khan University and the Ethics Committee of the Medical Research Council of South Africa approved this study. We used a multi-layer consent process. Each school principal was given an information sheet and asked to give written consent to the school's participation, including the randomization process.

Following school selection and consent from the principal, the research team met with the teachers at the school and established a day to send notices home with selected students regarding the parent's consent for child participation. Students were asked to submit their parent consent forms prior to participation. Many parents were illiterate, but previous research from Aga Khan University has shown that there is usually a relative living in the home who is literate to grade 7–8 and can read an information sheet to parents and help them sign consent. In addition, when distributing the informed consent forms to children, the forms were reviewed with the children to ensure the child could assist with reading. The researchers acknowledge this as a limitation and not ideal. However, our resources prohibited individual home visits to read the consent forms to parents or to use audio-recorded devices to be taken to the home due to safety concerns. After sufficient parental consent forms were received for a school, the research team placed the students with parental consent in a room and provided information to enable written consent to be given by the grade-6 students. Consenting students were asked to complete the tracking form and then the questionnaire. All participants are given study codes and only these are used on the questionnaires.

We recognize that the area of research on violence can generate an emotional response from research participants, possibly as a result of recalling their experiences of violence. Field staff was trained to provide immediate emotional support, and we provided back-up counseling from a psychologist if needed. The research protocol stated that should emotional responses (i.e., crying, becoming distraught) occur in the middle of a questionnaire, the questionnaire completion should be postponed. No compensation is given in the form of cash or gifts. However, refreshments (e.g., fruit and juice) are served each time participants complete the questionnaire.

In this study, we are particularly concerned about 2 serious adverse events: death and hospitalization for injury due to interpersonal violence. Our intervention is aimed at prevention of violence and so it is essential that we fully ascertain severe injury due to violence. We have asked schools to notify us if any of these occur to students at the study schools, and we will conduct a verbal autopsy on every death by having a trained nursing professional study team member visit the child's home. We will seek in the verbal autopsy any evidence that the death could have been linked to the intervention (in the intervention schools) or research. These events will be reported to the Ethical Review Committees of Aga Khan University and the Medical Research Council of South Africa as adverse events or serious adverse events indicating whether they are related or unrelated to study participation. Finally, and very importantly, our intervention partner Right To Play practices a child safeguarding policy that demonstrates its commitment to the welfare of children including treating all children equally, encouraging positive discipline strategies, and ensuring confidentiality (see supplementary material).

Baseline Data Cleaning and Validation

A validation check was conducted between the first baseline data entry and the second baseline data entry to observe possible discrepancies and to confirm them with actual item responses from the questionnaires. Once validation of the second dataset was complete, data preparation and assumptions testing was conducted.

Baseline Data Analysis

The analysis for the baseline study consisted of frequencies, percentages, and means and standard deviations of participant demographics and subscales stratified by gender in the intervention and control arms. Peer victimization and perpetration were also categorized using thresholds suggested by the U.S. Centers for Disease Control and Prevention (CDC) guidelines.[1] These guidelines define a participant score on the Peer Victimization Scale or Peer Perpetration Scale of 0 to 1 as low violence and 2 or greater as high violence.

Because this study used a randomized cluster design, sample design effects were taken into consideration when analyzing the data and the statistical analysis was treated accounting for school as a cluster. Standard errors (SE) for the means/proportions accounting for the sample design are presented in the subsequent tables. The analysis of the subscales provided comparisons of intervention and control groups by gender testing for

significant differences between intervention and control to establish whether randomization was successful. A multivariate test of each of the subscales was conducted to observe the independent effects of gender, treatment, and their interaction using random effects linear regression to account for the cluster effect of school. This trial data will be analyzed to assess whether the intervention was successful in subsequent studies. Pairwise comparisons of marginal linear predictions were conducted to evaluate multivariate group comparisons of intervention and control arms within gender groups.

BASELINE RESULTS

Background characteristics of the full sample are outlined in Table 3, specific to intervention arm and gender. On average, participants in each study group were between 12 to 13 years old, and the majority were 12 years old. We might have expected younger students to enroll in our study since eligibility criteria focused on grade-6 students, but most of the participants may have been older due to failing exams, which often occurs due to missing many school days. The mean number of people who lived in a household ranged from about 9 to 10 people for all groups. The mean number of brothers ranged between 2 to 3 for all groups as did the mean number of sisters.

Means and standard deviations of the primary outcome measures for the full sample are shown in Table 4, specific to intervention arm and gender. Boys showed a much higher prevalence for both peer victimization and peer perpetration than girls. For example, the average score for peer victimization among boys in the intervention arm was 12.32 (SE=0.58) compared with 7.89 (SE=0.47) among girls in the intervention arm. Boys had higher mean scores for child

Boys reported higher prevalence of peer victimization and perpetration than girls, as well as poorer scores on a number of mental health measures.

TABLE 3. Background Characteristics of Study Participants by Gender and Study Arm, Hyderabad, Pakistan, 2016

	Boys		Girls	
	Intervention	Control	Intervention	Control
Age				
N	446	375	480	447
Mean	12.53	12.49	12.16	12.39
SE	0.06	0.11	0.11	0.15
No. of people living in the home				
N	446	376	481	447
Mean	9.96	9.21	9.65	10.30
SE	0.20	0.47	0.27	0.41
No. of brothers				
N	443	376	483	447
Mean	2.77	2.61	2.21	2.21
SE	0.13	0.12	0.08	0.10
No. of sisters				
N	442	374	483	447
Mean	2.25	2.13	2.57	2.70
SE	0.07	0.10	0.13	0.13

Abbreviation: SE, standard error.

depression as well (11.07 [SE=0.24] for boys in the intervention arm vs. 9.52 [SE=0.43] for girls in the intervention arm). Additionally, boys reported higher negative mood and self-esteem scores compared with girls as well as more interpersonal and emotional problems. There was little difference between the intervention and control arms within gender groups. Independent sample *t* tests were conducted to observe the difference of means between intervention and control groups within gender. The results revealed that in most cases there was group equivalence across intervention and control groups within gender, all values of $P<.05$.

The Figure illustrates the percentage of participants in the intervention and control arms by gender that reported low- and high-violence perpetration and victimization at baseline before the intervention began. Based on the youths' reports and using the CDC cutoffs of 2 or more acts of violence perpetration or victimization as high-violence, the large majority of boys across study groups fell into the high-violence categories for both peer victimization and perpetration. Most girls also fell into the high-violence categories. Among the total sample of 1,752 youth (intervention and control groups combined) asked about victimization or perpetration of violence within

TABLE 4. Primary Outcome Measures Related to Peer Violence by Gender and Intervention and Control Arms, Hyderabad, Pakistan, 2016

	Boys		Girls	
	Intervention	Control	Intervention	Control
Peer victimization scale sum				
N	422	370	462	434
Mean	12.32	12.75	7.89	6.32
SE	0.58	0.89	0.47	0.60
Peer perpetration scale sum				
N	428	369	468	442
Mean	7.42	7.27	3.48	2.85
SE	0.48	0.55	0.40	0.28
Peer victimization impact scale sum				
N	435	372	482	438
Mean	3.91	3.48	3.07	2.46
SE	0.20	0.24	0.28	0.23
CDI 2 scale				
N	445	373	481	443
Mean	11.07	10.97	9.52	8.79
SE	0.24	0.44	0.43	0.32
CDI 2 Total T-score				
N	445	372	478	443
Mean	56.87	56.60	55.40	53.75
SE	0.40	0.73	0.84	0.63

Abbreviations: CDI, Children's Depression Inventory; SE, standard error.

TABLE 5. Frequencies and Percentages of Types of Peer Victimization Items by Gender, Hyderabad, Pakistan, 2016

Types of Peer Victimization	Boys, No. (%)	Girls, No. (%)
Called me bad names		
Never	387 (47.1)	596 (64.1)
Once	156 (19.0)	157 (16.9)
A few times (2 or 3)	128 (15.6)	86 (9.2)
Many times (4 or more)	149 (18.1)	91 (9.8)
Tried to get me into trouble with my friends		
Never	458 (55.7)	707 (76.0)
Once	176 (21.4)	128 (13.8)
A few times (2 or 3)	128 (15.6)	53 (5.7)
Many times (4 or more)	57 (6.9)	38 (4.1)
Took something of mine without permission		
Never	350 (42.6)	486 (52.3)
Once	208 (25.3)	196 (21.1)
A few times (2 or 3)	133 (16.2)	132 (14.2)
Many times (4 or more)	126 (15.3)	112 (12.0)
Made fun of me because of my appearance		
Never	544 (66.2)	762 (81.9)
Once	132 (16.1)	97 (10.4)
A few times (2 or 3)	88 (10.7)	43 (4.6)
Many times (4 or more)	54 (6.6)	26 (2.8)
Made fun of me for some reason apart from my appearance		
Never	490 (59.6)	713 (76.7)
Once	181 (22.0)	124 (13.3)
A few times (2 or 3)	95 (11.6)	61 (6.6)
Many times (4 or more)	56 (6.8)	24 (2.6)
Tripped me to make me fall		
Never	385 (46.8)	689 (74.1)
Once	223 (27.1)	167 (18.0)
A few times (2 or 3)	134 (16.3)	46 (4.9)
Many times (4 or more)	77 (9.4)	28 (3.0)

Continued

TABLE 5. Continued

Types of Peer Victimization	Boys, No. (%)	Girls, No. (%)
Pushed me to hurt me		
Never	399 (48.5)	634 (68.2)
Once	205 (24.9)	173 (18.6)
A few times (2 or 3)	139 (16.9)	80 (8.6)
Many times (4 or more)	78 (9.5)	40 (4.3)
Hurt me physically		
Never	497 (60.5)	720 (77.4)
Once	189 (23.0)	145 (15.6)
A few times (2 or 3)	85 (10.3)	43 (4.6)
Many times (4 or more)	50 (6.1)	19 (2.0)
Beat me so badly that I was injured		
Never	669 (81.4)	850 (91.4)
Once	80 (9.7)	49 (5.3)
A few times (2 or 3)	41 (5.0)	15 (1.6)
Many times (4 or more)	30 (3.6)	12 (1.3)
Deliberately broke something that belongs to me		
Never	462 (56.2)	653 (70.2)
Once	214 (26.0)	183 (19.7)
A few times (2 or 3)	88 (10.7)	65 (7.0)
Many times (4 or more)	56 (6.8)	26 (2.8)
Tried to make other children turn against me		
Never	376 (45.7)	557 (59.9)
Once	218 (26.5)	195 (21.0)
A few times (2 or 3)	126 (15.3)	93 (10.0)
Many times (4 or more)	99 (12.0)	84 (9.0)
Stole something from me		
Never	398 (48.4)	608 (65.4)
Once	221 (26.9)	168 (18.1)
A few times (2 or 3)	115 (14.0)	84 (9.0)
Many times (4 or more)	85 (10.3)	63 (6.8)
Refused to talk to me		
Never	478 (58.2)	597 (64.2)

Continued

TABLE 5. Continued

Types of Peer Victimization	Boys, No. (%)	Girls, No. (%)
Once	178 (21.7)	199 (21.4)
A few times (2 or 3)	97 (11.8)	83 (8.9)
Many times (4 or more)	66 (8.0)	48 (5.2)
Made other people not talk to me		
Never	485 (59.0)	655 (70.4)
Once	169 (20.6)	141 (15.2)
A few times (2 or 3)	108 (13.1)	83 (8.9)
Many times (4 or more)	58 (7.1)	50 (5.4)
Deliberately damaged something of mine		
Never	580 (70.6)	766 (82.4)
Once	142 (17.3)	94 (10.1)
A few times (2 or 3)	60 (7.3)	43 (4.6)
Many times (4 or more)	38 (4.6)	25 (2.7)
Swore at me		
Never	241 (29.3)	642 (69.0)
Once	168 (20.4)	143 (15.4)
A few times (2 or 3)	138 (16.8)	72 (7.7)
Many times (4 or more)	274 (33.3)	73 (7.8)

the preceding 4 weeks, 94% of the boys and 85% of the girls reported 1 or more episodes of victimization, with almost identical reporting percentages between intervention and control groups. Regarding perpetration of violence, 85% of the boys and 66% of the girls endorsed 1 or more behaviors of perpetration, again with almost identical reporting between intervention and control groups. Additional analyses revealed that within the boys group, 15.7% of the participants in the intervention arm and 13.6% in the control arm reported no perpetration. Within the girls group, 32.3% in the intervention arm and 35.7% in the control arm reported no perpetration. Conversely, within the boys group, only 5% in the intervention arm and 6.9% in the control arm experienced no victimization. Within the girls group, 14.3% in the intervention arm and 15.9% in the control arm experienced no victimization.

Frequencies and percentages for specific types of peer victimization by gender are presented in Table 5. It is clear that a gender difference exists for each type of victimization. Across all 16 items of the peer victimization instrument, boys reported experiencing greater frequency of types of victimization than girls while girls reported a higher percentage of the never frequency category across these items relative to boys. Pearson's chi-square tests of association confirmed these gender differences for all items ($P<.05$).

94% of boys and 85% of girls reported 1 or more episodes of peer victimization, and 85% of boys and 66% of girls reported perpetrating at least 1 of the same behaviors.

Frequencies and percentages for types of peer perpetration by gender are presented in Table 6. The results mirror the gender differences of peer victimization, with boys reporting greater frequency and type of perpetration relative to girls and girls reporting a higher percentage of the never category relative to boys. Pearson's chi-square tests of association confirmed these gender differences for all items($P<.05$).

The results of Table 7 reveal that boys had significantly higher scores on each of the 5 measures relative to girls. There was a significant difference

TABLE 6. Frequencies and Percentages of Types of Peer Perpetration by Gender, Hyderabad, Pakistan, 2016

Types of Peer Perpetration	Boys, No. (%)	Girls, No. (%)
Called another child bad names		
Never	373 (45.4)	614 (66.0)
Once	243 (29.6)	214 (23.0)
A few times (2 or 3)	118 (14.4)	70 (7.5)
Many times (4 or more)	87 (10.6)	30 (3.2)
Tried to get another child into trouble with friends		
Never	629 (76.5)	837 (90.0)
Once	119 (14.5)	68 (7.3)
A few times (2 or 3)	44 (5.4)	17 (1.8)
Many times (4 or more)	29 (3.5)	7 (0.8)
Upset or annoyed another child by taking something of theirs without permission		
Never	567 (69.0)	749 (80.5)
Once	152 (18.5)	138 (14.8)
A few times (2 or 3)	67 (8.2)	31 (3.3)
Many times (4 or more)	35 (4.3)	11 (1.2)
Made fun of another child because of their appearance		
Never	518 (63.0)	760 (81.7)
Once	192 (23.4)	126 (13.5)
A few times (2 or 3)	86 (10.5)	30 (3.2)
Many times (4 or more)	26 (3.2)	13 (1.4)
Made fun of another child for some reason apart from their appearance		
Never	506 (61.6)	733 (78.8)
Once	179 (21.8)	145 (15.6)
A few times (2 or 3)	107 (13.0)	37 (4.0)
Many times (4 or more)	29 (3.5)	14 (1.5)
Tripped another child to make him or her fall		
Never	551 (67.0)	809 (87.0)
Once	185 (22.5)	90 (9.7)
A few times (2 or 3)	61 (7.4)	20 (2.2)
Many times (4 or more)	25 (3.0)	10 (1.1)

Continued

TABLE 6. Continued

Types of Peer Perpetration	Boys, No. (%)	Girls, No. (%)
Pushed another child to hurt him or her		
Never	581 (70.7)	798 (85.8)
Once	151 (18.4)	104 (11.2)
A few times (2 or 3)	56 (6.8)	20 (2.2)
Many times (4 or more)	31 (3.8)	7 (0.8)
Hurt another child physically		
Never	628 (76.4)	858 (92.3)
Once	122 (14.8)	55 (5.9)
A few times (2 or 3)	50 (6.1)	7 (0.8)
Many times (4 or more)	19 (2.3)	9 (1.0)
Beat another child so badly that they were injured		
Never	693 (84.3)	894 (96.1)
Once	83 (10.1)	28 (3.0)
A few times (2 or 3)	24 (2.9)	3 (0.3)
Many times (4 or more)	20 (2.4)	2 (0.2)
Deliberately broken something that belong to another child		
Never	606 (73.7)	821 (88.3)
Once	165 (20.1	85 (9.1)
A few times (2 or 3)	28 (3.4)	17 (1.8)
Many times (4 or more)	22 (2.7)	5 (0.5)
Tried to make other children turn against another child		
Never	575 (70.0)	774 (83.2)
Once	167 (20.3)	126 (13.5)
A few times (2 or 3)	55 (6.7)	22 (2.4)
Many times (4 or more)	21 (2.6)	7 (0.8)
Stolen something from another child		
Never	697 (84.8)	862 (92.7)
Once	86 (10.5)	49 (5.3)
A few times (2 or 3)	24 (2.9)	9 (1.0)
Many times (4 or more)	9 (1.1)	8 (0.9)
Refused to talk to another child		
Never	500 (60.8)	627 (67.4)

Continued

TABLE 6. Continued

Types of Peer Perpetration	Boys, No. (%)	Girls, No. (%)
Once	207 (25.2)	243 (26.1)
A few times (2 or 3)	84 (10.2)	41 (4.4)
Many times (4 or more)	30 (3.6)	19 (2.0)
Made other children not talk to another child		
Never	572 (69.6)	777 (83.5)
Once	158 (19.2)	97 (10.4)
A few times (2 or 3)	63 (7.7)	39 (4.2)
Many times (4 or more)	27 (3.3)	15 (1.6)
Deliberately damaged something of another child's		
Never	665 (80.9)	861 (92.6)
Once	100 (12.2)	48 (5.2)
A few times (2 or 3)	33 (4.0)	15 (1.6)
Many times (4 or more)	21 (2.6)	5 (0.5)
Swear at another child		
Never	427 (51.9)	795 (85.5)
Once	198 (24.1)	86 (9.2)
A few times (2 or 3)	114 (13.9)	30 (3.2)
Many times (4 or more)	82 (10.0)	18 (1.9)

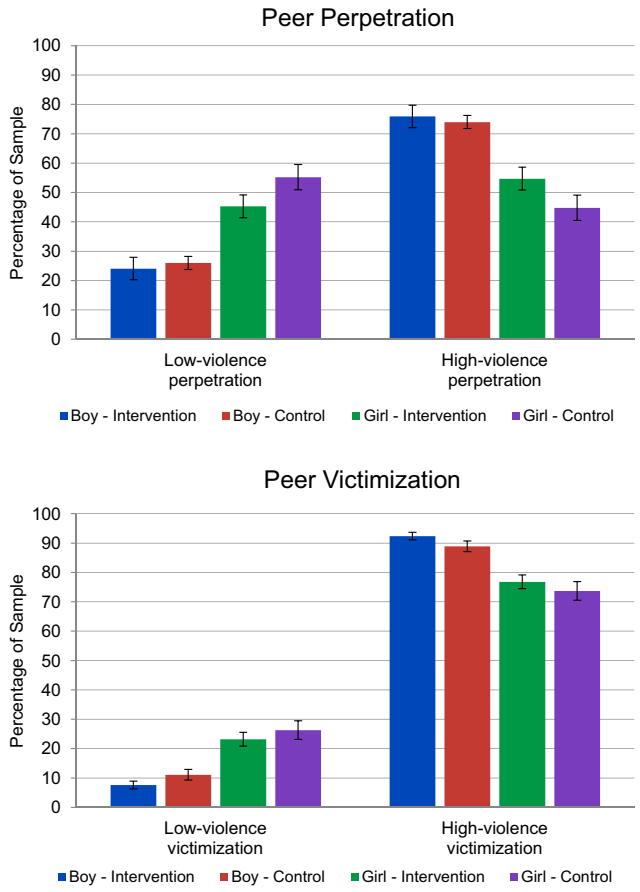
between intervention and control groups for peer victimization (β, 1.60; P=.04) but not for any of the other 4 measures. There was no significant interaction of gender and intervention in this regression (P>.05). When comparing treatment and control groups, there was only one significant comparison: peer victimization between treatment and control groups for girls (β, −1.60; P=.04). Mean difference testing revealed that group equivalence existed between intervention and control and that the randomized cluster sample design was successful.

DISCUSSION

Although we identified no studies measuring both youth victimization and perpetration among school-age youth, ages 12 to 14, with which we could compare our results, our prevalence of 89% of youth reporting peer victimization far exceeds global estimates of 50%.[1] Equally high is our finding of 75% of the youth perpetrating peer violence within the preceding 4 weeks. Although measurement time for victimization varies, other studies of school-age youth consistently report appreciably lower prevalence of victimization than we found, and the victimization is frequently defined as bullying.

For example, in the Global School-Based Health Survey for Pakistan completed in 2009 by the Ministry of Health in collaboration with the World Health Organization and the CDC, among students in grades 8–10 (slightly older than the youth in our study), overall prevalence of bullying victimization in the past 30 days was 41.3%.[25] The prevalence was 45.1% among male students and 35.5% among females. Loneliness and sleep disturbance were significantly more common among youth reporting bullying.[25] The same Global School-Based Health Survey question on bullying was administered in Thailand to youth in grades 7–9, revealing an overall prevalence of bullying

FIGURE. Percentage of Participants Exposed to Low-Violence and High-Violence Peer Perpetration and Victimization Using CDC Cutoffs[a] by Study Arm and Gender, Hyderabad, Pakistan, 2016



Abbreviation: CDC, U.S. Centers for Disease Control and Prevention.

Note: Error bars represent cluster design effect standard errors.

[a] Participant score of 0–1 is defined as low violence and ≥2 as high violence.

of 27.8% (32.9% among males and 23.2% among females). Youth who reported bullying were more likely to also report psychosocial problems.[26]

When 2,264 adolescents in Malawi were surveyed about bullying in a school health survey, almost equal percentages of boys and girls (44% and 45%, respectively) reported being bullied.[27] However, among a sample of 1,559 school-age youth in grades 7–10 in Zambia, more girls (65%) than boys (60%) reported being bullied in the past 30 days.[28]

Irrespective of prevalence, all these studies found appreciably higher psychological problems, such as anxiety, worry, and eating and sleeping disorders, among youth reporting victimization. In our study, boys reported appreciably more depression compared with girls as well as higher negative mood and self-esteem scores and more interpersonal and emotional problems. These gender differences and associations with health and functioning will be explored in future papers.

Limitations

The study is designed to evaluate Right To Play's intervention, but we can only test the intervention in one of the many countries in which it is

TABLE 7. Random Effects Linear Regression Model of Gender, Study Group, and their Interaction Predicting Key Peer Violence Scales With Pairwise Comparisons, Hyderabad, Pakistan, 2016

	Peer Victimization		Peer Perpetration		Victimization Impact		Child Depression		Child Depression T-Score	
Predictors	β	***P***	β	***P***	β	***P***	β	***P***	β	***P***
Gender, Boy (ref: female)	6.3	<.001	3.78	<.001	0.95	0.008	2.13	<.001	2.85	0.002
Group, Intervention (ref: control)	1.6	0.04	0.61	0.19	0.62	0.09	0.81	0.12	1.69	0.08
Interaction:	−1.79	0.17	−0.15	0.86	−0.08	0.87	−0.6	0.4	−1.3	0.31
Gender & Group (ref: female & control)										
Group Comparisons[a]	**Contrast**	***P***	**Contrast**	***P***	**Contrast**	***P***	**Contrast**	***P***	**Contrast**	***P***
Boys: Control vs. Intervention	0.19	0.86	−0.47	0.51	−0.54	0.09	−0.21	0.68	−0.39	0.64
Girls: Control vs. Intervention	−1.6	0.04	−0.61	0.19	−0.62	0.09	−0.81	0.12	−1.69	0.08

Note: All coefficients reported are unstandardized betas.
[a] Pairwise comparisons of marginal linear predictions

delivered. We cannot generalize our results to the whole of Pakistan, all school grades, or all Right To Play programs. However, the Pakistan program is very large and has been underway for over a decade, and so a rigorous evaluation is timely. This is an effectiveness trial and so we are monitoring fidelity to the intervention and report this information to the implementers, but in other respects we are not able to influence the fidelity of the intervention.

Pakistan may be a particularly challenging setting for evaluating Right To Play's intervention. For example, there is a serious problem in Pakistan of children not being able to attend school regularly, which impacts all school-delivered interventions. We ask about attendance in the questionnaire and important reasons for lack of attendance are lack of money for transport and a need for the children to engage in income-generating activities. There are also some difficulties with play-based activities when it is very hot, as for some months of the year it is over 40°C. Lack of food and drinking water for children also influences participation and attendance, and some children, both boys and girls, leave school early due to lack of school toilets. Days are also often lost from school due to severe weather during the monsoon, and there is often a delay in return to school after holidays. There may also be teachers' strikes. These factors will have an impact on the dose of Right To Play intervention that is delivered, and therefore considerable caution will be needed in generalizing from the study findings.

Children with disabilities are admitted to special public schools where their physical and/or emotional challenges can be accommodated and therefore are not part of this study. However, to learn if there are children with disabilities in public schools, we will ask in future interviews a series of questions related to disabilities.

Our research methodology has limitations that it may under- or overrepresent victimization, perpetration, and the functioning outcomes of the child participants. The questions may miss some episodes of victimization or perpetration and incorrectly classify others, particularly with respect to the 4-week reporting period. Children may not accurately recall the timing and type of victimization or perpetration they experienced (i.e., whether or not the exposure occurred within the last 4 weeks). The researchers acknowledge recall bias is operant in all questions.

The questionnaire focuses on a small number of measures that we believe can be more accurately recalled and reported by children and more reliably measured. This results in our failing to collect information on other impacts of the intervention. Further, the choice of a 24-month endline prevents us from studying sustainability or attrition of effect post-endline. Finally, our participants were limited to Sindhi and Urdu speakers, although these are the languages of teaching in the participating schools.

Despite these limitations, the researchers feel this study provides a framework for understanding impact of the Right To Play intervention and the most detailed and comprehensive data available on the frequency and severity of peer perpetration and victimization of grade-6 male and female children in urban public schools in Pakistan as well as associated gender attitudes and family life.

The Right To Play program in Pakistan focuses on 4 areas of child and youth development including physical, cognitive, social, and emotional components. At baseline, boys reported more depression and interpersonal and emotional problems than girls.

CONCLUSIONS

Some 89% of 6th-grade youth attending public schools in an urban area of Pakistan reported peer victimization within the last 4 weeks and 75% reported they perpetrated violence within the same time period. Evidence confirms violence against children transfers to poor health and increased mortality in adulthood as well as use of violence against women.[3,4] If girls are sexually abused in childhood, the risk for intimate partner violence doubles,[29] and women abused during pregnancy are at high risk for pregnancy

Violence against children transfers to poor health and increased mortality in adulthood as well as use of violence against women.

complications, fetal demise, and low birthweight offspring.[30] The intergenerational impact of abuse escalates from violence against children to traumatized mothers to dysfunctional offspring.[31,32]

More than 1 billion youth, 50% of the world's population, are victimized each year and more than one-third of all adult women experience violence.[33] Building the global evidence base for prevention of violence against children and women is critical if we are ever to be able to eradicate these problems and allow children and women to reach their full social and economic potential and optimal emotional well-being. In the medium-term, contributing to this evidence base enables optimum progress toward the 2030 Sustainable Development Goals.[6] This evaluation, scheduled to be completed in 2018, is poised to make an important contribution as Right To Play already has a large global footprint and extensive exposure among the more than 190 million people who live in Pakistan. Further, the intervention has the potential for enabling the next generation of young Pakistanis to live more empowered and peaceable lives, which is an incredibly important goal in a country that has been wracked by decades of political, religious, and criminal violence.

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FIELD ACTION REPORT

mJustice: Preliminary Development of a Mobile App for Medical-Forensic Documentation of Sexual Violence in Low-Resource Environments and Conflict Zones

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The MediCapt mobile app has promise for clinicians to capture medical and forensic evidence of sexual violence and securely transmit the data to legal authorities for potential use in prosecution. We believe this application broadens the traditional scope of mHealth to collecting evidence, and thus name it mJustice.

ABSTRACT

Digital health development and use has been expansive and operationalized in a variety of settings and modalities around the world, including in low- and middle-income countries. Mobile applications have been developed for a variety of health professionals and frontline health workers including physicians, midwives, nurses, and community health workers. However, there are no published studies on the development and use of digital health related to human rights fieldwork and to our knowledge no mobile health platforms exist specifically for use by frontline health workers to forensically and clinically document sexual violence. We describe a participatory development and user design process with Congolese end-users of a novel human rights app for clinicians intended to standardize the documentation of sexual violence evidence for forensic and legal purposes, called MediCapt. The app, yet to be launched and still in the future proofing phase, has included several development phases: (1) initial needs assessment conducted in 2011, (2) prototype development and field-testing in 2014 with 8 Congolese physicians, (3) prototype refinement and field-testing in 2015 with 9 clinicians. Feedback from the first field-testing phase was incorporated into the design of the second prototype; key features that were added to MediCapt include the ability for users to take photographs and draw on a pictogram to include as part of the evidence package, as well as the ability to print a form with the completed data. Questionnaires and key-informant interviews during the second and third field-testing phases revealed overall positive attitudes about MediCapt, but multiple perceived and actual barriers to implementation were identified, from personal behaviors, such as individual clinicians' comfort with new technology, to more systemic and infrastructure factors, such as strong cultural preferences for print documentation of evidence and limited Internet connectivity. Next phases of development include consideration of patients' acceptance of this technology, how it actually fits in the clinical workflow, and testing of how to transfer the collected evidence to law enforcement and legal authorities. Ultimately, we plan on conducting a robust evaluation to assess effectiveness of the app on medical, legal, and human rights outcomes. We believe our experience of collecting data that will potentially serve as legal evidence broadens the traditional scope of digital health and crosses a wide range of fields including medical, technological, legal, and ethical, and thus propose refining and defining this unique field of exploration as mobile justice, or mJustice.

INTRODUCTION

The move toward a technology-centered world has changed the way we practice medicine and public health. This is manifested by the rapid expansion in the field of digital health, which concerns the "use of information and communications technologies to improve human health, healthcare services, and wellness for individuals and across populations."[1] Within this broad field is the mobile health (mHealth) component that

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specifically uses mobile technologies such as mobile phones and personal digital assistants (PDAs).[2]

Between 2002 and 2016, an increasing number of digital health interventions were implemented around the world, many of them in developing countries.[3] These projects have been developed for health professionals including frontline health workers (FHWs) such as physicians, midwives, nurses, and community health workers.[4–6] A recent review found that digital health use enhances various aspects of FHWs' work activities and, in particular, that mobile phones help with data collection, reporting, communication, and health care delivery.[4] However, most digital health projects in low- and middle-income countries are conducted at relatively small scale, in the form of pilot projects, and the evidence for a positive impact on health outcomes of many such pilots is mixed.[2,7–10]

Although digital health has experienced rapid expansion in recent years, there are no published studies on the development and use of digital health for human rights fieldwork. The gray literature reveals several existing smartphone and tablet applications (apps) related to human rights, but the majority provide educational and news materials[11] and are not used for clinical or forensic data collection purposes.

Extensive conversations with leaders in the field suggest there are 3 categories of technology tools being used in human rights communities: (1) those created to assist activists to gather information and documentation to expose or highlight violations, such as WITNESS' Video as Evidence program[12] and Benetech's Martus tool[13]; (2) those aimed at securing or enhancing communication among activists and even providing protection, for example, Amnesty International's Panic Button app[14]; and (3) those directed at collecting, analyzing, and preserving evidence of crimes that could be admissible in a court, such as the International Bar Association's eyeWitness to Atrocities app.[15] To our knowledge, no mobile health platforms have been developed specifically for use among FHWs to forensically and clinically document human rights violations, specifically sexual violence. Since these data would potentially serve as evidence admissible in courts, we consider this a new niche in the digital health field of data collection—one we propose terming mobile justice, or mJustice.

In 2011, Physicians for Human Rights (PHR)—a U.S.-based NGO—launched the Program on Sexual Violence in Conflict Zones. One of the main activities of the program involved the development of a multisectoral training program for health, legal, and law enforcement professionals intended to enhance the forensic documentation and reporting of sexual violence incidents in the Democratic Republic of the Congo (DRC) and Kenya, among other places. Another major activity of the program has been to advocate the standardization of sexual violence medical information collection.

To that end, PHR, in conjunction with its local medical, law enforcement, and legal partners, has developed a Standard Sexual Violence form that is being used in parts of eastern DRC. The paper-based medical form was developed in-country with input from a network of doctors, lawyers, judges, and law enforcement officials, along with visiting international human rights scholars, practitioners, and experts. The information captured in the standard medical form is particular to the DRC and conforms to the local rule of law. The guiding principle behind the development of the form is that if the standard medical form is properly completed by a health professional trained in forensic medical evidence collection, more evaluations will be admissible in court, and consequently the success rate of prosecutions of sexual violence crimes will increase.

Most existing mobile apps in the human rights field focus on providing educational and news content.

One of the major problems with the paper form of the standard medical certificate is the lack of proper storage, preservation, and ability to transfer it securely to the police and justice sector. Digitizing the standard medical form minimizes the chances of loss or theft of medical evidence, while preserving chain of custody. With these considerations in mind, we aimed to develop a smartphone-based app, called MediCapt.

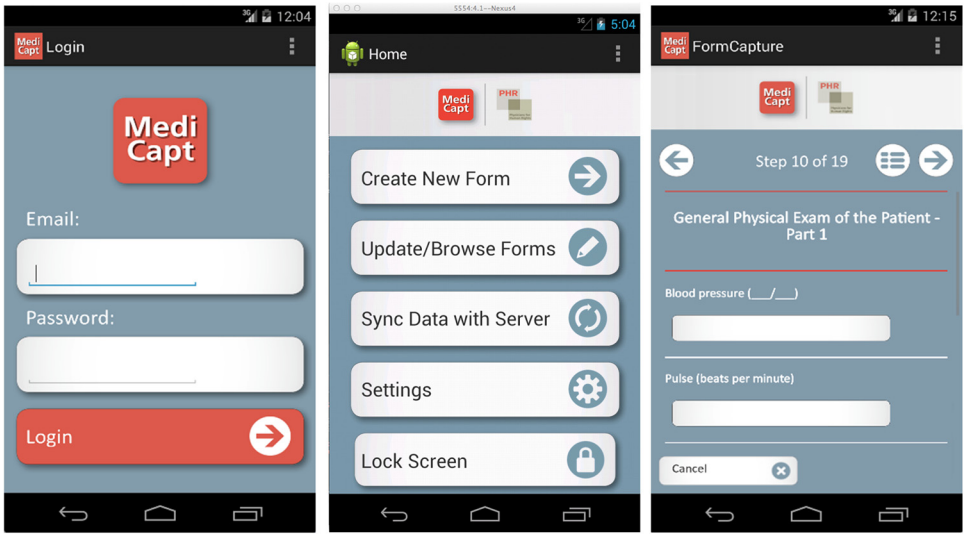
In this article, we describe the early development phases of MediCapt, a first-of-its-kind forensic app, via a participatory design process[16] with physicians from the DRC who work with survivors of sexual violence, as well as present qualitative findings on their feedback on how to improve the technology and user experience (Figure 1).

PARTICIPATORY DESIGN METHODS

We propose defining the use of digital health technology to collect human rights-related evidence that could potentially be admissible in courts as mJustice.

MediCapt is being designed with 2 goals in mind: (1) to enable health care providers to gather and compile medical evidence related to sexual violence in a standardized manner, and (2) to securely transmit the evidence to authorities engaged in prosecuting and seeking accountability for such crimes (such as investigating officers, gender desk officers in the police force, as well as

FIGURE 1. General Architecture of the MediCapt App



The screen on the left shows the home screen; the middle screen is the main menu that allows users to complete a new sexual violence form, browse saved forms, and sync their data when connected to the Internet; and the screen on the right shows an example of data-entry fields.

MediCapt, a smartphone-based app, is intended to enable health care providers to gather medical evidence related to sexual violence and securely transmit that evidence to legal authorities.

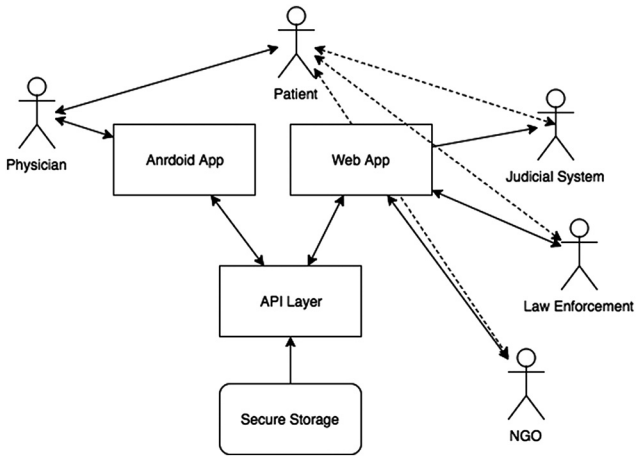
prosecuting lawyers, magistrates, and judges from the civilian and military justice sectors). MediCapt is meant to circumvent systemic and structural barriers to gathering and sharing evidence related to sexual violence that is particular to low-resourced environments, including conflict zones, by giving health care providers a platform to share that evidence (Figure 2). Although potential end-users of the app cross multiple sectors including the medical, law enforcement, and legal fields, we are focusing initially on meeting the needs of the medical data collectors—the clinicians—and assessing whether the app can be effectively integrated into their workflow.

As highlighted by several studies[3,4,7] and the Principles for Digital Development,[17] digital health tool development and implementation benefit from the active engagement of the intended end-users. Development of the MediCapt app to date has included several phases, each involving engagement of intended end-users, including (1) an initial needs assessment, (2) prototype development and field-testing, and (3) prototype refinement and field-testing. Table 1 reviews the MediCapt development process using the Principles for Digital Development as benchmarks, illustrating that our development process closely followed and incorporated many of these benchmarks.

Phase I: Needs Assessment

Between January 2011 and October 2011, we conducted 2 needs assessments in eastern DRC to explore general approaches to the documentation of sexual violence. A multidisciplinary team of U.S.-based clinical, legal, and policy experts conducted key informant interviews with several stakeholders at various sites, including clinicians at 3 major hospitals in Bukavu and Goma; members of local NGOs; lawyers and police officers; and civilian and military justice officials. The interviewees were asked open-ended questions about barriers, gaps, and deficits, each in their respective fields, when encountering cases of sexual violence. The interviews, conducted in French via translators, were summarized and the multisectoral input was used to design PHR's sexual violence program, training workshops, and the paper-based Standard Sexual Violence form.

FIGURE 2. Flow of Sexual Violence Evidence Using the MediCapt App



Abbreviation: API, application programming interface.

Phase II: Prototype Development and Field-Testing

Between October and December 2013 we converted the paper-based Standard Sexual Violence form to digital format (MediCapt 1.0) using simple logic features through the Magpi platform (http://home.magpi.com/).[18]

Magpi—one of the leading public health mobile open-source data collection platforms in the world—was selected initially because it was a third-party platform allowing for both the collection and aggregation (and eventual analysis) of data. It was especially appealing because non-programmers could easily develop customizable forms on the application and the interface was user-friendly.

MediCapt was developed for use on Android phones (and can also run on Android tablets) because of their availability in the DRC, the ease of developing and building Android applications, and the easy-to-use and high-quality cameras on Android phones that allow for the collection and storage of photographs alongside other digital data files.

In January 2014, we invited 8 Congolese physicians who had previously participated in PHR's sexual violence training sessions on medico-legal documentation to participate in a 2-day session to test the MediCapt 1.0 prototype. The session included training on how to use an Android phone, explanation of the Magpi platform, practice using the MediCapt app, and a focus group discussion on the experience, functionality, usability, and feasibility of the app in its early, prototype form. During the focus group discussion, we encouraged clinicians, using open-ended and semistructured questions, to describe what features they deemed important and would like to see in a future version. A questionnaire was administered to participants assessing their background characteristics and general experience with the use of smartphone technology.

Following the 2-day session, physicians were asked to use the prototype app while completing mock patient scenarios and to send feedback to the U.S.-based development team. The collective input was used to design the next prototype, MediCapt 2.0.

Phase III: Prototype Refinement and Usability Assessment

In January 2015, we invited 9 clinicians who had previously participated in PHR's multisectoral documentation training—3 of whom had used MediCapt 1.0—for a 1-day session with members of the MediCapt development team. The session included a demonstration of MediCapt 2.0, an examination of new and desired features, and in-depth key informant interviews about clinicians' workflow and perceived barriers to the use and

TABLE 1. MediCapt Development Process Compared With Principles for Digital Development Benchmarks

Principles for Digital Development[16]	MediCapt Development Process
Design with the user	
Develop context-appropriate solutions informed by user needs	✓
Include all user groups in planning, development, implementation, and assessment	✓
Develop projects in incremental and iterative manner	✓
Design solutions that learn from and enhance existing workflows, and plan for organizational adaptation	✓
Ensure solutions are sensitive to, and useful for, the most marginalized populations: women, children, those with disabilities, and those affected by conflict and disaster	✓
Understand the ecosystem	
Participate in networks and communities of like-minded practitioners	✓
Align existing technological, legal, and regulatory policies	✓
Design for scale	
Design for scale from the start, and assess and mitigate dependencies that might limit ability to scale	✓
Employ a systems approach to design, considering implications of design beyond an immediate project	✓
Be replicable and customizable in other countries and contexts	Planned
Demonstrate impact before scaling a solution	In process
Analyze all technology choices through the lens of national and regional scale	✓
Factor in partnerships from the beginning, and start early negotiations	✓
Build for sustainability	
Plan for sustainability from the start, including planning for long-term financial health	In process
Utilize and invest in local communities and developers by default, and help catalyze their growth	Not done
Engage with local governments to ensure integration into national strategy, and identify high-level government advocates	✓
Be data driven	
Design projects so that impact can be measured at discrete milestones with a focus on outcomes rather than outputs	In process
Evaluation innovative solutions and areas where there are gaps in data and evidence	✓
Use real-time information to monitor and inform management decisions at all levels	Planned for future
When possible, leverage data as a by-product of user actions and transactions for assessment	Planned for future

Continued

TABLE 1. Continued

Principles for Digital Development[16]	MediCapt Development Process
Use open data, open standards, open source, open innovation	
Adopt and expand existing open standards	Partially done
Open data and functionalities, and expose them in documented APIs	✓
Invest in software as a public good	✓
Develop software to be open source by default with the code made available in public repositories and supported through developer communities	Planned for future
Reuse and improve	
Use, modify, and extend existing tools, platforms, and frameworks when possible	✓
Develop in modular ways favoring approaches that are interoperable over those that are monolithic by design	✓
Address privacy and security	
Assess and mitigate risks to the security of users and their data	✓
Consider the context and needs for privacy of personally identifiable information when designing solutions and mitigate accordingly	✓
Ensure equity and fairness in co-creation, and protect the best interests of the end-users	✓
Be collaborative	
Engage diverse expertise across disciplines and industries at all stages	✓
Work across sector silos to create coordinated and more holistic approaches	In progress
Document work, results, processes, and best practices, and share them widely	✓
Publish materials under a creative commons license by default, with strong rationale if another licensing approach is taken	✓

Abbreviation: API, application programming interface.

integration of this revised tool in the clinical setting. Participants also completed a questionnaire that included questions about background characteristics of the participants and attitudinal questions that were informed by the use of an implementation science framework.[19] Attitudinal responses were examined using a 4-point Likert scale and captured several domains of implementation including: (1) experience with smartphone-based MediCapt; (2) experience with tablet-based MediCapt; (3) usability of MediCapt; (4) appropriateness of MediCapt; (5) acceptability of MediCapt; and (6) feasibility and sustainability of MediCapt.

Data Analysis

Members of the PHR-MediCapt development team, comprising clinicians, human rights lawyers, and technical experts, conducted the focus group discussions and key informant interviews during phases II and III. Qualitative data were analyzed for emergent themes that could be used to directly improve the technology and user experience of MediCapt. In the Phase III questionnaire, Likert-scale responses from the phase III questionnaire were recoded to numerical values (I strongly disagree=1; I disagree=2; I agree=3; I strongly agree=4) and averaged across

Congolese clinicians at Panzi Hospital in the Democratic Republic of the Congo participate in the collaborative design process of MediCapt.

participants to create mean scores for each question. We then transformed all Likert scale responses onto a 0–1 scale to ease interpretation, with 0 representing the least level of agreement and 1 representing greatest level of agreement.

Data were entered into Microsoft Excel and analyzed using SAS statistical software. Written consent was obtained from all participants. The questionnaire and protocol were reviewed by the Institutional Review Board (IRB) of RTI International.

FINDINGS

Needs Assessment Findings

Interviews with representatives from the medical, legal, and law-enforcement sectors revealed the following themes:

1. Forensic medical exams are rarely conducted or they are conducted poorly.
2. Medical charts fail to document findings sufficiently.
3. Storage and preservation of data are limited or nonexistent.
4. Aggregate data analysis is difficult to impossible to conduct due to gaps in storage.
5. Communication breakdowns between sectors (medical, law enforcement, legal) occur frequently.

During field-testing of a MediCapt prototype, 7 of 8 users thought such an app would have a positive impact on bringing sexual violence cases to justice.

Informed by the identified gaps, the objectives of PHR's sexual violence program evolved to address a number of other areas in addition to enhanced collection of evidence, including workforce development, strengthened reporting and dissemination of cases, enhanced communication between various sectors, and improved future surveillance and early detection.

Feedback on the MediCapt 1.0 Prototype

The focus group participants during the first prototype testing phase (N=8) were clinicians (n=5) or data managers (n=3), and the majority (n=7) practiced in a hospital (the other 2 worked in a mobile clinic). Almost all participants (n=7) were younger than 50 years old, and there was no gender discrepancy (half were men and the other half were women).

When asked about previous use of mobile phones, 6 respondents indicated they had ever used a *regular mobile phone* in the past, while 5 reported having used a *smartphone* (these types of phones were defined on the questionnaire). All participants said they were currently using a mobile phone (6 use only a regular mobile phone and 2 use both a regular mobile phone and smartphone). Half of the health workers indicated they felt very comfortable using both a regular mobile phone and a smartphone, and only 1 worker reported feeling very uncomfortable using them. In addition to making and receiving calls, the other most common reasons that health workers report using their phones were to send and receive texts (n=6 for regular phones; n=4 for smartphones), take photos (n=5 for regular phones; n=4 for smartphones), and connect to the Internet (n=3 for regular phones; n=4 for smartphones).

Participants were also asked to select their level of agreement with several statements related to their confidence in using the MediCapt technology and their beliefs about sexual violence documentation. The majority (n=7) of the respondents felt confident that they could master the use of both a smartphone and a mobile application. All the respondents believed that a mobile application would be useful in their professional work and practice in the future. When asked about documentation of sexual violence evidence, all but 1 health worker believed that documenting evidence of sexual violence using a mobile phone would have a positive impact on bringing sexual violence cases to justice and that the documentation should include an option to take photos of physical findings.

During the focus group discussion, participants provided feedback about what they thought were important features to include in the MediCapt app based on priority level (i.e., must-haves, should-haves, and could-haves) (Box). Some of the must-have features were foundational features of the first prototype, namely that it provided a digitized version of the paper-based Standard Sexual Violence form and offered secure data encryption. Some other features identified by participants as high priority were incorporated into the next iteration of MediCapt. For example, version 2.0 included the ability to take, store, and transmit photos as part of the evidence package, as well as a pictogram of the body that clinicians could draw on with the touch screen to identify parts of the patient's body affected by the assault (Figure 3). In addition, the participants deemed it necessary to have some type of physical, recognizable manifestation of the data entered into MediCapt—that is, a printed form—in order to document and store the information in health care facilities' print files and also because patients expect to receive a hard copy of their charts. Thus, in version 2.0 we added printing capabilities to allow clinicians to print a form with the completed data if needed.

Many of the features that users identified as important to include in the next iteration of MediCapt were not possible using the Magpi platform. After conducting a mapping exercise of existing technologies and platforms, we determined there were no off-the-shelf technology platforms that met these articulated needs. Therefore, we decided to develop a unique app from scratch.

BOX. User Feedback on Desired Features in the MediCapt App by Priority Level

Must-Have Features:

- Digitized version of the paper-based Standard Sexual Violence form
- Photo capture capability
- Secure data encryption
- Storage and transmission of data
- Chain of custody preserved
- Geocoding ability
- Printing capability
- Writable pictogram of the body to draw on with touch screen

Should-Have Features:

- Ability to link photo of injury to pictogram image
- Capacity to take photographs as clinician conducts the medical exam
- Ability to annotate photograph
- Option to insert e-signature
- Ability for patient to indicate his/her informed consent

Could-Have Features:

- Scanner feature
- Voice recognition
- Ability to audio record patient's narrative

Usability Assessment of MediCapt 2.0

All 9 participants in the Phase II usability assessment were physicians practicing in various locations within the Eastern DRC and had spent at least 3 years conducting sexual assault examinations. The majority (n=5) had previous experience using apps on a smartphone, and some had used a camera on a phone (n=3) or a digital camera (n=4).

More than half (n=5) of the respondents reported taking forensic photographs while conducting sexual assault examinations. Of those who ever used a smartphone (n=5), the most popular
app was the camera app (n=3) and WhatsApp (a free messenger service) (n=2).

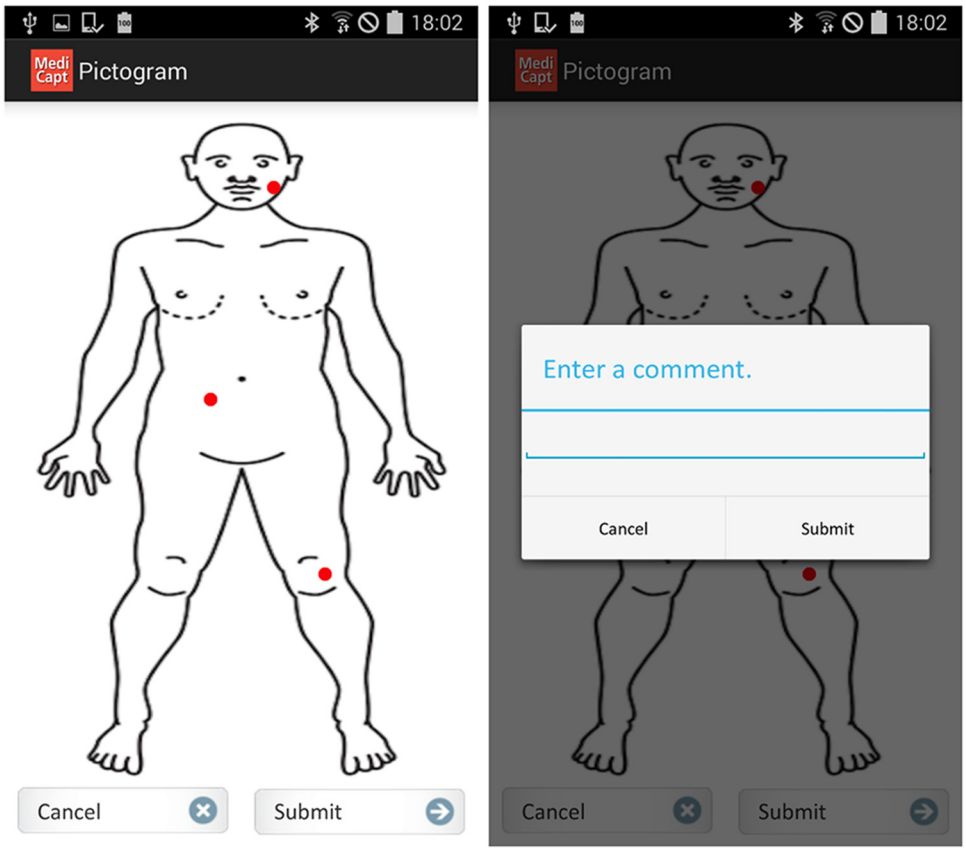
Attitudinal Questionnaire

Overall, respondents had slightly less positive **usability** ratings for using MediCapt on smartphones compared with tablet devices (Supplement Table). However, participants reported greater ease with holding the smartphone than the tablet and greater suitability of the smartphone for documenting sexual assault examinations. Respondents thought it was easy to take photographs with both the smartphone and tablet.

Respondents had favorable responses to items within the **appropriateness** domain (Supplement Table). In particular, respondents had positive opinions concerning the promise of MediCapt in helping personnel do a better job of documenting sexual assault and saving time in conducting sexual assault examinations.

User testing of the MediCapt protoype informed design of the next iteration including addition of photography, pictogram, and printing features.

FIGURE 3. Pictogram Feature in the MediCapt App to Document Location and Type of Injuries



Left: The provider can show the location of the patient's injuries on a pictogram, shown with red dots.

Right: The provider can also include additional clinical data (e.g., type, size, and depth) about a specific injury.

In the **acceptability** domain, respondents indicated (1) they would likely need special training in order to use MediCapt with a patient during an exam, (2) there would be cases where they would not use MediCapt with a sexual violence patient, and (3) existing practices of completing a paper-based medical certificate for examinations of sexual violence patients may make acceptability of technology more difficult (Supplement Table). Still, respondents had generally favorable attitudes about their patients accepting use of MediCapt during examination and feeling comfortable themselves with using MediCapt in clinical practice.

Regarding **feasibility and sustainability,** the largest area for improvement was that additional measures would need to be put into place to make sure the device gets used (Supplement Table). In particular, the respondents perceived it would be difficult to get reliable Wi-Fi or Internet access to transmit the files or even to have electricity to be able to charge the phones daily. In this domain, the most favorable responses were that (1) the respondents could foresee using MediCapt at their health care center, (2) they could train other colleagues on how to use MediCapt, (3) MediCapt would save time in documentation, and (4) MediCapt would ensure records are transferred to the appropriate law enforcement and legal personnel. In addition, the respondents generally felt that MediCapt was intuitive to use—even though their responses in

the acceptability domain suggested they needed special training to use the app.

Overall, the highest positive ratings were related to the helpfulness of the app in documenting sexual assault examinations and the ease with which they could take forensic photographs using MediCapt. The lowest ratings were related to smartphone size (too small), tablet size (too large), ease in learning to use MediCapt during an examination, and feasibility of adopting MediCapt for use in practice.

Key Informant Interviews

Key informant interviews identified multiple barriers to integrating MediCapt into the workflow in their respective health centers, which fell into 3 groups: infrastructural, systemic and organizational, and personal behavior (Table 2). The main barriers related primarily to contextual elements such as the strong cultural preference for the provision of stamped paper copies. It was noted by all interviewees that various stakeholders (e.g., patients, police) fully expect to have a hard copy of the report; also noted was the existing habit of documenting the findings in multiple places including the medical chart, carnet (small booklet containing a patient's medical information that the patient keeps), and the Standard Sexual Violence form.

DISCUSSION

We describe a collaborative development and design process with Congolese end-users of a novel human rights app for clinicians intended to standardize the documentation of sexual violence for forensic and legal purposes. NGOs working at the global, regional, state, and local levels are increasingly looking to mobile technology as a tool for the collection of documentation and evidence. To the best of our knowledge, this is the first report of a digital application in the field of human rights and forensic medicine designed specifically to incorporate local legal and forensic needs.

Current State of Development of the MediCapt App

In its current state, MediCapt is an Android-based app built with a NoSQL, eventually consistent database platform called Couchbase. Eventually consistent means changes made on 1 machine with a copy of the database, such as a user's mobile app, will eventually be transmitted to all other machines with that database, thus allowing the mobile app to work in cases without Internet connectivity through delayed, secure upload of information to the web-based system for use by external parties, such as police and justice officials.

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Documentation of sexual violence cases in the Democratic Republic of the Congo commonly entails use of several paper forms, including general ledgers, patient charts, and carnets.

All medical records, photos, and diagrams are stored using 256-bit Advanced Encryption Standard (AES) encryption. To ensure authenticity, metadata, including geolocation, network connectivity, and several other phone or tablet sensor data, are available. All activity is logged, and access is roles-based for security and authenticity. The photography technology relies on built-in hardware intended to bypass regular system storage to protect against access to the underlying data. For security and confidentiality purposes, the photos are stored within the local database on the app and *not* within the photo gallery of the phone.

Going Paperless

User feedback on MediCapt highlighted the challenges with successfully transitioning workflows from paper-based systems to digital data. In the DRC, one important issue is the lack of electronic health record systems in most health care settings. Clinical encounters, even if captured digitally, still have to be printed and stored in paper forms and in existing paper charts. This creates additional steps for app users, rather than simplifying the process. Moreover, material restrictions (e.g., lack of available printers and ink, copiers and supplies, interruptions in electricity and wireless services) further complicate this transition. The

During a second round of field-testing, users suggested the main barriers to integrating MediCapt into their workflows would be shifting cultural preferences for stamped paper copies of sexual violence evidence collection.

TABLE 2. Barriers to Integrating MediCapt Sexual Violence Documentation App Into Existing Workflows Reported by Key Informants (N=9)

Type of Barrier	Examples
Infrastructural	• Frequent periods with no electricity
	• No Wi-Fi availability during electricity stoppage time
	• Lack of clarity regarding data storage, cloud location, and capacity
	• Limited or no availability of printers and copiers and their associated supplies
Systemic and organizational	• Questions regarding organizational support of project (at hospital, district, regional, and national levels)
	• Long-standing workflow practices that promote redundancy and inefficiency (need for multiple copies including the patient chart, carnet, and Standard Sexual Violence form)
	• Need to train multiple clinicians in using app and allowing clinicians time off for training
	• Limited or no availability of electronic medical record system or links to hospital archives
Personal behavior	• Educational barriers for technology use (minimal)
	• Personal leadership attributes that affect workflow within health care facility
	• Presence of and ability to negotiate perceived jealously and peer resentment
	• Degree of willingness to try new things
	• Degree of willingness to invest more time initially in learning and using app

Lack of electronic health record systems in the DRC poses an important challenge to transitioning workflows from paper-based systems to digital data.

expectation of other sectors and stakeholders (patients, police, administrators) to receive paper copies of sexual violence reports is another issue to overcome in digital data collection and recordkeeping. To address these issues, we have added a Bluetooth-based printing capability, so that clinicians can print the completed forms and give them to the patient at the point-of-care, or any other stakeholders, when requested. At this point in time, we have yet to transfer data to law enforcement or legal authorities. Later phases of MediCapt development will include the transfer of these data to the police, then to local lawyers and judges, but only after specific training of these sectors. Any efforts to implement use of this app in its paperless form will have to include the education and buy-in of multiple players.

Data Security, Privacy, and Safety

Digital health technologies produce digital evidence, which is often difficult to manage and poses issues related to data security.[20] Data security and privacy were issues that arose early on with participants, owing primarily to the sensitive nature of the information and evidence collected. National or regional regulations with clear legal and policy guidelines are yet to be developed in that setting to ensure medico-legal data are properly protected, transmitted, and stored. Once information is collected by MediCapt in the clinical setting, there remain challenges in ensuring that it is correctly transmitted to the police officer responsible for the case, while adhering to a battery of password protections and other security measures to safeguard the sensitive documentation. This handover is a significant hurdle to consider as we seek to launch the app. We also are considering other unique challenges and pressing questions related to using digital technology for forensic data collection and documentation including how different legal systems permit or exclude electronically stored evidence, what responsibility the developers have to the end-users who may be

under great security threats as they use the app to collect forensic evidence, and who ultimately owns the information.

It is important to consider that currently common practice means that sensitive documentation (medical records, court records) are kept in the open, piled up on desks, or strewn on the floor in clinics, hospitals, and court facilities for anyone to access, compromise, or destroy. MediCapt aims to bring some measure of security and protection to ensure those records are stored in a secured, encrypted space, allowing only those key individuals with passwords to access the sensitive materials. There is a risk that third parties may hack into the system where the aggregated and consolidated sensitive materials are stored. However, we have retained a dedicated expert to build out strong security mechanisms to minimize that risk. We are also retaining an independent security expert to run a security audit to expose any potential weaknesses or gaps in the system. And we plan to make the app open-source code to allow for the widest opportunity for independent technologists to test and maintain the code and help us identify and rectify any issues that may arise.

Partnerships and Operational Capacity

The MediCapt development process has highlighted the importance of building an app within a larger ecosystem of training and partnerships and within an enabling environment. In the participatory context of this endeavor, MediCapt represents 5 years of ongoing conversations and feedback with professionals responsible for the collection of forensic evidence in sexual assault cases. Because the tool itself is a digital version of the documentation codeveloped and tested in-country, the Standard Sexual Violence form itself is known to end-users as credible and acceptable in local courts. Moreover, PHR has worked with key stakeholders in the hospitals and police force, as well as with justice officials at the grassroots level and government and ministry leaders at the highest levels. This has helped PHR and the MediCapt development team obtain the national political investment necessary to be able to pilot the app.

The participatory context of MediCapt's development and its alignment with local legal and regulatory policies places a premium on long-term, strategic, political, and technical investment in the stakeholders and the community where the app will be used. The challenge, of course, is the organization's ability to do that in other countries and settings and raises the question of scaling up and disseminating the app in a meaningful way elsewhere.

Another challenge is the need to invest heavily in technical human resources not only in the design phase but also at launch to make sure there is a dedicated IT person on the ground for troubleshooting at each point of use (at the hospital, police station, or court). This may be particularly burdensome for NGOs that are not traditionally used to handling and managing long-term technology projects.

Such organizations are advised to work closely with partners who have technical, political, and financial expertise from the earliest stages of the initiative, even before embarking on technological design. The use of validated toolkits will help anticipate and mitigate common hurdles experienced by many in the mHealth field. A particularly useful one is the mHealth Assessment and Planning for Scale (MAPS) toolkit—a self-assessment tool that guides project teams when developing or scaling up their innovations.[21]

Building for Sustainability

We have developed and built out MediCapt so that it can be scalable. This article describes early phases of development of the app in the DRC. However, we are working on extending the MediCapt pilot to Kenya in the near future, and comparing the experiences of users in these 2 very different settings. MediCapt has been designed to be ultimately used in many countries and it has been future-proofed to allow custom configuration of any standard national forms documenting not only sexual violence but also other kinds of human rights violations including torture, as well as configuration in multiple languages.

Limitations

Our study has several weaknesses. First, our project was carried out with a small number of participants in a unique setting with its own cultural and structural barriers. While this approach is appropriate for the specific purpose of obtaining qualitative feedback from intended end-users on prototypes and we believe our conclusions to be useful in informing future iterations of the app, the findings cannot be generalizable to other locales, sectors, and clinical data collection purposes. Second, during this pilot phase, we did not compare data collection with the app with the current standard process

of collecting data with paper forms to assess accuracy, completeness, and ease of use, among other possible outcomes. We plan to evaluate these issues in the near future, via a "standard practice" control group. Finally, our participants' input and experience may not reflect those of others in their field or geographic location because of inherent differences in education, technological savviness, and technical expertise.

CONCLUSION

Despite the increased usage of digital health applications, the majority have not been tested and properly evaluated.[22–24] Our article describes the preliminary user feedback on a mobile app in development, MediCapt, to document sexual violence evidence for forensic and legal purposes. In order to assess the efficacy and effectiveness of the app, a robust monitoring and evaluation process has been developed and will be carried out longitudinally. Determining the true impact of MediCapt on medical, legal, and human rights outcomes will require years of study and certain methodological revisions.

It is critical for the human rights and technology communities to explore together the technological, legal, and ethical issues posed by use of digital technology to document human rights abuses.

It is critical that the human rights and technology communities come together to explore these issues that cross a wide range of areas—not only technological but also legal and ethical. Future consideration and development of operational, technical, and legal frameworks may help NGOs ensure that the collection of evidence and documentation of human rights abuses using digital technology is done in a manner that enhances local capacity, strengthens documentation, reduces risks to the documenter, survivor, and witness, and promotes human rights principles and justice.

Finally, whereas digital health, and specifically mHealth, focuses on *data* collection for medical, health, and public health purposes, we believe that our experience of collecting data that will potentially serve as *evidence* broadens the traditional scope of digital health and mHealth. As more human rights-oriented NGOs rely on mobile technology for digital evidence collection, we see a need to refine and define this as a unique field of exploration, which we would like to term mobile justice, or mJustice.

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STUDENT ARTICLE – DOCTORAL

RAHI–SATHI Indo-U.S. Collaboration: The Evolution of a Trainee-Led Twinning Model in Global Health Into a Multidisciplinary Collaborative Program

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RAHI–SATHI presents an innovative twinning model of global health academic partnership, resulting in a number of successful research activities, that features trainees or students as the driving force, complemented by strategic institutional support from both sides of the partnership. Others can promote similar student-led initiatives by: (1) accepting an expanded role for trainees in global health programs, (2) creating structured research and program opportunities for trainees, (3) developing a network of faculty and trainees interested in global health, (4) sharing extramural global health funding opportunities with faculty and trainees, and (5) offering seed funding.

ABSTRACT

Background: In recent years there has been a surge in the number of global health programs operated by academic institutions. However, most of the existing programs describe partnerships that are primarily faculty-driven and supported by extramural funding.

Program Description: Research and Advocacy for Health in India (RAHI, or "pathfinder" in Hindi) and Support and Action Towards Health-Equity in India (SATHI, or "partnership" in Hindi) are 2 interconnected, collaborative efforts between the University of Massachusetts Medical School (UMMS) and Charutar Arogya Mandal (CAM), a medical college and a tertiary care center in rural western India. The RAHI–SATHI program is the culmination of a series of student/trainee-led research and capacity strengthening initiatives that received institutional support in the form of faculty mentorship and seed funding. RAHI–SATHI's trainee-led twinning approach overcomes traditional barriers faced by global health programs. Trainees help mitigate geographical barriers by acting as a bridge between members from different institutions, garner cultural insight through their ability to immerse themselves in a community, and overcome expertise limitations through pre-planned structured mentorship from faculty of both institutions. Trainees play a central role in cultivating trust among the team members and, in the process, they acquire personal leadership skills that may benefit them in their future careers.

Conclusion: This paradigm of trainee-led twinning partnership promotes sustainability in an uncertain funding climate and provides a roadmap for conducting foundational work that is essential for the development of a broad, university-wide global health program.

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BACKGROUND

Global health, described as a product of international and public health, has gained prominence over the

past decade or so, specifically in academic centers.[1] In the United States alone, there has been a tenfold increase in the number of global health programs from 2000 to 2012.[2]

Multiple factors underlie the surge in the number of global health programs in academic institutions, including an increased recognition of globally connected communities, a strong commitment to service and philanthropy, and growing student demand.[3] These collaborative efforts have led to significant advances in understanding global health disparities as well as curbing epidemics of HIV/AIDS, malaria, tuberculosis, and, most recently, Ebola.[4] Emerging evidence suggests that faculty and trainees worldwide also benefit from participating in these collaborations that transcend national borders[5] by heightening their awareness of social determinants of health, increasing self-awareness, and broadening their perspectives.[6]

The current global health landscape represents a paradigm shift from the historical activities of international health.[7] Specifically, the conventional model of professionals from high-income countries providing resources, services, and skills to "fix" problems ailing low- and middle-income countries are being replaced by a more bilateral, twinning approach whereby global and local entities share collective knowledge and resources to achieve a common goal.[8,9] Twinning for global health, which has been used in the fields of emergency medicine, pediatric oncology, and medical education, emphasizes the role and value of the partner in the host setting where the majority of activities occur.[8–12] However, most of the existing programs in peer-reviewed literature describe partnerships that are faculty-driven and supported by extramural sources of funding.[8–14] Faculty-driven global health programs are often limited to the interests and expertise of the faculty, and thus a multidisciplinary approach becomes difficult.[7]

By contrast, we present a student/trainee-led Indo-U.S. initiative that organically followed the twinning model and gradually evolved into a multidisciplinary program. The program overcame resource limitations by positioning the trainees as the driving forces behind the collaboration, complemented by strategic institutional support and stewardship. To the best of our knowledge, our collaboration represents the first account of a trainee-led twinning program for global health. We believe this account can serve as a roadmap for other trainee-led initiatives to expand into larger institution-based global health programs with the help of faculty and institutional support.

THE RAHI–SATHI COLLABORATION

Research and Advocacy for Health in India (RAHI, which is the Hindi word for pathfinder) and Support and Action Towards Health-Equity in India (SATHI, the Hindi word for partnership) are 2 sister collaborations between the University of Massachusetts Medical School (UMMS) and Charutar Arogya Mandal (CAM), a charitable trust that operates a tertiary care center and medical school in rural western India. RAHI was formed in 2013 through a formal Memorandum of Understanding between UMMS and CAM to support research activities between the 2 institutions. RAHI currently focuses on maternal and child health and noncommunicable disease and injury through a number of research studies and programs. SATHI was formed in 2015 based on the experience and feedback from personnel involved in RAHI to support bilateral capacity strengthening activities, including trainee-exchange, structured mentorship, and biannual seminars on research and teaching methodology. The impetus behind SATHI was to train learners from diverse backgrounds to grow the collaboration. Educational leadership from UMMS and CAM formed a coalition to support this endeavor.

The conventional model of professionals from high-income countries "fixing" problems in low-income countries has been replaced by a twinning approach whereby global and local entities share collective knowledge and resources to achieve a common goal.

We present a trainee-led Indo-U.S. twinning model that gradually evolved into a multidisciplinary program.

As the only publicly funded medical university in Massachusetts, UMMS strives to address health disparities locally in central Massachusetts and globally through its legacy partnerships with institutions from low- and middle-income countries. Similarly, CAM's mission is to care for the underserved of the community and train the next generation of health care providers for rural India. The Central Research Services and Community Extension Department are 2 specific examples of CAM's dedication for improving health of local Indian communities through community-centered research and service, respectively. Central Research Services was formed by CAM in 2009 in an effort to support investigator-initiated, community-based research studies and foster a research culture within the institution. The Community Extension Department is dedicated to delivering health programs to the local community. Through this department, CAM has established a network of Village Health Workers who receive training to perform disease screenings and deliver health education. Additionally, CAM operates 7 primary and secondary health centers within the region, which increases access to primary and specialist care among rural communities. The shared institutional commitment of UMMS and CAM to provide equitable health care

The RAHI-SATHI collaboration is supported by both pre- and postdoctoral students from the United States and India.

to the community formed the bedrock of the RAHI–SATHI collaboration.

The RAHI–SATHI collaboration has been championed thus far by 2 trainee-leaders [A.S. and N.F.] who have led the overall RAHI–SATHI collaboration with a vision of trainee-centered research and outreach initiatives. These trainee-leaders began as undergraduate students at Boston University and transitioned to medical school at UMMS. The RAHI–SATHI collaboration also receives support from both predoctoral and postdoctoral trainees from UMMS and CAM who support specific ongoing projects or lead development of new research efforts.

The trainee-leaders recruited predoctoral and postdoctoral trainees by leveraging existing structured opportunities at UMMS and CAM. For example, UMMS medical students are required to participate in a scholarly endeavor as part of the longitudinal 4-year Capstone Scholarship and Discovery course. In addition, selected UMMS medical students in the Global Health Pathway are required to participate in a global health activity in the summer after their first year of medical school. Furthermore, UMMS surgical research scholars are required to dedicate 2 years of their residency program to conduct research in a full-time capacity. Finally, CAM residents are required to produce a scholarly dissertation at the end of their training. Through their participation, trainees contribute to research and public health activities that directly address the needs of the rural Indian communities while also meeting their own educational requirements and developing their personal research portfolio.

The trainees are supported by faculty at both UMMS and CAM (and initially at Boston University). The involvement of faculties from both institutions range from high-level advising on a specific project or scientific product to working closely in one-on-one mentorship capacity. Typically, faculty who assume a less-involved role, meet with the trainees once a semester to discuss overall progress and respond to questions and solicitations via email or teleconference. Meanwhile, faculty mentors meet with the students once a week or once every 2 weeks.

TRAINEE-LED TWINNING MODEL FOR GLOBAL HEALTH

An international collaboration for strengthening emergency medicine in Ethiopia described 6 important phases of twinning[9]:

1. Initiate the partnership
2. Develop a shared work plan
3. Implement the program
4. Monitor outcomes
5. Evaluate results
6. Disseminate information

In this article, we describe the role of trainees as the driving force behind all 6 of these phases in the RAHI–SATHI twinning model for 4 different activities, selected specifically to illustrate the gradual evolution of the RAHI–SATHI collaboration and the transition of the workforce from the initial trainees to a new generation of trainees (Figure).

Activity 1: Community Health Needs Assessment in Rural Western India: Cross-Sectional Survey of Women

Phase 1: Initiate a partnership. The official RAHI–SATHI collaboration was preceded by the foundational work of the 2 U.S. trainee-leaders [A.S. and N.F.], supported by their clinical epidemiology professor [E.O.] from Boston University, and 2 local leaders from the Central Research Services at CAM in India (the head [S.M.N.] and the manager [A.G.P.]). The 2 U.S. trainee-leaders were introduced to the Central Research Services leaders through a mutual acquaintance who was a faculty member at CAM. After discussions and identification of shared interests and local needs, the group decided to conduct an assessment of women's health status and determinants to produce a snapshot of the community health needs, which would also act as a roadmap for future collaborative activities.

Phase 2: Develop a shared work plan. The trainee-leaders developed a first draft of study materials based on feedback from U.S. and Indian investigators. The trainee-leaders' active role in consolidating feedback from Boston University and CAM faculty during this iterative process became a crucial learning experience in building consensus, anticipating real-world complications, and understanding the practical limitations of research. This approach also lessened the burden on the faculty, who were providing in-kind support to this study. The trainee-leaders also gained experience in grant writing while successfully applying for an institutional grant identified by their Boston University mentor.

Phase 3: Implement the program. The trainee-leaders were limited to 5 weeks of travel

FIGURE. Timeline of RAHI–SATHI Evolution From Initial Study to a Multidisciplinary Collaboration

	2012: Community Health Needs Assessment*	2013: Understanding Predictors of Maternal and Child Health	2014: Preventing Trauma-Related Mortality and Morbidity	2015: Using Mobile Technology to Screen for Arrhythmias
Study Objective and Design	Identify common health problems and related factors of the community served by CAM through cross-sectional survey and stakeholder meetings	Understand perinatal trajectories of mothers and children and identify predictors using a prospective cohort study	Identify community-level injury burden through household surveys and ascertain types of injuries and outcomes through implementation of a trauma registry	Determine the community prevalence of AF using community health workers and mobile technology to screen for arrhythmias
Trainee Involvment	Trainee-leaders led the study in all phases: brainstorming, designing, implementation, and dissemination of the study and its findings	Trainee-leaders coalesced the team of investigators, procured funding, and implemented the study; new trainees supported and maintained the study	A new trainee, a surgical resident, led the study in all phases; the trainee spent 2 years of dedicated research team between UMMS and CAM to lead the study	Trainee-leaders brainstormed and designed the study; new trainees, medical students, traveled to CAM to implement the study
Faculty Suppport	A BU clinical epidemiologist, head of CRS at CAM, and manager of CRS	Bilateral involvement of pediatricians, gynecologists, psychiatrists, psychosocial, and health service researchers from UMMS and CAM	An acute care surgeon partnered with a team of surgeons and community-medicine faculty to support the community and hospital-level activities	Bilateral involvement of cardiologists, epidemiologists, and health service researchers from UMMS and CAM
Institutional Support	BU Dudley Allen Sargent grant ($7,000) to offset transportation and data collection costs, in-kind logistical support from CAM	UMMS OGH pilot project grant ($50,000) supported all research activities and clinical care of study participants; in-kind logistical support from CAM.	UMMS OGH pilot project grant ($35,000), supported all research activities and hiring of staff at CAM to implement trauma registry; in-kind logistical support from CAM	UMMS departmental funding from Office of Health Policy and Technology ($5,000) to support travel, research supplies, and stipends for community health workers
Significance for the Collaboration	Established trust and foundational partnership between trainee-leaders and local partners and findings helped inform the roadmap for RAHI	Established a prototype for multidisciplinary approach through RAHI-SATHI and helped develop a platform for introducing new trainees to participate in the collaboration	First project led completely by a new trainee; established a precedence for involving new generation of trainees in leadership role	First project to position new medical students traveling to CAM to lead implementation of the study

Abbreviations: AF, atrial fibrillation; BU, Boston University; CAM, Charutar Arogya Mandal; CRS, Central Research Services; OGH, Office of Global Health; RAHI, Research and Advocacy for Health in India; SATHI, Support and Action Towards Health-Equity in India; UMMS, University of Massachusetts Medical School.

*Study preceded RAHI–SATHI and was conducted by a joint collaboration between BU and CAM.

to India because of their employment and academic responsibilities. Therefore, the majority of the planning, including development of training protocols for research coordinators and a timeline of activities during the trainees' stay at CAM, were determined in the 3 months between submission of the research protocol to the Institutional Review Board (IRB) and approval. Aided by this preparation, the trainee-leaders interviewed, hired, and trained 5 female research coordinators in their first week onsite at CAM, and they supervised the research coordinators as they surveyed 700 reproductive-aged women from CAM outpatient clinics and surrounding villages over a period of 4 weeks.

Phase 4: Monitor outcomes. The trainee-leaders traveled with the research coordinators to the villages for community-based surveys. They spot-checked completed surveys in real-time and performed systematic quality checks on the surveys at the end of the day as well as during the data entry process. This exercise informed the trainees' understanding of research literacy among the research coordinators and participants. Their presence in the villages also provided the trainees an opportunity to interact with the local community and garner their thoughts on the concepts of health, public health, and research, which became instrumental in the development of subsequent projects.

Phase 5: Evaluate results. The trainee-leaders initially coordinated with statisticians from CAM and Boston University to derive findings from the data, led meetings with study investigators to discuss findings, and gathered feedback from the faculty to further guide the analysis. In

the later stages, after cultivating analytic skills, the trainee-leaders assumed the role of performing analysis with the support of faculty-level analysts.

The cross-sectional survey identified a high burden of anemia, common mental disorders, chronic pain, and exposure to traumatic events. The factors participants identified as important for seeking health care were discordant with the focus of the Indian National Rural Health Mission. For instance, we found that mothers prioritized quality of care over other factors when considering care for their children, and they prioritized cost over other factors when seeking health care for themselves. By contrast, the government's policies for maternal and child health largely focus on reducing costs with limited strategies for improving the quality of care provided.[15]

The preliminary work of the community health needs assessment identified 4 major needs, which serves as a roadmap for the RAHI collaboration.

This preliminary work identified 4 major needs, which serves as a roadmap for RAHI:

1. Understanding nutritional, psychosocial, and health care influences on mothers and children during the perinatal period in rural India.
2. Addressing mortality and long-term disability due to road-traffic accidents and other traumatic events.
3. Exploring the unique life-course and progression of cardiovascular and other noncommunicable diseases.
4. Identifying multidisciplinary approaches to combat chewable tobacco addiction among adolescents.

Phase 6: Disseminate information. Findings were disseminated using 2 mechanisms to support broad communication and further develop the partnership:

1. Peer-reviewed publication of manuscripts and conference abstracts: The trainee-leaders developed first drafts of conference abstracts and manuscripts based on findings from the analysis and sought specific feedback from Boston University and CAM investigators and, at later stages, the UMMS faculty mentors.[15,16]
2. Discussion of findings with local stakeholders in rural India: The trainee-leaders returned to rural India for a period of 8 weeks to help disseminate the findings from the study to local stakeholders. Engaging officials in the public sector, including health care providers and government health officers, through email and telephone proved difficult and thus required in-person visits by the trainee-leaders and the head of Central Research Services who had a longstanding presence as a clinician in the community. Discussion topics were tailored to match the purview of the Chief District Health Officer, the Reproductive and Child Health Officer, and the District Development Officer. A semi-structured interview format was abandoned in favor of a free-flowing conversation about their perception of community needs. The team presented findings from the cross-sectional survey in a large-group discussion format at CAM. The trainee-leaders met with clinicians from various clinical departments at CAM and local government primary care centers to ascertain their impressions about the clinical needs of their patient population and possible social determinants for health.

Activity 2: Understanding Predictors of Maternal and Child Health in Rural Western India: Cohort Study of Pregnant Women

Phase 1: Initiate a partnership. In 2012, one of the trainee-leaders [A.S.] matriculated to UMMS, where he connected with the institutional Office of Global Health to identify resources and opportunities for collaboration. Together, both trainee-leaders [A.S. and N.F.] prepared a proposal to study predictors of maternal and child health in rural western India, the first need identified through their previous community assessment.

India bears the greatest burden worldwide of child malnourishment (about 52 million children have stunting) and mortality (in 2008, 1.8 million children under the age of 5 years died).[17] Existing efforts made by the Indian government to improve health outcomes lack the support of evidence-based research.[18] The underlying causes of poor maternal and child health and undernutrition may be multifactorial in nature, and an understanding of the experiences of Indian women throughout the perinatal period is necessary to help identify entry points for multifaceted interventions.[18,19]

In developing their proposal, the trainee-leaders worked with a faculty mentor [J.A.], who codirects the UMMS Center for Health Equity Intervention Research, and the head of Central Research Services at CAM [S.M.N]. Lead investigators of the study sought UMMS faculty support based on their expertise in peripartum health [T.M.S.], pediatrics [P.M.], women's mental health [N.B.], and psychosocial determinants of health [M.R.]. Based on their previous ex-

perience, the trainee-leaders and the head of Central Research Services at CAM actively recruited counterpart faculty from CAM [N.R., A.P., J.V.] to match UMMS faculty in content expertise, thereby facilitating an exchange of clinical and cultural knowledge. The research team successfully applied for seed funding through the UMMS Office of Global Health Pilot Project Grant to conduct a prospective cohort study of pregnant women in rural India.

Phase 2: Develop a shared work plan. Due to the broad scope of the study, the trainee-leaders met separately with faculty from each discipline to identify specific questionnaires, biomarkers, and measurements to be collected during the study. Trainee-leaders consolidated the feedback from the investigators and identified critical and optional components of the study. The trainee-leaders moderated group meetings among UMMS investigators and communicated with CAM investigators before and after group meetings to build consensus and finalize the type of information to be collected through the study. Thus, the trainee-leaders acted as a bridge between UMMS and CAM investigators as well as principal investigators and co-investigators. The success of trainee-leaders as mediators while developing a shared work plan among this multidisciplinary team collaborating on a project in rural India for the first time was predicated on 3 important factors: (1) building on preexisting relationships between the investigators at their respective institutions, (2) engaging faculty early in the process, and (3) demonstrating consistent progress on research design by the trainees at each meeting with faculty. Ultimately, we designed a prospective cohort study that recruited and followed pregnant women from the first trimester to 2 years postpartum with multiple data collection time points.

Phase 3: Implement the program. The trainee-leaders traveled to CAM during the summer after their first year of medical school to implement the study. The prospective cohort study required establishment of standard operating procedures, research space, and sustained administrative effort in India. The trainee-leaders and the CAM principal investigator held meetings with CAM leaders, administration, and faculty from relevant departments to describe the study and outline their roles for supporting the study. To assist with recruitment of pregnant women from the community, the research team, including trainee-leaders, coordinators, and the CAM principal investigator, organized a town hall meeting for community health workers of nearby villages to describe the study to them, their role of referring pregnant women to participate in the study, and the honorarium for supporting the study.

Phase 4: Monitor outcomes. The trainee-leaders developed standardized forms to track participant enrollment, follow-up visits, and clinical data, which were completed by research assistants on a weekly basis. However, long-term oversight by the trainee-leaders was difficult due to growing commitments from medical school as they transitioned from preclinical to clinical years. Therefore, they recruited a new generation of SATHI trainees to overtake monitoring of the study. Two graduate students from CAM [N.P. and H.P.] performed periodic data-entry checks and reviewed medical records of the participants. In addition, 4 UMMS medical students [M.T., H.N., J.K. and H.R.] traveled to CAM after their first year of medical school to support the research staff with data-entry and quality checks. In addition to monitoring outcomes of the study, the UMMS trainees also gained cultural and clinical insight into the research questions being investigated through the study. They used the experience to develop their research interests, which they will pursue for the remainder of their training at UMMS through their capstone course requirement.

The trainee-leaders acted as a bridge between the 2 partner universities.

Phase 5: Evaluate results. One of the trainee-leaders [A.S.] led the analysis of the emerging data by leveraging skills acquired through the doctoral program at UMMS Quantitative Health Sciences and with support from faculty-level statisticians. Additionally, the trainee-leader and his mentor [J.A.] conducted biannual workshops in statistical analysis at CAM to train local statisticians in intermediate and advanced analyses. The analytical team produced findings that were shared by the trainee-leaders with UMMS and CAM investigators, faculty, and students and continue to be disseminated through peer-review mechanisms.

Phase 6: Disseminate information. Early findings from the study have identified a high burden of low birth weight as well as low maternal hemoglobin and deficiency of essential vitamins during pregnancy despite the provision of prenatal care.[20–22] Scholarly products, all first-authored by the trainee-leaders and second-generation trainees, were presented at scientific conferences, and 2 manuscripts are in development, which discuss the experiences of the pregnant women in rural western India.[20–22] Trainees responsible for the first draft of the scholarly products solicited feedback from faculty at both institutions and

incorporated their insights into the work. Additionally, preliminary data from this study played a vital role in successful applications by the CAM investigators [S.M.N., A.G.P, N.R., and A.P.] for research funding from the Indian Council of Medical Research to further study perinatal health.

Activity 3: Reducing Injury-Related Morbidity and Mortality in Rural Western India: Community-Based Survey and Trauma Registry

Phase 1: Initiate a partnership. Prior to implementation of the maternal and child health study (activity 2), the trainee-leaders and the UMMS principal investigator hosted the CAM principal investigator for a seminar at the UMMS campus. The group presented findings of their community health needs assessment and outlined the scope of the new maternal and child health study. The seminar was attended by an acute care surgeon and health services researcher with roots in the CAM catchment area [H.P.S]. The surgeon expressed interest in supporting the collaboration. As director of Surgical Research Scholars, the surgeon recruited a surgical resident [A.J.] entering a 2-year period of dedicated research to lead a program addressing the trauma care needs in rural western India. This undertaking represents the first example of a new-generation trainee at the postdoctoral level leading the design and implementation of a project. The postdoctoral trainee traveled to CAM to gather local feedback about the knowledge gaps that could be addressed through the research study and identified faculty from the Department for Surgery [S.S.] and Community Extension Department [S.R.] to collaborate on the study.

Phase 2: Develop a shared work plan. During the postdoctoral trainee's visit to CAM, 2 major needs were identified: understanding injury burden at a community level and developing a mechanism to track and assess outcomes of trauma patients at CAM.

Road traffic accidents are a leading cause of mortality in India.[23] One out of every 4 road traffic accidents in India results in a death, and nearly half of the fatal cases never receive any medical attention.[24] CAM's hospital is situated at the intersection of 2 major roadways in rural western India. The hospital has more than 20,000 admissions per year, and an estimated 70% of these are attributed to road traffic accidents. However, the specific burden of trauma-related injuries and outcomes at the hospital and community level remain unknown. Trauma registries are an integral part of emergency care systems in high-income countries but not in low- and middle-income countries.[25] They are important for quality improvement within an institution and surveillance of trauma-related outcomes.[26] Therefore, the UMMS and CAM team decided to conduct a community-based survey and develop a hospital-based trauma registry, which was financially supported by RAHI–SATHI's second UMMS Office of Global Health Pilot Project Grant.

Phase 3: Implement the program. UMMS and CAM investigators leveraged a preexisting sampling frame created by CAM as part of their community outreach efforts to carry out burden of injury surveys among 5,000 household from 36 villages in the surrounding region. The postdoctoral trainee and CAM's Community Extension Department supervised this implementation. Diffusion of trauma registry, a new initiative within the busy setting of emergency care in a resource-limited setting, required buy-in at multiple levels, including the registrar, casualty medical officers, trauma specialists, and hospital leaders. The UMMS postdoctoral trainee dedicated 2 research years to systematically build buy-in for the trauma registry at CAM through a pilot implementation phase, discussions with physician champions, and stakeholder round-table forums. The principal investigator of the study [H.P.S], as director of the Surgical Research Scholars program, modified program requirements and sought support from UMMS leadership to accommodate the trainee's time at CAM. A first-year UMMS medical student [B.N], a member of the third-generation of predoctoral trainees, spent 4 weeks in India working with the postdoctoral trainee during the implementation phase. Ultimately, the trauma registry was implemented as standard operating procedures, replacing the existing intake form in the emergency department for all trauma-related injuries, thereby reducing the additional burden imposed on care providers and assuring maintenance by existing health care staff at CAM.

Phases 4, 5, and 6: Monitor outcomes, evaluate results, and disseminate information. The community health workers conducting surveys provided daily tallies of households surveyed, and weekly meetings were held to summarize the number of injuries and disabilities captured. Data are emerging from this study and have not yet been analyzed. However, the postdoctoral trainee and Department of Surgery at UMMS and

CAM have shared their experience of studying trauma-related injuries in rural western India through departmental, institutional, and professional seminars. The understanding of barriers to trauma registry implementation identified in the pilot phase was shared at CAM as well as at meetings of the Massachusetts Committee on Trauma and the Association of Academic Surgery conference. Through this outreach, the UMMS team has identified the next surgical resident to assume responsibilities as the current postdoctoral trainee transitions back to clinical training.

Activity 4: Detecting Unrecognized Atrial Fibrillation in Rural Western India Using Mobile-Based Technology: Community-Based Screening

Phase 1: Initiate a partnership. The trainee-leaders approached the chief of Connected Cardiovascular Healthcare section at UMMS [D.D.M.] to leverage his research team's expertise in mobile technology to collaborate with CAM for a joint Indo-U.S. call for proposals. Together, the group decided to focus on mobile-based screening of atrial fibrillation due to recent innovations at UMMS for this technology and its apparent need in India.

Atrial fibrillation is understudied among Indians but may be an underlying contributor to the ongoing stroke epidemic in India.[27,28] Untreated atrial fibrillation can increase the risk of stroke, and in the context of India, where rapid stroke management is suboptimal, prevention of stroke through early diagnosis of atrial fibrillation becomes crucial.[29] The technology developed by the UMMS atrial fibrillation research group in collaboration with local biomedical engineers uses a mobile phone to screen for atrial fibrillation.[30] The trainee-leaders introduced the group to a member of the Office of Health and Technology at UMMS [M.C.] who codirects the Global Health Pathway at UMMS and thus oversees the SATHI component of the collaboration. The RAHI leadership team at CAM [S.M.N. and A.G.P.] recruited a cardiologist from CAM [S.T.] to collaborate on the study and provide clinical insight for conducting a feasibility study.

Phase 2: Develop a shared work plan. Conventionally, a 12-lead electrocardiogram (EKG) is required to obtain an electric signal of cardiac activity, which is interpreted by medically trained personnel to diagnose atrial fibrillation or other arrhythmias. However, a single screen for atrial fibrillation may miss cases of paroxysmal atrial fibrillation. Therefore, the research team decided to conduct a feasibility study that used algorithm-driven pulse waveform and single-lead EKG technology to screen participants for atrial fibrillation on 5 consecutive days. Partnership with CAM's Community Extension Department [S.R.] helped identify villages for community-based atrial fibrillation screening. CAM investigators suggested using community health workers to align the screening approach with the Indian government's model and develop a proof of concept that may be scalable across India.

Phase 3: Implement the program. Two first-year UMMS medical students [A.E. and A.H.], representing the third generation of SATHI trainees, were identified to implement the study. The trainees received training at UMMS by the study principal investigator, the trainee-leaders, and the atrial fibrillation research staff in using the mobile technology. They traveled to CAM with research equipment and materials with financial support from the UMMS Office of Health and Technology. They then trained research coordinators in the screening procedures. Ultimately, through a train-the-trainer model and medical students, local community health workers were able to recruit and screen more than 350 participants in their homes for 5 consecutive days. Although research design was formulated by the faculty principal investigator and the trainee-leaders, this pilot study represented the first account of a new generation of UMMS predoctoral trainees [A.E. and A.H.] leading the implementation of a study. It is noteworthy that neither of the trainees spoke the local Indian language. Partnering of UMMS and CAM trainees [D.P. and H.P.] helped overcome the linguistic and cultural implementation barriers.

Phase 4, 5, and 6: Monitor outcomes, evaluate results, and disseminate information. Data from this feasibility study was evaluated by a team of trainees with statistical [A.S.] and cardiovascular [N.F. and J.B.] training backgrounds. Early findings revealed a prevalence of atrial fibrillation substantially greater than previously reported in India and comparable with that found in the United States and other high-income countries. Although large-scale and more representative screening efforts are currently underway, noteworthy findings from the feasibility study were presented by a trainee-leader [A.S.] at the National Institutes of Health Special Topics Conference on Healthcare Innovations and Point-of-Care Technologies and were published in a leading mobile health journal.[31] A grant

proposal, coauthored by the trainee-leaders, to leverage public health infrastructure to establish a systematic screening program for atrial fibrillation was selected among the finalists for joint consideration by the National Institutes of Health and Indian Department of Biotechnology, but ultimately was not funded. The group is preparing a similar application in response to a call for proposals from the Fogarty International Center. Meanwhile, the UMMS Office of Global Health has awarded RAHI–SATHI its third Pilot Project Grant, which supports continued screening for atrial fibrillation using mobile technology based on the promising results from the feasibility study.

SUCCESSES AND CHALLENGES OF A TRAINEE-LED TWINNING PROGRAM

Positioning trainees as the driving force behind a twinning program has its advantages. For example, the student trainees tend to have greater flexibility than faculty to travel to the local site, and they can facilitate an interdisciplinary approach by coordinating inputs from a range of faculty (Table 1). However, we also highlight 4 major challenges that trainee-led approaches must overcome:

1. **Time management:** Trainees experience time constraints as they seek to balance their formal training with participation in global health activities. Aligning trainees' responsibilities with their mandatory requirements for their formal training, such as capstone projects, can offer a possible solution for this challenge.
2. **Technical expertise:** Trainees have limited experience in conducting research, especially in a leading role. Pairing trainees with mentors and offering structured mentorship to support them in technical and team-building aspects can help overcome this knowledge gap.
3. **Identifying faculty mentors and champions:** Faculty members, especially physician scientists, experience time constraints with their clinical and research responsibilities, therefore limiting their capacity to accept

TABLE 1. Advantages of a Trainee-Led Twinning Program in Global Health and Trainee Benefits Based on the RAHI–SATHI Experience

Twinning Phase	Advantages of Program	Benefits for Trainee
Initiate a partnership	Trainees typically have greater flexibility than faculty to travel and connect with the local community to build trust and act as a bridge between geographically separated investigators	Gain hands-on experience in professionalism and building trust with a new community
Develop a shared work plan	Trainees facilitate an interdisciplinary approach by coordinating inputs from multiple team members from varied disciplines and maximizing faculty investigators' contribution, in the context of their in-kind support	Acquire consensus-building skills and a multidisciplinary perspective
Implement the program	Trainees lead the implementation of the program and reduce the burden on international partners who face competing demands to provide care to their beneficiaries	Develop an understanding of real-world constraints and complications in implementation science
Monitor outcomes	Trainees identify potential sources of error early in the program and help sustain communication among the team and with the local community	Gain insight into potential pitfalls of programs
Evaluate results	Trainees provide insight gained by their involvement in the study and help guide evaluation of the results	Enhance scientific inquisition and analytical skills to interpret and discuss findings with peers
Disseminate information	Trainees disseminate information across a range of platforms including peer-reviewed manuscripts, conference presentations, and departmental or institutional seminars, resulting in greater exposure of the program and increased opportunities for potential collaborators to become involved	Develop scholarly skills that are critical in medicine and academics

Abbreviations: RAHI, Research and Advocacy for Health in India; SATHI, Support and Action Towards Health-Equity in India.

mentees. Identifying grant and manuscript opportunities can propel faculty to be involved.

4. **Continuity:** Trainees' involvement in the project is confined to their time in the academic program. Presence of a faculty champion and explicit transition plans including supporting recruitment of subsequent generation of trainees can help maintain continuity.

In addition to these 4 challenges, which are universal in nature, Indian trainees experienced unique challenges that limited their involvement. Medical education in India is intensely regulated by a national body, the Medical Council of India. Trainees' academic performance is heavily dependent on attendance and curricular-related activities, thereby limiting their elective time and participation in extracurricular scholarship. Despite our efforts to promote bilateral involvement, these constraints have limited more active participation of Indian trainees. However, in recent years there has been increased participation due to the combination of continued support from CAM's leadership and word-of-mouth promotion by CAM trainees who have participated in the RAHI–SATHI collaboration and accomplished peer-reviewed achievements in the form of published manuscripts and scientific conference presentations.

Unsuccessful Proposals

Our collaboration prepared and submitted 4 unsuccessful proposals for extramural funding.

1. The "Biological Determinants of Type 2 Diabetes Risk in Indian Populations" proposal was developed in response to a joint Indo-U.S. call from the National Institutes of Health and the Indian Council of Medical Research. The proposal aimed to investigate differences in adipose tissue biology among non-Hispanic whites and South Asian Indians as a potential mechanism for high risk of diabetes among Indians with low body mass index (BMI).
2. The "Support and Action Towards Health-equity in India" proposal was developed in response to the Obama-Singh Initiative funding opportunity for higher-education programs. The capacity strengthening proposal preceded SATHI formation and included exchange and development program for trainees.
3. The "Strengthening Kangaroo Mother Care Implementation in Gujarat" proposal was developed in response to a solicited opportunity from the Bill & Melinda Gates Foundation. The proposal aimed to enhance hospital and community-based Kangaroo Mother Care.
4. The "***S***martphone ***M***onitoring for ***A***trial fibrillation in ***R***eal-***T***ime–**India** (**SMART–India**)" proposal was developed in response to a joint Indo-U.S. funding opportunity from the Indian Department of Biotechnology and the National Institutes of Health. This proposal sought to expand community-based screening of atrial fibrillation using mobile technology.

Presence of a faculty champion and explicit transition plans can help maintain continuity of trainee-led twinning models.

Despite these disappointing outcomes, the grant writing and submission process mobilized trainees and faculty members and ultimately provided an opportunity to overcome lack of funding by seeking alternate resources. The formation of SATHI despite the unsuccessful application provides a salient example of this approach. In addition to SATHI activities described above, a virtual development program in global health for trainees and faculty in neurology is underway through a bilateral partnership between junior faculty from UMMS and CAM [A.D. and S.D.]. Such contingency plans can help gather preliminary data and feasibility results, which is becoming increasingly important for extramural funding. Additionally, experience from other programs has suggested that continuous interaction and activities, independent

BOX. Recommendations for Institutional Leadership and Faculty to Promote Establishment of Trainee-Led Twinning Programs for Global Health

- Accept an expanded role for trainees in global health programs
- Create structured opportunities for trainees to engage in research and global health activities
- Develop a network of faculty and trainees interested in global health
- Share extramural global health funding opportunities with faculty and trainees
- Offer application-based opportunities to seed funding for global health activities and promote perseverance among partnerships that lack extramural support

of extramural support, builds and fortifies trust in an academic partnership.[32]

Strategic Institutional Support

UMMS and CAM play a vital role in the growth and success of RAHI–SATHI by providing strategic support and fostering a collaborative environment that promotes faculty teamwork and encourages them to work with trainees. The Box outlines recommendations for the parent institutions and faculty mentors based on our experience with RAHI–SATHI.

Institutional leadership at both sites formalized the collaboration in its early stages through a memorandum of understanding, making it possible for the collaboration to harness existing institutional resources. Centers for Health-Equity Intervention Research (CHEIR) and Clinical and Translational Science (CCTS) have structured opportunities, which supported the trainees and faculty working with RAHI–SATHI. Additionally, the Office of Global Health at UMMS provided crucial seed funding to support the research studies. The International Medical Education Program partially supported trainees' travel to CAM. Similarly, CAM's leadership support of RAHI–SATHI positioned their faculty and trainees to assume an active and leading role in the collaboration. The establishment of Central Research Services in 2009 as part of the focus of the institution on development of research skills and projects among the faculty was germane to the support received by the research activities of RAHI–SATHI. CAM began funding internal research projects, capacity building in research and scientific writing, and also international travel to disseminate the work being done. The annual publication output by CAM in the last 3 years has more than quadrupled that in the past decade. The head of Central Research Services [S.M.N.] and his research team, including trainees, received complete financial support from CAM to travel to the United States for dissemination of their work at professional conferences such as the Pediatric Academic Societies and Consortium of Universities for Global Health. This travel fortified the interpersonal relationships between UMMS and CAM investigators and helped engage more faculty and trainees.

CONCLUSION

This paradigm of trainee-led twinning partnership presents unique challenges and successes in addition to the ones experienced by traditional, faculty-led collaborative models. Trainees can help mitigate geographical barriers by acting as a bridge between members from different institutions, garner cultural insight through their ability to immerse themselves in a community, and overcome expertise limitations through pre-planned structured mentorship from faculty of both institutions. In the process, trainees can play a central role in cultivating trust among the team members and acquire personal leadership skills that may benefit them in their future careers. Our experience shows strategic institutional support to trainee-led initiatives in global health promotes sustainability in an uncertain funding climate and provides a roadmap for conducting foundational work that is essential for the development of a broad, university-wide global health program.

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STUDENT ARTICLE – UNDERGRADUATE/MASTERS

American Mock World Health Organization: An Innovative Model for Student Engagement in Global Health Policy

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The American Mock World Health Organization (AMWHO) provides a platform for students to apply their knowledge of global health policy through simulations of the World Health Assembly (WHA). This model engages and empowers future global leaders in health policy while sharpening their skills in diplomacy, public speaking, and conflict resolution. The major theme for the AMWHO 2015 was Universal Health Coverage, reflecting what the WHA had discussed in preceding months.

ABSTRACT

The American Mock World Health Organization (AMWHO) is a model for experiential-based learning and student engagement in global health diplomacy. AMWHO was established in 2014 at the University of North Carolina at Chapel Hill with a mission to engage students in health policy by providing a simulation of the World Health Assembly (WHA), the policy-forming body of the World Health Organization that sets norms and transforms the global health agenda. AMWHO conferences are designed to allow students to take their knowledge of global health beyond the classroom and practice their skills in diplomacy by assuming the role of WHA delegates throughout a 3-day weekend. Through the process of developing resolutions like those formed in the WHA, students have the unique opportunity to use the lens of a stakeholder to understand the complexities behind the conflict and compromise that ensues. This article describes the structure of the first 2 AMWHO international conferences, analyzes survey results from attendees, and discusses the expansion of the organization into a multi-campus national network. The AMWHO 2014 and 2015 post-conference survey results found that 98% and 90% of participants considered the conference "good" or "better," respectively, and survey responses showed that participants considered the conference "influential" in their careers and indicated that it "allowed a paradigm shift not possible in class."

BACKGROUND

In January 2014, founder and author Neha Acharya created the American Mock World Health Organization (AMWHO) at the University of North Carolina at Chapel Hill, based on the Ontario Model World Health Organization (OMWHO) in Toronto, Canada, an organization holding conferences that simulate the annual World Health Assembly (WHA) held in Geneva, Switzerland. Its sister structure, Model United Nations, replicates the United Nations General Assembly, and is widely popular in both high schools and universities throughout the world. Within the United States, few students have similar opportunities to sharpen skills and explore a future in health policy. Mock World Health Organization conferences fill that gap by engaging students in health diplomacy by replicating the WHA debating a particular, complex global health issue.

While attending OMWHO, author Neha Acharya observed that diplomacy was key to realizing the goals of global health, a concept and skill not prevalent in global health policy curricula. As Ilona Kickbusch and coauthors note, it is necessary for public health professionals to have training in diplomacy and for diplomats to have training in public health to build necessary capacity in health diplomacy.[1] Yet while Lee and Smith agree that "negotiation of health-related agreements can benefit from the skills and experience of diplomats," they argue that "in the past, the 'toolbox' of the health policy maker has not included expertise in international negotiation."[2] With an increasingly integrated and globalizing world, future global health leaders are faced with multifaceted issues that require a skill set in negotiating and forming policies with other global health actors. WHO's significant challenges in effectively cooperating

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with key stakeholders make diplomacy training a practical tool that can better prepare aspiring public health professionals to listen, negotiate, and develop solutions.[3]

Since the founding 2014 AMWHO conference, 2 international AMWHO conferences have been held. In this article, we describe the structure and procedures of the AMWHO conference and roles that students play while illustrating the content of the debate with a case study from the Americas region during the AMWHO 2015 conference. We also present findings from online surveys of AMWHO 2014 and 2015 participants to inform successes and opportunities for growth.

STRUCTURE OF AN AMWHO CONFERENCE

Conference Roles

During each 3-day mock WHO conference, delegates assume the role of either a WHO Member State Ambassador, an NGO representative, or a media correspondent. Most delegates represent WHO member states as they debate, strategize, and form resolutions. A handful of delegates represent NGOs and the media. Reflective of the role of NGOs in global health governance, resolutions proposed by WHO Member State delegates can only pass with approval from a majority of the NGO delegates. Representing the role of the media in global health governance, media correspondents move between committees to report on the proceedings of debate, often influencing the direction of discussion.

Dais members are students from the host university who are trained in parliamentary procedures to ensure a realistic WHA simulation. Three key actors sit on the dais of each committee and facilitate debate during committee sessions:

- Chair: facilitates debate and ensures that procedural matters follow Robert's Rules of Order
- Vice Chair: assists delegates with the processes of drafting and approving resolutions
- Rapporteur: keeps committee order by maintaining the speakers' list, calling roll, tracking all resolutions and votes, and facilitating communiques between delegates

Conference Schedule

Participants spend the first 2 days of the conference in *committee sessions*, where they debate how to best address the chosen theme, negotiate draft working resolutions, and gather support for their proposed plan of action. They spend the third day in *plenary*, where all regional committees convene to amend and finalize draft resolutions (Table 1). Subject matter experts provide insight into the theme at scheduled presentations throughout the conference. The conference ends with closing ceremonies, where awards are announced for Best Delegate and Best Position Paper from each region.

TABLE 1. Sample American Mock World Health Organization Conference Schedule

Day and Time	Program
Friday	
1:00–1:45 pm	Delegate Training
1:45–3:00 pm	Opening Ceremonies
3:00–6:00 pm	Committee 1
6:00–7:00 pm	Speaker 1
7:00–9:00 pm	Delegate Dinner
Saturday	
8:30–9:00 am	Breakfast
9:00 am–12:00 pm	Committee 2
12:00–2:00 pm	Lunch & Learn
2:00–4:00 pm	Committee 3
4:00–5:00 pm	Speaker 2
5:00–7:00 pm	Committee 4
7:30–9:00 pm	Delegate Social
Sunday	
8:30–9:00 am	Breakfast
9:00 am–12:00 pm	Plenary 1
12:00–1:15 pm	Lunch
1:15–2:15 pm	Plenary 2
2:15–3:30 pm	Keynote Speaker
3:30–4:30 pm	Plenary 3
4:30–5:15 pm	Closing Ceremonies

Committee Sessions

Set Up and Training

Committee sessions comprise the majority of the first 2 days. During committee sessions, WHO Ambassador delegates convene in regional blocs

Future global health leaders require a skill set in negotiating and forming policies with other global health players.

At the American Mock World Health Organization, student delegates assume the role of either a WHO Member State Ambassador, an NGO representative, or a media correspondent.

The students convene in regional blocs at committee sessions during the first 2 days of the conference.

Delegates in the South-East Asia (SEARO) and Western Pacific (WPRO) committee in moderated caucus.

based on the WHO regions: Africa (AFRO), the Americas (AMRO), Europe (EURO), Eastern Mediterranean (EMRO), South-East Asia (SEARO), and Western Pacific (WPRO). SEARO and WPRO are combined into 1 region for the conference to allow for a substantive amount of delegate representation in the region.

On Day 1, AMWHO conferences begin with a delegate training session to familiarize the students with parliamentary procedure and the overall conference. The first committee session follows shortly thereafter. Within this session, delegates present ideas on setting the resolution agenda to a narrower, region-specific subtheme of the main conference theme. All subsequent resolutions are written on the agenda topic, which is set by majority vote.

Subject Matter Experts

After delegate training on Day 1, an opening ceremony features a subject matter expert who introduces the delegates to the conference theme. This speaker provides a framework and context for delegates to better understand and write their position paper on the topic of debate. Throughout the remaining days of the conference, 2 to 3 subject matter experts speak to provide insight from their fieldwork, research, and other experiences. See Table 2 for a list of speakers from the AMWHO 2014 and 2015 conferences.

Debate Procedures

On Day 2, committee sessions continue, and delegates engage in discourse on the best solutions to the committee subtheme. Delegates address the entire committee in *moderated caucuses* and obtain consensus on their proposed plan of action. Delegates later enter into an *unmoderated caucus* for informal discussions that move toward drafting resolutions.

Resolutions

Each region can form up to 2 resolutions. Between 1 and 3 *Sponsors* write the resolution and are responsible for seeing its passage. *Signatories* support the spirit of the resolution but may not fully agree with the entirety of the clauses. By the last committee session of Day 2, fully formed draft resolutions are submitted to the dais. At this time, delegates may

TABLE 2. Speakers at the American Mock World Health Organization 2014 and 2015 Conferences

Year	Day 1	Day 2	Day 3
2014	Steven Wayling: former technical officer with the Global Programme on AIDS in the WHO/EURO office in Copenhagen	Heather Davis: worked with PEPFAR and CARE in Ethiopia and the DRC	Mory Pagel: worked with SIT Study Abroad on field-based research within the WHO in Geneva, Switzerland
2015	Dr. Audrey R. Chapman: professor in the Division of Public Health Law and Bioethics, and the first Healey Endowed Chair in Medical Ethics and Humanities at the University of Connecticut Health Center	Dr. Timothy G. Maestro: Director of Global Health, Population and Nutrition at FHI 360	U.S. Ambassador Jimmy Kolker: Assistant Secretary for Global Affairs at the U.S. Department of Health and Human Services and the U.S. representative to the WHO under President Barack Obama

Abbreviations: DRC, Democratic Republic of the Congo; PEPFAR, The United States President's Emergency Plan for AIDS Relief; SIT, School for International Training; WHO/EURO, World Health Organization Regional Office for Europe.

amend each other's resolutions by adding or removing clauses, altering language, or adding specificity through sub-clauses. At the end of the day, each regional committee votes on all amended draft resolutions. If passed, the draft resolution goes to plenary on the last day for consideration by all member state representatives.

Plenary

Delegates from all regional blocs convene in plenary on the final day of the conference. Sponsors present an overview of each resolution, and the conference as a whole amends and votes on the regional resolutions. Those that pass plenary are sent to the World Health Organization in Geneva for review.

PUBLICITY AND OUTREACH

AMWHO recruited both undergraduate and graduate students through social media marketing, through the American Public Health Association, and emails to individual professors and to university listservs. Table 3 outlines the universities represented at both international conferences, as well as universities hosting regional or local conferences. AMWHO also received sponsorship from local and global health organizations.

CONTENT OF DEBATE

The AMWHO 2015 conference selected the theme of "Universal Health Coverage" in alignment with a topic discussed by the WHA in the months preceding the conference. Table 4 describes the content of discussions and debates that occurred in each region during this conference, and the Box provides more details about the debate that emerged specifically from the AMRO region. The experience concluded at plenary, where AMRO's resolution was passed with the addition of a few amendments. See the Appendix for the AMRO resolution that resulted from the plenary.

Student delegates from all regional blocs convene in plenary on the final day of the conference.

SURVEY FINDINGS AND DISCUSSION

In total, 124 and 113 attendees from around the world registered for the AMWHO 2014 and 2015 conferences, respectively. At the conclusion of each conference, we conducted an anonymous

TABLE 3. University Involvement at the AMWHO 2014 and 2015 Conferences

University	Represented at AMWHO 2014 and/or 2015	Chapter Organization	Regional Conference Host
University of North Carolina at Chapel Hill	✓	✓	✓
Emory University	✓	✓	✓
Virginia Tech	✓	✓	✓
University of Kentucky	✓	✓	✓
University of South Carolina	✓	✓	
Mercer University	✓	✓	
University of Georgia	✓	✓	✓
University of Denver	✓	✓	
Cornell University	✓	✓	✓
University of Washington	✓	✓	✓
Johns Hopkins Bloomberg School of Public Health	✓	✓	
Case Western Reserve University		✓	✓
. . .and 21 more universities	✓		

Abbreviation: AMWHO, American Mock World Health Organization.

TABLE 4. Determination of Resolution Topics at the American Mock World Health Organization 2015 Conference, by Region/Committee

Region	Proposed Subthemes	Selected Subtheme (Agenda)	Resolution Title	Resolution Topics
African Region (AFRO)	• Sustainable health systems • Diverse funding sources for health care • Teaching, managing, and organizing community health workers • Health education reform • Novel measurement and evaluation methods for health interventions • Emphasis on incorporating social determinants of health in health policy aimed at universal health coverage	Creating sustainable health systems in all African nations and achieving universal health coverage by holistically innovating health care infrastructure to meet nation-specific needs	The creation of sustainable health systems	• Retention, education, and training of a competent health care workforce • Methods to improve health education to educate different communities and demographics • Strengthening relationships between nations and NGOs • Creation of a novel framework to create and develop sustainable health systems • Addressing the health care needs of refugees
Americas Region (AMRO)	• Primary care accessibility • Definition of essential medicines • Health outcomes measurement • Health financing • Health workforce and resources • Vulnerable and neglected populations	Ensuring universal health coverage as defined by equitable access to health services for all, with an emphasis on access to care for vulnerable populations.	Ensuring universal health coverage as defined by equitable access to health services for all, emphasizing access to care for vulnerable populations	• Health information systems integration • Definition of essential medicines • Financial support • Service expansion and sustainable development • Appropriate training of community health workers
Eastern Mediterranean Region (EMRO)	• Community health worker training and curriculum development • Supportive health care units during times of crisis • Training primary health care doctors for both practice and retention in EMRO • Designing and implementing a crisis package for universal health coverage in conflicts areas • Universal policy to guarantee security and sustainability during times of natural and welfare crisis	Implementing universal health coverage including building the framework for health analytics, crisis funding, primary health care funding, education of medical professionals, and security within health care infrastructures	Immediate Relief Universal Health Care Package for Times of Crisis	• Provision of immediate relief resources • Establishment of an EMRO crisis fund • Creation of longitudinal health care approaches • Developing partnerships between governments and centers of excellence

Continued

TABLE 4. Continued

Region	Proposed Subthemes	Selected Subtheme (Agenda)	Resolution Title	Resolution Topics
	• Package that focuses on data analysis and primary health care delivery to target populations, encourages the increase of sanitation and water access across EMRO, sets aside a crisis fund, and improves medical education to train and retain primary health care doctors during times of crisis			
European Region (EURO)	• Education of health care workforce to address quantity and specialization of health care providers • Access to health care services for vulnerable populations • Bolstering preventative care to increase health care efficiency • Privatization of universal health care for health financing • Surveillance and sustainability of health care workforce	Addressing accessibility and availability of health care workforce as a means of providing universal health coverage with a focus on outreach to vulnerable populations	Increase the number, training, quality, and equitable distribution of workforce	• Restructuring of health care education • Redistribution of health care workforce • Financial sustainability and surveillance of novel educational programs
South-East Asian Region and Western Pacific Region (SEARO/WPRO)[a]	• Quality of service • Equal and affordable access • Rural access • Emergency services • Financing universal health coverage	Financing universal health care with a focus on improving service quality and decreasing health inequality	Financial Support for SEARO/WPRO Health Initiatives	• Creation of a regional financial management committee to manage and administer funds • Cost-sharing for NGOs and governments • Decentralized programs • Monitoring and assessment of efficient fund allocation

[a] For the purposes of creating similar-sized committees, SEARO and WPRO, the 2 smallest regions of the WHO, were combined for all AMWHO conferences.

BOX. Case Study of the Americas Region Committee Debate at the American Mock World Health Organization 2015 Conference

The theme of AMWHO 2015 was Universal Health Coverage. Over the 3-day conference, most participants were grouped into regional committees, based on the WHO regional offices. Some participants assumed the roles of NGO representatives or media correspondents. This case study of the Americas Region (AMRO) committee highlights illustrative examples of the experience of participants.

Day 1 Committee Session: Setting the Resolution Agenda

Upon arrival, each delegate had identified the issues relevant to his/her particular country in the form of position papers. The first committee session began in a disjointed fashion when delegates were given their initial opportunity to speak as a wide variety of concerns were presented.

Under the theme of universal health coverage, the dominant topics in AMRO were primary care accessibility, definitions of essential medicine, health outcomes measurement, health financing, and health workforce and resources. Delegates formed a consensus on the following established agenda: "Ensuring universal health coverage as defined by equitable access to health services for all, with an emphasis on access to care for vulnerable populations."

Day 2 Committee Sessions: Negotiating Draft Resolutions

Delegates aimed to clarify their agenda by agreeing upon key definitions. A comprehensive definition of vulnerable populations ultimately served as a pre-ambulatory clause to the resolution, which set the tone to recognize that each country has distinctive marginalized groups. Further discussion was also needed to define the intent of the phrase "equitable access to all" in the agenda; the delegates ultimately settled upon calling for child health care, primary care, and preventative care. Several countries advocated the inclusion of mental health in this definition, but it was not included.

Once these goals were more clearly defined, debate turned to topics that structurally supported the chosen agenda subtheme. Many of the dominant topics not chosen as the subtheme were later addressed as subtopics in the agenda. The committee discussed the importance of health information systems, accounting for financial hardships, and expansion of health services into underserved regions. Health information systems were proposed to monitor outcomes and thus assess the success of various universal health coverage systems. Finances were tackled with a call for collaboration between countries on international issues as well as better coordination of existing funds within countries.

Throughout debate, the delegates worked within the WHO's scope of power and avoided infringing upon any country's sovereignty. As delegates moved to unmoderated caucus to write resolution clauses, NGOs requested to modify clauses to maintain their influence but rejected any clause that would impose excessive responsibility upon them.

Resolution sponsorsthen presented the draft resolutions for amendments and approval. Among various amendments that dealt with slight wording changes, AMRO voted to include the aforementioned clause concerning mental health, which was pivotal for some delegates whose votes were unsecured. Due to the dichotomy of wealth in the region, the committee did not pass a contentious amendment that acknowledged responsibility to donor countries.

U.S. Ambassador Jimmy Kolker, keynote speaker to the AMWHO 2015 conference, also participated during the final AMRO committee session. Ambassador Kolker briefly represented the United States and offered a few amendments, including one that added lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) to the definition of vulnerable populations, which passed unanimously.

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U.S. Ambassador Jimmy Kolker, Assistant Secretary for Global Affairs at the U.S. Department of Health and Human Services and the U.S. representative to the WHO, works with students on a resolution at the American Mock World Health Organization 2015 conference.

Continued

BOX. Continued

Day 3 Plenary: Convening All Regional Committees to Amend and Finalize Resolutions

In his keynote, U.S. Ambassador Kolker illuminated that it was out of character for a number of countries in the AMRO region to vote in favor of LGBTQ recognition and advised the delegates to be careful to accurately represent their country's official positions in this simulation of international debate.

Similar to the resolutions of most regions, amendments proposed by countries of other regions during plenary were friendly and passed with little contention. The most substantive changes made included an amendment that removed a line requesting NGO collaboration in the WHO audit, which was recommended prior to implementing a universal health coverage system and an amendment to focus on evidence-based outcomes to determine universal health coverage success. Finally, a clause that provisioned for data protection throughout universal health coverage was added.

online survey of delegates to seek feedback on their experience, with 50 responses (40.3% response rate) following the 2014 conference and 39 responses (34.5% response rate) following the 2015 conference. Attendee feedback after each conference is used to inform successes and opportunities for growth in moving this nascent organization forward.

Successes

The vast majority (98%) of respondents from the AMWHO 2014 conference indicated the conference as being "good" or "better," and 90% of respondents indicated they would recommend the conference to a friend. Similarly, the majority (90%) of respondents from the AMWHO 2015 conference rated the experience as "good" or "better," and 97% indicated they would recommend AMWHO to a friend.

Survey respondents were also asked to summarize their AMWHO experiences. Table 5 presents some of the open-ended feedback received from respondents according to the objectives that AMWHO seeks to realize. For example, respondents indicated AMWHO provided opportunities to gain practical experience in formulating global health policy that is not possible in a classroom environment. Other respondents pointed to AMWHO's ability to allow participants to think from the perspective of policy makers and other stakeholders.

In addition, the International Federation of Medical Students' Associations (IFMSA) contact at WHO headquarters indicated that the AMWHO 2014 resolutions were succinct and practical and that only a few amendments exceeded the limitations of the WHO; as a whole, the IFMSA contact indicated the resolutions were similar in style, content, and urgency as those created in the WHA. AMWHO will receive feedback on the 2015 conference by March 2017.

Obstacles

Two major challenges identified in the AMWHO 2014 conference were the plenary structure and the desire for professional development opportunities. The AMWHO 2015 conference provided an opportunity to grow and address these challenges to improve participants' experience.

The vast majority of conference survey respondents rated the conference "good" or "better" and said they would recommend it to a friend.

Plenary

Many participants found the AMWHO 2014 plenary session to be less engaging and productive than the regional bloc sessions. In response, the dais of AMWHO 2015 received additional training to enable them to better facilitate debate, and we imposed time limits for the plenary debate of each resolution. We also placed limits on the number of resolutions each regional bloc could submit to plenary. The 2015 feedback showed that while plenary improved, there is still room for improvement in delegate engagement during plenary debate.

Professional Development Opportunities

Based on 2014 feedback, AMWHO 2015 expanded its professional development and networking opportunities. As a direct result, we hosted the "Lunch and Learn" event on Day 2, during which professionals from a variety of fields and sectors, e.g., business, education, and academia, were invited to eat with students and discuss their careers, paths, and interests. Another purpose of the "Lunch and Learn" event was to expose students to the various fields necessary to realize global health equity. Based on survey responses, the "Lunch and Learn" event was

TABLE 5. Feedback About the American Mock World Health Organization (AMWHO) Conferences: Qualitative Findings From Survey Respondents

AMWHO Objectives	Relevant Qualitative Survey Findings
Student engagement in global health diplomacy	Delegates noted that "AMWHO 2014 was a truly unique event; tackling international issues in healthcare by engaging in constructive debates and drafting resolutions allowed us to think critically about . . . solutions to promote health worldwide" and was "an ingenious way to engage students from various disciplines through *interactive and self-guided learning.*"
Guidance to future directions	One delegate reflected, "Coming with very little experience in the global public health arena, *AMWHO has allowed me to figure out where my purpose is*: at the intersection of public policy and public health. I truly give AMWHO significant credit for giving me clarity regarding my future plans." Another attendee said, "[AMWHO] *revived my passion for diplomacy and advocacy.* This was the first time I saw that my dream could actually be realized and that my potential and the possibilities are endless."
Putting theory and knowledge into practice	Several students commented on the practical nature of the conference. For example, 1 participant observed, "I learned that the intricacies and difficulties of forming global health policy are not something you can really learn in a lecture. The kinds of experiences provided at *AMWHO allowed a paradigm shift not possible in class.*"
Understanding other perspectives	One student remarked, "AMWHO is a unique opportunity because *we learn to think in the perspectives of policymakers, which helps us understand the difficulties involved with it.* As future public health leaders, it's important to understand why nations or parties support or deny certain policies. *If we can understand someone's perspectives, only then can we begin to cooperate* with him/her to create more comprehensive solutions to our world's greatest problems."
Introducing diplomacy and global health skills	One student noted, "As a scientist, it is important for me to understand how health policy is made since it both influences and is influenced by scientific research. *Because of AMWHO I feel much better prepared to be an active participant in bridging the gap between research and global health.*"

The American Mock World Health Organization fills a gap in global health policy education by providing students with the opportunity to develop skills essential to careers in global health governance.

very popular among participants as a profes-sional development tool. Additional networking opportunities included a "Delegate Social" held on Day 1.

CONCLUSION

AMWHO fills a gap in global health policy education by providing students with exposure to the mechanics and political dynamics of the World Health Assembly, and an experiential opportunity to develop skills essential to careers in global health governance. After 3 international conferences, AMWHO has developed an effective structure, with post-conference survey results indicating that AMWHO fulfills its objectives.

Since the creation of the conferences, AMWHO has sought to sustain its experiential education efforts by creating university chapters that engage in mock debate and that host regional conferences throughout the year (Table 3). This has filled an unmet need on campuses with growth from 5 to 12 chapters in 2016 alone.

AMWHO is working toward a future as a registered nonprofit that is in all high school and collegiate institutions in the United States, similar to Model United Nations. As AMWHO grows in scope, its purpose remains to develop, improve, and expand our capacity to create a generation of students who understand the complexities of diplomacy and policymaking. With continued growth, the organization has potential to contribute to developing a cadre of learned, well-trained, and capable global health practitioners for years to come.

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APPENDIX. RESOLUTION OF THE AMERICAS REGION (AMRO) SENT TO PLENARY AT THE 2015 AMERICAN MOCK WORLD HEALTH ORGANIZATION

Code: Resolution AMRO 2.1
Committee: AMRO

Subject: Ensuring universal health coverage as defined by equitable access to health services for all, with an emphasis on access to care for vulnerable populations

Sponsors: Costa Rica, Grenada, Haiti

Signatories: Argentina, Brazil, Canada, Chile, Colombia, Cuba, Dominican Republic, Ecuador, Honduras, Jamaica, Mexico, Peru, Saint Lucia, Uruguay

Defining vulnerable populations as sectors that currently lack or are at the risk of lacking access to health services,

Recognizing that vulnerable populations vary depending on the individual nation, including but not limited to: marginalized groups such as refugees, documented and undocumented immigrants, those of low socioeconomic status, mothers, children, the elderly, and LGBTQ+ populations, as well as geographically isolated populations or populations at high risk of natural disasters or violent conflict,

Affirming the need for the availability of a baseline set of health services for all people,

Noting that having a functional health information system is a prerequisite for achieving efficient and quality health care provision for all populations,

Realizing that the optimal method of health system financing varies among nations,

Recognizing that a successful UHC system must be sustainable,

The General Assembly Plenary,

1. *Requests* the creation of a health information system to collect data and monitor outcomes to tailor health systems to the needs of a given nation or area
   a. *Requests* that individual nations assess health care needs and available resources by creating health information systems to collect and analyze data and monitor outcomes
      i. *Recommends* that the World Health Organization (WHO) audit solutions that implement UHC as they're being carried out in these regions
      ii. *Recommends* that all systems will be maintained with the highest standard of data protection to ensure confidentiality and security
   b. *Suggests* a focus on evidence-based outcomes in determining the success level of a UHC program

2. *Urges* the provision of a basic set of services to be available to all, prioritizing promotion of primary and preventative care, emphasizing maternal and child care
   a. *Strongly suggests* that the basic scope of services in a given nation be expanded beyond the three broad areas stipulated above to encompass specific health needs of each country
      i. *Strongly urges* that the issue of mental health be made a priority when deciding to expand the scope of basic services provided
      ii. *Recommends* results-based implementation of services in accord with the data generated by health information systems and encourage innovative determinations of success in areas (such as mental health) for which data-base metrics of success do not completely address the situation
3. *Endorses* the development by member states of systems for Universal Health Care (UHC) in which all populations with a focus on aiding vulnerable ones, have access to needed health services without incurring financial hardships
   a. *Encourages* the creation of partnerships and collaborations between countries, which may be necessary to make the development of such a system feasible in some developing nations
   b. *Encourages* better targeting and coordination of existing funds to address international issues, including but not limited to migrant populations, disease epidemics, international information databases, and assistance to countries in need with regards to individual universal healthcare coverage systems.
   c. *Supports* the exploration of various financing schemes for individual contributions on a country-by-country basis
   d. *Affirms* countries' responsibility to develop cost-effective health coverage systems
      i. *Emphasizes* strengthening prevention-based programs as a way to potentially lessen financial burdens from preventable diseases, especially among vulnerable populations
4. *Urges* the expansion of health services into underserved regions to provide primary and preventive health services
   a. *Suggests* the development of health facilities in both rural and urban regions to help lessen the geographical barriers and opportunity cost to health care access for vulnerable populations
   b. *Encourages* the development of an able and plentiful health workforce to ensure that people of all regions have access to quality health care
      i. *Suggests* that the aforementioned workforce also serve to educate the local populous with regards to personal healthcare
      ii. *Calls* upon both individual nation as well as the international community to begin a self-sustainable training program, focusing on developing community health worker programs
      iii. *Calls* to be accomplished via the building of human capital of local individuals from communities and local indigenous groups. This will ensure sustainability, cultural relevancy, and trust from locals of health workers.
         1. *Encourages* the formation of Community Health Workers (CHW) programs that are integrated with existing or developing health systems, including supervision and remuneration
   c. *Suggests* utilizing existing and local infrastructure as well as creating and improving new health care infrastructure to maximize efficient resource allocation and ensure cultural sensitivity
5. *Expresses* its appreciation for Non-Governmental Organizations (NGO) participation, and encourages focused exit strategies for countries to remain self-reliant and sustainable

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LETTER TO THE EDITOR

Possible Reasons for Limited Effectiveness of a Skills and Drills Intervention to Improve Emergency Obstetric and Newborn Care

Helen A Allott,[a] Helen Smith,[a] Terry Kana,[a] Mselenge Mdegela,[a] Sarah Bar-Zeev,[a] Charles Ameh[a]

See related article by Varghese.

We read with interest the paper by Varghese et al.[1] regarding the limited effectiveness of a skills and drills intervention to improve emergency obstetric and newborn care and the accompanying editorial by Ricca.[2]

Ricca discussed some possible reasons as to why the intervention had limited effect when it came to improved diagnosis and management of maternal and newborn complications, including systems weaknesses, provider motivation and behavior, and barriers to teamwork in the workplace.

We would like to draw attention to a further possible reason for the limited effectiveness in translating the training into demonstrable improvements in clinical care. While there were statistically significant improvements in both knowledge and skills, as assessed by pre- and post-intervention knowledge and skills assessments, it may be that these improvements, albeit of significance, still did not cross a threshold of the improvement necessary to make a real difference in clinical practice. It could be argued, for example, that a score of 56% in understanding how to recognize and act in an obstetric emergency is simply still not enough.

We would, therefore, suggest that prior to implementing any further such intervention, both the content and mode of delivery of the training intervention be re-explored with a view to gaining an understanding as to why it was that participants' scores did not reach a higher level. Then appropriate changes can be implemented in the training in order to achieve a greater demonstrable level of knowledge and skills improvement, which may be more likely to have an impact on clinical practice.

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In our experience in the multi-country Making It Happen program,[3] setting up skills training rooms[4,5] and training of health care facility-based mentors and supervisors were successful approaches in bringing about change in behavior and practice after training.

As a final point, evaluating the effectiveness of training programs is the last step of an effective training program design but in order to improve the strength of the results, attention must be paid to more robust designs beyond pre- and post-training assessments. Having a matched comparison group with outcome indictors linked to the training intervention will minimize bias associated with the results. The stepped wedge research design[6] allows all clusters to receive the intervention at various times while being part of the control group at some point. This design is better suited for when it is known that an intervention has benefits, and therefore it is unethical to withhold the intervention from other groups.

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