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TAKING EXCEPTION

A False Dichotomy: RCTs and Their Contributions to Evidence-Based Public Health

Global public health should rely on those research methods that best answer the pressing questions at hand. Randomized controlled trials (RCTs) and other rigorous impact evaluation methods have a critical role to play in public health.

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http://dx.doi.org/10.9745/GHSP-D-14-00245

Response to ''A False Dichotomy: RCTs and Their Contributions to Evidence-Based Public Health''

While randomized controlled trials (RCTs) can and do make valuable contributions, they also have severe limitations, including in answering the basic question of ''Does it work?'' and, even more so, in steering how to proceed with complex public health programming at scale. They deserve no exalted position in the pantheon of methodologies for evidence-based public health.

James D Shelton

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EDITORIAL

ARVs: The Next Generation. Going Boldly Together to New Frontiers of HIV Treatment

Matthew Barnhart,[a] James D Shelton[b]

New antiretrovirals (ARVs), particularly the potentially "game-changing" ARV dolutegravir, offer major potential to meet the compelling need for simpler and better HIV treatment for tens of millions of people in the coming decade. Advantages include substantially lower manufacturing cost, fewer side effects, and less risk of resistance. But key obstacles must be addressed in order to develop and introduce new ARVs in specific combinations optimized for the needs of low- and middle-income countries. Strong leadership will be essential from the global health community to nurture more focused collaboration between the private and public sectors.

THE CRUCIAL NEED FOR BETTER ANTIRETROVIRAL THERAPY, ESPECIALLY FOR HIGH-BURDEN COUNTRIES

The current and projected need for HIV treatment is simply stunning. Already, among the estimated 35 million people living with HIV, 13.6 million are receiving antiretrovirals (ARVs),[1] with about 3 of every 4 people on antiretroviral therapy (ART) residing in sub-Saharan Africa.[2] However, achieving expanded 2013 treatment guidelines from the World Health Organization (WHO) would require ART provision to about twice the current number. And many have recommended that *all* people living with HIV infection should receive ARVs. Moreover, over time as survival improves substantially, the number of people living with HIV will increase markedly. Additional special demands are ARVs for people for whom first-line therapy has failed, people with tuberculosis (TB), pregnant and lactating women, and children.

At almost US$10 billion per year,[2] international funding for HIV is the lion's share of all global health funding, and within that, support for HIV treatment is also the lion's share. That level of support seems to have plateaued, and indeed pressure is mounting for resource-constrained countries affected by HIV to take over more of the burden. Actually, more of the site-level costs of providing treatment comes from service delivery costs than from costs of the ARVs themselves; provision of services for established patients (excluding the cost of ARVs) averages $177 (range, $129–$235) per patient year (ppy)[3] compared with $122 ppy[4] for generic versions of the WHO-preferred first-line ARV combinations. Furthermore, patient compliance and continuation with current ARV regimens are far from optimal.

All this argues for ARVs that are not only cheaper but also more patient- and service delivery-friendly and efficient. Importantly, in addition to the benefits for combatting HIV, simpler and less expensive ART should ultimately reap tremendous rewards for global health more broadly, freeing up human and financial resources for overstretched health systems to address other pressing needs.

The ability to simplify ART delivery and lower cost is constrained by characteristics of the available ARV regimens, including their resistance barrier, safety, tolerability, efficacy, toxicities, monitoring requirements, and cost of manufacturing. One key constraint is that at least 3 ARVs must typically be provided to promote treatment effectiveness and help forestall the development of drug resistance. To maximize compliance, these are optimally combined in a single daily tablet. Currently, the WHO-preferred first-line ART regimen is efavirenz, tenofovir disoproxil fumarate (TDF), and either lamivudine or emtricitabine. While offering major advantages over previous regimens, it remains less than ideal due to its suboptimal barrier to development of resistance, potential for renal toxicity, neuropsychiatric side effects, possible interaction with contraceptive implants, and relatively high cost. In terms of second-line regimens, cost is a major barrier because they involve the much more expensive-to-manufacture protease inhibitors, with the generic regimens costing over $300 ppy.[4] The numbers of patients requiring these regimens will increase dramatically over the next decade. Furthermore,

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Less expensive and more practical ARVs are needed to meet the growing treatment needs in resource-constrained countries.

with guidelines progressively recommending earlier initiation of ART, edging ever closer to a universal "test-and-treat" approach, the bar for regimen tolerability will rise further, since even relatively minor side effects may reduce willingness of patients who are clinically well to initiate, adhere to, or remain on lifelong treatment.

DOLUTEGRAVIR: A POTENTIAL "GAME-CHANGER" FOR BETTER ARV REGIMENS

Thankfully, a next generation of better ARVs is on the horizon (Table 1), and some of these individual ARVs could be combined in regimens that should be easier to implement, less toxic, more durable, and also substantially less expensive to manufacture (Table 2). Leading the way for this new generation is dolutegravir, a recently approved ARV that belongs to a class of agents called integrase inhibitors, which block the last stage of the viral life cycle in which the viral genome integrates into the host DNA. However, dolutegravir differs from its prior integrase cousins, raltegravir and elvitegravir, and indeed from all other previously approved ARVs, in having a constellation of attributes that taken together could create a firm foundation for new "game-changing" combinations to facilitate the expanded roll out of simplified, less expensive ART.

To begin with, dolutegravir has a very high barrier to drug resistance,[5] which is particularly advantageous in low-income countries where resistance testing is not widely available and treatment options are limited. Dolutegravir can

TABLE 1. Three Promising ARVs of the Next Generation

Drug Name	Innovator Company	Development Stage	Potential Advantages
Dolutegravir	ViiV	Approved	• Very high barrier to resistance and better regimen durability • Reduced manufacturing cost • Reduced side effects compared with efavirenz • Potential for first- or second-line treatment • More rapid decrease in viral load may increase efficacy for prevention of mother-to-child transmission among women initiating ART late in gestation • Low dosage convenient for pediatric formulations • May not reduce efficacy of progestin-containing contraceptive implants, which is a possible concern with efavirenz
TAF	Gilead	Late Phase III	• Lower risk of renal and bone toxicity than TDF • Lower manufacturing cost than TDF • Potential for first- or second-line treatment, with possible greater efficacy than TDF for viruses resistant to some nucleosides/nucleotides
Doravirine	Merck	Early Phase III	• Lower rates of central nervous system adverse events than efavirenz reported in phase II studies • Possible low manufacturing cost given low dose • May have better activity against many non-nucleoside reverse transcriptase resistant isolates common in sub-Saharan Africa, leading to possible utility in second-line combinations • Characteristics (lack of food requirement, shorter half-life, lower potential for TB medication interactions) might make it a better partner for dolutegravir than rilpivirine as part of a simplified, low-cost 2-drug maintenance regimen

Abbreviations: ART, antiretroviral therapy; ARV, antiretroviral; TAF, tenofovir alafenamide fumarate; TB, tuberculosis; TDF, tenofovir disoproxil fumarate.

TABLE 2. Currently Available and Improved Hypothetical Combination ARVs

ARV Drug Combinations	Innovator Companies	Estimated Cost per Year (US$)[a]	Comments
Current WHO-Recommended ARV Regimens for Adults			
Efavirenz + TDF + lamivudine or emtricitabine (Atripla is a comparable pill marketed in the US)	NA (generic available)	$122	• Preferred first-line regimen • Highly effective and well tolerated • Drawbacks include weak resistance barrier, potential for kidney and bone toxicity, neuropsychiatric side effects, possible interaction with contraceptive implants, and greater incidence of severe adverse birth outcomes in pregnancies receiving TDF-containing regimens compared with zidovudine-containing regimens
Lopinavir/ritonavir or atazanavir/ritonavir + zidovudine[b] + lamivudine	NA (generic available)	$305–$318	• Preferred second-line regimen • Not available as a fixed-dose combination • Resistance barrier suboptimal due to lack of second highly potent and robust agent to couple with the protease inhibitor • Drug-drug interactions increased by ritonavir
Highly Effective Alternatives, Not Ideal for Resource-Limited Settings			
Elvitegravir + TDF + emtricitabine + cobicistat (Stribild, the ''quad'' pill)	Gilead	$184	• Elvitegravir's resistance barrier is less robust than dolutegravir's • Cobicistat increases drug-drug interactions and cost • Bone and kidney toxicity possible with TDF • A second-generation ''quad'' with TAF is in development and should decrease side effects and cost to a degree
Dolutegravir + abacavir + lamivudine (Triumeq, the ''tri'' pill)	ViiV	$179	• Abacavir is expensive to manufacture and is associated with a rare but potentially life-threatening hypersensitivity syndrome • Has utility for pediatrics due to abacavir not affecting bone
Illustrative Improved (Hypothetical) 3-Drug Regimens			
Dolutegravir + TAF + lamivudine or emtricitabine	ViiV + Gilead	$60	• Higher resistance barrier and durability • Reduced risk of renal and bone toxicity and manufacturing cost with TAF compared with TDF • Primarily for first-line treatment, although it might have good activity as second-line for some patients
Dolutegravir + boosted protease inhibitor + TAF	ViiV + Gilead + Others	$266–$357 (or more[c])	• Improved second-line regimen, with a very robust resistance barrier that could make the need for third-line regimens very rare

TABLE 2 (continued).

ARV Drug Combinations	Innovator Companies	Estimated Cost per Year (US$)[a]	Comments
Dolutegravir + TAF + doravirine	ViiV + Gilead + Merck	$64	• Might be effective for first- or second-line treatment as doravirine has *in vitro* activity against non-nucleoside reverse transcriptase–resistant isolates common in sub-Saharan Africa
Illustrative Improved (Hypothetical) 2-Drug Maintenance Combinations (for use after undetectable viral load achieved)			
Dolutegravir + rilpivirine	ViiV + Janssen	<$40	• Excellent tolerability with minimal side effects • Both agents are already approved, allowing for expedited development • Proof of concept for efficacy available from LATTE study • Downsides include interactions with TB regimens, food requirement, and suboptimal efficacy for second-line treatment • Currently in late stage clinical development that could lead to licensure
Cabotegravir + rilpivirine (long-acting injectable)	ViiV + Janssen	$40	• Injection every 1–2 months may reduce risk of resistance due to non-adherence and increase confidentiality and quality of life • If patients are lost to follow-up, risk of resistance could be much higher than an oral formulation • Other advantages and disadvantages may be similar to dolutegravir/rilpivirine oral combination above • Currently in phase II development
Dolutegravir + doravirine	ViiV + Merck	$50	• Doravirine's different resistance profile, lack of food requirement, shorter half-life, and possibly lower potential for TB medication interactions might make it a better partner for dolutegravir than rilpivirine as part of 2-drug regimen • Might have efficacy in first- and/or second-line treatment • This is a hypothetical combination, not in development, and doravirine is now in early phase III development
Dolutegravir + lamivudine	ViiV	$46	• Might be effective and well tolerated in first-line treatment, preserving many second-line options • This is a hypothetical combination, not in development, but because one company makes both medicines, fewer obstacles might exist to develop it

TABLE 2 (continued).

ARV Drug Combinations	Innovator Companies	Estimated Cost per Year (US$)[a]	Comments
Dolutegravir + TAF	ViiV + Gilead	$39	• Hypothetical combination for first-line treatment, with some possible efficacy in second-line • Currently not in development
Dolutegravir + boosted protease inhibitor	ViiV + Others	$252–$343 (or more[c])	• Hypothetical combination, not currently in development • Could provide a very robust resistance barrier for second-line treatment

Abbreviations: ARV, antiretroviral; NA, not applicable; TAF, tenofovir alafenamide fumarate; TB, tuberculosis; TDF, tenofovir disoproxil fumarate; WHO, World Health Organization.

[a] For approved and available ARVs, these costs were based upon the generic prices from the Supply Chain Management Systems E-catalog, November 2014 version.[4] Costs do not include in-country logistic and storage costs. While these prices are more than the manufacturing cost, they are used as a proxy for the fully loaded costs, given that the generic market is competitive with a relatively low profit margin. For hypothetical ARV combinations, illustrative manufacturing costs were estimated as follows: (1) rilpivirine oral or injectable: $15, based upon expert consultation,[6] and assuming cost of oral rilpivirine ≤ cost of injectable; (2) dolutegravir oral: $25, based upon expert consultation,[6] and assuming cost of oral dolutegravir ≤ cost of injectable; (3) cabotegravir injectable: $25, assumed to be same cost as dolutegravir injectable and given similar structure of the 2 compounds; (4) TAF: $14 assumes TAF costs 1/3 of TDF at approximately 1/10 the dose; (5) cobicistat: $90; in the absence of other data, cost assumed to be the same as another pharmacokinetic booster, ritonavir[25]; and (6) elvitegravir (150 mg/day) and doravirine (100 mg/day), both

also be manufactured at scale very inexpensively, given its low dose of only 50 mg once daily for treatment-naive patients.[6] Additionally, dolutegravir is very well tolerated, with lower discontinuation rates due to side effects than efavirenz,[7] the common component of WHO-preferred first-line regimens. Furthermore, dolutegravir might be included as a component of improved second-line ART regimens. Along with these salient features, dolutegravir also has other characteristics that may be important to address the special needs of women and children (Table 1).

But a key obstacle is the needed marriage with other ARVs in a fixed-dose tablet. Dolutegravir has not yet been approved, or even tested for that matter, in a fixed-dose combination (FDC) with 2 other ARVs such as TDF and lamivudine that have favorable characteristics for implementation in low-income countries. Its developer, ViiV Healthcare (an HIV-focused company jointly owned by GlaxoSmithKline, Pfizer, and Shionogi), has developed its own "tri" pill, Triumeq, which contains dolutegravir, abacavir, and lamivudine, 3 medications for which it controls the rights. However, abacavir has some downsides from the perspective of resource-limited settings, especially its very high manufacturing cost, with generic versions priced at $133 per year as a single agent.[4] Therefore, for dolutegravir to realize its full potential for resource-constrained settings, it needs to find other partner ARVs beyond abacavir. Another downside to dolutegravir is that if given with the TB treatment drug rifampicin, it will require 50 mg twice-daily, rather than a once-daily dose.[8]

Tenofovir Alafenamide: A Promising Partner for Dolutegravir

Tenofovir alafenamide fumarate (TAF) is a next-generation ARV that has been recommended by experts to be considered for improved combinations with dolutegravir.[9] TAF's close relative, tenofovir disoproxil fumarate (TDF), is a common component of both first- and second-line treatment. But TAF is a much more potent prodrug than TDF: At a dose less than one-tenth of TDF, TAF produces intracellular levels of the active metabolite tenofovir diphosphate that are sevenfold higher.[10] This enhanced potency offers a number of advantages, including reduced manufacturing cost, less risk of renal and bone toxicity than TDF,[11] and also possibly greater activity in second-line regimens. In addition, with the recently announced results of the PROMISE study, which found that pregnancies in which women received a TDF-containing regimen were associated with significantly greater risks

of severe adverse birth outcomes than pregnancies in which women received a zidovudine-containing regimen,[12] the need to reduce toxicity of current TDF-containing regimens in resource-limited settings takes on greater importance, given the enormous numbers of pregnant women who receive ART in these countries.

Following the understandable proprietary route, Gilead, the developer of TAF, has been developing it in the context of a second-generation ''quad'' pill, combining TAF with 3 of its own compounds: the integrase inhibitor elvitegravir, emtricitabine, and a pharmacokinetic ''booster,'' cobicistat, which has no anti-HIV activity but is needed to increase elvitegravir levels. Although this ''quad'' is expected to be highly effective and well tolerated for first-line treatment, it has a few prominent disadvantages. First, compared with dolutegravir, elvitegravir has a less robust resistance barrier.[13] Second, the pharmacokinetic booster cobicistat not only creates greater potential for drug-drug interactions but also substantially increases manufacturing costs.

Obstacles to Combining Dolutegravir and TAF

Combining dolutegravir with TAF (and a third agent) could be one way forward to a better first-line combination ARV.

Combining dolutegravir and TAF, along with a third agent (either lamivudine or emtricitabine), in a single FDC could be one way forward to a better first-line combination for developing countries. Unfortunately, these 2 drugs are owned by 2 competing pharmaceutical companies.

Still, a mechanism exists to help with such situations. The Medicines Patent Pool (MPP) was created to enable originator (sometimes called innovator) companies to license out existing or new ARV agents to generic manufacturers.[14] The intended advantage of the MPP was not only that new individual ARV agents could be manufactured at low cost more rapidly by generic producers, but also that having licenses from multiple companies in the pool might enable the creation of better, low-cost ARV combinations specifically tailored to the needs of developing countries.

The good news is that in 2014 the MPP finalized individual agreements for TAF and dolutegravir that in principle provide for the development of a combination product for developing countries.[15,16] But celebrating such a marriage would be premature at this point, as a closer examination reveals some remaining steps that will be needed for these 2 ARVs to come together in a single pill (Table 3).

First, the details of such an arrangement would need to be ironed out, with good collaboration on all sides, including a plan for how this new combination would be manufactured and registered in many countries. Developing a novel formulation containing TAF and dolutegravir would require investment of additional time and resources, and the process of registering such a combination may in some cases require that the individual agents receive regulatory approval in specific countries first, which typically requires access to the master file for each agent. Accomplishing such tasks would likely be most efficient with active collaboration between Gilead and ViiV, although generic companies could take on these roles if given access to the necessary data and if they were confident enough in a return on investment to make the necessary upfront investments in formulation, manufacturing, and registration. Indeed, some precedent for generic firms taking the lead on such tasks comes from the early stages of HIV treatment roll out, in which these companies developed and gained rapid regulatory approval for novel FDCs that were not used in affluent countries, such as Triomune (stavudine, lamivudine, and nevirapine).

REDUCING TO JUST 2 ARVS AT A TIME: A SIMPLER APPROACH

On a different front, ViiV is now collaborating with Janssen (owned by Johnson & Johnson) to develop a novel 2-drug FDC of dolutegravir (50 mg daily) and the non-nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine (25 mg daily) as a simplified maintenance therapy for patients who have already achieved undetectable viral load on a 3-drug regimen.[17] While some other 2-drug ART regimens that have previously been tested as *initial* treatment of HIV have proven inferior to 3-drug ART,[18] strong proof of concept for this 2-drug *maintenance* approach was provided by data from the Long-Acting Antiretroviral Treatment Enabling (LATTE) study. The LATTE study was a phase IIb trial that reported high efficacy of a 2-drug oral maintenance therapy with rilpivirine and another integrase inhibitor cabotegravir (formerly known as GSK744),[19] which is closely related to dolutegravir. Although the LATTE study was designed to lay the groundwork for a once-monthly long-acting injectable combination of rilpivirine and cabotegravir, the plans to develop dolutegravir and

TABLE 3. Barriers to Developing a Combination ARV With Dolutegravir and TAF[a]

Obstacle	Explanation
Need for a company to manage the development and introduction of a new product with good collaboration from the other companies	If Gilead and/or ViiV are not willing to take leadership, generic companies or other partners might take the lead.
Access to data on each individual agent	Gaining regulatory permission to test agents together may require ability to reference the master file for each agent.
Financing of new product development	The cost of developing and introducing a new product would be substantial. Neither innovator nor generic manufacturers may have motivation to invest unless they have proprietary rights.
Formulation development	Combining the 2 agents into a single pill would require reformulation and expertise in this area.
Clinical testing of new combinations	Beyond showing bioequivalence of a combination to each agent given separately, further tests may be needed.
Manufacturing scale-up	A new, quality-assured process would need to be developed to manufacture the new product at large scale.
Registration of the products in many countries	A market authorization holder of the new product(s) would be needed, responsible for regulatory filing, marketing, and pharmacovigilance of the new product.
Introduction of the product in country programs	Country guidelines, policies, and plans would need to be adapted, and providers would need to be trained in how to use the new product.

Abbreviations: ARV, antiretroviral; MPP, Medicines Patent Pool; TAF, tenofovir alafenamide fumarate.
[a] Plus a third agent—either emtricitabine or lamivudine.

rilpivirine together in a combination tablet make it much more likely that a 2-drug oral maintenance combination might be available relatively soon, since both of these ARVs are already approved as individual agents.

Why might such a ''bi'' be beneficial as maintenance therapy compared with the current standard of triple-drug therapy? First, both dolutegravir and rilpivirine have excellent tolerability, without the bone or renal toxicities of TDF or the neuropsychiatric side effects of efavirenz. Second, the cost to manufacture this low-dose, 2-drug combination would be extremely low, probably less than $40 per year,[6]* or less than one-third the cost of current first-line regimens, a key point that seems to have gone largely unnoticed so far. Another potential advantage of using only these 2 agents is that it spares nucleosides/tides in first-line regimens, which could possibly create more options for second- and third-line treatment. However, on the downside, rilpivirine cannot be administered with the TB medication rifampicin and also must be taken with food. Given dolutegravir's very strong resistance barrier and potency, there may be other possible partners for dolutegravir as part of 2-drug maintenance first-line combinations that are worthy of exploration, including, for example:

- Doravirine (Merck), an NNRTI effective at a low dose of 25–100 mg daily that is now entering phase III development[20] (Table 1)
- TAF (if obstacles to collaboration could be overcome)
- Even possibly lamivudine, an approved nucleoside that is already included with dolutegravir as part of the 3-drug regimen Triumeq

*This cost estimate is derived from a consultation including manufacturing experts, which estimated a cost per year of $25 and $15 for hypothetical injectable formulations of rilpivirine and dolutegravir, respectively. The overall cost of an oral formulation is assumed to be in a similar range or less, although admittedly the dose of active pharmaceutical ingredient required for an injectable formulation may be lower than for an oral formulation.

IMPROVED SECOND-LINE COMBINATIONS WITH DOLUTEGRAVIR

Dolutegravir also holds promise for better second-line ARV combinations, in addition to improving first-line treatment.

In addition to strong potential for improving first-line treatment, dolutegravir also creates many new possibilities for better second-line treatment regimens. The potential advantages of dolutegravir as a component of either first- and/or second-line regimens raise the question of whether it should be prioritized for patients who are treatment-naive, treatment-experienced, or both. It would be a mistake at this juncture to assume in the absence of clear data that dolutegravir should be reserved for only one or the other. Rather, studies should be designed to answer specific questions regarding how best to maximize the value of dolutegravir via optimal sequencing of the various possible first- and second-line regimens.

Just as "bi" combinations of dolutegravir with an NNRTI would seem to hold promise for maintenance first-line therapy, 2-drug combinations of dolutegravir with boosted protease inhibitors could be envisioned for second-line maintenance therapy. In light of the very high resistance barriers of both of these classes of agents, such combinations would be expected to be extremely durable, making the likelihood of eventually requiring a third-line regimen very low. However, as the cost would still be quite substantial due to the protease inhibitor component, it should also be a priority to explore other non-protease inhibitor second-line regimens that might be possible by combining dolutegravir with other new agents as these become available. For example, doravirine has good in vitro activity against viruses that have developed resistance to other NNRTIs used in first-line treatment, such as efavirenz or rilpivirine.[21] Therefore, doravirine might merit exploration as a component of a 3-agent second-line regimen with dolutegravir and other existing ARVs that may have activity in this context, such as TAF or zidovudine.

LONG-ACTING INJECTABLE ARVS

ART in an injectable form could improve adherence and reduce the risk of drug resistance.

Another exciting frontier for future generations of ARVs is long-acting injectable agents, including the 2 aforementioned nanosuspension formulations of cabotegravir and rilpivirine, which are being developed as a maintenance therapy to be given every 1, or possibly 2, months. The promise of injectable ART is that it could ensure adherence, which might dramatically reduce the risk of resistance among patients who are retained in follow-up, thereby also possibly reducing the need for lab monitoring for virologic failure.

On the other hand, the long-acting nature of these formulations could be a double-edged sword; patients who are lost to follow-up (which happens at high rates over time in most ART programs) would experience a long tail of suboptimal drug levels lasting for months, rather than days with typical oral formulations, which might increase, rather than decrease, the overall risk of resistance. Cost of goods could also be a relative downside, because although the manufacturing costs of these injectable formulations may be reasonable at scale, they still might be expected to be somewhat more expensive to manufacture than oral formulations of the same medications. The high injection volumes required for the current agents is another potential drawback, which may decrease tolerability and willingness of some patients to opt for an injection.

Nevertheless, over the longer-term, injectable ART regimens are undoubtedly an area with great potential to simplify and improve ART. Further investments in discovery and earlier stage research are warranted to enable more rational design of optimal agents and delivery systems that would offer advances compared with the current agents in clinical development. In the medium-term, the largest impact of injectable ARVs in resource-limited settings may be for preexposure prophylaxis (PrEP). The cabotegravir nanosuspension injection has been shown to be completely protective against acquisition of simian/human immunodeficiency virus (SHIV) in low-dose viral challenge monkey models,[22,23] is cold-chain independent, and has pharmacology in humans compatible with dosing once every 3 months.[24] With HIV incidence rates remaining shockingly high in some populations, including young women under age 25 in several countries in eastern and southern Africa, who also have relatively high use of injectable contraceptives (typically also given every 3 months), such an agent could potentially have a very large public health impact if proven safe and effective.

JOINT ACTION NEEDED TOWARD BETTER ARV REGIMENS

The HIV community can take great pride in its remarkable history of collaboration for the common goal to combat AIDS. Actors such as

activists, researchers, United Nations agencies, the Global Fund to Fight AIDS, Tuberculosis and Malaria, government funding and regulatory agencies, foundations, governments of highly-affected countries, pharmaceutical companies, UNITAID, the Clinton Health Access Initiative, and the MPP have successfully taken action together to enable access to better ARV regimens and to build consensus on what new ARVs should be highest priority.

Now is the time to push the envelope even further. It is also time for other voices from the broader global health community to enlist their support, recognizing that development of better ARV regimens can have profound implications not only for HIV objectives but also for the feasibility of other health programs to ultimately reach their goals. As the above examples hopefully illustrate, the promise of the next generation of ARVs is bright. However, more focused collaboration and concrete steps are needed for this technical potential to be fully realized in the rapid timeframe that is required. And the free market penchant toward proprietary products must be balanced by the compelling need to come together to make this next generation of better ARVs available soon where they are needed most.

Strong leadership will be essential to take on this challenge and to nurture a more substantive, goal-driven level of collaboration between the public, private, and academic sectors. Active participation of originator pharmaceutical companies will be critically important, as these companies have the strongest capacity for developing new products. Pharmaceutical companies have taken a big step forward by licensing compounds to the MPP, but now is the time for these companies to step up to the plate and exercise further leadership in precisely those areas that are in their ''wheelhouse''—research and product introduction—demonstrating on a grand scale the importance of their innovative capacity for global heath. At the same time, the public sector can complement such efforts, providing every reasonable incentive for private-sector companies to collaborate and supporting activities where gaps remain. Given that substantial barriers exist for the private sector in cases where potential for a strong profit may not be evident (Table 3, for example), additional public investment would likely be needed to help expedite the development of ARV regimens optimized for developing countries.

Building on prior efforts such as the Conference on Antiretroviral Dose Optimization II,[9] public and private partners should come together to agree on a *short* list of ''best bets'' for better ARV regimens for developing countries, including combinations involving dolutegravir, TAF, doravirine, and possibly other new ARVs. A concrete development pathway should then be formulated with clear go/no-go criteria and timelines for expedited testing of these ''best bets,'' including realistic plans and mechanisms to address any obstacles to combining specific promising agents. Research is needed not only to enable regulatory approval of better products but also to inform policy on how to use such new ARV combinations optimally, including especially how to sequence various possible regimens as first- and second-line treatments, and giving adequate attention to the needs of special populations such as pregnant women and children. Gathering more data on long-term safety of the new agents among populations in developing countries is also important. In addition to these investments in research, well-coordinated support is needed to address bottlenecks across the value chain to introduction of new ARV products, including registration, financing, marketing, manufacturing, and global and country-level policy and planning issues. As dolutegravir is already approved and seems to have the most ''game-changing'' potential of any of the next-generation ARVs, a high priority should be put in the near-term on researching how to optimally use this agent and on expediting its registration and introduction in countries.

Development of better ARV combinations can help meet HIV as well as other health program objectives.

Effectively accomplishing the complex and interconnected set of research, development, and introduction efforts envisioned above would require a *strong coordination function*, through an organization or team focused on bringing the willing partners together. Estimating the cost of the activities required, accounting for what resources are already available, and identifying how funding could be provided and by whom to fill remaining gaps would be essential to better inform the diverse set of partners who may be able to contribute to these efforts. Although the cost of needed activities would undoubtedly be substantial, the potential return on investment would be very high. Furthermore, the absolute amount of additional funds needed would be relatively small compared with what is currently being spent on HIV treatment, with the basic

Public investment would likely be needed to help expedite the development of combination ARVs optimized for developing countries.

costs of developing the individual agents already being covered by the originator companies.

CONCLUSION

We as a global health community have an opportunity to take concrete steps to accelerate development and introduction of better drug combinations critical to ART access and scale-up. If we focus and act collaboratively, we can confidently expect that better ARV regimens will arrive sooner, rather than later. The benefits would be enormous, not only for the tens of millions of people who will need ART in the coming decades but also for countless others at risk from non-HIV-related conditions, as increasing efficiencies in HIV service delivery create opportunities for greater scale-up of the wide range of public health interventions needed by all.

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GHSP GLOBAL HEALTH: SCIENCE AND PRACTICE
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EDITORIAL

Stunning Popularity of LARCs With Good Access and Quality: A Major Opportunity to Meet Family Planning Needs

Given true choice, a very high proportion of women, perhaps most, would select one of the long-acting reversible contraceptives (LARCs)—implants or IUDs—for contraception. If implemented on a wide scale, it would not only drastically alter the current method mix but also serve client needs much better and prevent unintended pregnancy more successfully.

See related articles by Curry, Part I; Curry, Part II; and Ross.

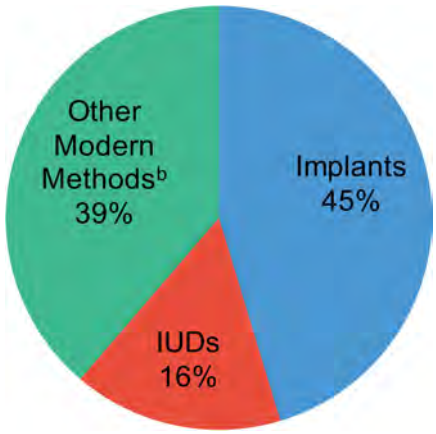
There is no such thing as a precisely optimal contraceptive method mix. Individual needs and preferences vary widely, as do cultures and stage of reproductive life. But what might the method mix look like if women and couples were really provided with good choice from among a full range of methods? The Contraceptive CHOICE project in the United States found that a majority of 2,500 young women chose to use one of the long-acting reversible contraceptive (LARC) methods of either implants or intrauterine devices (IUDs).[1]

Now also witness the striking findings from a very different setting—CARE's very large family planning intervention in 5 crisis-affected countries, reported in this issue of GHSP.[2,3] In this well-executed substantial program, in which more than 52,000 women who were given a wide choice of methods started using a modern method, overall a *remarkably high 61%* of them selected LARCs (Figure). To appreciate fully this high proportion, we can compare it to the extensive global data on method mix compiled by Ross et al., also in this issue of GHSP.[4] Overwhelmingly in low- and middle-income countries, especially in sub-Saharan Africa, short-acting methods by far predominate.

Why this difference? It seems inescapable that short-acting methods predominate because they are by far the most available in most settings. Providing pills, condoms, and injectables is relatively easy, but it is not so easy to provide LARCs and permanent methods. Still, IUDs are widely used in countries such as Egypt and Viet Nam, and sterilization is highly used in India and Latin America. And we have seen that, with robust service delivery models such as mobile outreach and social franchising, use of implants is highly acceptable in Africa.[5] So programs can successfully provide such methods.

Granted, it may well be true that women in crisis-affected situations are more interested in preventing pregnancy for a longer time. However, provision of LARCs in the CARE program was actually constrained somewhat. In Pakistan, implants provision was impaired by difficulty in securing supply and gaining government approval for community health workers

FIGURE. Method Mix Among New Modern Method Users at CARE-Supported Facilities in 5 Crisis-Affected Countries,[a] July 2011–December 2013



[a] Chad, Democratic Republic of the Congo, Djibouti, Mali, and Pakistan.

[b] Other modern methods included injectables, oral contraceptive pills, tubal ligation, and vasectomy.

(Lady Health Visitors) to insert implants. In Djibouti, training to provide implants and IUDs was delayed. And availability of sterilization was limited overall. Moreover, bear in mind the CARE data are on method selection *for new clients*. Over time, the proportion and prevalence of LARC use among that same set of women will increase, because continuation of LARCs is much better than that of short-acting methods. Notably, the proportion of new clients selecting IUDs increased progressively over time in crisis settings. And good availability of permanent methods would likely shift the method mix even more.

This all presents a major opportunity. Providing a more balanced method mix, by improving access to long-acting methods, allows family planning programs to meet clients' individual needs much better. And long-acting methods generally enable more successful contraception than short-acting methods, with much lower failure rates and far better continuation rates. Thus, a more optimal method mix will prevent unintended pregnancy better and increase the health benefits of healthy timing and spacing of pregnancy.

The program mandate is clear—priority for well-executed service delivery models, such as mobile outreach, social franchising, and other approaches, for robust, quality provision of LARCs and permanent methods, in the context of choice among a broad range of methods. –*Global Health: Science and Practice*

When provided with a wide choice of methods, 61% of women in crisis settings selected LARCs.

Provision of implants through mobile outreach and social franchising models has been highly acceptable in Africa.

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ORIGINAL ARTICLE

Delivering High-Quality Family Planning Services in Crisis-Affected Settings I: Program Implementation

Dora Ward Curry,[a] Jesse Rattan,[a] Jean Jose Nzau,[a] Kamlesh Giri[a]

Extending access to a wide variety of contraceptive methods, including long-acting reversible methods, is feasible in crisis-affected countries by focusing on best practices such as competency-based training, supply chain support, systematic supervision, and community mobilization. Prudent use of data helps drive program improvements.

ABSTRACT

In 2012, about 43 million women of reproductive age experienced the effects of conflict. Provision of basic sexual and reproductive health services, including family planning, is a recognized right and need of refugees and internally displaced people, but funding and services for family planning have been inadequate. This article describes lessons learned during the first 2.5 years of implementing the ongoing Supporting Access to Family Planning and Post-Abortion Care in Emergencies (SAFPAC) initiative, led by CARE, which supports government health systems to deliver family planning services in 5 crisis-affected settings (Chad, Democratic Republic of the Congo, Djibouti, Mali, and Pakistan). SAFPAC's strategy focuses on 4 broad interventions drawn from public health best practices in more stable settings: competency-based training for providers, improved supply chain management, regular supervision, and community mobilization to influence attitudes and norms related to family planning. Between July 2011 and December 2013, the initiative reached 52,616 new users of modern contraceptive methods across the 5 countries (catchment population of 698,053 women of reproductive age), 61% of whom chose long-acting methods of implants or intrauterine devices. Prudent use of data to inform decision making has been an underpinning to the project's approach. A key approach to ensuring sustained ability to train and supervise new providers has been to build capacity in clinical skills training and supervision by establishing in-country training centers. In addition, monthly supervision using simple checklists has improved program and service quality, particularly with infection prevention procedures and stock management. We have generally instituted a ''pull'' system to manage commodities and other supplies, whereby health facilities place resupply orders as needed based on actual consumption patterns and stock-alert thresholds. Finally, reaching the community with mobilization efforts appropriate to the cultural context has been integral to meeting unmet family planning needs rapidly in these crisis-affected settings. Despite the constraints in crisis-affected countries, such as travel difficulties due to security issues, in our experience, we have been able to extend access to a range of contraceptive methods, including long-acting reversible contraceptives, in such settings using best practice approaches established in more stable environments.

INTRODUCTION

In 2012, an estimated 61 million people needed humanitarian assistance in response to conflict and natural disasters, and about 43 million women of reproductive age experienced the effects of conflict.[1]

The Programme of Action of the International Conference on Population and Development recognizes the specific sexual and reproductive health (SRH) rights and needs, including family planning, of refugees and internally displaced persons (IDPs).[2] The *Humanitarian Charter and Minimum Standards in Humanitarian Response*, established by the Sphere Project (a global network of humanitarian agencies), requires provision of basic SRH services, known collectively as the minimum initial service package (MISP), during the acute phase of an emergency.[3] The MISP recommends immediate delivery of basic emergency obstetric care, prevention and management of sexual violence, and prevention of transmission of HIV and sexually transmitted infections (STIs), to

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be followed by comprehensive reproductive health services, such as family planning, as soon as the situation stabilizes.

Nonetheless, the provision of family planning services in conflict-affected populations has been inadequate.[4] Preliminary results from the second global evaluation of the Inter-Agency Working Group on Reproductive Health in Crises show that official development assistance (ODA) disbursement for SRH to 18 conflict-affected countries increased by 298% between 2002 and 2011.[5] However, overall ODA funding increased as well during this time period, and 56% of the increase in SRH funding was driven by HIV funding.[5] When taking these factors into account, it becomes apparent that the percentage of funding for non-HIV SRH did not change substantially between 2002 and 2011.

When family planning services are available in such settings, they generally are limited to oral contraceptives and condoms, even though a broad choice of methods is an essential component of good family planning programming.[6,7] Moreover, recent research in the humanitarian context, while not extensive, shows it is feasible to increase access to and use of a wide range of family planning methods including highly effective long-acting reversible contraceptives (LARCs).[8,9]

The situation may be changing. The global Family Planning 2020 (FP2020) initiative aims to expand access to family planning information, services, and supplies to an additional 120 million women and girls in the world's 69 poorest countries, many of which are experiencing crises, by the year 2020.[10] The FP2020 initiative explicitly recognizes that women and girls who live in or must flee from conflict zones, or who are displaced by natural disasters, have especially acute family planning needs. In May 2013, the United Nations Population Fund (UNFPA) established a fund to work with the International Planned Parenthood Federation (IPPF) to help an estimated 22 million women in territories emerging from conflicts and natural disasters gain access to family planning services.[11]

CARE's ongoing Supporting Access to Family Planning and Post-Abortion Care in Emergencies (SAFPAC) initiative attempts to meet that need for family planning in 5 crisis-affected countries—Chad, the Democratic Republic of the Congo (DRC), Djibouti, Mali, and Pakistan—through 4 broad intervention areas: competency-based family planning training, supply chain management, facility and provider supervision, and community mobilization. The countries in which SAFPAC operates face persistent challenges, including recurrent natural disasters, chronic conflict, and significant populations of IDPs or refugees.

The purpose of this article is to provide a detailed description of the program's activities, demonstrating that it is possible to deliver high-quality family planning services, including LARCs, in crisis-affected settings using a set of best practices established in more stable settings. This article also distills lessons learned from implementation during the first 2.5 years of the program (July 2011–December 2013). A companion article, also published in *Global Health: Science and Practice*, presents findings from program monitoring data on the effects of the program on contraceptive use.[12] See also the Box in this article for key findings on modern method use by country.

PROGRAM DESCRIPTION

Family planning services in conflict settings, when available, are usually limited to provision of oral contraceptives and condoms.

The SAFPAC initiative collaborates closely with provincial, district, and health facility management staff, service delivery staff, and community partners on both overall design and day-to-day implementation of the family planning program. In Djibouti, CARE works with the Office of the United Nations High Commissioner for Refugees (UNHCR) since it is the organization directly responsible for health services for refugees.

In all countries, SAFPAC supports basic first-level health centers, referral health centers providing basic delivery services, and district, regional, and provincial hospitals, which provide services to refugees, host country communities, IDPs, and other crisis-affected residents. We work with mid- and higher-level providers including nurses, medical technicians, Lady Health Visitors (community health workers), and doctors. At the time of publication, the project was providing services at 79 facilities across 8 districts in the 5 countries. The combined catchment population at that time was 2,428,145 people, of whom 698,053 were women of reproductive age.

SAFPAC supports the entire range of contraceptive methods sanctioned by the government in each country, including oral contraceptive pills, injectable contraceptives, implants, intrauterine devices (IUDs), permanent methods (although they are offered only in a few facilities that we support), condoms, and emergency contraception (in some countries).

In our program area in Pakistan, the population is largely stable, with recurring major disruption by

BOX. Modern Method Use Among SAFPAC Facility Clients: Country Snapshots

Despite the challenging environments in the 5 countries in which SAFPAC operates, in the first 2.5 years of the project (July 2011 through December 2013), SAFPAC and its government partners reached 52,616 new contraceptive users, significantly exceeding the target of 36,002 new users over the corresponding project period (Table). Of those new users, 61% chose and received a long-acting reversible contraceptive (LARC).

Choice of method varied by country. In Chad, the Democratic Republic of the Congo, and Mali, the method mix was heavily weighted toward LARCs, particularly implants. In Pakistan, the method mix was balanced between oral contraceptive pills, injectables, and intrauterine devices (IUDs); during the initial project period, access to implants was limited because only doctors could provide the method. Since then, national policy has been changed to allow Lady Health Visitors to also provide implants. In Djibouti, providers did not receive training in IUD and implant insertion until the end of 2013, so the method mix during the initial project period comprised mainly of oral contraceptives and injectables. In all countries, permanent methods represented a negligible portion of the total method mix.

For a more detailed analysis of the effects of the SAFPAC initiative on contraceptive use, please see the companion article published in *Global Health: Science and Practice*.[12]

SAFPAC focuses on 4 areas: competency-based training, supply chain management, regular supervision, and community mobilization.

flooding and somewhat restricted ability to reach populations with services due to local insecurity. In Djibouti, we serve 2 refugee camp populations, while in Mali we serve communities that are affected by insecurity or that are home to IDPs but have no formal IDP settlements or camps. In both Chad and the DRC, we serve a shifting mixture of host communities, refugee camps, and IDPs simultaneously.

SAFPAC's strategy focuses on 4 broad intervention areas:

1. Providing competency-based training with follow-up clinical assessment and coaching
2. Improving existing supply chain management
3. Conducting facility and provider supervision on a regular basis
4. Mobilizing communities to raise awareness about family planning and to shift norms that block women's access to family planning services

The initiative also conducts activities in the same intervention areas to improve delivery and use of postabortion care (PAC). Provision of family planning is an important part of PAC.

TABLE. New Modern Method Users Among SAFPAC-Supported Facilities, July 2011–December 2013

Country	Countrywide CPR for Modern Methods[a]	No. of SAFPAC Facilities	WRA in Catchment Area	New Modern Contraceptive Users[b]	% of LARCs Among All Modern Methods
Chad	5%	21	405,984	21,191	72%
DRC	8%	21	123,218	14,869	78%
Djibouti	18%[c]	2	5,040	575	1%
Mali	8%	8	14,210	3,093	51%
Pakistan	22%	27	149,601	12,888	29%
Total	**NA**	**79**	**698,053**	**52,616**	**61%**

Abbreviations: CPR, contraceptive prevalence rate; DRC, Democratic Republic of the Congo; LARCs, long-acting reversible contraceptives; NA, not applicable; WRA, women of reproductive age.

[a] Source of countrywide CPR data: Pakistan 2012–13 Demographic and Health Survey (DHS),[13] DRC 2013–14 DHS,[14] Mali 2012–13 DHS,[15] UNFPA 2011 State of the World's Midwifery (for Djibouti),[16] and Chad 2010 Multiple Indicator Cluster Survey.[17]

[b] Modern methods consisted of implants, injectables, IUDs, oral contraceptive pills, tubal ligation, and vasectomy.

[c] The CPR for modern methods was documented to be much lower in the Djibouti camps where SAFPAC works (5.1%).[18]

However, this article focuses on the initiative's family planning activities only.

Start-Up Activities: Facility Assessments and Stocking

In each project facility, we first conducted a health facility assessment (HFA) to identify gaps in basic infrastructure. The HFA reviewed the presence and condition of basic elements, such as adequate clean water, electricity, and infection prevention items (autoclaves, hand washing stations) and reviewed the stocks of supplies, medicines, and family planning commodities. In addition, the assessment identified how many health care providers in each cadre served each facility and who was offering family planning services. Program staff conducted the initial HFA in conjunction with staff at Columbia University, our evaluation partner, using a tool they developed (see supplementary materials).

Because the initiative prioritizes using data to drive program improvement, we also assessed the existing health information system and tools in the facilities and supported adaptations where necessary. Consequently, we redesigned family planning registers in Chad and the DRC and implemented a new PAC register in all settings. In addition to creating a monthly form for compiling data and reporting up to district and program levels, we also developed wall charts showing key indicators and oriented facility and district management teams on definitions and ways of using the indicators for decision making.

During the early phases of the project, we also reequipped facilities with supplies and equipment, including an initial supply of family planning commodities. Thereafter, the project has funded and procured only those family planning commodities that are part of the government-approved method mix but that are not provided routinely. For commodities supplied by the government, program staff have worked with facility staff and district-level counterparts to strengthen both accountability mechanisms and supply chain management in order to ensure a steady supply of those items.

Competency-Based Training: Building Clinical Capacity In-Country

Training of health care providers was competency-based, using training materials developed by Jhpiego. The training included both didactic theory sessions and practicums using anatomical models and actual clients under the supervision of an experienced clinician. In a second cohort of training, providers received in-depth family planning counseling training adapted from the Population Council's "Balanced Counseling Strategy Plus (BCS+)" strategy[19] and the World Health Organization's (WHO's) "Decision-Making Tool for Family Planning Clients and Providers" (DMT).[20] In our adapted approach, the provider determines the client's reproductive goals and contraceptive preferences and then presents both advantages and disadvantages of a full range of *relevant* methods, in the context of her expressed preferences, per WHO DMT guidance, and based on local concerns and national reproductive health policies. In line with the BCS+ approach, we also supplied providers with the high-quality, user-friendly BCS+ counseling cards to use with clients. In addition, providers received the "WHO Medical Eligibility Criteria Wheel"—a quick reference tool to rule out medical contraindications for specific methods—as well as copies of *Family Planning: A Global Handbook for Providers*.[21,22]

Baseline health facility assessments helped identify gaps in basic infrastructure and in the health information system.

In the initial phase, cohorts of 15–20 providers received clinical training for approximately 3 weeks focused on the 3 main clinical skills (PAC and insertion of implants and IUDs). Two weeks were devoted to clinical practicum experiences.

Providers receiving training have had a range of backgrounds, comprising mostly doctors, nurses, and midwives, and in Pakistan, Lady Health Visitors. As of June 2014, 304 providers had received training in at least 1 clinical family planning topic. Currently, 227 providers are serving in SAFPAC-supported posts within the government system. Turnover accounts for some of the discrepancy between the number trained and the number still serving in their post. In addition, some clinicians received training only to ensure buy-in and consistency with and from higher (non-practicing) levels of the government health systems and health care provider partners.

Once trained, providers receive a formal skills assessment at 2 opportunities: within 3 months of initial training and, subsequently, at least once a year. A clinical supervisor observes the provider performing the procedure in question and scores the provider's performance using a standardized checklist for each specific skill the project supports: IUD insertion and removal, implant insertion and removal, manual vacuum aspiration (as the preferred method for PAC), and family planning counseling using our adapted DMT/BCS+ counseling approach. Based on the provider's

score, the clinical supervisor determines whether the provider is competent. If a provider receives a failing score, the clinical supervisor recommends an appropriate follow-up action, which can include onsite mentoring from a more experienced provider, visits to a facility both staffed by experienced providers and with a higher client volume for the provider to improve confidence and experience, and retraining if necessary.

The project helped establish training centers in the DRC and Chad to make it easier to train new providers and provide ongoing follow-up support.

In the first training phase, professional trainers from regional training institutes (outside the countries) conducted the training workshops. Subsequently, the project supported the establishment of 1 training center in the DRC and 2 training centers in Chad (1 in the national capital and the other in the regional capital nearest our program sites). In each of these training centers, CARE staff first coordinated with management and clinical staff at a large referral facility (with a high client load) to establish a commitment to the idea of a training center and to maintain staff capacity. This included commitments to supervise trainee clinical experience and ensure adequate supplies and materials to meet minimum quality standards. If the training facility's client volume was below the level needed to provide practicum opportunities to each trainee, program and clinic staff carried out intensive social mobilization to increase volume during the training period. Now, with both national professionals prepared as trainers and training centers established, the project can reliably offer high-quality competency-based training both for new providers and for refresher events in settings closer to trainees' home facilities. This minimizes cost and disruption to service delivery at home facilities and makes it easier to offer ongoing follow-up support to providers.

Supervision and Quality Improvement: Consistent Support to Facilities and Their Communities

Program staff have continued to engage with both facility teams and community leaders to ensure the facility staff's commitment and capacity to maintain a clean, efficient, and respectful environment. Program staff or, whenever possible, district or zonal staff from the government conduct routine supervisory visits on a monthly basis. The facility supervision team may or may not include the clinician who conducts skills assessments and follow-up support, depending on the country. These facility supervision teams assess general clinic conditions, including infection prevention procedures and supplies, check stock levels, and collect data for program reporting as well as assess data consistency across forms, registers, and reports. For general facility supervision, we use a 2-page checklist co-designed by CARE and Columbia University (see supplementary materials).

The facility supervision teams also review and analyze the data displayed on the wall charts with the facility teams and community partners, including informal and formal leaders. This tripartite group (CARE, facility staff, and community leaders) engages in animated discussion of the underlying causes of upward and downward trends and develop action plans together based on those trends.

Supply Chain: Guaranteeing Availability of a Full Range of Contraceptive Choice

The SAFPAC initiative provides support for procurement, distribution, and management of family planning commodities and other related supplies and equipment. The initiative supplies both long- and short-acting family planning commodities, antibiotics, and pain medicine, where needed, as well as infection prevention supplies such as high-level disinfectant and sterile gloves, where needed. For any supplies and commodities already included in the government's budget and work plan, the initiative provides training in supply chain management directly to the government supply chain system with follow-up review and mentoring in stock management.

SAFPAC has transferred stock to the government system at the highest level practical, for example, supplying a district-level warehouse and then working within the government distribution system. In all countries, the national-level supply chain has not been reliably connected to facilities, either due to decentralization, as in Pakistan and the DRC, or to lack of resources to ensure timely delivery, as in Chad, Djibouti, and Mali. In addition, in Chad, Mali, and Pakistan, security issues sometimes have prevented transport between the provincial-level warehouses and those at the district level, requiring the project to coordinate directly with the districts.

Acquiring contraceptive methods and ensuring their timely delivery to each facility has occupied a major portion of the team's time. Some global-level issues have contributed to supply chain management challenges. For example, high global demand for Jadelle implants that exceeded supply meant the program experienced significant stockouts for several months. Equally problematic,

however, have been "last mile" issues—problems that have prevented commodities and supplies already procured and stored at the district or regional level from being transported to primary care facilities regularly and from being tracked systematically to avoid gaps in availability of the method or treatment.

The project information system tracks key commodities and supplies for each facility and facilitates stock forecasting and logistics management to avoid stock-outs. In general, the project uses a "pull" system, in which facilities estimate monthly average needs and have stock-alert thresholds based on those averages that dictate reordering. In situations where distance, insecurity, or impassable roads during the rainy season mean a delay of one or more months for resupply, the program activates a short-term "push" system, providing several months of stock for one facility. Stock-outs remained a problem until we began reviewing this information system in detail on a monthly basis. The review and feedback to the country teams have successfully reduced stock-outs to nearly zero, which used to occur especially frequently for items that the government systems have committed to supply.

Community Mobilization: Communities as Partners, Not Passive Recipients

Our interventions at the community level include awareness-raising via radio, participatory theater and songs, and large mixed-group dialogue about barriers to women accessing family planning and actions to reduce those barriers. We also work closely with religious leaders across Christian and Muslim faiths not only to raise awareness about services, clarify myths, and share information about the benefits of family planning for women and their families but also to reinforce a woman's right to access health services.

In Chad, the community committees consist of religious and other formal leaders, such as the police, to reinforce a woman's right to time, space, and limit births, using the little known Chadian reproductive health law that ensures this right. As a result, in Chad (as well as the DRC), religious leaders across faiths are dynamic champions of healthy birth spacing and limiting, and in Chad, they even go house-to-house to counsel couples directly. As discussed earlier, religious leaders also serve on our health committees together with the facility staff, representing the community in reviewing the data and in activity planning.

Religious leaders in the refugee camps in Chad and Djibouti have proved to be among the health facility teams' strongest allies, organizing group meetings and conducting one-on-one household visits with couples to promote birth spacing through modern contraception. In the 2 Djiboutian refugee camps where we work, new family planning users have increased markedly after our community leader training, despite a very conservative religious context and fertility norms that support very large families.

Using a "pull" supply system, facilities estimate monthly average needs and reorder supplies when they reach stock-alert thresholds based on those averages.

LESSONS LEARNED

Religious leaders have been among the project's strongest community allies in some countries.

Many women in crisis-affected settings have an acute, unmet need for family planning and very little access to services. Despite the many constraints in these settings, the approach used by the SAFPAC initiative has succeeded in making services available to severely underserved communities in challenging settings using relatively straightforward information and service strengthening interventions. In particular, routinely collecting reliable and relevant data and using that data to improve quality at the facility and program levels was an underpinning to the "4 pillars" of the project's approach.

Prudent use of data to inform decision making has laid a strong foundation for the project.

The initiative has faced some challenges that are unique to fragile, crisis-affected countries, such as travel constraints due to security issues making supervisory visits difficult. However, overall the challenges have been similar to those faced by any health or development program, such as ensuring systematic supervision, reaching the community with mobilization efforts appropriate to the cultural context, managing commodities and other supplies to avoid stock-outs, and ensuring accountability. Several lessons learned have emerged in these areas.

Competency-Based Training

The dearth of in-country clinical experts for training, ongoing coaching, and follow-up supervision has made continuing to support trainees difficult. Few, if any, providers have possessed adequate expertise with both training and implant and IUD insertion and removal to train new providers in the 5 countries. Initially, trainers were brought in from foreign countries or providers were sent out to foreign countries. Realizing that the more lasting solution to this problem is to develop in-country capacity to train clinicians, SAFPAC has started developing a cadre of trainers in Chad, the DRC, and Pakistan that is equipped to train new

health workers to provide a full range of contraceptive services.

Low patient volumes in some of the smaller facilities have made it challenging for clinical mentors to provide ongoing coaching and skills assessment. Providers remain reluctant to perform procedures with which they are uncomfortable, especially those requiring pelvic examinations, such as IUD insertion. The program has addressed this barrier by using anatomical models for skills demonstration during routine supervisory visits and in skills refresher sessions.

Tracking the skills assessments performed has been one of the most significant challenges with project monitoring, largely due to the difficulty of coordinating availability of clinical supervisors, trainees, and clients for each service. The lack of centralized personnel records has made maintaining records of each provider's training, assessment, follow-up history, and current status extremely difficult. We have met this challenge by developing a training and performance tracker that uses a Microsoft Excel datasheet to record the date of last assessment, its outcome, and follow-up steps planned for each provider and for each skill.

Supervision and Quality Improvement

We believe strengthening and fine-tuning supervision has been a key strategy of the program. The supervision staff fills 2 major functions: recurring, systematic feedback and problem solving. Key elements to our supervision approach include monthly checklists, regular site visits, and meetings with community leaders, clinic staff, and CARE facilitators to review progress.

Conducting monthly supervisory visits to every facility has been challenging. In the early stages of the program, road and security conditions and inadequate logistical arrangements sometimes contributed to missed supervision visits. In addition, guidance from program leadership had not adequately emphasized that a supervisory visit to every facility every month was a critical input, nor had it required data from supervisory checklists to be reported at the country or global level. Hiring additional supervisory staff and revising the supervisory protocol have been key approaches to achieving that standard.

Hiring additional staff to make supervision workloads manageable has helped ensure regular site visits.

Each SAFPAC supervisor now covers 5–9 facilities in the African countries (with the exception of Djibouti, where we cover only 2 facilities). In Pakistan, because of the much shorter distances and better infrastructure, 1 supervisor is responsible for general facility supervision for approximately 10–12 facilities, with 2 clinical supervisors covering assessments and coaching for approximately 13 facilities. Manageable workloads have made it feasible for supervisors to conduct thorough site visits on a regular basis.

The improvement in infection prevention procedures after the introduction of a simplified monthly supervisory checklist serves as an excellent example of the power of ongoing systematic feedback. Infection prevention had been a persistent problem. Initially, supervisors were supposed to use a lengthy checklist to assess adherence to infection prevention procedures and other issues, but they were not required to report the data to a higher level. The new 2-page checklist has replaced the lengthier one, and supervisors use the new one consistently. In addition, the new checklist enables supervisors to calculate a simple score that focuses their attention on infection prevention. Within 3 months after introduction of this new checklist, average scores increased significantly and infection prevention practices improved markedly.

In addition to consistent feedback from supervisors, flexibility in the supervisory approach also has been a key element contributing to our success. For example, in the DRC, program staff and zonal teams have resolved persistent stock management issues using a ''pull system'' that uses average stock levels and alert thresholds to stabilize stock levels, while in Chad, teams have chosen to push larger amounts of stock to the facilities and purchase some consumables locally to minimize stock-outs due to impassable roads, insecurity, or sudden increases in clients from escalating refugee populations. Stock-outs are now a rare occurrence in both countries.

Supply Chain

In terms of procurement, one of the biggest challenges for the program as a whole has been the difficulty of obtaining Jadelle implants, which have become so popular with family planning programs that demand often outstrips supply. (See companion article in *Global Health: Science and Practice* for more information about the popularity of implants in these settings.[12]) This has resulted in some pipeline breaks in Chad and the DRC. We have been responding to this is by creating buffer stocks in each country program, loaning stocks between countries, ensuring all providers are trained in inserting and removing both Jadelle and Implanon implants so that they can substitute for each other, and building

relationships with UNFPA and other large stock holders.

At the other end of the spectrum are the ''last mile'' issues—getting the contraceptives and related medical supplies to health facilities where they are needed and when they are needed. Health facilities in some countries continue to experience periodic stock-outs of contraceptives and medical supplies (e.g., pain medicine, gloves, high-level disinfectant) even when these items are available either in the warehouse or pharmacy that resupplies them or in the market place. These stock-outs are typically site-specific and of relatively short duration; however, our aim is to prevent all stock-outs in order to ensure high-quality service. In order to address this problem, the initiative has instituted a ''pull'' system as the general norm, as mentioned previously, whereby heath facilities place resupply orders as needed based on actual consumption patterns.

The monthly reports received by district health officials and CARE staff include some stock-related data for key commodities and related medical supplies. Having access to these data and providing feedback consistently have also been key approaches to resolving persistent problems with stock management. Regular reviews of such data every 6 weeks supported the country teams in: (1) solving problems with repeated stock-outs, (2) forecasting need to avoid stock-outs, and (3) determining how to advocate with local systems to ensure they provide basic supplies and medications (per agreements established at the beginning of the project) and also to ensure clinic conditions meet a minimum standard of quality at all times.

Community Mobilization

A deliberate evidence-based community mobilization strategy is integral to meeting unmet family planning needs rapidly in crisis-affected settings. Simply raising basic awareness of new and under-used methods among community members was a necessary first step in the settings where we work. In addition, in most settings, the key to successful community mobilization has been engaging and inspiring the whole community to consider the benefits and opportunities inherent not only in planning and spacing births but also in clearing the path for women to use services.

Specifically, each country program has incorporated a context-specific strategy to develop champions among influential men in the community, most often religious leaders and municipal authorities. In Pakistan, we have focused on the message that well-spaced pregnancies lead to healthy children, and we have mobilized municipal and health system leadership to agree that ensuring women's access to services was the expression of this theme. In Chad and the DRC, religious leaders across faiths have been dynamic champions of healthy birth spacing and limiting, going house-to-house to counsel couples directly. In Chad, there was initial resistance among men when they realized women were increasingly using family planning, resulting in several husbands filing complaints at the local police station. CARE has supported religious leaders and police in learning about and ensuring the application of a little-known national reproductive health law affirming women's right to use family planning, with or without their partner's permission. In the 2 Djiboutian refugee camps where we work, new family planning users have increased markedly after our community leader training, despite a very conservative religious context and fertility norms that support very large families.

Country-to-Country Variations

Some clear differences between countries have emerged, the most variable of which have been: (1) context set by the national government health system, (2) community norms related to gender, fertility, contraception, and community members' comfort level in talking publicly about these issues, and (3) the regularity of payment to government health workers.

National Government Health Systems

The strength of the national government health system has had an unexpected impact on our programming. The government health system in Chad was possibly the most over-taxed among SAFPAC countries before our program began. There, our efforts have been met with interest and enthusiasm. The program staff has collaborated directly with the ministry of health at district and national levels to support enhanced guidelines and has even reformulated policy. For example, the Chadian government has sanctioned the new family planning registers we designed at the national level. The government has also approved lower-level cadres of health workers (nurses and midwives) to provide implants and IUDs as well as guidance that allowed this service to be provided at the health center level. This guidance was eventually adopted as national family planning policy. In a very different context,

Ensuring women's right to access health services has been a key component of community mobilization efforts.

3 key strategies for delivering family planning services in fragile settings: build capacity in clinical skills training and supervision; incorporate quality improvement approaches gradually; and tailor community engagement efforts to the local context.

in Pakistan's large, decentralized health system, obtaining approval for piloting new registers and authorization for Lady Health Visitors to insert implants proved to be a lengthy process, which required involvement from multiple levels of the health system.

Community Norms

In our experience, successful approaches to community mobilization require more adaptation and flexibility than do those aimed at improving clinical quality. Our mobilization has relied most heavily on committees of interdenominational religious leaders in Chad, women's associations and health committees focused on social accountability in the DRC, and formal leaders, religious leaders, and various camp committees (such as youth and sport) in refugee-only programming in Djibouti. In Pakistan, we have worked with village health committees and Lady Health Visitors, who are more formally integrated into the health system than in other countries.

Compensation of Health Workers

The DRC provides a dramatic illustration of the significant and context-specific obstacle posed by inadequate, irregular, and missing compensation of health workers. In the other countries, frontline health workers are compensated more reliably. In the DRC, some health worker cadres receive only modest wages drawn from the nationally sanctioned system of cost-recovery, in which most services including family planning are at a cost to clients. However, the SAFPAC approach requires that family planning services be provided free of charge (in all countries). As a result, providers forego income by providing family planning services when they could be charging for curative care. The fact that we have still seen sustained, high levels of new users each month for more than 2 years demonstrates the motivational power of regular supervision and training opportunities.

RECOMMENDATIONS AND NEXT STEPS

SAFPAC has rapidly reached more than 52,000 new family planning users with a wide range of modern methods in diverse crisis-affected settings (see companion article in *Global Health: Science and Practice*[12]). Based on our experience, we recommend 3 strategies for establishing more comprehensive family planning services in such settings:

1. Prioritize building clinical skills training and supervision capacity to ensure continued ability to train and supervise new providers after the end of a donor-funded project
2. Incorporate selected quality improvement strategies, as feasible, adding additional elements with time
3. Conduct a local participatory situation analysis as early as possible to further refine global best practices in community engagement and social accountability strategies

While our first recommendation may seem simplistic, it is both more complex and has broader importance than it may seem. Skilled and confident frontline health workers and a minimum level of cleanliness and number of providers are prerequisites to reaching the population with health services and to improving the community's perception of and trust in the health facility. This is also important for the morale of providers. Not only does commitment to building national capacity for clinical supervision and program quality assurance improve results in the near term but it also makes a meaningful contribution to the country's long-term ability to reach refugees, IDPs, and other crisis-affected communities with high-quality family planning services.

The dramatic and rapid improvement of both our infection prevention procedures and stock management after the implementation of supervision checklists and monthly feedback provide clear evidence that many of the quality improvement techniques used in stable and even more developed settings can be effective in these challenging contexts. We are currently piloting client exit interviews as an additional quality assurance strategy and a mechanism to assess client satisfaction with services. In addition, the project plans on strengthening the current tracking system for removals of contraceptive devices and reasons for removal to assess women's satisfaction with their method choice, frequency of side effects, and perceptions of provider competency. This is especially important as implants provided early in the program will eventually lose effectiveness and will need to be removed.

Finally, the importance of community engagement cannot be underestimated and must be carefully tailored to the context. This recommendation does apply especially to health programming related to sex, sexuality, and fertility, such as

family planning, as well as to places where contraception is either unknown or feared and where people learn and share primarily through their local social networks. While all CARE's community engagement (and health systems strengthening) interventions take a rights-based approach as the starting point, each community has a preexisting context of norms, beliefs, and community institutions. Real community engagement at the most local level on issues of rights, fertility, and contraception must occur among men and women, across religious and ethnic lines, and between facility staff and community members for family planning to reach those who want it.

CONCLUSION

The SAFPAC experience so far has been one of iterative learning. Fragile states will not change overnight, but there is space to influence and make change, albeit slowly and incrementally, at the local and even national level. The unfortunate reality is that most crisis situations will not resolve in a matter of a few months but will last many months and often years. Considering these settings and time frames, programs should ensure that minimum services are available (including long-acting family planning methods) and, at the same time, incrementally tackle underlying causes of poor health services. Further, we show that strategies drawn from more stable development settings—competency-based training, supportive supervision, simple quality improvement tools, and community mobilization that works with local power structures while simultaneously exploring restrictive norms—can be modified to work in even these unstable settings. Implementation of quality improvement and clinical supervision through the government health system builds national capacity and can provide data and mobilize support for creating a more supportive policy environment. These approaches can not only lead to significantly expanded access to and use of family planning in a short timeframe but also support longer-term improvements in the fragile health systems themselves.

Competing Interests: None declared.

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ORIGINAL ARTICLE

Delivering High-Quality Family Planning Services in Crisis-Affected Settings II: Results

Dora Ward Curry,[a] Jesse Rattan,[a] Shuyuan Huang,[a] Elizabeth Noznesky[a]

A family planning program in 5 crisis-affected settings reached more than 52,000 new contraceptive users in just 2.5 years. Long-acting reversible contraceptives (LARCs) made up 61% of the method mix, with implants predominating in most countries. IUD use also increased over time as the program intensified its efforts to improve provider skills and user awareness. These findings demonstrate the strong popularity of LARCs and the feasibility of providing them in fragile settings even though they require more training and infrastructure support than short-acting methods.

ABSTRACT

An estimated 43 million women of reproductive age experienced the effects of conflict in 2012. Already vulnerable from the insecurity of the emergency, women must also face the continuing risk of unwanted pregnancy but often are unable to obtain family planning services. The ongoing Supporting Access to Family Planning and Post-Abortion Care (SAFPAC) initiative, led by CARE, has provided contraceptives, including long-acting reversible contraceptives (LARCs), to refugees, internally displaced persons, and conflict-affected resident populations in Chad, the Democratic Republic of the Congo (DRC), Djibouti, Mali, and Pakistan. The project works through the Ministry of Health in 4 key areas: (1) competency-based training, (2) supply chain management, (3) systematic supervision, and (4) community mobilization to raise awareness and shift norms related to family planning. This article presents data on program results from July 2011 to December 2013 from the 5 countries. Project staff summarized monthly data from client registers using hard-copy forms and recorded the data electronically in Microsoft Excel for compilation and analysis. The initiative reached 52,616 new users of modern contraceptive methods across the 5 countries, ranging from 575 in Djibouti to 21,191 in Chad. LARCs have predominated overall, representing 61% of new modern method users. The percentage of new users choosing LARCs varied by country: 78% in the DRC, 72% in Chad, and 51% in Mali, but only 29% in Pakistan. In Djibouti, those methods were not offered in the country through SAFPAC during the period discussed here. In Chad, the DRC, and Mali, implants have been the most popular LARC method, while in Pakistan the IUD has been more popular. Use of IUDs, however, has comprised a larger share of the method mix over time in all 4 of these countries. These results to date suggest that it is feasible to work with the public sector in fragile, crisis-affected states to deliver a wide range of quality family planning services, to do so rapidly, and to see a dramatic increase in the percentage of users choosing long-acting reversible methods.

BACKGROUND

In 2012, an estimated 61 million people needed humanitarian assistance for food and non-food items, water, sanitation, and health services in response to conflict and natural disasters.[1] Approximately 43 million women of reproductive age experienced the effects of conflict, and more than 15 million women of reproductive age were in acute need of humanitarian aid.[1]

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Women in crisis situations are already vulnerable from the insecurity and disruption of the emergency, and they also must face the continuing risk of unwanted pregnancy. Furthermore, women are at increased risk of sexual violence and its consequences (physical and emotional trauma, unwanted pregnancy, unsafe abortion) due to the insecurity and increased violence that often accompany humanitarian emergencies. Many women would choose not to be pregnant in these situations, but they are often unable to obtain family planning services.[2]

Women in crisis-affected settings are also at greater risk of pregnancy-related illness and death due to

Many women in crisis situations would choose not to be pregnant, but they are often unable to obtain family planning services.

interruptions or restricted access to pregnancy and delivery-related services. Worldwide, 9 of 10 countries with the highest maternal mortality ratios are affected by conflict.[3] These high maternal mortality ratios are related not only to poor emergency obstetric care but also to high unmet need for family planning.

CARE's ongoing Supporting Access to Family Planning and Post-Abortion Care in Emergencies (SAFPAC) initiative operates in Chad, the Democratic Republic of the Congo (DRC), Djibouti, Mali, and Pakistan—5 crisis-affected countries that face persistent challenges including recurrent natural disasters, chronic conflict, and significant populations of internally displaced persons (IDPs) or refugees. SAFPAC supports government health systems at the provincial level and below to apply family planning best practices established in more stable development settings to crisis-affected settings for refugees, host country communities, IDPs, and other crisis-affected residents.

The countries and geographic areas in which SAFPAC operates face a diverse range of challenges. Eastern DRC suffers protracted conflict, insecurity, and chronic displacement of people. Southern Chad is managing an influx of refugees from the Central African Republic. Major, recurrent flooding (and displacement) affect South Punjab, Pakistan. North-central Mali hosts IDPs from the far North. Djibouti hosts Somalian refugees in stable, long-running camps.

Although very different from one another, these countries share some important similarities. First, protracted conflict and/or natural disasters have caused large population displacement and have eroded the ability of the state to provide basic services, which in most cases are already weak. Second, unmet need for modern contraception is high and increases in contraceptive prevalence have been slow, resulting in their selection as Family Planning 2020 (FP2020) focus countries.[4] Contraceptive prevalence nationally ranges from less than 10% in Chad, the DRC, and Mali to 18% in Djibouti and 22% in Pakistan (Table 1). Third, their governments have signaled at least some commitment to increasing access to family planning services through various national policies and programs.

SAFPAC's implementation strategy focuses on 4 intervention areas, which have been shown to increase access to and use of family planning services in any setting[11–15]: (1) providing competency-based training with follow-up assessment and coaching, (2) conducting facility supervision on a regular basis in partnership with local government health officials, (3) ensuring a continuous supply of contraceptives and medical supplies, and (4) mobilizing communities to raise

TABLE 1. SAFPAC Project Settings

Country	Countrywide CPR for Modern Methods[a]	No. of SAFPAC Facilities	Estimated No. of WRA in Catchment Area[b]
Chad	5%	21	405,984
DRC	8%	21	123,218
Djibouti	18%[c]	2	5,040
Mali	8%	8	14,210
Pakistan	22%	27	149,601
Total	**NA**	**79**	**698,053**

Abbreviations: CPR, contraceptive prevalence rate; DRC, Democratic Republic of the Congo; NA, not applicable; SAFPAC, Supporting Access to Family Planning and Post-Abortion Care; WRA, women of reproductive age.

[a] Source of countrywide CPR data: Pakistan 2012–13 Demographic and Health Survey (DHS),[5] DRC 2013–14 DHS,[6] Mali 2012–13 DHS,[7] UNFPA 2011 State of the World's Midwifery (for Djibouti),[8] and Chad 2010 Multiple Indicator Cluster Survey.[9]

[b] These population figures may be inaccurate estimates for 2 reasons: (1) The catchment populations of regional and districts hospitals often contain the catchment populations of health centers that SAFPAC supports, leading to double-counting. (2) There were changes in the number and type of facilities that SAFPAC supported between 2012 and 2013, when the second phase of programming began, thus leading to changes in the actual population covered.

[c] The CPR for modern methods was documented to be much lower in the Djibouti camps where SAFPAC works (5.1%).[10]

awareness about family planning and to shift norms that block women's access to services.

CARE teams collaborate closely with provincial, district, and health facility management, service delivery staff, and community partners, on both overall design and day-to-day implementation of the program. SAFPAC supports basic first-level health centers, health centers providing basic delivery, and district and some regional/provincial hospitals, and works with a range of mid- and higher-level providers, including nurses, medical technicians, Lady Health Visitors (community health workers), and doctors. The initiative supports the entire range of contraceptive methods sanctioned by the government in each country and also supports postabortion care (PAC), which includes family planning services. The number of women of reproductive age in the project catchment areas ranges from 5,040 in Djibouti to 405,984 in Chad (Table 1).

For more details about the interventions and lessons learned during implementation, see the companion article in *Global Health: Science and Practice*.[16] In this article, we show the effects of the initiative's interventions on modern method use, using project monitoring data over the first 2.5 years of the project.

METHODS

We analyzed project service delivery data from July 2011 to December 2013 from all 5 countries. The program collected these data for the purpose of continuous quality improvement, not for the purpose of conducting systematic research in a strictly defined model.

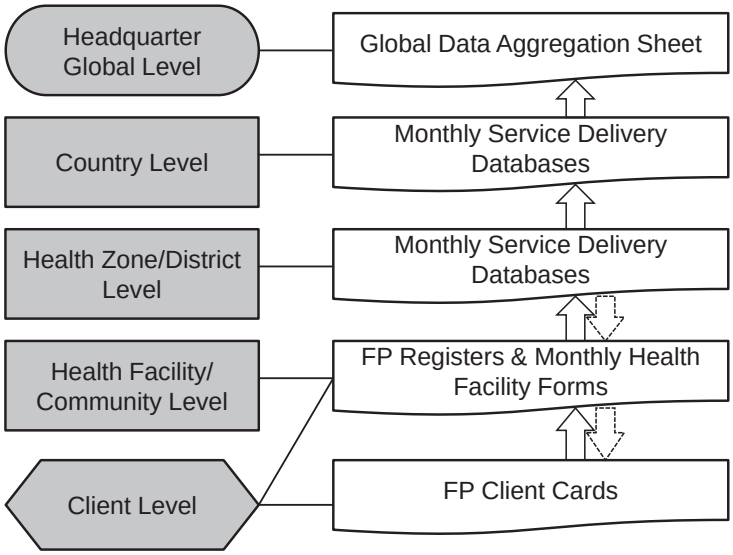
We focused data collection on the 4 contraceptive methods that are commonly offered at all health facilities—oral contraceptive pills, injectable contraceptives, implants, and intrauterine devices (IUDs). We also analyzed use of permanent methods, but they are offered in only a few facilities that we support. Health workers provide condoms and discuss their advantages and disadvantages in counseling; however, we do not track new condom users at the program, country, or global level to avoid double-counting those using them in combination with other methods and because of their relatively low effectiveness in reducing unwanted pregnancy during typical use. We also do not track use of emergency contraceptives at the program's national or global level because they are not an approved method in some countries.

The indicators reviewed in this article are the number and percentage of new users by contraceptive method, the percentage of new family planning users who adopted long-acting, reversible contraceptives (LARCs), and the number and percentage of PAC clients who adopted contraceptive methods.

Data Collection and Management

The project's patient recordkeeping and data collection system has been integrated into the government's health information system. Health facilities assign each client an individual client card, which serves as a record of the client's history and previous visits. In addition, family planning registers record details of each visit by client encounter. Each month, project staff or providers summarize the data from family planning registers from each facility and collect them in hard-copy forms designed specifically for the project. Then project staff record the data electronically in Microsoft Excel and send them to the SAFPAC country-level management team. At the country level, the management team analyzes the date to explore trends that could inform decision making, and then the team sends the data to headquarters for compilation and further analysis (Figure 1).

FIGURE 1. SAFPAC Assessment Tools and Data Flow Chart



Abbreviations: FP, family planning; SAFPAC, Supporting Access to Family Planning and Post-Abortion Care.

Supervisors conduct data quality checks regularly during monthly supervisory visits by comparing summary monthly reports, patient records, and visit registers. As the project has progressed, the supervisors have begun reporting the findings of their monthly supervisory checklists to the district, national, and global level as well. (See companion article in *Global Health: Science and Practice* for more information about our supervisory approach.[16])

The project attracted new family planning users as trained providers and contraceptive commodities became available.

Data Analysis and Use

In the health facilities, providers use wall charts to track service delivery progress. Project and government staff meet regularly at both facility and district levels to assess service delivery patterns and unexpected changes and to adjust programming as necessary. These teams also hold joint meetings with community leaders monthly or quarterly to discuss trends, develop specific action plans, and document next steps in handwritten supervisory logs. At the health zone/district and country levels, program staff use an Excel datasheet with built-in formulas and automatically generated graphics for data analysis. A globally aggregated datasheet compiles data and generates pivot tables and pivot charts for descriptive analysis.

RESULTS

New Modern Method Users

The first 2.5 years of the project have been characterized by high and sustained demand for modern methods of family planning in all 5 countries. In total, the initiative has reached 52,616 new users of modern methods in Chad, Djibouti, the DRC, Mali, and Pakistan (Table 2). The number of new modern method users has varied by country, from 575 in Djibouti to 21,191 in Chad.

An increase in new users was apparent immediately as trained providers and commodities became available. The first cohorts of providers completed their training in November 2011. Beginning in December 2011, a sharp increase in new users occurred in Chad, the DRC, and Pakistan (the 3 SAFPAC country programs active at the time). The upward trend continued through April 2012 as the final cohorts of providers received training (Figure 2). Subsequently, the 3 initial countries all experienced spikes and dips in monthly numbers of new users, many of which were correlated with changes in the active conflict (in the DRC) or recurring natural disasters (in Pakistan). Another major factor in periodic decreasing user trends was cultivation seasons, as SAFPAC covers primarily rural farming populations.

Method Mix

Use of LARCs has predominated, representing 61% of total new users of modern methods across the 5 countries (Table 2). This overall average masks differences between countries. For example, in the DRC and Chad, 78% and 72% of new users, respectively, have chosen LARCs. In Mali,

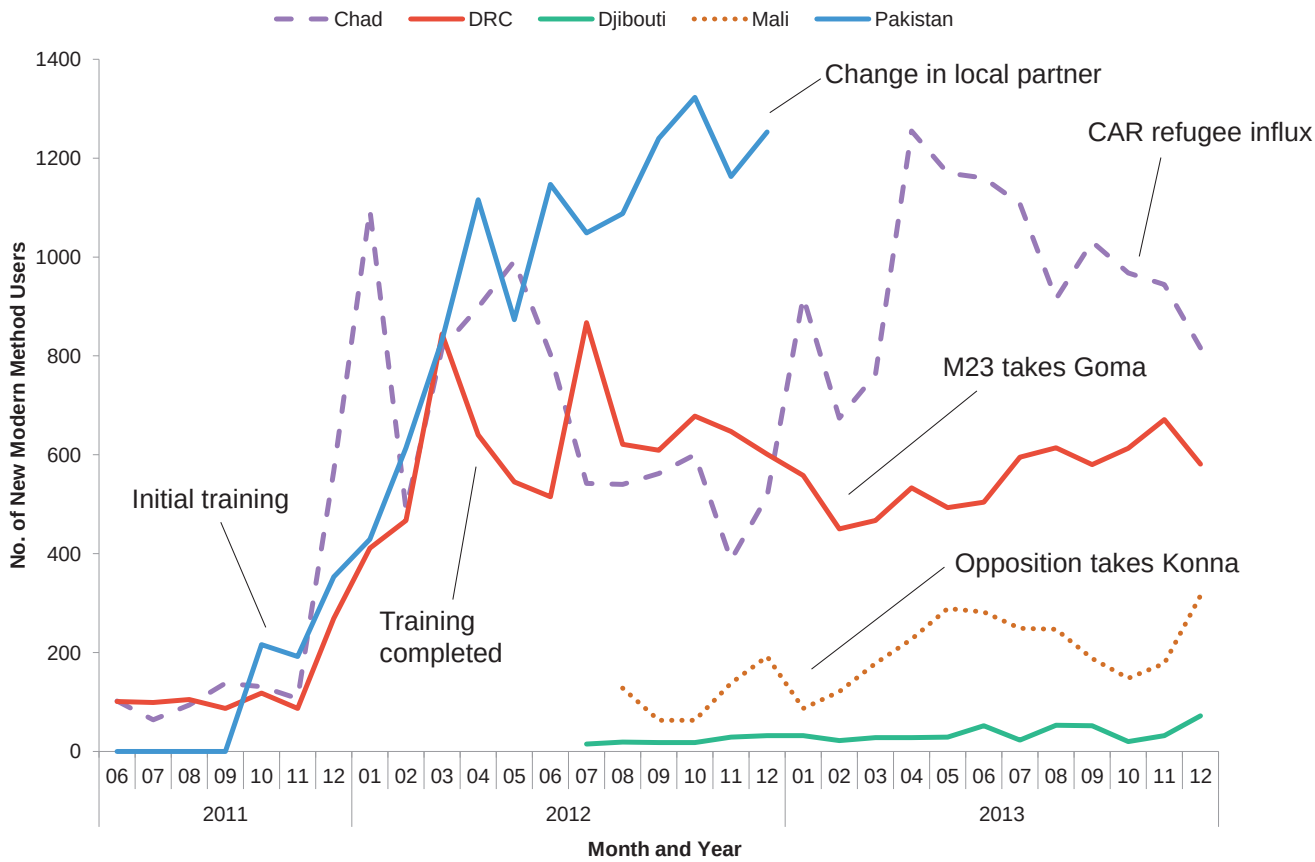
TABLE 2. Number of New Modern Method Users and Distribution of LARCs vs. Other Modern Methods Among SAFPAC Initiative Facilities, by Country (July 2011–December 2013)

Country	Any Modern Method[a]	LARCs		Other Modern Methods	% of LARCs Among All Modern Methods
		Implants	IUDs		
Chad	21,191	13,201	2,189	5,841	72%
DRC	14,869	9,132	2,289	3,310	78%
Djibouti	575	6	0	569	1%
Mali	3,093	1,317	270	1,506	51%
Pakistan	12,888	298	3,432	9,158	29%
Total	**52,616**	**23,852**	**8,380**	**20,384**	**61%**

Abbreviations: DRC, Democratic Republic of the Congo; IUDs, intrauterine devices; LARCs, long-acting reversible contraceptives; SAFPAC, Supporting Access to Family Planning and Post-Abortion Care.

[a] Modern methods consisted of implants, injectables, IUDs, oral contraceptive pills, tubal ligation, and vasectomy.

FIGURE 2. Number of New Modern Method Users Among SAFPAC Facilities, by Country and Month (July 2011–December 2013)



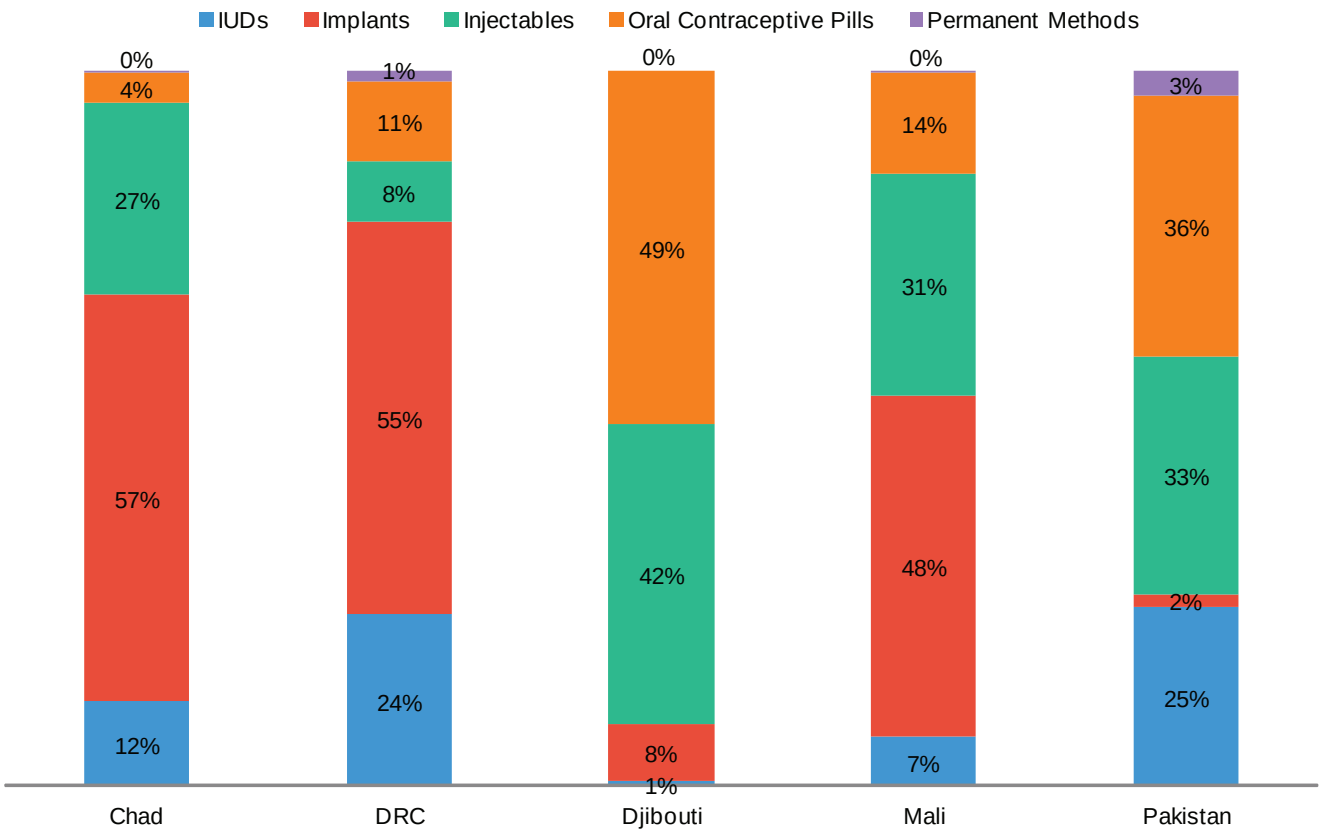
Abbreviations: CAR, Central African Republic; DRC, Democratic Republic of the Congo; M23, March 23 Movement, also known as the Congolese Revolutionary Army; SAFPAC, Supporting Access to Family Planning and Post-Abortion Care.

51% of new users have chosen LARCs while in Pakistan, the proportion has been 29%. In Djibouti, providers received training in implant and IUD insertion at the end of 2013, so those methods were not offered in the country through SAFPAC during the period discussed here.

Between the 2 LARC methods, use of implants has predominated in the African countries (excluding Djibouti) while IUD use has represented a small portion of LARC use (Figure 3), at 14% in Chad, 17% in Mali, and 21% in the DRC. Practically speaking, the popularity of implants has coincided with the introduction and availability of the method; before SAFPAC began its activities, implants were virtually unavailable in these settings except in private-sector clinics in larger urban areas. In Pakistan, on the other hand, IUDs have been the predominant LARC method, at 92% of total LARC use. This is due, in part, to difficulty in securing commodities and governmental approval for the use of implants.

In all 4 countries that offer IUDs, use of IUDs has comprised a larger share of the method mix over time. For example, IUDs as a percentage of total new users has shifted in the DRC from 11.3% in the first 6 months of project activities to 28.2% in the most recent 6 months, and from 1% to 18% in Chad. In Mali, the share of IUDs has increased only

FIGURE 3. Method Mix Among New Modern Method Users in SAFPAC Facilities, by Country (July 2011–December 2013)



Abbreviations: DRC, Democratic Republic of the Congo; IUDs, intrauterine devices; SAFPAC, Supporting Access to Family Planning and Post-Abortion Care.

slightly, from 6.2% to 6.8%. In Pakistan, IUDs represented a higher percentage of total new users initially than in other countries, at 23.0%, but the share has still increased to 28.8% (Figure 4).

Providing long-acting methods in fragile setting is feasible, even though they require more training and infrastructure support than short-acting methods.

Contraceptive Use Among PAC Clients

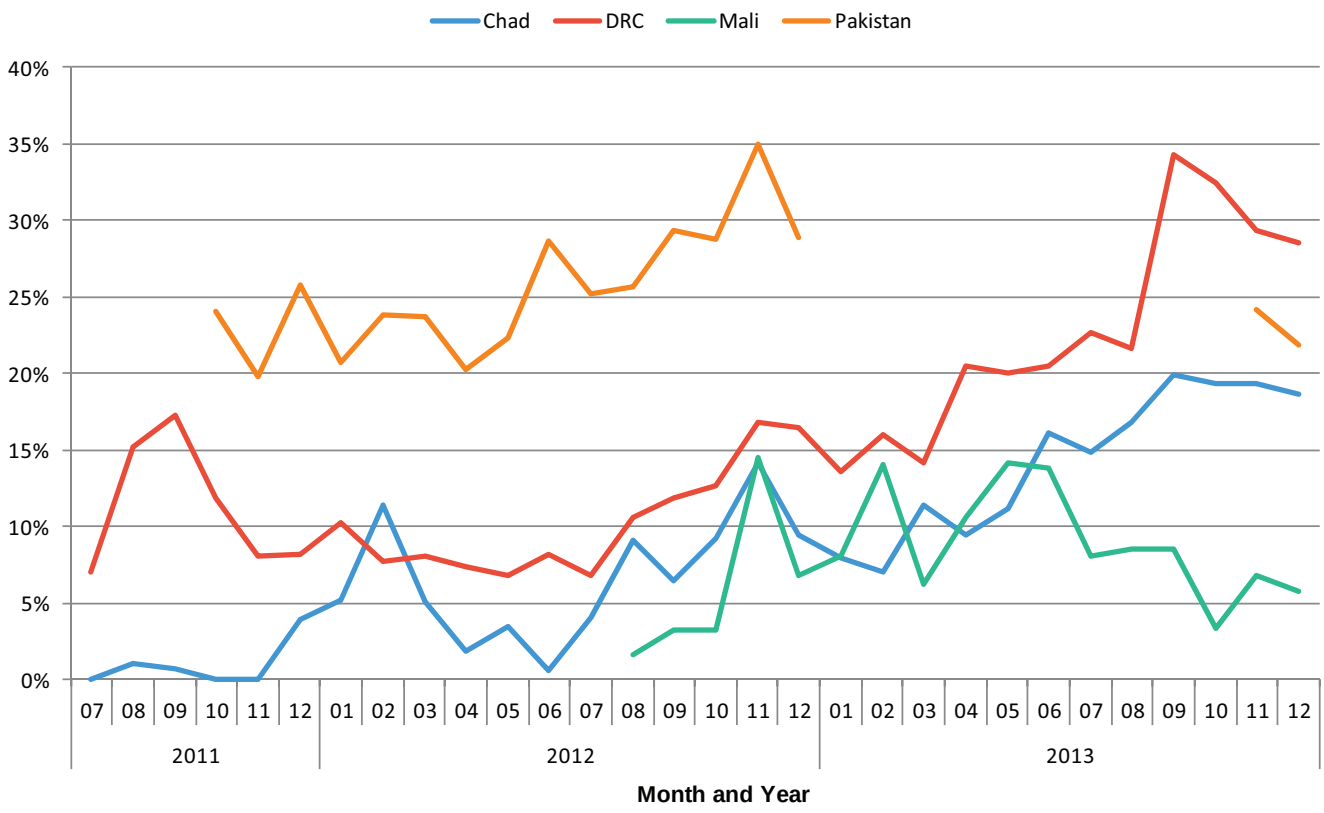
On average, over the project period, 28% of PAC clients in Djibouti have adopted a contraceptive method, compared with 57% and 59% in Chad and Pakistan, respectively, 65% in the DRC, and 77% in Mali.

DISCUSSION

Using project monitoring data, the SAFPAC initiative has demonstrated the feasibility of providing high-quality family planning services, including long-acting methods, in fragile settings and at a rapid pace. Over the initial 2.5-year period, the project reached 52,616 new modern method users among a catchment population of about 698,000 women of reproductive age in 5 crisis-affected country settings across Africa and Asia, exceeding the project's target of 36,002 new users over the corresponding project period.

Of particular note is the dramatic increase in use of LARCs as a percentage of the overall method mix, in particular in the sub-Saharan African countries of Chad, Mali, and the DRC. LARCs are increasingly representing a greater portion of the method mix generally throughout sub-Saharan

FIGURE 4. Share of IUDs of the Total Method Mix in SAFPAC Facilities, by Country and Month (July 2011–December 2013)



Abbreviations: DRC, Democratic Republic of the Congo; IUDs, intrauterine devices; SAFPAC, Supporting Access to Family Planning and Post-Abortion Care.

Africa. However, debate continues about the feasibility of providing LARCs in crisis-affected settings. The requirements both for provider training and for basic infrastructure required to insert IUDs and implants are significantly greater than those to dispense pills or administer injectable contraceptives. In SAFPAC-supported facilities, LARCs comprised 61% of the method mix, demonstrating not only that it is feasible to provide these methods in such settings but also that women in crisis-affected settings want and will use LARCs when the methods are available and they know about them, supporting earlier findings.[17]

Sullivan et al. note that while there is generally no ideal method mix, there may be reason for concern when 1 or 2 methods predominate in a country.[18] Use of implants has predominated in the areas supported by the SAFPAC initiative. Implants seem to appeal to both providers and clients. Providers at SAFPAC-supported clinics reported liking the ease and speed of implant insertion. Clients reported liking that the insertion procedure does not require disrobing (as with IUDs) and ease of using the method (no need to return for refill/reinjection). In addition, our conversations with communities, clients, and providers suggest that other major factors behind women choosing implants include availability of the method free of charge in SAFPAC-supported facilities, in contrast to private channels where the method is available but very expensive, and word-of-mouth through rural social networks.

Still, the project team wanted to ensure that the higher use of implants over IUDs was not the result of misinformation or bias against IUDs. Accordingly, the SAFPAC team conducted additional provider training to offer unbiased counseling, refresher training to increase their confidence in IUD insertion and removal, and tightened and improved messaging related to the advantages of IUDs.

Use of IUDs increased over time as the project intensified its efforts to improve provider training and potential clients' awareness.

Project efforts to increase access to IUDs appear to be correlated with the upward trend of increasing IUD use in Chad, the DRC, and Pakistan. In DRC facilities, in particular, the share of IUDs increased to more than 20% of the total method mix compared with an overall sub-Saharan African average of 3%.[19] We attribute this increase to 2 main factors: (1) Project supervisors began to clearly reinforce to providers the potential advantages of IUDs and the importance of presenting all options to women using our adapted DMT/BCS+ approach (even if they had heard of a different method before arriving for services), and (2) As more women began to try IUDs, influential satisfied clients, as well as male and female community leaders, shared positive experiences through their social networks.

In terms of family planning adoption among PAC clients, the project aims to meet a standard of 80% of PAC clients adopted a contraceptive method. The average rate of family planning acceptance among PAC clients, however, ranges from 3.2% in areas with no supportive interventions to anywhere from 45% to over 90% after implementing interventions.[20] In Mali, 77% of PAC clients at SAFPAC facilities have adopted family planning, which is near the global target of 80%. Although our facilities in the other 4 countries have not yet reached this target, we believe they are on the path to doing so, with current levels between 28% (in Djibouti) to 65% (in the DRC).

Strengths and Limitations

Our ability to assess true coverage of family planning services among the general population in the regions we cover, and to show causal relationships or make generalizable conclusions, is limited because the findings presented in this article come from routine monitoring data, not population-based surveys of randomly sampled, representative groups. While we have some information from client records on the characteristics of users, we cannot conclude with confidence that this group of users is fundamentally the same as the general population of women of reproductive age in terms of access, age, income level, and other demographic characteristics. Instead of diverting resources to such costly population-based surveys, the project has instead focused on collecting high-quality routine monitoring data and making maximum possible use of the data to continually improve the program.

We also face challenges in our ability to attribute the increase in new users of family planning to our efforts because we lack a comparison group among surrounding populations. It was not within the scope of the program to create such a comparison group. We are currently seeking ways to design a low-cost approach to collect household information to estimate contraceptive prevalence and unmet need and to determine whether women are unable to access services due to geographic distance, social or economic marginalization, or other unknown reasons. However, the notably higher numbers of clients per month and the rapid increase in contraceptive uptake shortly after trained providers and commodities became available do suggest that SAFPAC is meeting preexisting unmet need through high-quality service delivery. Furthermore, the sustained uptake in subsequent months suggests that CARE's community engagement activities are effective in accessing latent demand even after initial pent-up unmet need had been satisfied.

CONCLUSION

These results suggest that it is feasible to work with the public sector in fragile crisis-affected states across diverse settings to offer a wide range of family planning services and methods. Moreover, the project demonstrated that it is feasible to do so in a short time period (about 2 years), resulting in rapid uptake of family planning overall, as well as a dramatic increase in the percentage of users voluntarily choosing highly effective long-acting reversible methods. This can be done using a set of interventions, drawn from best practices in development settings, that tackle typical service delivery challenges, increase awareness of a range of different methods, and begin to challenge norms that restrict women's access to family planning. Marshalling resources to reach women in a wide range of crisis-affected settings worldwide could make a meaningful contribution to progress on Millennium Development Goal No. 5 to improve maternal health.

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ORIGINAL ARTICLE

Trends in the Contraceptive Method Mix in Low- and Middle-Income Countries: Analysis Using a New "Average Deviation" Measure

John Ross,[a] Jill Keesbury,[b] Karen Hardee[b]

Applying a standard measure of the method mix evenness suggests 4 patterns among 15 countries moving toward a more balanced mix: (1) rise of one previously underrepresented or new method, (2) replacement of traditional with modern methods, (3) continued but declining domination by a single method, and (4) general movement toward a balanced mix. Improving availability of underutilized or new methods can improve the method mix, although better implementation of more popular methods might increase contraceptive use more expeditiously.

ABSTRACT

The method mix of contraceptive use is severely unbalanced in many countries, with over half of all use provided by just 1 or 2 methods. That tends to limit the range of user options and constrains the total prevalence of use, leading to unplanned pregnancies and births or abortions. Previous analyses of method mix distortions focused on countries where a single method accounted for more than half of all use (the 50% rule). We introduce a new measure that uses the average deviation (AD) of method shares around their own mean and apply that to a secondary analysis of method mix data for 8 contraceptive methods from 666 national surveys in 123 countries. A high AD value indicates a skewed method mix while a low AD value indicates a more uniform pattern across methods; the values can range from 0 to 21.9. Most AD values ranged from 6 to 19, with an interquartile range of 8.6 to 12.2. Using the AD measure, we identified 15 countries where the method mix has evolved from a distorted one to a better balanced one, with AD values declining, on average, by 35% over time. Countries show disparate paths in method gains and losses toward a balanced mix, but 4 patterns are suggested: (1) rise of one method partially offset by changes in other methods, (2) replacement of traditional with modern methods, (3) continued but declining domination by a single method, and (4) declines in dominant methods with increases in other methods toward a balanced mix. Regions differ markedly in their method mix profiles and preferences, raising the question of whether programmatic resources are best devoted to better provision of the well-accepted methods or to deploying neglected or new ones, or to a combination of both approaches.

INTRODUCTION

It has long been recognized that the availability of only 1 or 2 contraceptive methods in a country constrains total contraceptive use and limits the options that women and couples have to manage their pregnancies. Conversely, adding methods expands choice for women and men and increases contraceptive use. With renewed attention to improving access to family planning services that respect and protect human rights, including access to a fuller, more informed choice of methods, experts have considered what it means for programs to offer a full range of contraceptive methods.[1,2] In some countries, governments or markets have not enabled access to certain modern methods; in other countries, some methods are inherently unpopular, as with vasectomy and the condom. In some settings, such as rural Africa, certain methods are not easily accessible because they are clinically difficult to implement, as with sterilization or the intrauterine device (IUD). Clearly, the current contraceptive method mix is severely unbalanced in many countries, with over 50% of all use by a single method or with only 2 methods accounting for most use.[3]

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Experiences with changes in the contraceptive method mix are of interest to policy makers and donors, since a broader mix expands contraceptive method choice, letting women and couples choose the method that suits them best and change methods as their circumstances and needs change. How to expand method mix remains an important programmatic question. This entails a focus mainly on the ''share'' of use held by each method—that is, the portion of all use, with the sum of the portions always adding to 100%. A totally balanced mix, with even shares for all methods, is never a program objective since it would mean, for example, that condom use would equal that of the implant and IUD use would equal that of male sterilization. Instead, the objective is to generally move away from an obviously distorted mix, without specifying precisely how fully balanced the mix should be, while enlarging access to a wider variety of method choices. In practice, it is easier to know when a mix is seriously distorted than it is to specify the ideal mix, due not only to program limitations but also to strong social norms that may block adoption of a particular method. Over time, countries will vary in which methods gain or lose shares, while total use in most cases will increase.

Exclusive attention to the contraceptive method mix, by itself, can give misleading results, since the same mix may prevail at both low and high levels of total use. A poor method mix can exist in a low-prevalence setting, such as Nigeria, but also in China, where the contraceptive prevalence rate (CPR) is in the eighties.[16] Further, a rapid change in the method mix may distort the mix but simultaneously raise the overall level of use, as with the injectable in eastern and southern Africa. In that case, a more distorted method mix has actually increased choice by making an important method more available than before. In short, an analysis of mix changes over time also requires attention to changes in levels of total contraceptive use.

This paper reviews previous work devoted to measuring distortions in the mix, and it builds on that work by analyzing trends over time in the distribution of users across 8 contraceptive methods, using data available in national surveys in low- and middle-income countries (LMICs). The paper introduces a new measure of distortions in the method mix—the ''average deviation'' of method shares around their own mean. This measure is used in conjunction with total contraceptive use to give a more complete and programmatically useful picture of trends over time, along with possible programmatic responses to improving the method mix.

PREVIOUS MEASURES OF METHOD MIX SKEW

In many countries, a single contraceptive method accounts for more than 50% of all contraceptive use.

A number of studies have focused on the ''skew'' in the method mix. A method mix is clearly distorted, or skewed, when a single method covers more than half of all use (the 50% rule). A series of 3 analyses has applied the 50% rule to large numbers of national surveys,[4–6] and we build on this work below. The latest report found that 30% of 109 developing countries suffered from a skewed method mix,[4] down from 35% in a 2006 analysis.[6] Among the contraceptive methods, the injectable showed increases in use, while sterilization and the IUD showed relative declines.

The aim is not to prescribe a specific ideal method mix but to generally increase access to a wider variety of method choices.

Other studies have analyzed the use of specific contraceptive methods within the method mix. A United Nations (UN) report covering both developed and developing countries found that, globally, more than half of all users relied on either female sterilization or the IUD.[3] Use was highly concentrated: in nearly every country, 1 or 2 methods accounted for over half of all use among married/in-union women. However, regions differed sharply in their particular method mixes. The UN found that little change occurred in the mix of methods between 1990 and 2011, either globally or within individual regions. Still, some increase occurred during that period for the injectable and some decline occurred for traditional methods. The pill had the widest geographic spread, and male methods the least; such imbalances limit easy movement between methods to adjust to personal circumstances and aims.

A poor method mix can prevail at both low and high levels of contraceptive use.

The increase in injectable use, noted in the UN review, has modified the method mix in eastern and southern African countries and elsewhere, as reviewed by Adetunji[7] and by Sutherland et al.[8] Ross and Agwanda[9] showed that the injectable increase has been mainly additive to the prior level of total use, rather than substituting for other methods. While its popularity has raised total use in many settings, it is a short-acting method, and questions still remain about the frequency of its discontinuation and switching to other methods. Little is known about which methods, if any, women turn to when they discontinue use; in a review of 23 countries, Ali and Cleland[10] found that among users of modern methods who discontinued, as of 3 months later, 26% were at

Increased injectable use has been mainly additive to prior levels of contraceptive use, rather than substituting for other methods.

risk of becoming pregnant (i.e., they were not using any method), 10% were pregnant, and 60% had switched to another method (median values).

Adding more methods to the method mix tends to increase total contraceptive use.

When the current mix is augmented by access to an additional method, total use tends to rise. Asian examples were noted by Freedman and Berelson[11] and by Jain,[12] who estimated for Taiwan that adding 1 method to the mix would increase total use by about 12 percentage points (e.g., from 30% to 42% total contraceptive prevalence). Ross and Stover[13] estimated that making 1 additional method available to at least half of the population raised modern contraceptive use by 4–8 percentage points, based on 27 years of data for 113 countries.

Some of the literature on method mix has occasionally been directed to specifying method mixes that are most appropriate for different user profiles and life objectives[14] or to tools that relate the individual needs of women to the characteristics of alternative contraceptive methods.[15]

DATA AND METHODS

This analysis draws on data from 666 national surveys in 123 countries.

The primary set of national surveys used in our analysis is a thorough compilation provided by the UN Population Division of some 700 surveys from both developed and developing countries.[16] After exclusions to remove surveys from developed nations, including eastern Europe, and those that lack breakdowns by individual method, 666 surveys from 123 countries were included in this analysis (Appendix 1). Most tabulations are for the most recent surveys for the 123 countries.

Regarding the latest surveys in these 123 countries, most were of 3 types: over 40% were from the Demographic and Health Surveys (DHS), about a fourth were from the Multiple Indicator Cluster Survey (MICS) series, another fourth from independent national surveys, and the rest from other sources. By region, 38% were for sub-Saharan Africa, 18% each for Asia and North Africa/West Asia, 21% for Latin America, and 4% for Central Asia. Regarding timing, 80% of surveys were conducted from 2005 onward. The percentages of surveys in each 5-year period starting in 1995 were 5% (1995–1999), 15% (2000–2004), and 57% (2005–2009), with an additional 23% between 2010 and 2012.

The average deviation provides a measure of the evenness of a country's method mix and allows for comparisons across countries.

The surveys provide the percentage of married women using the 8 contraceptive methods (i.e., contraceptive prevalence) that together account for most use and for which data are available for most countries. "Modern" methods include male and female sterilization, the IUD, oral contraceptive pills, the injectable, the condom, and the implant. Traditional methods are composed mainly of withdrawal and rhythm, in equal parts, representing 92% of all traditional method use (average across all DHS surveys). We could have performed separate analyses on small sets of countries where other methods were used by nontrivial percentages of women, but the aim of detecting marked changes in the overall mix in most countries required attention to the 8 methods studied here.

We converted contraceptive prevalence rates provided in the surveys (with all married women as the denominator) to the percentage of use due to each contraceptive method, totaling 100% (with users of any contraceptive method as the denominator). Changes in these latter percentages over time made up the focus of this study. Where regional or other averages (means) are given, they are unweighted, so every country receives the same importance in the averages. The patterns would be somewhat different if they were weighted by population size. Certain individual countries are selected for separate discussion, and country details appear in several tables.

The Average Deviation (AD) Measure

Countries differ in their method mixes, all falling between the possible extremes of reliance on a single method to reliance on all methods equally; moreover, mixes change over time. How large must a change be to signal an important shift? Small shifts in surveys can come from noise in the data and/or from sampling error, while very large shifts usually reflect real and important changes in behavior.

Therefore, a standard measure of the evenness of the method mix is needed, to gauge the extent of change and to compare one country or region with another. After a review of possible measures, we chose to use the "average deviation" (AD); it is the simple average of the absolute differences around the mean (average), whether positive or negative, and for our purposes is preferable to the standard deviation, which squares deviations, including those of extreme outliers.

If all 8 methods held equal shares, they would each have 12.5% of all users (100% divided by 8), and 12.5% is always the average value. In every country, the share of each method in the mix varies around that average. Almost always, the implant, male sterilization, and the condom fall below the average. Depending on the region and

country, any of the other methods (the pill, injectable, IUD, female sterilization, or traditional methods) can rank either above or below the average, e.g., female sterilization ranks below the average in sub-Saharan Africa and the IUD ranks above the average in the Middle East.

The AD measure captures the disparity in the mix, i.e., the sum of the 8 absolute differences around the average of 12.5%. The sum of those differences can range from 0 to 21.9: if every method is used equally, no differences exist and the sum is 0, and if a single method covers all use, the differences sum to 21.9. Most AD values range from 6 to 19; across all surveys, the interquartile range (i.e., the middle 50% of values, between the 25th and 75th percentiles) is from 8.6 to 12.2.

Thus, a high AD value indicates a skewed method mix, with dominance of a few methods, and a low AD value indicates a more uniform pattern across the methods. No country has a fully uniform mix with an AD value of 0, and as noted above, perfectly even shares would not likely be a program objective. In some cases, a rapid movement toward a new method might be sought programmatically, disturbing a relatively even mix.

The relationship between the mix and the total CPR must be kept in mind, as a low AD can occur at any level of the CPR. For example, in Nigeria the CPR is low whereas in Peru the CPR is high, and both have low AD scores.

TABLE 1. Percentage of Countries (Latest Surveys) and of All Surveys With Method Mix Skew According to the Cutoff Level[a]

	No. (%)	
Cutoff Level	Countries (Latest Surveys)	All Surveys
30%	115 (94.3)	609 (91.4)
40%	68 (55.7)	393 (59.0)
50%	35 (27.9)	225 (33.8)
60%	22 (18.0)	137 (20.6)
70%	10 (8.2)	62 (9.3)

[a] The ''50% rule'' is the most commonly used cutoff level, indicating that a single contraceptive method accounts for more than half of all contraceptive use in a given country. Changing the cutoff level changes the severity of the rule.

The AD can also be calculated for the 7 modern contraceptive methods, the ADM; however, the dynamics of changes in contraceptive method mixes depend upon the competition between modern methods and traditional methods, usually with the former partially replacing the latter, so the AD measure is preferred.

We also consider an alternative measure of method mix skew, since this work builds upon the publications described above that employ the ''50% rule'' as the measure of the mix's imbalance, and the results are compared below with those from the AD measure.

FINDINGS

Variations on the 50% Rule to Define Skew

The 50% rule tells whether a single contraceptive method accounts for more than half of all use. That has been a useful measure, and it is of interest to assess how sensitive the results are to exactly 50%. It is possible to vary it, to examine changes in the outlook according to the severity of the rule. If a single method must cover 60% of all use for skew to occur, fewer countries will qualify, and if the rule is 40%, more will qualify.

Table 1 presents the counts according to a range of cutoff rules, from 30% to 70%, first for the 123 countries using only the latest surveys, and second for all 666 surveys to encompass some of the historical experience. By the 50% rule, 28% of countries and 34% of surveys qualify as having a skewed method mix, a finding close to that of Bertrand et al.,[4] which is expected since the 2 sets of data contain many of the same countries. Both results suggest some improvement: the higher figures for all surveys reflect more skew in the past, which agrees with the finding by Bertrand et al. of a decline from 35% to 30% of countries that are skewed.

Under the 40% rule, the skewness counts jump to over half (56%) of all countries and nearly three-fifths (59%) of all surveys. In the other direction, by the 60% rule, about a fifth of countries are still skewed (18% of countries and 21% of surveys), which still indicates major imbalance among methods. For particular countries (not shown), the rules matter: Kenya and Uganda, each with a maximum of 47% use with a single contraceptive method, would be included under the 40% rule but not under the 50% rule. Tanzania would qualify only under the 30% rule. On the other hand, some countries that qualify by the 50% rule would not qualify with the

A high average deviation value indicates a skewed method mix while a low value indicates a more uniform pattern across methods.

The 50% rule, commonly used to measure method skew, identifies countries where a single method accounts for more than half of all use.

By the 50% rule, 28% of countries have a skewed method mix.

60% rule. Examples in sub-Saharan Africa are Malawi (56%), Niger (56%), and Rwanda (51%), and elsewhere, Egypt (59%) and Mexico (55%). Regardless of the rule used to measure skew, the results show major shortfalls in making a wide variety of contraceptive choices available.

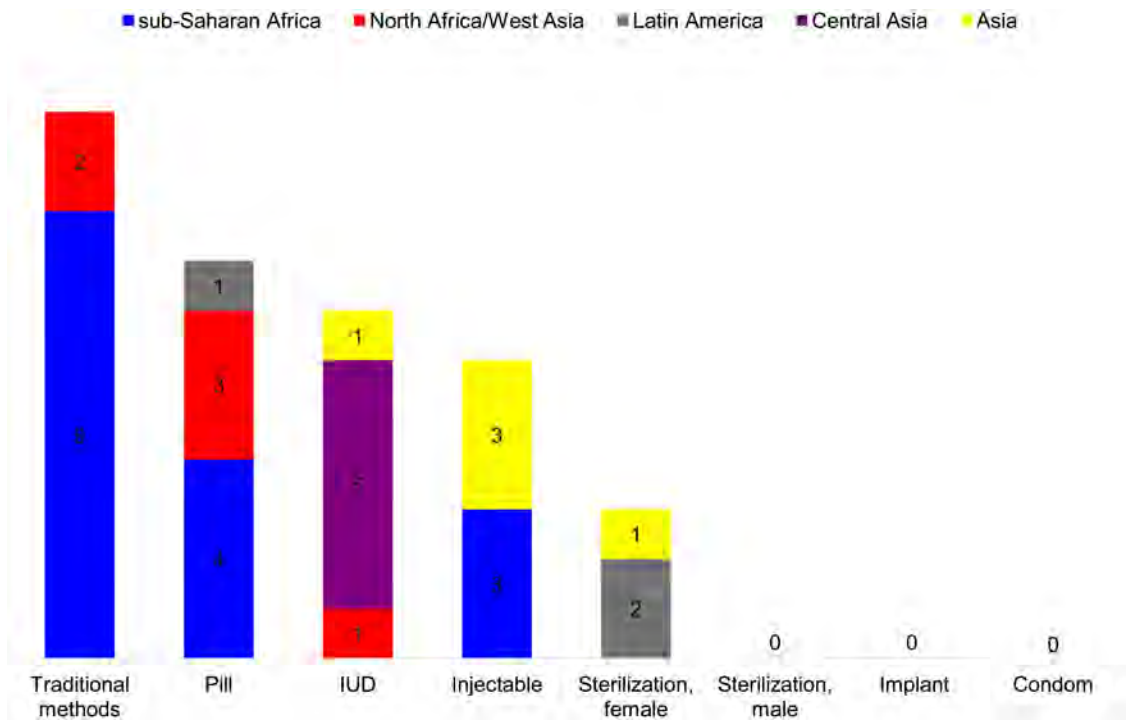
The dominant method in countries with skewed method mix (by the 50% rule) is quite different by region (Figure 1). Traditional methods stand out in sub-Saharan Africa and to a lesser extent in North Africa/West Asia, and the pill is also popular in these 2 regions. The injectable is prominent in sub-Saharan Africa as well as in Asia. The IUD is important, but 5 of its 7 countries are the 5 Central Asia Republics. Female sterilization is dominant in 2 Latin American countries and 1 Asian country. The other 3 methods (male sterilization, the implant, and the condom) do not show skew anywhere. The figure is based on 35 countries, and for each country meeting the 50% rule, there are others in the same region just below 50%.

61% of users rely on the pill, traditional methods, or the injectable, which represents about 25% of all married women.

Method Mix at the Global, Regional, and Country Levels

The overall pattern of contraceptive use by method appears in Figure 2, for married/in-union women using any method across the 123 countries (all methods sum to 100% of users). Among these contraceptive users, 22% use the pill and another 22% use traditional methods, but the levels are best understood with attention to the contraceptive prevalence among *all* married/in-union women by method. Those percentages are much lower, and are given along the x-axis with the method labels. Among all users, 61% rely either on the pill,

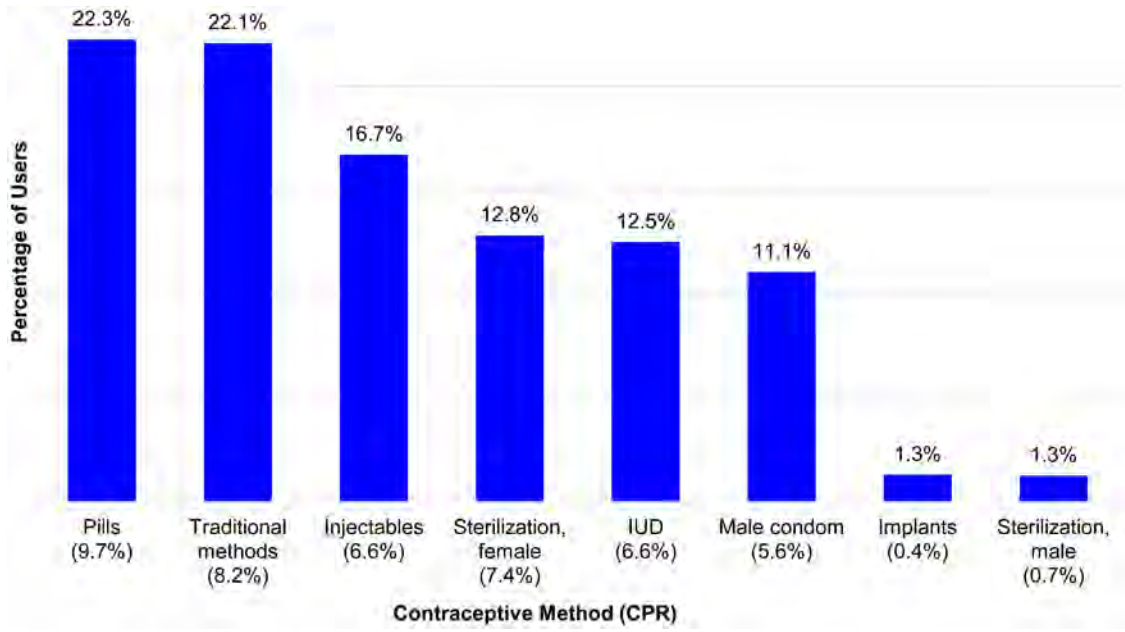
FIGURE 1. Number of Countries With Method Mix Skew According to the 50% Rule,[a] by Dominant Method (N=35 Countries)



Abbreviation: IUD, intrauterine device.

[a] Each method comprises over 50% of total contraceptive use in the country. Missing regions in the bars had no country with over 50% use of that method among contraceptive users; male sterilization, the implant, and the condom had no countries at all with over 50% use of those methods among contraceptive users.

FIGURE 2. Method Mix Among Contraceptive Users Based on Latest Surveys for 123 Countries



Abbreviation: CPR, contraceptive prevalence rate; IUD, intrauterine device.

traditional methods, or the injectable, but that represents only 24.5% of married/in-union women.

Regions differ greatly from these averages, as shown in Table 2. Many contraceptive users (lower panel) in sub-Saharan Africa rely on traditional methods while fewer do so in Central Asia, where the injectable is nearly ignored and the IUD is paramount. Male sterilization plays a minor role in each region, while female sterilization varies from 2% to 28% of users, with high values only in Latin America and Asia. The injectable ranges widely, from 2% in Central Asia and up to one-fourth of all users in sub-Saharan Africa. The condom varies less by region, and accounts for around 11% of users overall. The implant is nearly negligible, but its use has increased recently in some countries.

The actual contraceptive prevalence appears in the upper panel of Table 2, which provides the percentage of all married/in-union women using each method. As noted, a method with a high percentage of users commonly reflects a much lower percentage of all married/in-union women.

Among individual countries (data not shown), for modern methods, the IUD is most often the dominant method, for example, in all 5 Central Asian Republics, in Viet Nam, in Egypt, and in some other Middle Eastern countries. Female sterilization ranks first in Brazil, the Dominican Republic, El Salvador, Haiti, and India. The pill is first in Bangladesh, Niger, and Zimbabwe. The injectable is first in Ethiopia, Indonesia, Malawi, and Rwanda. Vasectomy, the condom, and the implant are never the most commonly used method. Apart from modern methods, the most common maximum is for traditional methods, usually in countries with a low CPR, many of which are in sub-Saharan Africa.

Method Mix by Age, Residence, and Wealth Quintiles

The DHS set permits analysis of contraceptive use by personal characteristics, including age, residence, and wealth quintiles. The method mix changes systematically as women age (Figure 3). As age advances, the most notable growth is for female sterilization; its share is quite low below age 25 but then increases sharply and peaks at ages 45–49. All age groups neglect male sterilization

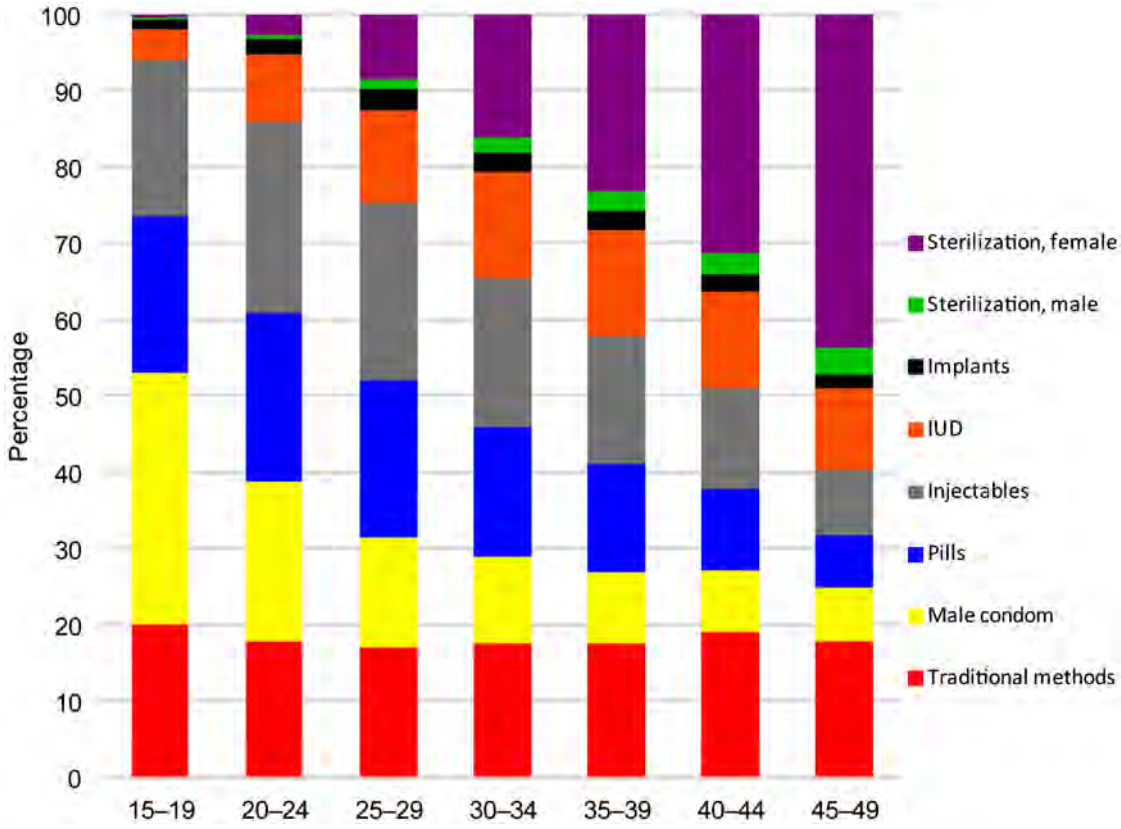
Method mix changes systematically as women age, with the most notable growth for female sterilization.

TABLE 2. Contraceptive Prevalence Among Married/In-Union Women and Method Mix Among Contraceptive Users, Based on Latest Surveys in 123 Countries

	Any Method	Any Modern Method	Sterilization, Female	Sterilization, Male	Pills	Injectables	IUD	Male Condom	Implants	Traditional Methods
Prevalence Among Married/In-Union Women										
All Regions	45.1	36.9	7.4	0.7	9.7	6.6	6.6	5.6	0.4	8.2
sub-Saharan Africa	27.2	21.3	2.0	0.1	6.4	7.3	0.9	3.2	0.7	6.1
North Africa & West Asia	52.6	36.5	3.5	0.1	14.2	1.6	12.1	4.5	0.1	16.2
Latin America	65.0	57.9	18.9	0.9	13.6	8.0	6.9	9.4	0.3	7.1
Central Asia	52.5	46.1	1.1	0.0	3.6	1.2	36.6	3.2	0.0	6.4
Asia & Pacific	52.3	44.8	9.9	2.0	9.5	8.9	8.2	5.3	0.4	7.5
Method Mix Among Contraceptive Users										
All Regions			12.8	1.3	22.3	16.7	12.9	10.7	1.3	22.1
sub-Saharan Africa			5.2	0.9	24.1	24.1	4.4	10.4	2.6	28.4
North Africa & West Asia			6.8	0.2	27.8	3.8	22.4	8.3	0.1	30.6
Latin America			27.9	1.2	21.3	13.0	10.3	14.5	0.5	11.3
Central Asia			2.0	0.0	7.3	2.2	70.1	6.4	0.0	11.9
Asia & Pacific			19.3	3.2	18.5	19.6	13.0	9.9	0.7	15.8

All data are presented as percentages.

FIGURE 3. Method Mix Among Contraceptive Users by Age



Abbreviation: IUD, intrauterine device.

and the implant. These results are for all regions merged; there is decidedly more selectivity by region and country. (For unmarried, sexually active adolescents, a clear shift occurs as youth age and gain more experience with contraceptive use. Between ages 15–19 and 20–24, reliance on the pill and injectable increases at the expense of the condom; data not shown.)

By residence, rural users show somewhat more use of traditional methods and injectables than urban users do, and less use of the condom (data not shown). However, the differences are relatively small. Total contraceptive prevalence averages 47.7% and 36.1% for urban and rural areas, respectively.

According to wealth quintiles, method shares are not greatly different (data not shown). While the quintiles differ sharply in total contraceptive prevalence (from 29.9% to 34.5% to 38.0% to 42.2% and 49.9% in sequence across the 5 quintiles), the profiles of their method preferences are basically similar. The main exception is the greater reliance on traditional methods by the bottom quintile as well as somewhat greater reliance on the injectable.

Dynamics of Method Mix Changes Using the Average Deviation Measure

The method mix in some countries has remained skewed over time, while in others it has changed substantially. Of particular interest are 15 countries with marked improvements to their method mixes, which show patterns that may suggest potential program actions for other countries wishing to adjust the mix.

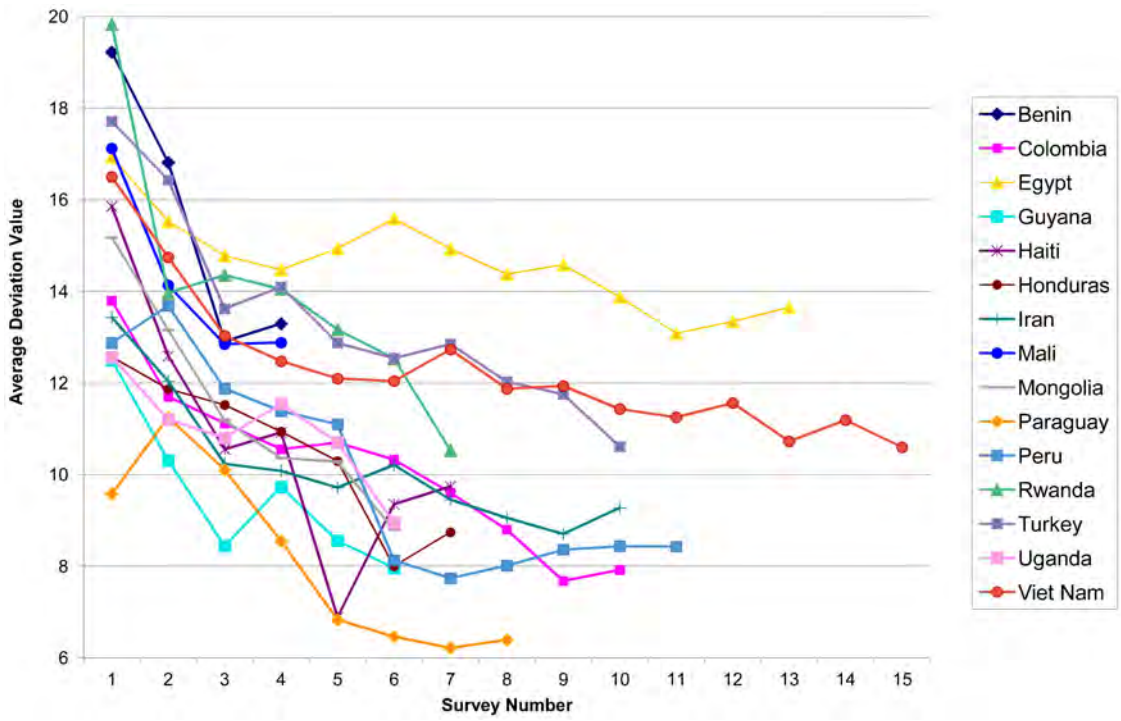
To identify these illustrative countries, the AD values for each country were themselves

assessed for their degree of variation and for the degree of linearity for the decline in the values. That isolated countries that had experienced a historic reduction and regular decline in skew. In more detail, first a statistical measure of variability was applied to the full series of AD values in each country. In many countries, variability was small, indicating little change over time. In others, the changes were erratic. Leaving those aside, the countries with large AD variability were examined to identify those with a linear pattern of decline in the values, suggesting a historic regularity in the changes. The 15 cases here represent countries where the method mix has changed considerably and fairly regularly over time, as holding the greatest interest for programmatic strategies to reduce extreme skews in the mix.

Downtrends in the AD values are shown in Figure 4, using the full sequence of available surveys for each country. For each line in the figure, survey number 1 represents the earliest survey conducted in that country, and each subsequent survey follows. (The dates for the data points differ among the countries and cannot be displayed separately; the time intervals also vary between surveys. See Appendix 2 for all survey dates and details on method use.) The longest series shown are 15 for Viet Nam, starting in 1988, and 13 for Egypt, starting in 1974–75.

In Figure 4, the AD values are highest at the left, at nearly 20 for Rwanda and Benin, for early dates when traditional methods dominated the mix and the CPRs were quite low. On the other hand, at the right, low AD values are shown for 3 countries clustered near the bottom, for Iran, Peru, and Colombia. In all 3 countries, traditional methods were very dominant at the start, fading steadily over the years. However, the 3 countries took quite different paths for which methods gained in the method mix share and which ones lost, as discussed below. In Iran, the pill declined in share as use of the IUD and female sterilization gained. Peru illustrates the opposite, where the IUD and female sterilization declined while the injectable and condom came into better balance with them. In Colombia, the trends were very regular

FIGURE 4. Declining Trends in Method Mix Skew Based on Average Deviation Values in 15 Selected Countries



over the years, with declines from high early values for the IUD and pill, while female sterilization, the injectable, and condom gained. Note that the shares for sterilization in all countries come from adoptions during numerous past years, unlike shares for resupply methods, which reflect behavior more recently and have shares that are more sensitive to program changes year by year.

Reflecting the long-term transitions toward a more even mix in these 15 countries, the changes in the AD from the initial to the latest surveys have been substantial, down by 5.3 points, on average, for a 35% decline (Table 3).

The overall CPR levels vary considerably among these countries, since the same AD value can occur at either a high or a low level of overall contraceptive use. However, there is evidence that lower AD values, i.e., a more even mix, and higher CPRs tend to go together. When all countries (latest surveys) are divided in half by low vs. high AD values (above and below the median), the average CPR value is 48.9% for low-AD countries, with less skew, and only 41.0% for the high-AD countries, with more skew. This holds true within both the low and the high range of contraceptive use. Within the low range (below the median) of CPRs, countries with high ADs average a CPR of only 19.6%, compared with a 23.7% CPR for countries with low ADs. Similarly, for countries in the high range of CPRs, the figures are 58.9% vs. 62.4%, respectively.

These patterns are consistent with the likelihood that broadening the method mix can help lead to a higher overall level of contraceptive use, as found for 64 countries cross-classified by the variability of access among methods and the overall level of access.[17] The highest CPRs were found where average access was both high and relatively even among methods.

Method Gains and Losses

The way by which the method mix changes takes many forms, and the interplay differs considerably for which methods gain and which ones lose. Table 4 summarizes the shifts in the 15 countries with marked changes to their method mixes over time, arranged by region. In most countries, women have been moving from traditional to modern contraceptive methods. The other notable trend is that the injectable, as a newer method, shows only gains, never a loss. In some countries, condoms have risen in the mix (and not necessarily in settings with high HIV/AIDS prevalence). In a few countries where one method was extremely dominant over the years, that method has lost some ground recently. In other countries, rather irregular shifts have occurred, following different paths, but the net effect has still been a steady decline in the AD values. Variability among the countries is the overriding tendency, as was evident also among regions.

Patterns of Movement Toward a More Balanced Method Mix

Notwithstanding the variability, we can take note of certain patterns, recognizing that these must be somewhat approximate. Four tendencies emerge, each of which is illustrated below in a chart for one of the countries to clarify how each

Average deviation in the method mix of 15 countries declined, on average, by 35% over time.

TABLE 3. Average Deviation (AD) Values for Method Mix Skew in Initial and Latest Surveys, 15 Countries

Country, Initial & Latest Survey Year	AD Value in Initial Survey	AD Value in Latest Survey	Decline
sub-Saharan Africa			
Benin, 1981/82 & 2006	19.2	13.3	5.9
Mali, 1987 & 2006	17.1	12.9	4.2
Rwanda, 1983 & 2010/11	19.8	10.5	9.3
Uganda, 1988/89 & 2011	12.6	8.9	3.7
North Africa & West Asia			
Egypt, 1974/75 & 2008	16.9	13.7	3.2
Iran, 1976/77 & 2002	13.4	9.3	4.1
Turkey, 1963 & 2008	17.7	10.6	7.1
Asia			
Mongolia, 1994 & 2008	15.2	8.8	6.4
Viet Nam, 1988 & 2010/11	16.5	10.6	5.9
Latin America			
Colombia, 1969 & 2010	13.8	7.9	5.9
Guyana, 1975 & 2009	12.5	8.0	4.5
Haiti, 1977 & 2005/06	15.9	9.7	6.2
Honduras, 1981 & 2005/06	12.6	8.7	3.9
Paraguay, 1977 & 2008	11.2	6.4	4.8
Peru, 1969/70 & 2010	12.9	8.4	4.5
Means	15.2	9.8	5.3

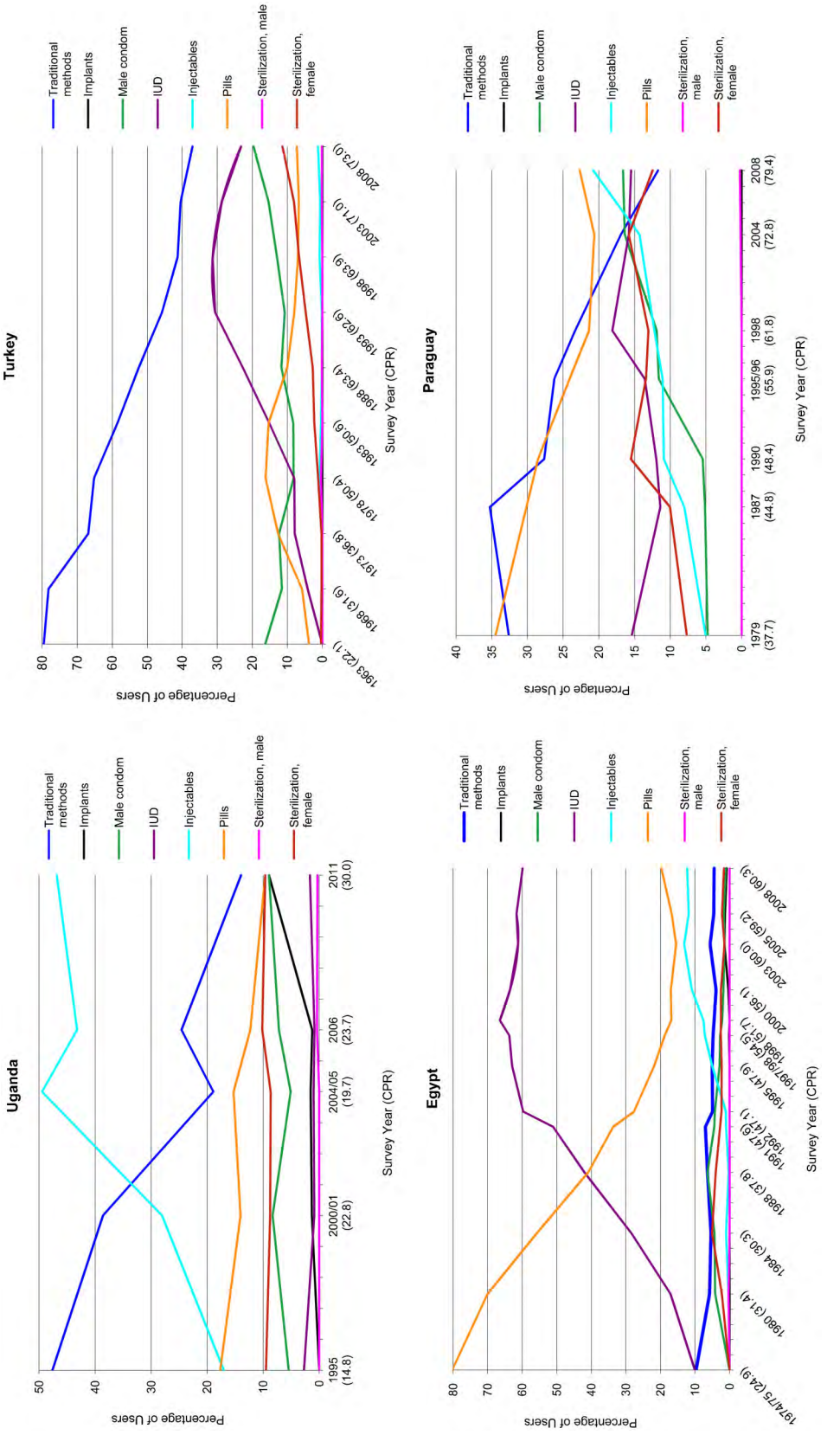
TABLE 4. Shifts in Contraceptive Method Mix by Country and Region for 15 Countries

Region/Country	Trends in the Method Mix
sub-Saharan Africa	
Benin	The injectable and pill have risen, while sterilization, the IUD, the condom, and especially traditional methods have fallen.
Mali	The injectable has risen substantially with declines in the pill and traditional methods.
Rwanda	Since the disruptions of the mid-1990s, the injectable has risen to over half of all use, while traditional methods have declined correspondingly. The implant gained in the latest survey.
Uganda	The injectable has risen at the expense of traditional methods, with a recent increase by the implant.
North Africa & West Asia	
Egypt	The IUD rose quite remarkably to a high level, with a corresponding decline for the pill. Recently, the injectable has shown some increase.
Iran	Sterilization has risen steadily; in the last survey, it lost ground to a resurgence in the pill, while traditional methods lost ground.
Turkey	The extensive use of traditional methods gave way to a rise in the IUD and condom, as well as female sterilization.
Asia	
Mongolia	The pill, injectable, and condom have risen while the IUD and traditional methods have fallen.
Viet Nam	The historic dominance of the IUD has weakened as shares of the pill and condom have gained.
Latin America	
Colombia	Sterilization rose very sharply over the years, along with a small rise for condoms. Shares for the pill, IUD, and traditional methods declined.
Guyana	The pill and traditional methods have lost ground, while the other methods show irregular trends that balance out to reduce skew.
Haiti	The picture changed sharply from 1994/95 onward. Sterilization declined while the injectable rose, with irregularities for other methods.
Honduras	The injectable share increased sharply with declines in the pill and in traditional methods.
Paraguay	Shares of the injectable and condom are up while shares of the IUD and traditional methods have fallen.
Peru	The IUD is down, as is sterilization slightly, while the injectable and especially the condom have risen.

mix developed over time. Because the method mix is often confused with the CPR level, the x-axis includes the CPR for each year so any point on the curve can be translated to the percentage of all married women using the method.

Takeoff of one method partially offset by changes among other methods. The first pattern, found in 7 countries (Benin, Haiti, Honduras, Mali, Peru, Rwanda, and Uganda) is a marked rise by one contraceptive method that is partially offset by changes among the other methods. The one method starts well below the average use of 12.5%, which would be its share if women were using all 8 contraceptive methods equally, and rises well above it; the overall result is less total dispersion in the shares among the methods than before, and a reduced AD value. The rise of the injectable is the primary example, illustrated by Uganda (Figure 5), where the rise in the injectable share is nearly a mirror image of the decline in the share of traditional methods. The pill has lost ground while the implant is up in the

FIGURE 5. Changes in the Method Mix Over Time, 4 Illustrative Countries



Abbreviation: CPR, contraceptive prevalence rate; IUD, intrauterine device.

latest survey. The other methods have been flat, and male sterilization has a trivial share, as it does elsewhere.

Both the 50% rule and the average deviation rule are useful measures of method mix distortion.

Systematic replacement of traditional methods with other methods. A second pattern is the systematic replacement of traditional method dominance by the IUD and condom. Turkey is an outstanding example; it was known for many years as the example of fairly high contraceptive prevalence based just on traditional methods, primarily withdrawal (Figure 5). The surveys, however, show a marked decline in withdrawal as modern methods replaced it, especially the IUD, with recent gains by the condom and female sterilization. Colombia is another example of nearly all methods having shares close together, except for female sterilization, the most-used method, whose high level reflects an accumulation over many years.

Continued but declining domination by a single method. A third pattern shows a single method that is both dominant and stable, with minor losses recently. This pattern is illustrated by Egypt and Viet Nam. In Egypt, the pill was the primary method at the start, with all other methods at low levels (Figure 5). However, it lost ground sharply in favor of the IUD, which rose to a stable level of three-fifths of all contraceptive use in the country. The pill plateaued at 15%–20%, while the injectable had a recent rise. The other methods are still minimal, including condoms and even traditional methods, which interestingly were never popular in Egypt. Over the 33 years shown, the CPR has risen from 25% to 60%.

Paraguay shows general movement from marked distortion to an unusually balanced method mix.

Declines in dominant methods with increases in other methods toward a balanced method mix. A fourth pattern, illustrated by Paraguay, shows movement from marked distortion to an unusually balanced mix (Figure 5); it has the lowest AD value of 6.4 among all the countries. At the beginning of the survey period, the pill and traditional methods were highest, but by the end, all methods had similar shares except for male sterilization and the implant. The CPR in Paraguay rose from 38% in 1979 to 79% by 2008, illustrating a case of improved choice along with widespread use of all methods.

Mixed patterns. Besides the countries mentioned above, the remaining 3 of the 15 selected countries, Guyana, Iran, and Mongolia, show somewhat irregular trends that involve different sets of methods.

DISCUSSION

Previous measurements of distortions in contraceptive method mix have used the 50% rule while our new measure uses the average deviation of method shares around their own mean. Using national survey data from 123 countries, our analysis finds that both rules are useful. The 50% rule detects whether a country stands out as having a distortion in its method mix when a single method accounts for over half of all contraceptive use, while the AD rule is sensitive to the net change across all methods, without necessarily showing whether any one method is very dominant. Each approach has limitations covered by the other one; the 50% rule does not provide the pattern for the non-dominant methods and the AD rule does not tell whether a single method takes an extreme value.

In many countries, the method mix is firmly entrenched, showing little movement for a long time. However, the possibility of change can never be discounted, given the historic surprises of the emergence of the injectable in Indonesia and South Africa and then in much of eastern and southern Africa. The pill may see increased use in the future, as it is acceptable and present in a wide variety of countries. The IUD, so popular in the Middle East, has never been used extensively in sub-Saharan Africa, but a myriad of pilot projects over the years for various methods have shown that intensive efforts can elicit impressive increases in the use of neglected methods.[18,19] In both sub-Saharan Africa and the Middle East, sterilization is minimal; for such a clinical method to increase its share in the method mix, a great deal of infrastructure work and training in the private or public sector is clearly necessary—a challenge in the poorest countries. However, the implant has shown small but definite gains in some African countries and will likely gain more users given increasing donor support for the method.[20] Male sterilization has not won a wide following in Latin America, the Middle East, or much of Asia; also where the CPRs are already quite high, they may signal relatively little potential for a change in method mix.

The prospects for favorable changes will almost certainly involve different paths in the various settings, as they have in the past. In some, 1 or 2 methods will account for most change, and that can either improve the balance among

methods or, while raising the CPR substantially, distort the method mix from its current state. In the longer run, new methods may emerge that gain popularity among users. In future surveys, repeated application of both the 50% rule and the AD measure can strengthen the monitoring of these developments and extend the time series, at very little effort.

Historically, it is likely that in the early days of experience with modern contraceptives, traditional methods held center stage in the method mix since they were the only ones known in the culture, including some abstinence and deliberate extensions of breastfeeding. As modern methods became better known and total contraceptive prevalence rose, the method mix moved toward a better spread among methods but in quite different ways. In each country, the public was experimenting and gaining experience with alternative choices. At the same time, a net reduction in unmet need for family planning occurred over time in many countries, as the rise in contraceptive use outpaced declines in the desired family size.

Regarding total contraceptive prevalence, few countries have CPRs in the seventies without a substantial share of sterilization in the mix, and even those countries with extensive IUD use have generally risen to CPRs only in the mid-sixties. In developing countries, total fertility rates are usually at replacement level only in those countries with considerable use of sterilization. Interesting exceptions are Viet Nam and Turkey, which rely on a combination of the IUD and traditional methods, with extensive use of abortion in Viet Nam and perhaps in Turkey as well.[21] Use of short-acting methods comes with high discontinuation rates, constraining total contraceptive use and the fertility effects.

How can both the method mix and the total contraceptive prevalence be improved? When we say that the method mix should be improved, we are really saying that some of the less-favored methods should be made more available and attractive and that promising new methods should be introduced. This would meet the needs of more women and couples, it would put the mix into better balance, and it would raise overall contraceptive use. However, there are questions of strategy. Apart from the usual counsel to ''try harder'' to improve accessibility and quality, with better training and supervision, and an expansion of services to the private sector, efforts to improve the method mix would focus on making the neglected methods in each country more available and on introducing new methods where feasible. However, the CPR itself may rise faster under a different strategy, posing the question of whether better implementation of the popular methods may prove more cost-effective than efforts to advance methods that so far have won little response. Where the public in a country clearly dislikes a method and the national authorities neglect it, as with male sterilization in most countries, the condom in many, and the IUD in some, it may be a better strategy to improve access to and quality for the established methods, both to enhance actual choice and to raise the CPR level. The answer to such questions will vary; sometimes a relatively new method shows promise, as the injectable clearly did and as the implant currently does in some countries. That points to a policy favoring a combination of improved implementation of established methods together with attention to neglected ones and to promising new ones. Whatever the strategy, it should embrace measures to advance free and informed choice.

Few countries have high contraceptive prevalence rates without a substantial share of sterilization in the mix.

Both the mix and the CPR may be improved through at least 2 basic approaches. The first is for special attention to go to the large market of discontinuers from resupply methods, both to prolong use for some users[22] and to offer ready alternatives for others. Very large numbers of injectable users are discontinuing use throughout eastern and southern Africa, by simply not showing up for the next shot. With proper counseling at the point-of-service, they can be encouraged toward a longer trial of the method or toward adopting alternative methods promptly after discontinuing their current method.

The second approach to improving both the mix and the CPR is the strategic focus on postabortion and postpartum women. The leverage in that focus is not generally recognized; it automatically separates out the relevant segment of the whole population as it moves through its next pregnancy experience. Apart from first births, most women who will ever have a next pregnancy or birth will do so within the next 5 years, and during that period many or most will encounter the various services related to pregnancy, birth, and child care. A more determined and disciplined focus on those programs would in many settings enlarge choice, meet women's needs faster, improve the balance of methods in the mix, and raise the CPR.

Survey findings of the kind reported here need to be augmented by local studies to investigate reasons why certain methods experience a take-off. Central program initiatives always interact with public preferences and private-sector initiatives. Lessons from such studies can be drawn from cases like Uganda's, where the injectable has replaced traditional methods and where other methods, including the implant, now claim larger shares. A different type is that of Egypt, in which the IUD has proven popular, as it has elsewhere in the Middle East. Egypt illustrates the case of a strong private medical sector, which may also have had a role in the recent increase of the injectable. In neither region has sterilization been substantial. In sub-Saharan Africa the IUD has also been quite minor, and the availability of long-acting methods remains very problematic.

Supply and demand factors drive both method availability and method use. Such factors include policy and programmatic changes undertaken by the public sector, but they can also include widespread changes in social norms, economies, and the growing availability (and popularity) of private-sector health care services. A more detailed historical analysis of the conditions surrounding these changes can be instructive to enhance the understanding of what mediates these transitions and the extent to which they are replicable in other countries.

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APPENDIX 1. 123 Countries Included in the "Average Deviation" Method Mix Analysis, by Region

Country	Latest Survey Year
sub-Saharan Africa	
Angola	2001
Benin	2006
Burkina Faso	2010/11
Burundi	2010/11
Cameroon	2011
Cape Verde	2005
Central African Republic	2006
Chad	2004
Comoros	2000
Congo	2011/12
Congo, Democratic Republic of	2010
Côte d'Ivoire	2006
Djibouti	2006
Equatorial Guinea	2000
Eritrea	2002
Ethiopia	2010/11
Gabon	2000
Gambia	2001
Ghana	2008
Guinea	2005
Guinea-Bissau	2006
Kenya	2008/09
Lesotho	2009/10
Liberia	2007
Madagascar	2008/09
Malawi	2010
Mali	2006
Mauritania	2007
Mauritius	2002
Mozambique	2011
Namibia	2006/07
Niger	2006
Nigeria	2011
Rwanda	2010/11
Sao Tome and Principe	2008/09
Senegal	2010/11
Sierra Leone	2008
Somalia	2006
South Africa	2003/04
South Sudan	2006
Sudan	2010

APPENDIX 1 (continued).

Country	Latest Survey Year
Swaziland	2010
Tanzania	2009/10
Togo	2006
Uganda	2011
Zambia	2007
Zimbabwe	2010/11
North Africa & West Asia	
Algeria	2006
Armenia	2010
Azerbaijan	2006
Bahrain	1995
Egypt	2008
Georgia	2005
Iran	2002
Iraq	2011
Jordan	2009
Kuwait	1999
Lebanon	1996
Libya	1995
Morocco	2003/04
Oman	2000
Qatar	1998
Saudi Arabia	1996
Syria	2006
Tunisia	2006
Turkey	2008
United Arab Emirates	1995
Yemen	2006
Latin America	
Argentina	2004/05
Belize	2006
Bolivia	2008
Brazil	2006
Chile	2006
Colombia	2010
Costa Rica	2010
Cuba	2006
Dominican Republic	2007
Ecuador	2004
El Salvador	2008
Guatemala	2002
Guyana	2009
Haiti	2005/06
Honduras	2005/06

APPENDIX 1 (continued).

Country	Latest Survey Year
Jamaica	2002/03
Mexico	2006
Nicaragua	2006/07
Panama	2009
Paraguay	2008
Peru	2010
Puerto Rico	2002
Suriname	2006
Trinidad and Tobago	2006
Uruguay	2004
Venezuela	1998
Central Asia	1998
Kazakhstan	2006
Kyrgyzstan	2005/06
Tajikistan	2007
Turkmenistan	2000
Uzbekistan	2006
Asia & Pacific	
Afghanistan	2010
Bangladesh	2011/12
Bhutan	2010
Cambodia	2010/11
China	2006
Hong Kong	2007
India	2007/08
Indonesia	2007
Korea, Republic of	2009
Lao People's Democratic Republic	2005
Malaysia	2004
Maldives	2009
Mongolia	2008
Myanmar	2009/10
Nepal	2011
Pakistan	2012/13
Papua New Guinea	1996
Philippines	2011
Singapore	1997
Solomon Islands	2006/07
Sri Lanka	2006/07
Thailand	2009
Timor-Leste	2009/10
Viet Nam	2010/11

APPENDIX 2. Method Mix Among Contraceptive Users: Improvements in 15 Countries

Country	Survey Year	Sterilization, Female	Sterilization, Male	Pills	Injectables	IUD	Condom	Implants	Traditional Methods	Average Deviation Value
sub-Saharan Africa										
Benin	1981/82	-	1.5	4.5	-	1.5	3.0	-	89.4	19.2
Benin	1996	2.5	-	6.1	4.3	3.1	4.3	-	79.8	16.8
Benin	2001	1.6	-	9.8	11.4	4.3	7.1	1.6	64.1	12.9
Benin	2006	1.8	-	8.9	10.7	3.6	6.5	3.0	65.7	13.3
Mali	1987	2.2	-	19.6	2.2	2.2	-	-	73.9	17.1
Mali	1995/96	4.6	-	47.7	3.1	4.6	6.2	-	33.8	14.1
Mali	2001	3.7	-	34.6	25.9	2.5	3.7	1.2	28.4	12.8
Mali	2006	3.7	-	35.4	30.5	1.2	4.9	1.2	23.2	12.9
Rwanda	1983	-	-	1.8	3.6	2.7	-	-	91.8	19.8
Rwanda	1992	3.3	-	14.2	39.8	0.9	0.9	1.4	39.3	14.0
Rwanda	1996	-	-	17.4	29.7	2.2	1.4	1.4	47.8	14.4
Rwanda	2000	6.0	-	7.5	14.3	2.3	3.0	-	66.9	14.1
Rwanda	2005	2.9	-	13.9	27.2	1.7	5.2	-	49.1	13.2
Rwanda	2007/08	1.9	0.3	17.6	41.8	0.5	5.2	4.4	28.3	12.5
Rwanda	2010/11	1.6	-	13.8	51.1	1.0	5.6	12.2	14.8	10.5
Uganda	1988/89	16.3	-	22.4	8.2	4.1	-	-	49.0	12.6
Uganda	1995	9.5	-	17.7	17.0	2.7	5.4	-	47.6	11.2
Uganda	2000/01	8.8	-	14.0	28.1	0.9	8.3	1.3	38.6	10.8
Uganda	2004/05	8.7	-	15.3	49.5	1.0	5.1	1.5	18.9	11.5
Uganda	2006	10.2	0.4	12.3	43.2	0.8	7.2	1.3	24.6	10.7
Uganda	2011	9.6	0.3	9.6	46.8	1.7	9.0	9.0	14.0	8.9
North Africa & West Asia										
Egypt	1974/75	-	-	80.2	-	10.1	-	-	9.7	16.9
Egypt	1980	2.3	0.3	70.0	0.3	17.1	4.2	-	5.8	15.5
Egypt	1984	5.1	-	55.7	1.0	28.4	4.4	-	5.4	14.8
Egypt	1988	4.0	-	40.9	0.3	42.0	6.4	-	6.4	14.5
Egypt	1991	2.8	-	33.7	1.1	51.1	4.4	-	7.0	14.9
Egypt	1992	2.4	-	27.6	1.1	59.7	4.3	-	4.9	15.6
Egypt	1995	2.3	-	21.8	5.0	62.9	2.9	-	5.0	14.9
Egypt	1997/98	2.6	-	18.8	7.2	63.7	2.8	0.2	4.8	14.4

APPENDIX 2 (continued).

Country	Survey Year	Sterilization, Female	Sterilization, Male	Pills	Injectables	IUD	Condom	Implants	Traditional Methods	Average Deviation Value
Egypt	1998	2.5	-	16.9	7.6	66.5	2.1	-	4.5	14.6
Egypt	2000	2.5	-	17.0	10.9	63.5	1.8	0.4	3.9	13.9
Egypt	2003	1.5	-	15.5	13.2	61.2	1.5	1.5	5.7	13.1
Egypt	2005	2.2	-	16.7	11.8	61.7	1.7	1.4	4.6	13.3
Egypt	2008	1.7	-	19.7	12.3	59.9	1.2	0.8	4.5	13.7
Iran	1976/77	5.7	-	49.7	-	4.0	11.5	-	29.0	13.4
Iran	1989	8.0	-	36.3	-	7.4	11.4	-	36.9	12.0
Iran	1992	11.8	1.4	35.0	-	11.0	9.9	-	31.0	10.2
Iran	1993	13.7	1.5	36.5	-	10.7	10.0	-	27.7	10.1
Iran	1994	16.3	1.8	32.3	0.7	11.5	9.7	-	27.8	9.7
Iran	1995	19.3	1.8	32.1	1.8	10.0	8.0	-	27.0	10.2
Iran	1996	20.6	2.2	30.0	3.4	11.4	7.7	-	24.7	9.5
Iran	1997	21.4	2.6	28.9	4.0	11.5	7.5	0.7	23.4	9.1
Iran	2000	23.2	3.7	25.0	3.8	11.5	8.0	0.7	24.2	8.7
Iran	2002	20.8	3.1	34.3	3.1	10.4	8.2	0.5	19.5	9.3
Turkey	1963	0.4	-	3.8	-	-	16.3	-	79.5	17.7
Turkey	1968	0.3	-	5.8	-	4.2	11.5	-	78.2	16.4
Turkey	1973	0.3	-	12.6	-	7.9	12.4	-	66.8	13.6
Turkey	1978	1.2	0.4	16.2	0.8	8.0	8.2	-	65.2	14.1
Turkey	1983	2.3	-	15.4	0.4	15.1	8.3	-	58.5	12.9
Turkey	1988	2.8	0.2	10.1	0.2	22.7	11.7	-	52.4	12.5
Turkey	1993	4.7	-	8.0	0.2	30.6	10.7	-	45.8	12.8
Turkey	1998	6.6	-	7.0	0.8	31.3	13.0	-	41.3	12.0
Turkey	2003	8.1	0.1	6.7	0.6	28.7	15.3	-	40.5	11.8
Turkey	2008	11.4	0.1	7.3	1.2	23.2	19.6	-	37.1	10.6
Latin America										
Colombia	1969	-	-	23.4	-	13.2	7.3	-	56.1	13.8
Colombia	1976	10.0	0.5	33.2	1.0	21.2	4.2	-	29.9	11.7
Colombia	1978	17.2	-	39.5	2.3	17.7	3.2	-	20.0	11.1
Colombia	1980	22.5	0.4	36.6	4.2	17.1	3.2	-	16.0	10.6
Colombia	1986	29.3	0.6	26.2	3.8	17.6	2.7	-	19.7	10.7
Colombia	1990	32.5	0.8	21.9	3.4	19.3	4.5	-	17.7	10.3

APPENDIX 2 (continued).

Country	Survey Year	Sterilization, Female	Sterilization, Male	Pills	Injectables	IUD	Condom	Implants	Traditional Methods	Average Deviation Value
Colombia	1995	36.3	1.0	18.2	3.5	15.7	6.1	1.0	18.2	9.6
Colombia	2000	35.5	1.3	15.5	5.2	16.3	8.0	0.3	18.0	8.8
Colombia	2004/05	40.2	2.3	12.5	7.5	14.4	9.1	0.4	13.6	7.7
Colombia	2010	44.2	4.3	9.6	11.6	9.5	8.9	3.9	8.0	7.9
Guyana	1975	27.9	-	29.5	-	18.4	-	-	24.3	12.5
Guyana	1991/92	17.3	-	35.1	5.2	24.1	14.8	-	3.6	10.3
Guyana	2000	12.2	0.3	30.4	10.0	17.1	23.8	2.7	3.5	8.4
Guyana	2005	8.8	-	36.0	11.2	22.4	18.0	0.3	3.2	9.7
Guyana	2006	5.1	-	38.1	10.7	16.4	17.3	8.0	4.5	8.6
Guyana	2009	12.5	-	21.7	11.3	17.2	30.4	0.5	6.4	8.0
Haiti	1977	1.1	1.1	17.4	1.1	2.6	5.8	-	71.1	15.9
Haiti	1983	10.1	1.4	31.9	2.9	2.9	7.2	-	43.5	12.6
Haiti	1987	18.8	-	33.3	11.6	5.8	2.9	-	27.5	10.6
Haiti	1989	24.8	-	40.6	15.8	5.9	5.0	-	7.9	10.9
Haiti	1994/95	17.1	-	17.1	14.9	3.3	14.4	6.6	26.5	6.9
Haiti	2000	9.9	-	8.2	41.8	2.1	10.3	7.1	20.6	9.4
Haiti	2005/06	6.5	-	10.2	34.1	1.9	16.4	5.0	26.0	9.7
Honduras	1981	30.5	0.8	44.7	1.1	9.2	1.1	-	12.6	12.6
Honduras	1984	35.0	0.6	36.7	0.9	11.0	2.6	-	13.3	11.9
Honduras	1987	31.3	0.5	33.3	0.7	10.7	4.5	-	18.9	11.5
Honduras	1991/92	33.6	0.4	21.8	1.1	11.0	6.3	-	25.9	10.9
Honduras	1996	36.3	0.2	19.8	2.2	17.0	6.4	-	18.0	10.3
Honduras	2001	29.1	0.3	16.8	15.5	15.5	5.2	-	17.5	8.0
Honduras	2005/06	32.5	0.5	17.3	21.2	10.1	4.4	-	14.0	8.7
Paraguay	1979	7.7	-	34.5	5.0	15.4	4.8	-	32.6	11.2
Paraguay	1987	10.0	-	30.1	8.0	11.4	5.1	-	35.3	10.1
Paraguay	1990	15.5	-	28.5	10.9	11.9	5.5	-	27.7	8.5
Paraguay	1995/96	13.4	-	24.1	11.1	13.6	11.6	-	26.3	6.8
Paraguay	1998	13.1	-	21.4	12.2	18.1	11.9	-	23.3	6.5
Paraguay	2004	15.8	0.1	20.6	14.3	15.8	16.4	-	16.9	6.2
Paraguay	2008	12.5	0.3	22.7	20.8	15.5	16.6	-	11.7	6.4

APPENDIX 2 (continued).

Country	Survey Year	Sterilization, Female	Sterilization, Male	Pills	Injectables	IUD	Condom	Implants	Traditional Methods	Average Deviation Value
Peru	1969/70	8.0	-	12.0	-	4.0	12.0	-	64.0	12.9
Peru	1977/78	9.2	-	13.7	3.3	4.2	3.6	-	66.0	13.7
Peru	1981	10.0	-	12.5	5.0	10.0	2.5	-	60.0	11.9
Peru	1986	13.6	-	14.5	2.9	16.5	1.6	-	50.9	11.4
Peru	1991/92	13.6	0.2	9.8	3.3	23.1	4.8	-	45.2	11.1
Peru	1996	15.0	0.3	9.8	12.6	18.9	6.9	0.5	36.1	8.1
Peru	2000	18.0	0.7	9.8	21.7	13.3	8.2	0.3	28.0	7.7
Peru	2004/06	14.6	0.6	10.1	20.7	7.9	11.9	-	34.3	8.0
Peru	2007/08	13.6	0.4	10.6	22.8	5.6	13.8	-	33.2	8.4
Peru	2009	12.9	0.6	10.5	24.9	5.2	13.8	-	32.1	8.4
Peru	2010	12.5	0.5	11.2	23.6	4.4	15.1	0.1	32.6	8.4
Asia										
Mongolia	1994	1.6	-	4.4	1.9	57.7	5.9	0.5	28.0	15.2
Mongolia	1998	4.0	-	7.0	5.2	53.8	5.8	0.3	23.9	13.2
Mongolia	2000	1.9	0.3	12.4	8.7	50.2	6.4	0.4	19.5	11.2
Mongolia	2003	4.4	-	16.0	8.4	47.6	7.8	0.4	15.4	10.4
Mongolia	2005	3.7	0.2	17.6	16.9	44.1	8.1	1.2	8.2	10.3
Mongolia	2008	4.7	-	17.7	14.4	40.6	12.2	0.4	10.0	8.8
Viet Nam	1988	5.1	0.6	0.8	0.4	62.1	2.3	-	28.9	16.5
Viet Nam	1994	6.0	0.3	3.2	0.3	51.3	6.2	-	32.7	14.7
Viet Nam	1997	8.4	0.7	5.7	0.3	51.2	7.8	-	25.9	13.0
Viet Nam	2000	8.2	0.8	7.3	0.5	49.9	8.2	-	25.0	12.5
Viet Nam	2000	7.9	0.6	9.5	0.7	57.4	8.0	-	16.0	12.1
Viet Nam	2001	7.7	0.5	10.0	0.7	55.8	7.9	-	17.3	12.0
Viet Nam	2002	7.5	0.6	8.0	0.5	48.0	7.4	-	27.9	12.7
Viet Nam	2002	7.2	0.5	10.4	0.9	56.6	8.5	-	15.9	11.9
Viet Nam	2003	6.9	0.5	11.4	0.9	57.0	7.4	-	15.7	11.9
Viet Nam	2004	6.6	0.4	11.9	1.1	56.0	9.3	-	14.7	11.4
Viet Nam	2005	6.3	0.4	12.5	1.2	55.5	9.7	-	14.5	11.3
Viet Nam	2006	5.5	0.2	10.6	1.5	54.9	11.0	-	16.3	11.6
Viet Nam	2006	7.7	0.7	11.9	1.6	47.6	10.1	0.1	20.3	10.7
Viet Nam	2007	5.6	0.4	13.2	1.1	55.4	10.5	0.1	13.7	11.2
Viet Nam	2010/11	5.0	0.1	13.0	2.2	40.0	16.4	0.3	23.0	10.6

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ORIGINAL ARTICLE

A Resource Planning Analysis of District Hospital Surgical Services in the Democratic Republic of the Congo

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District hospitals in the DRC, on average, could not provide 21% of lifesaving surgical interventions due to deficiencies in basic infrastructure and essential surgical equipment and supplies. Surgery's important health impact and proportionally low service delivery budget argue for greater emphasis on surgical interventions, including for obstetric care.

ABSTRACT

Background: The impact of surgical conditions on global health, particularly on vulnerable populations, is gaining recognition. However, only 3.5% of the 234.2 million cases per year of major surgery are performed in countries where the world's poorest third reside, such as the Democratic Republic of the Congo (DRC).

Methods: Data on the availability of anesthesia and surgical services were gathered from 12 DRC district hospitals using the World Health Organization's (WHO's) Emergency and Essential Surgical Care Situation Analysis Tool. We complemented these data with an analysis of the costs of surgical services in a Congolese norms-based district hospital as well as in 2 of the 12 hospitals in which we conducted the situational analysis (Demba and Kabare District Hospitals). For the cost analysis, we used WHO's integrated Healthcare Technology Package tool.

Results: Of the 32 surgical interventions surveyed, only 2 of the 12 hospitals provided all essential services. The deficits in procedures varied from no deficits to 17 services that could not be provided, with an average of 7 essential procedures unavailable. Many of the hospitals did not have basic infrastructure such as running water and electricity; 9 of 12 had no or interrupted water and 7 of 12 had no or interrupted electricity. On average, 21% of lifesaving surgical interventions were absent from the facilities, compared with the model normative hospital. According to the normative hospital, all surgical services would cost US$2.17 per inhabitant per year, representing 33.3% of the total patient caseload but only 18.3% of the total district hospital operating budget. At Demba Hospital, the operating budget required for surgical interventions was US$0.08 per inhabitant per year, and at Kabare Hospital, US$0.69 per inhabitant per year.

Conclusion: A significant portion of the health problems addressed at Congolese district hospitals is surgical in nature, but there is a current inability to meet this surgical need. The deficient services and substandard capacity in the surveyed district hospitals are systemic in nature, representing infrastructure, supply, equipment, and human resource constraints. Yet surgical services are affordable and represent a minor portion of the total operating budget. Greater emphasis should be made to appropriately fund district hospitals to meet the need for lifesaving surgical services.

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BACKGROUND

The impact of surgical conditions on global health, and particularly on vulnerable populations such as women and children, the poor, and rural communities, is gaining recognition. In fact, Debas and colleagues found that 11% of the worldwide global burden of disease is due to surgical conditions, including injuries, malignancies, congenital anomalies, and obstetrical complications.[1] However, of the estimated 234.2 million major surgical cases per year

performed,[2] only 3.5% of them are performed in countries where the world's poorest third reside, such as the Democratic Republic of the Congo (DRC).

Is surgery only for the rich? Emerging evidence sheds light on misconceptions regarding surgical care delivery, such as its high service resource needs with tertiary-level technical requirements.[3] Furthermore, studies have shown the critical need for access to quality surgical obstetric care to reduce maternal mortality. Based on data from a number of studies, Ronsmans et al. concluded that estimates falling below 1,000 surgical interventions per 100,000 live births in urban areas reflect a real deficit in access to lifesaving essential obstetric surgery.[4] Surgical care is needed not only for obstetrics and violence-related trauma but also for general morbidities in conflict zones, as demonstrated by a Médecins Sans Frontières study in the DRC province of North Kivu.[5] Of the 3,000 operations performed over a 2-year period in that study, only one-quarter were directly related to violence, suggesting that the need for general surgical interventions in the country is so acute that when surgical services are offered in the context of emergency humanitarian aid, the uptake for general surgery is actually greater than for trauma surgery.

DRC has a population of over 60 million, with health indicators trailing behind most other countries in the region,[6,7] mainly because of the deteriorated state of the health system and the continuous presence of armed conflict since the late 1990s. DRC's war was officially over in 2002, yet the devastating effects linger, reinforced by sporadic violence.[8] The need for general surgical and other medical services is widespread throughout the country.

In 2006, in an attempt to address these prevalent public health problems, the DRC Ministry of Health (MOH) expressed its commitment to the principles of primary health care with the creation of its *Stratégie du Renforcement du Système de Santé* (Health Systems Strengthening Strategy, or HSSS), which introduced a framework within which to provide primary health care services, including basic surgical and obstetric care, at the district level (called *zone de santé*).[9]

In this article, we assess the capacity of 12 district hospitals in the DRC to provide surgical services, using the World Health Organization's (WHO's) Emergency and Essential Surgical Care (EESC) Situation Analysis Tool. We also used another WHO tool, the integrated Healthcare Technology Package (iHTP) resource planning and costing tool, to perform a theoretical costing exercise for surgical and other health services using a Congolese norms-based district hospital (i.e., a district hospital that would provide all services according to national norms). Our hypothesis is that surgical services are affordable and represent a minor portion of a hospital's total operating budget.

Only 3.5% of major surgical cases are performed in countries where the world's poorest third reside.

METHODS

To operationalize the HSSS objectives, the Ministry of Health developed a comprehensive resource planning database in 2007–2008. This database detailed all resources and associated budget implications necessary to provide the minimum acceptable number and range of interventions to be included in a locally appropriate district health care package. The spectrum of health care provisions at the district level is referred to as the *Paquet Complémentaire d'Activités* (Complementary Package of Activities, or CPA, i.e., complementary to the Minimum Package of Activities that is offered at health center level). The CPA is a list of services that a district hospital should provide for a normative district population of 100,000. The CPA, in turn, created the foundation to generate a hypothetical hospital, referred to as the Model Normative Hospital, for DRC's MOH and for the purposes of this study. (The MOH also details the resources necessary for the minimum package of activities, but that is beyond the scope of this paper.)

The development of the Model Normative Hospital allows a dynamic understanding of what is a reasonable, appropriate, and attainable standard of health care in the DRC. In light of this standard, we conducted a situation analysis of the availability of emergency and essential surgical care in a sample of 12 existing district hospitals (Table 1). In addition, we modeled resource and budget data for 2 of the 12 hospitals in order to complement and validate the information from the situation analysis on resource needs and budget gaps in the DRC.

WHO EESC Situational Analysis Tool

The WHO ''Tool for Situational Analysis to Assess Emergency and Essential Surgical Care'' is a questionnaire that includes 108 data points, created to analyze the availability of emergency anesthesia and surgical services in health care

TABLE 1. Hospitals Included in the Situational Analysis and Their Locations, Democratic Republic of the Congo

Facility	Province	Region	District	Type of Hospital
Abuzi	Equateur	North	Abuzi	District
Bwamanda	Equateur	North	Bwamanda	District
Demba	Kasaï Occidental	Central	Demba	District
Goma	North Kivu	East	Goma	Tertiary level
Kabare	South Kivu	East	Kabare	District
Kinkanda	Bas-Congo	West	Matadi	District
Kirotshe	North Kivu	East	Kirotshe	District
Lubumbashi	Katanga	South	Lubumbashi	Tertiary level
Mulongo	Katanga	South	Mulongo	NGO/Mission
Panzi	South Kivu	East	Ibanda	NGO/Mission
Wapinda	Equateur	North	Wapinda	District
Yakoma	Equateur	North	Yakoma	District

The WHO Tool for Situational Analysis to Assess Emergency and Essential Surgical Care analyzes facility capacity in infrastructure, human resources, equipment, and surgical interventions.

facilities.[10] It was developed by the Global Initiative for EESC research group, with input from various MOHs, WHO country and regional offices, and health care providers representing all WHO regions. The tool has already been used in several developing countries to confirm enormous deficiencies in their capacity to deliver essential surgery and anesthesia care.[3]

The situational analysis tool is comprised of 4 sections assessing:

1. **Infrastructure:** availability of basic needs such as water, electricity, oxygen, operating rooms, and functioning anesthesia machines, among others
2. **Human resources:** numbers of health care providers at the facility, focusing on those who perform surgery, anesthesia, and obstetrics
3. **Equipment:** availability of items on the WHO generic list of ''Essential Emergency Equipment''
4. **Interventions:** surgical procedures provided versus referred and, if referred, whether due to lack of skills, supplies, or functional equipment

We collected the situation analysis data at 12 district hospitals through onsite visits and interviews, in collaboration with the WHO Country Office, the DRC MOH, and local health managers and providers.

Integrated Healthcare Technology Package Tool

The iHTP tool is an intervention-based tool for resource planning analysis, created with detailed input data reflecting specific local health care needs.[11] The tool links health care resources to disease profiles, patient demographics, clinical practice pathways, and technology requirements, providing resource needs and budget assessment for a given country.

Following the iHTP tool methodology, we divided and subdivided each health care intervention detailed in the CPA into specific building blocks that take into account all the essential components needed to perform the intervention (i.e., human resources, medical devices, consumable items, pharmaceuticals, and health facilities infrastructure, with corresponding resource prices and time use). All these components are connected in an algorithm format within the iHTP software tool. The algorithms are dynamic pathways of the various interventions. These can be used for simulation and analysis and tailored to

represent specific disease treatments, such as those created by the WHO *Surgical Care at the District Hospital* manual,[12] as well as preventive services and management. More information on the iHTP tool and the specific data entry process in the DRC has been described in a previous paper.[13]

Salaries and prices for each essential component were entered into the iHTP software tool in 2008 USD, and an operating budget was calculated, assuming that the basic capital equipment and the building exist and are functioning. Thus, only operating costs were calculated; capital investment costs were not included in this study (Table 2).

Large medical equipment depreciation was calculated according to the actual duration of time it was used per procedure across a defined equipment-specific life cycle (usually 5–20 years). Health facility depreciation was also calculated according to usage per procedure across a defined facility building cost. Building maintenance and utilities were added to the total health facility operating budget. Consumable items and drug quantities were calculated according to the total amount necessary for each procedure. Human resource salaries were taken from the Mbudi agreement between the Congolese government and labor unions on civil servant salaries.[14]

Establishing the DRC Benchmark: The Model Normative District Hospital

The Model Normative Hospital was designed to understand the specific needs of the Congolese population while keeping the limitations of health care delivery in the DRC at the forefront in its design. Based on the HSSS to represent a standard from the MOH, the Model Normative Hospital aims to provide essential primary health care services for all inhabitants. The hospital serves as a theoretical model for fully functioning DRC district hospitals to strive for in terms of functionality, resource usage, utilization, and interventions provided.

The main assumptions are that the hospital covers the CPA as described above for a normative district population of 100,000. The CPA includes medical, surgical, anesthetic, pediatric, and obstetrical interventions, as well as preventive and management services. Model Normative Hospital staff salaries were based on a national directive,[14] and medical devices, equipment, drugs, and infrastructure data were based on national clinical guidelines, textbooks used in local medical schools, and expert consensus opinion.

The Model Normative Hospital utilization rate of 0.15 cases per inhabitant per year was agreed upon within the MOH after surveying utilization rates across several well-run district hospitals in the DRC. Very few hospitals were able to demonstrate utilization rates above 0.2; hence, it was decided that a realistic utilization rate, even if not high, was necessary for planning purposes in order to stay within the Congolese context, even within the realm of the Model Normative Hospital.

Facilities in the DRC were assessed for 32 EESC situation analysis interventions, ranging from simple suturing to higher skilled laparotomy. These corresponded with the CPA interventions in the Model Normative Hospital, permitting correlation to surgical budget estimates in the iHTP tool.

Selection of Hospital Sites for Costing Data

Direct observation of patient care in 2 hospitals, Demba and Kabare Hospitals, was performed over a period of 1 month in 2008–2009. Demba Hospital is situated in Kasaï Occidentale province and Kabare Hospital in the Eastern Sud-Kivu province. These 2 hospitals were a convenience sample, selected as part of the MOH's efforts to harmonize health services across districts. Demba and Kabare districts were both supported by an NGO that expressed a need to study the costs of providing CPA services. The data and study led to the development of Demba and Kabare Hospital-specific algorithms using the iHTP software tool. The algorithms selected were based on the CPA. Hospital registries, price lists, procurement bills, and all other relevant materials were studied and discussed with the local District Management Team. Salaries were calculated by adding the government base salary and the local salary supplement paid by the NGO supporting the hospital. All data were entered into the iHTP software for resource and budget calculations. An overview of price data sources is given in Table 3.

RESULTS

We first present an analysis of the operating budget and utilization of surgical services for the Model Normative Hospital, Demba Hospital, and Kabare Hospital. Then we provide data from the situation analysis of surgical (including anesthesia and obstetrics) care in 12 district hospitals, including Demba and Kabare Hospitals.

TABLE 2. Costs Included and Not Included in the DRC Hospital Resource Planning Exercise

Costs	Examples
Included	
Clinical interventions	• General anesthesia • Applying a cast • X-ray
Referral costs as defined by country	• Ambulance • Medical services during transport
Health facility administration	• Hospital manager salary • Office equipment
District health administration	• District health manager salary • Supervisory visits
Not Included	
Capital investments to rehabilitate health facilities	• Building repairs or construction of new building
Preservice human resource training	• University education for medical officers
Infrastructure outside the health care facility	• Paved roads for better access

Abbreviation: DRC, Democratic Republic of the Congo.

TABLE 3. Source of Price Data in the DRC Resource Planning Exercise by Resource Type

Resource Type	Source of Price Data
Human	• Mbudi agreement + NGO salary top-up (Demba and Kabare)
Pharmaceuticals	• Price list from 3 medicine distribution centers[a] + IDA list price
Medical equipment	• MOH and donors (per unit purchase price)
Health facility infrastructure	• Building: Ministry of Infrastructure, Public Works, and Reconstruction (per m^2) • Cleaning: 2.5% of building per year • Utility management: 1.5% of building per month • Maintenance: 2.5% of building per year
Consumable/disposable items	• MOH and district hospitals (per unit purchase price)

Abbreviations: DRC, Democratic Republic of the Congo; IDA, International Development Assistance; MOH, Ministry of Health; NGO, nongovernmental organization.
[a] Association Régionale D'Approvisionnement en Médicaments Essentiels (ASRAMES), Centrale de Distribution de Médicaments Essentiels du Kasaï Occidental (CADIMEK), and La Centrale d'Achat et de Distribution de Médicaments Essentiels de Kinshasa (CAMESKIN).

iHTP Results

The total operating budget necessary for *all* hospital services at the Model Normative Hospital was calculated at US$11.86 per inhabitant per year at a utilization rate of 0.15 cases per inhabitant per year (Table 4). This total comprises all necessary health care resources, including human resources, consumable supplies, equipment, drugs, and infrastructure (including utilities), for a CPA that includes curative medical, obstetric, pediatric, surgical, and anesthesia services as well as preventive services and management activities. We calculated the operating budget for surgical services specifically (interventions ranging from simple wound suturing to obstetric and anesthesia interventions) at US$2.17 per inhabitant per year, representing 18% of the total operating budget for all hospital services and 33.3% of the total patient caseload.

At Demba Hospital, the operating budget required for surgical interventions, at US$0.08 per inhabitant per year, comprised 24% of the total operating budget necessary for all hospital services. The proportion of the patient caseload requiring surgery was found to be 9% of the total caseload.

At Kabare Hospital, the operating budget necessary for surgical interventions, at US$0.69 per inhabitant per year, comprised 20% of the total operating budget necessary for all hospital services. Only 3.33% of the total patient caseload represented surgical interventions.

For a detailed analysis of the cost of surgical services at Demba and Kabare Hospitals, see the supplementary material.

Situational Analysis Results

We completed the situational analysis tool for 12 district hospitals, each serving as the first referral level for a collection of health centers in a specific health district. The populations served at the district level ranged from 70,000 to 252,000, with notable differences in the capacities of individual facilities as detailed below.

The operating budget for surgical services at the Model Normative Hospital was US$2.17/ inhabitant/year, or 18% of the hospital's total operating budget.

The basic infrastructure varied between facilities (Table 5). The average number of beds was 150, with a range of 65 to 350. Hospital admissions ranged from 600 yearly to 5,000. Five hospitals had only 1 operating room, while 3 other hospitals had 4 or more operating rooms. Only 3 hospitals had uninterrupted running water and electricity. Four hospitals were without running water and 5 had interrupted running water. Five facilities had uninterrupted electricity, 5 others had interrupted electricity, and the remaining 2 did not have electricity at all.

Of the 12 hospitals, only 2 (Bwamanda and Panzi) were fully equipped with basic essential

TABLE 4. Calculated Operating Budget and Utilization Rate[a] for Selected DRC Hospitals by Type of Hospital Service

Hospital	Surgery (including obstetrics)	Total (for all hospital services)	Surgery Component of Total
Normative Hospital			
Costs	$2.17	$11.86	18.30%
Utilization rate	0.05	0.15	33.30%
Demba Hospital			
Costs	$0.08	$0.31	24.20%
Utilization rate	0.003	0.03	9.00%
Kabare Hospital			
Costs	$0.69	$3.40	20.20%
Utilization rate	0.01	0.15	3.33%

Abbreviation: DRC, Democratic Republic of the Congo.
[a] Costs are per inhabitant per year in US$. Utilization rate is the number of cases per inhabitant per year.

TABLE 5. Basic Infrastructure Capacity of Selected DRC District Hospitals

Equipment/Supplies	Abuzi	Bwamanda	Demba	Goma	Kabare	Kinkanda	Kirotshe	Lubumbashi	Mulongo	Panzi	Wapinda	Yakoma
Catchment area	80,000	200,000	252,000	100,000	155,000	165,000	280,000	200,000	100,000	150,000	70,000	100,000
No. of beds	65	242	65	245	150	150	150	200	150	350	90	65
No. of admissions/ year	850	5,000	1,500	5,000	5,000	4,000	5,000	4,032	3,500	5,000	600	1,500
No. of surgical cases/year	250	3,500	600	1,000	1,500	850	850	2,345	850	3,500	150	250
No. of operating rooms	1	2	1	2	4	4	1	3	3	5	1	1
Running water, frequency of availability	X	O	X	✓	O	✓	O	O	O	✓	X	X
Electricity, frequency of availability	O	✓	O	✓	O	✓	✓	O	X	✓	X	O

Abbreviations: DRC, Democratic Republic of the Congo; ✓, Always; X, Never; O, Sometimes.

equipment and supplies (Table 6). In addition, only 4 facilities had a functioning anesthesia machine and could provide general anesthesia (data not shown). Six facilities were without an oxygen supply. Similarly, 8 hospitals lacked consistent access to mask and tubing to connect to an oxygen source. Three facilities did not have a resuscitator bag valve and mask, 5 facilities did not have an oropharyngeal airway, and 6 facilities did not have chest tube insertion equipment.

From the 32 interventions surveyed on the situational analysis tool, only 2 hospitals, Panzi and Lubumbashi, were found to provide all the essential services (Table 7). The deficits in essential procedures varied from no deficits to 17, with an average of 7 essential procedures unavailable across this sample. For general and pediatric surgery, 7 of 12 facilities had deficiencies.

Six procedures in the general and pediatric surgery category were more commonly performed and were available at all facilities, consisting of abscess incision and drainage, hydrocele repair, hernia repair, appendectomy, laparotomy, and male circumcision (Table 7). For orthopedics and trauma, suturing and wound debridement were the only 2 services provided at all 12 facilities. However, treatment for dislocated joints was provided at only 5 of 12 facilities and open fracture repair at 6 of 12 facilities. Of the 10 orthopedic and trauma procedures, Yakoma was capable of offering only 2 of the procedures, Abuzi and Wapinda offered 3, and only 5 facilities offered all procedures. For obstetrics and gynecology, all facilities were able to offer cesarean deliveries and dilation and curettage. Obstetric fistula repair was available at 6 facilities. Anesthesia care was deficient at most facilities, with only 4 of 12 facilities offering general inhalation anesthesia.

The 12 facilities together lacked an average of 21% of interventions, ranging from 0% in Lubumbashi and Panzi to 56% at Yakoma (Table 8).

Patients traveled between 35 km and 150 km to seek surgical care in the district hospitals observed in this study. If the surgical need was not met in the district hospitals observed, the farthest distance to the next facility to access surgical care ranged from 8 km to 300 km, and in one extreme case, patients from Equateur province traveled as far as 2,000 km to the capital Kinshasa to be treated (Table 8). The median distance to the next closest facility was 65 km.

DISCUSSION

This article presents a comprehensive resource and operating budget analysis of anesthesia and surgical (including obstetrics) services within a cohort of Congolese district hospitals. As the first of its kind using a normative model, the in-depth analysis is based not on international standards but on what is considered locally appropriate. This method makes it possible to estimate the minimum operating budget for surgical services at the Model Normative Hospital, which demonstrated that the cost for surgery is proportionally low as a percentage of the total operating cost at the district hospital level in the DRC. This finding is important when comparing deficiencies between existing district hospitals and the normative model because of the resulting resource allocation implications.

Only 2 of 12 hospitals provided all essential surgical services.

Analysis of the operating budget necessary for surgical (including obstetrics and anesthesia) services at the Model Normative Hospital demonstrated that 18.3% of the total operating

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An ill-equipped operating room at a district hospital in the DRC (top) compared with a fully equipped one in another district (bottom).

TABLE 6. Frequency of Availability of Essential Equipment and Supplies at Selected DRC Hospitals

Equipment/Supplies	Abuzi	Bwamanda	Demba	Goma	Kabare	Kinkanda	Kirotshe	Lubum-bashi	Mulongo	Panzi	Wapinda	Yakoma
Gloves, sterile, sizes 6–8	O	✓	✓	✓	✓	✓	✓	✓	✓	✓	O	✓
Oropharyngeal airway, adult	X	✓	X	✓	✓	✓	X	O	✓	✓	X	X
Resuscitator bag valve and mask, adult	X	✓	X	O	✓	O	✓	✓	✓	✓	X	O
Mask and tubing to connect oxygen supply	X	✓	X	✓	X	O	✓	O	O	✓	X	X
Oxygen source (cylinder/concentrator)	X	✓	X	✓	X	O	✓	✓	X	✓	X	X
Chest tubes insertion equipment	X	✓	X	✓	X	✓	X	O	O	✓	X	X

Abbreviations: DRC, Democratic Republic of the Congo; ✓, Always; X, Never; O, Sometimes.

TABLE 7. Range of Surgical Interventions Performed at Selected DRC Hospitals

Procedure	Abuzi	Bwamanda	Demba	Goma	Kabare	Kinkanda	Kirotshe	Lubumbashi	Mulongo	Panzi	Wapinda	Yakoma
General and Pediatric Surgery												
Resuscitation	+	+	+	+	+	+	+	+	+	+	–	–
Abscess incision and drainage	+	+	+	+	+	+	+	+	+	+	+	+
Biopsy	–	+	–	–	+	+	–	+	+	+	–	–
Hydrocele	+	+	+	+	+	+	+	+	+	+	+	+
Hernia	+	+	+	+	+	+	+	+	+	+	+	+
Appendectomy	+	+	+	+	+	+	+	+	+	+	+	+
Laparotomy	+	+	+	+	+	+	+	+	+	+	+	+
Contracture release/skin graft	–	+	–	+	+	+	–	+	+	+	–	–
Tracheostomy/Cricothyroidotomy	–	+	–	+	–	+	+	+	+	+	–	–
Congenital hernia	+	+	+	+	+	+	+	+	+	+	+	–
Neonatal surgery	–	+	–	+	–	+	+	+	+	+	+	+
Male circumcision	+	+	+	+	+	+	+	+	+	+	+	+
Orthopedics and Trauma												
Suturing	+	+	+	+	+	+	+	+	+	+	+	+
Wound debridement	+	+	+	+	+	+	+	+	+	+	+	+
Burn	+	+	+	+	+	+	+	+	+	+	–	–
Foreign body removal	–	+	–	+	+	+	+	+	+	+	–	–
Joint dislocation	–	+	–	+	–	–	–	+	+	+	–	–
Closed fracture repair	–	+	–	+	–	+	+	+	+	+	–	–
Open fracture repair	–	+	–	+	–	+	–	+	+	+	–	–
Osteomyelitis/septic arthritis drainage	–	+	–	+	+	+	–	+	+	+	+	–
Amputation	–	+	–	+	+	+	+	+	+	+	–	–
Chest tube insertion	–	+	+	+	–	+	–	+	+	+	–	–

TABLE 7 (continued).

Procedure	Abuzi	Bwamanda	Demba	Goma	Kabare	Kinkanda	Kirotshe	Lubumbashi	Mulongo	Panzi	Wapinda	Yakoma
Obstetrics/Gynecology and Other												
Dilation and curettage	+	+	+	+	+	+	+	+	+	+	+	+
Tubal ligation	+	+	−	+	+	−	+	+	+	+	−	+
Cesarean delivery	+	+	+	+	+	+	+	+	+	+	+	+
Obstetric fistula	−	+	−	−	−	+	−	+	+	+	−	−
Cystostomy	+	+	−	+	+	+	+	+	+	+	+	+
Urethral stricture dilation	−	+	+	+	+	+	+	+	+	+	−	−
Anesthesia Care												
Ketamine	+	+	+	+	+	+	+	+	+	+	+	+
Regional	−	+	−	+	+	+	+	+	+	+	−	−
Spinal	+	+	+	+	+	+	+	+	+	+	+	+
General anesthesia	−	−	−	+	−	+	−	+	−	+	−	−

Abbreviation: DRC, Democratic Republic of the Congo.

TABLE 8. Summary of Surgical Deficiencies at Selected DRC Hospitals Compared With Benchmark of DRC Model Normative Hospital

	Normative	Abuzi	Bwamanda	Demba	Goma	Kabare	Kinkanda	Kirotshe	Lubumbashi	Mulongo	Panzi	Wapinda	Yakoma
Catchment area, thousands	100	80	200	252	100	155	165	280	1,000	100	1,000	70	100
Maximum distance to next facility, km	NA	65	2,000	90	300	65	250	15	8	–	10	65	65
EESC capacity (of total 32 interventions)	32	17	31	17	30	24	30	23	32	31	32	15	14
Surgical intervention deficiencies[a]	0%	47%	3%	47%	6%	25%	6%	28%	0%	3%	0%	53%	56%
Cost per inhabitant per year, US$	2.17	NA	NA	0.08	NA	0.69	NA	NA	NA	NA	NA	NA	NA

Abbreviations: DRC, Democratic Republic of the Congo; EESC, emergency essential and surgical care; NA, not applicable.
[a] Calculated as 100 – (EESC capacity/32).

budget, or US$2.17 per inhabitant per year, is necessary to deliver surgical services. Hence, providing surgical services in the DRC is not out of reach, as this 18.3% of the budget implies covering one-third of the total Model Normative Hospital patient caseload. At Demba Hospital, the operating budget required for surgical interventions, at US$0.08 per inhabitant per year, comprised 24% of the total operating budget necessary for all Demba hospital services. The proportion of the patient caseload requiring surgery was found to be 9% of the total caseload. At Kabare Hospital, the operating budget necessary for surgical interventions, at US$0.69 per inhabitant per year, comprised 20% of the total operating budget necessary for all Kabare hospital services. Only 3.33% of the total patient caseload represented surgical interventions. The explanation for this inverse finding is that the proportional budget allocated to surgery is higher if the overall and surgical caseload (utilization rate) of a given hospital is low.

As anticipated, there are remarkable shortcomings at the district hospitals within all categories of the situational analysis. From basic infrastructure such as running water and electrical power to the specific needs of surgical services, there is a glaring lack of basic supplies, personnel, and equipment. These deficiencies contribute to the limitations in availability and capacity to provide lifesaving surgical services across our sample of DRC district hospitals. An average of 21% of lifesaving interventions were absent from the facilities compared with the Model Normative Hospital.

On average, 21% of lifesaving interventions were absent from the surveyed facilities.

While the deficiencies in these hospitals are broad and pervasive, the situational analysis permits a degree of understanding of these facilities' capabilities and areas in which capacity is the weakest. Notably absent from many facilities is the capacity to provide general anesthesia with functioning anesthesia machines. Most hospitals rely on local, spinal, or IV sedation for anesthesia services without regard to complexity or length of operation. Furthermore, the provision of supplementary oxygen is essential in any first-referral facility yet only reliably available in 6 of 12 facilities we studied; it is entirely absent from 6 facilities. The need for supplementary oxygen is still largely unmet, despite the inclusion of oxygen concentrators in this study. On the other hand, all facilities provide certain general and pediatric procedures, including abscess incision and drainage, hydrocele repair, hernia repair, appendectomy, laparotomy, and male circumcision. These capabilities denote a baseline level of proficiency in surgical and anesthetic services, implying that building upon this framework to include all essential services is within reach.

In light of these challenges, deficiencies, and far-reaching effects of inadequate surgical and anesthetic care, our costing exercise with the Model Normative Hospital shows that bridging the existing surgical and anesthetic framework to meet HSSS standards is a rational and thoughtful expenditure. The surgical needs of the population can be inferred from the utilization rate of the Model Normative Hospital, which was calculated based on a survey of facility registries from well-run Congolese hospitals. At 33% of the total patient load at the Model Normative Hospital, surgical need is high. Yet looking more closely at Demba and Kabare Hospital surgical caseloads, these needs are not met. Only 9% and 3.33%, respectively, of the 2 hospitals' caseloads are surgical patients.

Reasons for the comparatively low caseloads (utilization rate) at Demba and Kabare Hospitals can be hypothesized by assessing these hospitals' infrastructure and resource base in general—patients are likely to bypass facilities within their health district due to health facility deficiencies. Both Demba and Kabare Hospitals are faced with unreliable electricity and water infrastructure as well as a total lack of an oxygen source. Both hospitals are fully or partially lacking equipment and supplies necessary for adequate surgical and anesthetic care. The situational analysis shows that Demba Hospital staff refer patients to facilities 90 km away for most orthopedic/trauma care. Similarly, Kabare Hospital refers patients with open and closed fractures and joint dislocations to facilities 65 km away. Thus, there is suboptimal use of the existing framework at these hospitals, and in the 12 facilities examined, patients traveled between 35 km and 150 km in an effort to seek surgical care within their health district, and up to 300 km (or in one extreme case, 2,000 km) to find care elsewhere. When the district hospital is insufficient, the result is unnecessary or difficult referrals to distant facilities.[15] As in many low-income countries, transfer to another facility is often the responsibility of the patient. The issues of safety, time, income, and lost work can be very difficult for a family to bear if a hospital transfer is needed.

Furthermore, the long distances are frequently prohibitive, particularly with severe medical conditions, leading to disability or death.

Because the Model Normative Hospital was developed by DRC's HSSS standards, deficiencies indicate a need for greater investment in the health sector and, more specifically, in surgical services. It can be inferred that bringing these hospitals to the level of the Model Normative Hospital will improve the health care system as a whole. At the population level, the detriment to a community when even 1 of the 32 essential procedures is absent is far-reaching beyond the implications for the individual patient. Striving to provide a full complement of services is essential because of the interconnectedness of clinical care.

Study Limitations

Limitations of this study are the general lack of available and reliable data, especially concerning utilization rates, caseloads, and other facility-based data. Another limitation is the nature of the convenience sample of district hospitals representing the North, South, East, West, and Central regions of the DRC. Findings cannot be generalized to the entire country. The situational analysis is only a ''snapshot'' needs assessment of district hospitals. Also, our resource planning study assessed only the resources and associated operating budget necessary at the district hospital level; large capital investments in roads as well as basic public infrastructure such as electricity and water will require much larger sums to be provided at the national level in order for the district level to function appropriately.

CONCLUSION

Surgery has been neglected from global health aid, but the accumulating proof of its large health impact and its proportionally low required service delivery budget are cause for a larger focus on making surgical (including obstetric) interventions available to the world's poorest communities. District (first-level referral) hospitals must be better funded to provide such services. More often than not, the level of service delivery used for surgical care (tertiary) is not appropriate in the DRC; given the low cost (i.e., <30% of overall functioning of the hospital) of providing surgical care at first-level referral hospitals, this should not be the case.

It is clear from the Demba and Kabare Hospital costing data that current spending on surgery, at least in these hospitals, is well below what is needed to achieve the DRC norm. We also know that households in the DRC contribute significantly (US$4.50/inhabitant/year[16]) to health care costs and thus directly or indirectly co-fund health services, including surgical services. Health care resource budgets must be restructured considerably in order to provide for lifesaving emergency and essential surgical care, including necessary infrastructure, human resources, equipment, pharmaceuticals, and supplies, within the primary health care package. We acknowledge the difficulty of putting in place structures and a system that would provide the necessary resources even with an adequate budget. However, these efforts to holistically strengthen the system are imperative in order to provide essential services that are not excessively expensive but will go a long way to improve population health.

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ORIGINAL ARTICLE

Successful Proof of Concept of Family Planning and Immunization Integration in Liberia

Chelsea M Cooper,[a] Rebecca Fields,[b] Corinne I Mazzeo,[c] Nyapu Taylor,[d] Anne Pfitzer,[a] Mary Momolu,[e] Cuallau Jabbeh-Howe[e]

Mobilizing vaccinators to provide mothers key family planning information and referrals to co-located, same-day family planning services was feasible in resource-limited areas of Liberia, leading to substantial increases in contraceptive use. Conversely, impact on immunization rates was less clear, but at a minimum there was no decrease in doses administered.

ABSTRACT

Globally, unmet need for postpartum family planning remains high, while immunization services are among the most wide-reaching and equitable interventions. Given overlapping time frames, integrating these services provides an opportunity to leverage existing health visits to offer women more comprehensive services. From March through November 2012, Liberia's government, with support from the Maternal and Child Health Integrated Program (MCHIP), piloted an integrated family planning and immunization model at 10 health facilities in Bong and Lofa counties. Vaccinators provided mothers bringing infants for routine immunization with targeted family planning and immunization messages and same-day referrals to co-located family planning services. In February 2013, we compared service statistics for family planning and immunization during the pilot against the previous year's statistics. We also conducted in-depth interviews with service providers and other personnel and focus group discussions with clients. Results showed that referral acceptance across the facilities varied from 10% to 45% per month, on average. Over 80% of referral acceptors completed the family planning visit that day, of whom over 90% accepted a contraceptive method that day. The total number of new contraceptive users at participating facilities increased by 73% in Bong and by 90% in Lofa. Women referred from immunization who accepted family planning that day accounted for 44% and 34% of total new contraceptive users in Bong and Lofa, respectively. In Lofa, pilot sites administered 35% more Penta 1 and 21% more Penta 3 doses during the pilot period compared with the same period of the previous year, while Penta 1 and Penta 3 administration decreased in non-pilot facilities. In Bong, there was little difference in the number of Penta 1 and Penta 3 doses administered between pilot and non-pilot facilities. In both counties, Penta 1 to Penta 3 dropout rates increased at pilot sites but not in non-pilot facilities, possibly due to higher than average background dropout rates at pilot sites prior to the intervention in Lofa and the disproportionate effect of data from 1 large facility in Bong. The project provided considerable basic support to assess this proof of concept. However, results suggest that introducing a simple model that is minimally disruptive to existing immunization service delivery can facilitate integration. The model is currently being scaled-up to other counties in Liberia, which could potentially contribute to increased postpartum contraceptive uptake, leading to longer birth intervals and improved health outcomes for children and mothers.

BACKGROUND

Giving women access to family planning during the first year postpartum provides an opportunity to prevent unintended pregnancies and promote healthy birth spacing. Pregnancies spaced less than 18–24 months apart have been associated with an increased risk of preterm birth; low birth weight; fetal, neonatal, and infant death; childhood malnutrition and stunting; and adverse maternal health outcomes.[1,2] More than 90% of women during their first year postpartum indicate a desire to delay the next pregnancy for at least 2 years, or to not get pregnant at all, yet there is substantial unmet need for family planning during this period.[3]

The Expanded Programme on Immunization (EPI) provides routine immunization to children in their first

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year of life, which corresponds to the extended postpartum period of their mothers. Routine immunization services are one of the most used and equitable health services: global coverage for the third dose of vaccine containing diphtheria, tetanus, and pertussis (DTP3) was estimated at 84% in 2013.[4]

Integrating postpartum family planning and immunization services leverages existing contacts with the health system to offer women more comprehensive services.

Given that the time frames for EPI and postpartum family planning services overlap, integrating these services provides an opportunity to leverage existing contacts with the health system to offer women a more comprehensive package of services. Such integration of services has been recognized as a ''promising'' high-impact practice for improving access to family planning.[5] Furthermore, the Global Vaccine Action Plan for 2011–2020 recognizes that strong immunization systems are an integral part of a well-functioning health system and states that immunization service delivery should continue to serve as a platform for providing other priority public health interventions.[6]

Quasi-experimental studies on integrating family planning and immunization services have been conducted in Ghana, Rwanda, Togo, and Zambia. The studies in Rwanda and Togo found a significant increase in contraceptive use with no change in use of immunization services after services were integrated.[7,8] On the other hand, in Ghana and Zambia, there was no statistically significant increase in contraceptive uptake, and immunization data were not monitored. However, process findings from Ghana and Zambia indicated that the model was not implemented as designed. In Zambia, family planning information was often given during group talks instead of during one-on-one counseling sessions, and in Ghana, family planning messages were not consistently communicated.[9]

Documented evidence and program learning around integrating immunization and family planning services remain fairly limited. Additional evidence is needed specifically on the effects of integrating family planning and immunization services on immunization coverage, especially in light of the extended negative impact on immunization programs in Cameroon, Nigeria, the Philippines, and elsewhere from past allegations by community or religious sectors that immunization was a disguised attempt to sterilize populations.[10–13] Because of these gaps and concerns, the immunization community has expressed reservation about family planning and immunization integration until there is a robust evidence base indicating that this practice is not detrimental to achieving immunization goals. This paper describes one experience from Liberia that contributes to building that evidence base.

Starting in 2011, the Maternal and Child Health Integrated Program (MCHIP) began collaborating with the Liberian Ministry of Health and Social Welfare (MOHSW) to launch a proof-of-concept initiative to integrate family planning and routine immunization services at fixed health facilities. The MOHSW recognized the significant role that family planning could play in reducing maternal mortality in the country.

The 2007 Liberia Demographic and Health Survey (DHS) was the most recent source of population-based data for family planning and immunization available at the time of program design. It revealed a low modern contraceptive prevalence of 10.3% for married women of reproductive age[14] (later increasing to 19.1% in the 2013 DHS[15]), and a special analysis of the 2007 DHS data showed short interpregnancy intervals (41% of pregnancies occurred within intervals shorter than 24 months).[16] In addition, women in Liberia who were within 2 years postpartum experienced high unmet need for family planning (82%).[16] Among women in this extended postpartum period, only 7% used any method of family planning, even though only 9% of women desired another birth within 2 years.[16]

The 2007 DHS data also indicated that among children aged 12–23 months, 75% received a first dose of DTP and 50% received the recommended 3 doses of DTP.[14] (Receipt of the first and third dose of DTP increased to 91% and 71%, respectively, in the 2013 DHS.[15]) Liberia's national immunization schedule recommends infant vaccination visits at birth, at 6, 10, and 14 weeks, and at 9 months, with immunization to be offered daily at static health facilities and through outreach programs. However, sessions do not necessarily offer all vaccines on a given day, and the ages at which these visits actually take place may be somewhat later.

With the government's commitment to reduce high levels of unmet need for family planning and maternal mortality, senior staff at the MOHSW supported the concept of using routine immunization contacts to increase access to family planning. They also highlighted the need to maximize limited human and financial resources to achieve as broad a health benefit as possible.

The purpose of this article is to present the results of 9 months of implementation of a contextualized model for integrating family planning

and EPI in Liberia as a means of increasing contraceptive use among postpartum women. The article also describes factors that enabled or hindered integrated service delivery and presents implications for integrating these services in other settings.

PROGRAM DESCRIPTION

From March through November 2012, Liberia's MOHSW, with technical support from MCHIP and the United States Agency for International Development (USAID), piloted a model for integrating immunization and family planning services in 10 health facilities in Bong and Lofa counties. As a result of discussions with the MOHSW, the pilot was not designed with a rigorous research design; rather, it was intended to be a proof of concept to generate learning that would inform creation of a scalable model for implementation. The MOHSW's EPI, Family Health, and Health Promotion Divisions were closely involved in providing input on the design of the model and in selecting intervention facilities. Key steps in planning, implementing, and evaluating the project are highlighted in Table 1.

Site Selection

The proof of concept was conducted at 10 health facilities in Bong and Lofa counties; these counties were selected due to their relatively strong EPI performance. Contraceptive prevalence in the regions where these counties are located fell below the national rate.[14] One hospital and 4 clinics were purposively selected in each county with guidance from the MOHSW. Fixed facilities were chosen instead of outreach services because a greater proportion of children are vaccinated at fixed facilities than through outreach services. In addition, fixed services tend to be more reliable and offer more privacy.

Pilot facilities had relatively strong immunization performance, but contraceptive use in the pilot regions was low.

TABLE 1. Time Frame and Key Activities for the Integrated EPI-Family Planning Pilot Initiative in Liberia

Time Frame	Activity	Remarks
Feb 2011	Initial discussions with the MOHSW; stakeholder meeting with national EPI and family planning officials, county health teams, partners	Decision to work in Bong and Lofa; consensus to work only on facility-based integration for routine immunization
Apr–May 2011	Formative research to inform details of integration model	Sensitivity and stigma regarding postpartum women's use of family planning services revealed
Jun–Sep 2011	Design, pretesting, and production of training materials	Addresses perceptions regarding use of contraceptives by postpartum women noted during formative assessment
Feb 2012	Training of staff at 5 facilities each in Bong and Lofa	3-day training for vaccinators and family planning providers, including field practice; 1-day orientation for county supervisors and officers in charge
Mar–Nov 2012	Pilot of integrated EPI-family planning service delivery, including monthly supervision visits to participating facilities	Supervision by MCHIP staff accompanied by representatives from Family Health Division, EPI, and county health teams
Jul–Aug 2012	Refresher training and midterm assessment using quantitative and qualitative methods	Based on facility staff feedback, introduced privacy screens in vaccination area to enhance confidentiality of the mother's family planning decision
Dec 2012	Final assessment using quantitative and qualitative methods	Included focus group discussions with referral acceptors and non-acceptors, interviews with service providers and facility officers in charge, and interviews with partner agency representatives and supervisors
Mar 2013	Final stakeholder meeting	Presentation of approach and key findings to the MOHSW, partners, and county health teams from 6 counties

Abbreviations: EPI, Expanded Programme on Immunization; MCHIP, Maternal and Child Health Integrated Program; MOHSW, Ministry of Health and Social Welfare.

The integrated model emphasized co-located provision of same-day immunization and family planning services.

Stigma about contraceptive use before the baby walks or turns 1 year of age prevented many women from using postpartum family planning.

Formative Assessment Findings

In 2011, we conducted a formative assessment in 4 of the intervention health facilities to inform development of the integration model, messages, and communication materials. The assessment consisted of focus group discussions (FGDs) with mothers of infants under 1 year of age and interviews with vaccinators, family planning providers, and health facility officers in charge.

The assessment revealed that stigma about returning to sexual activity and using family planning before the baby walks or turns 1 year of age acted as a major barrier to using postpartum family planning services. Many respondents also believed that premature return to sexual activity and contraceptive use could ''spoil'' the breast milk and harm the baby. Family planning providers and vaccinators highlighted the importance of privacy and one-on-one communication as factors that could affect women's willingness to seek family planning services. The assessment also revealed that women were not routinely referred from immunization to family planning services and that women rarely sought family planning services during immunization visits. Vaccinators, family planning providers, and clients all expressed support for the idea of linking family planning and immunization services.

Intervention Design

MCHIP, in consultation with the MOHSW, developed an integration model, which was informed by the formative assessment findings and experiences in other countries. The integrated model emphasized co-located provision of same-day, facility-based services: vaccinators were trained to provide brief, targeted family planning and immunization messages and same-day family planning referrals to mothers bringing their infants to the facility for routine immunizations. Specifically, at the completion of each vaccination contact, vaccinators were directed to use a simple job aid to share targeted messages one-on-one (not through group health talks) with each mother and to then offer her a referral to a co-located family planning room for more in-depth family planning counseling and services (Figure 1). The approach was designed to minimize the impact on the typical patient flow for immunization. The client flow within the health facility, from arrival at a facility to departure, is illustrated in Figure 2.

We developed strategically designed behavior change communication materials, including a job aid, poster, and brochure, to help standardize communication by vaccinators and reinforce key messages provided to mothers (see supplementary materials). The messages emphasized that family planning is safe for use by women with young babies and that it is acceptable for women to use family planning even before the baby walks. The job aid was designed to be simple and user-friendly, with clear step-by-step directions for vaccinators. The poster included a photo of a breastfeeding woman seeking family planning services, along with messages that ''family planning is good for baby ma'' and that encouraged women to ''Go for family planning today!'' The job aid guided vaccinators to reference the poster during the immunization contact. Women who declined to go for family planning services on the same day received a brochure as a take-home reference, highlighting information about the benefits of family planning for mother, father, baby, and for general family well-being. Clients were encouraged to share the brochure with their spouses, other family members, and friends in order to spark discussion about family planning.

After designing the integration model and preparing and pretesting the messages and materials, we trained at least 1 family planning provider and 1 vaccinator per health facility. The 3-day training covered concepts relevant to postpartum family planning and immunization and values clarification, oriented participants to the new integration approach and tools, and allowed participants to apply the skills in a service delivery

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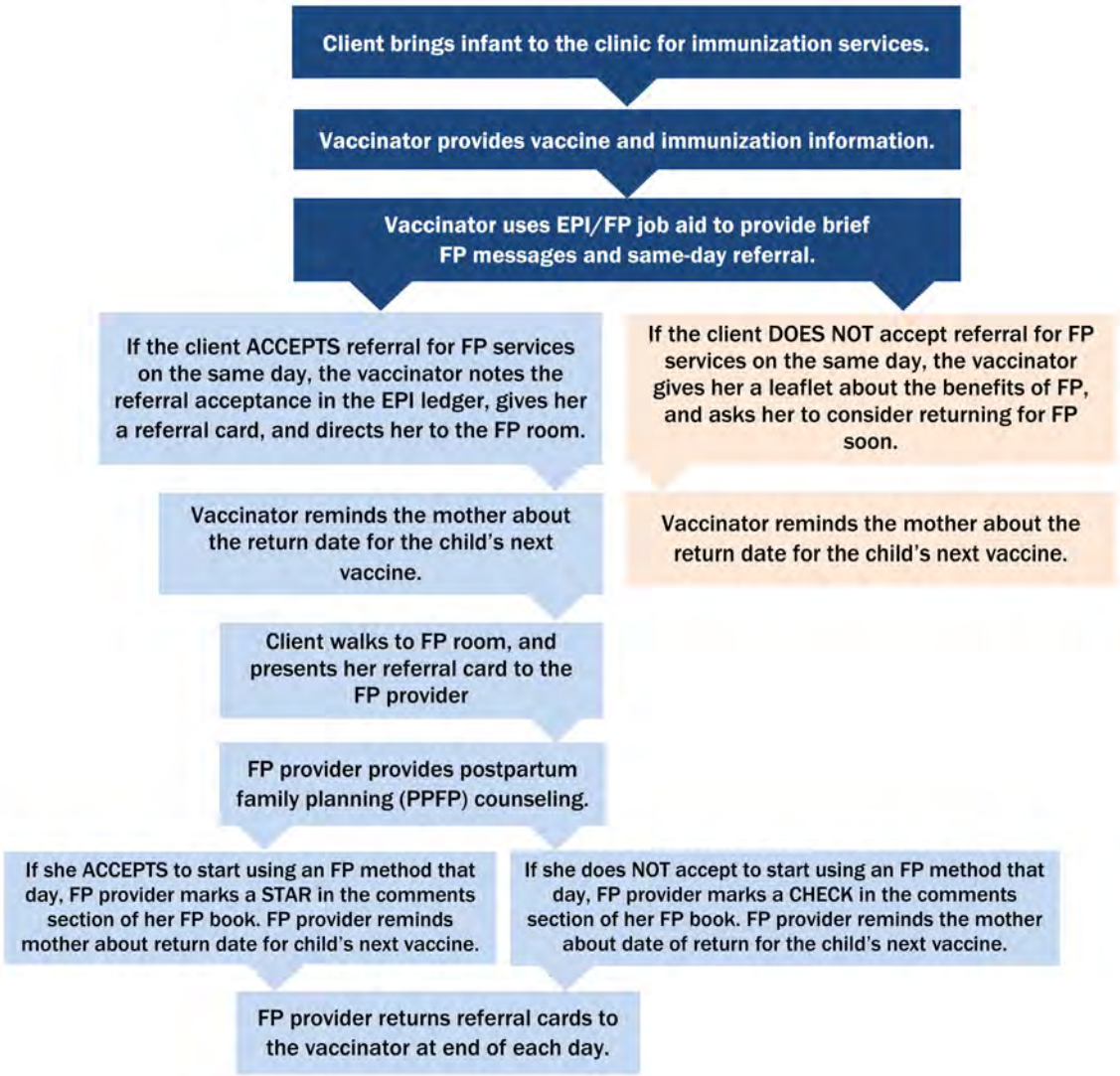
Mothers bringing their children for vaccination review a family planning brochure provided by the vaccinator.

FIGURE 1. Integrated EPI-Family Planning Service Delivery Model in Liberia



Abbreviations: EPI, Expanded Programme on Immunization; FP, family planning.

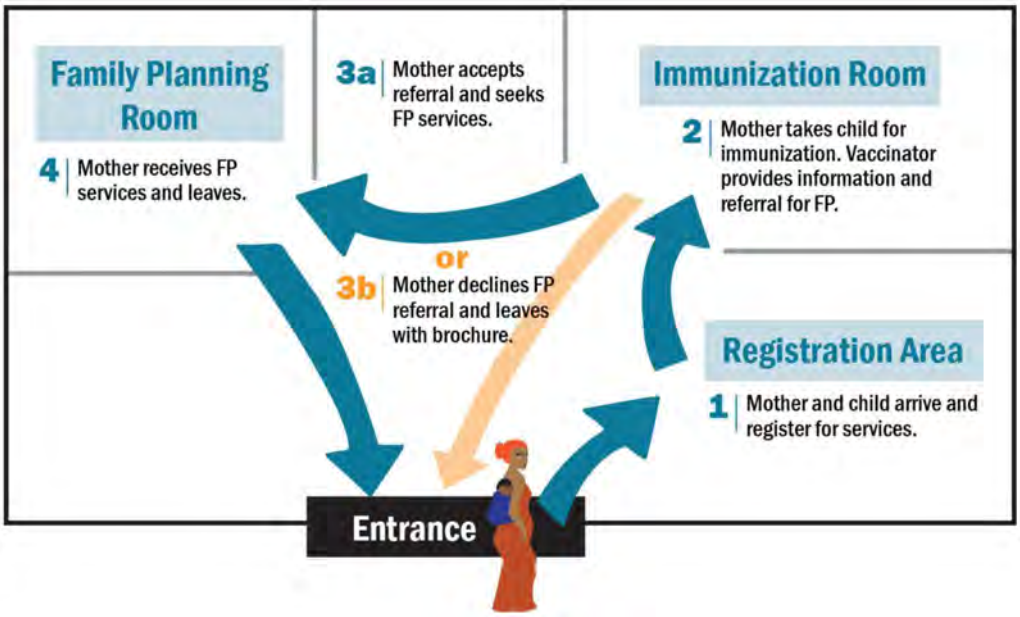
setting. We also oriented health facility, district, and county supervisors to the approach.

Monitoring and Supervision

During the 9-month implementation period, MCHIP staff and MOHSW representatives conducted monthly supervision visits to each site. Supervisors monitored service provision, collaboratively reviewed and documented service statistics (including immunization and family planning service data and referrals made from immunization to family planning services), conducted exit interviews with clients, and provided feedback and developed action plans with each of the facility teams. A refresher training and midterm assessment were also conducted halfway through the implementation period.

The midterm assessment and ongoing supervision indicated that the model was generally being implemented as planned, but several chal-

FIGURE 2. Client Flow for Integrated EPI-Family Planning Services



Abbreviation: EPI, Expanded Programme on Immunization.

Lack of privacy during immunization prevented some women from accepting family planning referrals.

lenges were uncovered. Most notably, a lack of privacy at the EPI station prevented some women from accepting family planning referrals, especially at facilities where vaccinations were given in a public space. Other challenges included human resource constraints, extended waiting times for family planning services, and vaccine and contraceptive commodity stock-outs.

In light of these and other observations, we made a number of important adjustments, including: encouraging teams to develop facility-specific plans for managing increased family planning client load; advocating improvements in the commodity supply chain; encouraging service providers (both vaccinators and family planning providers) to set weekly meetings in order to improve communication and coordination; and introducing privacy screens at facilities where vaccinations were conducted in public areas of the facility. These screens provided visual privacy for clients and a quieter space for child vaccination, and they reduced the likelihood of others watching or listening to clients' conversations with the vaccinator.

FINAL ASSESSMENT METHODS

In December 2012, MCHIP and the MOHSW conducted a final assessment of the integrated approach, consisting of a review of service statistics as well as in-depth interviews and FGDs. The objectives of the assessment were to evaluate whether the pilot was associated with changes in family planning and immunization outcomes and to gather qualitative information on lessons learned. A protocol for conducting secondary analysis of data generated by the program was submitted to and was exempted from human subjects review by the Johns Hopkins Bloomberg School of Public Health's Institutional Review Board.

Service Statistics

Family planning service data were gathered on the:

- Number of clients accepting family planning referrals from the vaccinators
- Number of EPI-referred clients who followed through on the family planning referrals
- Number of EPI-referred clients who accepted a contraceptive method the same day

- Total number of new contraceptive users at the intervention facilities (defined in this paper as both EPI-referred and other clients who either started using a contraceptive method or reinitiated use after childbirth)
- Contraceptive method mix among EPI referral acceptors

These data were obtained from family planning registers and supplemental "EPI-Family Planning registers" at participating facilities during monthly supportive supervision visits. The data were analyzed to compare service utilization at intervention sites during the pilot phase (March–November 2012) against the same months from the previous year (March–November 2011). It was not possible to compare family planning data from the pilot sites against other facilities in these counties, as county-level family planning data were not available from the MOHSW. Same-day referral acceptance was calculated by dividing the total number of referral acceptors by the total number of infants immunized (bacille Calmette-Guérin [BCG] + measles + Penta 1 + Penta 2 + Penta 3) in each facility during each month, as derived from vaccination registers.

Immunization indicators monitored included the number of Penta 1 and Penta 3 doses administered, as well as the dropout rate from the Penta 1 to Penta 3 doses administered. Penta 1, 2, and 3 refer to the first, second, and third doses of pentavalent vaccine, which contains antigens for diphtheria, pertussis, tetanus, hepatitis B, and *Haemophilus influenzae* type b. For this analysis, routine immunization administrative data provided by the MOHSW in February 2013 were used to compare the:

- Number of Penta 1 and Penta 3 doses administered at pilot sites from March–November 2012 with those administered at pilot sites during the same period in 2011
- Number of Penta 1 and Penta 3 doses administered at pilot facilities in the 2012 calendar year with those administered at all other facilities in Bong and Lofa counties in the same year
- Penta 1 to Penta 3 dropout rates at the pilot facilities in Bong and Lofa in 2012 with the dropout rates at all other facilities in each respective county in the same year.

Qualitative Data

We conducted in-depth interviews with purposively selected personnel: service providers (vaccinators and family planning providers), officers in charge, program managers, partner agency representatives, and supervisors (MCHIP, district, county, and MOHSW representatives). We also conducted FGDs with clients of participating health facilities—both those who had and those who had not accepted the family planning referrals from the vaccinators. Health facilities were randomly assigned to either recruit referral acceptors or non-acceptors for the FGDs. During the period preceding the assessment, at each facility selected to recruit family planning referral acceptors, vaccinators were directed to invite all women who accepted the family planning referral to participate in the FGDs until they had recruited 7–10 participants. At facilities assigned to conduct FGDs with referral non-acceptors, vaccinators were directed to invite every third mother who did not accept the family planning referral until they had recruited 7–10 participants. All interview and FGD participants provided oral consent to participate. Table 2 describes the number and characteristics of respondents in the final assessment.

Data Analysis

Quantitative data were entered into Microsoft Excel. Qualitative data were transcribed from

TABLE 2. Composition of Key Informant Interviews and Focus Group Discussions

Description of Participants	No. of Participants
Key Informant Interviews	**42**
Vaccinators	10
Family planning providers	10
Officers in charge	9
Program managers, partner agency representatives, supervisors	13
Focus Group Discussions (FGDs)[a]	**56**
4 FGDs with family planning referral acceptors	31
4 FGDs with non-acceptors	25

[a] Health facility staff were not present during FGDs to minimize their potential influence on client responses.

pre-formulated questionnaires into an electronic database. We then prepared simple frequencies and trend analyses from the quantitative service data and conducted a thematic analysis from the qualitative data.

RESULTS

Family Planning Referral Acceptance and Completion

Service data revealed wide variation in family planning referral acceptance across pilot facilities. On average, the percentage of mothers bringing their children for immunization who accepted a family planning referral on the same day ranged from 10% to 45% per month across facilities in the 2 counties (Table 3). There was no clear trend in referral acceptance over time, across facilities, or between the 2 counties; however, hospitals generally had lower percentages of clients accepting referrals than clinics.

Over 80% of mothers who accepted a family planning referral completed the referral, and, in turn, over 90% of these women accepted a method that day.

During the 9-month pilot period, a total of 1,490 mothers accepted a family planning referral from a vaccinator (426 in Lofa county, 1,064 in Bong county). Of mothers who accepted a family planning referral, 84% and 88% completed the same-day referral in Lofa and Bong, respectively. Among those women who completed the referral, 93% and 96% in Lofa and Bong, respectively, accepted a contraceptive method that day.

Adding privacy screens to immunization areas helped motivate family planning referral acceptance and follow-through. The screens enabled clients to focus more on the information shared by the vaccinator and helped clients to avoid feeling stigmatized when accepting the family planning referral.

The main reasons for not accepting a family planning referral cited by clients included long wait times to see a family planning provider, unclear pathways from the vaccination station to the family planning room, and lack of privacy (Table 4). For women who accepted a referral but did not accept a contraceptive method that day, common reasons included wanting to discuss the decision with their partner first, wanting to wait until the baby was older, and dissuasion by the family planning provider from using a contraceptive method before reaching a particular time postpartum (for example, waiting until 6 weeks after childbirth). All respondents (clients, service providers, supervisors, and partner organizations) expressed a desire for the integrated service delivery approach to continue.

TABLE 3. Family Planning (FP) Referrals and Use at Pilot Sites During Intervention Period (March–November 2012), by County

Facility	Average Monthly % of Mothers Accepting FP Referrals From Vaccinators	Total No. of Mothers Accepting FP Referrals	No. (%) of Referral Acceptors Who Went to the FP Provider	No. (%) of Referral Acceptors Who Went to the FP Provider and Accepted a Method That Day
Bong County		**1,064**	**934 (88%)**	**892 (96%)**
Fenutoli Clinic	26.0%	99	85 (86%)	80 (94%)
Garmu Clinic	45.2%	361	342 (95%)	328 (96%)
Zoweinta Clinic	15.7%	159	138 (87%)	126 (91%)
Salala Clinic	9.9%	241	191 (79%)	186 (97%)
Phebe Hospital	12.5%	204	178 (87%)	172 (97%)
Lofa County		**426**	**357 (84%)**	**332 (93%)**
Borkeza Clinic	12.4%	51	43 (84%)	40 (93%)
Ganglota Clinic	34.1%	86	54 (63%)	53 (98%)
Gbonyea Clinic	32.4%	80	72 (90%)	71 (99%)
Kpaiyea Clinic	24.3%	65	54 (83%)	52 (96%)
Curran Hospital	14.4%	144	134 (93%)	116 (87%)

TABLE 4. Factors Enhancing Implementation of the Integrated EPI-Family Planning Model: Results of In-Depth Interviews and Focus Group Discussions[a]

Category	Factor
Infrastructure	• Proximity of family planning and immunization services to each other and clarity of pathways between service sites • Privacy for clients (at immunization stations in particular)
Management, staffing, and coordination	• Availability of vaccinators and family planning providers on the same day • Frequent communication between vaccinators and family planning providers
Training and supportive supervision	• Regular supportive supervision • On-the-job training for new staff
Supplies	• Reliable commodity supply (vaccines and contraceptives)
Behavior change communication	• Job aids or reminder materials to reinforce key steps of the referral process • Good-quality counseling

Abbreviation: EPI, Expanded Programme on Immunization.
[a] With clients, service providers, supervisors, and partner organizations.

Trends in Family Planning Use

The total number of new contraceptive users at participating facilities (i.e., among EPI-referred clients who accepted a method the same day as well as other clients) increased by 90% in Lofa (517 to 983) and by 73% in Bong (1,182 to 2,039) between March–November 2011 and March–November 2012. It should be noted that during the pilot period (March–November 2012), the number of new contraceptive users in pilot sites included women who committed to using the lactational amenorrhea method (LAM). In 2011, LAM was not routinely tracked in family planning registers, but routine counseling on LAM by family planning providers and active use of LAM were suspected to be very low prior to the pilot.

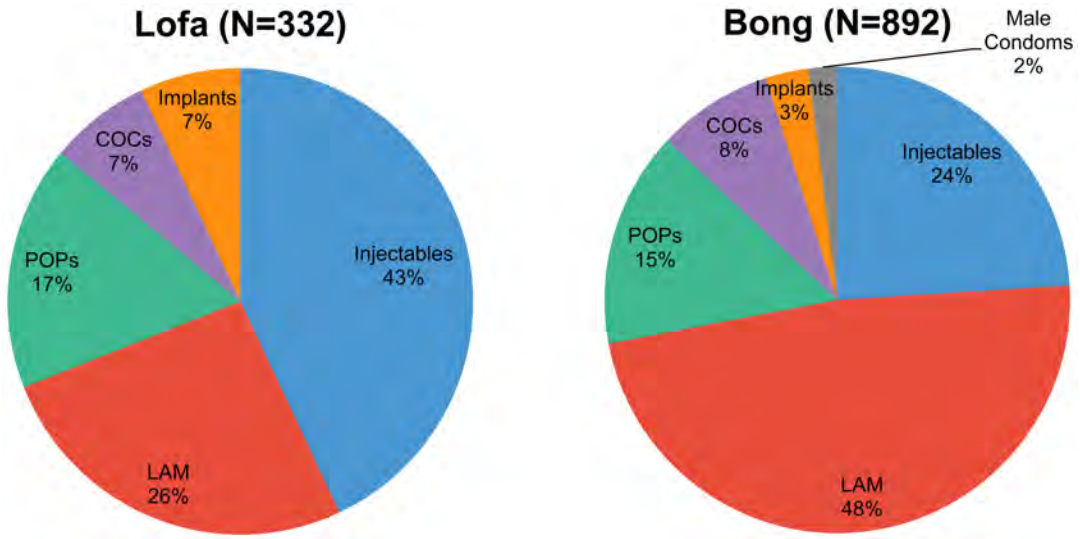
Women who were referred from EPI and who accepted a contraceptive method on the same day accounted for a substantial proportion of the total new contraceptive users at the pilot sites. In participating facilities in Bong and Lofa, 44% and 34%, respectively, of the total number of new contraceptive users were EPI-referred. No other major efforts to increase family planning uptake took place during the pilot phase of the integration initiative, except for 1 facility in Lofa county, which began providing community-based family planning during this time.

Among EPI-referred women who accepted a contraceptive method on the same day, the method mix varied between the counties. In Bong, nearly half of the same-day referred family planning acceptors committed to using LAM, while about one-quarter chose injectables and nearly one-quarter chose oral contraceptive pills (Figure 3). In Lofa, most same-day referral family planning acceptors (43%) chose injectables, while about one-quarter chose LAM and another quarter chose pills. Less than 10% of women chose implants in either county. Although intrauterine devices (IUDs) were offered in most facilities in Liberia, none of the family planning referral acceptors were provided an IUD on the same day. It should be noted that the method mix captured in this figure represents only EPI-referred women, not all contraceptive users. Method mix for all new contraceptive users beyond the same-day referral acceptors was not tracked.

LAM was the most popular method among immunization-referral acceptors in Bong, while injectables were the most popular in Lofa.

Results from FGDs indicated that the reach of this intervention was amplified beyond vaccinators' one-on-one communication with clients: many mothers reported sharing the information and take-home materials about family planning with friends, family members, and partners. One client said, ''My friend said that her baby was small, and I talked to her about family planning.

FIGURE 3. Contraceptive Method Mix Among Same-Day Referral Acceptors in Pilot Facilities, Lofa and Bong Counties, March–November 2012



Abbreviations: COCs, combined oral contraceptive pills; LAM, lactational amenorrhea method; POPs, progestin-only pills.

Penta 1 and Penta 3 administration increased across the pilot sites, but more so for Penta 1, resulting in a net increase in the Penta 1 to Penta 3 dropout rate.

I told her to come on her rightful time for vaccine and she can get family planning.'' The qualitative data also revealed that the integrated services improved knowledge and changed views about family planning among clients and providers alike. For example, several clients and family planning providers reported that before the intervention, they did not know that a woman with a young infant could use contraception.

Trends in Use of Immunization Services

Immunization data revealed an increase in the number of Penta 1 and Penta 3 doses administered across pilot sites during the implementation period compared with the same period of the previous year. In Lofa, pilot facilities administered 35% more Penta 1 doses and 21% more Penta 3 doses from March–November 2011 to March–November 2012 (Table 5). In contrast, the data for non-pilot facilities showed decreases in Penta 1 (11%) and Penta 3 (6%) administration during the same time period. In Bong, there was a modest increase in Penta 1 (9%) and Penta 3 (5%) doses given at pilot facilities from 2011 to 2012. However, these increases were smaller than those experienced in all other facilities in Bong county.

In both counties, the increase in Penta 1 was more than that of Penta 3 at the pilot facilities. The smaller increase in Penta 3 resulted in a net increase in the Penta 1 to Penta 3 dropout rate (a standard parameter in immunization program management and evaluation that is based on a simple ratio of Penta 3 to Penta 1 doses administered). In Lofa county, the Penta 1 to Penta 3 dropout rate increased from 14% in 2011 to 25% in 2012 at pilot facilities, while it decreased from 8% to 3% in all other facilities. In Bong county, the Penta 1 to Penta 3 dropout rate increased from 6% to 9% at pilot facilities, while it remained unchanged at 7% in all other facilities. The dropout rate in pilot facilities in Bong was still below the 10% threshold designated by the World Health Organization (WHO) as indicating a problem with immunization dropout.[17]

Further examination revealed that pilot facilities in Lofa had higher dropout rates than non-participating facilities even prior to participating in the intervention. In Bong, findings from the pilot facilities were disproportionately affected by data from 1 large facility that experienced a drop-off in immunization performance from 2011 to 2012, which was attributed to human

TABLE 5. Number of Penta 1 and Penta 3 Doses Administered at Pilot and Non-Pilot Facilities by County, Pre-Intervention Period (March–November 2011) vs. Intervention Period (March–November 2012)

	Lofa County						Bong County					
	Pilot Facilities (N=5)			All Other Facilities (N=48)			Pilot Facilities (N=5)			All Other Facilities (N=31)		
	Before	During	% Change	Before	During	% Change	Before	During	% Change	Before	During	% Change
Penta 1 doses	533	721	+35%	8,095	7,244	−11%	2,303	2,508	+9%	8,673	9,583	+10%
Penta 3 doses	458	553	+21%	7,456	7,012	−6%	2,175	2,280	+5%	8,063	8,926	+11%
Penta 1 to Penta 3 dropout rate	14%	25%		8%	3%		6%	9%		7%	7%	

resource constraints and internal supervisory turnover during the intervention period.

In qualitative interviews, some vaccinators reported greater confidence in their roles and perceived that their value within the health system and community had increased as a result of the intervention. In addition, interviews with service providers (vaccinators, in particular) suggested that the intervention may have contributed to greater staff appreciation for recordkeeping. None of the clients participating in the FGDs (neither referral acceptors nor non-acceptors) reported feeling discouraged to return to the facility for vaccinations. Rather, clients reported that they saw the value of vaccinating their child and would return regardless of their decision to accept a family planning referral.

DISCUSSION

The experience and results of this pilot project contribute to the global evidence base on the integration of 2 lifesaving services—immunization and family planning. In our proof of concept, we found that a simple model of counseling and referrals from immunization services to same-day, co-located family planning services increased postpartum contraceptive uptake in 2 counties of Liberia and, at a minimum, did not decrease vaccination administration.

Impact on Family Planning

It is likely that some of the women who accepted family planning referrals from the vaccinator may have come to use family planning anyway eventually, but given the high rate of short interpregnancy intervals in Liberia, any earlier uptake of postpartum family planning is also beneficial. Several women indicated during the FGDs that they had felt motivated by the family planning information shared by the vaccinator, but they had needed to speak with their husbands before making a decision and had returned for a contraceptive method at a later date. (These women would not have been captured as same day-referred family planning acceptors but could have contributed to overall increases in new contraceptive users.) Clients reported amplifying family planning messages provided by the vaccinators with other family members and peers.

In both pilot counties, there was high acceptance of LAM among same-day referral acceptors. LAM is a highly effective contraceptive method when practiced correctly, and it also has great

benefits for infant health. In addition, there is evidence that LAM is a gateway method to other modern contraceptives even though LAM is a temporary method.[18] However, it is important that health workers communicate effectively about LAM to ensure clients understand how to use the method correctly and understand the importance of follow-up to promote timely transition from LAM to another modern method.

The monthly average percentage of mothers bringing their children for immunization who accepted a family planning referral on the same day may underrepresent the actual same-day referral acceptance, as the denominator used was the total number of infants immunized (BCG + measles + Penta 1 + Penta 2 + Penta 3) in each facility each month, as derived from vaccination registers. For the purpose of these calculations, BCG, measles, Penta 1, Penta 2, and Penta 3 vaccinations were all treated as distinct contacts; however, in reality, infants may receive more than one of these vaccines during a contact with EPI services. Furthermore, a woman who accepts a contraceptive method at one visit and later returns for subsequent immunization visits is less likely to need or accept a family planning referral at those later visits.

It is critical for both vaccinators and family planning providers to inform mothers of when they need to return for their child's next vaccination.

Factors Contributing to Successful Family Planning Referrals

Routine use of a simple, strategically designed job aid was instrumental in supporting vaccinators to communicate intended family planning messages to clients. A formative assessment conducted to inform project design allowed for the issue of stigma around contraceptive use to surface and to be addressed in the design of the integration model and its communication materials. Improving client privacy at the vaccination stations also enabled women to more freely accept family planning referrals. The provider training contributed to changes in provider knowledge and attitudes about the acceptability and effectiveness of offering family planning services to women with infants, which seemed to improve subsequent provider practices.

Impact on Immunization

The immunization findings pose some challenge to interpretation. Administration of both Penta 1 and Penta 3 increased at the pilot sites in both counties relative to the same period for the previous year, albeit less so for Penta 3. In Bong, this increase was somewhat lower in pilot facilities than in all other facilities. The increased dropout rate at pilot facilities in Bong was still below the threshold that WHO considers representing a problem.[17] In Lofa, by contrast, an increase in the dropout rate was observed at pilot facilities whereas it fell at all other facilities. However, pilot facilities in Lofa experienced a dramatic increase of 35% and 21% in doses of Penta 1 and Penta 3 administered, respectively, whereas figures for Penta 1 and Penta 3 actually decreased in non-pilot facilities. That is, the pilot facilities experienced a substantial net gain in doses administered despite the increased dropout rate.

Follow-up visits to pilot facilities pointed to an unusual service delivery system in the Lofa subdistrict in which all 5 pilot facilities were located: Penta 1 doses were provided by each clinic whereas Penta 3 and other later doses in the vaccination schedule were administered mostly by an outreach team fielded by a nearby private hospital. This situation highlights the need to thoroughly understand the health system context at the micro level, particularly in the case of small-scale pilot activities.

Nevertheless, the increase in the dropout rates observed at pilot facilities in both counties underscores the need for vaccinators and family planning providers alike to inform mothers of the need to return for their child's next vaccination and the importance of fully completing the immunization series. Additional experience and learning is also needed on the development and use of robust data collection systems for integrated services, the types of changes to anticipate and monitor, and attribution of changes to the integration process itself, in particular to ensure that integrating family planning with existing immunization services does not have a negative impact on immunization performance.

Scaling-Up the Integrated Model

Previous experience with integration of family planning and immunization services in other countries revealed a need for systems that are clear and user-friendly and that pose minimal added burden to vaccinators.[9] While our service delivery model is fairly simple, we did provide significant program support, including formative assessment, training for both immunization and family planning providers, job aids, privacy screens, and monthly supervision. The stakeholders involved in this pilot viewed the proof-of-concept phase as an opportunity to refine an effective integration model; as such, more sub-

stantial inputs arguably were required during this phase (e.g., formative research, pretesting of messages and materials, midterm assessment, client exit interviews) than would be necessary on an ongoing basis within an expanded approach. At the same time, scale-up is well known to be a difficult process requiring additional inputs and adaptation. Using the proof-of-concept experience, MCHIP has developed an implementation package outlining the process, training materials, tools, and key implementation considerations to help government and other stakeholders adapt and scale-up the approach (see supplementary material).

Return visits to the implementation sites conducted several months after the pilot period revealed that the EPI-family planning referral process was still in place. District and county teams had been closely involved in the rollout of the activity and were committed to continuing the approach at the focus sites beyond the proof-of-concept phase. In addition, from the earliest stages of this activity, the MOHSW, county teams, and donors expressed interest in scaling-up the integrated approach to additional sites, should the proof of concept be successful. In light of the final assessment findings, the MOHSW officially endorsed the approach for scale-up within additional counties, with the caveat of incorporating additional mechanisms for reinforcing immunization services. Adjustments will be incorporated as the integrated model is expanded, in particular, to address the issue of immunization dropout—a known challenge in the Liberian context even in areas with strong overall EPI performance. These include taking appropriate measures to assure privacy during EPI and family planning service provision; ensuring that there is a clear pathway from one service to the other; and improving client-provider communication (for example, ensuring that family planning messages are given at every vaccination contact, and that vaccinators and family planning providers remind mothers to return for their child's next immunization visit).

Future recommendations include strengthening family planning and immunization commodity security and improving recordkeeping practices, such as recording acceptance or refusal of the family planning referral directly in the EPI register. The MOHSW also recommended that take-home communication materials with immunization messages should be provided to women during service contacts to reinforce key immunization information.

Findings from the 2013 Liberia DHS indicate that 71% of children 12–23 months old received 3 doses of pentavalent vaccine,[15] a marked increase from the 2007 figure of 50%.[14] This increase in immunization coverage offers a more favorable environment and stronger platform for reaching women with other needed services. Certainly, continued attention to further increasing immunization coverage, improving quality of care, enhancing data collection, and reducing dropout will be critical for further strengthening these services.

Limitations

This project has important limitations, including its small sample size (in terms of the facilities and individual respondents). In addition, the assessments were conducted by MOHSW and MCHIP representatives, not an external evaluator. The makeup of the final assessment team (MCHIP staff and MOHSW representatives who were familiar with staff at the facilities) could have influenced the feedback provided by some respondents. Challenges were encountered with data quality and availability during the final assessment, resulting in an inability to draw comparisons in family planning indicators between intervention and non-intervention sites in the 2 pilot counties. Finally, the assessment design did not allow obtaining data on family planning continuation rates or the incidence of closely spaced births.

CONCLUSION

In this proof of concept, integrating immunization and family planning services, using a referral model with co-located services designed for Liberia's health system and sociocultural environment, was feasible, resulting in increased contraceptive uptake among postpartum women. Immunization-related findings are encouraging but less clear, indicating that there was at least no decrease in the number of vaccination doses administered in conjunction with the integrated model. While continuous monitoring of immunization outcomes is needed, scaling-up this model could potentially contribute to large increases in postpartum contraceptive uptake, leading to longer birth intervals and, ultimately, to improved health outcomes for children and mothers and to other socioeconomic benefits for families.

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ORIGINAL ARTICLE

Predictors of Workforce Retention Among Malawian Nurse Graduates of a Scholarship Program: A Mixed-Methods Study

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Several non-remuneration strategies may help improve retention of public-sector nurses: availability of supplies, adequate housing, advancement opportunities, and a positive work environment. A scholarship program with close follow-up of graduates may also help improve retention.

ABSTRACT

Background: Malawi faces critical health care worker shortages of both physicians and nurses. The Global AIDS Interfaith Alliance (GAIA) began a nursing scholarship program in Malawi that requires graduates to work in the public sector for 4–5 years following graduation. The main objective of this study was to identify job satisfaction and retention factors of scholarship recipients after graduation.

Methods: We conducted a mixed-methods study consisting of 30 individual qualitative interviews and 56 quantitative surveys that evaluated job satisfaction, factors associated with retention, and impact of the GAIA Nursing Scholarship Program. Participants included GAIA scholarship recipients who had graduated. We used thematic analysis to analyze qualitative interviews. Kruskal-Wallis, Spearman correlation, and chi-squared tests were used to analyze survey data.

Results: The majority of survey and interview participants indicated it was unlikely that they would leave the public sector (70% and 90%, respectively). Most interview and survey participants cited a lack of supplies, inadequate human resources, and high workload as major challenges to their work. Poor working relationships with management or coworkers was significantly correlated with consideration of changing jobs in the next 6 months (correlation coefficient -0.28, $P < .05$ and -0.36, $P < .01$, respectively). Low salaries, high workload, poor accommodations, and a lack of appreciation were the most common reasons given for considering leaving the public sector while job security, desire to pursue further education, and public service agreement were primary motivations for continuing to work in the public system. Participants felt supported by GAIA staff and expressed a desire to serve their communities in return by working in government-supported health facilities.

Conclusions: Despite the many challenges faced by public-sector nurses, low-income countries such as Malawi can employ non-remuneration strategies to retain nurses in the public sector, including adequate housing, availability of supplies, advancement opportunities, and positive work environments. Scholarship programs with close follow-up of graduates may also help increase retention.

INTRODUCTION

Many countries in sub-Saharan Africa, including Malawi, face health care worker shortages, which directly affects the health of their populations. The estimated doctor-to-population ratio in Malawi is 0.2:10,000, and the nurse-to-population ratio is 3.4:10,000.[1–3] The nursing ratio is one-third of the WHO's recommended 10 nurses for every 10,000 people, leaving Malawian health facilities with a 65% vacancy rate for nurses and nurse-midwives.[4]

In 2004, the Malawi Ministry of Health (MOH) and the Christian Health Association of Malawi (CHAM) began a 6-year Emergency Human Resource Program (EHRP) to address the critical health worker shortage.[5,6]

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Malawi's 3.4:10,000 nurse-to-population ratio is one-third of WHO's recommendation.

The EHRP improved recruitment and retention of health workers in the country, expanded domestic health care training capacity, and employed international volunteer health care workers in the short term.[5,6] Through this program, the overall population of nurses increased by 39% between 2004 and 2009.[5] Despite the moderate success of the EHRP, the shortage of health workers in the public sector persists, with the largest vacancies in rural areas of Malawi.[5]

The MOH is the main supplier of health care, delivering about 76% of the country's services.[7] CHAM also delivers essential services free of charge through a service-level agreement with the MOH, which provides funding for limited services and human resources for health.[6,8] Although CHAM was established as a private health system made up of faith-based mission hospitals and training institutions, the MOH and CHAM work hand-in-hand to provide access to health care in rural areas.[6,8] The MOH also deploys 40% of nurse graduates to CHAM facilities while the other 60% are deployed to MOH facilities.[9]

With such a large percentage of the population dependent on publicly funded health care, retention strategies must address not only workers leaving Malawi, but also internal brain drain and worker preference for the private sector and urban areas. Salary is thought to be a main reason why nurses in Malawi leave government and CHAM-run health facilities, but it is often not the only reason.[6,10,11] Poor job satisfaction has been linked to burnout, absenteeism, intentions to leave, and high turnover rates.[12]

Low salaries as well as poor job satisfaction have been linked with high turnover in Malawi's public health care system.

One nonprofit organization attempting to address the nursing shortage in Malawi is the Global AIDS Interfaith Alliance (GAIA).[13] GAIA offers preservice scholarships for nurses who need assistance with college fees and who demonstrate a commitment to work in the public health system after graduation. The scholarship program supports nursing students who are predominantly orphans or from lower socioeconomic backgrounds. This strategy aligns with the "transformative education agenda" recommendations from the Commission on Education of Health Professionals for the 21st Century.[14] The scholarship recruitment phase targets needy students who have been accepted to nursing college (including one located in and serving a rural area) who are facing financial hardship and would otherwise be unable to complete a diploma/degree in nursing.[14]

The GAIA Nursing Scholarship Program provides tuition support to nursing students in Malawi and requires graduates to work for 4–5 years in the public health system in return.

The scholarship program aims to increase the number of nurses working in the public sector in 2 ways[13]:

- By providing tuition support, living stipends, uniforms, nursing supplies, and payment of council exam fees to improve yearly school progression of nursing students, on-time graduation rates, and licensing exam performance.
- By requiring students to sign a service agreement to work for the MOH or CHAM for 4–5 years after graduation from nursing school to retain them in the public sector.

GAIA monitors licensed GAIA nurse graduates deployed by the Malawi MOH into the public health system to ensure they fulfill their service agreement. While in school and after graduation (until 2 years after completion of the graduates' service agreement), GAIA maintains close follow-up with each scholar through site visits, text messaging, phone calls, and regional get-together events, providing academic assistance, psychosocial and clinical mentoring, and educational support, including opportunities for continuing professional development.[13] GAIA staff maintain follow-up data on all graduates in a continually updated database. GAIA's follow-up activities assist the MOH and CHAM with tracking whether GAIA scholars have reported to deployment sites.

The program has been operating in Malawi in collaboration with the MOH, CHAM, and the training institutions since 2005 and has awarded more than 400 scholarships to nursing students at the technician, diploma, bachelor's, and master's level. Although the program started before the 2010 WHO policy recommendations to improve retention of health workers in remote and rural areas, we have implemented some of the WHO recommendations, including targeted admission policies, supporting students attending rural nursing colleges, designing and conducting continuing professional development events for GAIA scholars, and ensuring a compulsory service agreement after graduation.[15]

The objectives of this study were to understand predictors of workforce retention among Malawian nurse graduates from the GAIA scholarship program and evaluate the effectiveness of the scholarship program. Although not all CHAM employees are hired through the MOH, for the purpose of this paper we are consider-

ing those nurses working under the service agreement to be public employees and those working for NGOs or for-profit organizations to be private employees. Retention is defined as a graduate who is currently serving or has completed his/her service agreement at the facility assigned by the MOH or CHAM.

METHODS

We undertook a mixed-methods study design consisting of semi-structured qualitative interviews and a survey. The study took place over a 6-week period between March 2014 and May 2014. The study was approved by the Committee on Human Research at the University of California San Francisco and the College of Medicine Research and Ethics Committee (COMREC) in Malawi. Prior to data collection, permission to conduct a program evaluation study was obtained from the MOH, CHAM, and GAIA. Written informed consent was obtained from all study participants.

Selection of Participants

The survey was distributed to all scholarship recipients who had graduated and for whom GAIA had current contact information. The convenience sample for the qualitative interviews was selected from this same database of 156 graduated GAIA scholarship recipients. Inclusion criteria for the interviews included being in accessible districts during the study period (i.e., could be reached by phone, email, or in person), including those who were currently working within their service agreement time period, those who had completed their agreement, and those who had defaulted on their service agreement. Exclusion criteria included any graduate who had returned to school, was not deployed, or could not be reached by phone, email, or in person.

Interview and Survey Instruments

Key interview topics were chosen based on a literature review of previous studies related to nurse retention, including job satisfaction factors such as preparedness, salary, availability of quality housing, availability of supplies, workload, opportunities for advancement, and relationships with coworkers and management.[16–23] Additional questions specific to the GAIA Nursing Scholarship Program were asked to evaluate successes and identify areas for improvement. We used 2 questionnaires: one targeting patient care nurses and midwives and the other for nurse educators at colleges or universities.

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At their induction ceremony, GAIA scholarship recipients receive essential nursing supplies and uniforms.

The survey included the 20-item Satisfaction of Employees in Health Care (SEHC) instrument.[24] This validated instrument measures health worker job satisfaction in low-income settings in areas of job content (condition of buildings, availability of supplies, workload, and organizational structure) and relationships with supervisors and coworkers.[24] We also included questions about the GAIA Nursing Scholarship Program and the participants' future career plans.

Data Collection

All interview and survey data were collected and analyzed by a single researcher who was not associated with GAIA staff.

We contacted eligible participants by phone for interviews, with a focus on reaching all 3 regions of Malawi and having variation among the type of facility and employer type and with consideration to urban-rural differences. The number of nurses ultimately interviewed in each region was directly proportional to the total number working in that region. Individual interviews took approximately 30–50 minutes to complete and were audio-recorded with permission of the participant.

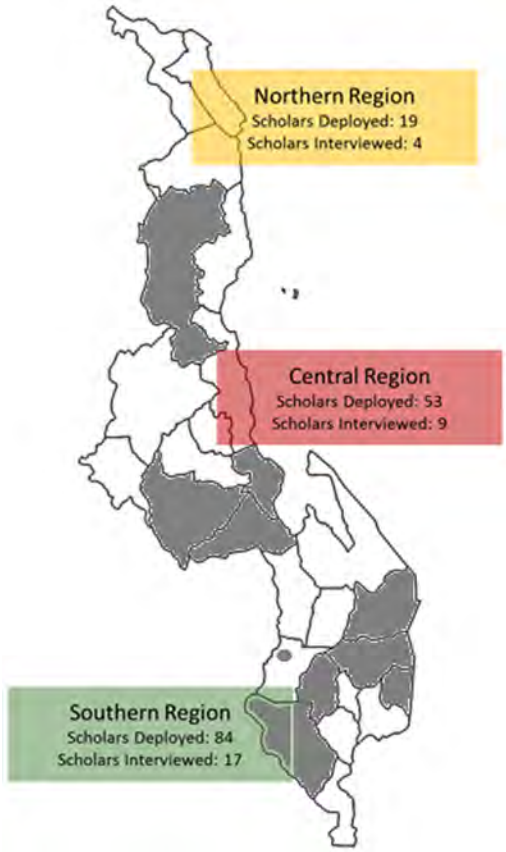
Quantitative surveys were distributed in person to those who could be reached or by email. All graduates participating in the qualitative interviews also completed the quantitative survey before the interview. For those who had an email address on file and were unable to be reached in person, a web-based survey using Qualtrics was distributed. To ensure that graduates did not complete multiple surveys, the graduates were given unique identification numbers that they returned with the paper or web-based survey. The number assigned was destroyed following distribution to the graduates and was not associated with survey responses.

Data Analysis

A single researcher analyzed the qualitative data using thematic analysis in Dedoose qualitative analysis software.[25,26] Data were analyzed first by reading through transcripts to become familiar with the content. The researcher developed initial codes by highlighting key phrases and searching for themes among these codes. Through an iterative process, themes were further refined and categorized. Data were reduced by clustering topics and key ideas into a summary of impressions.[25,26]

Quantitative data were examined as part of a program evaluation and to enrich and support the themes uncovered in the qualitative analysis. Kruskal-Wallis, Spearman correlation, and chi-squared tests were used to analyze survey data as appropriate. For all tests, a P value of less than .05 was considered to be statistically significant.

FIGURE. Locations of Deployed and Interviewed Global AIDS Interfaith Alliance (GAIA) Nursing Scholars



Malawi consists of 3 separate administrative regions: North, Central, and South. Gray areas in the map represent districts where GAIA Scholars were interviewed.

FINDINGS

Of the 156 GAIA scholarship recipients who had graduated, 141 met the inclusion criteria for the program evaluation study. We conducted 30 qualitative interviews throughout the 3 regions of Malawi in 10 districts (Figure). Surveys were sent to the GAIA scholars who had graduated and for whom we had current contact information; difficulties with Internet access and issues with the Qualtrics server resulted in a 36% response rate for the survey (N=56).

The nurses interviewed were predominantly women, with 74% working in government facilities, 23% in CHAM facilities, and 3% for an NGO (survey participants had a similar employer profile) (Table 1). The mean age of interview participants was 30 years, with a range of 23 to 63 years. Interview participants had an average 5.6 years of nursing experience, with 2.8 years at their current facility. Most (80%) of the interview participants were currently working within their service agreement, 17% had completed their service agreement, and 1 participant (3%) had defaulted on her agreement. (Comparable data were not collected from survey participants.) Most of the interview participants were working in urban areas (67% urban, 23% rural, and 10% peri-urban).

TABLE 1. Demographic Characteristics of Interview and Survey Participants

	Interview Participants (N=30)	Survey Participants[a] (N=56)
Gender, n (%)		
Male	1 (3%)	1 (2%)
Female	29 (97%)	55 (98%)
Employer Type, n (%)		
Government	22 (74%)	42 (75%)
CHAM	7 (23%)	11 (20%)
NGO	1 (3%)	3 (5%)
Facility Type, n (%)		
Central hospital	10 (33%)	13 (23%)
District hospital	3 (10%)	15 (27%)
Health center	6 (20%)	7 (13%)
Mission hospital	3 (10%)	4 (7%)
Nursing college	6 (20%)	15 (27%)
Other	2 (7%)	2 (6%)

Abbreviation: CHAM, Christian Health Association of Malawi.
[a] All interview participants also participated in the survey.

Five major themes emerged from the qualitative interview data, which were also supported by the quantitative survey data (Table 2).

Theme 1: Lack of resources and high nurse-to-patient ratios were main challenges faced by nurses. Participants cited a lack of resources, in terms of both supplies and staffing, and high nurse-to-patient ratios as reasons they were dissatisfied with their jobs. Almost all the interview participants (29/30) cited a lack of supplies as one of the greatest sources of dissatisfaction and the most challenging part of their job.

Lack of resources and high workload were the main challenges faced by nurses.

TABLE 2. Major Themes Derived From Qualitative Interviews With GAIA Nursing Scholars

Theme 1	Lack of resources and high nurse-to-patient ratios were main challenges faced by nurses.
Theme 2	Poor working relationship with management or other nurses were likely predictors of wanting to leave the current facility but not necessarily the public system.
Theme 3	Low salaries in relation to workload, poor housing options, and lack of appreciation were the most common reasons for leaving the public system.
Theme 4	Job security, continuing education, and public service agreement were primary motivations for continuing to work in the public system.
Theme 5	Nurses felt both supported and a sense of belonging, as well as a desire to give back to the community, due to the GAIA scholarship program.

Abbreviation: GAIA, Global AIDS Interfaith Alliance.

> *With enough resources, I think the work would be easier. Because without resources, when we're improvising it's tiresome. You are using your head, you think too much. What can I do? What should I do? Everyone is looking at you while there is nothing you can do, nothing to use.* (Surgical nurse, MOH facility)

The only nurse who did not cite this as a reason was working for an NGO. Among survey respondents, 75% either disagreed or strongly disagreed that their department provided all the necessary resources and supplies to perform their duties (Table 3). Overall, this item received the lowest score among survey statements about sources of job satisfaction, with a mean rating of 2.2. There was no statistically significant difference between those working at CHAM and MOH facilities.

Interview participants expressed an emotional toll from being unable to provide appropriate care due to lack of resources. Inadequate staffing and high workload were also frequently identified as a challenge. One nurse explained:

> *Like this season, malaria season, we normally have patients up to 300 against 8 nurses. We are supposed to be 8 nurses, but … you come here and find that there are only maybe 4 nurses and you work against 300 patients. It's a very busy ward and the job is just very stressful.* (Pediatric nurse, MOH facility)

Theme 2: Poor working relationships with management or other nurses were likely predictors of wanting to leave the current facility but not necessarily the

TABLE 3. Job Satisfaction Survey Findings, Malawi GAIA Nursing Scholarship Program Graduates

Statement About Current Job	% Disagreed or Strongly Disagreed	% Agreed
The management of this organization is supportive of me.	11%	89%
I receive the right amount of support and guidance from my direct supervisor.	20%	80%
I am provided with all trainings necessary for me to perform my job.	41%	59%
I have learned many new job skills in this position.	39%	61%
I feel encouraged by my supervisor to offer suggestions and improvements.	14%	86%
The management makes changes based on my suggestions and feedback.	41%	59%
I am appropriately recognized when I perform well at my regular work duties.	30%	70%
The organization rules make it easy for me to do a good job.	21%	79%
I am satisfied with my chances for promotion.	64%	36%
I have adequate opportunities to develop my professional skills.	39%	61%
I have an accurate written job description.	21%	79%
The amount of work I am expected to finish each week is reasonable.	48%	52%
My work assignments are always clearly explained to me.	23%	77%
My work is evaluated based on a fair system of performance standards.	46%	54%
My department provides all the equipment, supplies, and resources necessary for me to perform my duties.	75%	25%
My coworkers and I work well together.	7%	93%
I feel I can easily communicate with members from all levels of this organization.	11%	89%

Abbreviation: GAIA, Global AIDS Interfaith Alliance.

public system. Interview participants stated the importance of feeling appreciated by their supervisors and emphasized positive relationships with coworkers as factors associated with remaining in their current job. Three participants interviewed had previously transferred, and another was planning a transfer in the future because of a poor relationship with coworkers or management. Some participants felt that management in the private sector was generally harder on staff, less understanding of their personal lives, and more interested in making money than those in the public sector.

A nurse in a rural health center indicated that her relationship with management and her coworkers was a reason for her wanting to remain at her work site:

> *What I like most is that mostly the workers here are able to communicate effectively. We are united. We understand each other well. It's easy for us to cooperate and achieve one goal. That's what I like most.* (Health center nurse, CHAM facility)

One nurse who requested to be transferred to a different health facility in the CHAM system explained:

> *The management team has more effect on whether a nurse can be at a facility for a long time. It depends on the treatment you are receiving. If you are treated well you can … be there forever, but if you are not treated well it is easy for you to look for another place to work.* (Outpatient nurse, CHAM facility)

Nurses emphasized the importance of feeling appreciated by their supervisors.

Similarly, the surveys found that higher scores on the relationship with management scale (−0.28, $P < .05$), as well as higher scores on the relationship with coworkers scale (−0.36, $P < .01$), were negatively correlated with how likely a participant was to be interested in looking for a new job in the next 6 months (Table 3). Higher scores on the relationship with management scale were also negatively correlated with how likely a participant was to be interested in looking for a new job within the public sector (−0.33, $P = .02$) (Table 4). The survey data showed no other items to be significantly correlated with seeking a new job in the public health sector. There was also no statistically significant difference between those working for the MOH vs. CHAM.

Theme 3: Low salaries in relation to workload, poor housing options, and lack of appreciation were the most common reasons for leaving the public system. Although interview participants felt that resources were a major contributor to nurses'

TABLE 4. Spearman Correlations Between Job Satisfaction Measures and Likelihood of Leaving the Public Sector

	Job Satisfaction Measures			
Likelihood of Leaving Current Public-Sector Position to:	**Relationship With Management**	**Job Content**	**Relationship With Coworkers**	**Total**
Look for a new job in the next 6 months	**−0.28 (.04)**	−0.21 (.14)	**−0.36 (.01)**	**−0.30 (.03)**
Look for a new job in the next year	−0.20 (.15)	−0.13 (.34)	**−0.32 (.02)**	−0.23 (.09)
Look for a new job after service agreement is completed	−0.23 (.11)	−0.03 (.87)	−0.02 (.94)	−0.16 (.24)
Look for a different job in the public health system	**−0.33 (.02)**	−0.19 (.17)	−0.16 (.23)	**−0.30 (.03)**
Look for a job with a private employer	−0.15 (.26)	0.02 (.92)	0.05 (.74)	−0.10 (.47)
Look for a job outside the health care profession	−0.11 (.42)	0.00 (.99)	0.00 (.99)	−0.06 (.68)
Continue formal education	0.03 (.80)	0.15 (.30)	0.00 (.98)	0.07 (.61)
Look for a job outside Malawi	0.01 (.94)	0.14 (.33)	0.12 (.40)	0.09 (.51)

All data are presented as the correlation coefficient (*P* value). Negative correlation coefficients represent an inverse relationship while positive coefficients represent a constant relationship.
Data shown in boldface are statistically significant at $P < .05$.

job dissatisfaction, low salary was mentioned even more frequently as a reason nurses were leaving MOH or CHAM facilities.

> *The issue is about cash. [The private sector] is paying their nurses much money as compared to what they are receiving in CHAM; they do talk of leaving CHAM and joining some other facilities.* (Maternity nurse, CHAM facility)

Among the 5 nurses interviewed who had completed their service agreement, 4 have remained in MOH or CHAM facilities. The one who left the public system was currently employed privately and cited an increase in salary as her primary motivation for seeking new employment.

Other reasons participants cited for leaving the public sector were high workload, poor accommodations, and lack of appreciation.

> *I cannot manage to work the rest of my life in the public hospitals … because there is too much work overload.* (District hospital nurse, MOH facility)

Participants also reported a lack of appreciation for nurses by the general public.

> *No, in Malawi people don't value nursing … they just take us for granted. It's a demotivation because you are not appreciated. I think that's why some people always think of going to other places to work there, where they can be appreciated. Another country or maybe another organization.* (Male ward nurse, MOH facility)

Housing accommodations were not always immediately available after graduation.

A few participants mentioned that housing accommodations were not immediately available, which delayed deployment or required reassignment. Because of this delay, some nurses needed to look for their own employment outside the government before being deployed:

> *The government didn't deploy us [right away], so I had to search for somewhere to work for my own. So I got employed [privately].* (Health center nurse, NGO)

The transition between school and deployment was a difficult time for many of the participants. Most came from poor families that could not offer assistance when the participants could not afford to pay for their own housing. Several of the nurses took private jobs prior to their deployment by the MOH to supplement their income.

The majority of surveyed nurses said it was unlikely they would leave the public sector.

Survey data showed no statistical significance between any of the job satisfaction scales and likeliness to leave the public sector (Table 4). The majority of survey participants (70%) indicated that it was unlikely that they would leave the MOH or CHAM facilities.

Theme 4: Job security, continuing education, and public service agreement were primary motivations for continuing to work in the public system.

Nearly all the nurses interviewed (27/30) stated that they did not currently have plans to leave the public system now or after their service agreement was completed. There were no differences in plans to leave between those working at CHAM vs. MOH facilities in either the interviews or the surveys.

All participants expressed a desire to further their education through training and to pursue further education. Although they admitted such opportunities were rare, the belief that they might have the chance to continue their education motivated them to stay in the public sector and serve their communities. The 4 interview participants who completed their service agreement and remained in the public system all stated that they hoped to have the opportunity to continue their education.

In addition to continuing education opportunities, the other most common reason cited for continuing in government and CHAM facilities was job security. One nurse discussed how there is more freedom and security within the government system:

> *Most of the nurses like working in the public sector because it's free—what can I say? The rules are there, but they're not very stressed like in private hospitals … you can say you are sick and won't make it to work and they will understand. But when you are in private sector, it's very rare that you can do that. Mostly I feel like the benefits are the freedom in the public sector and that's what makes people stay.* (Health center nurse, NGO)

Several nurses mentioned the desire to work in the public system because it is where they can best serve their communities. One nurse who has completed her service agreement explained why she has chosen to stay at her current job:

> *I prefer the public system because I feel that is where I can benefit the most [people]. When I went for my training my aim was to work where I could serve the Malawian people at large. Because I know that most of the people that are affected by these conditions or illnesses in Malawi are the poor people. So where can you meet the poor people? These people, you meet them in the public*

institutions. So I feel better that if I work in the public institutions I can serve the Malawians at large unlike if I go to a private sector. (Health center nurse, MOH facility)

Theme 5: Nurses felt both supported and a sense of belonging, as well as a desire to give back to the community, due to the GAIA scholarship program. Interview participants felt supported by GAIA staff and indicated a sense of belonging through the program. Before graduation, the GAIA program elements receiving the highest ratings from survey participants (average score 4.0 or higher) were related to the monetary benefits (payment of fees, monthly stipend, clinical supplies, uniforms and shoes) (Table 5). After graduation, the highest score was for check-ins with GAIA staff (mean=4.5).

Interview participants expressed a desire to give back to the community because they were given the scholarship opportunity. They also reported that their relationships with the GAIA staff and other scholars extended beyond the element of monetary support.

It's good because it's not only that you have paid fees for me but it's also like a friendship. We have started a friendship and we can build from that. Not just a monetary bond, but also a friendship bond. (Central hospital nurse, MOH facility)

Several participants mentioned GAIA staff supported them through problematic situations. For example, GAIA staff helped one participant navigate a difficult deployment through CHAM:

I remember when I talked to her [GAIA staff] about what happened at my institution she was like, ''Oh, I never knew about this.'' So for me, I felt good that she was able to help. She went to CHAM and discussed it. (Nurse, CHAM facility)

Many participants mentioned the importance of close follow-up by GAIA staff. A participant working as a clinical instructor believed follow-up by GAIA staff has helped retain nurses in the public sector where the MOH has failed:

Scholarship graduates rated very highly the regular check-ins with scholarship program staff post-graduation.

If I'm faithful and I am committed, they [GAIA] will be able to sponsor other Malawians and help

TABLE 5. Value Ratings of the GAIA Nursing Scholarship Program (1–5 Scale)

Program Aspects	n	Mean	SD	Median
Before Graduation				
Payment of fees	52	4.9	0.5	5.0
Monthly stipend	48	4.2	1.2	5.0
Get-togethers	49	3.8	1.3	4.0
Clinical supplies	47	4.0	1.2	5.0
Uniforms and shoes	46	4.0	1.3	4.0
Talks by role models	46	3.7	1.4	4.0
Check-ins with GAIA staff	49	3.7	1.5	4.0
Availability of GAIA staff for assistance	51	3.6	1.5	4.0
After Graduation				
Get-togethers	48	3.7	1.5	4.0
Talks by role models	44	3.4	1.5	3.5
Check-ins with GAIA staff	52	4.0	1.2	4.5
Site visits with staff/donors	46	3.7	1.5	4.0
Availability of GAIA staff for assistance	50	3.5	1.4	4.0

Abbreviation: GAIA, Global AIDS Interfaith Alliance; SD, standard deviation.

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GAIA scholars working in 3 districts of Malawi attend a regional get-together to follow-up with the program after graduation and deployment and for professional networking opportunities.

Non-remuneration strategies to increase job satisfaction and retention include advancement opportunities, housing accommodations, and a positive work environment.

increase the health care in the public sector. With what GAIA is doing they are able to keep all of us in the public sector. But [the MOH], I think it is giving out to the community, paying fees for nurses and they are running away simply because the [nurses] don't have proper channels to follow. Because they don't keep in touch with them. (Nurse educator, CHAM facility)

DISCUSSION

Although there is abundant research documenting health care worker shortages and brain drain in sub-Saharan Africa, there is little that connects retention factors with programs that can motivate and retain nurses.[11,12,27–29] This evaluation was conducted to examine retention factors among graduates of the GAIA Nursing Scholarship Program and to inform future programming.

Major sources of job dissatisfaction for nurses were low pay, lack of resources, and staffing shortages.

The biggest challenges and sources of job dissatisfaction for Malawian nurses in this study were low pay, lack of resources, and staffing shortages. Most of the nurses did not indicate these as reasons to consider requesting a different deployment site through the MOH or CHAM, but lack of resources was mentioned as a reason to consider leaving the public system for private NGOs. As in many other countries, salary, perceived to be better within the private sector, appears to be the most important factor in prompting a move from the public to the private sector.[21,27,29–34]

Although most of the participants denied a personal desire to leave the public health sector, all expressed that Malawian nurses, in general, would rather work in the private sector. For low-income countries such as Malawi, matching the levels of remuneration provided by the private sector is not currently a feasible option.[32] Other studies have suggested that non-salary retention strategies are associated with increased job satisfaction and retention. These include incorporating opportunities for education and advancement, ensuring adequate accommodations near the hospital, reducing workload, and creating a work environment that encourages collaboration among staff and appreciation from management.[7,27,29–34]

A recurring theme in this study was a desire to have open communication with management and to feel appreciated for their work. The interviewed nurses suggested that there were not many channels to be recognized or appreciated for their hard work, and that supervisors were instead quick to reprimand them. They believed this attitude and treatment begins with their low salaries. Developing channels for communication and constructive feedback with supervisors could help nurses to feel valued and appreciated.[29]

All nurses expressed a desire to further their education through training workshops and advanced degrees. Although they acknowledged that such opportunities were rare in the public system, the chance for professional advancement motivated them to stay and serve their communities in the hopes that they would be rewarded. A study in Tanzania also found that medical doctors preferred the public sector for the opportunity to pursue additional education.[30]

Although increasing the number of nurses is a critical piece to solving the human resource crisis, retaining well-educated nurses where they are needed most is equally important. Focusing on non-wage-based strategies could motivate nurses to remain in the public sector. Ensuring adequate housing, especially for those being deployed to rural areas, is one way to increase satisfaction among nurses. In our study, nurses in rural areas were unsatisfied with accommodations and felt that this was a major area for the MOH to improve job satisfaction. Delays in deployment and lack of housing can result in prolonged staffing shortages and financial hardship for nurse graduates. This corresponds with results found in a Tanzanian study of medical doctors and dental surgeons, which found similar issues, naming the problem the "lost in transition syndrome."[28]

The GAIA Nursing Scholarship Program was designed to give qualified young Malawians, who

could otherwise not afford school, the opportunity to pursue an education in nursing. The close follow-up and relationship between GAIA staff and graduates resulted in 97% of the GAIA scholars remaining in the public sector throughout their service agreement and the majority continuing to at least 2 years past their service agreements.[35] This is supported by other research that found limited success with solely bonding graduates to the public sector due to issues of deployment and follow-up.[36,37] Nurses in this study believed that they should give back to their communities because of the opportunity that was given to them through GAIA and felt that the supportive relationships with GAIA staff and other GAIA scholars helped them transition into the workforce.

Limitations

Because participants were deployed nationwide, it was not possible to randomize the sample for the interviews or in-person surveys. There were a limited number of participants who completed their service agreement, and we did not interview or survey nurses who were not part of the GAIA scholarship program. Those that completed the online survey were more likely to be those in urban areas where access to the Internet was better than in some rural areas. Although we ensured that the interviewer was not associated with GAIA staff, it is still likely that there is some response bias. Despite these limitations, the study has practical applications for improving job satisfaction and retention among nurses working in low-resource settings. Additionally, lessons can be learned from the success of GAIA's Nursing Scholarship Program in retaining nurses in the public sector in Malawi.

CONCLUSIONS

Nurses working in Malawi's public health system face several challenges, including lack of supplies, shortage of human resources, limited housing options in rural areas, and low pay. Despite these challenges, nurses report many reasons to remain working in the public sector, such as opportunities for advancement, positive relationship with coworkers, and constructive feedback from managers. In addition to non-remuneration strategies, programs such as the GAIA Nursing Scholarship Program can help increase retention of health care workers by creating loyalty through careful follow-up monitoring both during and after schooling.

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Scholarship programs with close follow-up of graduates may help improve retention in the public sector.

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ORIGINAL ARTICLE

Female Health Workers at the Doorstep: A Pilot of Community-Based Maternal, Newborn, and Child Health Service Delivery in Northern Nigeria

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Deployment of resident female Community Health Extension Workers (CHEWs) to a remote rural community led to major and sustained increases in service utilization, including antenatal care and facility-based deliveries. Key components to success: (1) providing an additional rural residence allowance to help recruit and retain CHEWs; (2) posting the female CHEWs in pairs to avoid isolation and provide mutual support; (3) ensuring supplies and transportation means for home visits; and (4) allowing CHEWs to perform deliveries.

ABSTRACT

Introduction: Nigeria has one of the highest maternal mortality ratios in the world. Poor health outcomes are linked to weak health infrastructure, barriers to service access, and consequent low rates of service utilization. In the northern state of Jigawa, a pilot study was conducted to explore the feasibility of deploying resident female Community Health Extension Workers (CHEWs) to rural areas to provide essential maternal, newborn, and child health services.

Methods: Between February and August 2011, a quasi-experimental design compared service utilization in the pilot community of Kadawawa, which deployed female resident CHEWs to provide health post services, 24/7 emergency access, and home visits, with the control community of Kafin Baka. In addition, we analyzed data from the preceding year in Kadawawa, and also compared service utilization data in Kadawawa from 2008–2010 (before introduction of the pilot) with data from 2011–2013 (during and after the pilot) to gauge sustainability of the model.

Results: Following deployment of female CHEWs to Kadawawa in 2011, there was more than a 500% increase in rates of health post visits compared with 2010, from about 1.5 monthly visits per 100 population to about 8 monthly visits per 100. Health post visit rates were between 1.4 and 5.5 times higher in the intervention community than in the control community. Monthly antenatal care coverage in Kadawawa during the pilot period ranged from 11.9% to 21.3%, up from 0.9% to 5.8% in the preceding year. Coverage in Kafin Baka ranged from 0% to 3%. Facility-based deliveries by a skilled birth attendant more than doubled in Kadawawa compared with the preceding year (105 vs. 43 deliveries total, respectively). There was evidence of sustainability of these changes over the 2 subsequent years.

Conclusion: Community-based service delivery through a resident female community health worker can increase health service utilization in rural, hard-to-reach areas.

INTRODUCTION

About 342,900 women worldwide died from causes related to pregnancy and childbirth in 2008.[1] Sub-Saharan Africa bears a disproportionate burden of these deaths, with 3 of 5 of these deaths occurring in the region. Nigeria alone—with one of the highest maternal mortality ratios (MMRs) in the world—had an estimated 50,000 maternal deaths that year. Further, in contrast to many countries where the MMR has declined over recent decades, Nigeria is one of the few countries in the world where maternal mortality has shown no substantial reduction (516 per 100,000 live births in 1980 compared with 576 per 100,000 live births in 2013).[2] Thus, the country has for some time been signaled as one that will fail to meet the Millennium Development Goal (MDG) of reducing maternal mortality by 75% by 2015.[3] The situation is of

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Maternal mortality in northern Nigeria is significantly higher than the national average.

particular concern in northern Nigeria, where the MMR is estimated to be significantly higher than the national average. Recent estimates for the northern region exceed 1,000 per 100,000 live births compared with MMR estimates for the southern region, which are below 300 per 100,000 live births.[4,5]

In 2007, the Partnership for Reviving Routine Immunization in Northern Nigeria and the Maternal, Newborn and Child Health program (PRRINN-MNCH) was established, with support from the Department for International Development of the United Kingdom (DFID) and the Government of Norway, to address these issues in 4 states of northern Nigeria (Jigawa, Katsina, Yobe, and Zamfara).

In Jigawa state, the focus of the current study, a household survey had identified low rates of service utilization of basic primary health care services.[6] For example, only 21.5% of women had reported having their last baby in a health facility, and 21.2% of children between 6 and 23 months of age had received the recommended 3 doses of polio vaccine. Challenges of access and transport were reported as particularly extreme. Nearly 3 of 4 (71.5%) women reported that transportation and related access issues had prevented them from accessing health care services (compared with 49.9%, on average, in all 4 northern states).

Transportation and related access issues impede health care service utilization in northern Nigeria.

Renewed interest in the potential role and contribution of community health workers has gained momentum in recent years.[7,8] Many such cadres are community volunteers tasked with mobilizing community members to access the formal health system.[9–14] However, other cadres include trained employees deployed to bring services closer to the ''doorsteps'' of mothers and children, either through home visits or by being readily available at a local health facility or in emergencies.[15–17]

The Community Health Extension Worker (CHEW) is a long-established cadre of health workers in Nigeria designed for this ''doorstep'' role. Schools of health technology in Nigeria offer either a 2- or 3-year CHEW training program, the latter featuring more training in the actual delivery of infants. However, CHEWs in Jigawa (and other states in the north) are some way from fulfilling the promise to extend services to their communities. Outreach to homes is not within the usual scope of their practice, and distribution of CHEWs has been largely within urban areas. Rural areas that are served usually have not had resident CHEWs, severely restricting the functional hours that residents can access the health center (and virtually eliminating emergency access). Additionally, with the significant gender gap in educational attainment in the region, the majority of the CHEWs are male. This furthers restricts functional access to services in the community given cultural barriers to women receiving care from men.

The lack of reach of CHEWs into most communities was recognized by Jigawa's state health officials as a major factor in the low service utilization rates of primary health care services, including critical maternal and newborn care. In the context of the health system strengthening goals of the PRRINN-MNCH program, these officials sought examples of strategies to invigorate such a cadre for more effective community engagement. Ghana's Community-Based Health Planning Service (CHPS) strategy, originally developed in Navrongo to bring services to especially remote communities,[21] was recognized as a potentially relevant approach. Following a visit to Navrongo, Jigawa state health officials chose to pilot an adaptation of Ghana's CHPS strategy.[18]

The Navrongo CHPS model emphasizes the value of health workers living and working in the community where they are potentially able to provide truly community-based services. Nigerian CHEWs were considered broadly comparable to the community health officers and nurses of the Navrongo CHPS program, who had 18 months of training plus a 6-week orientation to community engagement and work based in the community.[19] However, an important adaptation of the Navrongo, and existing Nigerian, model was to explore the recruitment of only female CHEWs for such community-based work.

In this article, we report on a pilot study that examined the feasibility and outcomes associated with implementing this model of female, community-based CHEWs providing essential MNCH services within one Local Government Area (LGA) of Jigawa state. The lessons learned were expected to inform decisions about potential expansion of this model within the LGA, to other LGAs in Jigawa, to other states—and, indeed, to other nations—facing similar constraints.

METHODS

Site Selection

Jigawa state is divided into 5 emirates—Dutse, Hadejia, Kazaure, Ringim and Gumel—each

headed by an emir. For the pilot, we selected Jahun LGA, located 45 km from the state capital of Dutse and within the Dutse emirate. The Jahun Gunduma Council is the major governing structure for health provision in Jahun as well as Miga LGA, with responsibility for 30 primary health centers (PHCs) and Jahun General Hospital.

Jahun's population density of 152 persons/km^2 is typical for the state, and was thus considered an appropriate context for the pilot with potential for scale-up to other LGAs. The close location of the state School of Health Technology—the institution that trains CHEWs—also provided logistical benefits for initial phases of the work focused on curriculum review and training.

According to 2006 census figures, Jahun LGA had a total population of 229,094 people.[20] The specific target for this pilot were women of childbearing age, and particularly pregnant women. There were an estimated 57,000 women of childbearing age in Jahun LGA, with approximately 20% pregnant at any given time.

Within Jahun LGA, Kadawawa was selected to pilot the community-based service delivery program. Located approximately 36 km from the LGA headquarters, Kadawawa is a remote, rural community with a population of just under 16,000 people spread out across several hamlets. The terrain of the community is rough and barely accessible during the rainy season. Commercial vehicles and motorbikes get to Kadawawa once a week on market days. When health workers have to travel to and from the community, this is feasible only on market days, which fall on Fridays. Jahun General Hospital, approximately 1.5 hours away by vehicle, is the nearest basic or comprehensive obstetric care center to Kadawawa. Kadawawa is estimated to have a population of just under 3,000 women of childbearing age, with a little less than 800 pregnant women at any one time and some 600 women having children under 1 year of age. Before deployment of resident health workers, Kadawawa clinic was in a generally poor state of repair, serving only as a base for male CHEWs to provide immunization and related services on weekly visits to the community.

The community of Kafin Baka was selected as the control community because, although smaller in population, it otherwise had similar baseline characteristics to Kadawawa (Table 1). It is a rural village positioned within difficult terrain. It had a dilapidated and ill-equipped, although semi-functional, health center managed by non-resident male CHEWs who provided services on an irregular basis. As in Kadawawa, there were no female CHEWs at the health facility, and there were no outreach services by female health workers of any grade. The control site provided no ANC, deliveries, or postnatal care services, although the male health workers provided immunizations. The distance to Jahun General Hospital—the nearest basic/comprehensive obstetric care center—was similar to that for residents of Kadawawa, with similar transportation costs for the journey (around 5,000 Nigerian Nairas [NGN], or about US$25).

Transportation costs from the study communities to the nearest hospital were around US$25.

During the study period, both the intervention and control sites received general facility upgrades through Jigawa's implementation of a minimum service package. This focused on equipment and supplies but did not include staffing changes related to CHEWs.

TABLE 1. Selected Demographic Characteristics for Kadawawa (Intervention) and Kafin Baka (Control) Communities in Nigeria at Baseline

	No. (%)	
	Kadawawa	Kafin Baka
Population	15,954	6,748
Population under 1 year old	638 (4%)	270 (4%)
Women of reproductive age	2,712 (17%)	1,485 (22%)
Pregnancies at any given time	789 (5%)	337 (5%)

Pre-Intervention Studies

Pre-intervention qualitative studies were conducted to inform study design and pilot implementation, as well as to mobilize the community prior to implementation, a key feature of the Navrongo CHPS model. These studies included mapping of undeserved areas and focus group discussions (FGDs), key informant interviews, and community dialogues (*durbars*) to identify perceptions of factors contributing to the high rates of maternal and newborn mortality (including low service utilization) within the communities of Kadawawa and Kafin Baka.[21] FGDs were held with women of childbearing age, older women who had stopped childbearing, and young unmarried girls. Discussions were also held with older men, young married men, and young unmarried men, using similar FGD guides.

Consultations with community members helped shape the design of the pilot community-based service delivery program.

Key informant interviews were held with community leaders (men, women, youth, and religious leaders). Community dialogues were convened to ensure potential inclusion of community members who had not participated in other forms of consultation. Other pre-intervention studies involved in-depth interviews with CHEWs and health managers regarding the current practices and deployment of CHEWS, as well as a review of the CHEW training curriculum at the School of Health Sciences.

The pre-intervention qualitative research identified 3 major types of barriers to accessing existing services: household-level barriers, including cultural norms discouraging women's prompt access to care; facility-level barriers, largely lack of resources; and attitudinal issues, which further discouraged access to the referral facility in Jahun (Table 2).

In-depth interviews with CHEWs, health managers, and government leaders also identified a range of supply-side challenges, including a shortage of midwives, isolation, and problems in the operation of the ''Midwives Service Scheme'' (the national scheme deploying midwives to underserved communities). They also noted the circumstances that had resulted in CHEWs evolving from what were intended to be a community-based cadre to a clinic-based cadre. CHEWs were originally trained to spend 60% of their time within the communities doing home visits and 40% at designated rural health clinics. But their postings became increasingly politicized, and a majority of them were found living in urban areas and working in urban city clinics, avoiding rural areas. Men who married the few female CHEWs that had been trained in the state often did not allow their wives to live and work in rural areas.

The interviews with CHEWs and review of their training curricula indicated further barriers to effective deployment of this cadre. Deployed principally at urban general hospitals, CHEWS had had little opportunity alongside nurses and midwives to practice the skills they were taught at the School of Health Technology. Many functioned essentially as janitors or security staff at wards, or at best, were used as clerks to register hospital attendees. There was no clarity in the services that should be provided by CHEWs, and their training curriculum had neither been updated nor used as an active tool to shape the skills of students.

These findings led to a concerted effort to develop the CHEW training curriculum at the School of Health Technology to reflect contemporary approaches to community health provision and define more clearly a minimum service package that could be competently delivered by the cadre. The Jigawa state Ministry of Health and the Gunduma Health System Board (the body coordinating management of health services across a cluster of LGAs within the state) developed this minimum service package, mindful of state needs and concerns. The resulting document also was put into quality use and doggedly monitored. Notably, with revisions to the manuals guiding CHEW training, senior CHEWs were accepted as ''skilled birth attendants'' permitted to attend uncomplicated deliveries.

Data Sources for Pilot Evaluation

The pilot project was implemented over a 7-month period (February to August 2011). We adopted a quasi-experimental design to evaluate the pilot

intervention: routine service data collected through the established Health Management Information Systems (HMIS) were compared for Kadawawa (intervention area) and Kafin Baka (control area), with analysis focusing on the outcomes of health post visits, ANC attendance, and facility-based deliveries. We also compared state HMIS data from the 3-year period of 2008–2010 (before introduction of the pilot) with the 3-year period of 2011–2013 (during and after the pilot) to provide insight into the sustainability of changes following the intense pilot period. The protocol for the study was approved by the Ethics Review Sub-Committee of the Jigawa Operations Research Advisory Committee.

THE INTERVENTION

Based on findings from the pre-intervention qualitative studies, the planned pilot focused on issues of gender (using female workers), functionality (securing required drugs, equipment and supplies, transportation, etc.), and residence (identifying secure lodgings and infrastructure to support continuity of community engagement). Specific design elements included the following:

- Female CHEWs would be deployed, typically in pairs to support each other, to live and work in remote underserved areas.
- CHEWs would operate from previously dysfunctional health posts in the community (equivalent to the CHPS compounds in northern Ghana).
- CHEWs would be available 24/7 for primary and urgent care visits to the health post.
- They would undertake home visits on rotation with duties at the health post.
- They would be trained to handle normal deliveries; to refer complications of pregnancy and delivery to the hospital in Jahun; and to counsel women on child spacing and provide family planning methods if couples expressed interest, consistent with the cultural sensitivities of the region.
- CHEWs would be trained in the Integrated Management of Childhood Illnesses (IMCI) package and to use the IMCI triage method to refer relevant cases to the nearest PHC.
- They would be provided with the drugs, equipment, and supplies required to provide the basic services specified by the Gunduma Health System Board.
- CHEWs would collaborate with other community-level initiatives such as the Emergency

Female community health workers were deployed to live and work in remote underserved areas.

TABLE 2. Summary of Pre-Intervention Qualitative Study Findings in Jigawa State, Nigeria

Theme	Findings
Barriers hindering pregnant women from accessing health care	• Women have to seek approval from an authority figure to access health care. • Weak women were perceived to deliver at the hospital and strong women at home. • Community members lacked knowledge about pregnancy danger signs.
Barriers at the community health facility level	• Poorly equipped health facilities: ''We have to give birth on cement floors because there is only one bed …'' • Limited access to drugs: ''We need medicines, we need our hospitals to be repaired …'' • Limited access to health personnel, especially female personnel: ''The male CHEWs are afraid of touching us …''; ''[Female CHEWs] should be available in the facility at all times, not coming from time to time …'' • No emergency transport to Jahun General Hospital: ''The roads are bad and the hospital a long distance away … transportation is too high [costly] and if the only available car has gone to the market, that is all …''
Barriers at the referral facility level	• Perceived negative outcomes to delivering at Jahun General Hospital: ''If CHEWs referred us to Jahun General Hospital, we will not really be happy to hear that …'' • Feeling insulted and harassed by staff at Jahun General Hospital: ''They ignore us and call us villagers …''

Transport System and community volunteers leading community health dialogues.

- The local community and LGA would assume responsibility for health post renovations, along with provision of necessary furniture and equipment.

CHEW Selection Criteria

Criteria for selection of CHEWs were developed through discussions with communities. In addition to being female, priority was given to women who were married, ideally already with children born and raised, and who had completed their studies at the Jigawa School of Health Technology, had prior experience working as a CHEW at a health post in the state, were willing to travel to visit isolated hamlets, and had expressed willingness to live and work in a rural remote area without electricity or reliable vehicular access. CHEWs were recruited through advertisements in the local newspaper, at the Jigawa School of Health Technology, and at Jahun General Hospital.

The deployed community health workers received a rural residence allowance in additional to their standard salary.

Training

Selected candidates completed a self-assessment of training needs with respect to the expected duties that were communicated to them. We then provided a 2-week ''refresher'' training workshop (many of the required skills were formally within their existing scope of practice but had not been operationalized well), using instructors from the Jigawa School of Technology and technical advisors. These CHEWs then joined others from neighboring states that were also piloting community-based service delivery programs for an additional intensive training workshop on key IMCI elements and provision of basic ANC.

Four candidates from Jigawa completed the training and orientation program, 2 of whom were selected for redeployment in Kadawawa in February 2011. The 2 CHEWS rotated between home visits and delivering services at the health post.

Health post visits per capita increased by more than 500% after deployment of resident female community health workers.

Community-Based Service Delivery Package

The service delivery package at the health post included outpatient, ANC, and immunization services, supervision of normal deliveries, provision of supplementary feeding support, and referral to secondary services. Home visits—structured with respect to an approved protocol and record form—addressed preventive issues, health education, basic primary health care, and identification of family care needs, with referral to the health post or to secondary provision as appropriate (making use of the Emergency Transport System for emergency referrals). The CHEWS also held responsibility for liaising with local health volunteers, such as the nascent cadre of Village Health Workers, to share health education information and identify cases of concern.

Monthly ANC attendance increased substantially with deployment of resident community health workers.

Remuneration

CHEWs received their standard CHEW salary plus a monthly rural residence allowance of 20,000 NGN (about US$100). Salaries for newly trained CHEWs were 38,000–42,000 NGN (US$190–210) per month, while the most senior CHEWs could receive up to 70,000 NGN (about US$350) per month.

RESULTS

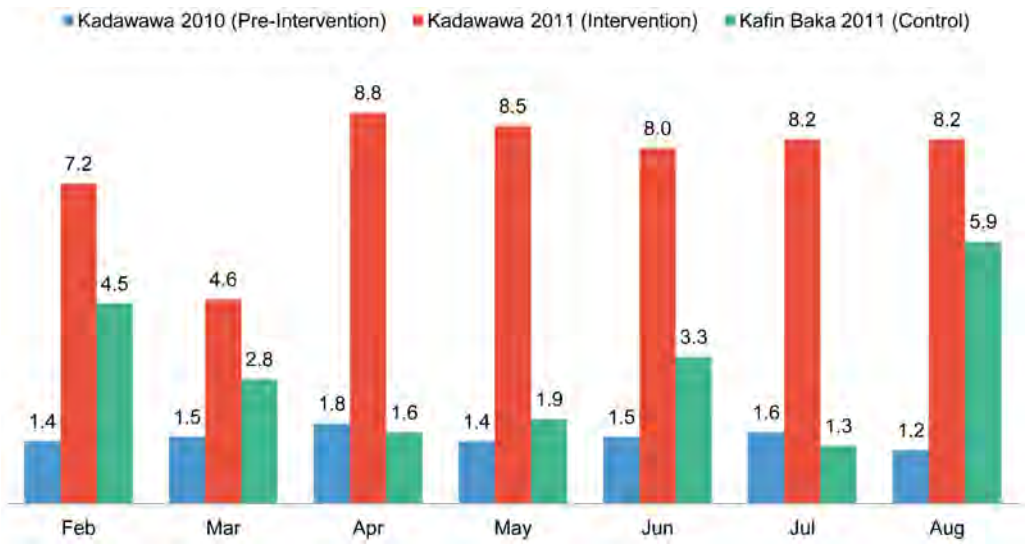
Visits to the Health Post

In Kadawawa, where the CHEWs were deployed, there were 7.2 health post visits per 100 population in February 2011, the first full month of deployment of the female CHEWs to the health post (Figure 1). In comparison, only 1.4 visits per 100 occurred during February of the preceding year and 4.5 per 100 in the control community clinic at Kafin Baka during the pilot period. After a slight decline in March 2011, health post visit rates in Kadawawa increased to 8.8 per 100 in April 2011 and then remained at or above 8.0 per 100 per month for the rest of the monitoring period. This represented more than a 500% increase of the per capita visit rates from the preceding year, which approximated to the Sphere humanitarian guideline of 1 consultation per capita per year. Although visit rates for Kafin Baka varied substantially from month to month (from 1.3 to 5.9 per 100), visit rates at Kadawawa were between 1.4 and 5.5 times higher than in the control community.

Antenatal Care

Between February and August 2011, the monthly percentage of pregnant women in Kadawawa receiving ANC ranged from 11.9% to 21.3% (Figure 2). In the preceding year, prior to the intervention, coverage had ranged from less than 1% to about 6% in that community. In the control community of Kafin Baka, coverage ranged from only 0% to 3%.

FIGURE 1. Number of Health Post Visits per 100 Population, Kadawawa Intervention Community (Before and During the Intervention) and Kafin Baka Control Community, Northern Nigeria



Delivery at a Health Facility

Following deployment of community-based, female CHEWs to Kadawawa, monthly facility-based deliveries by a skilled birth attendant steadily increased to reach 30 deliveries in June 2011 (Figure 3). Although there was some drop-off after this peak, over the 7-month study period facility-based deliveries by a skilled birth attendant more than doubled compared with the preceding year (105 vs. 43, respectively). There

FIGURE 2. Antenatal Care Attendance Rates per 100 Pregnant Women, Kadawawa Intervention Community (Before and During the Intervention) and Kafin Baka Control Community, Northern Nigeria

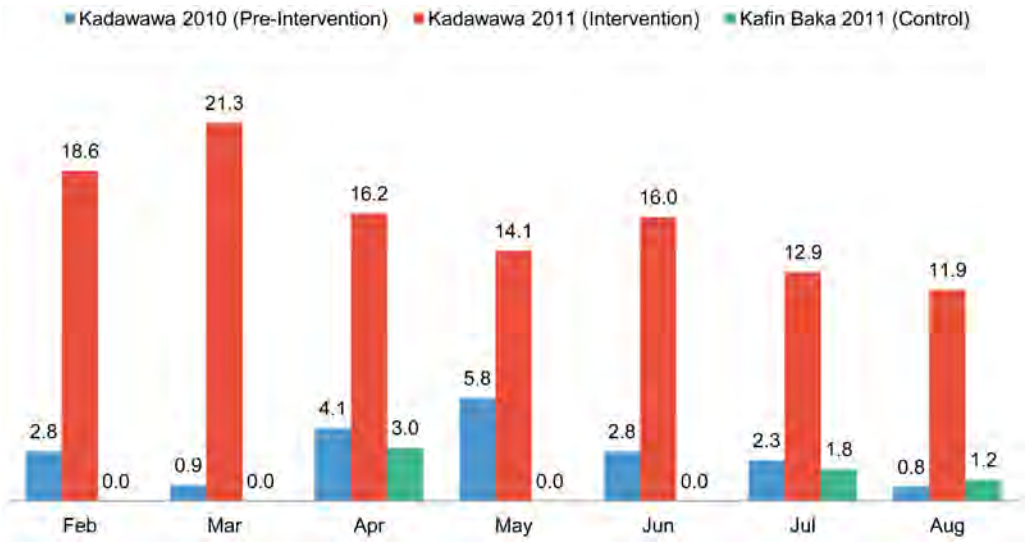
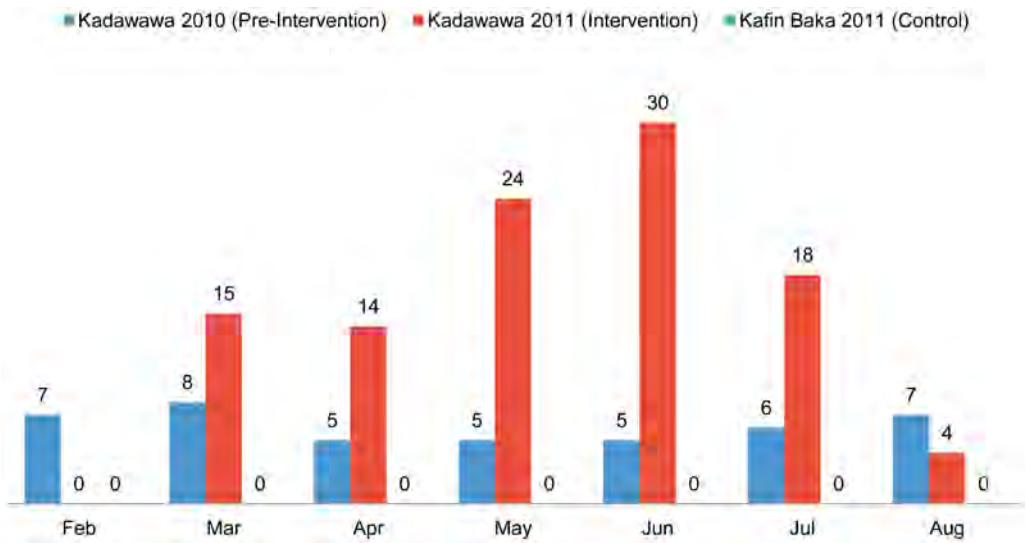


FIGURE 3. Number of Facility-Based Deliveries by Skilled Birth Attendants, Kadawawa Intervention Community (Before and During the Intervention) and Kafin Baka Control Community, Northern Nigeria



Monthly facility-based deliveries increased steadily following deployment of resident female community health workers, reaching 30 deliveries in June 2011.

were no recorded facility-based deliveries by a skilled birth attendant in the control site of Kafin Baka during the study period.

Home Visits

By the latter half of 2011, the CHEWs were making on the order of 40 home visits per month to the hamlets in Kadawawa, translating to an annualized home visit rate of over 800 children under 5 years old (approaching 40% of the estimated population of under-5 children).

Referral

Referrals by traditional birth attendants to CHEWs in Kadawawa for ANC or delivery more than doubled over the study period, according to records provided by CHEWs, suggesting increased confidence and trust in the CHEWs. Referrals from the Kadawawa health post to Jahun General Hospital also increased by over 75% from February to August 2011; prior to the intervention, such referrals had been virtually non-existent.

Service utilization improvements with deployment of resident female community health workers were sustained beyond the pilot period.

Sustainability of Changes

HMIS data indicated that improvements in service utilization in Kadawawa were generally sustained beyond the pilot monitoring period. The following trends were mapped to compare the 3-year period from 2008–2010 before introduction of the service innovation with the 3-year period from 2011–2013 during and after the pilot period:

- Average monthly ANC attendance (first visits): 28–169 vs. 860–1,140, respectively
- Facility-based deliveries: 10–47 deliveries per year vs. 192–260 deliveries per year, respectively
- Immunization: 26–89 children per year fully immunized in the former period vs. a steady increase from 195 in 2001 to 389 in 2012 and 476 in 2013

Comparable data are not available for the control site of Kafin Baka to consider the influence of wider health systems developments on these figures. However, it seems clear that increases in service utilization in Kadawawa cannot be solely attributed to activities associated with the start-up pilot phase.

Although a detailed cost-benefit analysis was not possible, general indications support the benefits of fielding CHEWs in community-based service delivery to substantially exceed the associated cost of operations. By May 2014, the Kadawawa community had recorded zero maternal and neonatal deaths for 3 consecutive years. PRRINN-MNCH program analysis estimated the overall package of interventions introduced in communities such as Kadawawa to represent an

investment of between US$25 and $50 (approximately 5,000–10,000 NGN) per maternal and infant death averted.[22]

DISCUSSION

After deployment of resident female community health workers to a rural community in northern Nigeria to provide reliable MNCH services at a local health post, 24/7 emergency coverage, and home visits, total health post visits, antenatal care coverage, and facility-based deliveries by a skilled birth attendant rose substantially compared with before the intervention, and were higher than in the control community that did not have resident, female CHEWs. The gains in ANC and skilled birth attendant deliveries were not consistent throughout the pilot intervention period of February–August 2011, but data from 2012 and 2013 indicate a longstanding trend for higher consultation and delivery rates in the intervention community compared with the 3-year period before the intervention.

Key challenges to implementation and scale-up of the community-based service delivery model, however, were identified, including gaps in skills of the CHEWs, training and supervision needs, procurement of supplies, transportation issues for home visits, and recruitment and retention of CHEWs.

Training and Supervision Needs

It was widely agreed during discussions with a broad range of stakeholder that community-based CHEWs can be an effective cadre to promote safe deliveries and immunization, assess social and support needs, and provide ANC, postnatal care, home visits, sick child case management, growth monitoring and nutritional counseling, and immunization. CHEWs were also considered well placed to provide support for birth spacing and family planning, to recruit and support community volunteers, to liaise with village health committees, and to generally monitor the health situation of a village.

However, during the pilot, we identified gaps in skills of the CHEWs with respect to these roles, and initial or refresher training curricula have subsequently been strengthened to address these gaps, particularly in lifesaving skills, leadership, and communication. Initially, the CHEWs were not trained to perform deliveries, but they reported that in many instances a woman's labor had advanced too far for a safe referral by the time the woman had reached the CHEW's residence or the CHEW encountered the woman during a home visit. Therefore, taking a harm reduction view, the CHEWs were trained to perform deliveries and were provided with delivery kits to be used as needed in these urgent cases.

There was a harm reduction benefit in allowing community health workers to perform deliveries.

Supervision of the deployed CHEWs was challenging during the study period. It had been envisioned that qualified supervisors from urban-based health facilities would be able to balance their work at their own facilities with visits to the staff at Kadawawa. However, personnel shortages and difficulties with travel logistics constrained the frequency and quality of such support.

Procurement and Transport

During the pilot, the CHEWs experienced irregular drug and non-drug supplies despite commitments made prior to launching the intervention. For example, vaccines were not regularly available partly because of unmet expectations that the Kadawawa health facility would obtain vaccine supplies from another health facility that had a solar refrigerator. However, there were also wider issues, such as periodic national stock-outs of vaccines. A generator for electricity and a refrigerator were eventually provided for vaccine storage at Kadawawa.

The pilot had provided initial ''seed stocks'' of medicines and supplies, pending the establishment of reliable procurement and supply mechanisms. While regular supply of immunizations and outpatient cards—which are dependent on federal supply sources—remained problematic throughout the study period, CHEWs subsequently received a fairly stable supply of essential drugs, with political, administrative, and financial support from the Gunduma Health System Board and Jahun LGA authorities.

CHEWs experienced difficulties in securing transportation for conducting home visits throughout the study period, especially during the rainy season. These difficulties reflected both logistical and cultural constraints. Local availability of transportation was severely limited, and access to it needed to be negotiated on a daily basis. While male CHEWs potentially could ride motorcycles supplied through the Gunduma Health System Board, there were cultural mores that prevented female CHEWs from having similar access. However, in August 2011, as a result of an advocacy visit to the traditional ruler, the Emir of Dutse, consent was given for female CHEWs to ride ''gender-sensitive'' motorcycles

Advocacy with a traditional ruler resulted in allowing the female community health workers to ride motorcycles for their work.

"Gender-sensitive" motorcycles that did not expose women's legs while riding were approved by traditional rulers for use by the female community health workers.

(which did not expose women's legs while riding) to facilitate their work. Although having no formal legislative role with respect to the health system (which is directed within the state at the level of the Gunduma), the Emir has significant cultural and political influence within this deeply conservative area.

Supply availability and transportation have emerged as recurrent themes in studies of effectiveness and retention of a range of community health worker cadres. For example, Brunie et al., in their study of community health workers in Uganda, found that transportation and commodity stock-outs were the most frequently reported challenges for workers.[14]

Recruitment and Retention

Ensuring adequate housing accommodations and providing an extra rural residence allowance were critical in recruiting and retaining rural-based community health workers.

At the outset of the study, it was clear there were a limited number of female CHEWs in the state who were motivated to live and work in rural areas. The majority of the available CHEWs were married and living in urban areas. Obtaining spousal support to relocate was problematic, and the working environment in rural areas was seen as unattractive. In order to motivate CHEWs to live in rural areas, we offered the deployed CHEWs an additional allowance of 20,000 NGN per month. CHEWs considered the total package (with accommodation, see below) attractive, and by the end of the study period, a number of CHEWs were applying to live and work in the rural areas to which the model was planned for expansion. Further, many Gunduma directors bought into the project by offering unemployed female CHEWs the same 20,000 NGN per month allowance, with accommodation, to live and work in the rural areas. This did not constitute a full employment offer by the councils, but it did help to enlist skilled female staff at the rural areas where 80% of pregnant women in the state reside.

Current practice favors the deployment of unmarried CHEWs for this community-based role, based on the assumption that being single increases the chances of CHEWs agreeing to live and work in a rural area. However, many young, single CHEWs are reported to marry shortly after graduation, and to marry civil servants or other elites who are unlikely to support such deployment. In such circumstances, likely critical incentives (in addition to the rural residence allowance) include employment of female CHEWs as regular health worker staff (rather than as contract staff) and limiting the minimum period of service, for example, to 2 years. Permission for spousal and other family member visits was an important element of support for the female CHEWs in Kadawawa, enabling them to stay in their posts longer and reducing their feelings of isolation from their families. Similarly, Abbey et al. report approval of the community and the health worker's immediate family as the most significant factors in predicting retention of community-based workers in Dangme West district in Ghana.[23] Over the long term, improving the quality of and gender parity in education and training is required to increase the pool of women from remote rural areas who are equipped to serve as health workers in their home areas (a major focus of the DFID-funded Women for Women Health initiative).[24]

A precondition for deploying and retaining female CHEWs was provision of adequate housing accommodations. To support retention of CHEWs in Kadawawa beyond the study period, part of the existing health facility was rehabilitated to create self-contained units (a bedroom and a sitting room) to accommodate the resident CHEWs. A kitchen was also created and toilets were rehabilitated, with provision of an external water tank that also supplied water to the CHEW consulting rooms. During the study period, the CHEWs in Kadawawa had been accommodated in the home of a local leader who was supportive of the intervention. Such community engagement in the model was vital in a context where delays and instability threaten service developments when dependent on formal governmental channels alone.

Finally, we found that deploying the CHEWs in pairs helped avoid feelings of isolation, which can help with retention and recruitment of health workers. In addition, they provided support to each other in their work. For example, the CHEWs rotated duties for home visits and staffing the health post.

Scale-Up of the Model

Jigawa state health officials presented the successful findings from the Kadawawa pilot study to the State Assembly and advocated employment of more female CHEWs to scale-up the service model. Their efforts were successful, and the Gunduma Health System Board subsequently budgeted for recruitment of additional female CHEWs. Communities and associated facilities were identified for the preliminary phase of expansion in 2013 to up to 30 locations, with associated plans for establishing CHEW residential accommodations. This entailed an allocation of an additional 20 million NGN in the Gunduma Health System Board budget, signaling endorsement of the pilot model as an effective and scalable strategy across the state.

Fifteen new health posts were refurbished and equipped, and an additional 60 female CHEWs were hired to expand the community-based service delivery model into 30 new sites. In addition, 30 ''gender-sensitive'' motorcycles were procured for female CHEWs to facilitate their home visits. Some of the budgeted funds were also used to purchase material incentives (baby wipes, soap, birth towels for newborn babies, wrappers, delivery kits) for pregnant women who delivered at the refurbished health facilities.

To ensure sustainability, the State Ministry of Health, the Ministry of Women Affairs and Social Development, the Gunduma Councils, and the Ministry of Local Government established a pooled fund to support community-based service delivery activities. In reflecting on the factors that enabled formulation and implementation of the pilot community-based service delivery model, and supported its subsequent planned scale-up, the value of an enabling governance environment should not be ignored. Since 2007, management of health facilities in Jigawa has been delegated from the State Ministry of Health to the Gunduma Health System Board, which then devolves services to the 9 Gunduma Councils.[25] The director of a Gunduma Council is thus the administrative head of both PHCs and general hospitals under that council, allowing an unusual degree of coordinated planning. Between 2009 and 2012, Jigawa nearly doubled its state health expenditure,[22] with 90% or more of health budget allocations fully released each year.

CONCLUSION

A pilot deploying female community health workers to residential postings in a rural area of northern Nigeria increased health post visits, antenatal care coverage, and facility-based deliveries by a skilled birth attendant. The positive findings mobilized authorities to scale-up this model within the state. Key lessons learned include the harm reduction benefit of allowing community health workers to perform deliveries, the need to ensure regular supplies and sufficient personnel to provide supportive supervision, the importance of arranging culturally sensitive transportation means to conduct home visits, and the critical need to provide health workers an additional rural residence allowance to recruit and retain them.

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Competing Interests: None declared.

State health officials expanded the community-based service delivery model to an additional 30 sites.

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FIELD ACTION REPORT

Barriers to Health Care in Rural Mozambique: A Rapid Ethnographic Assessment of Planned Mobile Health Clinics for ART

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Mobile health clinics can markedly decrease clients' transportation time and cost to access antiretroviral therapy (ART) and other health services in rural areas, potentially improving use. Close coordination with community leaders and regularly scheduled visits by the mobile clinics are critical.

ABSTRACT

Background: In Mozambique, 1.6 million people are living with HIV, and over 60% of the population lives in rural areas lacking access to health services. Mobile health clinics, implemented in 2013 in 2 provinces, are beginning to offer antiretroviral therapy (ART) and basic primary care services. Prior to introduction of the mobile health clinics in the communities, we performed a rapid ethnographic assessment to understand barriers to accessing HIV care and treatment services and acceptability and potential use of the mobile health clinics as an alternative means of service delivery.

Methods: We conducted assessments in Gaza province in January 2013 and in Zambezia Province in April–May 2013 in districts where mobile health clinic implementation was planned. Community leaders served as key informants, and chain-referral sampling was used to recruit participants. Interviews were conducted with community leaders, health care providers, traditional healers, national health system patients, and traditional healer patients. Interviewees were asked about barriers to health services and about mobile health clinic acceptance.

Results: In-depth interviews were conducted with 117 participants (Gaza province, n=57; Zambezia Province, n=60). Barriers to accessing health services included transportation and distance-related issues (reliability, cost, and travel time). Participants reported concurrent use of traditional and national health systems. The decision to use a particular health system depended on illness type, service distance, and lack of confidence in the national health system. Overall, participants were receptive to using mobile health clinics for their health care and ability to increase access to ART. Hesitations concerning mobile health clinics included potentially long wait times due to high patient loads. Participants emphasized the importance of regular and published visit schedules and inclusion of community members in planning mobile health clinic services.

Conclusion: Mobile health clinics can address many barriers to uptake of HIV services, particularly related to transportation issues. Involvement of community leaders, providers, traditional healers, and patients, as well as regularly scheduled mobile clinic visits, are critical to successful service delivery implementation in rural areas.

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INTRODUCTION

Globally, the annual numbers of new HIV infections and AIDS deaths are declining.[1] However, sub-Saharan Africa continues to bear the greatest HIV burden, with 70% of all cases occurring in the region. As of 2012, estimates indicate that only half of people living with HIV (PLHIV) in sub-Saharan Africa knew their HIV status.[1] While much progress has been made,

Almost half of people in sub-Saharan Africa who are eligible for ART don't have access to it.

and 54% of persons eligible for antiretroviral therapy (ART) in low- and middle-income countries are now receiving it, almost half remain without access. Health systems in the region face the difficulty of increasing the number of patients on ART while simultaneously caring for millions of people already on ART due in part to the critical shortage of health facilities and health care workers.[2]

Mozambique is one of the countries most affected by HIV/AIDS worldwide. The HIV epidemic is generalized with an estimated prevalence of 11.5%, although regional variations exist. Gaza province, for example, has the highest prevalence in the country at 25.1%.[3] Increasing ART coverage among the estimated 1.6 million PLHIV in the country remains a major challenge as over 60% of the population lives in rural areas and lacks access to health services.[3] ART coverage is low in key provinces throughout the country. For instance, Zambezia, Gaza, Sofala, and Manica provinces account for 52% of all PLHIV (20%, 12%, 11%, and 9%, respectively) but only 40% of the people currently receiving treatment in the country.[4] Targeted ART scale-up in these provinces will increase national treatment coverage.

Over 60% of Mozambique's population lives in rural areas with limited access to health services.

Mozambique is one of the world's poorest countries—185th of 187 countries in level of development according to the United Nations Development Index.[5] Mozambique's severe shortage of health facilities means patients must routinely travel long distances to access health care. In addition, stigma causes unnecessary suffering among PLHIV and has been cited as a barrier to HIV care and treatment services.[6–8] Another potential barrier to HIV care and treatment is the reliance on traditional healers,[9] which people use for a variety of reasons including easier access, confidence in their treatments, and local cultural practices.[10,11]

Mobile health clinics are special off-road vehicles capable of providing health services in rural areas.

Mobile health clinics are a potential solution to some of these barriers. Mobile health clinics are specially designed four-wheel drive trucks that are able to reach isolated destinations and are equipped to provide comprehensive health services. Services are provided in the vehicle as well as in tents or other structures nearby. Such mobile health clinics providing limited HIV, tuberculosis (TB), malaria, and sexually transmitted infection (STI) services have been successfully piloted in neighboring Malawi and South Africa.[12,13]

In 2013, the Ministério de Saúde (MISAU), with support through the US President's Emergency Plan for AIDS Relief (PEPFAR), implemented mobile health clinics in rural districts of Mozambique.[14] The objectives of the program are to scale-up HIV care and treatment services in areas with low treatment coverage, improve ART retention, provide integrated TB/HIV services, and provide selected primary health and maternal and child health services. By design, mobile health clinics address geographic and environmental access issues. However, the success of mobile health clinics in rural Mozambique depends on whether community members will accept and use them. Thus, a study was conducted prior to implementation of the mobile health clinics to: (1) establish current community health practices and attitudes, including potential acceptance and use of mobile health clinics, and (2) provide a baseline understanding of the health care seeking practices in high-burden HIV/AIDS rural communities in 2 provinces where mobile health clinics were to be introduced.

METHODS

We conducted a cross-sectional, rapid ethnographic evaluation in January and April–May 2013. This approach facilitates the collection of locally relevant data from the perspective of those most affected by the research question(s).[15] The process is inclusive of a triangulation method of structured interviews, semi-structured interviews, and observation. These modified procedures allow for relatively rapid research to enhance and guide program planning and evaluation and have been demonstrated to be a successful adaptation of traditional ethnographic research methods.[16]

Selected districts within Gaza and Zambezia provinces that were going to receive mobile health clinic services were included in the assessment because of their population size and current ART coverage. Within these districts, specific towns were selected for their representativeness of communities that would be receiving mobile health care services. Representation included availability of health care services and health care providers in the community, distance to services, and population size. In addition, the communities in Zambezia were chosen by matching population size and proximity to the nearest ART health facility to the communities that were chosen in Gaza. Approval for the assessment was obtained from the Centers for Disease Control and Prevention and from the Mozambique Ministry of Health.

Recruitment of Participants

In January 2013, a total of 57 participants (n=39 women, n=18 men) were interviewed in Gaza province. Gaza province is located in southern Mozambique, immediately north of the capital city of Maputo. The 57 interviews were conducted in 2 districts in Gaza province: Chibuto and Mandlakaze.

From April to May 2013, a total of 60 participants (n=17 women, n=43 men) were interviewed in Zambezia province, located in northern Mozambique and bordering Malawi. The 60 interviews were conducted in 2 districts in Zambezia province: Morrumbala and Milange.

Participants and sampling locations were purposively selected in close collaboration with the MISAU and PEPFAR implementing partners that provide HIV care and treatment services in the selected districts, including the Elizabeth Glaser Pediatric AIDS Foundation, the International Center for AIDS Care and Treatment Programs, and Friends in Global Health. Prior to arriving in the community, the implementing partners verbally communicated the purpose of the study to community leaders and sought permission to conduct interviews in the community.

Community leaders served as key informants, and chain-referral sampling was used to recruit participants. Community leaders were asked to help identify people in their communities where mobile health clinics were planned. Community leaders were also asked to help identify traditional healers who were willing to be interviewed, and, in turn, traditional healers were asked to identify patients willing to be interviewed. Hospital/clinic staff were informed of the assessment and asked to participate in the interviews and to help identify community members accessing national health services who were willing to be interviewed.

We conducted qualitative interviews with each of 5 populations: national health system providers (doctors, medical technicians, nurses, and lay counselors), persons accessing health care, traditional healers, persons accessing care from traditional healers, and community leaders. All participants were at least 18 years old and provided consent to be interviewed.

Data Collection

Audio-recorded interviews, lasting 0.5 to 2 hours, were conducted in either Portuguese or a local language (Shangana or Chope in Gaza, Chichewa or Lolo in Zambezia) and translated into English. Site visit teams were comprised of 2 primary investigators from CDC Atlanta, a Mozambique-assigned fellow from the Association of Schools and Programs of Public Health, and between 2 and 3 persons from local implementing partners. Interviews were conducted through a translator or, when possible, through one of the primary investigators.

Before beginning the interviews, the interviewer read each participant an informed consent form and obtained written consent to be interviewed. No participant declined participation or rescinded informed consent during the study. No compensation was provided for participation. After transferring the audio recordings to a computer and verifying transfer, the original recordings were deleted. The transferred recordings were stored on a password-protected computer. Consent forms and de-identified transcripts were stored in separate locked file cabinets belonging to the primary investigators.

Data Analysis

All coding and thematic analyses were conducted manually. The data analysis process included reading, coding, summarizing, and interpreting, leading to identification of common themes.

RESULTS

Slightly more than half (52%) of the participants in the interviews in both Gaza and Zambezia combined were men (Table). Among the participants who were patients (traditional healer patients and national health system patients), 48% were women, while all community leaders were males (n=13). Most (66%) health care providers (both traditional healers and providers from the national health system) were women. The average age of male participants was 47.4 years (range, 19–81 years), slightly older than the average age of female participants, which was 38.6 years (range, 22–65 years).

Interviews were conducted with community leaders, national health system providers and their patients, and traditional healers and their patients.

The interviews explored the following themes: community and health problems; barriers to health care; and knowledge and attitudes about mobile health clinics.

Community and Health Problems

Participants were asked to self-identify the 3 problems they perceived to have the biggest impact on their community, their personal health, and their family's overall health. The most commonly cited community problems were lack of schools, lack of

Commonly cited community problems included lack of schools, food, clean water, and access to health care.

TABLE. Number of Interviewees by Type and Sex, in Gaza and Zambezia Provinces of Mozambique

	Gaza		Zambezia		
	Men	Women	Men	Women	TOTAL
Community Leaders	5	0	8	0	13
NHS Providers	3	7	4	2	16
Traditional Healers	3	9	2	5	19
NHS Patients	6	14	19	10	49
Traditional Healer Patients	1	9	10	0	20
TOTAL	18	39	43	17	117

Abbreviation: NHS, national health system.

access to health care services, and lack of food (hunger). In Zambezia, many participants (n=26) also cited lack of clean water (compared with 6 participants in Gaza). Because of the lack of access to health care services, people frequently delayed going to health facilities for minor health problems. The most commonly cited health problems were malaria, HIV, diarrhea, and TB (in order of frequency reported).

Distance, cost, and lack of transportation were commonly cited barriers to health care access.

Lack of access to health services often had impacts beyond individual and family health. While the costs associated with obtaining medical care once at the facility are minimal, getting to the facility in the first place requires a large sum of money that is much needed for food, housing- and school-related costs, and other supplies. One patient stated:

> *They [health problems] have a negative impact because my family has to use money for transportation to hospital for medication. If I didn't have HIV, we could use that money for other things.*

In Gaza, lack of health services was the third most mentioned community problem behind lack of schools and lack of food. In Zambezia, lack of health facilities was also mentioned, but lack of water, food, schools, and transportation, and the poor condition of roads, were all mentioned more often. Beyond financial costs, time-associated costs with accessing health care were described as sometimes prohibitive, with round trips to health care facilities taking more than 24 hours in some areas. One patient described the impact of not having a health facility in the community:

> *Access to health care is a big problem. I left my home this morning to reach here. We have a small clinic, but they don't do blood tests. Sometimes we have transport, but today because of the rain it was difficult. It takes about 3 hours to walk, more if you are sick.*

Barriers to Health Care

The most commonly cited barriers to health care were distance from health facilities, lack of money, lack of available transportation, and poor health facility conditions. Distance was seen as a barrier to accessing health care services because of both the cost and the lack of transportation. Participants reported that it took them an average of 1 hour in Gaza and 3 hours in Zambezia to reach a health facility. Gaza participants stated that minibus taxis were used as their primary means of transportation. In Zambezia, few participants had access to minibuses and described arriving to clinics on foot or by bicycle. Participants in Milange district in Zambezia commonly used a boat to cross a crocodile-infested river in order to travel to the nearest health facility, which often meant going to Malawi. Many of the patients felt that the distance affected their ability to receive services.

One patient in Gaza explained:

> *People feel the services are at fault. People get up at 3 am to catch the chapa [minibus] to get here and wait for a consult, they go home about 4 pm. Most people have children, when they go to the hospital they have no person to give food or assistance to the children.*

In Milange district (Zambezia province), people faced especially grueling journeys to reach the HIV clinic. One provider described the barriers his patients overcame to access care:

People bicycle all day to come to the ART clinic—they start very early in the morning, travel 150 km, arrive very late at night, sleep in a family member's house, and then the next day come to the clinic for treatment.

Stock-outs combined with the long distances and high costs associated with reaching health care facilities in rural areas can negatively impact an individual's ability to remain adherent to their medications. This can ultimately have severe consequences for the individual. A patient explained the challenge of poverty in rural Mozambique and the inability to easily and/or frequently access health care:

My big concern is that I came here early in the morning to get pills for my son, he is sick. They [health care workers] only gave me one kind because they are out of the other. I don't have money to go to the hospital to get the pills. They tell me to come back tomorrow or next week to get the pills, but I don't have the money and it takes time to come here.

Many patients stated that they concurrently used traditional healers or would switch health systems if they were not feeling better after visiting one of the health systems. Traditional and formal health system treatments were described as being considerably different for some diseases; however, all interviewed patients stated that traditional healers had referred them to the formal health system for HIV treatment. The reasons for the use of traditional healers depended on the nature of the illness. One traditional healer patient described the concurrent use of traditional healers and the national health system:

You get sick, you go to the hospital and you get worse because you have a lack of blood and water in the body, and you get worse, so you go to traditional healer.

Other patients described their use of traditional healers when they could not reach a health facility. One traditional healer patient described her experience:

I couldn't go to the hospital, and I was having severe leg pain. The health center was far. I had no car, I had no phone. I crawled on my knees to the traditional healer's house. I got there at 1 am, when I got there I knocked, but no one answered, so I slept outside. The next day he treated me. I had xifulu. [*Xifulu was described as bad spirits sent from one person to another.*]

Potential Acceptance of Mobile Health Clinics

All participants supported the idea of mobile health clinics, stating they would use the clinics if available in their communities. One patient commented:

Distance and high costs associated with accessing health facilities can negatively impact medication adherence.

We would be proud to use the mobile clinics. Our children, our future, could receive treatment close to home. The only potential obstacle would be if the medications were expensive.

A national health system provider explained the potential benefit of offering multiple services at the mobile health clinics:

They will be good services if they really come to help. I would love to have services for the youngest, especially girls. If we see girls here that are just starting to look like women, they often come for contraception, but older people won't let the girls get contraception. It is thought that if a girl is looking for contraception, she is a prostitute. If anyone sees a girl this age at the clinic by herself, they will tell her parents, because they assume it is for contraception. Young girls are pregnant here, but we are not allowed to give contraception.

While universally supported, distance and money were potential barriers to using the mobile health clinics. One patient explained:

I live alone, and I work on a farm. It takes me 2 hours to get to the clinic, and costs 80 meticais [about US$2.41] round trip. I'd like to use the mobile clinics. The only barrier would be if they cost money and I didn't have it.

Coordination with community leaders and traditional healers is crucial for successful mobile health clinic implementation.

Participants explained that successful mobile health clinic implementation would depend on coordination with community leaders and traditional healers. They reported that community leader support was an important factor in use of the mobile health clinics.

In addition, after implementation of mobile health clinics, the community asked that they be kept informed of scheduled visit days and potential deviations from these days. There was concern regarding a lack of notification over scheduled visit dates and a fear of not being able to be seen because of the volume of people using the clinics. One patient of a traditional healer explained:

A [vaccination] clinic came to Chaimite last week but not all of the children were able to receive their shots because there were too many children.

Similarly, several participants were concerned that people from neighboring communities would discover the schedule for the mobile health clinics and travel to receive treatment, thus creating an additional burden on the clinics.

One participant felt that communication was integral to success of the mobile health clinic.

> *Mobile health clinics should have a nurse who knows the local language, so they can communicate with the people. This is very important.*

A provider emphasized the importance of mobile health clinics being adequately stocked with supplies:

> *Mobile health clinics must be equipped with sufficient stock of materials—HIV test kits, TB testing, all the supplies—this is very important.*

Traditional healers always referred patients to the national health system for HIV care, suggesting opportunities for collaboration.

DISCUSSION

Community members in rural Mozambique thought the most common health problems they faced (in order of frequency reported) were malaria, HIV, diarrhea, and TB. They indicated that the most common barriers to accessing health care were transportation costs, long distances, lack of transportation, and poor health facility services. Mobile health clinics present an opportunity to directly address these barriers by improving access to quality health care while decreasing the cost and time associated with accessing health services.

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The driver of a mobile health clinic in Gaza province, Mozambique, serves a dual role for data entry during mobile health clinic visits.

Stigma often remains an influencing factor on the decision to access HIV-related care in sub-Saharan Africa.[6] By offering a broad range of clinical services, mobile health clinics can minimize stigma often associated with receiving care at HIV-specific facilities. In addition, educational outreach provided through mobile health clinics is a key component of both stigma reduction and HIV and TB awareness.

Participants identified concurrent use of the national health system and of the traditional health system for routine care. Physicians and nurses in the national health system often disapprove of the care provided by traditional healers, leading to conflict between physicians and nurses, healers, and patients.[17,18] However, patients in this study indicated that traditional healers always referred them to the national health system for HIV care, suggesting an opportunity for collaboration between the 2 systems. For example, traditional healers could be used to provide health information and information on health care access with the arrival of mobile health clinics.

A positive finding from the interviews is that all participants were accepting of mobile health clinics in their communities, potentially an indicator that community members will use the mobile health clinics. Use of mobile clinics has been successful elsewhere,[12,13] and they have been shown to attract a greater proportion of first-time HIV testers than home-based and clinic-based testing.[19–21] Prior mobile health clinic experience in underserved areas of South Africa with high HIV prevalence showed that such clinics can help facilitate earlier HIV diagnosis, supporting the World Health Organization recommendation for initiation of ART at lower CD4 thresholds.[22]

Most of the research thus far has been on using mobile clinics to improve access to and use of HIV testing and counseling services. For example, research has shown mobile health clinics to be a cost-effective approach for expanding HIV testing and counseling and in reaching persons for referral to treatment and care. A few studies have assessed use of mobile health clinics in Zambia to deliver ART and report improved anti-tuberculosis treatment outcomes and uptake and retention of ART.[24,25] However, one potential limitation that must be accounted for is fuel, including availability of funding to purchase fuel to avoid visit delays or deviations from planned community visit days. A study in 3 African countries found that transportation cost and time and limited clinical hours are barriers to accessing health care.[23] By visiting the

community on a regular schedule, mobile health clinics have the potential to address these barriers, and hopefully reduce the financial cost of accessing health care, leaving more money to meet other necessary household expenses.

Through the Mozambique National Health Plan, the Government of the Republic of Mozambique and the MOH have called for a national health policy focused on strengthening primary health care, improving infrastructure, and increasing community-level engagement with an initial focus on Gaza, Sofala, and Zambezia provinces.[4] Our study suggests that mobile health clinics, working in collaboration with community health workers, can help strengthen selected primary care services, while increasing coverage of ART and improving retention of patients on ART over the long term. During multiple debrief sessions, results from this study were shared with partners to facilitate implementation of mobile health clinics in Gaza and Zamezia provinces.[26] Major challenges to mobile health clinics implementation will include financing, human resources, long-term sustainability, and maintaining community acceptance. Coordination with community stakeholders such as community leaders and traditional healers is necessary for successful implementation of mobile health clinics.

Study Limitations

Our study has several potential limitations, including the possibility of selection bias. National health system patients interviewed were already accessing health services, and traditional healers referred their own patients for interviews. This may have limited the range of perceptions gathered in our study, as persons not accessing the national or traditional health systems may have other opinions about mobile health clinics or on barriers to accessing care. Desirability bias could have led to participants giving answers that they thought would be viewed more favorably by the research team, and their answers may have been motivated by their desire to receive mobile health clinics or improved access to health care. As with all qualitative research, the generalizability of the findings is limited. However, the interviews were conducted in locations where mobile health clinics were planned for implementation.

CONCLUSION

Mozambique's mobile health clinic program should help address some of the major barriers to uptake of HIV services, such as distance and lack of transportation to health facilities. Involvement of community leaders, providers, traditional healers, and patients and regularly scheduled visits are critical to the successful implementation of mobile health clinics.

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FIELD ACTION REPORT

Engaging Communities With a Simple Tool to Help Increase Immunization Coverage

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Use of a simple, publicly placed tool that monitors vaccination coverage in a community has potential to broaden program coverage by keeping both the community and the health system informed about every infant's vaccination status.

ABSTRACT

The level of vaccination coverage in a given community depends on both service factors and the degree to which the public understands and trusts the immunization process. This article describes an approach that aims to raise awareness and boost demand. Developed in India, the ''My Village Is My Home'' (MVMH) tool, known as *Uma Imunizasaun* (UI) in Timor-Leste, is a poster-sized material used by volunteers and health workers to record the births and vaccination dates of every infant in a community. Introduction of the tool in 5 districts of India (April 2012 to March 2013) and in 7 initial villages in Timor-Leste (beginning in January 2012) allowed community leaders, volunteers, and health workers to monitor the vaccination status of every young child and guided reminder and motivational visits. In 3 districts of India, we analyzed data on vaccination coverage and timeliness before and during use of the tool; in 2 other districts, analysis was based only on data for new births during use of the tool. In Timor-Leste, we compared UI data from the 3 villages with the most complete data with data for the same villages from the vaccination registers from the previous year. In both countries, we also obtained qualitative data about perceptions of the tool through interviews with health workers and community members. Assessments in both countries found evidence suggesting improved vaccination timeliness and coverage. In India, pilot communities had 80% or higher coverage of identified and eligible children for all vaccines. In comparison, overall coverage in the respective districts during the same time period was much lower, at 49% to 69%. In Timor-Leste, both the number of infants identified and immunized rose substantially with use of the tool compared with the previous year (236 vs. 155, respectively, identified as targets; 185 vs. 147, respectively, received Penta 3). Although data challenges limit firm conclusions, the experiences in both countries suggest that ''My Village Is My Home'' is a promising tool that has the potential to broaden program coverage by marshalling both community residents and health workers to track individual children's vaccinations. Three states in India have adopted the tool, and Timor-Leste had also planned to scale-up the initiative.

BACKGROUND

Low vaccination coverage often reflects services that are not sufficiently accessible, convenient, reliable, or friendly. It may also be related to a lack of public understanding or trust in vaccination and/or vaccination services. In addition, various sociocultural factors commonly correlate with the likelihood of families getting their children immunized.[1,2]

Most interventions aimed at raising vaccination coverage focus on improving services or on informing and motivating families. This article describes an approach, piloted in India and Timor-Leste, which aims to improve demand and also has the potential to affect services: use of a tool that enables community members or community-based health workers to list all infants in the community and monitor their individual vaccinations. The tool is called ''My Village Is My Home'' (MVMH) in India and *Uma Imunizasaun* (immunization house or UI) in Timor-Leste.

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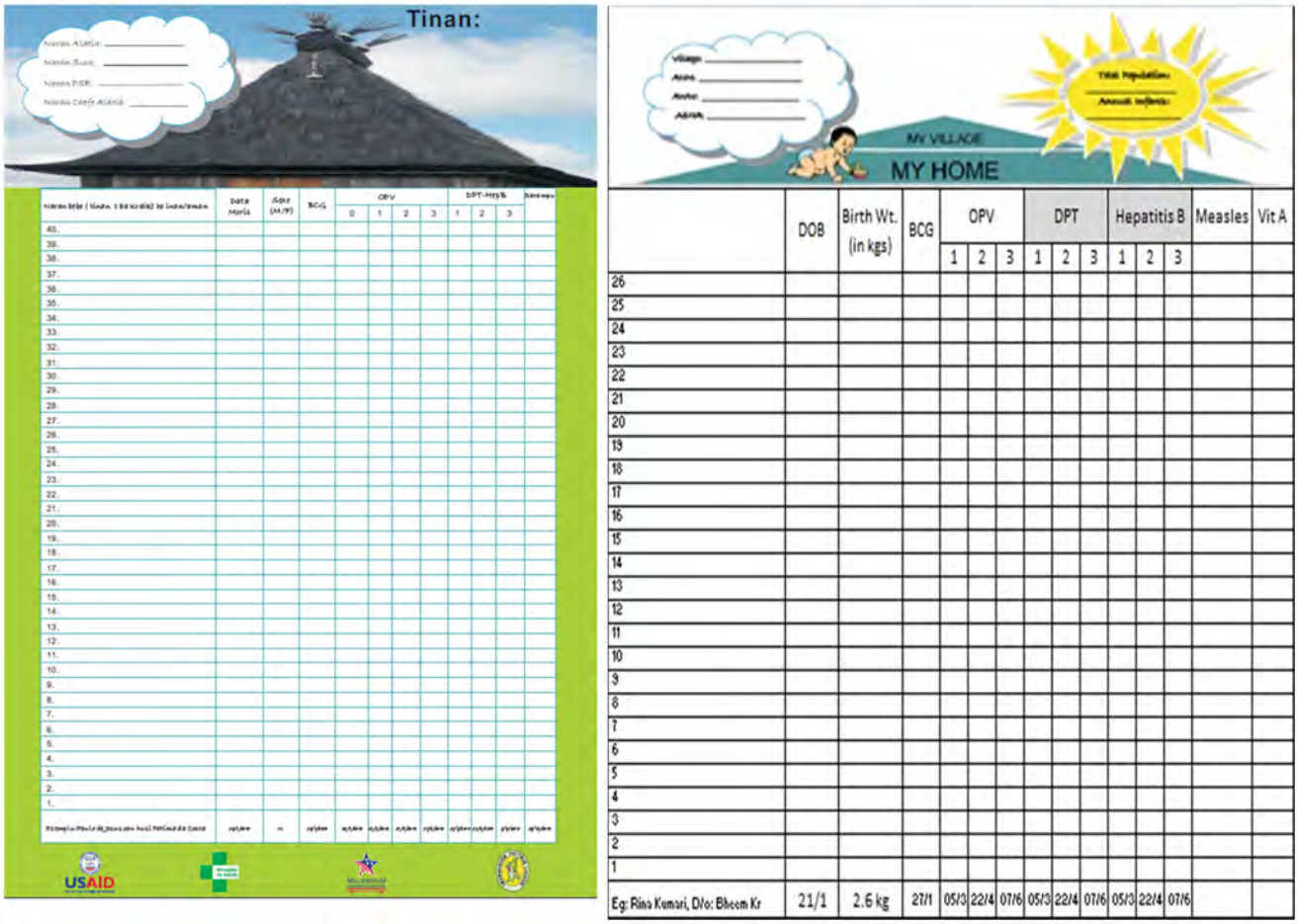
The "My Village Is My Home" tool allows a community to track all vaccinations for every infant in the population.

The MVMH/UI tool is a large, poster-sized record on which every infant in a community has his or her own row, with spaces for the child's name, date of birth, and dates of each vaccination (Figure 1). Yearly, local volunteers or health workers do a rapid census to fill in the names and birth dates of all infants, starting with the oldest in the bottom row and moving upward. Infants born or moving into the community during the year are added on the next open line above. A roof covers the listings, illustrating the idea that each vaccination of each child fills in a brick or board that strengthens the entire house, which is equivalent to adding protection for the entire community from vaccine-preventable diseases.

The tool was developed in India in 2003 to take advantage of the 700,000 Anganwadi Workers (AWWs) (community-based workers) who conducted annual censuses of infants and women. Posted in a public place such as a community center or local government office, the large MVMH/UI is meant to create social pressure to keep one's children up-to-date on vaccinations. Ideally, use of the tool should inform and motivate caregivers, local leaders, and volunteers, as well as professional health staff, to have more infants vaccinated, and sooner. (In some settings, posting such personal information in a public place might raise concerns about privacy issues; however, we heard no such concerns in the 2 pilot settings.)

FIGURE 1. Community-Based Tool to Monitor Immunization Coverage: *Uma Imunizasaun* in Timor-Leste (left) and "My Village Is My Home" in India (right)



COUNTRY PROGRAM DESCRIPTIONS

India

In India, most vaccinations are given through outreach services delivered at Anganwadi Centers (AWCs), which are government day care centers. The Maternal and Child Health Integrated Program (MCHIP), with support from the United States Agency for International Development (USAID), undertook the MVMH initiative from April 2012 to March 2013 in 28 AWCs in Deoghar and Jamtara districts of Jharkhand and between August 2012 and July 2013 in 15 AWCs in Banda, Gonda, and Varanasi districts in Uttar Pradesh. Project and government staff trained several cadres of health workers to use the MVMH tool, including Auxiliary Nurse-Midwives (ANMs), who deliver immunization services at these outreach session sites; Accredited Social Health Activists (ASHAs), who are the community volunteers from the health department; and AWWs, the community workers from the social welfare department, at all 43 AWCs. Training focused on listing infants' names in birth order and updating their row when they received each vaccination. Data entry into the MVMH tool rested primarily with the ANMs, while mobilization of children for services rested with the ASHAs and AWWs.

Recording new vaccinations was relatively easy in India, because under the Universal Immunization Program there are fixed days designated for immunization services at all outreach sites. The tool served as a displayed "due list" that showed the specific children and vaccinations due at the next session. It guided the local team to alert those families just before the vaccination day.

Timor-Leste

In Timor-Leste, the UI tool was an initiative of the *Imunizsaun Proteje Labarik* (Immunization Protects Children or IPL) project under MCHIP, with funding from the Millennium Challenge Corporation. IPL developed a Timorese version of the tool, a simple manual for community volunteers, and a curriculum for training local elected leaders and *Promotores Saude Familiar* (PSF) (family health promoters, or community health volunteers). Following a 2-day national workshop in September 2011 for national immunization partners, project and local Ministry of Health (MOH) staff trained the community implementers in late 2011 in 7 pilot *sucos* (villages), which introduced the tool in early 2012. Later in 2012, IPL collaborated with the NGO *Clinic Café Timor*, which introduced the tool into another 26 *sucos*. Prior to IPL's closure in December 2013, the project and the MOH introduced the tool in an additional 21 low-performing subdistricts.

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A health worker in India uses the "My Village Is My Home" tool at a vaccination session.

Local volunteers were trained to list all infants' names and birth dates and to record the date of each vaccination. They learned the ideal vaccination schedule and the required intervals between successive doses of polio and pentavalent vaccines (Table 1). The volunteers learned how to tell when a child was eligible or late for a particular vaccination and were encouraged to motivate caregivers of such infants to take them to community health centers, health posts, monthly integrated health outreach services, or mobile clinics to receive those vaccinations.

In Timor-Leste, the local volunteers completed a small UI at the *aldeia* (hamlet) level, and the information from all 5 to 10 *aldeias* in 1 *suco* was consolidated periodically on a large UI at the *suco* level. PSF, together with the elected hamlet or village chief, initially filled in the names and birth dates of the infants. Since vaccinations were not offered in most *aldeias,* the local volunteers met at the *suco* council office with the vaccinator from the subdistrict community health center, monthly if possible. IPL offered lunch and a small transport allowance for persons attending these meetings, at which the *aldeia* and *suco* tools were updated and discussed. If a PSF could not convince a family to have its children vaccinated, he or she could ask the vaccinator to visit that family. Unfortunately, too many children lacked their child health booklets for those to be the basis for local updating.

TABLE 1. Timor-Leste Immunization Schedule

Vaccines	When To Give	Do NOT Give
OPV 0	From birth to 2 weeks of age	After the first 2 weeks of age
BCG	As soon as possible after birth	After reaching 12 months of age
OPV 1/ Penta 1[a]	As soon as possible after 6 weeks of age	Before 6 weeks of age or after reaching 2 years of age
OPV 2/ Penta 2	As soon as possible after 10 weeks of age *And* at least 4 weeks after dose 1	Before 10 weeks of age or after reaching 2 years of age
OPV 3/ Penta 3	As soon as possible after 14 weeks of age *And* at least 4 weeks after dose 2	Before 14 weeks of age or after reaching 2 years of age
Measles	As soon as possible after reaching 9 months (39 weeks) of age	Before 9 months (39 weeks) of age

Abbreviations: BCG, bacille Calmette-Guérin; OPV, oral polio vaccine; Penta, pentavalent.
[a] Pentavalent vaccine in Timor-Leste protects against diphtheria, pertussis, tetanus, hepatitis B, and *Haemophilus influenzae* type b (Hib).

ASSESSMENT METHODS

Neither project planned a priori to evaluate use of the tool. However, given the impressions of all involved that the tools were working well, both projects carried out assessments. The Institutional Review Board of John Snow, Inc. granted exemptions from review for the analyses for both India and Timor-Leste.

In India, data from all session sites were entered into an Excel spreadsheet, and coverage and timeliness of vaccination were analyzed. At project start in Uttar Pradesh, the team collected vaccination data before implementing the intervention (for the period from April 1, 2011 to July 31, 2012). The intervention was initiated on August 1, 2012 and completed on July 30, 2013. Thus, pre-intervention data were available for 16 months and intervention data for 10 months.

The data from Jharkhand, however, included only the follow-up component without any pre-intervention data. In addition, the tool in Jharkhand was used to record only new births that occurred during the study period from April 2012–March 2013. Thus, the analysis was based on the number of children who were eligible for the different vaccine doses per their birth dates.

In addition to the quantitative data, we also obtained qualitative data in India on health workers' and community members' perceptions about the usefulness of the tool through informal conversations.

In Timor-Leste, IPL first monitored use of the UI tool by interviewing parents, local leaders and volunteers, and local health staff in May 2012. Several months before the project ended, the IPL monitoring officer asked IPL district staff to take digital photos of the *suco* tools and health facility registers of a comparable, non-intervention *suco* for comparison. Major data problems soon became clear. Some information on the tools was illegible or did not make sense. Both numerator and population data from the subdistrict facilities were

© Ruhul Amin/MCHIP Timor-Leste

Health workers in Timor-Leste explain the *Uma Imunizasaun* tool to caregivers.

incomplete and/or unreliable. It was decided to compare UI data with data from the vaccination registers for the same *sucos* from the previous year. The monitoring officer entered and cleaned the data in Excel from the 3 *sucos* with the most complete data and carried out various analyses to gauge timeliness and coverage.

RESULTS

India

All 455 children who were born in the Jharkhand communities during the study period (April 2012–March 2013) were eligible for BCG (bacille Calmette-Guérin), and 437 of them received the vaccine. Similarly, 445 with birth dates on or before February 15, 2013 were eligible for the first dose of diphtheria, tetanus, and pertussis vaccine (DTP 1), the first dose of oral polio vaccine (OPV 1), and the first dose of hepatitis B (Hep B 1); 410 infants with birth dates on or before January 15, 2013 were eligible for the second doses of the same vaccines (DTP 2, OPV 2, and Hep B 2); and 377 infants born on or before December 15, 2012 were eligible for the third doses (DTP 3, OPV 3, and Hep B 3). By March 2013, 128 infants had completed the age of at least 9 months and were evaluated for measles vaccination. Overall, the coverage rates for eligible children in the study areas in Jharkhand were consistently high, with coverage rates for all the vaccines at more than 80% (Table 2), and the unimmunized rates at just 1.9%.

The MVMH districts had been poor performing, and surveyed full immunization coverage during this period was 48.6% in Deoghar and 68.6% in Jamtara (Annual Health Survey 2011–12 data). The surveyed coverage put BCG–measles dropout rates in both districts at close to 25%, while it was 15% in the study area. Another important impact in the study areas was on the timeliness of vaccination. Only 2.3% of children for OPV 1 and 3.0% for DTP 1 were immunized before 42 days, and the intervals from OPV 2 to OPV 3 and DTP 2 to DTP 3 were less than the minimal 28 days in only 3.5% and 3.4% of beneficiaries, respectively.

In Uttar Pradesh, increased coverage rates were noted after the intervention for all vaccines except measles, and the rate of unimmunized children also decreased, from 12.6% to 6.7% (Table 3). During the intervention period, 9.6% of children were immunized before the recommended age for DTP 1, 5.0% for DTP 3, and 9.6% for measles vaccination.

In Uttar Pradesh, the rate of unimmunized children decreased with use of the tool, from 12.6% to 6.7%.

Almost all health workers and community members interviewed during the study period were satisfied with the tool and felt that it had

TABLE 2. Vaccination Coverage Rates During Use of the ''My Home Is My Village'' Tool, Jharkhand, India, April 2012–March 2013

Antigens	No. of Children Eligible	No. of Children Vaccinated	Vaccination Coverage
BCG	455	437	96.0%
OPV 1	445	417	93.7%
OPV 2	410	361	88.0%
OPV 3	377	306	81.2%
DTP 1	445	421	94.6%
DTP 2	410	367	89.5%
DTP 3	377	313	83.0%
Hep B 1	445	418	93.9%
Hep B 2	410	362	88.3%
Hep B 3	377	311	82.5%
Measles	128	104	81.3%

Abbreviations: BCG, bacille Calmette-Guérin; DTP, diphtheria, tetanus, pertussis; Hep B, hepatitis B; OPV, oral polio vaccine.

TABLE 3. Vaccination Coverage Rates Before (April 2011–July 2012) and During (August 2012–July 2013) Introduction of the ''My Home Is My Village'' Tool, Uttar Pradesh, India

	Pre-Intervention Cohort (N=565)			Intervention Cohort[a] (N=868)		
Vaccine	No. of Children Eligible	No. of Children Vaccinated	Vaccination Coverage	No. of Children Eligible	No. of Children Vaccinated	Vaccination Coverage
BCG	565	465	82.3%	868	768	88.5%
OPV 0	565	306	54.2%	868	510	58.8%
DTP 1	506	423	83.6%	868	747	86.1%
DTP 3	444	306	68.9%	848	611	72.1%
Measles	280	200	71.4%	642	430	67.0%

Abbreviations: BCG, bacille Calmette-Guérin; DTP, diphtheria, tetanus, pertussis; OPV, oral polio vaccine.
[a] Includes children from the pre-intervention cohort plus new children born during the intervention period.

greatly contributed to improving the community's overall awareness of the need and importance of the immunization program.

Timor-Leste

Table 4 contains illustrative data from the 3 *sucos* in Timor-Leste. The 2011 (pre-intervention) data for these areas suggested good immunization rates (over 90% for all antigens), so it is difficult to show a major impact of UI on vaccination coverage. During introduction of the UI tool, coverage seemingly dropped for some antigens. For example, the data suggest that coverage for Penta 3 decreased from 91% to 76%, and for measles, from 92% to 53%. However, the number of infants identified in 2012 (N=236) was much higher than in 2011 (N=155). This inconsistency suggests that the 2011 denominator used was too low, resulting in an inflated coverage rate for 2011. Even for 2012, the project staff believed that a small percentage of infants did not make it onto the UIs because they lived far from the community center or because their families traveled outside the community at times. (Much of the population lives in isolated mountain communities; 22.7% of 1-year-olds had no vaccinations in the 2009/10 Demographic and Health Survey.)

To do their intended job, vaccines must be given when they will work for each child, as laid out in the starting ages and intervals in national vaccination schedules. The data in Timor-Leste indicate a serious problem of vaccinations given to children who are too young (not yet eligible) and therefore who consequently may have gained no or reduced benefit from the administered antigen. This problem is particularly serious for Penta 1 and measles vaccinations, for which 21% and 16% of children, respectively, were vaccinated too early during use of the UI tool (Table 4). In contrast, before introduction of the UI tool, 11% and 14% of children were vaccinated too early for Penta 1 and measles, respectively.

In addition, the mean age for administration of OPV 0 was 27 days before introduction of the UI tool and 18 days during use of the UI tool (data not shown), indicating that many doses of OPV 0 were given to children over 14 days of age, the official cutoff age. OPV 0 vaccinations given after 2 weeks of age may reduce the antigenic response to the OPV 1 vaccination, depending on the interval between OPV 0 and OPV 1.

Almost no children were vaccinated for measles without having received BCG or DTP earlier (4% before use of the UI tool vs. 1% during use of the tool, data not shown). This is difficult to interpret but implies that health workers were not excessively missing opportunities to immunize. In addition, most children received all 3 Penta doses, although the data seem to suggest a small drop during use of the UI tool (94% before vs. 83% during, data not shown).

Overall, the prevalence of incomplete, inconsistent, and unexpected data reflected endemic problems with data in the health system.

The May 2012 interviews with parents, local leaders, volunteers, and local health staff uncovered that the purpose of the tool and processes were well understood and that most respondents felt very positively about the tool. Volunteers

TABLE 4. Coverage and Timeliness of Vaccination Before (2011) and During (2012) Introduction of the UI Tool, 3 Villages of Timor-Leste

	BCG		Penta 1		Penta 3		Measles	
	Before (N=155)	During (N=236)	Before (N=155)	During (N=236)	Before (N=155)	During (N=236)	Before (N=155)	During (N=236)
Eligible to receive antigen, n (%)	155 (100)	236 (100)	155 (100)	236 (100)	155 (100)	236 (100)	147 (95)	194 (82)
Received antigen, n (%)	154 (99)	232 (98)	152 (98)	218 (92)	147 (95)	184 (78)	137 (93)	110 (57)
Age at vaccination, mean, days for BCG, weeks for all others	35	24	12	9	24	21	44	41
Vaccinated within recommended age range,[a] n (%)	57 (37)	104 (45)	62 (41)	111 (51)	43 (29)	50 (27)	104 (76)	89 (81)
Vaccinated too early, n (%)	-	-	17 (11)	46 (21)	4 (3)	6 (3)	19 (14)	18 (16)

Abbreviations: BCG, bacille Calmette-Guérin; Penta, pentavalent; UI, *Uma Imunizasaun*.
[a] For BCG, data refer to those vaccinated between 0–13 days.

wanted support for transport and per diem. Implementation occurred as planned in 5 of the original 7 *sucos* but not in 2 due to inactive PSF.

The UI tool was one of a half dozen project interventions assessed in a program review just before the project closed in late 2013. When interviewed during the project's final assessment, two-thirds of MOH and national partner staff viewed the UI tool as one of IPL's most effective activities. Local informants noted that the UI allowed them to know whether individual and all children in a community were up-to-date on vaccinations. It enabled them to mobilize their communities and to motivate parents of children who had missed vaccinations. One participant said: ''It is easy to identify children under 1 year and follow-up for the next immunization. We also understand the immunization and interval dates.''

Most community leaders, PSF, vaccinators, and health managers hoped that the government would continue the activity and expand it to all *sucos*. However, several noted that this would require continued support for meals, fuel, and travel expenses, and that the MOH should be responsible for these costs. A few vaccinators and health managers commented that although it was a good tool, it increased their workload.

DISCUSSION

Recent studies and reviews have associated increased community participation in immunization with improvements in vaccination coverage.[3–5] Use of the MVMH/UI tool in 2 very diverse settings made health workers and families more aware of the current vaccination status of individual children and motivated them to improve coverage. Although lack of reliable comparative data did not allow a valid measurement of impact on coverage, positive impacts are very likely. In Timor-Leste, coverage from the previous year was based on a denominator that was likely much lower than the real target population, and the number of infants tracked and immunized rose substantially with use of the tool (155 vs. 236, respectively, identified as ''targets''; 147 vs. 185, respectively, received Penta 3). It appears that the apparent drop in coverage with use of the UI tool in Timor-Leste is attributable to the fact that previously only the most accessible infants were in the system and those harder to reach were left out. In India, coverage in pilot communities increased to much higher than overall coverage in their respective districts after MVMH was introduced.

Use of the tool improved awareness of vaccination status and motivated health workers and families to increase coverage.

Quantifying the tool's impact on coverage is also complicated by the fact that the projects in both India and Timor-Leste implemented multiple initiatives to improve services as well as community understanding and demand. The fact that the efforts of both projects were associated with coverage increases at the district level is likely attributable to this comprehensive approach.

Children receiving vaccines before they are eligible by age was a finding that deserves further study.

Data from both countries show improvements in vaccinations not being given late, which brings great benefits to children, particularly in settings where vaccine-preventable diseases are common. However, there may be a common problem of children receiving antigens *before* they are eligible by age. This was a potentially important and unexpected finding that deserves study in other settings. Children who are vaccinated too early may not develop a sufficient antigen response to the vaccine, leaving them more vulnerable to disease.

Qualitative feedback indicates that use of the tool helped increase awareness of vaccination and a sense of shared responsibility between health services and communities. Everyone involved—local health workers, volunteers, and caregivers—felt very positively about the tool and its impact on vaccination in the communities, although some vaccinators in Timor-Leste noted that updating the tool entailed time and extra work for them.

Cost-effectiveness was not analyzed, although it appears that the costs are modest and depend on many local factors. Regular updating of the tool may be relatively easy, as in India, or more challenging,

FIGURE 2. Revised MVMH Tool in India

Year : 1st April ..... to 31st march .....

My Village My Home

(To be filled up at each Routine Immunization session site)

BCG — Pentavalent / DPT — OPV — Measles

Village : ..... ANM : ..... AWW : ..... ASHA : .....

Population covered : ..... Annual Target .....

Fill the information of beneficiaries from bottom to top according to date of birth.

					At Birth			At 6 weeks		At 10 weeks		At 14 weeks		Between 9 to 12 months			Between 18 to 24 months			
	Child Name	Mother's name	D.O.B.	Birth Weight	B.C.G.	O.P.V. '0'	Hepatitis B 'Birth Dose'	O.P.V. '1'	Pentavalent '1'	O.P.V. '2'	Pentavalent '2'	O.P.V. '3'	Pentavalent '3'	Measles '1'	J.E. '1'	Vitamin A	D.P.T. Booster	O.P.V. Booster	Measles '2'	J.E. '2'
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Ex.	Ram Kumar	Janki Devi	1-Apr-13	2.75 kgs	5-Apr-13	5-Apr-13	5-Apr-13	19-May-13	19-May-13	19-Jun-13	19-Jun-13									

Guidelines for using 'My Village My Home' : Every year in 'My Village My Home' tool in a AWC : **1.** Fill the details of all the children born between 01st April of current year to 31st March of next year in Column 1 (from bottom to top). **2.** Details of children who migrated from another place to this AWC and will basically reside in this village now will have to be incorporated in this tool. **3.** The date on which a vaccine is given, has to be written in the space specified for that vaccine only. **4.** The rows in which blank cells are observed, home visits to the beneficiaries have to be undertaken with the beneficiaries motivated to complete the remaining doses. It is the responsibility of the Anganwadi worker and ASHA to ensure the immunization of all the left outs and drop outs. **5.** Prepare a chart every year and fill according to the guidelines. Keep the last year's chart safely for comparison purposes.

* In the districts where JE vaccine is included in the immunization schedule

Four key messages to be given to the beneficiaries: 1. What vaccine was given and what disease it prevents. 2. When to come next, and for which vaccine. 3. What minor adverse events could occur and how to deal with them 4. To keep immunization card safe and to bring it along for the next visit

as in Timor-Leste, depending on such factors as prevalence and completeness of home-based vaccination records, feasibility of communication via cell phone, and availability of community-based health workers and volunteers.

In India, the tool design has been modified to: (a) incorporate birth doses recently added to the immunization schedule; (b) order the columns by the ideal age for each antigen rather than grouping multiple doses of the same antigen together; (c) serve as a reminder of the correct site, dose, and route of administration as well as of the 4 key messages for caregivers; and (d) give clear instructions in the local language on how to use the tool (Figure 2).

The MVMH tool has been available in the Indian setting since 2003, and the current intervention suggests that the tool is beneficial and easy to adapt. It has already been adopted by the state governments of Jharkhand and Uttar Pradesh, with approval to use the tool across all 77,000 AWCs in the 2 states. In addition, Haryana state has adopted MVMH for implementation. In 2014, the Alliance for Immunization partnered with numerous civil society organizations in Bihar, Jharkhand, Rajasthan, and Uttar Pradesh to use MVMH.[6]

At the end of the IPL project in Timor-Leste, the MOH stated its intention of scaling-up use of the UI tool under a Gavi-funded health systems strengthening support project. In addition, other projects in the country were considering adapting the tool for communities to monitor recommended practices during pregnancy and postpartum.

While this tool shows promise, it is important to keep in mind that its scale-up for wider application, as with any scale-up, calls for attention to many implementation components, including the accompanying and critical community mobilization activities as well as local adaptation requirements.

CONCLUSION

"My Village Is My Home" is a promising tool that can strengthen community participation in immunization. It has the potential to increase demand for immunization within health services and among the public, increase identification of young children requiring immunization, improve timeliness of vaccination, and boost coverage. Further trials and evaluation of its ability to improve vaccination coverage as well as community participation are merited.

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Several state governments and civil society organizations in India have adopted the MVMH tool.

In Timor-Leste, the MOH is intending to scale-up use of the UI tool, and other projects are considering adapting it for pregnancy/postpartum tracking.

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TUTORIAL

Patient Flow Analysis in Resource-Limited Settings: A Practical Tutorial and Case Study

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Patient flow analysis (PFA), a simple quality improvement tool to identify patient flow patterns, can be used in resource-limited settings to inform service delivery improvements. A PFA at a Ghanaian hospital found that personnel constraints and a mismatch between staffing and patient arrival surges led to long wait and total attendance times. The median time from arrival to first-provider contact was 4.6 hours.

INTRODUCTION

Overcrowding of health care facilities and inefficient patient flow affect quality and timeliness of care,[1] as well as patient satisfaction.[2,3] The mismatch of supply and demand, often experienced in high-volume care settings, such as emergency departments (EDs) in developed countries, is amplified in medical facilities of low- and middle-income countries (LMICs), where they are burdened by a high volume of patients while coping with limited resources and staffing.

Patient Flow Analysis (PFA) is a quality improvement tool which can be used to help identify patient flow inefficiencies at any type of health care facility and inform areas for intervention to help improve care delivery processes.[4–8] This low-technology methodology involves 2 important aspects: *flow mapping*—which provides a qualitative perspective of the process of care delivery, and *cycle-time measurement*—which provides quantitative data on time throughout the patient's entire care delivery process.[9] Both aspects of PFA help investigators identify key constraints in flow as well as gaps in staffing and resources in the unique health care setting. Additionally, when arrival and throughput data are mapped to resource allocation, such as staffing availability, mismatches can be identified and can further inform reallocation or redirection of resources, or application of new resources. In the ideal setting, PFA is a part of a larger health care improvement initiative, and the findings lead to subsequent identification, implementation, and testing of interventions for improved care delivery.

Although PFA is regularly used in developed countries to help evaluate wait times and improve efficiency and patient care, it has been applied minimally in health care facilities of LMICs despite the opportunity for improving care systems in those environments. This article provides a basic tutorial on how to perform a PFA in a resource-limited setting and highlights a case study with lessons learned from a PFA performed in one Ghanaian municipal hospital.

CONDUCTING A PATIENT FLOW ANALYSIS

Every PFA is unique, and variation exists in the process. Regardless of the study setting, however, a step-wise approach can be helpful in implementing a successful PFA. The following suggested steps, which we have termed the 3Ps—preparation, piloting, and performing—can be used as a flexible guide of items to consider when performing a PFA. Importantly, after performing a PFA, the collected data should be analyzed as it relates to the objectives and process measures to help identify areas for improvement.

Phase 1: Preparation

While preparation may be informal, this aspect is an important first step to implementing a PFA. This period often entails processes such as building a team, understanding the system in which the PFA will occur, defining the objectives and process measures of the study, determining the study plan, developing PFA documents and ensuring that necessary equipment is

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available, identifying and training key personnel, and briefing the staff. Because none of these steps are mutually exclusive, it is helpful to have at least one investigator involved in all aspects.

- **Building a team:** Although one individual can define study objectives and process measures as well as identify potential challenges prior to PFA implementation, it is often advantageous to have 2 or more stakeholders contribute to this process. Ideally, this team will include leaders within the clinical environment and will represent different skill levels and work areas, helping foster support from the staff and thus influencing the success of the PFA.
- **Understanding the system:** Understanding the current system prior to commencing the PFA is important. Flow mapping or process mapping prior to performing the PFA helps depict potential pathways of current patient care. Additionally, it can highlight activities at each stage in a patient journey and identify current needs in terms of staffing and other resources. This flow mapping can be either a hand-drawn or computerized diagram.
- **Defining objectives and process measures:** Defining objectives to be addressed and process measures to be identified helps guide PFA methodology and the duration of the study. Although objectives and measures vary depending on the specific setting, most are time-based, such as determining the length of stay and/or length of queuing, or are capacity-based, such as patient arrival per hour and/or patient-staffing mismatch. Within these, it is also important to consider which patients the PFA will track and the times at which the PFA will occur.
- **Determining study plan:** Three time-based elements exist within most PFAs: (1) patient arrival time into the system (patient enters the clinical setting), (2) times between and at each stage of the patient care process, and (3) patient discharge time out of the system. Documentation of this time-based data occurs throughout the patient journey. Thus, most PFAs have patients carry a form throughout their visit, which is collected when they exit the system. Additionally, many PFAs have an observational aspect of the study in which investigators or personnel document qualitative observations regarding flow and processes. Determining the duration of the PFA can be challenging. The ideal duration is long enough to account for variations in patient surges/acuity, times/days, and staffing number/skill sets, and yet it remains short enough so that staff and key personnel are not overburdened and the PFA itself does not become part of the regular system.
- **Development of study documents and ensuring available equipment:** Study documents should fit the clinical environment and defined process measures. Time logs can be developed or modified to assist in documentation. Equipment needed for a PFA is minimal: a method for synchronized time documentation throughout the clinical environment (e.g., synchronized timers or watches stationed at each location), pencils/pens for documentation, and possibly a stapler to attach forms.
- **Identifying and training key personnel:** While it is possible for one individual to perform a PFA, having 2–3 key personnel who can assist during the PFA is extremely helpful. These individuals can help with timer synchronization, arrival documentation, collection of forms, and other activities. Training for these individuals is minimal but necessary to ensure that they follow the same system.
- **Briefing the staff:** Since PFAs happen within a functioning clinical environment, it is valuable to brief the staff about the study. In many cases, hospital staff are part of the PFA process, for example, by filling out time logs. While simple, this data collection aspect can add additional time and work for these individuals, thus having their buy-in is important. It helps to establish a defined time for staff to learn about the project, train in data collection if they are to assist, and ask questions and provide feedback. While the "Hawthorne effect" of improved or modified performance of staff while being observed is possible, these briefings should encourage staff to go about their normal daily work processes, in order to get an accurate perspective of the system.

Overcrowding and inefficient patient flow at health care facilities affect the quality and timeliness of care, as well as patient satisfaction.

Patient Flow Analysis uses qualitative and quantitative data to identify areas for improvement in patient care delivery.

PFAs should be long enough to account for variations in patient surges, times/days, and staffing, yet short enough to avoid overburdening personnel and making the PFA part of the regular system.

Phase 2: Piloting

Although piloting the PFA is not mandatory, it can be very helpful in revealing potential issues or flaws within the study plan and/or areas for improvement. Furthermore, piloting the PFA allows investigators to review pilot data to

determine its accuracy and decide whether a retraining session is necessary.

Phase 3: Performing

Performing the PFA is simple if it has been well planned and prepared, and piloted. The PFA should commence each day with a sufficient number of documents to cover the anticipated number of patients, and timers/watches should be verified to function and should be synchronized. Unforeseen circumstances can and do occur; however, these variances are important to understand and document. Key personnel should document observational findings throughout the PFA, with notations of time/date and descriptors of the event.

Two important aspects to consider during the PFA are the well-being of staff and the patients. Key individuals should have regular, scheduled breaks; however, ideally there should be no lapse in time or coverage of the individual's task (for example, if a key individual is documenting arrival times, there should be a transfer of that task to another individual prior to the break). Lastly, patient safety should always come before the PFA. If any personnel or staff feels the need to circumvent the PFA for the sake of patient safety/care, this should be done and observational documentation can follow.

Personnel should know that they can circumvent a PFA for the sake of patient safety.

A CASE STUDY FROM GHANA

We conducted a PFA at Kintampo Municipal Hospital, a district-level hospital in central Ghana that serves a population of over 100,000 individuals. The care model in this medical facility is similar to that of the acute care model of most US-based EDs: there are no scheduled appointment times, and evaluations typically occur on a first-come, first-served basis. Unlike US EDs, however, which operate 24 hours per day/7 days a week, the hours of operation for acute care in this facility are typically weekdays, between 5 am–5 pm. During these times, the general process of care involves registration, history taking, provider care, ancillary testing, and disposition.

This PFA quality improvement study protocol was reviewed by the institutional review board at Cincinnati Children's Hospital Medical Center and deemed not human subjects research.

Phase 1: Preparation for the Ghanaian Municipal Hospital PFA

The objectives of this PFA were to identify key constraints to patient flow, discordances between demand for service and staffing, and opportunities for increasing efficiency. Process measures included total visit time, time at and between each stage of care, patient arrival patterns, and staffing patterns. Our overarching goal was to use findings from this PFA to identify potential interventions that could improve care delivery at this hospital. We were unable to perform the anticipated follow-up PFA to evaluate such interventions due to unforeseen resource constraints.

FIGURE 1. Patient Flow Analysis Time Log

Patient Number: _____ Ward: Location _____
Date: _____ In _____
Arrival Time: _____

Registration: In _____ Consultation: Location _____ Laboratory: In _____
Out _____ In _____ Out _____
To _____ Out _____ To _____
To _____

History Taking: In _____ Consultation: Location _____ X-ray: In _____
Out _____ In _____ Out _____
To _____ Out _____ To _____
To _____

Injection Room: In _____ Consultation: Location _____ Dispensary: In _____
Out _____ In _____ Out _____
To _____ Out _____ To _____
To _____

To facilitate collection of time-based data throughout the patient's hospital visit, we developed a modified time log from previously published time logs[4,5,7] and purchased 15 basic watches (<US$1 each) at the local market. Time logs were used to document each patient's initial arrival time to the facility, time in/out of every stage within the hospital course, and final disposition (Figure 1). Watch times were synchronized, and one watch was stationed and secured at each hospital location.

Hospital staff and key personnel were briefed and trained on the project one week prior to the PFA. During this 30-minute educational session, hospital staff learned the objectives and methodology of the project and how to use the time log. Lunch was provided.

Phase 2: Piloting the Ghanaian Municipal Hospital PFA

We implemented a 1-day pilot test of data collection several days prior to the PFA, with review of data for discrepancies. Follow-up retraining of personnel occurred immediately following the pilot data collection period.

Phase 3: Performing the Ghanaian Municipal Hospital PFA

Data collection occurred from June 29–July 3, 2009, with real-time patient flow data collected for all patients arriving during typical hospital hours. Upon presentation to the hospital and prior to registration, each patient received a time log on which the arrival date and time were documented. At registration, the time logs were attached to patients' medical charts where they remained throughout their hospital visit. Patients presented their medical charts with attached time logs to hospital personnel at each hospital location. Time logs were purposely printed on bright green paper to increase their visibility on the patient's medical chart. Using study watches (synchronization confirmed twice daily), hospital staff documented the times in and out of each hospital location, as well as the next anticipated location. Time logs were collected at the end of the patient's visit.

We quantified hospital staffing and infrastructure by direct observation throughout the study. The number of hospital personnel and the hours of operation of 3 critical patient contact areas—registration, history taking, and consultation rooms—were recorded. Investigators also documented other process-related items that could affect patient throughput.

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At Kintampo Municipal Hospital in Ghana, patients wait for medical care, with green patient flow analysis time logs attached to their medical charts. Time logs were purposely printed on bright green paper and stapled to the front of patients' charts to increase their visibility.

Hospital personnel recorded patients' progress in and out of each location using synchronized watches and time logs.

Data Analysis

PFA data were analyzed using SAS v. 9.3. Median and mean duration times at each stage, between stages, and total duration were calculated. The use of median is important for reporting central tendency in skewed time flow data. Complementing this with use of the mean emphasizes the outliers, which have a significant effect on patient flow, care quality, and satisfaction. Student's t-test was used to test for differences between patients that were admitted or discharged home.

TABLE 1. Number of Patients Arriving to the Hospital per Hour

Arrival Hour	Mean	SD	Median	Minimum	Maximum
05:00–05:59	7.2	1.5	7.0	5.0	9.0
06:00–06:59	12.4	2.3	12.0	9.0	15.0
07:00–07:59	18.6	5.7	18.0	13.0	27.0
08:00–08:59	18.6	3.5	19.0	15.0	22.0
09:00–09:59	15.2	7.2	16.0	5.0	25.0
10:00–10:59	12.4	6.9	11.0	6.0	24.0
11:00–11:59	4.6	3.0	4.0	1.0	9.0
12:00–12:59	4.4	2.3	4.0	2.0	8.0
13:00–13:59	1.7	0.6	2.0	1.0	2.0
14:00–14:59	4.0	0.0	4.0	4.0	4.0
15:00–15:59	3.0	1.4	3.0	2.0	4.0

Abbreviation: SD, standard deviation.

RESULTS

Of the 564 time logs given to patients presenting to the hospital during this study, 487 (86%) were collected. Complete data, describing the patient's flow through their hospital visit, were available in 74% (362) of time logs, and partial data for 17% (81) of time logs. We excluded all data from potentially flawed time logs (9%, or 44 participants), which were defined as those having negative time points and those with data occurring over multiple days or visits.

The mean number of patients arriving to the hospital per hour during the study was 10.5 (standard deviation [SD]=7.1). Peak arrival occurred during the morning hours—between 7 am and 9 am (Table 1). The large majority (96%) of patients were discharged home after completion of their hospital visit; 4% were admitted.

Patients at the Ghanaian hospital experienced lengthy hospital visits and door-to-provider delays that were nearly 6 times the US median time of 46 minutes.

Patients experienced several different care paths throughout their hospital visit. Figure 2 highlights the most common care path. The overall total median visit time from arrival to disposition was 5.2 hours (interquartile range [IQR]=4.1–6.2 hours; mean=5.1 hours, SD=1.6). This duration did not differ significantly between admitted and discharged patients (P=.11). Additionally, median time between arrival and first-provider contact was 4.6 hr (IQR=3.4–5.6 hours; mean=4.4 hours, SD=1.6). Longest wait times were between arrival and registration (median=2.3 hours, IQR=1.4–3.2 hours; mean=2.2 hours, SD=1.3) and between history taking and first-provider contact (median=1.4 hours, IQR=0.7–2.1; mean=1.5 hours, SD=1.1). Other long delays were noted between registration and triage, and between laboratory testing and processing (Table 2).

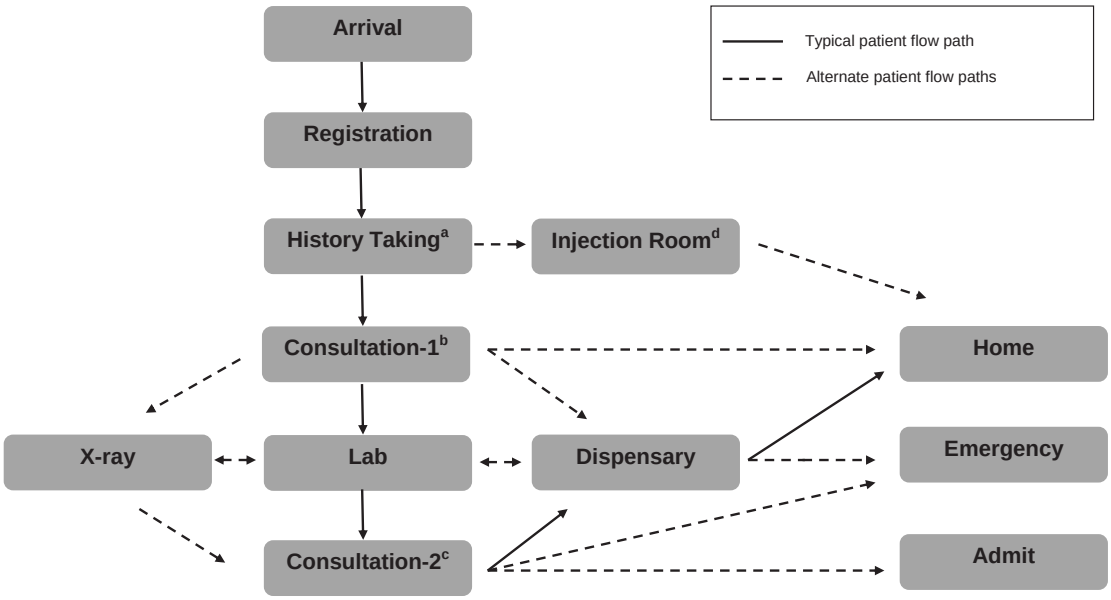
Table 3 describes hospital staffing over the study period. In general, although patient arrival peaked in the early morning hours, maximum staffing for the 3 patient contact areas assessed (registration, history taking, and consultation rooms) occurred only after this surge. This discrepancy had a cumulative effect for all other patients, as delays accumulated throughout the day. Additionally, the medical consultation rooms were open for only brief periods each day (mean=3–5 hours), and closed to patient care at similar times of day, resulting in many patients not being seen at all. Consultation rooms often closed regardless of patient volume or the presence of waiting patients (Box).

DISCUSSION

Health care facilities worldwide face the challenge of providing high-quality care while struggling with large patient volumes and process inefficiencies. PFA is a quality improvement tool that can help identify critical constraints in patient flow at any type of health care facility and improve allocation of resources. A step-wise approach considering items within the 3Ps—preparation, piloting, and performing—can be helpful in implementing a successful PFA.

Our case study demonstrates the utility of the PFA tool in the resource-limited setting of Ghana. We found that patients experienced lengthy hospital visits, with a median duration from arrival to disposition of 5.2 hours (independent of disposition). While comparison data from other LMICs are not publicly available, the total hospital visit duration in our case was significantly more than the US ED median duration of 3.2 hours.[10] Additionally, there were extensive delays prior to medical evaluation; most notably, between arrival and first-provider contact (median=4.6 hours). This "door-to-provider" time, which is an important quality indicator in other acute care settings, is nearly 6 times the US median time of 46 minutes.[10] Although the implication of long durations of patient care in this setting has not been evaluated, we would expect effects similar

FIGURE 2. Possible Patient Care Flow Paths Through the Kintampo Municipal Hospital in Ghana



[a] History Taking: Nurse solicits chief complaint and obtains patient's temperature and blood pressure.

[b] Consultation-1: First consultation with a medical provider (physician or medical assistant); history and physical performed, ancillary tests ordered, and/or the patient is discharged home via the dispensary.

[c] Consultation-2: Second consultation with a medical provider (depending on the time of day and availability of medical providers); if there is no second consultation, the patient is sent directly from ancillary testing to the dispensary for medications and discharged home.

[d] Injection Room: Patients undergo scheduled treatment for chronic diseases (e.g., tuberculosis).

to other acute care models where longer lengths of stay and total hospital durations are associated with increased morbidity, delays in definitive care, and poorer overall perceptions of care.[11] Furthermore, we would anticipate that significant delays prior to medical evaluation would be even more detrimental in an environment where acuity level is not assessed upon presentation to the facility and no formal triage exists.

Results from our direct observational assessment showed important inefficiencies and process-related items. Most notably, there was considerable mismatch between demand for and supply of services, which was amplified by daily inconsistencies in staffing and hours of operation and by miscommunication about staff availability.

Several subsequent changes in the care process at the Ghanaian Municipal Hospital have occurred since the PFA, including designated registration areas for differing patient populations, decreased duplications of history taking within the system, an increase in the number of consultation rooms, and the addition of some staff in selected areas.

Lessons Learned

Three main lessons were learned from implementing this PFA:

- **Increasing the study duration helps account for variation and potential lost patients**. Our study period was limited to one midsummer time period. Although 87% of charts were collected at the end of the study, it is unknown whether those patients who left the facility without care were also those most likely to not have forms collected at the end of their visit, and therefore were underrepresented in the study.
- **Having a more systematic observational assessment of hospital staffing and**

There was considerable mismatch between demand for and supply of services.

TABLE 2. Duration In and Between Hospital Locations (in Hours)

In/Between Location	Mean	SD	Median	IQR	Minimum	Maximum
Registration	0.15	0.19	0.12	0.08–0.18	0	3.10
History taking	0.07	0.07	0.07	0.05–0.08	0	1.03
Consultation-1	0.12	0.19	0.08	0.07–0.12	0	2.13
Consultation-2	0.07	0.10	0.05	0.03–0.08	0.02	0.83
Laboratory	0.79	0.56	0.72	0.45–0.97	0.05	2.82
X-ray	0.24	0.11	0.24	0.17–0.32	0.17	0.32
Dispensary	0.14	0.87	0.07	0.03–0.12	0	17.15
Arrival – Registration	2.24	1.25	2.30	1.35–3.22	0.02	6.47
Registration – History taking	0.65	0.55	0.45	0.23–0.92	0	2.55
History taking – Consultation-1	1.51	1.10	1.42	0.73–2.14	0	12.07
Consultation-1 – Laboratory	0.13	0.13	0.08	0.03–0.15	0.02	0.78
Laboratory – Consultation-2	1.00	2.70	0.29	0.12–0.53	0.02	15.17
Consultation-2 – Dispensary	0.17	0.14	0.13	0.08–0.24	0	0.62
Laboratory – Dispensary	0.52	0.67	0.28	0.12–0.59	0.08	2.08
Consultation-1 – Dispensary	0.22	0.30	0.15	0.07–0.28	0	3.15
TOTAL	5.06	1.58	5.18	4.07–6.20	0.60	9.42

Abbreviations: IQR, interquartile range; SD, standard deviation.

TABLE 3. Observational Findings of Hospital Staffing and Hours of Operation at Kintampo Municipal Hospital

Hospital Location	Range of Opening Times	Staff Number	Staffing Hours	Range of Closing Times	Total Daily Patient Care Hours (mean)
Registration	05:45	1	05:30–08:00	14:00–16:00	9
		2	08:00–09:00		
		3	After 09:00		
History Taking	08:00	1	08:30–09:00	14:45	7
		2	After 09:00		
Consultation Room 1	09:30–11:00	1		14:00–16:00	4.2
Consultation Room 2	10:00–11:30	1		13:00–15:00	3.3
Consultation Room 3	08:15–10:00	1		12:45–15:00	5.4
Consultation Room 4	11:00–12:00	1		14:00	3.0[a]
Laboratory	07:00				
Dispensary	08:30				

[a] Medical provider for Consultation Room 4 was not present on 3 days of the patient flow analysis; data available for only 2 days.

BOX. Process-Related Observational Findings From the Kintampo Municipal Hospital Patient Flow Analysis

- Unclear arrival procedures.
  - Many patients uncertain as to where registration line starts/ends.
  - Information provided to patients by non-hospital personnel (e.g., other patients), often resulting in patients receiving misinformation (e.g., patients waiting in wrong lines).
- Patient flow exceeds seating capacity; patients sit on floors while waiting.
- No process for initial triage or recognition of severely ill patients.
- Patients that are approached about or enrolled in research studies have different flow processes or are moved ahead in the flow process.
- Storage of supplies affects delivery of care (e.g., hospital staff unable to open history taking because head nurse has key for where blood pressure cuff is stored).
- Patient volume outstrips hospital staffing and hours.
  - Registration closes based on physician determination, not patient volume.
  - Consultation rooms close regardless of patient volume or waiting patients.
- Communication lapses.
  - Staff performing history taking not aware of consultation room closures (brief or extended).
  - Patients directed to closed consultation rooms.

infrastructure can improve the strength of resource allocation recommendations. While our study relied upon descriptive data, which is consistent with anecdotal descriptions of the staffing culture at this facility, a more robust evaluation of staffing would have strengthened our findings and recommendations.

- **Implementing changes based on recommendations with a follow-up PFA is critical to determining improvement.** Our case study is substantially limited by not having evaluated specific interventions after performance of the PFA. Despite this, the results have led to improved knowledge and culture competency around the importance of efficient patient flow, and several changes to the patient care process have been implemented subsequent to the PFA.

CONCLUSION

PFA is a simple, low-resource tool useful in evaluating health delivery processes and identifying areas for intervention. When ideally used within a larger health care improvement initiative, in combination with intervention implementation and follow-up evaluation, PFA can improve quality of care in resource-limited settings.

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INNOVATION

Biometric Fingerprint System to Enable Rapid and Accurate Identification of Beneficiaries

Daniel Matthew L Storisteanu,[a,b] Toby L Norman,[b,c] Alexandra Grigore,[b,d] Tristram L Norman[b,e]

Inability to uniquely identify clients impedes access to services and contributes to inefficiencies. Using a pocket-sized fingerprint scanner that wirelessly syncs with a health worker's smartphone, the SimPrints biometric system can link individuals' fingerprints to their health records. A pilot in Bangladesh will assess its potential.

With over 70% of births unregistered in least developed countries and 40% in developing countries, governments, multilateral health organizations, and NGOs increasingly recognize the ''identification gap'' as a major contributing factor to underdevelopment.[1] Lack of official identity documentation, such as birth certificates, social security numbers, and medical records, obstructs people's access to basic rights and services.[1–4] While health worker-driven mobile health (mHealth) programs are revolutionizing health care,[5] challenges still exist in patient identification arising from lack of official identification, common community names, unknown dates of birth, and human error.

Health workers may be responsible for tracking and monitoring the health of more than 1,000 individuals.[6] The identification gap wastes resources (e.g., redundant vaccinations), limits information, excludes individuals from health services, and costs lives. Whereas in many places informal systems of identification have historically sufficed, increasing urbanization and migration pose growing identification challenges even for well-established health care providers.[2] In order to tackle this issue, governments and NGOs are increasingly turning to biometrics.[2,7,8]

To help address the identification gap, we founded SimPrints, a nonprofit health technology organization centered on development of a pocket-sized fingerprint scanner that wirelessly syncs with a health worker's smartphone to link individuals' fingerprints to their health records (Figure 1).

Use of fingerprint identification makes economic and practical sense: the sensors are accurate and inexpensive,[2] and fingerprints are unique and cannot be lost. In order for the SimPrints system to function well in the field, we designed the hardware to be robust, low-cost, portable, and wireless. Its software will integrate with common mHealth platforms such as Open Data Kit (ODK) and CommCare, so that it can be easily used with most existing mHealth apps (Figure 2).

We envision this system enabling identification abilities in many of the most common mHealth and ICT applications,[9] such as point-of-care diagnostics, data collection and reporting, registries/vital events tracking, supply chain management, and financial transactions and incentives. We plan to address privacy and security concerns by storing fingerprint data as encrypted templates instead of images, through database anonymization, and by using the same SSL/TLS (Secure Sockets Layer/Transport Layer Security) encryption standard used in online banking for data transfer and storage.

BENEFITS OF THE SIMPRINTS SYSTEM

- High accuracy and secure identification
- Fast access and modification of records, allowing health workers in the field to make better decisions by providing immediate and reliable access to critical medical information
- De-duplication of records

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FIGURE 1. Use of the Simprints Biometric System by Health Workers

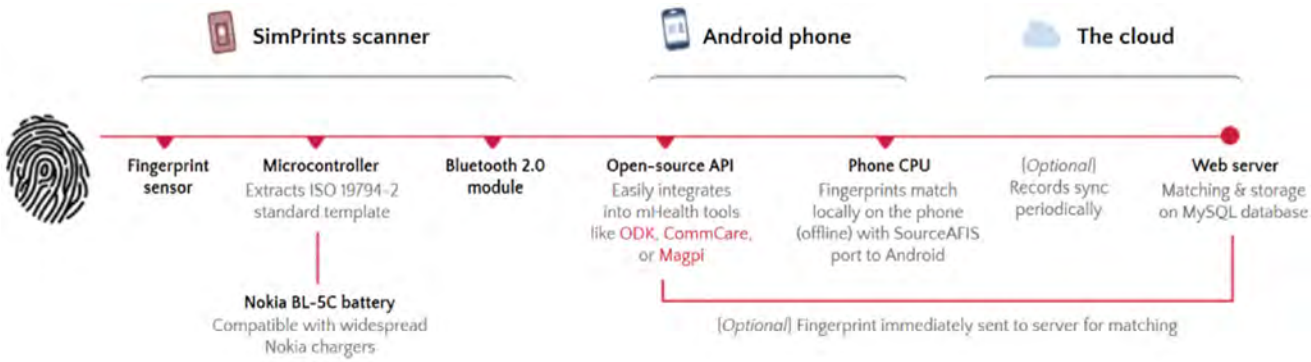
mHealth programs face challenges in patient identification due to lack of identity documentation.

- Enhanced privacy, as fingerprints do not convey personal details such as health status, gender, or race, and can be used in place of names
- Ensuring goods and services are reaching the intended beneficiaries
- Monitoring service delivery to enable the use of incentives for health workers, such as for successful prenatal visits
- Increasing program accountability by facilitating the measurement of indicators such as vaccination coverage
- Supporting civil registration and vital statistics systems by enabling tracking of vital events (e.g., births)

POTENTIAL CHALLENGES

In areas where connectivity in the field is poor, the SimPrints system can access and modify offline health records that have been previously downloaded and are stored in a local database on the phone. Any updates to the health records will then be synced with the central database once Internet connectivity is restored. In order to

FIGURE 2. Technical Process Flow Diagram of the Simprints Biometric System



increase access to charging points and make it easier to replace parts, the SimPrints scanner uses the same BL-5C Nokia batteries commonly used in mobile phones globally.

Challenges remain in fingerprint identification of infants, the elderly, and individuals with worn fingerprints due to manual labor. Strategies employed to prevent the exclusion of services to these individuals include connecting an infant's record to the fingerprints of their legal guardians and enrolling multiple fingerprints for manual laborers and the elderly to increase matching accuracy, as well as using secondary identification tags, such as their name or location, as a backup.

NEXT STEPS

Supported by funding from the Saving Lives at Birth innovation grant and ARM Ltd., we will conduct a pilot study in partnership with BRAC and the Johns Hopkins Global mHealth Initiative to test the system with health workers in Gaibandha, Bangladesh. The study will focus on threshold testing to assess false positive, false negative, and failure-to-enroll rates, and research on performance analysis, usability, acceptability, usage patterns, and key health indicators such as the number of successful antenatal health visits.

For more information about this biometric identification system, visit the SimPrints website at http://www.simprints.com.

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SimPrints is a nonprofit organization developing a small fingerprint scanner that syncs with a smartphone to link patients' fingerprints to their health records.

A pilot study of the SimPrints system is planned with health workers in Bangladesh.

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TAKING EXCEPTION

A False Dichotomy: RCTs and Their Contributions to Evidence-Based Public Health

Laurel E Hatt,[a] Minki Chatterji,[a] Leslie Miles,[a] Alison B Comfort,[a] Benjamin W Bellows,[b] Francis O Okello[a]

Global public health should rely on those research methods that best answer the pressing questions at hand. Randomized controlled trials (RCTs) and other rigorous impact evaluation methods have a critical role to play in public health.

See Shelton's response as well as related article by Shelton.

Editor-in-Chief James Shelton's editorial on September 12, 2014, concluded with a laudable call for studies in global health that increase understanding of the "'how and when' of implementation at scale"[1, p. 257]:

> *Bringing together evidence arising from different methodologies with sufficient detail to illuminate causal relationships is essential to applying such knowledge to real-world public health problems across diverse situations.*

Indeed, triangulating among different information sources and reviewing evidence systematically are the hallmarks of nuanced, ethically conducted, effective public health research. However, we take issue with Shelton's opening statement that "randomized controlled trials (RCTs) have limited utility for public health" (p. 253). Rigorously designed randomized experiments and other impact evaluation methods have a critical role to play in global public health—not just for answering small-scale questions of efficacy but also for gauging the effectiveness of scaled-up approaches.

Setting RCTs in opposition to other systematic approaches for generating knowledge creates a false dichotomy, and it distracts from the more important question that Shelton addresses—namely, which research method is best suited for the question at hand? The choice of a research method is not an either/or proposition but depends on the particular research question to be answered and the context. So, when do RCTs make sense, what value do they add, and how do they relate to other research methodologies?

Laying out a "theory of change" is a critical first step in designing any type of intervention or evaluative research, whether experimental or not; we agree strongly with Shelton on this point. Positing the causal pathway through which an intervention operates should frame *all* high-quality research. However, we view this as a prerequisite, not a substitute, for rigorous testing. Perhaps most fundamentally, it is still incumbent on global public health practitioners to answer definitively the question, "Does it work?" *before* asking, "How can it be made to work practicably at scale?" Programs that are assumed to work are sometimes shown—by random assignment—*not* to work; assumptions made based on common sense may turn out to be incorrect.

Rigorous experimental studies continue to generate some of the highest quality evidence for demonstrating the efficacy and effectiveness of interventions, and they continue to demonstrate that expert intuition, although important, is insufficient. Here is one example. Economists have theorized that charging small fees for public health goods (such as insecticide-treated nets, deworming medicine, or water purification solution) could promote use and reduce wastage, thus increasing the efficiency of public subsidies.[2,3] The logic is that the price would signal to consumers that a product had greater value than a free product, thus encouraging uptake, and also that the "sunk-cost" effect ("*I'd better use it since I already paid for it*") would promote use. But a series of RCTs has shown that these assumptions are often incorrect. Charging a nominal fee for such health products substantially lowered uptake, especially among the poor,[4,5] and distributing them for free did not make them more likely to be wasted by recipients.[4,6,7]

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Once we determine "whether it works," RCTs can also help assess whether a public health intervention is effective on a larger scale to inform roll out of health policy. In Rwanda, the phased, randomized roll out of a national performance-based payment scheme for primary health care providers (based on pilot experiences) enabled the government to demonstrate conclusively that this approach improved certain key utilization and quality indicators *at scale*.[8] A randomized study on deworming school children in Kenya is an especially compelling example of policy makers using RCT results to inform broad policy changes. In this case, mass-treating school-aged children with deworming drugs every 6 months was found to reduce school absenteeism by one-quarter, at a very low cost per additional year of school participation.[9] These findings ultimately led to several far-reaching initiatives: the Kenyan government launched a program to treat 5 million school-aged children annually; the State Government of Bihar in India implemented a mass deworming program; and the World Food Programme included deworming treatment in all of its school feeding programs.[10]

The best experimental research will also integrate qualitative, observational, and administrative data sources into the overall analysis. A rigorous mixed-methods approach is essential to untangle the *why* and *how* of the impact identified in an RCT—whether positive, negative, or absent. (As an aside, Shelton's editorial criticizes the World Health Organization's reliance on the GRADE system for the emphasis placed on RCTs in developing guidelines for public health, but the GRADE guidance itself notes the importance of observational studies and qualitative evidence.[11]) The evaluation of the PROGRESA conditional cash transfer program in Mexico illustrates the value of a mixed-methods approach. An experimental research design allowed researchers to establish that conditional cash transfers can improve child health, reduce anemia, and increase children's height.[12] But program implementation benefited from other types of research and analysis: household surveys from the study sample,[12] data from administrative sources, community questionnaires, school and clinic surveys, semi-structured interviews with stakeholders, and focus group discussions. This multipronged approach allowed researchers and policy makers to identify clearly *how* to refine and improve various structural and operational components of the complex program.[13] Since then, similar programs have been tested and implemented in Brazil, Honduras, and Nicaragua.[13]

RCTs do have well-documented limitations, some of which are outlined in Shelton's editorial, and conducting a randomized experiment may not always be possible even when it might be ideal. But one commonly made assertion is important to counter here—that RCTs have particularly burdensome cost requirements. Based on our experience, RCTs can be conducted for the same budget (or less) than pre-post or quasi-experimental design studies. In many instances, a baseline survey is not needed when interventions are allocated by random assignment. Furthermore, data analysis for RCTs is often more straightforward and therefore less expensive.[14] Several of us recently implemented an evaluation, using face-to-face provider interviewers and mystery client surveys, of randomized assignment of drug sellers in Ghana to a text-messaging intervention; because an entire round of data collection was unnecessary, costs were substantially reduced.[15]

As with those who work on education, poverty alleviation, and other social-sector programs in developing countries (who frequently rely on evidence from randomized evaluations),[16,17] global public health practitioners should use the most rigorous, systematic approaches available to answer questions and make decisions in the face of daily uncertainty. We can do far better than "intuition, trial and error, and experience."[1, p. 255]

Shelton uses a compelling metaphor, arguing that using RCTs to design and implement public health programs at scale is like trying to light up a football stadium with a laser pointer. But we would counter that no single type of study can "illuminate the stadium." We agree that RCTs cannot answer all public health questions, or light up the stadium alone, but neither can any other single method. It takes a combination of complementary research approaches to light up our field of public health, and RCTs have been shown to be a powerful and luminous force in that effort.

Setting RCTs in opposition to other systematic research approaches creates a false dichotomy.

It is imperative for public health practitioners to answer definitively, "Does it work?" before asking, "How can it be made to work practicably at scale?"

Mixed-method approaches are essential to untangle the *why* and *how* of the impact identified in an RCT.

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TAKING EXCEPTION

Response to "A False Dichotomy: RCTs and Their Contributions to Evidence-Based Public Health"

James D Shelton[a]

While randomized controlled trials (RCTs) can and do make valuable contributions, they also have severe limitations, including in answering the basic question of "Does it work?" and, even more so, in steering how to proceed with complex public health programming at scale. They deserve no exalted position in the pantheon of methodologies for evidence-based public health.

See related articles by Hatt and Shelton.

I appreciate the thoughtful response by Hatt et al.[1] to my editorial on evidence-based public health[2] and am happy we agree on several points:

1. There is some definite value to randomized trials.
2. Because public health operates in complex program environments, it is generally necessary to lay out a valid "theory of change" or causal pathway to understand and evaluate the intended and actual program effects.
3. Mixed-method approaches are essential to understand what is going on in such complex arenas.

"Does it work" is always affected by context. The paradigm Hatt et al. put forward asserts that one strength of randomized trials is to answer definitively, "Does it work?" But for the kinds of complex programs public health must muster, there is generally no absolute answer to that question or to its companion question, "How well does it work?" Rather, the answer much depends on how and in what situation "it" is done. That is often true even for fairly consistent biologic phenomena, such as the wide variation in polio vaccine efficacy that I cited in my editorial. Perhaps the most recent example is the use of antenatal corticosteroids to prevent newborn mortality, which is effective in developed countries with sophisticated health resources but was found to actually *increase* mortality in certain resource-constrained environments.[3] Yes, randomized trials and other research methods can answer, "Can it work?" and are often fairly generalizable for discrete biologic questions. But for programming at scale, that takes us only part of the way.

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How it might be made to work practically at scale is the key question for public health. A good example is the paper by Curry et al. in this issue of GHSP, describing the many programmatic elements implemented to provide contraception very successfully and at fairly large scale in crisis-affected situations.[4] Had the program failed to assure an effective supply chain, provide competency-based training, ensure good supervision, and mobilize communities, would the results have been so successful? Highly doubtful. And the richness of their evidence is enhanced by their description of the *effect of variation in country context*; for example, policy differences on the availability of contraceptive implants and the impact of poor compensation of health workers in certain places made big differences.

Ironically, some of the randomized studies Hatt et al. cite neither completely answer the question of "Does it work?" nor provide enough understanding through mixed methods of what is going on.

- The study on pay for performance in Rwanda found an increase in such outcomes as institutional deliveries and children's preventive health visits but no increase in completion of 4 prenatal care visits or of full immunization schedules.[5] And other than some "anecdotal evidence," we are left wondering about the crucial question of how the incentive system actually may have influenced the behavior of providers and clients.
- The deworming study in Kenya found a decrease in worms and an increase in school participation and attendance.[6] But there was no discernible impact on anemia (a commonly hypothesized mechanism to affect school attendance) through which deworming might improve school attendance and

Variation in country context can make big differences in the effects of interventions.

there was no impact on actual school achievement. Also the study was carried out in a situation with high worm infestation. Might the results be different in areas with less infestation? And we have no direct information from families themselves on what may have influenced school attendance.

Community deworming is actually a prime example of the very kind of variability that undermines the generalizability of randomized trials. Notably, a 2012 Cochrane review of numerous studies on community deworming concluded[7]:

> *For haemaglobin and cognition, community deworming seems to have* ***little or no effect****, and the evidence in relation to school attendance and school performance is generally poor, with* ***no obvious or consistent effect****. Our interpretation of these data is that it is probably* ***misleading to justify contemporary deworming programmes*** *[emphasis added] based on consistent benefit on nutrition, haemoglobin, school attendance or school performance as there is simply insufficient reliable information to know whether this is so.*

Most studies failed to show impact, inescapably because situations varied. So actually, the issue of whether an intervention "is effective on a larger scale" has no single answer. And the recent decision in India to extend mass deworming to large populations has been justifiably roundly criticized.[8]

RCTs are only one piece of the picture in triangulating evidence for public health programming.

While I really do appreciate randomized studies, perhaps my biggest concern is the "hierarchy" whereby some colleagues place controlled trials at the top of a pyramid as manifestly the best evidence. For understanding public health programming, I see that as quite misguided. Randomized studies help us to understand some things, but they are only one piece of the picture in "triangulating" evidence for programming. And evidence from real-world programming is especially key.

Building on the core randomized component and adding other methodologies to the conduct of those randomized trials makes them much more useful. The large Mexico PROGRESA conditional cash transfer program focusing on health, education, and nutrition[9] cited by Hatt et al. is to some extent an example of such a mixed-method approach and was conducted at large scale. My fear, however, is that the desire to control the research environment, and the resulting narrow focus and often artificiality of trials, limits understanding of the potential programmatic practicability. It also may limit the ability to use additional methodologies to help answer whether the intervention might work practicably at scale.

Thus, to answer the questions well of what, how, and why an intervention may have worked, we need lots of methodologies. Ultimately, some of the "best evidence" or gold standard comes from programs already operating successfully at scale, as illustrated by the paper by Curry.[4] For public health programming, there is no absolute methodological hierarchy. We need to respect and use all legitimate methodologies.

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LETTER TO THE EDITOR

Tightening Up the Nomenclature for Non-Physician Clinicians: Why Not Call All of Them Physician Assistants?

Dear Editor-in-Chief,

This Letter is in reference to the article by KD Rao et al., ''As good as physicians: patient perceptions of physicians and non-physician clinicians in rural primary health centers in India,'' published in the November 2013 edition of *Global Health: Science and Practice* (GHSP).[1] The authors have to be lauded for their efforts to produce evidence on patient perceptions of care provided by non-physician clinicians (NPCs)—an issue that receives little attention, as most of the focus is on the technical quality of care provided by such clinicians.

Debates have been ongoing about the best course of action to meet the health care needs of rural populations in India.[2,3] Given that the Indian health care sector is a vast system with diverse needs and attendant challenges, it is reassuring to know that there are potential viable alternatives to allopathic doctors in areas with physician shortages.

Rao and colleagues introduced GHSP readers to a cadre of health care workers called rural medical assistants (RMAs). We would like to introduce to readers another cadre that has been present for nearly 2 decades in the Indian health care sector and that has been largely ignored for just as long—that of the physician assistant (PA).

The Indian PA workforce consists of close to 1,000 qualified health care professionals who are mainly deployed in hospital settings in urban areas. The PA program as offered by several institutions and their affiliated universities varies in duration, but in general, requires 3 years of didactic medical education followed by a 1-year internship in a chosen medical specialty; graduates receive a Bachelor of Science degree.[4] Besides taking extensive coursework in basic and medical sciences and theory, PAs receive practical training to perform many medical tasks, including taking patients' medical history, conducting physical examinations, preparing medical notes, writing discharge summaries, counseling patients, and participating in clinical decision making and treatment. They undergo clinical rotations in major medical specialties throughout the program, and their performance is continually assessed.

Globally, the PA profession has its roots in the United States beginning in the early 1960s. As of 2013, the American PA workforce consisted of more than 90,000 certified clinicians, and training was offered at more than 173 programs throughout the country. Most programs grant a master's degree, and graduates are working in all medical specialties including primary care.[5] Meanwhile, many other countries have observed the success of the PA profession and successively have employed PAs as a way to overcome the imbalance between the demand and supply of medical care, including Australia, Canada, England, Germany, Ghana, The Netherlands, and Scotland.[6–9] Other countries are exploring the possibilities of deploying PAs, but clear documentation on their respective successes is still lacking.

Several local initiatives in India are currently employing different types of NPCs. Many look down upon such NPCs and set them aside as ''half-doctors.'' Understandably, there is concern that some NPCs have little medical education and/or training and are thus not qualified to diagnose and treat patients. But we appeal to all stakeholders involved in planning and managing the Indian health industry to grant a professional identity to those NPCs who are adequately trained. In this context, we feel it is very important to raise this topic to consider standardizing several local NPC initiatives into one new type of medical provider, regardless of whether they practice medicine in (rural and remote) family practices or in hospital settings. As long as the NPCs share more commonalities than differences in terms of educational outcomes and the medical tasks they are expected to perform, it may be plausible to classify them under one professional identity, i.e., as physician assistants. Classifying NPCs under the identity of the PA profession would also make it easier for societies to know whom to trust in a health care worker.

One reason why some countries have been successful in deploying PAs in their health systems may be because the initiatives were government-driven in contrast to the Indian situation. The State Medical University of Tamil Nadu in India has recognized the

importance of PAs and has established a PA program in collaboration with a number of hospitals in the state, but, sadly enough, the program is yet to be under the purview of the Ministry of Health and Family Welfare.

Some stakeholders in India want to explore allowing AYUSH practitioners to practice allopathy to address physician shortages.[10] AYUSH practitioners are trained in Indian systems of medicine (Ayurveda, Yoga, Unani, Siddha, Homeopathy). However, we think it would be more prudent to assist AYUSH practitioners in finding opportunities to practice within their own field and instead to explore the possibility of expanding the success of Indian PAs into rural areas. After all, several studies have demonstrated American PAs working successfully in rural and remote areas, including with respect to high patient satisfaction,[11] good job satisfaction for the PAs themselves,[12] and also to the satisfaction of the medical society.[13]

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