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GLOBAL HEALTH: SCIENCE AND PRACTICE

2017 | Volume 5 | Number 4

www.ghspjournal.org

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

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Front cover: A community health worker in India measures a participant's blood pressure in the community. © 2015 Aditya Khetan, SEHAT.

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EDITORIAL

Modeling Outputs Can Be Valuable When Uncertainty Is Appropriately Acknowledged, but Misleading When Not

Steve Hodgins[a]

While modeling approaches seek to draw on the best available evidence to project health impact of improved coverage of specific interventions, uncertainty around the outputs often remains. When the modeling estimates are used for advocacy, these uncertainties should be communicated to policy makers clearly and openly to ensure they understand the model's limits and to maintain their confidence in the process.

See related articles by Askew et al., Rodriguez et al., and Jones-Hepler et al.

In efforts to further the use of evidence for policy and planning decision making, there has been considerable use in global health—across a variety of technical areas—of quantitative modeling approaches that attempt to project health impact of improved coverage of specific "evidence-based" interventions. This approach has roots in analyses done for the World Bank's *World Development Report 1993: Investing in Health*,[1] which emphasized provision of a "minimum essential package of services" and modeled expected population-level impacts of improved coverage of "evidence-based" interventions in terms of disability-adjusted life years.

This issue of GHSP includes 3 papers on the use of such models, one in the family planning field (Askew[2]), another at the confluence of family planning and HIV/AIDS (Rodriguez[3]), and the third in maternal and newborn health (Jones-Hepler[4]).

AVOIDING CONFUSION IN FAMILY PLANNING IMPACT, WHEN A MULTIPLICITY OF ALTERNATIVE MODELS ARE AVAILABLE

As discussed by Askew et al.,[2] when multiple modeling approaches or packages are used to address the same question for the same setting and end up with disparate estimates, policy makers' confidence in the methodology can diminish. Because models used in the same field may be developed with different purposes in mind, there may be entirely valid reasons for them to yield differing estimates. To best serve the policy and program communities, however, ideally there should be some degree of harmonization across models. Askew et al. document one such effort at convergence, demonstrating that models can be modified, assumptions synchronized, and data sources aligned; however, some differences remain. This is not necessarily a problem, providing that modelers offer transparency regarding the assumptions and data inputs used, thereby better enabling users of the estimates to understand how the output was derived.

EXPLORING TRADE-OFFS IF PROGESTIN-ONLY INJECTABLE CONTRACEPTIVES MIGHT INCREASE HIV RISK

Rodriguez and colleagues[3] estimate life-years lost in a variety of settings and scenarios, comparing use or non-use of progestin-only injectable contraception. Specifically, they weigh possible reductions in HIV transmission (assuming, on the basis of ambiguous evidence to date, that use of progestin-only injectables increases such risk) against excess maternal mortality resulting from use of less effective contraception or none at all. The authors document well the assumptions and the "moving parts" in their model, finding that under most scenarios, fewer life-years are lost retaining use of these injectables.

AN ESTABLISHED MODEL IN MCH INTERVENTIONS AND A NEWCOMER COVERING SIMILAR GROUND

In the maternal and child health field, LiST (Lives Saved Tool) has a well-established presence. The pioneering 2003 *Lancet* Child Survival series included the first prominent use of an early version of the model,[5] projecting the expected impact of improvements in coverage for a

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prioritized set of simple interventions on the number of child deaths. The LiST website reports that since that time 82 peer-reviewed papers have been published based on analyses using LiST.[6] In addition to its use in the peer-reviewed literature, LiST has also been widely used for advocacy efforts (for example, in major *Lancet* series on child and newborn health and in Millennium Development Goal and Sustainable Development Goal visioning documents) and as an input to program planning by ministries of health, global technical agencies, and donors.

The website provides detailed documentation on how the model works, the evidence base for the intervention effect sizes, and the data inputs used. Further documentation has recently been published in a supplement in *BMC Public Health*.[7] As a demographic base, it uses the Spectrum modeling system, which projects the number of births by year, based on available fertility and age-structure data. The package includes built-in datasets allowing for generation of country-level and, in some instances, sub-national estimates. The LiST developers attempt to use a consistent methodology across interventions, allowing for simultaneous modeling of coverage changes across multiple interventions. Although initially developed to focus on interventions with expected direct impacts on child mortality, the family of LiST-related tools has subsequently been applied across other fields in global health and now includes a considerably wider range of interventions, with modules on demographics (DemProj), HIV/AIDS (the AIDS Impact Model, or AIM), and family planning (FamPlan). LiST now also includes maternal and newborn outcomes and a range of interventions or service delivery "packages" (e.g., essential childbirth care, basic emergency obstetrical and neonatal care).

A Particular Niche for MANDATE

As described in the article by Jones-Hepler et al.,[4] MANDATE (Maternal and Neonatal Directed Assessment of Technologies) represents a more recent approach and remains a much smaller-scale enterprise than LiST and thus should not be seen as an equivalent or direct competitor to LiST. The first peer-reviewed article using MANDATE dates to 2013,[8] and at least 6 more papers have been published since. Whereas LiST has its roots in child health and pediatrics, MANDATE's origins lie in maternal health and obstetrics, a domain which is less well developed in LiST. As the reader will see in the article by Jones-Hepler and colleagues, the developers of MANDATE argue for a modeling approach that (1) can incorporate, in a more granular way, the elements and process of care around delivery and childbirth, and (2) separately examines specific "subconditions," rather than only broad categories of causes of death. As an example, under the rubric of postpartum hemorrhage, uterine atony and retained placenta require different interventions. The Jones-Hepler article in this issue of GHSP traces how the various steps in management of postpartum hemorrhage are handled in their model.

In its current form, MANDATE has built-in datasets for India and sub-Saharan Africa and generates region-wide (rather than country-specific) estimates. In contrast to LiST, it has largely been used for exploring different scenarios to determine what strategies for improving care may be most effective in driving down mortality attributable to specific causes of maternal and newborn deaths. Also in contrast to LiST, it has not been used extensively for advocacy.

In short, LiST and MANDATE have been developed for somewhat different purposes and they are constructed somewhat differently. However, as with modeling for other areas of global health, the 2 approaches share similarities with regard to both utility and potential pitfalls. Importantly, both permit exploration of different possible scenarios, making use of best available epidemiologic data and intervention efficacy estimates. This is important and helpful. But there are also problems.

THE POWER AND PITFALLS OF MODEL USE FOR ADVOCACY

Bringing evidence to bear on strategy, prioritization, and policymaking is an essential, but challenging, process on multiple levels. Inevitably, policymaking is driven not solely by evidence. Power, stakeholder or special interests, and emotional appeals can weigh heavily. It is no accident that LiST uses the emotionally engaging metric of "lives saved" rather than the drier notion of "mortality rate reductions." But contributing to advocacy efforts raises a dilemma for those engaged in evidence generation. In principle, science has some tolerance of uncertainty and ambiguity. Indeed, in peer-reviewed scientific papers, modesty concerning causal claims is valued, and transparent discussion of assumptions, methods, and study limitations, including uncertainties associated with estimated quantities, is expected. But for advocacy, simplicity, certainty, and a good

When multiple modeling approaches are used to address the same question for the same setting and end up with disparate estimates, policy makers' confidence in the methodology can diminish.

Science has some tolerance of uncertainty and ambiguity, but advocacy prizes simplicity, certainty, and a good story.

When modeling is used for advocacy purposes, there is little, if any, acknowledgment of the uncertainties associated with the model outputs.

Models are valuable tools, but we should seek to play a more open, neutral role with our policymaking colleagues to represent any remaining uncertainty in the models.

relatable story are prized. These sets of values stand in tension with each other.

Modeling approaches such as LiST and those highlighted in this GHSP issue seek to draw upon the best available evidence. The reality, however, is that in many instances the best available evidence isn't very complete or robust, and much remains uncertain. Potential sources of uncertainty or bias remain in these models, for example:

- Threat of residual confounding when observational studies are used to estimate intervention effect size
- Important factors present in the original setting where these studies were conducted that could be effect modifiers, amplifying or attenuating effect size that could otherwise have been evident under other conditions
- Causal simplifications that do not model important potential interactions, for example between nutrition status and infection, or between different infectious diseases
- Measurement issues such as using verbal autopsy approaches for cause-of-death determinations or ascertaining coverage through population-based surveys
- Cause-of-death distributions in sub-populations (for example, demographic surveillance sites) that may not necessarily be generalizable to national scale or to neighboring jurisdictions
- Determining effect sizes from trials originally designed only to provide all-cause mortality effect estimates, requiring modelers to convene (fallible) experts to guess what proportion of averted death can be attributed to a specific cause
- In the absence of any trial evidence on mortality effects, relying on systematically collected expert opinion through Delphi-type processes

THE IMPORTANCE OF TRANSPARENCY

Those directly involved in reviewing and collating such diverse data sources—and who are thus well aware of the simplifying assumptions one must make with models like these—recognize the very considerable uncertainties associated with the output of these models. They can see both the strengths and the limitations of the model assumptions and data inputs, and are thus well positioned to take the model outputs with a grain of salt, or two. Unfortunately, in many instances, when the outputs of these models are pressed into the service of advocacy there is little, if any, acknowledgment of these uncertainties. As a result, rather than evidence-based policymaking, the process may become an appeal to the mystique of science, asking that the model output be heeded like the authoritative pronouncement of an oracle. Many policy makers may simply be overawed by the complexity of the mathematical modeling and assume that there *must* be some validity of the findings, when in fact findings may be highly misleading.

Models such as these are valuable tools—especially for exploring different scenarios, in our efforts to identify promising strategies for population health gains. But let's seek to play a more open, neutral role with our colleagues on the policymaking and resource-mobilization side, sharing insights from our evidence base as clearly as we can but not misrepresenting the remaining uncertainty.

Competing Interests: None declared.

REFERENCES

1. World Bank. *World Development Report 1993: Investing in Health*. New York: Oxford University Press; 1993. https://openknowledge.worldbank.org/handle/10986/5976. Accessed December 6, 2017.
2. Askew I, Weinberger M, Dasgupta A, et al. Harmonizing methods for estimating the impact of contraceptive use on unintended pregnancy, abortion, and maternal health. *Glob Health Sci Pract.* 2017;5(4). CrossRef
3. Rodriguez MI, Gaffield ME, Han L, Caughey AB. Re-evaluating the possible increased risk of HIV acquisition with progestin-only injectables versus maternal mortality and life expectancy in Africa: a decision analysis. *Glob Health Sci Pract.* 2017;5(4). CrossRef
4. Jones-Hepler B, Moran K, Griffin J, et al. Maternal and Neonatal Directed Assessment of Technologies (MANDATE): methods and assumptions for a predictive model for maternal, fetal, and neonatal mortality interventions. *Glob Health Sci Pract.* 2017;5(4). CrossRef
5. Jones G, Steketee RW, Black RE, Bhutta ZA, Morris SM; Bellagio Child Survival Study Group. How many child deaths can we prevent this year? *Lancet.* 2003;362(9377):65–71. CrossRef. Medline
6. Research Conducted With LiST. LiST: The Lives Saved Tool – software that estimates survival of mothers and children website. http://livessavedtool.org/research/research-conducted-with-list. Accessed November 4, 2017.
7. Walker N, Friberg I, editors. The Lives Saved Tool in 2017: updates, applications, and future directions. *BMC Public Health*. 2017; 17(suppl 4). https://bmcpublichealth.biomedcentral.com/articles/supplements/volume-17-supplement-4. Accessed December 6, 2017.
8. McClure EM, Rouse DJ, Macguire ER, et al. The MANDATE model for evaluating interventions to reduce postpartum hemorrhage. *Int J Gynaecol Obstet.* 2013;121(1):5–9. CrossRef. Medline

Cite this article as: Hodgins S. Modeling outputs can be valuable when uncertainty is appropriately acknowledged, but misleading when not. Glob Health Sci Pract. 2017;5(4):530-533. https://doi.org/10.9745/GHSP-D-17-00444

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COMMENTARY

Extended Effectiveness of the Etonogestrel-Releasing Contraceptive Implant and the 20 μg Levonorgestrel-Releasing Intrauterine System for 2 Years Beyond U.S. Food and Drug Administration Product Labeling

Moazzam Ali,[a] Luis Bahamondes,[b] Sihem Bent Landoulsi[a]

Recently published evidence from 2 large studies find that the duration of effectiveness of the etonorgestrel-releasing contraceptive implant to be at least 5 years (compared with the current 3-year label), and for the 20 μg levonorgestrel-releasing intrauterine system at least 7 years (compared with the current 5-year label).

BACKGROUND

Contraceptive implants, the levonorgestrel-releasing intrauterine system (LNG IUS), and the copper-bearing intrauterine device (IUD) are long-acting reversible contraceptives (LARCs) with high contraceptive effectiveness. The cumulative pregnancy rates in the first 3 years of use of LARCs is 0.9 per 100 woman-years.[1] In comparison, the percentages of women experiencing an unintended pregnancy during the first year of typical use of short-acting methods are much higher, including for male condoms (18%), the diaphragm (18%), Depo-Provera injectables (6%), and combined oral contraceptive pills or progestin-only pills (9%).[2]

The high effectiveness of LARCs is equal in women of all ages, whereas younger women using the pill, patch, or vaginal ring have a significant increase in contraceptive failure in comparison with failure rates among older women.[3] Moreover, LARCs convey many other advantages for clients in terms of convenience, satisfaction, ease of continuation, likelihood of avoiding unintended/unwanted pregnancy, and noncontraceptive benefits.[3–8] For these reasons, LARCs should also be among the readily available contraceptive choices for women, including young and nulliparous women. If their duration of effective use were to be extended, that would likely be another perceived benefit of LARCs.

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BRIEF DESCRIPTION OF HORMONAL LARCs

Etonogestrel-Releasing Implant

The etonogestrel (ENG)-releasing implant contains 68 mg ENG embedded in 1 ethylene-vinyl-acetate rod[9] (marketed in the United States as Implanon and Nexplanon, Merck & Co., Inc., Whitehouse Station, NJ, USA). ENG is the biologically active metabolite of desogestrel used in some combined and progestogen-only contraceptive pills. The ENG-releasing implant is currently labeled for 3 years of use. The original 1-rod ENG-releasing contraceptive implant had first regulatory approvals in 1998 in Indonesia.

Mechanism of action. Contraceptive implants act by binding to their receptors located in diverse target cells, which are distributed along the hypothalamic-pituitary-gonadal-genital tract axis. The implant has the ability to interfere with several key processes required for gamete encounter and fertilization. The progestins work both by suppressing and altering ovulation and by thickening the cervical mucus.[9] They also restrict or suppress the access of fertile spermatozoa to the site of fertilization.

Levonorgestrel-Releasing Intrauterine System

The LNG IUS is a T-shaped device that is labeled for up to 5 years of use. It has been available in Europe since 1990 and in the United States since 2000. It is marketed under the name Mirena (Bayer Schering Pharma, Berlin, Germany) and contains 52 mg levonorgestrel.[10] The LNG IUS consists of a rate-controlling membrane, which releases 20 μg/day, that serves to regulate the rate of hormonal release.[11]

Mechanism of action. The contraceptive and therapeutic effects of the LNG IUS are mainly based on 3 local effects of LNG in the uterus: thickening of the cervical mucus, inhibition of sperm motility and function inside the uterus and the fallopian tubes, and prevention of fertilization and endometrial growth.[11]

PHARMACOKINETIC DATA SUPPORT LONGER EFFICACY

ENG-Releasing Implant

The ENG-releasing implant, with 68 mg of ENG as the active ingredient, releases, on average, 60–70 μg/day in weeks 5–6, decreasing to about 35–45 μg/day by the end of the first year, 30–40 μg/day by year 2, and then to 25–30 μg/day at the end of the third year.[12] The bioavailability remains constant and close to 100%, and the elimination half-life of the parent compound is around 25 h.[13] Existing data suggest that an ENG concentration of >90 picograms per milliliter (pg/mL) is necessary to effectively prevent ovulation.[14] In normal-weight women (i.e., body mass index [BMI]=18.5–24.9 kg/m^2), the average ENG concentrations at 2 and 3 years post-insertion are 194 and 156 pg/mL, respectively. Pharmacokinetic (PK) analysis shows that at the end of the labeled life span of the ENG-releasing implant (i.e., 3 years), the serum hormone levels are above the threshold for effective contraception,[13,15] indicating that the ENG-releasing implant is likely to be effective for contraception up to the fourth and fifth years of use.[16–18]

Moreover, McNicholas et al.[17] reported that among ENG-releasing implant users with serum ENG results, the median ENG level was 207.7 pg/mL (range 63.8–802.6 pg/mL) at the end of the third year, 166.1 pg/mL (range 25.0–470.5 pg/mL) at the end of the fourth year, and 153.0 pg/mL (range 72.1–538.8 pg/mL) at the end of the fifth year. Thus, at the end of fifth year, the median ENG concentrations are above 90 pg/ml, which effectively prevents ovulation.[14] So even if blood levels with the ENG-releasing implant dropped lower in still later years to the point where some ovulation were to occur, efficacy should in principle remain excellent for a time beyond 5 years. Nevertheless, some caution should be taken as there may be variation among women.

LNG IUS

The LNG IUS has exceptionally good efficacy because it works by both a local effect of the hormone on cervical mucus and uterine milieu and a systemic effect to impair ovulation. Blood levels can be taken as indicative of both effects. During the first year of use, the LNG IUS releases 20 μg of LNG every 24 hours, declining slowly over the labeled lifetime of the device. Release of the hormone decreases to 11 μg per 24 hours by the end of 5 years, with an average release rate of 14 μg per day over the life of the device.[19,20]

A recent PK study showed that LNG plasma levels decline over time, with the greatest relative drop occurring between years 2–3 of use, followed by a sustained plateau from years 4–8.[21] Women who used the LNG IUS for ≥6 years had statistically significantly lower but still similar LNG serum levels than women who used the LNG IUS ≤5 years (126±44 pg/mL vs.157±62 pg/mL, respectively; *P*=.01); however, there were no pregnancies reported in either group.[21]

LARCs should be among the readily available contraceptive choices for women.

A recent pharmacokinetic study showed that the greatest relative drop in LNG plasma levels among LNG IUS users occur between years 2–3 of use, followed by a sustained plateau from years 4–8.

CLINICAL STUDIES ALSO SUPPORT LONGER EFFICACY

Extended Efficacy of the ENG-Releasing Implant to 5 Years

Recently, a multicenter clinical trial conducted by the World Health Organization (WHO) compared the clinical performance and contraceptive efficacy of Jadelle and Implanon with a non-randomized control group of women using the copper-bearing TCu380A IUD.[18] The trial was originally designed for 3 years and was conducted in Brazil, Chile, the Dominican Republic, Hungary, Thailand, Turkey, and Zimbabwe. Women in the IUD group were matched by age (in 5-year bands) to every second woman allocated to an implant. At the 36-month visit or earlier, all study participants were invited to participate in an extended phase of the study for an additional 2 years. A subset of 390 ENG-releasing implant and 522 LNG-releasing implant participants consented to extended use up to 5 years. The main outcome of the extended study was to obtain the 4- and 5-year annual and cumulative effectiveness rates, continuation rate, and side effects for both contraceptive implant systems.

During the extended period through 5 years of use, while the products were in situ, no subdermal implant user became pregnant among the 7,060 and 10,883 woman-months of observation for the ENG-releasing and LNG-releasing subdermal implant group, respectively (Table 1). At the completion of 5 years, the cumulative pregnancy rates among ENG- and LNG-releasing implant users

Pharmacokinetic analysis shows that at the end of the labeled life span of the ENG-releasing implant, the serum hormone levels are above the threshold for effective contraception.

A recent multicenter WHO clinical trial found no pregnancies among implant users through 5 years of use.

TABLE 1. Pregnancy Data Among LNG- and ENG-Releasing Subdermal Implant Users Through 5 Years of Use From Ali et al., 2016[18]

	LNG-Releasing Implant				ENG-Releasing Implant			
	Years 1–3[a]	Year 4[a]	Year 5	Years 1–5 (Cumulative)	Years 1–3[a]	Year 4[a]	Year 5	Years 1–5 (Cumulative)
No. of women	997	470	330		995	311	204	
Woman-months of observation	28670	6,254	4,629	30,325	28786	4,606	2,454	22,044
No. of pregnancies	3[b]	0	0	3	3[b]	0	0	3
Cumulative pregnancy rates per 100 woman-years[c] (95% CI)	0.4 (0.1–1.4)		0.8 (0.2, 2.3)		0.4 (0.1–1.4)			0.6 (0.2, 1.8)

Abbreviations: CI, confidence interval; ENG, etonogestrel; LNG, levonorgestrel.
[a] Cut-off for 3 years was at 38 months post-insertion while year-4 data started at 36 months post-insertion, resulting in a 2-month overlap in data. Woman-months of observation between these 2 time periods, however, is not additive.
[b] Pregnancy data from the first 3 years reported in Bahamondes et al., 2015.[22]
[c] Kaplain-Meier rates.

TABLE 2. Pregnancy Data Among ENG-Releasing Implant Users Through 5 Years From McNicholas et al., 2017[17]

	Year 4	Year 5
No. of women	223	102
Woman-years of observation	444.0	
No. of pregnancies	0	0
Pregnancy rate per 100 woman-years (1-sided 97.5% CI)	0 (0, 1.48)	0 (0, 2.65)

Abbreviations: CI, confidence interval; ENG, etonogestrel.

were statistically equivalent: 0.6 (95% confidence interval [CI], 0.2 to 1.8) and 0.8 (95% CI, 0.2 to 2.3), respectively. From the time of insertion to the extended phase of the study, ENG-releasing implant users accumulated more than 22,000 woman-months of use. During the same time frame, the 2-year pregnancy rate in the copper-bearing IUD group compared with the 2 implant groups combined was 4.1 per 100 woman-years (95% CI, 2.5 to 6.5).

Moreover, recently, McNicholas et al. reported results of a large follow-up study of the ENG-releasing implant and the LNG IUS.[17] For the ENG-releasing implant, 223 users who continued for more than 12 additional months beyond the labeled life span had no pregnancies per 100 woman-years (1-sided 97.5% CI, 0 to 1.48) at the fourth year of use, and 102 participants who continued for more than 24 additional months also had zero pregnancies per 100 woman-years (1-sided 97.5% CI, 0 to 2.65) at 5 years (Table 2).

In a multicenter WHO randomized controlled trial, the cumulative 7-year pregnancy rate of the LNG IUS was 0.5 per 100 woman-years.

Extended Efficacy of the LNG IUS to 7 Years

Results of a WHO-sponsored, open-label, 7-year randomized controlled trial were recently published from 20 centers, 11 of which were in China.[23] The main objectives were to compare rates of unintended pregnancy, method continuation, and reasons for removal among women using the 52-mg LNG IUS (daily release 20 μg) or the TCu380A IUD. Over the 7-year period, 7 pregnancies occurred among LNG IUS users, all intrauterine pregnancies. The cumulative 7-year pregnancy rate of the LNG IUS was 0.5 per 100 woman-years (95% CI, 0.3 to 0.8; standard error 0.2) (Table 3). No pregnancy occurred from 8 to 11 years of use in either the 1,342 woman-years of observation of the TCu380A or the 681 woman-years of observation of the LNG IUS, based on 682 TCu380A IUD users and 398 LNG IUS users starting the eighth year of use. The study data concludes that the 52-mg LNG IUS is safe with very high contraceptive efficacy and very low cumulative pregnancy rates through 7 years of use.[23]

Supporting the findings of the WHO study,[23] McNicholas et al.[17] also reported the effectiveness of the 52-mg LNG IUS into the sixth and seventh year. Among the 496 women using this LNG IUS, 696.9 woman-years of follow-up were completed, with only 2 total pregnancies reported in the sixth and seventh year (Table 4). The failure rate in the sixth year of use of the 52-mg LNG IUS is calculated as 0.25 per 100 woman-years (95% CI,

0.04 to 1.42), and in the seventh year, 0.43 per 100 woman-years (95% CI, 0.08 to 2.39). These failure rates are comparable with the published failure rate of the device's current U.S. Food and Drug Administration (FDA)-labeled period of 5 years. The study concluded that the LNG IUS continues to be highly effective for at least 2 years of additional use beyond its labeled life span.

Studies from the early development of the LNG IUS also found no pregnancies in years 5 to 7, further supporting the longer duration of efficacy.[24–28]

IMPLICATIONS

Highly effective LARCs can be an excellent contraceptive choice for clients wishing to avoid unplanned pregnancies. Recent studies find that both the ENG-releasing contraceptive implant and the 20 µg/day LNG IUS are highly effective for at least an additional 2 years beyond their FDA labels—from the current 3-year label for ENG-releasing implants to at least 5 years, and from the current 5-year label for the LNG IUS to at least 7 years—and with far better efficacy than many other contraceptive methods.

Extending the labeled duration of effective use for ENG-releasing subdermal implants and the LNG IUS would have many benefits for women and for family planning programming. Access to choice of contraceptive methods is considered a basic right for women and couples,[29] and extending use of these methods could help with access and choice for women when considering contraceptive methods. Longer duration is safer for users, requires less frequent removal and insertion cycles, and reduces the chances of procedural errors. Also, extended use saves the client time and money, and may be cost effective for the health system. For example, international donor agencies currently pay US$9 per unit for an ENG-releasing implant; if 2 additional years were added to its life span, the commodity cost per couple-year of protection would drop from US$3 to US$1.80.[18]

In interpreting these studies, a few limitations should be taken into account including the observational nature of one of the studies,[18] loss to follow-up, and limited data on women with a body mass index (BMI) >30 kg/m.[2,18]

The manufacturers of these products should take note of the findings of these studies and seriously consider relabeling their duration of use. In the current situation, it is unclear whether the licensed owners of these products will be interested in taking steps toward this change. Given the major advantages of these methods and the benefits to women to continue using a method they are already successfully using, programs, policy makers, and providers should take note of these findings and provide women using these methods the option, should they wish to continue their use for an additional 2 years. It is a matter of informed choice. A systematic review summarizing the safety and effectiveness of extended use of these LARCs would be an important step in making recommendations for WHO's medical eligibility criteria for extended use.

TABLE 3. Comparative Efficacy of the TCu380A IUD and the 52-mg LNG IUS Over 7 Years From Rowe et al., 2016[23]

	TCu380A IUD	LNG IUS
No. of women	1,871	1,884
Woman-years of observation	10,088	7,903
No. of pregnancies	33	7[a]
Cumulative pregnancy rate per 100 woman-years (95% CI)	2.5 (2.1, 2.9)	0.5 (0.3, 0.8)

Abbreviations: CI, confidence interval; IUD, intrauterine device; LNG IUS, levonorgestrel-releasing intrauterine system.
[a] No pregnancies were reported in years 6 and 7.

TABLE 4. Pregnancy Data Among Users of the 52-mg LNG IUS From McNicholas et al., 2017[17]

	Year 6	Year 7
No. of women	496	
Woman-years of observation	696.9	
No. of pregnancies	2	
Pregnancy rate per 100 woman-years (95% CI)	0.25 (0.04, 1.42)	0.43 (0.08, 2.39)

Abbreviations: CI, confidence interval; LNG IUS, levonorgestrel-releasing intrauterine system.

Acknowledgments: We would like to acknowledge James Kiarie, Mary Lyn Gaffield, Antonella F. Lavelanet, and Madeline Farron for their helpful comments on the final version of this manuscript.

Funding: This work was funded by the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), a cosponsored program executed by the World Health Organization (WHO).

Disclaimer: This report contains the collective views of an international group of experts, and does not necessarily represent the decisions or the stated policy of the World Health Organization.

Competing Interests: None declared.

Recent studies find that both the ENG-releasing implant and the 20 µg LNG IUS are highly effective for at least an additional 2 years beyond their FDA labels.

REFERENCES

1. Winner B, Peipert JF, Zhao Q, et al. Effectiveness of long-acting reversible contraception. *N Engl J Med.* 2012;366(21):1998–2007. CrossRef. Medline
2. Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M, editors. *Contraceptive Technology.* 20th rev. ed. New York: Ardent Media; 2011.
3. Bryant AG, Stuart GS, Narasimhan S. Long-acting reversible contraceptive methods for adolescents with chronic medical problems. *J Pediatr Adolesc Gynecol.* 2012;25(6):347–351. CrossRef. Medline
4. Hubacher D, Grimes DA. Noncontraceptive health benefits of intrauterine devices: a systematic review. *Obstet Gynecol Surv.* 2002;57 (2):120–128. CrossRef. Medline
5. Krajewski CM, Geetha D, Gomez-Lobo V. Contraceptive options for women with a history of solid-organ transplantation. *Transplantation J.* 2013;95(10):1183–1186. CrossRef. Medline
6. Cravioto MC, Jiménez-Santana L, Mayorga J, Seuc AH. Side effects unrelated to disease activity and acceptability of highly effective contraceptive methods in women with systemic lupus erythematosus: a randomized, clinical trial. *Contraception.* 2014;90(2):147–153. CrossRef. Medline
7. Cleland K, Peipert JF, Westhoff C, Spear S, Trussell J. Family planning as a cost-saving preventive health service. *N Engl J Med.* 2011;364(18):e37. CrossRef. Medline
8. Trussell J, Henry N, Hassan F, Prezioso A, Law A, Filonenko A. Burden of unintended pregnancy in the United States: potential savings with increased use of long-acting reversible contraception. *Contraception.* 2013;87(2):154–161. CrossRef. Medline
9. Croxatto HB. Mechanisms that explain the contraceptive action of progestin implants for women. *Contraception.* 2002;65(1):21–27. CrossRef. Medline
10. Mirena [package insert]. Wayne, NJ: BayerHealthCare Pharmaceuticals; 2013.
11. Bayer Inc. Product monograph: Mirena. Mississauga, Ontario, Canada: Bayer Inc.; 2017. http://omr.bayer.ca/omr/online/mirena-pm-en.pdf. Accessed December 8, 2017.
12. Merck & Co., Inc. Implanon Prescribing Information. http://www.merck.com/product/usa/pi_circulars/i/implanon/implanon_pi.pdf. Accessed December 4, 2017.
13. Huber J, Wenzl R. Pharmacokinetics of Implanon: an integrated analysis. *Contraception.* 1998;58(6 suppl):85S–90S. CrossRef
14. Diaz S, Pavez M, Moo-Young AJ, Bardin CW, Croxatto HB. Clinical trial with 3-keto-desogestrel subdermal implants. *Contraception.* 1991;44(4):393–408. CrossRef. Medline
15. Zheng SR, Zheng HM, Qian SZ, Sang GW, Kaper RF. A long-term study of the efficacy and acceptability of a single-rod hormonal contraceptive implant (Implanon) in healthy women in China. *Eur J Contracept Reprod Health Care.* 1999;4(2):85–93. CrossRef. Medline
16. Kiriwat O, Patanayindee A, Koetsawang S, Korver T, Bennink HJ. A 4-year pilot study on the efficacy and safety of Implanon, a single-rod hormonal contraceptive implant, in healthy women in Thailand. *Eur J Contracept Reprod Health Care.* 1998;3(2):85–91. CrossRef. Medline
17. McNicholas C, Swor E, Wan L, Peipert JF. Prolonged use of the etonogestrel implant and levonorgestrel intrauterine device: 2 years beyond Food and Drug Administration approved duration. *Am J Obstet Gynecol.* 2017;216(6):586.e1–586.e6. CrossRef. Medline
18. Ali M, Akin A, Bahamondes L, et al; WHO study group on subdermal contraceptive implants for women. Extended use up to 5 years of the etonogestrel-releasing subdermal contraceptive implant: comparison to levonorgestrel-releasing subdermal implant. *Hum Reprod.* 2016;31(11):2491–2498. CrossRef. Medline
19. ESHRE Capri Workshop Group. Intrauterine devices and intrauterine systems. *Hum Reprod Update.* 2008;14(3):197–208. CrossRef. Medline
20. Nilsson CG, Lahteenmaki PL, Luukkainen T, Robertson DN. Sustained intrauterine release of levonorgestrel over five years. *Fertil Steril.* 986;45(6):805–807. CrossRef. Medline
21. Seeber B, Ziehr SC, Gschliesser A, et al. Quantitative levonorgestrel plasma level measurements in patients with regular and prolonged use of the levonorgestrel-releasing intrauterine system. *Contraception.* 2012;86(4):345–349. CrossRef. Medline
22. Bahamondes L, Brache V, Meirik O, Ali M, Habib N, Landoulsi S; WHO Study Group on Contraceptive Implants for Women. A 3-year multicentre randomized controlled trial of etonogestrel- and levonorgestrel-releasing contraceptive implants, with non-randomized matched copper-intrauterine device controls. *Hum Reprod.* 2012;30 (11):2527–2538. CrossRef. Medline
23. Rowe P, Farley T, Peregoudov A, et al; IUD Research Group of the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development; Development and Research Training in Human Reproduction. Safety and efficacy in parous women of a 52-mg levonorgestrel-medicated intrauterine device: a 7-year randomized comparative study with the TCu380A. *Contraception.* 2016;93 (6):498–506. CrossRef. Medline
24. Diaz J, Faundes A, Diaz M, Marchi N. Evaluation of the clinical performance of a levonorgestrel releasing IUD, up to seven years of use, in Campinas, Brazil. *Contraception.* 1993;47(2):169–175. CrossRef. Medline
25. Hidalgo MM, Hidalgo-Regina C, Bahamondes MV, Monteiro I, Petta CA, Bahamondes L. Serum levonorgestrel levels and endometrial thickness during extended use of the levonorgestrel-releasing intrauterine system. *Contraception.* 2009;80(1):84–89. CrossRef. Medline
26. Sivin I, Stern J, Coutinho E, et al. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the Copper T380 Ag IUDS. *Contraception.* 1991;44(5):473–480. CrossRef. Medline
27. Rönnerdag M, Odlind V. Health effects of long-term use of the intrauterine levonorgestrel releasing system. A follow-up study over 12 years of continuous use. *Acta Obstet Gynecol Scand.* 1999;78 (8):716–721. CrossRef. Medline
28. Lahteenmaki P, Rauramo I, Backman T. The levonorgestrel intrauterine system in contraception. *Steroids.* 2000;65(10-11):693–697. CrossRef. Medline
29. World Health Organization (WHO). Ensuring Human Rights in the Provision of Contraceptive Information and Services: Guidance and Recommendations. Geneva: WHO; 2014. http://who.int/reproductivehealth/publications/family_planning/human-rights-contraception/en/. Accessed December 4, 2017.

Peer Reviewed

Received: August 2, 2017; **Accepted:** October 31, 2017; **First Published Online:** December 20, 2017

Cite this article as: Ali M, Bahamondes L, Bent Landoulsi S. Extended effectiveness of the etonogestrel-releasing contraceptive implant and the 20 μg levonorgestrel-releasing intrauterine system for 2 years beyond U.S. Food and Drug Administration product labeling. Glob Health Sci Pract. 2017; 5(4):534-539. https://doi.org/10.9745/GHSP-D-17-00296

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COMMENTARY

From Research to Policy: The WHO Experience With Developing Guidelines on the Potential Risk of HIV Acquisition and Progestogen-Only Contraception Use

Leo Han,[a] Eva Patil,[a] Nancy Kidula,[b] Mary Lyn Gaffield,[c] Petrus S. Steyn[c]

To develop guidance for women at high risk of HIV, WHO carefully considered the risks of maternal morbidity and mortality from unintended pregnancy against possible increased risk of HIV acquisition with injectable use. Among the many challenges: (1) balancing timeliness of changing the guidance against the potential impact of it; (2) engaging a range of stakeholders; (3) translating complex research and policy messages to clients; (4) needing additional research; and (5) monitoring and evaluating successes and challenges with implementing new guidelines.

The complex relationship between research and global health policy is no better illustrated than by the ongoing discussion regarding the association between HIV acquisition and hormonal contraception, and in particular, progestogen-only injectable contraceptives (POIs). Despite an array of epidemiological, translational, and basic science research, the question persists as to whether there exists a causal increased risk of HIV acquisition in women who use POIs. Most recently, in August 2016 Polis et al. published in the journal *AIDS* an updated systematic review of the available clinical literature.[1] The authors concluded that the highest-quality studies suggest a hazard ratio of 1.4 (95% confidence interval, 1.2 to 1.7) for HIV acquisition in women who use the POI depot medroxyprogesterone acetate (DMPA).

While the currently available scientific evidence demonstrates substantial uncertainty as to whether or not the association between DMPA use and HIV acquisition is causal, the need for up-to-date policy reflecting current findings is often more urgent than waiting for definitive research. The implications of this research for women in areas with high HIV prevalence, such as sub-Saharan Africa, are significant as many of the same countries with high HIV prevalence also experience high maternal morbidity and mortality. Contraceptive use plays a critical role in preventing maternal morbidity and mortality by helping women avoid unintended pregnancy.[2] But unmet need for contraception in sub-Saharan Africa (21%) is the highest in the world.[3] Furthermore, many countries in sub-Saharan Africa often have a limited variety of available contraceptive methods, and POIs such as DMPA and norethisterone enanthate (NET-EN) are familiar and widely used methods—indeed, DMPA is the single most widely used method in most sub-Saharan African countries (Figure 1).[5] For example, over 46% of modern method contraceptive users in the Southern Africa region use POIs.[3,5] At the country level, POIs comprise 56% of modern method use in Uganda, 51% in Ethiopia, and 46% in Kenya.[6]

Removing POIs from the contraceptive method mix in countries with high HIV prevalence as a reflexive response to uncertain associations could result in a large decrease in contraceptive use, which could in turn result in a marked increase in maternal morbidity and mortality from unintended pregnancy. These complicated risk-benefit scenarios have been modeled and indeed demonstrate that removing POIs without the majority of women switching to an alternative highly effective modern contraceptive method would result in more maternal deaths than HIV cases averted,[7,8] and an estimated 9,000 life-years would be lost per 100,000 women.[8] The alternative methods, such as intrauterine devices (IUDs) and contraceptive implants, are far less popular with women in areas of high HIV prevalence such as sub-Saharan Africa, and the number of women needed to switch to these methods in order to reach net neutral mortality is unrealistic in countries with the highest mortality rates.[5,9] For these reasons, conclusions from research like the recent systematic review must be carefully interpreted and communicated to key stakeholders and thoughtfully translated into appropriate practice.

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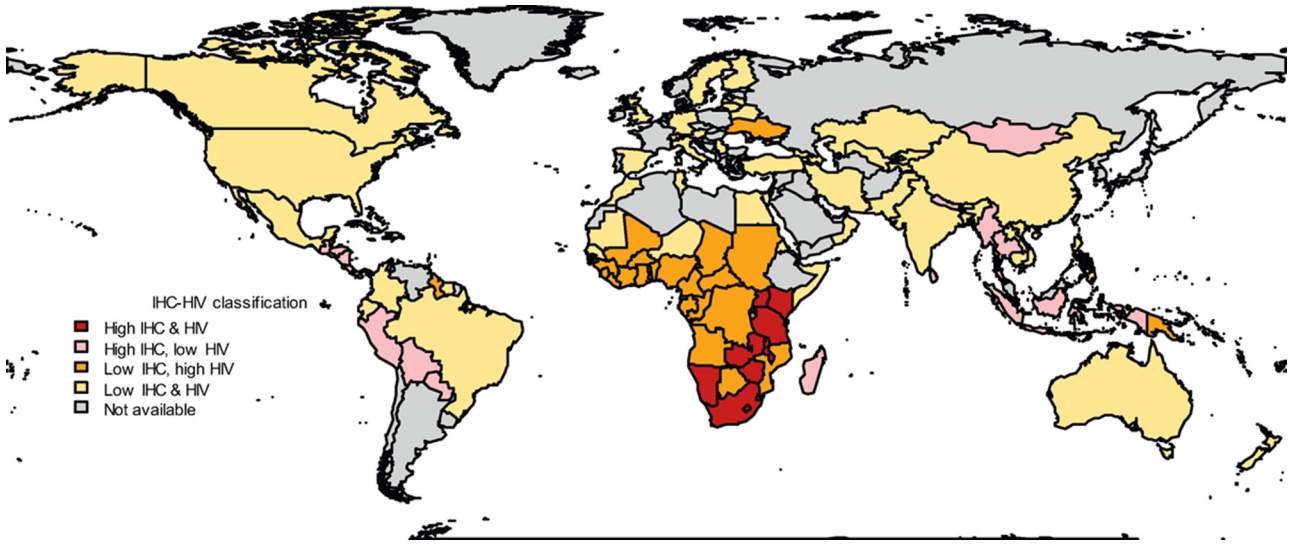
FIGURE 1. Prevalence of Injectable Contraceptive Use and HIV Prevalence by Country



Abbreviation: IHC, injectable hormonal contraception.

Note: sub-Saharan African countries in red have both high HIV prevalence and high injectable hormonal contraception use.

Source: Reproduced from Butler et al. 2013[4] with permission.

The World Health Organization (WHO), in an effort to provide evidence-based sexual and reproductive health guidance to its member states, continually reviews current research and creates and disseminates recommendations to reflect the best health practices with a human rights-based approach.[10] Our experience with the implementation of these evidence-based guidelines reflects how challenging creating health care policy can be. Policy must not only keep up with a changing research landscape but also account for the needs and concerns of multiple stakeholders as well as the people it ultimately will affect. We highlight several aspects of this experience to show just how challenging this process can be.

EVOLUTION OF WHO INJECTABLE USE POLICY

The cornerstone of WHO guidance on contraceptive safety is the maintenance of an up-to-date reference for policy makers, program managers, and health care providers called the *Medical Eligibility Criteria for Contraceptive Use* (MEC).[11] The MEC, now in its fifth edition, contains more than 2,000 recommendations for 25 different contraceptive methods and addresses more than 80 different medical conditions or patient characteristics. It uses a four-tiered classification level stratified by safety for using a contraceptive method given a specific condition (Table). In general, for situations where clinical judgment is limited (for example, in the case of frontline health workers who are often the main POI providers), a woman with a category 1 or category 2 condition can generally use the method, whereas a woman with a category 3 or category 4 designation should not.

The MEC category for POI contraceptive use in women who are at high individual risk for HIV acquisition started as category 1 in the first MEC and stayed a "1" through the fourth edition in 2009 (Figure 2). Up until that time, trials primarily consisted of smaller observational studies with mixed findings, many in populations of female sex workers, which limited generalizability.[12] Newer literature with positive associative findings, including a large analysis of serodiscordant couples from Heffron et al.,[13,14] led to an issuance of a WHO technical statement in 2012 addressing the issue and recommending that category 1 be retained. However, WHO added a specific clarification at that time (denoted by a "1*") that noted the findings of the potential increased risk of HIV acquisition with POI use in women who are at higher risk of acquiring HIV. WHO also

Conclusions from research on the potential increased risk of HIV acquisition with use of injectable contraceptives must be carefully interpreted and thoughtfully translated into appropriate practice.

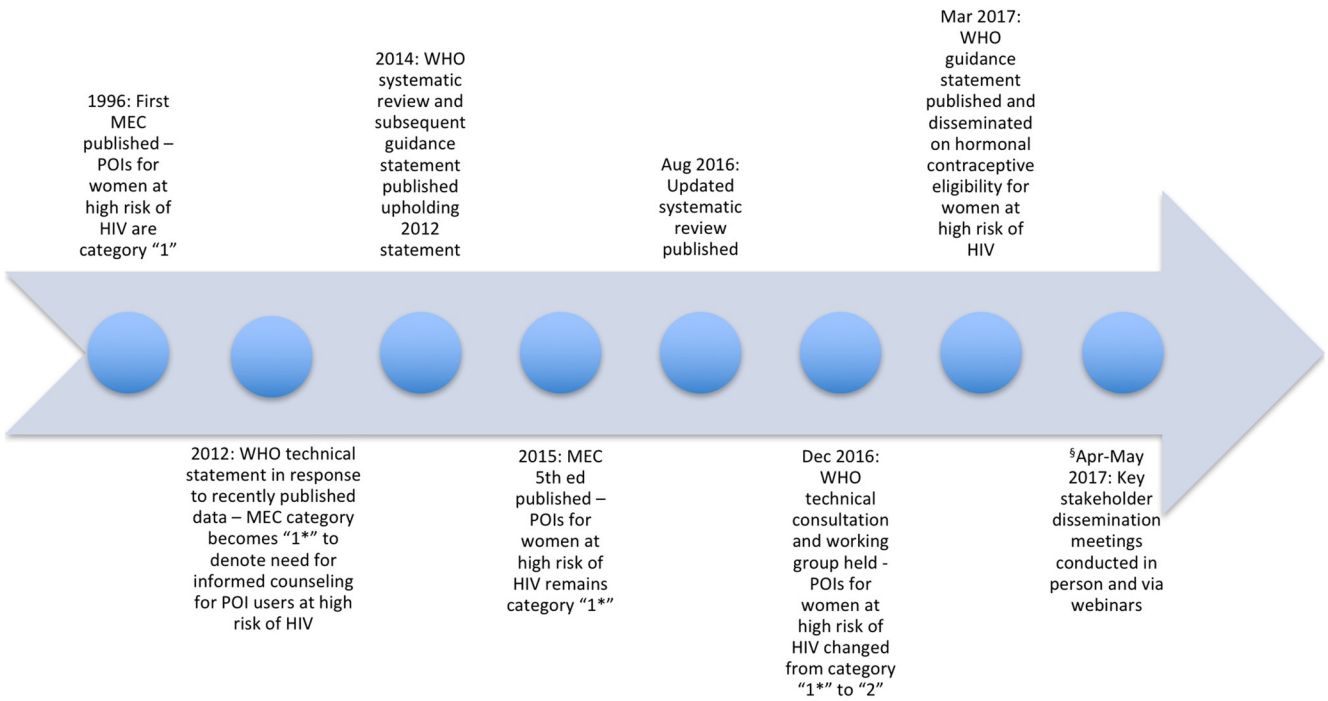
TABLE. Four-Tiered Categorization of Contraceptive Method Eligibility in the World Health Organization's *Medical Eligibility Criteria for Contraceptive Use*[11]

Category	Description
1	A condition for which there is no restriction for the use of the contraceptive method
2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks
3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method
4	A condition which represents an unacceptable health risk if the contraceptive method is used

subsequently sponsored a systematic review to synthesize and evaluate the existing literature.[12] In March 2014, a guideline development group reviewed and reaffirmed the "1*" status and included the upheld recommendation in the current fifth edition of the MEC.

As new data were published, WHO updated the systematic review on the association between hormonal method use and risk of HIV acquisition, resulting in a 2016 publication.[1] These new data, along with a technical consultation with experts in the field in December 2016, led to the most recent change in the MEC for use of POIs by women at high individual risk for HIV, from category 1* (no restriction) to category 2 (benefits outweigh risks). The rationale for this change was

FIGURE 2. WHO Timeline of Events From Publication of Research on Possible Increased Risk of HIV Acquisition in POI Users to Guideline Dissemination to Policy Implementation



Abbreviations: MEC, *Medical Eligibility Criteria for Contraceptive Use*; POI, progestogen-only injectables; WHO, World Health Organization.

§ Two webinars in February 2017 prepared 75 WHO country office team members, ministry of health representatives, family planning donors, and researchers for the publication of the updated guidelines. Following publication, a key stakeholder dissemination meeting was held in Johannesburg, South Africa, in April 2017 with 59 participants. Additional webinars to further disseminate the new guidance were held in April 2017 (156 participants) and May 2017 (98 French-speaking participants).

that the category "1*" designation had not resulted in the intended increased counseling around potential use of POI methods by high-risk individuals, which was explained within the added clarification. The official WHO updated guidance statement was published on March 2, 2017.[15]

CHALLENGES OF GUIDELINE DEVELOPMENT

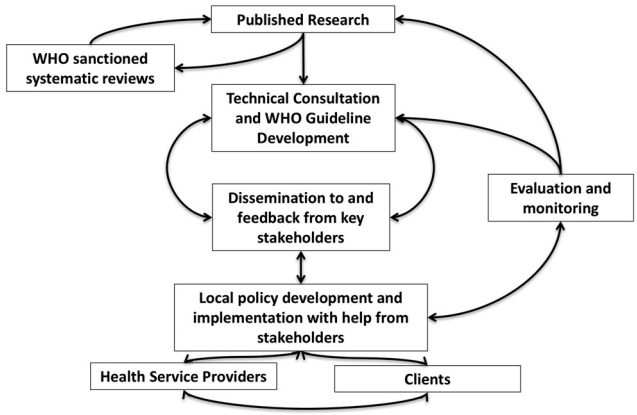
Timeliness

We recognize policy implementation often lags significantly behind research publication. This is usually the result of due diligence to investigate the potential impact of policy changes, including unintended consequences. In considering the possibility of changing the MEC recommendation for POIs, WHO consulted experts in infectious diseases, obstetrics and gynecology, evidence-based medicine, epidemiology, and pharmacology; stakeholders representing key populations at high risk of HIV infection; and managers of public health programs in highly affected settings to assess the strength of the evidence and establish consensus around global messaging prior any guideline changes. Given the high-stake implications of this topic—and the potential for the many nuances to be both oversimplified and sensationalized—WHO deemed a delay in addressing the issue until the next revision of the entire MEC (which takes place approximately every 5 years) was not an option. While the faster response shortened the interval from research to policy, it also meant that stakeholders and health care providers were asked to deal with more frequent changes to guidelines and adjust accordingly. WHO recognized that for some countries and organizations, this called for additional resources that were already limited.

Engagement

Translation of research findings to policy statements—especially those concerning important public health conditions like HIV, and with the potential to be distorted and/or misunderstood by the media—can have implications for a breadth of stakeholders (Figure 3). In the case of POI use and HIV acquisition, policy changes would have significant impact for governmental HIV and family planning programs as we all as NGOs supporting these programs, particularly in countries with a high HIV burden. Finally, civil society and patient advocate groups provide the most direct feedback of policy impact from consumers of family planning and HIV services. Recognizing the potential for an unanticipated and unwarranted impact for these stakeholders, WHO strived to include all relevant participants at the most important plenary meetings (Figure 2).

FIGURE 3. WHO Process of Translating Research to Health Policy



Abbreviations: WHO, World Health Organization.

The WHO reviews newly published research that has the potential to impact health policy during technical consultations with experts in the field. WHO may commission a systematic review of the topic to help collate data and interpret the potential global public health impact of the findings. Experts at the technical consultation will come to consensus on how the research should inform WHO guidelines. The guidelines are then disseminated to key stakeholders (e.g., ministries of health, NGOs, donors, and civil society) for review and comments. Stakeholders help develop policies at the national to the local service delivery levels and communicate updates to service providers and clients. Service providers and clients may provide feedback about policies, resulting in further changes. WHO and stakeholders evaluate and monitor the policies and their implementation, which then informs guideline updates and identifies research gaps.

In fact, we found engagement with stakeholders to be critical throughout this process. Discussions with these stakeholders ultimately led WHO to conclude that initial changes to the MEC from category 1 to category 1* were inadequate. While the initial intent was to retain a category 1 designation so that provision of POIs would not be adversely affected, concerns from stakeholders, particularly managers of national health programs, that the category 1* did not encourage adequate counseling led to a reevaluation of the data and revision of category 1* to category 2 in 2016. Similarly, once the WHO guidance was changed, we found direct engagement with stakeholders in the dissemination process facilitated transparency, increased buy-in to the changes, and encouraged collaborative strategizing with regards to implementation.

Engagement with stakeholders was critical throughout the process of considering WHO guideline changes.

From this experience, we acknowledge that the need for stronger communication and collaboration between the HIV and family planning communities is an area for improvement. While these communities have traditionally been siloed due to a variety of factors including the complex dynamics of donor funding, the organizational structure of ministry of health departments, and the providers of care in community health clinics, they share a large, important demographic of clients—women of reproductive age. In addition to integrating the messaging women receive so that the counseling around HIV and POI use can be optimized, integrating services could increase utilization of preventative services such as testing for HIV and other sexually transmitted infections (STIs) and ensure higher-quality reproductive health care for women living with HIV.[16,17]

Counseling messages and tips on POI use among women at risk for HIV will be included in the updated *Family Planning: A Global Handbook for Providers* (www.fphandbook.org).

Messaging

The gradual, measured evolution of the change in guidance for POI use in women at high individual risk for HIV from MEC category 1 to category 2 reflects a very deliberate attempt to make recommendations that adequately addressed the analyses of observational data that had serious limitations while avoiding drastic, and perhaps unfounded, shifts in global family planning policy. However, communicating this change to patients is exceedingly challenging. Questions like, "What defines high risk?" and "When and how should this message be communicated with women?" have imperfect answers that are particular to local contexts. This also demonstrates the limitation of the use of policy documents in direct clinical care. A policy document that notes "a possible increased risk" seems reasonable in order to reflect the uncertainty of research. In real life, women come to health care encounters with specific goals (i.e., obtain injectable contraception), with preexisting notions about HIV risk from previous messaging or other information sources and with individual levels of fear with regards to HIV transmission and unintended pregnancy based on their life experiences. In the often-brief amount of time women have with providers at these encounters, a nuanced discussion about research uncertainty and values clarification may not be possible.

Communicating complex policy and research data to patients is challenging.

To address these challenges and to optimize the messaging of the most recent policy changes, WHO held an official dissemination meeting in Johannesburg, South Africa, in April 2017 with WHO, ministry of health representatives from 12 of the 14 African countries with HIV prevalence greater than 5%, health organization donors, researchers, representatives from affected populations, and advocacy groups. The meeting was conducted in 2 parts. During the first part, WHO reviewed the research with stakeholders so that understanding was harmonized. While many country and organizational leaders are aware of the general concerns around POIs and HIV acquisition, conveying the nuance would help clarify why the guidance is not straightforward.

The second part of the meeting was focused on implementation. In order to harmonize messaging, WHO did not provide specific messaging but rather a framework that was extensively discussed and edited so that it could reflect the major concerns and suggestions of the stakeholders and also address the issues they anticipated. Following, brief counseling messages were created, which include a series of tips for health care providers to discuss with clients. The dialogue suggests providing clients with 5 key facts about POIs and then 2 key questions to help clients consider whether they want to use POIs. The counseling tips will be included in the updated *Family Planning: A Global Handbook for Providers*, to be released at the end of 2017 (www.fphandbook.org). These meetings also gave WHO an opportunity to reinforce the most important recommendations that were not altered by the change in MEC category:

1. Women and girls at high risk for HIV should not be denied any method of contraception, and rights-based counseling is necessary for them to make an informed choice.
2. Policies and programs need to emphasize dual protection from unplanned pregnancy and STIs/HIV.
3. Women and girls should be given a range of contraceptive options from which they can choose for preventing unwanted pregnancy.

WHO will continue to assist health departments and service providers by providing education and suggested communication techniques through regional meetings, webinars, updated global references, counseling tools, and job aids.

WHO and partners are coordinating a large RCT to provide more definitive evidence about the association of HIV acquisitions with use of Jadelle implants, DMPA injectables, and the copper IUD.

Research

Further research is needed to clarify the uncertainty surrounding POI use and HIV transmission. Most of the current research is observational and therefore limited by potential bias and confounding. Currently WHO, along with FHI 360, the University of Washington, and the Wits

Reproductive Health and HIV Institute, are coordinating a large randomized controlled trial (RCT) (called Evidence for Contraceptive Options and HIV Outcomes [ECHO]) of almost 8,000 women across 12 clinical sites in 4 different countries to provide more definitive evidence about the association of HIV acquisition with use of 3 common contraceptive methods: the levonorgestrel-releasing implant (Jadelle), DMPA, and the copper-bearing IUD.[18] The RCT is scheduled to be completed in 2018, and the findings are expected to provide important information that will inform future WHO guidance on this issue.

However, research should not be limited solely to the question of transmission. We also need a more rigorous study of attitudes and beliefs of women and health care workers in affected countries with regards to HIV and unintended pregnancy; while modeling may give us population-level projections of the impact of new policy, this does not necessarily reflect the values of individual women. Additionally, studies that help us understand not only the best avenues to reach women but also what communication strategies are most effective are sorely needed. This supporting body of research will ensure that the results of future scientific studies such as ECHO can be translated optimally into policy and practice.

Monitoring and Evaluation

We cannot take for granted that the changes to guidelines will automatically result in improved messaging or safer provision of contraceptives. WHO continues to follow the implementation of new guidelines among the most affected countries. For example, through regional and country representatives, WHO regularly audits progress and problems from the countries most affected and provides technical assistance accordingly. Regional meetings —in person and by webinar—are held so that countries may share their experiences with each other and other stakeholders in a formal setting. For example, in early 2018, a virtual meeting among the representatives of the 12 countries attending the April Johannesburg meeting is planned with the purpose of following up on the progress of the national action plans that were developed during the meeting and defining plans for continued monitoring. These ongoing efforts will be ultimately reincorporated into future guidance.

CONCLUSION

The process from publishing research to having impact on health outcomes is not straightforward. Often, major research findings rely on slow, organic infiltration into practice norms. Large normative health institutions such as WHO can shape, guide, and expedite this process by translating research into guidelines and systematically disseminating them to member states and organizations. However, the inputs into these guidelines—and the "translation" of guidelines into practice—are often imperfect as well. In the case of POI contraception and HIV acquisition, WHO sought to balance the risks of maternal morbidity and mortality associated with unintended pregnancy with the risk of HIV acquisition, ultimately putting forth recommendations that would serve to promote the "highest attainable standard of health" for women everywhere. However, depending on one's interpretation of the research, arguments can be made that the ultimate change from an MEC category 1 to category 2 was either premature or not timely enough. It remains to be seen, however, what the impact of these guidelines will be.

The translation of important, often-nuanced research findings from journal page to health policy to the provider-client interaction is complex and challenging work. This is made even more difficult as it is often the part of the process with the least funding and resources. WHO recognizes that even the best efforts are flawed and continues to learn from this experience on POIs and HIV acquisition. Future policy work can use these lessons to improve implementation, minimize harm, and continue disseminating important research to the global health community.

Competing Interests: None declared.

REFERENCES

1. Polis CB, Curtis KM, Hannaford PC, et al. An updated systematic review of epidemiological evidence on hormonal contraceptive methods and HIV acquisition in women. *AIDS*. 2016;30(17): 2665–2683. CrossRef. Medline
2. Guttmacher Institute. Adding it up: investing in contraception and maternal and newborn health, 2017. New York: Guttmacher Institute; 2017. https://www.guttmacher.org/sites/default/files/factsheet/adding-it-up-contraception-mnh-2017.pdf. Accessed November 27, 2017.
3. United Nations (UN), Department of Economic and Social Affairs, Population Division. *World Contraceptive Use 2011*. New York: UN; 2011. http://www.un.org/esa/population/publications/contraceptive2011/contraceptive2011.htm. Accessed October 18, 2017.
4. Butler AR, Smith JA, Polis CB, Gregson S, Stanton D, Hallett TB. Modelling the global competing risks of a potential interaction between injectable hormonal contraception and HIV risk. *AIDS*. 2013;27(1):105–113. CrossRef. Medline
5. United Nations (UN), Department of Economic and Social Affairs, Population Division. *Trends in Contraceptive Use Worldwide, 2015*.

New York: UN; 2015. http://www.un.org/en/development/desa/population/publications/pdf/family/trendsContraceptiveUse2015Report.pdf. Accessed December 5, 2017.

6. PMA2020: Publications: Briefs: Family Planning. Performance Monitoring and Accountability 2020 (PMA2020) website. https://pma2020.org/fp-briefs. Accessed October 18, 2017.
7. Rodriguez MI, Reeves MF, Caughey AB. Evaluating the competing risks of HIV acquisition and maternal mortality in Africa: a decision analysis. *BJOG*. 2012;119(9):1067–1073. CrossRef. Medline
8. Rodriguez M, Gaffield M, Han L, Caughey A. Re-evaluating the possible increased risk of HIV acquisition with progestin-only injectables versus maternal mortality and life expectancy in Africa: a decision analysis. *Glob Health Sci Pract*. 2017;5(4). CrossRef
9. Jacobstein R, Polis CB. Progestin-only contraception: injectables and implants. *Best Pract Res Clin Obstet Gynaecol*. 2014;28(6):795–806. CrossRef. Medline
10. World Health Organization (WHO). *Ensuring Human Rights in the Provision of Contraceptive Information and Services: Guidance and Recommendations*. Geneva: WHO; 2014. http://www.who.int/reproductivehealth/publications/family_planning/human-rights-contraception/en/. Accessed May 1, 2017.
11. World Health Organization (WHO). *Medical Eligibility Criteria for Contraceptive Use*. Fifth ed. Geneva: WHO; 2015. http://apps.who.int/iris/bitstream/10665/181468/1/9789241549158_eng.pdf. Accessed April 19, 2017.
12. Polis CB, Phillips SJ, Curtis KM, et al. Hormonal contraceptive methods and risk of HIV acquisition in women: a systematic review of epidemiological evidence. *Contraception*. 2014;90(4):360–390. CrossRef. Medline
13. Heffron R, Donnell D, Rees H, et al; Partners in Prevention HSV/HIV Transmission Study Team. Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study. *Lancet Infect Dis*. 2012;12(1):19–26. CrossRef. Medline
14. Delvaux T, Buvé A. Hormonal contraception and HIV acquisition - what is the evidence? What are the policy and operational implications? *Eur J Contracept Reprod Health Care*. 2013;18(1):15–26. CrossRef. Medline
15. World Health Organization (WHO). Hormonal contraceptive eligibility for women at high risk of HIV: guidance statement. Geneva: WHO; 2017. http://www.who.int/reproductivehealth/publications/family_planning/HC-and-HIV-2017/en/. Accessed May 4, 2017.
16. FHI 360. *Prevention of Mother-to-Child Transmission of HIV: FHI 360's Strategic Approach*. Durham, NC: FHI 360; 2012. https://www.fhi360.org/sites/default/files/media/documents/Prev%20of%20PMTCT%20FHI360%20strategies_brief.pdf. Accessed December 5, 2017.
17. Price J, Leslie JA, Welsh M, Binagwaho A. Integrating HIV clinical services into primary health care in Rwanda: a measure of quantitative effects. *AIDS Care*. 2009;21(5):608–614. CrossRef. Medline
18. ECHO: Evidence for Contraceptive Options & HIV Outcomes. http://echo-consortium.com/. c2017. Accessed May 4, 2017.

Peer Reviewed

Received: July 16, 2017; **Accepted:** October 31, 2017

Cite this article as: Han L, Patil E, Kidula N, Lyn Gaffield M, Steyn PS. From research to policy: the WHO experience with developing guidelines on the potential risk of HIV acquisition and progestogen-only contraception use. Glob Health Sci Pract. 2017;5(4):540-546. https://doi.org/10.9745/GHSP-D-17-00278

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REVIEW

Interventions for Preventing Unintended, Rapid Repeat Pregnancy Among Adolescents: A Review of the Evidence and Lessons From High-Quality Evaluations

Maureen Norton,[a] Venkatraman Chandra-Mouli,[b] Cate Lane[c]

Evidence shows that effective prevention of rapid repeat pregnancy among adolescents links adolescent-friendly clinical contraceptive services with non-clinical interventions that contribute to positive youth development.

ABSTRACT

Background: In 2017, of the 22.5 million parenting adolescents (ages 15–19) in 60 countries, approximately 4.1 million gave birth to a second or higher-order child. Adolescent pregnancy in general, and rapid repeat pregnancies specifically, expose young mothers and their children to multiple health and socioeconomic risks. The purpose of this article is to review the impact of interventions designed to prevent unintended, rapid repeat pregnancies among adolescents, including those aimed at changing norms to postpone "intended" closely spaced pregnancies to promote healthy spacing.

Methods: We searched PubMed and other databases for evaluations of interventions published in English from 1990 through 2016. We included evaluations that assessed a programmatic intervention specifically designed to prevent rapid repeat pregnancy (occurring less than 24 months after the index birth) or birth (occurring less than 33 months after the index birth), or that reported on contraceptive continuation for at least 2 years. We first assessed the quality of the evaluations, then ranked the interventions based on the quality of the evaluation and the level of impact on repeat pregnancy or birth (statistically significant impact, positive trends but not statistically significant, or no impact) to identify the most effective interventions. Finally, we extracted program design and implementation lessons from the interventions included in the high-quality evaluations.

Results: Our search identified 2,187 articles, of which 40 evaluations met the inclusion criteria (24=high quality, 14=moderate quality, 2=less rigorous). We found 14 high-quality evaluations in which the intervention achieved a statistically significant impact on repeat pregnancy or birth. These interventions fell into 5 broad categories: (1) contraceptive services and information, with proactive monitoring of contraceptive use and outreach to families; (2) postpartum contraceptive counseling and services provided soon after delivery; (3) activities that help adolescents improve planning skills, including preparing contraceptive plans; (4) social and behavioral change activities that help adolescents understand the role contraception can play in determining positive life outcomes, and the implications of their reproductive health decisions for their future; and (5) activities that provide mentoring, goal setting, and motivation.

Conclusion: Effective interventions that prevent rapid adolescent childbearing link clinical contraceptive services with non-clinical activities that build planning skills, enhance understanding of the role that contraceptives can play in determining positive life outcomes, and provide mentoring and goal setting. Recognizing potentially synergistic effects, we recommend testing various combinations of these interventions, with access to contraception as the foundational activity.

INTRODUCTION

The World Health Organization (WHO) and the United States Agency for International Development (USAID) define adolescents as those between the ages of 10 and 19 years of age.[1] The Demographic and Health Surveys (DHS) gather birth data on only the 15–19-year-old subgroup. Focusing on this subgroup, a 2017 analysis of DHS data in 60 USAID-assisted countries in more- and less-developed regions found that 22.5 million adolescents ages 15–19 gave birth (Table 1). Another assessment of adolescent pregnancy in 42 low-resource countries estimated that 2.5 million even-younger adolescents, ages 12–15, also give birth annually.[2]

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In 2017, 22.5 million adolescents ages 15–19 in 60 countries gave birth and, of these, approximately 4.1 million gave birth to a second or higher-order child.

Not all adolescent births are first births. A significant number of adolescents, having begun early childbearing, are at risk of experiencing a rapid repeat pregnancy. In fact, in 2017, of the 22.5 million total adolescent pregnancies occurring in 60 USAID-assisted countries, approximately 4.1 million adolescents gave birth to a second or higher-order child (Table 1). While the *percentages* of adolescents at the country level who have second or higher-order births are relatively small (for example, ranging from 0.1% in Albania and Kyrgyzstan to 9.2% in Niger), the *numbers* of adolescents experiencing a subsequent birth can be large (reaching nearly 1.6 million in India). While many adolescent births occur within marriage where sexual activity and pregnancy are socially sanctioned, it is likely that many of the closely spaced pregnancies are unintended. An analysis of 27 DHS surveys assessed the proportion of women ages 15–49 with unmet need for contraception who were within 1 year of their last delivery and those intending to use a contraceptive method within the next 12 months. The analysis found that "only trivial proportions of both of these groups want another birth within two years."[3]

Adolescent pregnancy exposes young mothers and their children to multiple health and socioeconomic risks. In the most recent and largest analysis known to date (>124,000 mothers in 29 countries), conducted by WHO, adolescent mothers ages 10–19 years had higher risks than mothers ages 20–24 years of eclampsia, puerperal endometritis, systemic infections, low birthweight, preterm delivery, and severe neonatal conditions.[4] In addition, adolescent mothers are less likely to complete school or participate in the labor force, and earn less in their jobs when they do work.[5,6] Short interpregnancy intervals, or rapid repeat pregnancies, also pose their own set of risks including increased risks of preterm birth, low birthweight, small for gestational age, and infant and early childhood mortality.[7–12]

In the United States, the Healthy People 2020 initiative has set forth, for all women and adolescents, a national goal of reducing the proportion of pregnancies conceived within 18 months of a previous birth (27 months between births) by 10%, from 33.1% of all births between 2006 and 2010 to 29.8% of all births in 2020.[13] In low-resource settings, however, few programmatic or policy activities have been devoted to helping pregnant and parenting adolescents (married or unmarried) make an informed choice about contraceptive use to delay or space subsequent pregnancies. Between 2013 and 2016, in 22 USAID priority countries, the percentages of adolescents ages 15–19 with birth intervals less than 24 months decreased notably (by at least 0.2 percentage points) in only 6 countries. Nine other countries were making encouraging progress while 7 other countries witnessed no progress or an increase (Figure 1).

The purpose of this article is to review interventions that were designed to prevent rapid repeat pregnancies among adolescents. This includes interventions focused on educating adolescents, families, and communities about the risks of closely spaced pregnancies and changing norms to promote healthy pregnancy spacing. Our goal is to make available to program designers and managers practical, evidence-based programmatic lessons to help adolescents and young adults avoid rapid childbearing.

METHODS

Study Objectives

Our review addressed the following questions:

- In high-quality evaluations, what is the impact of programmatic interventions on prevention of rapid repeat pregnancy among adolescents?
- In high-quality evaluations, which programmatic interventions are the most effective, and which are less effective, in preventing rapid repeat pregnancy among adolescents?
- What lessons can we learn?

Search Strategy

We conducted computerized searches of PubMed, PsycINFO, Sociological Abstracts, CINAHL, and Cochrane Reviews to identify evaluations of interventions that were published in English from 1990 to December 2016. Search terms included: "birth-to-birth interval," "birth-to-pregnancy interval," "birth interval," "short birth interval," "rapid, repeat pregnancy," "repeat pregnancy," and "adolescent repeat pregnancy." All retrieved literature was screened at the abstract level for relevance, and articles that recorded only shifts in knowledge were excluded. After this initial screening, we assessed eligibility of the remaining articles by reviewing the abstracts a second time to identify those

TABLE 1. Number and Percentage of Adolescents Ages 15–19 With a Birth in USAID-Assisted Countries, by Number of Births

Country	Total No. of Women 15–19	Number of Women 15-19 With:				Percentage of Women 15-19 With:			
		1 Birth	2 Births	3+ Births	Any Birth	1 Birth	2 Births	3+ Births	Any Birth
India 2005–2006	54,635,318	5,026,449	1,365,883	218,541	6,610,873	9.2	2.5	0.4	12.1
Bangladesh 2014	7,787,279	1,720,989	179,107	7,787	1,907,883	22.1	2.3	0.1	24.5
Nigeria 2013	9,955,173	1,353,904	298,655	49,776	1,702,335	13.6	3.0	0.5	17.1
Brazil 1996	8,510,147	966,753	221,264	34,041	1,222,057	11.4	2.6	0.4	14.4
DRC 2013–2014	4,718,045	778,477	188,722	33,026	1,000,226	16.5	4.0	0.7	21.2
Indonesia 2012	11,123,673	738,612	22,247	8,899	769,758	6.6	0.2	0.1	6.9
Tanzania 2015–2016	2,941,151	535,289	76,470	5,882	617,642	18.2	2.6	0.2	21.0
Pakistan 2012	10,722,312	493,226	85,778	10,722	589,727	4.6	0.8	0.1	5.5
Ethiopia 2016	5,805,546	516,694	63,861	5,806	586,360	8.9	1.1	0.1	10.1
Mozambique 2011	1,550,003	373,551	74,400	7,750	455,701	24.1	4.8	0.5	29.4
Angola 2015–2016	1,499,876	337,472	85,493	8,999	431,964	22.5	5.7	0.6	28.8
Uganda 2011	2,283,838	303,750	91,354	15,987	411,091	13.3	4.0	0.7	18.0
Philippines 2013	5,138,070	349,389	41,105	5,138	395,631	6.8	0.8	0.1	7.7
Kenya 2014	2,488,748	301,139	57,241	4,977	363,357	12.1	2.3	0.2	14.6
Madagascar 2008–2009	1,332,247	266,449	62,616	17,319	346,384	20.0	4.7	1.3	26.0
Niger 2012	1,043,873	246,145	82,466	13,362	341,973	23.6	7.9	1.3	32.8
Mali 2012-2013	971,050	241,791	67,974	11,653	321,418	24.9	7.0	1.2	33.1
South Africa 1998	2,372,020	298,875	9,488	2,372	310,735	12.6	0.4	0.1	13.1
Côte d'Ivoire 2011–2012	1,328,997	239,751	62,330	4,386	306,467	18.0	4.7	0.3	23.1
Egypt 2014	4,369,133	253,410	39,322	–	292,732	5.8	0.9	0.0	6.7
Colombia 2015	1,983,614	228,116	37,689	4,166	269,970	11.5	1.9	0.2	13.6
Malawi 2015–2016	1,091,464	223,750	16,372	2,183	242,305	20.5	1.5	0.2	22.2
Burkina Faso 2010	1,087,568	174,663	26,645	2,175	203,484	16.1	2.5	0.2	18.7
Nepal 2016	1,579,950	170,635	26,859	4,740	202,234	10.8	1.7	0.3	12.8
Zambia 2013–2014	859,608	176,220	21,490	2,579	200,289	20.5	2.5	0.3	23.3
Turkey 2003	3,230,340	155,056	19,382	9,691	184,129	4.8	0.6	0.3	5.7
Guinea 2012	654,601	142,572	36,789	3,731	183,092	21.8	5.6	0.6	28.0
Afghanistan 2015	1,992,100	123,510	31,874	3,984	159,368	6.2	1.6	0.2	8.0
Ghana 2014	1,377,890	139,167	15,157	1,378	155,702	10.1	1.1	0.1	11.3
Peru 2012	1,366,132	129,783	17,486	410	147,679	9.5	1.3	0.0	10.8
Guatemala 2014–2015	841,331	116,945	15,985	3,365	136,296	13.9	1.9	0.4	16.2
Zimbabwe 2015	773,876	119,177	10,834	–	130,011	15.4	1.4	0.0	16.8
Yemen 2013	1,567,150	97,163	26,642	4,701	128,506	6.2	1.7	0.3	8.2
Senegal 2016	796,791	81,273	15,936	1,594	98,802	10.2	2.0	0.2	12.4
Honduras 2011–2012	482,308	79,870	11,527	482	91,880	16.6	2.4	0.1	19.1
Dominican Rep. 2013	489,499	70,977	10,133	489	81,599	14.5	2.1	0.1	16.7
Benin 2011–2012	602,731	66,059	12,235	1,326	79,621	11.0	2.0	0.2	13.2

Continued

TABLE 1. Continued

Country	Total No. of Women 15–19	Number of Women 15-19 With:				Percentage of Women 15-19 With:			
		1 Birth	2 Births	3+ Births	Any Birth	1 Birth	2 Births	3+ Births	Any Birth
Bolivia 2008	552,238	65,109	12,591	1,491	79,191	11.8	2.3	0.3	14.3
Uzbekistan 1996	1,234,969	68,170	6,175	2,470	76,815	5.5	0.5	0.2	6.2
Liberia 2013	257,899	57,511	8,769	258	66,538	22.3	3.4	0.1	25.8
Haiti 2012	577,907	56,635	7,513	1,156	65,303	9.8	1.3	0.2	11.3
Morocco 2003–2004	1,451,561	56,611	5,806	1,306	63,724	3.9	0.4	0.1	4.4
Nicaragua 2001	305,869	50,774	10,828	1,499	63,101	16.6	3.5	0.5	20.6
Togo 2013-2014	403,711	48,163	5,410	–	53,572	11.9	1.3	0.0	13.3
Cambodia 2014	722,097	48,597	4,333	72	53,002	6.7	0.6	0.0	7.3
Burundi 2010	597,098	35,348	4,419	–	39,767	5.9	0.7	0.0	6.7
Eritrea 2002	311,661	28,673	5,298	623	34,594	9.2	1.7	0.2	11.1
Rwanda 2014–2015	631,072	32,816	1,262	–	34,078	5.2	0.2	0.0	5.4
Mauritania 2000–2001	200,101	18,609	6,603	1,001	26,213	9.3	3.3	0.5	13.1
Kazakhstan 1999	576,648	23,643	1,499	–	25,142	4.1	0.3	0.0	4.4
Ukraine 2007	930,583	20,938	3,629	–	24,567	2.3	0.4	0.0	2.6
Jordan 2012	500,920	14,527	3,006	–	17,532	2.9	0.6	0.0	3.5
Tajikistan 2012	398,873	14,479	878	120	15,476	3.6	0.2	0.0	3.9
Swaziland 2006–2007	82,377	13,180	2,059	–	15,240	16.0	2.5	0.0	18.5
Azerbaijan 2006	305,795	9,357	2,110	275	11,743	3.1	0.7	0.1	3.8
Kyrgyzstan 2012	228,641	8,917	183	91	9,191	3.9	0.1	0.0	4.0
Moldova 2005	93,573	4,323	159	–	4,482	4.6	0.2	0.0	4.8
Timor-Leste 2009–2010	71,039	3,104	717	199	4,021	4.4	1.0	0.3	5.7
Albania 2008–2009	117,252	2,075	94	–	2,169	1.8	0.1	0.0	1.9
Armenia 2015–2016	83,885	2,097	–	–	2,097	2.5	0.0	0.0	2.5
Total	**171,989,221**	**18,320,709**	**3,622,151**	**523,979**	**22,466,839**				**13.1**
Total no. (%) with subsequent births				**4,146,130 (2%)**					

Abbreviations: DRC, Democratic Republic of the Congo; USAID, United States Agency for International Development.
Sources of data: Population of women ages 15–19 from 2017 U.S. Census Bureau data; number of women ages 15–19 with births from the most recent Demographic and Health Survey for each country. Analysis conducted by the USAID Knowledge Management Services II project.

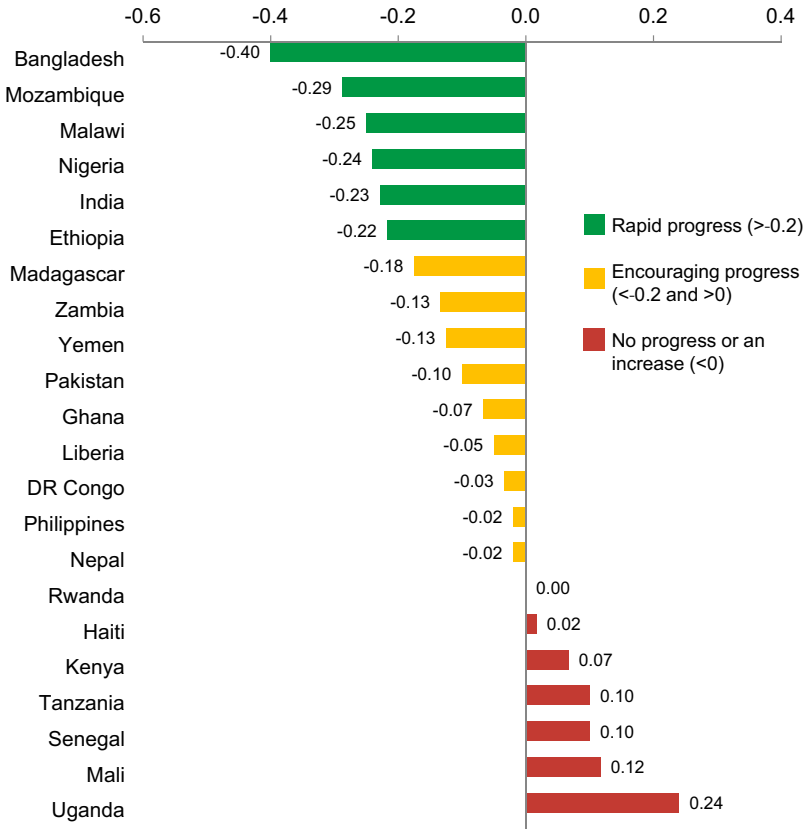
articles that met the inclusion criteria for this review.

Inclusion/Exclusion Criteria

Using the following criteria, we included evaluations that:

- Evaluated a programmatic intervention specifically designed to prevent rapid repeat pregnancy or birth, or that reported on contraceptive continuation for 2 years or more
- Were published in a peer-reviewed journal between 1990 and 2016
- Were conducted in high-, middle-, or low-income countries
- Presented quantitative data that measured:
  - Subsequent pregnancies after the index birth at 6, 9, 12, 18, 24, or 30 months or prior to 6 months for Lactational Amenorrhea Method (LAM) interventions, or

FIGURE 1. Annual Percentage Point Change in Adolescent Repeat Pregnancy Among USAID Priority Countries,[a] 2013–2016



[a] Data are shown for 22 of 24 USAID priority countries; no data were available for South Sudan and trend data were unavailable for Afghanistan.

Source of data: Trends are extrapolated from the last 2 survey data points from Demographic and Health Surveys and Reproductive Health Surveys. Analysis conducted by the USAID Knowledge Management Services II project.

- Births at 18 months or more after the index birth, or
- Contraceptive use at 6, 9, 12, 18, 24, or 30 months postpartum

If we encountered several evaluations of the same program, we included the most recent evaluation.

We excluded evaluations if they:

- Did not assess interventions that were explicitly designed to prevent adolescent or adult rapid repeat pregnancy or short birth or pregnancy intervals, or did not report on contraceptive continuation for at least 2 years
- Did not measure:
  - Pregnancy at 6, 9, 12, 18, 24, or 30 months after the index birth, or prior to 6 months for LAM interventions, or
  - Births at 18 months or more after the index birth, or
  - Continued use of contraception for at least 2 years
- Were implemented with incarcerated populations or populations in drug or alcohol treatment programs
- Evaluated a single contraceptive method and its effects on repeat pregnancy, and did not describe accompanying service delivery interventions
- Were designed to prevent the first adolescent pregnancy
- Were designed to increase postpartum family planning use by providing a range of contraceptives but did not describe educational or other programmatic interventions specifically aimed at preventing rapid repeat pregnancy

It was beyond the scope of this study to consider broad literature reviews on adolescent pregnancy and related topics. Also, while some evaluations reported pregnancy termination data, most did not do so, so it was not possible to assess how these events influenced program outcomes.

Definitions

Rapid repeat pregnancy or birth: Pregnancy occurring less than 24 months after a live birth, or birth occurring less than 33 months after a live birth. (These are equivalent measures, translating into almost 3 years between births.) In 2005, a WHO technical consultation reviewed evidence on birth spacing and health outcomes and concluded[14]:

> *After a live birth, the recommended interval before attempting a pregnancy is at least 24 months . . . to reduce the risk of adverse maternal, perinatal, and infant outcomes.*

Many of the evaluations in this review measured pregnancy occurring at 24 months after the index birth. Some measured births occurring during a specified time after the index birth. While DHS collects birth-to birth-data, other researchers often gather birth-to-pregnancy data. In this article, we will discuss both, depending on the categorization used in the evaluation.

Intervention: An activity, or set of activities, intended to achieve a defined outcome; in this case, the desired outcome is the reduction or prevention of rapid repeat pregnancy or birth in a specified population. Often, multiple, individual interventions are implemented as part of a broader intervention. For example, a postpartum contraceptive intervention might include multiple interventions such as counseling, contraceptive services, education of partners and families, and preparing a contraceptive plan. For ease of discussion, we define all of these activities as interventions and point out when they are implemented as part of a broader programmatic intervention.

Evaluation: The assessments of interventions included in this review.

Data Collection and Analysis

We undertook a quality review of the evaluations included in this review using various study quality assessment tools as guides, such as those from the U.S. National Institutes of Health.[15] Specifically, we rated the quality of each evaluation against the following 6 criteria:

1. Use of quantitative analyses to attribute change to the intervention (yes/no)
2. Randomization of individual subjects (yes/no)
3. Use of concurrent comparison group (yes/no)
4. Sample size ≥99 (yes/no)
5. Baseline and endline evaluation (yes/no)
6. Length of subject observation; measurement of:
   - Repeat pregnancy not <9 months after the index birth (<6 months for LAM evaluations) (yes/no)
   - Birth not <24 months after the index birth (yes/no)
   - 2-year continued use of contraceptives (yes/no)
   - Birth or pregnancy during not <3 years of program implementation (yes/no)

Evaluations with 5–6 "yes" classifications with respect to the criteria were rated high quality; 3–4 "yes" classifications were rated moderate quality; and 1–2 "yes" classifications were rated less rigorous.

We then extracted information on the intervention approaches implemented in the included evaluations as well as data on the impact of the interventions on repeat pregnancy or birth. We ranked the evaluations by their quality and by impact of the intervention on repeat pregnancy or birth (statistically significant impact, positive but not statistically significant trends, or no impact). In a separate analysis, we examined the magnitude of effect of interventions assessed in high-quality evaluations that measured similar outcomes at similar time periods—that is, they measured repeat pregnancy or birth at 18–24 months postpartum.

After ranking the quality of the evaluations and categorizing the level of impact, we then focused only on the high-quality evaluations. We classified interventions that achieved a statistically significant impact on repeat pregnancy, birth, or 2-year or more contraceptive continuation rates as "most effective" for preventing rapid repeat pregnancy. In contrast, we classified those interventions (assessed in high-quality evaluations) that showed either no impact or only positive trends toward preventing repeat pregnancy/birth but that did not achieve statistical significance as "less effective."

To draw program design and implementation lessons from the interventions that could be

applied in future programs, we examined the various types of interventions included in the high-quality evaluations. If we found 3 or more high quality evaluations of similar types of interventions that addressed similar design or implementation issues, we considered such findings to convey a lesson. For each lesson, we described the interventions and their impact in greater detail. As relevant, we added findings from high-quality evaluations of interventions that were less effective to illustrate how certain elements that were lacking could reduce effectiveness of the intervention. For some lessons, we identified evaluations that provided evidence but did not discuss the evaluations in detail. Finally, we identified additional factors, discussed in the high-quality evaluations, that may have reduced effectiveness of the interventions.

RESULTS

Selection and Characteristics of the Evaluations

Our database search identified a total of 2,187 articles (Figure 2). After excluding evaluations that recorded only shifts in knowledge, 122 articles remained, of which 40 met the inclusion criteria. In addition, we drew separately on 2 analyses[16,17] of interventions that were included in our review of evaluations but were published as separate studies. These analyses, which we refer to as "studies," advance understanding of the factors that contributed to impact.

Of the 40 evaluations included in this review, 15 were randomized controlled trials,[18–32] 15 used quasi-experimental designs that included comparison arms,[33–47] 9 used pre-post or other designs,[48–56] and 1 used longitudinal survey data to measure contraceptive continuation for 2 years.[57] Based on our quality review of the 40 evaluations, we rated 24 evaluations as high quality[18–33,36–40,43,44,57] (15 of which were randomized controlled trials), 14 as moderate quality,[34,35,41,42,45–49,51–54,56] and 2 as less rigorous.[50,55] (See Supplement Table 1 for detailed results of our quality assessment.) The outcome measured by most evaluations consisted of percentages or numbers of subjects in the intervention and comparison groups experiencing a repeat birth or pregnancy at a specified time period, usually 24 months, after the index birth. See Table 2 for an overview of intervention approaches employed in the 40 evaluations included in this review.

FIGURE 2. Article Selection Process

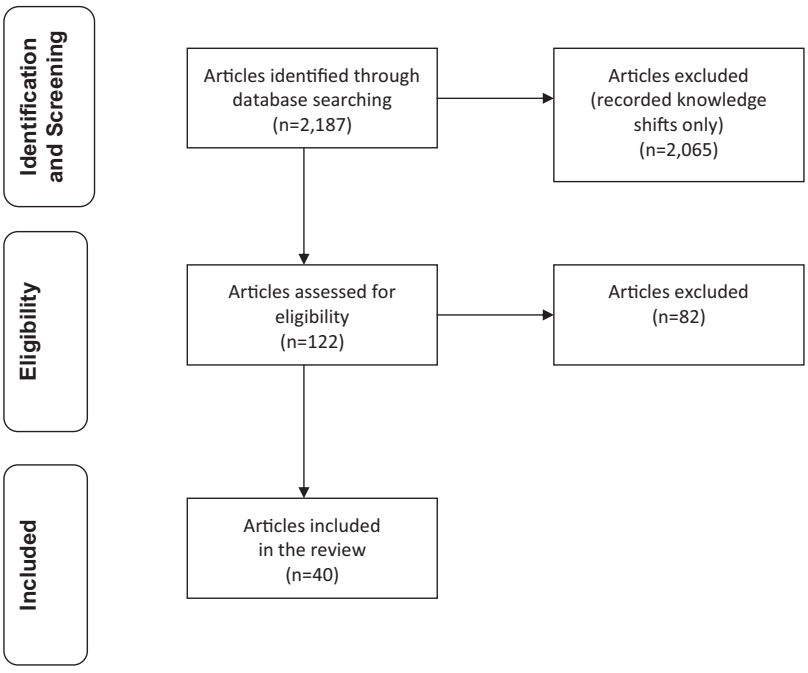


TABLE 2. Intervention Approaches Used in the Evaluations Reviewed (N=40)

Interventions	Description
Comprehensive Services	
Provision of multiple services	May include contraceptive services, contraceptive education, maternal/infant/child health services, child care, social work services, and/or home visitation
Contraceptive Information and Services	
Provision of contraceptive services	Through clinical or home-based delivery, includes counseling on correct method use and side effects
Comprehensive sexuality education	Includes contraceptive education, availability and correct use of contraceptives, sexual health and responsibility, dispelling myths about contraceptives
Pregnancy testing	Provision of monthly pregnancy tests
Surveys of contraceptive use	Regular assessments to monitor contraceptive use
Counseling on use of LAM with or without emergency contraception	Contraceptive services organized to provide LAM counseling and education; may include take-home supply of emergency contraception
Postpartum contraception	Provision of contraceptive services and counseling in the immediate or extended (24 months) postpartum period
Planning for Contraceptive Use and Pregnancy Planning	
Antenatal contraceptive plan	In antenatal period, clients encouraged to articulate fertility intentions and prepare contraceptive plan to achieve fertility intentions
"Implementation Intention Formation" training	Training in "if-then" planning: "If I am brushing my teeth in the morning, then I will take my contraceptive pill."[21]
Planning the next pregnancy	Clients encouraged to state the preferred timing of their next pregnancy
Community-Based Social and Behavioral Change Communication	
Interpersonal counseling on fertility return after live birth	Clients advised that fertility can return before menses returns and, to avoid unintended pregnancy, not to wait for menses return before starting use of contraceptives
Interpersonal counseling on healthy pregnancy spacing	Clients advised of health/quality of life benefits of spacing next pregnancy 24 months after last birth, and potential adverse outcomes for mother and infant of closely spaced births
Social networks/group discussions in homes of village influentials	Group discussions to convey accurate information about contraceptive methods, advance understanding of the positive benefits of contraceptive use, and encourage discussions about contraceptive use with husbands and friends
Peer counseling interactions	Counseling by and discussion with social groups who have similar age, background, and social status as subjects
Motivating, Mentoring, Goal Setting	
Cell phone counseling	Using cell phones, project counselors use standardized curricula (based on teen's goals and needs) to hold weekly counseling calls for the first 6 months, followed by calls every 2 weeks for the next 12 months, for a total of 42 counseling sessions over 18 months. Cell phone service provided 450 minutes per month of use without surcharge.
Goal setting	Nurses/social workers assist teens in preparing short- and long-term plans to achieve life goals
Mentorship curriculum	Use of planned mentorship curriculum by providers who have had similar life experiences and often serve as "big sisters"
Home visitation	Periodic visits by nurses/community health workers to the homes of postpartum women, usually once a month over a 1–2-year period, to provide education, counseling, and/or contraceptive services
Motivational interviewing	Use of a counseling style that "emphasizes an individual's personal goals and self-efficacy in relation to complex behaviors"[20]

Continued

TABLE 2. Continued

Interventions	Description
Skills training and job placement	Educational support for adolescent mothers under age 16 to return them to school, and skills training and job placement for adolescent mothers over age 18

Abbreviation: LAM, Lactational Amenorrhea Method.

Impact of Interventions on Prevention of Rapid Repeat Pregnancy Among Adolescents

We found 14 high-quality evaluations in which the intervention achieved a statistically significant impact on rapid repeat pregnancy or birth up to 24 months after the index birth, or on contraceptive continuation for 24 months (Supplement Table 2). Eight of these were randomized controlled trials,[18–25] 2 were cohort studies,[40,57] and 4 used a quasi-experimental design.[33,36,37,39] Of these 14 high-quality evaluations of interventions that achieved impact, 5 were conducted in developing-country settings (Bangladesh,[39,57] Egypt,[22] India,[37] and Jamaica[40]); 8 were conducted in the United States[18–20,23–25,33,36]; and 1 was conducted in the United Kingdom.[21] Nine evaluations focused exclusively on adolescents[18–21,23,24,33,36,40]; 2 on subjects that included adolescents and young adults ages 15–24[37,39]; and 3 on women of reproductive age.[22,25,57] Finally, some evaluations, and studies related to the evaluations, examined the impact of interventions included in a broader program. For example, 1 evaluation[33] assessed 8 individual interventions that could have contributed to the positive outcome of a school-based intervention.

An additional 3 high-quality evaluations reported that the interventions resulted in positive trends in reducing repeat pregnancies but that the outcomes were not statistically significant (Supplement Table 2). Two were randomized controlled trials and the third used a quasi-experimental design. In contrast, 7 high-quality evaluations reported no impact of the intervention on repeat pregnancies or births (Supplement Table 2). Five of these were randomized controlled trials and 2 used quasi-experimental designs. These evaluations recorded only a minimal or no difference between the intervention and comparison groups' rates of repeat pregnancies or births.

Most Effective Interventions for Preventing Rapid Repeat Pregnancy Among Adolescents

In our review of high-quality evaluations, interventions that achieved a statistically significant impact on adolescent, rapid repeat pregnancy or birth rates, or on contraceptive continuation rates, fell into the following 5 broad categories (Table 3).

We identified 14 high-quality evaluations in which the intervention achieved a statistically significant impact on rapid repeat pregnancy or birth up to 24 months after the index birth, or on contraceptive continuation for 24 months.

Contraceptive services coupled with education about modern contraceptive methods and reproductive health: Comprehensive health and social services with strong emphasis on contraceptive services[18,36] and inclusion of partners and families in the contraceptive education activities.[16,18,36,37,39,57] Such services were provided for either postpartum adolescents or for non-postpartum adolescents and young adult parents.

Postpartum contraceptive services: Postpartum check-ups and contraceptive service provision within 2 months postpartum in a school setting[33]; education about the use of LAM and the need to transition to another modern method of contraception at 6 months postpartum[39]; and education about LAM and provision of 1 package of emergency contraceptive pills and training on their use should unprotected intercourse occur while practicing LAM when 1 of the 3 LAM conditions was not met.[22] (WHO classifies LAM as a modern contraceptive method.[58]) The 3 conditions that must be met for LAM use to effectively to protect against pregnancy are: (1) the woman is fully or almost fully breastfeeding, (2) menses have not returned, and (3) the baby is less than 6 months old.

Planning interventions: Program emphasis on "planning the next pregnancy," rather than on avoiding unintended pregnancy[24,25]; preparation by adolescents of a contraceptive plan (in the antenatal or postnatal period)[17,24]; and training adolescents in "if-then" planning to facilitate effective use of oral contraceptives.[21]

Community-based social and behavioral change communication: Interpersonal counseling and community education on the possibility of postpartum fertility return before the return of menses, and the importance of using contraceptives before menses return to prevent unintended pregnancy[16,39]; interpersonal counseling and community education on the benefits of healthy pregnancy spacing and the use of

TABLE 3. Interventions Achieving Statistically Significant Impact on Rapid Repeat Pregnancy or Birth Among High-Quality Evaluations (n=14)

Intervention Description	Evaluation	Country	Outcome Measured During Postpartum Period	Repeat Pregnancy or Birth Rate		*P* Value
				Intervention	Control	
Contraceptive Services and Information						
Proactive monitoring of contraceptive use, contraceptive education, and inclusion of partner and families	Sullivan 1992[18]	US	Pregnancy <18 months	12%	28%	<.003
Proactive monitoring of contraceptive use, contraceptive education, and inclusion of partner and families	Rabin 1991[36]	US	Pregnancy over 9 years	9%	70%	<.001
Postpartum Contraceptive Services						
Postpartum check-ups and provision of contraceptive services within 2 months of index birth in school setting	Seitz 1993[33]	US	Birth <24 months	12%	36%	<.005
Education on the use of LAM and, for intervention group participants only, education on the use of EC in the event of unprotected intercourse and provision of take-home supply of EC	Shaaban 2013[22]	Egypt	Pregnancy <6 months	0.3%[a]	5%	<.001
Education on the use of LAM and support/increased messaging to transition to another modern method by 6 months postpartum (a sub-intervention of a larger birth spacing intervention evaluated by Ahmed 2015[39])	Ahmed 2015[39]	Bangladesh	Birth <24 months	14%[b]	17%[b]	<.01
Planning Interventions						
Preparation of contraceptive plan in the antenatal period (a sub-intervention of a larger pregnancy spacing intervention evaluated by Olds 2002[24])	Gray 2006 study[17] (secondary analysis of Olds 2002[24])	US	Pregnancy 13–24 months	–[c]	–[c]	–[c]
Home visitation by nurses to help women plan the timing of the next pregnancy, rather than avoid unintended pregnancies	Olds 2002[24]	US	Pregnancy <24 months	29%	41%	<.02
Home visitation by nurses to help women plan the timing of the next pregnancy, rather than avoid unintended pregnancies	Kitzman 1997[25]	US	Pregnancy <24 months	36%	47%	<.01

Continued

TABLE 3. Continued

Intervention Description	Evaluation	Country	Outcome Measured During Postpartum Period	Repeat Pregnancy or Birth Rate		
				Intervention	Control	*P* Value
Training adolescents in "if-then" planning for oral contraceptive use	Martin 2011[21]	UK	Pregnancy <24 months	7%	12%	<.02
Community-Based Social and Behavioral Change Communication						
Education on postpartum fertility return before return of menses. This was a sub-intervention of birth spacing intervention evaluated by Ahmed 2015.	Cooper 2014 study[16] (analysis of sub-intervention carried out in Ahmed 2015[39])	Bangladesh	Birth <24 months	14%[d]	17%	<.01
Interpersonal counseling and community education on the benefits of healthy pregnancy spacing and potential consequences of short pregnancy intervals, with a focus on adolescents and young adults ages 15–24	Sebastian 2012[37]	India	Pregnancy at 9 months	10.5%[e]	16.4%	<.01
Group discussions in homes of influentials to promote positive views of contraceptives and encourage discussions with husbands and friends	Kincaid 2000[57]	Bangladesh	Contraceptive continuation over 2.5 years	–[f]	–[f]	–[f]
Motivating, Mentoring, and Goal Setting						
Assistance to adolescents to prepare plans for achieving short- and long-term life goals (a sub-intervention of a larger pregnancy spacing intervention evaluated by Olds 2002[24])	Gray 2006 study[17] (secondary analysis of Olds 2002[24])	US	Pregnancy 7–12 months	–[c]	–[c]	–[c]
Use of mentorship curriculum by women from the community who made home visits to postpartum adolescents every 2 weeks until infant's first birthday	Black 2006[19]	US	Birth <24 months	11%	24%	<.05
Cell phone counseling emphasizing teens' own goals and needs, positive youth assets, healthy relationships, and positive reproductive health practices	Katz 2011[23]	US	Pregnancy <24 months	26%[g]	39%[g]	<.01
Motivational interviewing of adolescents, emphasizing personal goals and self-efficacy	Barnet 2009[20]	US	Birth <24 months	–[h]	–[h]	–[h]

Continued

TABLE 3. Continued

Intervention Description	Evaluation	Country	Outcome Measured During Postpartum Period	Repeat Pregnancy or Birth Rate		
				Intervention	Control	*P* Value
Provision of skills training and job placement for adolescent mothers over age 16 and educational support for mothers under age 16	Drayton 2000[40]	Jamaica	Pregnancy over 4 years	37%	60%	<.05

Abbreviations: EC, emergency contraception; LAM, Lactational Amenorrhea Method.
[a] Shaaban 2013 reported 2 pregnancies among 579 participants in the intervention group, for a pregnancy rate of 0.3%. The article reported a pregnancy rate of 0.8%, but it is likely a transcription error.
[b] At 3 months postpartum, contraceptive use was 36% (of which 23% was LAM use) in the intervention group compared with 11% (with no LAM use) in the comparison group. In the intervention group, in part due to LAM users' transition to another method at 6 months postpartum, contraceptive use remained significantly higher in the intervention group than the comparison group at 24 months postpartum (46% vs. 35%, respectively; *P*<.001).
[c] The study indicated that adolescents with a prenatal contraceptive plan were significantly less likely to conceive at 13–24 months postpartum than adolescents without a plan. 18.6% of adolescents who prepared such a plan did not conceive by 13-24 months, while 0% of those who conceived by 13-24 months had prepared a prenatal contraceptive plan (*P*<.005). Adolescents who formulated short- and long-term goals were significantly less likely to conceive at 7–12 months postpartum than those who did not formulate such goals (*P*<.05).
[d] Sub-intervention analyzed in Cooper 2014[16] focused on improving knowledge of postpartum fertility return. The analysis found that 98% of women knew fertility could return before return of menses, and women stated this information motivated them to begin using contraceptives.
[e] 93% of those in the intervention group reported counseling on use of spacing methods after delivery, whereas 69% of those in the control group reported such counseling (*P*<.01). Women in the intervention group who knew at least 2 spacing messages and at least 2 spacing methods were more likely to adopt a modern method postpartum (*P*<.05).
[f] Outcome measured was contraceptive continuation for 2.5 years at any point in a woman's life, not necessarily during the postpartum period. In the intervention group, contraceptive continuation for 2.5 years was 43.9% vs. 25.5% in the comparison group (*P*<.001).
[g] Among adolescents ages 15–17 years.
[h] Controlling for baseline difference, adolescents who received motivational interviews and home visits were more likely to defer a repeat birth than those in the control group (hazards ratio, 0.4; *P*<.05).

contraceptives to prevent adverse outcomes associated with closely spaced births[16,37,39]; and group discussions in homes of village influentials to encourage positive views of contraceptives and the use of communication skills to share learning with husbands.[57]

Motivating, mentoring, and goal-setting interventions: Preparation of plans by adolescents to achieve short–term life goals (e.g., improved parenting) and long-term goals (e.g., education)[17,24]; use of a mentorship curriculum by women from the community who presented themselves as "big sisters" to adolescent mothers during home visits[19]; motivational interviewing of adolescents, a counseling style that emphasizes an individual's goals and self-efficacy in relation to complex health behaviors and aims to promote the individual's intention to change[20]; use of a cell phone counseling approach that incorporated aspects of youth asset development models and emphasized teens' own goals and needs, communication skills, and connections with school and adult role models[23]; and skills training and job placement for adolescents over age 16 and educational support for mothers under age 16.[40]

Less Effective Interventions for Preventing Rapid Repeat Pregnancy Among Adolescents

Seven high-quality evaluations found that the intervention did not achieve a statistically significant impact on rapid repeat pregnancy or births. Four of these were home-based interventions such as home visitation or family support services.[28–30,32] One was a cash transfer to female heads of households,[43] one was a peer education and support/monetary incentive intervention,[31] and one was a prenatal education program.[44] All but two[29,43] focused exclusively on adolescents. Five evaluations were randomized controlled trials[28–32] and two were quasi-experimental designs.[43,44] The less effective interventions helped to highlight design and implementation flaws, which we have included in the lessons.

Magnitude of Effect on Repeat Pregnancy Rates

We examined the magnitude of effect of selected interventions on repeat pregnancy rates, as reported by 6 high-quality evaluations. The evaluations measured repeat pregnancy or birth at similar time periods (Table 4). While all 6 evaluations reported statistically significant effects, some intervention impacts were greater than others, highlighting the importance of going beyond statistical significance in considering impact on target populations and underscoring the importance of assessing implementation factors that may reduce intervention effectiveness.

For example, in 3 high-quality evaluations, at 18–24 months postpartum, the repeat pregnancy or birth rates in the intervention groups were relatively low, ranging from 7% to 12%, compared with repeat pregnancy or birth rates in the comparison groups at 12% to 28%. However, in 3 other high-quality evaluations, the interventions achieved a statistically significant effect on the repeat pregnancy rate, yet the repeat pregnancy rate in the intervention groups was still relatively high, at 26% to 36% and 39% to 47% in the comparison groups.

All 3 of the evaluations that showed a lower magnitude of effect reported challenges that may have influenced outcomes. For example, the evaluation of a cell phone intervention[23] reported that the adolescents "would not always answer calls" for scheduled counseling sessions, and some teens lost or damaged their phones. The Olds 2002 evaluation[24] of a home visitation intervention reported that 40% of the subjects, after review and testing, were characterized as having "low psychological resources." The Kitzman 1997 evaluation[25] of a home visitation program reported that all subjects had at least 2 sociodemographic risk characteristics such as being unmarried, having less than 12 years of education, or being unemployed.

We also note that the magnitude of the effect may be greater in populations where the repeat pregnancy rate is already lower; compare the repeat pregnancy rate in the comparison groups of the evaluations showing a higher magnitude of effect (20% to 30%) with the repeat pregnancy rate of the intervention groups of the evaluations showing a lower magnitude of effect (26% to 36%). This could suggest that the success of a specific intervention may be partially dependent on the broader program environment, including norms around adolescent childbearing and contraceptive use.

Program Design and Implementation Lessons

We identified 5 program design and implementation lessons from interventions that are linked with statistically significant reductions in rapid repeat pregnancy.

Based only on the 24 high-quality evaluations included in our review, we identified 5 program design and implementation lessons about interventions that are linked with prevention of rapid repeat pregnancy.

Proactive Program Monitoring of Contraceptive Use, Providing Contraceptive Education, and Involving Partners and Families Are Linked to Reductions in Rapid Repeat Pregnancy

Three evaluations[18,28,36] emphasized the importance of proactive program monitoring of adolescents' contraceptive use and contraceptive education. These evaluations observed that, in comprehensive programs that work across sectors and disciplines, the contraceptive service delivery component must be well-designed, easily accessible, well-implemented, and closely monitored. Programs should include quality counseling, method provision, and services by trained providers at the time that services are requested. These may seem like rather obvious activities to be included in interventions to reduce repeat pregnancies, but we found a distinct lack of attention to contraceptive services in a number of evaluations of comprehensive service programs. In addition, 5 evaluations[18,36,37,39,57] and 1 study[16] stressed inclusion of partners and families in program activities.

In interventions that achieved impact, providers paid intense attention to educating the adolescents and their partners and families about contraceptives, and proactively monitored contraceptive use. For example, one evaluation of a comprehensive health care program for adolescent mothers[18] was carried out in a well-baby clinic for teen mothers and staffed by a nurse practitioner, a pediatrician, and a social worker. Key goals were prevention of repeat pregnancy and the mother's return to school. The evaluation observed that the providers were proactive—"all three providers tracked contraceptive use, satisfaction with the method, referral for a different method, and engaged in active follow-up if appointments were missed." Providers wrote notes in subjects' charts on "whether the mother was using family planning and whether she liked her method." The providers insisted on "talking with the mother about her plans for the future," along with her use of family planning, and focused on the mother's plans to return to school. The program managers urged that entire families be

TABLE 4. Magnitude of Effect on Repeat Pregnancy or Birth Among High-Quality Evaluations Measuring Similar Outcomes at Similar Time Periods[a] (n=6)

Evaluation	Intervention Description	Outcome Measured During Postpartum Period	Repeat Pregnancy Rates		*P* Value
			Intervention	Control	
Higher Magnitude of Effect					
Sullivan 1992[18]	Health care model delivered at teen baby clinic for teen mothers, including social workers, pediatrician, and referral for contraceptive service provision; focused on prevention of repeat pregnancy, return to school, immunizations, and reduced use of emergency room.	Pregnancy <18 months	12%	28%	<.003
Black 2006[19]	Postpartum home-visitation mentoring intervention; curriculum delivered every other week until infant's first birthday by women from community who served as mentors.	Birth <24 months	11%	24%	<.05
Martin 2011[21]	Training for adolescents in "implementation intention formation" (if-then planning) in relation to use of contraceptives.	Pregnancy <24 months	7%	12%	<.02
Lower Magnitude of Effect					
Katz 2011[23]	Intensive cell phone counseling intervention to prevent subsequent teen pregnancies by strengthening healthy relationships, reproductive practices, positive youth assets, and teen's own goals and needs.	Pregnancy <24 months	26%[b]	39%[b]	<.01
Olds 2002[24]	Nurse home-visitation intervention to improve health behaviors, prevent rapid repeat pregnancies, improve parent care of children, and maternal life-course development.	Pregnancy <24 months	29%	41%	<.02
Kitzman 1997[25]	Home visitation by nurses to improve newborn and child health and mental development, and to prevent injuries and rapid repeat pregnancies.	Pregnancy <24 months	36%	47%	<.006

[a] All 6 evaluations were randomized controlled trials and reported statistically significant impact of the intervention on rapid repeat pregnancy or birth rates. All were conducted in the United States, except Martin (2011),[21] which was conducted in the United Kingdom.
[b] Among mothers ages 15–17 years.

involved in these discussions because "chang(ing) attitudes about the future will do more to delay these pregnancies than working only with the adolescent mother."[18] At 18 months postpartum, the repeat pregnancy rate among the intervention group was 12% (13/108) compared with 28% (32/113) among the comparison group ($P<.003$).

Another evaluation assessed a comprehensive, experimental prenatal and family planning program carried out by a multidisciplinary hospital team consisting of a gynecologist, pediatrician, social worker, and health educator.[36] The experimental program included a reproductive health and family life education program for the mother, her partner, and family every other week, and emphasized program attendance. Over 75% of the intervention group participated regularly; in contrast, only 18% of the control group attended similar activities offered by routine services. The evaluators reported that "primary pregnancy prevention efforts (sexual education) and secondary efforts (the importance of sexual responsibility and contraceptive education, availability, and utilization) are important front-line strategies ..." Critical activities to prevent second pregnancies included "mobilization of the partner, family, teachers, and social support systems to ... engage in a dialogue which stresses sexual education and contraceptive responsibility." Over the 9-year implementation period, 9% of intervention group participants experienced a repeat pregnancy, while 70% of comparison group participants did ($P<.001$). Contraceptive use in the intervention group was 85% compared with 22% in the control group ($P<.001$).

In a community-based intervention that did not achieve impact, trained home visitors provided services to adolescent parents until the index child was 2 years old.[28] They delivered a

parenting curriculum, encouraged contraceptive use, connected the teen with primary care, and promoted school continuation. The program linked teens with primary care physicians, but program managers "did not assess the content of primary care . . . consequently we were unable to determine whether primary care physicians provided appropriate contraceptive services." At 24 months after the index birth, the repeat pregnancy rate was 45% in the intervention group and 38% in the comparison group.

Providing Postpartum Mothers Contraceptive Counseling and Services Soon After Delivery Are Linked to Reductions in Rapid Repeat Pregnancy

Four evaluations provide evidence to support this lesson.[22,29,33,39] An evaluation of a public school-based intervention found that teen mothers who spent longer than 7 weeks attending a special school for adolescent parents before returning to their regular school were much less likely to have had a second child over the next 5 years, compared with teen mothers who returned to their regular school less than 7 weeks after delivery.[33] The authors analyzed 8 potential causal mechanisms that might have contributed to this result, but only 2 were statistically significant: avoidance of sexual activity and a "postpartum check-up before exiting" the special school. Those who attended the school longer than 7 weeks were required to have a postpartum check-up, which took place within 2 months of delivery. During the check-up, the new mothers received a contraceptive counseling session, at which almost three-quarters of participants accepted injectable contraceptives. Within 2 years of the index birth, only 12% (6/50) of students who received the postpartum check-up delivered a second child, compared with 36% (19/52) of students who did not receive a check-up ($P<.005$).

In a community-based, home visitation intervention in Bangladesh,[39] 10th-grade-level community health workers (CHWs) educated postpartum women on the use of LAM and the importance of transitioning to another modern method at 6 months postpartum. In addition, "LAM Ambassadors" (practicing LAM users with their healthy infants) served as role models and actively promoted LAM as an immediate postdelivery contraceptive method particularly appropriate for this rural area. The evaluation found that "a major increase in contraceptive use in the early postpartum period was attributable to a higher use of LAM in the intervention area." At 3 months postpartum, contraceptive use was 36% in the intervention group (of which 23% reported use of LAM) and 11% in the comparison group ($P<.001$). Women in the comparison area did not report use of LAM during any survey round. In part due to subjects' transition from LAM to another modern method at 6 months, contraceptive prevalence remained significantly higher in the intervention area at 24 months after the index birth (46% versus 35%, respectively; $P<.001$). In addition, the rate of reporting a short birth interval of less than 24 months was significantly lower ($P<.01$) in the intervention area (14%) than in the comparison area (17%).

An evaluation of a clinic-based intervention in Egypt described how pregnant intervention group clients were counseled on use of LAM and use of emergency contraception if unprotected intercourse occurred when 1 of the 3 LAM conditions was not met.[22] Intervention group clients were given 1 packet of emergency contraceptive pills to take home while the comparison group received only counseling about LAM. Among the intervention group, 44% used emergency contraception, while none in the comparison group used it. At 6 months postpartum, the repeat pregnancy rate was only 0.3% (2/579) in the intervention group, compared with 5% (29/579) in the comparison group ($P<.001$). In addition, significantly more women in the intervention group initiated regular contraception within or shortly after 6 months postpartum than those in the comparison group (30.5% vs. 7.3%, respectively; $P<.001$).

In contrast, an evaluation of a U.S. home visitation program that did not achieve impact found that, at 24 months after enrollment, 21% (29/141) of intervention group participants and 20% (22/112) of control group participants experienced repeat pregnancies.[29] The evaluation noted that the "lack of program effects can be traced to the program's design and implementation." The program required only that family planning be introduced any time during a family's first year of enrollment. The authors observed "(B)ecause conception can occur very soon after an index birth . . . a better design would be to introduce family planning counseling early in a family's enrollment in home visiting."

Helping Adolescents Plan for the Next Pregnancy, Plan Contraceptive Use, or Prepare a Contraceptive Plan Is Linked to Reductions in Rapid Repeat Pregnancy

Three evaluations[21,24,25] and 1 study[17] provide evidence to support this lesson. The evaluations

identified 3 contraceptive planning interventions that were designed to help women and girls plan to avoid rapid repeat pregnancies:

- Training in planning to use contraceptives[21]
- Planning the timing of the next pregnancy, rather than trying to prevent unintended pregnancy[24,25]
- Preparing a contraceptive plan[17]

A contraceptive plan is intended to help women and girls clarify and act on their reproductive intentions and make an informed choice about contraceptive use to achieve their reproductive life goals. (In 2006, the U.S. Centers for Disease Control and Prevention, in its guidelines for improved preconception care, issued a recommendation encouraging all women, men, and couples to prepare a reproductive life plan, to avoid unintended pregnancies and reduce adverse pregnancy outcomes.[59])

A 16-year-old girl holds her first child at a district health facility in Tanzania. © 2014 Megan Ivankovich/WI-HER LLC, Courtesy of Photoshare

One evaluation assessed the effect of an intervention that assisted adolescent girls in practicing "implementation intention formation" or "if-then planning."[21] This is a planning approach that specifies in advance the "when, where, and how" of behaviors involved in contraceptive use. (For example, "If I am in the bathroom after brushing my teeth in the morning, then I will take my contraceptive pill!") The evaluation found that this intervention was effective in helping adolescent girls use contraception for 2 years, and significantly reduced the percentage of intervention group participants who received a positive pregnancy test (7%, or 8/112) compared with comparison group participants (12%, or 14/115) at the 2-year follow up ($P<.02$).

Two evaluations assessed similarly designed nurse home visitation programs targeted to low-income mothers.[24,25] The theoretical foundations of the home visitation model reflect the importance of enhancing mothers' self-efficacy.[60] Specifically, the curricula-based, home visitation intervention aimed to improve pregnancy outcomes, parental caregiving, and maternal life-course development (defined as helping women return to work or school and to plan future pregnancies). The emphasis was on the women's desired timing of the next pregnancy, rather than on avoiding unintended pregnancies. In both interventions, nurses made an average of 7 home visits during pregnancy and 26 visits up to the index child's second birthday. The nurses "encouraged women to clarify plans for completing their education, returning to work, and bearing additional children," aiming to help women achieve what they considered their optimal family size.[61] At 24 months postpartum in both programs, women who had received visits by nurses were significantly less likely to have had a subsequent pregnancy than women in the control group (29% vs. 41%, respectively; $P<.02$ in the Olds 2002 evaluation[24]; 36% vs. 47%, respectively; $P<.01$ in the Kitzman 1997 evaluation[25]).

The home visitation intervention evaluated by Olds 2002 achieved a statistically significant effect, yet the magnitude of effect was relatively low (repeat pregnancy rate, 29% intervention vs. 41% control; $P<.02$).[24] A study by Gray (2006)[17] of the data generated by the Olds 2002 evaluation[24] asked what could have been done to achieve greater impact. Gray found that having an antenatal contraceptive plan was significantly associated with not conceiving at 13–24 months postpartum ($P<.005$).[17] But few program participants reported having a

contraceptive plan. Of the 29% of adolescents who reported a subsequent pregnancy by 24 months postpartum, *none* had prepared an antenatal contraceptive plan. In contrast, 19% of those who were not pregnant had prepared such a plan ($P<.01$).[17] Gray notes that "the nurses rarely documented that they explicitly tried to help the teens postpone a second pregnancy. Assistance ... that might motivate the teen to keep using birth control were only recorded during 30 percent of the visits."[17]

Enhancing Understanding of Contraceptives' Role in Determining Positive Life Outcomes Is Linked to Reductions in Rapid Repeat Pregnancy

Three evaluations[37,39,57] and 1 study[16] provide evidence to support this lesson. The interventions described in these evaluations were designed to change the way that clients thought about contraception—that is, rather than focusing on side effects, for example, intervention messages were designed to help clients understand the role that contraceptives could play in determining positive life outcomes. The evaluations showed that such messages were strongly linked with increased use of contraceptives.

For example, one evaluation examined a community-based, social networks approach that diffused new and positive ideas related to contraception across communities and social networks, and assessed contraceptive use and continuation over a period of 2.5 years.[57] In the intervention, government field workers were trained to organize village-level group discussions with women in the homes of opinion leaders and facilitate the development of positive attitudes toward contraceptives. Group discussions focused on 4 messages: (1) practicing family planning to have fewer children may help your family avoid poverty; (2) couples that practice family planning are better able to provide food for their children; (3) having fewer children helps families to raise them properly; and (4) practicing family planning improves the relationship between a husband and a wife. It was anticipated that holding discussions in the homes of village opinion leaders would provide greater opportunities for validation and support of these ideas, compared with field workers' home visits with individual women. After 2 years, overall ideation (e.g., knowledge of and support for new ideas and practices related to contraceptives) increased by 0.79 points among social networks participants and by 0.39 points among women with home visits, and declined 1.32 points among women having no contact with government field workers. Over 2 years, contraceptive prevalence increased 4.7% among social networks participants and 0.9% among women who continued to be visited at home, and declined 9.4% among women with no health worker contact at all. The evaluation concluded that the strong impact of the social networks intervention on contraceptive use was due primarily to its impact on contraceptive continuation: the family planning continuation rate at 2.5 years was 43.9% for social networks participants, 25.5% for women who received home visits, and 6.7% for women with no health worker contact ($P<.001$).[57]

An evaluation in Uttar Pradesh, India, assessed a community-based behavior change communication intervention.[37] CHWs were trained to educate mothers (with a focus on women ages 15–24 years) and mothers-in-law using leaflets, posters, and wall hangings on postpartum care and healthy timing and spacing of pregnancy, advising them to wait at least 24 months after a live birth before conceiving again. At the pre-test, 14% of CHWs answered all test questions correctly except the one on the 3 conditions of LAM, while 95% answered all test questions correctly (including the LAM question) in the post-test. After 5 months of implementation, adolescents and young adults achieved significantly increased knowledge about 6 of 8 variables ($P<.05$):

- IUD is placed in the uterus and is effective for 10 years
- Correct use of emergency contraception
- Three conditions that must be met for effective use of LAM
- Three adverse outcomes of short-interval pregnancies
- Health of woman, last child, and fetus are affected by closely spaced pregnancies
- Correct condom use

Those with greater knowledge of at least 2 healthy spacing messages ($P<.05$) and correct knowledge of methods ($P<.01$) were more likely to adopt a modern contraceptive method. At 9 months postpartum, modern contraceptive use for spacing was 57% in the intervention group and 30% in the comparison group, while the repeat pregnancy rate was 10.5% in the intervention group and 16.4% in the comparison group ($P<.01$).[37]

A study conducted by Cooper (2014) in Bangladesh[16] reported on the introduction of

ideas related to birth spacing and fertility return before menses, in a community-based postpartum program.[39] This social and behavior change communication intervention was designed to help women, men, and mothers-in-law understand that fertility could return before menses return; use of contraception before menses return may prevent an unintended pregnancy; and newborn health is improved with spacing pregnancies at least 24 months after the preceding live birth. (After delivery, among non-breastfeeding women, ovulation may occur at approximately 6 weeks and, for some women, as early as 3 weeks.[62]) The Cooper study, based on 40 in-depth interviews, found almost universal exposure to information about the return of fertility before menses, with 97.5% of the women recognizing that a woman could become pregnant prior to menses return. Interviews revealed "thirty-five of forty respondents reported that this information led them to make a change in their behavior" and begin using postpartum contraception. In addition, 58% of women understood that 3-year birth intervals were healthy. No respondent, including men and mothers-in-law, expressed the view that women should conceive less than 2 years after the index birth. At 24 months postpartum, the modern contraceptive prevalence rate was significantly higher among the intervention group than the control group (46% vs. 35%; $P<.001$), and short birth intervals of less than 24 months significantly lower (14% vs. 17%, respectively; $P<.01$).

An evaluation examining the effect of monetary incentives and peer group discussions on repeat adolescent pregnancies in 3 treatment groups and 1 control group illustrates the importance of ensuring positive messages.[31] The evaluation found that monetary incentives draw the teens to the sites where they could discuss use of contraception, but the peer group discussions did not prevent repeat pregnancies. The evaluation commented that "at times one participant would hear another talking about the benefits of having another child . . . thereby reinforcing and validating the very practices and thinking patterns the groups were designed to extinguish." In this intervention, on average, 39% in all groups experienced pregnancy within 24 months of delivery of the index child.

Mentoring, Motivating, and Goal Setting Are Linked to Reductions in Rapid Repeat Pregnancy

Three evaluations[19,20,23] and 1 study[17] showed that curriculum-based interventions that include motivational, mentoring, and goal-setting elements can positively influence rates of repeat pregnancy.

One evaluation examined a home visit mentorship and curriculum-based intervention for African-American teen mothers delivered every other week until the index infant's first birthday by college-educated, African-American, single mothers who presented themselves as "big sisters."[19] This mentoring intervention stressed negotiation skills, personal development, and parenting. The mentors emphasized "personal values and decision-making regarding subsequent pregnancies, access to birth control, and goal setting" rather than overt messaging on avoiding a second birth. Having at least 2 home visits increased the likelihood of not having a second child by more than threefold (odds ratio 3.3; 95% confidence interval, 3.0 to 5.1). At 24 months postpartum, 11% (8/70) of intervention group participants experienced repeat births compared with 24% (19/79) of the control group ($P<.05$). There were no second births at 24 months postpartum among women who attended 8 sessions.

Another evaluation assessed an intervention called "motivational interviewing" combined with home visiting.[20] Motivational interviewing is a counseling style that emphasizes an individual's goals, using a tool called CAMI (Computer-Assisted Motivational Interviewing). The evaluation notes that "motivational interviewing aims to highlight the discrepancies between current behaviors and personal goals and self-efficacy, in relation to complex behaviors." At 24 months postpartum, mothers who received at least 2 CAMI sessions coupled with home visitation were significantly less likely to experience a repeat birth (13.8%, or 11/80) than participants in the usual care group (25%, or 17/68) ($P<.05$).

A cell phone counseling intervention randomized adolescent subjects to a cell phone counseling group and usual care.[23] The intervention aimed to strengthen healthy relationships, improve reproductive practices, and prevent second pregnancies while emphasizing positive youth assets. Trained counselors scheduled 35–45-minute phone sessions once a week for the first 6 months postpartum and then every 2 weeks over the next 12 months. Curriculum content emphasized building knowledge of health risks and developing positive teen attitudes and skills while emphasizing the teens' own goals and needs. The curriculum also addressed improving partner communication and negotiation skills and resisting peer pressure for risk behaviors. Among mothers 15–17 years, the

rate of subsequent pregnancy was 26% in the intervention group and 39% in the usual care group ($P<.01$). In the 15–17-year-old age group, increasing treatment intensity was associated with longer time to subsequent pregnancy.

A study by Gray (2006)[17] of data generated in a high-quality home visitation evaluation[24] found that adolescent participants' formulation of short- and long-term educational goals was significantly associated with not conceiving at 0–6 months postpartum ($P<.001$) and at 7–12 months postpartum ($P<.05$).

An evaluation of an intensive home visitation intervention that did *not* achieve impact observed that a key shortcoming was lack of goal setting.[29] The evaluation found that there was "no evidence that family planning was linked to motivating the parents to avoid rapid, repeat births to achieve personal life goals and to promote effective parenting of the index child." There was "no evidence of protocols for addressing fertility and for relating subsequent births to parents' abilities to achieve their personal goals for life course development." At 1-year follow up, the repeat birth rates in the intervention and control groups were 21% and 20%, respectively.

Gray (2006)[17] found that goal setting was strongly linked with not conceiving. In the Olds 2002 intervention,[24] however, while almost all teens (94.6%) developed short-term goals such as returning to school, only 20% made efforts "toward a long-term goal, such as developing a 4–5 year contraceptive and work-study plan." In this intervention, the repeat pregnancy rate in the intervention group, although statistically significant, was still quite high at 29% compared with 41% in the comparison group ($P<.02$).

Additional Factors That Influence Rapid Repeat Pregnancy

Additional factors identified in the high-quality evaluations included in this review that reduced the effectiveness of the interventions included:

- Depression[23,28]
- Reduced program intensity (e.g., a postpartum program ended 1 year early)[26]
- Cultural factors (e.g., in Bangladesh, husbands of intervention group subjects worked in the Middle East and it was unacceptable for a woman to use contraceptives while the husband was away)[39]
- Lack of male and family involvement[30]
- Lack of shared goals (i.e., program participants did not share the goal of preventing a second birth)[32]

DISCUSSION

This review demonstrates that well-designed and implemented interventions can reduce rapid repeat pregnancy among adolescents. We identified 14 high-quality evaluations of interventions that achieved a statistically significant reduction of postpartum repeat pregnancy or birth rates, or increased contraceptive continuation for at least 2 years. The interventions assessed in these high-quality evaluations fell into the following 5 broad categories:

- Provision of contraceptive services, monitoring contraceptive use, provision of contraceptive education, and inclusion of partners and families
- Postpartum counseling and contraceptive services provided soon after delivery
- Pregnancy or contraceptive use planning interventions
- Community-based social and behavioral change communication interventions that help adolescents understand the role that contraceptives can play in determining positive life outcomes
- Motivating, mentoring, and goal-setting interventions

We are not recommending that all 5 types of interventions that were shown to be effective be implemented simultaneously. However, recognizing potentially synergystic effects, we do recommend testing various combinations of these interventions, with access to contraception as the foundational activity. Experience from the field (and not yet necessarily reflected in the published literature) recognizes the value of a socioecological approach to adolescent pregnancy prevention that intervenes at the individual, family, and community level. We anticipate that some combination of these interventions may create both individual motivation and family/community support for pregnancy spacing. These interventions may also be effective in preventing the first adolescent pregnancy or induced abortion, and as part of postabortion care activities to prevent repeat abortion. The recommended interventions should be tested as part of activities to achieve these outcomes.

A recent global review conducted by the YouthPower project found 5 life/soft skills contribute significantly to adolescents' ability to engage in

healthy behaviors that lead to positive sexual and reproductive health outcomes—goal orientation, positive self-concept, self-control, higher-order thinking, and communications skills.[63] Indeed, the high-quality evaluations of interventions in this review addressed the development of most of these skills across the range of study populations, such as helping adolescents develop contraceptive plans and short- and long-term plans (goal setting); strengthening engagement and communication with husbands, partners, and families (communication); and understanding the health implications for their newborn of closely spaced births (higher-order thinking skills).

Effective interventions to prevent rapid repeat pregnancy link adolescent-friendly clinical contraceptive services with non-clinical interventions that contribute to positive youth development.

A key finding of our review is that effective interventions to prevent rapid repeat pregnancy link adolescent-friendly clinical contraceptive services *with non-clinical interventions that contribute to positive youth development*. This could be, for example, an intervention that facilitates access to contraception, helps adolescents plan and envision a future for themselves, and supports the acquisition of life skills and better understanding of the value of contraception for achieving one's life goals. Civil society organizations, with deep knowledge of their communities, could possibly be well-suited to test and adapt the non-clinical, evidence-based approaches identified in this review. However, these activities cannot stand alone and must be aligned with a contraceptive service delivery component, whether clinical or community-based.

Our findings are consistent with the literature that finds that interventions can be effective in improving adolescent cognitive capacities,[64] i.e., executive functions that encompass an individual's ability to organize thoughts and activities, prioritize tasks, manage time effectively, and make decisions.[65] This research sees adolescence as a time of risk and opportunity. Because of recent scientific advances, we now know that brain development—with changes in structure and function—occurs well into the twenties. The limbic system and the amygdala, which are responsible for pleasure and excitement seeking, develop ahead of the forebrain, which is responsible for executive functions, including planning, self-management, and impulse control.[66] As a result, a young person may know and understand the negative consequences of a particular action, such as having unprotected sex or driving under the influence of alcohol, but may not be able to stop him or herself or resist peer pressure to carry out the action. The research recognizes the "plasticity" of the adolescent brain. This characteristic contributes to abilities to learn and adapt new skills during adolescence, thus marking adolescence as a "period of vulnerabilities, but also great opportunities in terms of . . . interventions."[64,67]

Our review also calls to attention the need for continued thinking about the concepts of "intended" and "unintended" pregnancy. In some contexts, a pregnancy may be "intended" by a young woman only because it is socially and culturally expected. On the other hand, it may not be "intended" by her but occurs because she does not have the power to resist community and family social pressures related to childbearing. The individual interventions (counseling, planning, goal setting) and social interventions (community education and influencing norms) discussed in this review may help young women, and their families, become more informed and help change behavioral intentions and behaviors.

Recommendations for Action

We recommend the following programmatic actions, which we believe are practical, will substantially strengthen the design and implementation of adolescent programs, and can be implemented at scale.

- **Target contraceptive services and information to first-time mothers/parents.** Services should be targeted during antenatal care, as well as before discharge from the delivery facility, during the immediate or early postpartum period, and during childhood immunization visits at 1–2 months postpartum, with a special focus on very young first-time parents (ages 12–15).
- **Convey information that helps adolescents understand the positive role that contraceptives can play in their lives.** Include the messages identified in the evaluations reviewed here (Box), as they are strongly linked with increased contraceptive use and prevention of rapid repeat pregnancy, and test other evidence-based messages as culturally relevant.
- **Help first-time mothers/parents identify their short- and long-term reproductive intentions and prepare contraceptive use plans to achieve those intentions.** Test the effectiveness of using antenatal or postnatal contraceptive plans to help women and girls achieve 2- to 3-year reproductive intentions. Address cultural norms, and involve influential

members in the family and community who may limit adolescents' ability to act on their intentions and carry out their plans.

- **Test, adapt, and scale up the 3 community-based interventions included in this review.**[37,39,57] Include their social and behavioral change messages (Box), especially for first-time parents, and for spouses, mothers-in-law, and other persons who are influential in adolescents' lives, as relevant.[68]
- **Test engaging civil society organizations to motivate and mentor new mothers and first-time parents, help set goals, and support the adoption of new social norms and practices.** Such organizations might be able to assist with introducing the messages used in effective programs, and facilitate setting of short- and long-term life goals especially for first-time parents. They might adapt the motivational and goal-setting curricula used in the interventions reviewed in this article. Partnerships are needed between government and civil society to deliver these multicomponent interventions.

Limitations

This review has several important limitations and caveats. First, as we limit our conclusions to the findings from high-quality evaluations of effective interventions that show statistical impact on the outcomes of interest, we limit the number of studies from which to draw lessons. However, by using these stringent criteria we are confident in the results. Second, some of the evaluations have small sample sizes (<250 subjects), but other evaluations were based on relatively large samples, some with more than 1,000 subjects. Third, although there were interventions that demonstrated success, analysis of intervention subcomponents to better identify the causal pathway to impact was lacking. Caution is needed before implementing, replicating, or taking to scale these "successful" interventions, especially those that were designed for adolescents based in the United States or United Kingdom, in different sociocultural and/or economic settings. At the same time, while translational research is needed, there is evidence that interventions that have been shown to be effective in one setting have been successfully applied in very different settings.[69]Given the number of high-quality U.S.-based studies in our review, careful attention nevertheless should be paid to their implementation in developing countries.

BOX. Messages Conveyed in High-Quality Evaluations of Interventions Contributing to Prevention of Rapid Repeat Pregnancy or Contraceptive Continuation

Topics of Messages to Prevent Rapid Repeat Pregnancy

- Intrauterine device is placed in the uterus and is effective for 10 years
- Correct use of emergency contraception
- Promotion of the Lactational Amenorrhea Method (LAM) for first 6 months postpartum; 3 conditions that must be met for effective use of LAM; transition from LAM to another modern contraceptive method
- Benefits of longer birth intervals; adverse outcomes of short-interval births or pregnancies
  - After a live birth, wait at least 24 months before attempting a pregnancy to reduce the risk of adverse maternal, perinatal, and infant outcomes
  - Benefits of healthy timing and spacing of pregnancies are reduced risk of preterm births and small for gestational age, increased chance that infants will experience the health benefits of breastfeeding for full 2 years
- Health of woman, last child, and fetus are affected by closely spaced pregnancies
- Correct condom use
- Essential newborn care, including exclusive breastfeeding
- Timing of, and signs indicating, return to fertility
- Discussion of contraceptive methods, potential side effects, strategies to minimize side effects
- Referral to health facility for contraceptive methods, if needed

Group Messages to Promote Contraceptive Continuation

- Practicing family planning to have fewer children may help your family avoid poverty
- Couples that practice family planning are better able to provide food for their children
- Having fewer children helps families to raise them properly
- Practicing family planning improves the relationship between a husband and a wife

Sources: Cooper 2014,[16] Shaaban 2013,[22] Sebastian 2012,[37] Ahmed 2015,[39] Kincaid 2000,[57] and Ahmed 2013.[68]

While not a limitation, it is essential to ensure that interventions are designed to address the heterogeneity of adolescent populations within and between countries as seen in several of the studies. For example, the interventions targeted diverse populations such as young married couples in North India; urban, better-educated adolescents in Jamaica; poor rural women in Northeast Bangladesh; and largely urban, poor populations in the United States and United Kingdom. Clearly, interventions must be tailored differently to the contexts and prevailing social and cultural norms of country and regional settings. In some settings, early marriage is common and nearly all fertility occurs within the context of marriage. In others, adolescents are mostly sexually active

outside of a formal union and lack adequate access to contraceptive information and services. In both settings, postpartum contraception should be a focus of interventions, but the approaches used to increase contraceptive uptake will likely differ. In any event, more interventions need to be designed that address the root causes of rapid repeat pregnancy, such as social norms that promote early marriage and inequitable gender norms, as well as missed opportunities (in antenatal and postpartum care) to provide rights-based contraception.

CONCLUSIONS

Evidence from high-quality evaluations suggests that providing adolescent-friendly contraceptive services, with involvement of partners and influential family members, is critical to preventing rapid repeat pregnancies among adolescents. Linking such clinical contraceptive services with non-clinical activities that build adolescents' life skills, enhance understanding of the positive role that contraceptives can play in determining life outcomes, and provide mentoring and goal setting is an evidence-based approach to preventing rapid adolescent childbearing. As new programs are designed and implemented, it will be important to keep in mind a lesson from one of the studies —that is, to enhance program effectiveness "frame child spacing as a means to an end" while "helping the teens understand that the goal of family planning (is) not (necessarily) to postpone the birth of the next child for two years, but to optimize the chance of obtaining what they most want for themselves in life."[17]

Acknowledgments: We acknowledge the expert guidance of Dr. Michelle J. Hindin who thoughtfully reviewed earlier drafts of the manuscript. Katherine Weaver, Analysis Team Lead, and her staff, Susan Higman and Kathryn Morris, at the USAID Knowledge Management Services II Project, prepared the analysis of the numbers and percentages of second and higher-order births to adolescents in 60 countries, as well as the trends in adolescent repeat pregnancies in 22 USAID priority countries. They also helped with the initial review of abstracts of evaluations. We are grateful for their superb assistance.

Funding: USAID funded the analyses provided in Table 1 and Figure 1.

Disclaimer: The views, conclusions, and findings expressed in this article are those of the authors and do not necessarily represent the views of the United States Agency for International Development or the World Health Organization.

Competing Interests: None declared.

REFERENCES

1. Adolescence: a period needing special attention. Age–not the whole story. World Health Organization website. http://apps.who.int/adolescent/second-decade/section2/page2/age-not-the-whole-story.html. Accessed December 18, 2017.
2. Neal S, Matthews Z, Frost M, Fogstad H, Camacho A, Laski L. Childbearing in adolescents aged 12-15 years in low resource countries: a neglected issue. New estimates from demographic and household surveys in 42 countries. *Acta Obstet Gynecol Scand.* 2012;91(9):1114–1118. CrossRef. Medline
3. Ross JA, Winfrey WL. Contraceptive use, intention to use, and unmet need in the extended postpartum period. *Int Fam Plan Perspect.* 2001;27(1):20–27. https://www.guttmacher.org/journals/ipsrh/2001/03/contraceptive-use-intention-use-and-unmet-need-during-extended-postpartum. Accessed December 12, 2017.
4. Ganchimeg T, Ota E, Morisaki N, et al; WHO Multicountry Survey on Maternal Newborn Health Research Network. Pregnancy and childbirth outcomes among adolescent mothers: a World Health Organization multicountry study. *BJOG.* 2014;121(suppl 1):40–48. CrossRef. Medline
5. Hoffman S, Maynard R. Kids having kids: economic costs and social consequences of teen pregnancy. Washington, DC: The Urban Institute; 2008.
6. Bissell M. Socio-economic outcomes of teen pregnancy and parenthood: a review of the literature. *Can J Hum Sex.* 2000;9(3):191–204.
7. Conde-Agudelo A, Rosas-Bermúdez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. *JAMA.* 2006;295(15):1809–1823. CrossRef. Medline
8. Fotso JC, Cleland J, Mberu B, Mutua M, Elungata P. Birth spacing and child mortality: an analysis of prospective data from the Nairobi urban health and demographic surveillance system. *J Biosoc Sci.* 2013;45(06):779–798. CrossRef. Medline
9. Wendt A, Gibbs CM, Peters S, Hogue CJ. Impact of increasing interpregnancy interval on maternal and infant health. *Paediatr Perinat Epidemiol.* 2012;26(suppl 1):239–258. CrossRef. Medline
10. Davanzo J, Hale L, Razzaque A, Rahman M. The effects of pregnancy spacing on infant and child mortality in Matlab, Bangladesh: how they vary by the type of pregnancy outcome that began the interval. *Popul Stud.* 2008;62(2):131–154. CrossRef. Medline
11. Rutstein SO. Further evidence of the effects of preceding intervals on neonatal, infant, and under-five-years mortality and nutritional status in developing countries: evidence from the Demographic and Health Surveys. *Demographic and Health Surveys Working Paper No. 41.* Calverton, MD: Macro International; 2008. https://dhsprogram.com/pubs/pdf/WP41/WP41.pdf. Accessed December 12, 2017.
12. Williams EK, Hossain MB, Sharma RK, Kumar V, Pandey CM, Baqui AH. Birth interval and risk of stillbirth or neonatal death: findings from rural north India. *J Trop Pediatr.* 2008;54(5):321–327. CrossRef. Medline
13. 2020 Topics & Objectives: Family Planning: Objectives. HealthyPeople.gov website. https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning/objectives. Accessed December 12, 2017.
14. World Health Organization (WHO). Report of a WHO technical consultation on birth spacing: Geneva, Switzerland, 13-15 June 2005. Geneva: WHO; 2007. http://www.who.int/maternal_child_adolescent/documents/birth_spacing.pdf. Accessed December 12, 2017.
15. Study Quality Assessment Tools. National Institutes of Health website. https://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools. Accessed November 23, 2017.
16. Cooper CM, Ahmed S, Winch PJ, Pfitzer A, McKaig C, Baqui AH. Findings from the use of a narrative story and leaflet to influence shifts along the behavior change continuum toward postpartum contraceptive uptake in Sylhet District, Bangladesh. *Patient Educ Couns.* 2014;97(3):376–382. CrossRef. Medline

17. Gray S, Sheeder J, OBrien R, Stevens-Simon C. Having the best intentions is necessary but not sufficient: what would increase the efficacy of home visiting for preventing second teen pregnancies? *Prev Sci.* 2006;7(4):389–395. CrossRef. Medline
18. O'Sullivan AL, Jacobsen BS. A randomized trial of a health care program for first-time adolescent mothers and their infants. *Nurs Res.* 1992;41(4):210–215. Medline
19. Black MM, Bentley ME, Papas MA, et al. Delaying second births among adolescent mothers: a randomized, controlled trial of a home-based mentoring program. *Pediatrics.* 2006;118(4): e1087–e1099. CrossRef. Medline
20. Barnet B, Liu J, DeVoe M, Duggan AK, Gold MA, Pecukonis E. Motivational intervention to reduce rapid subsequent births to adolescent mothers: a community-based randomized trial. *Ann Fam Med.* 2009;7(5):436–445. CrossRef. Medline
21. Martin J, Sheeran P, Slade P, Wright A, Dibble T. Durable effects of implementation intentions: reduced rates of confirmed pregnancy at 2 years. *Health Psychol.* 2011;30(3):368–373. CrossRef. Medline
22. Shaaban OM, Hassen SG, Nour SA, Kames MA, Yones EM. Emergency contraceptive pills as a backup for lactational amenorrhea method (LAM) of contraception: a randomized controlled trial. *Contraception.* 2013;87(3):363–369. CrossRef. Medline
23. Katz KS, Rodan M, Milligan R, et al. Efficacy of a randomized cell phone-based counseling intervention in postponing subsequent pregnancy among teen mothers. *Matern Child Health J.* 2011; 15(suppl 1):S42–S53. CrossRef. Medline
24. Olds DL, Robinson J, OBrien R, et al. Home visiting by paraprofessionals and by nurses: a randomized, controlled trial. *Pediatrics.* 2002;110(3):486–496. CrossRef. Medline
25. Kitzman H, Olds DL, Henderson CR Jr, et al. Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing. A randomized controlled trial. *JAMA.* 1997;278(8):644–652. CrossRef. Medline
26. Koniak-Griffin D, Verzemnieks IL, Anderson NLR, et al. Nurse visitation for adolescent mothers: two-year infant health and maternal outcomes. *Nurs Res.* 2003;52(2):127–136. CrossRef. Medline
27. Ford K, Weglicki L, Kershaw T, Shram C, Hoyer P, Jacobson ML. Effects of a prenatal care intervention for adolescent mothers on birth weight, repeat pregnancy, and educational outcomes at one year postpartum. *J Perinatal Ed.* 2002;11(1):35–38. CrossRef. Medline
28. Barnet B, Liu J, DeVoe M, Alperovitz-Bichell K, Duggan AK. Home visiting for adolescent mothers: effects on parenting, maternal life course, and primary care linkage. *Ann Fam Med.* 2007;5(3):224–232. CrossRef. Medline
29. El-Kamary SS, Higman SM, Fuddy L, McFarlane E, Sia C, Duggan AK. Hawaii's healthy start home visiting program: determinants and impact of rapid repeat birth. *Pediatrics.* 2004;114(3):e317–e326. CrossRef. Medline
30. Cherniss C, Herzog E. Impact of home-based family therapy in maternal and child outcomes in disadvantaged adolescent mothers. *Fam Relat.* 1996;45(1):72–79. CrossRef
31. Stevens-Simon C, Dolgan JI, Kelly L, Singer D. The effect of monetary incentives and peer support groups on repeat adolescent pregnancies. A randomized trial of the Dollar-a-Day Program. *JAMA.* 1997;277(12):977–982. CrossRef. Medline
32. Sims K, Luster. Factors related to early subsequent pregnancies and second births among adolescent mothers in a family support program. *J Fam Issues.* 2002;23(8):1006–1031. CrossRef
33. Seitz V, Apfel NH. Adolescent mothers and repeated childbearing: effects of a school-based intervention program. *Am J Orthopsychiatry.* 1993;63(4):572–581. CrossRef. Medline
34. Key JD, Gebregziabher MG, Marsh LD, ORourke KM. Effectiveness of an intensive, school-based intervention for teen mothers. *J Adolesc Health.* 2008;42(4):394–400. CrossRef. Medline
35. Solomon R, Liefeld CP. Effectiveness of a family support center approach to adolescent mothers: repeat pregnancy and school dropout rates. *Fam Relat.* 1998;47(2):139–144. CrossRef
36. Rabin JM, Seltzer V, Pollack S. The long term benefits of a comprehensive teenage pregnancy program. *Clin Pediatr (Phila).* 1991; 30(5):305–309. CrossRef. Medline
37. Sebastian MP, Khan ME, Kumari K, Idnani R. Increasing postpartum contraception in rural India: evaluation of a community-based behavior change communication intervention. *Int Perspect Sex Reprod Health.* 2012;38(2):68–77. CrossRef. Medline
38. Lewis CM, Faulkner M, Scarborough M, Berkeley B. Preventing subsequent births for low-income adolescent mothers: an exploratory investigation of mediating factors in intensive case management. *Am J Public Health.* 2012;102(10):1862–1865. CrossRef. Medline
39. Ahmed S, Ahmed S, McKaig C, et al. The effect of integrating family planning with a maternal and newborn health program on postpartum contraceptive use and optimal birth spacing in rural Bangladesh. *Stud Fam Plann.* 2015;46(3):297–312. CrossRef. Medline
40. Drayton VL, Montgomery SB, Modeste NN, Frye-Anderson BA, McNeil P. The impact of the Women's Centre of Jamaica Foundation programme for adolescent mothers on repeat pregnancies. *West Indian Med J.* 2000;49(4):316–326. Medline
41. Kan ML, Ashley OS, LeTourneau KL, et al. The adolescent family life program: a multisite evaluation of federally funded projects serving pregnant and parenting adolescents. *Am J Public Health.* 2012; 102(10):1872–1878. CrossRef. Medline
42. Ruch-Ross HS, Jones ED, Musick JS. Comparing outcomes in a statewide program for adolescent mothers with outcomes in a national sample. *Fam Plan Pers.* 1992;24(2):66–71, 96. CrossRef. Medline
43. Feldman BS, Zaslavsky AM, Ezzati M, Peterson KE, Mitchell M. Contraceptive use, birth spacing, and autonomy: an analysis of the Oportunidades program in rural Mexico. *Stud Fam Plann.* 2009; 40(1):51–62. CrossRef. Medline
44. Jones ME, Mondy LW. Lessons for prevention and intervention in adolescent pregnancy: a five-year comparison of outcomes of two programs for school-aged pregnant adolescents. *J Pediatr Health Care.* 1994;8(4):152–159. CrossRef. Medline
45. Donnelly BW, Davis-Berman J. A review of the chance to grow project: a care project for pregnant and parenting adolescents. *Child Adol Soc Work J.* 1994;11(6):493–506. CrossRef
46. Marsh JC, Wirck MA. Evaluation of Hull house teen pregnancy and parenting program. *Eval Program Plann.* 1991;14(1-2):49–61. CrossRef
47. Maynard R, Rangarajan A. Contraceptive use and repeat pregnancies among welfare-dependent teenage mothers. *Fam Plann Perspect.* 1994;26(5):198–205. CrossRef
48. Omar HA, Fowler A, McClanahan KK. Significant reduction of repeat teen pregnancy in a comprehensive young parent program. *J Pediatr Adolesc Gynecol.* 2008;21(5):283–287. CrossRef. Medline
49. Sangalang BB, Barth RP, Painter JS. First-birth outcomes and timing of second births: a statewide case management program for adolescent mothers. *Health Soc Work.* 2006;31(1):54–63. CrossRef. Medline
50. Schaffer MA, Jost R, Pederson BJ, Lair M. Pregnancy-free club: a strategy to prevent repeat adolescent pregnancy. *Pub H Nursing.* 2008;25(4):304–311. CrossRef. Medline
51. Sant' Anna MJC, Carvalho KAM, Melhado A, Coates V, Omar HA. Teenage pregnancy: impact of the integral attention given to the pregnant teenager and adolescent mother as a protective factor for repeat pregnancy. *ScientificWorldJournal.* 2007;7:187–194. CrossRef. Medline
52. Fischer RL. Evaluating the delivery of a teen pregnancy and parenting program across two settings. *Res Soc Work Pract.* 1997;7(3): 350–369. CrossRef

53. Cox JE, Buman MP, Woods ER, Famakinwa O, Harris SK. Evaluation of raising adolescent families together program: a medical home for adolescent mothers and their children. *Am J Public Health*. 2012; 102(10):1879–1885. CrossRef. Medline

54. Sadler LS, Swartz MK, Ryan-Krause P, et al. Promising outcomes in teen mothers enrolled in a school-based parent support program and child care center. *J Sch Health*. 2007;*77*(3):121–130. CrossRef. Medline

55. Brown HN, Saunders RB, Dick MJ. Preventing secondary pregnancy in adolescents: a model program. *Health Care Women Int*. 1999; 20(1):5–15. CrossRef. Medline

56. Kuziel-Perri P, Snarey J. Adolescent repeat pregnancies: an evaluation study of a comprehensive service program for pregnant and parenting black adolescents. *Fam Relat*. 1991;40(4):381–385. CrossRef

57. Kincaid DL. Social networks, ideation, and contraceptive behavior in Bangladesh: a longitudinal analysis. *Soc Sci Med*. 2000;50(2): 215–231. CrossRef. Medline

58. Malarcher S, Spieler J, Fabic MS, Jordan S, Starbird EH, Kenon C. Fertility awareness methods: distinctive modern contraceptives. *Glob Health Sci Pract*. 2016;4(1):13–15. CrossRef. Medline

59. Johnson K, Posner SF, Biermann J, et al; CDC/ATSDR Preconception Care Work Group; Select Panel on Preconception Care. Recommendations to improve preconception health and health care–United States. A report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. *MMWR Recomm Rep*. 2006;*55*(RR-6):1–23. Medline

60. Olds D, Kitzman H, Cole R, Robinson J. Theoretical foundations of a program of home visitation for pregnant women and parents of young children. *J Commun Pschyology*. 1997;*25*(1):9–24. CrossRef

61. Olds DL, Henderson CR Jr, Tatelbaum R, Chamberlin R. Improving the life-course development of socially disadvantaged mothers: a randomized controlled trial of nurse home visitation. *Am J Public Health*. 1988;78(11):1436–1445. CrossRef. Medline

62. Jackson E, Glasier A. Return of ovulation and menses in postpartum nonlactating women: a systematic review. *Obstet Gynecol*. 2011;117(3):657–662. CrossRef. Medline

63. Gates S, Lippman L, Shadowen N, Burke H, Diener O, Malkin M. Key soft skills for cross-sectoral youth outcomes. Washington, DC: USAID's YouthPower: Implementation, YouthPower Action; 2016. https://www.fhi360.org/sites/default/files/media/documents/resource-soft-skills-report.pdf. Accessed December 12, 2017.

64. Crone EA. Executive functions in adolescence: inferences from brain and behavior. *Dev Sci*. 2009;12(6):825–830. CrossRef. Medline

65. *American Heritage Dictionary of the English Language*. Fifth ed. Houghton Mifflin Harcourt Publishing Company; 2016.

66. Raising Children Network; Centre for Adolescent Health, The Royal Children's Hospital, Melbourne. Brain development: teenagers. Raising Children Network (Australia) website. http://raisingchildren.net.au/articles/brain_development_teenagers.html. Last updated November 12, 2017. Accessed December 12, 2017.

67. Arain M, Haque M, Johal L, et al. Maturation of the adolescent brain. *Neuropsychiatr Dis Treat*. 2013;9:449–461. CrossRef. Medline

68. Ahmed S, Norton M, Williams E, et al. Operations research to add postpartum family planning to maternal and neonatal health to improve birth spacing in Sylhet District, Bangladesh. *Glob Health Sci Pract*. 2013;1(2): 262–276. CrossRef. Medline

69. Catalano RF, Fagan AA, Gavin LE, et al. Worldwide application of prevention science in adolescent health. *Lancet*. 2012;379(9826): 1653–1664. CrossRef. Medline

Peer Reviewed

Received: April 7, 2017; **Accepted:** November 15, 2017

Cite this article as: Norton M, Chandra-Mouli V, Lane C. Interventions for preventing unintended, rapid repeat pregnancy among adolescents: a review of the evidence and lessons from high-quality evaluations. Glob Health Sci Pract. 2017;5(4):547-570. https://doi.org/10.9745/GHSP-D-17-00131

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ORIGINAL ARTICLE

Maternal and Neonatal Directed Assessment of Technologies (MANDATE): Methods and Assumptions for a Predictive Model for Maternal, Fetal, and Neonatal Mortality Interventions

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MANDATE is a mathematical model designed to estimate the relative impact of different interventions on maternal, fetal, and neonatal lives saved in sub-Saharan Africa and India. A key advantage is that it allows users to explore the contribution of preventive interventions, diagnostics, treatments, and transfers to higher levels of care to mortality reductions, and at different levels of penetration, utilization, and efficacy.

ABSTRACT

Maternal, fetal, and neonatal mortality disproportionately impact low- and middle-income countries, and many current interventions that can save lives are often not available nor appropriate for these settings. Maternal and Neonatal Directed Assessment of Technologies (MANDATE) is a mathematical model designed to evaluate which interventions have the greatest potential to save maternal, fetal, and neonatal lives saved in sub-Saharan Africa and India. The MANDATE decision-support model includes interventions such as preventive interventions, diagnostics, treatments, and transfers to different care settings to compare the relative impact of different interventions on mortality outcomes. The model is calibrated and validated based on historical and current rates of disease in sub-Saharan Africa and India. In addition, each maternal, fetal, or newborn condition included in MANDATE considers disease rates specific to sub-Saharan Africa and India projected to intervention rates similar to those seen in high-income countries. Limitations include variance in quality of data to inform the estimates and generalizability of findings of the effectiveness of the interventions. The model serves as a valuable resource to compare the potential impact of multiple interventions, which could help reduce maternal, fetal, and neonatal mortality in low-resource settings. The user should be aware of assumptions in evaluating the model and interpret results accordingly.

BACKGROUND

Nearly 98% of all maternal, fetal, and neonatal mortality occurs in low- and middle-income countries (LMICs).[1–3] Most maternal, fetal, and neonatal mortality arises from conditions that are preventable or treatable if appropriate care is available.[1,4,5] However, about half of births in LMICs occur outside a health facility, and about half of home births are not attended by a birth attendant.[6] With only about half of all deliveries occurring in facilities in LMICs, many lifesaving interventions are unavailable to pregnant women.[7,8] Even when they are available, existing interventions are often too complex for unskilled workers, and many maternal, fetal, and neonatal problems began before the onset of childbirth. The high skill level required and the lack of infrastructure hinder widespread adoption of many interventions that could reduce maternal, fetal, and neonatal mortality. To address the challenges to safe pregnancy and childbirth in LMICs, innovative solutions are needed.

When researchers assess the impact of a health intervention, it is often based on efficacy in a controlled clinical setting or on the availability of the intervention within LMICs.[9] In addition, clinical research is expensive, and randomized trials of known efficacious interventions are often difficult to conduct in LMICs. Therefore, knowledge gaps exist between the potential benefit of interventions in controlled clinical trial settings and the potential benefit of realistic maternal, fetal, and neonatal care in LMICs. The context is critical to consider when evaluating which interventions have the greatest potential to save lives in LMICs.

One way to address these knowledge gaps is by using mathematical models to estimate the impact of

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Knowledge gaps exist between the potential benefit of interventions in controlled clinical trial settings and realistic care in low- and middle-income countries.

interventions in different settings. Important to interpreting model results is understanding the assumptions that inform the model as well as the limitations and uncertainty of model results. Examples of modeling considerations include the variance in quality of data to inform baseline estimates, especially for low-resource settings; the applicability of efficacy for an intervention studied in a hospital versus clinic versus home setting; the difficulties of supply chain or worker skills in LMICs; and the definition of the intervention itself (i.e., whether providing treatment also assumes that the patient was already diagnosed correctly).

Maternal and Neonatal Directed Assessment of Technologies (MANDATE) is a mathematical model that assesses the potential of individual interventions and combinations of interventions to reduce maternal, fetal, and neonatal mortality in sub-Saharan Africa and India. It is a web-based decision-support tool (www.mnhtehc.org) that compares the relative effect of different maternal, fetal, and neonatal interventions and provides insights on potential bottlenecks that might prevent an intervention from saving the maximum number of maternal, fetal, and neonatal lives.[9–11] Researchers, universities, technology developers, and ministries of health could potentially use MANDATE as a tool for developing and optimizing their maternal, fetal, and neonatal interventions.

MANDATE evaluates the major conditions that cause maternal, fetal, and neonatal mortality and the impact of interventions to prevent, diagnose, or treat each condition.

The objective of this paper is to describe the modeling methods used to develop the MANDATE model as well as the data and processes used to calibrate and validate the model. We also discuss the strengths and limitations of the MANDATE model, which may be applicable to other models.

METHODS FOR DEVELOPING THE MANDATE MODEL

Source of the Data

To collect information on maternal, fetal, and neonatal conditions and interventions, we conducted a literature review that included all literature on maternal, fetal, and newborn mortality and interventions published in English from 1980 through April 2015 in PubMed, the Cochrane Library, and the World Health Organization database, resulting in the review of 1,401 articles. Specifically, literature was reviewed that addressed maternal, fetal, and neonatal mortality rates and interventions in sub-Saharan Africa and India. Where available, Cochrane reviews were used to establish the efficacy of interventions to reduce maternal, fetal, and neonatal mortality in LMICs. Demographic and Health Surveys data were used to estimate the availability of interventions, and United Nations reports were used to estimate the number of live births per region or country. Incidence and mortality rates from conditions affecting maternal, fetal, and neonatal health were established using journal articles that addressed all-cause mortality in LMICs.[1–5,12–16]

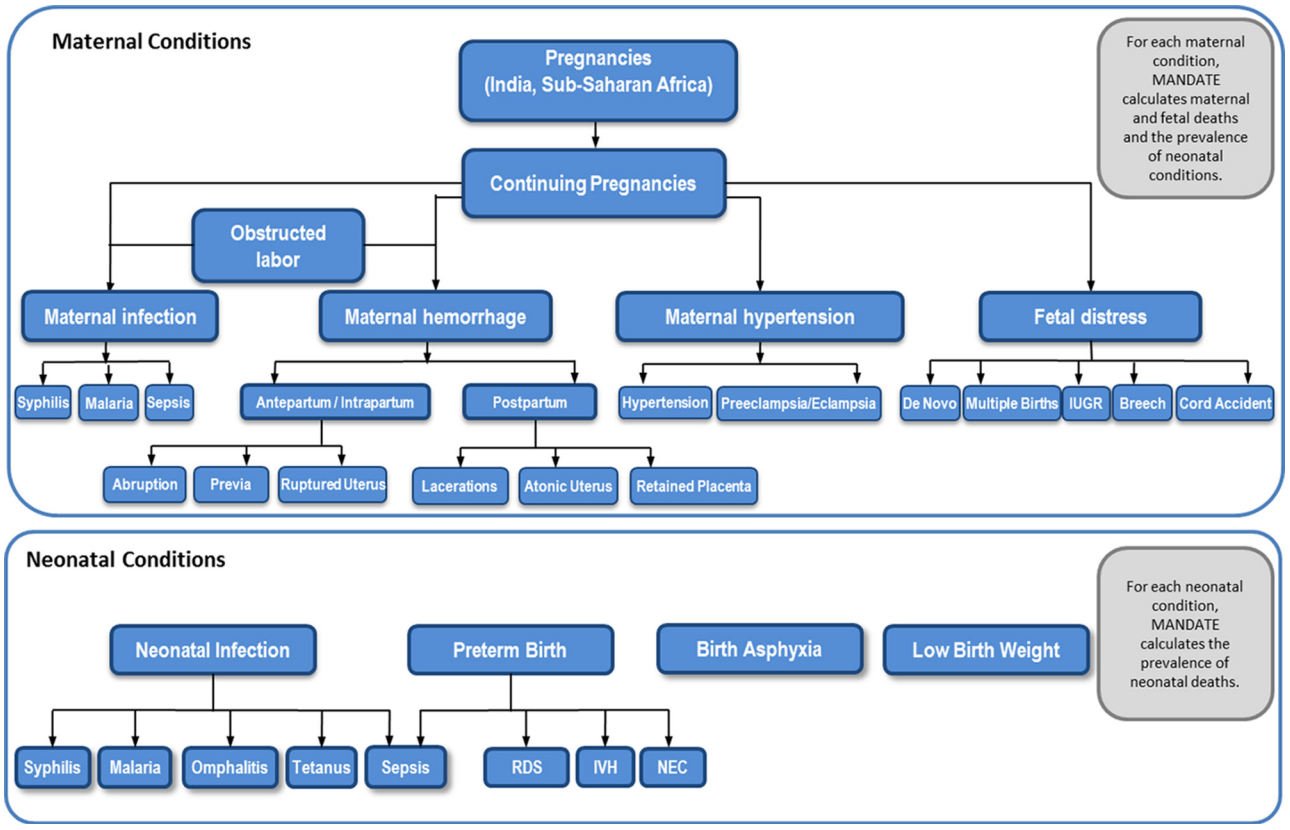
When data were unavailable from these sources, we gathered data through expert opinion, including the Global Network for Women's and Children's Health Research,[17] a research network in Argentina, the Democratic Republic of the Congo, Guatemala, India, Kenya, Pakistan, and Zambia. Key citations are available for each intervention on the MANDATE website (www.mnhtech.org). Finally, a modified graph decorrelation (GraDe) algorithm was applied, which used the estimates from the highest quality sources as primary, with support from other sources where no other data were available. Key references are denoted beside each intervention on the MANDATE website, and can be seen by clicking the question mark beside each intervention.

Modeled Conditions

MANDATE evaluates the major conditions that cause maternal, fetal, and neonatal mortality, excluding unsafe abortion, and the impact of a range of interventions to prevent, diagnose, or treat each condition. To develop the model, we first determined the conditions that have the greatest impact on maternal, fetal, and neonatal mortality in sub-Saharan Africa and India. The model includes conditions affecting maternal, fetal, and neonatal mortality and their related sub-conditions, as identified through the WHO International Classification of Diseases.

Modeled conditions associated with maternal mortality include obstructed labor, maternal infection, maternal hemorrhage, and maternal hypertensive disorders. Modeled conditions associated with stillbirth include obstructed labor, maternal hemorrhage, maternal hypertensive disorders, fetal distress, and maternal infections. Modeled neonatal conditions include infection, birth asphyxia, and preterm birth. Within each condition, sub-conditions that are attributed to each cause were also defined (Figure 1). Sub-conditions refer to specific etiologies of conditions; for example, maternal infection, which is the main condition, includes sepsis, syphilis, and malaria as its sub-conditions.

FIGURE 1. Conditions Modeled in MANDATE



Abbreviations: IUGR, intrauterine growth restriction; IVH, intraventricular hemorrhage; NEC, necrotizing enterocolitis; RDS, respiratory distress syndrome.

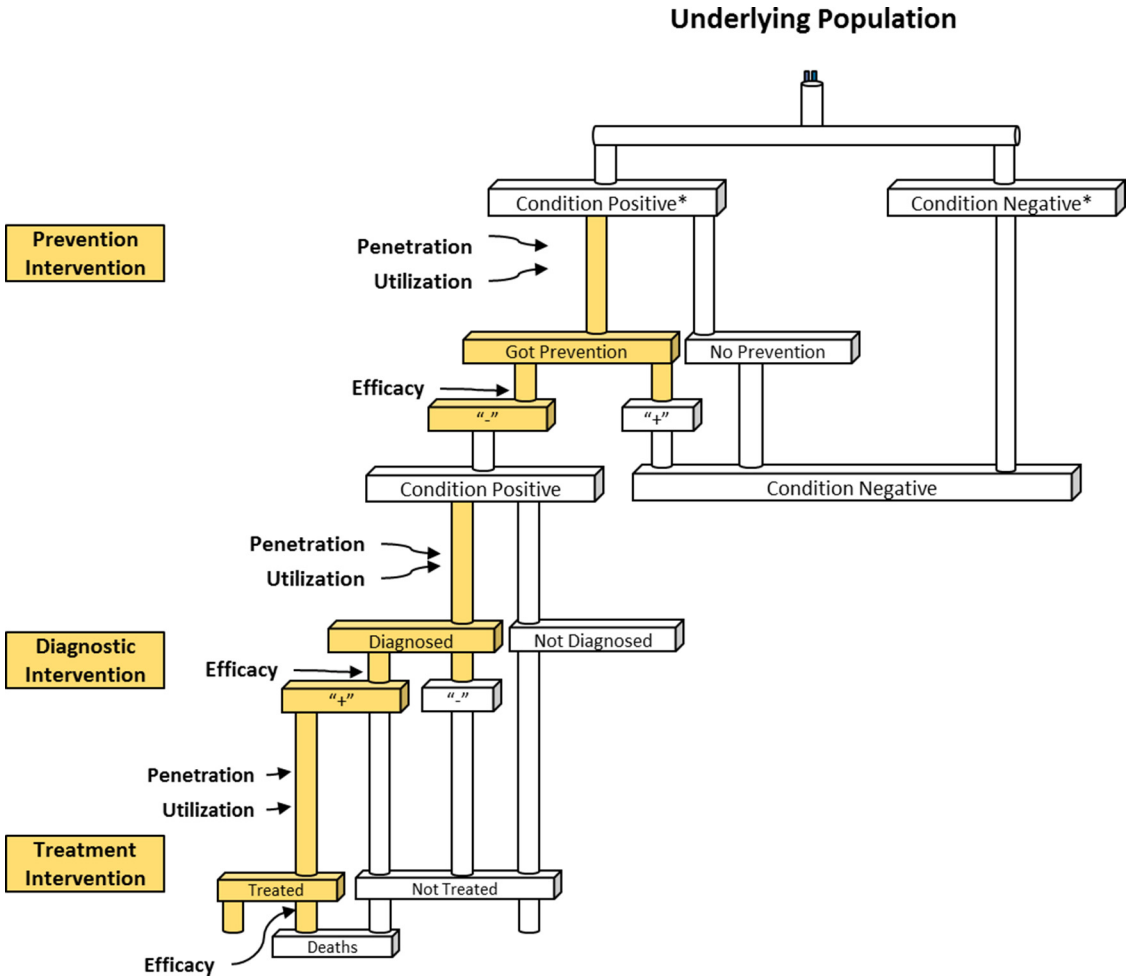
Evaluating each sub-condition allows for interventions to be applied only to the appropriate population that could benefit from the intervention. For example, even though maternal hemorrhage is often discussed as a cause of maternal mortality, hemorrhage is caused by several sub-conditions such as placental abruption, placenta previa, ruptured uterus, lacerations, atonic uterus, or retained placenta. Treatments for these sub-conditions vary. For example, with the antepartum or intrapartum hemorrhages (e.g., placental abruption, placenta previa, and ruptured uterus), clinicians need to consider the status of the fetus (i.e., alive or dead), whereas with postpartum hemorrhages the fetus will not directly benefit from maternal interventions. Similarly, if the cause of a hemorrhage is a retained placenta, suturing the cervix will not treat the underlying cause of the hemorrhage. Interventions within the model are specific to each sub-condition and are only applied to the sub-condition that they impact. The interventions in the model focus on current best practices as well as promising or emerging clinical practices.

After interventions are applied, the maternal sub-conditions are associated with rates of maternal death, fetal death, and the prevalence of a neonatal condition. Neonatal sub-conditions are associated with risk for neonatal mortality and have no impact on maternal or fetal outcomes.

Mathematical Modeling

MANDATE is a decision tree mathematical model based on the conditions and sub-conditions (Figure 2). For each of these sub-conditions, the model calculates the number of pregnancies in a particular time frame in the designated geographic region. The model is calibrated using several scenarios. First, the model's initial inputs are calibrated using historical incidence rates (e.g.,

FIGURE 2. Decision Tree Modeling Methodology



*Condition positive and negative is based on an "un-prevented" incidence rate (i.e., the proportion of the population who would get a condition if no preventive interventions were available).

incidence rates before the existence of antibiotics for the bacterial infection model, or incidence rates before the use of uterotonics or active management of the third stage of labor for hemorrhage) that assume no interventions are available in the population to determine the population at risk of having a sub-condition. Then interventions are added to prevent, diagnose, and treat maternal, fetal, and neonatal sub-conditions using baseline estimates of their availability (i.e., penetration), use when available (i.e., clinically significant/appropriate utilization), and efficacy (i.e., benefit under ideal, controlled conditions). Finally, MANDATE uses untreated case fatality rates to estimate the likelihood of mortality if no interventions are used.

Interventions

The interventions included in the model to compare their relative impact consist of preventive interventions, diagnostics, treatments, and transfers to different care settings.

Preventive Interventions

A preventive intervention is defined as an intervention that reduces the incidence of a sub-condition. In the model, preventive interventions decrease the number of people who develop the sub-condition. Members of the population whose condition was successfully prevented are moved from the pool of individuals with the condition to the condition-negative group. When a condition is

successfully prevented, it no longer contributes to the risk of dying from the sub-condition in the model.

Diagnostics

MANDATE defines diagnostics as interventions that successfully recognize or diagnose a disease status, assuming the subject is a true positive diagnosis for a particular condition. MANDATE does not allow for false positive diagnoses to receive benefit from treatment, as these individuals in actuality would receive no benefit from the treatment. The model requires a diagnosis of the condition to prompt actions such as treatment or transfer to a facility for treatment. Diagnostics typically fall into 3 categories: (1) recognition of symptoms—made by a patient or unskilled care provider; (2) clinical diagnostics—made by a skilled health care provider; or (3) technology-based diagnostics—technologies used to formally diagnose a condition.

Treatments

Treatments are defined as interventions that impact mortality among the sub-conditions; the patient must first be appropriately diagnosed to receive a treatment within the model. A treatment for a mother can also impact fetal sub-conditions or reduce the likelihood of a neonate developing a sub-condition. For example, a cesarean delivery used to treat a mother with preeclampsia may prevent the mother's mortality from preeclampsia and may also prevent fetal mortality and neonatal birth asphyxia.

Transfers to Different Care Settings

Preventive interventions, diagnostics, and treatments are each evaluated using 3 constructs: penetration, utilization, and efficacy. Penetration is the availability of an intervention. Utilization is the appropriate use of an intervention. Efficacy is the ability of an intervention to successfully prevent, diagnose, or treat a given sub-condition under ideal conditions. Even though efficacy is defined in the model as constant, regardless of location where the intervention is applied, medical care and availability of interventions often varies based on level of care. These variations are captured by evaluating each intervention option (i.e., preventive interventions, diagnosis, and treatment) in 3 different settings: home, clinic, and hospital.

The setting represents where an intervention will occur, which usually corresponds to the location of antenatal or delivery care, or, for conditions with long latency periods, where symptoms emerge. Home settings are defined by having very limited availability of skilled providers, no cesarean or surgical capabilities, and no technology-based interventions. Clinic settings are defined as having some availability of skilled providers who can provide basic obstetric and neonatal care, with no cesarean or invasive surgical capabilities.[18] Hospital settings are defined as having the availability of skilled providers such as nurses and physicians. Hospitals have varying degrees of emergency obstetric and neonatal care capacity, including cesarean and surgical capabilities in some hospitals.[18] As such, some interventions are only available or utilized in the clinic or hospital settings. By explicitly modeling the differences in the availability (penetration) and utilization of interventions in home, clinic, and hospital settings, the MANDATE model calculates the differences in mortality by care in different settings.

Transfers are captured in MANDATE as the ability of pregnant women and neonates to move from one setting to another for care. For example, a diagnosis in a home setting might increase the proportion of patients who transfer to a different care setting, such as a clinic or hospital, for additional intervention.

Simultaneous Use of Multiple Interventions

The model allows for more than one preventive intervention, diagnostic, or treatment to be available at the same time for any specific sub-condition. In this case, we have assessed whether the interventions can be given independently or if they are dependent (e.g., one intervention must be given before the second intervention). To address the model's ability to assess multiple interventions at once, the MANDATE model uses the modeling concepts of lines and layers.

The concept of a "line of intervention" refers to any intervention that is given based on previous interventions that were tried and failed (i.e., the sub-condition was not successfully prevented, diagnosed, or treated). For example, if a newborn was given oxygen for respiratory distress syndrome, and oxygen was not sufficient, then a more advanced treatment, such as ventilation, could be given next. Technologies that must be given in a specific order and are dependent on other interventions being offered first are called "lines of intervention."

The model allows for more than one preventive intervention, diagnostic, or treatment to be available at the same time for any specific sub-condition.

The variance in medical care and availability of interventions is captured by evaluating each intervention option in 3 different settings: home, clinic, and hospital.

Interventions that are not dependent on any other technology are defined as "layered interventions." In this case, it does not matter if any other preventive intervention, diagnosis, or treatment is being offered at the same time, and the order in which those interventions are modeled is not relevant. An example is the use of bimanual uterine massage and the use of uterotonics, such as oxytocin, to prevent atonic uterus. Using one of these interventions does not preclude the use of the other, nor does the order in which they are used depend on the other.

MANDATE also accounts for interventions that can be given only once or at specific times based on different interventions. For example, a woman who receives a cesarean delivery cannot receive a cesarean delivery twice for the same pregnancy. However, some interventions can be given multiple times and have different benefits based on the timing of the intervention. One example is the use of oxytocin. Oxytocin helps prevent and treat hemorrhage by contracting the uterus. It can be used as a preventive intervention and as a treatment, so using oxytocin twice on the same mother at different points in her care is allowable in MANDATE.

Validation and Calibration

Every sub-condition within MANDATE was validated and calibrated by running a minimum of 4 scenarios:

1. No intervention based on literature about the natural course of disease or the known course of disease before modern interventions
2. Current-care intervention that reflects current intervention rates in sub-Saharan Africa or India
3. Intervention rates in high-income countries
4. Change(s)-in-care rates for each intervention in the model

Each model was validated by estimating the number of maternal, fetal, and neonatal deaths resulting from each condition with treatments that are currently available in sub-Saharan Africa and India.

The no-intervention scenario uses historical disease rates to evaluate how many women, fetuses, or newborns died from each sub-condition before interventions became available. For example, when calibrating the sepsis models, we used historical disease rates from the early 1900s, before the advent of antibiotics. Similar historical data were used for each sub-condition.

Each model was validated by estimating the number of maternal, fetal, and neonatal deaths resulting from each condition with treatments that are currently available in sub-Saharan Africa and India. Input data for penetration, utilization, and efficacy of each intervention in each care setting were based on estimates of current rates of intervention in sub-Saharan Africa and India. The aggregate outputs result in mortality rates that reflect the current total mortality in sub-Saharan Africa and India, adjusted for mortality causes not included in the model.

Next, the models had data inputs for penetration, utilization, and efficacy in care settings reflective of where care is sought in high-income countries. (Efficacy remained constant because efficacy by definition is the clinical benefit under ideal conditions.) When interventions in MANDATE are improved to the standard of care provided in high-income countries, the mortality for each condition declines to levels consistent with mortality rates in high-income countries.

The final scenarios were specific to each intervention in the model. Each condition was also evaluated using a high estimate and low estimate for expected mortality as well as a high and low estimate for penetration, utilization, and efficacy for each intervention. The results of these scenarios needed to be logical and appropriately scaled when compared with the no-intervention and high-income countries scenarios. These scenarios were validated by experts in the field of maternal, fetal, and neonatal mortality in LMICs.[9–11,19–21]

DISCUSSION

No model can provide a comprehensive understanding of maternal, fetal, and neonatal mortality alone, and MANDATE is just one of many resources available to analyze interventions in LMIC settings. When assumptions are understood and models are used judiciously, models can provide unique insights to contribute to improvements in maternal, fetal, and neonatal mortality. Therefore, it is important to acknowledge complementary resources available to support critical decisions about maternal, fetal, and neonatal interventions.

One complementary resource is the Lives Saved Tool (LiST), a free software-based tool (part of the Spectrum suite of tools) that estimates mortality averted due to maternal and child health interventions.[19,20] Originally funded by the Bill & Melinda Gates Foundation and the United Nations Children's Fund (UNICEF), LiST is widely used by the global maternal and child health community to advocate for needed interventions in LMICs. The model also includes modules on HIV/AIDS and family planning interventions, and has

TABLE. Similarities and Differences Between LiST and MANDATE

	LiST	MANDATE
Purpose	A Microsoft Windows-based software tool used to model the impact of scaling up health interventions aimed at reducing mortality and morbidity in mothers, newborns, and children under 5 years of age	A web-based, mathematical model designed to estimate maternal, fetal, and neonatal lives saved in sub-Saharan Africa and India
Conditions Included	Maternal, fetal, newborn, and child health interventions; malaria interventions; and HIV/AIDS interventions	Maternal, fetal, and neonatal health interventions, excluding HIV/AIDS; malaria is only evaluated based on deaths directly attributable to malaria
Condition Specificity	Condition level	Condition and sub-condition level
Intervention Specificity	Sometimes packages interventions (e.g., active management of the third stage of labor)	Generally unpackages interventions to focus on a specific component of an intervention (e.g., oxytocin, uterine massage, types of diagnostics)
Intervention Constructs	Coverage, effectiveness; rates available for some interventions by setting, dependent on topic	Penetration, utilization, efficacy, and transfer between care settings; rates available for each intervention by setting
Type of Software	Spectrum software package	Web-based
Training and Tutorials	User manual, online tutorials, webinars, and technical assistance	Online 15-minute tutorial and technical assistance
Cost to Use	Free	Free
Outputs	Number of maternal and child (up to 5 years) deaths, mortality rates/ratios, deaths averted, intermediate outcomes (e.g., stunting, breastfeeding), and single- and multiple-country scenarios	Number of maternal, fetal, and newborn (up to 28 days) deaths, deaths averted, cases averted (e.g., postpartum hemorrhage, eclampsia), and single- and multiple-country scenarios

Abbreviations: LiST, Lives Saved Tool; MANDATE, Maternal and Neonatal Directed Assessment of Technologies.

proven itself an important resource for the global health community.

There are several similarities and differences between LiST and MANDATE that are noted in the Table.[20] While both models contribute to the body of knowledge about how to intervene in LMICs, we believe that any user of a model should understand the underlying assumptions, strengths, and limitations of that model, and use model estimates as a contributing piece of evidence for optimizing interventions in LMICs.

One of best ways to understand the differences between the 2 models is to consider a case example, such as providing broader coverage of magnesium sulfate ($MgSO_4$) in sub-Saharan Africa to treat preeclampsia. Using LiST's model for 2012, we aggregated all countries in sub-Saharan Africa to examine the impact of adding 100% coverage (i.e., similar to MANDATE's availability times penetration) of $MgSO_4$ in settings with skilled providers compared with sub-Saharan Africa's baseline coverage of $MgSO_4$. LiST assumes that the efficacy of $MgSO_4$ prevents mortality, and therefore, $MgSO_4$ is a potentially lifesaving treatment. In this scenario, perfect access to and use of $MgSO_4$ in settings with skilled providers (i.e., hospitals and clinics) in sub-Saharan Africa would result in approximately 10,000 maternal lives saved in 2012 as estimated by LiST. When the same analysis is done using the current data version of MANDATE (online model version 1.1.81, data version 1.1.122), with $MgSO_4$ penetration and utilization of 100% in clinic and hospital settings, MANDATE estimates that only a little over 700 lives would be saved with the addition of $MgSO_4$ to all care settings. To understand the differences between the 2 estimates, it is necessary to know the differences in methodologies and assumptions.

Building on a previous MANDATE analysis, we conducted an abbreviated series of analyses using the current data version of MANDATE to understand better the difference in estimated lives saved between the 2 models with the use of $MgSO_4$.[21] The first critical difference is to understand that in MANDATE, the assumption is that $MgSO_4$ does not directly prevent mortality, whereas with LiST the efficacy applied to $MgSO_4$ is to prevent mortality. Instead, MANDATE models the efficacy of $MgSO_4$ to prevent seizures and

MANDATE allows the user to explore each component that contributes to reduction in mortality at different levels of penetration, utilization, and efficacy.

recurrent seizures. Another critical difference is that MANDATE does not assume diagnosis is available to each $MgSO_4$ recipient. While we understand that $MgSO_4$ would not be given if a diagnosis had not been made, we also feel that diagnosis is often a complex step toward getting appropriate treatment, and it cannot be taken for granted as a step toward providing safer pregnancies and childbirth in LMICs. If we assume that diagnosis were available to and used (e.g., provided) by every pregnant woman and $MgSO_4$ was given when appropriate, MANDATE estimates that approximately 7,500 maternal lives would be saved. Building on this analysis, we could also use MANDATE to estimate lives saved with the assumption that all women were diagnosed and all women were given access to a cesarean delivery or induction if they are given $MgSO_4$, and that all women in need of $MgSO_4$ receive it. In this scenario, MANDATE estimates that approximately 10,000 maternal lives would be saved. Finally, we could consider a scenario where all women were diagnosed, transferred to an appropriate care setting, provided $MgSO_4$ and cesarean delivery or induction, and then we would see mortality decline from approximately 17,000 maternal deaths per year to approximately 5,000 deaths per year, which means that just over 12,000 maternal lives would be saved by this scenario.

This example illustrates some of the important differences between the LiST and MANDATE approaches (e.g., diagnosis assumptions and transfer assumptions), and highlights the importance of understanding the underlying assumptions used for any modeling. Both models start with similar assumptions regarding the population of pregnancies (using the United Nations data).

LiST allows the user to scale up coverage of the known intervention (in this case $MgSO_4$) with use in currently acceptable settings (e.g., health facilities with skilled providers). The LiST model with $MgSO_4$ assumes that everyone who gets $MgSO_4$ and has preeclampsia/eclampsia could be diagnosed, and that $MgSO_4$ (rather than induction or cesarean delivery) prevents death directly, regardless of whether the mother receives an emergent or emergency delivery. Thus, even though LiST allows the user to estimate the impact of scaling up the use of $MgSO_4$, LiST also assumes the supporting interventions (e.g., diagnoses and treatment options) are available. In doing this, the assessment of the impact of $MgSO_4$ by LiST on lives saved focuses on the overall outcome of $MgSO_4$ and assumes that the complex steps needed to appropriately manage preeclampsia/eclampsia are available.

MANDATE allows the user to further explore each of the components that contribute to reduction in mortality (e.g., diagnostics, facility care, access to cesarean delivery and labor induction, and transfers, in addition to $MgSO_4$) and to explore each of these at different levels of penetration, utilization, and efficacy.

We see that when all of the coverage is provided, MANDATE and LiST have similar reductions in maternal mortality, and both provide valuable insights to the lifesaving abilities of $MgSO_4$. However, MANDATE also highlights the important interactions between $MgSO_4$ and other needed steps for maternal care, including diagnosis, transfer between care settings, and treatment capabilities.

Limitations of MANDATE

As with all models, MANDATE has a defined scope and includes simplifying assumptions. Limitations relate to either scope or data availability. The scope of MANDATE is limited to 2 geographic regions, sub-Saharan Africa and India. The base assumptions regarding a condition's incidence and intervention penetration and utilization are at the continent level for sub-Saharan Africa and at the country level for India. These numbers can be modified by the user if more accurate information or country-specific data are available; however, literature does not currently provide sufficient data to support country-specific data for every modeling assumption. Though incidence, penetration, utilization, and efficacy are not reflective of each country's specific conditions, the proportion of the population flowing through the model may be restricted to the country level in sub-Saharan Africa (e.g., Ethiopia) and state level in India (e.g., Uttar Pradesh). In addition, a user has the ability to modify assumptions online as long as they disclose the rationale for their modifications.

Data availability and data concordance were a challenge for the MANDATE model. Although we searched the peer-reviewed literature, gray literature, and data from sub-Saharan Africa and India, substantial gaps in the data remain. These gaps reflect the relative scarcity of data regarding disease burden and interventions in LMICs. Further, MANDATE is not a stochastic model and does not account for random variation in population flows through the decision tree; this limitation is primarily due to the lack of data to appropriately calibrate a stochastic model. In

addition, some conditions may appear to result in rates of mortality that are lower than rates reported by some experts in that field; however, estimates are calibrated based on global estimates of mortality that consider all causes of mortality together.[1,2,4,14–16]

We attempted to mitigate data availability issues by using expert clinical opinions and data from RTI International, gathered through the Global Network for Women's and Children's Health Research.[17] Further, we sought to be transparent about the data availability by embedding critical references for each intervention within the online model. In addition, the model allows a user to change the baseline estimates if they are privy to more accurate local data estimates.

MANDATE also requires rigorous data maintenance to ensure updated estimates for penetration, utilization, and efficacy, and without support to update data, the model will be obsolete within a few years.

MANDATE is currently limited to sub-conditions that directly account for the predominance of maternal, fetal, and neonatal mortality. Comorbidities are not modeled in MANDATE, including HIV/AIDS, which is known to have important impacts on many of the modeled conditions. The technologies included in MANDATE are limited to those that (1) focus on preventing maternal, fetal, and neonatal mortality, and (2) are currently part of clinical standard of care or are highly visible, promising interventions.

Finally, we would like to emphasize that the lessons derived from modeling are limited by the extent to which the user understands, accounts for, and respects the limitations of the underlying modeling assumptions. There is always a risk that inappropriate use of a model can result in the over- or underestimation of the potential impact of an intervention. However, when used thoughtfully, models serve as a useful tool to guide conversations, thoughts, or advocacy around specific interventions.

CONCLUSIONS

MANDATE is the only model that evaluates maternal, fetal, and neonatal conditions and sub-conditions resulting in mortality. Further, MANDATE considers care settings, transfers to facilities for further interventions, and the impact of maternal conditions on fetal and neonatal outcomes. MANDATE is an important decision-making model that the global maternal and child health community can use to assess the relative impact of interventions on maternal, fetal, and neonatal mortality. In countries with limited resources, it is critical to identify and pursue interventions that can most effectively prevent maternal, fetal, and neonatal mortality. MANDATE can serve as a resource to determine the relative benefit of many potential interventions for maternal, fetal, and neonatal mortality in sub-Saharan Africa and India.

Acknowledgments: This study was funded through a grant from the Bill & Melinda Gates Foundation to RTI International for Maternal and Neonatal Directed Assessment of Technologies (MANDATE).

Funding: Bill & Melinda Gates Foundation.

Competing Interests: None declared.

REFERENCES

1. Black RE, Cousens S, Johnson HL, et al; Child Health Epidemiology Reference Group of WHO and UNICEF. Global, regional, and national causes of child mortality in 2008: a systematic analysis. *Lancet.* 2010;375(9730):1969–1987. CrossRef. Medline
2. Khan KS, Wojdyla D, Say L, Gülmezoglu AM, Van Look PFA. WHO analysis of causes of maternal death: a systematic review. *Lancet.* 2006;367(9516):1066–1074. CrossRef. Medline
3. Lee ACC, Katz J, Blencowe H, et al; CHERG SGA-Preterm Birth Working Group. National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. *Lancet Glob Health.* 2013;1(1):e26–e36. CrossRef. Medline
4. Liu L, Johnson HL, Cousens S, et al; Child Health Epidemiology Reference Group of WHO and UNICEF. Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. *Lancet.* 2012;379(9832):2151–2161. CrossRef. Medline
5. Ronsmans C, Graham WJ; Lancet Maternal Survival Series steering group. Maternal mortality: who, when, where, and why. *Lancet.* 2006;368(9542):1189–1200. CrossRef. Medline
6. Montagu D, Yamey G, Visconti A, Harding A, Yoong J. Where do poor women in developing countries give birth? A multi-country analysis of demographic and health survey data. *PLoS One.* 2011;6(2):e17155. CrossRef. Medline
7. Crowe S, Utley M, Costello A, Pagel C. How many births in sub-Saharan Africa and South Asia will not be attended by a skilled birth attendant between 2011 and 2015? *BMC Pregnancy Childbirth.* 2012;12(1):4. CrossRef. Medline
8. World Health Organization (WHO); United Nations Population Fund (UNFPA); The World Bank; United Nations Population Division. Trends in Maternal Mortality: 1990 to 2013. Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division. Geneva: WHO; 2014. http://www.who.int/reproductivehealth/publications/monitoring/maternal-mortality-2013/en/. Accessed November 9, 2017.
9. McClure EM, Rouse DJ, MacGuire ER, et al. The MANDATE model for evaluating interventions to reduce postpartum hemorrhage. *Int J Gynaecol Obstet.* 2013;121(1):5–9. CrossRef. Medline
10. Goldenberg RL, McClure EM, MacGuire ER, Kamath BD, Jobe AH. Lessons for low-income regions following the reduction in hypertension-related maternal mortality in high-income countries. *Int J Gynaecol Obstet.* 2011;113(2):91–95. CrossRef. Medline

MANDATE is the only model that evaluates maternal, fetal, and neonatal conditions and sub-conditions resulting in mortality.

11. Kamath-Rayne BD, MacGuire ER, McClure EM, Goldenberg RL, Jobe AH. Clinical algorithms for the identification of sick newborns in community-based settings. *Acta Paediatr.* 2012;101(4):344–351. CrossRef. Medline
12. Blencowe H, Cousens S, Kamb M, Berman S, Lawn JE. Lives Saved Tool supplement detection and treatment of syphilis in pregnancy to reduce syphilis related stillbirths and neonatal mortality. *BMC Public Health.* 2011;11(suppl 3):S9. CrossRef. Medline
13. Lawn JE, Lee ACC, Kinney M, et al. Two million intrapartum-related stillbirths and neonatal deaths: Where, why, and what can be done? *Int J Gynaecol Obstet.* 2009;107(suppl):S5–S19, S19. CrossRef. Medline
14. Kassebaum NJ, Bertozzi-Villa A, Coggeshall MS, et al. Global, regional, and national levels and causes of maternal mortality during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet.* 2014;384(9947):980–1004. CrossRef. Medline
15. Lawn JE, Blencowe H, Pattinson R, et al; Lancets Stillbirths Series steering committee. Stillbirths: Where? When? Why? How to make the data count? *Lancet.* 2011;377(9775):1448–1463. CrossRef. Medline
16. Lawn JE, Kerber K, Enweronu-Laryea C, Cousens S. 3.6 million neonatal deaths—what is progressing and what is not? *Semin Perinatol.* 2010;34(6):371–386. CrossRef. Medline
17. Bose CL, Bauserman M, Goldenberg RL, et al. The Global Network Maternal Newborn Health Registry: a multi-national, community-based registry of pregnancy outcomes. *Reprod Health.* 2015;12 (suppl 2):S1. CrossRef. Medline
18. Paxton A, Bailey P, Lobis S, Fry D. Global patterns in availability of emergency obstetric care. *Int J Gynaecol Obstet.* 2006;93(3):300–307. CrossRef. Medline
19. Friberg IK, Bhutta ZA, Darmstadt GL, et al. Comparing modelled predictions of neonatal mortality impacts using LiST with observed results of community-based intervention trials in South Asia. *Int J Epidemiol.* 2010;39(suppl 1):i11–i20. CrossRef. Medline
20. Walker N, Tam Y, Friberg IK. Overview of the lives saved tool (LiST). *BMC Public Health.* 2013;13(suppl 3):S1. CrossRef. Medline
21. Goldenberg R, Griffin J, Kamath-Rayne B, et al. Clinical interventions to reduce stillbirths in sub-Saharan Africa: a mathematical model to estimate the potential reduction of stillbirths associated with specific obstetric conditions. *BJOG.* 2016 Oct 5. [Epub ahead of print] CrossRef. Medline

Peer Reviewed

Received: May 31, 2016; **Accepted:** October 31, 2017

Cite this article as: Jones-Hepler B, Moran K, Griffin J, McClure EM, Rouse D, Barbosa C, et al. Maternal and Neonatal Directed Assessment of Technologies (MANDATE): methods and assumptions for a predictive model for maternal, fetal, and neonatal mortality interventions. Glob Health Sci Pract. 2017;5(4):571-580. https://doi.org/10.9745/GHSP-D-16-00174

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ORIGINAL ARTICLE

Re-Evaluating the Possible Increased Risk of HIV Acquisition With Progestin-Only Injectables Versus Maternal Mortality and Life Expectancy in Africa: A Decision Analysis

Maria Isabel Rodriguez,[a] Mary E Gaffield,[b] Leo Han,[a] Aaron B Caughey[a]

Our model suggests that removing progestin-only injectables in Africa would have a net negative effect on maternal health, life expectancy, and mortality under a variety of scenarios.

ABSTRACT

Objective: The association between increased risk of HIV acquisition and use of progestin-only injectables (POIs) is controversial. We sought to compare the competing risks of maternal mortality and HIV acquisition with use of POIs using updated data on this association and considering an expanded number of African countries.

Methods: We designed a decision-analytic model to compare the benefits and risks of POIs on the competing risks of maternal mortality and HIV acquisition on life expectancy for women in 9 African countries. For the purposes of this analysis, we assumed that POIs were associated with an increased risk of HIV acquisition (hazards ratio of 1.4). Our primary outcome was life-years and the population was women of reproductive age (15–49 years) in these countries, who did not have HIV infection and were not currently planning a pregnancy. Probabilities for each variable included in the model, such as HIV incidence, access to antiretroviral therapy, and contraceptive prevalence, were obtained from the literature. Univariate and multivariate sensitivity analyses were performed to check model assumptions and explore how uncertainty in estimates would affect the model results.

Results: In all countries, discontinuation of POIs without replacement with an equally effective contraceptive method would result in decreased life expectancy due to a significant increase in maternal deaths. While the removal of POIs from the market would result in the prevention of some new cases of HIV, the life-years gained from this are mitigated due to the marked increase in neonatal HIV cases and maternal mortality with associated life-years lost. In all countries, except South Africa, typical-use contraceptive failure rates with POIs would need to exceed 39%, and more than half of women currently using POIs would have to switch to another effective method, for the removal of POIs to demonstrate an increase in total life-years.

Conclusion: Women living in sub-Saharan Africa cope with both high rates of HIV infection and high rates of pregnancy-related maternal death relative to the rest of the world. Based on the most current estimates, our model suggests that removal of POI contraception from the market without effective and acceptable contraception replacement would have a net negative effect on maternal health, life expectancy, and mortality under a variety of scenarios.

INTRODUCTION

The global community has made a commitment to reach 3 key milestones by 2020 to prevent and treat HIV: (1) reduce new HIV infections to fewer than 500,000 globally; (2) decrease AIDS-related deaths to fewer than 500,000 globally, and (3) eliminate HIV-related stigma and discrimination.[1] While marked improvements have been made in reducing AIDS-related deaths through improved access to therapy, efforts to reduce new HIV infections have stagnated.[1] Prevention efforts have been limited by inconsistent usage of barrier methods (male or female condoms), lower-than-expected uptake of male circumcision, and slow implementation and uptake of preexposure prophylaxis.[2–5] Africa continues to be the area of the world most affected by the HIV epidemic, and women are at particularly high risk of HIV infection.[1] In fact, the factors that affect HIV infection acquisition disproportionately impact women of reproductive age in sub-Saharan Africa.

Risk of HIV acquisition, especially in sub-Saharan Africa, must be considered within the context of maternal mortality. Sub-Saharan African countries experience the highest maternal mortality rates in the world, accounting for two-thirds of the world's maternal

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Risk of HIV acquisition, especially in sub-Saharan Africa, must be considered within the context of maternal mortality.

An updated meta-analysis from 2016 suggests a possible increased risk of HIV acquisition with use of DMPA injectables.

Progestin-only injectables are currently the predominant contraceptive method used across sub-Saharan Africa.

Our model sought to understand how the overall balance between maternal mortality and HIV acquisition would shift if progestin-only injectables were removed from the method mix.

deaths.[6] Use of contraception plays a critical role in preventing maternal deaths by allowing women to delay early childbearing, limit childbearing, and avoid unintended pregnancies and subsequent unsafe abortions.[7] However, there is high unmet need for contraceptive services across Africa,[8,9] with only 22% of married women using a modern method of contraception.[8,10] As a continent, Africa has the highest rates of unintended pregnancy annually, with an estimated 35% of all pregnancies unintended.[11] High rates of unintended pregnancy are of particular concern in Africa, where acesss to safe abortion services is highly restricted.[11] Between one-quarter to one-half of all unintended pregnancies end in abortion, and nearly all (>98%) abortions in Africa are unsafe.[12,13]

Multiple challenges exist to accessing the most effective forms of modern, reversible contraception, including the intrauterine device (IUD), the progestin-only implant, and progestin-only injectables (POIs), in Africa and other areas. With perfect use, tthese methods are over 99% effective in preventing unintended pregnancy.[14] Key barriers to accessing these methods include commodity stock-outs, workforce shortages, and differences in acceptability of the methods. Insertion of the IUD and implant requires specialized training, whereas POIs can be provided safely by community health workers. Currently POIs are the predominant method of contraception used across sub-Saharan Africa, accounting for 43% of modern contraceptive methods used.[15]

Within this context, data on the potential association between the use of POIs and acquisition of HIV has generated considerable attention and controversy.[16] Prior data on the relationship between HIV acquisition and use of hormonal contraceptives has been mixed, with some studies showing a protective effect and others showing an increased risk.[17–26] Few studies have found a statistically significant association, and interpretation of the data has been challenging due to important limitations in the methodology of existing studies. A key limitation has been significant variation in controlling for potential confounders. These potential confounders include pregnancy, coital frequency, condom usage, marital status, transactional sex, and percentage of participants at baseline in the comparison group using nonhormonal contraceptives (≤10% versus >10%). No randomized trial or definitive data exist to guid health care decisions. The World Health Organization (WHO) has followed the evidence closely to provide guidance on use of different types of contraceptives among women at increased risk for HIV acquisition.[16,27]

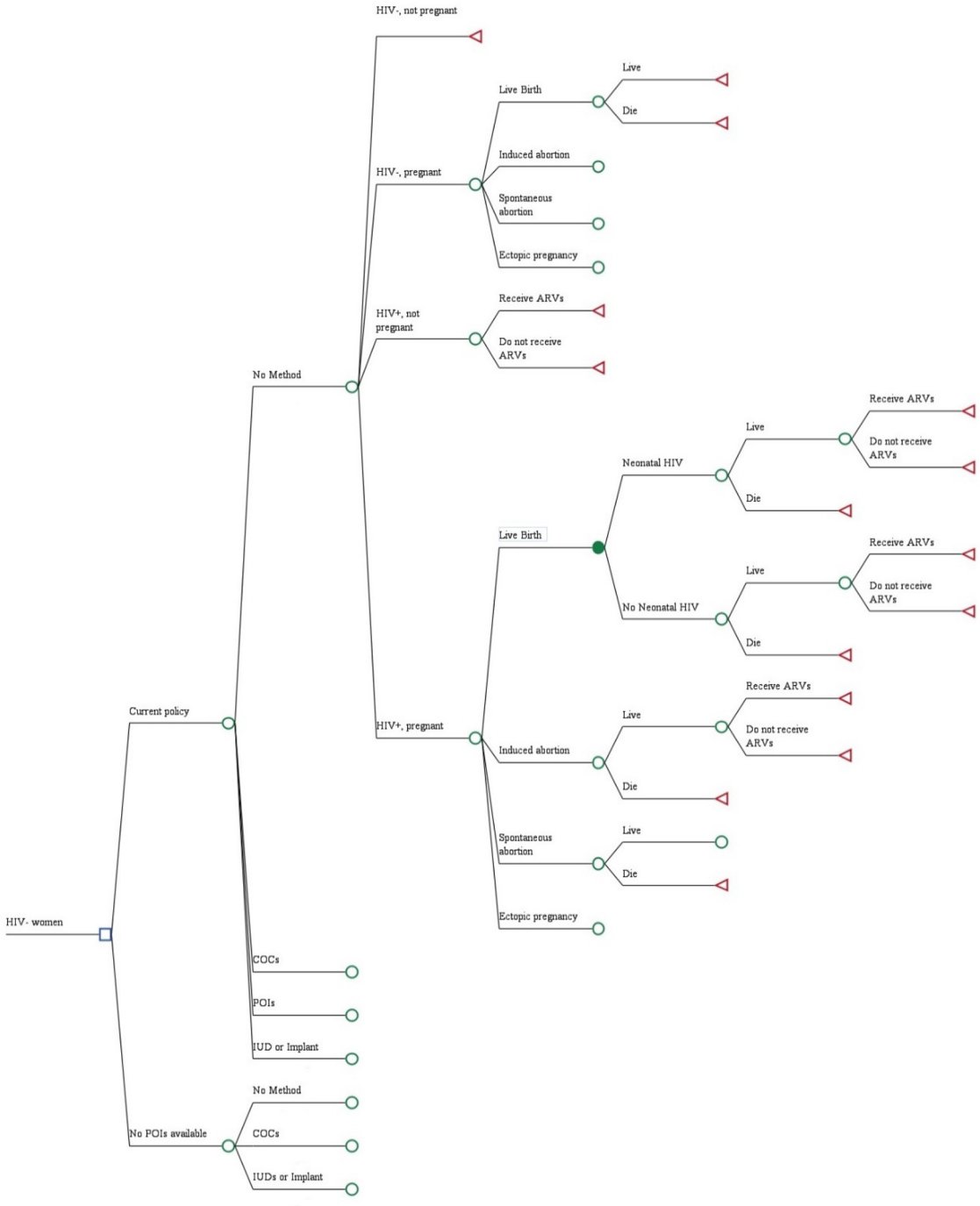
A 2016 meta-analysis provides an updated assessment of the potential increased risk of HIV acquisition associated with use of hormonal contraception.[28] While data for implants is limited, data for all hormonal contraceptive methods are largely reassuring, with the exception of depot medroxyprogesterone acetate (DMPA), a commonly used POI. While confounding remains an important consideration when assessing the data on DMPA and risk of HIV acquisition, with only observational data available, the updated meta-analysis from 2016 suggests a possible stronger and consistent signal of an increased risk across the summarized studies. If the association observed in these pooled studies is causal, the magnitude is estimated at a hazards ratio (HR) of 1.4 (95% confidence interval [CI], 1.23 to 1.59).[28]

These issues ares of considerable public health importance globally, and represent a significant challenge for women, health care providers, program managers, and policy makers. This dilemma is most pressing in sub-Saharan Africa, where both rates of HIV acquisition and maternal mortality are the highest. In the absence of definitive studies, we sought to explore the potential impact of changing family programs and policy in response to the possible increased risk of HIV acquisition associated with POI use. Specifically, we wanted to understand how the overall balance between maternal mortality and HIV acquisition would shift if contraception policies resulted in the removal of POIs from countries' method mix. In the absence of definitive causality data, and the competing demands placed on reproductive health programs, decision analysis can provide guidance in weighing the associated risks and benefits in differing contexts. We sought to build on previous work by incorporating updated estimates for the risk of HIV acquisition with POI use and for maternal mortality.[29–31] Our model considers an expanded range of African countries and accounts for variation in HIV incidence, availability of alternative forms of contraception, access to safe abortion, and average life expectancy in each setting.

METHODS

We designed a decision-analytic model to compare the use the of POIs and their competing risks of maternal mortality and HIV acquisition on life expectancy, or life-years, for women in 9 African countries (Burkina Faso, Chad, Democratic Republic

FIGURE. Decision Analysis Model



Abbreviations: ARVs, antiretrovirals; COCs, combined oral contraceptives; IUD, intrauterine device; POI, progestin-only injectable.

All branches are followed to the same outcome of life expectancy; truncated here for clarity. Red triangles represent terminal nodes while green circles represent decision nodes.

When calculating the number of HIV cases averted if no POIs were available, we considered 2 scenarios for women currently using POIs: (1) they all switch to no method, and (2) they switch to another reversible modern method (COCs, an IUD, or an implant).

of the Congo, Kenya, Senegal, South Africa, Malawi, Tanzania, and Uganda). Decision analysis allows a stepwise comparison of probabilities and outcomes associated with differing policies.[32–34]

For the purposes of this analysis, we assumed that POIs were associated with an increased risk of HIV acquisition. We used the reported magnitude of association of 1.4 from the pooled meta-analysis as our base estimate.[28] HIV incidence, access to antiretroviral therapy (ART), maternal mortality, and contraceptive prevalence vary widely within Africa.[6,8,35,36] We therefore selected 9 African countries across distinct subregions and specifically included South Africa, a country where previous modeling has demonstrated that the balance between benefit and harm is most nuanced.[29,30] The population of focus was women of reproductive age in these countries, who did not have HIV and who were not currently planning a pregnancy.

We included 9 African countries across distinct subregions in the model.

The model begins by comparing a scenario where POIs are available (i.e., current policy) with a scenario where POIs have been eliminated (Figure). POIs include both DMPA and norethisterone enanthate (NET-EN). The model focuses on use of modern, reversible methods; it does not consider use of permanent methods. In the model, a woman may choose to use (1) nonhormonal contraception (copper IUD), (2) hormonal contraception (POIs, implant, or combined oral contraceptives [COCs]), or (3) no method (including traditional methods).

We estimated the impact progestin-only injectables have on life-years by calculating the difference between the number of years expected in the absence of POI use compared with what is observed with current POI use.

While consistent condom usage is known to decrease HIV transmission, reported use remains low.[10] Our baseline assumption was that condom usage was the same between groups. All pathways are followed over 1 year. Our primary outcome was life-years. We estimated the impact POIs have on life-years by calculating the difference between the number of years we would expect in the absence of POI use compared with what is observed with current POI use. We assumed an average maternal age of 25 at the time of birth, and followed women to the average life expectancy for each country. Life-years were predominantly impacted in 2 ways: maternal mortality and HIV acquisition. Maternal deaths were assumed to occur at the beginning of the model sequence. A woman dying in childbirth would thus not contribute any life-years. HIV acquisition reduced life-years as well. Evidence supports that with ART, even in low-resource settings, life expectancy is greatly improved.[37,38] Based on these data, we assumed that for women diagnosed with HIV, access to ART would lead to a 25% reduction in life expectancy compared with a woman from the same country without HIV.[38] For a woman diagnosed with HIV and unable to receive ART, the model assumes that her life expectancy would be reduced by 75%. Secondary outcomes included maternal mortality and new cases of HIV annually (both maternal and neonatal). A standard discount rate of 3% was applied to life expectancy calculations to adjust for inflation.[39]

The model was evaluated with both univariate and multivariate sensitivity analyses to explore how changes in parameters could affect the observed results.

We searched the literature for probabilities for each model variable and data specific to sexually active women of reproductive age (15–49 years) in each country (Table 1). Incidence of HIV by country and country-level probabilities of obtaining ART were obtained from the Joint United Nations Programme on HIV/AIDS (UNAIDS).[36] Use of ART among women with HIV was assumed to decrease maternal-to-child transmission of HIV from 25% to 2%.[40]

Data on contraceptive prevalence and distribution of methods used were obtained for each country from the United Nations.[42] Data on typical-use contraceptive failure rates were obtained from an analysis of Demographic Health Survey data.[9] We relied on WHO estimates for maternal mortality rates for both live births and induced abortions.[6] The probability of a pregnancy ending in induced abortion was obtained for each country from Sedgh and colleagues.[12,13]

Average life expectancy by country was obtained from the United Nations.[41] We assumed that POIs are associated with an increased risk of HIV acquisition, and used the summary odds ratio from the published meta-analysis as our baseline estimate (HR 1.4, 95% CI, 1.23 to 1.54).[28] We calculated the number of cases of HIV averted as the total number of new cases of HIV (maternal and neonatal) that would be expected in each country both with and without POI use. When calculating expected cases without POI use, we considered 2 scenarios: (1) all women currently using POIs switched to no method, and (2) all women currently using POIs switched to another reversible modern contraceptive method, either COCs, an IUD, or an implant. Cases of HIV averted were compared with the difference in maternal deaths we would expect both with POI use and without. In order to assess the impact on mortality, we used the outcome value of "life-years" and calculated it across both scenarios.

The robustness of the model was evaluated with both univariate and multivariate sensitivity analyses to explore how changes in parameters such as HIV incidence, maternal mortality, and contraceptive prevalence could affect the observed

TABLE 1. Model Inputs

Variable	All Regions								
Increase in HIV acquisition with POI use[28]	40%								
Average maternal age at time of birth	25 years								
Reduction in life expectancy for women with HIV on ART[38]	25%								
Reduction in life expectancy for women with HIV not on ART[38]	75%								
Probability of maternal-to-child transmission of HIV if ARVs used in labor[40]	2%								
Probability of maternal-to-child transmission of HIV if ARVs not used in labor[40]	25%								
Standard discount rate[a,39]	3%								
	Regional Inputs								
	Central Africa		**Eastern Africa**			**Southern Africa**		**Western Africa**	
	Chad	**DRC**	**Kenya**	**Tanzania**	**Uganda**	**Malawi**	**South Africa**	**Burkina Faso**	**Senegal**
Life expectancy (years)[41]	51.5	58.7	61.6	65.0	58.5	62.7	57.2	58.2	66.4
HIV[36]									
HIV incidence	.001	.0003	.003	.002	.005	.004	.015	.0005	.0001
Probability of ARVs in labor	.46	.67	.74	.86	.97	.79	.99	.89	.36
Probability of accessing ARVs	.36	.33	.59	.57	.57	.61	.48	.54	.40
Contraceptive use[8,9]									
POIs	.09	.012	.14	.087	.14	.32	.28	.061	.052
COCs	.005	.007	.07	.06	.03	.02	.05	.02	.041
Implant	.00	.007	.016	.005	.025	.09	.00	.08	.012
IUD	.00	.002	.023	.002	.005	.01	.01	.001	.006
Sterilization	.001	.007	.041	.041	.027	.10	.14	.002	.002
Unmet need for contraception[b,8]	.22	.28	.29	.26	.35	.38	.13	.25	.31
Maternal mortality[6]									
Live birth[c]	856	693	510	546[d]	343	634	138	371	315
Unsafe abortion[d,e]	80	80	100	100	100	40	40	80	80
Pregnancy outcomes (per 100 women)[13]									
Live birth	.77	.77	.76	.76	.76	.66	.66	.78	.78
Induced abortion	.13	.13	.14	.14	.14	.24	.24	.12	.12
Spontaneous abortion	.09	.09	.09	.09	.09	.09	.09	.09	.09
Ectopic pregnancy	.01	.01	.01	.01	.01	.01	.01	.01	.01

Abbreviations: ART, antiretroviral therapy; ARVs, antiretrovirals; COC, combined oral contraceptive; DRC, Democratic Republic of the Congo; IUD, intrauterine device; POI, progestin-only injectable.

[a] The standard discount rate is routinely used in decision analysis to account for the fact that goods (dollars, health) are not as valuable in the future as they are in the present. Anywhere between 1.5% and 5% is considered a reasonable rate to discount health outcomes.[37]

[b] The number of women of reproductive age who are married or living with a partner who are fecund, are not using contraception, and report that they do not want any more children or wish to delay their next pregnancy, divided by the number of women of reproductive age who are married or living with a partner.

[c] 2015 WHO estimates of maternal mortality ratio (per 100,000 live births).

[d] Country-level data were not available and so regional estimates were used.

[e] 2008 WHO unsafe abortion rates (per 1,000 women ages 15–44 years).

results. Every variable was investigated for a threshold value. A threshold value marks the point at which a change in a variable's value would affect the model's conclusion. We ranged each variable from 50% to 200% of the baseline estimate to assess how uncertainty in the estimates would affect our model's conclusions. Two-way sensitivity analysis was performed on all variables with threshold values and other key variables, such as the efficacy of contraceptive methods and availability of IUDs or implants. We performed a Monte Carlo simulation using 1,000 trials to evaluate how simultaneous multivariable changes would affect outcomes. The Monte Carlo simulation enabled variation of all probability estimates simultaneously by sampling distributions around the baseline estimate.

Averting new HIV cases through the removal of progestin-only injectables would result in increased maternal deaths in all countries included in the model.

Ethics Approval

As a decision analysis using publicly available information, this project was exempt from review by an Institutional Review Board.

RESULTS

Replacement of POIs With No Method Use

Discontinuation of progestin-only injectables without replacement with an equally effective reversible method would result in decreaed life-years.

In the model, discontinuation of POIs without replacement with an equally effective reversible contraceptive method would result in decreased life-years in each country due to a significant increase in maternal deaths from unintended pregnancy. On average, we estimate that 9,000 life-years per 100,000 women would be lost across all countries. While the policy change would result in the prevention of some new cases of maternal HIV in the model, the life-years gained from this are mitigated due to the marked increase in neonatal HIV cases and maternal mortality with associated life-years lost (Table 2). The increased number of neonatal HIV cases and increased maternal mortality are the result of increases in births among women with HIV infection since they are no longer using POIs and thus are lacking contraceptive protection. This analysis takes into account the probability of provision of ARVs during labor (which can reduce mother-to-child transmission of HIV to the newborn).

Within individual countries, however, large variations are observed. For example, the number of incident HIV infections prevented if POIs were removed from the national formulary ranged from 1 per 100,000 women in Burkina Faso and Senegal to 30 per 100,000 in Uganda (Table 2). However, this action would also be accompanied by more maternal deaths (177 and 157 per 100,000 women in Burkina Faso and Senegal, respectively, and 210 per 100,000 in Uganda) and overall decreases in life expectancy in both countries. Averting new cases of HIV through the removal of POIs would result in increased maternal deaths in all countries; this varied from 146 additional maternal deaths in South Africa to 391 in Chad. This finding persisted across all values of maternal mortality, HIV incidence, and contraceptive failure rates and ranged from baseline to twice the initial estimate. In South Africa, the HIV incidence rate would need to increase to more than .018, or the failure rate of POIs would need to exceed 29.4%, for POI use to not be associated with increased life-years.

Replacement of POIs With the IUD or Implant and Sensitivity Analysis

We then considered the effect of replacing POI use with an IUD or implant. Switching from POIs to an IUD or implant would decrease new HIV cases while maintaining or improving life expectancy. However, these findings assume that nearly all women would transition from a POI to an IUD or implant in order for the removal of POIs from the method mix to result in increased life-years. The threshold value of the percentage of women who would need to switch to an IUD or implant for the removal of POIs to result in such an increase varied by country (Table 3). In South Africa, a country with high HIV incidence and relatively low maternal mortality, the lowest threshold value was observed: at least 15.2% of women would need to transition from POIs to an IUD or implant in order for the removal of POIs to result in increased life-years. A very different situation emerged in Chad, where HIV incidence and access to ART and contraception are all comparatively low, yet maternal mortality is high: 96.9% of women currently using POIs would need to transition to an IUD or implant in order for the removal of POIs to result in an increase in life-years (Table 3).

Contraceptive effectiveness rates are thought to vary internationally due to imperfect use and method discontinuation.[43] We closely examined contraceptive failure rates in our model. Table 3 shows the threshold values for the contraceptive failure rate, or pregnancy rate, of POIs by country. In all countries, except South Africa, the failure rate with POIs would need to be between 78% to 85% for the removal of POIs to be associated with an increase in life-years. In South Africa, the

TABLE 2. Comparison of Baseline Scenario of Current POI Use With the Scenario of Eliminating POIs From the Market and All POI Users Switching to No Method (per 100,000 Women)

	Baseline	Remove POIs	Difference
CENTRAL AFRICA			
Chad			
Change in life-years			−9000 life-years lost
New HIV cases (total)	171	155	−16 HIV cases
New maternal HIV cases	161	134	−27 HIV cases
New neonatal HIV cases	10	21	+11 HIV cases
Maternal deaths	363	755	+391 maternal deaths
Democratic Republic of the Congo			
Change in life-years			−6600 life-years lost
New HIV cases (total)	422	409	−13 HIV cases
New maternal HIV cases	390	342	−48 HIV cases
New neonatal HIV cases	32	67	+35 HIV cases
Maternal deaths	190	500	+310 maternal deaths
EASTERN AFRICA			
Kenya			
Change in life-years			−6600 life-years lost
New HIV cases (total)	423	409	−14 HIV cases
New maternal HIV cases	398	349	−49 HIV cases
New neonatal HIV cases	25	60	+35 HIV cases
Maternal deaths	190	551	+341 maternal deaths
Tanzania			
Change in life-years			−7000 life-years lost
New HIV cases (total)	267	259	−8 HIV cases
New maternal HIV cases	248	217	−31 HIV cases
New neonatal HIV cases	19	42	+23 HIV cases
Maternal deaths	201	406	+210 maternal deaths
Uganda			
Change in life-years			−5000 life-years lost
New HIV cases (total)	622	592	−30 HIV cases
New maternal HIV cases	581	509	−72 HIV cases
New neonatal HIV cases	41	83	+ 42 HIV cases
Maternal deaths	196	406	+210 maternal deaths
SOUTHERN AFRICA			
Malawi			
Change in life-years			−7500 life-years lost
New HIV cases (total)	489	473	−16 HIV cases
New maternal HIV cases	456	400	−56 HIV cases

Continued

TABLE 2. Continued

	Baseline	Remove POIs	Difference
New neonatal HIV cases	33	73	+40 HIV cases
Maternal deaths	252	565	+313 maternal deaths
South Africa			
Change in life-years			−1000 life-years lost
New HIV cases (total)	1774	1771	−3 HIV cases
New maternal HIV cases	1624	1507	−117 HIV cases
New neonatal HIV cases	150	264	+114 HIV cases
Maternal deaths	186	332	+146 maternal deaths
WESTERN AFRICA			
Burkina Faso			
Change in life-year			−4700 life-years lost
New HIV cases (total)	47	46	−1 HIV case
New maternal HIV cases	43	38	−5 HIV cases
New neonatal HIV cases	4	8	+ 4 HIV cases
Maternal deaths	172	349	+177 maternal deaths
Senegal			
Change in life-years			−4500 life-years lost
New HIV cases (total)	13	12	−1 HIV case
New maternal HIV cases	12	10	−2 HIV cases
New neonatal HIV cases	1	2	+1 HIV case
Maternal deaths	147	304	+157 maternal deaths

Abbreviation: POI, progestin-only injectable.

TABLE 3. Sensitivity Analysis Results: At What Threshold Value[a] Would Removal of POIs Result in an Increase in Life-Years?

	Central Africa		Eastern Africa			Southern Africa		Western Africa	
Variable	Chad	DRC	Kenya	Tanzania	Uganda	Malawi	South Africa	Burkina Faso	Senegal
POI contraceptive failure rate	82.8%	78.7%	79.3%	81.4%	81.1%	81.0%	14.4%	84.2%	84.7%
% of women switching to an equally effective method[b]	96.9%	92.8%	93.5%	96.1%	95.4%	94.9%	15.2%	99.6%	100.0%
Maternal mortality ratio	–[c]	–[c]	–[c]	–[c]	–[c]	–[c]	−23%	–[c]	–[c]

Abbreviation: DRC, Democratic Republic of the Congo.

[a] A threshold value indicates the value a variable would need to reach or exceed for removal of POIs to result in increased life-years. For example, in South Africa the maternal mortality ratio would need to decrease by 23% for the removal of POIs to be associated with increased life-years, assuming all other variables remain the same.

[b] Intrauterine device or implant.

[c] No threshold value exists; across all values of the maternal mortality ratio, removal of POIs results in loss of life-years.

threshold value for contraceptive failure was much lower, at 14.4%.

We performed 2-way sensitivity analyses on probability of method failure with each contraceptive and HIV incidence, as well as probability of switching methods. In all countries, except South Africa, contraceptive failure rates with POIs would need to exceed 39% and more than half of women would have to switch to another method for removal of POIs to demonstrate an increase in total life-years. In South Africa, contraceptive failure rates with POIs would need to exceed 18%, and 45% of women would have to switch to another method, for the removal of POIs to yield an increase in life-years.

In Chad, Kenya, and Uganda, the removal of POIs decreased life-years even if we assumed a 3% incidence of HIV annually and a 40% contraceptive failure rate of POIs. In South Africa, a country where safe abortion is accessible, use of modern contraceptives is relatively high, and access to ART is widespread, a lower threshold is identified: if the failure rate with POIs exceeds 29%, at the current HIV incidence of 1.5% annually, the removal of POIs would increase life-expectancy.

Monte Carlo simulations, which sample the distribution around each input of the model allowing for simultaneous consideration of uncertainty, were performed for each country. These analyses revealed our results to be robust. In every country, except for South Africa, the use of POIs was associated with increased life-years in nearly all simulations (range 98% to 100%). In South Africa, however, POI use was the preferred strategy in only 81% of trials.

DISCUSSION

Women living in sub-Saharan Africa cope with both high rates of HIV infection and high rates of pregnancy-related maternal death relative to the rest of the world. Based on the most current data on the possible increased risk of HIV acquisition with POIs and on maternal mortality for 9 diverse sub-Saharan African countries, our model suggests that removal of POI contraception from the market without effective and acceptable contraception replacement would have a net negative effect on maternal health, life expectancy, and mortality. In the base case where POIs are removed without substituting POI use with another effective reversible method, we estimate an average loss of 9,000 life-years per 100,000 women across all countries in this region. Even where another equally effective method, such as IUDs or implants are substituted, in countries with the highest maternal mortality rates, an unrealistically large proportion of women would need to transition to the new method in order to reach net neutral mortality thresholds. In countries with high HIV incidence and a relatively low maternal mortality rate, such as South Africa, the balance of benefits and harms is narrower. Our findings support previous research.[29,30,31] Other studies modeling the withdrawal of POIs from the market found a similar increase in maternal mortality, as well as a large increase in unintended pregnancy. These simulations highlight the critical role contraception provision plays in preserving maternal life in Africa and the perils faced by women in this region.

In countries with the highest maternal mortality rates, an unrealistically large proportion of the women would need to transition from progestin-only injectables to another effective method in order to reach net neutral mortality thresholds.

The implications of changes to contraceptive policies and programs surrounding POIs are significant, particularly in sub-Saharan Africa. Most countries with high HIV prevalence offer few contraceptive options for women to choose from; injectables such as DMPA and NET-EN are familiar and widely used methods. With 28.8% of the contraceptive users in sub-Saharan Africa choosing POIs,[42] a rapid removal of POIs from the method mix could lead to the unintended consequence of greatly increasing maternal morbidity and mortality. Even if the contraceptive method mix were to broaden in this region, significant efforts would need to be made to ensure women found the new methods to be both accessible and acceptable.

Rapid removal of progestin-only injectables from the method mix could lead to the unintended consequence of greatly increasing maternal morbidity and moratlity.

The impact of family planning provision has been recognized by policy and program organizations as critical to improving health outcomes worldwide. Moreover, family planning has been identified as a key accelerator to achieving the Sustainable Development Goals including impacting maternal, child, and adolescent health, shaping regional economic development, and progressing human rights and gender equity.[44] These far-reaching implications of family planning mean that implementing new contraceptive policy must take into account the broader picture. Even our analysis, which accounts for maternal mortality, likely underestimates the health and socioeconomic implications of reduced access to widely used contraceptives.

Limitations

We must caution that our analysis uses data from a research area of continued controversy and debate. Our model assumes that the observed association between POI usage and HIV acquisition is real, and our base analysis used the pooled

risk ratio (HR 1.4) from this presumed association. However, this association is not consistently seen in previous studies and more definitive studies are still in process.

Another limitation to our analysis is that we relied on data from the UN to estimate contraceptive use rates and HIV incidence. These data, despite being the best available, are notoriously difficult to estimate as contraceptive use is not routinely collected or reported to national and global monitoring bodies. However, our sensitivity analysis used wide ranges to account for uncertain inputs. Even in the setting of much higher HIV incidence or contraceptive failure, our conclusions remained the same.

Finally, our models also assume condom usage and coital frequency to be identical across all groups. If real-life differences between groups exist, this could impact both the risk of HIV acquisition and the rate of pregnancy.

CONCLUSION

The important link between the HIV epidemic, contraception provision, and maternal health was long established before controversy on POI usage and HIV acquisition emerged. HIV infection remains a large cause of maternal death in sub-Saharan Africa and the availability and usage of barrier methods and dual protection systems remain critical to prevent the spread of HIV.[45] Furthermore, ART and preexposure prophylaxis both play important roles in HIV transmission and acquisition and reproductive health. Our model found that removal of POIs from the market without effective and acceptable contraception replacement would have a net negative effect on maternal health, life expectancy, and mortality, and this persisted under a variety of modeled scenarios. Policy and programmatic decisions about the role of POIs in family planning programs must therefore be made cautiously, with continued recognition of the interconnectedness of these health issues.

Disclaimer: The authors alone are responsible for the views expressed in this publication, and they do not necessarily represent the decisions, policy, or views of the World Health Organization.

Funding: World Health Organization, Department of Reproductive Health and Research.

Competing Interests: None declared.

REFERENCES

1. Joint United Nations Programme on HIV/AIDS (UNAIDS). *Prevention Gap Report*. Geneva: UNAIDS; 2016. http://www.unaids.org/sites/default/files/media_asset/2016-prevention-gap-report_en.pdf. Accessed November 19, 2017.
2. Garnett GP, White PJ, Ward H. Fewer partners or more condoms? Modelling the effectiveness of STI prevention interventions. *Sex Transm Infect*. 2008;84(suppl 2):ii4–ii11. CrossRef. Medline
3. Kharsany ABM, Karim QA. HIV infection and AIDS in sub-Saharan Africa: Current status, challenges and opportunities. *Open AIDS J*. 2016;10(1):34–48. CrossRef. Medline
4. Sgaier SK, Reed JB, Thomas A, Njeuhmeli E. Achieving the HIV prevention impact of voluntary medical male circumcision: lessons and challenges for managing programs. *PLoS Med*. 2014;11(5): e1001641. CrossRef. Medline
5. Cowan FM, Delany-Moretlwe S, Sanders EJ, et al. PrEP implementation research in Africa: what is new? *J Int AIDS Soc*. 2016;19(7(suppl 6)):21101. CrossRef. Medline
6. World Health Organization (WHO), United Nations Children's Fund (UNICEF), United Nations Population Fund (UNFPA), World Bank Group, United Nations Population Division Trends in Maternal Mortality: 1990 to 2015: Estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Geneva: WHO; 2015. http://www.who.int/reproductivehealth/publications/monitoring/maternal-mortality-2015/en/. Accessed November 19, 2017.
7. Singh SD, JE. Adding it up: investing in contraception and maternal and newborn health, 2017. New York: Guttmacher Institute; 2017. https://www.guttmacher.org/sites/default/files/factsheet/adding-it-up-contraception-mnh-2017.pdf. Accessed November 27, 2017.
8. Alkema L, Kantorova V, Menozzi C, Biddlecom A. National, regional, and global rates and trends in contraceptive prevalence and unmet need for family planning between 1990 and 2015: a systematic and comprehensive analysis. *Lancet*. 2013;381(9878):1642–1652. CrossRef. Medline
9. Polis CB, Bradley SEK, Bankole A, Onda T, Croft T, Singh S. Typical-use contraceptive failure rates in 43 countries with Demographic and Health Survey data: summary of a detailed report. *Contraception*. 2016;94(1):11–17. CrossRef. Medline
10. Bayer LL, Edelman AB, Caughey AB, Rodriguez MI. The price of emergency contraception in the United States: what is the cost-effectiveness of ulipristal acetate versus single-dose levonorgestrel? *Contraception*. 2013;87(3):385–390. CrossRef. Medline
11. Sedgh G, Singh S, Hussain R. Intended and unintended pregnancies worldwide in 2012 and recent trends. *Stud Fam Plann*. 2014;45 (3):301–314. CrossRef. Medline
12. Guttmacher Institute. Facts on abortion in Africa. New York City: Guttmacher Institute; 2015. https://www.guttmacher.org/sites/default/files/pdfs/pubs/IB_AWW-Africa.pdf
13. Sedgh G, Bearak J, Singh S, et al. Abortion incidence between 1990 and 2014: global, regional, and subregional levels and trends. *Lancet*. 2016;388(10041):258–267. CrossRef. Medline
14. Hatcher RA. Contraceptive Technology. 19th rev. ed. New York: Ardent Media; 2007.
15. Jacobstein R, Polis CB. Progestin-only contraception: injectables and implants. *Best Pract Res Clin Obstet Gynaecol*. 2014;28(6):795–806. CrossRef. Medline
16. World Health Organization (WHO). Hormonal contraceptive eligibility for women at high risk of HIV: guidance statement. Geneva: WHO; 2017. http://www.who.int/reproductivehealth/publications/family_planning/HC-and-HIV-2017/en/. Accessed November 19, 2017.
17. Baeten JM, Benki S, Chohan V, et al. Hormonal contraceptive use, herpes simplex virus infection, and risk of HIV-1 acquisition among Kenyan women. *AIDS*. 2007;21(13):1771–1777. CrossRef. Medline

18. De Vincenzi I; European Study Group on Heterosexual Transmission of HIV. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. *N Engl J Med.* 1994;331(6):341–346. CrossRef. Medline
19. Feldblum PJ, Lie CC, Weaver MA, et al. Baseline factors associated with incident HIV and STI in four microbicide trials. *Sex Transm Dis.* 2010;37(10):594–601. Medline
20. Kapiga SH, Lyamuya EF, Lwihula GK, Hunter DJ. The incidence of HIV infection among women using family planning methods in Dar es Salaam, Tanzania. *AIDS.* 1998;12(1):75–84. CrossRef. Medline
21. Kiddugavu M, Makumbi F, Wawer MJ, et al; Rakai Project Study Group. Hormonal contraceptive use and HIV-1 infection in a population-based cohort in Rakai, Uganda. *AIDS.* 2003;17(2):233–240. CrossRef. Medline
22. Kleinschmidt I, Rees H, Delany S, et al. Injectable progestin contraceptive use and risk of HIV infection in a South African family planning cohort. *Contraception.* 2007;75(6):461–467. CrossRef. Medline
23. Kumwenda JJ, Makanani B, Taulo F, et al. Natural history and risk factors associated with early and established HIV type 1 infection among reproductive-age women in Malawi. *Clin Infect Dis.* 2008;46(12):1913–1920. CrossRef. Medline
24. Laga M, Manoka A, Kivuvu M, et al. Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women: results from a cohort study. *AIDS.* 1993;7(1):95–102. CrossRef. Medline
25. Reid SE, Dai JY, Wang J, et al. Pregnancy, contraceptive use, and HIV acquisition in HPTN 039: relevance for HIV prevention trials among African women. *J Acquir Immune Defic Syndr.* 2010;53(5):606–613. Medline
26. Curtis KM, Nanda K, Kapp N. Safety of hormonal and intrauterine methods of contraception for women with HIV/AIDS: a systematic review. *AIDS.* 2009;23(suppl 1):S55–S67. CrossRef. Medline
27. World Health Organization (WHO). Medical Eligibility Criteria for Contraceptive Use. Geneva: WHO; 2015. http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/. Accessed November 19, 2017.
28. Polis CB, Curtis KM, Hannaford PC, et al. An updated systematic review of epidemiological evidence on hormonal contraceptive methods and risk of HIV acquisition in women. *AIDS.* 2016;30(17):2665–2683. CrossRef. Medline
29. Butler AR, Smith JA, Polis CB, Gregson S, Stanton D, Hallett TB. Modelling the global competing risks of a potential interaction between injectable hormonal contraception and HIV risk. *AIDS.* 2013;27(1):105–113. CrossRef. Medline
30. Rodriguez MI, Reeves MF, Caughey AB. Evaluating the competing risks of HIV acquisition and maternal mortality in Africa: a decision analysis. *BJOG.* 2012;119(9):1067–1073. CrossRef. Medline
31. Morof D, Steinauer J, Haider S, Liu S, Darney P, Barrett G. Evaluation of the London Measure of Unplanned Pregnancy in a United States Population of Women. *PLoS One.* 2012;7(4):e35381. CrossRef. Medline
32. Detsky AS, Naglie G, Krahn MD, Naimark D, Redelmeier DA. Primer on medical decision analysis: part 1–getting started. *Med Decis Making.* 1997;17(2):123–125. CrossRef. Medline
33. Detsky AS, Naglie G, Krahn MD, Redelmeier DA, Naimark D. Primer on medical decision analysis: part 2–building a tree. *Med Decis Making.* 1997;17(2):126–135. CrossRef. Medline
34. Rodriguez MI, Caughey AB. Cost-effectiveness analyses and their role in improving healthcare strategies. *Curr Opin Obstet Gynecol.* 2013;25(6):487–493. CrossRef. Medline
35. World Health Organization (WHO). Unsafe Abortion: Global and Regional Estimates of the Incidence of Unsafe Abortion and Associated Mortality in 2008. Geneva: WHO; 2008. http://www.who.int/reproductivehealth/publications/unsafe_abortion/9789241501118/en/. Accessed November 19, 2017.
36. AIDSinfo. http://aidsinfo.unaids.org/. Accessed November 2, 2016.
37. Braitstein P, Brinkhof MW, Dabis F, et al; Antiretroviral Therapy in Lower Income Countries (ART-LINC) Collaboration; ART Cohort Collaboration (ART-CC) groups. Mortality of HIV-1-infected patients in the first year of antiretroviral therapy: comparison between low-income and high-income countries. *Lancet.* 2006;367(9513):817–824. CrossRef. Medline
38. Mills EJ, Bakanda C, Birungi J, et al. Life expectancy of persons receiving combination antiretroviral therapy in low-income countries: a cohort analysis from Uganda. *Ann Intern Med.* 2011;155(4):209–216. CrossRef. Medline
39. Simoens S. Health economic assessment: a methodological primer. *Int J Environ Res Public Health.* 2009;6(12):2950–2966. CrossRef. Medline
40. Siegfried N, van der Merwe L, Brocklehurst P, Sint TT. Antiretrovirals for reducing the risk of mother-to-child transmission of HIV infection. *Cochrane Database Syst Rev.* 2011;(7):CD003510. Medline
41. UNdata: A world of information. http://data.un.org/. c2017. Accessed May 17, 2017.
42. United Nations (UN), Department of Economic and Social Affairs, Population Division. Trends in Contraceptive Use Worldwide 2015. New York: UN; 2015. http://www.un.org/en/development/desa/population/publications/pdf/family/trendsContraceptiveUse2015Report.pdf. Accessed November 19, 2017.
43. Ali MM, Cleland JG, Shah IH. Causes and Consequences of Contraceptive Discontinuation: Evidence From 60 Demographic and Health Surveys. Geneva: World Health Organization; 2012. http://www.who.int/reproductivehealth/publications/family_planning/9789241504058/en/. Accessed November 19, 2017.
44. Starbird E, Norton M, Marcus R. Investing in family planning: key to achieving the Sustainable Development Goals. *Glob Health Sci Pract.* 2016;4(2):191–210. CrossRef. Medline
45. Kendall T, Danel I, Cooper D, et al. Eliminating preventable HIV-related maternal mortality in sub-Saharan Africa: what do we need to know? *J Acquir Immune Defic Syndr.* 2014;67(suppl 4):S250–S258. CrossRef. Medline

Peer Reviewed

Received: June 26, 2017; **Accepted:** November 11, 2017

Cite this article as: Isabel Rodriguez M, Gaffield ME, Han L, Caughey AB. Re-evaluating the possible increased risk of HIV acquisition with progestin-only injectables versus maternal mortality and life expectancy in Africa: a decision analysis. Glob Health Sci Pract. 2017;5(4):581-591. https://doi.org/10.9745/GHSP-D-17-00243

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ORIGINAL ARTICLE

Improving Contraceptive Access, Use, and Method Mix by Task Sharing Implanon Insertion to Frontline Health Workers: The Experience of the Integrated Family Health Program in Ethiopia

Yewondwossen Tilahun,[a] Candace Lew,[b] Bekele Belayihun,[a] Kidest Lulu Hagos,[a] Mengistu Asnake[a]

Between 2009 and 2015, 1.2 million women received Implanon implants from trained Health Extension Workers. Of the approximately 7,000 implant service visits made during the first 6 months, 25% were among women who had never used contraception before.

ABSTRACT

In 2009, the Ethiopian Federal Ministry of Health launched an Implanon scale-up program with the goal of improving the availability of long-acting reversible contraceptive (LARC) methods at the community level. The Integrated Family Health Program (IFHP) supported the ministry to train Health Extension Workers (HEWs), a cadre of frontline health workers, on Implanon insertion. Prior to this task-sharing initiative, HEWs were only permitted to provide short-acting contraceptive methods; Implanon insertion services were only available at higher-level health facilities, such as health centers and above. To train HEWs on Implanon insertion, IFHP followed a phase-based approach, which consisted of a learning phase (July to September 2009) that transitioned into a scale-up phase (December 2009 to December 2015). Training began with a series of service delivery-based training of trainers (TOT) sessions for clinical care providers selected from health centers followed by rollout trainings on Implanon insertion for HEWs selected from health posts. Immediately after the Implanon rollout trainings, each trained HEW was provided with consumables and Implanon implants to enable them to initiate the Implanon services at their respective health post. To reinforce knowledge and skills, we conducted mentoring visits and performance review meetings. From July 2009 to September 2015, 98 TOT sessions trained 2,328 clinicians and 320 rollout trainings reached 8,436 HEWs. A total of 1,382,318 women received contraceptive services through any IFHP-supported service delivery point, 1,273,990 of whom received an Implanon implant. The IFHP approach proved to be a successful model for increasing access to contraceptive methods in the community, and the program supported the integration of Implanon services into the existing public health service delivery system.

INTRODUCTION

With an estimated 102 million people,[1] Ethiopia has the second largest population in Africa. The average Ethiopian woman gives birth to 4.6 children in her reproductive years, and an estimated 22.3% of currently married women aged 15 to 49 have an unmet need for family planning.[2] Modern contraceptive prevalence among all women has steadily increased over the last decade—from 9.7% in 2005[3] to 18.7% in 2011[4] and to 35.3% in 2016.[2] Despite this increase, access to and use of long-acting reversible contraceptives (LARCs) remains limited in Ethiopia, with implants and intrauterine devices (IUDs) accounting for just 9.9% of total modern contraceptive use among all women in 2016 (7.9% and 2.0%, respectively).[2]

LARCs offer highly effective protection from unintended pregnancy and contribute significantly to reducing unmet need for family planning.[5] LARCs also prevent maternal and neonatal deaths by allowing women to delay childbearing, space births, avoid unintended pregnancy and abortion, and stop childbearing when they have reached their desired family size.[6] LARCs are characterized by their effectiveness, length of efficacy, reversibility, and rapid and predictable return of fertility after discontinuation of the method. Implanon, a single rod subdermal implant that is inserted under the skin of the upper arm, prevents unintended pregnancy for at least 3 years. When removed, return to fertility is prompt.

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In many countries, the severe shortage of skilled health care workers trained in contraceptive service provision is a key constraint to improving access to family planning services, including LARCs.[7] Highly trained health care workers—typically stationed in health care facilities—often do not reach more marginalized populations, such as the unmarried, the young, the poor, migrants, and rural women. Task sharing, "the process of enabling lay and mid-level health care professionals—such as nurses, midwives, clinical officers and community health workers—to provide clinical tasks and procedures safely that would otherwise be restricted to higher-level cadres,"[8] represents an important option for addressing the shortage and uneven distribution of health care workers.

In 2003, the government of Ethiopia launched the Health Extension Program, its flagship community-level health program, which created a new cadre of Health Extension Workers (HEWs) and shifted provision of certain health services to this all-female cadre. Women interested in becoming HEWs are eligible after they complete high school. They receive 1 year of training on 16 Health Extension Program packages, including family planning counseling and provision of short-acting contraceptive methods, specifically, combined oral contraceptive pills, progestin-only pills, progestin injectables, and condoms. The Ethiopian Federal Ministry of Health (FMOH) deploys 2 HEWs to each health post, the lowest level of the Primary Health Care Unit (PHCU). Each PHCU is composed of a health center and an average of 5 satellite health posts. The health center is responsible for providing administrative and technical support to the health posts.

In 2009, in order to increase the availability of LARCs at the community level, the FMOH asked organizations working in the health sector to pilot a task-sharing program to train HEWs to insert Implanon at health posts. After a successful pilot, the Integrated Family Health Program (IFHP)—implemented by Pathfinder International in partnership with John Snow, Inc. and funded by the United States Agency for International Development (USAID)—supported the FMOH to scale up provision of Implanon by HEWs.

IFHP supports the FMOH to provide integrated family planning and maternal, newborn, and child health services and improve the quality of reproductive health services in public sector health facilities in Amhara; Oromia; the Southern Nations, Nationalities, and People's Region (SNNPR); and Tigray. The program supports and strengthens primary health care services provided by HEWs in their communities as well as services provided at health centers. The program is active in more than 300 *woredas* (districts) in these regions, supporting a total of 1,378 health centers and 6,378 health posts.

In Ethiopia, an estimated 22.3% of currently married women aged 15 to 49 have an unmet need for family planning.

The primary aim of this article is to describe the process by which Implanon insertion services were shifted to HEWs in Ethiopia, so that implementers may use our experience to pursue task sharing of contraceptive service provision in their own settings. By identifying gaps in the program, exploring key programmatic findings, and evaluating results from service delivery data collected during program implementation, as well as a client survey, our aim is also to contribute to the evidence base on how best to increase access to a wide range of contraceptive methods.

METHODS

Program Implementation

Pre-Program Implementation Activities

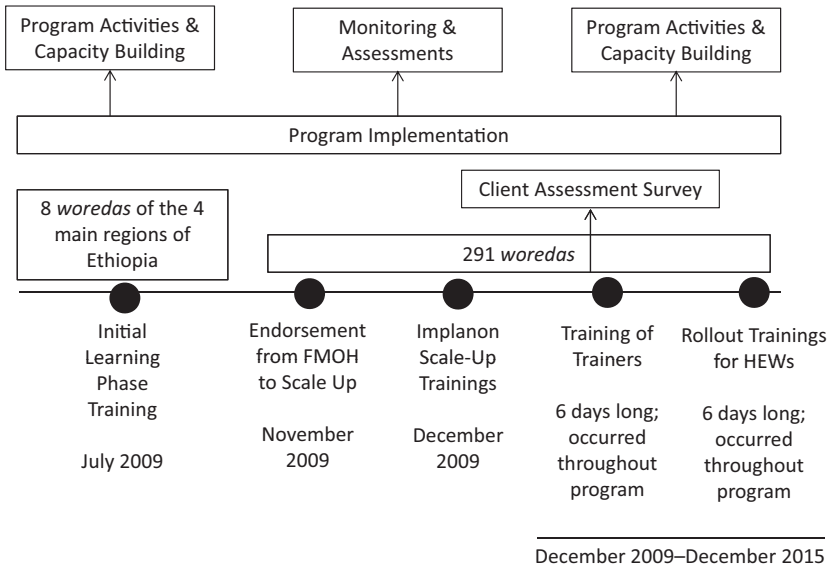
In May 2009, the FMOH convened a consultative meeting with organizations involved in the health sector to discuss their roles in supporting the government's program to increase access to Implanon at the community level through capacity-building trainings, commodity and supplies support, and monitoring and evaluation of the program. At the FMOH's request, IFHP prepared a proposed implementation plan for the Implanon scale-up program, which was eventually validated and approved by the FMOH.

The Initial Learning Phase

In 2009, in order to increase the availability of LARCs at the community level, the FMOH asked organizations working in the health sector to pilot a task-sharing program to train HEWs to insert Implanon at health posts.

The initial learning phase ran from July to September 2009 (Figure). The FMOH, in partnership with IFHP, selected 36 PHCUs from 8 *woredas* located in the 4 IFHP intervention regions of Amhara, Oromia, SNNPR, and Tigray to participate in the learning phase. These PHCUs were composed of 36 health centers and 192 health posts. IFHP and the FMOH organized 4 training-of-trainers (TOT) sessions in July 2009 for 72 clinical care providers—18 to 20 participants in each session—from the participating health centers. The TOT sessions included a total of 6 days of in-class theoretical training, practical sessions simulating Implanon insertion and removal practice on arm models, and, finally, supervised clinical practicums with clients. After successfully completing the session, the newly certified

FIGURE. Implanon Scale-Up Program Components and Implementation



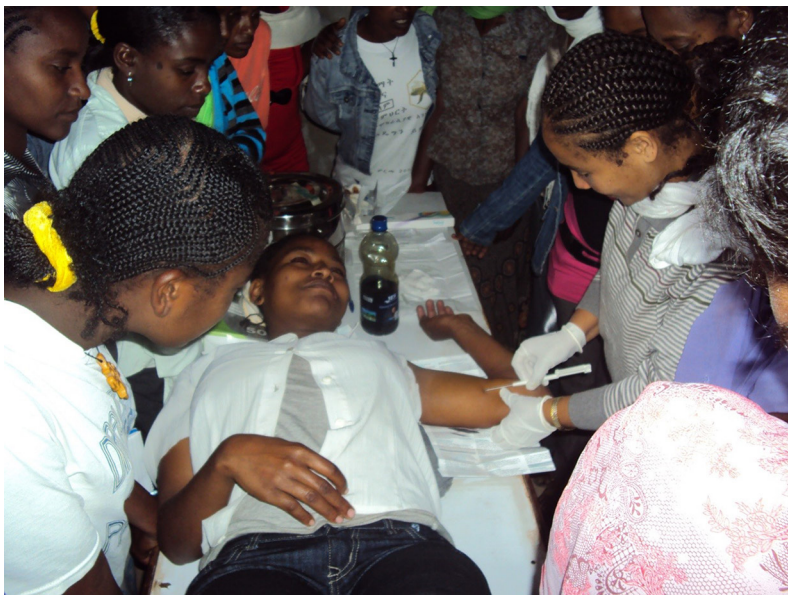
Abbreviations: FMOH, Federal Ministry of Health; HEWs, Health Extension Workers.

Health Extension Workers learn about Implanon during a theoretical training session. © Pathfinder International Ethiopia.

An instructor simulates Implanon insertion on an arm model to Health Extension Workers during a training session. © Pathfinder International Ethiopia.

trainers conducted a series of rollout trainings with HEWs.

During the learning phase, a total of 218 HEWs were trained on contraceptive counseling and Implanon insertion through a series of 9 rollout trainings, with an average of 25 HEWs in each rollout training session. Both the TOT and the rollout trainings were conducted in accordance with the national Implanon curriculum, as instructed by the FMOH. Recognizing the critical importance of comprehensive family planning counseling, this curriculum includes instruction



Under the supervision of an instructor, a Health Extension Worker inserts an Implanon implant in a client during training, as other trainees watch the procedure. © Pathfinder International Ethiopia.

During the learning phase, a total of 218 HEWs were trained on contraceptive counseling and Implanon insertion through a series of 9 rollout trainings, with an average of 25 HEWs in each rollout training session.

on appropriate ways to counsel clients on all contraceptive methods, an essential component of ensuring informed consent and wide method choice, and proper pre-insertion Implanon counseling, which includes discussion of possible side effects and information about how to access Implanon removal services.

HEWs were required to satisfactorily insert a minimum of 5 Implanon implants before they were considered competent. IFHP supported the FMOH by providing post-training commodities and supplies to trainees to allow them to immediately begin offering Implanon services at their respective health posts. To increase awareness and generate demand for the services, 2 weeks prior to the learning phase service days, IFHP deployed a mobile van with a speaker to inform the community about different family planning services, including Implanon, to be offered through the training sessions.

Implanon removal services. A critical element of rights-based contraceptive programming is implant removal services, yet, as data suggest, too often programs fail to adequately plan for equitable access to removals.[9] Because HEWs are not permitted to remove Implanon in Ethiopia, IFHP supported the FMOH to implement the following 3 key strategies to ensure accessibility of removal services: (1) the program provided comprehensive implant removal training to 72 health care providers—doctors and nurses—stationed at health centers during the learning phase and an additional 2,328 health care providers from December 2009 to December 2015; (2) IFHP supported regular "back-up services," wherein doctors and nurses from the health centers traveled to health posts at a prespecified time to offer removal services to clients at the community level; and (3) IFHP sent mobile teams to *woredas* that were outside of IFHP's catchment area to serve women in need of Implanon removal. Prior to 2010, implant removal services in Ethiopia were only available at a limited number of public health facilities and at a few clinics operated by NGOs such as Marie Stopes International. Details about these implant removal strategies will be explained in a separate publication.

From December 2009 to December 2015, IFHP, in partnership with the FMOH, conducted 98 TOT sessions with 2,328 clinical care providers and 320 rollout training sessions with 8,436 HEWs from 291 participating *woredas* within the IFHP program area.

Evaluation of the learning phase. Following the TOT and rollout trainings held during the learning phase, IFHP supported the FMOH to conduct post-training follow-up/mentorship visits to health posts at least twice during the 3-month follow-up period—September to December 2009. During follow-up visits, IFHP used a competency-based checklist to assess the HEWs' skills as well as general service provision at health posts, such as contraceptive counseling, infection prevention practices, and availability of commodities. As part of follow-up, HEWs collected information on the number of implants inserted; occurrence of side effects, defined as menstrual changes during the first 2 years of Implanon use, such as amenorrhea or no bleeding, infrequent or frequent bleeding or spotting, prolonged bleeding, headache, nausea, breast pain, and mood changes; complications; and requests for premature—within 3 to 6 months of insertion—removal of implants.

After 3 months of post-training follow-up, IFHP facilitated performance review meetings in each region with family planning experts; FMOH managers; regional, zonal, and district health officers; NGO representatives; trainers and trained HEWs; and health center heads. During these meetings, participants reviewed client service data, summary reports documenting follow-up and mentorship visits, client testimony on Implanon services provided by HEWs, and participant observations of counseling, insertion procedure skills, and infection prevention techniques during live demonstrations by HEWs.

Implanon Scale-Up Phase

In November 2009, the FMOH evaluated the results of the learning phase and began a nationwide scale-up of the program. During the scale-up phase—December 2009 to December 2015—IFHP, in partnership with the FMOH, conducted 98 TOT sessions with 2,328 clinical care providers and 320 rollout training sessions with 8,436 HEWs from 291 participating *woredas* within the IFHP program area. Both the TOT sessions and the rollout trainings for HEWs were facilitated using the same approach as that of the learning phase with 2 exceptions: (1) the clinical practicum session for HEWs was extended from 2 to 3 days to ensure that HEWs had sufficient time to practice their skills under supervision; and (2) the number of practicum sites and clinical trainers was increased to a minimum of 6 sites and 6 trainers for each training session—up from 3 to 4 during the learning phase—in order to ensure a sufficient level of client demand and HEW competency.

Furthermore, in September 2011, based on findings from a client survey conducted from December 2009 to June 2010 and performance review meetings, IFHP supported the FMOH to introduce a 3-part program support system to increase Implanon service access and coverage, including implant removals, as detailed below.

1. **Increase the amount of post-training consumables and commodities support provided to trainees:** IFHP increased the number of immediate post-training commodity and supply kits provided from 30 to 60 per HEW, in order to meet client demand and allow immediate initiation of services after training.
2. **Provide gap-filling of commodities and consumables:** To support uninterrupted continuation of services after the HEWs' post-training supplies and commodities were exhausted, IFHP filled commodity and consumable gaps during regular Implanon service follow-up and technical support visits through "gap-filling" support.
3. **Promote and support participation of the public health sector in the program:** In all of the 291 program-supported *woredas*, IFHP worked to transfer skills and experience to the districts to promote local ownership of the program through activities such as program planning, organization and facilitation of trainings, post-training follow up and mentoring, facilitation of review meetings, and use of client service data for decision making, thus ensuring sustainability of the program.

Although program activities during the learning phase were focused on the provision of Implanon by HEWs, all clients were provided with family planning counseling and offered the full method mix of contraceptive methods available during the Implanon trainings, and, subsequently received the method of their choice.

Data Collection and Analysis

To assess programmatic performance and understand client needs, we collected and analyzed data from the Implanon scale-up phase, including the number of TOT and rollout trainings, number of providers trained, and number of clients served during the learning and scale-up phases through available service delivery points—health centers, health posts, and back-up family planning service support to health posts.

From December 2009 to June 2010, IFHP also conducted a series of client assessment surveys to identify areas for programmatic improvements and the need for Implanon services at the community level. All clients contacted by IFHP who sought an implant during the TOT sessions, rollout trainings, and clinical practicum period (N=7,254) agreed to participate in the assessment. (In our experience, we have found that clients in the IFHP catchment area are usually willing to provide information if they know that the assessment is to be used for program improvement). We used a structured questionnaire to collect client sociodemographic data, current and/or previous family planning use, and source of information about Implanon services. Health care providers asked clients the survey questions after counseling them and before providing their method of choice. We derived aggregate total service delivery indicators and basic descriptive statistics from 2 data sources: routine quantitative programmatic data and client assessment data.

RESULTS

Availability of Trained Providers

From July 2009 to December 2015, IFHP facilitated 98 TOT sessions with 2,328 clinical health care providers stationed at the health-center level. The program's subsequent 320 rollout trainings trained 8,436 HEWs on Implanon insertion, representing 73.5% of the total 11,476 HEWs in the IFHP area (Table 1). By December 2015, Implanon insertion services were available at 6,079 health posts—96.4% of all the health posts within the IFHP catchment areas (Table 1). The addition of back-up services from health centers to health posts resulted in a greater than anticipated number of acceptors of all methods during these support services.

Use of Implanon Insertion and Removal Services

As shown in Table 2, from July 2009 to December 2015, a total of 82,702 service visits were made for family planning services through TOT sessions and rollouts. During the same period, an additional 1,181,000 women received Implanon insertion services from HEWs at the health-post level with implants supplied through IFHP's post-training and gap-filling commodity interventions. By ensuring sufficient supplies, the IFHP enabled HEWs to immediately initiate the service after training and thus continue to exercise their Implanon insertion skills. This support also increased use and coverage of family planning in the community.

Over 6 years, nearly 83,000 service visits were made for family planning services through TOT sessions and rollouts, and an additional 1.2 million women received Implanon from HEWs at health posts.

A further 89,177 service visits were provided through the back-up resource (Table 2). Out of which 28,991 (32.5%) service visits were for Implanon insertion, another 39,139 (43.9%) received other contraceptive methods. Nearly 20% (17,302) of back-up clients received Implanon removal services and about 4% (3,745) received removal of other LARC methods. Anecdotal evidence from health

TABLE 1. Number of HEWs Trained on Implanon Insertion and Number of Health Posts With Trained HEWs,[a] by Region, July 2009 to December 2015

	HEWs			Health Posts		
Name of Region	Total No. of HEWs	No. of Trained HEWs	% of HEWs Trained	Total No. of Health Posts	No. of Health Posts With Trained HEWs	% of Health Posts With Trained HEWs
Amhara	3,885	2,204	56.7	1,891	1,891	100.0
Oromia	3,861	2,997	77.6	2,553	2,501	98.0
SNNPR	2,934	2,536	86.4	1,467	1,310	89.3
Tigray	796	699	87.8	398	377	94.7
Total	**11,476**	**8,436**	**73.5**	**6,309**	**6,079**	**96.4**

Abbreviations: HEW, health extension worker; SNNPR, Southern Nations, Nationalities, and People's Region.
[a] Includes health posts with at least 1 HEW trained on Implanon insertion.

care provider observations, suggests that the back-up strategy likely positively affected client satisfaction, as they no longer needed to travel long distances to health centers to receive their method of choice.

By strengthening health-center level static implant removal services, 20,498 implant removals—70.2% Implanon, 12% Jadelle, and 16.9% Norplant—were provided to clients between September 2011 and August 2012. Finally, a total of 8,931 women living outside the IFHP catchment area had their implants removed through support provided to other *woredas*. Throughout the data collection period, IFHP supported 53,196 service visits made for implant removal services (Table 2).

Method Mix

As mentioned earlier, by December 2015, 6,079 (96.4%) IFHP-supported health posts had added Implanon insertion services by HEWs to their existing family planning method mix (Table 1). In addition, regularly scheduled back-up services from health centers to health posts were designed to provide community access to implant removal services. Table 2 illustrates that in addition to removals, these back-up services provided a significant number of clients with both long- and short-acting methods, demonstrating access to and acceptance of a wider method mix than previously available at the community level. These back-up services provided contraceptive methods for an additional 4,321 Jadelle service visits, 2,102 IUD service visits, 25,231 Depo-Provera service visits, 4,950 oral contraceptive pill service visits, and 2,535 condom service visits (Table 2).

In addition to removals, back-up services provided a significant number of clients with both long- and short-acting methods, demonstrating access to and acceptance of a wider method mix than previously available at the community level.

Client Assessment

As shown in Table 3, of the 7,254 clients seeking an implant from December 2009 to June 2010, 25.3% (1,837) were new family planning acceptors who had never used contraception before. An additional 63.6% of clients switched from Depo-Provera and 6.3% switched from pills, illustrating shifts from short- to long-acting methods. The majority (86.4%) of respondents received Implanon insertion, and the remaining clients chose either the Jadelle insertion (12.7%) or other family planning methods (0.9%) (Table 3).

The client assessment survey also revealed areas for programmatic improvement. First, effective demand creation resulted in a significant need for LARC services at the community level that was not being met by HEWs. Second, a shortage of resources limited the capacity of health posts to meet client needs—even for other family planning services routinely provided by the HEWs at the health-post level. Third, demand for implant removal services at the community level increased. Last, we saw a greater demand for a range of family planning services not normally provided at the health-post level by HEWs, such as IUDs and Jadelle insertion and removals.

DISCUSSION

In low- and middle-income countries where resource shortages and health-system weaknesses complicate service delivery, community health workers can play a critical role in expanding access to contraception. Through task sharing, the contraceptive method mix available at the community level can be increased; however, task sharing

TABLE 2. Contraceptive Services Provided to Clients by HEWs During and After Training, and by Nurses and Doctors through Back-Up and Outreach Services[a]

	No. (%) of Service Visits Served by HEWs			No. (%) of Service Visits Served by Other Health Care Providers			
	During Training Sessions[b]	With Post-Training Supplies Provided to HEWs[c]	With Gap-Filling Supply Support to Health Posts After Post-Training Supplies Exhausted[c]	During Back-Up Services[d]	During Implant Removal Service Support at Health Centers[e]	During Outreach Implant Removal Service Support[f]	Total No. (%) of Service Visits
	Jul 2009 to Dec 2015	Jul 2009 to Dec 2015	Sep 2011 to Dec 2015	Sep 2011 to Dec 2015	Sep 2011 to Aug 2012	Sep 2011 to Aug 2012	Jul 2009 to Dec 2015
Total service visits	**82,702 (100.0)**	**446,010**	**735,000**	**89,177 (100.0)**	**20,498 (100.0)**	**8,931 (100.0)**	**1,382,318 (100.0)**
LARC insertions	**67,662 (81.8)**	**446,010**	**735,000**	**35,414 (39.7)**			**1284086 (92.9)**
Implanon insertions	63,989 (77.4)	446,010	735,000	28,991 (32.5)			1,273,990 (92.2)
Jadelle insertions	3,590 (4.3)			4,321 (4.8)			7,911 (0.6)
IUD insertions	83 (0.1)			2,102 (2.4)			2,185 (0.2)
Short-acting methods	**12,320 (14.9)**			**32,716 (36.7)**			**45036 (3.3)**
Depo-Provera injectables	10,214 (12.4)			25,231 (28.3)			35,445 (2.6)
Oral contraceptive pills[g]	2,106 (2.5)			4,950 (5.6)			7,056 (0.5)
Condoms				2,535 (2.8)			2,535 (0.2)
LARC removals	**2,720 (3.3)**			**21,047 (23.6)**	**20,498 (100.0)**	**8,931 (100.0)**	**53,196 (3.8)**
Implanon removals	1,163 (1.4)			17,302 (19.4)	14,389 (70.2)	4,321 (48.4)	37,175 (2.7)
Jadelle removals	191 (0.2)			1,461 (1.6)	2,637 (12.9)	686 (7.7)	4,975 (0.4)
IUD removals	23 (0.03)			75 (0.1)			98 (0.01)
Norplant removals	1,343 (1.6)			2,209 (2.5)	3,472 (16.9)	3,924 (43.9)	10,948 (0.8)

Abbreviations: HEW, Health Extension Worker; IFHP, Integrated Family Health Program; IUD, intrauterine device; LARC, long-acting reversible contraceptive; TOT, training of trainers.

[a] Data for the different program activities in the table were collected at different points during the program period; this table does not include insertions performed by doctors and nurses at the health center level.

[b] Includes both TOT and rollout training sessions.

[c] Post-training supplies were provided to HEWs to allow them to provide immediate services and gap-filling supply support was provided to health posts after post-training supplies were exhausted. HEWs also provided other contraceptive services to clients post-training, but these data are not included in this table.

[d] IFHP supported regular back-up services, whereby doctors and nurses from health centers traveled to health posts to offer removal services for LARC clients.

[e] In addition to doctors and nurses traveling from the health centers to health posts to offer removal services, the doctors and nurses also provided removal services at the health centers.

[f] IFHP mobile teams traveled to *woredas* outside the project catchment area to serve women in need of implant removals.

[g] Includes both combined oral contraceptive pills and progestin-only pills.

is often challenging to execute.[10] Several programs have succeeded at improving access to contraception at the community level by engaging community health workers to deliver a range of methods, most notably injectables.[11]

This practice has been recognized as a USAID high-impact practice.[12] Our experience contributes to this evidence by demonstrating the successful use of task sharing to increase access to LARCs at the community level in Ethiopia.

TABLE 3. Sociodemographic Characteristics of Implant Clients, December 2009 to June 2010 (N=7,254)[a]

Characteristics	Frequency	Percentage
Age, years		
<24	1582	21.9
25–29	2254	31.2
30–34	1850	25.6
35–39	1097	15.2
≥40	448	6.2
Place of residence		
Urban	531	7.3
Rural	6720	92.7
Educational status		
Illiterate	6442	88.8
Literate	812	11.2
Parity		
1	712	10.2
2	999	14.4
3–6	4108	59
≥7	1138	16.4
Previous use of family planning		
New user (no previous method)	1837	25.3
Oral contraceptive pills	454	6.3
Depo-Provera injectables	4616	63.6
Other method	344	4.8
Current method		
Implanon implants	6221	86.4
Jadelle implants	916	12.7
Other method	61	0.9
Length of use, years		
<1	2959	57.5
1–3	1668	32.4
4–5	389	7.6
≥6	133	2.6
Source of information about implant		
Health Extension Worker	4786	71.1
Health worker	457	6.8
Volunteer community health worker	884	13.1
Other	609	9.1

[a] Totals for each variable do not always equal 7,254 because some respondents did not answer all questions. Percentages are calculated based on the total number of respondents for each individual question.

1 in 4 Implanon acceptors in our client assessment survey was a new family planning acceptor.

In 2013, the IFHP endline survey showed that the modern CPR had substantially increased from baseline (27.4% in 2008 to 2009) to endline (39.1% in 2013) in the 4 program regions.

We discovered a larger-than-anticipated unmet need for Implanon in our program areas. One in 4 Implanon acceptors in our client assessment survey was a new family planning acceptor. This is in line with the findings of a 2013 survey, which discovered that 23.1% of Implanon acceptors during training events in the 4 IFHP regions were new family planning users.[13] This evidence suggests that when implant insertion services are brought closer to the community, those with a latent need are able to seek out and demand these services.

Moreover, by training providers at the health-center level to remove implants, initiating back-up services, and supporting non-IFHP affiliated *woredas* with removals, the program supported the FMOH to increase access to removal services for women in settings that prohibit lower-level health workers from performing the service. As shown in Table 2, IFHP saw a substantial number of women seeking LARC removal services at both the health centers (38.5% of total removals) and back-up services at health posts (32.5% of total removals).

The FMOH's ability to scale the program is also noteworthy. Implementers often face substantial challenges when scaling up a successful pilot program. As shown in Table 2, IFHP achieved considerable scale through the Implanon scale-up program. From July 2009 to December 2015, a total of 1,273,990 Implanons were inserted in the IFHP areas.

Further illustrating scale, the IFHP endline survey—conducted in 2013—showed that the modern contraceptive prevalence rate (CPR) had substantially increased from baseline (27.4% in 2008 to 2009) to endline (39.1% in 2013) in the 4 program regions.[14] The baseline survey indicated implant prevalence was at 0.7%; by 2013, this prevalence had increased to 6.3%, due in large part to the Implanon scale-up program.[13] Moreover, the Ethiopia 2015 contraceptive commodity and service assessment showed that implant availability among

HEWs and health posts exceeded 70%, mostly due to availability of Implanon.[15] By 2013, almost 75% of all health posts provided Implanon insertion services. This report also showed that across all methods and cadres, 20% of total couple-years of protection came from HEW and health post implant insertions.[14]

From the beginning of the Implanon scale-up initiative, the FMOH owned the Implanon scale-up program and IFHP provided support to launch the program and increase service utilization at the community level. This created an enabling environment, which filtered down to the district level and facilitated program ownership and sustainability. The FMOH led the program design and implementation processes, and held a consultative meeting with regional- and district-level health office experts. Representatives from these levels also actively participated in trainings and conducted post-training follow-up mentoring. The program design allowed the regional health managers to organize and conduct the post-training performance review meetings in their respective *woredas*. Each *woreda* also benefits from having a standing pool of trainers from the public sector, which was organized through the TOT trainings in the Implanon scale-up program. These trainers are able to quickly organize and conduct Implanon trainings. Public-sector ownership is evidenced by the regional health bureaus funding back-up support to health posts—about 60 PHCUs in Oromia and 10 PHCUs in SNNPR have done this so far.

Finally, our experience shows that the TOT and rollout-training approaches appear to have been effective. Almost all the HEWs proved to be competent at Implanon insertion immediately following the skills training. Their skills were further reinforced through mentoring. Providing HEWs with commodities and supplies immediately following the training was an important strategy that made it possible for the immediate and sustained quality provision of implants at the community level.

Limitations

Our study design is subject to several limitations. First, because our study was descriptive in nature, we were unable to determine whether alternative strategies, such as training HEWs on Implanon in a preservice setting, may have achieved the same results as our strategies. Further, the client assessment was conducted only at the beginning of the program. We were unable to repeat the client assessment toward the end of the program, which would have allowed us to determine whether client profiles had changed over time. We would recommend that future studies explore client satisfaction, particularly with regard to which service setting is preferable to clients. Finally, from a programmatic sustainability perspective, despite good engagement with the public sector throughout the Implanon task-sharing initiative, allocation of public-sector resources to the new service has been slow.

CONCLUSION

The Implanon scale-up program in Ethiopia is a successful model of increasing access to LARC methods in the community. Scale up was possible through task sharing of LARC services by training frontline health providers, specifically HEWs, and establishing program support interventions to address identified gaps. The program demonstrated unmet demand for LARCs in the community and showed that access to quality services can be improved with interventions, such as task sharing, regional and local health system support, and a strong commodity supply system.

Acknowledgments: The Integrated Family Health Program is a USAID-funded health program implemented by Pathfinder International and John Snow, Inc. in partnership with the Ethiopian health sector at various levels—the FMOH; the regional health bureaus of Amhara, Oromia, SNNPR and Tigray; and *woreda* health offices, health centers, health posts, and *kebeles* (municipalities). Due acknowledgement is extended to the above institutions. Our deep gratitude also goes to health service providers. We would like to express special heartfelt thanks to USAID for funding this task-shifting program. Finally, we would like to thank Olivia Moseley, Julio Pacca, and Bram Brooks— for their valuable inputs, guidance, support, and encouragement.

Funding: USAID.

Competing Interests: None declared.

REFERENCES

1. The World Bank. World Bank Open Data: Ethiopia. Washington, DC: The World Bank; 2017. http://data.worldbank.org/country/ethiopia. Accessed August 14, 2017.
2. Central Statistical Agency (CSA); ICF. *Ethiopia Demographic and Health Survey 2016: Key Indicators Report.* Addis Ababa, Ethiopia, and Rockville, Maryland: CSA and ICF; 2016. http://www.dhsprogram.com/pubs/pdf/FR328/FR328.pdf. Accessed October 19, 2017.
3. Central Statistical Agency (CSA); ORC Macro. *Ethiopia Demographic and Health Survey 2005.* Addis Ababa, Ethiopia, and Calverton, Maryland: CSA and ORC Macro; 2006. https://www.dhsprogram.com/pubs/pdf/FR179/FR179%5B23June2011%5D.pdf. Accessed October 19, 2017.
4. Central Statistical Agency (CSA); ICF International. *Ethiopia Demographic and Health Survey 2011.* Addis Ababa, Ethiopia, and Calverton, Maryland: CSA and ICF International; 2012. https://dhsprogram.com/pubs/pdf/FR255/FR255.pdf. Accessed October 19, 2017.

5. U.S. Centers for Disease Control and Prevention (CDC). *Effectiveness of Family Planning Methods.* Atlanta, GA: CDC; 2017. https://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/contraceptive_methods_508.pdf. Accessed August 14, 2017.
6. Ahmed S, Li Q, Liu L, Tsui AO. Maternal deaths averted by contraceptive use: an analysis of 172 countries. *Lancet.* 2012;380(9837):111–125. CrossRef. Medline
7. Clifton D. Expanding access to family planning. Washington, DC: Population Reference Bureau; 2010. http://www.prb.org/Publications/Articles/2010/expandfpaccess.aspx. Accessed August 14, 2017.
8. Marie Stopes International (MSI). *Task Sharing: Increasing Access to Family Planning.* London: MSI; 2013. http://fpconference.org/2013/wp-content/uploads/2013/07/Marie-Stopes-International-Task-Sharing-Factsheet.pdf. Accessed October 16, 2017.
9. Christofield M, Lacoste M. Accessible contraceptive implant removal services: an essential element of quality service delivery and scale-up. *Glob Health Sci Pract.* 2016;4(3):366–372. CrossRef. Medline
10. Schaefer L. Task sharing implant insertion by community health workers: not just can it work, but how might it work practically and with impact in the real world. *Glob Health Sci Pract.* 2015;3(3):327–329. CrossRef. Medline
11. Weidert K, Gessessew A, Bell S, Godefay H, Prata N. Community health workers as social marketers of injectable contraceptives: a case study from Ethiopia. *Glob Health Sci Pract.* 2017;5(1):44–56. CrossRef. Medline
12. High-Impact Practices in Family Planning. Community health workers: bringing family planning services to where people live and work. Washington, DC: United States Agency for International Development; 2015. https://www.fphighimpactpractices.org/briefs/community-health-workers/. Accessed October 16, 2017.
13. Asnake M, Henry EG, Tilahun Y, Oliveras E. Addressing unmet need for long-acting family planning in Ethiopia: uptake of single-rod progestogen contraceptive implants (Implanon) and characteristics of users. *Int J Gynaecol Obstet.* 2013;123(suppl 1):e29–e32. CrossRef. Medline
14. Kassie G, David P, Asnake M, Zerihun H, Ali I. *Integrated Family Health Program: Endline Household Survey Summary Report. Pathfinder International Research and Evaluation Working Paper.* Watertown, MA: Pathfinder International; 2015. https://www.pathfinder.org/wp-content/uploads/2016/09/Integrated-Family-Health-Program-Endline-Household-Survey-Summary-Report.pdf. Accessed August 14, 2017.
15. Population Services International (PSI); FPwatch. Ethiopia 2015 contraceptive commodity and service assessment: findings from public and private sector outlets. FPwatch Research Brief. Washington, DC: PSI and FPwatch; 2016. http://www.psi.org/wp-content/uploads/2017/06/FPwatch-Ethiopia-outlet-survey-findings-brief.pdf. Accessed August 14, 2017.

Peer Reviewed

Received: May 29, 2017; **Accepted:** August 29, 2017; **First Published Online:** December 11, 2017

Cite this article as: Tilahun Y, Lew C, Belayihun B, Lulu Hagos K, Asnake M. Improving contraceptive access, use, and method mix by task sharing Implanon insertion to frontline health workers: the experience of the Integrated Family Health Program in Ethiopia. Glob Health Sci Pract. 2017; 5(4):592-602. https://doi.org/10.9745/GHSP-D-17-00215

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ORIGINAL ARTICLE

Equal Opportunity, Equal Work: Increasing Women's Participation in the U.S. President's Malaria Initiative Africa Indoor Residual Spraying Project

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Promotion of gender policies led to increased hiring of women in supervisory roles in a large indoor residual spraying (IRS) program with no meaningful differences in IRS output between men and women spray operators.

ABSTRACT

Background: One of the primary control measures for malaria transmission is indoor residual spraying (IRS). Historically, few women have worked in IRS programs, despite the income-generating potential. Increasing women's roles in IRS requires understanding the barriers to women's participation and implementing measures to address them. The U.S. President's Malaria Initiative (PMI) Africa Indoor Residual Spraying (AIRS) Project is the largest implementer of IRS globally. To address gender inequity in IRS operations, PMI AIRS assessed the barriers to the participation of women and developed and implemented policies to address these barriers.

Methods: The PMI AIRS Project initially identified barriers through a series of informal assessments with key stakeholders. PMI AIRS then implemented a series of gender-guided policies, starting in 2015, in Benin, Ethiopia, Ghana, Mali, Madagascar, Mozambique, Rwanda, Senegal, Zambia, and Zimbabwe. The policies included adapting physical work environments to ensure privacy for women; ensuring the safety of women in the workplace; guaranteeing safety and job security of women during pregnancy; and encouraging qualified women to apply for supervisory positions. The project collected routine programmatic data on staff, spray quality, and spray efficiency; data from 2012 through the end of 2015 were analyzed (up through 1 year after implementation of the gender policies). In addition, PMI AIRS conducted surveys in 2015, 2016, and 2017 before and after the spray campaigns in 4 countries to determine changes in gender norms among spray operators through questions about decision making and agency.

Results: The PMI AIRS Project increased women's employment with the program. Specifically, women's employment increased overall from 23% in 2012 to 29% in 2015, with a 2015 range from 16% (Mali) to 40% (Madagascar). Growth among supervisor roles was even stronger, with the percentage of women in supervisory roles increasing from 17% in 2012 to 46% in 2015, with a 2015 range from 9% (Mali) to 50% (Madagascar). While the data showed that in most countries women sprayed fewer houses per day than men in 2015, the differences were not meaningful, ranging from 0.1 to 1.2 households per day. Gender norms shifted toward more egalitarian views in 2 of the 4 countries with survey data.

Conclusion: Preliminary results suggest the PMI AIRS Project gender policies are increasing the engagement of women in all aspects of spray operations, especially in supervisory roles. Expansion of these policies to all countries implementing IRS and to malaria control implementation more broadly is recommended.

INTRODUCTION

The U.S. President's Malaria Initiative (PMI) Africa Indoor Residual Spraying (AIRS) Project implements indoor residual spraying (IRS), entomological monitoring, or both in 19 African countries. The PMI AIRS Project's goal is to reduce malaria morbidity and mortality through high-quality application of residual insecticides in the sleeping structures of malaria-endemic communities.[1]

In the past, women have had few operational roles in IRS programs. Yet the PMI AIRS country programs offer

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The PMI AIRS Project's IRS programs offer opportunities for paid employment to women in 19 African countries.

economic opportunities through paid positions that have the potential to enhance a woman's role in society. Engaging women in IRS may also increase communities' uptake of IRS, thus decreasing the need for revisits and increasing the efficiency of operations.

Several factors maximize the protective effect of IRS against malaria: susceptibility of mosquitoes to the insecticide, high coverage, and spray quality. High coverage of IRS relies on householders agreeing to have their homes sprayed. If too many individuals refuse, transmission can persist even where the mosquitoes are susceptible to the insecticide. Acceptance rates and factors related to acceptance of IRS vary by geographic region and include level of malaria transmission, sense of civic duty,[2] perception of the effectiveness of IRS to reduce insects,[3] distrust of political motivations,[4] lack of understanding of IRS program objectives, and logistical constraints.[5]

In most African countries, including many sub-Saharan African countries, men traditionally are the authorities and have greater power to make household decisions,[6–8] which may include whether or not to agree to have their home sprayed. However, spray activities occur during the daytime, when many men are out of the home for work. Women are often the ones at home when the IRS teams arrive to spray. It is therefore imperative that women understand and participate fully in the IRS process to ensure IRS programs' success and sustainability.

Entering the formal labor market is a route out of poverty for women and their families.

Although men are frequently seen as decision makers, gender norms also often support women's engagement in community building, health advocacy, and dissemination of knowledge through women's groups or women's roles as community health volunteers.[9,10] Substantial information, education, and communication campaigns are conducted before any IRS activities; women are integral to these campaigns as community mobilizers (some are paid while others are volunteers, depending on the country). Thus, having women on IRS spray teams may garner even more support for the operations from women in the community. Moreover, employing women in these roles provides them the same opportunity as men for paid employment in a community program.

The PMI AIRS Project has developed a set of gender-focused employment strategies in line with USAID's Gender Equality and Female Empowerment policy.

The PMI AIRS Project, with a mandate to promote gender equality and female empowerment at all levels of operations, developed a set of gender-based strategies in line with the U.S. Agency for International Development (USAID) Gender Equality and Female Empowerment policy.[11] The intent was to (1) improve gender equality in employment by improving opportunities for women; (2) improve program outcomes; and (3) secure shared benefits of IRS, including economic benefits, across communities.

This article describes how a large-scale malaria vector control project can mainstream gender equality. We use the definition of *gender equality* given by the Interagency Working Group on Gender[11,12]:

> *the state or condition that affords women and men equal enjoyment of human rights, socially valued goods, opportunities, and resources. Genuine equality means more than parity in numbers or laws on the books; it means expanded freedoms and improved overall quality of life for all people.*

The expected results are improved employment opportunities for women and women's economic and social empowerment. Based on a literature review, the PMI AIRS Project further hypothesized that mainstreaming gender considerations into project operations would increase productivity and acceptance of IRS by more beneficiaries. Equality also was expected to spread the economic benefits of the project to a broader range of community members.

Literature Review: Women in the Workforce

Although women have made great strides in education and employment globally, women are still less likely to hold leadership positions and more likely to live in poverty than men.[13] To bring about long-term, sustained economic growth and healthy communities, governments and private-sector actors must engage both men and women. The recently adopted United Nations Sustainable Development Goals highlight this with Goal 5: Achieve gender equality and empower all women and girls.[14] Entering the labor market and accessing formal employment is a route out of poverty for women and their families. According to the International Labour Organization, women account for 40% of the global workforce, yet their contribution receives little recognition[15] and only half of all women are employed compared with 78% of men.[16] Furthermore, women who work often work in sectors with lower pay, longer hours, and informal working agreements. This means that women make fewer monetary, social, and structural gains than men do. Moreover, nearly a quarter of women do unpaid family work.[8]

In African countries these gaps between women's and men's roles are even wider.[17–19] Social norms still dictate that household chores and child-rearing be predominantly carried out by women.[15] These norms limit women's economic opportunities and ability to participate in the workplace. A greater proportion of women who work in sub-Saharan Africa are limited to work in the informal sector.[7] This situation leads to fewer investments in women's health: given men's greater earning power and control over income, women's health may not be valued as highly as men's health. The McKinsey Global Institute Report *The Power of Parity* confirms this. It found that although the level of gender equality in work in sub-Saharan Africa is comparable to that found in East and Southeast Asia, women in sub-Saharan Africa have the lowest levels of equality in access to essential services, financial services, and leadership roles. When women enter the formal employment sector, however, their contributions can lead to greater, systematic growth for their corporate employers. For example, in Chile, a study found that equalized gender distribution in the workplace increases hospitality, professionalism, worker efficiency, and motivation.[20] Thus, promoting gender equality is an important aspect of business success and productivity improvement.[21–23] Women bring rich and diverse perspectives to the workplace, including management styles which may differ from and be complementary to those of men.[24]

Although the scientific literature has called for a stronger emphasis on involving women in vector control for more than 30 years,[25] these calls have until recently had little impact (Box). Historically, vector control programs have employed men because of the different roles that men and women traditionally fill in communities, with women being in charge of the domestic domain while men work outside the home.[26]

This affects not only women's employment in IRS operations but also the efficacy of IRS operations. That is because as the primary caretakers of the household, women are the first household members that vector control personnel such as IRS spray teams will encounter.[26] However, cultural norms and safety precautions may not permit a woman to allow an unknown adult male to enter the house.[25] This can impede vector control programs, which can miss houses or whole communities during program implementation. Including women in vector control programs may improve the acceptance and uptake of vector control strategies in some settings—thus increasing coverage and success.[26]

BOX. Research in Context

Evidence Available Before This Study

The literature includes scarce evidence on the role of women in vector control. Publications that explicitly examine women's roles in vector control generally look at 2 issues: Some review the household, focusing on women as decision makers for uptake of protective measures for their families. Other publications look at women as volunteers in women's groups that provide community-level support through environmental management or distribution of larval control products. We identified no publications that examined attainment of gender equity in large-scale vector control programs. We searched PubMed, Scopus, and Web of Science in English with the search terms *women*, *vector or mosquito*, *indoor residual spray*, and *employment*.

Implications of the Available Evidence

There is little evidence that gender equity has been achieved within vector control programs. There is also scarce evidence of programs that have developed and evaluated policies focused on enhancing gender equity in vector control.

Added Value of This Study

The role of women in vector control activities, particularly paid vector control activities, is limited. Understanding mechanisms that work to improve women's participation is essential to reduce the gender gap in these activities. The PMI AIRS Project can serve as a model for implementing gender initiatives in vector control programs worldwide.

Evidence suggests that when women are directly involved in all parts of health interventions within their community, acceptance and compliance, and thus impact, increase. Enhancing women's participation in development efforts such as water supply, sanitation, and agriculture has been integral to the success of some vector control programs.[27,28] It is now essential to understand how women's participation in vector control programs affects program outcomes.

Research has shown that integrating women can not only improve business outcomes[20–24] but also improve uptake and outcomes of malaria prevention projects.[29–32] For example, in Thailand, a program that empowered a group of women to create malaria prevention plans and encouraged the use of long-lasting insecticide-treated bed nets resulted in significantly increased levels of malaria prevention behavior. Moreover, the women in the treatment villages felt more empowered to control malaria in addition to the empowerment that came from being a leader in the community and earning an income.[33] These studies demonstrate the importance of considering gender and social norms when designing malaria prevention projects. However, most of these studies examine the role of women in their household-level decision-making abilities or how women engage as volunteers to motivate other community members to carry out malaria

Including women in vector control programs may improve IRS acceptance and uptake in some settings.

In 2015, PMI AIRS developed and implemented strategies to recruit and retain women, including in supervisory positions.

prevention strategies. The literature does not describe well engaging women in malaria prevention and control through the formal employment sector.

In this article, we outline the PMI AIRS Project's strategy to engage women in IRS operations. We present preliminary results of the strategy's impact on the percentage of women PMI AIRS employs and on changing gender norms.

METHODS

PMI AIRS Project Description and Gender Issues

The PMI AIRS Project has programs in 19 African countries: Angola, Benin, Burkina Faso, Burundi, Democratic Republic of the Congo, Ethiopia, Ghana, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Nigeria, Rwanda, Senegal, Tanzania, Zambia, and Zimbabwe. The first PMI AIRS Project contract spanned the years 2011 through 2014. During this time, PMI AIRS implemented spraying in 14 countries, spraying approximately 10 million houses and protecting more than 36 million people.

During its first 3 years, PMI AIRS hired 88,000 seasonal workers. Only 25% were women.

During these initial 3 years (2011–2014), PMI AIRS hired more than 88,000 seasonal workers. Only 25%, or 21,000, of these seasonal workers were women. In general, these women held lower-level and lower-paying positions such as washers or mobilizers. When PMI AIRS analyzed spray operations and operational sites, it found various reasons for the low number of women trained and hired. One was a strong social norm against women working on IRS activities, which have been perceived as "men's work." The belief that women are not physically strong enough to do the work is a gender stereotype that discouraged PMI AIRS managers from offering women positions. Another barrier was project sites' lack of proper disposal facilities for menstruation supplies. In some cases, literacy and educational prerequisites prevented women from applying or qualifying for IRS-related work. But those requirements may not be necessary for all positions. For example, entomological data collection work is technical, yet has minimal education requirements. Lastly, some country programs require spray teams to camp overnight when spraying distant villages, and this is often not socially acceptable for women.

PMI AIRS Project's Gender Policy Framework

In 2014, PMI awarded Abt Associates another 3-year contract for PMI AIRS, to run from 2015 through 2018. The contract specified that the project must mainstream gender equality and female empowerment across project operations, in compliance with USAID's Gender Equality and Female Empowerment policy.[11] During this contract, the PMI AIRS Project developed and implemented a multipronged policy to recruit and retain women in its program. Specifically, PMI AIRS implemented the strategies described below and summarized in Figure 1 starting in 2015 and will continue doing so through the end of the project in 2018.

Policy Focus 1: Privacy at the Work Environment

To attract and retain female employees, the PMI AIRS Project adapted its physical work environments to ensure privacy for women. IRS has been operating since the 1950s, and men traditionally design operational sites for men's needs. IRS operational sites need changing areas, bathrooms, and showers, because spray operators should change and shower after spraying to minimize the risk of insecticide contamination. In these sites, women had minimal privacy. They lacked separate changing areas because so few women used the facilities.

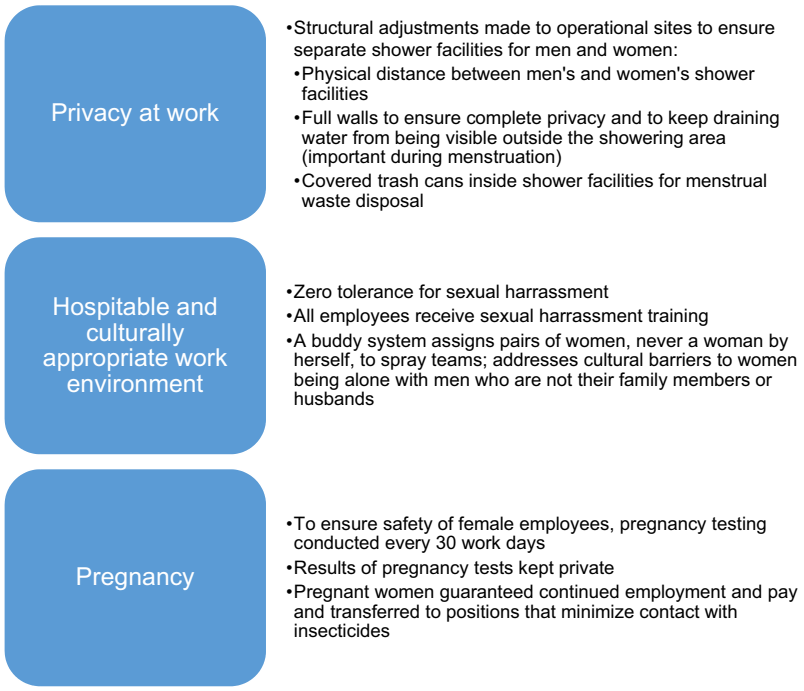
PMI AIRS requires all operational sites to provide separate, private shower areas for men and women spray operators.

The PMI AIRS Project policy now requires that every operational site have separate changing areas, separate bathrooms with trash cans, and separate shower areas. Women's showers must be far from men's. Shower walls must start at the ground and be high enough to ensure privacy. Showers also must have proper drainage so that others cannot see the residual water; this is extremely important for women when they are menstruating. PMI AIRS has put these requirements into the environmental compliance checklists so all operational sites guarantee the same level of privacy. PMI AIRS spray campaigns cannot begin unless the environmental compliance officer verifies that operational sites are compliant.

Policy Focus 2: Hospitable and Culturally Appropriate Work Environment

The PMI AIRS Project instituted policies to ensure a hospitable work environment that maximizes the safety of women in the workplace. PMI AIRS has zero tolerance for sexual harassment. All workers, both temporary and full-time staff, can anonymously report any sexual misconduct. At each operational site, PMI AIRS posts sexual harassment guidelines with a phone number to call to report any misconduct. The project has incorporated gender and sexual harassment awareness

FIGURE 1. Overview of Gender-Focused Policies Implemented by the PMI AIRS Project



into training for government partners, supervisors, and seasonal employees.

PMI AIRS also instituted a buddy-system policy for female spray operators. Any woman on a team must have a second woman as a buddy on the team. The PMI AIRS Project put this policy in place to make women feel more comfortable, since spray days are extremely long and can involve long travel time to remote villages. Social norms in many countries where PMI AIRS operates discourage women from working all day alone with men who are neither their husbands nor family members.

Policy Focus 3: Safety and Job Security During Pregnancy

Exposure to insecticides is not safe for pregnant or lactating women, and spray teams spend hours in close proximity to insecticides. This is problematic for gender mainstreaming of IRS activities, because women of childbearing age are the women most likely to be attracted to and qualified for these positions. To uphold safety standards while attracting and retaining women on the team, the PMI AIRS Project implemented a pregnancy policy to protect women, their developing fetuses, and their breastfeeding infants.

All female seasonal workers take a pregnancy test every 30 days of work during the spray campaign. Procedures for testing and giving results ensure the woman's privacy. The project guarantees a position at the initial salary for any woman who has signed a contract and then becomes pregnant. The teams must find the pregnant woman another position without insecticide exposure, such as data verification assistant or mobilizer. Finally, although pregnancy before signing an employment contract is normally a disqualifier for women who aspire to work with PMI AIRS, the project makes an exception for women with prior spray campaign experience. The project employs these women in other positions for which they are qualified and that avoid exposure to insecticides. The objective is to retain and promote qualified women and enable professional growth and income generation during the childbearing years.

PMI AIRS implemented a buddy system for female spray operators to make them more comfortable during long work or travel days.

PMI AIRS guarantees employment at the initial salary for any woman who has signed an employment contract and then becomes pregnant.

Policy Focus 4: Women in Supervisory Positions

The PMI AIRS Project seeks to achieve gender equity. Gender equity is[6]:

the process of being fair to women and men, boys and girls. To ensure fairness, measures must be taken to compensate for cumulative economic, social, and political disadvantages that prevent women and men, boys and girls from operating on a level playing field.

PMI AIRS identifies, mentors, and promotes talented women into supervisory positions.

The project identifies, mentors, and promotes talented women into supervisory positions. Project teams also implement affirmative action policies that give hiring priority to qualified female applicants for team leader and supervisor roles.

All country teams set annual targets for and track and report on the percentage of supervisory roles held by women, with the eventual goal of gender parity among IRS supervisors. Women should have access to these positions and continue to be leaders in the community. Women who demonstrate that they can successfully take on these roles become role models to younger generations.

Policy Focus 5: Country-Level Flexibility

The PMI AIRS Project operates in a wide range of countries across sub-Saharan Africa, each with distinctive gender and social norms and IRS operations adapted to the local malaria epidemic and terrain. While all PMI AIRS country teams adhere to the basic policy standards outlined above, the project encourages country teams to include country-specific policies to advance gender equality and female empowerment within the project's vector control activities. A few examples of such policies follow:

Ghana: Ghana was the first country to mentor women for leadership roles and as part of an affirmative action plan. Because this policy worked so well and helped the Ghana team achieve its gender equality targets, PMI AIRS has made this a project-wide policy.

Benin: In Benin, the project team understood that to recruit more women, the team needed the support of local leaders who could create recruitment lists and make hiring decisions. The Benin team worked closely with local leaders to ensure that recruitment and hiring decisions were made in line with the project's gender equality goals.

Rwanda: The PMI AIRS Project in Rwanda currently hires the highest percentage of female spray operators of any PMI AIRS Project country. So the team decided to design a policy for hiring more women in other positions. The team has been working with the local authorities to change some job descriptions to be able to include both men and women. For example, to be a mobilizer, one currently must be a village chief. That excludes women. The team is changing the job description so that mobilizers can be village elders, which include men and women.

Evaluation of PMI AIRS Project Gender Policy Implementation

To evaluate the impact of the project's gender policies, PMI AIRS examined several endpoints in Stata and Microsoft Excel using routine program data. This analysis included only countries that had at least 2 data points, to allow comparison before and after implementation of the gender policies.

PMI AIRS collects routine data that can be analyzed by gender of spray operator.

During operations, teams routinely collect data for each spray operator on the number of houses sprayed each day, the number of refusals, and basic reasons for refusal. PMI AIRS also tracks team composition, permitting analysis by gender composition. The project uses standard forms to collect all data, which are ultimately aggregated and entered into a central database.

Women's Employment in the PMI AIRS Project

We analyzed the data on the number of women receiving training for supervisory roles over 5 years in 9 of 10 project countries that adopted the project's gender policies. We excluded Zimbabwe because the PMI AIRS Project supports IRS implementation in Zimbabwe but does not manage the project or its hiring. Our analysis includes time before policy implementation (2012–2014) and for up to 1 year after the 2015 policy implementation (i.e., through 2016). The team calculated the percentage of women in positions such as team leader or site supervisor where they train and supervise others, to determine if the project trained and hired more women generally or hired women for higher-level positions. PMI AIRS conducted chi-square tests to determine whether the proportion of female supervisors rose between 2014 and 2015.

Women's Spraying Efficiency and Refusal Rates

Many people involved in IRS believe that female sprayers are not as efficient as men because of the hard labor involved. The project analyzed the average number of dwellings men and women sprayed in 9 countries in 2015. The analysis also explored the interaction between gender and IRS refusal. PMI AIRS used *t* tests to help determine if the average number of houses sprayed in each country varied by gender. Chi-square tests determined if refusal rates varied by gender.

IRS Team Members' Perception of Gender Norms

In 4 PMI AIRS Project countries—Ethiopia, Madagascar, Rwanda, and Zimbabwe—2,937 seasonal workers in randomly selected operational sites took a survey on gender norms and attitudes before the start and at the end of the 2015 spray campaign. The survey, adapted from the Gender Norm Attitudes Scale,[34] examined spray operators' gender norms through questions about decision making and agency in the spray operators' households. The survey was translated into local languages and approved by the Abt Associates Internal Review Board (IRB) as well as by the appropriate local IRB in each country. Respondents indicated agreement or disagreement with the following statements:

1. Daughters should be sent to school only if they are not needed to help at home.
2. The only thing a woman can really rely on in her old age is her sons.
3. A good woman never questions her husband's opinions, even if she is not sure she agrees with them.
4. A woman must talk to her husband about her expenditures.
5. A woman should have her own money that she can use for what she would like to purchase.
6. If the woman works outside the home, her husband or partner does not need to help her with the daily housework.
7. A husband should not let his wife work outside the home, even if she would like to do it.
8. A woman must accept that her husband or partner beats her in order to keep the family together.
9. When it is a question of children's health, it is best to do whatever the father wants.
10. Women have the skills or the natural ability to make complex decisions.
11. It is ok for a supervisor to joke with his or her team members even if it makes them feel uncomfortable.

For these statements, less agreement with the statement that men have more rights and privileges than women reflects a more egalitarian perspective (coded as 1) compared with a more traditional perspective (coded as 0). PMI AIRS tallied the scores of individual items and then computed the mean of the scores expressed as a continuum from traditional beliefs (0) to egalitarian beliefs (1). Higher scores indicated more egalitarian beliefs. Country-level analyses examined changes in mean scores from preseason (before exposure to the PMI AIRS work environment and its gender policies) to postseason (after work with PMI AIRS). The project was not able to match pre- and postseason surveys for some respondents, however, due to errors in the assignment of anonymous identification numbers. Comparisons between scores used paired *t* tests for employees who could be matched as well as unpaired *t* tests which included all respondents. PMI AIRS stratified all analyses in Ethiopia, Madagascar, and Rwanda by demographic variables, including gender, head of household status, and educational status. Project staff in Zimbabwe did not collect this biographical data from respondents.

RESULTS

The PMI AIRS Project continues to collect data on gender policy endpoints. Here we present the results of changes following the first year of implementation of the policies in 2015. We categorize the results and discussion below by changes in gender composition, spray quality, and social norms.

Increasing Women's Employment in the PMI AIRS Project

Table 1 shows the number of people PMI AIRS has trained since 2012, including the number of women trained and the percentage of people trained who were women. Figure 2 shows progress over time in recruitment of women and progress toward equity among those hired to implement IRS. The increases in the proportion of women participating across the time period, particularly in the category of supervisory positions, are noteworthy. Between 2012 and 2015, the overall proportion of women whom the PMI AIRS Project trained to deliver IRS increased by 6 percentage points, from 22.8% to about 29.1%. In that time, the number of women holding supervisory roles rose more than 29 percentage points: the percentage of women supervisors increased from 16.9% in 2012 to 31.1% in 2014, and then to 46.4% in 2015, after the gender policy was established. Figure 3 compares the increases in women supervisors from 2012 to 2015 across 8 PMI AIRS Project countries.

TABLE 1. PMI AIRS Project Training Data by Country and Year, 2012–2015

	2012	2013	2014	2015
Benin				
No. of people trained	1748	1543	2487	3333
No. of women trained	262	276	443	591
% trained who were women	15%	18%	18%	18%
Ethiopia				
No. of people trained	4213	3987	4390	4452
No. of women trained	992	1072	1472	1631
% trained who were women	24%	27%	34%	37%
Ghana				
No. of people trained	1265	1681	1657	1544
No. of women trained	200	233	300	292
% trained who were women	16%	14%	18%	19%
Madagascar				
No. of people trained	14,818	2241	3450	3302
No. of women trained	3583	482	1593	1337
% trained who were women	24%	22%	46%	40%
Mali				
No. of people trained	2371	2426	2066	1370
No. of women trained	303	409	271	226
% trained who were women	13%	17%	13%	16%
Mozambique				
No. of people trained	1953	1368	1677	2119
No. of women trained	596	303	625	624
% trained who were women	31%	22%	37%	29%
Rwanda				
No. of people trained	6062	9558	7801	8998
No. of women trained	1556	2738	2185	2581
% trained who were women	26%	29%	28%	29%
Senegal				
No. of people trained	1657	3973	1263	1287
No. of women trained	218	1221	218	397
% trained who were women	13%	31%	17%	31%
Zambia				
No. of people trained	–	–	1592	2105
No. of women trained	–	–	616	625
% trained who were women	–	–	39%	30%
Total				
No. of people trained	34,087	26,777	26,383	28,510
No. of women trained	7710	6431	7723	8304
% trained who were women	23%	25%	28%	29%

[a] No employee training data available for Zambia in 2012 and 2013, because until 2014, the PMI AIRS Project in Zambia provided only technical assistance.

Evaluating Women's Spraying Efficiency and Refusal Rates

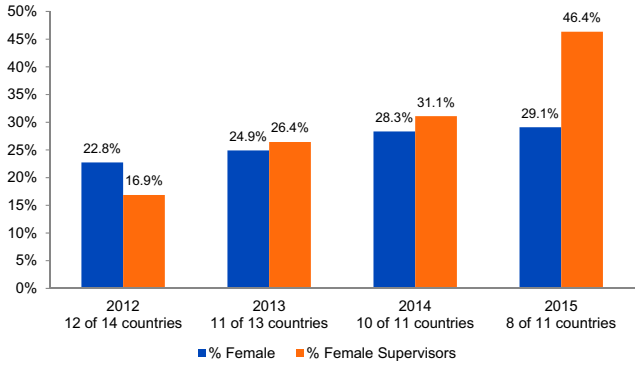
Analyses demonstrated that in most PMI AIRS countries, women sprayed fewer houses per day than men in 2016 (Table 2). In Benin, women sprayed the same average number of structures per day as men. Where there was an observed difference, the differences ranged from 0.1 household per day (Rwanda) to 1.2 households (Ghana) and were statistically significant ($P<.05$) only in Ghana, Ethiopia, Mozambique, and Zambia.

There were significant differences in refusal rates between men and women spray operators in 4 of the 9 countries for which 2016 data were available: Ghana, Mozambique, Senegal, and Zambia (Table 3). In Senegal, women spray operators had lower rates of refusals than men, while in the other 3 countries, women had higher rates of refusals. In Benin, Ethiopia, Madagascar, Mali, and Rwanda, refusal rates did not differ significantly between men and women.

Changing IRS Team Members' Perception of Gender Norms

PMI AIRS identified 465 pairs of matching pre- and postseason surveys for Madagascar (38% of all preseason or baseline surveys), 628 pairs of surveys for Rwanda (79% of baseline surveys), 190 for Zimbabwe (79% of baseline surveys), and 115 for Ethiopia (17% of baseline surveys). Because of the high level of mismatch between surveys, we also examined the median survey scores of all

FIGURE 2. Percentage of Women Trained by the PMI AIRS Project, 2012 to 2015



respondents in each country and compared the pre- and postseason scores. As Table 4 shows, among all respondents, there was a 0.06 point increase in the mean gender index score in Madagascar (P=.48) and a 0.21 point increase in Rwanda (P=.03), where increases in scores indicate movement toward more egalitarian gender norms. There was a 0.37 point decrease in Zimbabwe (P=.04); and a 0.61 point decrease in Ethiopia (P=.001), where decreases in scores indicate movement toward more traditional gender norms.

For the matched pairs, we also identified some significant differences in gender index scores after the spray campaign. We can see a statistically significant change toward more egalitarian gender norms in Madagascar, from a mean score of 7.59 preintervention to 8.00 postintervention (P<.001). In Rwanda also we find a statistically significant increase in the mean gender index score, from 7.17 to 7.47 (P<.001), suggesting a shift toward more egalitarian attitudes. In Zimbabwe, there was a statistically significant drop in the mean gender index score, meaning a shift toward more traditional gender norms, from 8.37 preintervention to 8.04 postintervention (P=.048). Ethiopia had no statistically significant change in the gender index score in the individuals with matched preseason and postseason

Surveys showed movement toward more egalitarian gender norms among PMI AIRS spray operators in some countries, and the opposite in other countries.

FIGURE 3. Percentage of Women in PMI AIRS Project Supervisory Positions by Country, 2012 to 2015

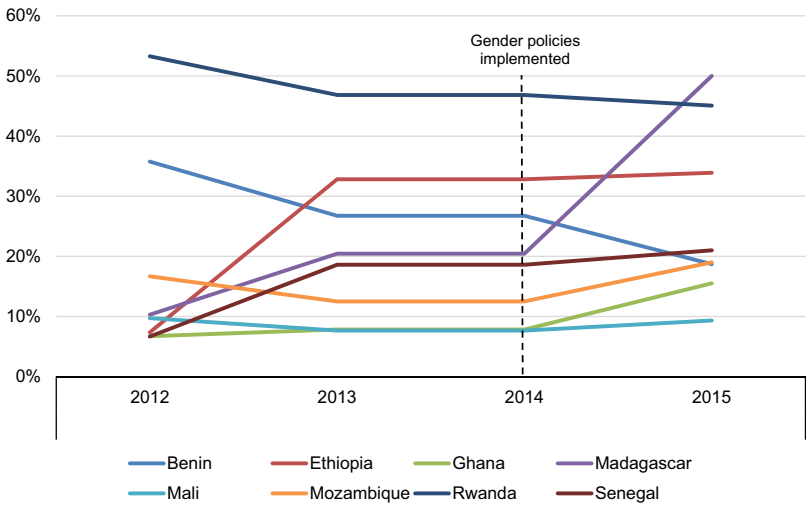


TABLE 2. Average Number of Structures Sprayed per Day by Country and Sex of Spray Operators, 2016

Country	Mean No. of Structures Sprayed per Day (N)		Difference Between Men and Women	*P* Value
	Men	Women		
Benin	14.6 (883)	14.6 (129)	0	.96
Ghana	17.1 (293)	15.9 (151)	1.2	<.001
Ethiopia	17.1 (1446)	16.3 (47)	0.8	<.001
Madagascar	14.3 (780)	14.1 (174)	0.2	.23
Mali	14.0 (695)	13.3 (299)	0.7	.15
Mozambique	8.0 (1089)	7.3 (403)	0.7	<.001
Rwanda	8.8 (534)	8.7 (729)	0.1	.42
Senegal	14.9 (340)	14.1 (157)	0.8	.49
Zambia	15.1 (741)	14.2 (374)	0.9	<.001

surveys, but only a small percentage of respondents were able to be matched due to challenges in administering the survey in the field.

When we analyzed the survey data by gender of the spray operators, we found no statistically significant differences between men's and women's scores (Table 5). In Madagascar, women's preseason scores were higher (more egalitarian) than those of their male counterparts. The men's scores then increased more than women's did at the postseason survey, so that the men's scores approached the women's scores. In Ethiopia, we see men having an initially higher (more egalitarian) gender norms score, which dropped at postseason. Men's gender norms scores remained higher than women's in Ethiopia even with the men's decrease and the women's very slight increase. These can only be interpreted as associations.

DISCUSSION

Overall, there appear to be several promising indicators of success for the gender policies implemented by the PMI AIRS Project. As originally

TABLE 3. Average Spray Refusal Rates by Country and Sex of Spray Operators, 2016

Country	Refusal Rate[a] (N)		Difference Between Men and Women	*P* Value
	Men Spray Operators	Women Spray Operators		
Benin	2.4% (883)	2.4% (129)	0.0%	.96
Ghana	1.0% (293)	1.4% (151)	−0.4%	<.001
Ethiopia	0.1% (1446)	0.1% (47)	0.0%	.60
Madagascar	0.3% (780)	0.2% (174)	0.1%	.06
Mali	0.7% (695)	0.7% (299)	0.0%	.47
Mozambique	11.3% (1089)	13.3% (403)	−2.0%	.005
Rwanda	0.1% (534)	0.1% (729)	0.0%	.71
Senegal[b]	0.5% (340)	0.4% (157)	0.1%	<.001
Zambia	1.2% (741)	1.3% (374)	−0.1%	<.001

[a] No. of households refusing to be sprayed per total structures found.
[b] Senegal's data were based on the number of rooms (not number of structures) that were *not* treated, due to refusals, over the number of rooms found.

TABLE 4. Changes in Gender Index Scores by Country, 2015

Country	No. Surveyed at Baseline	No. Surveyed at Endline	No. With Matched Baseline and Endline Surveys	% With Matched Baseline and Endline Surveys	Respondents Matched at Baseline and Endline: Gender Index Score[a] at Baseline	Gender Index Score[a] at Endline	Difference in Gender Index Score From Baseline[a] (SE)	*P* Value	All Respondents: Adjusted Difference in Mean Gender Index Scores[b] (SE)	*P* Value
Madagascar	1,227	937	465	38%	7.59	8.00	0.41 (0.11)	<.001	0.06 (0.08)	.48
Rwanda[c]	795	796	628	79%	7.17	7.47	0.30 (0.08)	<.001	0.21 (0.10)	.03
Zimbabwe	239	225	190	79%	8.37	8.04	−0.33 (0.16)	.048	−0.37 (0.18)[d]	.04
Ethiopia	676	499	115	17%	7.72	7.47	−0.25 (0.18)	.16	−0.61 (0.12)	< .001

Abbreviation: SE, standard error.
Notes: The PMI AIRS Project collected survey data among a sample of spray operators in 4 countries. Surveys were completed both before the 2015 spray season began (baseline or preseason) and after the season ended (endline or postseason).
[a] The gender index score is the average number of questions, out of a total of 11, answered in favor of gender egalitarianism.
[b] Adjusted results control for sex, previous experience working with the PMI AIRS Project (self-reported), ability to read, education, whether respondents live where they work, whether the respondents are heads of household, and (in Madagascar) district of the survey.
[c] Rwanda's 2015 spray season included 2 rounds of spraying.
[d] Covariates were not collected; results are not adjusted.

TABLE 5. Changes in Gender Index Scores by Country and Sex of Spray Operators, 2015

Country	Sex	No. Surveyed at Baseline	No. Surveyed at Endline	No. (%) With Matched Baseline and Endline Surveys	Respondents Matched at Baseline and Endline: Gender Index Score[a] at Baseline	Gender Index Score[a] at Endline	Difference-in-Difference in Gender Index Scores (SE)	*P* Value	All Respondents: Adjusted Difference-in-Difference in Gender Index Scores[b] (SE)	*P* Value
Madagascar	Men	686	617	147 (21)	7.32	7.78	0.16 (0.24)	.51	0.03 (0.17)	.88
	Women	537	320	319 (59)	8.19	8.49				
Rwanda[c]	Men	523	564	439 (84)	6.99	7.20	0.30 (0.17)	.09	0.14 (0.21)	.51
	Women	261	228	187 (72)	7.56	8.07				
Ethiopia	Men	532	390	106 (20)	7.80	7.53	0.29 (0.65)	.66	−0.15 (0.31)	.64
	Women	132	82	9 (7)	6.76	6.78				

Abbreviation: SE, standard error.
Notes: The PMI AIRS Project collected survey data among a sample of spray operators in 4 countries. Surveys were completed both before the spray season began (baseline or preseason) and after the season ended (endline or postseason). Zimbabwe is not included in this table because Zimbabwe's survey did not ask for the respondent's gender, due to government restrictions. Sex-disaggregated totals do not match overall total because demographic data were not collected from all respondents.
[a] The gender index score is the average number of questions answered, out of a total of 11, in favor of gender egalitarianism.
[b] Adjusted results control for sex, previous experience working with the PMI AIRS Project (self-reported), ability to read, education, whether respondents live where they work, whether respondents are heads of household, and (in Madagascar) the district of the survey.
[c] Rwanda's 2015 spray season included 2 rounds of spraying.

stated, we hypothesized that the gender-focused strategies would (1) improve employment opportunities for women, (2) increase productivity and acceptance of IRS by beneficiaries, and (3) spread the economic benefits of the project to a broader range of community members. Following implementation of the gender-focused policies, there was a substantive increase in the proportion of PMI AIRS supervisors who were women, indicating that access to employment opportunities had improved. However, there was variability by country. We found no substantive difference in acceptance of IRS by households in general, but in some cases a marginal increase in refusal for female spray operators. Finally, given the increased employment for women, we assume indirectly that the economic benefits were distributed to those who did not have such opportunities previously.

Though there were overall increases in the proportion of women employed in the PMI AIRS country programs between 2012 and 2015, there were some exceptions. In Ethiopia and Senegal, there was no significant increase in the proportion of women in supervisory roles between 2014 and 2015 after implementation of the gender policies. In addition, the overall proportion of women trained increased only slightly from 2014 to 2015. Although the increase in the percentage of women trained from 2012 to 2015 is only 6 percentage points, and there is less than a percentage point of increase since the PMI AIRS Project implemented the gender policies, the project has become more equitable in its hiring of women across all positions, with notable increases in the percentage of women in supervisory roles.

In terms of efficiency, our results indicate that perceptions that women are not able to carry out as much IRS work as men do not hold true across a range of settings in sub-Saharan Africa. We found marginal observed differences in the number of houses sprayed per day between men and women; these differences achieved statistical significance in 4 of the 9 countries where data were available. PMI AIRS, however, considers these observed differences to be too small to have an impact on programmatic efficiency. Meanwhile, contrary to our hypothesis that women would receive a lower rate of refusal than men, the opposite was true in several countries evaluated. On average, men experienced a higher rate of refusals than women in Senegal, while women experienced a higher rate of refusals in Ghana, Mozambique, and Zambia. While these differences are statistically significant, they are again quite small and unlikely to have a meaningful impact on operational results.

Differences found in spray efficiency between men and women were considered too small to affect overall efficiency of the program.

Discussions with field personnel indicate several possible explanations for the higher refusal rates observed when women act as spray operators, which are consistent with previous literature. It has been documented that women tend to be less assertive than men.[35,36] While women may be more likely to accept other women into their home for spraying, female sprayers may be less assertive when approaching households for spraying. In male-dominated societies, it may be less acceptable for a woman to refuse a male request than a request presented by a female. The level of comfort that a female householder may have with a female spray operator may lead her to decline spraying more readily. Culturally, menstruation is considered taboo in many countries, and in some cases, women are shunned while menstruating.[37,38] In some areas, women spray operators may be turned away by male householders because social norms deem menstruation "unclean" and men are reluctant to have an unknown woman in the home who may be menstruating. PMI AIRS will investigate this gap in refusal further to determine key factors that can be addressed. Training spray operators on recruitment strategies is a potential solution that could improve not only women's but also men's ability to obtain consent to spray a home.

Gender norms pre- and postimplementation of the gender-focused policies shifted toward more egalitarian views in 2 of 4 countries under study. Employees in Zimbabwe showed a significant shift toward more traditional gender norms. PMI AIRS will repeat this analysis to better understand the link between seasonal employment and stated expression of egalitarian or traditional gender norms. One limitation of the current gender norms survey is that it is focused broadly on changes in core gender norms that are not related to vector control. It is likely that gender mainstreaming in vector control may alter perceptions about women in vector control more readily than it affects broad-based gender norms. Therefore, in future surveys, additional items will be included to obtain information on perceptions surrounding women's role in vector control activities.

Since this is a multiyear assessment, the project will continue to analyze the data, but the preliminary results suggest that the gender-focused strategies are increasing the engagement of women in all aspects of the spray operations, in particular in supervisory roles. Moderate shifts in reported gender norms among seasonal employees participating

in the gender norms survey are also encouraging. The project recognizes that it employs seasonal workers for very short periods of time. Spray campaigns last approximately 35 days out of the year. Therefore, we did not expect to see a large change in gender norms after the first year of the project's gender policies. Further work is needed to investigate the reasons for higher IRS refusal rates for women-led teams.

CONCLUSION

The PMI AIRS Project has demonstrated that it is possible to integrate gender considerations into project operations. The project has shown that by designing IRS operations in a manner that recognizes that women can play key roles, IRS campaigns can become gender equitable, attract and hire more women, and give women an opportunity to gain professional skills. Yet there is still room to improve the project's responsiveness to women's needs.

It has been harder to quantify the effect of increasing gender equality on spray operations. The project has collected data that indicate increased hiring of women in all positions, but the data that measure whether increased participation by women in spray operations changes either spray quality or social norms is not conclusive. Since this is a new initiative, the PMI AIRS Project will continue to monitor and quantify these questions.

Funding: This work was conducted by the United States Agency for International Development's Africa Indoor Residual Spraying Project, with financial support from the U.S. President's Malaria Initiative.

Disclaimer: The opinions expressed herein are those of the authors and do not necessarily reflect the views of USAID.

Competing Interests: None declared.

REFERENCES

1. U.S. President's Malaria Initiative Africa Indoor Residual Spraying Project. www.africairs.net/about-airs/. Accessed November 2, 2017.
2. Montgomery CM, Munguambe K, Pool R. Group-based citizenship in the acceptance of indoor residual spraying (IRS) for malaria control in Mozambique. *Soc Sci Med.* 2010;70(10):1648–1655. CrossRef. Medline
3. Munguambe K, Pool R, Montgomery C, et al. What drives community adherence to indoor residual spraying (IRS) against malaria in Manhiça district, rural Mozambique: a qualitative study. *Malar J.* 2011;10(1):344. CrossRef. Medline
4. Kaufman MR, Rweyemamu D, Koenker H, Macha J. My children and I will no longer suffer from malaria: a qualitative study of the acceptance and rejection of indoor residual spraying to prevent malaria in Tanzania. *Malar J.* 2012;11(1):220. CrossRef. Medline
5. Mazigo HD, Obasy E, Mauka W, et al. Knowledge, attitudes, and practices about malaria and its control in rural northwest Tanzania. *Malar Res Treat.* 2010:2010;794261. CrossRef. Medline
6. Fantahun M, Berhane Y, Wall S, Byass P, Högberg U. Women's involvement in household decision-making and strengthening social capital–crucial factors for child survival in Ethiopia. *Acta Paediatr.* 2007;96(4):582–589. CrossRef. Medline
7. World Bank. *World Development Report 2012: Gender Equality and Development.* Washington, DC: International Bank for Reconstruction and Development and World Bank; 2011. https://openknowledge.worldbank.org/handle/10986/4391. Accessed November 14, 2017.
8. Singh K, Bloom S, Haney E, Olorunsaiye C, Brodish P. Gender equality and childbirth in a health facility: Nigeria and MDG5. *Afr J Reprod Health.* 2012;16(3):123–129. Medline
9. Zamawe CO, Mandiwa C. Understanding the mechanisms through which women's group community participatory intervention improved maternal health outcomes in rural Malawi: was the use of contraceptives the pathway? *Glob Health Action.* 2016; 9(1):34096. CrossRef. Medline
10. Houweling TAJ, Morrison J, Alcock G, et al; EquiNaM group. Reaching the poor with health interventions: programme-incidence analysis of seven randomised trials of women's groups to reduce newborn mortality in Asia and Africa. *J Epidemiol Community Health.* 2016;70(1):31–41. CrossRef. Medline
11. United States Agency for International Development (USAID). Gender Equality and Female Empowerment Policy. Washington, DC: USAID; 2012. https://www.usaid.gov/sites/default/files/documents/1865/GenderEqualityPolicy_0.pdf. Accessed November 2, 2017.
12. Developing a shared vocabulary. Interagency Gender Working Group website. https://www.igwg.org/training/developing-a-shared-vocabulary/. Accessed November 2, 2017.
13. Organisation for Economic Co-operation and Development (OECD). Gender equality in education, employment and entrepreneurship: final report to the MCM 2012. Paper presented at: Meeting of the OECD Council at Ministerial Level; 2012; Paris, France. https://www.oecd.org/employment/50423364.pdf. Accessed November 14, 2017.
14. Goal 5: Achieve gender equality and empower all women and girls. United Nations Sustainable Development Goals website. http://www.un.org/sustainabledevelopment/gender-equality/. Accessed November 2, 2017.
15. International Labour Office. *Women in Labour Markets: Measuring Progress and Identifying Challenges.* Geneva: International Labour Organization; 2010. http://www.ilo.org/wcmsp5/groups/public/—ed_emp/—emp_elm/—trends/documents/publication/wcms_123835.pdf. Accessed November 2, 2017.
16. . International Finance Corporation. *Investing in Women's Employment: Good for Business, Good for Development.* Washington, DC: International Finance Corporation; 2013. https://openknowledge.worldbank.org/handle/10986/16257. Accessed November 14, 2017.
17. Woetzel J, Madgavkar A, Ellingrud K, et al; McKinsey Global Institute. *The Power of Parity: How Advancing Women's Equality Can Add $12 Trillion to Global Growth.* McKinsey & Company; 2015. https://www.mckinsey.com/global-themes/employment-and-growth/how-advancing-womens-equality-can-add-12-trillion-to-global-growth. Accessed November 14, 2017.
18. Duflo E. Women empowerment and economic development. *J Econ Lit.* 2012;50(4):1051–1079. CrossRef
19. Brunori P, Ferreira F, Peragine V. *Inequality of Opportunity, Income Inequality and Economic Mobility: Some International Comparisons.*

Gender-focused policies in IRS programs can increase opportunities for women to gain formal employment, income, and professional skills.

Bonn, Germany: The Institute of the Study of Labor; 2013. http://ftp.iza.org/dp7155.pdf. Accessed November 14, 2017.

20. Wu R, Cheng X. Gender equality in the workplace: the effect of gender equality on productivity growth among the Chilean manufacturers. *J Dev Areas.* 2016;50(1):257–274. CrossRef
21. Sainsbury D. *Gender, Equality and Welfare States.* New York, NY: Cambridge University Press; 1996.
22. Inglehart R, Norris P. *Rising Tide: Gender Equality and Cultural Change Around the World.* New York, NY: Cambridge University Press; 2003.
23. O'Connor J, Orloff S, Shaver S. *States, Markets, Families: Gender, Liberalism and Social Policy in Australia, Canada, Great Britain and the United States.* New York, NY: Cambridge University Press; 1999.
24. Tata Global Beverages Limited. Annual Report and Financial Statements 2012–13. Mumbai, India: Tata Global Beverages Limited; 2013. http://www.tataglobalbeverages.com/investors/investor-relations/annual-reports. Accessed November 2, 2017.
25. Jeffery P. *Frogs in a Well: Indian Women in Purdah.* London: Zed Press; 1979.
26. Winch PJ, Lloyd LS, Hoemeke L, Leontsini E. Vector control at the household level: an analysis of its impact on women. *Acta Trop.* 1994;56(4):327–339. CrossRef. Medline
27. Elmendorf M, Isely R. Public and private roles of women in water supply and sanitation programs. *Hum Organ.* 1983;42(3):195–204. CrossRef
28. Rahman SA. Women's involvement in agriculture in northern and southern Kaduna State, Nigeria. *J Gend Stud.* 2008;17(1):17–26. CrossRef
29. Deressa W, Ali A. Malaria-related perceptions and practices of women with children under the age of five years in rural Ethiopia. *BMC Public Health.* 2009;9(1):259. CrossRef. Medline
30. Diiro GM, Affognon HD, Muriithi BW, Wanja SK, Mbogo C, Mutero C. The role of gender on malaria preventive behaviour among rural households in Kenya. *Malar J.* 2016;15(1):14. CrossRef. Medline
31. Östlin P, Eckermann E, Mishra US, Nkowane M, Wallstam E. Gender and health promotion: a multisectoral policy approach. *Health Promot Int.* 2006;21(suppl 1):25–35. CrossRef. Medline
32. Tolhurst R, Nyonator FK. Looking within the household: gender roles and responses to malaria in Ghana. *Trans R Soc Trop Med Hyg.* 2006;100(4):321–326. CrossRef. Medline
33. Geounuppakul M, Butraporn P, Kunstadter P, Leemingsawat S, Pacheun O. An empowerment program to enhance women's ability to prevent and control malaria in the community, Chiang Mai Province, Thailand. *Southeast Asian J Trop Med Public Health.* 2007;38(3):546–559. Medline
34. Gender Norm Attitudes Scale. Compendium of Gender Scales website. https://www.c-changeprogram.org/content/gender-scales-compendium/attitudes.html. Accessed November 2, 2017.
35. Costa PT, Terracciano A, McCrae RR. Gender differences in personality traits across cultures: robust and surprising findings. *J Pers Soc Psychol.* 2001;81(2):322–331. CrossRef. Medline
36. Leaper C, Ayres MM. A meta-analytic review of gender variations in adults' language use: talkativeness, affiliative speech, and assertive speech. *Pers Soc Psychol Rev.* 2007;11(4):328–363. CrossRef. Medline
37. Ssewanyana D, Bitanihirwe BKY. Menstrual hygiene management among adolescent girls in sub-Saharan Africa. *Glob Health Promot.* 2017 May 1. [Epub ahead of print] CrossRef. Medline
38. Tan DA, Haththotuwa R, Fraser IS. Cultural aspects and mythologies surrounding menstruation and abnormal uterine bleeding. *Best Pract Res Clin Obstet Gynaecol.* 2017;40:121–133. CrossRef. Medline

Peer Reviewed

Received: May 18, 2017; **Accepted:** September 29, 2017; **First Published Online:** December 14, 2017

Cite this article as: Donner A, Belemvire A, Johns B, et al. Equal opportunity, equal work: increasing women's participation in the U.S. President's Malaria Initiative Africa Indoor Residual Spraying Project. Glob Health Sci Pract. 2017;5(4):603-616. https://doi.org/10.9745/GHSP-D-17-00189

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ORIGINAL ARTICLE

Jordan's 2002 to 2012 Fertility Stall and Parallel USAID Investments in Family Planning: Lessons From an Assessment to Guide Future Programming

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Jordan's limited method mix, which has shifted toward less effective methods such as withdrawal and condoms, is a likely contributor to the plateau, coupled with social and cultural norms that discourage contraceptive use, such as preference for large family size and pressure to have a child immediately after marriage. Greater investment in social and behavior change and advocacy for stronger programming efforts are warranted.

ABSTRACT

Health practitioners, researchers, and donors are stumped about Jordan's stalled fertility rate, which has stagnated between 3.7 and 3.5 children per woman from 2002 to 2012, above the national replacement level of 2.1. This stall paralleled United States Agency for International Development (USAID) funding investments in family planning in Jordan, triggering an assessment of USAID family planning programming in Jordan. This article describes the methods, results, and implications of the programmatic assessment. Methods included an extensive desk review of USAID programs in Jordan and 69 interviews with reproductive health stakeholders. We explored reasons for fertility stagnation in Jordan's total fertility rate (TFR) and assessed the effects of USAID programming on family planning outcomes over the same time period. The assessment results suggest that the increased use of less effective methods, in particular withdrawal and condoms, are contributing to Jordan's TFR stall. Jordan's limited method mix, combined with strong sociocultural determinants around reproduction and fertility desires, have contributed to low contraceptive effectiveness in Jordan. Over the same time period, USAID contributions toward increasing family planning access and use, largely focused on service delivery programs, were extensive. Examples of effective initiatives, among others, include task shifting of IUD insertion services to midwives due to a shortage of female physicians. However, key challenges to improved use of family planning services include limited government investments in family planning programs, influential service provider behaviors and biases that limit informed counseling and choice, pervasive strong social norms of family size and fertility, and limited availability of different contraceptive methods. In contexts where sociocultural norms and a limited method mix are the dominant barriers toward improved family planning use, increased national government investments toward synchronized service delivery and social and behavior change activities may be needed to catalyze national-level improvements in family planning outcomes.

BACKGROUND

The total fertility rate (TFR) in Jordan plateaued between 2002 and 2012, despite nearly universal knowledge of contraceptive methods, high rates of female literacy, support for spacing births, and several years of increases in the contraceptive prevalence rate (CPR). After a steep drop in TFR from 6.6 to 3.7 children per woman between 1983 and 2002, the following decade saw only a slight decline from 3.7 to 3.5.[1] Such a period of little to no decline in the fertility rate in countries in transition to replacement-level fertility (2.1 children per woman) is usually referred to as a "stall" in fertility. A 2012 analysis of Jordanian fertility patterns found that the stall was not due to data errors, and it was one of the longest-lasting periods of stagnation assessed worldwide.[2]

A TFR stall is typically accompanied by stalls in multiple parallel measures, including the modern contraceptive prevalence rate (mCPR), unmet need and demand for family planning, and the desired fertility rate, all of which have also stalled in Jordan.[3] From 2002 to 2012, Jordan's CPR increased from 56% to 61%. However, the increase was primarily due to use of traditional methods, which rose from 15% to 19%. The mCPR increased only marginally over the same period (41% to 42%).[1,4] Unmet need for family planning is relatively low in Jordan, hovering between 11% and 12% from 2002 to 2012. However, if individuals using traditional

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The fertility stall in Jordan between 2002 and 2012 was one of the longest-lasting periods of stagnation assessed worldwide.

methods are classified as having an unmet need, the met demand for family planning drops from over 80% to about 60%, below the global target of 75%.[1]

Jordan's stalled TFR of 3.5 children per woman poses challenges for the country's population and development goals. Jordan is a small country, about the size of the U.S. state of Maine, with scarce water and environmental resources. At the same time, Jordan is experiencing a population boom, from 5.3 million people in 2004 to 9.5 million people in 2015.[5,6] The population growth is in part due to a migration influx. In 2015, about one-third of Jordan's population was non-Jordanian, with approximately 1.3 million Syrians, 636,000 Egyptians, 634,000 Palestinians, and 130,000 Iraqis, among other nationalities.[7,8] To ease the pressures of massive population growth and scarce natural resources, Jordan's national family planning goal is to reach a replacement level of fertility by 2030.[7]

During the fertility stall, USAID obligated close to US$307 million in Jordan's health sector.

Jordan receives a sizable assistance package from the U.S. government for economic and development programs. From 2002 to 2012, we estimated that the United States Agency for International Development (USAID) obligated close to US$307 million in Jordan's health sector, with the majority focused on maternal and child health, and reproductive health programming.[8] This USAID investment paralleled the fertility stagnation, prompting the USAID/Jordan Mission to request an external assessment of their family planning programs. This article describes key insights from the assessment.

METHODS

A programmatic assessment of USAID-funded reproductive health programs in Jordan was conducted between October 2015 and March 2016. Our evaluation team reviewed program documentation that included primary USAID project reports, briefs, external evaluations, and studies, and conducted interviews with key stakeholders. The assessment focused on 3 research questions:

1. What factors contributed to the TFR and mCPR stagnation in Jordan?
2. What projects did USAID funding support during the stagnation and what impact was attributed to those projects?
3. What insights were gained from earlier programming that can guide USAID's future reproductive health strategy in Jordan?[8]

To answer these research questions, assessment methods included a desk review of more than 83 documents and 69 interviews with 168 participants—including 23 U.S.-based key informants and 145 respondents in Jordan.

Desk Review

We reviewed multiple data sources, including 30 project reports, 42 external studies and evaluations, and 11 project briefs. The documents were identified through the USAID Development Experience Clearinghouse and online journal searches, and provided by USAID/Jordan staff. Two evaluation team members reviewed the documentation and entered the data in a desk review matrix, categorized by type of documentation, project, funding amount, geographic coverage, time period, target population, type of activities, evaluation methods, key outcomes, and recommendations. We identified a total of 20 USAID-funded projects focused on reproductive health and family planning outcomes over a 20-year period (1995 to 2015). To understand the USAID portfolio distribution over time, we categorized the projects according to 3 different funding streams: service delivery, policy and advocacy, and social and behavior change (SBC) programming.

Key Informant Interviews

We developed a semistructured questionnaire guide for key informant interviews that generated information about each of the 3 research questions. Data were analyzed by comparing salient themes across the following groups of key informants: (1) central Ministry of Health (MOH) officials, (2) regional MOH officials, (3) private-sector health professionals, (4) other government officials, (5) donor staff, (6) international experts, and (7) USAID project contractors (Table 1). We entered interview transcripts and notes in Dedoose, a qualitative data analysis software, and systematically coded them in accordance with the research questions. Coded excerpts were subsequently exported to Microsoft Excel for thematic analysis. The team conducted qualitative salience analysis by following these 2 steps: (1) aggregating the frequency that a thematic code was applied within a given transcript (e.g., number of times "son preference" is coded as a factor of TFR stagnation), and (2) dividing the total aggregate number of times a thematic code was applied by the number of transcripts for that given key informant group. The resulting salience score was the mean frequency of each theme calculated for that given key informant subgroup. A higher

TABLE 1. Key Informant Interview Groups (N=69)

Interview Group	No. of Interviews
Central MOH officials *MOH administrative employees in Amman*	11
Regional MOH officials *MOH employees in regional hospitals and health centers*	17
Private-sector health professionals *Physicians, outreach workers, and NGO project directors in the private sector*	6
Other government officials *Officers at non-MOH government departments (e.g., Higher Population Council, Royal Medical Services)*	10
Donor staff *Staff at donor organizations (e.g., USAID, UNFPA, JICA, WHO)*	6
International experts *Experts in family planning familiar with, but working outside of, Jordan*	9
USAID project contractors *Contractors implementing USAID family planning projects in Jordan*	10

Abbreviations: JICA, Japan International Cooperation Agency; MOH, Ministry of Health; UNFPA, United Nations Population Fund; USAID, United States Agency for International Development; WHO, World Health Organization.

salience score represented greater relative importance of the theme within that subgroup of key informants.[9]

One limitation of this analysis is the lack of a current national assessment of TFR and mCPR trends in Jordan. The most recent national-level data available are from the 2012 Jordan Demographic and Health Survey (DHS). To address this gap in the data, we collected couple-years of protection (CYP) data from the Jordanian MOH online database from 2010 to 2015. In addition, our findings are in part derived from interview data that reflect the views and belief systems of those stakeholders. We recognize that information shared by key informants may reflect biases related to the positive outcomes of their projects and experiences. The salience analysis, described above, aimed to reduce these potential biases by systematically analyzing and scoring interview data. Similarly, USAID's end-of-project reports tend to be biased toward positive outputs related to key milestones and successes, whereas less successful programmatic activities receive less representation in the reports. The evaluation team addressed these biases by triangulating data from multiple sources, including study briefs and external evaluations whenever available.

Finally, conducting an assessment of 20 years' worth of programming is a feasible but large undertaking. Given the diversity of intervention approaches and evaluation methodologies, we cannot attribute a quantitative change, or lack thereof, in national-level TFR and mCPR outcomes to USAID programmatic efforts. Rather, we situate the USAID programming efforts in the context of the fertility stall, providing an assessment methodology and programmatic case study for other contexts facing similar population and family planning issues.

FINDINGS

What Is Causing the TFR Stall in Jordan?

Documentation on Jordan's TFR stall exists, and evidence suggests that the increased use of less effective methods is a key contributing factor.[2,10] Al-Massarweh[10] applied Bongaarts' classic framework on the proximate determinants of fertility to Jordan,[11] and found that the increase in CPR was not enough to offset the increase in proportion of married women during the same time period, as most of the increase was attributed to use of less effective traditional methods.[10] Rashad and Zaky[12] found similar TFR stalling trends over the same time period in Egypt, Jordan, and Syria. They suggested that in Jordan, use of contraception—and traditional methods in particular—played a stronger role than other proximate determinants (e.g., age at first marriage). The authors conclude that addressing women's concerns about side effects and improving the method mix could potentially shift women's use of traditional methods toward more effective modern methods.

Increased use of traditional contraceptive methods in Jordan played a strong role in the fertility stall.

TABLE 2. Average Salience Scores for Reasons for TFR Stagnation in Jordan, by Interview Group

	Desire for Large Families	Fear of Side Effects With Modern Methods	Influence of Husbands and Mothers-in-Law	Preference for Sons	Short Birth Intervals; Rapid Pregnancy After Marriage
Central MOH officials (n=11)	2	1	0	0	0
Regional MOH officials (n=17)	7	12	6	4	2
Private sector health professionals (n=6)	4	3	2	3	1
Other government officials (n=10)	7	5	2	2	3
Donor staff (n=6)	3	1	3	1	0
International experts (n=9)	5	1	1	3	1
USAID project contractors (n=10)	3	6	3	1	2
Average salience score, all key informants (N=69)	**4.4**	**4.1**	**2.4**	**2.0**	**1.3**

Abbreviations: MOH, Ministry of Health; TFR, total fertility rate; USAID, United States Agency for International Development.

Sociocultural and environmental factors, such as fear of side effects and limited method mix, are influencing the types of methods used in Jordan. The average salience scores from key informant interviews showed that key informants regarded these sociocultural factors—typically referred to as "indirect determinants" of fertility under Bongaarts' framework[11]—as key contributor factors of the stalled fertility in Jordan. As shown in Table 2, commonly cited factors among the interviewees for TFR stagnation included the desire for large families, fear of side effects with modern method use, influence of husbands and mothers-in-law, and preference for sons. Key informant interviews also cited issues related to Jordan's limited method mix and method stock-outs, in addition to provider behavior and bias, albeit less frequently. Overall, the assessment findings suggest that Jordan's limited method mix, coupled with social and cultural determinants of contraceptive use, may be influential factors of Jordan's stalled fertility outcomes, both of which are further explored in the sections that follow.

Factors such as the desire for large families, fear of side effects, influence of family, and preference for sons also influence use of contraception.

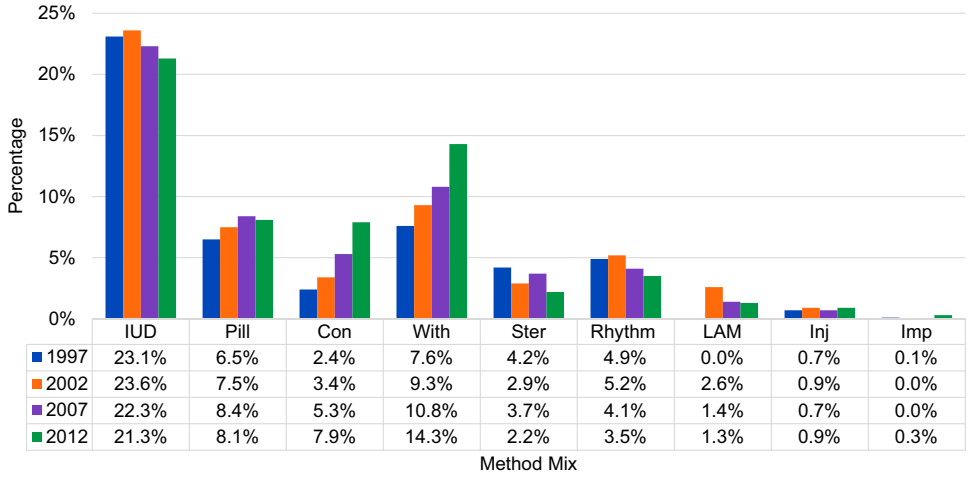
Limited Method Mix

Jordan provides a context where family planning access and use are relatively high, but the diversity of methods available to clients is low. In recent years, the method mix has shifted toward less effective methods such as withdrawal and condoms. As shown in Figure 1, withdrawal use increased from 9.3% to 14.3% between 2002 and 2012, whereas more effective methods such as the intrauterine device (IUD) decreased from 23.6% to 21.3%.

To better understand the impact of Jordan's limited method mix and shift in method use, we applied John Bongaarts' "index of non-contraception" to quantify the changing contraceptive method mix in Jordan.[11,13] This index provides a way to gauge the effectiveness of the method mix in relation to the prevalence of each method in the target country. Index figures closer to 1.0 reflect a *less* effective method mix. To put this in perspective, Bongaarts provides the example of the United States' score improvement from 0.31 in 1965 to 0.22 in 1973, which represents substantial increases in availability of different family planning methods in less than 10 years. Figure 2 shows that over the 15 years from 1997 to 2012, the index score in Jordan decreased only two-tenths of a point (from 0.83 to 0.81), suggesting a method mix with limited effect.

This limited method mix, combined with women and men's concerns about side effects, is a likely contributor to Jordan's high rates of contraceptive discontinuation. According to the 2012 DHS, more than half of the women using injectables, male condoms, and oral contraceptives discontinued use of their method within 1 year.[1] The most frequent reason for discontinuation was the desire to become pregnant (33%), followed by method failure (18%), side effects or health concerns (15%), and the desire to have a more effective method (13%).[1] Studies have shown that misconceptions about methods persist. A 2015 study highlighted that only two-

FIGURE 1. National Contraceptive Method Mix Among Contraceptive Users in Jordan by Year, 1997–2012

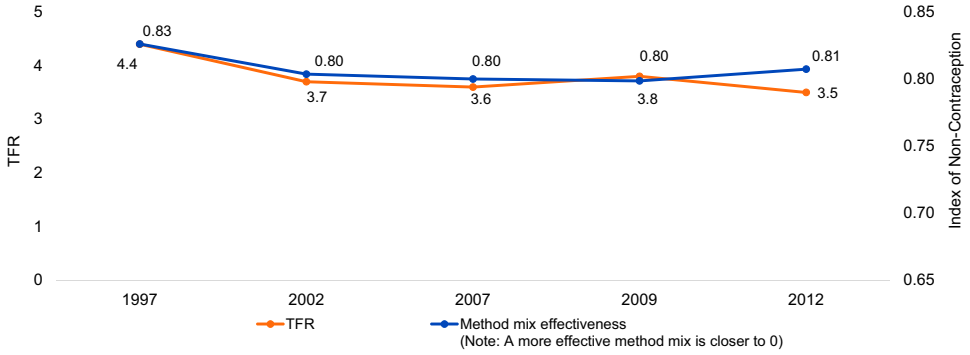


	IUD	Pill	Con	With	Ster	Rhythm	LAM	Inj	Imp
1997	23.1%	6.5%	2.4%	7.6%	4.2%	4.9%	0.0%	0.7%	0.1%
2002	23.6%	7.5%	3.4%	9.3%	2.9%	5.2%	2.6%	0.9%	0.0%
2007	22.3%	8.4%	5.3%	10.8%	3.7%	4.1%	1.4%	0.7%	0.0%
2012	21.3%	8.1%	7.9%	14.3%	2.2%	3.5%	1.3%	0.9%	0.3%

Abbreviations: Con, condoms; Imp, contraceptive implant; Inj, injectable contraception; IUD, intrauterine device; LAM, lactational amenorrhea method; Pill, oral contraceptive pills; Rhythm, rhythm or calendar method; Ster, female or male sterilization; With, withdrawal.

Data from Jordan's Demographic and Health Surveys.

FIGURE 2. Changes in TFR and Contraceptive Method Mix Effectiveness[a] in Jordan, 1997–2012



Abbreviation: TFR, total fertility rate.

[a] Based on Bongaarts' index of non-contraception,[11,13] which gauges the effectiveness of the method mix in relation to the prevalence of each method in a particular country. Index values range from 0 to 1.0, with values closer to 1.0 indicating a *less* effective method mix.

Data from Jordan's Demographic and Health Surveys.

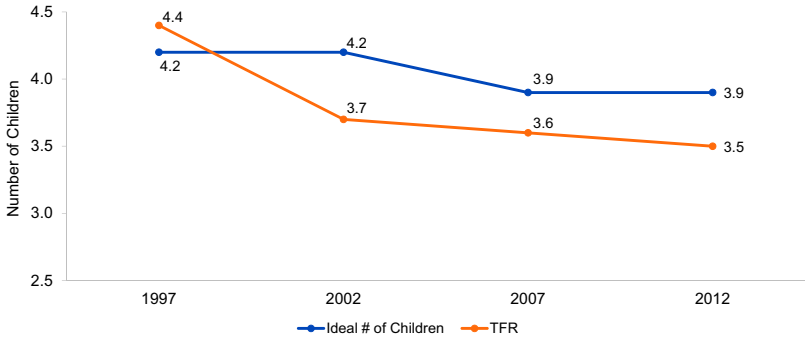
thirds (65%) of women in Jordan thought that modern methods were more effective than traditional methods, reflecting a lack of accurate knowledge about family planning methods, which may further fuel the use of traditional methods in Jordan.[14] Given the limited method mix and high rates of discontinuation described above, our assessment suggests that low *contraceptive effectiveness* is the key determinant of fertility stagnation in Jordan.

Indirect Social Determinants of Fertility

In Jordan, the cultural and social normative factors influencing contraceptive use and effectiveness include expectations around family size and

Low contraceptive effectiveness is likely the key determinant of fertility stagnation in Jordan.

FIGURE 3. Changes in TFR and Mean Ideal Number of Children in Jordan, 1997–2012



Abbreviation: TFR, total fertility rate.

Data from Jordan's Demographic and Health Surveys.

preference for sons, pressure to have a child immediately after marriage, and diffusion of incorrect information about contraceptive methods and their side effects.[15–19] Figure 3 highlights the persisting norms around fertility desires: the ideal number of children has declined only slightly, from 4.2 in 1997 to 3.9 in 2012, a decrease that parallels the TFR stagnation. The desire for 4 children is nearly ubiquitous among Jordanians. As a key informant interview participant affirmed: "You want 2 boys, because 2 is better than 1, and 2 girls so they can keep each other company."

Pregnancy and fertility can be perceived as a means of upward mobility and status for women in Jordan.

Similar to other contexts, pregnancy and fertility are perceived as a means of upward mobility and status for women in Jordanian society.[16] Ethnographic research conducted on motherhood in Jordan suggests that reproductive power is generationally passed down from mothers-in-law to daughters-in-law. As young Jordanian women become future mothers-in-law, they may apply the same authority and control they experienced as a newlywed to their daughters-in-law.[16] Key informant interviewees repeatedly confirmed that both husbands and mothers-in-law can be equally influential in determining use of family planning, including type of method used and continuation or discontinuation.

USAID has largely focused on service delivery programs, constituting about 75% of its investments in reproductive health programming in Jordan.

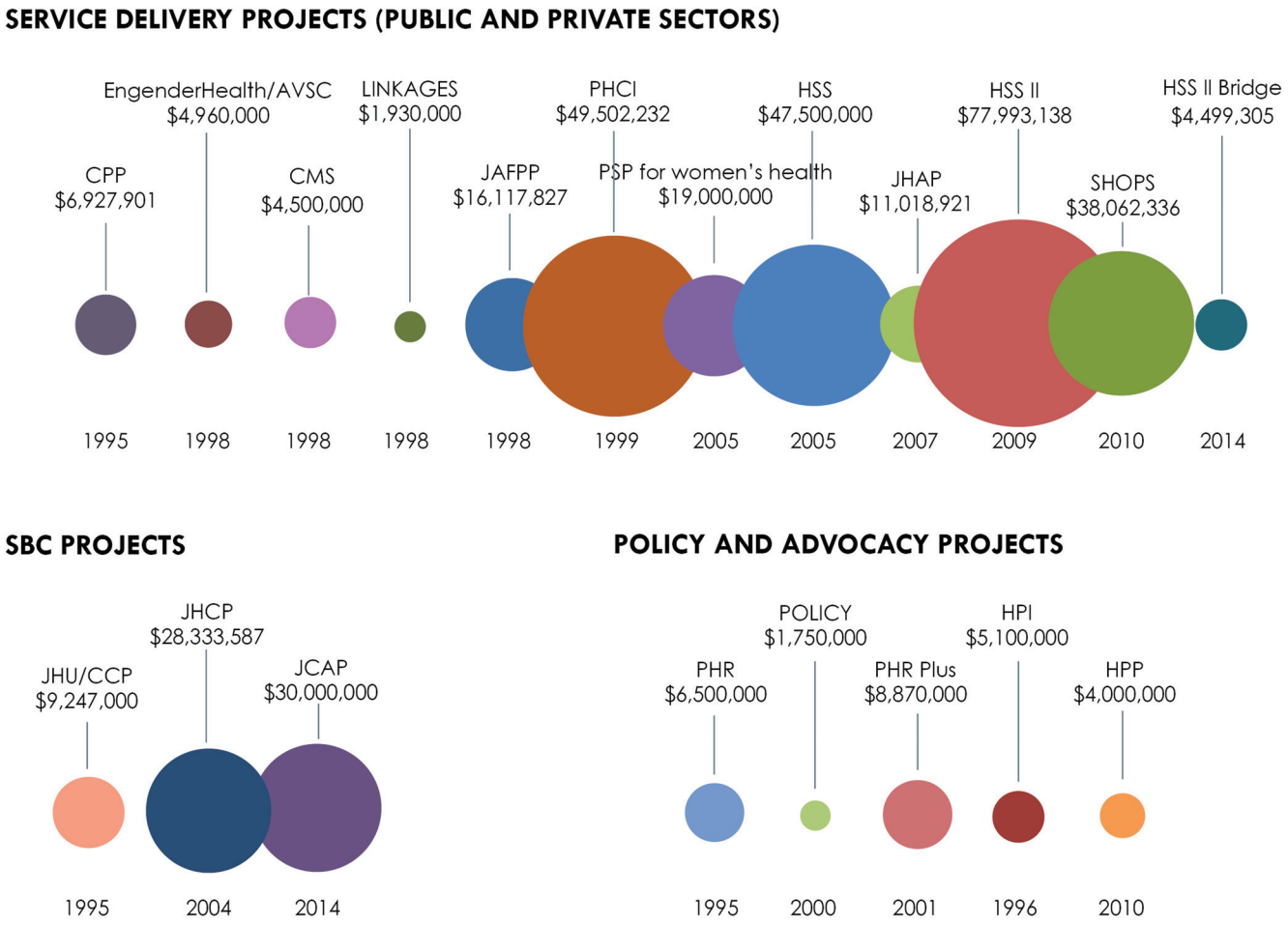
The reproductive power of women in Jordan is inevitably linked with their participation—or lack thereof—in the professional workforce. Despite high education levels, the annual Employment and Unemployment Survey in Jordan showed only a small increase in the participation of women in the labor market, from 12.4% in 1993 to 14.7% in 2011.[7] The National Reproductive Health/Family Planning Strategy 2013–2017 notes the strong relationship between TFR and women's participation in the labor market, showing that a 1% increase in women's participation in the labor market reduces the TFR by 0.5%.[7] Other studies in Jordan have come to similar conclusions; for example, a 2012 study asserted that "by limiting women's employment options, the society effectively encourages reproduction, an area where women receive positive social and familial reinforcement,"[20]—a theme that also resonated during key informant interviews.

Overall, the assessment findings showed that the limited method mix, combined with sociocultural determinants of reproduction and fertility desires, have contributed to low contraceptive effectiveness in Jordan.

What Effect Did USAID Programs Have on Jordan's Family Planning Outcomes?

USAID is a key donor to reproductive health programming in Jordan. Exact numbers are not readily available, but a donor landscape report from the Henry J. Kaiser Family Foundation estimated that between 2009 and 2011, USAID provided up to 81% of all foreign government donor funding in reproductive health and family planning.[21] Figure 4 shows estimated distribution allocations from the 20 USAID projects identified during our desk review from 1995 to 2015, based on project documentation provided by USAID/Jordan. The portfolio distribution shows that USAID reproductive health investments in Jordan have largely focused on service delivery programs, constituting

FIGURE 4. USAID Investment in Family Planning Projects in Jordan, 1995–2015 (in US$ estimates)



(Note: Funding figures are estimates from USAID programming documents received)

Abbreviations: AVSC, Association for Voluntary Surgical Contraception; CMS, Commercial Market Strategies; CPP, Comprehensive Postpartum Project; HPI, Health Policy Initiative; HPP, Health Policy Project; HSS, Health Systems Strengthening; JAFPP, Jordanian Association for Family Planning and Protection; JCAP, Jordan Communication, Advocacy, and Policy Activity; JHAP, Jordan Healthcare Accreditation Project; JHCP, Jordan Health Communication Partnership; JHU-CCP, Johns Hopkins Center for Communication Programs; PHCI, Primary Health Care Initiative; PHR, Partners for Health Reform; PHR Plus, Partners for Health Reform Plus; PSP, Private Sector Project for Women's Health; SBC, social and behavior change; SHOPS, Strengthening Health Outcomes through the Private Sector; USAID, United States Agency for International Development.

Projects are grouped by category (i.e., service delivery, social and behavior change, and policy and advocacy) and then listed in chronological order based on date of project start; estimated project budgets are in US dollars.

about 75% (US$281.9 million) of USAID investments in reproductive health programming (both public and private). The focus on SBC projects and policy and advocacy projects has been less intensive, with investments totaling 18% (US$67.6 million) and 7% (US$26.2 million) of total USAID investments in reproductive health and family planning in Jordan, respectively.[22]

A comprehensive listing and review of projects according to the 3 investment streams—service delivery, SBC, and policy and advocacy—are provided elsewhere.[8] For the purposes of this article, however, we highlight key programmatic contributions related to the following categories: (1) increasing access to and use of family planning services, (2) task shifting family planning

counseling and services, (3) addressing provider behavior, (4) expanding the method mix, and (5) increasing community demand and support for family planning.

Increasing Access to and Use of Family Planning Services

The assessment results showed improvements in the quality of services and access to reproductive health services from facilities at the tertiary, secondary, and primary levels. Improvements include training and capacity development interventions, establishing health facility and community linkages, and renovating health facility structures and investments in medical devices and infrastructure.

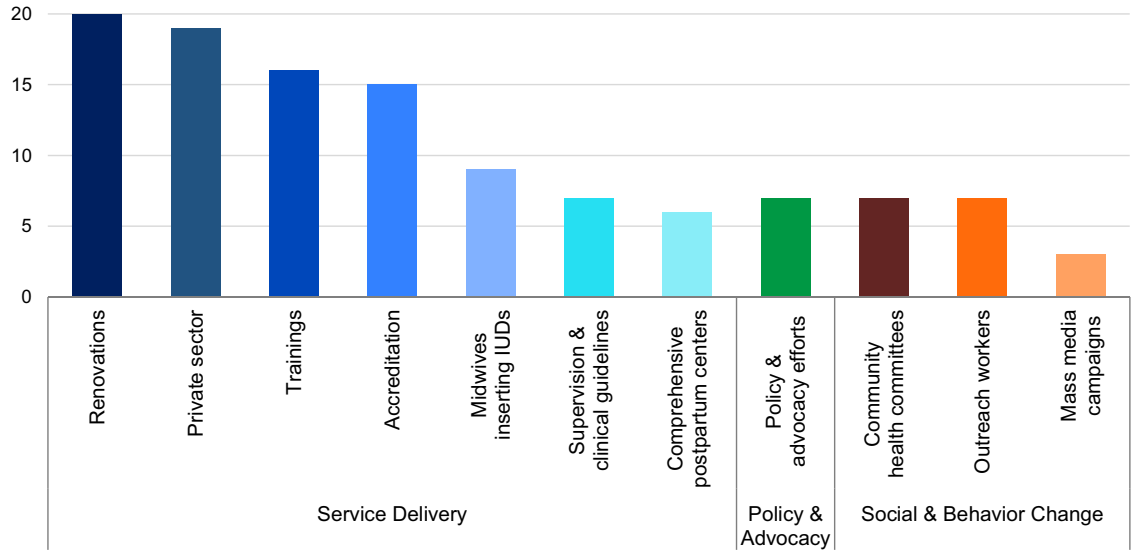
In 2011, 439,439 counseling visits for family planning and reproductive health services were conducted in the public sector, increasing to 550,470 counseling visits by 2014.[23] In particular, the reactivation of community health committees and community awareness activities, under the Health Systems Strengthening II Bridge (HSS II Bridge) project's improvement collaborative, generated immediate demand for family planning services. The exclusive focus on family planning in HSS II Bridge led to reported gains: within 6 months, CYP increased by 50% in the targeted health facilities.[24]

Key informants commonly attributed increases in access to and use of family planning to USAID-funded programmatic efforts. In particular, key informants cited the contributions of renovation efforts, as shown by the frequency of mentions during interviews that renovations were successful (Figure 5). For example, key informants said that renovations of hospitals' comprehensive postpartum centers in the late 1990s increased access to postpartum family planning services by providing separate, private family planning counseling rooms.

Task Shifting of IUD Insertion Services

Jordan has a shortage of female medical providers given women's limited participation in the workforce. In response, Jordan's Higher Population Council, with support from USAID, advocated for shifting the task of IUD insertions and removals to midwives within MOH facilities. However, this effort was constrained by national policy legislation. In 2010, Jordan's MOH temporarily banned midwives from inserting IUDs.[25] The ban was eventually overturned due to efforts from the Higher Population Council and USAID. After midwives began inserting IUDs again, MOH CYP increased slightly from 119,995 in 2011 to 126,696 in 2014.[25] Concurrently, the number of

FIGURE 5. Number of Times Family Planning Successes Were Attributed to USAID Across All Key Informant Interviews (N=69)



Abbreviations: IUD, intrauterine device; USAID, United States Agency for International Development.

MOH health centers providing IUDs each year increased from 88 to 160 health centers between 2011 and 2014.[18] Staff turnover was also reported as a barrier to providing family planning services. During interviews, health service providers in primary health centers and hospitals expressed frustration at the departure of midwives previously trained by USAID in IUD insertion and family planning counseling.

Evidence also suggests that decentralizing family planning counseling to community outreach workers can be effective in lowering the use of traditional family planning methods. A 2015 study in Jordan evaluating a home visit outreach voucher program conducted by social workers showed 48% and 59% gains in modern method uptake among women-only counseling and couples-counseling intervention groups, respectively, relative to control. The study, evaluated under the Strengthening Health Outcomes through the Private Sector (SHOPS) project, also showed lower use of traditional methods and fewer concerns about side effects in both women-only counseling and couples-counseling intervention groups.[26]

Addressing Provider Behavior

The assessment findings suggest that both public- and private-sector providers have misconceptions about hormonal methods and side effects, despite repeated USAID investment in training initiatives.[27–29] One initiative included the evidence-based medicine program, a 3-month education and training program for providers on injection counseling, conducted by the SHOPS project. A 2014 randomized study showed that evidence-based medicine training provided to private-sector physicians improved their attitudes and confidence in providing injectables, but did not improve knowledge of the method or counseling practice scores.[27]

In contrast, the "Consult and Choose" initiative, under the Jordan Health Communication Partnership, pilot-tested a client-centered family planning program in the governate of Irbid, synchronizing service delivery and community outreach activities to increase access to family planning services among women with a high unmet need. The study results showed that 83% of clients reported being "very satisfied" with their counseling visit, with health care providers completing 5.6 of the 7 counseling protocol steps. Descriptive results also suggested an increase in new family planning users and CYP after program start.[30]

Expanding the Method Mix

A few projects, such as SHOPS, have attempted to expand the method mix and access to underutilized methods in Jordan, including injectables and implants. Although a number of methods have been introduced in Jordan, methods such as injectables and implants are still not routinely or widely available. Under the HSS II project, the number of MOH primary comprehensive health centers offering 4 or more family planning methods increased from 106 to 145 health centers between 2011 and 2014.[18] At the time of the assessment, however, few health centers offered more than 4 methods, and some key informants reported frequent stock-outs of implants and injectables.

Increasing Community Demand and Support for Family Planning

Social communication strategies in the late 1990s were instrumental in garnering social support for family planning, including mobilizing religious leaders to support family planning as a method of child spacing. Mass media campaigns targeted husbands and mothers-in-law, and other familial networks who played an influential role in disseminating information about family planning methods and who pressured for pregnancies soon after marriage. For instance, the "Together for a Happy Family" campaign targeted more than 2 million people and was the first-ever national campaign to specifically target men. During the campaign from 1996 to 2000, the number of surveyed men who considered IUDs safe for their wives rose from 34% to 50%, and the number of men who considered the pill safe increased from 25% to 36%.[31]

More recent mass media campaigns have shown mixed results in sustaining family planning demand. Evaluation results of the SHOPS social marketing campaign from 2011 to 2013 showed that 91% of respondents remembered the campaign slogan when prompted. The evaluation results also showed that the likelihood of being an oral contraceptive user increased with increased exposure to the campaign. While evidence suggests that the SHOPS social marketing campaign for IUDs boosted the uptake of IUD services, demand dropped after the campaign ended.[32]

Enabling a Supportive Policy Environment for Family Planning

Two key components of USAID/Jordan's strategy for family planning include supporting (1) Jordan's policy environment and implementation of the reproductive health/family planning strategy and (2) the capacity of local partners, such as the Higher Population Council, to advocate and conduct awareness-raising and policy reform activities.[33] Key contributions include supporting the development of a contraceptive security strategy to support the national population strategy, creating several national and MOH reproductive health and family planning strategies (e.g., MOH Strategy 2008–2012, MOH Strategy 2013–2017, and MOH Family Planning Strategy 2013–2017), and increasing the legal age of marriage from 15 to 18 for women and 16 to 18 for men, through the POLICY project among others.[7]

The government's limited financial commitment and ownership affects the potential sustainability and scale-up of effective family planning programs in Jordan.

Given Jordan's competing priorities, and the growing influx of refugees, financial commitment from the central government toward family planning programs is waning. The government's limited financial commitment and ownership affects the potential sustainability and scale-up of effective family planning programs. At the time of the assessment, key informants commonly reported that scale-up efforts were limited, and effective pilot projects were often discontinued despite reported gains. These include successful initiatives such as the "Consult and Choose" client-centered counseling pilot study and family planning awareness-raising activities conducted by community health committees under the service delivery projects to generate local family planning demand.

DISCUSSION: MOVING FORWARD WITH FAMILY PLANNING PROGRAMMING IN JORDAN

The examination and analysis of 2 decades of family planning programs in Jordan provides an opportunity to make recommendations for future programming. Stakeholders in Jordan have expressed interest in increasing the scale and sustainability of programs and capitalizing on recent reproductive health gains. Fertility stalls are not uncommon and some lessons can be extracted from other countries. For example, in 2005 USAID studied family planning stalls in Senegal[34] and Tanzania,[35] both of which have since seen CPR increases. In both countries, increased government commitment to family planning was a key factor in improving outcomes. In particular, Senegal followed through on its 2012 London Summit on Family Planning commitment to double their domestic investment in health.

Expanding the method mix should be a government priority in Jordan. In 2010, the Higher Population Council, with support from USAID's Health Policy Initiative, conducted a simulation to assess how changing the method mix would affect TFR. The results showed that reducing traditional method use (e.g., withdrawal) by half could contribute to reducing TFR by 0.35 points, from 3.80 to 3.45 children per woman. Desk review findings highlight 3 issues that need to be prioritized to improve the method mix: (1) fear of side effects/health concerns, (2) provider behavior and bias, and (3) female provider availability.[36]

Programs addressing cultural norms around family planning and fertility desires also need to be prioritized. A 2011 USAID-funded SBC program report concluded that access, cost, and quality of care are not the main constraints to adoption and use of contraception in Jordan. The authors stated that "improved quality of care can affect fertility timing, but will not change fertility levels without a change in desired fertility."[37] Beyond the mass media campaigns described in this article, there have been less investment and programming in SBC activities that can address the strong social norms among close-knit families and communities concerning large family size and son preference.

SBC activities should, and can be, synchronized with service delivery programming. As some evidence supports, strengthening effective and sustainable health systems cannot occur without systematically integrating behavior change approaches within these health systems.[38] A few notable models exist, including the Health Communication Capacity Collaborative's Circle of Care Model, a programmatic framework that interweaves SBC programming along the service delivery continuum.[39] Specifically, this service delivery continuum offers 3 points of contact—before, during, and after services—to influence attitudes and behaviors of both clients and providers.

The Syrian refugee crisis was a recurring, looming topic during key informant interviews that should be addressed. The exact impact of the Syrian refugee influx on national CPR and TFR outcomes is unknown. Some key informants in Jordan shared perceptions that the new Syrian refugees bear more children, do not believe in

family planning methods, and are polygamous. Yet, findings from a 2016 qualitative gender study conducted by the Jordan Communication, Advocacy, and Policy (JCAP) project showed that Syrian and Jordanian women have similar preferences for family size and desired number of children.[16] Some key informants cited the influx of Syrian refugees as a reason for TFR stagnation. However, this is more a reflection of perceptions and tensions around the refugee situation than actual causality, as the stagnation predated the latest influx of refugees.[40]

It is possible that some improvements in TFR and mCPR occurred from 2012 to 2015, which are not captured in the latest DHS data. In fact, a number of interviewed Jordanian stakeholders rebuked the existence of a TFR stall, pointing to several improvements in family planning outcomes over the last 2 decades. Interestingly, a new calculation indicates that there might have been a TFR reduction in the last few years, estimated as 3.1 for 2014.[41] This new calculation, based on Schoumaker's model,[42] uses data from birth registries, which is considered a strong data source because 99% of women in Jordan give birth in health facilities. One strength of this measure is that it can be calculated more regularly, rather than waiting 5 years for each DHS study. USAID and the MOH have accepted the new TFR measure as accurate, but at the time of the field interviews in early 2016, it was unclear how accepted it would become within the wider body of stakeholders in Jordan. One challenge with this new calculation is that it includes only women of Jordanian nationality or who are registered as living in Jordan, which leaves out a large and growing refugee population.

Our additional analysis of CYP data collected from the online MOH logistics system, which covers the public sector and most of the NGOs receiving MOH contraceptives, confirmed a similar stalling in line with the DHS data, from 227,531 CYP in 2012 to 227,600 in 2015.[25] One issue with this measure is the quality and reliability of the data, which is shared through an online MOH logistics system, after collection from local health facilities. Finally, our review of USAID programs included at least 2 projects (HSS II Bridge and JCAP) that began after the last recorded DHS period, and therefore the effect of these programs on family planning outcomes cannot be fully ascertained.

CONCLUSION

The government of Jordan, with support from USAID, has made substantial progress in increasing access to and use of family planning services. However, much more can be done to address the limited method mix and sociocultural determinants of contraceptive use. In contexts where sociocultural norms are the dominant barriers to use of family planning, increased investments in SBC and advocacy programming may be needed to catalyze behavior change toward improved and sustained family planning use.

Lastly, while we use the Jordan case study as an example of a family planning programming approach in the context of a fertility stall, we recognize that shifting gender and social norms around fertility intentions can be difficult, intensive, and contentious. Addressing such influential norms requires the help of practitioners, researchers, and donors to critically unpack what we can and cannot change about values and belief systems deeply rooted within social norms and expectations around pregnancy and family aspirations. Ultimately, programmatic activities that address community and familial fertility norms, increase family planning options available to couples, and empower governments to implement and sustain project activities will contribute to an evolving landscape of improved reproductive health service delivery, and will enable countries like Jordan to meet their fertility goals.

Some improvements in total fertility and use of modern contraceptives may have occurred from 2012 to 2015; however, the new calculation does not include a portion of the refugee population.

Acknowledgments: This article was prepared under the Fertility Awareness for Community Transformation (FACT) Project. This article and the FACT Project are made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the Cooperative Agreement No. AID-OAA-A-13-00083. The contents are the responsibility of the Institute for Reproductive Health and do not necessarily reflect the views of Georgetown University, USAID, or the United States Government. The authors wish to thank the USAID/Jordan Mission, including Maysa Al-Khateeb and Nagham Abu Shaqra, for their guidance during the program assessment. Jordan Tompkins supported the programmatic assessment and analysis, and Victoria Jennings provided valuable editorial suggestions for this article. Lastly, our sincere gratitude to the many stakeholders interviewed both in Jordan and elsewhere; without their contributions and insights, this article would not have been possible.

Funding: USAID.

Competing Interests: The authors disclose the receipt of a grant from the United States Agency for International Development (USAID) to conduct the programmatic assessment described in this article.

REFERENCES

1. Department of Statistics [Jordan] and ICF International. *Jordan Population and Family Health Survey 2012*. Calverton, MD: Department of Statistics and ICF International; 2013. https://dhsprogram.com/pubs/pdf/FR282/FR282.pdf. Accessed December 1, 2017.
2. Cetorelli V, Leone T. Is fertility stalling in Jordan? *Demogr Res*. 2012;26(13):293–318. CrossRef
3. Bongaarts J. The causes of stalling fertility transitions. *Stud Family Plann*. 2006;37(1):1–16. CrossRef

4. Department of Statistics [Jordan] and ICF International. *Jordan Population and Family Health Survey 2002*. Calverton, MD: Department of Statistics and ICF International; 2003. https://dhsprogram.com/pubs/pdf/FR138/FR138.pdf. Accessed December 1, 2017.
5. Department of Statistics [Jordan]. *Jordan Population and Housing Census: 2015*. Amman: Department of Statistics, Ministry of Health; 2016.
6. Ghazal M. Population stands at around 9.5 million, including 2 million guests. *Jordan Times*. January 30, 2016. http://www.jordantimes.com/news/local/population-stands-around-95-million-including-29-million-guests. Accessed March 1, 2016.
7. Higher Population Council. *National Reproductive Health/Family Planning Strategy 2013–2017*. Amman: Higher Population Council; 2013. http://data.unhcr.org/syrianrefugees/download.php?id=4774. Accessed December 1, 2017.
8. Institute for Reproductive Health. *Final Report: Jordan Family Planning Assessment*. Washington, DC: Institute for Reproductive Health, Georgetown University; 2016. http://irh.org/resource-library/jordan-family-planning-assessment/. Accessed January 23, 2017.
9. Bernard HR. *Research Methods in Anthropology: Qualitative and Quantitative Approaches*. Lanham, MD: AltaMira Press; 2006.
10. Al-Massarweh I. The proximate determinants of fertility stalling in Jordan 2002–2009. *Jordan J Social Sciences*. 2013;6(1):89–105. http://journals.ju.edu.jo/JJSS/article/view/4226. Accessed December 1, 2017.
11. Bongaarts J. A framework for analyzing the proximate determinants of fertility. *Population and Development Review*. 1978;4(1):105–132. CrossRef
12. Rashad H, Hassan Z. *A Comparative Analysis of Fertility Plateau in Egypt, Syria and Jordan: Policy Implications*. Cairo: Social Research Center, The American University in Cairo; 2013.
13. Bongaarts J, Odile F, Lesthaeghe R. The proximate determinants of fertility in sub-Saharan Africa. *Popul Dev Rev*. 1984;10(3):511–537. CrossRef
14. Jordan Communication, Advocacy, and Policy (JCAP). Knowledge, attitudes, and practices toward family planning and reproductive health among married women of reproductive age in selected districts in Jordan. JCAP; 2015. https://jordankmportal.com/resources/knowledge-attitudes-and-practices-toward-family-planning-and-reproductive-health-among-married-women-of-reproductive-age-in-selected-districts-in-jordan. Accessed March 30, 2016.
15. Sedgh G, Ashford LS, Hussain R. Unmet need for contraception in developing countries: examining women's reasons for not using a method. New York: Guttmacher Institute; 2016. https://www.guttmacher.org/report/unmet-need-for-contraception-in-developing-countries. Accessed February 19, 2016.
16. Jordan Communication, Advocacy, and Policy (JCAP). Exploring gender norms and family planning in Jordan: a qualitative study. JCAP; 2016. https://usaidjordankmportal.com/resources/exploring-gender-norms-and-family-planning-in-jordan. Accessed February 19, 2016.
17. Maffi I. *Women, Health and the State in the Middle East: The Politics and Culture of Childbirth in Jordan*. London and New York: I.B. Tauris & Co.; 2013.
18. Jordan Communication, Advocacy, and Policy (JCAP). Findings and recommendations from a key informant interview study on previous USAID-funded SBCC and A/P activities in Jordan. *JCAP*; 2015. Accessed February 19, 2016.
19. Arbaji A. Evaluation of utilization of health services delivery and health status. Bethesda, MD: Primary Health Care Initiatives (PHCI) and Abt Associates; 2005. http://pdf.usaid.gov/pdf_docs/Pdacm071.pdf. Accessed February 19, 2016.
20. Bryan PJ, Naffa RJ. Gender and social soundness analysis of the population and family health environment in Jordan. Washington, DC: Global Health Technical Bridge Project; 2012.
21. Kates J, Michaud J, Wexler A, Valentine A. *Mapping the Donor Landscape in Global Health: Family Planning and Reproductive Health*. Menlo Park, CA: The Henry J. Kaiser Family Foundation; 2014. https://kaiserfamilyfoundation.files.wordpress.com/2014/01/8541-mapping-the-donor-landscape-in-global-health-family-planning-and-reproductive-health.pdf. Accessed November 27, 2017.
22. United States Agency for International Development (USAID). *USAID's Vision for Health Systems Strengthening, 2015–2019*. Washington, DC: USAID; 2015. https://www.usaid.gov/sites/default/files/documents/1864/HSS-Vision.pdf. Accessed January 23, 2017.
23. United States Agency for International Development (USAID). *Dollars to Results: Family Planning and Reproductive Health in Jordan (Results of USAID's Family Planning and Reproductive Health Spending)*. Washington, DC: USAID; 2016. https://www.usaid.gov/data/dataset/a1ca9979-901c-4771-abe5-8ffb68223467. Accessed November 27, 2017.
24. Enhancing performance of health systems: end of project report for USAID-funded Health Systems Strengthening II Bridge project October 2014 to October 2015. Bethesda, MD: Abt Associates; 2015. http://pdf.usaid.gov/pdf_docs/PA00KTDG.pdf. Accessed February 19, 2016.
25. About Ministry of Health. Ministry of Health [Jordan] website. http://apps.moh.gov.jo/MOH/En/about.php. Accessed February 19, 2016.
26. Research insights: counseling women and couples in family planning: evidence from Jordan. Bethesda, MD: Abt Associates; 2015. http://pdf.usaid.gov/pdf_docs/PA00M11J.pdf. Accessed February 19, 2016.
27. El-Khoury M, Thornton R, Chatterji M, Choi SK. Effectiveness of evidence-based medicine on knowledge, attitudes, and practices of family planning providers: a randomized experiment in Jordan. *BMC Health Serv Res*. 2015;15:449. CrossRef. Medline
28. Al-Massarweh I. The challenges and barriers to population policy in the Jordanian society: a comprehensive evaluation based on empirical evidences. *Human Soc Sci*. 2008;(2):191–211.
29. EngenderHealth. EngenderHealth/Jordan end of project summary report: 1998–2004. New York: EngenderHealth; 2004.
30. Kamhawi S, Underwood C, Murad H, Jabre B. Client-centered counseling improves client satisfaction with family planning visits: evidence from Irbid, Jordan. *Glob Health Sci Pract*. 2013;1(2):180–192. CrossRef. Medline
31. Cobb L, Becker G, Boussen C, and et al. Evaluation of USAID/Jordan's Strategic Objective 3: Improved Quality of and Access to Reproductive and Primary Health Care. *Camden PopTech*; 2003.
32. Strengthening Health Outcomes through the Private Sector (SHOPS). Evaluation report: reach and effect of the social marketing campaign for oral contraceptive pills, 2011–13. Bethesda, MD: SHOPS, Abt Associates; 2013.
33. Health Policy Project (HPP). The Health Policy Project in Jordan: end of project report. Washington, DC: Futures Group; 2013.
34. Wickstrom J, Diagne A, Smith A. *Senegal Case Study: Promising Beginnings, Uneven Progress. A Repositioning Family Planning Case Study*. New York: EngenderHealth, ACQUIRE Project; 2006. http://www.acquireproject.org/fileadmin/user_upload/ACQUIRE/Publications/Senegal-case-study-final.pdf. Accessed December 1, 2017.
35. Pile J, Simbakalia C. *Tanzania Case Study: A Successful Program Loses Momentum. A Repositioning Family Planning Case Study*. New York: EngenderHealth, ACQUIRE Project; 2006. http://

repositioningfp.org/sites/repofp/files/tanzania_case_study_final.pdf. Accessed December 1, 2017.

36. Health Policy Initiative. Reducing discontinuation of contraceptive use and unmet need for family planning: policy options. Washington, DC: Health Policy Initiative; 2011. http://www.healthpolicyinitiative.com/Publications/Documents/1488_1_Jordan_Unmet_Need_Brief_Jan_2011.pdf. Accessed November 27, 2017.
37. USAID/Jordan. Evaluation of Jordan health communication program. Global Health Technical Assistance Project; 2011.
38. Shelton JD. The 6 domains of behavior change: the missing health system building block. *Glob Health Sci Pract.* 2013;1(2):137–140. CrossRef. Medline
39. Health Communication Capacity Collaborative (HC3). The Circle of Care Model: social and behavior change along the service delivery continuum. Baltimore, MD: HC3; 2017. https://healthcommcapacity.org/hc3resources/circle-care-model/. Accessed October 8, 2017.
40. Jordan Communication, Advocacy, and Policy (JCAP). Policies, legislation, and strategies related to family planning in Jordan: review and recommendations (December 2014–May 2015). Amman: JCAP; 2015. http://www.tawasol-jo.org/sites/default/files/policies_legistlations_and_stratgies_related_to_family_planning_in_jordan_review_and_recommendations.pdf. Accessed November 27, 2017.
41. USAID/Jordan. TFR new calculation. Internal presentation: November 11 2015; Amman, Jordan.
42. Schoumaker B. A Stata module for computing fertility rates and TFRs from birth histories: tfr2. *Demogr Res.* 2013;28(article 38):1093–1144. CrossRef

Peer Reviewed

Received: May 13, 2017; **Accepted:** November 11, 2017

Cite this article as: Spindler E, Bitar N, Solo J, Menstell L, Shattuck D. Jordan's 2002 to 2012 fertility stall and parallel USAID investments in family planning: lessons from an assessment to guide future programming. Glob Health Sci Pract. 2017;5(4):617-629. https://doi.org/10.9745/GHSP-D-17-00191

GLOBAL HEALTH: SCIENCE AND PRACTICE
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ORIGINAL ARTICLE

Food Security and Nutrition Outcomes of Farmer Field Schools in Eastern Democratic Republic of the Congo

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A farmer field school program in food-insecure areas had positive impacts on household food security but not child nutritional status. Similar agricultural interventions may benefit food security, but the more difficult-to-achieve improvements in child nutrition status may require more focused and integrated programming approaches.

ABSTRACT

Background: Food and nutrition security in eastern Democratic Republic of the Congo are threatened by political instability and chronic poverty. The Jenga Jamaa II project, implemented between 2011 and 2016 in South Kivu Province, aimed to improve household food security and child nutritional status using various intervention strategies, including farmer field school (FFS) programs.

Objective: To characterize the changes in agricultural production techniques, household food security, and child nutritional status associated with participation in FFS programs.

Methods: We used a community-matched design to select FFS intervention and control households from 3 health zones in which the project was operating. Data on food security (Household Dietary Diversity Score [HDDS] and Household Food Insecurity Access Scale [HFIAS]) and child anthropometry were collected semiannually for 3.5 years in both groups. Additional data on agricultural practices were collected annually in the FFS group only. Focus groups with FFS staff and beneficiaries were conducted in the final project year. Statistical analyses included basic descriptive statistics such as paired *t* tests and analysis of covariance; regression models using a bootstrap were applied to generate *P* values and confidence intervals while accounting for differences between groups.

Results: The study enrolled 388 FFS beneficiaries and their households in the intervention group and 324 non-FFS households in the control group. FFS participants reported increasing the number of different agricultural techniques they used by an average of 2.7 techniques over the project period, from 5.1 in 2013 to 7.9 in 2016 ($P<.001$). The mean HDDS and HFIAS improved more in the FFS group than in the control group (mean difference between intervention and control for HDDS was 0.9 points and for HFIAS was −4.6 points; $P<.001$). However, the prevalence of child stunting (60.2% intervention vs. 58.8% control) and underweight (22.3% intervention vs. 29.8% control) were similar in both groups at endline ($P>.05$).

Conclusion: Although FFS participants diversified their agricultural production strategies and experienced improvements in household food security, there was not a positive impact on child nutritional status. In this food-insecure context, improvements in agricultural production alone are unlikely to significantly change child nutritional status—a health outcome with a complex, multilevel causal chain.

INTRODUCTION

The eastern provinces of the Democratic Republic of the Congo (DRC) have been in a protracted state of emergency. Between 1998 and 2007, there were an estimated 5.4 million excess deaths, many of which occurred after the war officially concluded in 2002; most mortality was the result of nonviolent causes including malnutrition, diarrhea, and maternal complications.[1] The conflict has disrupted agricultural production and decreased harvests.[2] South Kivu, a region where insecurity and violence endure today,[3] is one of the most food- and nutrition-insecure provinces in the country.[4] Stunting affects more than half (53%) of children under 5 in South Kivu—the highest prevalence nationwide. Underweight prevalence, at 26%, is similarly high relative to other provinces, and almost two-thirds of households are moderately or severely food-insecure.[5,6]

The relationship between agriculture and nutrition is complex. While it may seem obvious that agriculture influences nutrition, numerous reviews have determined

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that the data linking agricultural interventions to nutritional impacts are often either inconclusive or incomplete.[7–12] These reviews covered a diverse range of agricultural interventions (e.g., training and/or material inputs for home gardens, household livestock production, or biofortification), which in some instances successfully increased agricultural production.

These reviews did not focus on farmer field school (FFS) programs, which are increasingly widespread development approaches to strengthen farmers' capacity to adopt ecologically friendly technologies and crop management practices, and ultimately to increase crop yields. FFS programs, which were first developed in Indonesia in 1989, are now used globally with adaptations in context and approach based on the local environment (for example, in sub-Saharan Africa, the topics covered have been expanded to include nutrition and malaria).[13]

FFS programs employ a participatory approach in which groups of farmers, steered by facilitators, engage in practical investigations, observations, and synthesis.[14] Findings on the benefits of FFS programs are mixed: some studies have shown that FFS programs have potential to change participants' agricultural practices[15] and increase revenue and productivity,[16] while other studies have suggested that FFS participation alone does not necessarily increase crop yields in the long term, but rather that additional interventions are required in combination with FFS for such gains.[17,18] Such mixed results may relate to study methodology; case studies generally show positive impacts possibly reflective of short-term effects, while relatively little improvement may be observed in longitudinal studies measuring medium-term impacts.[18]

Although questions have been raised about the cost-effectiveness and sustainability of FFS programs, there is support for the FFS approach and its benefits for participants.[13] Few studies to date have examined the food security and nutritional impacts of FFS programs. There is a complex relationship between agriculture, food security, and child nutrition, and this article examines the changes in agricultural production practices, household food security, and child nutritional status that are associated with participation in FFS programs. Our goal is to contribute to the wider body of literature concerning linkages between agriculture and health.

METHODS

This article characterizes outcomes of an FFS intervention that was one component of the Jenga Jamaa II project, a development food assistance program funded by the U.S. Agency for International Development (USAID) Office of Food for Peace. Jenga Jamaa II sought to address household food insecurity and child undernutrition. It was implemented by Adventist Development and Relief Agency (ADRA) in Fizi and Uvira territories of South Kivu Province between 2011 and 2016 (Figure) and reached more than 258,000 beneficiaries with the following objectives:

Jenga Jamaa II was a 5-year development food assistance program that sought to address food insecurity and child undernutrition.

1. Increasing incomes among farming households through FFS and farmer-to-farmer training interventions
2. Improving the health and nutritional status of children under 5 years of age through the Preventing Malnutrition in Children under 2 Approach (PM2A)
3. Empowering women via women's empowerment groups

Farmer field schools are increasingly common approaches to improving both ecological practices and crop yields.

The research reported here derives from a subset of the data from the parent study of Jenga Jamaa II outcomes. Additional findings, including a comparison of all interventions, are presented elsewhere, along with more detailed information about overall study methods and statistical analyses.[19,20] Here we summarize the methods relevant to the current research, as well as information specific to the FFS analysis.

Intervention

The FFS intervention provided farmers with experience-based education on farming practices and postharvest handling as well as business and natural resource management skills. Each FFS group received semimonthly trainings from ADRA field agents for 2 years. Each FFS group had a community demonstration plot, and group members also received starter packages of seeds and tools for use on individual farms. The FFS programs focused on a variety of common crops in the region, including cassava, maize, rice, beans, banana, and peanuts. The first year of training focused on knowledge of production systems and technologies; adoption of techniques and technologies and behavior change were the focus in the second year. Content was designed to be crop-specific and seasonally appropriate. After completing the FFS intervention, many beneficiaries transitioned to farmer business associations, which were intended to improve access to credit and marketing opportunities.[19]

The Jenga Jamaa II farmer field schools provided education on farming practices, postharvest handling, and business and natural resource management skills.

FIGURE. Map of the Jenga Jamaa II Project and Study Area

Adapted from User:Profoss. File:Democratic Republic of the Congo (26 provinces)-Sud-Kivu.svg. Wikimedia Commons. February 16, 2016. https://commons.wikimedia.org/wiki/File:Democratic_Republic_of_the_Congo_(26_provinces)_-_Sud-Kivu.svg. Accessed November 28, 2017.

Sample Size

For this article, we analyzed 2 of the 5 comparison groups recruited for the parent study of Jenga Jamaa II: the FFS intervention group (388 participants) and the control group (324 participants). The primary outcome measure was reduction in household food insecurity, and we conducted calculations for varying levels of reduction, assuming 80% power and a significance level of .05. With a minimum sample size of 325 households per group (or 1,625 households in total for the parent study), the study was powered to detect a 10% or greater reduction in prevalence of food insecurity indicators within each comparison group, as compared to baseline levels.[19]

Study Design and Data Collection

The Jenga Jamaa II parent study used a quasi-experimental matched design in which communities planned to receive 1 intervention (versus multiple interventions) selected for participation so that the effect of individual interventions could be assessed. The 4 Jenga Jamaa II interventions were women's empowerment groups, PM2A, FFS, and farmer-to-farmer training; a fifth comparison group was recruited as a control group. Participating communities within each territory (Fizi and Uvira) were matched by livelihood zone (mountains, plains, or lakeside) and proximity into sets of villages with each type of intervention. The final sample had 13 sets of 3 villages; within each set of villages, one village received agricultural interventions, the second received PM2A, and the third received women's empowerment groups. In each set of villages, intervention groups were formed (i.e., 1 intervention per village) and all beneficiaries in the group were enrolled in the study. In agricultural intervention villages, the entire FFS group of approximately 30 beneficiaries was enrolled in the study. Controls were selected from women's empowerment group villages, where each beneficiary was matched with a female neighbor not participating in Jenga Jamaa II interventions, and that woman's household was enrolled as a control.

The Jenga Jamaa II project enrolled study participants between August and October 2012, follo-

wing identification of beneficiaries for each intervention. A total of 1,820 beneficiaries and their households were enrolled; this included 1,385 child household members born between July 2010 and December 2012 (this age group was identified specifically for the PM2A intervention). All children in enrolled households born during the eligibility period were included in the anthropometric assessments.

Study households were followed for 3.5 years, from enrollment in the fall of 2012 (baseline) through February or March 2016 (endline), regardless of whether the Jenga Jamaa II beneficiary graduated or dropped out of the intervention. Data were collected in 8 semiannual surveys (August/September and February/March) to account for seasonal variations in food security.[20] Both data collection periods were at the beginning of local rainy seasons.[21]

The survey questionnaire focused on measures of food security, household economy, dietary intake, and nutritional status. The study team also collected annual data from the FFS group on agricultural practices related to production, adoption of farming practices, postharvest storage methods, and 18 agricultural technologies (mulching, crop rotation, row planting, weeding, contour lines, hoeing, organic fertilizer, intercropping, organic pesticide, mounding, improved seeds, resistant cassava varieties, resistant banana suckers, animal traction, sprayers, tractors, other techniques, other technologies).

The questionnaire was developed using validated measures such as those from Demographic and Health Surveys, food security assessments, and Food for Peace program indicators.[19] Food security indicators included the Household Dietary Diversity Score (HDDS) and the Household Food Insecurity Access Scale (HFIAS),[22–24] both of which are validated and widely used, including as Food for Peace program indicators. HDDS is a proxy measure of household food access that assesses household dietary quality based on reported consumption of 12 food groups in the preceding 24 hours; households consuming 5 or more food groups are classified as achieving target dietary diversity.[23] HFIAS measures household food insecurity over the preceding month using a 9-item questionnaire that measures key domains of food access; responses are summed to create a total score between 0 (most food secure) and 27 (most food insecure), which can also be interpreted categorically.[24] The questionnaire was developed in English and translated to Swahili, the predominant local language; it was finalized after Jenga Jamaa II pilot testing and translation review.[19]

The primary measures for child growth were stunting, or low height-for-age, and underweight, or low weight-for-age. Anthropometric data (weight and height) were collected at each semiannual survey for all children in enrolled households born between July 2010 and December 2011. Weight was measured using Tanita Mommy and Baby Infant Scales, Model 1582 (Arlington Heights, IL, USA), and Shorr Productions height boards (Olney, MD, USA); recumbent length was measured for children 6 to 23 months of age and height for children older than 24 months.[20]

The study began collecting data with paper questionnaires, then transitioned to electronic data collection, using the Magpi platform (Datadyne, LLC), approximately halfway through the study. Due to high levels of illiteracy, oral consent was obtained at enrollment and at each subsequent survey; participants were reminded that participation was voluntary and that declining to participate in the study would not affect benefits received from participating in Jenga Jamaa II. Study participants received a small incentive, most often soap, worth approximately US$1, for participation in each survey.[20]

Semiannual surveys assessed household food security and dietary diversity.

Qualitative research included 7 focus groups of 6 to 8 FFS beneficiaries; 2 group interviews with ADRA field agents; and 7 individual key informant interviews with community leaders. ADRA management and technical staff also participated in interviews and responded to queries related to program delivery. Qualitative data collection occurred at the end of the project period and focused on (1) overall perceptions of problems currently faced by communities, (2) if and how the FFS intervention helped to mitigate these difficulties, and (3) identifying which program elements were most useful and most challenging. Focus group and key informant interview results were analyzed using qualitative description and content analysis.

Focus groups and interviews at the end of the project solicited feedback on if and how the farmer field schools helped address identified community problems.

Statistical Analysis

Data analysis was performed using Stata 13 (StataCorp, 2013). Exploratory analysis included calculating unadjusted means and prevalence of binary indicators for each survey and identifying outliers; assessing patterns of missing data and dropouts across study groups and assessing differences in outcomes between those who had dropped out or been absent for the previous survey and those who had

not; and assessing correlation over time using autocorrelation matrices for continuous outcomes and lorelograms for binary outcomes.[25]

With the exception of imputation procedures for the child anthropometric data, our analysis did not consider interim measures of each indicator because after exploratory analysis, it became clear that inclusion of interim data points did not change results and conclusions, and thus eliminating analysis of interim measures would facilitate the interpretation of findings. The strengths of the analysis are (1) its use of propensity scores to account for differences between groups, (2) its ability to account for baseline differences in the outcome indicators between groups, and (3) its controls for differences in territory and livelihood zones (mountains, plains, or lakeside).

The results presented include only the 82% of study participants who were present for both baseline and endline surveys (both of which were conducted in the February/March time period). The village of Kibirizi, which included 1 FFS group, was not included in the final endline survey (and thus was excluded from the final evaluation) due to security concerns. Despite our inability to access Kibirizi for the final survey, participant follow-up was considered high given the context and the 3.5-year data collection period that was necessary for adequate assessment of medium-term changes in food security indicators.[19]

To estimate differences in outcomes between groups over time, we used analysis of covariance (ANCOVA) to estimate mean change in the outcome variable. We compared the last follow-up to baseline for each treatment group separately; the outcome at endline for the intervention group was then compared to the endline outcome for the control group. ANCOVA allows precise estimates by accounting for chance imbalance across intervention groups in baseline variables that are prognostic for the outcome of interest (e.g., stratification variables and the baseline outcome). We used a linear model for the outcome at the last follow-up, with main terms for the intervention group (4 dummy variables), the baseline outcome, and 2 stratification variables (territory and livelihood zone). Maternal age and education were also included in models for child diet and nutritional outcomes. For binary outcomes, prevalence at the last follow-up was estimated for each intervention group; the treatment effect was defined as the difference in prevalence found by comparing each intervention group to the control. The analysis included adjustment for the stratification variables, baseline outcome in the case of child outcomes, and maternal characteristics. To estimate the treatment effects, an outcome regression estimator referred to as the doubly robust weighted least squares estimator was used, which is analogous to the ANCOVA approach but applies to non-continuous outcomes.[26,27] Standard errors, confidence intervals (CIs), and *P* values were generated using a bootstrap.

Anthropometric *z* scores for children 6 to 59 months of age were calculated using the 2006 World Health Organization (WHO) child growth standards with the user-written Stata program zscore06.[28] Anthropometric *z* scores for children over 5 years of age were calculated using the 2007 WHO reference for children 5 to 19 years, using the Stata program zanthro.[29] Children with a height-for-age *z* score (HAZ) less than −2 were classified as stunted, and those with a HAZ less than −3 as severely stunted; similarly, children with a weight-for-age *z* score (WAZ) less than −2 were classified as underweight and those with a WAZ less than −3 as severely underweight. We used a multiple imputation approach for anthropometric outcomes, where missing values were replaced by values sampled from a distribution defined by the fit of a linear regression model at a given follow-up as a function of previous outcomes, as well as of child age and sex.

The methods described here were applied to each survey data set and then averaged using Rubin's method to obtain final estimates.[30] Propensity scores were used to account for the non-randomized design. Propensity score weights were defined using beneficiary age, sex and education (for the control group maternal age and education were used in lieu of beneficiary characteristics); household landownership and number of income sources; and number of children under 2 years old in the household. Models for child outcomes accounted for within-household clustering. Children who died were excluded from the analysis, and missing values for maternal age and education were assigned the mean and mode of those variables, respectively, so they could be included in the analysis. The model coefficient for the FFS group represents the estimated difference compared to the control group.[20]

Ethical Approvals

Approval to conduct the parent study was obtained from local authorities in the relevant administrative areas of South Kivu and from the Institutional Review Board of the Johns Hopkins Bloomberg School of Public Health.

TABLE 1. Baseline Demographic Characteristics for Intervention and Control Groups, 2012

	Intervention Group: FFS Beneficiaries (n=388)	Control Group: Non-FFS Participants (n=324)	*P* Value[a]
Respondent Characteristics[b]			
Sex, % Female	69.4	100	**<.001**
Age, years			
Median	35	28	–
Mean (SD)	37.9 (13.4)	31.1 (10.2)	**<.001**
Highest level of education, %			.07
None	72.1	75.0	
Primary	25.0	25.0	
Secondary	2.9	0.0	
Household Characteristics			
Household size			
Median	6	6	–
Mean (SD)	6.2 (2.4)	6.3 (2.4)	.58
Maternal highest level of education, %			
None	90.1	74.5	
Primary	9.9	24.5	**.002**
Secondary	0.0	1.0	
Maternal age			
Median	29	28	–
Mean (SD)	32.8 (11.3)	31.1 (10.2)	.15
Number of children ages 2–4 years			
Median	1	2	–
Mean (SD)	1.5 (1.1)	1.8 (1.1)	**<.001**
Number of children ages <2 years			
Median	0	1	–
Mean (SD)	0.5 (0.5)	0.7 (0.5)	**<.001**
Households with farmer, %	98.7	95.4	**.007**
Households owning farmland, %	69.4	68.6	.85

Abbreviations: FFS, farmer field school; SD, standard deviation.
[a] *P* values in boldface indicate differences significant at the $P<.05$ level. *P* values were generated from Pearson's chi-square test for binary and categorical variables, and *F* test for means (analysis of covariance, or ANCOVA) for continuous variables.
[b] FFS respondents were the primary beneficiaries of the FFS intervention, whereas respondents in the control group were most often mothers of children in the household.

RESULTS

Demographic Characteristics

This study enrolled 388 FFS beneficiaries and their households in the intervention group and 324 non-FFS adults and their households in the control group (Table 1). For the control group, we enrolled the primary caretaker of children, and 100% were women. For the FFS group, we enrolled the FFS beneficiary and his or her household, and 69% of those enrolled were women ($P<.001$). The FFS and control groups were

similar with respect to household size (median=6), but the intervention group households had significantly fewer young children ($P<.001$ for both children under 2 years and children between 2 and 4 years old). The groups were similar with respect to land ownership (69% owned land), and more than 95% of households in each group reported having farmers, though this proportion was significantly higher in the FFS group ($P=.007$). FFS beneficiaries were significantly older than those enrolled as control group participants (mean age 38 years vs. 31 years, $P<.001$). In both groups, maternal educational attainment was low overall, with over 90% of FFS group mothers and 74% of control group mothers having not completed any formal schooling ($P=.002$).

Use of Agricultural Techniques Among FFS Beneficiaries

Farmers who attended farmer field schools increased the number of different agricultural techniques they used.

Over the 4-year intervention period (2012–2016), the number of agricultural techniques and technologies that the FFS beneficiaries used increased from an average of 5.1 reported in 2013 to 7.9 in 2016 ($P<.001$) (Table 2). Of the 18 techniques and technologies assessed, 6 techniques saw both statistically significant increases in use and were used by more than 20% of the FFS households at the end of the project period in 2016. Weeding (96.2%), hoeing (95.9%), and row planting (92.7%) were the most commonly used techniques. Crop rotation, mulching, and row planting had the highest adoption rates, with increases of 58.8%, 48.9%, and 40.4%, respectively, of households adopting the techniques following FFS participation. Statistically significant increases in use of sprayers, organic pesticide, organic fertilizer, tractors, and animal traction were also observed, but adoption was below 20% at the end of the project. No significant changes were observed in use of improved banana suckers, contour lines, hoeing, intercropping, and other techniques. Use of resistant cassava varieties saw a significant decrease (−12.4%, $P=.02$), although adoption remained high at endline (59%); other technologies also decreased significantly ($P<.001$), with adoption under 1% at endline.

Use of Marketing and Financial Services Among FFS Beneficiaries

After participating in a farmer field school, farmers adopted several new marketing techniques.

Before FFS participation, the most commonly used marketing strategy was individual crop sales, reported by 64% of households; other marketing strategies were used by less than 1% of households (Table 2). We found high levels of adoption of the various marketing strategies following the FFS intervention, with statistically significant increases in the proportion of households reporting use of joint negotiation at the FFS (68.8%) and farmer business association levels (56.3%), as well as in sales through agricultural collection centers (29.8%; $P<.001$ for all comparisons) (Table 2). Use of financial services also changed over the course of the intervention. Before FFS, informal credit was the most common financial service, used by 22.6% of households, whereas by the end of the project period, use of informal credit decreased by 8.4% ($P=.006$) and use of savings increased by 43.1% ($P<.001$). Both use of formal credit and use of insurance increased during the intervention period, but these increases were not significant and rates of adoption by FFS households were below 10% at the end of the project, due largely to poor access to these types of services in study areas.

Household Food Security Outcomes

At enrollment, mean HDDS among the FFS group was 3.4; this increased to 5.6 at the end of the project (mean change=2.1; 95% CI, 1.9 to 2.4; $P<.001$) (Table 3). In comparison, a smaller increase, from 3.4 to 4.8, was observed among the control group (mean change=1.4; 95% CI, 1.0 to 1.7; $P<.001$). In the adjusted analysis at endline, the mean difference between the 2 groups was 0.9 points (95% CI, 0.5 to 1.3; $P<.001$). Similarly, the difference in the adjusted proportion of FFS and control households achieving target dietary diversity at endline was 21.7% (95% CI, 12.3 to 31.1; $P<.001$). HFIAS scores decreased by 8.6 points (95% CI, −9.4 to −7.9; $P<.001$) in the FFS group and 4.7 points in the control group (95% CI, −5.7 to −3.7; $P<.001$) over the project period. After adjustment, the difference in mean HFIAS change between the 2 groups was −4.6 points (95% CI, −5.0 to −4.2; $P<.001$). At end of the project period, the proportion of households that improved an HFIAS category was 22.9% higher in the FFS group than in the control group (95% CI, 12.7 to 33.1; $P<.001$).

Child Nutrition Outcomes

At the end of the project, the FFS group had an adjusted stunting prevalence of 60.2% as compared to 58.8% in the control group (Table 4); the 1.4% difference in stunting prevalence between groups was not statistically significant ($P=.81$). Similarly, the FFS group had an adjusted underweight prevalence of 22.3% as compared to

TABLE 2. Percentage of Intervention Households That Used Agricultural Techniques and Business Development Strategies in the Most Recent Growing Season,[a] 2013–2016

	2013 (n=370)		2014 (n=350)		2015 (n=388)		2016 (n=317)		Change (2013–2016)	
	Point[b]	95% CI	Point	95% CI	Point	95% CI	Point	95% CI	Point	*P* Value[c]
Agricultural techniques[d]										
All techniques (mean)	5.1	(5.0 to 5.4)	6.5	(6.3 to 6.7)	7.6	(7.3 to 7.8)	7.9	(7.7 to 8.2)	2.7	<**.001**
Mulching	28.9%	(24.2 to 34.1)	46.7%	(41.3 to 52.1)	71.5%	(66.7 to 76.0)	77.8%	(72.9 to 82.3)	48.9%	**.001**
Crop rotation	18.1%	(14.2 to 22.6)	32.8%	(27.8 to 38.0)	59.4%	(54.2 to 64.4)	76.9%	(71.9 to 81.4)	58.8%	**.001**
Row planting	52.3%	(46.9 to 57.7)	63.5%	(58.2 to 68.6)	84.1%	(80.0 to 87.6)	92.7%	(89.3 to 95.3)	40.4%	**.001**
Weeding	82.7%	(78.3 to 86.6)	93.0%	(89.8 to 95.0)	97.6%	(95.5 to 98.9)	96.2%	(93.4 to 98.0)	13.5%	**.001**
Contour lines	80.1%	(75.5 to 84.2)	76.5%	(71.7 to 80.9)	72.1%	(67.3 to 76.6)	79.1%	(74.2 to 83.4)	−1.0%	.68
Hoeing	93.3%	(90.1 to 95.7)	97.4%	(95.1 to 98.8)	97.4%	(95.2 to 98.7)	95.9%	(93.1 to 97.8)	2.6%	.38
Intercropping	41.9%	(36.6 to 47.4)	50.4%	(45.0 to 55.8)	49.1%	(43.9 to 54.2)	42.7%	(37.2 to 48.4)	0.8%	.80
Mounding	18.2%	(14.2 to 22.7)	22.0%	(17.8 to 26.8)	30.1%	(25.5 to 35.1)	30.7%	(25.7 to 36.1)	12.5%	**.006**
Improved seeds	41.1%	(35.9 to 46.6)	73.6%	(68.6 to 78.2)	81.0%	(76.7 to 84.9)	75.0%	(69.8 to 79.7)	33.9%	<**.001**
Resistant cassava varieties	71.6%	(66.4 to 76.3)	75.4%	(70.5 to 79.8)	74.1%	(69.4 to 78.5)	59.2%	(53.5 to 64.6)	−12.4%	**.02**
Marketing strategies[d]										
Individual	64.0%	(58.4 to 68.9)	71.3%	(66.2 to 76.0)	63.8%	(58.6 to 68.9)	58.8%	(53.2 to 64.3)	−5.2%	.35
Agriculture collection center	0.3%	(0.0 to 1.6)	0.0%	(0.0 to 1.1)	5.5%	(3.4 to 8.4)	30.1%	(25.1 to 35.4)	29.8%	<**.001**
Joint negotiation at FFS level	0.8%	(0.1 to 2.5)	1.4%	(0.5 to 3.3)	22.1%	(17.9 to 26.7)	69.6%	(64.2 to 74.6)	68.8%	<**.001**
Joint negotiation at FBA level	0.3%	(0.0 to 1.6)	0.6%	(0.1 to 2.1)	15.9%	(12.3 to 20.1)	56.6%	(51.0 to 62.1)	56.3%	<**.001**
Financial services[e]										
Informal credit	22.6%	(18.3 to 27.4)	4.3%	(2.5 to 7.1)	7.4%	(4.9 to 10.6)	14.2%	(10.6 to 18.6)	−8.4%	**.006**
Savings	7.2%	(4.7 to 10.5)	22.3%	(18.0 to 27.1)	36.7%	(31.8 to 41.9)	50.3%	(44.7 to 56.0)	43.1%	<**.001**

Abbreviations: CI, confidence interval; FBA, farmer business association; FFS, farmer field school.
[a] "Most recent growing season" refers to the season preceding interviews conducted in February/March of indicated year.
[b] "Point" refers to point estimate (% or mean) in each column.
[c] *P* values in bold text indicate differences significant at the $P < .05$ level.
[d] Results for agricultural techniques with less than 20% adoption at endline (e.g., organic pesticide, organic fertilizer, virus-resistant banana suckers, tractors, animal traction for tillage, sprayers, other techniques, and other technology) are not presented in the table.
[e] Results for marketing strategies and financial services with less than 10% adoption at endline (e.g., formal credit and insurance) are not presented in the table.

29.8% in the control group, and the 7.6% difference in underweight prevalence between groups was also not statistically significant (*P*=.13).

Beneficiary Perceptions of FFS Programming

Participants described the FFS programs as leading to many benefits. First, they noted that the improved agricultural techniques they learned were helpful, particularly in poor growing seasons. In addition, beneficiaries explained that working in a group improved their leadership skills and ability to work cooperatively. The FBAs that some FFS programs formed were perceived to improve business skills (e.g., assessing markets, setting fair prices, and negotiating jointly via group contracts).

Although beneficiaries had generally positive impressions of participation in the FFS, the FFS program was not without challenges. Crop diseases, particularly the emergence of cassava brown streak disease and the widespread prevalence of cassava mosaic disease and banana wilt, posed problems and diminished the participants' harvests. Delayed arrival of seeds was another

Participants described the farmer field schools as leading to many benefits, including improved agricultural, leadership, and business skills.

TABLE 3. Differences in Household Food Security Outcomes Between the Intervention and Control Groups

	Intervention Group: FFS Beneficiaries (n=317)	Control Group: Non-FFS Participants (n=254)	Difference Between Groups	*P* Value
Household Dietary Diversity Score[a]				
Baseline, mean (SD)	3.4 (1.4)	3.4 (1.5)	–	–
Endline, mean (SD)	5.6 (2.1)	4.8 (2.1)	–	–
Change over time,[b] adjusted[c] mean (CI)	2.1 (1.9 to 2.4)	1.4 (1.0 to 1.7)	0.9 (0.5 to 1.3)	<.001
Achieved target at endline,[c] % (CI)	69.7 (63.6 to 75.9)	48.0 (40.6 to 55.3)	21.7 (12.3 to 31.1)	<.001
Household Food Insecurity Access Scale				
Baseline, mean (SD)	14.4 (4.6)	14.8 (5.3)	–	–
Endline, mean (SD)	5.7 (5.1)	10.1 (6.1)	–	–
Change over time,[b] adjusted[c] mean (CI)	−8.6 (−9.4 to −7.9)	−4.7 (−5.7 to −3.7)	−4.6 (−5.0 to −4.2)	<.001
Improved a category[c] (baseline to endline), % (CI)	55.3 (48.8 to 61.9)	32.4 (24.6 to 40.3)	22.9 (12.7 to 33.1)	<.001

Abbreviations: CI, confidence interval; FFS, farmer field school; SD, standard deviation.
[a] Each point corresponds to a food group.
[b] Paired *t* test.
[c] Adjusted for baseline Household Dietary Diversity Score, territory, and agro-ecological zone.
[c] Adjusted for baseline score on the Household Food Insecurity Access Scale, territory, and agro-ecological zone.

TABLE 4. Differences in Child Nutrition Outcomes at Endline Between the Intervention and Control Groups

	Intervention Group: Children of FFS Beneficiaries (n=265)	Control Group: Children of Non-FFS Participants (n=206)	Difference Between Groups	*P* Value
Adjusted endline stunting prevalence,[a] % (CI)	60.2 (50.8 to 69.6)	58.8 (50.1 to 67.5)	1.4 (−10.7 to 13.6)	.81
Adjusted endline underweight prevalence,[b] % (CI)	22.3 (14.8 to 29.8)	29.8 (22.0 to 37.7)	−7.6 (−17.7 to 2.5)	.13

Abbreviations: CI, confidence interval; FFS, farmer field school; SD, standard deviation.
[a] Adjusted for baseline stunting status, territory, agro-ecological zone, maternal age, and maternal education; children with a height-for-age *z* score less than −2 SD using the 2006 WHO child growth standards (for children ages 6–59 months) and the 2007 WHO reference (for children over 5 years) were classified as stunted.
[b] Adjusted for baseline underweight status, territory, agro-ecological zone, maternal age, and maternal education; children with a weight-for-age *z* score less than −2 SD using the 2006 WHO child growth standards (for children ages 6–59 months) and the 2007 WHO reference (for children over 5 years) were classified as underweight.

contributor to weakened production. Participants also referenced obsolete and inefficient tools as barriers to improved income, and proposed mechanization and use of improved technologies (e.g., tractors and motorized mills) as solutions.

Staff Perceptions of FFS Programming

The challenges described by FFS program staff differed from those recognized by beneficiaries. Staff identified the lack of coordination between organizations in the region as a principal challenge, where the types and amounts of agricultural inputs and incentives provided to beneficiaries varied, leading to disappointment among participants. Staff agreed with participants that late seed arrival posed a significant challenge. In addition, some communities were remote and inaccessible, making it hard for beneficiaries to move their goods to markets. Even with these difficulties, field agents and staff felt that the FFS interventions offered benefits to the participants; for example, by the end of the program, staff indicated that participants were more likely to sell crops to

improve their household's dietary diversity, demonstrating a change in mind-set. Furthermore, marketing activities contributed to sales at more stable prices.

DISCUSSION

Over the course of the 4-year implementation period (from enrollment in 2012 through endline data collection in 2016), participants in the FFS intervention increased use of improved agricultural techniques, diversified their business strategies, and experienced improvements in household food security. However, these gains did not translate into improvements in child nutritional status. These findings highlight the complex relationship between agriculture, food security, and nutrition and the difficulties of achieving sustained changes in health status in low-resource settings. While changes in the yields or income of participating farmers are not presented here, there was a statistically significant increase over time in the number of improved agricultural techniques used, and farmers noted in focus group discussions that these techniques helped improve production; the focus groups also indicated that the diversified marketing and sales strategies were beneficial. Thus, our findings appear to support other reports of the agriculturally beneficial effects of FFS programs.[15,16]

While many FFS programs aim to improve food security,[31] there have been relatively few studies that have assessed whether FFS participation impacts household food security. One study that examines this relationship, conducted in Tanzania, found "strong and sustained positive effects on food security among the participating households . . . in terms of access to food, food consumption, and quality of diet."[32(p853)] In Malawi, FFS programs were incorporated into a complex program designed to impact health and HIV vulnerability, and the intervention group had decreased odds of food insecurity.[33] Similarly, the Jenga Jamaa II FFS group, when compared to the control group, had significantly increased HDDS and decreased HFIAS scores, thus reflecting improvements in household food access. It is important to note, however, that nearly half of all Jenga Jamaa II participants overall were still considered severely food-insecure at endline.[19]

Our study found that improvements in household food security did not appear to translate into improved nutritional status among children. This finding is aligned with several other reviews that failed to find consistent positive effects on nutrition from a variety of agricultural projects.[7–12] Similarly, a systematic review was unable to find evidence of the effect of FFS programs on farmer health outcomes.[31] While agricultural programs have sometimes been found to improve indicators associated with child nutrition and diet, significant changes in child anthropometry are rare. For example, one homestead agriculture and behavior change intervention in Burkina Faso demonstrated benefits in terms of reductions in child diarrhea and child anemia, with a marginal improvement in child wasting; no benefits were observed with respect to child underweight or stunting.[34] In Nepal, a homestead food production and nutrition education program demonstrated similar findings, with improvements in maternal underweight and child anemia, but no significant gains in child anthropometric outcomes.[35] Another study, in Cambodia, compared food security and nutrition outcomes between comparison areas receiving only agricultural programming (including an FFS) and intervention areas receiving both agricultural programming and nutrition education. While child dietary diversity improved significantly more in the intervention areas, child anthropometry *z* scores did not appear to be influenced by the intervention.[36] There are many pathways through which agriculture can influence health, but successful changes in nutritional status are most likely when the emphasis is not on food production alone, but also on improving livelihoods, empowerment, and capacity.[37]

Changes in nutritional status are most likely when the emphasis is not on food production alone, but also on improving livelihoods, empowerment, and capacity.

The concept of nutrition-sensitive agriculture has been promoted in recent years as a programming strategy that can raise incomes, increase female empowerment, bolster food production, and improve health. To accomplish these goals, however, the programs must explicitly set out to change child nutritional status. Furthermore, nutrition-sensitive agriculture seeks to connect disciplines and interventions on multiple levels,[38] with programming that encourages education, behavior change, sustainability, and cross-sectoral collaboration.[39] In this vein, the parent Jenga Jamaa II project included women's empowerment, FFS programs, and behavior change education components (the latter being focused on child health and accompanied by supplementary rations); households in the study reported here, however, benefited from the FFS programs only. In the future, increased nutritional impact may be found where beneficiaries are exposed to interventions that cut across multiple sectors.

Improvements in household food security from 2012 to 2016 did not translate to improvements in child nutritional status.

In the case of our FFS intervention group, there are many potential reasons, apart from the FFS not being an integrated approach, for the

failure of improved agricultural productivity and household food security to lead to improved child nutrition. Since child health outcomes are the product of multilevel factors at multiple life stages, improvements in household food security in this context may not outweigh the chronic impacts of poor sanitation, unstable livelihoods, and poverty.

For example, in rural DRC, access to improved sanitation and water sources is limited; diarrheal diseases are common among children (the 2013–2014 Demographic and Health Survey showed that almost one-fifth of children in the DRC had experienced diarrhea in the 2 weeks preceding the survey).[6] There are physiological, social, and economic pathways through which long-term exposure to enteric infectious agents, and generally poor water, sanitation, and hygiene conditions, can increase the risk for chronic malnutrition.[40] Thus, even if children are eating more and better food, their growth may still be compromised by, for example, poor absorption of nutrients and persistent immune response caused by subclinical infections and environmental enteric dysfunction.[41]

Furthermore, rain-fed agriculture is a risky undertaking, with harvests dependent on factors completely outside the control of the farmer. In the case of the Jenga Jamaa II FFS participants, crop diseases also posed a significant challenge, threatening harvests and perhaps attenuating some of the benefits of FFS participation, particularly among cassava-growing households. Finally, extreme poverty (in 2012, 65% of DRC's rural population lived below national poverty lines[42]) and low agricultural productivity are linked in a self-perpetuating cycle that exacerbates food insecurity in the DRC.[43] Thus, optimal child growth is undermined on multiple levels by multisectoral challenges.

Children in the households participating in our FFS and control groups had baseline mean height-for-age z scores of −1.8 and −1.5, respectively, reflecting their poor nutritional status before the FFS programs commenced. It is difficult to reverse stunting that occurs before the age of 2 years.[44] Although all children were under age 2 when enrolled in this study, some children were exposed to the program for only a short time before completing their first 1,000 days. As stunting is an indicator of chronic undernutrition, it is not likely that short-term exposure to an intervention will dramatically change the nutritional status of older children who already have poor nutritional status. More intensive and long-term programming may be needed to achieve sustained food security and nutrition improvements in low-resource and post-emergency contexts.

Stunting is an indicator of chronic undernutrition, and short-term exposure to an intervention is unlikely to dramatically change the nutritional status of older children.

Behavioral and knowledge barriers may also prevent improvements in household food security from affecting the nutritional status of children within those households. For example, focus group discussions with other Jenga Jamaa II participants in the DRC revealed that high-quality animal-source foods were frequently saved for the adult men in the households. Furthermore, women who worked in agricultural fields sometimes needed to leave their children with someone outside the household, and that person may not have been able to provide a diverse diet. In addition, caregivers were often unaware of ways to add nutritious foods to enrich the starchy porridges that are a common complementary food in the DRC.[45]

One limitation of the Jenga Jamaa II FFS intervention was lack of availability and timeliness of inputs. Seeds were sometimes delivered late and could not be planted at the optimal time in the growing season, thus limiting their usefulness.[46] Insecurity also complicated both program delivery and data collection in some communities. The FFS intervention required a community-matched design; a randomized controlled trial would have been preferred but was not feasible. Selection bias may have resulted; program staff endeavored to enumerate comparable groups to minimize any impact, and key confounding variables were controlled for in the analyses through propensity score matching. Because the design was not randomized, however, we cannot rule out the possibility that factors other than the intervention were responsible for the changes observed. It is also possible that spillover from the intervention areas affected the control areas.

In addition, we made several decisions to streamline overall data interpretation: The food security results presented here include information only for participants who responded at both endline and baseline; interim measures were not included in the analysis. Due to lower child participation rates toward the end of the study, a multiple imputation approach was used for child nutrition outcomes: missing child outcomes were replaced by imputed values sampled from the fit of a linear regression model for the child outcomes at a given follow-up as a function of previous outcomes, as well as of child age and sex, then averaged using Rubin's method to obtain final estimates. It was not desirable to compare endline child nutrition outcomes to baseline because study enrollment occurred while many women were pregnant, making baseline anthropometric data unavailable for a large number of children.

Finally, data quality was a limitation for some indicators. We intended to measure agricultural yields, with the aim of reporting outcomes in terms of changes in agricultural techniques, crop production, household food security, and child nutritional status. However, due to concerns about the quality and consistency of agricultural yield data and our inability to validate the data collection approach, we concluded that the yield data were unreliable and should not be presented. We were thus unable to characterize FSS outcomes across the full pathway of outcomes as initially intended.

CONCLUSIONS

Participation in the Jenga Jamaa II project's FFS intervention in South Kivu was associated with improvements in agricultural production and household food security, but it did not have a significant impact on child nutrition outcomes. To date, few studies have investigated the links between FFS programs, household food security, and child nutrition outcomes; this study therefore begins to address a gap in the evidence.

Several recommendations emerge from the Jenga Jamaa II FFS experience that can inform future implementation of similar agricultural interventions. First, efforts to procure and ensure supply chain function should be established early so that input delivery and planting can happen at ideal times to maximize crop yields. In places where crop diseases are a major challenge, agricultural inputs should include resistant seeds and FFS curricula should include a strong focus on techniques to mitigate and prevent prevalent crop diseases. Since improved agricultural production will be less meaningful if farmers are unable to effectively sell their harvests, FFS programs and similar interventions should be paired with marketing training and, when appropriate, the formation of agricultural collection centers.

Further research is needed to understand whether FFS programs combined with nutrition-sensitive strategies and behavior change communication can improve child nutrition. Agricultural interventions similar to FFS programs may show increased impact on child growth outcomes if beneficiaries are exposed to focused and integrated programming specifically designed to improve nutritional status.

Funding: The Jenga Jamaa II project and this research were funded through a USAID Office of Food for Peace Cooperative Agreement (AID-FFP-A-11-00006).

Competing Interests: None declared.

REFERENCES

1. Coghlan B, Ngoy P, Mulumba F, et al. *Mortality in the Democratic Republic of Congo: An Ongoing Crisis*. New York, NY: International Rescue Committee; 2007. https://www.rescue.org/sites/default/files/document/661/2006-7congomortalitysurvey.pdf. Accessed February 9, 2017.
2. Kandala NB, Madungu TP, Emina JBO, Nzita KPD, Cappuccio FP. Malnutrition among children under the age of five in the Democratic Republic of Congo (DRC): does geographic location matter? *BMC Public Health*. 2011;11(1):261. CrossRef. Medline
3. Democratic Republic of the Congo. World Food Programme website. http://www1.wfp.org/countries/democratic-republic-congo. Published 2017. Accessed March 16, 2017.
4. U.S. Agency for International Development (USAID). *USAID Office of Food for Peace Food Security Desk Review for Katanga, North Kivu, and South Kivu, Democratic Republic of Congo*. Washington, DC: FHI 360/FANTA; 2015. https://www.fantaproject.org/sites/default/files/resources/FFP-Kivu-Katanga-Desk-Review-Nov2015.pdf. Accessed October 13, 2017.
5. World Food Programme, International Food Policy Research Institute, Democratic Republic of Congo. *Comprehensive Food Security and Vulnerability Analysis (CFSVA): Democratic Republic of Congo*. Rome, Italy: World Food Programme; 2014. http://documents.wfp.org/stellent/groups/public/documents/ena/wfp266329.pdf?iframe. Accessed January 10, 2017.
6. Ministère du Plan et Suivi de la Mise en óuvre de la Révolution de la Modernité (MPSMRM), Ministère de la Santé Publique (MSP), ICF International. *Democratic Republic of Congo Demographic and Health Survey 2013-14: Key Findings*. Rockville, MD: MPSMRM, MSP, and ICF International; 2014. http://dhsprogram.com/pubs/pdf/SR218/SR218.e.pdf. Accessed January 10, 2017.
7. Masset E, Haddad L, Cornelius A, Isaza-Castro J. Effectiveness of agricultural interventions that aim to improve nutritional status of children: systematic review. *BMJ*. 2012;344:d8222. CrossRef. Medline
8. Berti PR, Krasevec J, FitzGerald S. A review of the effectiveness of agriculture interventions in improving nutrition outcomes. *Public Health Nutr*. 2004;7(5):599–609. CrossRef. Medline
9. Webb P, Kennedy E. Impacts of agriculture on nutrition: nature of the evidence and research gaps. *Food Nutr Bull*. 2014;35(1):126–132. CrossRef. Medline
10. Girard AW, Self JL, McAuliffe C, Olude O. The effects of household food production strategies on the health and nutrition outcomes of women and young children: a systematic review. *Paediatr Perinat Epidemiol*. 2012;26(suppl 1):205–222. CrossRef. Medline
11. Leroy JL, Frongillo EA. Can interventions to promote animal production ameliorate undernutrition? *J Nutr*. 2007;137(10):2311–2316. Medline
12. Ruel MT, Alderman H; Maternal and Child Nutrition Study Group. Nutrition-sensitive interventions and programmes: how can they help to accelerate progress in improving maternal and child nutrition? *Lancet*. 2013;382(9891):536–551. CrossRef. Medline
13. Braun A, Jiggins J, Röling N, van den Berg H, Snijders P. *A Global Survey and Review of Farmer Field School Experiences*. International Livestock Research Institute (ILRI) Final Report. https://www.researchgate.net/profile/J_Jiggins/publication/228343459_A_Global_Survey_and_Review_of_Farmer_Field_School_Experiences/links/0046353bd1e61ab7f7000000.pdf. Published June 12, 2006. Accessed January 10, 2017.
14. Fanzo J, Marshall Q, Dobermann D, et al. Integration of nutrition into extension and advisory services: a synthesis of experiences, lessons, and recommendations. *Food Nutr Bull*. 2015;36(2):120–137. CrossRef. Medline

Participation in Jenga Jamaa II project's farmer field schools was associated with improvements in agricultural production and household food security, but did not have a significant impact on child nutrition outcomes.

15. Tripp R, Wijeratne M, Piyadasa VH. What should we expect from farmer field schools? A Sri Lanka case study. *World Dev.* 2005;33 (10):1705–1720. CrossRef
16. Davis K, Nkonya E, Kato E, et al. Impact of farmer field schools on agricultural productivity and poverty in east Africa. *World Dev.* 2012;40(2):402–413. CrossRef
17. Tsiboe F, Dixon BL, Nalley LL, Popp JS, Luckstead J. Estimating the impact of farmer field schools in sub-Saharan Africa: the case of cocoa. *Agric Econ.* 2016;*47*(3):329–339. CrossRef
18. Yamazaki S, Resosudarmo BP. Does sending farmers back to school have an impact? Revisiting the issue. *Dev Econ.* 2008;*46*(2):135–150. CrossRef
19. Doocy S, Emerson J, Colantouni E, Strong J, Amundson Mansen K, the Jenga Jamaa II Study Team and Menakuntuala J. Improving household food security in eastern Democratic Republic of the Congo: a comparative analysis of four interventions. *Food Security.* In press 2017.
20. Doocy S, Emerson J, Colantouni E, Strong J, Amundson Mansen K; the Jenga Jamaa II Study Team and Menakuntuala J. Evaluating interventions to improve child nutrition in Democratic Republic of the Congo. Unpublished manuscript.
21. Famine Early Warning Systems Network (FEWS NET). *Consolidated Report on the Livelihood Zones of the Democratic Republic of Congo.* http://www.fews.net/sites/default/files/documents/reports/DRC-consolidated-zoning-report.pdf. Published December 2016. Accessed October 20, 2017.
22. Swindale A, Bilinsky P. Development of a universally applicable household food insecurity measurement tool: process, current status, and outstanding issues. *J Nutr.* 2006;136(5):1449S–1452S. Medline
23. Swindale A, Bilinsky P. *Household Dietary Diversity Score (HDDS) for Measurement of Household Food Access: Indicator Guide (version 2).* Washington, DC: FHI 360/FANTA. https://www.fantaproject.org/sites/default/files/resources/HDDS_v2_Sep06_0.pdf. Published September 2006. Accessed April 19, 2017.
24. Coates J, Swindale A, Bilinsky P. *Household Food Insecurity Access Scale (HFIAS) for Measurement of Food Access: Indicator Guide (version 3).* Washington, DC: FHI 360/FANTA. http://www.fantaproject.org/sites/default/files/resources/HFIAS_ENG_v3_Aug07.pdf. Published August 2007. Accessed April 19, 2017.
25. Heagerty PJ, Zeger SL. Lorelogram: a regression approach to exploring dependence in longitudinal categorical responses. *J Am Stat Assoc.* 1998;93(441):150–162. CrossRef
26. Robins J, Sued M, Lei-Gomez Q, Rotnitzky A. Comment: Performance of double-robust estimators when "inverse probability" weights are highly variable. *Stat Sci.* 2007;22(4):544–559. CrossRef
27. Colantuoni E, Rosenblum M. Leveraging prognostic baseline variables to gain precision in randomized trials. *Stat Med.* 2015;34 (18):2602–2617. CrossRef. Medline
28. Leroy JL. ZSCORE06: Stata module to calculate anthropometric z-scores using the 2006 WHO child growth standards [computer program]. https://EconPapers.repec.org/RePEc:boc:bocode:s457279. Published April 27, 2011. Revised October 4, 2011.
29. Vidmar SI, Cole TJ, Pan H. Standardizing anthropometric measures in children and adolescents with functions for egen: update. *Stata J* 2013(2):366–378. https://EconPapers.repec.org/RePEc:tsj:stataj:y:13:y:2013:i:2:p:366-378.
30. Rubin DB. Multiple Imputation for Nonresponse in Surveys. New York, NY: John Wiley & Sons; 1987.
31. Waddington H, Snilstveit B, Hombrados J, Vojtkova M, Anderson J, White H. Farmer field schools for improving farming practices and farmer outcomes in low- and middle-income countries. *Campbell Syst Rev.* 2014;10. CrossRef
32. Larsen AF, Lilleør HB. Beyond the field: the impact of farmer field schools on food security and poverty alleviation. *World Dev.* 2014;64:843–859. CrossRef
33. Weinhardt LS, Galvao LW, Yan AF, et al. Mixed-method quasi-experimental study of outcomes of a large-scale multilevel economic and food security intervention on HIV vulnerability in rural Malawi. *AIDS Behav.* 2017;21(3):712–723. CrossRef. Medline
34. Olney DK, Pedehombga A, Ruel MT, Dillon A. A 2-year integrated agriculture and nutrition and health behavior change communication program targeted to women in Burkina Faso reduces anemia, wasting, and diarrhea in children 3-12.9 months of age at baseline: a cluster-randomized controlled trial. *J Nutr.* 2015;145(6):1317–1324. CrossRef. Medline
35. Osei A, Pandey P, Nielsen J, et al. Combining home garden, poultry, and nutrition education program targeted to families with young children improved anemia among children and anemia and underweight among nonpregnant women in Nepal. *Food Nutr Bull.* 2017;38(1):49–64. CrossRef. Medline
36. Reinbott A, Schelling A, Kuchenbecker J, et al. Nutrition education linked to agricultural interventions improved child dietary diversity in rural Cambodia. *Br J Nutr.* 2016;116(8):1457–1468. CrossRef. Medline
37. World Bank. *From Agriculture to Nutrition: Pathways, Synergies and Outcomes.* Report No. 40196-GLB. http://siteresources.worldbank.org/INTARD/825826-1111134598204/21608903/January2008Final.pdf. Published 2007. Accessed March 16, 2017.
38. Jaenicke H, Virchow D. Entry points into a nutrition-sensitive agriculture. *Food Security.* 2013;5(5):679–692. CrossRef
39. U.S. Agency for International Development (USAID). Nutrition-sensitive agriculture: nutrient-rich value chains. Technical guidance brief. https://www.usaid.gov/what-we-do/global-health/nutrition/nutrition-sensitive-agriculture-nutrient-rich-value-chains. Updated February 8, 2016. Accessed January 12, 2017.
40. Cumming O, Cairncross S. Can water, sanitation and hygiene help eliminate stunting? Current evidence and policy implications. *Matern Child Nutr.* 2016;12(suppl 1):91–105. CrossRef. Medline
41. Mbuya MNN, Humphrey JH. Preventing environmental enteric dysfunction through improved water, sanitation and hygiene: an opportunity for stunting reduction in developing countries. *Matern Child Nutr.* 2016;12(suppl 1):106–120. CrossRef. Medline
42. World Bank. DataBank: World Development Indicators [database online]. Washington, DC: World Bank; 2017. http://databank.worldbank.org/data/reports.aspx?source=world-development-indicators#. Accessed March 17, 2017.
43. Rossi L, Hoerz T, Thouvenot V, Pastore G, Michael M. Evaluation of health, nutrition and food security programmes in a complex emergency: the case of Congo as an example of a chronic post-conflict situation. *Public Health Nutr.* 2006;9(5):551–556. CrossRef. Medline
44. Vir SC. Improving women's nutrition imperative for rapid reduction of childhood stunting in South Asia: coupling of nutrition specific interventions with nutrition sensitive measures essential. *Matern Child Nutr.* 2016;12(suppl 1):72–90. CrossRef. Medline
45. Burns J, Emerson JA, Amundson K, Doocy S, Caulfield LE, Klemm RDW. A qualitative analysis of barriers and facilitators to optimal breastfeeding and complementary feeding practices in South Kivu, Democratic Republic of Congo. *Food Nutr Bull.* 2016;37(2):119–131. CrossRef. Medline
46. Baharanyi BB, Crawford-Garrett B, Hughes CK, Tilford K, Tingbo A. M6id-Term Evaluation Report: Jenga Jamaa II Project. http://pdf.usaid.gov/pdf_docs/PA00KB41.pdf. Published October 2014. Accessed April 10, 2017.

Peer Reviewed

Received: May 24, 2017; **Accepted:** October 31, 2017

Cite this article as: Doocy S, Cohen S, Emerson J, Menakuntuala J, Menakuntuala J, Santos Rocha J. Food security and nutrition outcomes of farmer field schools in eastern Democratic Republic of the Congo. Glob Health Sci Pract. 2017;5(4):630-643. https://doi.org/10.9745/GHSP-D-17-00203

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ORIGINAL ARTICLE

What Factors Contribute to Postabortion Contraceptive Uptake By Young Women? A Program Evaluation in 10 Countries in Asia and sub-Saharan Africa

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Across the 10 countries, 77% of 921,918 women left with a contraceptive method after receiving abortion care. While contraceptive uptake was high among all age groups, adolescents ages 15–19 were less likely to choose a method than women 25 years or older.

ABSTRACT

Background: Unintended pregnancy disproportionately affects young women and adolescents in developing countries. The abortion care setting offers a unique opportunity for adolescents and young women to access a full range of contraceptive services. This evaluation assesses the factors that influence contraceptive uptake among adolescents and young women seeking abortion care in health facilities.

Methods: Following provider training, we analyzed client log book data from 921,918 abortion care cases in 4,881 health facilities in 10 countries from July 2011 through June 2015. Log book data included client characteristics such as age, pregnancy gestation, type of service provided, and contraceptive method provision. Health facility characteristics were obtained through administration of a site baseline form prior to initiation of programmatic support by Ipas, an international NGO. Programmatic support included integration of postabortion contraceptive services with abortion care, improvements in commodities logistics, health worker training, upgraded recordkeeping, and post-training follow-up with providers and sites to solve problems and improve performance. We analyzed abortion cases by 3 age categories, ≤19 years, 20–24 years, and ≥25 years, and conducted unadjusted and adjusted analyses for the primary outcomes of interest: receipt of a contraceptive method at the time of care; type of contraceptive method selected; and the client, clinical care, and facility characteristics associated with contraceptive uptake.

Results: Overall, 77% of women left the facility with a contraceptive method. The majority (84%) of contraceptive acceptors selected a short-acting method, especially oral contraceptives. In the adjusted model, women ≤19 were less likely to choose a method than women 25 years or older (odds ratio [OR], 0.87; 95% confidence interval [CI], 0.79 to 0.96). Adolescents and young women were also significantly less likely to choose a long-acting, reversible contraceptive than those ages 25 or older (≤19 years: OR, 0.59; 95% CI, 0.52 to 0.67; 20–24 years: OR, 0.68; 95% CI, 0.63 to 0.73). Women treated by an Ipas-trained provider were significantly more likely to select postabortion contraception than women treated by non-Ipas-trained providers (OR, 1.37; 95% CI, 1.20 to 1.57).

Conclusions: Programmatic support to health systems, including provider training in contraceptive counseling and provision, was associated with women's higher acceptance of postabortion contraception. However, gaps remained for young women, especially adolescents, who were significantly less likely than older women to accept postabortion contraception. Health systems and facilities should pay increased attention to meeting the contraceptive needs of young women and adolescents.

INTRODUCTION

About one-half of pregnancies to adolescents 15–19 years of age are unintended and about one-half of these end in abortion.[1] Adolescents and young women seeking abortion are more likely to obtain care at later gestations in their pregnancies, use less-skilled practitioners, and experience delays in care when complications occur.[1–3]

Unsafe abortion disproportionately affects adolescents and young women in developing countries. Between 2010 and 2014, almost 25.1 million unsafe abortions occurred globally each year, most in developing countries.[4] Adolescents aged 15–19 and young women 20–24 comprised an estimated 41% of unsafe abortions globally in 2008, and in Africa about one-half of unsafe abortions were among these age groups.[5]

Underlying these findings are low and/or inconsistent use of contraception among adolescents and young women leading to unintended pregnancies. An estimated 38 million adolescents 15–19 years of age in

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developing countries are married or unmarried and sexually active and do not wish to have a child within the next 2 years, yet only 40% are using a modern method of contraception.[1] The most commonly used method is male condoms, comprising 38% of methods used by adolescent acceptors; condoms require partner collaboration and suffer from higher failure rates than other modern methods. An analysis of contraceptive use and discontinuation in more than 40 countries found that failure rates were about 25% higher within the first year of method use among 15–19-year-old adolescents compared with women 20 or older.[6] Use of modern contraception among married women 20–24 years of age in least-developed countries is 29%.[7]

Abortion care services include provision of induced abortion as well as treatment of incomplete abortion resulting from complications of unsafe abortion or spontaneous abortion; the latter is referred to as postabortion care (PAC). Abortion care services also include postabortion contraceptive counseling and method provision. The terms "induced abortion" and "PAC treatment" are used in this article if a particular setting or finding refers to one or the other type of service. The abortion care setting offers a unique opportunity for adolescents and women to access contraceptive information and methods, if they wish to use one. They are present in a health facility and may not return for subsequent care. Ovulation returns quickly after an abortion and contraception can enable women to avert an unintended pregnancy.[8,9] For women who wish to become pregnant again following a spontaneous abortion, current evidence recommends 6-month spacing of the subsequent pregnancy for optimal outcomes.[10]

Multiple studies have demonstrated the effectiveness of interventions to provide contraceptive counseling and methods to abortion clients prior to discharge from health facilities.[11–14] Most have demonstrated high uptake of methods at the time of services, although fewer studies have assessed contraceptive continuation and longer-term reproductive outcomes. Assessments of postabortion contraceptive interventions to reach young women and adolescents obtaining abortion care have also reported the effectiveness of contraceptive care offered at the time of the abortion.[15–17]

Only a few studies have assessed the client, clinical care, and institutional factors that affect women's acceptance of postabortion contraception.[13,18,19] The analysis described in this article examines the factors that are associated with postabortion contraceptive uptake among young women and adolescents so that health systems can use the findings to strengthen services for this population. While some countries have limitations on contraceptive provision to young women and/or unmarried women, many are increasing women's awareness of contraceptive options, strengthening providers' skills, and expanding access to long-acting, reversible contraceptives (LARCs) as part of commitments made at the 2012 London Summit on Family Planning.[20]

Unsafe abortion disproportionately affects adolescents and young women in developing countries.

We report results of programmatic support to health facilities in 10 countries that aimed to improve provision of contraception to women seeking induced abortion or PAC treatment. Support was provided by Ipas, an international NGO, and its network partner, the Ipas Development Foundation, a local NGO in India, in collaboration with ministries of health and other local entities. The countries in our analysis were Ghana, Nigeria, Sierra Leone, Uganda, and Zambia in sub-Saharan Africa, and Bangladesh, India, Myanmar, Nepal, and Pakistan in Asia.

Objectives of this article are to: (1) describe an intervention aimed at improving postabortion contraceptive counseling and method provision; (2) assess the factors that influence contraceptive uptake among clients at the time of abortion care, by age; and (3) recommend steps to improve the quality of postabortion contraceptive services in health facilities for young women and adolescents.

The abortion care setting offers a unique opportunity for adolescents and women to access contraceptive information and methods, if they wish to use one.

PROGRAM DESCRIPTION

The type of abortion care provided in facilities varied by the legal, policy, and cultural contexts of the 10 countries. In Nepal, for example, most clients sought an induced abortion, while in Pakistan, Sierra Leone, and Uganda, most women sought PAC treatment of incomplete abortion. In other countries, such as Bangladesh and India, both induced abortion and PAC cases were included in the analysis. Postabortion contraceptive counseling and methods were incorporated into both types of abortion care.

Postabortion Contraceptive Support

Postabortion contraceptive support to health systems and facilities fell into 9 domains:

1. Development of technical standards, guidelines, and protocols for provision of care to all women, regardless of age, marital status, or

This article examines the factors associated with postabortion contraceptive uptake among young women and adolescents.

other barriers, based on World Health Organization (WHO) guidance

2. Physical upgrades in facilities to facilitate contraceptive availability at the time of abortion care
3. Improvements in logistics processes for commodities
4. Training-of-trainers and in-service training of physicians, midwives, clinical officers, and other cadres in clinical care, including contraceptive counseling and provision
5. Values-clarification training for service providers and staff to reduce stigma toward women and adolescents who need reproductive health services
6. Provision of contraceptive counseling and methods at the same location and time as abortion care
7. Separate, specialized training of providers in counseling and provision of available LARC methods in selected countries, including on medical eligibility, method side effects, counseling approaches at the time of abortion care and afterward, and method insertion
8. Improvements in abortion case recordkeeping and regular use of data to monitor service availability and quality
9. Routine follow-up of facilities and trained providers to identify and resolve barriers to care.

In most countries, providers received periodic in-person visits and phone check-ins from Ipas clinical mentors, program staff, and/or health systems supervisors following training, along with a review of their individual summary monitoring data, which underscored contraception as a routine component of comprehensive care.

Clinical training courses for providers usually lasted 5 days, but in some countries were held for 10–12 days. The courses were led by clinical master trainers who had previously completed training-of-trainers courses in abortion care. Training participants included obstetrics and gynecology specialists, general physicians, midwives, clinical officers, nurses, and other cadres, depending on the country setting. Follow-up contacts with trained providers usually occurred within 3–4 weeks post-training, either by phone or in-person at their facility. During the check-ins, the mentor/program support specialist assessed the newly trained provider, identified and resolved clinical or programmatic concerns, reviewed log book records (if in-person), and agreed to a follow-up contact time. Subsequent support visits from the program support team member also included review of individualized performance data with the provider. Frequently addressed issues included stock-outs of commodities, need for additional clinical practice, reinforcement of infection prevention practices, insufficient support of upgraded care by facility management, and low caseloads. Examples of strategies to resolve these problems included making contacts with supply chain officials at the facility or higher level; discussions with department heads, facility administrators, and district supervisors on the importance of the service; use of clinical practice job aids; and expanded outreach to inform the community about the service.

In-person support to trained providers occurred at their health facility, as noted, but often included interactions and refresher sessions with providers who did not participate in the training but were part of the larger team of caregivers. Technical assistance to and monitoring of health facilities was also carried out, recognizing that providers require a supportive environment in which to practice.

While programmatic support in all countries encompassed core training curricula, standard log book formats, and monitoring tools, each program was designed and implemented to reflect local service delivery contexts, including compliance with Ministry of Health standards and guidelines. Women selected from the abortion methods available in the facility and for which they were medically eligible. Contraceptive commodities included only those methods currently approved and available in each country's health system. The timing of contraceptive counseling, prior to or after the abortion procedure, also varied by the client's clinical condition, type of contraceptive methods available in the setting, and other factors. Ipas does not recommend the inclusion of clients' marital status in abortion care log books since this information can be used to deny women care. However, the Ministries of Health of some countries required this information to be recorded. Client exit interviews were conducted annually in selected facilities in many of the countries to gather women's perspectives on the quality of information that providers shared during their visit, provision of women's preferred contraceptive methods, and source of referral to the facility. Despite these programmatic differences between countries and changes over time, implementation of the core Ipas training curriculum for

development of providers' clinical and counseling skills was relatively standardized but updated as new, published evidence became available.[21] WHO recommendations and new findings from scientific literature, including provision of hormonal methods on the first day of a medical abortion, were incorporated into training although their integration into country-level standards and guidelines varied.[21,22] More details on Ipas programmatic support have been published elsewhere.[18]

Support for Reaching Young Women and Adolescents With Postabortion Contraception

Programmatic support for reaching young women and adolescents was carried out in all countries but varied by the specific context. Program components included assessments of existing youth-focused services in health facilities to assist in program planning, upgrades to sites to improve client privacy and confidentiality, provider training on clinical and counseling issues relevant to young clients, sensitization of facility managers and health officials to the needs of young women, and an array of community outreach activities for young women and adolescents. Counseling training focused on a woman-centered approach to identify and address clients' individual needs and preferences in preventing pregnancy and providing voluntary, informed consent. Trainers in India, Nepal, Nigeria, and Zambia also received in-depth skills training on rights-based approaches to contraception. Some programs began as pilot projects in a few health facilities and were subsequently expanded in several countries to broader health systems efforts. Ipas resources such as a training toolkit for abortion care for young women helped guide the design and implementation of programmatic support.[23]

METHODS

Data Collection and Processing

Data were collected from abortion care log books in public- and private-sector facilities in the 10 countries. Intervention sites were selected by Ipas and collaborating partners, based on geographic priorities for coverage, Ministry of Health strategies, weak reproductive health indicators, potential for integration of a new/upgraded service, and other criteria. Individual case information on abortion care clients was recorded by providers over a 4-year period from July 2011 through June 2015, and collected by Ipas during monitoring visits to the sites; frequency of the visits varied by country but usually occurred monthly, quarterly, or every 6 months. Collection of monitoring data began after provider training due to the poor quality of log books prior to start-up of the intervention. Client names, their record numbers, or other identifying data were not collected.

Abortion care log books were part of the routine health recordkeeping system and included client characteristics such as age, pregnancy gestation (in weeks), and type of service (induced abortion, PAC, or other); the treatment regimen such as the method used for the abortion (manual or electric vacuum aspiration [MVA/EVA], medical abortion, or other), pain management, and contraceptive method provided at the time of care, by method type; adverse events; and provider signature or identification. While Ipas recommends that providers indicate women's desire for contraception, in addition to whether they received a method at the time of care, most health systems did not include this information in log books. Many abortion care providers had participated in an Ipas-supported in-service clinical training and were assigned a unique provider ID. During training, providers were instructed on how to complete the log book and asked to add their signature to cases they treated. Log book cases with a signed entry were assumed to have been attended by a provider who had participated in an Ipas-supported training. Information about clients treated in the facility by providers not trained by Ipas were also included in the dataset. Information about facility type, level, and other characteristics was obtained on a site baseline form completed by Ipas before initiation of programmatic support.

All log book and site data were entered into Ipas's programmatic monitoring database and cleaned and analyzed using Stata version 11.0. The protocol was approved by the Allendale Institutional Review Board (US).

Data Analysis

We analyzed abortion cases by 3 age categories: $\leq$19 years, 20–24 years, and $\geq$25 years. Primary outcomes of interest included: receipt of a contraceptive method at the time of care; type of contraceptive method selected; and the client, clinical care, and facility characteristics associated with contraceptive uptake within and across each age category.

Rates of missing data on age were low, 2% overall; these cases were removed from the dataset. We treated data conservatively, classifying those cases without contraceptive information in the log books as not having received a method. The abortion care delivery setting for each client age category was described by region, health sector (public or private facility), level of the facility (primary, secondary, or tertiary), and whether the health care worker who offered the abortion participated in an Ipas-supported training. Additional client data included gestational age, type of abortion (induced abortion or PAC treatment), and the abortion method used.

We conducted unadjusted and adjusted analyses for the outcomes of interest. For each age group, we describe overall contraceptive uptake; type of contraceptive method such as condoms, oral contraceptives, or intrauterine devices (IUDs); and method category (short-acting or LARC). Short-acting methods consisted of condoms, oral contraceptives, and injectables. LARC methods were implants and IUDs. The percentage of clients receiving a sterilization procedure was low across all age groups (7%) and not included in our analysis. Percentages are reported for non-missing data.

77% of women left the health facility with a contraceptive method.

Bivariate analysis of overall contraceptive uptake and by method category was carried out with facility and clinical characteristics. Chi-square tests were applied to determine statistical significance. Adjusted analysis was conducted using logistic regression, controlling for facility clustering and country-level variations. We conducted tests of collinearity and model fit to select the most parsimonious model. Significance levels were set at 0.05.

Oral contraceptive pills were the most commonly selected method for each age group, followed by condoms and injectables.

RESULTS

Background Characteristics

Findings are based on 921,918 abortion cases treated in 4,881 health facilities: India (3,178 health facilities); Nigeria (464); Nepal (383); Ghana (278); Pakistan (200); Bangladesh (175); Zambia (104); Uganda (48); Myanmar (37); and Sierra Leone (14). A large majority of cases, 67%, occurred in sites in Asia (Table 1). Clients receiving abortion care in India (41%), Nigeria (18%), and Bangladesh (17%) made up more than three-quarters of all cases. In total, 7% of clients were 19 years old or younger and 31% were 20–24 years old.

Women under age 20 were less likely to choose a method than women 25 years or older.

The women served in Africa were younger than those in Asia. Almost two-thirds (64%) of women 19 years and under were from Africa while 36% were from Asia. Most (95%) women sought care during the first trimester of pregnancy, but 9% of clients age 19 or younger obtained care at 13 weeks of pregnancy or later compared with 5% each of women ages 20–24 and those ages 25 and older. In addition, a higher percentage of adolescents ages 15–19 received PAC treatment (45%) than women ages 25 or older (40%). Service delivery characteristics varied little by age. Most (89%) clients were seen in primary- or secondary-level public facilities, and Ipas-trained providers attended 60% of the clients. Almost three-quarters of cases were performed with vacuum aspiration (MVA or EVA).

Postabortion Contraceptive Uptake

Overall contraceptive uptake was high for all age categories in the unadjusted analysis, with 77% of women leaving the health facility with a contraceptive method. Highest uptake was among women ≥25 years of age (78%), and lowest among women under age 20 (71%) (Table 2).

Of those clients who chose contraception, 84% received a short-acting method. This did not vary markedly across age groups: a slightly higher percentage of women 25 and older (18%) selected a LARC method compared with those under 25 (14%) (Table 2). The specific types of methods chosen followed similar trends across the age groups: oral contraceptive pills were the most commonly selected method for each age group, followed by condoms and injectables. The least commonly chosen method was the IUD for women under 20 and implants for women in the other age groups. Of note, a lower percentage of women under 20 chose pills than women 20 or older (35% vs. 44%, respectively), and a higher percentage of women under 20 chose injectables than women 20 or older (25% vs. 14%–18%, respectively) (Table 2).

Factors Associated With Postabortion Contraceptive Uptake

Factors positively associated with postabortion contraceptive uptake among women of all ages included obtaining services in a private facility, receiving care from a provider trained as part of an Ipas-supported intervention, being ages 25 years or older, first-trimester gestational age, seeking an induced abortion (compared with receiving PAC services), and choosing a medical abortion. In the adjusted analysis, facility sector was not significantly associated with postabortion contraceptive acceptance, and women under age

TABLE 1. Background Characteristics of Abortion Clients Treated in Health Facilities in 10 Countries, by Client Age, 2011–2015

	Age Group (in years)			
	≤19 (n=68,265) No. (%)	20–24 (n=282,695) No. (%)	≥25 (n=570,958) No. (%)	Total (N=921,918) No. (%)
Region				
Africa	43,741 (64)	86,356 (31)	170,101 (30)	300,198 (33)
Asia	24,524 (36)	196,339 (69)	400,857 (70)	621,720 (67)
Country				
India	12,351 (18)	140,765 (50)	227,526 (40)	380,642 (41)
Nigeria	18,639 (27)	45,592 (16)	94,631 (17)	158,862 (18)
Bangladesh	7,959 (12)	35,162 (12)	112,872 (20)	155,993 (17)
Ghana	13,534 (20)	21,990 (8)	42,639 (7)	78,163 (8)
Zambia	10,221 (15)	17,301 (6)	30,981 (5)	58,503 (6)
Nepal	3,352 (5)	14,144 (5)	36,914 (6)	54,410 (6)
Pakistan	697 (1)	5,437 (2)	20,234 (4)	26,368 (3)
Myanmar	165 (<1)	831 (<1)	3,311 (1)	4,307 (<1)
Uganda	844 (1)	1,006 (<1)	1,359 (<1)	3,209 (<1)
Sierra Leone	503 (1)	467 (<1)	491 (<1)	1,461 (<1)
Facility sector[a]				
Private	18,062 (26)	72,249 (26)	142,644 (25)	232,955 (25)
Public	50,203 (74)	210,446 (74)	428,314 (75)	688,963 (75)
Facility level[b]				
Primary	30,014 (44)	135,047 (48)	295,074 (52)	460,135 (50)
Secondary	30,239 (44)	115,472 (41)	212,371 (37)	358,082 (39)
Tertiary	8,012 (12)	32,176 (11)	63,513 (11)	103,701 (11)
Ipas-trained provider				
Yes	43,373 (64)	165,235 (58)	342,928 (60)	551,536 (60)
No	24,892 (36)	117,460 (42)	228,030 (40)	370,382 (40)
Gestational age, weeks[c]				
≤12 weeks	59,940 (91)	257,377 (95)	525,011 (95)	842,328 (95)
≥13 weeks	5,657 (9)	12,927 (5)	25,087 (5)	43,671 (5)
Missing	2,668	12,391	20,860	35,919
Type of abortion[c]				
Induced abortion	35,712 (55)	155,123 (59)	327,872 (60)	518,707 (60)
Postabortion care	29,374 (45)	107,331 (41)	215,776 (40)	352,481 (40)
Missing	3,179	20,241	27,310	50,730
Abortion method[c]				
MVA/EVA	48,400 (71)	202,512 (73)	413,550 (75)	664,462 (74)
Medical abortion	16,241 (24)	58,114 (21)	113,812 (21)	188,167 (21)

Continued

TABLE 1. Continued

	Age Group (in years)			
	≤19 (n=68,265) No. (%)	20–24 (n=282,695) No. (%)	≥25 (n=570,958) No. (%)	Total (N=921,918) No. (%)
D&C/D&E/Other	3,086 (5)	15,488 (6)	24,530 (4)	43,104 (5)
Missing	538	6,581	19,066	26,185

Abbreviations: D&C, dilation and curettage; D&E, dilation and evacuation; EVA, electric vacuum aspiration; MVA, manual vacuum aspiration.
[a] NGO-sponsored facilities were recategorized as public or private based on country context.
[b] Approximately 6% of cases in India and Uganda were served in facilities that were categorized as "other"; these were recategorized as "primary."
[c] Missing data were not included in the calculation of percentages.

Adolescents and young women were significantly less likely to select a LARC than women 25 years or older.

20 were less likely to choose a contraceptive method than women 25 years or older (odds ratio [OR], 0.87; 95% confidence interval [CI], 0.79 to 0.96) (Table 3). All other associations from the bivariate analysis remained in the adjusted analysis.

Factors Associated With Choice of a LARC

In the adjusted model, acceptance of a LARC method was more likely if a client received care in a public facility, was 25 years of age or older, sought an induced abortion (compared with those who sought PAC services), or had a vacuum aspiration abortion (MVA or EVA) compared with medical abortion (Table 4). Adolescents and young women were significantly less likely to select a LARC method than women 25 years or older (age ≤19 years: OR, 0.59; 95% CI, 0.52 to 0.67; age 20–24 years: OR, 0.68; 95% CI, 0.63 to 0.73).

DISCUSSION

Key Results

Overall, in the nearly 1,000,000 abortion cases treated in 10 countries of sub-Saharan Africa and

TABLE 2. Contraceptive Uptake at the Time of Abortion Care Among Clients in 10 Countries, by Client Age, 2011–2015

	Age Group (in years)			
	≤19 (n=68,265) No. (%)	20–24 (n=282,695) No. (%)	≥25 (n=570,958) No. (%)	Total (N=921,918) No. (%)
Any uptake of postabortion contraception				
Yes	48,725 (71)	215,964 (76)	444,503 (78)	709,192 (77)
No	13,948 (20)	39,631 (14)	77,857 (14)	131,436 (14)
Missing	5,592 (8)	27,100 (10)	48,598 (9)	81,290 (9)
Method category				
Short-acting	42,104 (86)	186,685 (86)	366,709 (82)	595,498 (84)
Long-acting reversible	6,621 (14)	29,279 (14)	77,794 (18)	113,694 (16)
Method type				
Condoms	13,142 (27)	60,007 (28)	92,072 (21)	165,221 (23)
Oral contraceptive pills	16,900 (35)	95,821 (44)	194,932 (44)	307,653 (43)
Injectables	12,062 (25)	30,857 (14)	79,705 (18)	122,624 (17)
Implants	4,471 (9)	7,669 (4)	20,296 (5)	32,436 (5)
Intrauterine device	2,150 (4)	21,610 (10)	57,498 (13)	81,258 (11)

TABLE 3. Service Delivery and Clinical Care Characteristics of Clients Receiving Any Postabortion Contraception[a] at the Time of Abortion Care in 10 Countries, Bivariate and Adjusted Analysis, 2011–2015

	Accepted Postabortion Contraception (n=709,192) No. (%)	Did Not Accept Postabortion Contraception (n=212,726) No. (%)	Bivariate Analysis (n=921,918)		Adjusted Analysis[b] (n=816,880)	
			OR	95% CI	AOR	95% CI
Facility sector						
Private	187,124 (26)	45,831 (22)	Reference		Reference	
Public	522,068 (74)	166,895 (78)	0.77***	(0.76, 0.78)	0.88	(0.71, 1.10)
Ipas-trained provider						
Yes	449,492 (63)	102,044 (48)	1.88***	(1.86, 1.90)	1.37***	(1.20, 1.57)
No	259,700 (37)	110,682 (52)	Reference		Reference	
Client age						
≤19	48,725 (7)	19,540 (9)	0.71***	(0.70, 0.72)	0.87**	(0.79, 0.96)
20–24	215,964 (30)	66,731 (31)	0.92***	(0.91, 0.93)	0.96	(0.92, 1.01)
≥25	444,503 (63)	126,455 (59)	Reference		Reference	
Gestational age, weeks[c]						
≤12	663,391 (96)	178,937 (91)	Reference		Reference	
≥13	25,777 (4)	17,894 (9)	0.39***	(0.38, 0.40)	0.73***	(0.65, 0.81)
Missing	20,024	15,895				
Type of abortion[c]						
Induced abortion	438,742 (65)	79,965 (41)	Reference		Reference	
PAC	238,504 (35)	113,977 (59)	0.38***	(0.38, 0.39)	0.55***	(0.45, 0.67)
Other/missing	31,946	18,784				
Abortion method[c]						
MVA/EVA	514,163 (75)	150,299 (72)	Reference		Reference	
Medical abortion	151,801 (22)	36,366 (17)	1.22***	(1.20, 1.24)	1.20*	(1.01, 1.43)
D&C/D&E/other	20,645 (3)	22,459 (11)	0.27***	(0.26, 0.27)	0.34***	(0.27, 0.42)
Other/missing	22,583	3,602				

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; D&C, dilation and curettage; D&E, dilation and evacuation; EVA, electric vacuum aspiration; MVA, manual vacuum aspiration; OR, odds ratio; PAC, postabortion care.
* $P<.05$; ** $P<.01$; *** $P<.001$.
[a] Sterilization excluded.
[b] Adjusted odds ratios control for country variation and cluster on facility (using non-missing data only).
[c] Other/missing data were not included in the calculation of percentages.

Asia, we found high rates of postabortion contraception acceptance among the clients, but adolescents were significantly less likely than women 20 years of age or older to choose to use contraception. Women 15–19 years old and those 20–24 years old had similar uptake of LARC methods, and women 25 or older had significantly higher odds of receiving a LARC method than these younger women. Women cared for by a provider who participated in an Ipas-supported training were significantly more likely to choose a postabortion contraceptive method, but differences by age remained. While contraceptive uptake was high in our analysis (77% of women left the health facility with a contraceptive method), our findings underscore that young women, especially adolescents, may not have access to the full range of contraceptive methods

Young women, especially adolescents, may not have access to the full range of contraceptive methods for which they are medically eligible.

TABLE 4. Service Delivery and Clinical Care Characteristics of Clients Receiving a LARC at the Time of Abortion Care in 10 Countries, Bivariate and Adjusted Analysis, 2011–2015

	Accepted LARC (n=113,694) No. (%)	Did Not Accept LARC (n=595,498) No. (%)	Bivariate Analysis (n=709,192)		Adjusted Analysis[a] (n=638,666)	
			OR	95% CI	AOR	95% CI
Facility sector						
Private	36,785 (32)	150,339 (25)	Reference		Reference	
Public	76,909 (68)	445,159 (75)	0.71***	(0.70, 0.72)	1.42**	(1.16, 1.74)
Ipas-trained provider						
Yes	72,856 (64)	376,636 (63)	1.04***	(1.02, 1.05)	0.97	(0.85, 1.11)
No	40,838 (36)	218,862 (37)	Reference		Reference	
Client age, years						
≤19	6,621 (6)	42,104 (7)	0.74***	(0.72, 0.76)	0.59***	(0.52, 0.67)
20–24	29,279 (26)	186,685 (31)	0.74***	(0.73, 0.75)	0.68***	(0.63, 0.73)
≥25	77,794 (68)	366,709 (62)	Reference		Reference	
Gestational age, weeks[b]						
≤12	107,155 (96)	556,236 (96)	Reference		Reference	
≥13	3,899 (4)	21,878 (4)	0.93***	(0.89, 0.96)	1.04	(0.93, 1.27)
Missing	2,640	17,384				
Type of abortion[b]						
Induced abortion	78,926 (72)	359,816 (63)	Reference		Reference	
PAC	30,918 (28)	207,586 (37)	0.68***	(0.67, 0.69)	0.44***	(0.38, 0.50)
Other/missing	3,850	28,096				
Abortion method[b]						
MVA/EVA	83,998 (80)	430,165 (74)	Reference		Reference	
Medical abortion	19,382 (18)	132,419 (23)	0.75***	(0.74, 0.76)	0.52***	(0.44, 0.63)
D&C/D&E/other	2,204 (2)	18,441 (3)	0.61***	(0.59, 0.64)	0.86	(0.68, 1.08)
Missing	8,110	14,473				

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval; D&C, dilation and curettage; D&E, dilation and evacuation; EVA, electric vacuum aspiration; LARC, long-acting reversible contraceptive; MVA, manual vacuum aspiration; OR, odds ratio; PAC, postabortion care.
* $P<.05$; ** $P<.01$; *** $P<.001$.
[a] Adjusted odds ratios control for country variation and cluster on facility (using non-missing data only).
[b] Other/missing data were not included in the calculation of percentages.

for which they are medically eligible,[24] and additional attention to this group is needed to enable them to prevent unintended pregnancy.

Trained Providers and Clients' Contraceptive Uptake

Abortion care clients of providers who participated in an Ipas-supported training were significantly more likely to select a postabortion contraceptive method, but no differences in LARC acceptance by clients of Ipas-trained versus non-Ipas-trained providers were observed. While we do not have data on providers who did not directly participate in the trainings or who did not receive post-training follow-up, non-Ipas-trained providers may not have prioritized postabortion contraception, or they may have perceived their counseling or clinical skills as insufficient. Another possibility is that they may have held misconceptions about contraceptive methods

during the postabortion period. For example, non-Ipas-trained providers may have been unaware that women who select medical abortion and also wish to use a hormonal method of contraception (i.e., pills, injectables, or implants) may start the method on day 1 of the abortion medication regimen, per WHO guidelines.[22,24] The findings suggest a need for further reinforcement of these guidelines, as well as a need to emphasize counseling and LARC method provision as part of training and follow-up and to implement approaches for updating providers who do not attend trainings.

Pregnancy Gestation and Clients' Contraceptive Uptake

Women with gestations of 13 weeks or more were significantly less likely to choose a contraceptive method than women presenting at 12 weeks or less, a troubling finding since adolescents and young women were disproportionately represented among clients seeking care in later stages of pregnancy.

Abortion care clients in later pregnancy gestations are more likely to obtain services in hospital settings than primary-level sites. Hospital environments present special challenges for postabortion contraception, with several studies reporting that women obtaining abortion care in hospitals are less likely to receive any contraception than those in primary health centers or clinics.[18,25] A variety of factors likely contribute to this finding, including the multiple health care workers attending a single client in a hospital, logistical difficulties in ensuring that contraceptive commodities are routinely available in the abortion treatment area, the perception that contraceptive provision is not a physician's task, provider workloads that prioritize more acute care, and administrative barriers to linking 2 different services. With their lower uptake of contraception, clients seeking abortion at 13 weeks or greater gestation therefore represent a group at risk of subsequent unintended pregnancy.

However, in our study, clients who received contraception were more likely to obtain a LARC method in public facilities than private sites. Larger, public hospitals may be more likely to have had trained and experienced providers with access to LARC supplies and commodities than smaller, private facilities; many primary-level providers who participated in training were new to abortion care and may not have had experience in LARC provision. These findings underscore the importance of access to an array of contraceptive methods and a trained provider across facility sectors and levels for all women seeking abortion care.

Type of Abortion Care and Clients' Contraceptive Uptake

PAC clients include women who require treatment of abortion complications from induced abortions obtained elsewhere; women who have used medical abortion outside of a health facility and present with bleeding; those presenting for miscarriage management of wanted pregnancies and who wish to have another pregnancy soon; and other miscarriage patients who want to delay a subsequent pregnancy. In the adjusted model, women seeking induced abortion were much more likely to choose a contraceptive method than those obtaining PAC services. This finding could partly be due to provider bias if they assumed that most PAC clients had had a miscarriage and wanted to become pregnant again soon. In addition, providers treating patients with severe abortion complications such as septic abortion and shock often prioritize immediate medical needs. While a significant amount of research has been conducted on the uptake of postabortion contraception by PAC clients, a better understanding of women's needs and preferences at the time of care and competing provider constraints could contribute to improved quality.[14,26,27] In addition, while most induced abortion clients experience unintended pregnancies and want to prevent a subsequent one, some may want to become pregnant again.

Women with gestations of 13 weeks or more were significantly less likely to choose a contraceptive method than women presenting at 12 weeks or less.

These diverse circumstances underscore the importance of counseling that incorporates clients' fertility preferences and offers adolescents and women their choice of contraceptive methods. Induced abortion clients who accepted contraception were highly significantly more likely to choose a LARC method than PAC clients accepting contraception. Our data do not allow us to determine precise reasons for this finding, but they suggest that PAC clients who want to use contraception may prefer short-acting methods until they recover from the incomplete abortion and are ready to make decisions about pregnancy. Furthermore, PAC clients with septic abortion are not medically eligible for IUD insertion at the time of the abortion, which may also contribute to the finding.

Method of Abortion and Clients' Contraceptive Uptake

Differences in contraceptive uptake by abortion technology have also been found in other studies

using monitoring data from Ipas-supported facilities, with similar or higher acceptance of any contraceptive method with medical abortion compared with MVA/EVA but lower LARC uptake.[18,25] Women receiving induced abortion and contraception in Indian NGO clinics found that acceptance of any method was similar for MVA and medical abortion clients within 2 months following services, although method mix varied. Women who had an MVA were more likely to have had an IUD or sterilization, while medical abortion clients mainly chose IUDs and condoms. This likely reflects clinical protocols for MVA clients that permit sterilization or IUD insertion at the time of the procedure.[28] Health facilities should stock contraceptive implant commodities and abortion providers should be trained in their insertion on the first day of a medical abortion if the adolescent or woman desires this method.

Uptake of LARC Methods

Provision of LARC methods to adolescents has received increasing attention in recent years. In the United States, both the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists have issued statements on the safety and appropriateness of IUDs and implants for adolescents who desire these methods.[29,30] WHO's medical eligibility criteria indicate that age is not a contraindication to LARC provision.[31] Research on contraceptive services that incorporated information on method types and their risks and benefits, especially for LARCs, and provided methods at no cost to the client demonstrated high uptake of LARCs among adolescents. In a follow-up period that lasted 2 to 3 years, adolescents in the study had lower rates of pregnancy, births, and abortion compared with all U.S. adolescents.[32] A systematic review of research on IUDs in the United States found that the method is safe and effective for young women and adolescents.[33]

The Ipas training curriculum, clinical guidelines, and post-training technical support to providers and facilities are consistent with WHO's guidance on abortion care and postabortion contraception and more recent published evidence. These state that all contraceptive methods may be provided to women at the time of an uncomplicated first- or second-trimester abortion procedure performed with vacuum aspiration or medical abortion, according to their medical eligibility.[22,24] This recommendation includes LARC methods consisting of IUDs and implants. For women treated for septic abortion who select an IUD, insertion should be delayed until the infection is resolved. As previously noted, hormonal methods can be started on day 1 of administration of a medical abortion regimen. For medical abortion clients who wish to have an IUD, providers should first be certain that the woman is no longer pregnant and that the abortion was successful.[24] This usually precludes IUD insertion at the time of a medical abortion unless the woman completes the abortion at the facility; women selecting medical abortion and desiring an IUD should be offered a short-acting method to prevent pregnancy until they are able to return to the facility for the insertion. This guidance should be a part of routine training and supervision of abortion providers so that they apply the latest clinical evidence in their practices, especially for young clients.

The provision of LARCs to adolescents, especially those who have not given birth, remains a relatively new concept in many countries in Africa, Asia, and Latin America.[34,35] The lack of availability of certain methods also limits young women's choices. One important example is India, where implants are unavailable and injectables have only recently been approved by the national Ministry of Health. India represented a large proportion of cases in our analysis, and women and adolescents there had access to only 1 LARC method, IUDs, following their abortion.

Strengths and Limitations

Our analysis had the advantages of including a large number of abortion care cases in a variety of service delivery environments in 10 countries. Recordkeeping on client information was of good quality with generally low rates of missing data, and data were available on individual clients. Literature focused specifically on increasing use of LARCs among adolescents in developing countries is quite limited.[34] Published research on interventions to provide LARCs to adolescents following abortion care in these countries is virtually unavailable. Our analysis provides new evidence on an intervention that included provision of LARC methods to adolescent abortion clients.

Limitations of our analysis and findings include the fact that data were not available before Ipas began programmatic support due to the initial poor quality of abortion care log books in most settings. Resource limitations did not permit data collection in comparison facilities that had not received specialized abortion training for providers

nor site upgrades. Furthermore, log book data were recorded by providers themselves and therefore had the potential for error or underreporting, especially given the stigma associated with abortion care.

Abortion care log book entries rarely include women's fertility desires, and even if noted, the data are unreliable. Women's preferences about if and when they wish to become pregnant again can be collected through other methodologies such as client exit interviews or observation of provider-client interactions during service delivery. Ideally, log book data on contraceptive uptake would be paired with clients' responses on the quality of services, contraceptive method preferences, appropriateness of information offered, and their fertility plans.

Our data did not include an important group, women who use medical abortion on their own or with the help of individuals outside a clinical setting. Very little is known of their postabortion contraceptive patterns; the methodological challenges of reaching these women are daunting.[36] With the increasing availability of mifepristone and misoprostol in pharmacies and medicine shops and through the Internet and other outlets, researchers will need to develop approaches to learn if and how women, especially adolescents, access contraception following medical abortion obtained outside a health facility setting.

PROGRAMMATIC RECOMMENDATIONS

Although this study found relatively high rates of postabortion contraceptive acceptance, gaps remain, especially for adolescents. Any programmatic recommendations to improve postabortion contraception as part of facility-based abortion care for adolescents and young women must maximize the available evidence from other sexual and reproductive health interventions. "Youth-friendly" sexual and reproductive health services are common but often suffer from fragmentation and spotty implementation.[37] The evidence points to the value of youth-friendly services that include health worker training and creation of welcoming environments for young people, integrated with community outreach and demand creation efforts to young people and community members.[37–39] Adolescents are not a homogenous group, and comprehensive abortion care services that seek to improve postabortion contraceptive provision, should be assessed to determine if they meet the needs of subgroups of adolescent clients (e.g., married/unmarried, in/out-of-school, those in humanitarian settings).

Our recommendations to improve postabortion contraception for adolescents and young people receiving health facility care include the following:

- Update policies and protocols to eliminate barriers such as requirements that women and adolescents have to be married or have parental or spousal consent for contraceptive services, and ensure that hormonal methods are indicated as appropriate on the same day of medical abortion
- Implement provision of a wide choice of contraceptive methods for adolescents and young women to select from, including LARC methods
- Ensure that contraceptive methods are available in all locations within a facility where induced abortion services and PAC are offered
- Train providers, clinic managers, and facility staff to improve counseling and client interactions, upgrade clinical skills on postabortion contraceptive methods, and implement efforts to reduce stigma
- Consider post-training follow-up support of providers and facilities to reinforce new skills and resolve obstacles to care
- Upgrade facilities to ensure privacy, especially for adolescents, and ensure confidentiality of client interactions and records
- Reduce or eliminate out-of-pocket costs of all contraceptive methods, especially for adolescent clients
- Include frequent client and community interviews to determine the preferences of young women and adolescents, and assess the quality of postabortion contraceptive care they receive

Although postabortion contraceptive uptake was relatively high among the population studied, gaps remain, especially for adolescents.

While our study finds that important progress has been achieved in improving postabortion contraceptive care in Ipas-supported facilities, many health facilities in developing countries still do not offer comprehensive services. This gap is especially tragic for young women and adolescents who are most vulnerable to unintended pregnancy and unsafe abortion. Increased contraceptive use, including after abortion, is critical to their improved sexual and reproductive health and well-being.

Acknowledgments: We appreciate the skill and dedication of Ipas research, health systems, and program staff working in the 10 countries

that are part of our study. Allison Long, Ali Buehler, and Ros Schwartz assisted with references and we greatly appreciate their efforts.

Funding: Ipas and Ipas Development Foundation.

Competing Interests: None declared.

REFERENCES

1. Darroch JE, Woog V, Bankole A, Ashford LS. *Adding it Up: Costs and Benefits of Meeting the Contraceptive Needs of Adolescents.* New York: Guttmacher Institute; 2016. https://www.guttmacher.org/sites/default/files/report_pdf/adding-it-up-adolescents-report.pdf. Accessed December 5, 2017.
2. Mutua MM, Maina BW, Achia TO, Izugbara CO. Factors associated with delays in seeking post abortion care among women in Kenya. *BMC Pregnancy Childbirth.* 2015;15(1):241. CrossRef. Medline
3. Sowmini CV. Delay in termination of pregnancy among unmarried adolescents and young women attending a tertiary hospital abortion clinic in Trivandrum, Kerala, India. *Reprod Health Matters.* 2013;21 (41):243–250. CrossRef. Medline
4. Ganatra B, Gerdts C, Rossier C, et al. Global, regional, and subregional classification of abortions by safety, 2010-14: estimates from a Bayesian hierarchical model. *Lancet.* 2017;390(10110):2372–2381. CrossRef. Medline
5. Shah IH, Åhman E. Unsafe abortion differentials in 2008 by age and developing country region: high burden among young women. *Reprod Health Matters.* 2012;20(39):169–173. CrossRef. Medline
6. Blanc AK, Tsui AO, Croft TN, Trevitt JL. Patterns and trends in adolescents' contraceptive use and discontinuation in developing countries and comparisons with adult women. *Int Perspect Sex Reprod Health.* 2009;35(2):63–71. CrossRef. Medline
7. Clifton D, Hervish A. *The World's Youth 2013 Data Sheet.* Washington, DC: Population Reference Bureau; 2013. http://www.prb.org/Publications/Datasheets/2013/youth-datasheet-2013.aspx. Accessed December 5, 2017.
8. Schreiber CA, Sober S, Ratcliffe S, Creinin MD. Ovulation resumption after medical abortion with mifepristone and misoprostol. *Contraception.* 2011;84(3):230–233. CrossRef. Medline
9. Forrest Boyd E Jr, Holmstrom EG. Ovulation following therapeutic abortion. *Am J Obstet Gynecol.* 1972;113(4):469–473. CrossRef. Medline
10. International Federation of Gynecology and Obstetrics (FIGO); International Confederation of Midwives (ICM); International Council of Nurses (ICN); United States Agency for International Development (USAID); White Ribbon Alliance; Department for International Development (DFID); Bill & Melinda Gates Foundation. Post abortion family planning: a key component of post abortion care: consensus statement. FIGO;2013. https://www.figo.org/news/figo-consensus-statement-family-planning-key-component-post-abortion-care-0014089. Accessed December 5, 2017.
11. Huber D, Curtis C, Irani L, Pappa S, Arrington L. Postabortion care: 20 years of strong evidence on emergency treatment, family planning, and other programming components. *Glob Health Sci Pract.* 2016;4(3):481–494. CrossRef. Medline
12. Tripney J, Kwan I, Bird KS. Postabortion family planning counseling and services for women in low-income countries: a systematic review. *Contraception.* 2013;87(1):17–25. CrossRef. Medline
13. McDougall J, Fetters T, Clark KA, Rathavy T. Determinants of contraceptive acceptance among Cambodian abortion patients. *Stud Fam Plann.* 2009;40(2):123–132. CrossRef. Medline
14. Johnson BR, Ndhlovu S, Farr SL, Chipato T. Reducing unplanned pregnancy and abortion in Zimbabwe through postabortion contraception. *Stud Fam Plann.* 2002;33(2):195–202. CrossRef. Medline
15. Alemayehu T, Biru D, Brahmi D, Fetters T. An evaluation of postabortion contraceptive uptake following a youth-friendly services intervention in Ethiopia. Chapel Hill, NC: Ipas; 2016. http://www.ipas.org/en/Resources/Ipas%20Publications/An-evaluation-of-postabortion-contraceptive-uptake-following-a-youth-friendly-services.aspx. Accessed December 5, 2017.
16. McCarraher DR, Chen-Mok M, Oronoz AS, et al. Meeting the needs of adolescent post-abortion care patients in the Dominican Republic. *J Biosoc Sci.* 2010;42(4):493–509. CrossRef. Medline
17. Zhu JL, Zhang WH, Cheng Y, et al. Impact of post-abortion family planning services on contraceptive use and abortion rate among young women in China: a cluster randomised trial. *Eur J Contracept Reprod Health Care.* 2009;14(1):46–54. CrossRef. Medline
18. Benson J, Andersen K, Brahmi D, et al. What contraception do women use after abortion? An analysis of 319,385 cases from eight countries. *Glob Public Health.* 2018;13(1):35–50. CrossRef. Medline
19. Maxwell L, Voetagbe G, Paul M, Mark A. Does the type of abortion provider influence contraceptive uptake after abortion? An analysis of longitudinal data from 64 health facilities in Ghana. *BMC Public Health.* 2015;15(1):586. CrossRef. Medline
20. London Summit on Family Planning. Summaries of commitments. London: UKAID and Bill & Melinda Gates Foundation; 2012. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/67328/london-summit-family-planning-commitments.pdf. Accessed December 5, 2017.
21. Ipas. Clinical Updates in Reproductive Health. Chapel Hill, NC: Ipas; 2017. http://www.ipas.org/clinicalupdates. Accessed November 14, 2017.
22. World Health Organization (WHO). *Clinical Practice Handbook for Safe Abortion.* Geneva: WHO; 2014. http://www.who.int/reproductivehealth/publications/unsafe_abortion/clinical-practice-safe-abortion/en/. Accessed December 5, 2017.
23. Turner KL, Börjesson E, Huber A, Mulligan C. *Abortion Care for Young Women: A Training Toolkit.* Chapel Hill, NC: Ipas; 2011. http://www.ipas.org/en/Resources/Ipas%20Publications/Abortion-care-for-young-women-A-training-toolkit.aspx. Accessed December 5, 2017.
24. World Health Organization (WHO). *Safe Abortion: Technical and Policy Guidance for Health Systems.* 2nd ed. Geneva: WHO; 2012. http://www.who.int/reproductivehealth/publications/unsafe_abortion/9789241548434/en/. Accessed December 5, 2017.
25. Banerjee SK, Gulati S, Andersen KL, Acre V, Warvadekar J, Navin D. Associations between abortion services and acceptance of postabortion contraception in six Indian states. *Stud Fam Plann.* 2015;46 (4):387–403. CrossRef. Medline
26. Billings DL, Benson J. Postabortion care in Latin America: policy and service recommendations from a decade of operations research. *Health Policy Plan.* 2005;20(3):158–166. CrossRef. Medline
27. Solo J, Billings DL, Aloo-Obunga C, Ominde A, Makumi M. Creating linkages between incomplete abortion treatment and family planning services in Kenya. *Stud Fam Plann.* 1999;30(1):17–27. CrossRef. Medline
28. Kalyanwala S, Acharya R, Francis Zavier AJ. Adoption and continuation of contraception following medical or surgical abortion in Bihar and Jharkhand, India. *Int J Gynaecol Obstet.* 2012;118 (suppl 1):S47–S51. CrossRef. Medline
29. Committee on Adolescence. Contraception for Adolescents. *Pediatrics.* 2014;134(4):e1244–e1256. CrossRef. Medline
30. Committee on Adolescent Health Care Long-acting Reversible Contraception Working Group, The American College of Obstetricians and Gynecologists. Committee opinion no. 539: adolescents and long-acting reversible contraception: implants and

intrauterine devices. *Obstet Gynecol.* 2012;120(4):983–988. CrossRef. Medline

31. World Health Organization (WHO). *Medical Eligibility Criteria for Contraceptive Use.* 5th ed. Geneva: WHO; 2015. http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/. Accessed December 5, 2017.
32. Secura GM, Madden T, McNicholas C, et al. Provision of no-cost, long-acting contraception and teenage pregnancy. *N Engl J Med.* 2014;371(14):1316–1323. CrossRef. Medline
33. Jatlaoui TC, Riley HEM, Curtis KM. The safety of intrauterine devices among young women: a systematic review. *Contraception.* 2017;95(1):17–39. CrossRef. Medline
34. Health Communication Capacity Collaborative (HC3). Barriers to LARC uptake among youth, highlights from the research. Baltimore, MD: HC3, Johns Hopkins Center for Communication Programs; 2014. http://healthcommcapacity.org/wp-content/uploads/2015/04/Barriers-to-LARC-Uptake-Among-Youth-Brief.pdf. Accessed January 30, 2017.
35. Chandra-Mouli V, McCarraher DR, Phillips SJ, Williamson NE, Hainsworth G. Contraception for adolescents in low and middle income countries: needs, barriers, and access. *Reprod Health.* 2014;11(1):1. CrossRef. Medline
36. Kapp N, Blanchard K, Coast E, et al. Developing a forward-looking agenda and methodologies for research of self-use of medical abortion. *Contraception.* 2017 Sep 18. pii:S0010–7824(17)30439-0. Epub ahead of print. CrossRef. Medline
37. Chandra-Mouli V, Lane C, Wong S. What does not work in adolescent sexual and reproductive health: a review of evidence on interventions commonly accepted as best practices. *Glob Health Sci Pract.* 2015;3(3):333–340. CrossRef. Medline
38. Rankin K, Heard A, Diaz N. *Adolescent Sexual and Reproductive Health: Scoping the Impact of Programming in Low- and Middle-Income Countries. 3ie Scoping Paper 5.* New Delhi: International Initiative for Impact Evaluation (3ie); 2016. http://www.3ieimpact.org/media/filer_public/2016/12/29/sp5-asrh.pdf. Accessed December 5, 2017.
39. Denno DM, Hoopes AJ, Chandra-Mouli V. Effective strategies to provide adolescent sexual and reproductive health services and to increase demand and community support. *J Adolesc Health.* 2015;56(1 suppl):S22–S41. CrossRef. Medline

Peer Reviewed

Received: March 9, 2017; **Accepted:** November 21, 2017

Cite this article as: Benson J, Andersen K, Healy J, Brahmi D. What factors contribute to postabortion contraceptive uptake by young women? A program evaluation in 10 countries in Asia and sub-Saharan Africa. Glob Health Sci Pract. 2017;5(4):644-657. https://doi.org/10.9745/GHSP-D-17-00085

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METHODOLOGY

Harmonizing Methods for Estimating the Impact of Contraceptive Use on Unintended Pregnancy, Abortion, and Maternal Health

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Five models estimate the impact of family planning on health outcomes, but the estimates previously have diverged because the models used different assumptions, inputs, and algorithms. After a collective harmonization process, the models now produce more similar estimates although they retain some minimal differences. These models assist in planning, resource allocation, and evaluation.

ABSTRACT

Estimates of the potential impacts of contraceptive use on averting unintended pregnancies, total and unsafe abortions, maternal deaths, and newborn, infant, and child deaths provide evidence of the value of investments in family planning programs and thus are critically important for policy makers, donors, and advocates alike. Several research teams have independently developed mathematical models that estimate the number of adverse health outcomes averted due to contraceptive use. However, each modeling approach was designed for different purposes, and as such the methodological assumptions, data inputs, and mathematical algorithms initially used in each model differed; consequently, the models did not produce comparable estimates for the same outcome indicators. To address this, a series of expert group meetings took place in which 5 models—Adding it Up, Impact 2, ImpactNow, Reality Check, and FamPlan/Lives Saved Tool (LiST)—were reviewed and harmonized where possible. The group identified the main reasons for the inconsistencies in the estimates generated by the models for each of the adverse health outcome indicators. The group then worked together to align the methodologies for estimating numbers of unintended pregnancies, abortions, and maternal deaths averted due to contraceptive use, and reviewed the challenges with estimating the impact of contraceptive use on newborn, infant, and child deaths, including the lack of a conceptually clear pathway and rigorous evidence. The assumption that most influenced harmonization was the comparison pregnancy rate used by the models to estimate the counterfactual scenario—that is, if women who are currently using contraception were not using a method, how many would become pregnant? All the models now base this on the number of unintended pregnancies among women with unmet contraceptive need, bringing the estimates for unintended pregnancies, total and unsafe abortion, and maternal deaths much closer together. The agreed approaches have already been adopted by the Family Planning 2020 (FP2020) initiative and Track20, a project that supports FP2020. The experts will continue to update their models collaboratively to ensure that the most current estimation methodologies and data available are used. Valid and reliable methodologies for estimating these impacts from family planning are critically important, not only for advocacy to sustain resource allocation commitments but also to enable measurement and tracking of global development indicators. Conflicting estimates can be counterproductive to generating support for family planning programs, and this harmonization process has created a more unified voice for quantifying the benefits of family planning.

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BACKGROUND

The London Summit on Family Planning in 2012, and the ensuing Family Planning 2020 (FP2020) initiative,[1] has mobilized substantial resources to support the expansion of family planning services. Specifically, the initiative aims to enable an additional 120 million women in 69 countries to use modern contraception by 2020 compared with the total number of users of modern contraceptive methods in 2012. The primary purpose for mobilizing these resources is to enable women to protect themselves against an unintended pregnancy,

defined here as a pregnancy that was not wanted at all (i.e., unwanted) or that occurred earlier than intended (i.e., mistimed).

Reducing unintended pregnancies is frequently stated as a policy goal by governments, donors, and service delivery organizations. For example, the UK's *Framework for Results for Improving Reproductive, Maternal and Newborn Health in the Developing World* has a strategic priority to "prevent unintended pregnancies by enabling women and adolescent girls to choose whether, when and how many children they have" [2]; one of the core development objectives of the United States Agency for International Development (USAID) is to "prevent 54 million unintended pregnancies" [3]; and FP2020 tracks and reports annually on the estimated number of unintended pregnancies averted due to use of modern methods of contraception.[4]

Protection against an unintended pregnancy through use of contraception also potentially averts several adverse health outcomes that may occur had the pregnancy happened. These outcomes can include an unsafe abortion if the unintended pregnancy had been terminated; morbidity or death if the woman had suffered complications related to or aggravated by pregnancy; and morbidities or deaths of newborns, infants, and children if the pregnancy had resulted in a live birth. Clearly, it is not possible to *observe* and *measure* these outcomes directly because the unintended pregnancies have not occurred. However, being able to *estimate* these potential impacts is critically important for policy makers and donors because such estimates provide evidence of how family planning contributes to maternal and child health, thus providing strong advocacy messages to support investments in family planning from national and global funding sources. These estimates also demonstrate the link between use of family planning and achievement of the Sustainable Development Goals.[5]

The impact of reducing unwanted pregnancies on national fertility rates, and consequently on economic and social development including through a "demographic dividend," has been well documented. In contrast, efforts to estimate the broader impact of contraceptive use on maternal, infant, and child health are less mature. But several models have been developed recently to estimate the impact of contraceptive use on averting adverse health outcomes. The purpose of this article is to describe these models, including how they are similar and different, and to report on collaborative efforts to better align the assumptions and inputs used in the models in order to produce more comparable results.

CHALLENGES IN ESTIMATING THE HEALTH IMPACTS OF FAMILY PLANNING

Over the past few years, several research teams have independently developed models that estimate the number of adverse health outcomes averted due to contraceptive use. The development of these estimation models has been uncoordinated, however, with each approach being conceptualized and designed for complementary, yet different, purposes. Because the methodological assumptions for each model have differed, the data inputs required and mathematical algorithms used for each model have varied, and so the models did not produce comparable estimates for the same outcome indicators. For example, using the same dataset from Malawi, Figure 1 depicts estimates from 5 models for the numbers of unintended pregnancies, unplanned births, and abortions averted due to women using family planning. The generation of different estimates for the same indicator has confused policy makers, managers, and donors, even when the reasons for the differences are explained.

Different estimates of the impact of contraceptive use on health outcomes has confused policy makers, managers, and donors, even when the reasons for the differences are explained.

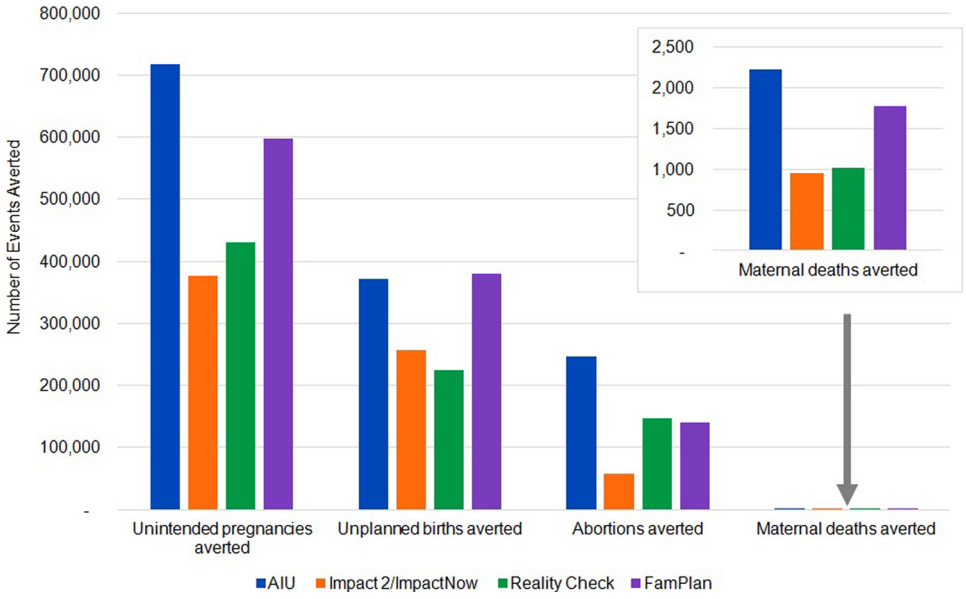
Each estimation model has been designed to serve a particular purpose and for different audiences, and so it would not be appropriate or desirable to try to consolidate them into 1 model. However, the scale of the differences shown in Figure 1 has raised concerns as to whether the assumptions for the models are sufficiently aligned. It has also highlighted the need to better communicate to decision makers the different purposes of each model so that they can select the appropriate model to generate the type of data needed to inform a particular decision.

To address these concerns, the Population Council's consortium for *Strengthening Evidence for Programming on Unintended Pregnancy* (STEP UP), funded by UKAID from the Department of International Development, convened a series of expert group meetings in September 2013, March 2014, and December 2014 to review and harmonize, where possible, the 5 most commonly used modeling approaches:

1. Adding It Up from the Guttmacher Institute
2. Impact 2 from Marie Stopes International
3. ImpactNow from the USAID-supported Health Policy Project
4. Reality Check from EngenderHealth's USAID-supported RESPOND Project

A series of expert group meetings was convened to review and harmonize, where possible, the 5 most commonly used modeling approaches to estimate the impact of contraceptive use on health outcomes.

FIGURE 1. Different Estimates of the Health Impact of Contraceptive Use in Malawi From 5 Models, Before Harmonizing the Modeling Approaches



Abbreviation: AIU, Adding It Up.

5. FamPlan and the Lives Saved Tool (LiST) from the Spectrum suite of models hosted by Avenir Health

Participants at these meetings included those responsible for designing and using these 5 approaches as well as recognized experts in demography, forecasting and modeling, and program evaluation. This was the first time that representatives from all 5 modeling teams had met together. The meetings provided a unique opportunity for the modelers to openly discuss the strengths and weaknesses of their modeling approaches among their peers in a neutral setting hosted and moderated by an organization that does not have a vested interest in any particular modeling approach.

The expert group worked together to align the methodologies used in their models to estimate the number of unintended pregnancies, abortions, maternal deaths, and infant and child deaths averted due to contraceptive use.

The initial meetings identified and highlighted the main reasons for the inconsistencies in the estimates generated by the models for each of the key adverse health outcome indicators (unintended pregnancy, abortion, maternal death, infant death, and child death). The group then worked together to seek and reach agreement on alignment of 4 methodologies:

1. Methodology for estimating the number of unintended pregnancies averted due to contraceptive use, including the comparison pregnancy rate to use for the counterfactual of contraceptive use (e.g., if women had not been using contraception, how many would have become pregnant)[6] and failure rates to use for each type of contraceptive method (defined as the probability of a woman using a method becoming pregnant during 12 months of use[7])
2. Methodology for estimating the number of abortions averted due to contraceptive use
3. Methodology for estimating the number of maternal deaths averted due to contraceptive use
4. Methodology for estimating the numbers of infant and child deaths averted due to contraceptive use

This article will describe the purpose for each estimation model, review how each model used the 4 methodologies, and report on the alignments achieved through the collaborative process. (For a more detailed description and comparison of the 5 modeling approaches, see STEP UP, 2014.[8]) It is important to bear in mind that these are estimation models, which are used to generate measures for events that cannot be empirically observed and so they cannot be empirically validated either.

PURPOSE OF EACH MODEL

The Guttmacher Institute's ***Adding It Up*** model uses tabulations from the most recent sources to estimate need, coverage, cost and impacts of modern contraceptive services, maternal and newborn health care, antiretroviral care for pregnant women living with HIV and their newborns, and treatment for 4 common sexually transmitted infections; varying scenarios of coverage and the costs and impacts across different levels of coverage are estimated. These scenarios and impacts are estimated individually and for combinations of these service needs. Impacts are expressed in terms of unintended pregnancies and their outcomes, including unplanned live and stillbirths, induced abortions and miscarriages, maternal and neonatal deaths and disability-adjusted life years (DALYs), and transmission of HIV to newborns. Adding It Up estimates have been calculated using multiple country-level datasets in Excel files, although most results are reported for geographical and other groupings of countries because of frequent limitations in the quality of original datasets. Although Adding It Up does not provide a template model, results and detailed tabulations are made available widely.[9]

Impact 2 is a spreadsheet-based model developed by Marie Stopes International that is designed to use existing service provision data. It can be used to estimate the impact of family planning, safe abortion, or postabortion care services provided by a particular organization or across an entire country. Impact 2 can estimate past, current, and future contributions of a service provision program to the additional number of contraceptive users and increases in contraceptive prevalence. It also estimates the wider health, demographic, and economic impacts of these services. In addition, Impact 2 can be used to estimate the quantity of service utilization needed to reach a goal, as well as to monitor progress over time. It has been used by managers of service delivery programs and for planning national strategies by governments.[10]

ImpactNow is a spreadsheet-based model developed by the USAID-supported Health Policy Project that estimates the health and economic impacts of family planning in the near term (2- to 7-year time horizon). It is designed to model the impacts of different policy scenarios and to compare the results of those scenarios in advocacy materials. It can help to estimate the impacts of many "what if" questions about policy options. The outcomes are focused on both reproductive health and economic metrics. Model results have been used to advocate for family planning programs in a number of countries, primarily in sub-Saharan Africa.[11]

Designed by EngenderHealth under the USAID-funded RESPOND Project, **Reality Check** is a Windows application for use in low-resource settings that can be used to set family planning goals and plan for service expansion to meet those goals; it can also provide advocacy data by estimating program requirements for implementation, along with the impact of achieving contraceptive goals. The tool enables users to test future goal scenarios, including changes in the method mix, and to compare those future scenarios with past performance to determine whether current goals are realistic. Reality Check can be used at any geographic level for which population and contraceptive prevalence rate data can be defined. The tool has been used to establish evidence-based family planning goals and to inform holistic plans to meet those goals in several sub-Saharan African countries.[12]

FamPlan and **LiST** are modules in the Spectrum modeling system. FamPlan[13] estimates the family planning requirements to meet goals, such as reducing unmet need, and the consequences of scaling up contraceptive use, in terms of outcomes such as fertility, births, and unintended pregnancies. The module uses the proximate determinants of fertility to model the impact of change on the total fertility rate (TFR), and then makes demographic projections of the resulting population size and structure. At the time this work was taking place, FamPlan did not estimate impacts averted but rather events that happen (e.g., births, abortions); however, by comparing multiple projections one could arrive at estimates of impacts averted. (FamPlan has now been updated with an option to calculate the number of unintended pregnancies, total and unsafe abortions, and maternal deaths averted.)

LiST[14] supports the development of plans for child survival programming by estimating the current distribution of child deaths by cause and the effects of health interventions, including family planning, on child mortality rates. Both the LiST and FamPlan modules have been applied by a large number of countries to develop national family planning and child survival plans and for global analyses for planning and resource mobilization.

The Guttmacher Institute's Adding It Up model estimates need for and cost of modern contraception, maternal and newborn health care, antiretroviral care for pregnant women living with HIV and their newborns, and treatment for 4 common sexually transmitted infections.

Marie Stopes International's Impact 2 model uses existing service provision data to estimate the health, demographic, and economic impacts of family planning and other services.

The Health Policy Project's ImpactNow model estimates the health and economic impacts of family planning in the near term.

EngenderHealth's Reality Check can be used to set family planning goals and plan for service expansion to meet those goals.

FamPlan, from the Spectrum modeling system, estimates family planning requirements to meet specific goals and the consequences of scaling up contraceptive use in terms of health outcomes.

LiST, also from the Spectrum modeling system, estimates the current distribution of child deaths by cause and the effects of health interventions on child mortality rates.

METHODS FOR ESTIMATING HEALTH OUTCOMES

Estimating Unintended Pregnancies Averted

In all of the models except FamPlan, a pregnancy rate is used to estimate the counterfactual scenario—that is, if women who are currently using contraception were not using a method, how many would become pregnant? Including this is important because not all contraceptive users will become pregnant if they are not using contraception. The FamPlan model generates and compares multiple scenarios, rather than directly estimating numbers of pregnancies, by using the proximate determinants model to estimate the impact of contraceptive prevalence rate changes on the TFR. Following this harmonization process, a new option has been added to FamPlan to allow for estimation of impacts using the counterfactual approach employed by the other models.

Moreover, the expert group reached agreement on the particular pregnancy rate variable that should be used as a default in all the models; prior to this harmonization process, the models had been using different pregnancy rates (see below). The default value in all models is now a "non-user at risk of unintended pregnancy," which serves as a proxy for the counterfactual. The group defined this unintended pregnancy rate as the likelihood of a pregnancy over 12 months for sexually active, fecund women who do not want to become pregnant and are not using contraception–that is, among women with an unmet need for contraception. The models use the Demographic and Health Survey (DHS) definition of unmet need because it is widely understood and facilitates comparisons across datasets, time periods, and countries. This definition assumes sexual activity among married women.

The group agreed to use the pregnancy rate estimated using the Adding It Up methodology,[9] which divides the number of unintended pregnancies among women with unmet need (i.e., non-users at risk of unintended pregnancy) by the total number of women with unmet need. This methodology estimates the pregnancy rate among women who do not wish to become pregnant, whereas the previous comparison pregnancy rates used by ImpactNow, Impact 2, and Reality Check had been for all women not using contraception. The agreed-upon pregnancy use estimates are based on (1) country-level data for the numbers of women by contraceptive need and use; (2) typical-use failure rates among developing country and U.S.-based contraceptive users; and (3) Adding It Up's sub-regional estimates of numbers of unintended pregnancies. The global pregnancy rate is the median of these country-specific pregnancy rates (which at the time of the meeting was 31%, with an interquartile plausibility range of 23% to 38%). Previously, the various models had used pregnancy rates of either 85%, representing the pregnancy rate among women in the United States who stopped using contraception to become pregnant,[15] or 40%, representing a previous revision to the 85% rate to capture a rate of women not actively trying to get pregnant. Thus, moving to the agreed rate has led to substantial changes in the results from some models. Furthermore, the group also agreed to use one global pregnancy rate rather than trying to estimate potential regional or country variations.

Because no method is 100% effective at preventing pregnancy and because methods may not always be used correctly and consistently, "typical-use method failure rates," are included in the models. The typical-use failure rate is the probability of pregnancy during a specified time period among women using a method as *typically* used (i.e., not necessarily correctly and consistently, which is referred to as the "perfect-use" failure rate).[16] The original versions of all models used several sources for method-specific typical-use failure rates, largely based on research by Cleland, Ali, and Shah[17] (using data from DHS, which includes non-permanent method users only) and by Trussell[15] (for data on permanent method users from clinical trials with large study populations). The group had concerns about mixing failure rates estimated differently and for different populations but agreed to continue to use both sources. It was acknowledged that more needs to be known about method effectiveness, consistency, and correctness of use, and how these affect method effectiveness. The group committed to consider further evidence as it emerges and to coordinate updating assumptions and data inputs to continue improving the models. For example, recent estimates of failure rates in 43 developing countries using DHS data were published in 2016[18] and could be reviewed for potential use in the models.

The group discussed whether method failure rates should be adjusted for individual countries. Failure rates by method are only available from a limited set of national datasets and as the only data available, these failure rates are generally accepted as being valid globally. Within the group, the Impact 2, ImpactNow, Reality Check, and

FamPlan modelers decided to continue to use these "global" failure rates for all countries, whereas the Adding It Up approach will continue to use method failure rates that are adjusted against sub-regional estimates of unintended pregnancies.

Estimating Abortions Averted

Using contraception will reduce the number of unintended pregnancies, which in turn will reduce the number of induced abortions—safe or unsafe—that some women use to terminate an unintended pregnancy. Previously, the models used different methodologies to estimate the number of abortions averted, leading to some very large discrepancies. Given the very limited data available on abortion, it is difficult to have a clear methodological approach for modeling this outcome. Recognizing the importance of harmonization, the group agreed that all 5 models would base their estimates on the sub-regional proportion of unintended pregnancies that end in induced abortion, using the rates published by Sedgh et al. in 2014.[19] The number of abortions averted by use of modern contraception is thus estimated as the number of unintended pregnancies averted by use of modern contraception multiplied by the proportion of unintended pregnancies that end in induced abortion; the number of induced abortions is estimated from available data, special country studies, and consultations with experts, including the World Health Organization (WHO). Recent estimates of abortion levels and safety can be used for future inclusion in the models.[20,21]

Some unintended pregnancies end through spontaneous abortion (i.e., a miscarriage), and a very small proportion end in an ectopic pregnancy. Reducing the number of unintended pregnancies, therefore, will also reduce the number of miscarriages and ectopic pregnancies. Reliable statistics for these rates do not exist, however, and the models estimate these numbers slightly differently, but the differences are very minor. Therefore, no change was deemed necessary.

Estimating Maternal Deaths Averted

The causes of maternal mortality are several. WHO defines a maternal death as[22]:

> *The death of a woman while pregnant, or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management (from direct or indirect obstetric death), but not from accidental or incidental causes.*

For the purpose of these models, a maternal death can be categorized according to whether the woman died from *complications of an induced abortion* or due to other *obstetric causes* during pregnancy, delivery, or up to 42 days after delivery.[23]

Estimates are available for the maternal mortality ratio (MMR) in each country—the number of maternal deaths during a given time period per 100,000 live births during the same time period.[24] Applying the national MMR to the number of births averted would not be correct, however, because the national MMR reflects the risk of dying related to the national distribution of all pregnancies and their outcomes (live births, miscarriages, abortions). All of the models agreed to use the "percentage of unintended pregnancies ending in induced abortion" to estimate the number of abortions averted through use of family planning. As the distribution of outcomes of *unintended* pregnancies is different from that of *all* pregnancies, the MMR does not represent the risk of dying associated with an unintended pregnancy. Rather, a new MMR must be constructed to represent the risk of dying associated with an unintended pregnancy to account for the risk associated with each pregnancy outcome: live birth, miscarriage, and abortion.

The group recommended, therefore, that all of the models should estimate an unintended pregnancy MMR that is appropriate for each model. An estimation approach has been developed and is now being used by Impact 2, ImpactNow, and FamPlan. Further work is needed to understand the proportion of deaths due to unsafe abortion represented within the all-cause estimations by WHO,[25] since those causes due to unsafe abortion are not always clearly recorded (e.g., a hemorrhage could be a result of unsafe abortion or non-abortion causes). The group agreed to work with WHO to better interpret these data and to consider further changes to this methodology, given the large differences in MMRs that remained in the models after the harmonization process.

All 5 models now base their abortions averted estimates on the sub-regional proportion of unintended pregnancies that end in induced abortion.

The models have to construct a new maternal mortality ratio, different than the UN published estimates, that represents the risk of dying associated specifically with an *unintended* pregnancy.

Newborn, Infant and Child Deaths Averted

For more than 3 decades, contraceptive use has been promoted as a key strategy for reducing newborn, infant, and child deaths. This causal relationship is most frequently conceptualized in terms of *risk reduction*: women using contraception can determine the timing and number of children so that they can reduce the likelihood of

experiencing one of the 4 "toos"—having a birth when they are *too young*; having births spaced *too soon*; having *too many* births; and having a birth when they are *too old*. Evidence indicating that such births are generally *correlated* with adverse outcomes is well established through cross-sectional surveys,[26–33] particularly for "too young" and "too soon" births and their correlation with newborn or infant death and stunted growth and development in children surviving such births.

To guide policy and programming advocacy and implementation, however, it is critically important that claims to *causal pathways* between contraceptive use, timing of births, and newborn, infant, and child mortality and morbidity be more fully understood and justified empirically. The estimates of newborn, infant, and, especially, child deaths averted due to contraceptive use are recognized as the weakest elements of all of these models. While the relationships between risky pregnancies (as defined above in the 4 "toos") and newborn and infant mortality and morbidities, and with poorer child development, are relatively well supported with the evidence available, the correlation with *child mortality* is poorly understood because many other factors may intervene by the time of childhood (i.e., between 1 and 5 years old). The estimation models must produce valid measures based on logically consistent causal pathways in order for policy statements and initiatives advocating investments in family planning to legitimately cite quantified reductions in newborn and infant, as well as child, mortality as among the anticipated returns on investment for family planning. (FP2020 has chosen not to include these impact indicators in its analysis due to the uncertainties of attribution.) Consequently, there is some urgency to better understand the nature of these relationships to prevent any inappropriate expectations of causality.

The estimates of newborn, infant, and child deaths averted due to contraceptive use are recognized as the weakest elements of these models due to a lack of conceptually clear casual pathway and lack of rigorous evidence.

These pathways are being analyzed further using recent datasets and new analytical techniques to seek explanations for *biological mechanisms* that link high-risk births (the 4 "toos") to adverse birth outcomes for newborns (e.g., small for gestational age, preterm births) and to infant mortality.[34] They are also being analyzed for the *behavioral pathways* that include, for example, lower utilization of health services by women with many births, who have experienced unintended pregnancies, and with inequitable access.[35,36]

The lack of conceptually clear pathways based on rigorous evidence made it challenging for this group of modelers to agree on an approach for estimating such impacts. All models, except Reality Check, currently estimate these impacts; given the lack of agreement on conceptual pathways, the group agreed that each team would continue to use their own estimation methods. The group also agreed that descriptions of the models should make it clear if the impacts being modeled are based on reductions in risk, as is the case for Impact 2 and ImpactNow, or on the demographic impact of fewer pregnancies resulting in fewer deaths and morbidities, as is the case for Adding it Up. These different approaches are not comparable and produce estimates of differing orders of magnitude.

RESULTS OF HARMONIZATION

Following the consultations, the models were rerun using the harmonized assumptions. As Figure 2 shows, the measures generated for the Malawi dataset are now much closer, indicating that the harmonization process was successful. It should be noted that in this example all models used the same input assumptions to assess whether, given the same assumptions, results would be comparable, thus isolating any differences due to methodologies and default data. It may not always be the case that all models are using the same input data as defaults. In addition, because methodological differences exist due to the different uses of the models, it is not possible to reach perfect agreement. However, comparing Figure 2 with Figure 1 shows that results have become much more consistent across all 4 estimated impacts.

After the harmonization process, the measures generated by the models are now much closer.

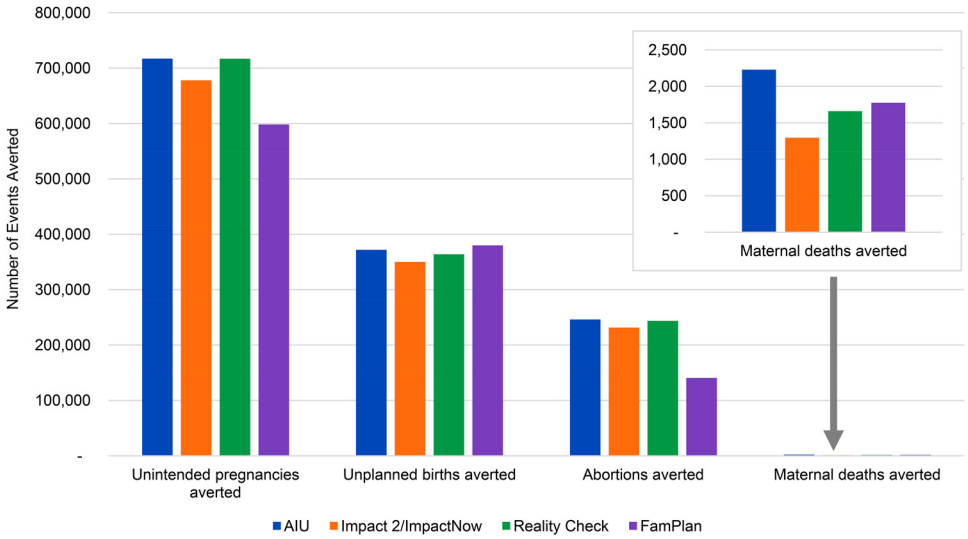
The assumption that most influenced harmonization was the comparison pregnancy rate used by the models. The group had agreed to use the comparison pregnancy rate being used by Adding it Up, which is why the Adding It Up outputs did not change considerably pre- and post-harmonization. Conversely, Impact 2/ImpactNow and Reality Check outputs changed the most because these models changed the comparison pregnancy rate that they had been using. FamPlan does not include this concept in its modeling calculations, but its outputs did change somewhat because it adjusted the contraceptive failure rates used in the model.

The assumption that most influenced harmonization was the comparison pregnancy rate used by the models.

LIMITATIONS AND FURTHER IMPROVEMENTS

This consultative process provided an important and unique opportunity for those involved in the development of methodologies to estimate the health impacts of contraceptive use to convene

FIGURE 2. More Uniform Estimates of the Health Impact of Contraceptive Use in Malawi From 5 Models, After Harmonizing the Modeling Approaches



Abbreviation: AIU, Adding It Up.

and discuss the various approaches used. The group also discussed variations in the quality of the existing data and identified ways in which each model could take this variability into account. The process enabled the group to clarify and differentiate the intended use(s) for each model, to identify where and why similarities and differences exist, and to better align key assumptions for the modeling approaches where needed, while taking into account the critical differences in purpose and approach for each model. As a result of this process, consensus has been reached to ensure that, wherever possible, the models do not generate conflicting estimates that may confuse decision makers. A key lesson learned is the importance of making sure that decision makers understand the purpose of each model and select the model most appropriate for their needs. The group also agreed that each model was sufficiently different to warrant continued use of all models and not to attempt to combine or eliminate any of them.

The results reported in this article comparing the model outputs pre- and post-harmonization were generated in mid-2014; further work and updates have been done on the models since then. The experts will continue to update their models collaboratively to ensure that the most current estimation methodologies and data available are used and that any changes are made harmoniously. This alignment and consensus-building process has strengthened the models by enabling their developers to benefit from each other's experience and research. Moreover, decision makers and managers using the different models can more clearly understand the assumptions behind each model in order to make informed choices between them. This alignment process has shown that through transparent and participatory engagement it is possible to make concrete steps toward harmonization.

It is important for decision makers to understand the purpose of each model and to select the model most appropriate for their needs.

Further, the consensus approaches have been adopted by FP2020 to estimate 3 of its 17 core indicators: (1) unintended pregnancies averted by modern contraceptive use, (2) maternal deaths averted by modern contraceptive use, and (3) unsafe abortions averted due to modern contraceptive use. Moreover, Track20, a project of Avenir Health that supports FP2020, has developed a simple Excel-based tool to estimate these indicators following the agreements made during this harmonization process.

This process has also highlighted the need for continued research to better understand the causal pathways and to estimate the input parameters for each model, as well as the benefit of sustained cooperation within the modeling community to ensure that further methodological developments

are shared to benefit all approaches. Four priorities identified by the group include:

- Further research to elucidate the relationships between contraceptive use, birth timing, and newborn, infant, and child mortality and morbidities
- Definition and measurement of pregnancy intendedness and whether and how intentionality impacts pregnancy and birth outcomes
- Definition and measurement of unsafe abortion-related maternal mortality, including identifying abortion-related mortality that is possibly subscribed to other causes (e.g., hemorrhage) and accounting for the impact of wider access to drugs such as misoprostol
- Consensus on method failure rates and the factors influencing variability across various subpopulations

CONCLUSION

Contraception enables women and couples to achieve their fertility intentions by having the number of children they want, at the time they want. In addition to benefiting women individually and their families and communities, family planning also impacts a number of health outcomes, which substantially increases the return on investment in family planning programs. Consequently, valid and reliable methodologies for estimating these broader impacts are critically important, not only for advocacy to sustain family planning allocation commitments but also to enable measurement and tracking of global indicators for elements of the Sustainable Development Goals, and for strategic planning to reduce maternal, infant, and child mortality and morbidities. Conflicting estimates can be counterproductive to generating support for family planning programs, and this harmonization process has created a more unified voice for quantifying the benefits of family planning.

Acknowledgments: The harmonization process described in this article was supported by UKAid from the Department of International Development (DFID) through the Strengthening Evidence for Preventing Unintended Pregnancies (STEP UP) Research Programme Consortium, which is coordinated by the Population Council. The initial impetus for this exercise was provided by Nel Druce (DFID), who highlighted the differences between these models and the resultant challenges for decision makers; her vigorous encouragement and support for this review and alignment process has been instrumental in bringing together the modeling community. In addition to the article's authors, the contributions from other participants in the series of expert meetings is highly appreciated (affiliations were at the time of the consultations): Jacob Adetunji (USAID), Angela Baschieri (United Nations Children's Fund), Ann Biddlecom (United Nations Population Division), John Bongaarts (Population Council), Win Brown (Bill & Melinda Gates Foundation), Sennen Hounton (United Nations Population Fund), Anrudh Jain (Population Council), Amy Ratcliffe (Population Services International, PSI), Meghan Reidy (PSI), Amani Selim (USAID), and Susheela Singh (Guttmacher Institute). The views expressed in this article are entirely those of the authors and do not necessarily reflect the views of the United Nations.

Funding: UKAid from the Department of International Development.

Competing Interests: None declared.

REFERENCES

1. Family Planning 2020 (FP2020). http://www.familyplanning2020.org. c2017. Accessed October 31, 2017.
2. Department for International Development (DFID). *Choices for Women: Planned Pregnancies, Safe Births and Healthy Newborns*. London: DFID; 2010. https://www.gov.uk/government/publications/choices-for-women-planned-pregnancies-safe-births-and-healthy-newborns. Accessed October 30, 2017.
3. United States Agency for International Development (USAID). *USAID Policy Framework 2011-2015*. Washington, DC: USAID; 2011. https://www.usaid.gov/sites/default/files/documents/1870/USAID%20Policy%20Framework%202011-2015.PDF. Accessed October 30, 2017.
4. Data and Measurement Hub. FP2020 website. http://www.familyplanning2020.org/microsite/measurement-hub/core-indicators. Accessed October 30, 2017.
5. Starbird E, Norton M, Marcus R. Investing in family planning: key to achieving the Sustainable Development Goals. *Glob Health Sci Pract*. 2016;4(2):191–210. CrossRef. Medline
6. Bradley SEK, Croft TN, Fishel JD, Westoff CF. *Revising Unmet Need for Family Planning*. DHS Analytical Studies No. 25. Calverton, MD: ICF International; 2012. https://dhsprogram.com/publications/publication-as25-analytical-studies.cfm. Accessed October 30, 2017.
7. Trussell J. Contraceptive failure in the United States. *Contraception*. 2011;83(5):397–404. CrossRef. Medline
8. STEP UP. *Measuring the Impact of Contraceptive Use on Unintended Pregnancy and Other Health Outcomes*. New York: Population Council; 2014. http://www.popcouncil.org/uploads/pdfs/2014STEPUP_MeasuringImpact.pdf. Accessed October 30, 2017.
9. Darroch JE, Singh S, Weissman E. Adding It Up: *The Costs and Benefits of Investing in Family Planning and Maternal and Newborn Health 2014—Estimation Methodology*. New York: Guttmacher Institute; 2016. https://www.guttmacher.org/sites/default/files/pdfs/pubs/AIU-methodology.pdf. Accessed October 30, 2017.
10. Impact 2: An innovative tool for measuring the impact of reproductive health programmes. Marie Stopes International website. http://mariestopes.org/impact-2. Accessed October 30, 2017.
11. Health Policy Project; United States Agency for International Development; Marie Stopes International. ImpactNow: estimating the health and economic impacts of family planning use. Washington, DC: Futures Group, Health Policy Project; 2014. http://www.healthpolicyproject.com/index.cfm?id=publications&get=pubID&pubID=357. Accessed October 30, 2017.
12. The RESPOND Project. *Reality Check: A Planning and Advocacy Tool for Strengthening Family Planning Programs: Version 3. User's Guide*. New York: EngenderHealth; 2014. http://www.respond-project.org/archive/files/4/4.1/4.1.4/RealityCheck-Files/Reality-Check-User-Guide-Version3.pdf. Accessed October 30, 2017.
13. Stover J, Heaton L, Ross J. *FamPlan: Version 4. A Computer Program for Projecting Family Planning Requirements*. Washington, DC: Policy Project; 2006. https://www.jhsph.edu/research/centers-and-institutes/institute-for-international-programs/_documents/manuals/FamPlanManual.pdf. Accessed October 30, 2014.

14. Winfrey W, McKinnon R, Stover J. Methods used in the Lives Saved Tool (LiST). *BMC Public Health.* 2011;11(suppl 3):S32. CrossRef. Medline
15. Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson AL, Cates W Jr., Stewart F, Kowal D. *Contraceptive Technology.* 19th ed. New York: Ardent Media; 2007.
16. Guttmacher Institute. *Contraceptive Use in the United States.* New York: Guttmacher Institute; 2015. https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states. Accessed October 30, 2017.
17. Cleland J, Ali MM, Shah I. Dynamics of contraceptive use. In: United Nations (UN), Department of Economic and Social Affairs, Population Division. *Levels and Trends of Contraceptive Use as Assessed in 2002.* New York: UN; 2006:87–115. http://www.un.org/esa/population/publications/wcu2002/WCU2002_Report.pdf. Accessed October 30, 2017.
18. Polis CB, Bradley SEK, Bankole A, Onda T, Croft TN, Singh S. *Contraceptive Failure Rates in the Developing World: An Analysis of Demographic and Health Survey Data in 43 Countries.* New York: Guttmacher Institute; 2016. http://www.guttmacher.org/report/contraceptive-failure-rates-in-developing-world. Accessed October 30, 2017.
19. Sedgh G, Singh S, Hussain R. Intended and unintended pregnancies worldwide in 2012 and recent trends. *Stud Fam Plann.* 2014;45(3):301–314. CrossRef. Medline
20. Sedgh G, Bearak, J, Singh S, et al. Abortion incidence between 1990 and 2014: global, regional, and subregional levels and trends. *Lancet.* 2016;388(10041):258–267. Medline. CrossRef
21. Ganatra B, Gerdts C, Rossier C, et al. Global, regional, and subregional classification of abortions by safety, 2010-14: estimates from a Bayesian hierarchical model. *Lancet.* 2017 Sep 27. [ePub ahead of print]. CrossRef. Medline
22. World Health Organization (WHO). *International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10). Volume 2, Instruction manual.* Geneva: WHO; 2011. http://www.who.int/entity/classifications/icd/ICD10Volume2_en_2010.pdf?ua=1. Accessed October 30, 2017.
23. World Health Organization (WHO). *International Classification of Diseases and Related Health Problems, 10th Revision (ICD-10).* Geneva: WHO; 2016. http://www.who.int/classifications/icd/icdonlineversions/en/. Accessed October 30, 2017.
24. Alkema L, Chou D, Hogan D, et al; United Nations Maternal Mortality Estimation Inter-Agency Group collaborators and technical advisory group. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. *Lancet.* 2016;387(10017):462–474. CrossRef. Medline
25. Gerdts C, Tunçalp O, Johnston H, Ganatra B. Measuring abortion-related mortality: challenges and opportunities. *Reprod Health.* 2015;12(1):87. CrossRef. Medline
26. Rutstein S, Winter R. *The Effects of Fertility Behavior on Child Survival and Child Nutritional Status: Evidence from the Demographic and Health Surveys, 2006 to 2012.* DHS Analytical Studies No. 37. Rockville, MD: ICF International; 2014. https://dhsprogram.com/publications/publication-as37-analytical-studies.cfm. Accessed October 30, 2017.
27. Cleland J, Bernstein S, Ezeh A, Faundes A, Glasier A, Innis J. Family planning: the unfinished agenda. *Lancet.* 2006;368(9549):1810–1827. CrossRef. Medline
28. Conde-Agudelo A, Rosas-Bermúdez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. *JAMA.* 2006;295:1809–1823. CrossRef. Medline
29. Zhu BP. Effect of interpregnancy interval on birth outcomes: findings from three recent US studies. *Int J Gynaecol Obstet.* 2005;89 (suppl 1):S25–S33. CrossRef. Medline
30. Smits LJ, Essed GG. Short interpregnancy intervals and unfavourable pregnancy outcome: role of folate depletion. *Lancet.* 2001;358(9298):2074–2077. CrossRef. Medline
31. Rutstein SO. Effects of preceding birth intervals on neonatal, infant and under-five years mortality and nutritional status in developing countries: evidence from the demographic and health surveys. *Int J Gynaecol Obstet.* 2005;89 (suppl 1):S7–S24. CrossRef. Medline
32. DaVanzo J, Razzaque A, Rahman M, Hale L. The effects of birth spacing on infant and child mortality, pregnancy outcomes and maternal morbidity and mortality in Matlab, Bangladesh. RAND Labor and Population Working Paper. Santa Monica, CA: RAND; 2005. https://www.rand.org/content/dam/rand/pubs/working_papers/2004/RAND_WR198.pdf. Accessed October 30, 2017.
33. Black RE, Morris SS, Bryce J. Where and why are 10 million children dying each year? *Lancet.* 2003;361(9376):2226–2234. CrossRef. Medline
34. Kozuki N, Lee ACC, Silveira MF, et al; Child Health Epidemiology Reference Group Small-for-Gestational-Age-Preterm Birth Working Group. The associations of birth intervals with small-for-gestational-age, preterm, and neonatal and infant mortality: a meta-analysis. *BMC Public Health.* 2013;13(suppl 3):S3. CrossRef. Medline
35. Sonneveldt E, DeCormier Plosky W, Stover J. Linking high parity and maternal and child mortality: what is the impact of lower health services coverage among higher order births? *BMC Public Health.* 2013;13(suppl 3):S7. CrossRef. Medline
36. Kost K, Lindberg L. Pregnancy intentions, maternal behaviors, and infant health: investigating relationships with new measures and propensity score analysis. *Demography.* 2015;52(1):83–111. CrossRef. Medline

Peer Reviewed

Received: April 2, 2017; **Accepted:** October 17, 2017; **First Published Online:** December 7, 2017

Cite this article as: Askew I, Weinberger M, Dasgupta A, et al. Harmonizing methods for estimating the impact of contraceptive use on unintended pregnancy, unsafe abortion, and maternal health. Glob Health Sci Pract. 2017;5(4):658-667. https://doi.org/10.9745/GHSP-D-17-00121

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FIELD ACTION REPORT

An NGO-Implemented Community–Clinic Health Worker Approach to Providing Long-Term Care for Hypertension in a Remote Region of Southern India

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Paid community health workers screened for hypertension in the community, referred cases to the clinic for diagnosis and initial treatment by a physician, and then monitored patients who had well-controlled blood pressure including dispensing maintenance medications prescribed by the physician. Blood pressure control was successful in the majority of such patients.

ABSTRACT

Poor blood pressure control results in tremendous morbidity and mortality in India where the leading cause of death among adults is from coronary heart disease. Despite having little formal education, community health workers (CHWs) are integral to successful public health interventions in India and other low- and middle-income countries that have a shortage of trained health professionals. Training CHWs to screen for and manage chronic hypertension, with support from trained clinicians, offers an excellent opportunity for effecting systemwide change in hypertension-related burden of disease. In this article, we describe the development of a program that trained CHWs between 2014 and 2015 in the tribal region of the Sittilingi Valley in southern India, to identify hypertensive patients in the community, refer them for diagnosis and initial management in a physician-staffed clinic, and provide them with sustained lifestyle interventions and medications over multiple visits. We found that after 2 years, the CHWs had screened 7,176 people over age 18 for hypertension, 1,184 (16.5%) of whom were screened as hypertensive. Of the 1,184 patients screened as hypertensive, 898 (75.8%) had achieved blood pressure control, defined as a systolic blood pressure less than 140 and a diastolic blood pressure less than 90 sustained over 3 consecutive visits. While all of the 24 trained CHWs reported confidence in checking blood pressure with a manual blood pressure cuff, 4 of the 24 CHWs reported occasional difficulty documenting blood pressure values because they were unable to write numbers properly. They compensated by asking other CHWs or members of their community to help with documentation. Our experience and findings suggest that a CHW blood pressure screening system linked to a central clinic can be a promising avenue for improving hypertension control rates in low- and middle-income countries.

INTRODUCTION

Over the past decade, there has been a dramatic increase in rates of coronary heart disease (CHD) in the developing world. This trend is expected to continue with a projected increase in rates of CHD in low- and middle-income countries by 6 million deaths over the next 20 years.[1] Globally, hypertension is responsible for more cardiovascular disease and premature death than any other modifiable risk factor. Uncontrolled hypertension leads to ischemic heart disease, renal failure, and strokes. Of the 31.1% of adults in the world with hypertension in 2010, only 7.7% had their blood pressure controlled to a rate of less than 140 systolic over 90 diastolic.[2] The global Prospective Urban Rural Epidemiology (PURE) study showed that rates of cardiovascular disease and death were higher in low-income countries compared with high-income countries, and that the lack of adequate risk-factor control in low-income countries was likely driving this difference.[3]

A shift in disease burden from communicable diseases to noncommunicable diseases, such as hypertension, diabetes, and myocardial infarction, has been documented in both urban and rural regions of India.[4] In 2012, the prevalence of hypertension in rural India was between 15.4% and 21.9%.[5] The South Asian cohort of the PURE study showed poor control of CHD risk factors, with more than 80.0% of patients with a history of CHD or stroke not receiving any protective drug therapy at the median of 4 years after diagnosis.[6]

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Improved control of hypertension is vital in order to decrease overall rates of CHD mortality in low- and middle-income countries.[2]

Two of the major barriers to patients accessing health care in under-resourced regions are the lack of adequate numbers of providers in those regions and the challenge and cost of traveling from remote regions to available health care providers. Community health worker (CHW) systems, which train individuals from within villages to provide first-line care, have been successfully implemented for a variety of public health concerns, including childhood vaccinations, maternal and child health, and tuberculosis and HIV monitoring programs. CHW programs have been discussed as a way to improve the screening, diagnosis, and management of noncommunicable diseases in resource-poor settings.[7] Accordingly, CHW programs in remote regions, where clinical services are difficult to access, hold potential for improving care of hypertension, especially because this condition requires frequent follow up.

In September 2017, a cluster randomized controlled trial in Argentina showed that a CHW-led multicomponent intervention was superior to usual management of hypertension.[8] An earlier study in India, published in 2010, showed that health aides in Tamil Nadu could accurately screen for hypertension and refer patients for hypertension management; however, patients were not followed longitudinally to determine whether adequate blood pressure control was achieved.[9] A cluster randomized controlled trial conducted in 2009 in Karachi, Pakistan, showed that home health worker visits, coupled with education by physicians, were effective at decreasing rates of hypertension in the primarily urban and educated study population.[10]

The Sittilingi Valley is a remote, tribal region in the southern Indian state of Tamil Nadu with difficult-to-access dirt roads and limited options for public transportation. According to Indian government census data from 2011, the primary occupation of the Sittilingi Valley population is farming, the primary language is Tamil, and less than 10% of the population receives higher than a sixth-grade education.[11] Accessing the central clinic is a major barrier for patients in this region, and providers at the central tribal clinic have had difficulty providing consistent hypertension management using only the central clinic as an access point for patients. Poor access and inadequate treatment are exacerbated by poor health literacy, patients' reluctance to seek care for asymptomatic conditions, and a culture that prioritizes health care for younger people. In this setting, a CHW model has the potential to provide a higher level of hypertension management to patients in the valley.

In this article, we describe the development, implementation, and initial achievements of a CHW hypertension program in this area of rural India.

Health workforce shortages and transportation costs are major barriers to patients accessing health care in under-resourced regions.

PROGRAM DESCRIPTION

Setting

In August 2013, the University of California San Francisco (UCSF) and the Tribal Health Initiative (THI) established a partnership to implement and study the effects of adapting an existing CHW program to include hypertension management in the rural under-resourced tribal region served by THI.

A "tribal region" in India is a government designation for areas with populations that were historically marginalized and are now officially recognized by the government as neglected.

THI is an Indian nonprofit organization founded in 1994 by 2 Indian physicians committed to improving the health of the rural tribal population. It is fully nongovernmental, in the sense that it does not interface directly with any governmental system. When THI was first formed, there was no government clinic in the designated tribal region. Since then, a government clinic has been established 11 km outside the tribal area. However, very few patients seen at the THI clinics and none of the patients enrolled in the hypertension program also seek care at the government clinic. The organization now serves the 12,000 people who live in the 21 villages located in the tribal region of the Sittilingi Valley through their 24-bed tribal hospital and outpatient clinic. Approximately 8 physicians work at the tribal hospital and outpatient clinic.

THI also has a CHW program that trains selected women to provide basic medical care in the villages. A CHW is a married woman from each village—aged 30 to 40 years with at least a tenth-grade education—who was chosen by her fellow villagers. Each CHW receives 2 days of training every 2 weeks for 18 months on the basics of sanitation, hygiene, childbirth, nutrition, and methods of communicating this knowledge to the community through stories and songs. A total of 24 CHWs are currently employed by THI and are paid an hourly rate using local standards for competitive wage compensation. Every week, CHWs see patients for 6 hours in their village, providing immunizations for children, prenatal care to pregnant women, and advice, treatment, and follow-up care for adult patients with other medical concerns. Patients with more complex complaints are referred by the CHWs to a THI tribal clinic.

Stepwise Community Health Worker Hypertension Program

In January 2014, THI staff and UCSF faculty developed a curriculum for CHWs that teaches blood pressure measurement, diagnosis, management, and prevention based on the 2014 American Society of Hypertension and International Society of Hypertension (ASH/ISH) guidelines for hypertension management.[12] The goal of the curriculum was to teach CHWs how to incorporate blood pressure measurement, documentation, and referral of hypertensive patients to the central clinic into their weekly responsibilities seeing patients in their villages each week. An additional 5 to 6 hours of work each week was allocated for this purpose. The training of the CHWs took place in a stepwise manner (Figure 1).

The goal of the curriculum was to teach CHWs how to incorporate blood pressure measurement, documentation, and referral of hypertensive patients to the central clinic.

Phase 1. Initial Training

Over a 7-month period, beginning in March 2014, the 24 CHWs at THI received monthly 3-hour hypertension training sessions led by the head nurse. The CHWs were taught about the physiology of blood pressure, what happens during systole and diastole parts of the cardiac cycle, and why measuring blood pressure is important. The CHWs also received 1 to 2 hours of practical training at the end of each session on the use of the Ashok Nisco-09 electronic arm blood pressure cuffs (Ashok Enterprises, Delhi, India), which record systolic and diastolic blood pressure and heart rate. They were also taught to record blood pressure and heart rate for each patient in a medical record. After the training was completed, each CHW's level of understanding of the training materials and equipment was evaluated by nurses and physicians observing a CHW's blood pressure measurement technique, checking their ability to record blood pressure numbers accurately, and assessing general understanding of what blood pressure is and why hypertension control is important. Two of the CHWs were found to have knowledge deficits and were required to undergo additional training to reinforce key points. Following completion of the training, the CHWs met monthly with the head nurse for continued mentoring and feedback about the CHW hypertension program.

Phase 2. Hypertension Screening in the Community

In November 2014, the CHWs began screening all patients over the age of 18 for hypertension during their weekly field clinics in the villages. The screening sites were located at a central setting in

FIGURE 1. Stepwise Implementation of Community Health Worker Hypertension Program, Sittilingi Valley, Tamil Nadu, India

Initial Training *Started March 2014*	Hypertension Screening *Started November 2014*	Hypertension Management Training *Started April 2015*	Hypertension Management *Started June 2015*
• CHWs taught about physiology of BP, what hypertension is, and how to measure BP • Nurses and physicians evaluated CHW knowledge about hypertension and proficiency checking BP	• All patients over 18 screened for hypertension by CHW • If SBP>140 or DBP>90, BP rechecked by CHW • If BP still high on recheck, referred by CHW to clinic to see physician • Physician to diagnose hypertension	• CHWs taught when interventions need to be initiated for hypertension management • CHWs taught about salt reduction and exercise as lifestyle interventions for hypertension • CHWs taught about five classes of medications for hypertension management	• All patients seen by CHW in the villages with SBP<130 and DBP<80 given by the CHW lifestyle advice and medications previously prescribed by physician • If SBP>140 or DBP>90, BP rechecked and if persistently high, patient referred to clinic to see physician

Abbreviations: BP, blood pressure; CHW, community health worker; DBP, diastolic blood pressure; SBP, systolic blood pressure.

the village, usually a school or temple, where villagers would gather and meet with the CHW. The screening process was simple: a person would rest in a chair for 5 minutes with both feet on the ground, after which their blood pressure was measured. Anyone with either a systolic blood pressure greater than 140 or a diastolic blood pressure greater than 90 would receive a second blood pressure check. If the second check also was high, the patient was classified as having screened positive and was sent to the clinic, where he or she was seen by a physician. The physician would recheck the patient's blood pressure and, if it was elevated, the patient would receive a hypertension diagnosis and be enrolled in the hypertension program. From that point, the physician would manage the patient's hypertension in accordance to standard practices, providing lifestyle advice and medications, if warranted.

During the first month following the screening event, a visiting nurse would monitor hypertensive patients every week. In the subsequent months, CHWs who had completed their first month of training screened patients for hypertension, recorded blood pressure values in a log, and referred patients for follow up either with the clinic (if screening suggested hypertension) or the CHW (if screening suggested normal blood pressure) (Figure 2). A visiting nurse would monitor patients' blood pressure measurements every 4 to 6 weeks and provide the CHWs with real-time feedback and additional teaching/mentoring.

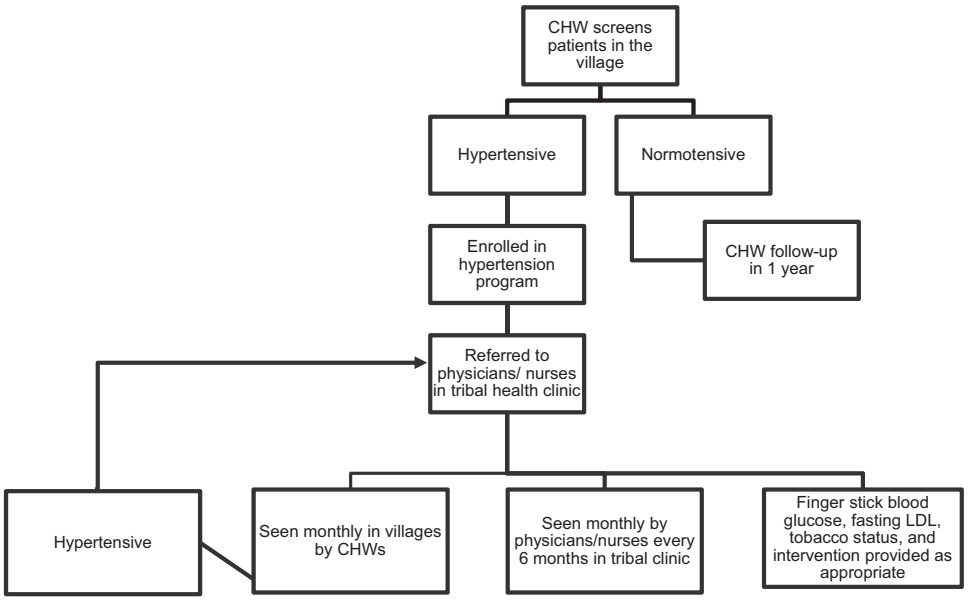
A visiting nurse would monitor patients' blood pressure measurements every 4 to 6 weeks and provide the CHWs with real-time feedback.

A simple algorithm for hypertension management was formulated based on the 2014 ASH/ISH guidelines.[12] In addition to measuring blood pressure, CHWs asked patients what antihypertensive medications they were taking, and documented this information in the record. During this phase of screening for hypertension, the CHWs continued to return to the clinic monthly for 2 hours of teaching, during which the head nurse reviewed hypertension management with the CHWs and answered questions that came up during their clinical work.

Phase 3. Training in the Management of Hypertension

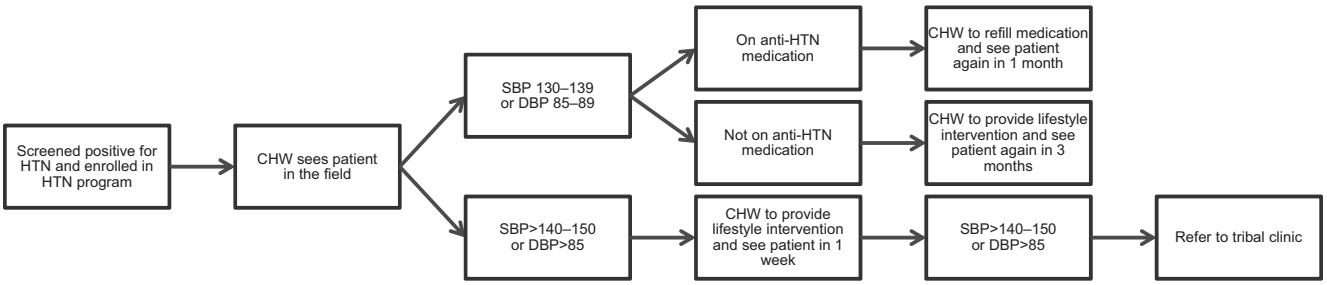
In April 2015, the CHWs began to receive teaching during their monthly 2-hour sessions with the head nurse and clinic physician about hypertension management. Specifically, the head nurse and the clinic physician taught the CHWs about goal blood pressure ranges, the 5 classes of blood pressure medication available for patients

FIGURE 2. Community Health Worker Hypertension Program Screening Algorithm, Sittilingi Valley, Tamil Nadu, India



Abbreviations: CHW, community health worker; LDL, low-density lipoprotein cholesterol.

FIGURE 3. Community Health Worker Hypertension Program Clinical Decision Tree Algorithm, Sittilingi Valley, Tamil Nadu, India



Abbreviations: CHW, community health worker; DBP, diastolic blood pressure; HTN, hypertension; SBP, systolic blood pressure.

(hydrochlorothiazide, amlodipine, lisinopril, metoprolol, and valsartan), potential side effects of the medication, and lifestyle interventions for blood pressure control.

The teaching augmented and reinforced the algorithm that CHWs had been trained to follow as to what blood pressure ranges and complaints necessitated immediate referral of patients to the clinic. The CHWs were also taught to refill medications with the same dosages for patients already on medication who were found to be normotensive during the field visits. They were also taught to refer all enrolled patients on medication to the clinic every 6 months for laboratory monitoring of kidney function and electrolytes and refer all enrolled patients not on medication to the clinic every year for routine laboratory monitoring.

While the CHWs received this more in-depth teaching monthly until October 2014, they continued to only screen patients for hypertension and send uncontrolled hypertensive patients to the clinic. The CHWs did not start providing any hypertension management interventions during the orientation period.

Phase 4. Management of Chronic Hypertensive Patients by Community Health Workers

In June 2015, the CHWs began giving lifestyle advice and dispensing medications for chronic conditions to patients with well-controlled blood pressure, based on a decision tree (Figure 3). The lifestyle advice that the CHWs provided to patients included restricting the amount of salt in their diets and performing moderate physical activity daily for 30 minutes. Patients on medication with well-controlled blood pressure, defined by a systolic blood pressure less than 130 and a diastolic blood pressure less than 80, were given maintenance medication by the CHWs during their monthly blood pressure check. For these patients, CHWs were able to continue to dispense previously prescribed medication to the patient without first consulting the physician. The CHWs never dispensed any new medications or new medication levels on their own. The CHWs referred patients with a systolic blood pressure greater than 130 or a diastolic blood pressure greater than 80 to the clinic in accordance with their prior teaching.

Supervision of the Community Health Workers

Supervision of the CHWs began well before the initiation of the hypertension program. Visiting nurses made trips to each village every 2 months, to observe and supervise CHWs providing clinical care and to address illness and treatment management concerns of the villagers that could be taken care of by the CHWs. Additionally, the nurses provided ongoing trainings and educational meetings with CHWs based on deficiencies observed in the field. Once every 6 months, a physician would accompany the visiting nurses to the villages in order to provide additional CHW observation, on-the-ground training, and quality assurance. After the hypertension program was initiated, the visiting nurse and physician supervision was expanded to assess blood pressure measurement, management, and referral by CHWs.

Consent, Screening, and Clinical Documentation

Before screening village members, each CHW asked all patients over the age of 18 for consent using a verbal consent script that explained in Tamil the purpose of the intervention and the potential harms.

All patients who gave verbal consent were screened for hypertension. Documentation of patient care began with assessments by CHWs. Once measured, a patient's blood pressure value was written on a white medical record card by the CHW and given to the patient. All screened patients, regardless of blood pressure level, were given a white card. If the patient screened positive for hypertension they were given a referral to see a physician at the clinic and were told to bring their medical record card with them to all visits because a clinician would not be able to see them unless they had their card with them. The referral included both a verbal notification that the patient needed to be seen at the clinic and a written note stating this fact. When the patient arrived at the clinic, the clinic administrative assistant would transcribe the date and blood pressure value from the patient's white medical record card on to a blue medical record card. The blue card is the patient's hypertension record for the clinic, which stays in the clinic. When patients are seen in the clinic, blood pressure values from the clinic visit are entered onto both the white and blue medical record cards. Weekly, the clinic staff enters blood pressure data from the blue cards into the computer system; the data are then uploaded onto a secure server for access by authorized local and UCSF program personnel using a password-protected front end.

Care in the Clinic

Patients who screened positive for hypertension were sent to the clinic, where they received care from 1 of 4 physicians who rotated through the clinic. The physician rechecked blood pressure and diagnosed hypertension in patients with systolic blood pressure over 140 or diastolic blood pressure over 90 in accordance with the ASH/ISH 2014 guidelines. Patients diagnosed with hypertension were enrolled in the hypertension program and seen by the physician weekly until blood pressure control was achieved. All patients in the program were also screened for diabetes and received baseline laboratory chemistry panels and blood urea nitrogen and creatinine levels. Patients who screened positive for diabetes or chronic kidney disease were managed in the clinic for these conditions. All patients enrolled in the hypertension program were referred to the clinic every 6 months to 1 year in order to check routine lab work. Each year, physicians attend an hour-long refresher lecture from a visiting UCSF faculty member about hypertension diagnosis and management guidelines.

After blood pressure control was achieved, a patient would be seen by their CHWs for monthly blood pressure checks. If the blood pressure remained within goal range during the CHW visits, the CHW would continue to provide lifestyle advice and medications as outlined above. If the blood pressure was elevated during a visit, the patient would be referred back to the clinic. Communication between CHWs and physicians occurred monthly, when the CHWs would visit the clinic for ongoing education, feedback, and communication of any patient-specific concerns with the physicians.

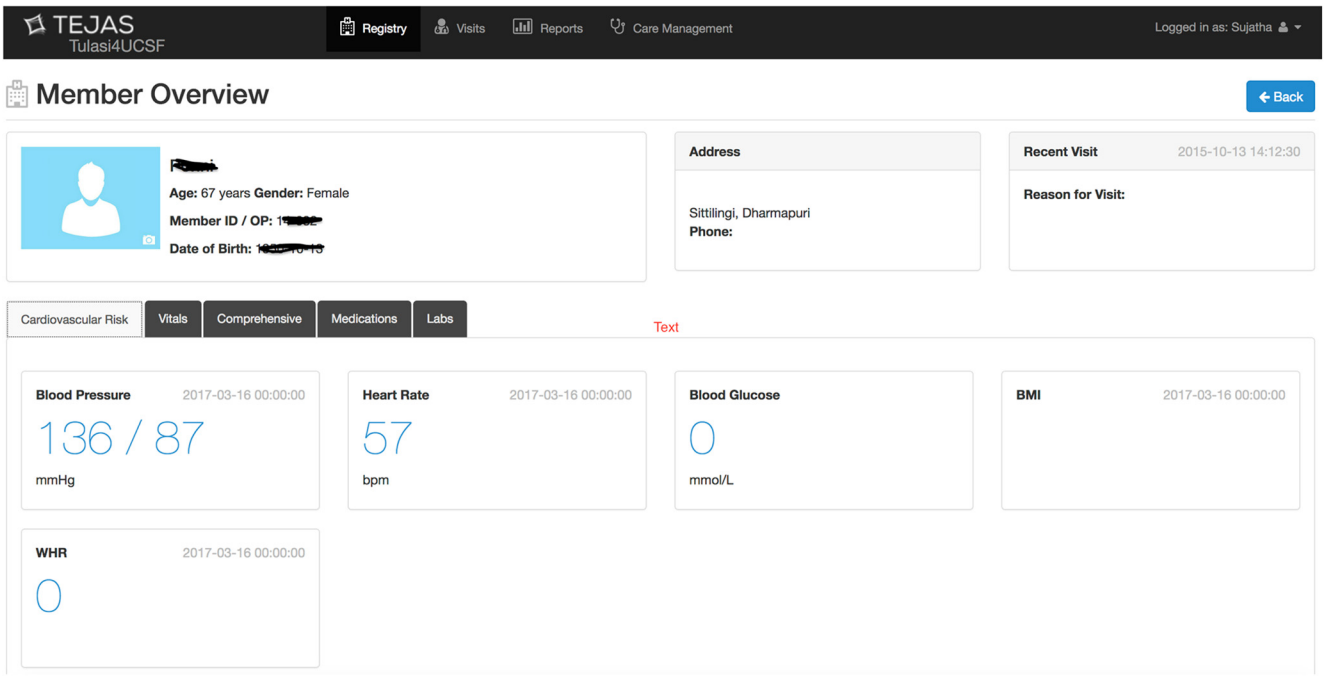
Communication between CHWs and physicians occurred monthly, when the CHWs would visit the clinic for ongoing education, feedback, and communication of any patient-specific concerns.

Medication Recording

Beginning in June 2015, THI trained CHWs to document the medications using a color code—each medication having its own color sticker. When a physician, nurse, or CHW dispensed medication, the same color sticker would be placed on the patient's white medical record card. The CHW subsequently would check to ensure that the medication she is dispensing has the same color code as the medication the patient is already on. This acts as a safety measure to ensure that the correct medication is given to the patient, and is particularly important because 7 of the 24 CHWs are semiliterate and not able to read or document numbers accurately some of the time. Because the semiliterate CHWs initially had trouble documenting numbers correctly, the head nurse and visiting nurses spend an additional hour at the end of each monthly teaching session with these CHWs to teach them how to document blood pressure values correctly. When visiting nurses observed

Clinic staff members see patients enrolled in the hypertension program. © 2017 Tribal Health Initiative.

FIGURE 4. Screenshot of the Front-End Interface Used by Clinic Personnel to Enter Patient Demographic and Clinical Data for the Hypertension Program



the CHWs in the field, their subjective observations suggested no difference in the care rendered by the semiliterate and literate CHWs.

METHODS

Patient demographic and clinical data, including blood pressure data, from the patient blue cards were entered by clinic personnel through a front-end interface (Figure 4) and stored on a secure HIPAA (Health Insurance Portability and Accountability Act)-compliant virtual server developed by an Indian nonprofit organization, Tulasi. The server only stored patient data from hypertensive patients. Information about patients who did not screen positive for hypertension was kept by the CHW and later given to study personnel. Patient data recorded by the CHW at each follow-up visit were recorded on the white card, and entered into the server when the patient was seen at the clinic at least once every 6 months. The data were audited monthly to determine population hypertension control rates, demographic distribution, medication use, and time to control.

Regular informal feedback sessions were held separately with the head nurse, all 24 CHWs at the central clinic, all THI physicians, and a subset of patients who volunteered to talk to the program team. During these feedback sessions, participants discussed their perceptions of the hypertension program, program strengths and weakness, areas for improvement, ways in which the program benefitted or harmed the community, and thoughts about the future trajectory of the program. No formal qualitative data analysis or audio recording were completed during the informal feedback sessions, but we provide a summary of key comments expressed during these sessions. Informal oral patient questionnaires were conducted with 235 randomly selected patients enrolled in the hypertension program 1 year after the program began

Ethical Approval

The University of California San Francisco Institutional Review Board and Indian Ethics Committee approved this program.

TABLE. Hypertension Rates in Patients Over Age 18 Screened by Community Health Workers, Sittilingi Valley, Tamil Nadu, India, 2014–2016

	Age Group (in Years)			
	18–39	40–59	≥60	Total
Hypertensive[a]	314 (8.0)	424 (20.0)	446 (40.0)	1184 (16.5)
Normotensive[b]	3622 (92.0)	1700 (80.0)	670 (60.0)	5992 (83.5)
Total	3936 (100.0)	2124 (100.0)	1116 (100.0)	7176 (100.0)

All data are shown as No. (%).
[a] Systolic blood pressure >140 or diastolic blood pressure >90 on 2 checks.
[b] Systolic blood pressure <140 and diastolic blood pressure <90

PROGRAM ACHIEVEMENTS

The program had 3 main objectives: (1) a majority of community members over the age of 18 should be screened for hypertension by CHWs, and hypertensive patients were to be enrolled in the program; (2) continuing care should primarily occur in the villages by CHWs, while patients with uncontrolled hypertension should be referred to the clinic; and (3) hypertension control rates should be non-inferior to clinic-based hypertension control rates.

Screening

By 2016, at the 2-year assessment point, the program had met the first objective, with a majority of people over the age of 18 screened for hypertension and appropriate patients enrolled in the program. A total of 7,176 people over the age of 18 had been screened: 3,445 (48.0%) were women and 3,731 (52.0%) were men (Table). Of those screened, 3,936 were between 18 and 39 years old, 314 (8.0%) of whom were hypertensive; 2,124 were between 40 and 59 years old, 424 (20.0%) of whom were hypertensive; and 1,116 were 60 years old or above, 446 (40.0%) of whom were hypertensive. In total, 1,184 (16.5%) of the 7,176 screened were hypertensive.

Community-Based Care

The program staff were able to successfully meet the second objective of training the CHWs to perform hypertension management in the field, with chronic care being provided in the community by CHWs, and the clinic being use primarily for care of uncontrolled hypertension. The main outcome assessed was whether CHWs were able to effectively measure and document blood pressure, refer patients with elevated numbers to the physician at the clinic, and provide continuing interventions that were previously given by a physician to patients with well-controlled blood pressure. We were not assessing how well the CHWs were controlling blood pressure, but rather that they were able to successfully implement the system. While all of the 24 CHWs successfully completed training, the 7 semiliterate CHWs needed additional training with the nurses in order to achieve competence. The CHWs were trained to check blood pressure, document blood pressure values, provide lifestyle counseling and medication, and refer patients to the clinic as needed.

The competence of the CHWs to check blood pressure, document blood pressure values, provide lifestyle counseling and medications, and refer appropriate patients to the clinic, as described above, was repeatedly assessed with visiting nurse observations that initially took place weekly and later monthly, visiting physician observations twice annually, and monthly didactic sessions with a question-and-answer component at the central clinic. Initially, 4 of the 24 CHWs encountered occasional difficulty recording blood pressure values, but by the end of the training period, these difficulties improved and the visiting nurses assessed all CHWs as competent. Confidence of the CHWs was assessed by monthly feedback sessions with the nurses and physicians at the central clinic.

At the 2-year assessment point, CHWs had screened more than 7,000 people for hypertension, and about 17% were hypertensive at baseline.

The CHWs reported varying degrees of confidence in their ability to do their job. When the program began, many of the CHWs felt intimidated by the new skills they were asked to master, but after 1 year of implementation, all the CHWs said they felt confident checking blood pressure with a manual blood pressure cuff. Four of the 24 CHWs reported occasional difficulty documenting values because they were unable to write

numbers properly. These CHWs reported that they asked other CHWs or members of their community to help with documentation. None of the CHWs expressed uncertainty or difficulty with dispensing medication. The CHWs expressed satisfaction with their work during informal feedback sessions and expressed interest in continuing the work in the future.

During one feedback session, a CHW stated, "people in my village respect me now because they know I have knowledge."

During one feedback session, a CHW stated, "people in my village respect me now because they know I have knowledge." Another CHW stated, "now people come to me for help. They don't feel so nervous about being so far from the hospital. I'm here to calm them down. This makes me feel good." The main challenge CHWs cited was their inability to convince patients to take directed advice. As one CHW stated, "[patients] don't believe me. I tell them not to eat salt but they do anyway." As the program progressed, THI administration was able to incorporate CHW roles and responsibilities into the work they were already performing in the community.

While CHWs were successfully trained to manage hypertension in the field, feedback from CHWs and patients revealed that the reasons a patient chose to use the clinic instead of community-based care were highly subjective and patient-specific. Informal oral patient questionnaires were conducted with 235 randomly selected patients enrolled in the hypertension program 1 year after the program began. The respondents were asked 2 open-ended questions: (1) "Are you satisfied with the care you are receiving through the hypertension program?" and (2) Do you visit the tribal clinic for hypertension only when directed by your CHW or at other times as well?" Of these respondents, 96 patients (40.9%) expressed satisfaction with the CHWs and stated that they only chose to visit the clinic when directed by the CHW or if they were experiencing an urgent concern. However, 28 patients (11.9%) expressed concern that the care they were receiving from the CHW was inferior to physician and nursing care, and reported visiting the clinic for hypertension management even when their CHW told them it was not necessary. When checked against clinic program data, 165 of the respondents (70.2%) had poorly controlled hypertension, while 70 (29.8%) had well-controlled hypertension. Of the 70 patients, 64 were recorded as having had well-controlled hypertension on their previous CHW encounter in the community, implying that their use of the clinic was due to patient preference as opposed to CHW referral.

Using a CHW system linked to a central clinic can be an effective mechanism to shift chronic care management from physicians and nurses to CHWs.

Hypertension Control Rates

For the third objective of achieving hypertension control rates that were non-inferior to clinic-based hypertension programs, we found that after 2 years of the program, 898 of 1,184 (75.8%) patients diagnosed as hypertensive achieved blood pressure control, which is defined as a systolic blood pressure less than 140 and a diastolic blood pressure less than 90 sustained over 3 consecutive visits either at the clinic or in the community. An average of 68 days or 2.9 visits were needed to first achieve blood pressure control in these patients with hypertension.

DISCUSSION

We describe a program that used an existing CHW system linked to a central clinic as a mechanism to provide management of hypertension in a remote under-resourced community. We found that after 2 years, this program screened, enrolled, diagnosed, and managed the population of patients with hypertension and met expected objectives. This work demonstrates a feasible model for providing diagnosis and management of chronic conditions that consists of: (1) deliberate stepwise training and supervision of CHWs, (2) empowerment of CHWs with new skills of value to the community, (3) design of a CHW program that includes maintenance and follow up of a chronic condition, and (4) close integration of the CHW program with a clinic and referral system. The training program that was designed for our cohort of CHWs was delivered in separate components—to first screen patients for hypertension, then refer appropriate patients to the central clinic, and lastly manage chronic hypertensive patients in the field—in order to build CHW competence and confidence. From the qualitative data from our CHW training program, we found the CHWs were confident about their ability to do the separate components and found value in their work.

This work also demonstrates that using a CHW system linked to a central clinic can be an effective mechanism to shift chronic care management from physicians and nurses to CHWs, despite the subset of patients who seemed to prefer clinic-based care. We were able to show hypertension control rates of 75.8% in this community after 2 years were higher than the approximately 50% control rates reported in the general U.S. population,[13] and considerably higher than those found in samples of the general Indian population, which are approximately 10% and 20% for rural and urban populations, respectively.[14]

While our program was successful, 24.2% of patients identified as hypertensive did not achieve control within 2 years—this may be attributed to lack of adherence to medications, refractory hypertension, or lifestyle factors that were not addressed. Further study is needed to better understand factors related to poor control. We acknowledge that many factors contribute to achievement of blood pressure control, including dietary modification, exercise, adherence to medications, and trust in the health care system. Economic analyses are also needed to determine the cost differential between the CHW program and a physician-staffed clinic program, as the cost of long-term care is a known barrier to CHD risk-factor control in low- and middle-income countries.[15] A CHW intervention may be effective at establishing an intact system, but these other factors must also be addressed in order to achieve optimal control. Future work examining the extent to which this CHW program increases access to hypertension care in remote, rural villages will further elucidate the benefits of this program and will help inform how this program can be used by ministries of health to improve hypertension care in remote areas.

In conclusion, our program suggests that a CHW system linked to a central clinic is a promising avenue for achieving improvements in hypertension control rates in low- and middle-income countries.

Funding: University of California San Francisco Division of Hospital Medicine and the International Cardiovascular Health Alliance.

Competing Interests: None declared.

REFERENCES

1. Yusuf S, Hawken S, Ôunpuu S, et al.; INTERHEART Study Investigators. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. *Lancet.* 2004;364(9438):937–952. CrossRef. Medline
2. Ibrahim MM, Damasceno, A. Hypertension in developing countries. *Lancet.* 2012;380(9841):611–619. CrossRef
3. Chow CK, Teo KK, Rangarajan S, et al.; PURE (Prospective Urban Rural Epidemiology) Study investigators. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries. *JAMA.* 2013;310(9):959–968. CrossRef. Medline
4. Patel V, Chatterji S, Chisholm D, et al. Chronic diseases and injuries in India. *Lancet.* 2011;377(9763):413–428. CrossRef
5. Rajasekar VD, Krishnagopal L, Mittal A, et al. Prevalence and risk factors for hypertension in a rural area of Tamil Nadu, South India. *Indian J Med Specialties.* 2012;3(1):12–17. CrossRef
6. Gupta R, Islam S, Mony P, et al. Socioeconomic factors and use of secondary preventive therapies for cardiovascular disease in South Asia: the PURE study. *Eur J Prev Cardiol.* 2015;22(10):1261–1271. CrossRef. Medline
7. Neupane D, Kallestrup P, McLachlan CS, Perry H. Community health workers for non-communicable diseases. *Lancet Glob Health.* 2014;2(10):e567. CrossRef
8. He J, Irazola V, Mills KT, et al.; HCPIA Investigators. Effect of a community health worker–led multicomponent intervention on blood pressure control in low-income patients in Argentina: a randomized clinical trial. *JAMA.* 2017;318(11):1016–1025. CrossRef. Medline
9. John J, Muliyil J, Balraj V. Screening for hypertension among older adults: a primary care "high risk" approach. *Indian J Community Med.* 2010;35(1):67–69. CrossRef. Medline
10. Jafar TH, Hatcher J, Poulter N, et al; Hypertension Research Group. Community-based interventions to promote blood pressure control in a developing country: a cluster randomized trial. *Ann Intern Med.* 2009;151(9):593–601. CrossRef. Medline
11. Office of the Registrar General and Census Commissioner, India. Ministry of Home Affairs, Government of India. 2011 Census Data. http://www.censusindia.gov.in/2011-Common/CensusData2011.html
12. Weber MA, Schiffrin EL, White WB, et al. Clinical practice guidelines for the management of hypertension in the community: a statement by the American Society of Hypertension and the International Society of Hypertension. *J Clin Hypertens.* 2014;16(1):14–26. CrossRef. Medline
13. Egan BM, Zhao Y, Axon RN. US trends in prevalence, awareness, treatment, and control of hypertension, 1988-2008. *JAMA.* 2010;303(20):2043–2050. CrossRef. Medline
14. Anchala R, Kannuri NK, Pant H, et al. Hypertension in India: a systematic review and meta-analysis of prevalence, awareness, and control of hypertension. *J Hypertens.* 2014;32(6):1170–1177. CrossRef. Medline
15. Banerjee A, Khandelwal S, Nambiar L, et al. Health system barriers and facilitators to medication adherence for the secondary prevention of cardiovascular disease: a systematic review. *Open Heart.* 2016;3(2):e000438. CrossRef. Medline

Peer Reviewed

Received: May 14, 2017; **Accepted:** October 24, 2017

Cite this article as: Sankaran S, Ravi PS, Wu YE, et al. An NGO-implemented community-clinic health worker approach to providing long-term care for hypertension in a remote region of southern india. Glob Health Sci Pract. 2017;5(4):668-677. https://doi.org/10.9745/GHSP-D-17-00192

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FIELD ACTION REPORT

More Than Bar Codes: Integrating Global Standards-Based Bar Code Technology Into National Health Information Systems in Ethiopia and Pakistan to Increase End-to-End Supply Chain Visibility

Liuichi Hara,[a] Ramy Guirguis,[b] Keith Hummel,[c] Monica Villanueva[d]

Bar codes can help track and trace health products in the supply chain. But to do so efficiently, they should be based on global standards rather than a proprietary system, and the captured data should be integrated into national health information systems to achieve end-to-end data visibility.

ABSTRACT

The United Nations Population Fund (UNFPA) and the United States Agency for International Development (USAID) DELIVER PROJECT work together to strengthen public health commodity supply chains by standardizing bar coding under a single set of global standards. From 2015, UNFPA and USAID collaborated to pilot test how tracking and tracing of bar coded health products could be operationalized in the public health supply chains of Ethiopia and Pakistan and inform the ecosystem needed to begin full implementation. Pakistan had been using proprietary bar codes for inventory management of contraceptive supplies but transitioned to global standards-based bar codes during the pilot. The transition allowed Pakistan to leverage the original bar codes that were preprinted by global manufacturers as opposed to printing new bar codes at the central warehouse. However, barriers at lower service delivery levels prevented full realization of end-to-end data visibility. Key barriers at the district level were the lack of a digital inventory management system and absence of bar codes at the primary-level packaging level, such as single blister packs. The team in Ethiopia developed an open-sourced smartphone application that allowed the team to scan bar codes using the mobile phone's camera and to push the captured data to the country's data mart. Real-time tracking and tracing occurred from the central warehouse to the Addis Ababa distribution hub and to 2 health centers. These pilots demonstrated that standardized product identification and bar codes can significantly improve accuracy over manual stock counts while significantly streamlining the stock-taking process, resulting in efficiencies. The pilots also showed that bar coding technology by itself is not sufficient to ensure data visibility. Rather, by using global standards for identification and data capture of pharmaceuticals and medical devices, and integrating the data captured into national and global tracking systems, countries are able to lay the foundation for interoperability and ensure a harmonized language between global health stakeholders.

INTRODUCTION

Low- and middle-income countries often rely on inaccurate and labor-intensive processes to manage key health commodity supply chains.[1] However, recent innovations in supply chain technology have helped improve the efficiency of commodity acquisition, management, and delivery systems, thus reducing stockouts and ensuring health commodities, such as pharmaceuticals and medical devices, reach the end user.[1,2] The challenge has been finding a consistent, effective, and inclusive approach to increasing supply chain data visibility, as the availability of quality and timely data often varies greatly within developing countries.

Supply chain visibility is "the awareness of, and control over, specific information related to product orders and physical shipments, including transport and logistics activities, and the statuses of events and milestones that occur prior to and in-transit."[3] Data visibility requires a robust data collection system that is agile and incorporates and synchronizes the needs of various partners into a single multitiered responsive system that begins with the production of the health product (drug or device) and ends with it in the hands of the end user.[3]

Adopting global standards and using bar code technology can help countries to address accuracy, interoperability, and timeliness of data across supply chain

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levels; achieve end-to-end (E2E) data visibility; and directly help improve forecast and quantification as well as improve procurement and supply coordination among the donor agencies.

To that end, the United States Agency for International Development (USAID) DELIVER PROJECT and the United Nations Population Fund (UNFPA) worked with the governments of Ethiopia and Pakistan to design and test pilot studies to validate the conclusion that automatic identification and data capture (AIDC) systems could be used to improve E2E supply chain visibility of health commodities.[1,2] AIDC is a method of identifying items, collecting data, and transmitting that data directly electronically—in these pilots, through bar codes.

ACHIEVING END-TO-END SUPPLY CHAIN DATA VISIBILITY

AIDC is a key tool for improving product visibility in the global supply chain. While there are various approaches used to achieve AIDC, bar codes and radio frequency identification are the most commonly used.

Leveraging AIDC provides an organization the ability to track and trace tangible assets in real-time or near real-time. The International Organization for Standardization defines track and trace as a "means of identifying every individual material goods or lots or batch in order to know where it has been (track) and where it is (trace) in the supply chain".[4] Unique product identification linked with the item's batch number or serial number and expiration date are rapidly becoming a prerequisite to track and trace health care products to create an E2E supply chain.[5]

With an efficient track and trace system, an organization or a country can effectively address complex integrity issues, such as distribution of counterfeit pharmaceutical products and theft or diversions of shipments. This can only be achieved by improving the E2E supply chain data visibility. Using a bar coding system that complies with global standards is crucial to maintain an organization's supply chain integrity and to safeguard public health.

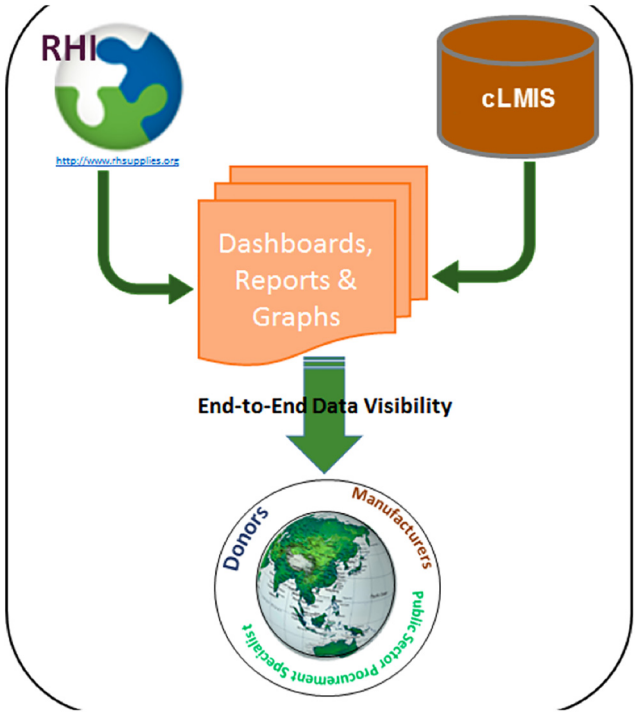
USING GLOBAL STANDARDS

As part of their formative research, UNFPA and the USAID DELIVER PROJECT identified a clear

Automatic identification and data capture systems are a key tool for improving product visibility in the global supply chain.

UNFPA and the USAID DELIVER PROJECT identified a clear need to raise awareness of existing global standards, such as bar codes, and the value of integrating their use into the health care sector.

FIGURE 1. Pakistan End-to-End Dashboard Structure



Abbreviations: cLMIS, contraceptive logistics management information system; RHI, Reproductive Health Interchange.

The transition from proprietary tracking methods to global standards-based bar codes allowed Pakistan to leverage the original bar codes that were preprinted by global manufacturers, as opposed to printing new bar codes at the central warehouse.

need to raise awareness of existing global standards, such as bar codes, and the value of integrating their use into the health care sector. Global standards for identification, capture, and sharing are provided by GS1, a "neutral, not-for-profit, international standards organization that develops global standards to improve the efficiency and visibility of supply chains across industries."[3]

Although bar codes have been used to improve inventory tracking in low- and middle-income countries, there is limited documentation of cases that have led to the adoption of bar code systems beyond the pilot phase or to realize their value across all the systems in the supply chain.[6] This may be explained by a lack of adoption of internationally accepted standards for AIDC among the key stakeholders—such as donors, pharmaceutical companies, logistics providers, regulatory agencies, and implementing partners—and resulted in each donor or provider developing a proprietary solution specific to a funded project.

However, there is growing acceptance among many donors, countries, and the private sector regarding the value of adopting a global standard for product identification and bar codes to improve supply chain efficiency. This is because GS1 global standards are product-agnostic and provide a framework to scale onto all products across the different health programs—such as childhood vaccines and HIV/AIDS—and build the foundation for interoperability. In effect, the use of global standards help to improve patient safety and reduce exposure to supply chain integrity issues.

APPLYING THEORY TO PRACTICE: THE JOURNEY

Pakistan and Ethiopia conducted proof of concepts for an E2E supply chain data visibility approach using bar codes with logistics information dashboards. The 2 cases are discussed individually in this section and their findings and lessons learned are compared in the following reflections section.

Pakistan

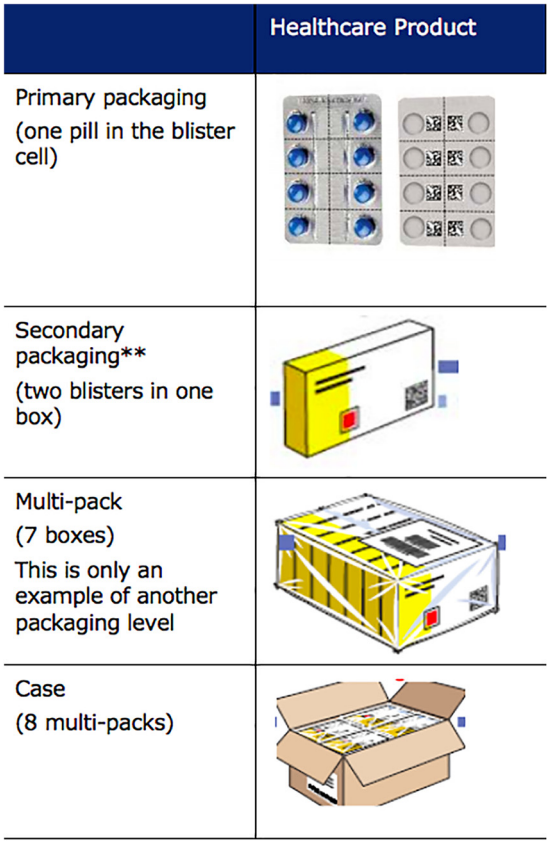
The USAID DELIVER PROJECT in Pakistan developed a web interface with global procurement information through the Reproductive Health Interchange (https://www.unfpaprocurement.org/rhi-home), and combined the interface with Pakistan's contraceptive logistics management information system, which tracks the distribution and stock status of family planning commodities across the entire country (Figure 1). This system informs federal and provincial procurement actions.

Pakistan was not new to the idea of using bar codes, as it already implemented use of proprietary bar codes for inventory management of contraceptive supplies in 2012.[1] However, the pilot conducted in 2015 emphasized the value of transitioning from proprietary tracking methods to bar codes based on global standards.

The transition allowed the Pakistan team to leverage the original 2-dimensional DataMatrix bar codes preprinted by global manufacturers as opposed to printing new bar codes at the central warehouse. In order to read the original bar codes, the team invested in a new Windows mobile-based Motorola MC9200 handheld optical scanner, as the previous handheld scanner was limited to 1-dimensional linear bar codes only.

The Pakistan bar code pilot experience highlighted 2 key aspects for future work in E2E supply

FIGURE 2. GS1 Package Hierarchy Examples



chain data visibility: (1) the lack of an inventory management information system at the district level posed a challenge to consolidating the captured bar code data; and (2) products arriving into the districts were primary-level packaging—for example, single blister packs—that lacked bar codes (Figure 2). Therefore, extending information system installation and applying bar codes at the primary package will be required if tracking and tracing is to be extended down to the district level.

Ethiopia

Similarly, the USAID DELIVER PROJECT in Ethiopia followed the approach of developing a web interface with the project's "My Commodities" system and the Reproductive Health Interchange to merge the global procurement information with the national warehouse management software (called the Health Commodity Management Information System). My Commodities provides registered users with shipment information of health supplies, contraceptives, condoms, personal protective equipment for avian influenza control, antimalarials, and other commodities.

The Ethiopia pilot test was an important milestone, as it expanded beyond the Pakistan experience. The Ethiopia team developed an open-sourced smartphone application using the built-in CMOS image sensors (the camera technology) commonly found on standard Android smartphones. Bar code scanning was performed through the CMOS camera via the mobile application, which then pushed the captured data from the bar code to Ethiopia's data mart and E2E dashboard. Real-time tracking and tracing was demonstrated from the central warehouse to 2 major distribution points: the Addis Ababa distribution hub and 2 subsequent health centers. Furthermore, the Android smartphone's GPS coordinates were integrated with a geographical information system to display transactional information—the issuance and receipt of products—onto a Google Map (Figure 3).

Lastly, UNFPA sent the bar code requirements to the supplier in advance of on-the-ground testing. This enabled the Ethiopia team to enter the standardized unique product information—the

The Ethiopia pilot demonstrated the immediate benefits that could be achieved by using globally standardized bar codes and integrating data systems; namely, by reducing manual steps for recording inbound and outbound goods and reducing the chance of human error via misentry of data.

FIGURE 3. Ethiopia End-to-End Dashboard Sample

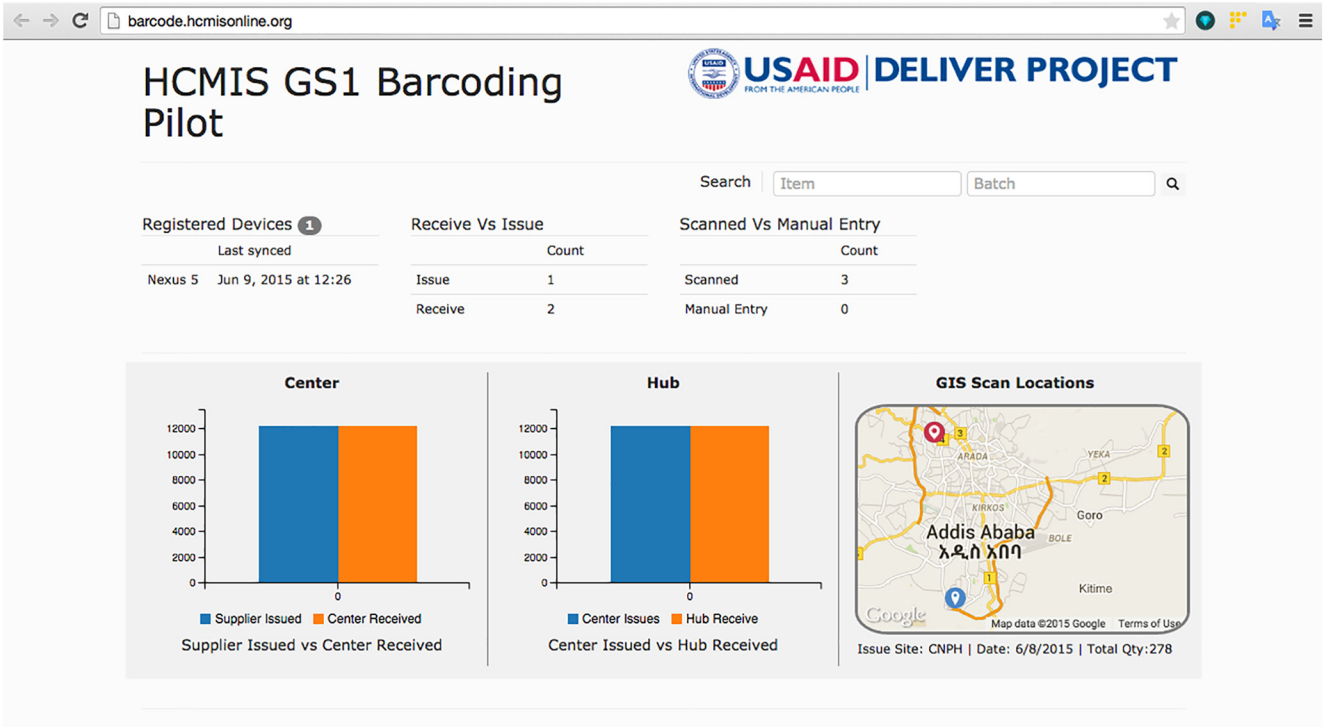


TABLE 1. Time for Scanning and Recording the Digital Bar Code Information, Ethiopia Pilot Test

Location	Transaction	No. of Scans	Time to Scan and Record Information From Bar Code	Comments
Central store	Inbound receipt	13 tertiary-level shipper boxes	3 minutes and 37 seconds	Recorded time included physically moving the packages and obstacles
Central store	Inbound receipt	63 secondary-level packages	24 minutes and 38 seconds	Software optimization made during the test; used smartphone torch feature and improved scanning technique based on experience at the central store
Addis Ababa distribution hub	Inbound receipt	13 tertiary-level shipper boxes	2 minutes	
Addis Ababa distribution hub	Inbound receipt	50 secondary-level packages	15 minutes	Quantity split between 2 local health centers
Addis Ababa distribution hub	Outbound to local health center	230 secondary-level packages	Less than 25 minutes	

global trade item number, batch number, and expiry date—into the national health information system prior to receipt of incoming goods. The time for scanning and recording the digital information was measured and is summarized in Table 1. This preparation allowed the team to validate and cross reference the cargo received at the central warehouse in real-time once they scanned the bar codes. This pilot demonstrated the immediate benefits that could be achieved by using globally standardized bar codes and integrating data systems; namely, by reducing manual steps for recording inbound and outbound goods and reducing the chance of human error via misentry of data.

In Ethiopia, a team member at the Addis Ababa central warehouse uses a mobile phone app to scan bar codes on shipping boxes when receiving incoming goods. © 2015 L Hara

REFLECTIONS

While the 2 country experiences were distinct, they both showcased the potential and challenges in realizing E2E visibility. A comparison of the 2 pilots is summarized in Table 2.

The Ethiopia experience more realistically demonstrated what full E2E bar code track and trace could look like: A digital cargo manifest identifier is encoded in the bar codes at the tertiary-level shipper boxes. Upon arrival of the shipment, the receiving party can digitally authenticate the cargo manifest by simply scanning the bar codes and automatically recording the data into the dashboard. Encoded data about the products from the bar codes on the secondary-level packages can continue to be scanned as the products move downstream inside the country so that track and trace can be achieved down to the last mile of the supply chain.

The Pakistan experience, on the other hand, clearly demonstrated the barriers at the lower levels of supply chain, such as the availability of a consistent digital information system and use of bar codes at the lowest product unit level. Depending on the product origin and product presentation, such as blister packs or vials, bar coding at the lowest unit level may be easier for some products than others. It is important to

TABLE 2. Comparison of the Pakistan and Ethiopia Pilot Tests

Features	Pakistan	Ethiopia
In-country electronic logistics management information system	cLMIS	HCMIS
Bar coding	Transition from proprietary to GS1 bar codes	GS1 bar codes, from the outset
E2E dashboard	Achieved by integrating RHI with cLMIS and incorporating data from bar code scanning	Achieved by integrating RHI with HCMIS and incorporating data from bar code scanning
Serialization	Not part of the pilot test	Serialization was done at the secondary package level
Scanning approach	Handheld optical scanners	Open-sourced Android smartphone app developed locally (HCMIS barcode scanner)
Where track and trace was pilot tested	Central Warehouse and Supplies, Karachi to Lahore district store	Central warehouse to Addis Ababa distribution hub to Woreda health center and Nefas Silk Lafto health center
Result	Full E2E track and trace was not achieved due to lack of inventory management system at the district level and lack of bar codes at the primary unit level	Full E2E track and trace via digital scanning demonstrated to the exact number of packages distributed between the 2 health centers

Abbreviations: cLMIS, contraceptive logistics management information system; E2E, end-to-end (supply chain); HCMIS, Health Commodity Management Information System; RHI, Reproductive Health Interchange.

communicate this issue to the original manufacturer to begin dialogue for bar coding at the primary unit level.

However, without a proper digital information system to receive the scanned data, the value of AIDC greatly diminishes. Therefore, an ecosystem is needed that combines bar codes and the appropriate digital information system(s) and processes in place to ensure that scanned and recorded information are used for proper decision making.

Another point that needs consideration is deciding which scanning approach is most appropriate for the country context. In Ethiopia, the

TABLE 3. Comparison Between Smartphone and Handheld Scanners

Approach	Pros	Cons
Smartphone scanner	• Flexibility to customize and update app software • Ability to leverage existing personal smartphones • Ability to adopt or adapt the app (open-source)	• Poor ergonomic design for scanning • Slower scan speed rate • Function depends on mobile penetration in the country • Several mobile apps, which can be confusing for the user • Higher battery burn rate to smartphone
Handheld scanner	• Faster scan speed rate • Good ergonomic design for scanning	• Stable funding is needed to procure, maintain, and/or upgrade handheld scanners at all distribution touch points
Hybrid handheld scanner connected to a smartphone via Bluetooth (as an alternative for future consideration)	• Lower cost than traditional handheld scanner • Faster scan speed rate • Good ergonomic design for scanning • Can leverage smartphone app software	• Higher battery burn rate to smartphone

Without a proper digital information system to receive the scanned data, the value of AIDC greatly diminishes.

team used a locally developed open-sourced smartphone application, while in Pakistan the team procured new handheld optical scanners. Although both options served their intended purpose, we recommend that countries consider their national technology capacity, and then choose the approach and type of investment—short- or long-term—that best suits a country's needs. A brief comparison between smartphone and handheld scanners has been compiled in Table 3.

While the penetration of mobile services is on the rise in developing countries, according to the International Telecommunication Union, mobile cellular subscriptions for 2015 was reported at 43 per 100 people in Ethiopia and 67 per 100 people in Pakistan.[7] Based on the 2015 Pew Research Center analysis, Ethiopia and Pakistan were rated as having 2 of the lowest smartphone ownership rates globally (4% and 11%, respectively).[8] Ethiopia has the added challenge of being captive to only 1 operator, which supports 42.1 million mobile connections in the country.[9] In contrast, Pakistan has 8 operators supporting 127.9 million mobile connections in the country.[10] These are important factors to consider when incorporating mobile technology into track and trace designs. If a country has insufficient mobile network coverage, then handheld optical scanners, which do not rely on mobile networks, should be considered. Along the same logic, if a high number of operators support a vibrant mobile network coverage, smartphones may be the best option to perform the scanning.

The pilots demonstrated the value of implementing an automated logistic management information system based on global standards and using bar code technology to improve the efficiency of the supply chain operation, address the data quality issues, and achieve near real-time data visibility.

CONCLUSION

The collective experience from the Pakistan and Ethiopia pilots highlights the importance of adopting bar codes as part of a global standardized system for product identification and data capture that serves as a foundation for interoperability and data sharing that is essential to achieve end-to-end data visibility in the supply chains.

The pilots demonstrated the value of implementing an automated logistic management information system based on global standards and using bar code technology to improve the efficiency of the supply chain operation, address the data quality issues, and achieve near real-time data visibility. This ultimately helps to ensure that patients have continuous and consistent access to high-quality medicines at the right time and right place.

While there is still considerable work to do before countries can reach optimal E2E data visibility, the results from these and related pilots indicate that we can reach this goal by adopting the same global standards and practice for public health supply chains.

Acknowledgments: We would like to thank Al Shiferaw from John Snow, Inc. (JSI) Ethiopia and Muhammad Tariq from JSI Pakistan for their strong support and commitment to the pilots in each of their respective countries.

Funding: UNFPA, USAID.

Competing Interests: None declared.

REFERENCES

1. USAID DELIVER PROJECT. *Case Study. Barcoding: Modernizing Warehouses to Lighten the Workload.* Washington, DC: USAID DELIVER PROJECT; 2012. http://1i4rh11vccjs3zhs5v8cwkn2.wpengine.netdna-cdn.com/wp-content/uploads/2016/05/Barcoding-Case-Study_Pakistan.pdf. Accessed October 24, 2017.
2. USAID DELIVER PROJECT. *Traceability in Ethiopia's Health Sector: Piloting GS1 Barcodes with Global Trade Item Number Serialization to Track Health Commodities from Supplier to Health Facility.* Brief. Washington, DC: USAID DELIVER PROJECT; 2016.
3. Heaney B. *Supply Chain Visibility: A Critical Strategy to Optimize Cost and Service.* Waltham, MA, USA: Aberdeen Group; 2013. https://www.gs1.org/docs/visibility/Supply_Chain_Visibility_Aberdeen_Report.pdf. Accessed October 24, 2017.
4. International Organization for Standardization (ISO). *ISO 12931:2012(en): Performance Criteria for Authentication Solutions Used to Combat Counterfeiting of Material Goods.* Geneva: ISO; 2012. https://www.iso.org/obp/ui/#iso:std:iso:12931:ed-1:v1:en. Accessed October 15, 2016.
5. GS1. Healthcare GTIN Allocation Rules: GS1 Global Healthcare User Group. Issue 8, June 2013. Brussels, Belgium: GS1; 2013. https://www.gs1ca.org/pages/n/sectors/hc/GS1_Healthcare_GTIN_Allocation_Rules.pdf. Accessed October 24, 2017.
6. Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. *Promising Practices: Warehousing and Inventory Management.* Arlington, VA: Management Sciences for Health; 2014. http://www.lifesavingcommodities.org/wp-content/uploads/2014/08/Copy-of-3_Warehousing-final.pdf. Accessed October 24, 2017.
7. The World Bank. 5.11 World Development Indicators: Power and Communications. World Development Indicators website. c2014. http://wdi.worldbank.org/table/5.11#. Accessed October 24, 2017.
8. Poushter J. *Smartphone Ownership and Internet Usage Continues to Climb in Emerging Economies: But Advanced Economies Still Have Higher Rates of Technology Use.* Washington, DC: Pew Research Center; 2016. http://www.pewglobal.org/files/2016/02/pew_research_center_global_technology_report_final_february_22__2016.pdf. Accessed October 24, 2017.
9. Ethiopia Data Dashboard. GSMA Intelligence website. https://www.gsmaintelligence.com/markets/1013/dashboard/. Accessed April 13, 2017.
10. Pakistan Data Dashboard. GSMA Intelligence website. https://www.gsmaintelligence.com/markets/2733/dashboard/. Accessed April 13, 2017.

Peer Reviewed

Received: November 5, 2016; **Accepted:** September 5, 2017

Cite this article as: Hara L, Guirguis R, Hummel K, Villanueva M. More than bar codes: integrating global standards-based bar code technology into national health information systems in Ethiopia and Pakistan to increase end-to-end supply chain visibility. Glob Health Sci Pract. 2017;5(4):678-685. https://doi.org/10.9745/GHSP-D-16-00350

GLOBAL HEALTH: SCIENCE AND PRACTICE
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STUDENT ARTICLE – DOCTORAL

High Background Congenital Microcephaly in Rural Guatemala: Implications for Neonatal Congenital Zika Virus Infection Screening

Anne-Marie Rick,[a,b] Gretchen Domek,[a,b] Maureen Cunningham,[a,b] Daniel Olson,[b,c,d] Molly M Lamb,[b,c] Andrea Jimenez-Zambrano,[b] Gretchen Heinrichs,[e] Stephen Berman,[a,b] Edwin J Asturias[b,c,d]

A variety of microcephaly case definitions detect high background prevalence in rural Guatemala, which complicates congenital Zika screening efforts. In addition, gestational age is needed for most screening tools but is usually unknown in low-resource settings. Fenton growth curves, originally designed for use in preterm infants, offer a standardized approach to adjust for unknown gestational age and may improve screening efforts.

This is a winning article from the 2016 Consortium of Universities for Global Health (CUGH)-Global Health: Science and Practice (GHSP) Annual Student Manuscript Contest.

ABSTRACT

Background: Congenital microcephaly is the result of a disturbance in early brain development and can have multiple etiologies. Establishing background prevalence of microcephaly in Zika virus (ZIKV)-affected areas is important for improving identification of ZIKV-affected newborns. However, to date, there is limited consistent guidance for the accurate identification of microcephaly in infants of unknown gestational age, a common concern in low- and middle-income countries.

Methods: Occipital frontal head circumference (OFC) obtained from infants (0–13 days) of unknown gestational age at enrollment in a pregnancy registry in rural Guatemala from August 2014 to March 2016 were retrospectively reviewed. Trained community health nurses recorded anthropometry in an online database. In April 2015, ZIKV was identified in this population. Gestational age was approximated in 2 ways: presumed term and estimated using z-score of zero for height on modified Fenton growth curves. After which, z-scores for OFC and weight were obtained. Microcephaly and microcephaly background prevalence were estimated using 7 established microcephaly case definitions from national and international organizations and 3 proposed definitions using Fenton growth curves. Independent associations with microcephaly and OFC, including relationship with date of birth, were assessed with prevalence ratios and linear regression.

Results: For 296 infants, the mean OFC was 33.1 cm (range, 29.5 to 37 cm) and the mean OFC z-score was −0.68. Depending on case definition, 13 to 125 infants were classified as having microcephaly (background prevalence 439 to 4,223 per 10,000 live births), and 1 to 9 infants were classified as having severe microcephaly (<−3 standard deviation [SD]) (34 to 304 per 10,000 live births). Five (1.7%) infants met all the microcephaly case definitions. Weight ≤−1 SD (prevalence rate [PR], 3.77; 95% confidence interval [CI]: 1.6 to 8.8; *P*=.002) and small for gestational age (PR, 4.68; 95% CI, 1.8 to 12.3; *P*=.002) were associated with microcephaly. Date of birth was not associated with OFC z-score or OFC after adjusting for gestational age and gender.

Conclusions: Estimated background microcephaly is high in rural Guatemala compared with reported rates in Latin America prior to ZIKV epidemic, which has important implications for neonatal screening programs for congenital ZIKV infection. Fenton growth curves offer a standardized approach to the identification of microcephaly in infants of unknown gestational age.

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INTRODUCTION

Congenital microcephaly is the result of a disturbance in early brain development leading to an abnormally small head circumference and structural abnormalities of the brain, and can have multiple etiologies.[1] Prior to the Zika virus (ZIKV) epidemic, the estimated prevalence of microcephaly in Latin America was 3.30 per

10,000 live births; in Brazil it was 1.98 per 10,000 live births.[2,3] As of 2015, Brazil has reported a microcephaly rate more than 20 times higher than the pre-epidemic rate, which has been attributed to congenital ZIKV infection.[3,4] However, the use of more conservative and stringent diagnostic criteria reflected in the case definitions, combined with an under-recognition of microcephaly prior to the ZIKV epidemic, may have contributed to the low background prevalence estimates of this condition.[5] Prior to the ZIKV epidemic, the Latin American Collaborative Study of Congenital Malformations (ECLAMC) defined microcephaly as a head circumference measuring greater than 3 standard deviations (SD) below the mean growth curve, adjusted for age and gender.[6] In contrast, current case definitions use a cut-off of greater than 2 SD below the mean, or below the third percentile of the growth curve, in addition to identifying structural brain abnormalities.[1] Hence, the proportion of microcephaly attributed to ZIKV may be overestimated, which may have widespread implications for congenital ZIKV infection screening programs.

Measurement of the occipital frontal head circumference (OFC) is the screening tool used to identify infants with microcephaly who may suffer or not from a structural brain abnormality. However, interpretation of OFC is dependent upon gestational age, gender, and race, which makes provision of a universal screening cut-off for microcephaly challenging. Furthermore, in the setting of the ZIKV epidemic, it is important that the microcephaly case definition leads to the identification of the greatest number of congenital microcephaly cases while limiting false positives to avoid unnecessary medical evaluations—specialist visits, neuroimaging, laboratory—and the associated financial costs and emotional stress. This has resulted in changing microcephaly case definitions throughout this ZIKV epidemic, using different methods and estimates.

The development of a consistent and accurate case definition is further complicated by the large number of infants born in low- and middle-income countries (LMICs) with unknown gestational age. In Guatemala, approximately 25% of women do not receive appropriate antenatal care, and only 65% of births are attended by a skilled birth attendant.[7] Gestational age has been integral to case definitions of microcephaly used before and during the early ZIKV epidemic. However, it was not until August 2016 that World Health Organization (WHO) published the first recommendations for defining microcephaly in infants of unknown gestational age.[1] It is important to note that these guidelines have several important limitations, including a tendency toward a high false positive rate, and do not address suspected premature infants of unknown gestational age. As a result, there is a pressing need to develop a more robust approach to identifying infants of unknown gestational age at risk for congenital ZIKV infection.

Therefore, we sought to: (1) estimate the background prevalence of microcephaly in a neonatal population of unknown gestational age born primarily before the ZIKV epidemic in a rural area of Guatemala, using various case definitions of microcephaly as used in Latin America during the ZIKV epidemic; and (2) explore the applicability of new case definitions for microcephaly among our local population, which could serve as a better screening tool for microcephaly when gestational age is unknown.

METHODS

Population

A dataset collected as part of a quality improvement project of the Creciando Sanos community health program was retrospectively reviewed to examine OFC measurements obtained from infants (0–13 days) from August 1, 2014, to March 31, 2016. This longitudinal child growth and development program is operated by the Fundacion para la Salud Integral de los Guatemaltecos (FUNSALUD) and sponsored by the Fundacion Jose Fernando Bolanos and Agroamerica in the coastal lowlands, known as the southwest Trifinio region, located at the intersection of the departments of San Marcos, Quetzaltenango, and Retalhuleu, in rural Guatemala. Through the program, children 0 to 3 years are monitored by regularly scheduled home visits using health screenings and development assessments with trained community health nurses (CHNs). Although serologic evidence of ZIKV transmission was first identified in this area in April 2015, the first clinical cases were not reported by the Ministry of Health until November 2015.[8,9]

The proportion of microcephaly attributed to ZIKV may be overestimated and, therefore, may have widespread implications for congenital ZIKV infection screening programs.

The development of a consistent and accurate case definition is further complicated by the large number of infants born in low- and middle-income countries with unknown gestational age.

Anthropometric Measurements

Anthropometric measurements were taken by CHNs who first measured body length, weight, and head circumference of newborns during their program enrollment visit, and then recorded the measurements in an online database. Body length was measured to the nearest 0.1 cm using a portable Seca measuring board (Seca 210, Chino, California, USA) for infants. Weight was recorded to the nearest 0.1 kg using a Salter Brecknell hanging scale (Fairmont, Minnesota, USA). The CHNs

were instructed to use flexible tape measures to measure an infant's head circumference from the most prominent part of the forehead around to the widest part of the back of the head, and to measure at least 2 times, recording the largest number to the nearest 0.1 cm.

Estimated Gestational Age

A total of 7 case definitions for microcephaly were in widespread use in Latin America during the ZIKV epidemic.

Determining gestational age by ultrasound or last menstrual period was not possible for all infants. Therefore, gestational age was estimated using 2 methods. First, all infants were assumed as having reached full term (≥37 weeks gestational age). This is a reasonable assumption as the majority of infants were home births, did not receive clinical interventions, and were all still living at time of enrollment. However, it is likely that at least some of these infants were actually preterm or late preterm—34 to 37 weeks gestational age—births. Second, all infants were given an estimated gestational age by centering their length at a z-score of zero on gender-adjusted Fenton growth curves. Fenton growth curves provide postnatal anthropometric growth standards for preterm infants derived from large population-based studies of infants born in developed countries.[10,11] Once gestational age was estimated, percentiles and z-scores for OFC and weight could then be obtained on gender-adjusted Fenton growth curves.

Microcephaly Case Definitions

A total of 7 case definitions for microcephaly with widespread use in Latin America during the ZIKV epidemic were identified through literature review (Table 1). Two case definitions from the Brazil Ministry of Health (MOH) were used, the first (MOH 1) during the early ZIKV epidemic—from approximately November 8 to December 8, 2015[12]—and the second (MOH 2) was a revised definition employed until approximately March 13, 2016.[13] Two case definitions from the Pan American Health Organization (PAHO) were employed, the first (PAHO 1) was issued through an epidemiologic alert on December 1, 2015,[4] and the second (PAHO 2) was a revised definition released in early 2016.[14] The World Health Organization (WHO) issued new recommen-

TABLE 1. Established and Proposed Microcephaly Case Definitions

Origin of Case Definition	Microcephaly Case Definition
Brazil MOH 1	Term: OFC ≤33.0 cm for all infants Preterm: OFC ≤3rd percentile Fenton GC adjusted for GA and gender
Brazil MOH 2	Term: OFC ≤32.0 cm for all infants Preterm: OFC ≤3rd percentile Fenton GC adjusted for GA and gender
PAHO 1	Term: OFC <−2 SD WHO GC for males (<31.9 cm) and females (<31.5 cm) Preterm: OFC <−2 SD Fenton GC adjusted for GA and gender
PAHO 2	Term: OFC <3rd percentile WHO GC for males (<32.0 cm) and females (31.6 cm) Preterm: OFC <3rd percentile Fenton GC adjusted for GA and gender
WHO 1	Unknown GA, suspected term: OFC <−2 SD WHO GC 0–6 days: males: <31.9 cm; females: <31.5 cm 7–13 days: males: <32.7 cm; females: <32.2 cm
WHO 2	Unknown GA, suspected term: OFC <3rd percentile WHO GC 0–6 days: males: <32.0 cm; females: <31.6 cm 7–13 days: males: <32.8 cm; females: <32.4 cm
WHO 3	Unknown GA, suspected term: OFC <−3 SD WHO GC[a] 0–6 days: males: <30.7 cm; females: <30.3 cm 7–13 days: males: <31.5 cm; females: <31.1 cm
Fenton 1	All infants: <−2 SD Fenton GC adjusted for gender and estimated GA
Fenton 2	All infants: <3rd percentile Fenton GC adjusted for gender and estimated GA
Fenton 3	All infants: <−3 SD Fenton GC adjusted for gender and estimated GA[a]

Abbreviations: GA, gestational age; GC, growth curve; MOH, Ministry of Health; OFC, occipital frontal head circumference; PAHO, Pan American Health Organization; SD, standard deviation; WHO, World Health Organization.
[a] <-3 SD defines severe microcephaly.

dations and guidelines (WHO 1–3) released in August 2016.[1] While these most recent guidelines from WHO recommend that InterGrowth-21 curves be used as a reference standard in infants of known gestational age, for suspected term infants of unknown gestational age, the recommendation is to use WHO growth curves. We also defined 3 new case definitions based on estimated gestational age on the Fenton growth curves adjusted for gender for microcephaly in infants of unknown gestational age using cut-offs of <-2 SD (Fenton 1), below the third percentile (Fenton 2), and <-3 SD (Fenton 3)—the latter identifies severe microcephaly.

Identification of Microcephaly and Estimated Background Prevalence

The case definitions were then applied to our dataset to identify suspected cases of microcephaly in this population and estimate microcephaly background prevalence prior to the ZIKV epidemic. When the case definition required a gestational age, the estimated gestational age was derived from the Fenton growth curves. When the case definition did not require a gestational age, all infants were assumed full term (≥37 weeks gestational age). The percent agreement of identified suspected cases was then assessed by the established Brazil MOH, PAHO, and WHO case definitions and our proposed Fenton growth curve case definitions.

Statistical Analysis

Using our proposed Fenton 2 case definition, associations of independent variables with microcephaly were explored with prevalence ratios on univariate analysis including weight ≥1 SD below the mean and small for gestational age. As some of the infants were born after identification of local ZIKV transmission, potential impact of ZIKV on microcephaly was explored in several ways. First, prevalence ratios were estimated for birth date as a continuous variable and for infants born before and after May 1, 2015—allowing for first local serologic evidence of ZIKV in April 2015—and before and after December 1, 2015—allowing for an approximate full-term gestation after onset of regional ZIKV epidemic and first clinical reports of ZIKV infection—using microcephaly as a binary outcome. Finally, in order to assess if there were changes in OFC over time, regression coefficients for birth date as a continuous variable were estimated using measured OFC and OFC z-score as continuous outcomes, first as a univariate analysis and then controlling for gender and estimated gestational age.

RESULTS

Anthropometric Measurements and Estimated Gestational Age

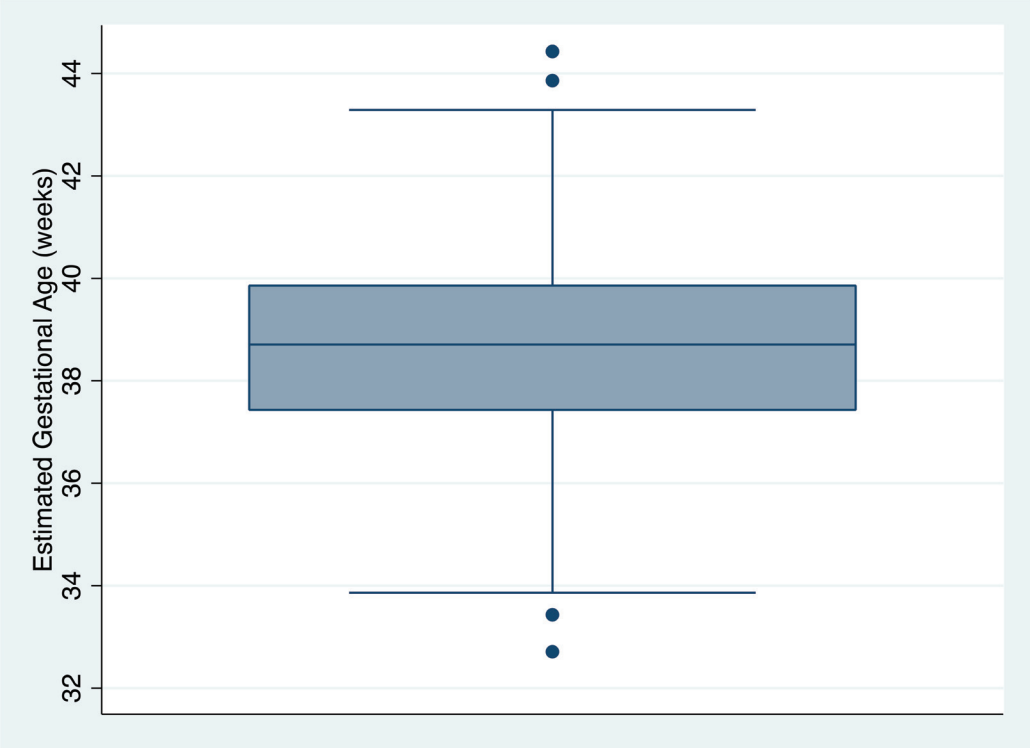
A total of 296 infants, ages 0 to 13 days old, were identified from the pregnancy registry with 1 exclusion due to erroneous length entry (Table 2). About a quarter (65; 22%) of the infants were born prior to May 1, 2015, while almost three-quarters (213; 72%) were born prior to December

TABLE 2. Characteristics of Neonates Born Between August 1, 2014, and March 31, 2016, in Rural Guatemala (N=296)

Characteristic	No. (%)
Gender	
Male	143 (48.3)
Female	153 (51.7)
Birth year	
2014	20 (6.8)
2015	214 (72.3)
2016	62 (20.9)
Age, days	
0–6	257 (86.8)
7–13	39 (13.2)
Weight, kg	
1.5 to <2.0	2 (0.7)
2.0 to <2.5	8 (2.7)
2.5 to <3.0	78 (26.4)
≥3.0	208 (70.3)
Length, cm	
40 to <45	4 (1.4)
45 to <50	139 (47.0)
≥50	153 (51.7)
OFC, cm	
≤30	7 (2.4)
>30 to ≤31	17 (5.7)
>31 to ≤32	48 (16.2)
>32 to ≤33	91 (30.7)
>33	133 (44.9)

Abbreviation: OFC, occipital-frontal head circumference.

FIGURE 1. Box Plot With Whiskers of Estimated Gestational Age[a]



Note: Median gestational age is 38.7 weeks, and the interquartile range is 37.4 to 39.9 weeks.

[a] Gestational age was estimated by centering an infant's height at a z-score of zero on gender-adjusted Fenton growth curves.

1, 2015. Data on most (257; 87%) of the infants were collected in their first week of life: the mean OFC was 33.5 cm (range, 30 cm to 37 cm) for males and 32.9 cm (range, 29.5 cm to 36.4 cm) for females; the mean length was 50.0 cm (range, 43 cm to 55 cm) for males and 49.2 cm (range, 44 cm to 54 cm) for females, and the mean weight was 3.2 kg (range, 1.8 kg to 4.3 kg) for males and 3.1 kg (range, 2.2 kg to 4.5 kg) for females. The median estimated gestational age, based on the Fenton growth curves, was 38 weeks and 5 days (range, 32 weeks 5 days to 44 weeks 3 days) (Figure 1); the mean OFC z-score was −0.68 (95% confidence interval [CI], −0.78 to −0.58) (Figure 2); and the mean weight z-score was −0.12 (95% CI, −0.21 to −0.04).

Estimated background prevalence of microcephaly determined by the 10 studied case definitions ranged substantially—from 34 to 4,223 per 10,000 live births.

Identification of Microcephaly and Estimated Background Prevalence

The Brazil MOH 1 case definition identified the highest number of suspected cases of microcephaly, with 125 infants meeting the case definition, giving an estimated background rate of microcephaly of 4,223 cases per 10,000 live births (Table 3). The Brazil MOH 2 case definition identified the second highest number of suspected cases—48 with an estimated background rate of 1,622 cases per 10,000 live births—although the number was substantially lower than with the MOH 1 definition. The WHO 1 and 2 definitions, which reflected the current recommendations for infants of unknown gestational age, identified 36 and 43 infants, respectively, giving an estimated background prevalence between 1,216 and 1,453 cases per 10,000 live births. The PAHO 1 and 2 definitions identified 15 and 20 infants, respectively, giving an estimated background prevalence of between 507 and 676 cases per 10,000 live births. The proposed definitions of Fenton growth curves <−2 SD (Fenton 1) and less than third percentile (Fenton 2) identified 13 and 20 infants, respectively, giving an estimated background prevalence between 439 and 676 cases per 10,000 live births. The WHO 3 definition (<−3 SD on WHO growth curves) identified 9 infants with

FIGURE 2. Measured Head Circumference and Z-Score for All Infants by Month of Birth

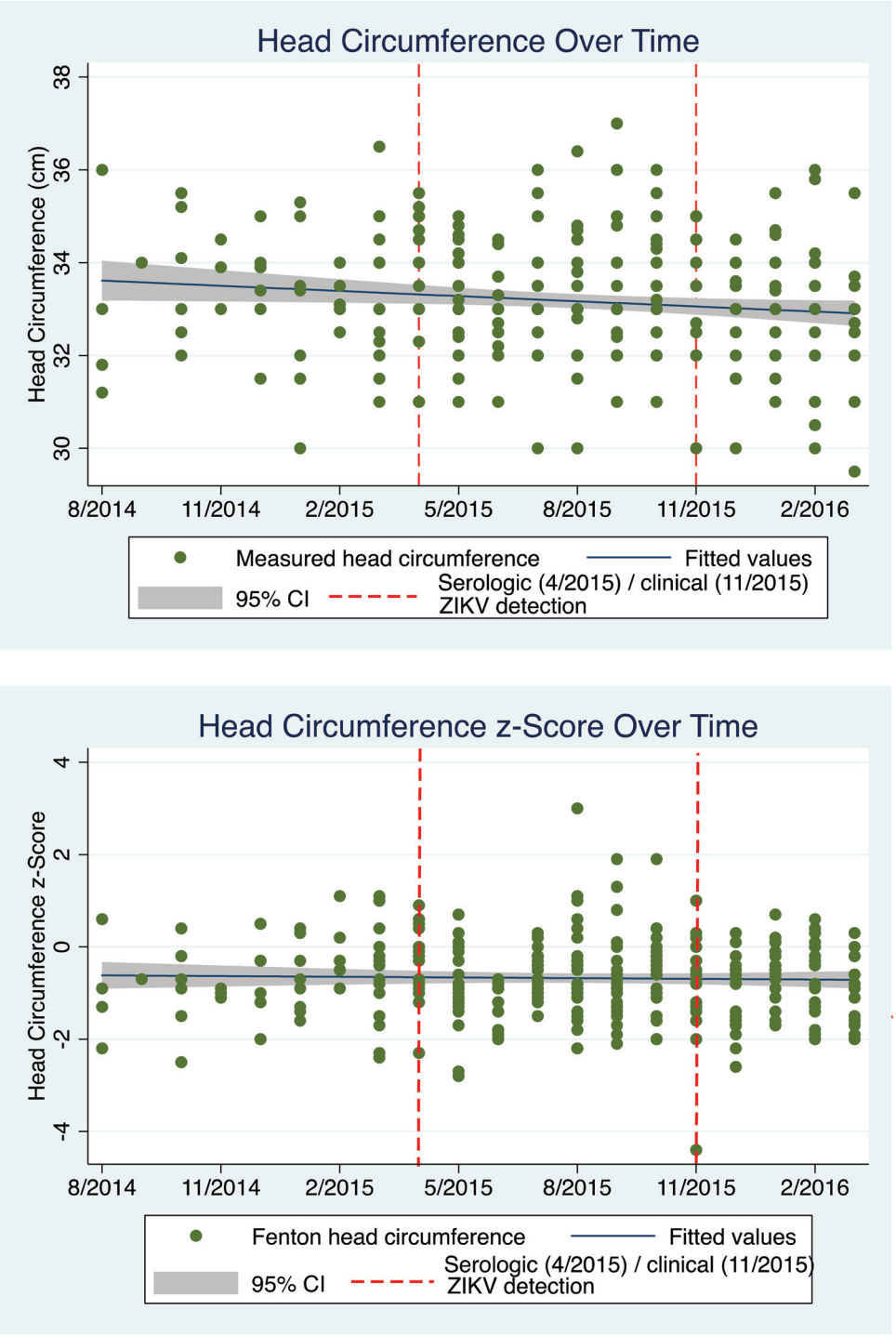


TABLE 3. Estimated Microcephaly Cases and Microcephaly Background Prevalence Using Established and Proposed Microcephaly Case Definitions in Neonates Born Between August 1, 2014, to March 31, 2016, in Rural Guatemala

Origin of Case Definition	Microcephaly No. (%)	Microcephaly Background Prevalence per 10,000 Live Births
Brazil MOH 1	125 (42.2)[a]	4,223
Brazil MOH 2	48 (16.2)[a]	1,622
WHO 2	43 (14.5)[b]	1,453
WHO 1	36 (12.2)[b]	1,216
PAHO 2	20 (6.8)[a]	676
Fenton 2	20 (6.8)[a]	676
PAHO 1	15 (5.1)[a]	507
Fenton 1	13 (4.4)[a]	439
WHO 3	9 (3.0)[b]	304
Fenton 3	1 (0.3)[a]	34

Abbreviations: MOH, Ministry of Health; PAHO, Pan American Health Organization; WHO, World Health Organization.
[a] Based on infant's estimated GA using z-score of zero for length on Fenton growth curve adjusted for gender. Term if estimated GA ≥37 weeks; preterm if estimated GA <37 weeks.
[b] Assumes term (≥37 weeks) GA for all infants.

severe microcephaly, while the proposed Fenton 3 definition for severe microcephaly (<−3 SD on Fenton growth curves) identified 1 infant.

Thirteen (65%) infants identified by the Fenton growth curve less than third percentile definition (Fenton 2) and 6 (46%) infants identified by Fenton growth curve <−2 SD definition (Fenton 1) were also identified by the WHO growth curve less than third percentile definition (WHO 2) and WHO <−2 SD definition (WHO 1), respectively (Table 4). Overall, 5 (1.7%) infants met all case definitions for microcephaly (proposed and established) and 1 infant met the 2 definitions for severe microcephaly.

TABLE 4. Percent Agreement Between Established Microcephaly Case Definitions and Proposed Fenton Growth Curve Definitions

	Fenton GC <−2 SD (n=13) No. (%)	Fenton GC <3rd Percentile (n=20) No. (%)	Fenton GC <−3 SD (n=1) No. (%)
Brazil MOH 1	13 (100.0)	20 (100.0)	1 (100.0)
Brazil MOH 2	11 (84.6)	18 (90.0)	1 (100.0)
PAHO 1	5 (38.5)	11 (55.0)	1 (100.0)
PAHO 2	6 (46.2)	12 (60.0)	1 (100.0)
WHO 1	6 (46.2)	12 (60.0)	1 (100.0)
WHO 2	7 (53.8)	13 (65.0)	1 (100.0)
WHO 3	2 (15.4)	2 (10.0)	1 (100.0)
Identified on all case definitions	5 (38.5)	11 (55.0)	1 (100.0)

Abbreviations: GC, growth curve; MOH, Ministry of Health; PAHO, Pan American Health Organization; SD, standard deviation; WHO, World Health Organization.

Factors Associated With Microcephaly

Weight ≤-1 SD (prevalence rate [PR], 3.77; 95% CI, 1.6 to 8.8; *P*=.002) and small for gestational age (PR, 4.68; 95% CI, 1.8 to 12.3; *P*=.002) were associated with microcephaly. Microcephaly was not associated with birth before or after May 1, 2015 (around when the first serologic Zika exposure was identified locally) (PR, 0.65; 95% CI, 0.3 to 2.6; *P*=.37), before or after December 1, 2015 (around when the first clinical Zika case was identified nationally) (PR, 0.64; 95% CI, 0.2 to 1.9; *P*=0.41), or birthdate (PR, 0.998; 95% CI, 0.995 to 1.001; *P*=0.25).

Measured OFC was found to be associated with birthdate (β −0.001; 95% CI, −0.002 to −0.0002; *P*=.02) on univariate analysis, but after adjusting for gender and estimated gestational age this association was no longer significant (β −0.0006, 95% CI, -0.002 to 0.0003; *P*=.19) (Figure 2). The OFC z-score was not associated with birthdate (β −0.0002; 95% CI, −0.0009 to 0.0006; *P*=.63) (Figure 2).

DISCUSSION

Regardless of the case definition used, the estimated background congenital microcephaly of 34 to 4,233 per 10,000 live births in this rural community prior to and during Guatemala's early ZIKV epidemic was significantly higher than the overall background rate of 3.30 per 10,000 live births reported in Latin America before the ZIKV outbreak.[2] Based on our analysis, using the current WHO congenital ZIKV screening guidelines would give a high false-positive rate and result in high numbers of referrals for diagnostic evaluation, creating significant ramifications at the individual, family, and community levels. These results raise important issues relevant to this community and other communities within LMICs affected by the ZIKV epidemic, including the need to further investigate the causality of high background rates of microcephaly and to determine the best screening methods and guidelines to be applied in areas where the gestational age of infants is often unknown. The substantial difference we identified in estimated background rates is likely the result of changing case definitions of microcephaly before and during the ZIKV epidemic as well as additional factors not accounted for in this analysis. Prior to the ZIKV epidemic, Brazil (and most of the world) defined microcephaly as <−3 SD, although some regions and hospitals did use alternative definitions.[2,3] Subsequent to the ZIKV epidemic, less restrictive definitions were applied to improve the identification of suspected cases of congenital ZIKV infection. This was clearly illustrated in Brazil by Victora et al., where the sensitivity for definitions used during the ZIKV epidemic were between 80% and 92%, compared with 57% of the standard <-3 SD OFC definition.[15]

Underreporting of microcephaly prior to the ZIKV epidemic may also be contributing to these differences. A large retrospective review of head circumference in infants born prior to the ZIKV epidemic in Northeast Brazil (n=16,208) found that microcephaly rates were significantly higher than nationally reported rates over a similar time frame.[5] Even when using a conservative cut-off of <-3 SD on Fenton growth curves adjusted for age and gender, their findings give an estimated rate of 3.7 cases per 10,000 live births—more than double the national rate reported in Brazil prior to ZIKV epidemic. It is reasonable to speculate that underreporting also occurred in other countries in Latin America where large proportions of infants are delivered outside of hospitals and where measurement of OFC is not obligatory.

The higher burden of microcephaly identified in our population may also reflect other population-specific factors, such as prenatal malnutrition, toxins, genetics, or other unrecognized congenital infections, like cytomegalovirus, that result in unique anthropometric characteristics at birth (smaller OFC, shorter length).[16] Additionally, the level of microcephaly in our population may also be affected by the accuracy of anthropometric measurements taken by community health workers in the field. While accurate birth weights are often not known, especially for home deliveries, weight measurements can be successfully obtained shortly after birth at the community level.[17] Accurate head circumference measurements, however, may be harder to obtain in the community setting. If the measurement is not taken around the widest possible circumference of the head, then the measurement may provide a false result. The Creciando Sanos program took several steps to try to minimize mistakes. The program employs auxiliary or professional CHNs who were trained to perform anthropometric measurements. Furthermore, the CHNs were required to measure the head circumference of each child at least 2 times and to record the largest number.

Our findings have important implications for congenital ZIKV infection screening programs. Currently, once an infant with microcephaly is identified, additional screening procedures—

Using the current congenital ZIKV screening guidelines would give high false-positive rate and result in high numbers of referrals for diagnostic evaluation, creating significant ramifications at the individual, family, and community levels.

The level of microcephaly in our population may also be affected by the accuracy of anthropometric measurements taken by community health workers in the field.

Fenton growth curves may offer an opportunity to capture infants of unknown gestational age—who are of the greatest concern for pathologic congenital microcephaly—while at the same time reducing false-positive rates.

such as physical and neurological evaluations, laboratory testing, and, often, neuroimaging—are recommended to confirm a congenital ZIKV infection.[1] However, if a population has a high background prevalence of microcephaly, using a measurement that indicates microcephaly alone as a criterion for ordering more invasive and expensive screening will lead to overutilization of scarce resources and to increased emotional and financial burdens experienced by families. For example, after Brazilian state-level medical teams investigated the laboratory and neuroimaging results of more than 1,500 infants with suspected congenital ZIKV infection, more than half of the suspected cases were determined to be unlikely to be infected and, therefore, their results were discarded.[18] Assuming the cost of neuroimaging in Brazil is comparable to the cost in rural Guatemala, where a head ultrasound is approximately US$20 and an MRI is $250, this means neuroimaging costs of between $15,000 and $187,500 may have been spent on suspected cases that were all ultimately discarded.

Exploring alternative microcephaly definitions for screening, particularly for infants of unknown gestational age, may be one way to significantly improve specificity while maintaining sensitivity and provide an alternative to the current screening practices for infants of known gestational age. Until the recent ZIKV epidemic, there has been limited discussion on how to approach microcephaly screening for infants of unknown gestational age. The application of a case definition that optimizes sensitivity and specificity without requiring a gestational age could help improve screening for ZIKV-affected infants. Although originally designed for use in preterm infants, the Fenton growth curves offer a standardized approach to addressing and adjusting for unknown gestational age. The use of the sensitive WHO growth curves for presumed full-term infants can result in a high false-positive rate, which was recognized as a limitation by WHO itself.[1] This appears to be consistent with the findings in our dataset, where the WHO growth curves estimated a microcephaly background prevalence between 1,216 and 1,453 per 10,000 live births in our population. This overestimation may be due in part to an unknown percentage of infants being late-preterm births. In our experience with this Guatemalan community, the WHO growth curves would significantly overestimate the number of infants with congenital microcephaly and lead to an excessive and unnecessary referral pattern overburdening community health, material, and financial resources.

Approximately 46% to 65% of suspected cases on Fenton growth curves were also identified by the WHO definitions. Therefore, Fenton growth curves may offer an opportunity to capture infants of unknown gestational age—who are of the greatest concern for pathologic congenital microcephaly—while at the same time reducing false-positive rates. An additional advantage is that this method allows for identification of infants with asymmetric growth restriction—that is, disproportionately small heads and weight compared to length. Identification of disproportionate weight and OFC may prove useful as lower birth weight is associated with confirmed and probable congenital ZIKV cases compared with non-cases.[18] However, the utility of using the Fenton growth curves as we did for identification of infants with microcephaly who have symmetric growth restriction—or proportionately small length, head circumference, and weight—is limited because of centering on a length z-score of zero.

Despite this, the benefit of using the Fenton growth curves is that it accommodates infants whose anthropometric data are collected beyond the immediate delivery period. Although WHO recommends assessment of head circumference at 24 hours of life, many of the infants born in rural communities are not given an anthropometric assessment within this period. Therefore, if an infant of unknown gestational age is instead assessed during their second or third week of life, it becomes unclear which WHO growth curve is most appropriate to accurately assess for microcephaly as these growth curves are only available at weekly intervals. For example, an 8-day-old male infant with an OFC of 33 cm would be classified as greater than the third percentile if using the WHO 1-week cut-off of 32.9 cm but less than the third percentile if using the WHO 2-week cut-off of 33.7 cm. Meanwhile, the Fenton growth curves have standardized estimates for anthropometric data at daily intervals through 50 weeks gestational age. This means that using an infant's length at the time of first assessment to estimate a gestational age—which would also account for postnatal age—a more individualized assessment of the infant's anthropometric data can be obtained beyond the immediate delivery period.[10]

Limitations

Several limitations need to be considered when using Fenton growth curves in the proposed manner. First, these growth curves were derived primarily from large dataset analysis of infants born

primarily in developed countries. It has been well established that children in developing countries often have unique anthropometry compared to children of developed countries. Thus, the Fenton growth curves may not fully reflect the anthropometry of infants from LMICs. It may be more appropriate to center length on a z-score other than zero to accurately estimate gestational age in certain LMICs. However, since we primarily use the Fenton growth curves to identify disproportional head circumference compared to length, this bias may not significantly impact our results. We did consider employing a similar approach with InterGrowth-21 growth curves, which provide fetal and newborn growth standards consistent with WHO growth curves and are derived from children in developed and developing countries. However, 22% of infant lengths in our population exceeded InterGrowth-21's maximum standards for length which extend up to 51 cm at a z-score of zero, therefore preventing estimation of gestational age for that group.[19] In contrast to the InterGrowth-21 curves, which provide growth standards through 42 weeks gestational age, the Fenton growth curves extend through 50 weeks gestational age (length up to 57 cm at a z-score of zero). Nevertheless, if growth standards for InterGrowth-21 curves are expanded, they may be preferred to Fenton growth curves, as they are the current standard used for infants of known gestational age. Another consideration is that Fenton growth curves were designed for assessing postnatal growth of preterm infants, who demonstrate unique growth characteristics postnatally, compared to term infants, particularly with regard to weight gain velocity.[11] However, the transition incorporated into these curves—from preterm to post-term growth—has been validated and thus it seems reasonable to use them in a mixed population of preterm and term infants.

Second, despite the application of the multiple case definitions, the dataset for this evaluation is limited by our lack of gestational age estimates, thus making a direct comparison of Fenton growth curves to other case definitions difficult. In order to validate our theory, it will be important to replicate these findings in a population of infants with known and accurate gestational age. Similarly, as several of the case definitions require a known gestational age, our use of estimated gestational age inherently led to a degree of uncertainty that may underestimate or overestimate the number of suspected cases and the background prevalence. These challenges, however, reflect the reality in many LMICs, and, to that end, we believe it is important to explore alternative case definitions that can address potential challenges currently faced by practitioners on the field.

Lastly, infants born before and during the ZIKV epidemic were included in our dataset, which could have influenced the detection of congenital microcephaly. In fact, on regression analysis, we did find a significant association between measured OFC and date of birth. However, once adjusted for gender and estimated gestational age, both of which are critical to the interpretation of head circumference, we found there was no longer a significant association. Similarly, we found no associations between identified microcephaly or head circumference z-score when examining birthdate, considering onset of regional ZIKV transmission, and accounting for time for gestation. Therefore, we conclude that it is unlikely that the onset of local ZIKV transmission significantly impacts our results.

Fenton growth curves may not fully reflect the anthropometry of infants from LMICs. It may be more appropriate to center length on a z-score other than zero to accurately estimate gestational age in certain LMICs.

CONCLUSION

It is important to consider how our understanding and the case definition of microcephaly has evolved during the ZIKV epidemic and what effect changing knowledge of congenital ZIKV infection has on the development of screening programs in LMICs. As the case definitions to date have not fully addressed the limitations of evaluating children of unknown gestational age, the definitions should continue to be reviewed and adjusted as we better understand the clinical presentation of congenital ZIKV infection. However, the research on the causality and long-term implications of microcephaly in developing countries should be prioritized. These are children living in the most resource-constrained settings, with limited access to health care, but having the highest risk factors for exposure to mosquito-borne illnesses. Hence, part of the legacy from this ZIKV epidemic to the global community will be to highlight the need to develop more robust and clear guidelines for identifying which infants require further evaluation.

As the case definitions to date have not fully addressed the limitations of evaluating children of unknown gestational age, the definitions should continue to be reviewed and adjusted as we better understand the clinical presentation of congenital ZIKV infection.

Acknowledgments: We would like to acknowledge the community health nurses at the Creciando Sanos Program including Claudia Rivera, Karen Altun, Yoselin Velasquez, Silvia Aragon, Alba Gabriel, Alisse Hernandez, and Cristabel Gonzalez. We would also like to thank Dr. Susan Niermeyer for her assistance in the design and implementation of the neonatal registry and the Jose Fernando Bolanos Menendez Foundation and the Center for Global Health at the University of Colorado for financial support of the Creciendo Sanos Program.

Funding: Jose Fernando Bolanos Menendez Foundation and the Center for Global Health at the University of Colorado.

Competing Interests: None declared.

REFERENCES

1. World Health Organization (WHO). *Screening, Assessment and Management of Neonates and Infants with Complications Associated with Zika Virus Exposure in Utero. Rapid Advice Guideline. 30 August 2016*. Geneva: WHO; 2016. http://apps.who.int/iris/bitstream/10665/204475/1/WHO_ZIKV_MOC_16.3_eng.pdf. Accessed October 3, 2017.
2. Estudio Colaborativo Latino Americano de Malformaciones Congénitas (ECLAMC). Microcefalias en el ECLAMC y en Brasil. Buenos Aires, Argentina: ECLAMC; 2015. http://www.eclamc.org/descargas/1.MicrocefalianoECLAMCenoBrasil.docx. Accessed October 11, 2017.
3. Estudio Colaborativo Latino Americano de Malformaciones Congénitas (ECLAMC). Documento ECLAMC final: resumo e conclusões dos documentos 1-5. Buenos Aires, Argentina: ECLAMC; 2015. http://www.eclamc.org/descargas/6.DocumentoECLAMCFinalV3.docx. Accessed October 11, 2017.
4. Pan American Health Organization (PAHO). Epidemiological alert: neurological syndrome, congenital malformations, and Zika virus infection. Implications for public health in the Americas. 1 December 2015. Washington, DC: PAHO; 2015. http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&Itemid=270&mmgid=32405. Accessed October 3, 2017.
5. Soares de Araújo JS, Regis CT, Gomes RGS, et al. Microcephaly in north-east Brazil: a retrospective study on neonates born between 2012 and 2015. *Bull World Health Organ*. 2016;94(11):835–840. CrossRef. Medline
6. Moreno MT, Vargas S, Poveda R, Sáez-Llorens X. Neonatal sepsis and meningitis in a developing Latin American country. *Pediatr Infect Dis*. 1994;13(6):516–520. CrossRef. Medline
7. Ministerio de Salud Pública y Asistencia Social (MSPAS); Instituto Nacional de Estadística (INE); ICF International. *VI Encuesta Nacional de Salud Materno Infantil (ENSMI) 2014—2015. Informe de Indicadores Basicos*. Guatemala City, Guatemala: MSPAS; 2015. http://pdf.usaid.gov/pdf_docs/PBAAD728.pdf. Accessed October 11, 2017.
8. Olson DAE. Zika virus in children (unpublished raw data). Denver: University of Colorado; 2016.
9. Departamento de Epidemiologia, Ministerio de Salud Publica y Asistencia Social (MSPAS). Semana epidemiológica 2016. Semana epidemiológica, del 29 de Mayo al 4 de Junio 2016. Guatemala City, Guatemala: MSPAS; 2016. http://epidemiologia.mspas.gob.gt/files/Publicaciones%202016/SEMEPI/SEMEPI_22_2016.pdf. Accessed October 3, 2017.
10. Fenton TR, Kim JH. A systematic review and meta-analysis to revise the Fenton growth chart for preterm infants. *BMC Pediatr*. 2013;13(1):59. CrossRef. Medline
11. Fenton TR, Nasser R, Eliasziw M, Kim JH, Bilan D, Sauve R. Validating the weight gain of preterm infants between the reference growth curve of the fetus and the term infant. *BMC Pediatr*. 2013;13(1):92. CrossRef. Medline
12. Ministério da Saúde, Secretaria de Vigilância em Saúde. Nota informativa No 01/2015 – COES microcefalias. Emergência de Saúda Pública de Importância Internacional – ESPII. Brasília, Brazil: Ministério da Saúde; 2015. http://www.cosemspa.com.br/wordpress/wp-content/uploads/2015/11/microcefalia-nota-informativa-17nov2015-c-1.pdf. Accessed October 3, 2017.
13. Ministério da Saúde, Secretaria de Vigilância em Saúde. *Protocolo de Vigilância e Resposta à Ocorrência de Microcefalia e/ou Alterações do Sistema Nervoso Central (SNC). Emergência de Saúda Pública de Importância Internacional – ESPII*. Brasília, Brazil: Ministério da Saúde; 2016. http://combateaedes.saude.gov.br/images/sala-de-situacao/Microcefalia-Protocolo-de-vigilancia-e-resposta-10mar2016-18h.pdf. Accessed October 3, 2017.
14. Pan American Health Organization (PAHO). *Lineamientos Preliminares de Vigilancia de Microcefalia en Recién Nacidos en Entornos con Riesgo de Circulación de Virus Zika*. Washington, DC: PAHO; 2016. http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=33046&Itemid=270&lang=es. Accessed October 11, 2017.
15. Victora CG, Schuler-Faccini L, Matijasevich A, Ribeiro E, Pessoa A, Barros FC. Microcephaly in Brazil: how to interpret reported numbers? *Lancet*. 2016;387(10019):621–624. CrossRef. Medline
16. Martorell R, Schroeder DG, Rivera JA, Kaplowitz HJ. Patterns of linear growth in rural Guatemalan adolescents and children. *J Nutr*. 1995;125(suppl 4):1060S–1067S. Medline
17. Gisore P, Shipala E, Otieno K, et al. Community based weighing of newborns and use of mobile phones by village elders in rural settings in Kenya: a decentralised approach to health care provision. *BMC Pregnancy Childbirth*. 2012;12(1):15. CrossRef. Medline
18. França GVA, Schuler-Faccini L, Oliveira WK, et al. Congenital Zika virus syndrome in Brazil: a case series of the first 1501 livebirths with complete investigation. *Lancet*. 2016;388(10047):891–897. CrossRef. Medline
19. INTERGROWTH-21st. Intergrowth-21st newborn size at birth chart. Published March 30, 2015. https://intergrowth21.tghn.org/articles/intergrowth-21st-newborn-size-birth-chart/. Accessed November 10, 2016.

Peer Reviewed

Received: February 15, 2017; **Accepted:** July 25, 2017

Cite this article as: Rick A-M, Domek G, Cunningham M, et al. High background congenital microcephaly in rural Guatemala: implications for neonatal congenital Zika virus infection screening. Glob Health Sci Pract. 2017;5(4):686-696. https://doi.org/10.9745/GHSP-D-17-00116

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LETTER TO THE EDITOR

Authors' Response to Editorial: Maternal Death Surveillance and Response: A Tall Order for Effectiveness in Resource-Poor Settings

Helen Smith,[a] Charles Ameh,[a] Pamela Godia,[b,c] Judith Maua,[b] Kigen Bartilol,[d] Patrick Amoth,[e] Matthews Mathai,[a] Nynke van den Broek[a]

See related articles by Koblinsky and by Smith et al.

We thank Marge Koblinksy for her considered editorial[1] on the Maternal Death Surveillance and Response (MDSR) approach used in Kenya and lessons learned, described in our recent article published in GHSP.[2] Her views on the potential effectiveness of MDSR in resource-limited settings, however, seem pessimistic.

Firstly, Koblinsky argues that MDSR is too complicated and demanding in low- and middle-income countries, and should be abandoned in favour of investment in lifesaving interventions. We argue, however, that investment must be made in ensuring availability of care as well as quality of this care for interventions to be lifesaving. Most maternal deaths in low- and middle-income countries result from obstetric complications. The care packages to prevent and manage these complications are established and evidence-based. Most maternal deaths occur because complications are not recognized on time, women do not receive these interventions on time, or care given may be substandard.

Secondly, Koblinsky criticizes the assessment of factors contributing to maternal deaths in the national report from Kenya—incorrect management, insufficient monitoring, and delay in taking action when needed—as being too general. Yet these are exactly the reasons why women die. For example, the failure to identify severe hemorrhage early and to take timely and adequate action is what leads to death in women with hemorrhage in many cases. It is only by understanding these factors through a systematic review process such as maternal death audit that health care providers can identify what actions need to be undertaken to improve the quality of care and outcomes. Similarly, by aggregating information across settings, regional and national governments can identify cross-cutting themes and formulate priority recommendations, such as the need to strengthen blood transfusion services. In places where MDSR is currently implemented including the Republic of South Africa, Malaysia, and several states in India, there is emerging evidence that this results in measurable improvements in availability and quality of care with renewed priority setting and investment in maternal and newborn health.[3,4]

The editorial also levels criticism more generally at the country-level efforts in Kenya and remarks that the results presented fall short of what is needed. In the first year of MDSR implementation at the national level using the Confidential Enquiry into Maternal Deaths (CEMD) approach, the decision was to start with the identification and review of maternal deaths in major comprehensive emergency obstetric care facilities. A total of 52% of all maternal deaths reported to have occurred in these facilities were included in the report. In a country with 62% of births occurring in a health care facility, the review process discovered that maternal deaths occurring at the health facility level were underreported and that the District Health Information System 2 (DHIS 2) database did not capture deaths occurring at the community level. In response, the government is reorganizing the maternal death surveillance system to ensure that *all* maternal deaths are reported through DHIS 2.[5] Furthermore, criticism of the lack of action following the recommendations made in the report is premature—the report has only just been completed, and the Ministry of Health (MOH) will formally launch it by the end of 2017. We can confirm that for the first time in Kenya, specific recommendations for action by various stakeholders (e.g., the MOH, county governments, professional associations, and civil society)

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with indicators and targets to guide the 'Response' have been produced. This is a significant step forward

Koblinsky summarizes the history of maternal death audit and its evolution into CEMD in high-income countries. However, her point that MDSR is likely to be more successful in countries with low maternal mortality ratios (MMRs) is not based on sound evidence. In the United Kingdom, the use of maternal death reviews started small as a practitioner-led activity in Rochdale, in northwest England, between 1931 and 1934. Prior to this, the MMR in Rochdale was estimated to be 900 per 100,000 live births, twice the national average. In 1934, at a time of severe economic depression, because of actions taken following the Rochdale Enquiry, the MMR decreased to 280, "without any alteration in personnel or any substantial increase in public expenditure."[6] The first full national enquiry into maternal deaths in the United Kingdom was not conducted until 30 years later in 1952 and has successfully continued to date as an important quality improvement process.

The impetus and commitment that drove the process in Kenya was from the highest administrative level, the Cabinet Secretary for Health, and supported by the professional medical and midwifery associations and regulatory bodies. The running of the committee was not a "gray area." There was no precedent, so it was initially challenging to get the committee up and running. Despite these challenges, the committee is well-established and has terms of reference agreed by all stakeholders and approved by the MOH. The committee is actively led and managed by the national MDSR secretariat situated within the MOH.

In our article, we document implementation of MDSR in a 'real-life' setting, reporting on experiences and lessons learned working in partnership with the MOH in Kenya to implement their previously agreed guidelines on Maternal and Perinatal Death Surveillance and Response (MPDSR) based on the World Health Organization MDSR guidelines.[7] We do not advocate that MDSR is the *only* solution to reducing maternal mortality, nor do we suggest it is easy to implement. We do, however, provide a careful analysis of what needs to be in place for successful implementation and what could facilitate the maturation of the process in a country like Kenya. We certainly acknowledge that there is still more to do. Aware that other low- and middle-income countries are currently embarking on establishing MDSR, we wish to share the important lessons learned in Kenya.

Competing Interests: None declared.

REFERENCES

1. Koblinsky M. Maternal death surveillance and response: a tall order for effectiveness in resource-poor settings. *Glob Health Sci Pract.* 2017;5(3):333–337. CrossRef. Medline
2. Smith H, Ameh CA, Godia P, et al. Implementing maternal death surveillance and response in Kenya: incremental progress and lessons learned. *Glob Health Sci Pract.* 2017;5(3):345–354. CrossRef. Medline
3. Ravichandran J, Ravindran J. Lessons from the confidential enquiry into maternal deaths, Malaysia. *BJOG.* 2014;121(suppl 4):47–52. CrossRef. Medline
4. Paily VP, Ambujam K, Rajasekharan Nair V, Thomas B. Confidential review of maternal deaths in Kerala: a country case study. *BJOG.* 2014;121(suppl 4):61–66. CrossRef. Medline
5. Kenya National Bureau of Statistics (KNBS); ICF Macro. *Kenya Demographic and Health Survey 2014.* Calverton, MD: KNBS and ICF Macro; 2014. https://dhsprogram.com/publications/publication-FR308-DHS-Final-Reports.cfm. Accessed December 7, 2017.
6. Topping A. Maternal mortality in Rochdale. *Br Med J.* 1935;1:386. CrossRef
7. World Health Organization (WHO). *Maternal Death Surveillance and Response: Technical Guidance. Information for Action to Prevent Maternal Death.* Geneva: WHO; 2013. http://www.who.int/maternal_child_adolescent/documents/maternal_death_surveillance/en/. Accessed October 1, 2017.

Received: November 7, 2017; **Accepted:** November 21, 2017

Cite this article as: Smith H, Ameh C, Godia P, Maua J, Bartilol K, Amoth P, et al. Authors' response to editorial: Maternal Death Surveillance and Response: a tall order for effectiveness in resource-poor settings. Glob Health Sci Pract. 2017;5(4):697-698. https://doi.org/10.9745/GHSP-D-17-00407

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CORRECTION

Corrigendum: Igras et al., Systems Approach to Monitoring and Evaluation Guides Scale Up of the Standard Days Method of Family Planning in Rwanda

Susan Igras,[a] Irit Sinai,[b] Marie Mukabatsinda,[c] Fidele Ngabo,[d] Victoria Jennings,[a] Rebecka Lundgren[a]

See *corrected article*.

In the article "Systems approach to monitoring and evaluation guides scale up of the Standard Days Method of family planning in Rwanda" by Susan Igras, Irit Sinai, Marie Mukabatsinda, Fidele Ngabo, Victoria Jennings, and Rebecka Lundgren, which appeared in the May 2014 issue (Volume 2, Number 2) of GHSP, the authors had declared that they had no competing interests. This has been corrected to indicate that Georgetown University, the employer of some of the authors at the time of the writing of the article, owns the patented CycleBeads technology, and that a company owned by a relative of Victoria Jennings has the exclusive license to commercialize the technology. Victoria Jennings has no financial relationship to the company and neither she nor any of the other authors receives royalties or other income related to the licensed technology.

The article has been corrected accordingly.

Cite this article as: Igras S, Sinai I, Mukabatsinda M, Ngabo F, Jennings V, Lundgren R. Corrigendum: Igras et al., Systems approach to monitoring and evaluation guides scale up of the Standard Days Method of family planning in Rwanda. Glob Health Sci Pract. 2017;5(4):699. https://doi.org/10.9745/GHSP-D-17-00359

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