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Lois Schaefer

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Paula Braitstein

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Venkatraman Chandra-Mouli, Catherine Lane, Sylvia Wong

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Ariel Pablos-Mendez, Scott R Radloff, Kamiar Khajavi, Sally Ann Dunst

Glob Health Sci Pract. 2015;3(3):341-351  
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John Stanback, Markus Steiner, Laneta Dorflinger, Julie Solo, Willard Cates, Jr

Glob Health Sci Pract. 2015;3(3):352-357  
<http://dx.doi.org/10.9745/GHSP-D-15-00096>

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Care Groups use volunteers to motivate mothers to adopt key MCH behaviors. The volunteers meet as a group every 2–4 weeks with a paid facilitator to learn new health promotion messages. Key ingredients of the approach include: peer-to-peer health promotion, selection of volunteers by the mothers, a manageable workload for the volunteers (no more than 15 households per volunteer), frequent (at least monthly) contact between volunteers and mothers, and regular supervision of the volunteers.

Henry Perry, Melanie Morrow, Sarah Borger, Jennifer Weiss, Mary DeCoster, Thomas Davis, Pieter Ernst

Glob Health Sci Pract. 2015;3(3):358-369  
<http://dx.doi.org/10.9745/GHSP-D-15-00051>

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Care Group projects resulted in high levels of healthy behavior, including use of oral rehydration therapy, bed nets, and health care services. Accordingly, under-5 mortality in Care Group areas declined by an estimated 32% compared with 11% in areas with child survival projects not using Care Groups.

Henry Perry, Melanie Morrow, Thomas Davis, Sarah Borger, Jennifer Weiss, Mary DeCoster, Jim Ricca, Pieter Ernst

Glob Health Sci Pract. 2015;3(3):370-381  
<http://dx.doi.org/10.9745/GHSP-D-15-00052>

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Zulfiya Charyeva, Olugbenga Oguntunde, Nosa Orobato, Emmanuel Otolorin, Fatima Inuwa, Olubisi Alalade, Dele Abegunde, Saba'atu Danladi

Glob Health Sci Pract. 2015;3(3):382-394  
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Christine L Gray, Brian W Pence, Jan Ostermann, Rachel A Whetten, Karen O'Donnell, Nathan M Thielman, Kathryn Whetten

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Adam C Levine, Justin Glavis-Bloom, Payal Modi, Sabiha Nasrin, Soham Rege, Chieh Chu, Christopher H Schmid, Nur H Alam

Glob Health Sci Pract. 2015;3(3):405-418

<http://dx.doi.org/10.9745/GHSP-D-15-00097>

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John Ross

Glob Health Sci Pract. 2015;3(3):419-445

<http://dx.doi.org/10.9745/GHSP-D-15-00124>

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Corey L Luthringer, Laura A Rowe, Marieke Vossenaar, Greg S Garrett

Glob Health Sci Pract. 2015;3(3):446-461

<http://dx.doi.org/10.9745/GHSP-D-15-00171>

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Marc Cunningham, Ariella Bock, Niquelle Brown, Suzy Sacher, Benjamin Hatch, Andrew Inglis, Dana Aronovich

Glob Health Sci Pract. 2015;3(3):462-481

<http://dx.doi.org/10.9745/GHSP-D-15-00116>

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The volume of literature on health systems in sub-Saharan Africa has been expanding since the 2000 MDG era. Focus has remained generally on categorical health themes rather than systems concepts. Topics such as scaling-up, organizational development, data use for decision making, logistics, and financial planning remain underrepresented. And quite surprisingly, implementation science remains something of a "black hole." But bibliometric evidence suggests there is a shift in focus that may soon address these gaps.

James F Phillips, Mallory Sheff, Christopher B Boyer

Glob Health Sci Pract. 2015;3(3):482-502

<http://dx.doi.org/10.9745/GHSP-D-15-00034>

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Hally Mahler, Sarah Searle, Marya Plotkin, Yusuph Kulindwa, Seth Greenberg, Erick Mlanga, Emmanuel Njeuhmeli, Gissenje Lija

Glob Health Sci Pract. 2015;3(3):503-515

<http://dx.doi.org/10.9745/GHSP-D-15-00151>

### INNOVATIONS

## Remote Sensing of Vital Signs: A Wearable, Wireless "Band-Aid" Sensor With Personalized Analytics for Improved Ebola Patient Care and Worker Safety

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Steven R Steinhubl, Mark P Marriott, Stephan W Wegerich

Glob Health Sci Pract. 2015;3(3):516-519

<http://dx.doi.org/10.9745/GHSP-D-15-00189>

# Women's Groups to Improve Maternal and Child Health Outcomes: Different Evidence Paradigms Toward Impact at Scale

The Care Group model, with relatively intensive international NGO implementation at moderate scale, appears successful in a wide variety of settings, as assessed by high-quality evaluation with rich program learning. Another women's group approach—Participatory Women's Groups—has also been implemented across various settings but at smaller scale and assessed using rigorous RCT methodology under controlled—but less naturalistic—conditions with generally, although not uniformly, positive results. Neither approach, as implemented to date, is directly applicable to large-scale integration into current public programs. Our challenge is to distill the elements of success across these approaches that empower women with knowledge, motivation, and increased self-efficacy—and to apply them in real-world programs at scale.

➔ See related articles by [Perry \(Care Groups I\)](#) and [Perry \(Care Groups II\)](#).

## CARE GROUPS VS. PARTICIPATORY WOMEN'S GROUPS

There is a long history of community-level health education and participatory problem solving in global health. From the late 1990s, two such approaches—Care Groups and Participatory Women's Groups—have been developed and implemented across a variety of settings and have shown promise.

In this issue of GHSP, we have included two papers documenting program experience to date with Care Groups focusing on maternal and child health.<sup>1,2</sup> This model involves use of paid facilitators who, during periodic meetings, deliver focused sets of health messages to Care Group members, who are female community volunteers. These community volunteers, in turn, share the messages with neighboring households.

Similar to Care Groups, Participatory Women's Groups make use of paid facilitators who meet with female community volunteers (Table). But rather than simply passing on specific health messages, the primary emphasis is on participatory learning and action bearing on factors contributing to poor maternal and newborn outcomes in their community. This model was first piloted in the Warmi project in Bolivia,<sup>3</sup> which showed reduction in perinatal mortality. Based on this experience, the strategy has subsequently been tested in 7 cluster-randomized controlled trials (RCTs), conducted in Bangladesh, India, Malawi, and Nepal, and has shown promising but mixed results with regard to mortality impact.<sup>4</sup> Across the 7 trials, approximately 130,000 mother-newborn dyads were enrolled. Based in part on the available RCT evidence

from these trials, last year the World Health Organization (WHO) formally endorsed this approach.<sup>5</sup>

Experience with Care Groups is not captured as well in the peer-reviewed literature, but—as with the Participatory Women's Group approach just described—these programs also trace their origin to the late 1990s. The model was first developed and tested by World Relief in Mozambique, under the United States Agency for International Development (USAID) Child Survival and Health Grants Program.<sup>6</sup> The approach has been picked up by at least 24 other international NGOs and has been implemented in 28 countries.<sup>1</sup> Across a selection of 8 of these programs reported in the paper by Perry et al.,<sup>1</sup> the total number of beneficiaries was 738,000. Overall, experience with such programs has consistently suggested mortality impact, albeit with less rigorous study designs.

## DIFFERENT KINDS OF EVIDENCE

Although the two approaches were introduced around the same time and are similar in some respects, the course they've charted over the past decade and a half has differed markedly. With the peer-reviewed publication of 7 cluster RCTs on Participatory Women's Groups, this approach has now accrued an "evidence base" and, as mentioned, has given rise to WHO guidance. By contrast, the Care Group model has accumulated what could be described as a reasonably large and fairly well-documented (although not well-published) "experience base."

The inputs applied have varied across settings but, for both of these initiatives, have been reasonably significant, exceeding what the public sector could or would

**TABLE.** Comparing Care Groups With Participatory Women’s Groups

	Care Groups	Participatory Women’s Groups
Skilled external facilitators	Required	Required
Importance of group interaction	Contributes to effectiveness	Central focus
Health message communication	Central focus	Secondary focus
Role of women’s group members	Peer health educators to neighboring households	Problem solvers developing community solutions
Population coverage strategy	Blanket coverage, through group members, of households with pregnant women and children under 5	Initially no explicit strategy aiming at coverage, but—based on RCT results—for achieving impact, recommend reaching ≥30% of pregnant women

otherwise have provided to the populations targeted for such activities. Although some of the Participatory Women’s Group trials enrolled up to 30,000 mother-newborn dyads, overall the reach of program efforts using the Care Group model has exceeded that of Participatory Women’s Groups by at least *an order of magnitude*.

The Participatory Women’s Group program experiences, however, have been evaluated using rigorous population vital registration and RCT designs, allowing for firmer inferences on mortality effects. So with regard to “internal validity,” the available evidence allows us more confidently to conclude that, “It worked *there*,”<sup>7</sup> at least in the particular settings of the trials that showed a mortality effect. By contrast, the Care Group program experiences do not have the benefit of systematic mortality documentation, and—although they used pre-post designs with important service utilization and household practice endpoints in all the documented instances—generally they did *not* use designs tracking pre-post changes in an equivalent comparison area. As such, they do not meet the conventional methodologic threshold for “high-quality evidence” generally used by global normative bodies such as WHO for developing program guidance (which, in its evidence reviews, often discounts studies lacking concurrent comparison arms).

**What Care Group evaluations lacked in “rigor,” they have made up with “naturalistic” program experiences, making the findings arguably more relevant for decision making.**

**“RIGOR” VS. RELEVANCE**

What Care Group projects lacked in conventional “rigor,” they have made up for as more “naturalistic” program experiences and as such are, arguably, *more broadly relevant* for decision making in the real world. In most instances, the Care Group projects were implemented district-wide, usually linking with

government health services. The intensity of inputs per beneficiary reached was generally significantly more modest than in the Participatory Women’s Group RCTs. Of course, for the documented Care Group experiences, with the lesser degree of rigor in measurement and design, we need to approach causal claims more tentatively. But the consistency in improved household practices and service utilization across cases strongly suggests that, providing that conditions for effective implementation are met, the Care Group approach yields mortality reduction benefit.

The authors of the two Care Group papers in this issue suggest that a more rigorous RCT design may be needed to test the Care Group approach. *We disagree*. Under current institutional norms, there may not be WHO recommendations forthcoming for a Care Group approach without evidence derived from stronger research methodology than what has been used to date (although the WHO guidelines development process does not automatically exclude non-experimental studies). Nevertheless, funders and other decision makers already have a sufficiently solid “experience base,” if not an RCT-grounded “evidence base,” for the Care Group approach to warrant further such program work.

**THE RIGHT PARADIGM FOR SCALING-UP COMPLEX INTERVENTIONS?**

The current tension between contesting views of what constitutes a valid source of insight to inform decision making suggests that some are getting hung up on a misapplied paradigm. The RCT methodology is very useful in isolating the effect of a particular intervention from other possible contributing effects. But RCTs often trade off real-world generalizability (and utility)

for internal validity, *particularly when not complemented with other information*.<sup>8</sup> Even if an RCT gives us considerable confidence that “it worked *there*” (often under very case-specific conditions), it doesn’t necessarily tell us much about whether it would work *here*, i.e., in the range of other settings where policy makers and funders may be considering a similar effort.<sup>7</sup> In particular, that a program approach worked under very controlled and rigorously implemented conditions tells us little about how it would perform under usual ministry of health program conditions.

The dominant evidence paradigm in global health, as illustrated in the [Figure](#), starts with the question, “Does it work?” It seeks a universal, context-free answer, asking, “Is it effective, yes/no?” According to this paradigm, the definitive answer to this question is obtained from an RCT or, even better, from a multi-center trial or a systematic review of multiple RCTs.<sup>9</sup> On the basis of a positive answer to this “efficacy” question, one proceeds directly to widespread adoption. For a discrete clinical intervention (e.g., innovative cancer regimen vs. standard regimen), this paradigm may be appropriate. However, generally it is inadequate for behavioral interventions or complex, multi-element approaches or strategies, for which contextual factors are usually very important.<sup>8</sup>

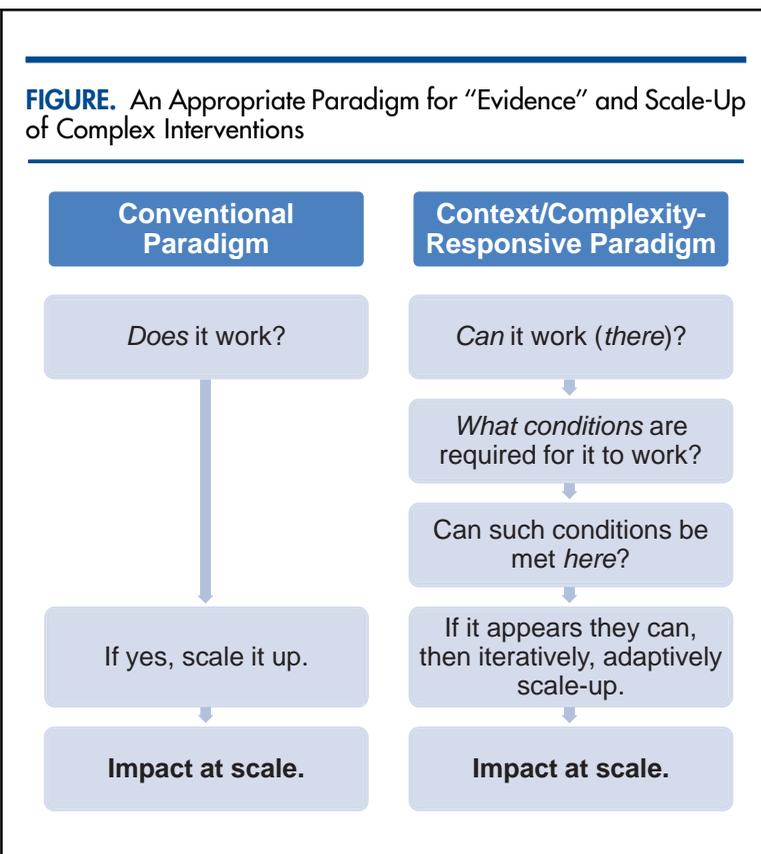
Instead, more appropriate for behavioral interventions and multi-element intervention packages—that are overwhelmingly the focus of global health program work—we need a paradigm that is conscious of and responsive to context and complexity. Instead of accepting the notion that all we need is “evidence” of effectiveness (understood as universal and context-free), such a paradigm recognizes both the utility and limitations of RCT evidence as generally demonstrating only that an intervention or approach *can* work in the particular conditions and setting under which the original trial(s) was or were conducted.<sup>7</sup> Beyond such proof of concept, to make judgments on whether the intervention or strategy could subsequently work in the program setting where it is being considered, we then need to understand, beyond the intervention itself, what the needed support factors were to produce the effect observed in the original study or studies (what Cartwright refers to as “lateral search”<sup>7</sup>).

### HOW BEST TO APPLY EVIDENCE?

*For both Participatory Women’s Groups and Care Groups, we now have reason to believe they can be effective, but also that neither of these approaches is*

*necessarily or automatically effective. So, it is inappropriate simply to label either of these as “evidence-based” and then enjoin governments and donors to “get with the program” and roll them out (as our usual paradigm prescribes). Instead, for both we need to better understand, based on evidence available and experience to date, what set of conditions needs to be met for effectiveness. Then, in each particular setting where government, donors, or others are considering similar program efforts, there needs to be a process of exploring what it might take to meet the needed conditions, as best as we understand them. Early tentative steps can then be taken, validating to what degree we’re actually achieving what we had hoped to for optimal performance. In most instances, we’ll find gaps between expected and actual performance; *no battle plan survives contact with the enemy*. In some cases, we may determine that in our particular setting, in the way we’ve tried to implement a particular solution, it won’t give us what we want. In such cases, the best choice may be *to cut our losses and try something else*. In other cases, certain aspects*

**Even if RCTs give us confidence that “it worked *there*,” they don’t necessarily tell us much about whether it would work *here*.**



**“Positive RCT result → efficacy established → scale it up.” Maybe we’re missing a step or two.**

may perform well and others less well—and the best choice may be to adapt the approach.

For both Participatory Women’s Groups and Care Groups, we have promising indications that—under the right conditions—important shifts in behavior can be achieved, resulting in population-level improvements in maternal, newborn, or child health outcomes, as well as other benefits. In both instances, tentative efforts in new settings and through new implementation modalities (possibly including under government primary health care services) are warranted—but not under the paradigm of “efficacy established; scale it up.”

Unfortunately neither the Participatory Women’s Group nor the Care Group approach is a natural fit for typical primary health care services in low- and middle-income countries. However, in both cases there may be key principles or practices that can be abstracted and applied in programs in ways that may look quite different from the original two models but that may fit the conditions in a new receiving system and deliver benefit. Is there some “secret sauce” for empowering women with knowledge, motivation, and increased self-efficacy that we can draw out of these experiences that might be applied in some more practicable way in current programming?

## WHERE NEXT?

**To inform global health programming, we need “incubator” experiences—intermediate experiences between proof-of-concept RCTs and large-scale implementation under ministries of health.**

Beyond RCTs, there is a need for well-documented and well-evaluated “incubator” experiences, experiences intermediate between proof-of-concept cluster RCTs (as conducted for Participatory Women’s Groups) and large-scale implementation under ministries of health. The Care Group experience documented in the two papers in this issue provides a good example of such an incubator experience. At this point, one can say that through NGO delivery modalities and with significant external resources, the Care Group approach can be effective across a fairly wide range of settings. Moving to a further phase of (well-studied) incubation, efforts could now be made to tap the power of women’s groups to improve maternal and child health through larger-scale Care Group efforts under ministries of health.

Of course, there are many worthwhile initiatives that continue to produce widespread benefit without being delivered through government health services. Regardless of whether either of these approaches is ever demonstrated to perform effectively in such an institutional context, both demonstrate a potentially powerful local dynamic that could be tapped in many settings—women meeting and taking action together for a better future for themselves, their families, and their communities. —*Global Health: Science and Practice*

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# Task Sharing Implant Insertion by Community Health Workers: Not Just Can It Work, but How Might It Work Practically and With Impact in the Real World

Lois Schaefer<sup>a</sup>

**Demonstrating that a health service, such as providing contraceptive implants, can be safely task shared to less highly trained workers is crucial but is only one step toward effective implementation at scale. Providers need dedicated time, enough clients, supplies, supervision, and other system support, allowing them to maintain their competency, confidence, and productivity.**

➔ See related article by [Charyeva](#).

Task shifting is defined as “the rational redistribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from more highly qualified health workers to health workers with shorter training and fewer qualifications, in order to make more efficient use of the available human resources for health.”<sup>1</sup> It is becoming more commonly known as task sharing, a change intended to convey the message that tasks are not taken away from one cadre and given to another, but rather that additional cadres are given the capacity to take on identified tasks.

Most commonly, task sharing has been used to shift skills from nurses, midwives, and doctors to community health workers (CHWs), in order to increase the availability of selected services, including family planning, child health monitoring, and postpartum follow-up, at the community level. However, task sharing is increasingly being implemented with mid-level providers to increase access to clinical skills, such as insertion of contraceptive implants or provision of antiretroviral therapy, by sharing such tasks from physicians to nurses and midwives. It has also been used to create new cadres of workers, for example, clinical officers who can provide cesarean deliveries or other simple surgeries, when there is no appropriate existing cadre.

## EFFECTIVE IMPLEMENTATION AT SCALE?

Most frequently, the question that is addressed in pilots or other studies is whether a cadre can safely and competently complete the task that is to be shared—for example, can

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CHWs learn to give injectable contraceptives? Or, as in the case of an operations research project described by Charyeva and colleagues in this issue of GHSP,<sup>2</sup> can community health extension workers (CHEWs) in northern Nigeria insert and remove implants? The design of such task sharing interventions focuses on demonstrating that there is no harmful effect on recipients of those services. But documenting that a worker can safely provide a service is only one of the questions that need to be answered for safe, efficient, effective, equitable, and sustainable implementation of task sharing.

## Context Matters

Of crucial importance is the context or environment in which task sharing takes place. First and foremost, health workers must receive adequate preparation for assuming the new tasks, which often includes competency-based training, and then be supported by supervision, mentoring, and functional referral systems as they provide services. In general, they must also receive adequate incentives and compensation for the new workload, something that is often overlooked and underestimated for building worker motivation and performance. They must be offered adequate legal protection for their new roles through updated laws, regulations, policies, and guidelines. Finally, they must operate in a service delivery system organized to be conducive to large-scale effect.

Few countries provide such an environment, however, and so efforts to introduce and pilot task sharing often address creating an enabling environment. But concerns for safety and proving feasibility often mean

**Task sharing pilots tend to be designed in such a way that they are not replicable in resource-limited settings.**

that the intervention is designed in such a way that, while it leads to a successful pilot, it is not replicable in the resource-limited reality of most countries. Intensive, specialized training courses are beyond the capacity of local training systems, for example, or post-training supervision is of a frequency and intensity that is beyond what the standard supervision system can provide. Worker incentives that the health system cannot absorb or sustain are often used to improve motivation in pilot settings. Although this may be necessary to achieve that first important step of demonstrating that a cadre can, in fact, take on a new skill or task, it does not provide a model that can be replicated, much less scaled-up.

### **Making Task Sharing More Practicable**

Moving forward, task sharing interventions need to be designed more carefully, with an eye to local capacity for ongoing implementation. This begins with a strong understanding and acknowledgment of the specific service delivery context and includes plans for transfer of activities to local partners, whenever possible. In the design stage, selecting interventions that are feasible and sustainable should be a primary consideration. Providing a clear and detailed description of the pre-project context when documenting the experience will help others assess the feasibility of the project's interventions in other settings. Discussion of the results needs to demonstrate thinking that goes beyond project mode and includes a hard look at how the intervention could go to scale and be sustained.

**Successful task sharing of implants requires providers with dedicated time, supplies, and enough client demand to maintain competency.**

### **RELEVANCE FOR PROVISION OF IMPLANTS**

In this issue of GHSP, Charyeva and colleagues clearly present the need to increase the number of health workers able to provide contraceptive implants, as part of a larger reasonable emphasis on increasing access to long-acting and permanent methods.<sup>2</sup> The authors provide a description of how such services are currently provided and effectively convey the role for CHEWs in achieving that goal. For example, they make sure the reader knows what CHEWs are—how they are trained, their current scope of work, and how they fit into the health system—important information for replication, given that the definition of CHWs varies widely and that these factors affect their ability to assume new skills.

The authors are less successful, however, in addressing the feasibility and sustainability of their project interventions. Their model for task

sharing was based on 2 to 3 weeks of training for the CHEWs, followed by high-frequency supervision—from 1 to 8 visits within the following 6 months—a level that the project itself struggled to provide and which the existing supervision system cannot maintain. The CHEWs interviewed post-intervention acknowledged the usefulness of the supervision—and requested it be increased to 1 to 2 times per month, a level even farther removed from local reality. Although the authors identify the need for “continuous supportive supervision” as a lesson learned, they unfortunately do not offer any insights on how that could be achieved.

Most importantly, the sum total output of this intensive intervention was only 4 implants per health facility per month, providing little confidence of a pathway to large-scale effect. In contrast, other approaches to implant provision such as mobile outreach and social franchising are providing more implants by many orders of magnitude.<sup>3-6</sup> Clearly, issues such as the need for demand creation may have limited provision, but organization of work and system demands may be another major constraint. To successfully integrate a service, especially one requiring specialized skills such as implants, requires that providers have dedicated time, all the necessary supplies, and sufficient opportunities to use their skills so they can maintain their competency and confidence. While the CHEWs in the intervention were able to perform 4 insertions per month without adding significantly to their workload, and special systems kept them stocked with implants, this may not be true post-project and with the desired increased demand. This issue could prove an insurmountable constraint on this approach to providing implants.

The authors' finesse of issues related to scale-up and sustainability with the statement, “Future investigation should rigorously examine factors that support scale-up and sustainability of the intervention,” leaves many unanswered questions. I applaud the work of Charyeva and colleagues as a sound initial “proof of concept,” but we must have more robust discussion on how to fully implement task sharing across contexts from all who share similar results.

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# Institutional Care of Children in Low- and Middle-Income Settings: Challenging the Conventional Wisdom of Oliver Twist

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**Whether institutions or extended families are better suited to care for orphans depends on the specific circumstances. Reported rates of traumatic experiences among orphans and vulnerable children are high in both institutions and extended families; improving the quality of care for such children should be the paramount priority in all settings.**

➔ See related article by [Gray](#).

Acting in the best interest of the child is the fundamental principle that is supposed to guide local, national, and international policy, programming, research, and care for children. Most people would agree, yet there is a raging debate among scientists about how, what, where, and when to measure and interpret “best interests.” The stakes are high as there are millions of children lacking one or both parents (orphans) and millions more whose parents are alive but due to poverty or other circumstances such as substance abuse can’t, or at least don’t, provide them with an optimal care environment—or sometimes even one that meets their basic needs. Consequently, millions of children, especially in low- and middle-income countries, turn to the streets in an effort to take care of themselves.

On one side is a large body of evidence, mostly historical and from Eastern Europe and North America, about the negative physical and mental health outcomes of children in institutions.<sup>1</sup> In essence, the evidence clearly demonstrates that socially and emotionally deprived environments are bad for children and that institutions caring for infants, particularly in Eastern Europe and North America, have embodied neglectful environments. As a result of this evidence, there are global demands for universal deinstitutionalization.

Yet the paper by Gray and colleagues published in *Global Health: Science and Practice* challenges stakeholders to perhaps rethink these sweeping conclusions.<sup>2</sup> Their data, from a multicenter cohort of school-aged children in 5 low-income countries, indicate that children in family-

based settings actually had a higher risk of physical or sexual abuse compared with those living in institutions, and children in family-based environments were as likely as those in institutions to report experiencing at least one potentially traumatic event. Although limited by the self-reported nature of the data, these findings are supported by a rapidly growing body of evidence to suggest that, at least in low- and middle-income countries, institutional environments may sometimes be better equipped and prepared to care for children in need than many extended families and other family-based configurations of care.<sup>3–8</sup>

It is a counter-intuitive idea. Charles Dickens brought us *Oliver Twist* and with it enduring social and cultural icons of institutions being inherently harmful for children. Residential schools in Australia, Canada, and the United States have strongly reinforced this idea by leaving aboriginal communities and First Nations struggling to cope with lasting multigenerational trauma resulting from the schools. When Nicolae Ceaușescu was eventually deposed and Romania exposed to the outside world, horrifying images of children in institutions imprinted themselves onto our collective mind with the undisputed message that institutions are bad for children.

Truly, it is doubtful that any child would wish *a priori* to grow up in an institution, and there is no denying the potential for neglect and severe abuse to occur in institutions in the absence of appropriate resources, regulation, and oversight. The question is whether institutional environments themselves are *necessarily* bad environments for children. The vast majority of data about children in institutional environments has come from high- and very high-income settings, and often without comparison groups. This

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literature may be subject to publication bias, because the more shockingly negative findings are, the more likely they are to get published. The horrific images and data from children in Romania stay with us and lead us to draw the strong conclusions to which Gray and her coauthors allude: institutions should all be closed. But steadily, piece by piece, there is another picture emerging that just maybe, given the widespread poverty, rapid urbanization,<sup>9</sup> and high dependency ratios that characterize many extended families in sub-Saharan Africa<sup>10</sup> and Asia, institutions are not so bad for children in those places, particularly when compared with their compatriots living with extended family. At least, they appear to be no worse.

Regardless of which side of the deinstitutionalization debate one takes, what also especially deserves attention from this paper is the fact that over 90% of participating children in *both* environments reported experiencing at least one potentially traumatic event *other than* the death of a parent.<sup>2</sup> Over 50% of both groups reported at least one episode of physical or sexual abuse by age 13, and physical or sexual abuse was the leading cause of incident trauma in the cohort. One might surmise these to be unsurprising findings for children living in institutional environments given the background circumstances that presumably led to them becoming institutionalized. However, the fact that so many children in both care environments experienced potentially traumatic events—and physical and/or sexual abuse in particular—is alarming. These rates are unacceptably high, but why could they be higher in families than in institutions?

There are several theories, all of which need testing. One is that at least in some settings, the majority of institutions are funded through adequately resourced religious organizations and so are better able to respond to the material needs of children.<sup>5</sup> There is evidence that orphaned girls, especially, exchange sex for material goods in order to survive; if this need is taken away their risk of sexual abuse will be lessened.<sup>11,12</sup> It may also be possible that many of the staff, or at least founders, of institutions in low-income settings are working in, or have set up, the institution explicitly because they want to take care of children. In contrast, there is a broad literature indicating many extended families are forced into caring for orphans because of family or cultural expectations. They may already be struggling financially and view the orphaned child as an

added burden. There is a body of evidence that indicates that orphans are often systematically discriminated against within the household in which they are living.<sup>13,14</sup> In essence, extended families in many areas are stretched to the limit financially and perhaps emotionally. Families are not generally supported to care for orphaned children although thanks to support from governmental and nongovernment organizations, more and more families are receiving small cash subsidies. The subsidies do seem to help significantly.<sup>15</sup>

The evidence is mounting that at least in some places, institutional environments actually create family-like environments.<sup>5</sup> Moreover, there is plenty of evidence including the paper by Gray et al. that illustrates a high burden of abuse and neglect among orphans living with family.<sup>16</sup> Indeed the one potentially traumatic event that was higher for institutionalized children in Gray et al.'s study was being forced to leave the home or care setting—the authors speculate that this is likely due to the closing of institutions in which they were living.

Thus, the answer to the question posed earlier appears to be: “No, there is nothing *necessary* about living in an institution that seems to be inherently bad for a child.” As more and higher quality data from low- and middle-income countries emerge, the idea that it is the quality and characteristics of the care within an environment, rather than the type of environment itself, that most likely impacts a child's health and well-being, is likely to grow.

In many ways, the debate on institutionalization is asking the wrong question. The questions we should be asking ourselves are how do we prevent traumatic events among vulnerable children across the board—regardless of the care environment? How do we create a world in which most children can grow into their teens without experiencing a potentially traumatic event? How do we support those who have experienced a traumatic event? How do we support families to take better care of the children in their charge in the context of poverty, culture, urbanization, and the rapidly changing world we are all trying to adapt to? What is the role of institutions for children in need of a safety net? How should they be structured to respond adequately to the physical and emotional needs of infants, toddlers, young children, and adolescents? What are the optimal care characteristics within any environment that maximize resiliency and break the cycles of poverty, exploitation, and abuse among young people?

**A growing body of evidence suggests institutions may sometimes be better equipped to care for children in need than extended families, especially in low- and middle-income countries.**

**Extended families in low- and middle-income countries may be financially, and perhaps emotionally, stretched to care properly for orphans.**

**The quality and characteristics of care within an environment might be more important to a child's health and well-being than the type of environment itself.**

These are the next questions that need to be asked—and answered—by scientists engaged in the debate about what is in the best interests of vulnerable children globally. One can only hope that all stakeholders in the discussion can keep open minds, let the evidence evolve, and develop best practices that are truly in the best interests of children in all regions of the world—ones that do not hang on the image of poor little Oliver Twist.

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COMMENTARY

# What Does Not Work in Adolescent Sexual and Reproductive Health: A Review of Evidence on Interventions Commonly Accepted as Best Practices

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Youth centers, peer education, and one-off public meetings have generally been ineffective in facilitating young people's access to sexual and reproductive health (SRH) services, changing their behaviors, or influencing social norms around adolescent SRH. Approaches that have been found to be effective when well implemented, such as comprehensive sexuality education and youth-friendly services, have tended to flounder as they have considerable implementation requirements that are seldom met. For adolescent SRH programs to be effective, we need substantial effort through coordinated and complementary approaches. Unproductive approaches should be abandoned, proven approaches should be implemented with adequate fidelity to those factors that ensure effectiveness, and new approaches should be explored, to include greater attention to prevention science, engagement of the private sector, and expanding access to a wider range of contraceptive methods that respond to adolescents' needs.

## INTRODUCTION

The 1994 International Conference on Population and Development (ICPD) was a landmark event for adolescent sexual and reproductive health (ASRH). Thanks to the efforts of advocates from around the world, the pressing need to address the sexual and reproductive health (SRH) of young people including adolescents was acknowledged in the ICPD's Programme of Action.<sup>1</sup>

We submit that in 1994, while there was some awareness and understanding of the SRH needs and concerns of (mostly unmarried) adolescents in low- and middle-income countries (e.g., high rates of early and unintended pregnancy, early childbearing, unsafe abortion, and sexually transmitted infections), there was limited understanding of effective ways of responding to these needs and problems.<sup>2</sup> The knowledge available at that time suggested that adolescents and young people lacked understanding of sexuality, reproduction, and sexual and reproductive health; that they were not getting the information and education they needed at home, at school, or elsewhere in their communities; and that they were neither able nor willing to obtain health services because

they were not "youth friendly." The social environment was not conducive to acknowledging adolescent sexuality or their right to healthy sexual development. Laws and policies around providing information and services to unmarried adolescents were generally restrictive, and even where supportive laws and policies existed, these were contradicted by others or not enforced.

There was little evidence based on research or practical experience on effective ways of providing young people with information, education, and health services, or equipping them with skills to protect them from risks. Further, there was limited understanding of approaches to address deeply held community norms and biases against premarital sexual activity among adolescents.

Moreover, existing reproductive health programs were primarily targeted to adult women. Married adolescents fell into this category, as marriage usually conferred adult status and thus the right to access services. Yet while it was acceptable for married adolescents to access these services when compared with their unmarried peers, the quality of the services they received was wanting, as they were not sensitive to the age-specific and developmental needs of young women who might want to delay their first pregnancy or who were pregnant for the first time.

Much has happened over the last 20 years. Interventions that acknowledge the rights of adolescents and respond to their needs have been designed and piloted; policies and strategies formulated; projects and programs implemented; and research studies and evaluations conducted. Although there are still many gaps in our

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knowledge and understanding, we have a much better picture of the needs and problems of adolescents in low- and middle-income countries.<sup>3,4</sup> We also have a better understanding of what works—and what does not—in responding to their needs and problems.

**Although there are gaps in our understanding of adolescent needs and problems in low- and middle-income countries, a growing body of evidence points to interventions that work and ones that do not.**

A number of recent publications have pointed to interventions and intervention-delivery mechanisms that have been shown to improve adolescent sexual and reproductive health.<sup>5–7</sup> They also argue that some of the interventions and intervention-delivery mechanisms have been shown to be ineffective. Despite this evidence, ineffective interventions and ineffective ways of delivering them continue to be widespread, and interventions that have been shown to be effective are often delivered ineffectively. As a result, human and financial resources are invested without any positive outcomes, and questions are raised about the value of investing in ASRH policies and programs, especially at scale.

Our review suggests at least 5 thematic areas that challenge our ability to demonstrate significantly positive results in ASRH programming:

1. Significant numbers of adolescents are not adequately reached by the interventions intended for them.
2. Interventions that have been shown to be ineffective continue to be implemented.
3. Interventions that have been shown to be effective are delivered ineffectively.
4. Interventions have limited effects because they are delivered piecemeal.
5. Interventions are delivered with inadequate dosage (i.e., they are of low intensity or for a short duration) resulting in limited or transient effects.

**Many adolescents, especially those who are most marginalized or vulnerable, are not being reached by adolescent health programs.**

**Youth centers, peer education, and high-profile meetings on ASRH have been shown to be ineffective yet remain popular approaches among implementers.**

### **Adolescents Are Not Adequately Reached by Interventions Intended for Them**

For an intervention to have an effect on adolescents' knowledge, attitudes, beliefs, and behavior, it must first be able to reach them. Studies suggest that many adolescents, especially those with the most pressing SRH needs or who are most marginalized or vulnerable, are not being reached by interventions as intended by program planners. Additionally, many first-generation adolescent health programs implemented broad-based interventions intended to reach all adolescents in a given community or catchment area, rather than identifying and targeting those most vulnerable to health and social problems.

While it is unrealistic to expect that 100% of all adolescents in a given setting will be reached by an intervention, a study by Erulkar et al.<sup>8</sup> is illustrative of the limited reach of many programs against what is intended. The study showed that in a peri-urban setting on the outskirts of Addis Ababa, Ethiopia, only 1 in 5 boys aged 10–19 and less than 1 in 10 girls of the same age made a visit to a local youth center over a period of 1 year. During the same period, just over 1 in 4 boys and less than 2 in 10 girls were contacted by a peer educator from projects operating in the area. For boys and girls in the 10–14 years age group, the visit and contact rates were substantially less.

Similar results were found in other countries and settings; without dedicated outreach for specific subgroups of vulnerable adolescents (such as very young adolescents or married adolescents), the more advantaged (e.g., older and unmarried adolescents and youth) are more likely to be reached by traditional youth programs.<sup>9</sup>

A recent evaluation of the TARUNYA Project, which supported the Government of Jharkhand State, India, to implement its ASRH Program, found that community-education sessions conducted by trained community volunteers over a period of 5 years reached around 1 in 4 girls aged 10–14, compared with 1 in 3 girls aged 15–19.<sup>10</sup> Among the 1,288 girls surveyed, the project was predominantly reaching older, unmarried and literate adolescent girls. Even in a part of the state where levels of community education were high, they reached only 1 in 5 boys aged 18–19, out of 210 boys surveyed.

### **Popular Interventions Shown to Be Ineffective for Adolescents Continue to Be Implemented**

Three widely implemented interventions—youth centers, peer education, and high-profile meetings on ASRH—have been shown to be ineffective in changing ASRH health knowledge, attitudes, beliefs, and behaviors, yet remain popular approaches among program implementers.

#### *Youth Centers to Increase Uptake of Contraception and Other Health Services*

Youth centers are usually conceptualized as meeting points and “one-stop shops,” which are intended to be a friendly, safe, and non-clinical environment where SRH information and services can be provided alongside other social services, such as recreational activities or Internet cafés. This has been and continues to be a very popular approach,

beginning in the 1980s in Latin America. Yet a number of evaluations have shown this approach is not effective as it does not result in increased use of SRH services or in any meaningful SRH behavior change. A review of evaluations of 18 youth center programs from around the world found<sup>11</sup>:

- The youth centers were mainly used by a relatively small proportion of young people who lived nearby, mostly male.
- These young men were attending school or college, and were much older than the intended target age.
- The youth centers were mainly frequented for recreation purposes.
- There were no or very limited/transient effects on the use of SRH services or contraceptive methods.
- The cost per beneficiary was very high.

Results definitively show that despite being a popular strategy for ASRH programming, youth centers are not cost-effective for increasing uptake of SRH services among adolescents. It should be noted that while youth centers have not been shown to be effective in changing adolescent SRH behaviors, youth centers may provide other social benefits through the provision of recreational and other youth development programs and may promote socially desirable outcomes such as reductions in gang activity or the development of employable skills.

#### *Peer Education to Encourage Safe Sexual Behavior*

Peer education is widely applied to capitalize on the perceived social networks of adolescents, as well as being seen as an inexpensive and easy-to-implement intervention. Peer education is also believed to provide opportunities for repeat contact and to be more effective than adult-led approaches in reaching marginalized or vulnerable young people.

Five meta-analyses of peer education programs implemented in widely different contexts over many years have concluded that while these programs result in information sharing, on their own, they have very limited effects in promoting healthy behaviors and improving health outcomes among target groups.<sup>12–16</sup> The meta-analyses also show that peer education programs mainly benefit peer educators (who are usually the recipients of training and supervision) rather than their intended beneficiaries.

Two recent studies reiterate the limited benefits of peer education. A study by Michielsen et al. in Rwanda reported that “time trends in sexual risk behavior ... were not significantly different in

students from intervention and control schools, nor was the peer education intervention associated with increased knowledge, perceived severity or perceived susceptibility.”<sup>17</sup> Sexual risk behaviors comprised being sexually active, having sex in the last 6 months, and not using condoms at last sex. The study did find significantly reduced reported stigma with the peer education intervention. Similarly, an evaluation in South Africa found that even with intensive support to strengthen peer education programs (e.g., “developing an adult infrastructure of training and support, alongside a cohort of trained and supported peer educators”), positive changes were limited and piecemeal.<sup>18</sup>

Given this evidence, and the fact that peer education programs have been shown to contribute to information sharing, the authors agree with the suggestion by Michielsen et al. that “peer education might be more effective if it is integrated in holistic interventions and if the role of peer educators is redefined in a way that makes them more of a source of sensitization and referral to experts and services.”<sup>17</sup>

#### *High-Profile Public Meetings to Inform Communities About Harmful SRH Practices and to Urge Them to Abandon These Practices*

Bringing community members together to inform them about the risks of early marriage and female genital mutilation and urging them to abandon these practices—often in well-publicized one-off public sessions—has been shown to have little effect in changing these practices. Yet such activities continue to be conducted because they are relatively easier to organize and are more visible compared with approaches that initiate and sustain longer-term community conversations. Such longer-term approaches would include ongoing dialogue with community leaders and members to encourage them to critically examine their traditions and help them identify and address the factors that contribute to poor outcomes.<sup>19–21</sup>

#### **Interventions Shown to Be Effective Are Delivered With Inadequate Fidelity**

For an intervention to have the desired effect on an adolescent’s knowledge, attitudes, practices, and behaviors (KAPB), it must be delivered effectively. Two interventions that have been shown to improve adolescents’ KAPB are providing them with comprehensive sexuality education and with appropriate SRH services. However, these interventions are often poorly implemented, lacking fidelity to the

**Peer education programs mainly benefit peer educators rather than their intended beneficiaries.**

**Comprehensive sexuality education and appropriate SRH services are proven practices but are often poorly implemented.**

elements of the interventions that make them effective in the first place, or picking and choosing among a few approaches rather than implementing them together as a whole.

*Providing Adolescents With Comprehensive Sexuality Education*

Comprehensive sexuality education (CSE) has been well-evaluated and has been shown to improve adolescent SRH knowledge, attitudes, and behaviors when implemented well. In 2009, the United Nations Educational, Scientific and Cultural Organization (UNESCO) with other UN partners developed technical guidance on the development and implementation of quality CSE.<sup>22</sup> Based on research by Kirby et al.,<sup>23</sup> the document identified 18 characteristics of quality sexuality education programs that effectively increased knowledge, clarified values and attitudes, improved skills, and positively affected behavior. Twelve of these characteristics are related to the development, content, and delivery of sexuality education. These characteristics emphasize the importance of providing factual information and specifically addressing risky behaviors and strengthening protective factors. Participatory teaching methodologies are also essential so as to ensure the development of skills and self-efficacy to act on information.

More recently, Haberland conducted an analysis of evaluated CSE programs and noted that programs that incorporate an empowerment approach emphasizing gender and rights were particularly effective in improving reproductive health outcomes.<sup>24</sup> Haberland's analysis suggests that young people who have egalitarian attitudes about gender roles in their intimate relationships are more likely to delay sexual debut, use condoms, and practice contraception.

Studies show, however, that many school-based CSE programs are not implemented with adequate attention to these characteristics, and the curriculum content tends to be weak. This is illustrated by 3 key findings of a review, carried out by UNESCO and the United Nations Population Fund (UNFPA), of the CSE curricula in 10 countries of East and Southern Africa, which a region-wide initiative aims to address<sup>25</sup>:

1. Most curricula did not contain enough basic information about male/female condoms and contraception (including emergency contraception).
2. Key aspects of sex and sexual health were lacking, including information about reproduction, sexually transmitted infections, abortion, and where to access condoms and sexual health services.

3. Most curricula did not pay enough attention to empowering young people, building agency, or teaching advocacy skills.

These findings are consistent with an earlier review by Galand and Maticka-Tyndale.<sup>26</sup>

Weak content is compounded by a second problem—weak delivery. The UNESCO/UNFPA review further notes: “Any curriculum rises or falls on the skill of teachers and the culture or environment of the classroom.”<sup>25</sup> Teachers are often extremely uncomfortable teaching about sexuality and are usually inadequately prepared, as illustrated by a 2006 study in Nepal.<sup>27</sup> The study reported that “...most of the teachers did not want to deal with sensitive topics and feared censure by their colleagues and society. Some lacked the skills to give such instruction.”<sup>27</sup> A similar study in 2013, also conducted in Nepal, reiterated that “...students’ needs and expectations regarding HIV and sexual health education are not being met through their schools.”<sup>28</sup>

*Providing Adolescents With Appropriate SRH Services*

A number of evaluations have shown that adolescent use of SRH services can be increased, especially when the following 4 complementary approaches are implemented together<sup>29–31</sup>:

- Providers are trained and supported to be nonjudgmental and friendly to adolescent clients.
- Health facilities are welcoming and appealing.
- Communication and outreach activities inform adolescents about services and encourage them to make use of services.
- Community members are supportive of the importance of providing health services to adolescents.

While many projects and programs around the world aim to provide “youth-friendly services,” careful examination suggests that most programs do not implement these 4 approaches together. This is illustrated by a study in Brazil, which reported<sup>32</sup>:

*The findings indicate that the Project [an integrated school- and health clinic-based adolescent reproductive health initiative] was successful in increasing the flow of sexual and reproductive health information to secondary-school students and that it had an impact on adolescents’ intentions to use public health clinics in the future. No effects on sexual or contraceptive-use behaviors or on use of public clinics were observed, however.*

The authors admit the project was not well designed<sup>32</sup>:

*...although the project trained clinic staff to provide reproductive health services appropriate to adolescents, few of the features of clinics believed to make health services adolescent friendly were incorporated into the project.*

Because of practical constraints, the weak design was further compromised by weak implementation, thus it is not surprising that the project did not succeed in increasing adolescent use of clinic services.<sup>32</sup>

An evaluation of the Government of Malawi's youth-friendly health services (YFHS) program was conducted in 2013.<sup>33</sup> The YFHS program was initiated in 2007 to make all health services more acceptable, accessible, and affordable to young people, and the evaluation aimed to measure progress since the program was launched. The evaluation found that despite the national attention paid to YFHS, awareness of YFHS was low, with less than one-third of youth surveyed having heard of YFHS and only 13% ever having made use of YFHS. Young people, parents, and community leaders lacked information on and showed only weak support for YFHS, with many adolescents expressing skepticism about the quality of services available. Around 60% of facilities reported having copies of government-issued YFHS standards, but less than one-third reported they were implementing key aspects of the standards including the availability of signage, trained providers, outreach to adolescents, and adolescent-specific educational materials. One of the constraints to providing YFHS, according to some supervisors, was weak supervision. On the plus side, the majority of young people who reported having visited a YFHS facility had done so in the 12 months prior to the assessment and expressed satisfaction with the care received.

### Interventions Are Delivered Piecemeal

Adolescents' SRH outcomes are determined by a complex web of interrelated factors that operate at different levels.<sup>34</sup> Individuals make choices to engage in specific behaviors based on what they know, believe, and are able to do. They make these choices within the context of their relationships, families, and communities, their economic circumstances, and the prevailing social norms and traditions. The laws, policies, and regulations may help or hinder their choices, and more often than not, it is the latter. (The reality is that many adolescents have limited

control on what they can do and on what happens to them. Especially for girls, their choices are constrained or made by others on their behalf.) In order to improve the health of adolescents, action is needed at each of these levels, often by different sectors other than health.<sup>35</sup>

Yet in many places, interventions are implemented in an uncoordinated and piecemeal fashion, and so—not surprisingly—they do not result in positive outcomes. Sometimes, the fragmented implementation of interventions can even have negative effects. A case in point is a sole focus on legal reform to end harmful traditional practices such as early marriage or female genital mutilation, which can actually drive the practice underground.

A number of advocacy efforts have addressed the need to repeal laws that permit early marriage or to pass new laws that raise the age of marriage and/or prohibit female genital mutilation. A review by Lee-Rife et al. concluded that there is little evidence that laws on their own make any substantial contribution to discouraging or eradicating child marriage.<sup>19</sup> In fact, among the 12 African countries where there has been a more than 10% decrease in early marriage, only 3 (Ethiopia, Liberia, and Sierra Leone) have a strong legal framework.<sup>36</sup> Berg et al. and Johansen et al. similarly conclude that laws alone do not prevent female genital mutilation.<sup>20,21</sup> More recently, Mackie argues that an exclusive focus on laws can even lead to greater harm by triggering active legal disobedience.<sup>37</sup> Efforts to address harmful practices may be more effective if they are linked to holistic interventions, such as keeping girls in schools or strengthening their employment options, and if they address sociocultural norms that support early marriage or female genital mutilation.<sup>38</sup>

Convincing evidence of the importance of implementing coordinated and complementary interventions comes from a 2014 review of England's multi-year effort to reduce teenage pregnancies. Beginning in 1999, the Government of the United Kingdom established a 10-year strategy to reduce teenage pregnancy rates. One of the 4 key themes of the strategy was to ensure coordinated action of better prevention activities for boys and girls, which included providing comprehensive sexuality and relationship education through a variety of channels, improving access to contraception through a variety of means, supporting a communication campaign to reach young people and their parents, and strengthening support for young parents.

A midcourse review in 2005 showed that while overall the under-18 conception rate had declined

**There is little evidence that laws on their own make any substantial contribution to ending child marriage or female genital mutilation.**

by 11%, there was wide variation in results across other areas. This prompted an in-depth review: 3 local government areas where under-18 conception rates declined since 1998 were compared with 3 areas with similar demographics but where conception rates were static or increasing. The review found that areas with better reduction rates were implementing all aspects of the strategy whereby all relevant agencies were involved to create a “whole systems” approach. Strong leadership was also an important factor. In areas with little progress, only some aspects of the strategy were being implemented, even though considerable effort was being made. As a result of the 2005 review, the Government identified and disseminated nationwide 10 “must-do” activities, and it established a system for self-assessment and external assessment. Teenage pregnancy rates began to decline in all 150 local government areas of the country, and the decline continues to this day.<sup>39</sup>

### Interventions Are Delivered in a Low “Dosage” and Are Not Sustained

Dosage refers to how intensively and/or how long an intervention or a package of interventions is delivered.<sup>40</sup> In practical terms this means a program that reaches young people with complementary messages using a variety of delivery mechanisms (e.g., teaching sessions in school, billboards, and radio or television chat shows), has a higher “dosage” than another program that uses fewer and less-intensive approaches. An outreach worker who conducts monthly discussion sessions with a youth group over a period of 12 months also delivers an intervention with “higher dosage” than another who only conducts a single session.

Dosage matters. A review of behavioral interventions to reduce HIV, sexually transmitted infections, and pregnancy in adolescents showed that programs delivered with greater intensity or for a longer duration were more effective than shorter programs,<sup>41</sup> perhaps because they allow for more in-depth discussion of and reflection on cultural and gender norms and other social structures that have a powerful effect on individual behaviors and capacity to change.

For programs to improve and change knowledge, understanding, attitudes, beliefs, and behaviors over the long term and at the community level, programs must be delivered regularly, consistently, and with intensity over a sustained period of time. We do not yet know what level of intensity and/or duration is optimal. What we do know is

that interventions (or dosages) that are not sustained do not bring about long-term change at the community level. A striking example of this comes from a 20-month comprehensive community-based sex education and reproductive health service project in Shanghai, China. At the end of the project, the endline survey indicated the project had had a positive effect on contraceptive use among unmarried youth who had been exposed to the intervention.<sup>42</sup> A little over 2 years (28 months) after the end of the project, a follow-up survey found that without the consistent and sustained dosage from the intervention, young people appeared to revert to behaviors seen at baseline.<sup>43</sup>

## NEW FRONTIERS

There is a strong need for coordinated and complementary approaches that improve the health of adolescents as well as a need to abandon those approaches that are wasteful and ineffective. Furthermore, we need to explore new approaches that show promise, such as strengthening private-sector engagement to reach adolescents and improving adolescent access to long-acting reversible contraceptives (LARCs).

According to Catalano et al.,<sup>44</sup> the standard approaches to improving adolescent health have focused on health promotion, prevention, and treatment of “problem behaviors” often with a focus on a single behavior, such as abstinence, delay of sexual initiation, or contraceptive/condom use. These single-focus prevention interventions have been criticized, and greater consideration of the co-occurrence of problem behaviors and improved understanding of the overlap in predictors across many behaviors is needed.<sup>44</sup>

In a growing number of high-income countries, the adolescent health field is embracing the concept of prevention science. The Society for Prevention Research indicates the primary goal of prevention science is “to improve public health by identifying malleable risk and protective factors, assessing the efficacy and effectiveness of preventive interventions and identifying optimal means for dissemination and diffusion.”<sup>45</sup> Catalano et al. note that behavioral factors are the major cause of adolescent morbidity and mortality.<sup>44</sup> Based on a number of controlled trials, they advocate for the implementation of interventions that simultaneously address risk factors and also increase those protective factors that mitigate against risky behaviors. The research base that has been developed in high-income countries has recently begun to be applied to low- and

**Behavioral interventions delivered with greater intensity or for longer duration are more effective than shorter programs.**

middle-income countries by translating existing approaches and developing and testing new preventive interventions in lower-income contexts.<sup>44</sup>

## CONCLUSION

Research studies and programmatic experiences over the last 20 years have without a doubt improved our knowledge and understanding of adolescent programs and interventions. We have a clearer understanding of the effective components of sexual and reproductive health education and health services. We are also better at delivering programs to adolescents, with greater consideration of the antecedents that influence the sexual and reproductive health of adolescents.

Nevertheless, there are still glaring gaps in our knowledge and understanding of effective adolescent health programming, especially at scale. With a sizeable and growing youth population, it is urgent that we accelerate the expansion of proven approaches while safeguarding fidelity to those factors that ensure quality and success. In any event, we must stop the implementation of ineffective interventions that waste human and financial resources and raise questions about the value of policies and programs that do not demonstrate results. Further, we recommend greater attention to the adaptation of evidence-based prevention science approaches that simultaneously address risk and protective factors for adolescents in lower- and middle-income countries. This should include the creation of a database that documents best and promising practices in prevention science and adolescent health.

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## COMMENTARY

# The Demographic Stretch of the Arc of Life: Social and Cultural Changes That Follow the Demographic Transition

Ariel Pablos-Mendez,<sup>a</sup> Scott R Radloff,<sup>b</sup> Kamiar Khajavi,<sup>a</sup> Sally Ann Dunst<sup>b</sup>

**The demographic transition from high to low levels of mortality and fertility brings about changes that stretch the “arc of life,” making each stage of life longer and creating new ones—a phenomenon we call “the demographic stretch.” This stretch can transform societal structure, for example, by extending childhood, shifting working ages up, delaying marriage and childbearing, improving women’s status and equity, and pushing the burden of chronic disease and disability to older ages. Global health efforts must address the resultant economic and social changes.**

The demographic transition, when countries shift from high to low levels of mortality and fertility, has been underway for 2 centuries, with differences in onset and pace across countries and regions of the world.<sup>1-3</sup> Over the course of the transition, average life expectancy more than doubles, from about 40 years to 80 years, while the average fertility rate declines from about 7 children per woman to 2.5 children per woman—nearing replacement levels.

Living longer does not mean simply adding more years of decrepitude to the end of life. We posit that unprecedented increases in life expectancy stretch the “arc of life,” making each stage of life longer and creating new ones—a phenomenon we call “the demographic stretch.”

The clearest example of the demographic stretch is the transition from child to adult: the concept of “adolescence” was popularized only in the 20th century, and the term “teenager” was unknown before World War II. (G. Stanley Hall coined the term “teenager” in 1904 to describe the stage of life made possible by child labor laws and universal education, before youth faced the responsibilities of adulthood.<sup>4</sup>) Rather than work and marry, young people are more likely to go to college and postpone marriage, and sexual and reproductive activity may be likewise postponed or take on different guises—a phenomenon not yet fully captured by rigorous scientific studies.<sup>5</sup> The total fertility rate (TFR) declines despite an increase in fecundity (due to earlier menarche and older age at menopause).<sup>6</sup> Social and

cultural changes tend to follow the demographic changes and need to be consciously articulated.

In this paper, we explore the social and cultural implications of this “demographic stretch” and the impact of different timing across generations and geographical regions using publicly available country data from United Nations agencies and other sources. We conclude the paper with recommendations for a research agenda to better understand the demographic stretch and its drivers and implications.

## THE DEMOGRAPHIC TRANSITION

For centuries, the world was relatively poor, with low life expectancy and high fertility rates. This changed with the demographic transition, which first began in France and then in the United States around the turn of the 19th century.<sup>2,7</sup> In France, between 1750 and 2000 life expectancy more than tripled, from 25 years to 80 years.<sup>8</sup> Similarly in the United States, life expectancy for whites nearly doubled over 150 years, increasing from 40 years in 1850 to 77 years in 2000.<sup>7</sup> (Prior to the 20th century, data on life expectancy of blacks in the United States, which differed significantly from that of whites due to slavery, were scarce.) Declines in fertility accompanied increases in life expectancy. In France, the fertility decline began around the 1820s, with the TFR falling from about 4 children per woman in 1800 to 2.2 children per woman in 1930.<sup>9</sup> The TFR in the United States fell from 7.0 in 1800 to 2.3 in 1940.<sup>7</sup>

The demographic transition occurred next in other parts of Europe, with dates of the initiation of fertility

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**The demographic transition in Africa, Asia, and Latin America is fast approaching that of richer nations.**

decline varying among countries. Fertility rates in Belgium, Germany, and Switzerland began to fall in the 1880s, while in Ireland and Spain fertility levels started to decline only around the 1920s.<sup>9</sup> Life expectancy also increased. Today, more than half of babies born in rich nations will live to 100 years.<sup>10</sup>

Since 1950, regions at earlier stages in their demographic transitions have accelerated their progress with many approaching a “grand convergence”<sup>11</sup> with richer nations: Africa, Latin America, and Asia have added 21, 24, and 29 years, respectively, to the life expectancy (Figure 1). Whereas in 1950 less than 1% of the world’s population lived in countries with life expectancy of 70 years or older, now over half do.<sup>12</sup> There has also been a dramatic convergence in TFRs. The TFRs in Latin America and Asia have reached near replacement (2.2 children per woman). Africa’s TFR has declined since 1950, but it is still 4.7 today.<sup>13</sup>

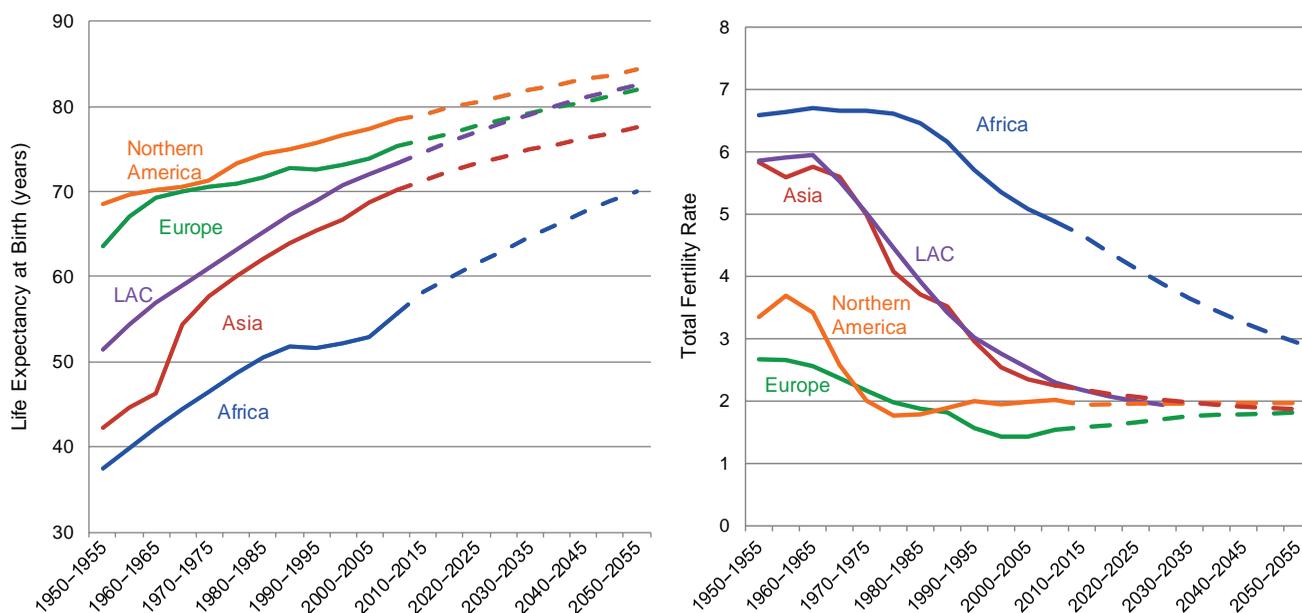
However, life expectancy has not increased linearly and consistently in all parts of the world,

and regional averages conceal a range of country differences. In the 1990s, life expectancy stagnated in Africa and actually decreased dramatically in some countries, mainly due to the HIV/AIDS epidemic. Eastern Europe also saw a stagnation or decrease in life expectancy in the 1990s.<sup>12</sup> Likewise, there is significant variation in the TFR within regions and within countries. Despite this variation, people generally live longer and have fewer children, decoupling sexual activity from its reproductive function.

**STRETCHING THE ARC OF LIFE: SOCIAL AND CULTURAL IMPLICATIONS**

Reductions in mortality across the span of life and changes in fertility patterns transform the population age structure, resulting in a net increase in median age.<sup>12</sup> Early in the transition, progress is typically greatest in reducing under-5 mortality; reductions in older-age mortality follow.<sup>12</sup> From

**FIGURE 1.** Life Expectancy at Birth and Total Fertility Rate, by World Region, 1950–2055



Abbreviation: LAC, Latin America and Caribbean.

Dotted lines indicate projected data.

Data Source: United Nations, 2012 (medium-variant fertility).<sup>13</sup>

1950 to 2010, the median age increased from 30 years to 40 years in Northern America and Europe and from 20 years to 30 years in Latin America and Asia.<sup>13</sup> Africa's median age has stayed at about 18 or 19 years since 1950.<sup>13</sup> By 2050, however, Africa is expected to reach a median population age of 25 years, and Asia and Latin America will converge with Northern America and Europe at about 40 years.<sup>13</sup>

As the median age rises and fertility declines, there are initially fewer dependent children relative to those in working productive ages. This creates an opportunity for increased economic growth known as the demographic dividend.<sup>14</sup> This demographic dividend has been well documented in countries in East Asia, such as South Korea and Thailand,<sup>15</sup> and it is now seen as playing a significant role in the ongoing economic success in developing regions of the world.<sup>16</sup> This opportunity may diminish as median ages advance to 50 years or beyond unless workers increase their productivity or postpone retirement.<sup>17</sup> The epidemiologic and economic implications of longevity are well studied.

Social and cultural structures also evolve in response to the demographic stretch and the disjunction and upheaval that might accompany it. We explore such social and cultural transformations through cross-sectional, ecological associations between longevity and various dependent variables, modeled using linear and logistic regressions while adjusting for gross domestic product (GDP) per capita.

### Childhood Is Lengthened

A clear, quick transition from childhood to adulthood is replaced with a more drawn-out progression through a series of sub-stages categorized by schooling (e.g., pre-Kindergarten through college) or by ages (e.g., preteen, teenager).<sup>18</sup> In the stage of "emerging adulthood," individuals have not yet achieved independence from parents due to increases in the number of years of schooling and delays in reaching other "adult" milestones such as marriage and entry into the formal workforce.<sup>19</sup> Young adults' continued dependence on their parents increases the cost of raising children.<sup>20</sup> Recognizing these trends in the United States, the Affordable Care Act increased the age of health insurance eligibility in the family from 21 years to 26 years.<sup>21</sup>

### Education Is Prized More

Primary school becomes compulsory, more children complete high school, and more go on to

college. In the United States, the percentage of the population completing college has grown from 5% in 1940 to 30% in 2009.<sup>22</sup> An increase in a country's median age by 1 year is associated with an average increase of 0.24 years of schooling ( $P < .001$ ) (Figure 2). Even after controlling for log GDP per capita, an increase in a country's median age by 1 year is associated with an average increase of 0.14 years of schooling ( $P < .001$ ). Societies confront issues of equity in access to education, and public subsidies of education expand into later years of schooling. In more economically advanced countries, post-graduate education becomes more common and a prerequisite for a professional career.

### Working Ages Are Shifted Upward

Entry into the formal workforce and the start of a career are pushed back to older ages. This delay impacts family formation, which is often postponed to later ages as well. Increasingly, people form families and launch careers in their late 20s rather than their late teens, which was common at the start of the demographic stretch. With this transition, societies progressively protect childhood by establishing child labor laws and minimum working ages for full-time labor. These transformations occurred in North America and Europe in the late 1800s and early 1900s while efforts to end exploitative child labor practices continue in the developing world today.<sup>23</sup>

At the same time, as societies restrict child labor, the average age of retirement recedes to older ages. This can create disjunctions if retirement systems and health insurance benefits do not keep pace with longer life expectancies. For example, violent protests in Greece and elsewhere have broken out in recent years in response to proposals to increase the retirement age and cut pensions.<sup>24</sup> In the United States, debate is ongoing regarding changing the national social security system that provides benefits to retired workers. Because of the increase in life expectancy, the system may need to raise the onset of retirement payments to later years in order to ensure its solvency.<sup>25</sup>

The upward shift in the working age calls for a redefinition of how we view "dependency." Demographers classify children under age 15 as dependent, with the implication that once reaching age 15, children become independent. While this may have typified agrarian societies, it does not reflect the realities of today. Research using national transfer accounts data shows that for

**The demographic transition results in a net increase in median age of populations.**

**Entry into the workforce, along with family formation, is pushed back to later ages as a result of the demographic transition.**

most all countries, individual levels of consumption outweigh production at ages well into the 20s, and in some cases into the early 30s.<sup>17</sup> The threshold for old-age dependency, at times 60 years or 65 years, likewise, needs to be rethought as retirement is pushed to higher ages and as older people remain active and independent.

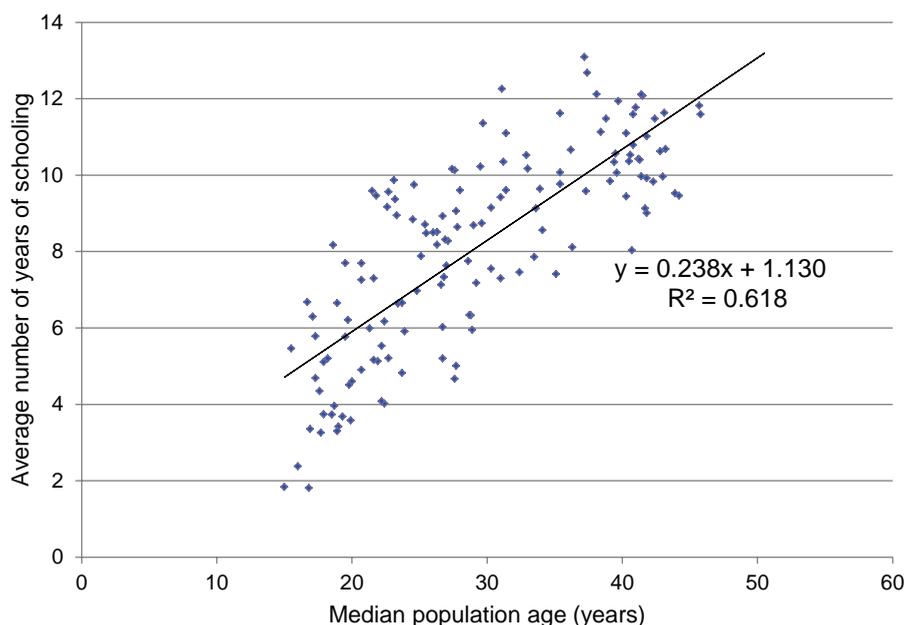
### Marriage Is Delayed While Non-Marital Childbearing and Cohabitation Increase

Longer childhood, more schooling, decreased fertility expectations, and later entry into the workforce delay marriage for both men and women. In 1880s Russia, an unmarried woman of 24 years was considered a “spinster.”<sup>26</sup> Today, a woman unmarried in her 20s would be commonplace in many parts of the world. In the United States, between 1950 and 2009, the median age at first marriage increased from 23 years to 28 years for men and from 20 years to 26 years for women.<sup>27</sup> A similar trend has already been noted in many

developing countries such as India,<sup>28</sup> Côte d’Ivoire,<sup>29</sup> and Senegal.<sup>29</sup> As shown in Figure 3, there is a significant association between median population age and age at first marriage, which is deferred, on average, by 0.35 years for females ( $P < .001$ ) and by 0.26 years for males ( $P < .001$ ) as median population age rises by 1 year. When controlling for log GDP per capita, median age at first marriage is delayed by 0.16 years for females ( $P < .001$ ) and 0.14 years for males ( $P < .001$ ), on average, with each year increase in a country’s median age.

Cohabitation shifts from a taboo to a commonplace precursor or alternative to marriage. In the United States, the rate of cohabitation has increased from near zero 100 years ago to 33% in 1987 and to 50% in 2002.<sup>30</sup> Global comparisons show that non-marital cohabitation is common in more developed regions, including the Americas, Europe, and Oceania, while it is still rare in other regions.<sup>30</sup> With delays in marriage sometimes come increases in out-of-wedlock births. In Iceland, 66% of births are to unmarried women,

**FIGURE 2.** Relationship Between Average Years of Schooling and Median Population Age (138 Countries)



Data Sources: Median population age in 2013 from The Kaiser Family Foundation Global Health Facts,<sup>52</sup> and average years of total schooling (age 15+ in 2005–2011) are from the World Bank Open Data.<sup>53</sup>

and in Sweden this proportion is 55%.<sup>31</sup> In the United States, about 40% of children are born to unmarried mothers; this proportion was just 5% in 1960.<sup>31,32</sup> Having children within a cohabiting union becomes more common as cohabiting couples who become pregnant feel less pressure to wed. About 60% of out-of-wedlock births in the United States are to cohabiting couples.<sup>32</sup>

### Childbearing Is Delayed and Teenage Pregnancy Declines

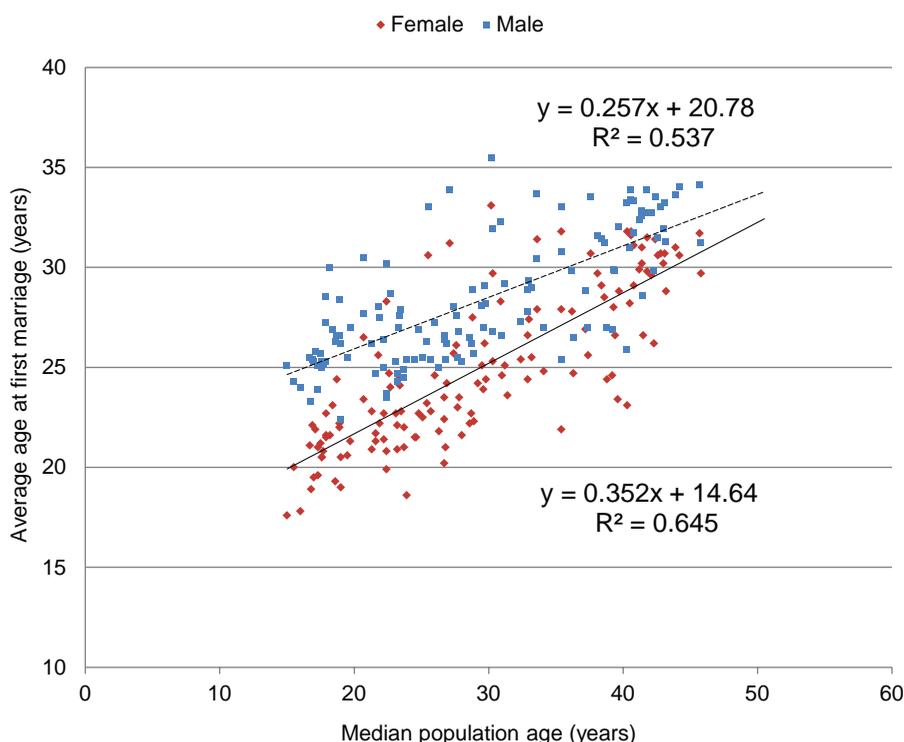
The average age of a US mother at first birth increased from 21.4 years in 1970 to 25.0 years in 2006.<sup>33</sup> Similar trends have occurred in other countries of the Organisation for Economic Cooperation and Development (OECD), where there has been a near-universal shift in age at first birth from the late teens to the late twenties.<sup>33</sup> With

greater access to contraceptives for youth, the rate of teen childbearing has declined significantly in Europe and North America (including among black and Hispanic teenagers); all the while, the proportion of teen births to unmarried youth has increased significantly—from less than 15% to 80% in the United States over the last 50 years (Figure 4).<sup>34</sup> Sexual education and family planning have been critical to the decline in overall teenage pregnancy in the context of delayed marriage.

In the United States in 1970, only 1 of 100 first births were to women 35 years and older; in 2006 this proportion was 1 of 12.<sup>33</sup> Postponement of childbearing increases the mean length between generations and results in a changing “tempo” of childbearing.<sup>35</sup> As postponements push childbearing into ages with lower fecundity, interest increases in induced ovulation methods, which produce greater chances for twins/multiple births. Rates of multiple

**Age at first birth in the United States and other developed countries has increased to the late 20s.**

**FIGURE 3.** Relationship Between Median Age of the Population and Average Age at First Marriage (120 Countries)



Data Sources: Median population age in 2013 from The Kaiser Family Foundation Global Health Facts,<sup>52</sup> and average age at first marriage (in 2005–2011) are from the World Bank Open Data.<sup>53</sup>

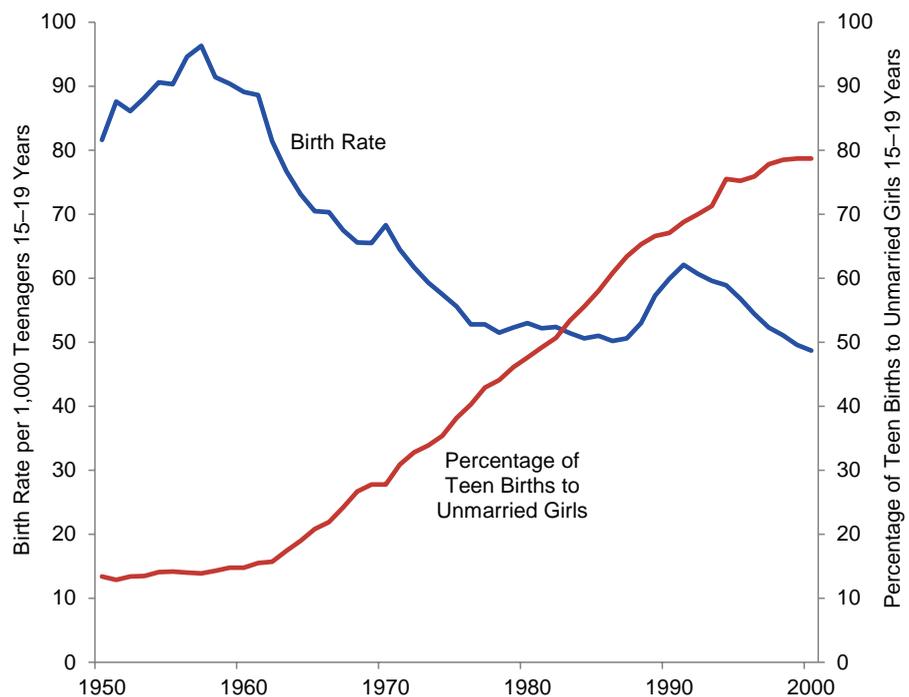
births have increased substantially in many developed countries, including Canada, England and Wales, France, and the United States, over the past few decades in part because of increased maternal age and fertility treatment.<sup>36</sup> These multiple births are associated with increased risk factors for infant mortality and long-term morbidity such as preterm birth and low birth weight. Increased maternal age is also associated with increased risk of congenital defects and gestational diabetes.<sup>37</sup> However, the decrease in the number of children in families leads to higher investments in children. Parents with fewer children are able to spend more time with children and provide them with more resources and support.<sup>38</sup>

### Women’s Status and Equity Evolves

A central feature of these transitions is the changing role of women in society. With reductions in fertility, women experience greater

opportunity for social participation. Gender gaps in education, work opportunities, income levels, and legal rights generally narrow. Control of fertility allows women to engage in educational, economic, and political activities and leads to changes in traditional gender roles.<sup>16,38,39</sup> In the United States, women have outnumbered men in higher education since the late 1970s.<sup>40</sup> Even Muslim-majority countries, which are often criticized for constraining women’s rights, have experienced concomitant increases in contraceptive use and equitable access to education over the past few decades.<sup>41</sup> In Iran, where about 60% of women use a modern method of family planning and the TFR is 1.9, nearly equal proportions of males and females are enrolled in primary, secondary, and tertiary levels of school.<sup>42,43</sup> In Egypt and Indonesia, the contraceptive prevalence rate and the male-to-female school enrollment ratio are about the same as in Iran, although fertility rates are slightly higher.<sup>42,43</sup> Despite

**FIGURE 4.** Births to Teenagers in the United States, 1950–2000



Source: Reproduced from the National Center for Health Statistics, 2001.<sup>54</sup>

progress in gender equality in educational attainment, women in these countries lag behind men in workforce and political participation, highlighting that progress in all aspects of women’s empowerment is not automatic and immediate. In fact, we did not find a simple correlation between nations’ life expectancy (or their GDP) and the proportion of women working.

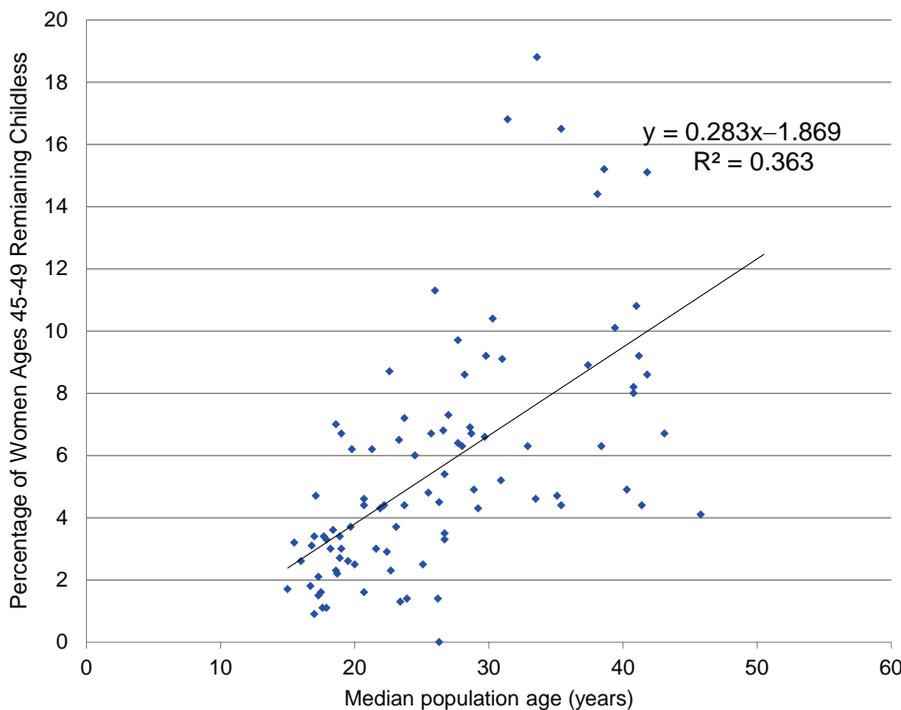
### Non-Traditional Lifestyles Are Increasingly Accepted

Not only are there overall delays in the initiation of life stages with the demographic stretch, there is also increasing freedom to deviate altogether from the traditional sequence of marriage followed by childbearing. Individuals and couples have increasingly chosen to remain childless. In some developed countries such as Australia,

Germany, Italy, and the United States, the proportion of women in their late 40s who have no children has doubled over the past 30 years.<sup>44</sup> As shown in Figure 5, countries with higher median population ages have higher rates of women ages 45–49 with no children ( $P < .001$ ), although this relationship is not statistically significant after adjusting for log GDP per capita.

As sexual activity is decoupled from reproduction, people are more able to explore, discover, or assert different sexual orientations. Societies increasingly accept homosexuality and, more recently, have come to accept same-sex unions. Based on recent reports, 76 (41%) of 184 countries criminalize homosexuality.<sup>45</sup> Figure 6 demonstrates that countries with the lowest life expectancies are least tolerant of homosexuality (72% of such countries criminalize homosexuality), and those with the highest life expectancies criminalize it the

**FIGURE 5.** Relationship Between Median Age of the Population and the Percentage of Women Ages 45–49 Remaining Childless (92 Countries)



Data Sources: Median population age in 2013 from The Kaiser Family Foundation Global Health Facts,<sup>52</sup> and the percentage of childless women (in the most recent year available between 2000 and 2008) are from the United Nations, 2009.<sup>55</sup>

**The burden of chronic disease and disability is pushed to older ages with the demographic transition.**

least (12% of such countries). In a logistic regression model, controlling for log GDP per capita, each 1-year increase in life expectancy is associated with a 12% decrease, on average, in the odds that a country criminalizes homosexuality ( $P=.006$ ). The causal relationship here needs further exploration (e.g., what role do education, increasing secularization, or the decoupling of sexuality and reproduction have?). Clearly, tradition and political will can still strongly affect policy: 3 of the 4 high life expectancy countries that criminalize homosexuality have majority Muslim populations (Brunei, Lebanon, and Qatar). On the other hand, South Africa with a relatively low life expectancy has laws protective of sexual choice.

**Good Health Continues Through Middle Age and Often Beyond**

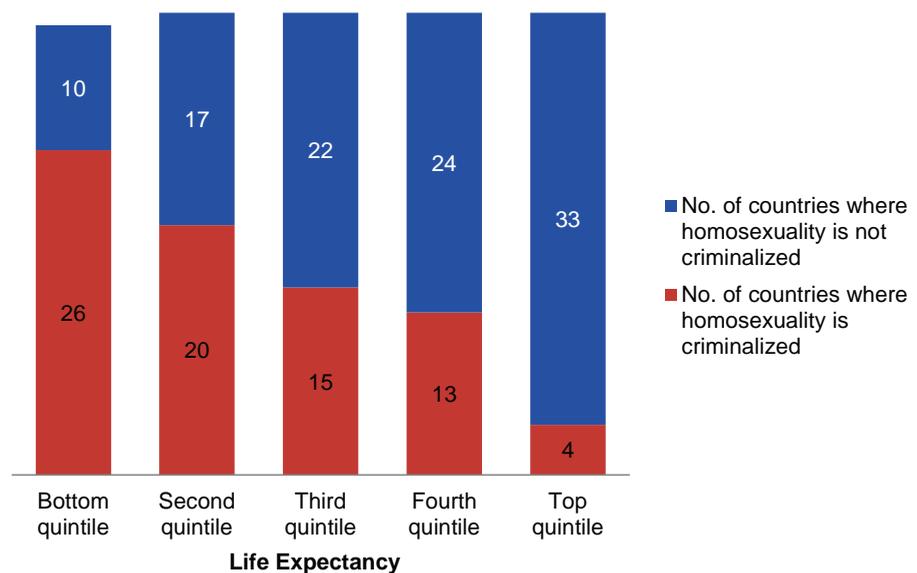
The epidemiologic transition that follows the demographic one brings chronic diseases to the fore.<sup>46</sup> The burden of chronic disease and

disability increases<sup>47</sup> but is pushed to older ages,<sup>48</sup> and the functional status of individual octogenarians improves over previous generations. As new cohorts imprinted by the demographic stretch reach old age, sexual behaviors evolve since attitudes are more significant influences on sexual desire than biomedical factors.<sup>49</sup> Many people remain sexually active after retirement: in the United States, 67% of 65- to 74-year-old men and 40% of women are sexually active.<sup>50</sup> For 75- to 85-year-olds, 39% of men and 17% of women are sexually active.<sup>50</sup>

**DISCUSSION**

The world has undergone an unprecedented transition from high levels of fertility and mortality to much lower levels. The transition has not been uniform in onset or pace across countries, but it is nearly universal and progressing. It began 2 centuries ago in the countries of Europe and North America that are now considered “more

**FIGURE 6.** Relationship Between Life Expectancy and Criminalization of Homosexuality (182 Countries)



Data Sources: Data on criminalization of homosexuality are from Clark, 2014,<sup>45</sup> and data on life expectancy are from the United Nations, 2012.<sup>13</sup>

developed” and has been followed in the past 50 years in many countries in Asia, Africa, and Latin America—and often at a much faster pace than in the more developed world. The transition continues today as child survival and fertility rates in poor countries converge with those of upper middle-income countries. This paper posits that these demographic shifts lead to a demographic stretch of the arc of life. Added years of life do not simply translate to added years of decrepitude. Rather, each stage of life is extended: we spend more years in childhood, more years as healthy adults, and more years in retirement. New sub-stages of life are added (e.g., “teenage”), and complex social changes emerge with some degree of predictability based on demographic transitions.

These shifts in the arc of life are not smooth or without economic and social upheavals: the staggered transition across generations, socioeconomic groups, and whole nations may create tensions due to the asynchronous evolution of norms in different groups or populations. At the macroeconomic level, they can require changes in the social contract, for example, in the need to raise the age at which retirement and health benefits become available. At the social level and in private life, we see impacts of the demographic stretch on child transitions to adulthood, transitions in family formation, and the role of women in society. The age of marriage moves from the teens to the late twenties, and sexual activity is decoupled from biological reproduction. The asynchronous nature of change means that moral and legal norms and the power relationships and attitudes they reflect may collide with the rapid demographic changes visiting the modern world, for example, in the recognition of gender equality or the acceptance of same-sex relationships.

The preliminary associations presented here are just that: simple, descriptive, ecological observations that suggest the need for a research agenda to better understand the drivers of the demographic stretch of the arc of life changes, and of their implications. No single variable can explain complex sociocultural phenomena. The demographic stretch is the result of a complex interplay of increasing life expectancy, greater economic wealth, lower fertility rates, and the empowerment of women; changes in life expectancy and fertility correlate with such important variables as income and education, and sexuality measurement is far from perfect in much of the world. Rapid changes in information and

communication technology and continued globalization will no doubt accelerate the changes. Panel data and time series analyses are needed to better understand the complex causal paths and interactions suggested by our hypothesis of a demographic stretch—in the context of a rich literature from psychology and anthropology. This growing understanding will help us develop a useful framework that will help policy makers and opinion leaders anticipate change and prepare for it.

The evidence presented here suggests the demographic stretch is a natural phenomenon followed rather predictably by changes in behaviors and social norms. It cannot by itself explain changing gender roles, sexual orientation, or the social acceptance of either phenomenon, but it does provide insight into the direction and drivers of change and is therefore a useful indicator of change. Countries that have undergone the demographic stretch cannot ignore their own historical evolution nor expect others to simply skip it as we do in more technical areas such as decreasing child mortality. In responding to countries where human rights appear to have been limited by local law or customs, being aware of the demographic stretch might help fast-track reform through more creative and effective approaches.

The demographic transition is well underway through much of the world. What might we expect to see as the arc of life continues to stretch? In countries where the transition is more advanced, we would expect to see more intergenerational conflict over, and changes in laws relating to, social welfare programs that benefit the elderly as declining numbers of younger people support increasing numbers of older people. We might see more countries entering a “birth dearth,” i.e., birth rates falling significantly below replacement levels, which Japan and other places are experiencing. While there will be economic consequences, these countries will still continue to see an increase in life expectancies and the demographic stretch. We look for further shifts toward later working ages as demand for labor increases relative to supply (and as life expectancies continue to increase), and possibly for the relaxing of and/or adjustments to immigration policies to address labor shortages.

At the other end of the wealth spectrum, low-income countries are witnessing the start of the transition. As their economies begin to expand,

**Added years of life do not simply translate to added years of decrepitude.**

**The shifts in the arc of life may pose economic and social challenges that countries must address.**

**In countries where the demographic transition is advanced, more intergenerational conflict may be expected.**

**With faster spread of ideas through technology, accelerated transitions might be expected in low-income countries at the start of the demographic transition.**

and with the faster spread of ideas through technology, we anticipate accelerated transitions over the next few decades—perhaps in a more compressed time period than observed elsewhere. Total fertility rates in the 48 least developed countries have been historically high but are beginning to fall, today at 4.3 compared with 5.7 children per woman just 40 years ago.<sup>51</sup> Life expectancies have been historically low but are now rapidly increasing, today at 61 years compared with 44 years just 40 years ago.<sup>51</sup> These countries have an aggregate population of 916 million, 40% of whom are less than 15 years old.<sup>51</sup> For these countries, the social and economic changes that we have witnessed elsewhere and described in this paper could be amplified. We look for these countries to move at an accelerated pace toward social and political liberalization although with potential for a conservative backlash as social institutions and more traditional segments of a population resist these rapid changes.

**Competing Interests:** None declared.

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# WHO Tiered-Effectiveness Counseling Is Rights-Based Family Planning

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**Contraceptive effectiveness is the leading characteristic for most women when choosing a method, but they often are not well informed about effectiveness of methods. Because of the serious consequences of “misinformed choice,” counseling should proactively discuss the most effective methods—long-acting reversible contraceptives and permanent methods—using the WHO tiered-effectiveness model.**

Improving access to long-acting, reversible methods of contraception (LARCs)—which provide highly effective, long-term, and easy-to-use protection against unintended pregnancy—is of crucial importance to the lives of countless individual women. Yet, among family planning experts, consensus remains elusive on the important issue of whether and how client counseling should emphasize this top tier of highly effective contraceptive methods. Research consistently shows women believe effectiveness is one of the most important factors—usually *the* most important factor—when choosing a contraceptive method,<sup>1</sup> but accurate knowledge of contraceptive effectiveness remains poor.<sup>2</sup>

In this paper, we argue for proactive counseling based on the World Health Organization (WHO) tiered-effectiveness chart that begins with the relative effectiveness of various methods as a way to provide truly informed choice. All contraceptives are not created equal. Counseling that does not focus on effectiveness can lead to “misinformed choice,” which may undermine rights-based approaches.

## RIGHTS-BASED FAMILY PLANNING

Recent WHO guidance, summarizing findings of a technical consensus meeting on contraceptive choice and human rights, advises programs on how to ensure human rights are respected and protected when services are scaled-up to reduce unmet need for family planning.<sup>3</sup> This seminal document was reinforced and extended through a new conceptual framework for human rights-based family planning.<sup>4,5</sup>

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The guidance was in part a reaction to civil society concerns about the ambitious, numerical goals of the Family Planning 2020 (FP2020) initiative, launched in London in 2012, which aims to extend modern contraceptive access to 120 million additional clients by 2020.<sup>6</sup> In addition, this new series of publications also builds upon the international family planning community’s nearly 50-year history of commitment to voluntarism and promoting clients’ right to free choice in family planning.<sup>3</sup> This rights-based message was affirmed at international population conferences such as the landmark International Conference on Population and Development in Cairo in 1994 and in a variety of reproductive health and rights frameworks adopted by normative bodies before and since.

Taken together, the new documents about rights-based family planning are an important reminder of the need for voluntary, coercion-free contraceptive services. Those committed to the sexual and reproductive health field should have these values at their core.

## IMPACT OF LARCS

The renewed focus on rights-based family planning coincides with emerging findings from a variety of recent programs in both developed<sup>7,8</sup> and developing<sup>9-13</sup> countries to increase access to LARCs. In the most well known of these, the St. Louis CHOICE study, thousands of women were offered free, same-day contraceptive services and followed for up to 3 years to document reproductive health and other outcomes.<sup>7</sup> Given availability of free contraception, 70% to 75% of women (including teens) chose LARCs,<sup>14,15</sup> and both continuation and satisfaction were significantly higher among LARC users than

non-LARC users.<sup>16</sup> Non-LARC users in St. Louis were 20 times more likely to become pregnant in the next 3 years than LARC users.<sup>14</sup> The powerful results from CHOICE have been a clarion call for the importance of making LARCs widely available in family planning programs.

The CHOICE program offered a wide variety of methods and actively counseled clients about methods using the gradient of WHO's "tiered" contraceptive effectiveness chart (Figure 1). Trained counselors described the full range of contraceptive methods and used internationally accepted counseling methods and tools, such as GATHER,<sup>20</sup> to provide personalized counseling based on clients' reproductive health needs.<sup>21</sup> Within this framework of client-centered counseling, providers proactively spoke first about and emphasized the LARC methods of intrauterine devices (IUDs) and implants in the highest tier of contraceptive effectiveness. This counseling approach was dubbed "LARC-first."<sup>22</sup>

## BALANCING REPRODUCTIVE JUSTICE AND TIERED COUNSELING

While the response to these programs has been overwhelmingly positive, some observers have begun a constructive dialogue about the potential pitfalls of embracing "LARC-first" without also emphasizing the necessary rights-based framework.<sup>23-25</sup> They rightfully caution that in some situations tiered counseling could become too directive, or perhaps even coercive. This is especially worrisome in dealing with more vulnerable populations. We agree with these authors that the answer lies in striking a "delicate balance."<sup>25</sup> In particular, we support the position that "reproductive justice would enable women to access and use LARC if they wish to, but also to dispense with LARC and/or have LARC methods removed if they wish to."<sup>24</sup>

Clinicians should not and, indeed, have no need to "push" LARCs. Evidence shows that when LARCs are available and affordable, most clients, if fully informed about effectiveness and relevant method characteristics, will choose them of their own accord.<sup>7-11</sup> On the other hand, we disagree with the notion that other method characteristics should *a priori* be on par with that of effectiveness. In our view, the effectiveness of any contraceptive method is its paramount characteristic, and counseling that does *not* use

WHO tiers (with the most effective methods discussed proactively) fails to meet the true needs and desires of the majority of women.

## OUR PREMISES: CLIENT AUTONOMY, SAFETY, AND ACCURATE INFORMATION

We take as given the new WHO guidance (excerpted below), highlighting the paramount importance of client autonomy in decision making<sup>3(p.19)</sup>:

*Respecting autonomy in decision-making requires that any counselling, advice or information that is provided by health workers or other support staff should be non-directive, enabling individuals to make decisions that are best for themselves. People should be able to choose their preferred method of contraception, taking into consideration their own health and social needs.*

We also take safety as a given, assuming that the global regulatory framework properly ensures the safety of modern contraceptives and, for the purpose of this paper, that the appropriate methods are safely provided to, and safely used by, clients.

Finally, we assume a right to non-directive counseling that conveys accurate information, including information about effectiveness and likelihood of pregnancy. This right is also emphasized in the new WHO guidance (excerpted below),<sup>3(p.19)</sup> as well as in earlier international conventions and covenants<sup>26,27</sup>:

*Individuals have the right to be fully informed by appropriately trained personnel. Health-care providers have the responsibility to convey accurate, clear information, using language and methods that can be readily understood by the client, together with proper, non-coercive counselling, in order to facilitate full, free and informed decision-making. ... The information provided to people so that they can make an informed choice about contraception should emphasize the advantages and disadvantages, the health benefits, risks and side-effects, and should enable comparison of various contraceptive methods. Censoring, withholding or intentionally misrepresenting information about contraception can put health and basic human rights in jeopardy.*

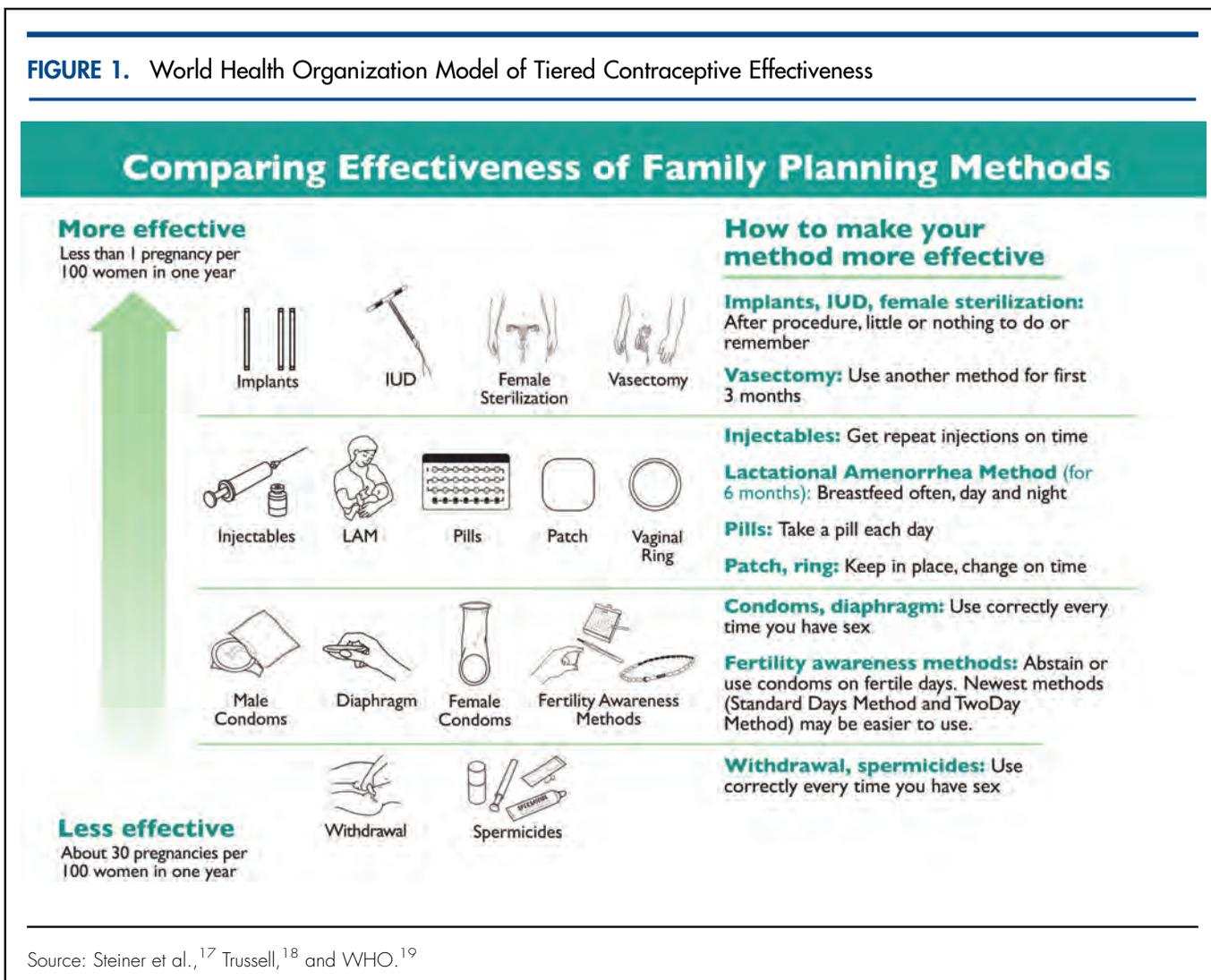
## EFFECTIVENESS AND OTHER METHOD CHARACTERISTICS

Research consistently shows women believe effectiveness is one of the most important factors when choosing a contraceptive method<sup>28-30</sup>;

**In the large CHOICE study, in which 70%-75% of women chose LARCs, continuation and satisfaction were higher, and pregnancy rates much lower, among LARC vs. non-LARC users.**

**Providers must strike a delicate balance between embracing "LARC-first" counseling while emphasizing reproductive rights.**

**FIGURE 1.** World Health Organization Model of Tiered Contraceptive Effectiveness



Source: Steiner et al.,<sup>17</sup> Trussell,<sup>18</sup> and WHO.<sup>19</sup>

**Effectiveness is one of the most important factors, and indeed often the most important factor, when women choose a method.**

in many studies, effectiveness is mentioned as most important by a clear majority of women.<sup>1,17,31-33</sup> Issues of side effects, the ability to use the method covertly, or the ability to control initiation and/or cessation of use are also important to women and should always be discussed. In some situations, they may “trump” effectiveness for certain women. However, to ensure that decision making is based on accurate information, effectiveness should be the fundamental starting point in describing methods for women seeking contraceptive services.

Given the evidence of women’s stated preferences, the 20-fold increased protection from unintended pregnancy that LARCs can provide, as well as the reality that approximately 40% of unintended pregnancies end in abortion,<sup>34</sup>

proactive counseling using the WHO tiers is simple, common sense. Among the many who have come to agree with counseling about the most effective methods first are the American Academy of Pediatricians (AAP), the American College of Obstetricians and Gynecologists, and the Centers for Disease Control and Prevention.<sup>35-37</sup> The AAP 2014 policy statement on contraception for adolescents encourages providers to counsel by “discussing the most effective contraceptive methods first.”<sup>35</sup> Internationally, the highly regarded “Balanced Counseling Strategy,” developed by the Population Council, also makes use of WHO-tiered counseling. Users of this popular counseling tool first help the client rule out certain classes of methods, then are guided by the strategy’s algorithm to: (1)

visually present the remaining methods in order of effectiveness, (2) fully explain the concept of effectiveness, and (3) counsel the client beginning with the most effective methods.<sup>38</sup>

## COMPREHENSIVE COUNSELING

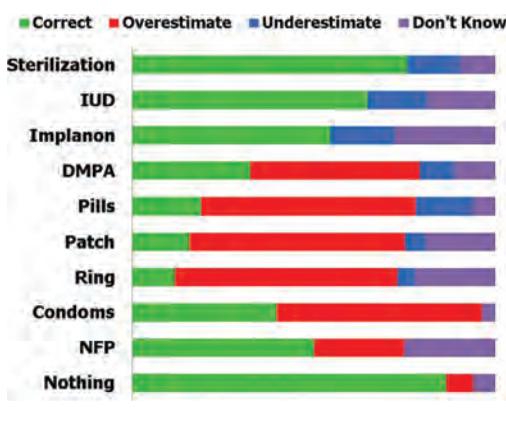
The WHO contraceptive effectiveness tiers are only one piece in a larger framework of comprehensive counseling that must include private, client-centered conversation about a woman's reproductive needs and desires. WHO-tiered counseling should not be equated with directive counseling, and it does not assume that a woman *should* choose a LARC. Nor does it dismiss the side effects or other characteristics of any method. Rather, it should help a client put those characteristics in a perspective that includes contraceptive effectiveness and pregnancy risk.

Conveying that risk, i.e., an understanding of the relative effectiveness of different methods, is challenging. Often, the absolute and relative effectiveness of different contraceptive methods are misunderstood by clients. For example, at enrollment, women in the St. Louis CHOICE study significantly overestimated the effectiveness of various non-LARC methods, while significantly underestimating the effectiveness of LARCs (Figure 2).<sup>2</sup> Such misconceptions are widespread, leading to “misinformed choice” among women unless these misunderstandings are corrected by providers. While “misinformed choice” does not rise to the level of coercion, we agree with WHO<sup>3</sup> that programs that do not fully and comprehensively educate women about method effectiveness and ensure that clients understand the differences between methods are not rights-based.

## NO LARCS IS NO EXCUSE

Another reason that providers may deemphasize LARCs during counseling is that long-acting methods may not be available or affordable in their setting. When this happens, we fail women by providing both counseling *and* service delivery that are not rights-based. Lack of access to LARCs remains a major problem both in the developed and the developing worlds. In low-resource regions, LARCs may not be available at all, or, where available in theory, may be unaffordable or impossible to access due to provider bias, outdated knowledge, or lack of training.<sup>39</sup> Thus,

**FIGURE 2.** Knowledge of Contraceptive Effectiveness Among Participants in the St. Louis CHOICE Study (N=4,144)



Abbreviations: DMPA, depot medroxyprogesterone acetate; IUD, intrauterine device; NFP, natural family planning.

Source: Reprinted from Eisenberg et al.,<sup>2</sup> with permission from Elsevier.

millions of women are not receiving rights-based provision of family planning because they lack either information about and/or access to the full range of modern methods, and especially to LARCs. Our priority is increasing access to WHO tier-1 methods themselves, along with accurate education about their advantages and disadvantages.

## CONCLUSION

For societies to reap the many benefits of family planning, both at the individual and macro levels, all methods of family planning, reversible *and* permanent, should be widely—indeed universally—available. Provision of these methods must include free choice, discontinuation on demand, and comprehensive counseling that proactively focuses on the WHO tiers of effectiveness. Until then, we are failing to accurately inform women with rights-based family planning programs.

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**Providers have a responsibility to educate women about method effectiveness to help avoid “misinformed choice.”**

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## ORIGINAL ARTICLE

# Care Groups I: An Innovative Community-Based Strategy for Improving Maternal, Neonatal, and Child Health in Resource-Constrained Settings

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**Care Groups use volunteers to motivate mothers to adopt key MCH behaviors. The volunteers meet as a group every 2–4 weeks with a paid facilitator to learn new health promotion messages. Key ingredients of the approach include: peer-to-peer health promotion, selection of volunteers by the mothers, a manageable workload for the volunteers (no more than 15 households per volunteer), frequent (at least monthly) contact between volunteers and mothers, and regular supervision of the volunteers.**

## Abstract

In view of the slow progress being made in reducing maternal and child mortality in many priority countries, new approaches are urgently needed that can be applied in settings with weak health systems and a scarcity of human resources for health. The Care Group approach uses facilitators, who are a lower-level cadre of paid workers, to work with groups of 12 or so volunteers (the Care Group), and each volunteer is responsible for 10–15 households. The volunteers share messages with the mothers of the households to promote important health behaviors and to use key health services. The Care Groups create a multiplying effect, reaching all households in a community at low cost. This article describes the Care Group approach in more detail, its history, and current NGO experience with implementing the approach across more than 28 countries. A companion article also published in this journal summarizes the evidence on the effectiveness of the Care Group approach. An estimated 1.3 million households—almost entirely in rural areas—have been reached using Care Groups, and at least 106,000 volunteers have been trained. The NGOs with experience implementing Care Groups have achieved high population coverage of key health interventions proven to reduce maternal and child deaths. Some of the essential criteria in applying the Care Group approach include: peer-to-peer health promotion (between mothers), selection of volunteers by mothers, limited workload for the volunteers, limited number of volunteers per Care Group, frequent contact between the volunteers and mothers, use of visual teaching tools and participatory behavior change methods, and regular supervision of volunteers. Incorporating Care Groups into ministries of health would help sustain the approach, which would require creating posts for facilitators as well as supervisors. Although not widely known about outside the NGO child survival and food security networks, the Care Group approach deserves broader recognition as a promising alternative to current strategies for delivering key health interventions to remote and underserved communities.

## INTRODUCTION

There is a recognized need to accelerate progress in reducing maternal and child mortality in the 75 countries of the world where 95% of the world's

maternal and child deaths take place.<sup>1–3</sup> The Millennium Development Goals (MDGs), established in the year 2000, called for achieving by the year 2015 reductions of three-fourths and two-thirds, respectively, in maternal and child mortality based on 1990 levels.<sup>4</sup> These goals will not be achieved by the great majority of these countries, particularly in sub-Saharan Africa, where only 5 of 44 countries are on track to achieve the maternal health MDG and only 14 are on track to achieve the child health MDG.<sup>5</sup>

One of the important reasons for lack of progress has been the low population coverage of key interventions proven to be effective for reducing maternal and

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child deaths. Although the median population coverage of immunizations and vitamin A supplementation is in the range of 80%, coverage of other key interventions is 60% or less, and for a number of interventions, the median range of coverage is 30% or less.<sup>5</sup> In some countries, levels of coverage are less than 10%.<sup>5</sup>

There is a lack of evidence that facility-based services by themselves in resource-constrained settings with high mortality can achieve high levels of population coverage of key maternal and child health interventions and mortality impact, and some evidence that they cannot.<sup>6–8</sup> Expanding coverage of key interventions and achieving documented reductions in maternal, neonatal, and child mortality will require approaches that are not only low-cost and effective on a short-term, pilot basis in small populations but also low-cost, effective, and feasible at scale over the longer term. This requires, among other things, approaches that engage the community as partners, empower women and communities, and reach a high proportion of households with health education that encourages healthy behaviors and appropriate use of health facilities.<sup>9</sup>

Interest in and experience with community health workers (CHWs) is growing rapidly, and CHW programs are expanding in many countries.<sup>10,11</sup> CHW programs in some countries (such as Bangladesh, Brazil, Ethiopia, and Nepal) have been widely credited with achieving high levels of population coverage of key maternal and child health interventions and marked improvements in child survival, while in other countries such as India and Pakistan progress has lagged behind in spite of large-scale CHW programs.<sup>5</sup> There is a wide diversity of CHW programs and cadres, with some using “professionalized” workers with 1 year or more of training, a broad scope of preventive and curative skills, and a full-time government salary while others engage volunteers working only a few hours a week on a highly specialized activity such as immunizations, HIV/AIDS control, or distribution of bed nets. In all cases, CHWs are formally trained and engaged with the health system but work at the community level outside of facilities and receive no formal professional or paraprofessional certificate and no tertiary education degree.

This article describes the Care Group approach—a delivery strategy for expanding coverage of maternal and child health interventions using volunteer CHWs. We describe what Care Groups are, the key ingredients (the “secret

sauce”) that seem to be important for their successful implementation, their history, the field experience with use of this delivery strategy, modifications that are emerging in Care Group implementation, and how Care Groups might be integrated into government health programs. Finally, we highlight Care Groups as one example of the growing importance of participatory women’s groups in improving maternal and child health. A companion article in *Global Health: Science and Practice* summarizes the evidence on the effectiveness, cost, and cost-effectiveness of Care Groups to improving child survival.<sup>12</sup>

## WHAT ARE CARE GROUPS?

The formal definition of a Care Group is the following<sup>13</sup>:

*A Care Group is a group of 10–15 volunteer, community-based health educators who regularly meet together with project staff for training and supervision. They are different from typical mother’s groups in that each volunteer is responsible for regularly visiting 10–15 of her neighbors, sharing what she has learned and facilitating behavior change at the household level. Care Groups create a multiplying effect to equitably reach every beneficiary household with interpersonal behavior change communication.*

A representation of a Care Group intervention delivery system is shown in the [Figure](#). The system is established initially by identifying 1 volunteer (called a Care Group Volunteer) who is responsible for about 12 mothers (pregnant women and mothers of young children, usually 0–59 months of age or 0–23 months of age). The Care Group Volunteer is often selected by the mothers themselves; sometimes community leaders participate in the selection process. Supervisory field staff are recruited and trained to set up Care Groups in collaboration with community leaders so that: (1) Care Group Volunteers are in place and are responsible for about 12 mothers who are their neighbors, and (2) all pregnant women and mothers of young children are linked to a Care Group Volunteer.

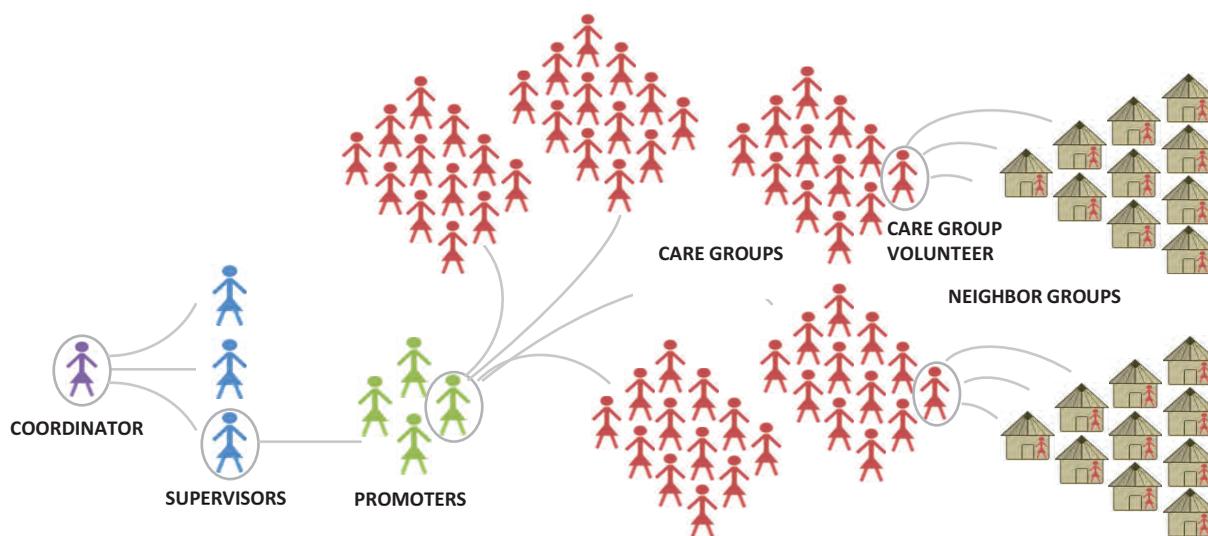
Depending on the size of the population covered by the project or program, several layers of paid program staff are required so that a Care Group Facilitator (referred to in the [Figure](#) as a Promoter and who is a low-level paid project staff person) can meet with each Care Group every 2–4 weeks for 2 hours or so. At that time,

**Care Groups are a community-based strategy for expanding coverage of MCH interventions using volunteer health workers.**

**Engaging communities will be necessary to expand coverage of key maternal and child health interventions around the world.**

**Care Group Volunteers are often selected by the mothers themselves.**

**FIGURE.** Structure of a Typical Care Group Delivery Strategy



<p>Each <b>Coordinator</b> (paid staff) is responsible for 3–6 Supervisors.</p> <p>A project may hire multiple Coordinators (overseen by a <b>Manager</b>) if needed to meet the desired coverage.</p>	<p>Each <b>Supervisor</b> (paid staff) is responsible for 4–6 Promoters.</p>	<p>Each <b>Promoter</b> (paid staff) supports 4–9 Care Groups.</p>	<p>Each <b>Care Group</b> has 10–15 Care Group Volunteers who are elected by Neighbor Group members.</p>	<p>Each <b>Care Group Volunteer</b> shares lessons with 10–15 <b>Neighbor Women</b> and their families, known as a <b>Neighbor Group</b>. (There is a maximum of 15 Neighbor Women in each Neighbor Group.)</p>
<p><b>Each Promoter reaches about 500–1,200 women through the Care Group Volunteers.</b></p>				

the Care Group Facilitator teaches one or a small number of health promotion messages for the Care Group Volunteers to share with the women for whom they are responsible. The Facilitator uses participatory learning, including role play and composition of songs and skits, to convey messages. During the following 2–4 weeks (depending on the schedule established by the program), each Care Group Volunteer meets with each of the women for whom she is responsible (and other family members who may be present, such as grandmothers, husbands, and older children)—either by visiting the woman at her

home or by meeting with her and a few neighbors as a small group. At the subsequent Care Group meeting, the Care Group Volunteers discuss their experience in sharing the previous messages and learn a new set of messages. In most Care Group programs, the Care Groups Volunteers also report births and deaths to the Care Group Facilitators/Promoters, who report this information upward through the health information system. (A manual outlining how to monitor mortality using the Care Group approach is available at: <http://www.coregroup.org/resources/271-the-mortality-assessment-for-health-programs-system>.)

### BOX 1. Essential Criteria for Application of the Care Group Approach

1. Peer-to-peer (mother-to-mother for maternal and child health and nutrition behaviors) health promotion is essential.
2. Care Group Volunteers are selected by mothers within the group of households they will serve or by the leadership in the village.
3. Because they are volunteers, the Care Group Volunteers must limit their workload. There should be no more than 15 households per Care Group Volunteer. The terrain and distance between households may affect the number of households for which Care Group Volunteers can take responsibility. In settings where households are dispersed or the terrain is difficult to traverse, Care Group Volunteers may need to take responsibility for fewer households.
4. There should be between 6–16 members in a Care Group.
5. Contact between the Care Group Volunteer and her assigned beneficiary mothers is monitored; contact should occur at a minimum once a month, but preferably twice monthly.
6. The plan is to reach 100% of the households in the targeted group on at least a monthly basis and to attain at least 80% monthly coverage of households within the target group. Coverage is monitored.
7. Care Group Volunteers collect vital events (data on pregnancies, births, and deaths). This is very important as they can discuss and solve problems as a group related to what kind of follow-up is needed and how similar deaths might be prevented in the future.
8. The majority of what is promoted through the Care Group is directed toward reduction of maternal and child mortality and malnutrition (e.g., Essential Nutrition Actions and Essential Hygiene Actions). It could be a useful strategy to include other topics but this is what Care Groups were originally intended to do.
9. Care Group Volunteers should use some sort of visual teaching tool (e.g., job aids, flip charts) for health promotion at the household level.
10. Participatory methods of behavior change communication are important. This is not specific only to Care Groups, but Care Groups should use best practices for behavior change.
11. No more than 1–2 hours should be spent in a meeting of Care Group Volunteers. Such “drip training” involves small amounts of information, and then the information is applied. The Care Groups can fit the time needed for the meeting into their schedule. Care Group Volunteers then bring the information and messages to the women in their catchment area as they have time.
12. Supervision of Promoters and of at least one of the Care Group Volunteers should occur at least monthly. This is an important part of the Care Group approach and part of the cascade.
13. All of a Care Group Volunteer’s beneficiaries should live less than a 1-hour’s walk from the Volunteer’s home.
14. The implementing agency needs to successfully create a project/program culture that conveys respect for women, for the Care Group Volunteers, and for the beneficiaries.

The Facilitators/Promoters along with higher-level supervisory staff meet together every few months to learn the health promotion messages that they will later convey to the Care Group Volunteers. The Facilitators/Promoters are also taught participatory methods for behavior change promotion, including demonstrations, role plays, stories, and songs (often composed by the Care Group Volunteers themselves) to convey these messages.

The educational content focuses on key knowledge about maternal and child health, important household practices for promoting maternal and child health, and indications for use of health facilities, including danger signs for

which medical care should be sought. Messages are often based on results of formative research such as positive deviance studies and barrier analysis<sup>14</sup> studies that identify behavioral determinants of key behaviors.

Further details regarding what are considered to be essential criteria for the Care Group approach are shown in [Box 1](#). Additional suggested criteria are shown in [Box 2](#). The rationale for these lists is described in greater detail elsewhere.<sup>13</sup> The degree to which each criterion in [Box 1](#) and [Box 2](#) is required for the Care Group approach to be effective and whether or not the approach would function if one or more criteria were not met is unknown at present, but fidelity

## BOX 2. Suggested Additional Criteria for Optimal Functioning of the Care Group Approach

1. Formative research should be conducted, especially on the key behaviors that will be promoted. If the key behaviors promoted are not the leading causes of child death in the program area, an impact on mortality may not be achieved.
2. Care Group Promoters are paid staff who meet with and directly train Care Group Volunteers. Care Group Promoters should have no more than 9 Care Groups for which they are responsible. This is particularly important when Care Groups meet every 2 weeks. For a Care Group Promoter to develop a personal relationship and really know those with whom s/he is working, the Promoter should not work with more than about 150 people. This can be achieved if a Care Group Promoter is not responsible for more than 9 Care Groups. A Care Group should have at the most 15 members.
3. Measurement of many of the results-level indicators should be conducted annually at a minimum. This is achieved by carrying out a survey of a random sample of households in the project or program area. Assuming households are selected at random, 96 households are needed for the survey. Supervisory staff can carry out this survey in the course of their regular field supervision activities. These data are needed to manage any program well.
4. Differences between Care Group Promoters and Care Group Volunteers in their social characteristics and in educational levels should not be too great. For example, an extreme difference is when a Care Group Promoter has a bachelor-level university degree and her Care Group Volunteers are illiterate. A great social distance makes it difficult for Care Group Promoters to connect with Care Group Volunteers in an effective way.
5. The “care” in Care Groups may not be quantifiable, but it is supremely important for an entire system based on volunteerism. Care and respect need to be modeled from the senior leadership all the way through to the volunteers.
6. Ensuring that each Care Group Volunteer does not have more than 3–4 hours of work per week is essential in order not to overload and overburden her.
7. Peer selection of Care Group Volunteers helps to identify the most effective recruits.
8. Field Supervisors and Care Group Facilitators/Promoters need support from their supervisors on a regular and intensive basis, and they need to be provided with the tools to make their work effective, including transport and educational materials/visual tools such as flip charts.
9. Participatory methods of behavior change communication should be used, including songs, role play, games, and stories. Oftentimes Care Groups make up their own songs to use.
10. Flexible management and supervision that enable the Care Group principles to be upheld while adjusting to local contextual realities and implementation hurdles is recommended. The number of Field Supervisors and Care Group Promoters as well as the number of Care Group members needs to be adjusted based on local geographical conditions and ease of transport.

to most, if not all, criteria seems to be essential at this stage in the development of the approach. Over time, with further experience and evaluation, variations in the approach could be tested. [Box 3](#) provides a case study of how one Care Group project in Mozambique functioned.

### HOW DID CARE GROUPS EMERGE?

The Care Group approach was first developed in 1995 in the Guija and Mabalane districts of Gaza Province in Mozambique by staff members of World Relief (Pieter Ernst and Muriel Elmer, later with support from Warren and Gretchen Berggren) as they were developing an implementation plan for a child survival project funded by the United States Agency for International

Development (USAID) Child Survival and Health Grants Program. This program proved to be highly successful in achieving impressive gains in coverage of key child survival interventions. Two years later, in 1997, after receiving training from World Relief, Food for the Hungry initiated a Care Group project in the Sofala Province of Mozambique under the leadership of Tom Davis and with funding from the USAID Title II Food for Peace program. This was the first replication of the model by another organization; the project achieved substantial decreases in moderate and severe stunting. A second World Relief Mozambique child survival project, implemented between 1999 and 2003 in the Chokwe district of Gaza Province (excluding the town of Chokwe), was similarly successful; its impact on under-5

### BOX 3. An Illustrative Care Group Child Survival Project in Mozambique Implemented by Food for the Hungry

In 5 districts of Mozambique with a total population of 1.1 million people, the Care Group project recruited 5 Field/District Supervisors (with three Supervisors serving one district each, and two Supervisors serving two districts each), each with technical or professional training, such as in nursing or as a medical technician. Each District Supervisor recruited about 13 Promoters/Facilitators (for a total of 65 Promoters) by working with community leaders to identify candidates living in the area with at least 5 years of education and who could read and write and perform simple mathematical calculations.

With the help of community leaders and teachers, the District Supervisor working with each Promoter registered all the pregnant women and women with a child 0–23 months of age as “beneficiary mothers.” These women selected Leader Mothers (Care Group Volunteers). A total of 325 Care Groups with 4,095 Leader Mothers were created: 5 Care Groups for each Promoter and 12–13 Leader Mothers per Care Group.

All the District Supervisors and Promoters met together to learn the first module to be taught to the Care Groups, entitled “Working Together with Communities.” Each module had 4–5 lessons. The District Supervisors and Promoters met together 3–4 times a year to learn new modules. A sample of training materials and training aids can be found in Annexes 13 and 14 of the project’s final evaluation, located at: [http://caregroups.info/docs/FH\\_Final\\_Eval\\_Report\\_27Dec2010.pdf](http://caregroups.info/docs/FH_Final_Eval_Report_27Dec2010.pdf).

Every 2 weeks, each Promoter met with each of his/her 5 Care Groups. Each Care Group meeting lasted about 1.5 to 2 hours. At each meeting, 15–20 minutes were spent reviewing the previous activities since the last Care Group meeting 2 weeks previously. The Leader Mothers also informed the Promoter of any births or deaths that had occurred during the previous 2 weeks. Then they learned 3–4 new key messages to share with their households and practiced among themselves how to best present them to the beneficiary mothers.

Over the next 2 weeks, the Leader Mothers met with each of their 12 or so beneficiary mothers, either individually or in small groups. Over time, these beneficiary mothers “graduated” as their child reached 2 years of age, and newly pregnant women or those with a newborn became a beneficiary mother. Leader Mothers used a flip chart to illustrate the lesson being given.

When it became apparent that neonatal deaths were frequent, the Leader Mothers began to visit newborns as soon as possible after birth and then on a daily basis during the first week, 3 times a week during the second week, twice during the third week, and once during the fourth week. Leader Mothers received training in danger signs of neonates, used a checklist, and counseled mothers during these visits using flip charts and a checklist for newborns.

One Leader Mother in each Care Group was selected as a C-IMCI Leader Mother and received 5 days of training. C-IMCI refers to Community-based Integrated Management of Childhood Illness. She served as a resource and a referral point for the other Leader Mothers in the Care Group.

The project had only one vehicle, which was used to transport the project leadership team from the project headquarters in the city of Beira to and from the project area. Each of the 5 District Supervisors had a motorbike and each of the Promoters had a bicycle.

mortality, as estimated by expansions of coverage of key maternal and child health interventions using the Lives Saved Tool (LiST), was one of the highest achieved up to that time by USAID-supported child survival projects.<sup>15</sup> Later, the CORE Group provided a grant to carry out an independent assessment of the mortality impact of the project and to prepare a manual describing the Care Group delivery strategy.<sup>16</sup>

As evidence of the effectiveness and feasibility of Care Groups began to accumulate among NGO

child survival projects, other NGOs began to try the approach. Again, under the leadership of Tom Davis, Curamericas Global in Huehuetenango, Guatemala implemented the Care Group approach. World Relief, Food for the Hungry, and Curamericas Global also began to apply the Care Group approach at their other project sites in different countries. The success of these projects, the technical support offered to other organization by Melanie Morrow (then working with World Relief) and Tom Davis (then working with



Henry Perry

A Care Group Promoter from Mozambique meets with the volunteers she oversees to teach them new health promotion messages to share with their beneficiary mothers. The project provided each Care Group Promoter with a bicycle to facilitate supervision visits.

**Care Group projects in 28 countries have reached an estimated 1.3 million households, mostly in rural areas.**

**Because all early Care Group projects were funded by USAID, they all had both baseline and endline outcome measurements obtained from household surveys.**

Food for the Hungry), and the availability of a very useful implementation guide<sup>16</sup> all fueled adoption of the approach by other NGOs funded by the USAID Child Survival and Health Grants Program. (A recently updated version of the implementation guide is available at: <http://www.fsnnetwork.org/care-groups-training-manual-program-design-and-implementation>.) Other early adopters of the Care Group approach included the American Red Cross in Cambodia, Plan International in Kenya, the Salvation Army World Service Office in Zambia, Concern Worldwide in Burundi, Medical Teams International in Liberia, and Catholic Relief Services in Malawi.

The fact that all the early Care Group projects were funded by the USAID Child Survival and Health Grants Program meant they all had baseline measurements of population coverage of key interventions obtained from household surveys as well as end-of-project measures using similar survey instruments since this was required of all grantee projects. The projects were therefore able to assess changes in practice and coverage over the course of the projects. This success was shared with the NGO community through a workshop led by World Relief in Mozambique in 2005 and through presentations at CORE Group meetings, leading to adoption of the Care Group strategy by a number of other NGOs with funding from a variety of sources in

addition to the USAID Child Survival and Health Grants Program.

## WHAT IS THE EXPERIENCE SO FAR WITH CARE GROUP IMPLEMENTATION?

A small number of NGOs working in a variety of countries and settings continued to successfully achieve high levels of intervention coverage in populations of 100,000–200,000 people. (See the companion paper in *Global Health: Science and Practice* for details about effectiveness of the Care Group approach.<sup>12</sup>) And with this, enthusiasm for the Care Group approach began to grow. In 2010, 14 NGOs had implemented Care Group projects in 16 countries. Only 5 years later, that number had grown to 25 NGOs in 28 different countries in all regions of the world (Box 4). In all cases, NGOs have implemented Care Groups in collaboration with ministry of health (MOH) programs and in accordance with MOH policies and strategies. And in all cases, Care Group projects promote use of MOH services and programs, including facility-based services. At present, based on available information, we estimate that 1.3 million households have been reached using the Care Group implementation system, and at least 106,000 Care Group Volunteers have been trained.

Almost all the Care Group projects implemented so far have been in rural areas of low-income countries. To our knowledge, there is only one example of Care Group implementation in an urban or peri-urban setting,<sup>18</sup> although several rural projects have had “pockets” of peri-urban populations. Projects often vary in terms of the specific interventions implemented (such as nutrition, diarrhea control, newborn health, immunizations, and so forth) depending on the local epidemiological context. The details of supervision and training also vary from project to project and from NGO to NGO.

International NGOs have initiated implementation of all known Care Group projects to date. The major donors for these projects have been the USAID Child Survival and Health Grants Program, in-country USAID missions, the USAID Food for Peace (Title II) programs, and the USAID Office of U.S. Foreign Disaster Assistance. However, donor support has expanded to include the World Bank (for Care Group projects in Malawi and Mozambique), the Canadian International Development Agency (CIDA), the British Department for International Development (DfID), the European Commission’s Humanitarian Aid and Civil Protection department (formerly called the European

## BOX 4. Organizations and Countries With Experience Implementing Care Groups as of 2015

### Organizations with experience implementing Care Groups:

1. ACDI/VOCA (<http://acdivoca.org/>)
2. ADRA (<https://adra.org/>)
3. Africare (<https://www.africare.org/>)
4. American Red Cross (<http://www.redcross.org/>)
5. CARE (<http://www.care.org/>)
6. Concern Worldwide (<https://www.concern.net/>)
7. Catholic Relief Services (<http://www.crs.org/>)
8. Curamericas (<http://www.curamericas.org/home>)
9. Emmanuel International ([www.eim-us.org/](http://www.eim-us.org/))
10. Feed the Children (<http://www.feedthechildren.org/>)
11. Food for the Hungry (<http://fh.org/>)
12. Future Generations (<http://www.future.org/>)
13. GOAL (<https://www.goalglobal.org/>)
14. International Aid (<http://www.internationalaid.org/>)
15. International Medical Corps (<https://internationalmedicalcorps.org/>)
16. Living Water International (<http://www.water.cc/>)
17. Medair (<http://relief.medair.org/en/>)
18. Medical Teams International (<http://www.medicalteams.org/>)
19. PLAN (<http://plan-international.org/>)
20. Project Concern International (<http://www.pciglobal.org/>)
21. Salvation Army World Service Office (<http://www.sawso.org/>)
22. Save the Children (<http://www.savethechildren.org/>)
23. World Renew (<http://www.worldrenew.net/>)
24. World Relief (<http://worldrelief.org/>)
25. World Vision (<http://www.worldvision.org/>)

### Countries in which Care Group projects have been or are currently being implemented:

1. Bangladesh
2. Bolivia
3. Burkina Faso
4. Burundi
5. Cambodia
6. Democratic Republic of the Congo
7. Ethiopia
8. Guatemala
9. Haiti
10. Indonesia
11. Kenya
12. Liberia
13. Malawi
14. Mexico
15. Mozambique
16. Nicaragua
17. Niger
18. Peru
19. Philippines
20. Rwanda
21. Senegal
22. Sierra Leone
23. Somalia
24. South Sudan
25. Sudan
26. Uganda
27. Zambia
28. Zimbabwe

Source: Care Groups Info.<sup>17</sup>

Community Humanitarian Aid Office and still referred to as ECHO), the United Nations Children's Fund (UNICEF), and private NGO funds.

There is now early experience in applying the Care Group delivery strategy within MOH rural health care delivery systems. Concern Worldwide has carried out an operations research project in Burundi comparing the effectiveness of the traditional NGO Care Group project structure (in which the Care Group Facilitators/Promoters are paid by

the NGO) with an alternative approach in which Care Group Facilitators/Promoters are MOH CHWs (who are unpaid volunteers). The findings indicate that—with NGO technical and financial support during the time of the study—the effectiveness of the Care Group strategy using MOH CHWs as Care Group Facilitators/Promoters is similar to the traditional NGO implementation of the approach.<sup>19</sup> In this case, the MOH CHWs served as Care Group Facilitators/Promoters in addition to their usual

**A project in Burundi has tested the feasibility of embedding Care Group Facilitators within the Ministry of Health.**



Adelle Fox, Concern Worldwide

A Care Group Volunteer in Burundi shares a health message during a home visit. Care Group Volunteers make home visits to each woman for which they are responsible on a monthly or twice-monthly basis.

duties, but they each supervised only 2 Care Groups rather than the usual 5–9 Care Groups in the typical NGO implementation. (A short user's guide on how to integrate Care Groups into MOH health systems is available at [http://www.fsnnetwork.org/sites/default/files/resource\\_uploads/integrating\\_care\\_groups\\_into\\_moh\\_systems\\_a\\_users\\_guide.pdf](http://www.fsnnetwork.org/sites/default/files/resource_uploads/integrating_care_groups_into_moh_systems_a_users_guide.pdf).)

## OTHER EMERGING MODIFICATIONS OF THE CARE GROUP APPROACH

One important example of a modified Care Group approach is in Rwanda.<sup>20</sup> There, 3 international NGOs (Concern Worldwide, The International Rescue Committee, and World Relief) worked with the MOH to modify the Care Group delivery system to fit within the current role and functions of government CHWs (where the CHWs are volunteers who receive performance-based incentives). In this case, there were 4 CHWs in each village:

- Two (one male and one female) were assigned to carry out integrated community case management of childhood illness
- Another was responsible for maternal health (a female CHW)
- The fourth was responsible for social affairs (either a male for female)

The 4 CHWs were responsible together for the entire village of 60–80 households, but each focused on his/her specialty area. The Care Group methodology was modified so that the CHWs from 2–5 neighboring villages were organized into CHW Peer Support Groups with each group having up to 20 CHW members, about half of whom were men.

**Incorporating the Care Group approach into Ministries of Health would help make it sustainable.**

The CHWs divided up households so each CHW was responsible for 15–20 households, and they visited each household monthly to provide behavior change communication. The project helped to organize and oversee training of the CHW Peer Support Groups in behavior change interventions. CHW Peer Support Groups elected unpaid CHW Cell Coordinators to help with the training and supervision of the CHW Peer Support Groups.

There were about 100 CHWs working in a health center's catchment area. Each health center had an MOH employee in charge of supervising the CHWs working in the health center's catchment area. This Community Health In-Charge at the health center also functioned as a CHW Peer Support Group Facilitator. This approach was implemented in a catchment area of 1.7 million people, reaching 18% of Rwanda's population. Appropriate treatment for malaria, point-of-use water purification, and the proportion of caretakers who increased fluid or food during diarrheal episodes doubled or almost doubled.<sup>21</sup> Care seeking for respiratory symptoms more than tripled, and skilled attendance during childbirth increased from 39% to 91%.<sup>21</sup> Care seeking for fever, diarrhea, and symptoms of pneumonia in children were significantly greater in the catchment area with CHW Peer Support Groups than in the non-project districts.<sup>20</sup>

Another example of a modified Care Group approach is in Mozambique, where World Relief has just completed a 5-year Care Group project focused on tuberculosis (TB) control in the same locale where Care Group projects had been previously implemented. For the TB project, World Relief used many of the same Care Group Volunteers and similar supervisory structures as those that had been established over the previous 2 decades in 6 districts of Gaza Province. The project was able to achieve marked improvements in awareness about TB, its treatable nature, and the availability of free treatment at government health centers.<sup>22</sup>

## INTEGRATION OF CARE GROUPS INTO MINISTRY OF HEALTH DELIVERY SYSTEMS

As previously mentioned, the field experience with Care Groups has been primarily with projects implemented by NGOs. Opportunities for incorporating the Care Group approach into existing MOH programs would help give the approach a long-term, sustainable "home" that NGOs are not usually able to provide. There is room for new creative partnerships between NGOs and MOHs to implement the Care Group approach, from

contracting out service delivery to engaging NGOs for training, monitoring, or quality assurance.

The essential link needed in MOH programs is the creation of formal postings for what we refer to in the [Figure](#) as Promoters (who meet with, teach, and support Care Group Volunteers) and Supervisors (who meet with, teach, and support the Facilitators/Promoters). Simply adding the duty of the Care Group Facilitator/Promoter to the existing duties of currently functioning CHWs would seem to be fraught with high risk of failure, as would adding the duty of the Supervisor to the MOH supervisor of MOH CHWs since these persons are already likely overburdened with too many responsibilities. However, the Concern Worldwide experience in Burundi revealed that in a situation in which CHWs were already overloaded with responsibilities that included community mobilization, integrated community case management (for pneumonia, diarrhea, and malaria), and home visits, giving them responsibility for supervising Care Groups actually lightened their workload—better prevention led to fewer cases and earlier home-based treatment and, at the same time, earlier referral led to fewer seriously ill children for CHWs to manage.<sup>19</sup>

One option—aside from creating new posts specifically for these functions (which we acknowledge is quite difficult within the government system)—might include recruiting more MOH CHWs and supervisors of CHWs so that the additional Care Group workload would be manageable. Whatever strategy might be adopted, there would need to be additional resources devoted to high-quality, community-based delivery. Even though the costs of Care Group programs are quite modest (as is discussed in the companion article<sup>12</sup>), the success of Care Group implementation rests in large part on having well-trained, highly motivated, and well-supported field workers.

## CARE GROUPS AS AN EXAMPLE OF PARTICIPATORY WOMEN'S GROUPS

Care Groups are an example of how programs are gradually learning to harness the power of women working together to improve their own health and the health of their children. Women's groups have been in use now for decades, but well-delineated methods for engaging them and mobilizing them to deliver key evidence-based interventions that result in scientifically demonstrated improvements in either population coverage

of these interventions or improved population-level health outcomes have been lacking until recently.

A similar but nonetheless distinct approach to engaging the power of groups of women is women's participatory learning and action (PLA) groups. In this approach, a facilitator meets with women in a village, and together they discuss health recommendations for pregnancy, birth, and neonatal care and how they could apply them in their own particular situation.<sup>23</sup> Although pregnant women and those with newborns are targeted, anyone in the village can attend the meetings. This approach has benefited from rigorous implementation research in a variety of settings, all being led initially by the same research group based at the University of London. Robust evidence finds the approach can reduce maternal and neonatal mortality if there are an adequate number of facilitators to ensure high levels of service coverage.<sup>24</sup> A key difference between Care Groups and PLA Groups is that with Care Groups, there is a systematic approach to reaching every household where there is a pregnant woman or young children with specific, carefully crafted messages. With PLA Groups, the focus is on the PLA Group discussing key health messages, formulating how they might incorporate these messages in their context, and then, through spontaneous dissemination, engaging other women who do not attend the facilitated sessions.<sup>25</sup>

Most certainly, other approaches are emerging now or will emerge in the future to harness the potential of participatory women's groups. The enthusiasm for and the demonstrated results of Care Groups and PLA Groups indicate this is a fruitful area for further field experimentation with rigorous evaluation and broader implementation.

## CONCLUSIONS

Although not widely known about outside of NGO child survival and food security networks, Care Groups are a rapidly growing innovative approach to implementing maternal, neonatal, and child health and nutrition interventions. Care Groups are able to motivate women volunteers to assist their neighbors in adopting positive health behaviors and seeking health care from the formal health system when needed. The NGOs that have implemented the Care Group approach in a variety of field settings throughout the world

have been uniformly enthusiastic about the effectiveness of the approach in changing behaviors, improving appropriate health care utilization, achieving demonstrable benefits in the health of mothers, neonates, and children, and empowering women and their communities. The Sustainable Development Goals, scheduled for adoption at the 2015 meeting of the United Nations General Assembly, call for the achievement of universal access to quality essential health services and the end of preventable deaths of newborns and under-5 children by the year 2030.<sup>26</sup> Care Groups and related approaches hold great promise in helping to achieve these goals.

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## ORIGINAL ARTICLE

# Care Groups II: A Summary of the Child Survival Outcomes Achieved Using Volunteer Community Health Workers in Resource-Constrained Settings

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**Care Group projects resulted in high levels of healthy behavior, including use of oral rehydration therapy, bed nets, and health care services. Accordingly, under-5 mortality in Care Group areas declined by an estimated 32% compared with 11% in areas with child survival projects not using Care Groups.**

## ABSTRACT

The Care Group approach, described in detail in a companion paper in this journal, uses volunteers to convey health promotion messages to their neighbors. This article summarizes the available evidence on the effectiveness of the Care Group approach, drawing on articles published in the peer-reviewed literature as well as data from unpublished but publicly available project evaluations and summary analyses of these evaluations. When implemented by strong international NGOs with adequate funding, Care Groups have been remarkably effective in increasing population coverage of key child survival interventions. There is strong evidence that Care Groups can reduce childhood undernutrition and reduce the prevalence of diarrhea. Finally, evidence from multiple sources, comprising independent assessments of mortality impact, vital events collected by Care Group Volunteers themselves, and analyses using the Lives Saved Tool (LiST), that Care Groups are effective in reducing under-5 mortality. For example, the average decline in under-5 mortality, estimated using LiST, among 8 Care Group projects was 32%. In comparison, among 12 non-Care Group child survival projects, the under-5 mortality declined, on average, by an estimated 11%. Care Group projects cost in the range of US\$3–\$8 per beneficiary per year. The cost per life saved is in the range of \$441–\$3,773, and the cost per disability-adjusted life year (DALY) averted is in the range of \$15–\$126. The Care Group approach, when implemented as described, appears to be highly cost-effective based on internationally accepted criteria. Care Groups represent an important and promising innovative, low-cost approach to increasing the coverage of key child survival interventions in high-mortality, resource-constrained settings. Next steps include further specifying the adjustments needed in government health systems to successfully incorporate the Care Group approach, testing the feasibility of these adjustments and of the effectiveness of Care Groups in pilot programs in government health systems, and finally assessing effectiveness at scale under routine field conditions in government health programs.

## INTRODUCTION

Evidence-based interventions—those that have been shown to improve the health of resource-constrained

populations under research conditions—provide the basis for much of global health programming.<sup>1</sup> Rigorous evaluation of field programs that implement multiple interventions together under more routine conditions, unfortunately, has not been given sufficient attention. The need to conduct such evaluations, however, is increasingly becoming a top priority for global health.<sup>2</sup>

Much of the existing evidence upon which programming is based has been obtained from testing single interventions in highly controlled field settings—often referred to as efficacy studies. Assessing the effectiveness

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of approaches that integrate multiple interventions under more routine field conditions constitutes a logical next step in building a strong evidence base in global health programming. Furthermore, fully understanding the contextual requirement for effective implementation of the intervention(s) is essential for broader application. That is to say, under what conditions is/are the intervention(s) likely to be effective?

Community-based approaches are now recognized as one of the most important avenues for improving nutrition and reducing child mortality, particularly in high-mortality settings with weak health systems, scarce resources, and facilities that are difficult for most of the population to access.<sup>3</sup> However, much of the evidence is based on efficacy studies of individual interventions rather than on testing of the delivery of multiple interventions in more typical field settings.<sup>4,5</sup>

Care Groups, on the other hand, provide a means to implement multiple maternal and child health interventions for improving household behaviors and health care seeking by using volunteers who visit their neighbors frequently and who provide peer-to-peer counseling. In a companion article in the current issue of *Global Health: Science and Practice*, we described this approach, providing details on what they are, how they emerged as a service delivery strategy, and the field experience with using this particular strategy.<sup>6</sup> The purpose of this article is to summarize the evidence regarding the effectiveness, cost, and cost-effectiveness of the Care Group approach to improving child survival, all of which has been generated in relatively routine field conditions, and then attempt to provide further specification of the “secret sauce” that makes this approach as effective as the available evidence indicates that it is.

## METHODS

We undertook a review of the evaluations of Care Group child survival projects, which included unpublished project evaluations, presentations about Care Group projects given at global health conferences, and peer-reviewed publications. In addition, we also reviewed the findings from 2 Technical Advisory Group (TAG) meetings held in 2010 and 2014. These TAG meetings provide the opportunity for those engaged with Care Group child survival and child nutrition project implementation to review the progress, achievements, and limitations of the Care Group approach.

All but one of the early Care Group projects were funded by the United States Agency for International Development (USAID) Child Survival and Health Grants Program. These grantee projects were required to conduct household surveys to collect baseline measurements of population coverage of key interventions as well as end-of-project measures using similar survey instruments. Thus, these baseline and endline surveys provide a way to assess changes in practice and coverage over the course of the projects.

## FINDINGS

### Initial Evidence of Effectiveness: Pre/Post-Analysis of Individual Care Group Projects

Early evidence of effectiveness of the Care Group approach arose in the late 1990s and early 2000s from comparisons of baseline with end-of-project measures of population coverage of key interventions. The international NGO World Relief carried out a retrospective assessment with researchers from Johns Hopkins University of the mortality impact of its Care Group child survival project in Mozambique.<sup>7</sup> This project had been implemented between 1999 and 2003 in a population of 130,000 people living in rural villages of Chokwe District. Interviewers with experience in collecting data for the Mozambique Demographic and Health Survey (DHS) were hired to obtain pregnancy histories from a representative sample of women in the project area using the standard DHS retrospective complete birth history questionnaire for measuring mortality in children younger than 5 years of age. The independent mortality assessment demonstrated that the under-5 mortality rate had declined by 44.2%, from 163 per 1,000 births (95% confidence interval [CI]= 130, 230) to 91 per 1,000 births (95% CI= 57, 124) over the course of the project.

These findings were supported by marked increases in population coverage of key maternal and child interventions and increases in health care utilization. For example, the percentage of children with diarrhea who were treated with oral rehydration therapy increased from 53% (95% CI=43.9, 62.1) to 94% (95% CI=89.6, 98.4); the percentage of children who slept under an insecticide-treated bed net increased from 0% to 85% (95% CI=80.5, 89.5); and the percentage of children with fast or difficult breathing treated at a health center/post increased from 2.0% (95% CI= 1.9, 5.9) to 60.0% (95% CI=35.2, 84.8). Furthermore, vital events registration data collected

**Community-based approaches are one of the most important avenues for improving child health.**

by the Care Group Volunteers themselves indicated a decline in under-5 mortality of 62.2%, from 119 per 1,000 births (95% CI=110, 128) to 45 per 1,000 births (95% CI=40, 50). Using the Lives Saved Tool (LiST), which estimates mortality impact based on change in population coverage of evidence-based maternal and child health interventions, the estimated decline in under-5 mortality was 34%, very similar to the 38% decline estimated from the DHS birth history.<sup>8</sup> This overall decline represents an annual decline in under-5 mortality of 9.5% per year during the life of the project compared with an annual average rate of decline (based on DHS data) of 3.0% in Gaza Province (the province where the project was located) and 4.6% per year nationally, based on DHS data.<sup>9,10</sup> There were no other occurrences taking place during the project area during this time that could have produced the marked changes in coverage of key maternal and child health interventions.

**Under-5 mortality declined by an estimated 32% in areas with Care Group projects.**

World Relief conducted another Care Group project in Kampong Cham province in Cambodia from 2000–2004, which showed a similar dramatic decline in under-5 mortality of 71% according to vital events data collected by the Care Group Volunteers. In comparison, the ongoing secular decline in the province during the same period was 42%.<sup>11</sup> The mortality decline in Kampong Cham province was also accompanied by marked increases in population coverage of key maternal and child health interventions and in use of health care services.<sup>12</sup>

World Relief later developed and implemented similarly successful Care Group projects in Malawi and Rwanda, which achieved high levels of coverage of key interventions.<sup>13,14</sup> Other NGOs started to try the Care Group approach, most notably Food for the Hungry in the Sofala Province of Mozambique in 1997 and Curamericas Global in Huehuetenango, Guatemala, in 2002. Additional international NGOs, with funding from the USAID Child Survival and Health Grants Program, adopted the Care Group approach soon thereafter: American Red Cross in Cambodia, Plan International in Kenya, the Salvation Army World Service Office in Zambia, Concern Worldwide in Burundi, Medical Teams International in Liberia, and Catholic Relief Services in Malawi.

**A Growing Evidence Base: Comparison of Effectiveness Across Care Group Projects**

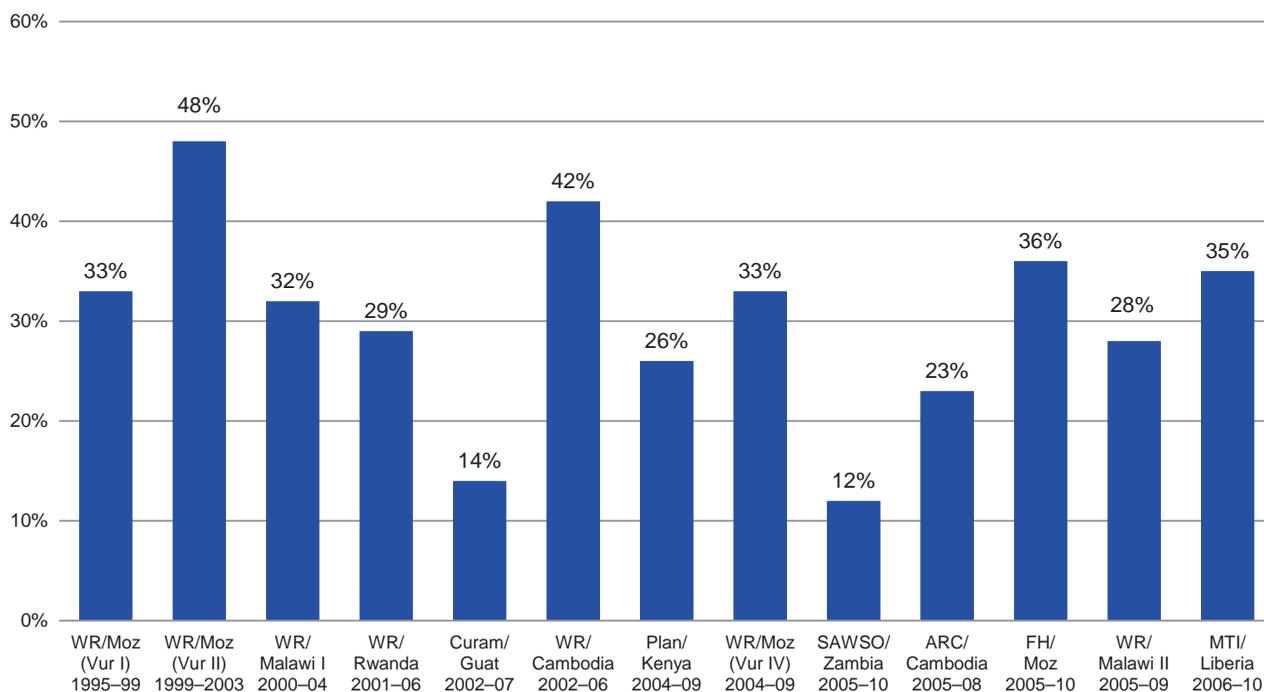
NGOs using the Care Group approach were achieving remarkable increases in population

coverage of key maternal and child health interventions in their project areas. This became more apparent when outcomes were directly compared between different projects supported by the USAID Child Survival and Health Grants Program that were using this particular service delivery strategy and undergoing similar approaches to evaluation.<sup>15</sup> The comparison was done by using an early and subsequent versions of what is known today as the LiST<sup>16</sup> to estimate mortality impact indirectly based on changes in population coverage of evidence-based interventions. Among 13 such projects, the estimated decline in the under-5 mortality rate ranged between 12% and 48%, with more than half of the projects achieving mortality declines above 30% (Figure).

Detailed data are available for 8 of these Care Group projects that had been implemented by 3 different international NGOs during the period from 1995–2010, allowing for more in-depth analysis (Table 1). Among these 8 Care Group projects, the average decline in under-5 mortality, estimated using LiST, was 32%. For a crude comparison, we can look to a separate analysis of 13 Child Survival and Health Program projects supported by USAID—only 1 of which was a Care Group project—that ended between June 2004 and June 2005.<sup>17</sup> That analysis estimated (using the version of LiST current at that time) a decline in under-5 mortality of 13% among the 13 child survival projects. This comparison (32% mortality reduction among Care Group projects versus 13% reduction among general child survival projects) is only suggestive, not conclusive, of a stronger mortality impact of the Care Group approach since the comparison group does not include projects ending during the same time period as the Care Group projects, and the comparison group also includes 1 Care Group project, making it an “impure” comparison. When this Care Group project is removed from the analysis, the estimated decline in mortality is 11% for the remaining 12 non-Care Group projects (personal communication with James Ricca, first author of the original analysis of the 13 child survival projects,<sup>17</sup> July 2015).

Food for the Hungry, another international NGO, implemented a Care Group child survival project funded by the USAID Child Survival and Health Grants Program in 7 districts of Sofala Province in Mozambique between 2005 and 2010 in a total population of 1.1 million people. As shown in Table 2, the project achieved an annual decline in the percentage of undernourished

**FIGURE.** Estimated Decline in the Under-5 Mortality Rate<sup>a</sup> Among 13 Care Group Projects in 8 Countries, 1995–2010



Abbreviations: ARC, American Red Cross; Curam, Curamericas; FH, Food for the Hungry; Guat, Guatemala; Moz, Mozambique; MTI, Medical Teams International; SAWSO, Salvation Army World Service Office; Vur, *Vurhonga*; WR, World Relief.

Projects are listed in chronological order of initiation (from left to right).

<sup>a</sup> Based on the Lives Saved Tool (LiST).<sup>15</sup>

children that was approximately 4 times greater than the underlying secular decline (2.2% versus 0.6%, respectively).<sup>18</sup> The results were accompanied by major increases in the coverage of key child survival interventions related to nutrition (such as rates of exclusive breastfeeding during the first 6 months of life, frequent feeding after 6 months of age, provision of vitamin-A rich and oily foods after 6 months of age, feeding after childhood illness, and vitamin A supplementation), as well as by increased coverage of interventions to prevent and treat diarrhea (such as treatment of drinking water, hand washing, knowledge of how to prepare oral rehydration solution [ORS], and administration of ORS to children with diarrhea).

More recently, the Care Group approach was used in a randomized controlled trial to assess the

effectiveness of a behavioral change communication (BCC) intervention in reducing diarrheal prevalence in a peri-urban setting on the outskirts of Cochabamba, Bolivia.<sup>19</sup> Care Groups were randomly assigned to 1 of 4 interventions: (1) the use of a special water filter (Sawyer PointONE) *without* BCC, (2) a special water filter *with* BCC, (3) BCC *without* the special water filter, and (4) a control arm in which Care Groups were used to promote an intervention unrelated to diarrhea prevention (weekly messages on life skills and attitudes such as household budgeting, valuing children, and environmental stewardship). Over a 6-month period, the 2-week prevalence of diarrhea remained in the range of 40% to 60% in the control arm while in both the Care Group BCC arm and in the Care Group BCC + water filter arm, the prevalence of diarrhea declined to one-fourth of baseline levels

**TABLE 1.** Characteristics and Cost-Effectiveness of 8 Care Group Projects<sup>a</sup>

Care Group Project	Estimated Percentage Reduction in Under-5 Mortality <sup>b</sup>	No. of Beneficiaries <sup>c</sup>	Total Project Cost (US\$) <sup>c</sup>	Average Cost per Beneficiary per Year	Estimated No. of Lives Saved	Cost per Life Saved	Cost per DALY Averted
World Relief/Mozambique, <i>Vurhonga</i> I (1995–1999)	33%	57,277	\$1,811,895	\$7.91	819	\$2,212	\$27.30
World Relief/Mozambique, <i>Vurhonga</i> II (1999–2003)	48%	53,418	\$1,397,531	\$6.54	769	\$1,817	\$60.57
World Relief/Malawi I (2000–2004)	32%	68,917	\$1,333,335	\$4.84	557	\$2,394	\$79.80
World Relief/Rwanda (2001–2006)	29%	54,451	\$1,733,333	\$6.37	676	\$2,564	\$85.47
Plan/Kenya (2004–2009)	26%	110,735	\$2,300,000	\$4.15	826	\$2,785	\$92.82
World Relief/Mozambique, <i>Vurhonga</i> IV (2004–2009)	33%	101,757	\$2,000,000	\$6.56	1,217	\$1,643	\$54.77
World Relief/Malawi II (2005–2009)	28%	72,226	\$2,022,034	\$7.00	537	\$3,773	\$125.77
FH/Mozambique (2005–2010)	30% overall (32% in Area A; 26% in Area B)	219,617	\$3,024,166	\$2.78	6,848	\$441	\$14.72
Average of 8 Care Group projects above	32%	92,300	\$1,956,016	\$5.77	1,531	\$2,204	\$67.65
Average of 13 recent USAID-supported child survival projects <sup>e</sup>	13%						

Abbreviations: DALY, disability-adjusted life year; FH, Food for the Hungry; LiST, Lives Saved Tool; USAID, United States Agency for International Development.

<sup>a</sup> Source of data for the 8 Care Group projects: project final evaluations and personal communication with World Relief, Food for the Hungry, and Plan International child survival staff.

<sup>b</sup> Based on calculations using the LiST tool, uncorrected for underlying secular trends.<sup>15</sup>

<sup>c</sup> Number of women of reproductive age and children 0–59 months of age served by the project.

<sup>d</sup> USAID expenses plus matching funds provided by the implementing NGO.

<sup>e</sup> Ricca, 2005.<sup>17</sup>

**An analysis of Care Group vs. non-Care Group projects found the average rate of decline in under-5 mortality was 1.5 times greater for the Care Group projects.**

(9% to 14%, depending on the arm). The Care Group BCC intervention was as effective as the special water filter intervention alone and as the Care Group BCC + water filter intervention.

Using LiST, a recent analysis has compared the estimated mortality impact of 10 Care Group projects with 7 non-Care Group projects implemented in the same countries. All these projects were funded by the USAID Child Survival and Health Grants Program and were carried out between 1998 and 2010. The Care Group projects

demonstrated an average annual rate of reduction in under-5 mortality that was 1.5 times greater than the rate among the non-Care Group projects (4.8% versus 3.1%, respectively).<sup>20</sup> Overall, the Care Group projects yielded higher increases than the non-Care Group projects in population coverage of all 17 indicators for high-impact interventions. For example, the Care Group projects had more than twice the increase in population coverage compared with non-Care Group projects for antenatal care visits, tetanus toxoid vaccination, multiple micronutrient

**TABLE 2.** Average Annual Rate of Decline in Undernutrition in Care Group Mozambique Project Areas Compared With Mozambique Nationwide, 2006–2010

Location	% of Children < 2 SD Below the Standard Median Weight-for-Age Score		Difference	No. of Years Between Endline and Baseline	Average Annual Rate of Decline
	Baseline (Dates)	Endline (Dates)			
Project areas	26.5% (2006)	16.7% (2010)	9.8 percentage points	4.4	2.2%
Nationwide	20.0% (2003)	14.9% (2011)	5.1 percentage points	8	0.6%

Abbreviation: SD, standard deviations.  
Source of data: Davis, 2013.<sup>18</sup>

supplementation, complementary feeding, hand washing with soap, use of ORS to treat diarrhea, use of oral antibiotics to treat pneumonia, and malaria treatment.

These findings take on additional significance because child survival projects funded by the USAID Child Survival and Health Grants Program (both Care Group and non-Care Group projects) have a documented track record of accelerating under-5 mortality reduction within their project areas over the duration of the projects. Estimates of under-5 mortality impact (using LiST) of 12 of these projects that ended between 2006–2007 have been compared with changes in under-5 mortality measured by DHS in the same countries or regions of those countries.<sup>21</sup> In these countries, there was a national DHS finished within 3 years of project *initiation* and also a DHS finished within 3 years of project *completion*. The analysis demonstrated that the estimated annual under-5 mortality decline for the USAID-funded child survival projects was twice as great as the underlying secular trend in under-5 mortality decline (5.8% versus 2.5%, respectively) across a variety of settings. The results can be thought of as the “typical” results of the projects funded through this mechanism.

As part of the end-of-project evaluations of the Care Group projects, qualitative analyses were carried out in the form of key informant interviews and focus group discussions with project staff and other respondents typically including project beneficiaries, community leaders, and ministry of health (MOH) staff. Care Group Volunteers and beneficiaries have uniformly indicated that Care Groups are an effective delivery mechanism for child survival interventions. Care Groups are also empowering to the Care Group Volunteers. Many

of these volunteers go on to leadership positions in their communities and beyond.

The great majority of Care Group projects that have been implemented so far have independently conducted end-of-project evaluations led by external evaluation consultants. A list of Care Group projects and their final project evaluation reports are publicly available.<sup>22</sup> They all show marked increases in population coverage of key interventions and strongly positive assessments by project beneficiaries, community leaders, Care Group Volunteers, and project staff.

### Cost and Cost-Effectiveness of Care Group Projects

Costs of the initial Care Group projects, which were mostly funded by the USAID Child Survival and Health Grants Program, are known. This, along with the availability of LiST to estimate the number of lives saved according to the change in coverage of key child survival interventions, makes it possible to compute a cost per life saved and a cost per disability-adjusted life year (DALY) averted. Table 1 provides this information for 8 of the early Care Group projects completed in 2010 or earlier.

The average cost per beneficiary (mothers and children 0–59 months of age) per year is in the range of US\$3–\$8, which translates to approximately \$1–\$3 per population of all age groups. So, for example, the annual average cost of the Food for the Hungry/Mozambique Care Group Project was \$600,000 for a population of 1.1 million people, or \$0.54 per capita (for all age groups) per year. This is less than 1% of the \$86 per capita recommended for spending on health services by all countries, recognizing that the poorest countries will need external support to achieve this

**Care Group projects cost, on average, US\$1–\$3 per capita.**

**Care Groups also empower the volunteer health workers.**

goal.<sup>23</sup> (The recommendation is by the Working Group on Health Financing in the Centre on Global Health Security at Chatham House.)

The cost per life saved (as estimated by LiST) is in the range of \$441 to \$3,773, and the cost per DALY averted (again, using LiST and assuming that 30 DALYs were gained for each averted death of an under-5 child) is in the range of \$15 to \$126 (Table 1). It should be noted that the cost per DALY gives a conservative estimate, as it does not include any measure of morbidity improvement. The accepted international standard established by the World Health Organization for a highly cost-effective intervention is a cost per DALY averted of less than the per capita gross domestic product (GDP) for the country or region where the intervention is implemented.<sup>24</sup> The per capita GDP for least developed countries (where almost all Care Group projects have been implemented) is in the range of US\$848 to \$2,046—far above the cost per DALY averted range of \$15 to \$126 for Care Groups.<sup>25</sup>

Few studies of the cost-effectiveness of integrated community-based child survival projects and programs have been published, so comparing these findings with other approaches is a challenge. Table 3 compares cost-effectiveness data for Care Group child survival projects with data from a comprehensive primary health care program in Bolivia,<sup>26</sup> a comprehensive primary health care and hospital program in Haiti,<sup>27</sup> a hypothetical package of key community-based interventions,<sup>28</sup> and Participatory Learning and Action (PLA) groups.<sup>29,30</sup> In terms of cost per life saved and cost per DALY averted, the cost-effectiveness

of Care Group projects compares favorably with that of other approaches for which mortality impact and costs have been measured or estimated.

### Limitations of the Evidence

The evidence presented here has definite limitations. Some of the data are unpublished in the peer-reviewed literature. Even so, the previously unpublished data that have been presented in this paper have been collected in a rigorous fashion. The data were derived from evaluations of USAID Child Survival and Health Grants Program child survival projects and are widely known to be of high quality. The evaluations were carried out under guidelines established by USAID Child Survival and Health Grants Program, which used accepted scientific criteria for indicator definition and measurement of population coverage. The guidelines for indicator measurement and analysis followed many of the standards established by the DHS.

There are surprisingly limited comparative data on the mortality impact and costs of integrated, community-based child survival programs. Thus, the evidence base for Care Group effectiveness, although arising from many sources and using many different criteria of effectiveness, is not as strong as it could be. This is in part because data are lacking in other quarters against which to benchmark these results. Nevertheless, the evidence is important and merits reporting in the peer-reviewed literature as a comparison for further analyses of existing data and for future studies of Care Group effectiveness, which are definitely warranted in our view.

**TABLE 3.** Cost-Effectiveness of Care Group Child Survival Projects Vs. Other Illustrative Integrated, Community-Based Approaches

Project	Cost per Life Saved (US\$)	Cost per Year of Life Saved (US\$)	Cost per DALY Averted (US\$)
Average of 8 Care Group projects reported in Table 1	\$2,204	—	\$68
A census-based, impact-oriented child survival project in Bolivia <sup>26</sup>	\$4,817	\$55	—
A comprehensive and integrated health service delivery system in Haiti <sup>27</sup>	\$3,172	—	\$88
Estimated cost of a package of vitamin A and zinc supplementation, case management of pneumonia, measles immunization, and oral rehydration therapy <sup>28</sup>	Not available	—	\$100
Participatory Learning and Action (PLA) groups <sup>29,30</sup>	Not available	\$33-211	—

Abbreviation: DALY, disability-adjusted life year.

## DISCUSSION

### What Is Required for Care Groups to Be Effective?

The Care Group approach as implemented thus far encompasses several elements, such as a certain number of households under the responsibility of each Care Group Volunteer and a certain number of Care Group Volunteers per Care Group. (See companion article in this issue of *Global Health: Science and Practice* for implementation details about the Care Group approach.<sup>6</sup>)

Are there specific aspects of the Care Group approach that account for its effectiveness, or is it the net sum of the various elements of the Care Group approach rather than any single element that makes Care Groups effective? This is a question that is not readily answered; no firm data exist to support specific hypotheses. However, plausible essential ingredients required for Care Group effectiveness that have been given by those with experience with Care Group implementation include:

- Identification of all target households and delivery of health education to all households
- Peer-support counseling and modeling of key behaviors by volunteer women selected by their peers (who are more likely to be “hubs” in their social networks), resulting in community-wide uptake of new behaviors and changes in community norms
- Well-designed lessons provided in small “drips” along with visual aids such as flip charts to assist the low-literacy Care Group Volunteers in sharing key practices (or behaviors) with their neighbors
- The iterative empowering nature of Care Groups, which meet every 2–4 weeks and support individual Care Group Volunteers to learn progressively how to effectively promote change with those in their catchment areas (and how to review deaths and what could be done to prevent future deaths)
- The social support the Care Group Volunteers provide to each other that is motivating and provides positive social pressure to do things well
- A combination of some or all of the above, or perhaps even a synergistic effect of some or all of the above

Exploring the relative importance of these elements is basically “virgin territory” for research regarding how and why community-based programming is effective (or not). A call has recently gone out for a better understanding of the mechanisms that account for the effectiveness of participatory women’s groups.<sup>31</sup>

Regarding the second plausible reason listed above (peer-support counseling and modeling of key behaviors), a recent groundbreaking cluster randomized controlled trial compared how different methods of targeting of potential influencers in communities affected, in turn, the influencers promoting 2 health behaviors—chlorine for water purification and multivitamins to prevent micronutrient deficiencies—to their neighbors.<sup>32</sup> Villages were randomized (separately for each intervention) to 1 of 3 targeting methods, introducing the interventions to samples of either: (1) randomly selected villagers, (2) villagers with the most social ties (i.e., the largest “hubs” in the social network), or (3) “nominated friends” of random villagers (i.e., “minor hubs” in the social network). Targeting nominated friends (i.e., minor hubs in the social network) led to a 12.2% increase in adoption of the nutritional intervention compared with random targeting (95% CI=6.9, 17.9) while targeting the *most* highly connected individuals (i.e., the major hubs in the social network) produced no greater adoption of either intervention compared with random targeting. This may be relevant to explaining the available evidence of Care Group effectiveness since Care Group Volunteers are nominated and chosen by a group of about 12 of their neighbors. These volunteers are similar to the “minor hubs.”

A “realist synthesis” of the available evidence regarding the effectiveness of the Care Group approach might be useful as a further analysis. This type of synthesis would involve “accounting for context as well as outcomes in the process of systematically and transparently synthesizing relevant literature,”<sup>33</sup> with a focus on understanding the mechanisms by which an intervention works (or not).<sup>34</sup> Some of the contextual features of Care Group implementation that seem important but have not been mentioned above include the following:

- The extensive amount of time spent by the Care Group Volunteer with each beneficiary mother month by month

**Peer-to-peer counseling and modeling of key behaviors is a key ingredient of the Care Group approach.**

**Care Group Volunteers are given minimal workloads (usually 3–4 hours a week) to avoid overburdening them.**

- The engagement of beneficiaries in the selection of Care Group Volunteers
- The organization of beneficiaries into small, interactive groups that meet often and have close linkages with community leaders and health facility staff
- The minimal workloads of Care Group Volunteers (usually 3–4 hours per week) that avoid overburdening them and that enables them to perform their assigned tasks well
- The conduct of rapid formative research to select key behaviors and their determinants and to develop educational messages based on this research

We are not aware of any studies that measure the amount of time a community-level worker spends on average with each woman in the project. For one Care Group project (the Food for the Hungry Care Group Project in Mozambique<sup>18</sup>), we have estimated that each beneficiary mother spent 3.3 hours per month with her Care Group Volunteer (personal communication with T. Davis, Senior Director of Program Quality Improvement, Food for the Hungry, July 2010). We think this is a reasonable estimate for other Care Group projects as well.

It is unusual for other community health worker (CHW) programs to have a case load of only 10–12 households and for the CHW to regularly visit each household—and to visit each household twice a month. Most other programs make routine visits once a month at the most to a larger number of households. In some cases, this is possible to achieve, such as in Mali where CHWs working with the United Nations Children’s Fund’s (UNICEF’s) Accelerated Strategy of Child Survival and Development are responsible for 35 households,<sup>35</sup> and in Nepal where Female Community Health Volunteers are responsible for 50 households,<sup>36</sup> and in Brazil where Community Health Agents are responsible for 150 households.<sup>37</sup> However, in many cases it just is not practical or possible for a CHW to visit each household in his/her catchment area each month. For instance, in Eritrea, Kenya, Mozambique, and Zimbabwe, CHWs provide community case management for up to 500 households, and in Ethiopia, Malawi, and Zambia for up to 1,000 households.<sup>38,39</sup>

Such an analysis goes beyond the scope of this paper but could serve as a fruitful approach to better appreciate the conditions and contexts

that contributed to the effectiveness of the Care Group approach as well as the conditions and contexts that would be needed in order to achieve effectiveness of the Care Group approach if implemented by MOHs at scale. The specification of elements of the Care Group approach that we think are important in explaining effectiveness, as described above, is a beginning attempt in this direction.

### **Should Care Groups Be Incorporated Into Government Health Programs?**

In spite of the impressive accumulated evidence regarding the effectiveness of Care Groups as a community-based intervention delivery system, the projects employing this system have all ended, unfortunately, once external donor support ended. However, NGOs are using new sources of funding—from DFID to the World Bank—to implement Care Group projects, and national NGOs are beginning to implement the approach as well. Furthermore, there is considerable anecdotal evidence as well as evidence from a follow-up survey in one project that Care Group Volunteers remain active by meeting as a Care Group and visiting the homes in their catchment area for at least several years following the end of external funding. Nonetheless, there has not yet emerged a clear approach to implementing and sustaining the Care Group approach in MOH delivery systems. This is because effective Care Group implementation requires a small number of well-trained and well-supervised Facilitators/Promoters who can focus their attention to working with Care Group Volunteers, and so far no MOH has dedicated any of its peripheral staff to carry out this task exclusively on a full-time basis.

Before MOHs are willing to do this, the current evidence regarding Care Group effectiveness will have to be disseminated, endorsement from global policy influencers will be needed, and more evidence may be necessary. Some think that that evidence will need to be in the form of controlled trials. Each controlled trial would have to determine how many interventions to include. Another school of thought is that Care Groups have proven that they are an effective vehicle for lifesaving interventions and that the basic effectiveness question has been answered. Therefore, new evidence needs to focus on how to maximize the use of this vehicle and/or on how to combine its organizing processes with other similar proven

approaches such as PLA women's groups. MOHs may be more interested in processes for packaging sets of community-based health interventions defined in their context and testing how far this integration can go, with emphasis on equity and sustainability of the model. In addition, operations research projects modeled after the Concern Worldwide/Burundi project,<sup>40</sup> described in the companion paper in this series,<sup>6</sup> will be needed to document how the Care Group approach might be integrated effectively and sustainably into existing MOH systems through various measures (including partnerships and contracting). In addition to meeting the requirements for effective Care Group implementation specified earlier in this paper and of having MOH staff members serve as Care Group Facilitators/Promoters, an effective Care Group project would need to have at a minimum a tight supervisory structure, highly motivated staff, and transport support to enable the staff to interact with each other and with the Care Groups.

### Next Steps

The Care Group approach, as implemented by strong international NGOs with adequate funding and in collaboration with the MOH and existing health services, has achieved an impressive record of success in terms of enthusiasm for the approach among implementers and beneficiaries as well as in terms of effectiveness (in expanding coverage of key child survival interventions, in mortality impact, and in cost-effectiveness). Unfortunately, the experiences and evidence have not yet been widely disseminated and are not well-known. The current evidence of effectiveness is sufficiently robust to justify: (1) further rigorous evaluations of the Care Group approach as implemented by NGOs in collaboration with government health programs, (2) further specification of the leadership, management, and support functions needed to implement the Care Group approach within government programs, (3) testing the effectiveness of the Care Group approach when implemented by government health programs on a pilot basis, and, assuming the results are sufficiently promising, (4) implementing and rigorously assessing the effectiveness of the Care Group approach at scale under routine field conditions in government health programs.

The minimum requirements and necessary conditions required for effective functioning of the Care Group approach in government health systems need to be defined. We have made a

first attempt at this earlier in this paper and in the companion paper of this 2-part series. If the Care Group approach can be successfully integrated into government health systems, it will be important to test the effectiveness of the approach at scale. Experience with implementing the Care Group approach in urban slum settings is also needed. Given the expertise that NGOs have developed in working effectively with communities, it might turn out to be the case that long-term public-private partnerships between MOHs and NGOs may be essential for achieving sustainable effectiveness of the Care Group approach at scale.

Care Groups are not the only possible approach conceivable for educating and empowering women to adopt healthy behaviors. However, the Care Group approach is a simple and practical approach for reaching all targeted households with health promotion messages that takes advantage of peer-to-peer counseling—important elements, we believe, for strengthening the population coverage and overall effectiveness of maternal and child health programs. We encourage more experience and evaluation not only of the Care Group approach but also of other similar community-based approaches that use women's groups in an empowering way. Over time, with more experience and rigorous evaluations of these types of approaches, stronger programs that are cost-effective will emerge.

### CONCLUSIONS

When implemented by strong international NGOs with adequate funding, Care Groups appear to be a promising approach for expanding coverage of key maternal and child interventions and for accelerating reductions in under-5 mortality and potentially maternal mortality as well—at a per capita cost of less than 4% of the current recommendation for what countries should be spending for health care services. The approach also has great potential for controlling HIV, tuberculosis, and malaria. Since the Care Group approach has been applied by many different organizations in a wide variety of settings across the world, the field experience is now extensive, and evidence of effectiveness is accumulating. More rigorous testing of the Care Group approach is now needed, as implemented by NGOs and also as implemented by government health programs. The conditions needed for Care Group effectiveness need further specification, and the Care Group approach should be implemented within

government health systems on a small pilot scale to assess their feasibility and effectiveness and then, if promising, tested at scale. Assessing different ways of engaging NGOs in the process of government implementation may prove important as well.

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## ORIGINAL ARTICLE

# Task Shifting Provision of Contraceptive Implants to Community Health Extension Workers: Results of Operations Research in Northern Nigeria

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**With training and supportive supervision, male and female Community Health Extension Workers (CHEWs) in Nigeria safely and effectively provided contraceptive implants, and virtually all clients said they were satisfied. Most CHEWs achieved competency after 5 client insertions. However, the CHEWs provided only an average of 4 insertions per health facility per month. Realizing the true potential of providing implants calls for a context with dedicated providers and robust outreach.**

## ABSTRACT

**Background:** Contraceptive use remains low in Nigeria, with only 11% of women reporting use of any modern method. Access to long-acting reversible contraceptives (LARCs) is constrained by a severe shortage of human resources. To assess feasibility of task shifting provision of implants, we trained community health extension workers (CHEWs) to insert and remove contraceptive implants in rural communities of Bauchi and Sokoto states in northern Nigeria.

**Methods:** We conducted 2- to 3-week training sessions for 166 selected CHEWs from 82 facilities in Sokoto state (September 2013) and 84 health facilities in Bauchi state (December 2013). To assess feasibility of the task shifting approach, we conducted operations research using a pretest–posttest design using multiple sources of information, including surveys with 151 trained CHEWs (9% were lost to follow-up) and with 150 family planning clients; facility observations using supply checklists (N=149); direct observation of counseling provided by CHEWs (N=144) and of their clinical (N=113) skills; as well as a review of service statistics (N=151 health facilities). The endline assessment was conducted 6 months after the training in each state.

**Results:** CHEWs inserted a total of 3,588 implants in 151 health facilities over a period of 6 months, generating 10,088 couple-years of protection (CYP). After practicing on anatomic arm models, most CHEWs achieved competency in implant insertions after insertions with 4–5 actual clients. Clinical observations revealed that CHEWs performed implant insertion tasks correctly 90% of the time or more for nearly all checklist items. The amount of information that CHEWs provided clients increased between baseline and endline, and over 95% of surveyed clients reported being satisfied with CHEWs' services in both surveys. The study found that supervisors not only observed and corrected insertion skills, as needed, during supervisory visits but also encouraged CHEWs to conduct more community mobilization to generate client demand, thereby promoting access to quality services. CHEWs identified a lack of demand in the communities as the major barrier for providing services.

**Conclusion:** With adequate training and supportive supervision, CHEWs in northern Nigeria can provide high-quality implant insertion services. If more CHEWs are trained to provide implants and greater community outreach is conducted to generate demand, uptake of LARCs in Nigeria may increase.

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## INTRODUCTION

Among family planning methods, long-acting reversible contraceptives (LARCs), consisting of intrauterine devices (IUDs) and implants, have a

proven record of high effectiveness and high user satisfaction,<sup>1-3</sup> and they are not dependent on user adherence.<sup>4,5</sup> Their reversibility also makes them suitable for a vast number of women who have not completed their families.<sup>2</sup> However, despite the many advantages of LARCs, contraceptive implants, which are among the most effective LARCs,<sup>3</sup> make up a very small proportion of the world's contraceptive use.<sup>6</sup> In Nigeria, only 0.3% of women use implants.<sup>7</sup> Among the 11% of Nigerian women who reported use of any modern method of contraception, injectables, oral contraceptives, or male condoms were most common.<sup>7</sup>

A study that examined 27 years of international data shows that modern contraceptive use increases with the rising number of methods available to a population.<sup>8</sup> In Nigeria, most family planning clinics offer a limited method mix, namely oral contraceptive pills, injectables, and condoms. With 16% of women in Nigeria having unmet need for family planning,<sup>7</sup> providing access to a variety of contraceptive methods may increase the contraceptive prevalence rate (CPR). Access to LARCs is limited in various settings due to several factors such as women's inadequate knowledge of LARCs, lack of LARC commodities in health facilities, and inadequately skilled health care providers to render the services.<sup>9</sup>

Of these barriers, the dearth of skilled providers capable of providing LARCs has been shown to be one of the most difficult to address.<sup>10</sup> Evidence suggests that in settings with an insufficient number of skilled health care providers, task shifting of certain services—that is, delegating tasks to less specialized health workers—has yielded positive results.<sup>11-14</sup> For example, in Ethiopia, health extension workers were trained to provide implants, and implants were more available and within the reach of many women as a result. The project was estimated to have averted 978 maternal deaths over its 3-year duration.<sup>11</sup>

Shifting provision of contraceptive implants to lower-cadre providers such as community health extension workers (CHEWs) may be an option in addressing some of the pressing reproductive health needs in Nigeria. The purpose of this article is to describe results of an operations research study that assessed the feasibility of task shifting provision of contraceptive implants to CHEWs in 2 states of northern Nigeria and to examine facilitating factors

and challenges to CHEWs providing implant insertions.

## INTERVENTION DESCRIPTION

The Targeted States High Impact Project (TSHIP), funded by the United States Agency for International Development (USAID), and the State Primary Health Care Development Agency (SPHCDA) implemented a pilot intervention to increase access to and use of contraceptive implants among rural community members in Nigeria's Bauchi and Sokoto states. The intervention aimed to reduce unmet need for family planning in the pilot areas, improve method mix at health facilities, increase couple-years of protection (CYP), and ultimately increase the CPR in the 2 states. The intervention focused on strengthening the capacity of CHEWs to provide implants through training and supportive supervision and to document the services provided. The intervention also sought to improve commodity security and logistics systems, create demand, improve access to quality implant services, and strengthen the referral system.

## Training of CHEWs

CHEWs in Nigeria complete 2 to 3 years of formal health-related training depending on their education level at enrollment.<sup>15</sup> They are full-time salaried employees in their health facilities. CHEWs were introduced primarily for community-based services (80% of their time) and some clinic-based services (20% of their time). However, as a result of acute shortages of nurses, midwives, and physicians in health facilities, the situation has been reversed with CHEWs spending 60% to 80% of their time in health facilities to provide services. For family planning services, CHEWs provide condoms, oral pills, injectables (in sites where injectables training has occurred), and emergency contraception.<sup>15</sup>

Family planning master trainers from the SPHCDA, with technical support from TSHIP's family planning technical advisors, conducted a 3-week training for CHEWs from Sokoto state and a 2-week training for CHEWs in Bauchi state (the latter was shortened due to a health workers' strike). The training aimed to provide the CHEWs with skills in administration of contraceptive implants—both Implanon (1-rod implant) and Jadelle (2-rod implant). Experienced nurses and midwives served as master trainers. Given the relatively lower level of education of the CHEWs compared with physicians, nurses, and midwives,

**Modern contraceptive use increases with the rising number of methods available to a population.**

**Task shifting provision of contraceptive implants to lower-level health workers may improve access to and use of the method.**

it was important to assure that their knowledge, skills, and attitudes with respect to implant service delivery was optimal. The training for CHEWs was organized into three 7-day phases:

1. Modular teaching/learning sessions
2. Practicum sessions on implant insertions and removals on arm models
3. Supervised insertions on actual clients

In the 2-week course in Bauchi, both the didactic sessions and practice sessions on anatomic models were completed in the first week, while trainees practiced insertions on clients in the clinic during the second week. Modules focused on insertion and removal of implants and infection prevention using the competency-based approach. Other modules on interpersonal communication, balanced counseling strategy techniques, commodity logistic management system (CLMS), and using registers for recordkeeping were also essential training elements. The modules were tailored to adult learners and used participatory facilitation techniques. (See [supplementary material](#) for training materials.)

In the practicum sessions that followed, participants acquired implant insertion and removal skills under supervision. The learner's guide developed for the training was available as a supportive reference. The master trainers observed each CHEW providing at least 15 implant

insertions and removals on the arm model, and performance was documented using the implant procedure checklist (see [supplementary material](#)). A written pre- and post-test assessed the knowledge and skills of the CHEWs and provided insight into their level of apprehension as well as areas for improvement. After achieving competency of implant insertion and removal on the arm models, CHEWs proceeded to insert implants under supervision on actual clients in selected facilities.

### Supportive Supervision

At the end of the training sessions, the trainees and trainers jointly developed a 6-month post-training supportive supervision plan. During this period, trainers would visit trained CHEWs at health facilities to confirm they were providing services in accordance with approved standards, and the trainers would provide remedial training as needed. This period of supportive supervision also provided CHEWs the opportunity to strengthen their skills on implant insertion. We used the procedure checklists to assess skill maintenance during post-training follow-ups.

To create community awareness and increase client flow for implant uptake at various sites, trained CHEWs, in collaboration with Ward Development Committee (WDC) members and Community Based Health Volunteers (CBHVs), conducted monthly community mobilization. This helped ensure that each CHEW was provided with an adequate number of insertions under supervision. All insertions prior to certification were made in the presence of supervisors. When there were no clients during supportive supervision visits, skills were observed on anatomic models, and additional on-the-job training was provided as needed. CHEWs were certified after inserting 15 implants at their respective sites.

At the end of 6 months, the trained CHEWs were linked to the state and local government area (LGA) integrated supportive supervision team for continuous service improvement. As LGA maternal and child health (MCH) coordinators, the government supervisors were previously trained on LARC methods. We provided them with a brief training to refresh their skills on implant insertion and removal as well as on supervision.

**CHEWs were certified as competent to provide implants after inserting 15 implants.**



Nafisatu Manu Omar/USAID Targeted Stated High Impact Project (TSHIP)

A Community Health Extension Worker (CHEW) at Dorowa Dispensary, Dambam LGA, in Bauchi state, practices inserting contraceptive implants on an arm model. After achieving competency on the arm model, CHEWs inserted implants under supervision on actual clients.

### Commodity Security and Logistics Support

The pilot intervention included ensuring adequate availability of implants (Implanon and

Jadelle) in the states' commodity stores. Monthly stock level inventories informed the timely placement of commodity orders and the delivery of implants to the 2 states. An emergency stock replenishment system that linked CHEWs with the LGA MCH coordinators was also established to promote an adequate commodity supply.

### **Demand Creation Activities**

WDC members, CBHVs, and CHEWs conducted sensitization activities and mobilization meetings to increase knowledge about contraceptive implants and to promote awareness and acceptance among men and women of the implant services provided by CHEWs. These activities were a part of regular family planning outreach conducted in the communities. In addition, periodic advocacy visits were made to inform key stakeholders and community gatekeepers such as religious leaders of the benefits of family planning. Demand creation activities started prior to the beginning of and continued throughout the intervention.

Implants were provided to clients free of charge. Clients were asked to pay for some of the materials needed for implant insertions.

### **Provision of Implants by CHEWs Through Multiple Outlets**

Trained CHEWs provided quality implant services to women through fixed clinic and mobile outreach outlets. CHEWs adhered to approved standards such as the World Health Organization's medical eligibility criteria and national family planning/reproductive health service delivery protocols.

### **Strengthening Referrals System**

A 2-way referral system was established between trained CHEWs from the participating health facilities and existing primary and secondary health care facilities where midwives and doctors also provided implant services. Participating CHEWs were able to refer clients to these facilities for removals, in case of complications, and to receive feedback on the services provided and on clinical outcomes. Although CHEWs were trained in implant removal, they did not have an opportunity to practice removal skills themselves during the pilot due to low client demand for removals. Instead, we encouraged CHEWs to

accompany clients requesting removal services to experienced service providers in order to gain more experience.

## **METHODS**

### **Study Purpose and Objectives**

Operations research was conducted to measure and document the feasibility and impact of the CHEWs' task shifting pilot intervention and to report on the key lessons learned for future programming. The main objectives for the study included:

1. Assess the knowledge and skills of trained CHEWs in the provision of implants
2. Determine satisfaction of clients with services provided by CHEWs
3. Assess the extent to which the mechanisms to support CHEWs' provision of implants functioned as intended
4. Determine facilitators and challenges encountered by CHEWs in the provision of implants

### **Study Design and Sampling**

We used a pre- and post-intervention study design. A random sample of 84 health facilities in Bauchi and 82 health facilities in Sokoto was selected from a sampling frame of 453 and 536 health facilities in each state, respectively. From each of the sampled facilities, 1 CHEW was randomly selected to participate in the study (166 total). To be eligible for the study, CHEWs already had to be providing family planning services in the health facility where they practiced. In addition, 1 family planning client per health facility who received services from the CHEW was randomly sampled for exit surveys. Clients were selected from women who agreed to receive implants. When no implant acceptors were available on the day of the survey, we selected respondents for exit surveys among clients who received other family planning services from the CHEW. At endline, data were collected from 151 health facilities.

### **Data Collection**

The study involved quantitative data collection from multiple sources, including surveys with CHEWs, client exit questionnaires, and supply checklists. We also asked CHEWs open-ended

questions to examine facilitators and barriers that affected provision of implants. Additional data were gathered through a review of service statistics at health facilities and from observations of the counseling and clinical skills of CHEWs when providing implant services at health facilities.

The study protocol and all instruments were approved by the Bauchi and Sokoto State Health Research Ethics Committees and the Health Media Lab Corporation in Washington, DC. Written or verbal informed consent, depending on literacy status, was obtained from each participant.

Provider training and baseline data collection took place in September 2013 in Sokoto and in December 2013 in Bauchi. Endline data were collected 6 months later. Data were collected by nurses and midwives who received a 3-day training on the study methodology and on interviewing, observation, and documentation skills, as well as on ethics in health research.

**Most CHEWs were certified in implant provision within 6 months of training.**

### Data Analysis

We triangulated data from the different data sources to provide a full picture of the feasibility of using CHEWs to provide implants to women in primary health care facilities. Frequency distribution and binary analysis were conducted using Epi Info 7. Monthly analysis of service statistics was conducted for detecting trends in selected indicators.

## RESULTS

### Background Characteristics of CHEWs

The CHEWs selected for the intervention (N=166) worked in basic and comprehensive primary health care facilities (58%), MCH units (23%), and dispensaries (19%). Some CHEWs (9%) were lost to follow-up due to their relocation to other communities or their attending college. At baseline, the median number of years working as CHEWs was 9 years (range, 1 to 35 years), and 59% of CHEWs were females. Over 70% reported they had received training in basic family planning and reproductive health in the 5 years prior to the study (72.2%, N=162). Of the 166 CHEWs in the sample, 31% received training in family planning/reproductive health counseling, 60% in provision of oral contraceptive pills, 56% in injectable provision, 4% in insertion of IUDs, and 1% in implant insertion. Almost all CHEWs (98%) at baseline assessment reported a desire to have a refresher course in family planning. While almost all CHEWs at endline reported being able

to apply the knowledge and skills acquired during implant insertion training (95%, N=148), over 80% felt that they needed a refresher course on family planning.

Baseline data indicated that most of the health facilities where CHEWs worked (N=166) provided pills (81%), injectables (80%), and male condoms (65%), with fewer providing female condoms (31%), and especially implants (7%) and IUDs (3%). LARCs were provided by a higher-level provider in health facilities. Family planning services were offered 5 or more days a week (88.3%, N=137) at baseline.

### Change in CHEWs' Implant Knowledge and Skills

The majority (94.7%, n=143) of CHEWs received certification in implant insertion within 6 months after training. The percentage of CHEWs stating they were able to correctly insert implants without assistance increased from 6% at baseline (N=166) to 93% at endline (N=149) ( $P<.001$ ). Most CHEWs who reported they were able to insert implants (n=137) rated their skills to do so as "very good" (49%) or "good" (37%). About 14% rated their skills as "excellent." Qualitative data analysis supports this, with most CHEWs reporting they were satisfied with their skills in implant insertion and had no difficulties or complications. Some noted that with time and with more opportunities to practice, their skills have improved.

Observation of CHEWs' counseling skills indicated statistically significant increases ( $P<.05$ ) from baseline to endline on 10 of the 11 observation items that addressed respectful and complete information sharing (Table 1). Endline observations confirmed that CHEWs provided accurate information on all topics related to effectiveness of contraceptive implants. The majority of CHEWs provided information on contraceptive implants (86%), explained that the method does not protect against sexually transmitted infections (STIs) including AIDS (61%), provided information about duration of protection from pregnancy (84%), gave accurate information about side effects (83%), discussed the need for the client to come back to the health facility if she experienced side effects with use (85%), reviewed the implant information card with the client (73%), provided the client with the implant information card (74%), provided the client with information on removal (83%), encouraged the client to tell friends about LARC insertion service availability at the health facility (75%),

**TABLE 1.** Results of Observation of CHEWs' Counseling Skills, Bauchi and Sokoto States of Nigeria, 2013–2014 (%)

Checklist Item	Baseline (N = 164)	Endline (N = 144)
Welcomed the client in a friendly manner	99	100
Provided information on different types of contraceptives (to new clients)	70*	96*
Asked open-ended questions	76*	88*
Encouraged client to ask questions	67*	90*
Treated client with respect	95*	100*
Saw client in private	77*	94*
Discussed a return visit	78*	89*
Asked client her concerns with any method	62*	83*
Used visual aids	31*	72*
Used client record	59*	82*
Assured client of confidentiality	52*	91*

Abbreviation: CHEW, community health extension worker.

\* $P < .05$ .

Source: Observation checklist for counseling and clinical procedures.

provided services in a respectful, professional manner (85%), and asked the client if she agreed to receive the implant (84%).

Clinical observation of 113 CHEWs' doing implant insertions at endline documented high-quality service provision. Correct task performance was observed 90% of the time or more for 16 of 19 checklist items. The remaining 3 items (hand washing, asking clients to wait post-procedure, and decontamination of used items) were performed 85% of the time or more.

### Background Characteristics of Clients

We conducted exit surveys with 163 family planning clients at baseline and 150 clients at endline. Demographic characteristics of the clients were similar at both baseline and endline, with the exception of occupation and age of the youngest child. The respondents, on average, were 30 years old, had 4 children, and wanted to have 3 or 4 more children. At both assessments, over 90% of the respondents were Muslims, over 95% were married, over 75% wanted to have more children, and about 60%

lacked formal education. There were more full-time housewives and fewer petty traders in the endline group than the baseline group (for housewives, 80% at endline vs. 43% at baseline,  $P < .05$ ). On average, the age of the youngest child of the clients at endline was lower than the age of the youngest child at baseline (1.9 vs. 3.6 years,  $P < .05$ ).

### Client Satisfaction With CHEWs' Services

Over 95% of family planning clients at both baseline and endline reported being satisfied with the services provided on the day of the exit survey and stated that CHEWs treated them well, were friendly during the appointment, and were responsive to clients' needs. Between baseline and endline, statistically significant increases in client satisfaction measures were documented for the percentage of respondents who felt their family planning needs were met (from 90% to 99%), who were satisfied with the amount of information provided on contraceptive methods (from 65% to 88%), and who would recommend the health facility to a friend (from 94% to 99%) ( $P < .05$ ) (Table 2).

**CHEWs performed implant tasks correctly 90% of the time or more for nearly all observation checklist items.**

**Virtually all clients were satisfied with the services provided by CHEWs.**



Nafisatu Manu Omar/USAID Targeted Stated High Impact Project (TSHIP)

A family planning client from Bauchi state receives counseling on Jadelle implants by a Community Health Extension Worker (CHEW). Observation of counseling sessions confirmed that CHEWs provided accurate and complete information.

In addition, the amount of information provided by CHEWs to clients about their chosen method increased between the 2 assessments. For example, a statistically significant increase was noted in the percentage of clients at endline who reported that CHEWs described side effects (from 79% to 95%) and told clients what to do if they had any problems (from 83% to 97%) (Table 3). There were no significant increases on 2 measures—explaining how to use the method effectively and when to return for a follow-up visit—but levels were already very high at baseline (97% and 96%, respectively).

**Some facilities did not have all the supplies needed for implant insertion, such as sterile gloves.**

### Uptake of Implants

The proportion of health facilities that provided implants increased from 7% at baseline (N=166) to 91% (N=150) at endline ( $P<.001$ ). According to service statistics, a total of 3,588 implants were inserted at 151 health facilities by endline (2,723 Implanon and 865 Jadelle insertions), or 4 implants per health facility per month. Over a period of 6 months, 10,088 CYP were generated through implant insertion.

Almost 90% of clients at endline did not pay for the services provided (89%, N=146). Those who paid reported paying for hospital cards and disposable materials and felt those expenses were affordable.

## Performance of Structural Support Mechanisms

### Training

Most CHEW respondents were satisfied with the training. In their responses to open-ended questions, CHEWs noted a good balance between theory and practice and a high quality of instruction, and they said they were provided with enough opportunities to practice. They also said their knowledge and skills had improved. Participants were happy to learn about the reproductive system and other contraceptive methods during the training. Also, they were thrilled to be able to practice on actual clients. Some respondents said they needed more time for practicing their skills so that “practical skills are perfected.” Knowledge based on the post-test and skills assessment based on observations did not differ significantly between participants completing the 2-week vs. the 3-week training.

### Supply System

According to facility observations using supply checklists (N=149), implants were available in 90% of all facilities on the day of the endline survey. Guidelines and protocols for inserting implants were available in two-thirds of the facilities (67%). Nearly all (90%) of the health facilities kept clients’ records in a secured area. Availability of supplies necessary for implant insertions improved significantly from baseline to endline ( $P<.001$ ). Nevertheless, only about two-thirds of all surveyed health facilities at endline had the supplies necessary for implant insertions (e.g., xylocaine, sterile gloves, adhesive bandages).

According to responses to open-ended questions, CHEWs reported using daily consumption registers, national health information system monthly summary forms, and family planning review meeting summary forms. CHEWs report monthly to the MCH in the LGA and every 2 months to the CLMS review meeting. CHEWs reported receiving their supply of implants from MCH coordinators and resupply at the review meetings. If needed, they could use emergency orders, in which case supplies would be provided within 2 days. In closed-ended survey questions, only 8% of CHEWs reported stock-outs of implants in the last 6 months (N=134), which could be resupplied in 1 week or less in over 80% of cases.

### Supportive Supervision

Essentially all (95%; N=145) of the CHEWs who received training on contraceptive implants at

**TABLE 2.** Client Satisfaction With Services Provided by CHEWs, Bauchi and Sokoto States of Nigeria, 2013–2014

Assessment	Baseline, % (N)	Endline, % (N)
Satisfied with the services provided today	99 (156)	100 (146)
Felt that needs for family planning were met	90 (159)*	99 (144)*
Thought that the right amount of information was provided on family planning method of choice	65 (153)*	88 (144)*
Thought other clients could hear what clients said	27 (148)	20 (142)
Believed the information shared with the provider would be kept confidential	86 (152)	93 (145)
Had any questions	46 (163)	56 (150)
The CHEW let clients ask the questions	90 (68)	98 (82)
The CHEW responded to questions to clients' satisfaction	96 (53)	97 (78)
Stated that CHEW treated them well	99 (163)	99 (145)
Stated that CHEW was friendly during the appointment	97 (163)	99 (146)
Stated that CHEW was attentive and responsive to clients' needs	99 (163)	100 (145)
Satisfied with CHEWs' activities	98 (163)	100 (144)
Would recommend a friend to receive family planning services at this health facility	94 (156)*	99 (146)*

Abbreviation: CHEW, community health extension worker.

\* $P < .05$ .

Source: Client exit surveys.

baseline also received supervisory and monitoring visits in the post-training time frame. The number of visits ranged from 1 to 8 over a 6-month period. According to CHEWs' responses to open-ended questions, supervisors observed implant insertions and made corrections if needed, answered questions, and provided feedback on counseling. For the CHEWs who had not done any insertions, supervisors gave advice on how to increase client flow. Thus, they encouraged CHEWs to work more on community mobilization, provide more counseling, and sensitize women in the community.

The majority of CHEWs reported the supervision and feedback to be very helpful. According to their reports, visits encouraged them to perform better and provided opportunities to communicate their problems and receive support. Most CHEWs received feedback during and immediately after the supervision visit. However, a few reported not receiving any feedback. To improve supervision, CHEWs recommended more

frequent supervision visits—once or twice every month—to provide feedback during and after each visit. CHEWs also recommended providing supervisors with logistics support, e.g., transportation to hard-to-reach areas.

### CHEWs' Satisfaction With Providing Implant Services

CHEWs' responses to open-ended questions provided information on changes in their workload due to task shifting, facilitating factors and challenges to their providing implants, and suggestions for making their work sustainable in the community. Most of CHEWs who worked on implant insertions reported there was no substantial increase in workload, although they reported having more responsibilities and duties such as filling out reporting forms. Regardless, CHEWs stated they enjoyed their service to the community. CHEWs felt privileged for receiving this opportunity, found inserting implants

**Most CHEWs indicated there was no substantial increase in workload with the addition of implant insertion responsibilities.**

**TABLE 3.** Information CHEWs Provided to Clients on Their Chosen Contraceptive Method, Bauchi and Sokoto States of Nigeria, 2013–2014

Information Provided by CHEWs	Baseline, % (N)	Endline, % (N)
Explained how to use the method effectively	97 (160)	99 (145)
Described possible side effects	79 (159)*	95 (145)*
Told what to do if clients have any problems	83 (157)*	97 (146)*
Explained that only condoms provide protection against STIs	54 (159)*	71 (143)*
Told how many years of protection against pregnancy the method provides	82 (158)*	97 (144)*
Told when to return for a follow-up visit	96 (158)	92 (144)

Abbreviation: CHEW, community health extension worker; STIs, sexually transmitted infections.

\* $P < .05$ .

Source: Client exit survey.

interesting and satisfying, and felt comfortable implementing this new task. While the task added extra work for CHEWs, they were happy to gain new experience, skills, and knowledge. Also, they felt honored that women who came for implant insertions trusted that CHEWs would do a good job. Some stated that now they are respected more by community members.

Among the main facilitating factors in identifying implant clients, CHEWs noted community mobilization efforts, advocacy work, and work of volunteers to increase women's awareness on the method. Among other facilitators of increased uptake, CHEWs cited consistent availability of implants and provision of the method free of charge.

CHEWs remarked that their main challenges included low acceptance of implants by community members due to misconceptions (e.g., "implants cause infertility," "they can't be removed from the body," "they can't be found after insertion since they move inside the body") and religious beliefs against family planning in general. Also, some women were used to receiving injectables and were reluctant to try a new contraceptive method. Fear of side effects such as headache, spotting after insertion, irregular periods, and the necessity to purchase some of the consumables were stated as other challenges.

In terms of additional support needed to administer implants, CHEWs expressed a strong desire for training and retraining. They also suggested training more staff in implant insertion to increase the number of available service providers.

CHEWs offered suggestions for making their work sustainable in the community. Most suggestions related to increasing demand for implants in the community via community mobilization (Box). Other suggestions included providing high-quality services, ensuring regular supply of free implants and all materials for implant insertion, and offering clients small gifts or incentives. Family planning clients at endline (N=150) recommended the following ways to encourage more women in the community to receive family planning services: increasing women's awareness on family planning service availability (85%), receiving encouragement from religious leaders (45%), and having CHEWs communicate with husbands (41%).

## DISCUSSION

Shifting provision of contraceptive implants to CHEWs in northern Nigeria was successful—clinical observations showed that CHEWs consistently followed the standard protocols and consequently delivered high-quality services, confirming previous findings from other countries.<sup>11</sup> In addition, although the CHEWs reported a slight workload increase as a result of the task shifting intervention, they were satisfied with their performance and results of their work. CHEWs rated their skills in implant insertions as high and felt confident in performing the procedure. We also found that CHEWs' counseling skills improved over time and that they retained these skills throughout the duration of the study. Furthermore, the CHEWs'

**CHEWs in northern Nigeria were able to provide high-quality implant insertion services.**

reported increased job satisfaction, which was directly associated with their added responsibility of implant insertion. Their satisfaction is a welcome development in overall health worker motivation and could extend to other aspects of the CHEWs' work.

This study provides evidence in support of the potential to replicate task shifting of contraceptive implants to CHEWs in Nigeria. It also provides evidence in support of a recently adopted national policy statement by Nigeria's Council of Health in October 2014, wherein task shifting was adopted as a national policy.<sup>16</sup> Although the number of implant insertions per health facility per month was relatively low in this pilot study, we think this underscores the importance of working with communities to address misconceptions about implants and to increase demand for implant services in addition to scaling-up training of CHEWs to provide the service. Initially, as client demand for implant services begins to grow, training and using "dedicated providers" to offer implant insertions and removals might be the most practical solution to ensure providers have an opportunity to practice and maintain the skills they learn during training. These providers can then become mentors to their (trained) colleagues to offer similar services in the future.

Such an expansion of trained providers with increased client demand will accelerate the trend of declining total fertility rate (TFR) in Sokoto state, which dropped from 8.7 in 2008 to 7.0 in 2013.<sup>7,18</sup> Similarly, this intervention could contribute to a decline in Bauchi state's TFR, which remained stagnant at 8 during the same period. Evidence of increased demand for services will be a strong advocacy tool to health or district managers for assigning additional staff to the family planning clinics. With increasing popularity of LARCs,<sup>17</sup> the study suggests that providing contraceptive implant services via task shifting might be a good way to meet family planning needs.

To our knowledge, this is the first study that trained CHEWs in insertion of both 1-rod and 2-rod implants. While there were no differences in the availability of Implanon and Jadelle for the CHEWs and clients, Implanon composed three-quarters of all insertions. This could be explained by preferences of clients to space their births 3 years apart (effective duration of Implanon) rather than 5 years, the effective duration of Jadelle (although Jadelle, as with any long-acting method, can be removed before the effective duration of the method expires). Also, because Implanon contains only 1 rod, it is quicker to insert than the 2-rod Jadelle implant. For Jadelle, providers need to learn

### BOX. Ways to Increase Demand for Implants via Community Mobilization

CHEWs offered the following suggestions as ways to increase demand among communities for implants:

- Provide continuous health education and distribute more information, education, and communication (IEC) materials, especially in the local (Hausa) language.
- Use more volunteers to carry out home-to-home visits to increase awareness and address fears and misconceptions.
- Conduct advocacy among community and religious leaders; involve Ward Development Committee members and husbands at a larger scale.
- Use all opportunities to create demand such as antenatal care visits, immunization visits, health talks, and community gatherings.

**Community outreach is needed to address misconceptions and to generate demand for implant services.**

to insert the first rod, then turn the trocar 20 degrees to insert the second rod. We noticed that for less than a quarter of CHEWs, this skill took longer to master than that of Implanon insertion. However, as soon as competency was achieved, the only difference between Implanon and Jadelle insertion was the duration of insertion, which is usually only a difference of a few seconds.

The crucial role of supportive supervision in maintaining quality assurance was also noted. The number of supervision visits varied depending on individual needs of CHEWs until competency was achieved. The project's integration of supportive supervision into the government-run supervision system is likely to increase the sustainability of such a support system for CHEWs. However, the CHEWs' preferred frequency of 3 to 6 supervisory support visits per quarter exceeds the project's current routine supportive supervision guidelines. It will be important to monitor and establish the minimum level of supervisory contact required for the optimal functioning of the LARC task shifting endeavor; this could be the basis of further operations research.

The study collected data about policies and procedures at health facilities. Client satisfaction with CHEW services was high, indicating that staff were friendly and able to answer clients' questions. Since over 40% of the CHEWs in the study were men, the high level of client satisfaction suggests the acceptance of male providers by women to



Nafisatu Manu Omar/USAID Targeted States High Impact Project (TSHIP)

A male Community Health Extension Worker (CHEW) from Muzuwa Dispensary, Dambam LGA, in Bauchi state, inserts a contraceptive implant. Over 40% of the CHEWs in the pilot task shifting study were men, revealing the acceptance of male providers by women to deliver implant services.

deliver contraceptive implant services in the context of northern Nigeria. Guidelines on implant insertions were available in most health facilities, and adequate reporting systems were in place. However, several areas for improvement need to be addressed, including improving availability of information, education, and communication (IEC) materials, providing more frequent supportive supervision, and providing immediate feedback after each supervision visit.

The study also looked at issues of availability of implants, including stock-outs, and materials at health facilities. While implants were available in most health facilities, supply of consumables such as sterile gloves, adhesive bandages, and antiseptics in both states was insufficient, a situation that needs to be addressed urgently to prevent infection.

Several studies have identified country-specific barriers for uptake of family planning methods overall<sup>19,20</sup> and of some particular methods such as IUDs and tubal ligation.<sup>21</sup> Our study contributes to the existing research by identifying barriers to uptake of implant services. These include women's fears of implants causing infertility, of the side effects of implants, or that implants can't be removed and could disappear in the body. Targeted health communication messages need to be developed and disseminated to community members to correct these misconceptions and to encourage use of implants and other contraceptive methods.

## Strengths and Limitations

This study has several limitations. First, although the results of the study may be used to inform interventions in Bauchi and Sokoto states, we need to exercise caution generalizing findings and recommendations to other states of Nigeria. In addition, the selected CHEWs in these 2 states had prior family planning training conducted by TSHIP and other organizations. Therefore, CHEWs in other states might need to be trained in family planning prior to being trained on implant insertion. Also, in the surveys with CHEWs and clients, we relied on self-reported data, which may be subject to social desirability bias. We tried to minimize biases by training data collectors on proper survey techniques and ensuring respondents of data confidentiality. Attrition could be a threat to internal validity in our study; however, characteristics of those 9% of CHEWs who were lost to follow-up did not differ from those who stayed in the study. We did not assess the costs of the provision of implants by CHEWs. Future research should conduct cost-effectiveness analysis to answer questions regarding affordability and relative effectiveness of this intervention versus alternative options to promote and increase use of contraceptive implant services. Trainees were not able to practice implant removal skills on clients due to low demand for these services. Currently, health facilities are linked to general hospitals where CHEWs are able to remove implants under the supervision of experienced service providers. We plan to retrain CHEWs on removals as the client load for removal increases. Additional research is needed to compare off-site group-based training with on-site, shorter yet more frequent training for CHEWs. The benefit of the latter is that health care workers are not taken away from the job posts for a long time period. Finally, although we presented CHEWs' insights regarding keeping the intervention sustainable in the future, this topic was beyond the scope of our study. We believe the approved national task shifting policy that allows CHEWs to be trained to provide implants and increasing interest in LARCs facilitated the task sharing intervention. Future investigations should rigorously examine factors that support scale-up and sustainability of the intervention.

Among the study's strengths is that the findings are based on results of surveys and clinical observations as well as a review of service statistics. In addition to survey questions with set response options, we asked CHEWs open-ended questions to get respondents' insight on facilitating factors and

barriers for providing services. We are confident in our findings because triangulation of results from different data sources indicates that the findings reinforce each other.

## LESSONS LEARNED

The following are key lessons learned from our pilot intervention in Nigeria that can be used to improve access to implants in underserved communities.

1. CHEWs can provide quality contraceptive implant services with adequate support including continual supportive supervision and regular refresher training. Continual supervision is necessary to ensure high-quality services are provided. Regular feedback during and after each supervisory visit motivates CHEWs to improve their performance. We also recommend refresher training on counseling and clinical skills to improve quality of services.
2. The 2-week training duration was adequate to ensure competently trained CHEWs. We did not find differences in knowledge and skills between participants in the 2-week vs. 3-week trainings, suggesting that 2 weeks is adequate if the training is competency-based and focused on implant insertion and removal.
3. Implant insertions with 5 clients were sufficient to achieve competency and confidence. At the beginning of the pilot, we set an arbitrary goal of 15 insertions per CHEW to gain competency. Experience, however, has shown that when trainees master skills repeatedly on anatomic models in the classroom, they need a much lower number of insertions on clients to achieve competency and confidence. Based on our experience, trainees who achieved competency on anatomic models during classroom simulation practice with appropriate procedure checklists also achieved competency on clients after 4–5 procedures. This is similar to the findings from an IUD competency-based training in Thailand where 70% of learners were judged to be competent after 2 insertions with clients and 100% were competent after 6 insertions.<sup>22</sup>
4. A combination of interventions addressing the demand and supply sides of implant provision would increase uptake and use of services. Future programs should make efforts to:
  - **Ensure availability of implants and other supplies:** Policies to ensure

availability of implants and other materials necessary for implant insertion should be in place to prevent stock-outs.

- **Create demand:** Demand for implant services in communities should be created prior to introducing the services, and community mobilization work should be ongoing. Misconceptions and fears regarding implants and family planning overall are common. While some CHEWs reported an increased uptake in implants, a few did not insert any implants because they had no clients. As part of the pilot program, we conducted community mobilization activities in all communities where sampled CHEWs worked. However, we did not promote implants exclusively; instead, we promoted use of family planning methods, including implants. A more focused and intense effort toward demand creation that is based on volunteerism and informed choice could have yielded a higher uptake of implants among women in the communities.
- **Develop and disseminate targeted messages to community members using information materials in a local language:** Key messages for community mobilization activities need to be developed and disseminated to promote implant uptake. Distribution of information materials in a local language would facilitate the acceptance of implants by community members.

**Most CHEWs achieved competency in implant insertion after 5 insertions with client.**

## CONCLUSION

With adequate training that included supportive supervision, CHEWs provided high-quality implant insertions. Despite their increased workload due to new reporting requirements and administration of implants, CHEWs enjoyed learning new skills and applying them in their daily work. With training of more CHEWs in implant insertion and additional community outreach to generate demand for services, uptake of LARC methods in Nigeria may increase. Investing in supportive supervision and use of a standards-based supervisory checklist will help ensure sustainability of the task shifting intervention.

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## ORIGINAL ARTICLE

# Prevalence and Incidence of Traumatic Experiences Among Orphans in Institutional and Family-Based Settings in 5 Low- and Middle-Income Countries: A Longitudinal Study

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Contrary to some conventional wisdom, in this large study that randomly sampled orphans and separated children from 5 countries, prevalence of reported traumatic events was no worse among those institutionalized than among those in family-based care. Reported incidence of physical or sexual abuse was actually higher for those in family-based care. Understanding the specific context, and elements contributing to potential harm and benefits in both family-based and institutional care, are essential to promoting the best interest of the child.

## ABSTRACT

**Background:** Policy makers struggling to protect the 153 million orphaned and separated children (OSC) worldwide need evidence-based research on the burden of potentially traumatic events (PTEs) and the relative risk of PTEs across different types of care settings.

**Methods:** The Positive Outcomes for Orphans study used a 2-stage, cluster-randomized sampling design to identify 1,357 institution-dwelling and 1,480 family-dwelling orphaned and separated children in 5 low- and middle-income countries (LMICs) in sub-Saharan Africa and Asia. We used the Life Events Checklist developed by the National Center for Posttraumatic Stress Disorder to examine self-reported PTEs among 2,235 OSC ages 10–13 at baseline. We estimated prevalence and incidence during 36-months of follow-up and compared the risk of PTEs across care settings. Data collection began between May 2006 and February 2008, depending on the site.

**Results:** Lifetime prevalence by age 13 of any PTE, excluding loss of a parent, was 91.0% (95% confidence interval (CI)=85.6, 94.5) in institution-dwelling OSC and 92.4% (95% CI=90.3, 94.0) in family-dwelling OSC; annual incidence of any PTE was lower in institution-dwelling (23.6% [95% CI=19.4, 28.7]) than family-dwelling OSC (30.0% [95% CI=28.1, 32.2]). More than half of children in institutions (50.3% [95% CI=42.5, 58.0]) and in family-based care (54.0% [95% CI=50.2, 57.7]) had experienced physical or sexual abuse by age 13. Annual incidence of physical or sexual abuse was lower in institution-dwelling (12.9% [95% CI=9.6, 17.3]) than family-dwelling OSC (19.4% [95% CI=17.7, 21.3]), indicating statistically lower risk in institution-dwelling OSC (risk difference=6.5% [95% CI=1.4, 11.7]).

**Conclusion:** Prevalence and incidence of PTEs were high among OSC, but contrary to common assumptions, OSC living in institutions did not report more PTEs or more abuse than OSC living with families. Current efforts to reduce the number of institution-dwelling OSC may not reduce incidence of PTEs in this vulnerable population. Protection of children from PTEs should be a primary consideration, regardless of the care setting.

## INTRODUCTION

The appropriateness of institutional care for orphaned children has become a central question for international aid policy affecting many low- and middle-income countries (LMICs). Research has convincingly demonstrated that infants raised in emotionally and socially deprived orphanages in Eastern Europe suffered significant cognitive delays and

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long-term negative effects.<sup>1–4</sup> A meta-analysis of 42 studies in 19 countries also reported lower Intelligence Quotient (IQ) values among institutionalized children compared with those in family-based care.<sup>5</sup>

In the meta-analysis, however, differences between institutionalized and non-institutionalized children were not observed in 3 of the 4 countries ranking low on the Human Development Index, a widely accepted measure of health, education, and standard of living, suggesting that conclusions about what is broadly labeled “institution” may not hold for institutionalized orphans in LMICs. Yet the findings from the literature have led to a generalization that all institutional care is harmful to all children and have fueled international policies aimed at reducing the number of institutions and using them exclusively as a temporary option until family-based care can be reestablished.<sup>6–8</sup> At the same time, the numbers of street children are on the rise in these same countries. Furthermore, quality of care in institutional settings varies substantially, and more recent research in a wide range of countries has suggested that orphans raised in institutions have comparable health and cognitive outcomes as their peers raised in family-based settings.<sup>9–11</sup>

**Orphans in institutional settings are perceived to be at higher risk for traumatic experiences than those raised in family settings.**

Among the concerns raised about institutional care for orphans is the perceived increased risk for traumatic experiences, such as sexual abuse and physical assault. In addition to the suffering imposed by the trauma itself, traumatic experiences can have long-lasting consequences for children, including adverse effects on their achievements and functioning, even if the children do not meet criteria for posttraumatic stress disorder.<sup>12–15</sup> While several studies have described abuse, neglect, and adversity of orphans in institutional settings,<sup>16–20</sup> these studies were limited by small sample sizes and were not designed to compare experiences of orphans in different settings. Furthermore, a systematic review of 15 studies suggested that orphans living in extended families in sub-Saharan Africa suffered from substantial maltreatment.<sup>21</sup> Importantly, no longitudinal studies compare institutions with family-based settings based on statistically representative samples of orphans to estimate prevalence and incidence of exposure to traumatic events.

The purpose of this study is to estimate the lifetime prevalence and annual incidence of potentially traumatic events experienced by statistically representative samples of orphaned or

separated children (OSC) living in institutional and family-based settings in 5 culturally diverse LMICs. Specifically, we examine the hypothesis that orphans in institutional care experience more potentially traumatic events than their counterparts living in family-based settings.

## METHODS

### Population

We used data from the Positive Outcomes for Orphans (POFO) study, a longitudinal study conducted at 6 culturally, politically, and geographically diverse sites in 5 LMICs: Battambang District, Cambodia; Addis Ababa, Ethiopia; Hyderabad, India; Nagaland, India; Bungoma District, Kenya; and Kilimanjaro Region, Tanzania.

A 2-stage sampling design was used to identify a random sample of 1,480 family-dwelling OSC and a random sample of 1,357 institution-dwelling OSC ages 6–12 years old at baseline. Data collection began between May 2006 and February 2008, depending on the site. The samples were designed to be statistically representative of the institution-dwelling and family-dwelling OSC populations in the regions from which children were selected.

### Sampling Frame

#### *Institution-Dwelling Children*

An institution was defined as a structure with at least 5 OSC from at least 2 different families with caregivers not biologically related to the OSC. The number of children per institution ranged from 5 to 376, with a mean of 63 and median of 42 children; approximately 35% of institutions in the study had 25 children or fewer.<sup>22</sup> Comprehensive lists of all institutions in each of the 6 sites were developed through inquiries with local government officials, schools, and organizations working with orphans. For each site, institutions were randomized for selection and sequentially approached until 250 total children were enrolled. Up to 20 children ages 6–12 were randomly selected from each institution; if there were fewer than 20 age-eligible children in the institution, all were selected. At 3 sites, the number of children selected per institution was increased to attain the target sample of 250 per site.

#### *Family-Dwelling Children*

Fifty sampling areas (“clusters”) were defined for each study site using geographic or administrative

boundaries. Up to 5 children from each cluster were selected through random sampling of available lists or through a house-to-house census. Some clusters had 6 to 10 children enrolled due to substitutions from clusters with insufficient enrollment or insufficient numbers of eligible children. In homes with more than 1 age-eligible child, the child whose first name was first alphabetically was selected. Most, but not all, family-dwelling OSC lived with the remaining parent or other biological relatives.

## Measures

### *Administration of Questionnaire*

Children were interviewed at approximately 6-month intervals for up to 3 years for a total of 7 rounds of data collection. Trauma measures were administered at baseline and annually during follow-up, for up to 4 assessments for each child included in the analysis.

### *Potentially Traumatic Events*

We used potentially traumatic experiences self-reported by OSC ages  $\geq 10$  at the time of assessment; based on both pilot testing as well as Institutional Review Board (IRB) recommendations, children younger than 10 were not administered trauma assessments. This analysis uses self-reported trauma exposures because a prior study in this population showed discordance between self-report and caregiver report, with caregivers reporting significantly fewer potentially traumatic events.<sup>23</sup> This discordance is consistent with underreporting of child trauma exposure by parents and caregivers in other populations.<sup>24–26</sup> In most cases, caregivers of orphans have not been present for the orphan's entire childhood and may have limited knowledge of the child's trauma history and are also less likely to report violence and abuse within the current caregiving setting.

Potentially traumatic experiences were assessed at baseline and at 3 annual follow-up surveys, using the Life Events Checklist (LEC) developed by the National Center for Posttraumatic Stress Disorder (PTSD) to aid in PTSD detection.<sup>27</sup> The LEC has been widely used in cross-cultural settings and is predictive of anxiety, depression, and PTSD.<sup>28</sup> Children responded to a list of 17 "things I have seen and heard," indicating whether the event had been experienced 1 time, more than 1 time, or not at all; at follow-up assessments the child

also indicated if he or she had experienced the event in the past year (i.e., approximately since the last trauma assessment), prior to the past year, or both.

For analysis, the 17 PTEs were collapsed into 6 categories: disasters or accidents; war, riots, or killings; physical or sexual abuse; witnessing violence in the care setting; witnessing family death; and being forced to leave the care setting (Supplementary Table A). These categories are the same as those used previously in similar work, as well as to describe PTEs in this population.<sup>9,29</sup> Being an orphan in and of itself was not included as a traumatic event because that was a defining characteristic for inclusion in the study. However, if the child personally watched the death of their parent happen, that was included in the "witnessing family death" category.

Lifetime prevalence was assessed at baseline and at each annual follow-up interview. At follow-up interviews, children were also asked whether each type of event had been experienced in the past year. In this analysis, incident trauma was defined as reporting having experienced the event within the past year, regardless of whether the child had experienced the event previously.

### *Child Characteristics*

Demographic information such as gender, age, setting (institution-dwelling or family-dwelling), OSC type (single orphan, double orphan, or separated; maternal death, paternal death, or both) were collected at baseline.

## Analyses

Because trauma measures were not administered to children under age 10, age-specific estimates of lifetime prevalence and 12-month incidence of PTEs were calculated based on interviews at which the child's current age was at least 10 years old.

We used logistic regression to estimate the lifetime prevalence of trauma reported by age 13 in each of the 6 trauma categories, as well as lifetime prevalence of any trauma. We used current age, a squared term for current age, and study round in the models and calculated lifetime predicted prevalence at age 13 in round 7 (the final round of follow-up). We predicted lifetime prevalence at age 13 because most study participants included in this analysis were age 13 at some time during follow-up.

We estimated the proportion and 95% confidence interval (CI) of participants reporting any PTE and each type of PTE in the past year as the 12-month incidence using log binomial regression.

To provide a direct estimate comparing the prevalence difference for each trauma category between OSC in institution-based care and those in family-based care, we used a linear risk model (identity link and binomial distribution) that included a parameter estimate for the setting (family-based vs. institution-based), age centered at 13, a squared term for age centered at 13, and product terms between setting and each of the age terms. The parameter estimate for setting is reported as the prevalence difference (PD) and 95% CI.

To provide a direct comparison of incidence, we used a linear risk model with a term for setting (family-based vs. institution-based); that parameter estimate is reported as a risk difference (RD) and 95% CI.

Finally, between institutional and family-based care, we compared cumulative prevalence and annual incidence by year of age (10–15 years) for any PTE reported and for physical or sexual abuse specifically. The few 16-year-old participants at the final round of data collection were combined with 15-year-olds to prevent unstable estimates.

All prevalence and incidence estimates and CIs described above accounted for the complex survey design through incorporation of sampling weights and specification of the site and sampling unit levels of the design, as previously described.<sup>22</sup> All analyses were conducted using Stata 13.<sup>30</sup>

### Ethical Approval

The POFO study was approved by the IRB at Duke University and by the IRB at each of the study sites. Caregiver consent and child assent were obtained and recorded on IRB-approved consent forms. Local interviewers were trained on site-specific protocols created for this study for addressing reported or observed abuse of children. This included an advisory board consisting of local child professionals to which reports of abuse and other difficult situations were reported. All study personnel were trained in maintaining confidentiality of all information shared in the course of data collection or analysis. All data are kept on a secure server

accessible only by study personnel who had completed IRB training, including local study site coordinators. For follow-up, key personnel accessed the minimal information necessary to locate a child.

## RESULTS

### Sample Characteristics

In total, 2,235 OSC (1,182 family-dwelling and 1,053 institution-dwelling) were  $\geq 10$  years old at 1 or more interviews and were included in this analysis (Table 1). Over half of OSC (58% in institutions and 53% in family-based care) in this analysis were male, and most (94% in institutions and 96% in family-based care) had their first trauma interview by or at age 12. A greater percentage of institution-dwelling (39%) than family-dwelling OSC (18%) were double orphans. Among single orphans, 77% of institution-dwelling OSC and 78% of family-dwelling OSC had lost their father.

### Prevalence and Incidence of Overall Trauma

By age 13, over 90% of children both in institutions and in family-based care had experienced at least 1 PTE beyond the loss of a parent; the predicted lifetime prevalence of any trauma was approximately the same in both settings: 91.0% (95% CI=85.6, 94.5) in institution-based care vs. 92.4% (95% CI=90.3, 94.0) in family-based care (Table 2). Annual incidence of any trauma was lower in institution-dwelling OSC (23.6% [95% CI=19.4, 28.7]) than in family-dwelling OSC (30.0% [95% CI=28.1, 32.2]), but the risk difference was not statistically significant (RD=6.4% [95% CI=-0.2, 13.0]) (Table 3).

Follow-up subgroup analyses (not shown) indicated similar results. We observed no gender differences in prevalence or incidence of any trauma in either setting: 91.7% (95% CI=85.0, 95.5) of males and 90.3% (95% CI=84.2, 94.1) of females in institution-based care compared with 92.0% (95% CI=89.0, 94.2) of males and 92.9% (95% CI=89.8, 95.1) of females in family-based care reported any trauma. While there was some variation in both prevalence and incidence of any trauma by study site, there were no differences between institution-dwelling and family-dwelling OSC at any site.

**By age 13, nearly all children had experienced at least 1 potentially traumatic event beyond the loss of a parent.**

**TABLE 1.** Characteristics of OSC in Institution-Based and Family-Based Care (N=2,235)

Characteristic	No. (%) of Institution-Dwelling OSC (n=1,053)	No. (%) of Family-Dwelling OSC (n=1,182)
Sex		
Male	614 (58.3)	631 (53.4)
Female	439 (41.7)	551 (46.6)
Site		
Cambodia	112 (10.6)	199 (16.8)
Ethiopia	175 (16.6)	192 (16.2)
Hyderabad (India)	209 (19.8)	222 (18.8)
Kenya	188 (17.9)	192 (16.2)
Nagaland (India)	150 (14.2)	163 (13.8)
Tanzania	219 (20.8)	214 (18.1)
Age at first trauma interview, years		
10	395 (37.5)	457 (38.7)
11	379 (36.0)	462 (39.1)
12	214 (20.3)	210 (17.8)
13	56 (5.3)	45 (3.8)
14	4 (0.4)	7 (0.6)
15	5 (0.5)	1 (0.1)
OSC deceased parent		
Neither (separated)	178 (16.9)	120 (10.2)
Mother	105 (10.0)	188 (15.9)
Father	358 (34.0)	663 (56.1)
Both	412 (39.1)	211 (17.9)

Abbreviation: OSC, orphaned or separated children.

### Prevalence and Incidence of Specific Types of Trauma

The most commonly experienced category of trauma was witnessing a family death, reported by 72.5% (95% CI=67.6, 76.9) of institution-dwelling and 71.8% (95% CI=68.5, 74.9) of family-dwelling OSC (Table 2). Endorsement of this category means the child personally saw the death of a family member, whether from illness or violence, including watching the death of a parent.

More than half of children both in institutions (50.3% [95% CI=42.5, 58.0]) and in family-based care (54.0% [95% CI=50.2, 57.7]) had experienced physical or sexual abuse by age 13 (Table 2). In both settings, the 12-month incidence of physical or sexual abuse had the highest incidence (>13%) relative to other trauma categories, which all had an incidence of less than 10% (Table 3). Institution-dwelling OSC had similar or lower predicted prevalence of PTEs than family-dwelling OSC for each type of trauma except

**More than half of children had experienced physical or sexual abuse by age 13.**

**TABLE 2.** Prevalence of Lifetime Trauma by Age 13 Among Orphaned or Separated Children (OSC) by Care Setting, 6 Sites in 5 Low- and Middle-Income Countries<sup>a</sup>

	Institution-Based OSC		Family-Based OSC		Prevalence Difference <sup>b</sup>	
	%	95% CI	%	95% CI	%	95% CI
Any trauma	91.0	(85.6, 94.5)	92.4	(90.3, 94.0)	0.0	(-4.4, 4.4)
Witnessing a family death	72.5	(67.6, 76.9)	71.8	(68.5, 74.9)	-2.7	(-9.0, 3.5)
Physical or sexual abuse	50.3	(42.5, 58.0)	54.0	(50.2, 57.7)	3.5	(-7.9, 15.0)
Violence in family or care setting	30.9	(25.1, 37.4)	36.8	(33.1, 40.7)	6.6	(-3.6, 16.8)
Forced to leave home or care setting	27.6	(21.2, 35.2)	15.0	(12.5, 17.9)	-14.8	(-24.8, -4.8)
War, riots, killings	20.0	(14.6, 26.8)	22.0	(19.2, 25.0)	-1.6	(-9.1, 5.9)
Disaster or accidents	5.9	(3.7, 9.5)	9.5	(7.5, 11.9)	3.5	(-1.7, 8.8)

<sup>a</sup> Battambang District, Cambodia; Addis Ababa, Ethiopia; Hyderabad, India; Nagaland, India; Bungoma District, Kenya; and Kilimanjaro Region, Tanzania.

<sup>b</sup> Differences were modeled separately from the prevalence estimates and may be slightly different than an exact subtraction of the institution-based and family-based prevalences. Institution-based OSC were the referent; positive differences indicate family-based OSC had higher prevalence while negative differences indicate institution-based OSC had higher prevalence.

being forced to leave the care setting (Table 2). Similarly, annual incidence of PTEs was similar or lower among institution-dwelling OSC for all trauma types except being forced to leave home (Table 3). In particular, the annual incidence of physical or sexual abuse was 12.9% (95% CI=9.6, 17.3) in institution-based care, compared with 19.4% (95% CI=17.7, 21.3) in family-based care, indicating statistically significantly higher risk in family-dwelling OSC (RD=6.5% [95% CI=1.4, 11.7]) (Table 3).

The Figure compares cumulative prevalence and annual incidence of any trauma and of physical or sexual abuse at each age (10–15 years) across settings. In general, estimates at each age are similar but slightly higher in family-based settings than in institution-based settings.

## DISCUSSION

This study of a large and statistically representative sample of orphans and separated children from 5 LMICs, followed prospectively for 3 years, documented a substantial burden of potentially traumatic events that extended beyond the trauma of losing a parent. Nearly all OSC—regardless of care setting—had experienced at least 1 PTE by age 13, nearly three-quarters had witnessed a family death, and half had

experienced physical or sexual abuse. Moreover, exposure to PTEs continued throughout the 3-year follow-up period of the study, during which time 24% of institution-dwelling OSC and 30% of family-dwelling OSC experienced an incident PTE each year, and 13% of institution-dwelling OSC and 19% of family-dwelling OSC experienced physical or sexual abuse each year.

Importantly, we found that over 3 years of longitudinal follow-up, the incidence of PTEs in general, and of physical or sexual abuse in particular, was not higher among institution-dwelling OSC compared with family-dwelling OSC. This finding is noteworthy because deinstitutionalization has been advocated, in part, based on assumptions about pervasive abuse and neglect in institutional care settings relative to other settings.<sup>6–8</sup> However, our longitudinal data, designed to draw comparisons across such settings, do not support the conclusion that orphans in institutional care are exposed to potentially traumatic events with greater frequency than their counterparts in family-based care.

Physical or sexual abuse had, by far, the highest incidence of any trauma type. Annual risk of physical or sexual abuse was statistically significantly higher for OSC in family-based care relative to those in institution-based care,

**Annual incidence of physical or sexual abuse was significantly higher among orphans in family-based care (19%) than in institutional care (13%).**

**Our findings do not support the conclusion that orphans in institutional care are exposed more than those in family-based care to potentially traumatic events.**

**TABLE 3.** Annual Trauma Incidence Among Orphaned and Separated Children (OSC) Over the Course of the Study,<sup>a</sup> by Care Setting, 6 Sites in 5 Low- and Middle-Income Countries<sup>b</sup>

	Institution-Based OSC		Family-Based OSC		Risk Difference <sup>c</sup>	
	%	95% CI	%	95% CI	%	95% CI
Any trauma	23.6	(19.4, 28.7)	30.0	(28.1, 32.2)	6.4	(−0.2, 13.0)
Witnessing a family death	3.6	(2.5, 5.2)	6.0	(5.1, 7.0)	2.3	(0.5, 4.2)
Physical or sexual abuse	12.9	(9.6, 17.3)	19.4	(17.7, 21.3)	6.5	(1.4, 11.7)
Violence in family or care setting	6.6	(4.9, 9.0)	9.1	(7.7, 10.6)	2.4	(−0.5, 5.4)
Forced to leave home or care setting	3.4	(1.9, 6.1)	1.0	(0.7, 1.6)	−2.4	(−4.6, −0.1)
War, riots, killings	5.1	(3.4, 7.5)	5.8	(4.9, 7.0)	0.8	(−2.4, 3.9)
Disaster or accidents	0.7	(0.3, 1.5)	0.9	(0.6, 1.4)	0.2	(−0.5, 0.9)

<sup>a</sup> Data collection began between May 2006 and February 2008, depending on the site, and continued for 36 months of follow-up.

<sup>b</sup> Battambang District, Cambodia; Addis Ababa, Ethiopia; Hyderabad, India; Nagaland, India; Bungoma District, Kenya; and Kilimanjaro Region, Tanzania.

<sup>c</sup> Differences were modeled separately from the incidence estimates and may be slightly different than an exact subtraction of the incidence-based and family-based incidences. Institution-based OSC were the referent; positive differences indicate family-based OSC had higher risk while negative differences indicate institution-based OSC had higher risk.

although estimates were somewhat imprecise. The prevalence of these experiences was comparable in both institutional and family-based settings. Because the prevalence rates take into account the life history of the child, it is possible that the similar rates between institutional and family-based children are due to abuse that occurred to institutional-based children before their entry into the institution and may have been the reason for their entry. Another large longitudinal study in Kenya following more than 3,000 children found that of those in institutions, approximately half (52%) had been abused before entering the institution.<sup>31</sup>

Additionally, incidence of abuse at younger ages is higher than incidence at older ages, suggesting that focusing on identifying trauma, particularly abuse, in younger children may increase the opportunity for intervention and provision of support services. Younger children are perhaps at greater risk for abuse from other children and adults due to their smaller physical size and the ability to manipulate them emotionally. The higher prevalence and incidence of being forced to leave the home or care setting among institution-dwelling than family-based OSC may be attributable, in part, to closing of institutions. Interventions targeting communities with OSC should focus on preventing

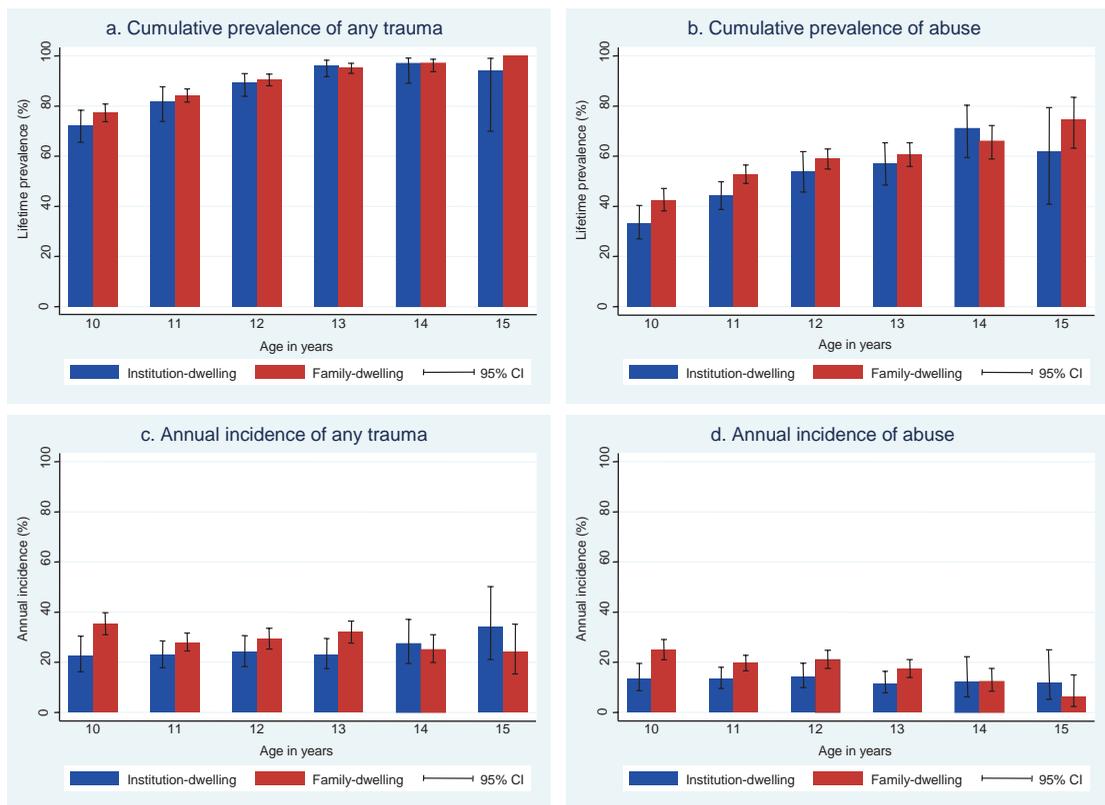
abuse and providing counseling and support for survivors of abuse, in both types of settings.

Poverty underlies the conditions in which many OSC live; protection from abuse can be difficult if caregivers spend long hours working outside the home or if the perpetrator is a family member. Community-wide efforts may provide preventive measures and protection. Emerging interventions tailored to resource-poor settings may mitigate sequelae from PTEs; at least 1 recent trauma-focused cognitive behavioral therapy program has shown promise and can be provided by trained lay professionals.<sup>32,33</sup>

Two key characteristics differentiate this work from previous research that demonstrated significant and long-term impairment in institutional-based orphans in Eastern Europe.<sup>1–4</sup> First, prior studies focused on particularly problematic institutions where gross negligence was known to have occurred. In contrast, the present study used a probabilistic sampling method based on a census of institutions in a defined geographic area to recruit a cohort of OSC statistically representative of the population of orphans and separated children living in institutional care. Second, the prior research focused on orphans who had entered the institution in infancy, whereas the present study recruited children ages 6–12, of whom only a small portion

**Incidence of abuse is higher at younger than older ages.**

**FIGURE.** Prevalence and Incidence of Any Trauma and of Abuse by Age in Institution-Based vs. Family-Based Settings



had entered institutional care in infancy. Given that 95% of children who are orphaned and in need of care are over the age of 5, it is critically important that policies for these children be based on evidence derived from those over the age of 5.

### Strengths and Limitations

This study has several important strengths. The POFO data were collected longitudinally for 3 years on representative samples of both institution-dwelling and family-dwelling OSC using a cluster-randomized design, with a very high rate of 3-year follow-up (82%). Retention in this analytic sample is difficult to summarize since children enter at later rounds as they become eligible at age 10 to answer trauma-related questions, but [Supplementary Table B](#) demonstrates the overall POFO retention. A prior analysis showed that follow-up did not differ by

care setting.<sup>34</sup> The 6 study sites in 5 LMICs reflect broad cultural, geographic, and economic diversity. Importantly, this study incorporates institution-dwelling OSC and longitudinal follow-up to expand upon earlier studies in the POFO population. To our knowledge, no other study uses longitudinal data to quantify the lifetime prevalence or annual incidence of traumatic experiences among OSC in sub-Saharan African and Asian regions, which account for over two-thirds of the world’s OSC population.<sup>35</sup> Furthermore, we describe the prevalence and incidence among specific categories of trauma and provide evidence against the hypothesis that physical and sexual abuse is more pervasive in institutions than in family-based settings.

We note several limitations to our study. First, reporting bias is a possibility. Traumatic events are likely to be underreported, implying this study underestimates the actual burden of PTEs in this

population. We do not have reason to believe that this bias would be stronger in one setting or the other. Second, the total number of traumatic events is unknown; respondents endorsed occurrence of each trauma as “never,” “one time,” or “two or more times.” Third, the chronology of traumatic events with respect to orphaning (which events came before or after being orphaned) is unknown. Fourth, although our study included diverse LMICs, South America and Eastern Europe were not represented. We recognize our results may not be generalizable to those cultural contexts. Finally, although the POFO study has a sample of non-OSC for comparison, it is too small to include in these analyses. Therefore, we did not include those estimates in the present paper.

## CONCLUSION

Caring for the sheer number of OSC worldwide (153 million, including 17 million orphaned by AIDS) presents a complex problem that demands evidence-based solutions.<sup>35</sup> When developing interventions or policies for this vulnerable population, the magnitude of PTEs is a critical concern. While protecting OSC from trauma in general and abuse in particular must be a high priority, the results presented here suggest that risk of trauma and abuse is not restricted to OSC living in institutional care but is at least equally common among OSC living in family-based settings. Protection of children from PTEs should be a primary consideration in care for OSC, regardless of setting.

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**Protection of orphans and separated children from potentially traumatic events should be a primary consideration, regardless of the care setting.**

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## ORIGINAL ARTICLE

# Empirically Derived Dehydration Scoring and Decision Tree Models for Children With Diarrhea: Assessment and Internal Validation in a Prospective Cohort Study in Dhaka, Bangladesh

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The DHAKA Dehydration Score and the DHAKA Dehydration Tree are the first empirically derived and internally validated diagnostic models for assessing dehydration in children with acute diarrhea for use by general practice nurses in a resource-limited setting. Frontline providers can use these new tools to better classify and manage dehydration in children.

## ABSTRACT

**Introduction:** Diarrhea remains one of the most common and most deadly conditions affecting children worldwide. Accurately assessing dehydration status is critical to determining treatment course, yet no clinical diagnostic models for dehydration have been empirically derived and validated for use in resource-limited settings.

**Methods:** In the Dehydration: Assessing Kids Accurately (DHAKA) prospective cohort study, a random sample of children under 5 with acute diarrhea was enrolled between February and June 2014 in Bangladesh. Local nurses assessed children for clinical signs of dehydration on arrival, and then serial weights were obtained as subjects were rehydrated. For each child, the percent weight change with rehydration was used to classify subjects with severe dehydration (>9% weight change), some dehydration (3–9%), or no dehydration (<3%). Clinical variables were then entered into logistic regression and recursive partitioning models to develop the DHAKA Dehydration Score and DHAKA Dehydration Tree, respectively. Models were assessed for their accuracy using the area under their receiver operating characteristic curve (AUC) and for their reliability through repeat clinical exams. Bootstrapping was used to internally validate the models.

**Results:** A total of 850 children were enrolled, with 771 included in the final analysis. Of the 771 children included in the analysis, 11% were classified with severe dehydration, 45% with some dehydration, and 44% with no dehydration. Both the DHAKA Dehydration Score and DHAKA Dehydration Tree had significant AUCs of 0.79 (95% CI=0.74, 0.84) and 0.76 (95% CI=0.71, 0.80), respectively, for the diagnosis of severe dehydration. Additionally, the DHAKA Dehydration Score and DHAKA Dehydration Tree had significant positive likelihood ratios of 2.0 (95% CI=1.8, 2.3) and 2.5 (95% CI=2.1, 2.8), respectively, and significant negative likelihood ratios of 0.23 (95% CI=0.13, 0.40) and 0.28 (95% CI=0.18, 0.44), respectively, for the diagnosis of severe dehydration. Both models demonstrated 90% agreement between independent raters and good reproducibility using bootstrapping.

**Conclusion:** This study is the first to empirically derive and internally validate accurate and reliable clinical diagnostic models for dehydration in a resource-limited setting. After external validation, frontline providers may use these new tools to better manage acute diarrhea in children.

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## INTRODUCTION

Despite major advances in prevention and management, diarrhea remains one of the most common and most deadly conditions affecting children today.

Each year, children worldwide experience 1.7 billion diarrheal episodes, leading to 124 million outpatient visits and 9 million hospitalizations.<sup>1,2</sup> While most episodes of diarrhea in children resolve uneventfully, approximately 36 million cases each year progress to severe disease, resulting in 700,000 deaths, or 10% of all child deaths worldwide.<sup>3</sup>

As the severity of diarrhea in children varies widely, accurately assessing dehydration status is critical to prevent mortality and morbidity. While children with severe dehydration require immediate intravenous fluids (IVF) to prevent hemodynamic compromise, organ ischemia, and death, children with mild to moderate dehydration have shorter hospital stays and fewer adverse events when treated with oral rehydration solution (ORS) alone.<sup>4</sup> Accurately assessing dehydration status can also improve the cost-effectiveness of diarrhea treatment in resource-limited settings by limiting the use of expensive and resource-intensive IVF.

Global health authorities therefore recommend classifying children with acute diarrhea into 3 categories based on their initial clinical presentation: no dehydration, some dehydration, or severe dehydration.<sup>5–8</sup> Children with no dehydration should receive only expectant management, those with some dehydration should be rehydrated using ORS, and those with severe dehydration should be resuscitated with IVF.

Unfortunately, the diagnostic tools available to clinicians in resource-limited settings to assess the degree of dehydration in children with diarrhea are limited. A large meta-analysis found that no individual clinical sign, symptom, or laboratory test demonstrated adequate sensitivity, specificity, and reliability for detecting dehydration in children.<sup>9</sup> The World Health Organization (WHO) Integrated Management of Childhood Illness (IMCI) guidelines recommend using a combination of clinical signs to classify children as having no, some, or severe dehydration ([Supplementary Appendix 1](#)).<sup>10</sup> However, the WHO algorithm was developed based largely on expert opinion, and recent studies have not found it to be an accurate predictor of dehydration in children.<sup>11–13</sup>

To date, no clinical diagnostic model for dehydration in children with diarrhea has been empirically derived and validated for use in a low-income country. This study aims to derive such a clinical diagnostic model for dehydration in children, which can be used by nurses and other

non-physician health workers to determine the best management strategy for children with acute diarrhea worldwide.

## METHODS

### Study Design

Data were collected as part of the Dehydration: Assessing Kids Accurately (DHAKA) study, a prospective cohort study of children presenting to the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). The DHAKA study was preregistered at ClinicalTrials.gov (NCT02007733), and ethical approval was obtained from the Lifespan Institutional Review Board and the icddr,b Ethical Review Committee.

### Study Setting

Enrollment for this study took place in the icddr,b rehydration (short stay) unit between February and June 2014. With a catchment area of more than 17 million people, icddr,b provides free clinical services to the population of Dhaka and surrounding rural and suburban districts.<sup>14</sup> Approximately 90% of children present primarily to the icddr,b rehydration ward, with the remainder referred there from other facilities.

### Study Population

All children under 60 months of age presenting with acute diarrhea were eligible for enrollment. Study staff randomly selected children for screening on arrival 24 hours per day, 7 days per week by pulling blue (selected) or white (not selected) marbles from a blind pouch. Once selected, study staff determined if the child met any of the predefined exclusion criteria:

- Fewer than 3 loose stools per day
- Diarrhea lasting longer than 14 days
- A diagnosis other than gastroenteritis as determined by the treating physician
- Prior enrollment in the study

For patients who did not meet exclusion criteria, research staff approached the parent/guardian, explained the risks and benefits of the study, and obtained consent in the local language, Bengali.

### Choosing Diagnostic Variables

Candidate diagnostic variables, which included signs and symptoms typically associated with dehydration in children, were chosen *a priori*

**Treatment of children with acute diarrhea varies depending on their dehydration status.**

**Clinicians in resource-limited settings have limited diagnostic tools to assess dehydration severity in children with diarrhea.**

based on their prior performance in published studies, including their accuracy and reliability, and in consultation with expert clinicians at icddr,b regarding their generalizability to resource-limited settings. Ten potential clinical diagnostic variables were identified in this manner:

- General appearance
- Skin pinch
- Sunken eyes
- Tears
- Radial pulse
- Deep breathing
- Extremity warmth
- Heart rate
- Mucous membranes
- Capillary refill

Each of these 10 variables was categorized into 3 levels of severity. In consultation with expert clinicians at icddr,b, detailed procedures were developed to ensure the objective measurement of each clinical sign ([Supplementary Appendix 2](#)).

## Staff Training

Local general practice nurses with 4–6 years of clinical experience collected all data for this study. These research nurses were hired outside of the icddr,b clinical nursing pool specifically to collect data for this study and had no other clinical responsibilities during the study period. Prior to the start of the study, they received 5 days of training in all study procedures. This included an in-depth review of the clinical signs of dehydration, with explicit didactic and video instruction in how to appropriately assess each sign as outlined in [Supplementary Appendix 2](#). Nurses also received practical training, with each nurse performing a full assessment of at least 10 children in the rehydration unit at icddr,b under the guidance of the primary investigator prior to the start of the study.

## Data Collection

### Baseline Data

Immediately after obtaining informed consent, children were undressed and weighed to the nearest tenth of a kilogram using an electronic scale. If a child received intravenous fluid before

baseline weight was obtained, study staff recorded the amount of fluid received prior to measurement.

Subjects were then assessed clinically by a study nurse for presence of the 10 clinical signs of dehydration noted above. Subjects were also assessed clinically by a second study nurse when available, blinded to the exam performed by the first nurse.

Study nurses collected baseline historical and demographic data for each child from their parent/guardian including location, age, gender, days of diarrhea, diarrheal episodes in the past 24 hours, and type of diarrhea (bloody, watery, rice water). Study nurses also measured mid-upper arm circumference (MUAC) on arrival to the nearest millimeter using a standard measuring tape.

### Follow-Up Data

Patients were then treated according to standard icddr,b protocols. Emergent care was not delayed for consent, measurements, or weights. All enrolled children received a unique bar-coded study label on their admission card, matching the bar code on their case report forms, to ensure accurate collection of all data.

Patients were weighed every 8 hours, on the same scale and without clothing, to determine their post-hydration stable weight, which was used as a proxy for their pre-illness weight. Children who did not achieve a stable weight prior to discharge were telephoned daily after discharge until their diarrhea resolved, then asked to return for a post-illness weight check.

## Data Analysis

### Baseline Data

Baseline historical, demographic, and nutritional data were summarized for all children enrolled in our study. The proportion of children with undernutrition was calculated using a MUAC <115 mm for severe acute malnutrition (SAM) and MUAC 115–125 mm for moderate acute malnutrition (MAM).<sup>15</sup>

### Analysis of Dehydration Status

For each patient enrolled, we averaged the 2 highest consecutive weight measurements that differed by less than 2% to determine a stable weight, as described in the literature.<sup>16</sup> In general, children with dehydration rapidly gain weight as they are rehydrated until they achieve

**Ten clinical signs typically associated with dehydration in children were identified and measured in this study.**

**Dehydration status was based on the child's stable weight after rehydration and the weight at admission.**

their pre-illness weight, or stable weight, at which point they will stop gaining weight as their kidneys diurese excess fluid. For each patient with a valid stable weight, we calculated the percent weight change with rehydration, our criterion standard for percent dehydration, using the following formula:

$$\text{Percent Dehydration} = [( \text{Stable Weight} - \text{Admission Weight} ) / \text{Stable Weight}] * 100$$

For children who did not achieve a stable weight prior to discharge, their post-illness weight was used instead of their stable weight in the formula above to calculate the percent dehydration. We then calculated the proportion of children with severe dehydration (>9% weight change), some dehydration (3–9%), and no dehydration (<3%). Children who lost significant weight during their stay in the rehydration unit, suggesting inadequate hydration in the face of ongoing diarrhea or an erroneous admission weight, were excluded from analysis, as their dehydration category could not be determined.

#### *Analysis of Diagnostic Variables*

We calculated the proportion of children presenting with each of the 10 signs of dehydration defined previously. Two signs, slow capillary refill and cool extremities, were found to be present in less than 5% of cases and were therefore excluded from analysis. While rare signs might still be strong diagnostic criteria, they are unlikely to be efficient criteria (since they require effort to collect and are unlikely to influence the patient's diagnosis in the vast majority of cases). Additionally, it would be difficult for less experienced practitioners to reliably identify clinical signs encountered so infrequently.

For the remaining 8 clinical signs, we performed a bivariate analysis to assess the association of each variable with the true dehydration status of the child based on our criterion standard. We also assessed the test characteristics of each diagnostic variable for the presence of severe dehydration in children, based on our criterion standard. Finally, for the subset of children with a repeat exam, we calculated the inter-rater reliability of each diagnostic variable using Cohen's Kappa (weighted).

#### *Derivation of Clinical Diagnostic Models*

Standard guidelines from the literature, including the recently published "Transparent Reporting of a Multivariable Prediction Model for Individual

Prognosis Or Diagnosis" (TRIPOD) guidelines, were used to develop clinical diagnostic models for dehydration severity.<sup>17-20</sup> Primary analyses were performed using R 3.0.2 (R Development Core Team, Vienna, Austria). Figures were produced using STATA 12.0 (STATA Corp, College Station, TX, USA).

The 8 candidate diagnostic variables were entered into an ordinal logistic regression (proportional odds) model for the outcome of dehydration category (none, some, or severe). A stepwise backward selection algorithm was used to derive a final clinical diagnostic model using a stopping rule of  $P < .10$ . In this way, clinical variables that were only weakly associated with the true dehydration status of the child, after controlling for all other clinical variables, were sequentially dropped until only statistically significant variables remained. An alternative stepwise selection algorithm using the Akaike Information Criterion (AIC) was also performed, which is a different means of selecting variables that does not rely on the  $P$  value alone to select the final variables for the model. Since only 3 patients were missing any data on clinical diagnostic variables (1 patient was missing data on heart rate and 2 patients were missing data on tears), we used case-wise deletion to handle missing data instead of single or multiple imputation. The final logistic regression model was then converted into a scoring system by ordering the final clinical variables in tabular format and converting the log odds ratio for each variable into an integer score as described previously in the literature.<sup>19</sup> We refer to this new scoring system as the Dehydration: Assessing Kids Accurately (DHAKA) Dehydration Score.

We developed a second clinical diagnostic model using recursive partitioning, an alternative method that may perform better than standard regression analysis when all components of the model can be broken down into a series of yes/no questions and when there are important interactions among the predictors.<sup>18,21</sup> Using the R *tree* package, we performed recursive binary splitting on our dataset using our 8 candidate variables to grow an initial decision tree. We then performed cost complexity pruning to determine the cost complexity factor ( $\alpha$ ) for trees of different sizes. Finally, we performed 10-fold cross validation to determine the level of  $\alpha$  that minimized the average mean squared prediction error in our cross validation test sets to select the sub-tree that was least likely to overfit the data and most likely to perform similarly in a new dataset. We refer to

**Logistic regression modeling was used to develop a dehydration scoring system based on clinical signs, called the DHAKA Dehydration Score.**

**Recursive partitioning was used to develop a dehydration decision tree based on clinical signs, called the DHAKA Dehydration Tree.**

this new clinical decision tree as the Dehydration: Assessing Kids Accurately (DHAKA) Dehydration Tree.

### Model Assessment

We assessed the discrimination of both our DHAKA Dehydration Score, derived using ordinal logistic regression, and our DHAKA Dehydration Tree, derived using recursive partitioning, by calculating the area under the receiver operating characteristic (ROC) curves (AUC), or c-statistic, for each model against the true dehydration category of the child. The shape of a ROC curve and the AUC help estimate the discriminative power of a diagnostic test. The closer the curve is located to the upper-left hand corner of a graph and the larger the area under the curve, the better the test is at discriminating between people with the disease (in this case, dehydration) and without the disease. The AUC can have a value between 0 and 1; a perfect diagnostic test has an AUC of 1.0 while a non-discriminating test has an area of 0.5.

The test characteristics for the DHAKA Dehydration Score at its best cut-points and the DHAKA Dehydration Tree were also assessed against the true dehydration category of the child. We also assessed the inter-rater reliability of each model by testing its agreement between the initial exam and repeat exam for the subset of children that had repeat exams using Cohen's Kappa (weighted).

### Model Validation

In the absence of an external validation cohort, internal validation was performed using the bootstrap method to assess the optimism of our clinical diagnostic models.<sup>17,18</sup> In this context, optimism refers to how much better a diagnostic model performs in the population in which it was derived compared with a new population in which it is validated. A bootstrap (with replacement) sample was randomly selected from our study population and used to derive both models again using the same algorithms used to derive the original models. The AUCs for these models were calculated both in the bootstrap sample and in the full dataset. This process was repeated 1,000 times, and the average differences between the AUCs for the bootstrap samples and the full dataset were used to calculate an unbiased estimate of the optimism of the original AUCs calculated for both models. The optimism represents the amount by which the AUC in our study population would be expected to exceed the AUC in a new test population. A low

optimism score suggests the model would perform as well in a new population as in the current study population.

### Sample Size

While there is no formal method for calculating the study sample size for the development of a clinical diagnostic model, a general rule of thumb in the literature calls for at least 10 positive events per variable (EPV) considered for the model, although more recent statistical research has suggested that 5 EPV may be sufficient.<sup>17,18,22</sup> Given 8 candidate variables, each with 2 levels of comparison, this would require a minimum of 80 positive outcomes, or 80 children with severe dehydration, to achieve 5 EPV.

## RESULTS

### Enrollment and Baseline Characteristics

Of the 1,025 eligible patients randomly selected, 850 were enrolled in the study and 771 were included in the final analysis (Figure 1). Among the 850 enrolled subjects, there were no significant differences in baseline demographic, historical, or anthropometric characteristics between those included and excluded from analysis (Table 1).

### Dehydration Status

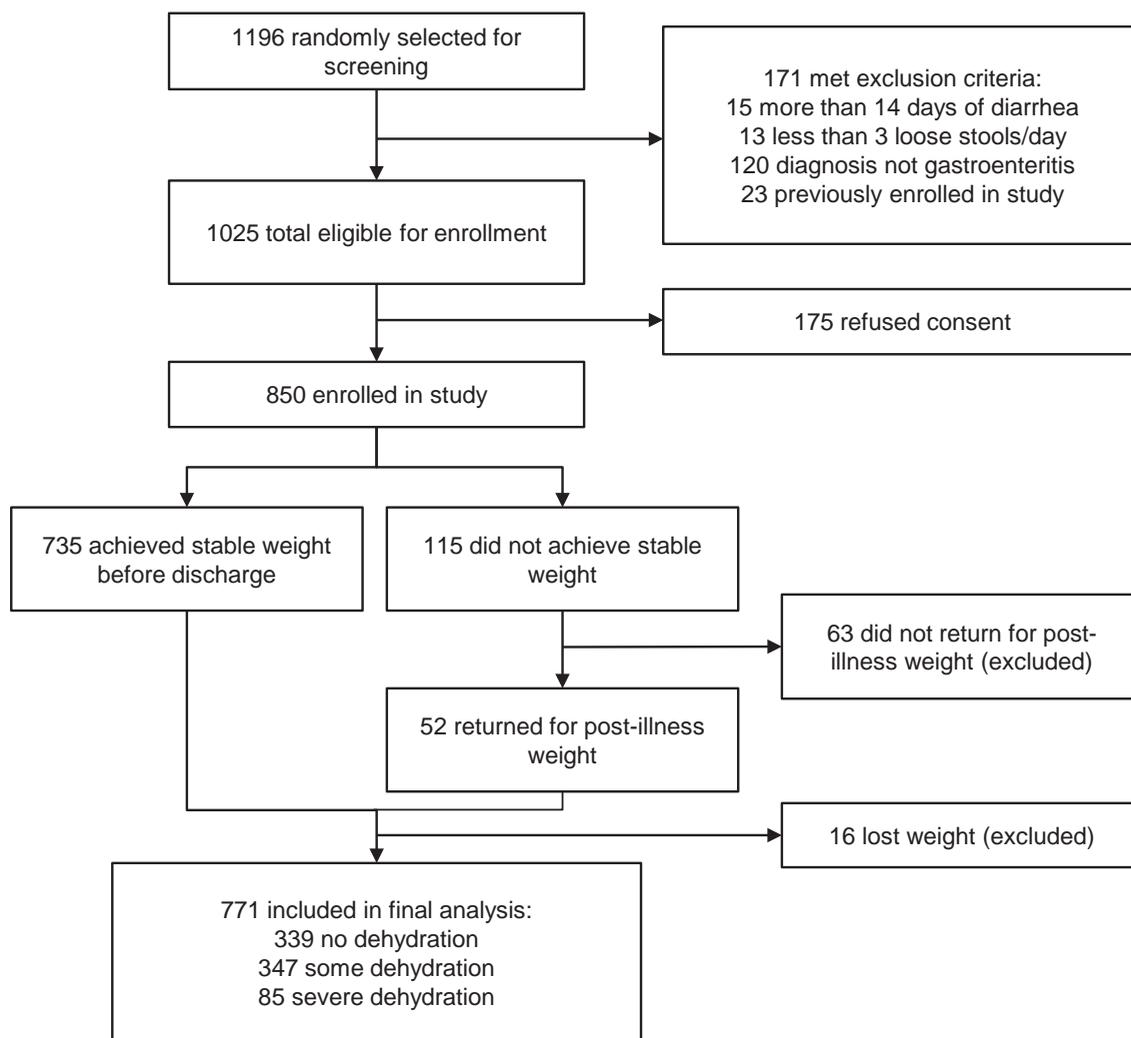
The median percent weight change with rehydration was 4% (interquartile range [IQR]=1%, 7%). Of the 771 children included in the final analysis, 85 (11%) children were classified with severe dehydration, 347 (45%) with some dehydration, and 339 (44%) with no dehydration. Median time from arrival to stable weight was 14 hours (IQR=11, 19; n=735), and median time from arrival to post-illness weight was 87 hours (IQR=56, 99; n=52). About one-quarter (28%) of children received fluids prior to their initial weight, with the median amount of fluid received just 1.5 ml/kg (IQR=1.0, 2.7).

### Association of Clinical Signs With Severe Dehydration

The median time from subject arrival to assessment of clinical signs was 4 minutes (IQR=2, 5). Approximately half of study subjects (n=419) had a repeat clinical exam performed, with a median time of 6 minutes (IQR=5, 8) between exams. All 8 clinical variables were significantly associated with the presence of severe dehydration in bivariate

**Internal validation was performed to assess how well the new clinical diagnostic models would perform in a new population other than the one in which they were derived.**

**All 8 clinical variables assessed were significantly associated with severe dehydration status in bivariate analysis.**

**FIGURE 1.** Flowchart for DHAKA Study Enrollment

**The DHAKA Dehydration Score comprised 4 clinical signs: general appearance, skin pinch, tears, and respiration.**

analysis, although their individual accuracy and reliability varied (Table 2). For example, sunken eyes had a sensitivity of 94% but a specificity of only 13%, resulting in a positive predictive value (PPV) of just 12% but a negative predictive value (NPV) of 95%.

#### Logistic Regression to Derive the DHAKA Dehydration Score

Stepwise backward selection of our full ordinal regression model produced a final model with 4 variables:

- General appearance
- Skin pinch
- Tears
- Respiration

The regression coefficients for each level of each of these variables were converted into integer scores, producing a 12-point scoring system (Table 3). Alternative selection using the AIC instead of a *P*-value rule produced an identical final scoring system.

**TABLE 1.** Baseline Characteristics of Enrolled Children < 60 Months of Age With Acute Diarrhea, Dhaka, Bangladesh, 2014 (N = 850)

	Included in Final Analysis (n = 771)	Excluded, Lost Weight (n = 16)	Excluded, No Final Weight (n = 63)	P value
Age in months, median (IQR)	15 (9–29)	18 (13–29)	22 (12–36)	.07 <sup>a</sup>
Sex				.84 <sup>b</sup>
Female, No. (%)	336 (44)	6 (38)	26 (41)	
Male, No. (%)	435 (56)	10 (62)	37 (59)	
Home district				.99 <sup>b</sup>
Urban (Dhaka), No. (%)	478 (62)	14 (88)	45 (71)	
Rural/suburban, No. (%)	293 (38)	2 (12)	18 (29)	
Nutritional status (MUAC)				.30 <sup>b</sup>
No acute malnutrition, No. (%)	614 (80)	16 (100)	53 (84)	
Moderate acute malnutrition (MAM), No. (%)	121 (16)	0 (0)	7 (11)	
Severe acute malnutrition (SAM), No. (%)	35 (4)	0 (0)	3 (5)	
Days of diarrhea prior to arrival, median (IQR)	2 (1–4)	2 (1.5–3.5)	2 (1–3)	.13 <sup>a</sup>
Loose stools in past 24 hours, median (IQR)	15 (10–20)	15 (11–20)	15 (10–20)	.79 <sup>a</sup>
Diarrhea type				.69 <sup>b</sup>
Watery, No. (%)	448 (58)	12 (75)	36 (57)	
Rice-water, No. (%)	317 (41)	4 (25)	27 (43)	
Bloody, No. (%)	4 (1)	0 (0)	0 (0)	

Abbreviation: IQR, interquartile range; MUAC, mid-upper arm circumference.

<sup>a</sup> Equality of medians.

<sup>b</sup> Chi-square test.

The AUC for this new DHAKA Dehydration Score was 0.79 (95% CI=0.74, 0.84) for severe dehydration and 0.78 (95% CI=0.74, 0.81) for some (any) dehydration (Figure 2). For those children with a repeat clinical exam, the DHAKA Dehydration Score had 90% agreement between independent raters, with a Cohen's Kappa of 0.75 (95% CI=0.66, 0.85). Table 4 demonstrates the proportion of children with no, some, or severe dehydration by DHAKA Dehydration Score category, and Table 5 demonstrates the test characteristics of the DHAKA Dehydration Score for assessing some and severe dehydration in children. For example, the DHAKA Dehydration Score had a sensitivity of 87% and a specificity of 57%, a positive likelihood ratio (LR+) of 2.0, and a negative likelihood ratio (LR-) of 0.23 for the outcome of severe dehydration.

### Recursive Partitioning to Derive the DHAKA Dehydration Tree

Recursive binary splitting followed by cross validation produced a final tree with 4 terminal nodes using just 3 variables: general appearance, eyes, and skin pinch (Figure 3). The AUC for this new DHAKA Dehydration Tree was 0.76 (95% CI=0.71, 0.80) for severe dehydration and 0.75 (95% CI=0.72, 0.78) for some (any) dehydration (Figure 2). For those children with a repeat clinical exam, the DHAKA Dehydration Tree had 90% agreement between independent raters, with a Cohen's Kappa of 0.77 (95% CI=0.67, 0.87). Table 4 demonstrates the proportion of children with no, some, or severe dehydration by DHAKA Dehydration Tree category, and Table 5 demonstrates the test characteristics of

**The DHAKA Dehydration Score was significantly accurate in diagnosing severe and any dehydration.**

**TABLE 2.** Association of Clinical Signs With Severe Dehydration in Bivariate Analysis

	Sensitivity	Specificity	PPV	NPV	LR+	LR-	Reliability	Chi-Square	P Value
Eyes							0.60	61.54	<.001
Sunken	0.94	0.13	0.12	0.95	1.08	0.46			
Very sunken	0.47	0.87	0.31	0.93	3.55	0.61			
General appearance							0.72	64.01	<.001
Restless/irritable	0.84	0.55	0.19	0.96	1.84	0.30			
Lethargic/unconscious	0.62	0.77	0.25	0.94	2.69	0.49			
Heart rate							0.47	10.28	.006
Fast	0.59	0.57	0.15	0.92	1.38	0.72			
Very fast	0.02	0.99	0.33	0.89	4.04	0.98			
Mucous membranes							0.42	18.79	<.001
Dry/sticky	0.88	0.34	0.14	0.96	1.35	0.34			
Very dry	0.02	0.99	0.25	0.89	2.69	0.99			
Radial pulse							0.60	40.77	<.001
Decreased	0.64	0.71	0.21	0.94	2.17	0.52			
Weak	0.38	0.84	0.23	0.92	2.37	0.74			
Respirations							0.58	35.08	<.001
Deep	0.61	0.69	0.20	0.94	2.00	0.56			
Very deep	0.07	0.98	0.33	0.90	4.04	0.95			
Skin pinch							0.71	69.18	<.001
Slow	0.85	0.53	0.18	0.97	1.79	0.29			
Very slow	0.31	0.93	0.35	0.92	4.37	0.75			
Tears							0.63	54.28	<.001
Decreased	0.85	0.52	0.18	0.96	1.75	0.30			
Absent	0.29	0.92	0.30	0.91	3.43	0.78			

Abbreviations: LR-, negative likelihood ratio; LR+, positive likelihood ratio; NPV, negative predictive value; PPV, positive predictive value.

**The DHAKA Dehydration Tree, comprising 3 clinical signs of general appearance, eyes, and skin pinch, was also significantly accurate in diagnosing severe and any dehydration.**

the DHAKA Dehydration Tree for assessing some and severe dehydration. For example, the DHAKA Dehydration Tree had a sensitivity of 81% and a specificity of 67%, a LR+ of 2.5, and a LR- of 0.28 for the outcome of severe dehydration.

### Model Validation

The average AUC for the DHAKA Dehydration Score derived in the bootstrap samples was 0.80 for diagnosing severe dehydration, and the

average performance of each of the bootstrap-derived models on the original dataset was 0.78, yielding an estimated optimism of 0.02 for the AUC. The average AUC for the DHAKA Dehydration Tree model derived in the bootstrap samples was 0.76 for the diagnosis of severe dehydration, and the average performance of each of the bootstrap-derived models on the original dataset was 0.74, yielding a similarly small estimated optimism of 0.02 for the AUC. The small optimism scores suggest that neither model is

**TABLE 3.** 12-Point DHAKA Dehydration Scoring System With Assigned Dehydration Categories

Clinical Sign	Finding	Points
General appearance	Normal	0
	Restless/irritable	2
	Lethargic/unconscious	4
Respirations	Normal	0
	Deep	2
Skin pinch	Normal	0
	Slow	2
	Very slow	4
Tears	Normal	0
	Decreased	1
	Absent	2
DHAKA Dehydration Score Categories		Points
No dehydration		0–1
Some dehydration		2–3
Severe dehydration		≥4

overly optimistic and both would likely perform similarly when tested in a new population of children.

## DISCUSSION

The DHAKA study has produced the first empirically derived and internally validated diagnostic model for assessing dehydration in children with acute diarrhea by general practice nurses in a resource-limited setting. The DHAKA Dehydration Score and DHAKA Dehydration Tree are clinical tools that may significantly assist nurses and other non-physician health workers to determine the best management strategy for children with acute diarrhea. Both the DHAKA Dehydration Score and DHAKA Dehydration Tree had significant positive and negative likelihood ratios, 90% inter-rater agreement, and modest optimism on bootstrap analysis.

Global health authorities recommend classifying children with acute diarrhea into 3 categories based on their initial clinical presentation, with significant differences in management based on the category assigned.<sup>5–8</sup> Children classified as no dehydration (Plan A) receive only expectant outpatient management, with instructions given to continue breastfeeding as appropriate, provide the child with a normal diet, and encourage fluid intake. Children classified with some dehydration (Plan B) are rehydrated using ORS, an inexpensive but logistically intensive process. According to WHO guidelines, the child should be observed in the health facility for a minimum of 4 hours while the mother slowly spoons or drips 75 ml/kg of ORS into the child's mouth, a few milliliters every minute.<sup>10</sup> If the child still has some dehydration at the end of that period, the process is repeated for another 4 hours, requiring both a sufficient amount of space and an adequate number of health workers to observe this process over a prolonged time period. Finally, children with severe dehydration (Plan C) are resuscitated with IVF, which generally requires the child to be transferred to an inpatient facility. Not only is IVF more expensive and human resource-intensive than ORS (requiring careful vigilance to ensure the child is not overhydrated), but it also can cause more adverse events than ORS in children without severe dehydration, including seizures and death, and can lead to longer hospital lengths of stay.<sup>4</sup>

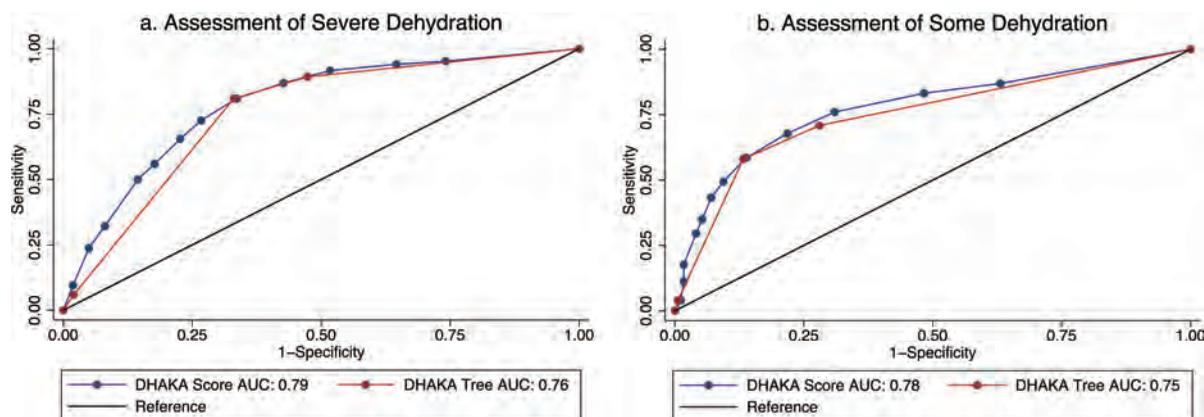
As such, the initial categorization of the dehydration status of a child with diarrhea has significant consequences, both to the individual child and to the health system as a whole. Inappropriate categorization, at best, will result in overutilization of precious health care resources. At worst, it will result in direct harm to the child. Despite the incredible importance of this initial diagnostic decision, however, the most accurate and reliable method for estimating the dehydration category of children with diarrhea in resource-limited settings has yet to be determined.

Early dehydration scales were created based on expert opinion alone and never validated for their performance in children with diarrhea.<sup>23,24</sup> In the past 2 decades, 4 clinical scales have been derived empirically using data from prospective cohorts of children against a valid criterion standard.<sup>16,25–27</sup> All 4 scales, however, were developed in high- or middle-income countries based on the clinical assessments of highly skilled providers. It is unclear

**Internal validation of the DHAKA Dehydration Score and Tree indicated the models would likely perform similarly well when tested in a new population of children.**

**Accurate diagnosis of dehydration status in a child with diarrhea has significant consequences both to the individual child and to the health system as a whole.**

**FIGURE 2.** Receiver Operating Characteristic (ROC) Curves of the DHAKA Dehydration Score and DHAKA Dehydration Tree



Abbreviation: AUC, area under the receiver operating characteristic curve.

**Clinical diagnostic models derived in high- and middle-income countries may not perform as well in low-income countries.**

how well these scales might perform when used by less experienced providers in resource-limited settings, where the vast majority of diarrhea morbidity and mortality occurs. Clinical diagnostic models empirically derived in high- and middle-income countries may not perform as well in low-income countries where a higher proportion of acute diarrhea is caused by bacterial infections and where children tend to have higher rates of malnutrition. In addition, frontline providers in low-income countries are predominantly general practice nurses and health auxiliaries with limited training, which may also reduce the accuracy of clinical diagnostic models developed for use by physician specialists in high-resource settings. For the DHAKA study, all data were collected by research nurses without extensive experience in the management of dehydration in children, in order to ensure that the results would be as generalizable as possible to frontline health workers in other resource-limited settings.

Additionally, prior derivation studies of clinical diagnostic models have generally failed to provide explicit information about *how* study staff assessed each of the clinical signs of dehydration. For a clinical diagnostic model to perform as accurately in practice as it did in its derivation study, health workers worldwide must be able to assess each of the clinical variables within the model in the exact same way as the research staff who initially collected the study data. This means

that it is not enough for a clinical diagnostic model to instruct health workers to assess for the presence or absence of sunken eyes or tears, but it must also specify how each of those signs was assessed by research staff in the original study. To achieve this objective, detailed protocols were developed *a priori* for the assessment of each of the clinical signs included in the DHAKA study, which have been included as a supplement to this article ([Supplementary Appendix 2](#)).

Finally, none of the 4 previously derived dehydration scales was based on cohorts of children large enough to develop a stable clinical diagnostic model. While a minimum number of 5–10 events per variable is required for the derivation of a stable model, the 4 prior studies each had 1–2 events per variable, making it unlikely for them to perform similarly in future datasets.<sup>17,18,22</sup> Indeed, the Clinical Dehydration Scale, the only 1 of these 4 scales to be externally validated, has performed with mixed results in new populations of children.<sup>11,12,27–31</sup> Not only is the DHAKA study the largest prospective study of dehydration assessment in children, enrolling more subjects than all 4 previously mentioned studies combined together, but it is also the first such study with more than 5 cases of severe dehydration per variable entered into the diagnostic model.

Worldwide, the most common clinical tool for assessing dehydration in children remains the

**TABLE 4.** Assigned DHAKA Dehydration Score and DHAKA Dehydration Tree Categories Compared With True Dehydration Status, No. (%)

True Dehydration Status	DHAKA Dehydration Score Category			DHAKA Dehydration Tree Category		
	No Dehydration (n=247)	Some Dehydration (n=156)	Severe Dehydration (n=365)	No Dehydration (n=369)	Some Dehydration (n=106)	Severe Dehydration (n=296)
No dehydration	175 (71)	91 (58)	73 (20)	244 (66)	50 (47)	45 (15)
Some dehydration	67 (27)	59 (38)	219 (60)	116 (31)	49 (46)	182 (61)
Severe dehydration	5 (2)	6 (4)	73 (20)	9 (2)	7 (7)	69 (23)

WHO algorithm, which has been incorporated into the WHO IMCI guidelines and integrated into official ministry of health protocols in many low-income countries (Supplementary Appendix 1).<sup>5,10</sup> While the WHO algorithm was originally created based on expert consensus, several recent studies have evaluated its capacity to discriminate between children with and without dehydration in both low- and high-income countries. A small study by Pringle et al. of 52 children presenting with acute diarrhea to 3 rural hospitals in East Africa found the WHO algorithm to be a poor predictor of severe dehydration in children, with an AUC of 0.58 (95% CI=0.39, 0.78) for the prediction of moderate dehydration and 0.58

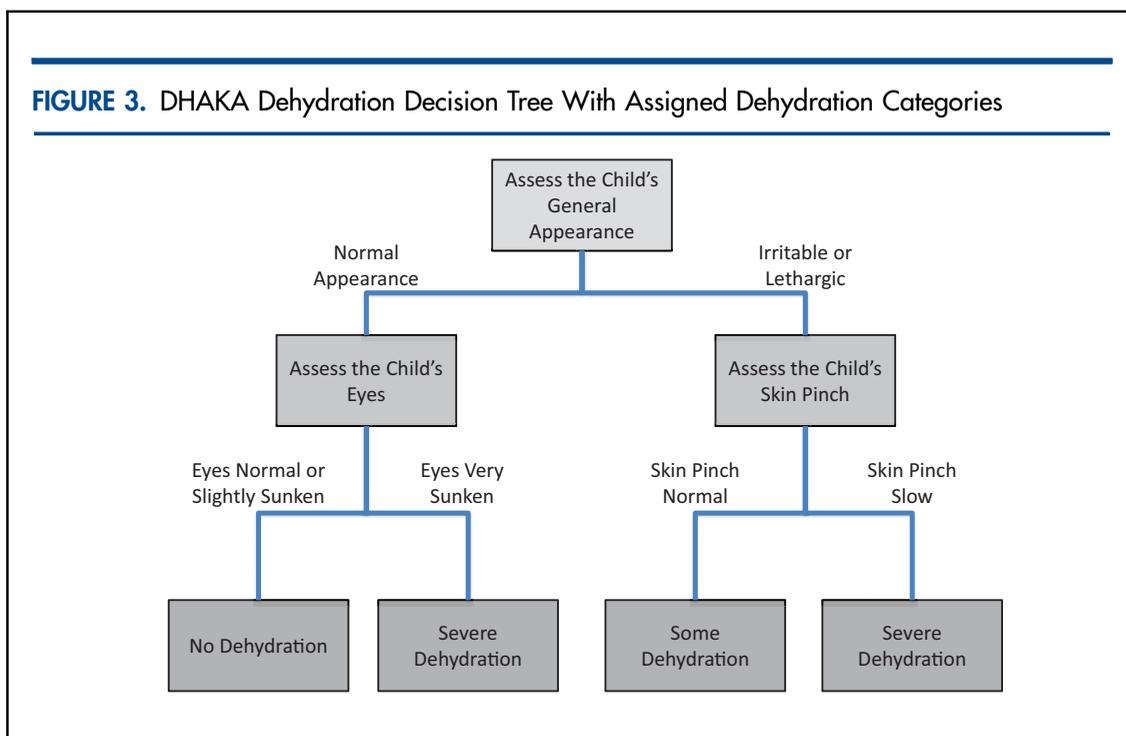
(95% CI=0.41, 0.75) for the prediction of severe dehydration, neither of which were statistically different from chance.<sup>11</sup> A somewhat larger study by Jauregui et al. of 113 patients presenting to an urban pediatric emergency department in the United States found the WHO algorithm to have an AUC of 0.61 (95% CI=0.45, 0.77) for the prediction of moderate dehydration, also no different from chance.<sup>13</sup> A final study conducted by Levine et al. among 178 children with acute diarrhea in Rwanda found the WHO algorithm to have a non-significant AUC of 0.65 (95% CI=0.47, 0.83) for the prediction of severe dehydration when applied by general practice nurses.<sup>12</sup> Overall, the study found the sensitivity of the WHO

**Recent studies have found that the WHO algorithm does not discriminate well between children with and without dehydration.**

**TABLE 5.** Test Characteristics for DHAKA Dehydration Score and DHAKA Dehydration Tree

Clinical Diagnostic Model/Dehydration Category	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	LR+ (95% CI)	LR- (95% CI)
<b>DHAKA Dehydration Score</b>						
Some dehydration	83% (80%, 87%)	52% (46%, 57%)	69% (65%, 73%)	71% (65%, 77%)	1.7 (1.5, 1.9)	0.33 (0.26, 0.41)
Severe dehydration	87% (80%, 94%)	57% (54%, 61%)	20% (16%, 24%)	97% (96%, 99%)	2.0 (1.8, 2.3)	0.23 (0.13, 0.40)
<b>DHAKA Dehydration Tree</b>						
Some dehydration	71% (67%, 75%)	72% (67%, 77%)	76% (72%, 81%)	66% (61%, 71%)	2.5 (2.1, 3.0)	0.40 (0.34, 0.47)
Severe dehydration	81% (73%, 89%)	67% (63%, 70%)	23% (18%, 28%)	97% (95%, 98%)	2.5 (2.1, 2.8)	0.28 (0.18, 0.44)

Abbreviations: CI, confidence interval; LR-, negative likelihood ratio; LR+, positive likelihood ratio; NPV, negative predictive value; PPV, positive predictive value.

**FIGURE 3.** DHAKA Dehydration Decision Tree With Assigned Dehydration Categories

algorithm to be 67% and the specificity to be 68% for predicting severe dehydration in children.

As part of the DHAKA study, we have developed both a logistic regression model (referred to as the DHAKA Dehydration Score) and a recursive-partitioning model (referred to as the DHAKA Dehydration Tree) for the categorization of dehydration status in children with acute diarrhea. While the DHAKA Dehydration Score and DHAKA Dehydration Tree were found to have similar accuracy in our study, the latter may be easier to use by less experienced clinicians in resource-limited settings, since it does not require any computation and can be made into a completely visual decision tree. In addition, the DHAKA Dehydration Tree takes into account important interactions among variables. For instance, there appears to be an interaction between general appearance and sunken eyes, whereby very sunken eyes act as a strong predictor of severe dehydration in children with normal general appearance but add little to the diagnosis of severe dehydration in children with a lethargic appearance. Lack of the normal facial expressions seen in a happy, healthy child may make the eyes of a lethargic child appear quite sunken, even when they are not actually so.

On the other hand, the DHAKA Dehydration Score can be more easily adapted to different

settings, because it allows clinicians to choose their own cut-points for the 3 dehydration categories. For instance, if a clinician wanted a more sensitive test for severe dehydration, so as to be sure not to miss any children at risk for death, they could choose a lower cut-point than the score of 4, which we chose for this paper. Alternatively, if they wanted a more specific (though less sensitive) test, perhaps due to limitations in the availability of IVE, they could choose to use a higher cut-point for the diagnosis of severe dehydration.

While the DHAKA Dehydration Score and DHAKA Dehydration Tree share some elements with the current WHO algorithm, there are important differences. The primary difference is the absence of the clinical sign thirst, which requires differentiating between children who are refusing to drink because they are not thirsty and those who are refusing to drink because they are severely dehydrated. In addition, some providers may find either the DHAKA Dehydration Score or the DHAKA Dehydration Tree more intuitive and easier to use in practice than the WHO algorithm. Finally, both the DHAKA Dehydration Score and the DHAKA Dehydration Tree avoid the interaction between sunken eyes and lethargy, while the WHO algorithm does not.

**The DHAKA Dehydration Tree may be easier to use than the Score by less experienced clinicians in resource-limited settings.**

**The DHAKA Dehydration Score can be easily adapted to different settings.**

## Strengths and Limitations

Our study population is not representative of all children in the world with diarrhea, most of whom never present to a health facility for clinical care, nor is it intended to be. However, we believe that our study population is reasonably representative of children with acute diarrhea who *do* present for medical care in low-income countries, and this is the population for which a clinical diagnostic model will be of most use. Since all clinical services are free, icddr,b cares for children from across the socioeconomic spectrum. Our study population includes a mix of children from both urban and rural settings, and a mix of children with both acute watery diarrhea and rice-water (typically cholera) diarrhea. Finally, about 90% of the children presenting to the rehydration unit at icddr,b arrive directly from home, with only 10% referred from other health facilities, making its case-mix more similar to a primary health center than a secondary referral hospital.

Moreover, since determination of the percent weight change with rehydration requires weighing children at regular intervals until they achieve a stable weight, it is not possible to conduct this study in a purely ambulatory setting, where patients are assessed only briefly and then discharged home or referred elsewhere. The rehydration unit at icddr,b provides the opportunity to observe ambulatory patients in a controlled setting long enough for the vast majority to achieve a stable weight before discharge home.

While the best physiologic criterion standard for dehydration remains the percent difference between pre-illness and admission weight, accurate pre-illness weights are rarely available for children in resource-limited settings. Instead, we used the percent weight change with rehydration as the criterion standard for percent dehydration in our study, which correlates almost perfectly with percent volume loss and has been used in nearly all prior studies of dehydration in children.<sup>9,16,32</sup>

We were able to assess the inter-rater reliability of the DHAKA Dehydration Score and DHAKA Dehydration Tree for only about half of patients enrolled in the study (those presenting during times of day when a second research nurse was available to perform a repeat exam). Even so, the lower bound of the 95% confidence intervals for the weighted kappa statistics for both the DHAKA Dehydration Score and DHAKA Dehydration Tree

are greater than 0.60, which would generally be considered good reliability in the literature.

While internal validation using bootstrap sampling found good statistical reproducibility for both models, both the DHAKA Dehydration Score and the DHAKA Dehydration Tree require external validation in a new study population before they can be recommended for widespread clinical use. In addition, since these models were developed under relatively controlled conditions using data collected by dedicated research nurses with 4–6 years of clinical experience, they should be further assessed in other clinical settings with a variety of different providers in order to determine their generalizability.

## CONCLUSION

This is the first study to empirically derive stable clinical diagnostic models for dehydration in children with diarrhea. If validated in new cohorts of children, these new clinical tools should be incorporated into international and local guidelines for the management of childhood illness.

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## ORIGINAL ARTICLE

# Improved Reproductive Health Equity Between the Poor and the Rich: An Analysis of Trends in 46 Low- and Middle-Income Countries

John Ross<sup>a</sup>

**In light of advocacy efforts to reach the poorest with better health services, an examination of recent history reveals that overall the poor-rich gap in contraceptive use is already narrowing substantially, and more so where family planning programs are stronger. For most of 18 other reproductive health indicators, the gap is also narrowing. However, contraceptive use gaps in many sub-Saharan African countries have not diminished, calling for strong family planning program efforts to improve equity.**

## ABSTRACT

While several indicators for reproductive health have improved for entire populations, few analyses are available for trends over time in the gaps between the poor and the rich. This paper tracks improvements in the equitable distribution of reproductive health indicators according to wealth quintiles, especially for contraceptive use, in 46 low- and middle-income countries based on national population-based surveys conducted between 1990 and 2013. It focuses on the gaps between the poorest and richest quintiles in the earliest and latest survey rounds across a number of reproductive health indicators related to family planning, fertility desires, antenatal care, and infant and child mortality, as well as on improvements in the absolute levels of contraceptive use by the poorest quintile. Gap changes were decomposed to show how the gaps can either diminish or grow due to either the bottom or top quintile, or both. In addition, bivariate correlation analysis was conducted to examine the relationship of the gaps, and of contraceptive use by the poor, to national family planning program efforts. Overall, the gaps between the poorest and richest have narrowed, due primarily to faster improvements among the poor than the rich. For example, the gap between the richest and poorest in the modern contraceptive prevalence rate has declined by 25%, from a 20.4 percentage point difference to a 15.4 point difference. And the gap has decreased more where family planning programs have been stronger. Across most of 18 other reproductive health indicators, the gaps have also been narrowing. For instance, the poor-rich gap for antenatal care decreased by over a third, from a difference of 30.7 percentage points to 19.6 percentage points. Gaps in infant and child mortality also have declined by about one-third. The pattern for contraceptive use in sub-Saharan Africa, however, has been mixed, with the gap actually increasing in some countries with strong programs. This disparity may largely reflect that family planning in the region is generally at an earlier stage in its history, and so programs may initially be reaching better-off clients, especially in urban areas. To promote additional equity, programs should emphasize efforts to increase access to voluntary family planning services to the least well-off, including those in rural and peri-urban areas.

## INTRODUCTION

While several indicators for reproductive health have improved for entire populations, the gaps between the poor and the rich are another matter. This article assesses the gaps between the poor and the rich regarding contraceptive use and selected reproductive

health topics. The core question is whether the serious gaps between the poor and rich in measures of reproductive health have diminished over time and, if so, whether this is due to absolute improvements among the poor.

There is rather little literature on these topics. Some documentation is available on the actual differences among quintiles for reproductive health services. For example, Singh, Darroch, and Ashford show the

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systematic gradient across the 5 wealth quintiles for delivery in a health facility and for care for sexually transmitted infections (STIs) or STI symptoms.<sup>1</sup> The series of national Demographic and Health Survey (DHS) reports include quintile differences for a range of indicators; see, for example, the initial tables on “Characteristics of Survey Respondents.”<sup>2</sup> However, few analyses are available for trends over time in the poor-rich gaps.

Gakidou and Vayena, writing in 2007, compared modern contraceptive use by the poorest quintile with national averages of use.<sup>3</sup> They found that modern contraceptive use by the poor remained quite low even while use nationally was rising: “Over time the gaps in use persist and are increasing.” The authors conclude, “The secular trend of increasing rates of modern contraceptive use has not resulted in a decrease of the gap in use ...” While they did not study the trend or gaps for all contraceptive use, only modern use, at least as of 2007 the broad nature of the findings would probably not be much different for all use. However, the use of traditional methods may be relatively greater among the poor and among rural populations, which would lessen the gap for all use.

Another analysis, by Hosseinpoor and colleagues,<sup>4</sup> argues that multiple indicators of health inequality should be used and that both gaps and absolute measures of inequality should be examined. Besides wealth quintiles, differences in residence, education, and gender should be considered to capture inequality. Moreover, since there are numerous dimensions to health inequality, proportional improvements in each should be the focus rather than any single standard. They illustrate the use of both absolute and relative inequalities in 30–31 countries for antenatal care received and births attended by health personnel, using DHS and other surveys conducted between 1993 and 2011 (9- to 11-year intervals between initial and latest surveys). That work is greatly expanded in a recent publication from the World Health Organization that includes interactive data visualization features, with an extensive analysis of some 23 indicators for reproductive health including maternal and child health.<sup>5</sup> It covers 86 low- and middle-income countries, of which 42 have data on time trends. Four dimensions of inequality are traced, for economic status, education, residence, and gender, and countries are compared on a composite index of 8 of the 23 indicators. Contraceptive use

is examined especially according to education differentials. In general, improvements over time have occurred faster among the least advantaged, but large gaps remain.

A predecessor of wealth quintiles is the possession of modern objects to assess personal socioeconomic status. This method was used as early as 1963, in a large-scale experiment of family planning adoption in Taichung, Taiwan. Freedman and Takeshita asked respondents whether they owned any of 9 objects such as a bicycle, radio, or sewing machine.<sup>6</sup> The authors found close correlations between the number of modern objects owned and ever use of contraception or abortion, as well as attitudes toward traditional family values.

The purpose of this article, as stated above, is to examine wealth gaps over time in low- and middle-income countries regarding a number of reproductive health indicators, especially contraceptive use, using national population-based surveys conducted between 1990 and 2013.

## DATA AND METHODS

The data sets used here come from the DHS series, which offers standardized tabulations with wealth quintiles that are not available in other sources such as the Reproductive Health Surveys (RHS) or the Multiple Indicator Cluster Survey (MICS) series. All data were accessed online through the DHS Program STATcompiler ([www.statcompiler.com](http://www.statcompiler.com)), which contained 249 surveys as of April 2015. Of these, 62 lacked breakdowns by quintiles and 25 countries had only a single survey, leaving 162 surveys (for 46 different countries). The analyses here compare the earliest survey to the most recent survey in each country (total of 92 surveys) to capture the maximum time interval in which changes could be observed (Table 1).

The intervals between the paired surveys for each country varied, averaging 14 years of observation time. The set of 92 surveys occurred between 1990 and 2013, with 2002 as the midpoint. The interquartile range was between 11 years and 16.5 years, so half of the surveys were clustered within that interval of 5.5 years. The 46 countries included the largest ones of Bangladesh, India, Indonesia, Nigeria, and Pakistan as well as numerous middle-sized ones; altogether they contain two-thirds (67.3%) of the developing world’s population outside of China. (However, each country has equal importance in

**Improvements in reproductive health status over time have generally occurred faster among the least advantaged, but large gaps remain, finds a recent WHO study.**

**TABLE 1.** Countries and Survey Years Included in the Analysis

Region/Country	Initial Survey Year	Latest Survey Year	Region/Country	Initial Survey Year	Latest Survey Year
<b>sub-Saharan Africa</b>			<b>North Africa/West Asia</b>		
Benin	1996	2006	Armenia	2000	2010
Burkina Faso	1998-99	2010	Egypt	1995	2008
Cameroon	1991	2011	Jordan	1990	2009
Chad	1996-97	2004	Morocco	1992	2003-04
Côte d'Ivoire	1994	2011-12	<b>Central Asia</b>		
Eritrea	1995	2002	Kazakhstan	1995	1999
Ethiopia	2000	2011	<b>South &amp; Southeast Asia</b>		
Gabon	2000	2012	Bangladesh	1993-94	2011
Ghana	1993	2008	Cambodia	2000	2010
Guinea	1999	2005	India	1992-93	2005-06
Kenya	1993	2008-09	Indonesia	1997	2012
Lesotho	2004	2009	Nepal	1996	2011
Madagascar	1997	2008	Pakistan	1990-91	2012-13
Malawi	1992	2010	Philippines	1993	2008
Mali	1995-96	2006	Viet Nam	1997	2002
Mozambique	1997	2011	<b>Latin America &amp; Caribbean</b>		
Namibia	1992	2006-07	Bolivia	1994	2008
Niger	1998	2006	Colombia	1990	2010
Nigeria	1990	2008	Dominican Republic	1996	2007
Rwanda	1992	2010	Guatemala	1995	1998-99
Senegal	1997	2010-11	Haiti	1994-95	2012
Tanzania	1996	2010	Honduras	2005-06	2011-12
Uganda	1995	2011	Nicaragua	1998	2001
Zambia	1996	2007	Peru	1991-92	2012
Zimbabwe	1994	2010-11			

the averages below since the averages are not weighted by population size.)

Limitations of the data occur partly because STATcompiler offers quintile breakdowns only on selected variables; nevertheless the variety is fairly inclusive. Some country questionnaires omit questions on a variable so that a few tabulations are for only 42 to 45 countries rather than 46; for example, the question for

“ever had sex” was omitted in several countries. A few measures of potential interest are not included for lack of available quintile breakdowns, for example, the proportion of demand for contraception not yet satisfied by modern methods.<sup>7</sup>

### Dependent Variables

The **contraceptive prevalence rate** (CPR), which includes use of any type of contraceptive method,

was analyzed for currently married women ages 15–49. We also analyzed the **modern contraceptive prevalence rate** (mCPR), which includes all methods except the “traditional” ones of rhythm and withdrawal. Here, we follow the DHS specifications of modern methods; they are the sum of male and female sterilization, intrauterine devices (IUDs), oral contraceptive pills, injectables, implants, male and female condoms, diaphragm/foam/jelly, the lactational amenorrhea method (LAM), the Standard Days Method (SDM), and “other” modern methods. However, across all DHS surveys, 5 of these methods (pills, IUDs, injectables, male condoms, and female sterilization) account for 96% of all modern method use.

We also explored 18 additional indicators to document whether any progress has been made in past years across a broad range of reproductive health concerns. The 18 indicators, along with the DHS definitions, are:

**Poor-rich gaps were examined for the CPR, mCPR, and 18 other reproductive health indicators.**

1. **Antenatal care (ANC):** percent distribution of live births in the 3 years (or in some surveys, 5 years) preceding the survey by source of ANC during pregnancy; also percent distribution of women who had a live birth in the 3 (5) years preceding the survey by number of ANC visits and by the timing of the first visit. The analyses here use only the percentage who had no ANC visits.
2. **Signs of pregnancy complications:** among women receiving antenatal care, percentage informed of signs of pregnancy complications.
3. **Receipt of iron or syrup:** percentage of women with a live birth in the 3 (5) years preceding the survey who received iron tablets or syrup or anti-malarial drugs for the most recent birth.
4. **Receipt of tetanus injections:** percent distribution of last live birth in the last 3 (5) years preceding the survey by number of tetanus toxoid injections given to the mother during pregnancy.
5. **Place of delivery:** percent distribution of live births in the last 3 (5) years preceding the survey, by place of delivery.
6. **Assistance during delivery:** percent distribution of live births in the last 3 (5) years preceding the survey, by type of assistance during delivery.
7. **Distance problems:** percentage of women who reported they have big problems in accessing health care for themselves when they are sick, by type of problem.
8. **Perinatal mortality:** number of stillbirths and early neonatal deaths, for the 5-year period preceding the survey.
9. **Infant mortality:** percent of births dying within the first year of life.
10. **Under-5 mortality:** percent of births dying within the first 5 years of life.
11. **Total wanted fertility rate:** for the 3 years preceding the survey. Similar to the total fertility rate but excludes unwanted births.
12. **Total fertility rate:** for the 3 years preceding the survey.
13. **Want to limit childbearing:** percentage of currently married women who want no more children by number of living children.
14. **Ideal number of children:** percent distribution of currently married women by ideal number of children, according to number of living children.
15. **Ideal number of children at age 20–24:** ideal number of children for currently married women aged 20–24.
16. **Unmet need for family planning:** percentage of currently married women with unmet need for family planning, i.e., the percentage of women currently married or in union who are fecund and who desire to either stop or postpone childbearing, but who are not currently using a contraceptive method.
17. **Unmet need for limiting:** separates women with unmet need for those who wish to *stop* future childbearing.
18. **Unmet need for spacing:** separates women with unmet need for those who wish to *postpone* the next birth; usually defined as at least 2 years later.

### Independent Variables

One analysis in this article examines the relationship of gaps in contraceptive use to the **efforts of national family planning programs**. The latter are measured in a series of studies in some 80 developing countries through ratings by local experts and are available approximately 5 years apart from 1982 through 2014. Termed the Family Planning Program Effort Index, the ratings comprise 31 items under the 4 components of policies, services, evaluation, and access

to methods. A total score is included as the average of the 31 items, as well as summary scores for each of the 4 components. Details are given in a series of publications on the various rounds.<sup>8</sup>

The analysis here used the Family Planning Program Effort Index cycles from 1994 through 2009, and it focused on the total score as well as the specific access score as a more immediate measure of provision of contraceptive supplies and services to the general population.

In relating gaps in contraceptive use to program effort, it is awkward to align the dates for the 2 measures, since the program effort studies occurred at fixed dates whereas the gaps are measured in surveys that were conducted at different dates and at different intervals. The surveys occurred between 1990 and 2013, so one way to explore the relationships is to examine the correlations between the gaps and all of the program cycles from 1994 through 2009, which occurred at the approximate midpoints of many survey intervals. This was done in relation to both the CPR and to the mCPR.

The analysis of contraceptive use gaps and family planning program efforts considers the sub-Saharan African region separately from the other countries due to the region's special character and because its levels of contraceptive use are low, which tends to constrain the size of gaps in use between the poor and the rich. Of the 46 countries, 25 were in sub-Saharan Africa and 21 elsewhere (8 in Latin America, 8 in South and Southeast Asia, 4 in North Africa/West Asia, and 1 in the Central Asia Republics). Those 21 countries outside sub-Saharan Africa were combined since the individual numbers were too small for separate estimates.

The **wealth index** is a composite measure of a household's living standard, using its ownership of selected assets such as bicycles and televisions; materials used in the housing construction; and types of water access and sanitation facilities.<sup>9</sup> The index itself is divided into quintiles, then each household is scored on each of the index's components to obtain the overall rating. The overall rating assigns the household to 1 of the 5 parts of the index. (Because the quintiles are defined on the weighted index, the final country distribution can differ from 20% of households in each quintile; however, generally the differences are small.) Finally, the household rating is applied to each individual member. The various DHS reports compare the influence of wealth on various

population, health, and nutrition indicators, as noted above. For example:

- In Nigeria, children from the wealthiest households are nearly 15 times more likely to be vaccinated than those from the poorest households (58% vs. 4% are fully immunized, respectively).<sup>10</sup>
- In the Philippines, 96% of women in the wealthiest households are assisted by a health professional at delivery, compared with only 42% of women in the poorest households.<sup>11</sup>
- In Tanzania, HIV prevalence is nearly 2 times higher among women in the wealthiest households (8.0%) compared with those in the poorest households (4.8%).<sup>12</sup>

The wealth index is particular to each country, and the 5 quintiles are relative to each other, not to any international standard. Since they are gauged within each country, the absolute levels of poverty in the poorest quintile can be different from those in a neighboring country. However, Winfrey and colleagues have produced a standardized version of the wealth index that allows for comparisons across time for countries and across countries for any point in time.<sup>13</sup> (See Rutstein and Staveteig for an earlier analysis.<sup>14</sup>) Winfrey and colleagues have used the standardized version to disaggregate the contribution of improvements in family planning for women at particular levels of economic status versus the improvements in overall economic status. This unusual effort echoes the call by Hosseinpoor and colleagues<sup>4</sup> for attention to cross-country criteria.

Unlike the intermediate quintiles, the top and bottom ones include the extreme cases. That is, the wealth range within the top group can contain exceptionally well-off persons, and the bottom group can contain the most desperately poor. All quintile comparisons in this article are between the poorest and the wealthiest quintiles; preliminary tabulations were done to broaden the view to compare the bottom 2 quintiles to the top 2 quintiles. Those results closely paralleled the ones for the bottom vs. the top; only the contrasts were reduced (softened) compared with those between the bottom alone and the top alone.

All 5 quintiles can be examined through other techniques that examine the interplay of all 5 quintiles, but this analysis uses the simpler approach of comparing the poorest and the richest, which also reflects the focus of current discussions.

**The Family Planning Program Effort Index measures program efforts across policies, services, evaluation, and access to methods.**

Any of the available measures of inequality can be studied in relationship to such determinants as the nation's modernization or urbanization levels, the allocation of public resources, or other characteristics.

### Data Analysis

For each feature of reproductive health examined, the analysis started with the values for all 5 quintiles, in the initial and latest surveys for each country. Next, the differences between the bottom and top quintiles in the initial and latest survey rounds were calculated to highlight the gap between the poor and the rich, along with the improvement in the gap. Further analysis was then conducted to decompose the gap changes, to show how they can either diminish or grow, due to changes in either the bottom or top quintile. In addition, for contraceptive use, an analysis explored how large the absolute increase in use was among those in the poorest wealth quintile;

for both the CPR and the mCPR, ratios of the starting level to the ending level were calculated for each country, and then mean and median ratios for each region and for all 46 countries combined were calculated. Bivariate correlation analysis was performed to explore the relationship between contraceptive use gaps and family planning program effort.

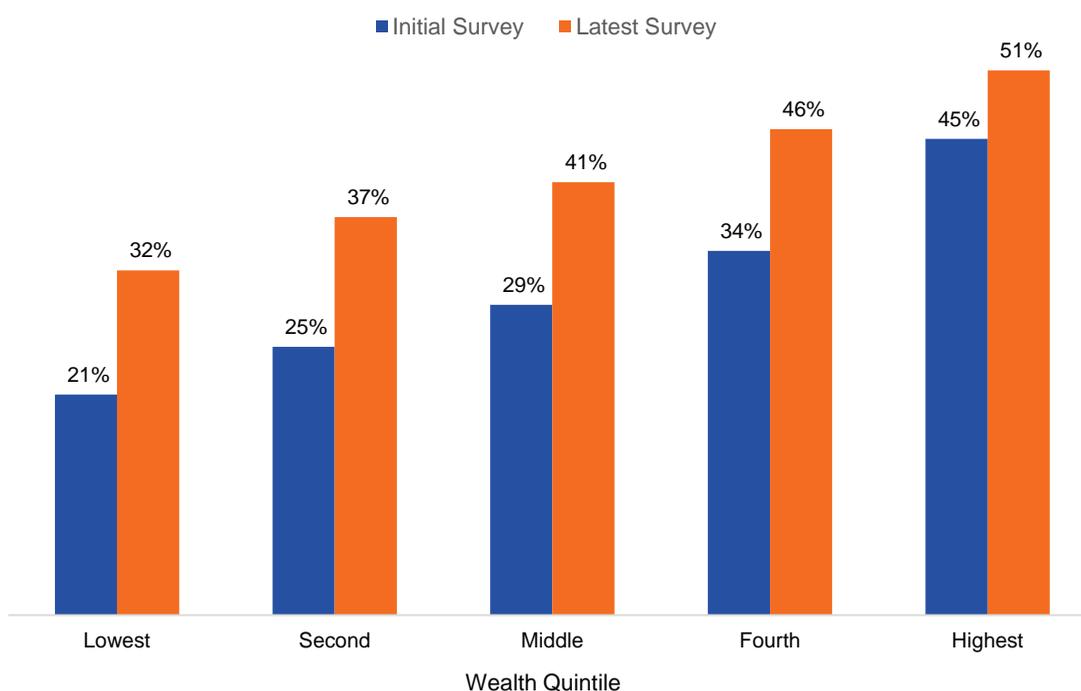
## FINDINGS

### Contraceptive Use by Wealth Quintile

For all 46 countries included in the analysis, CPR increased with increasing wealth quintile (Figure 1). For example, among married women in the lowest quintile, the CPR was 21% in the initial survey rounds, and it grew to 32% in the latest surveys. Among the highest wealth quintile, the CPR was 45% in the initial surveys, growing to 51% in the latest surveys.

The gap between the poor and the rich in contraceptive use has in fact declined over the

**FIGURE 1.** Contraceptive Prevalence Rates at Initial and Latest Surveys,<sup>a</sup> by Wealth Quintile, 46 Low- and Middle-Income Countries



<sup>a</sup> Survey years varied by country, ranging from 1990 in the initial surveys to 2013 in the latest surveys.

years. In the initial survey rounds, the CPR gap between the highest and lowest wealth quintile was 24 percentage points (Figure 2). In the latest survey rounds, the CPR gap shrunk by 5 points, for a 19-percentage point difference between the highest and lowest wealth quintiles.

### Decomposition of Gap Changes

In what ways can the gaps change, either growing or shrinking? A gap change is the net result of moves by either or both of the 2 quintiles being compared. It can come from an up or down move by the poor quintile and/or by the rich quintile.

Table 2 illustrates, for the CPR and mCPR, the ways in which a gap may increase (Ethiopia) or decline (Eritrea). The decomposition of the rising gap in Ethiopia shows CPR gains in both quintiles, but a far larger one in the rich quintile: 23.5 vs. only 9.8 in the poor quintile, so the gap increased by nearly 14 points. Eritrea illustrates a reverse dynamic, in which the CPR fell in both quintiles, but more so in the rich quintile: 5.1 vs. 0.8 in the poor quintile, shrinking the gap by 4.3 points. Parallel results occurred for the mCPR.

The type of change is decomposed for all 46 countries in Table 3. Countries are divided into those with increasing gaps (12 countries) and those with decreasing gaps (34 countries). The rows further separate countries by whether both rates fell, or both rose, or showed a mixed combination. In each cell, Q1 refers to the poorest quintile and Q5 to the richest quintile. For example, in the first row the CPR in both quintiles fell, but the CPR in the wealthiest quintile fell more, thereby shrinking the gap.

The second row of Table 3 contains 33 countries, 7 cases in which the gap worsened as contraceptive use among the rich rose faster than among the poor. However, in the majority (26 of 46 countries, or 57%), the poor increased contraceptive use faster than the rich did. The third row shows 5 countries in which use fell among the poor and rose among the rich, enlarging the gap, together with 6 countries in which the opposite occurred, reducing the gap.

In short, a diverse picture emerges for the ways in which the CPR gap can rise or fall over time. Mainly, however, the CPR gap has fallen as contraceptive use has increased faster among the poor than among the rich.

In absolute terms for the CPR itself, 39 of 46 cases (85%) can be viewed as having favorable results for the poor; the CPR rose among both

poor and rich in 33 countries and among the poor but not the rich in 6 more.

Note that all countries with increasing gaps, in the first column, are in sub-Saharan Africa except Armenia. It is likely that contraceptive use has spread more rapidly in the cities than in the rural areas, which overlap with the bottom quintile. Again however, in absolute terms contraceptive use in 7 of the 12 countries has risen among both the poor and the rich.

### Gaps and Gap Improvements for Contraceptive Use

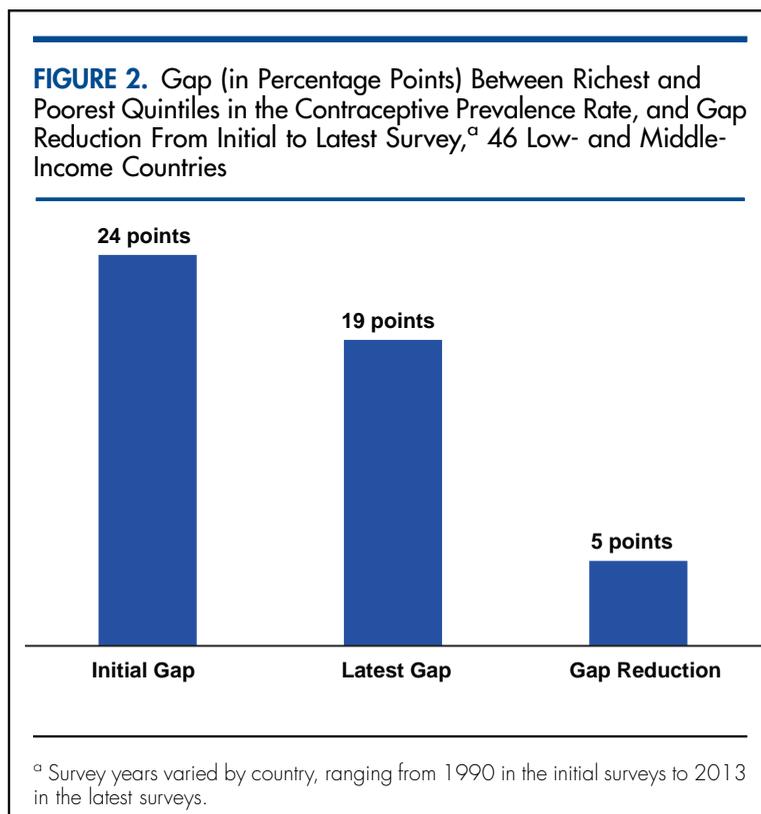
The gap between the richest and the poorest quintiles for contraceptive use has been shrinking overall, for both the CPR and the mCPR (Table 4, last row).

For the CPR, the decline of 5.7 points against the starting level of 24.3 represents a 23% fall in the CPR gap, and the decline of 5.0 points on the starting mCPR level of 20.4 is a 25% fall in the mCPR gap. The average interval between surveys is 14 years, which converts the declines to 0.41 (5.7/14) and 0.36 points (5.0/14) per year, respectively.

**Gaps between the poor and the rich in contraceptive use have declined over the years.**

**The poor increased contraceptive use faster than the rich did in the majority of countries examined.**

**The poor-rich gap for modern contraceptive use overall has declined by 25%.**



**TABLE 2.** Two Types of Changes<sup>a</sup> in Quintile Gaps for Contraceptive Use, Illustrative Examples From Ethiopia and Eritrea

	Ethiopia: Rising Gaps			Eritrea: Declining Gaps		
	Gap at Initial Survey	Gap at Latest Survey	Gap Change	Gap at Initial Survey	Gap at Latest Survey	Gap Change
<b>CPR</b>						
Poor	3.5	13.3	9.8	2.5	1.7	-0.8
Rich	28.3	51.8	23.5	25.5	20.4	-5.1
Gap	24.8	38.5	13.7	23.0	18.7	-4.3
<b>mCPR</b>						
Poor	2.7	13.0	10.3	0.3	1.4	1.1
Rich	22.9	48.2	25.3	18.9	17.9	-1.0
Gap	20.2	35.2	15.0	18.6	16.5	-2.1

<sup>a</sup> The rising CPR and mCPR gaps in Ethiopia are a reflection of larger gains among the rich than among the poor. On the other hand, in Eritrea the CPR and mCPR fell among both quintiles but more so in the wealthiest quintile, resulting in shrinking gaps.

**The average gap change in contraceptive use overall in sub-Saharan Africa has been relatively static.**

Sub-Saharan Africa is different: the average gap change for its 25 countries has been nearly zero. There is diversity, however; 10 countries show a worsening gap for the CPR (12 for the mCPR), in some cases by a considerable margin of 10 or more points, while the other 15 countries show lessening gaps. The picture is mixed, as it is for the other regions.

However, the other regions have experienced appreciable improvements in their gaps (leaving Central Asia aside with only Kazakhstan): changes of 14.0 (CPR) and 12.9 (mCPR) points in North Africa/West Asia, 9.8 and 10.6 points, respectively, in South and Southeast Asia, and 15.7 and 12.1 points, respectively, in Latin America and the Caribbean. Over 14 years, the annual paces for the CPR are 1.0 for North Africa/West Asia, 0.70 for South and Southeast Asia, and 1.1 for Latin America and the Caribbean, and 0.92, 0.76, and 0.86, respectively, for the mCPR (not shown).

Again, the picture is uneven: among countries, the smallest gap changes for the mCPR in these regions (excluding sub-Saharan Africa and Central Asia) range from -2.6 to 3.2; numerous others are about 8.0 to 11.2; and others exceed 15, with highs at 25.0 in Morocco, 21.0 in Colombia, and 20.2 in Peru.

Each measure, the CPR and the mCPR, has its own story to tell. Where the CPR gap closed more than the mCPR one did, equity for the use

of traditional methods improved in addition to the improvement for modern methods, a welcome outcome. But where the mCPR gap improved more, the equity improvement for traditional methods was less; in fact if the CPR and mCPR gap reductions were equal there was no gap reduction in traditional method use. In [Table 4](#), 13 of the 46 countries show a larger improvement for the mCPR than for the CPR, whereas in 16 other countries the CPR improvement was greater, reflecting an improvement for traditional methods in addition to that for modern methods. Most of the other countries show mixed patterns, with a worsening gap in either the CPR or mCPR or both. In some cases the CPR improved while the mCPR did not, so the improvement in the traditional method gap more than compensated for the worsening mCPR gap.

There is also substantial diversity in the sizes of the gaps themselves (not the gap changes), whether at the initial or latest surveys. Where contraceptive use has reached moderately high levels in the general population, the gap between rich and poor can be quite large, as in Kenya, Lesotho, Madagascar, and Namibia, ranging from 37 to nearly 50 points for the gaps in the CPR in the initial surveys, and none of these have shrunk very much.

[Appendix 1](#) and [Appendix 2](#) provide the full set of CPR and mCPR values, respectively, in the initial and latest surveys for each of the 46 countries by

**TABLE 3.** List of Countries According to Type of Change in the CPR Gap and CPR Decrease or Increase Between Surveys, Q1 (Poorest) Compared With Q5 (Richest)

	Increasing CPR Gap	Decreasing CPR Gap	TOTAL
<b>Both rates fell</b>	<b>0</b>	<b>Q1 fell; Q5 fell more: 2</b> Eritrea Senegal	<b>2</b>
<b>Both rates rose</b>	<b>Q1 rose; Q5 rose more: 7</b> Ethiopia Guatemala Mozambique Nigeria Rwanda Tanzania Uganda	<b>Q1 rose; Q5 rose less: 26</b> Bangladesh Bolivia Cambodia Colombia Côte d'Ivoire Dominican Rep. Egypt Guinea Haiti Honduras India Jordan Kazakhstan Kenya Lesotho Madagascar Malawi Morocco Namibia Nepal Nicaragua Pakistan Peru Philippines Zambia Zimbabwe	<b>33</b>
<b>Mixed</b>	<b>Q1 fell; Q5 rose: 5</b> Armenia Benin Burkina Faso Cameroon Chad	<b>Q1 rose; Q5 fell: 6</b> Gabon Ghana Indonesia Mali Niger Viet Nam	<b>11</b>
<b>TOTAL</b>	<b>12</b>	<b>34</b>	<b>46</b>

region, for the lowest and highest quintiles with the changes, the gap, and the gap reduction.

### Absolute Increases in Contraceptive Use by the Poorest Quintile

It is good news that the gaps in use between the poorest and wealthiest are narrowing, but how large is the absolute increase in use among the poorest? Gaps can narrow simply

because contraceptive use declines among the wealthiest, as noted previously. Table 5 provides the absolute increases in use for both the CPR and the mCPR among those in the poorest quintile, as well as the ratios between the starting and ending levels, by region. Note that each ratio shown is the average of all 46 individual country ratios, so it does not necessarily reconcile with the overall starting and ending levels in each row. It is

**TABLE 4.** Initial and Latest Gaps (in Percentage Points) Between Richest and Poorest Quintiles and Gap Changes Between Initial and Latest Survey, for the Contraceptive Prevalence Rate (CPR) and Modern Contraceptive Prevalence Rate (mCPR), 46 Low- and Middle-Income Countries

Country, Latest Survey Year	CPR			mCPR		
	Gap at Initial Survey	Gap at Latest Survey	Gap Change	Gap at Initial Survey	Gap at Latest Survey	Gap Change
<b>sub-Saharan Africa</b>						
Benin, 2006	17.0	25.9	– 8.9	7.7	10.8	– 3.1
Burkina Faso, 2010	16.7	30.0	– 13.3	14.3	26.5	– 12.2
Cameroon, 2011	31.2	38.3	– 7.1	11.8	23.3	– 11.5
Chad, 2004	6.6	10.3	– 3.7	4.7	7.3	– 2.6
Côte d'Ivoire, 2011–12	24.5	16.3	8.2	11.4	12.2	– 0.8
Eritrea, 2002	23.0	18.7	4.3	18.6	16.5	2.1
Ethiopia, 2011	24.8	38.5	– 13.7	20.2	35.2	– 15.0
Gabon, 2012	23.1	14.9	8.2	12.6	10.0	2.6
Ghana, 2008	22.4	17.2	5.2	13.7	9.0	4.7
Guinea, 2005	13.4	11.8	1.6	8.2	10.0	– 1.8
Kenya, 2008–09	37.0	34.6	2.4	34.8	31.0	3.8
Lesotho, 2009	36.9	31.6	5.3	37.8	32.3	5.5
Madagascar, 2008–09	39.9	37.4	2.5	21.5	18.8	2.7
Malawi, 2010	15.9	14.3	1.6	13.3	13.5	– 0.2
Mali, 2006	19.2	15.4	3.8	14.8	13.6	1.2
Mozambique, 2011	16.8	27.4	– 10.6	16.0	26.6	– 10.6
Namibia, 2006–07	48.6	39.2	9.4	51.5	38.8	12.7
Niger, 2006	18.9	10.0	8.9	17.3	13.5	3.8
Nigeria, 2008	18.9	31.8	– 12.9	11.7	19.8	– 8.1
Rwanda, 2010	8.8	14.0	– 5.2	6.3	11.1	– 4.8
Senegal, 2010–11	20.6	19.7	0.9	22.6	18.5	4.1
Tanzania, 2010	26.3	27.7	– 1.4	24.0	18.5	5.5
Uganda, 2011	22.3	31.5	– 9.2	23.7	26.4	– 2.7
Zambia, 2007	20.5	13.7	6.8	25.9	17.7	8.2
Zimbabwe, 2010–11	19.5	10.3	9.2	24.6	11.2	13.4
<b>Mean</b>	<b>22.9</b>	<b>23.2</b>	<b>– 0.3</b>	<b>18.8</b>	<b>18.9</b>	<b>– 0.1</b>

Table 4 (continued).

Country, Latest Survey Year	CPR			mCPR		
	Gap at Initial Survey	Gap at Latest Survey	Gap Change	Gap at Initial Survey	Gap at Latest Survey	Gap Change
<b>North Africa/West Asia</b>						
Armenia, 2010	-2.4	9.2	-11.6	13.7	16.3	-2.6
Egypt, 2008	30.7	10.0	20.7	29.2	10.4	18.8
Jordan, 2009	30.0	11.8	18.2	22.8	12.6	10.2
Morocco, 2003-04	40.4	11.6	28.8	30.4	5.4	25.0
<b>Mean</b>	<b>24.7</b>	<b>10.7</b>	<b>14.0</b>	<b>24.0</b>	<b>11.2</b>	<b>12.9</b>
<b>Central Asia</b>						
Kazakhstan, 1999	12.8	4.5	8.3	5.8	6.2	-0.4
<b>South &amp; Southeast Asia</b>						
Bangladesh, 2011	13.3	-0.7	14.0	8.2	-1.8	10.0
Cambodia, 2010	23.1	10.8	12.3	12.9	-3.8	16.7
India, 2005-06	29.7	25.3	4.4	25.7	23.4	2.3
Indonesia, 2012	13.7	5.1	8.6	10.7	2.4	8.3
Nepal, 2011	31.4	19.2	12.2	29.2	13.3	15.9
Pakistan, 2012-13	30.2	25.0	5.2	22.0	13.5	8.5
Philippines, 2008	17.4	9.2	8.2	15.7	7.2	8.5
Viet Nam, 2002	16.9	3.2	13.7	8.5	-6.3	14.8
<b>Mean</b>	<b>22.0</b>	<b>12.1</b>	<b>9.8</b>	<b>16.6</b>	<b>6.0</b>	<b>10.6</b>
<b>Latin America &amp; Caribbean</b>						
Bolivia, 2008	45.7	24.6	21.1	39.9	23.9	16.0
Colombia, 2010	30.9	4.5	26.4	27.4	6.4	21.0
Dominican Rep., 2007	13.8	5.6	8.2	12.5	2.8	9.7
Guatemala, 1998-99	60.1	64.5	-4.4	51.7	54.3	-2.6
Haiti, 2012	23.6	1.3	22.3	16.0	-2.2	18.2
Honduras, 2011-12	20.0	8.8	11.2	23.5	12.3	11.2
Nicaragua, 2001	27.0	22.0	5.0	24.0	20.8	3.2
Peru, 2012	36.5	1.0	35.5	37.8	17.6	20.2
<b>Mean</b>	<b>32.2</b>	<b>16.5</b>	<b>15.7</b>	<b>29.1</b>	<b>17.0</b>	<b>12.1</b>
<b>Overall Mean</b>	<b>24.3</b>	<b>18.6</b>	<b>5.7</b>	<b>20.4</b>	<b>15.4</b>	<b>5.0</b>

**More use of modern methods accounts for nearly all the increase in contraceptive use across regions.**

more accurate to rely upon the 46 ratios than upon the relation of the average starting level to the average ending level.

Clearly, the poorest quintile has substantially increased its contraceptive use across regions. Focusing just on the mCPR:

- On average, the mCPR has risen by 13 points, from 14% of married women using a modern method to 27%. (Total use has risen from 21% to 33%.)
- Overall, the average ratio of the ending-use level to the starting-use level is 3.5 (mean) or 2.6 (median). Note that these are averages across the individual ratios for the 46 countries, which include some quite high ratios, so

the median is preferred (see footnote in Table 5 concerning ratios).

- Modern methods account for nearly all of the increase in contraceptive use. The average rise in modern use, of 12.7 points, slightly exceeds the average rise in all use of 12.3 points. That means that, on average, any substitution of modern for traditional use has been tiny, only 0.4 point.
- Sub-Saharan Africa is special since its starting-use levels were so far below those of the other regions: only 4.6% of married women used a modern method (mean) or 2.1% (median). It increased those levels about fourfold between starting and ending. However, a large proportionate increase is easier from a low starting level since a small absolute rise can

**TABLE 5.** Initial and Latest Levels of Contraceptive Use, by Region, for the Poorest Quintile

Region	Initial CPR Level	CPR Rise	Latest CPR Level	Ratio, Latest/Initial	Initial mCPR Level	mCPR Rise	Latest mCPR Level	Ratio, Latest/Initial <sup>a</sup>
Overall								
Mean	20.6	12.3	32.9	1.9	13.8	12.7	26.5	3.5
Median	14.6	10.6	31.8	1.7	5.5	10.3	24.3	2.6
sub-Saharan Africa								
Mean	9.5	7.6	17.1	2.0	4.6	9.6	14.2	4.2
Median	8.0	4.5	13.3	2.0	2.1	6.3	11.6	3.9
North Africa/West Asia								
Mean	34.0	21.1	55.1	2.0	19.2	21.2	40.3	2.1
Median	27.4	27.1	54.5	2.0	16.7	22.6	44.0	2.1
Central Asia								
Kazakhstan	52.8	10.9	63.7	1.2	43.8	5.1	48.9	1.1
South & Southeast Asia								
Mean	31.7	16.0	47.7	1.7	25.7	13.5	39.2	1.8
Median	28.3	13.2	43.7	1.5	20.3	10.6	35.4	1.6
Latin America & Caribbean								
Mean	33.6	19.1	52.8	1.9	24.1	18.2	42.3	3.8
Median	38.9	18.8	53.7	1.8	24.1	18.2	45.1	2.4

Abbreviations: CPR, contraceptive prevalence rate; mCPR, modern contraceptive prevalence rate.

<sup>a</sup> These ratios average the 46 individual country ratios. They do not reconcile with the average starting and ending levels in the same row since those smooth out the overall numerators and denominators of the ratios. It is preferable to use the 46 individual country ratios.

become a large proportion. Most other regions started much higher and their absolute increases were much larger, yet their ratios are well below those of sub-Saharan Africa, except for the mean of 3.8 in Latin America.

- For total use (CPRs), the ratios are generally lower, principally because the starting levels are higher than for modern use (and in sub-Saharan Africa, the increases are less than for modern methods).
- Individual countries show substantial variation around each summary (Appendix 1).

### Family Planning Program Effort and Gaps in Contraceptive Use

Can the efforts of national family planning programs reduce gaps in contraceptive use, perhaps by helping the poor increase use faster than among the rich? Bivariate correlation analysis was performed to explore this relationship (Table 6).

A positive “r” correlation value indicates that a greater gap reduction accompanies greater program effort, generally due to a faster increase in use by the poorest than the richest quintile, shrinking the disparity between the groups.

In **sub-Saharan Africa**, several points stand out (top of Table 6):

- In the top panel, most correlations are of substantial size, suggesting greater gap reductions accompanying greater program effort. The gaps have narrowed more where program effort has been stronger.
- Most correlations are closer with the mCPRs than with the CPRs, which reflects the focus of national programs on only modern methods.
- Most mCPR correlations are greater with the “Access Scores” than with the “Total Effort Scores” in both 2004 and 2009; they are about equal in 1994 and 1999. Normally we would expect correlations between access and contraceptive use to be relatively close since access is a necessary condition for contraceptive use and the two are intimately connected. However, correlations to gaps rather than levels are a different matter.
- The correlations with the 2004 scores are small, which is something of an anomaly since the correlations before, in 1999, and after, in 2009, are sizeable.
- To augment the analysis, we can examine actual use levels by the poorest quintile in

relation to program effort; this follows on the evidence presented previously that the absolute levels of contraceptive use by the poor have risen. Since most gap reductions are due to a faster rise in contraceptive use among the poor than among the rich, how does use by the poor relate to program effort? The right panel of the sub-Saharan Africa section of Table 6 shows the positive relationship, with substantial correlations in all years, although less so for effort in 2004. Where program effort is stronger, use by the poorest quintile is higher. That in turn has translated into the shrinking gaps in contraceptive use between the poor and the rich, as mentioned previously.

For **all other countries** (lower part of Table 6), the patterns are generally similar, although with less regularity. We place less emphasis on these correlations due to small numbers in each sub-region; however, the correlations for the relation of gap reductions to program effort are mostly positive, as they are for access. For unclear reasons, the figures for 1994 are weak, and even negative for access. Greater regularity and higher correlations appear in the right panel of the “all other countries” section, for more contraceptive use by the poor where programs are stronger. The pattern is consistent across all years.

Overall, the starting hypothesis is supported in both regions, that stronger program effort is accompanied by larger reductions in the gaps and by more contraceptive use among the poor that helps explain the gap reductions.

Finally, it is important to recognize that the poorest quintile is dominated, in most countries, by the rural population. The changes noted previously appear to occur disproportionately: “rural” and “poorest quintile” overlap considerably, as seen from two perspectives: (1) the percentage of the total rural population that falls into the bottom quintile, and (2) the percentage of the bottom quintile that is composed of rural people.

To illustrate, with examples taken from 3 DHS surveys in different regions, from the first perspective, in Indonesia, Egypt, and Malawi, 33%, 30%, and 23% of the rural population, respectively, fall into the poorest quintile. The second perspective is more telling: of all women in the poorest quintile, a remarkable 84%, 94%, and 98% live in rural areas, respectively. These high percentages reflect the features of which the wealth index is composed. Rural people are generally disadvantaged when it comes to

**Greater family planning program effort was correlated with greater gap reductions in contraceptive use.**

**TABLE 6.** Correlations (*r* Values) for Relation of Family Planning Program Efforts to Gap Changes Between Richest and Poorest Quintiles and to Contraceptive Use by the Poorest, 46 Low- and Middle-Income Countries

	Gap Change		CPR for Poorest Quintile	mCPR for Poorest Quintile
	CPR	mCPR		
<b>sub-Saharan Africa (N=25 Countries)</b>				
Total Effort Score				
2009	0.58	0.49	0.43	0.43
2004	(0.04)	0.12	0.13	0.21
1999	0.26	0.39	0.36	0.42
1994	0.38	0.45	0.43	0.44
<b>Mean</b>	<b>0.30</b>	<b>0.36</b>	<b>0.34</b>	<b>0.38</b>
Access Score				
2009	0.55	0.52	0.60	0.61
2004	0.09	0.25	0.24	0.29
1999	0.34	0.49	0.38	0.41
1994	0.19	0.39	0.42	0.43
<b>Mean</b>	<b>0.29</b>	<b>0.41</b>	<b>0.41</b>	<b>0.44</b>
<b>All Other Countries (N=21 Countries)</b>				
Total Effort Score				
2009	0.25	0.41	0.32	0.47
2004	0.19	0.29	0.29	0.50
1999	0.20	0.22	0.28	0.36
1994	(0.02)	—	0.28	0.38
<b>Mean</b>	<b>0.16</b>	<b>0.23</b>	<b>0.29</b>	<b>0.43</b>
Access				
2009	0.32	0.35	0.44	0.53
2004	0.05	0.01	0.45	0.56
1999	0.32	0.09	0.40	0.26
1994	(0.11)	(0.25)	0.22	0.23
<b>Mean</b>	<b>0.15</b>	<b>0.05</b>	<b>0.38</b>	<b>0.40</b>

the indicators of which the wealth index is composed. Appendix 3 provides fuller details. When we say “bottom quintile,” we are most likely saying “rural.” As contraceptive use, for example, has risen in the bottom quintile, it has risen primarily among rural residents.

### Gaps for Additional Indicators of Reproductive Health

The previous sections have focused in detail on contraceptive use; now we look at 18 additional reproductive health indicators for patterns in the changing gaps between the bottom and top quintiles.

Among the 18 indicators, most gaps have shrunk, while a few have not changed and 2 have increased (Table 7). In nearly all cases, the initial gap occurs because the poor rating was higher than the rich rating (so nearly all figures are positive). The exception is with desire to limit childbearing, since the rich typically want to limit further childbearing more than the poor do, and the rich are slightly more likely than the poor to say that the last birth was wanted later or not at all.

The overriding finding is that the gaps have diminished on most indicators, which is good news for the field of reproductive health, although the annual pace of improvement may have been slow. In Table 7, the final column shows the percentage declines in the gaps. The annual pace of improvement is not shown; on average, for the 46 countries the interval between surveys is 14 years, but

depending on the particular country the interval can be less or more, affecting the annual rate of change in the gap.

For lack of antenatal care, in the initial survey, the percentage of poor women who lacked ANC altogether was 30.7 percentage points higher than for rich women (pertains to births within the last 3 years). By the time of the most recent surveys, that gap had declined to 19.6 percentage points. Thus, the gap declined by over one-third (11.1/30.7).

The gains have been positive and substantial for the next 3 pregnancy-related services, for being told of possible pregnancy complications, receiving iron or syrup (or in some countries also malaria tablets), and receiving tetanus shots. Next, an exception is delivering in a health facility, but interestingly, the gap for having a skilled attendant at birth has improved, perhaps reflecting

**Gaps in lack of antenatal care have declined by over one-third.**

**TABLE 7.** Gaps Between the Poorest and Richest Quintiles (Poor Minus Rich) at Initial and Latest Survey<sup>a</sup> and Gap Changes, by Reproductive Health Indicator, 46 Low- and Middle-Income Countries

Reproductive Health Indicator	Gap at Initial Survey	Gap at Latest Survey	Gap Reduction	% Improvement
% with no antenatal care	30.7	19.6	11.1	36.1
% not told of pregnancy complications	27.9	20.9	7.0	25.1
% not receiving iron or syrup	31.7	24.3	7.4	23.2
% not receiving tetanus	21.9	14.8	7.1	32.3
% not delivering in health facility	48.3	49.1	(0.7)	(1.6)
% lacking skilled attendant at birth	51.4	46.8	4.6	8.9
% with distance problem	52.6	35.5	17.1	32.5
Perinatal mortality	14.4	9.6	4.8	33.1
Infant mortality rate	37.1	24.2	13.0	34.9
Under-5 mortality rate	66.8	46.8	20.0	30.0
Total fertility rate	2.9	2.9	0.03	0.9
Wanted fertility rate	2.1	1.9	0.2	8.8
Want to limit childbearing	(7.1)	(2.5)	4.6	64.4
Ideal no. of children	1.38	1.28	0.10	7.4
Ideal no. of children at ages 20–24	1.17	1.02	0.14	12.0
Unmet need for family planning	7.9	7.8	0.1	1.4
Unmet need for limiting	3.7	3.6	0.2	5.1
Unmet need for spacing	4.1	4.2	(0.1)	(1.4)

<sup>a</sup> Survey years varied by country, ranging from 1990 in the initial surveys to 2013 in the latest surveys.

Note: Data in the last 2 columns were calculated with more decimals than shown and can reflect rounding.

**Declining gaps across many indicators are due to faster relative increases by the poor than by the rich.**

more services at home among the poor. Distance as a serious barrier during sickness has improved sharply, again by about a third (17.1/52.6). Those gains are echoed in narrowed infant and child mortality gaps; they too have declined by about a third.

The gaps between the poor and the rich for the total fertility rate have remained unchanged, at 2.9 births, but the gap in the wanted fertility rate has declined slightly. The original rates that compose the gaps have fallen considerably (not shown); as the earlier sections explain, a gap can increase, decrease, or remain constant while the constituent rates behind the gaps move in various directions.

In *Table 7*, the gap can be negative if the rich rating is above the poor rating, as with “wanting to limit childbearing” (7.1%), since more of the rich wish to limit than the poor do. Then if later the gap narrows, the change itself is positive. Also, where the gap is small to begin with the absolute change is necessarily small, but the percentage change can be large, as also with the item for wanting to limit childbearing. The gaps are small for the ideal number of children and have not varied much over the years, either for all women or for young women aged 25–29. The gap for “ever had sex” is consistent with an earlier onset of sexual activity among the poor.

Finally, gaps in unmet need for family planning have changed very little, while in many countries unmet need overall has declined. All the unmet need gaps are subject to differing rates of change by the poor and the rich, which in turn can reflect a moving balance between increased contraceptive use and a decline in number of children wanted.

## DISCUSSION

Data from 46 low- and middle-income countries show equity improvements across a surprisingly wide range of reproductive health features. Differences have been shrinking between the poor and the rich for contraceptive use, for 5 of 6 major indicators of antenatal and delivery care, for reduced distances to urgent health services, and for infant/child mortality. The gaps have declined as well for the wanted fertility rate and, in smaller degrees, for ideal number of children and unmet need for limiting births. Methodologically, it is straightforward for any country to update or retrace its quintile gaps from a new survey or a review of past ones, and given the data, provincial comparisons are possible.

Gap improvements are not to be confused with general improvements for populations at large. The share held by the poor can remain constant or

worsen as overall population rates improve. However, the findings here are that the declining gaps found in many indicators are due to faster relative increases by the poor than by the rich. That reflects improvements in the absolute levels for the poor, which can be separate and even more significant than the gap reductions.

Overall the gaps in the indicators examined have diminished, but the diversity is considerable among regions and, within each region, among countries. For a few indicators, in some countries the gaps have worsened. Especially for the poorest quintile, some sub-Saharan African countries have not done well. However, even in such cases there may be internal contrasts in the levels (rather than the gaps) that suggest some progress, particularly if the levels have risen in each sector. For example, in Nigeria the CPR in cities was about 3 times higher than in the rural sector (25.9% vs. 9.4%, respectively) in 2008, and both had risen from the 2003 survey (16.7% urban and 6.5% rural, also a threefold difference).

## Programmatic Implications

The analyses above clarify how gap changes can occur in a mechanical sense, i.e., by whether the relative shift is faster in one quintile than another, with changes in either or both quintiles, to go up or down. Behind those trends, however, stand the actual reasons for the substantive changes. Where any quintiles, but especially the poor ones, show improvements, what are the reasons? For contraceptive use, the evidence is that national family planning programs are helpful, and they tend to focus on the general population rather than just on the upper wealth quintiles. It is heartening that the “equity gap” in contraceptive use is narrowing in most countries and narrowing more where program efforts, especially for access to methods, are stronger. This calls for continued and increasing program efforts to advance contraceptive use and to provide more equitable services. However, sub-Saharan Africa is a partial exception, with the overall gap remaining rather constant. And in some countries with notably strong family planning programs (e.g., Ethiopia and Rwanda), the gap actually increased over this time period. This disparity, however, may largely reflect that family planning in sub-Saharan Africa is in general at an earlier stage in its history, in which there is typically more demand for contraception among those who are better off. Further, early program efforts tend to focus on those easiest to reach, particularly in urban areas. And as we have seen, a lack of wealth is highly

**Equity between the poor and the rich has improved across a wide range of reproductive health indicators.**

correlated with rural residence, and sub-Saharan Africa is more highly rural than any other region. As programs mature, they are able to serve a broader proportion of the population.

Thus, these findings reinforce the need for strong voluntary family planning programming to reduce gaps further. Where programs are deliberately focused on the rural or the poor, that reinforces the tendency for the bottom to improve faster than the top. The “equity gap” remains sizable in many countries, and programs should emphasize efforts to provide access to the least well-off, including those in rural areas and the poorer parts of urban areas. Examples include mobile outreach and social franchising approaches, which are especially successful in reaching rural and poorer clients,<sup>15,16</sup> community health workers, vouchers, and use of the “total market approach,” which seeks to encourage the better-off to use private-sector services so as to free up public-sector services for less well-off clients. Meanwhile, the poor have been doing better over the past period of about 14 years, although the pace of doing so has been uneven across indicators. Overall, however, the narrowing poor-rich gaps across multiple indicators is rather remarkable.

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**Strong family planning programming is needed to reduce gaps between the poor and rich further.**

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**APPENDIX 1.** Contraceptive Prevalence Rate (CPR), CPR Changes, Quintile Gaps, and Changes in Quintile Gaps Between Initial and Latest Survey, 46 Low- and Middle-Income Countries

Country, Survey Year	Lowest Quintile		Highest Quintile		Quintile Gap	Gap Change
	CPR	CPR Rise	CPR	CPR Rise		
<b>sub-Saharan Africa</b>						
Benin 2006	7.7	-1.5	33.6	7.4	25.9	-8.9
Benin 1996	9.2		26.2		17.0	
Burkina Faso 2010	7.4	-0.6	37.4	12.7	30.0	-23.6
Burkina Faso 1998-99	8.0		24.7		16.7	
Cameroon 2011	2.9	-1.9	41.2	5.2	38.3	-7.1
Cameroon 1991	4.8		36.0		31.2	
Chad 2004	0.0	-3.5	10.3	0.2	10.3	-3.7
Chad 1996-97	3.5		10.1		6.6	
Côte d'Ivoire 2011-12	11.7	8.0	28.0	-0.2	16.3	8.2
Côte d'Ivoire 1994	3.7		28.2		24.5	
Eritrea 2002	1.7	-0.8	20.4	-5.1	18.7	4.3
Eritrea 1995	2.5		25.5		23.0	
Ethiopia 2011	13.3	9.8	51.8	23.5	38.5	-13.7
Ethiopia 2000	3.5		28.3		24.8	
Gabon 2012	21.3	2.5	36.2	-5.7	14.9	8.2
Gabon 2000	18.8		41.9		23.1	
Ghana 2008	14.2	2.4	31.4	-2.8	17.2	5.2
Ghana 1993	11.8		34.2		22.4	
Guinea 2005	5.3	3.6	17.1	2.0	11.8	1.6
Guinea 1999	1.7		15.1		13.4	
Kenya 2008-09	20.1	5.4	54.7	3.0	34.6	2.4
Kenya 1993	14.7		51.7		37.0	
Lesotho 2009	30.1	12.5	61.7	7.2	31.6	5.3
Lesotho 2004	17.6		54.5		36.9	
Madagascar 2008-09	19.9	14.1	57.3	11.6	37.4	2.5
Madagascar 1997	5.8		45.7		39.9	
Malawi 2010	38.7	29.3	53.0	27.7	14.3	1.6
Malawi 1992	9.4		25.3		15.9	
Mali 2006	3.7	2.4	19.1	-1.4	15.4	3.8
Mali 1995-96	1.3		20.5		19.2	

**APPENDIX 1 (continued).**

Country, Survey Year	Lowest Quintile		Highest Quintile		Quintile Gap	Gap Change
	CPR	CPR Rise	CPR	CPR Rise		
Mozambique 2011	2.9	1.6	30.3	12.2	27.4	-10.6
Mozambique 1997	1.3		18.1		16.8	
Namibia 2006-07	31.9	22.4	71.1	13.0	39.2	9.4
Namibia 1992	9.5		58.1		48.6	
Niger 2006	10.9	7.3	20.9	-1.6	10.0	8.9
Niger 1998	3.6		22.5		18.9	
Nigeria 2008	3.2	2.3	35.0	15.2	31.8	-12.9
Nigeria 1990	0.9		19.8		18.9	
Rwanda 2010	43.1	23.6	57.1	28.8	14.0	-5.2
Rwanda 1992	19.5		28.3		8.8	
Senegal 2010-11	4.8	-1.8	24.5	-2.7	19.7	0.9
Senegal 1997	6.6		27.2		20.6	
Tanzania 2010	22.9	12.8	50.6	14.2	27.7	-1.4
Tanzania 1996	10.1		36.4		26.3	
Uganda 2011	14.7	4.5	46.2	13.7	31.5	-9.2
Uganda 1995	10.2		32.5		22.3	
Zambia 2007	40.5	20.5	54.2	13.7	13.7	6.8
Zambia 1996	20.0		40.5		20.5	
Zimbabwe 2010-11	54.3	14.2	64.6	5.0	10.3	9.2
Zimbabwe 1994	40.1		59.6		19.5	
<b>MEAN CHANGES</b>		<b>7.6</b>		<b>7.9</b>		<b>-0.3</b>
<b>North Africa/West Asia</b>						
Armenia 2010	53.2	-8.4	62.4	3.2	9.2	-11.6
Armenia 2000	61.6		59.2		-2.4	
Egypt 2008	55.4	25.0	65.4	4.3	10.0	20.7
Egypt 1995	30.4		61.1		30.7	
Jordan 2009	53.5	29.1	65.3	10.9	11.8	18.2
Jordan 1990	24.4		54.4		30.0	
Morocco 2003-04	58.3	38.6	69.9	9.8	11.6	28.8
Morocco 1992	19.7		60.1		40.4	
<b>MEAN CHANGES</b>		<b>21.1</b>		<b>7.1</b>		<b>14.0</b>

**APPENDIX 1 (continued).**

Country, Survey Year	Lowest Quintile		Highest Quintile		Quintile Gap	Gap Change
	CPR	CPR Rise	CPR	CPR Rise		
<b>Central Asia</b>						
Kazakhstan 1999	63.7	10.9	68.2	2.6	4.5	8.3
Kazakhstan 1995	52.8		65.6		12.8	
<b>South &amp; Southeast Asia</b>						
Bangladesh 2011	61.5	21.1	60.8	7.1	-0.7	14.0
Bangladesh 1993-94	40.4		53.7		13.3	
Cambodia 2010	45.2	30.8	56.0	18.5	10.8	12.3
Cambodia 2000	14.4		37.5		23.1	
India 2005-06	42.2	14.1	67.5	9.7	25.3	4.4
India 1992-93	28.1		57.8		29.7	
Indonesia 2012	56.2	7.9	61.3	-0.7	5.1	8.6
Indonesia 1997	48.3		62.0		13.7	
Nepal 2011	40.4	22.7	59.6	10.5	19.2	12.2
Nepal 1996	17.7		49.1		31.4	
Pakistan 2012-13	20.8	19.2	45.8	14.0	25.0	5.2
Pakistan 1990-91	1.6		31.8		30.2	
Philippines 2008	40.8	12.3	50.0	4.1	9.2	8.2
Philippines 1993	28.5		45.9		17.4	
Viet Nam 2002	74.3	10.2	77.5	-3.5	3.2	13.7
Viet Nam 1997	64.1		81.0		16.9	
<b>MEAN CHANGES</b>		<b>17.3</b>		<b>7.5</b>		<b>9.8</b>
<b>Latin America &amp; Caribbean</b>						
Bolivia 2008	46.2	23.6	70.8	2.5	24.6	21.1
Bolivia 1994	22.6		68.3		45.7	
Colombia 2010	75.5	29.0	80.0	2.6	4.5	26.4
Colombia 1990	46.5		77.4		30.9	
Dominican Rep. 2007	67.5	12.7	73.1	4.5	5.6	8.2
Dominican Rep. 1996	54.8		68.6		13.8	
Guatemala 1998-99	8.4	1.8	72.9	6.2	64.5	-4.4
Guatemala 1995	6.6		66.7		60.1	
Haiti 2012	31.7	24.1	33.0	1.8	1.3	22.3
Haiti 1994-95	7.6		31.2		23.6	

**APPENDIX 1 (continued).**

Country, Survey Year	Lowest Quintile		Highest Quintile		Quintile Gap	Gap Change
	CPR	CPR Rise	CPR	CPR Rise		
Honduras 2011–12	67.3	14.0	76.1	2.8	8.8	11.2
Honduras 2005–06	53.3		73.3		20.0	
Nicaragua 2001	52.5	10.3	74.5	5.3	22.0	5.0
Nicaragua 1998	42.2		69.2		27.0	
Peru 2012	72.9	37.4	73.9	1.9	1.0	35.5
Peru 1991–92	35.5		72.0		36.5	
<b>MEAN CHANGES</b>		<b>19.1</b>		<b>3.5</b>		<b>15.7</b>
<b>OVERALL MEAN CHANGES</b>		<b>12.5</b>		<b>6.8</b>		<b>5.4</b>

**APPENDIX 2.** Modern Contraceptive Prevalence Rate (mCPR), mCPR Changes, Quintile Gaps, and Changes in Quintile Gaps Between Initial and Latest Survey, 46 Low- and Middle-Income Countries

Country, Survey Year	Lowest Quintile		Highest Quintile		Gap	Gap Change
	mCPR	mCPR Rise	mCPR	mCPR Rise		
<b>sub-Saharan Africa</b>						
Benin 2006	2.4	1.1	13.2	4.2	10.8	-3.1
Benin 1996	1.3		9.0		7.7	
Burkina Faso 2010	7.1	6.3	33.6	17.2	26.5	-10.9
Burkina Faso 1998-99	0.8		16.4		15.6	
Cameroon 2011	2.4	1.7	25.7	13.2	23.3	-11.5
Cameroon 1991	0.7		12.5		11.8	
Chad 2004	0.0	-0.1	7.3	2.5	7.3	-2.6
Chad 1996-97	0.1		4.8		4.7	
Côte d'Ivoire 2011-12	7.4	6.3	19.6	7.1	12.2	-0.8
Côte d'Ivoire 1994	1.1		12.5		11.4	
Eritrea 2002	1.4	1.1	17.9	-1.0	16.5	2.1
Eritrea 1995	0.3		18.9		18.6	
Ethiopia 2011	13.0	10.3	48.2	25.3	35.2	-15.0
Ethiopia 2000	2.7		22.9		20.2	
Gabon 2012	11.9	6.3	21.9	3.7	10.0	2.6
Gabon 2000	5.6		18.2		12.6	
Ghana 2008	11.6	6.2	20.6	1.5	9.0	4.7
Ghana 1993	5.4		19.1		13.7	
Guinea 2005	2.7	1.7	12.7	3.5	10.0	-1.8
Guinea 1999	1.0		9.2		8.2	
Kenya 2008-09	16.9	6.6	47.9	2.8	31.0	3.8
Kenya 1993	10.3		45.1		34.8	
Lesotho 2009	28.6	13.2	60.9	7.7	32.3	5.5
Lesotho 2004	15.4		53.2		37.8	
Madagascar 2008-09	17.6	15.3	36.4	12.6	18.8	2.7
Madagascar 1997	2.3		23.8		21.5	
Malawi 2010	34.9	31.0	48.4	31.2	13.5	-0.2
Malawi 1992	3.9		17.2		13.3	
Mali 2006	2.8	2.3	16.4	1.1	13.6	1.2
Mali 1995-96	0.5		15.3		14.8	

**APPENDIX 2 (continued).**

Country, Survey Year	Lowest Quintile		Highest Quintile		Gap	Gap Change
	mCPR	mCPR Rise	mCPR	mCPR Rise		
Mozambique 2011	2.9	2.0	29.5	12.6	26.6	-10.6
Mozambique 1997	0.9		16.9		16.0	
Namibia 2006-07	29.6	24.2	68.4	11.5	38.8	12.7
Namibia 1992	5.4		56.9		51.5	
Niger 2006	2.3	1.5	15.8	-2.3	13.5	3.8
Niger 1998	0.8		18.1		17.3	
Nigeria 2008	2.5	2.0	22.3	10.1	19.8	-8.1
Nigeria 1990	0.5		12.2		11.7	
Rwanda 2010	38.5	26.7	49.6	31.5	11.1	-4.8
Rwanda 1992	11.8		18.1		6.3	
Senegal 2010-11	4.4	3.4	22.9	-0.7	18.5	4.1
Senegal 1997	1.0		23.6		22.6	
Tanzania 2010	19.2	14.3	37.7	8.8	18.5	5.5
Tanzania 1996	4.9		28.9		24.0	
Uganda 2011	12.7	10.6	39.1	13.3	26.4	-2.7
Uganda 1995	2.1		25.8		23.7	
Zambia 2007	30.6	25.2	48.3	17.0	17.7	8.2
Zambia 1996	5.4		31.3		25.9	
Zimbabwe 2010-11	52.4	21.2	63.6	7.8	11.2	13.4
Zimbabwe 1994	31.2		55.8		24.6	
<b>MEAN CHANGES</b>		<b>9.6</b>		<b>9.7</b>		<b>-0.1</b>
<b>North Africa/West Asia</b>						
Armenia 2010	21.4	5.9	37.7	8.5	16.3	-2.6
Armenia 2000	15.5		29.2		13.7	
Egypt 2008	51.9	23.7	62.3	4.9	10.4	18.8
Egypt 1995	28.2		57.4		29.2	
Jordan 2009	36.6	21.5	49.2	11.3	12.6	10.2
Jordan 1990	15.1		37.9		22.8	
Morocco 2003-04	51.4	33.5	56.8	8.5	5.4	25.0
Morocco 1992	17.9		48.3		30.4	
<b>MEAN CHANGES</b>		<b>21.2</b>		<b>8.3</b>		<b>12.9</b>

**APPENDIX 2 (continued).**

Country, Survey Year	Lowest Quintile		Highest Quintile		Gap	Gap Change
	mCPR	mCPR Rise	mCPR	mCPR Rise		
<b>Central Asia</b>						
Kazakhstan 1999	48.9	5.1	55.1	5.5	6.2	-0.4
Kazakhstan 1995	43.8		49.6		5.8	
<b>South &amp; Southeast Asia</b>						
Bangladesh 2011	52.9	18.4	51.1	8.4	-1.8	10.0
Bangladesh 1993-94	34.5		42.7		8.2	
Cambodia 2010	35.2	22.7	31.4	6.0	-3.8	16.7
Cambodia 2000	12.5		25.4		12.9	
India 2005-06	34.6	9.7	58.0	7.4	23.4	2.3
India 1992-93	24.9		50.6		25.7	
Indonesia 2012	53.0	6.8	55.4	-1.5	2.4	8.3
Indonesia 1997	46.2		56.9		10.7	
Nepal 2011	35.6	19.9	48.9	4.0	13.3	15.9
Nepal 1996	15.7		44.9		29.2	
Pakistan 2012-13	18.1	16.9	31.6	8.4	13.5	8.5
Pakistan 1990-91	1.2		23.2		22.0	
Philippines 2008	25.9	10.2	33.1	1.7	7.2	8.5
Philippines 1993	15.7		31.4		15.7	
Viet Nam 2002	57.9	10.9	51.6	-3.9	-6.3	14.8
Viet Nam 1997	47.0		55.5		8.5	
<b>MEAN CHANGES</b>		<b>14.4</b>		<b>3.8</b>		<b>10.6</b>
<b>Latin America &amp; Caribbean</b>						
Bolivia 2008	22.6	21.0	46.5	5.0	23.9	16.0
Bolivia 1994	1.6		41.5		39.9	
Colombia 2010	68.5	30.8	74.9	9.8	6.4	21.0
Colombia 1990	37.7		65.1		27.4	
Dominican Rep. 2007	66.5	15.3	69.3	5.6	2.8	9.7
Dominican Rep. 1996	51.2		63.7		12.5	
Guatemala 1998-99	5.4	0.0	59.7	2.6	54.3	-2.6
Guatemala 1995	5.4		57.1		51.7	
Haiti 2012	29.7	24.8	27.5	6.6	-2.2	18.2
Haiti 1994-95	4.9		20.9		16.0	

**APPENDIX 2 (continued).**

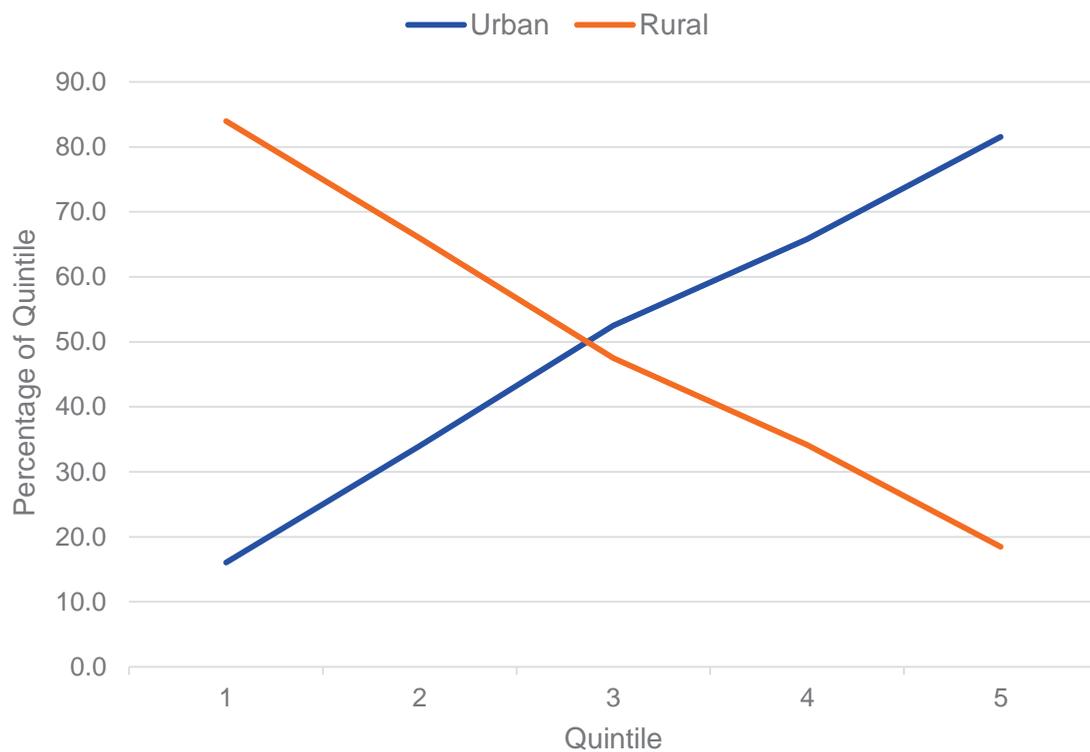
Country, Survey Year	Lowest Quintile		Highest Quintile		Gap	Gap Change
	mCPR	mCPR Rise	mCPR	mCPR Rise		
Honduras 2011–12	55.1	14.0	67.4	2.8	12.3	11.2
Honduras 2005–06	41.1		64.6		23.5	
Nicaragua 2001	50.2	10.0	71.0	6.8	20.8	3.2
Nicaragua 1998	40.2		64.2		24.0	
Peru 2012	40.5	30.0	58.1	9.8	17.6	20.2
Peru 1991–92	10.5		48.3		37.8	
<b>MEAN CHANGES</b>		<b>18.2</b>		<b>6.1</b>		<b>12.1</b>
<b>OVERALL MEAN CHANGES</b>		<b>12.9</b>		<b>7.8</b>		<b>5.0</b>

**APPENDIX 3.** Distribution of Survey Respondents by Quintile and Urban-Rural Residence

Country, Survey Year	Quintile					Total
	1	2	3	4	5	
<b>Indonesia, 2012</b>						
Urban	6.4	13.6	21.0	26.4	32.7	100
Rural	33.5	26.4	19.0	13.7	7.4	100
Urban	16.0	34.0	52.5	65.8	81.5	
Rural	84.0	66.0	47.5	34.2	18.5	
<b>Total</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	
<b>Egypt, 2014</b>						
Urban	3.1	2.8	4.6	35.8	53.7	100
Rural	30.0	30.2	29.2	10.6	0.0	100
Urban	5.6	5.1	8.3	66.1	100.0	
Rural	94.4	94.9	91.7	33.9	0.0	
<b>Total</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	
<b>Malawi, 2010</b>						
Urban	2.9	3.4	7.5	19.9	66.3	100
Rural	23.3	23.1	22.3	20.0	11.3	100
Urban	2.3	2.7	5.9	15.7	52.4	
Rural	97.7	97.3	94.1	84.3	47.6	
<b>Total</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	

Note: The first "Urban" and "Rural" rows under each country represent the percentage of the urban and rural population, respectively, falling under each wealth quintile. The second set of "Urban" and "Rural" rows under each country represent the percentage of respondents from each wealth quintile who live in urban or rural areas, respectively.

**APPENDIX FIGURE 3.** Quintile Membership by Rural and Urban Residence: Illustrative Example From Indonesia, 2012



## ORIGINAL ARTICLE

# Regulatory Monitoring of Fortified Foods: Identifying Barriers and Good Practices

Corey L Luthringer,<sup>a</sup> Laura A Rowe,<sup>b</sup> Marieke Vossenaar,<sup>a</sup> Greg S Garrett<sup>a</sup>

**Food fortification with micronutrients often is not compliant with relevant standards, in large part because poor regulatory monitoring does not sufficiently identify and hold producers accountable for underfortified products. We propose these reinforcing approaches: clear legislation, government leadership, strong enforcement of regulations, improved financial and human capacity at the regulatory agency and industry levels, civil society engagement, simplified monitoring processes, and relationship building between industry and government.**

## ABSTRACT

While fortification of staple foods and condiments has gained enormous global traction, poor performance persists throughout many aspects of implementation, most notably around the critical element of regulatory monitoring, which is essential for ensuring foods meet national fortification standards. Where coverage of fortified foods is high, limited nutritional impact of fortification programs largely exists due to regulatory monitoring that insufficiently identifies and holds producers accountable for underfortified products. Based on quality assurance data from 20 national fortification programs in 12 countries, we estimate that less than half of the samples are adequately fortified against relevant national standards. In this paper, we outline key findings from a literature review, key informant interviews with 11 fortification experts, and semi-quantitative surveys with 39 individuals from regulatory agencies and the food fortification industry in 17 countries on the perceived effectiveness of regulatory monitoring systems and barriers to compliance against national fortification standards. Findings highlight that regulatory agencies and industry disagree on the value that enforcement mechanisms have in ensuring compliance against standards. Perceived political risk of enforcement and poorly resourced inspectorate capacity appear to adversely reinforce each other within an environment of unclear legislation to create a major hurdle for improving overall compliance of fortification programs against national standards. Budget constraints affect the ability of regulatory agencies to create a well-trained inspector cadre and improve the detection and enforcement of non-compliant and underfortified products. Recommendations to improve fortification compliance include improving technical capacity; ensuring sustained leadership, accountability, and funding in both the private and the public sectors; and removing political barriers to ensure consistent detection of underfortified products and enforcement of applicable fortification standards. Only by taking concrete steps to improve the entire regulatory system that is built on a cooperative working relationship between regulatory agencies and food producers will a nutrition strategy that uses fortification see its intended health effects.

## INTRODUCTION

Large-scale food fortification is widely recognized as a cost-effective strategy to improve the micronutrient status of populations,<sup>1–3</sup> and it has been linked to economic benefits resulting from improved productivity,

increased earnings potential, and GDP growth.<sup>4–8</sup> As part of a comprehensive approach to support increased intake of critical micronutrients, fortification is a highly sustainable intervention when properly applied and regulated.<sup>9,10</sup> Fortification will increasingly become more relevant as food industries consolidate and penetrate markets in rural areas while at the same time populations urbanize and increase their consumption of centrally processed foods.<sup>11,12</sup>

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Fortification has gained global traction, especially in middle-income countries. Governments, industry, and civil society have come together to implement salt iodization programs in more than 140 countries worldwide<sup>13</sup>; 83 countries have mandated at least one kind of cereal grain fortification,<sup>14</sup> 23 countries have mandated fortification of edible oils,<sup>15</sup> and nearly a dozen countries fortify condiments. According to the Food Fortification Initiative and the Iodine Global Network, 31% of commercially milled wheat flour is fortified, reaching more than 2 billion people, and 76% of households are consuming iodized salt.<sup>13,14,16</sup>

Despite progress, there exists evidence of non-fortification and underfortification among products claiming to be fortified. Among mandatory fortification programs in low- and middle-income countries in Africa and Asia, fortification coverage and compliance can be triangulated from a variety of data sources. From household coverage data, available for 10 national salt iodization programs, a population-weighted average of 50% of households have access to adequately iodized salt.<sup>17</sup> From industry self-reported quality assurance and quality control (QA/QC) results from national fortification programs in 5 countries, representing 2 maize flour, 5 wheat flour, 1 sugar, and 4 vegetable oil programs, it is estimated that 45% of product samples are adequately fortified per national standards.<sup>18,19</sup> Accelerated degradation of certain fortificants has been seen in some climates, leading to products being underfortified when tested. These cases can and should be controlled by improving overall QA/QC practices and storage conditions by industry. This can be successfully undertaken by industry when strong regulatory monitoring practices are in place.<sup>20,21</sup>

Evidence of underfortification confirms the slow progress in improving compliance against fortification standards. Identified challenges at industry, government, and retail levels suggest critical points along the food value chain that prevent consistent compliance (Figure 1). Challenges also exist at the humanitarian level since food-related assistance often occurs in parallel with national fortification initiatives and can present barriers to compliance. Good regulatory monitoring and QA/QC practices can help ensure that food products advertised as, or required by law to be, fortified are *adequately* fortified, meaning compliant with relevant regulations or fortified as claimed. There is limited value in measuring the health impact of fortification programs if fortified foods

are not adequately fortified with a bioavailable fortificant and government regulatory monitoring systems are unable to detect underfortified products and hold their producers accountable.<sup>20,22,23</sup> Ensuring adequate fortification is necessary to improve micronutrient consumption via national fortification programs.

Regulatory monitoring is the continuous collection and review of information at key delivery points to ensure fortified foods meet national standards.<sup>21</sup> Regulatory monitoring encompasses internal control, including QA/QC activities that are the responsibility of the food producer, and external monitoring, including inspections and audits that are the responsibility of government authorities.<sup>24</sup> The purpose of internal control is to identify and remedy irregularities throughout the production and packaging processes. Governments use external monitoring to verify that manufacturing steps are properly implemented and result in a quality product. External monitoring by governments should *complement*, not replace, QA/QC processes and tests related to fortification at the production level.<sup>24</sup>

**Regulatory monitoring of food fortification includes internal quality assurance and control measures as well as external monitoring by government.**

**Of households with access to fortified foods, less than half are consuming adequately fortified foods, according to data from 22 national fortification programs.**

**FIGURE 1.** Critical Challenges Along the Food Value Chain That Present Barriers to Consistent Compliance Against National Fortification Standards



Many documents outline key elements required for successful fortification programs. These requirements focus mainly on technical, infrastructural, and socioeconomic constraints that affect the supply and demand of fortified foods; they do not focus on what is needed for effective regulatory monitoring.<sup>24,25</sup> Several manuals discuss regulatory monitoring of fortified foods; however, they focus on ideal QA/QC processes and product sampling and testing methods at the production site.<sup>22,24,26–28</sup>

The legal framework specific to food fortification provides the basis for ensuring product quality, safety, and the achievement of public health nutrition goals. Legislation should provide the basis for external monitoring systems, including clear delineations of stakeholder roles and responsibilities and a prescription of enforcement tools to deter non-compliance.<sup>29–31</sup> There is little practical guidance in the literature beyond the rationale and theory underpinning external monitoring of food fortification programs.

Many governments struggle to identify good practices in regulatory monitoring, including their role in external monitoring and in supporting industry to improve their internal control. There is insufficient practical knowledge on elements of effective and efficient external monitoring systems and a clear need to communicate lessons learned in this area. This study intends to fill this gap by providing a qualitative assessment of the barriers and successes experienced by regulatory monitoring systems and industries that fortify in low- and middle-income African and Asian countries and their perspectives on factors that contribute toward regulatory monitoring effectiveness.

## METHODS

The World Health Organization (WHO) has developed guidelines on fortification that describe key functions of regulatory monitoring and that identify criteria for evaluating monitoring systems.<sup>24</sup> These criteria include having an established set of procedures, methodologies, and reporting requirements to continuously assess the fortification program; a clear delineation of responsibilities; and an efficient feedback mechanism that facilitates the implementation of corrective measures.<sup>24</sup> These are corroborated by similar criteria identified in the FORTIMAS approach for tracking fortification impact.<sup>32</sup> This study builds on these criteria by asking individuals involved in regulatory monitoring to reflect upon their successes,

and it challenges them to create a picture of what effective monitoring would look like in their country context. This was done through a literature review, key informant interviews, and a semi-quantitative questionnaire.

A desk review of gray and published literature was conducted from the authors' personal libraries and a PubMed search on keywords of "regulatory monitoring" or "regulatory compliance" as it relates to "food and drug manufacturing" or "food fortification." Key informant interviews were conducted with experts from fortification project personnel and public and private entities involved in fortification. The literature review and interview results were used to generate key themes, learn success stories, and develop 2 structured, semi-quantitative questionnaires on elements of regulatory monitoring within a mandatory fortification environment. One questionnaire was designed for respondents from government regulatory agencies and the other for respondents from industrial corporations that fortify a staple food, with overlapping questions and themes. The questionnaires were designed to elicit responses in each of the 5 major components of food control as designated by the Food and Agricultural Organization (FAO) and WHO<sup>29</sup>:

- Food law and regulations
- Food management
- Inspection services
- Lab services
- Information, education, communication, and training

While many food producers in low- and middle-income countries in Africa and Asia lack adequate QA/QC and good manufacturing practices, certainly contributing to persistently underfortified foods reaching consumers, the questionnaire focused on external monitoring and the role of government regulatory agencies.

Questionnaires were deployed to contacts in regulatory agencies and industry in 28 countries with a focus on low- and middle-income countries in Africa and Asia.<sup>33</sup> Snowball sampling was employed, asking respondents to suggest others in their networks who would qualify for participation. Questionnaires were administered via an online survey available in both English and French. Country staff from the Global Alliance for Improved Nutrition (GAIN) and Project Healthy Children (PHC) were encouraged to work

with respondents in a structured interview format to translate and facilitate question understanding.

In total, 55 respondents participated in the questionnaire; 39 (71%) were included in the analysis. Inclusion criteria for the analysis comprised answering a set of key questions (9 responses excluded) and, in the case of industry respondents, a requirement that the food vehicle fortified on site was included in the country's mandatory fortification legislation (4 responses excluded). In all but 2 cases, exclusion due to non-completion was due to technical and Internet connectivity issues; a subsequent questionnaire was completed from these countries as a second attempt with the online survey tool or via an identical paper version.

Analyses were conducted at the respondent level. Some countries had multiple respondents; however, the lack of agreement between respondents within the same country and sector as well as the nature of the study design led to the choice not to average and weight responses or analyze data at the country level. Additionally, it was not the aim of this study to compare progress and practices across countries but to gain a sense of respondents' perspectives on regulatory monitoring effectiveness, barriers, and best practices.

## FINDINGS

Key informant interviews were conducted with 11 fortification experts from program implementers, industry, and government. Questionnaire responses were completed by 18 individuals from regulatory agencies in 15 countries and by 21 individuals from the food fortification industry in 13 countries. A total of 17 countries were represented. Eleven countries provided at least 1 completed response from both the regulatory agency and industry (Afghanistan, Bangladesh, Ethiopia, Ghana, Indonesia, Kenya, Nigeria, Pakistan, the Philippines, Senegal, and Tajikistan). Two countries provided respondents from industry only (Egypt and Kazakhstan) and 4 countries provided respondents from regulatory agencies only (Kyrgyzstan, Liberia, Mozambique, and Nepal).

As reported by regulatory agencies across the 17 countries at the time of the survey, every country mandates salt iodization. Eight countries also mandate fortification of wheat flour, and 9 countries mandate fortification of vegetable oil. Four countries mandate the fortification of 4 or more vehicles (salt plus some combination of wheat flour, maize flour, rice, sugar, and vegetable oil). Thirteen industry

respondents fortify salt at their facilities, 6 fortify wheat flour, 2 fortify vegetable oil, and 1 fortifies maize flour. Industry respondents indicated they began iodizing salt between 1991 and 2009, while the fortification of other vehicles began between 2000 and 2013.

Survey respondents prioritized a list of regulatory monitoring elements needing improvements at the regulatory agency level to ensure compliance against relevant national fortification standards (Figure 2). Respondents from both regulatory agencies and industry placed a high importance on improving regulations so they are clear and provide a good regulatory environment including delineating the roles and responsibilities of stakeholders. However, regulatory agencies and industry inversely prioritized the remaining elements: Industry respondents rated incentives and penalties for enforcement, communication between sectors, and industry engagement as their next highest priorities for regulatory agency improvement, whereas these components were among the lowest priorities for regulatory agencies.

Industry respondents were asked to prioritize a list of barriers they and other producers of fortified foods face in ensuring adequate fortification (Figure 3). Two barriers dominated the list perceived by the food industry: the high price of premix (the powdery blend of vitamins and minerals used in fortification), which drives up the cost of processing, and competition with non-fortifying or non-compliant producers, which illustrates the need for mandatory legislation and enforcement to level the playing field.

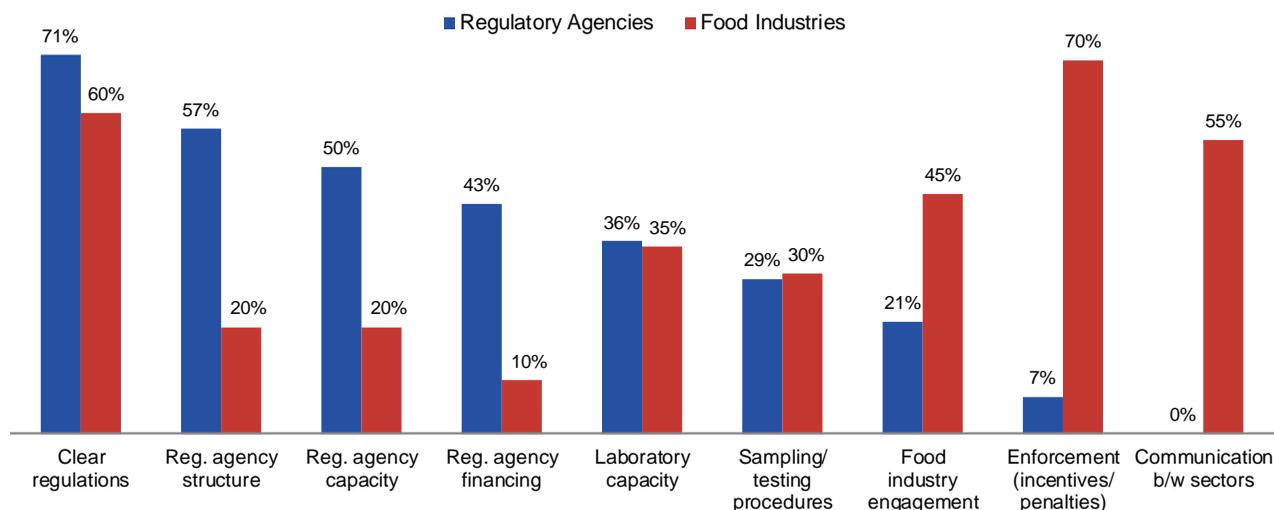
Based on the perceived importance of each element and the identified barriers, 3 main themes were chosen for further investigation during analysis: (1) food law and legislative environment, (2) mechanisms of regulation enforcement, and (3) prioritized human and financial resources at regulatory agencies.

### Food Law and Legislative Environment

The lack of clarity in the roles of government authorities in monitoring fortified foods was a barrier faced by 6 of 20 industry respondents (30%), while 22 of 34 respondents from both sectors (65%) identified the need for clear regulations as a top priority for fortification compliance. Figure 4 depicts the challenges regulatory agencies reported facing in creating a

**Both regulatory agency and industry respondents placed high importance on improving clarity of regulations.**

**FIGURE 2.** Top Regulatory Monitoring Priorities Requiring Improvements at the Regulatory Agency Level to Ensure Industry Compliance With Fortification, According to Rankings<sup>a</sup> by Questionnaire Respondents From Regulatory Agencies (n=14) and Food Industries (n=20)<sup>b</sup>



<sup>a</sup> Respondents ranked each element as 1 of their top 3 priorities.

<sup>b</sup> The 14 respondents from regulatory agencies came from 12 countries, and the 20 respondents from food industries came from 13 countries (a total of 16 countries represented). Four respondents from regulatory agencies and one from industry left this question blank.

**Half of regulatory agency respondents perceived a political risk to taking regulatory action against the food industry.**

**Both regulatory agency and industry respondents believed that incentives could encourage compliance with fortification regulations.**

legislative environment conducive to fortification compliance. Half of the respondents perceived a political risk to taking regulatory action, and 44% indicated a lack of trained inspectors and analysts as a key challenge.

Legislative instruments should be robust enough to prevent risks to safety and quality while also flexible enough to allow for changing technology and local nutrition contexts. Fifteen of 39 respondents (38%) considered their country's regulatory system responsive to new technologies; 3 respondents (8%) considered it very responsive (data not shown).

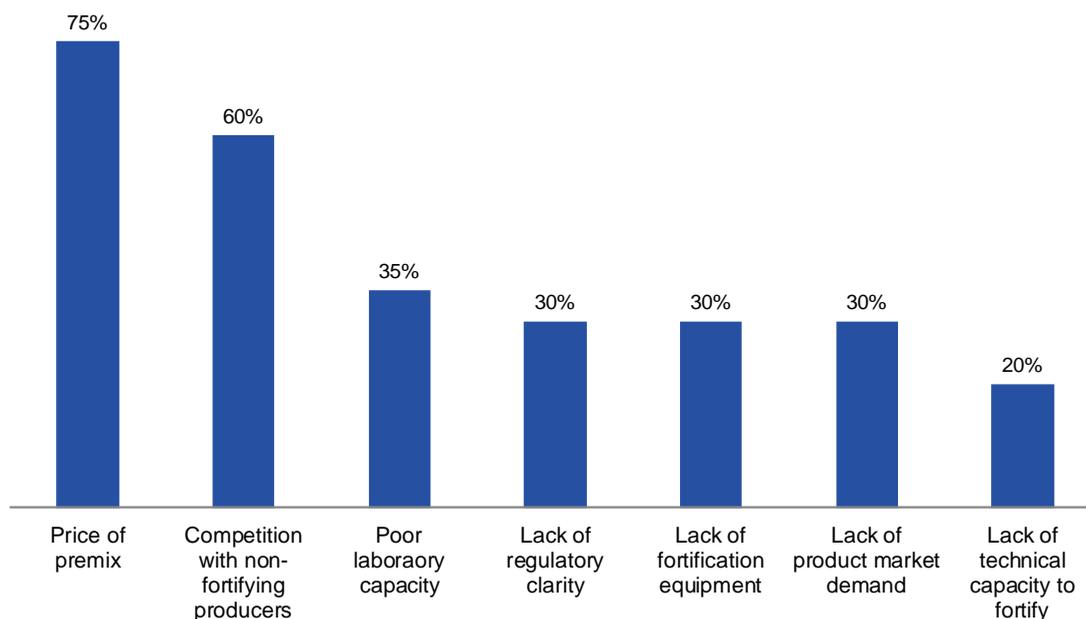
Technical regulations are delineations of a product's characteristics, such as size, shape, or performance, which are mandatory for producers to conform to. In this way, they are legally enforceable and can be more easily modified without having to pass entirely new laws. One questionnaire respondent stated that using technical regulations "... made the standard a mandatory tool without having to go to Parliament for a new legislative instrument."

## Mechanisms of Regulation Enforcement

Key informant interviews with government and industry stakeholders opined that economic incentives send a strong message to the private sector that the government will share in the risks and rewards of fortification and make a financial commitment. As one questionnaire respondent described, "Compliant industries are recognized publicly, and messages about the purpose of enforcement are regularly communicated, helping to gain industry buy-in."

Among regulatory agency questionnaire respondents, 14 of 17 (82%) reported deploying an incentive, and 11 of 20 from food industries (55%) reported that an incentive had been used to sway their behavior toward compliance against national fortification standards. Positive brand naming was reportedly used most often by regulatory agencies, followed by subsidies for inputs such as premix or equipment. Respondents from both sectors believed that incentives, as they are currently used, could improve in their effectiveness in encouraging compliance with

**FIGURE 3.** Top Barriers<sup>a</sup> Fortified Food Producers Face in Ensuring Fortification Compliance, According to Rankings by Questionnaire Respondents From Food Industries (n=20)<sup>b</sup>



<sup>a</sup> Respondents ranked each element as 1 of their top 3 barriers.

<sup>b</sup> The 20 respondents came from 13 countries; 1 respondent left this question blank.

mandatory fortification legislation; 8 of the 27 respondents (30%) reported incentives are “very” effective, while 9 (33%) considered incentives “moderately” effective, and 10 (37%) considered them “slightly” or “not at all” effective.

Over 90% of questionnaire respondents (34 of 37) reported that penalties have been used to deter non-compliance, although 28 of 34 (82%) admitted inconsistent use or ineffective enforcement of penalties. Fines, operating license suspension, and factory closure were reportedly used most often. Similar to their views on incentives, of 34 respondents, 10 respondents from both sectors (29%) viewed current use of penalties as “very” effective, while 15 (44%) considered penalties “moderately” effective, and 9 (26%) reported penalties are “slightly” or “not at all” effective.

A recurrent theme from key informant interviews and questionnaires was a perceived political risk surrounding consistent enforcement. Eleven of 18 respondents from regulatory agencies (61%)

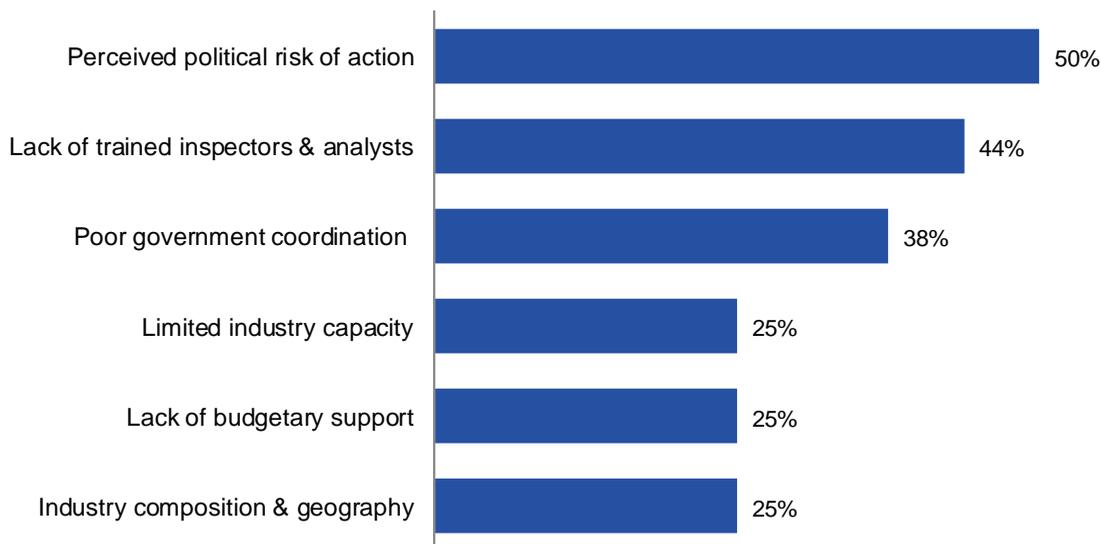
believed this lack of willingness to take on the political risk of enforcement is a major barrier. Regulatory agencies claimed using penalties is politically risky due to perceived or real resistance from interest groups. One respondent described it as risky “... for political reasons, because of backlash and strike threat by the mill association.”

Respondents opined that the political risk of enforcement leads to penalties that are not severe enough to encourage adequate fortification or are inconsistently applied due to insufficient resources required to navigate lengthy bureaucratic systems. One interview respondent said, “Fines are so low that industry would rather pay the annual fine than the cost to upgrade equipment to fortify.”

Respondents from both sectors believed that credibility and perceived effectiveness of regulatory bodies comes largely from consistent follow-through on enforcement measures, regular and unannounced inspections, and acting in a fair and transparent manner with all industrial entities.

**Perceived effectiveness of regulatory agencies comes from consistent follow-through on enforcement measures and transparency with industry.**

**FIGURE 4.** Greatest Challenges Faced in Creating a Legal and Regulatory Environment That Allows for High Compliance With Fortification Regulations, According to Open-Ended Responses From Regulatory Agency Respondents (n=16)<sup>a</sup>



<sup>a</sup> The 16 respondents came from 13 countries, with some respondents providing multiple answers; 2 respondents left this question blank.

This also includes monitoring at the most appropriate place for enforcement. As one questionnaire respondent said, *“At the retail level, their point is, ‘Why are we to be penalized instead of factories?’”*

Thirteen of 36 questionnaire respondents (36%) reported that factory inspections are announced beforehand. Even if visits are not announced, one questionnaire respondent noted, *“[News of inspection] spreads in advance by local people, media, etc. Once visits start in one factory, often surrounding factories quickly shut down and hide operations to avoid regulators from visiting.”*

Six of 18 questionnaire respondents from regulatory agencies (33%) believed that their regulatory system is robust and responds quickly to non-compliance. When asked about data management, 10 of 16 regulatory agency respondents (63%) reported that data is well managed or translated into action to improve compliance, and 9 respondents (56%) reported sharing their data regularly with stakeholders.

Another emerging theme from interview and questionnaire responses was that attitudes of respect and trust are lacking between the sectors.

Of the 20 industry respondents, 12 (60%) reported that regulatory agencies do not believe industry puts effort into producing quality fortified food, and the same number reported they do not believe regulatory agencies do their job fairly. Seven of 20 industry respondents (35%) reported having a poor working relationship with their counterparts in regulatory agencies. As one interviewee suggested, *“Good governance calls for well-trained, motivated food inspectors who make an effort to be constructive, cooperative, and helpful, rather than having an attitude of policing, only trying to find what’s wrong.”*

### Prioritized Human and Financial Resources

Most questionnaire respondents (14 of 17, or 82%) from regulatory agencies noted their current funding is not completely sustainable over the next 5 years, and 16 of 18 respondents (89%) felt national budget allocations are the most stable source of funding necessary for regulatory success. Some respondents have detailed success stories in stretching their limited budgets. Of the

18 questionnaire respondents from regulatory agencies, 8 mentioned introducing a network of local offices that saves on inspector travel costs; 6 mentioned generating incomes through inspection, licensing, and testing services; and 5 cited the use of civil society, consumer, or industry groups to assist with monitoring activities. Respondents echoed the importance of securing a sustainable budget for general inspections and food control first, allowing for a smooth introduction of fortification regulation into the system later.

A recurring theme among key informant government interviewees was that limited budget allocations resulted in low compensation and few opportunities for professional training, leading to high staff turnover. Of 16 regulatory agency respondents, 2 reported inspectors never receive a travel budget; overall, half reported inspectors received one on an irregular basis (less than 40% of the time). Interview respondents noted that workloads are taxing for regulatory agency staff who must prioritize food safety issues above those of quality and fortification. This was also a common theme among questionnaire respondents. One noted, “[There is] pressure on limited human resources, equipment, and consumables to allocate ... among competing regulatory priorities.”

Of 18 questionnaire respondents from regulatory agencies, 13 (72%) agreed that more inspectors were needed to effectively distribute the workload, and 15 of 17 (88%) believed that compliance at the industry level would improve with greater monitoring frequency. Thus, regulatory agency respondents believed they should be doing more, but they lacked financial and human resources. A recurring theme throughout the interviews and surveys was that lack of technically trained staff prevented regulatory agencies from being more effective overall. This was pervasive along the continuum of regulatory monitoring and was discussed in questions on a variety of topics (Figure 5).

Finally, the importance of an adequately resourced laboratory was emphasized by respondents. Of the 16 regulatory agency respondents, 6 (38%) reported a lack of equipment and inputs for laboratories while a lack of trained staff and technical capacity were reported by 8 respondents (50%). Interview respondents noted that the lack of laboratory capacity slowed the testing process and prohibited inspectors from making cost-efficient judgments about required follow-up action. Even where resources and trained staff

were available, regulatory agencies faced additional challenges. As one respondent said, “*The greatest challenge is getting test results acted upon for compliance.*”

## DISCUSSION

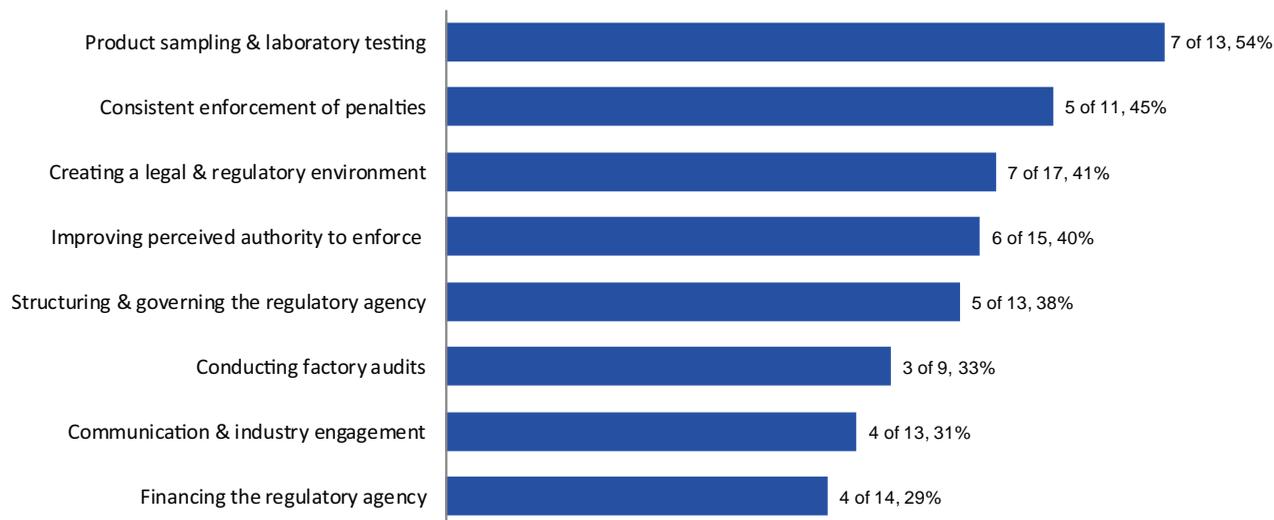
In this paper, we highlighted the barriers and successes experienced by professionals working in regulatory monitoring and industries that fortify foods. Our methodology’s strength in eliciting rich qualitative descriptions of respondents’ perspectives enabled us to identify barriers and good practices in regulatory monitoring, classifying them into themes for further discussion. Insufficient and inconsistent monitoring persists because of perceived low risk of detection for non-fortified and underfortified foods. These perceptions can be due to actual resource and capacity constraints within regulatory agencies and unclear legislation, but as many of the respondents described, a major contributor is a sense of political unwillingness.

Attitudes toward established food safety laws and compliance with them based on the probability of detection and prosecution has been explored previously; parallels can be drawn to similar issues of food quality and fortification.<sup>34,35</sup> Some businesses are “political citizens” who comply with regulations unless they consider rules unreasonable; some are “economic actors” who comply when it is profitable; and some are “incompetent organizations” who are willing to comply but are not well enough equipped or knowledgeable to do so.<sup>36</sup> The first attitude can be found among food producers who attempt to fortify but are non-compliant due to challenges in technical or laboratory capacity. The second is prevalent among food producers in contexts where there is competition with non-fortifying producers or imports and where access to affordable premix is lacking. The third attitude is most often found in countries just beginning to fortify, where a lack of knowledge or clarity in the regulations must be overcome. As will be echoed throughout, regulatory agencies could improve their ability to communicate with industry to fully understand how to engage them and meet compliance targets.

Figure 6 depicts the relationship between regulatory monitoring elements and a positive impact on health. Enforcement mechanisms and human and financial resource capacity form a strong feedback loop. In many regulatory monitoring systems, budget constraints lead to insufficient resources devoted to fortification regulation, often

**Regulatory agency respondents believed they should be doing more but lacked the necessary financial and human resources.**

**FIGURE 5.** Regulatory Monitoring Areas Lacking a Trained Cadre of Regulatory Inspectors and Analysts, According to Open-Ended Responses From Regulatory Agency Respondents About Key Challenges<sup>a</sup>



<sup>a</sup> The analysis was based upon the responses of 18 respondents from 15 countries. A range of 9 to 17 respondents provided answers in each regulatory monitoring area.

**Mandatory legal instruments requiring food fortification may help level the playing field for industry.**

**Insufficient regulatory monitoring and enforcement is at the root of underfortified products.**

because of competing priorities. Low enforcement and compliance result largely from a lack of resources or an unwillingness to detect underfortified foods and hold industry accountable. Without strong political willingness to enforce, justifying investments in resources for enforcement is difficult. Injections of positive interventions into this cycle, such as using a systems approach, simplifying data collection and management, and increasing the role of civil society, can help to decrease the strain on resources. There is a need for an enabling environment to underpin technical enforcement capacity with legal and political commitment and willingness. This includes clear legislation and sustained leadership and accountability in both the private and public sectors. The schematic is further described in the following sections.

### Food Law and Legislative Environment

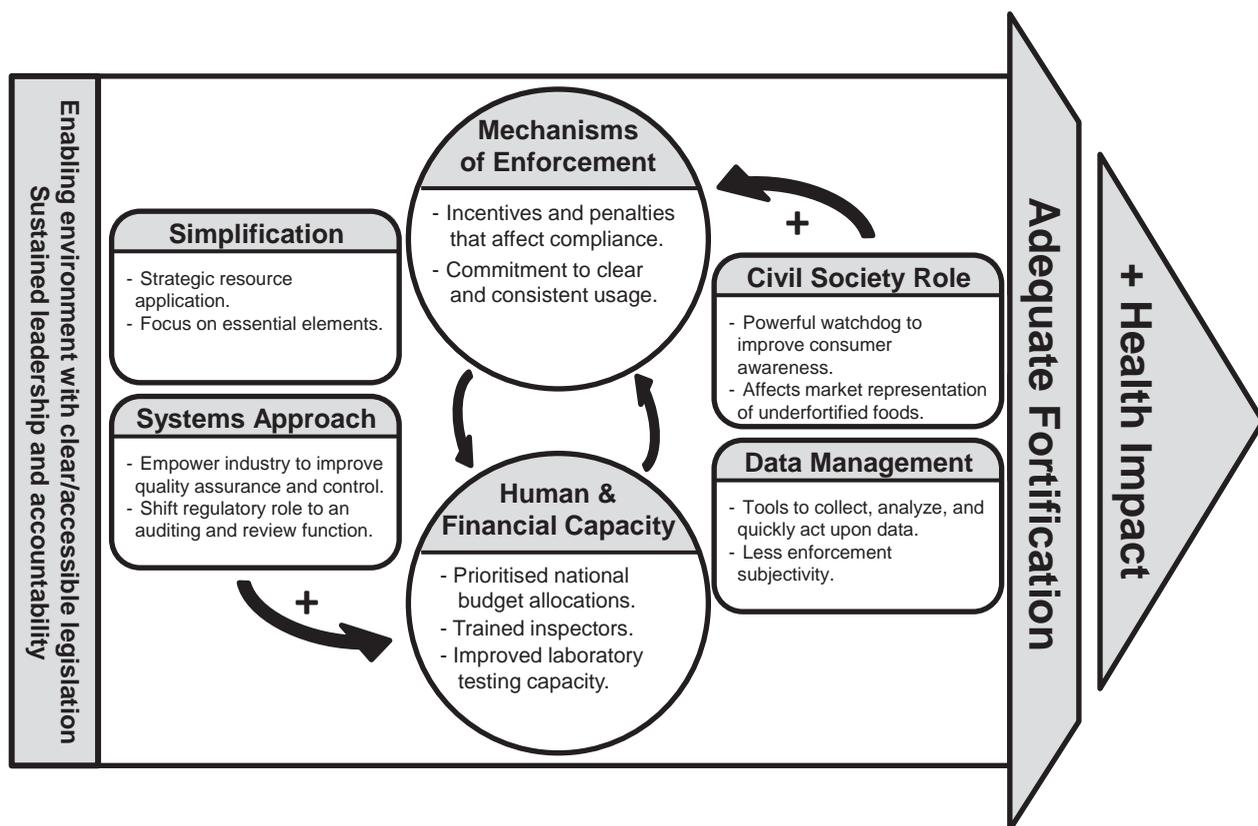
Food laws, regulations, and standards related to mandatory fortification are frequently fragmented and do not clearly present the roles of stakeholders or the array of enforcement mechanisms that can be used legally. Many interview and questionnaire

respondents described clear and consolidated legislation as a prioritized step in improving compliance with national fortification regulations. Clear laws and regulations can foster an enabling environment and good working relationships between producers and regulatory agencies. Requiring fortification through mandatory legal instruments has been a recommended strategy to level the playing field, incentivizing industry to fortify by removing competition from non-fortifying producers and providing the basis for consistent legal enforcement.<sup>37</sup> When the mandate is not enforced, industries may choose to stop fortifying to increase profits, jeopardizing the nutritional impact on the population.

### Mechanisms of Regulation Enforcement

One of the most critical themes drawn from this study's findings, especially from the perspective of industry, is that enforcement is an important driver of compliance with national standards. At the root of underfortified products is insufficient regulatory monitoring and enforcement that lead to non-compliance among industries.<sup>38-40</sup> Industry sees regulatory monitoring as related to how

**FIGURE 6.** Relationship Between Regulatory Monitoring Elements in Ensuring Food Vehicles Are Adequately Fortified and Can Contribute to a Positive Health Impact



often and how well regulatory agencies inspect facilities and consistently implement enforcement measures. Moral authority can be garnered through perceptions of effectiveness and coordination, which are linked to agency structure, governance, transparency in decision making, and funding prioritization.<sup>41</sup>

While most respondents reported using some combination of incentives and penalties for enforcement, it is their effectiveness in strength and application that matter most. Regulation on paper will not improve fortification compliance without incentives and consequences that are real, strong enough to drive underfortified foods out of markets and production facilities, and consistently applied. Good enforcement requires the capacity of regulatory agencies and their public laboratories to detect and act upon non-compliance.

Claiming that enforcement of penalties presents political risk was a common theme among respondents and has been previously encountered.<sup>20,42</sup> To combat this, regulatory agencies must show proper leadership and communicate with industry to ensure the reasons for regulations and penalties are understood as useful in leveling the playing field for industry.

### Human and Financial Resources

Funding is a critical element of food control management and governance, providing the resources necessary for action and a sense of government prioritization. Food safety is typically prioritized more highly than food quality, including fortification, because food safety issues generally present a higher and more immediate risk than an issue of sub-standard quality.<sup>24</sup> A few

**Regulation on paper will not improve fortification compliance alone.**

cases of *E. coli* are a more immediate threat to public health than the long-term, cumulative health consequences of micronutrient deficiencies, even though the detrimental effects of nutrient deficiencies, such as poor cognitive development, immunity, and productivity, affect a greater proportion of the population.<sup>29,43</sup>

Without a stable funding source, countries must cope with uncertainty in their budgets, impacting the quality of their regulatory capabilities. The effectiveness of inspection and verification services relies on qualified, trained, efficient, and honest food inspectors who are able to collect samples for laboratory testing and carry out quality and safety evaluations.<sup>44,45</sup> Questionnaire data reveal that many countries lack adequate public-sector laboratory capacity, including equipment, supplies, and trained personnel. Sampling quantity and data quality are likely to reflect the quality of technical and human resources available within laboratories.

Regulatory agencies are more likely to succeed with a core team of trained inspectors who will remain in the position long-term, which may require incentives and other motivational elements such as travel budgets and recognition for timely results. Such a workforce must be accompanied by an operating environment that places a strong emphasis on food quality, inspector honesty and integrity in reporting, and communicating with industry to remedy issues of overall quality control. Inspectors also need to understand the relevant food laws and regulations, including methods they can legally use to inspect industry facilities and hold producers accountable for the findings.

Industry also has a role to play in enacting QA/QC measures and consistently producing foods that are compliant against mandated national standards. To address overall food quality, industry capacity must be improved in using good manufacturing practices and working with regulatory agency counterparts to remedy issues of access and affordability of inputs and premix.

### Increasing the Role of Civil Society

Fortified foods are considered credence goods, those that consumers cannot easily evaluate in order to demand a higher quality. Fortified and non-fortified products are virtually identical and without the use of some form of analytical equipment, consumers have little indication as to whether vitamins and minerals have been added in the declared amounts

or will perform as claimed. They must take the stated claims of manufacturers on faith. This same information asymmetry can also describe the relationship between fortified food producers and their micronutrient premix suppliers.

For some credence goods, including fortified foods, product demand depends largely on branding and marketing to provide consumers with a recognizable way to distinguish between products.<sup>46</sup> Since consumers are easily cheated into paying higher prices for claims of higher-quality products, there is little market incentive for food producers to invest in improvements to increase the quality of their products. Food producers who wish to pawn off lower-quality goods as higher ones will therefore drive out legitimate business.<sup>47</sup> The burden for increasing incentives to invest in fortification (and food quality more broadly), therefore, largely falls on regulatory agencies.

As success stories from respondents detail, regulatory agencies have benefited from working with civil society organizations, including industry and consumer associations. There have been documented successes where village health committees helped to monitor small and local retailers.<sup>48</sup> Civil society can be a powerful watchdog, improving consumer awareness of those food producers that pass off their underfortified products as good consumer choices. Civil society can also be an important regulatory assistant, lessening the financial and workload burden of the national regulatory offices as a stopgap measure until local offices can be built and properly staffed.<sup>44,49</sup>

### Simplifying Data Collection and Management

It is advantageous to streamline workflows and apply resources strategically to essential elements. Even with a consolidated wheat milling sector in a small geographic area, Jordan's regulatory inspectors faced difficulties in their ability to conduct on-site surveillance and monitoring on a regular basis. To overcome this, a simple external monitoring system was adopted that collects 3 indicators (monthly production of wheat flour, number of boxes of premix used, and iron concentration in a flour sample) that can be easily analyzed and used to make programmatic decisions by a low-resource regulatory agency.<sup>50</sup> Similarly, Egypt's fortified *Baladi* bread producers introduced an online fortification monitoring system in 2011 that generates automated alerts

**Civil society can be a powerful watchdog by improving consumer awareness of food producers that underfortify.**

in cases of outliers from the normal fortification range, shortages in warehoused premix stock, and other system disturbances that may result in underfortified products.<sup>51</sup> Just 2 years after implementation, the latest compliance data claim that 95% of Egypt's flour is adequately fortified to national standards.<sup>51</sup> Finally, Zimbabwe's Ministry of Health and Child Care is in the process of incorporating key fortification monitoring indicators into their District Health Information Software. This allows for the efficient and consistent tracking of monitoring data that can be disaggregated by location, date, brand, or producer through an already-existing centralized data capture system (personal communication with Arthur Pagiwa, Zimbabwe Country Coordinator, Project Healthy Children, Jul 2015).

Inspections are most appropriately conducted at the point of production and/or import, where it is most efficient and affordable to remediate underfortification.<sup>52</sup> Monitoring at retail outlets may have a role in creating awareness among retailers and consumers or as verification of nutrient retention, but it is ineffective as an enforcement tool since it is often difficult to trace non-compliant products back to their production or import source.<sup>20</sup>

### A Systems Approach to Monitoring

Many countries have focused solely on laboratory testing of final product samples for conformance with national standards; however, this strategy is costly.<sup>20,29</sup> Furthermore, final product sampling and analysis techniques have large margins of error for some micronutrients, random samples are not always a true reflection of overall performance, and the turnaround of information is often too slow to make timely modifications. A "systems" approach to monitoring facilitates preventive measures at all stages of the food value chain so that underfortified products can be identified and remedied earlier along the chain. This approach, which is in conjunction with the principles of Good Manufacturing Practices (GMP) and Hazard Analysis/Quality Analysis and Critical Control Points (HACCP/QACCP), has been the industry standard in many countries for the manufacture of pharmaceuticals and, in many cases, processed and fortified foods, for over a decade.<sup>24,53–56</sup> This approach facilitates industry to keep good records and entrusts them with the primary responsibility for safety and quality, leaving regulatory inspections to verify whether industrial entities have the

adequate raw materials, equipment, systems, and procedures in place for the manufacturing processes to result in consistent production of adequately fortified foods. Testing product samples is still required and is critical but relegated to a validation role.<sup>24,53</sup>

Using the systems approach requires a cooperative working relationship between regulatory agencies and food producers with a mutual understanding that sustained violation will be addressed.<sup>37,57,58</sup> Effective inspections also require a platform for information exchange to build cooperation and trust. Success stories have proven that the systems approach does have broad applicability and relevance to developing countries.<sup>50,59</sup> Codes of practice that delineate monitoring activities using the systems approach have been drafted and are awaiting approval in South Africa,<sup>60</sup> Zimbabwe,<sup>61</sup> and Mozambique, and the idea is gaining traction elsewhere in Africa and Asia (personal communication with Philip Randall, Director, PCubed, Jul 2015). Many questionnaire respondents in our study agreed that it is a better use of scarce resources, although there are a number of constraints along the food value chain that present a barrier to this approach, including a lack of trust between government inspectors and industry personnel, a lack of training among industry staff, and a lack of standard operating procedures that prevent consistent recordkeeping. More operational research is needed in this area to further develop the systems approach for regulatory monitoring of fortified foods, specifically in the context of low- and middle-income countries in Africa and Asia.

### Recommendations for Policy and Practice

Taking into consideration lessons learned from food safety control<sup>34,35</sup> and pharmaceutical safety and quality control,<sup>42,44,45</sup> 7 broad-reaching recommendations for improving fortification compliance can be synthesized from this study:

1. **Legislation:** Develop and implement clear legislation that outlines roles and responsibilities of all stakeholders, provides an enabling environment within the private and public sectors, and includes applicable enforcement mechanisms.
2. **Leadership:** Identify strong leadership within government that facilitates the prioritization of fortification programming and subsequent enforcement and national budget allocations.

**Integrating key fortification indicators into existing health and nutrition monitoring systems helps with efficient and consistent tracking of compliance.**

**A systems approach to monitoring requires a cooperative working relationship between regulatory agencies and food industry.**

3. **Enforcement:** Focus on strong, effective enforcement mechanisms that influence compliance with national standards. Encourage leadership to consistently use enforcement mechanisms to hold industry accountable.
4. **Financial and Human Capacity:** Improve capacity at the regulatory agency and industry levels. Prioritize funding for inspector training, sample collection and laboratory testing, and technology transfer to industry.
5. **Community:** Engage civil society and community organizations as a third-party to build consumer support and knowledge and to reduce the regulatory resource burden.
6. **Data Capture:** Simplify regulatory monitoring management processes, including streamlined data collection and feedback mechanisms for action.
7. **Relationship Building:** Build relationships and trust with industry counterparts so the systems approach can be an achievable goal.

Sustained government funding, in addition to external funding, is required to improve these critical areas of regulatory monitoring. While questionnaire respondents stressed the importance of national budget allocations to ensure funding sustainability, international donors must respond to this call to action to provide the impetus for countries as they build capacity, improve systems, and allocate additional funds from national budgets. Recommendations should be made by donors and technical assistance groups on which regional agencies and experts to use for adequate inspector trainings. Public-private partnerships must also be motivated and leveraged as key drivers of capacity strengthening, trust building, and funding for continued improvements at both industry and regulatory agency levels.

### Limitations

This assessment is not without limitations that must be considered. Selection bias may have been introduced since respondents may have been better informed or may consider fortification efforts more important than non-respondents. Thus, if those respondents that consider fortification important agree that more attention and resources must be directed toward regulatory monitoring, the authors assume the issues surrounding poor monitoring are similar or worse for those countries where fortification efforts are not prioritized. Data analysis did not distinguish between food vehicles or the

year that fortification was mandated. There is the possibility that monitoring processes are different for each food vehicle, due to differences in industry structure and consolidation, while regulatory monitoring is likely to improve over time as experience and knowledge increase.

We anticipated a degree of social desirability bias to occur, especially on the part of regulatory agencies overstating their capacity and monitoring activities. This calls into question the validity of their responses, although it likely underestimates the prevalence of discussed behaviors, making the recommendations even more pertinent. Industry respondents were mostly from larger corporations and come from the perspective of 1 vehicle, whereas regulatory monitoring respondents may answer from the perspective of up to 5 vehicles that are mandated within their country and covering the range of industry sizes. Some findings may not be relevant for small- and medium-sized producers that operate under different constraints and monitoring contexts.

The sample size was relatively small; thus, this study intended to summarize perspectives and experiences from a qualitative point of view while providing an inference that the quality of fortified foods and the systems in place through which they are monitored needs improvement, particularly in low- and middle-income African and Asian countries. The study does not attempt to present a comprehensive quantitative survey of fortification program compliance globally. Nor does it claim to provide evidence-based solutions to improve compliance of fortification programs. Further research and independent evaluations will be required to do this. The authors hope this manuscript will provide a call to action for independent researchers to initiate critical evaluations exploring specific areas of need in greater depth. The chosen methodology of the questionnaire dissemination, which relied upon country staff from GAIN and PHC to assist respondents, was designed to elicit a higher response quality, rather than quantity, especially since the technical subject matter may have affected question comprehension.

### CONCLUSION

Regulatory monitoring of food fortification is a complex process requiring leadership, good governance, and coordination. Mandatory legislation will not automatically lead to increased coverage of fortified products without proper enforcement

**Public-private partnerships must be leveraged as key drivers of capacity strengthening, trust building, and funding for continued improvements.**

and adequate capacity; likewise, focusing investment on upgrading technical skills and facilities will not automatically lead to the feedback mechanisms necessary to identify and recall underfortified products. Only by taking concrete steps to improve the entire regulatory system will a nutrition strategy that uses fortification see its intended health effects.

Challenges to enabling fortification compliance include economic disincentives at the industry level and a lack of prioritization and perceptions of political risk around enforcement at the government level. Investment strategies should focus on strong and consistent enforcement mechanisms that include a well-trained cadre of food inspectors, quality laboratories, clear legal instruments, simplified data capture mechanisms, and the use of civil society, all underpinned by strong government leadership. By improving these components of implementation, detection and prosecution of underfortified foods will improve and fortification programs will reach beyond the current 45% coverage of adequately fortified foods to attain their intended health impact.

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## ORIGINAL ARTICLE

# Estimating Contraceptive Prevalence Using Logistics Data for Short-Acting Methods: Analysis Across 30 Countries

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Three models showed strong correlation between public-sector logistics data for injectables, oral contraceptives, and condoms and their prevalence rates, demonstrating that current logistics data can provide useful prevalence estimates when timely survey data are unavailable.

## ABSTRACT

**Background:** Contraceptive prevalence rate (CPR) is a vital indicator used by country governments, international donors, and other stakeholders for measuring progress in family planning programs against country targets and global initiatives as well as for estimating health outcomes. Because of the need for more frequent CPR estimates than population-based surveys currently provide, alternative approaches for estimating CPRs are being explored, including using contraceptive logistics data.

**Methods:** Using data from the Demographic and Health Surveys (DHS) in 30 countries, population data from the United States Census Bureau International Database, and logistics data from the Procurement Planning and Monitoring Report (PPMR) and the Pipeline Monitoring and Procurement Planning System (PipeLine), we developed and evaluated 3 models to generate country-level, public-sector contraceptive prevalence estimates for injectable contraceptives, oral contraceptives, and male condoms. Models included: direct estimation through existing couple-years of protection (CYP) conversion factors, bivariate linear regression, and multivariate linear regression. Model evaluation consisted of comparing the referent DHS prevalence rates for each short-acting method with the model-generated prevalence rate using multiple metrics, including mean absolute error and proportion of countries where the modeled prevalence rate for each method was within 1, 2, or 5 percentage points of the DHS referent value.

**Results:** For the methods studied, family planning use estimates from public-sector logistics data were correlated with those from the DHS, validating the quality and accuracy of current public-sector logistics data. Logistics data for oral and injectable contraceptives were significantly associated ( $P < .05$ ) with the referent DHS values for both bivariate and multivariate models. For condoms, however, that association was only significant for the bivariate model. With the exception of the CYP-based model for condoms, models were able to estimate public-sector prevalence rates for each short-acting method to within 2 percentage points in at least 85% of countries.

**Conclusions:** Public-sector contraceptive logistics data are strongly correlated with public-sector prevalence rates for short-acting methods, demonstrating the quality of current logistics data and their ability to provide relatively accurate prevalence estimates. The models provide a starting point for generating interim estimates of contraceptive use when timely survey data are unavailable. All models except the condoms CYP model performed well; the regression models were most accurate but the CYP model offers the simplest calculation method. Future work extending the research to other modern methods, relating subnational logistics data with prevalence rates, and tracking that relationship over time is needed.

## BACKGROUND

Access to contraceptives and reproductive choice are considered basic human rights.<sup>1,2</sup> Increased access to and use of contraceptives for family planning have been linked to improved economic growth and decreased

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maternal and child mortality.<sup>3–5</sup> However, more than 220 million women in developing countries want to space or limit their pregnancies but are not using a modern method of contraception.<sup>6</sup> In recent years, there have been concerted program efforts to increase the availability and use of contraceptives through demand generation, improved service delivery, and supply chain strengthening.

Monitoring contraceptive prevalence rates (CPRs) is key for maternal and reproductive health programs to identify areas in need of increased focus and to guide resource allocations from national governments, donors, and civil society. CPR estimates have historically been collected every 5 years through population-based surveys, such as the Demographic and Health Surveys (DHS).<sup>7</sup> However, updates every 5 years are proving to be insufficient for informing optimal allocation of limited resources; up-to-date estimates, obtained at shorter intervals, are needed to allow for adequate tracking.<sup>8</sup> This is particularly true given that there is less than 5 years left to meet the Family Planning 2020 (FP2020) partnership goal of enabling 120 million more women and girls to use modern contraceptives by 2020.<sup>6</sup>

Because of the need for more frequent CPR estimates than the DHS series currently provides, alternative approaches for estimating CPRs are being explored. These include continuous or annual population-based surveys,<sup>9,10</sup> extrapolations from previous surveys,<sup>11</sup> and using contraceptive logistics data.<sup>11–13</sup> However, continuous and annual population-based surveys require substantial resources that countries might not be prepared to invest, while extrapolations from previous surveys provide no information about recent changes to CPRs if these countries do not follow historical trends—precisely what we would expect in the context of the intensified focus on dramatically increasing CPRs by 2020.

Since the late 1960s, family planning programs have used contraceptive service delivery data to calculate couple-years of protection (CYP) to estimate program impact.<sup>14,15</sup> CYP conversion factors are applied to contraceptive service delivery data on commodities distributed in order to estimate client use within programs.<sup>16,17</sup> By combining client use with population data, programs can estimate their contribution to overall country CPR.<sup>16,18</sup> Information on client use can typically be found in a country's routine health information system or in its logistics management information system (LMIS).

Logistics data are collected primarily to help manage stock levels and determine resupply

quantities. Three essential logistics data points reported by health facilities and warehouses include<sup>19</sup>:

- The quantities of products in stock, referred to as stock on hand
- The quantities of products dispensed to patients or clients or issued to a lower-level warehouse or health facility during the reporting period
- Any losses or adjustments to the stock balance due to damage, expiries, or transfers between facilities

Of supply chain management data collected for health products, data capturing the quantities of commodities dispensed to clients are considered the best approximation of client use. Other approximations of client use are based on quantities of commodities issued by facility storerooms to dispensaries, quantities of commodities issued by warehouses and stores to service delivery points, and forecasted dispensed-to-user data.<sup>19</sup> Where accurate contraceptive logistics data reflect client use, it is reasonable to assume that such data can provide a low-cost alternative to surveys for regularly estimating CPRs.

A recent study in Rwanda found a strong positive correlation between the quantities of public-sector injectable contraceptives dispensed to users and the DHS-reported, public-sector injectable prevalence rate, leading to the conclusion that Rwanda's public-sector LMIS appeared to be accurately capturing logistics data and that logistics data reflect client use.<sup>12</sup> With the expansion of national-level LMISs as part of efforts to strengthen government supply chains, such logistics data are more readily accessible for other countries as well. Despite this accessibility, there have been limited examples of using logistics data to estimate national CPR.

To help address this gap, this study examines the relationship between public-sector prevalence levels of short-acting methods and contraceptive logistics distribution data from 30 countries. We argue that logistics data can be used to generate prevalence estimates for short-acting contraceptives when up-to-date survey data are unavailable, and we evaluate 3 models for doing so.

## METHODS

We calculated country-level, public-sector prevalence estimates for short-acting contraceptives (injectable contraceptives, oral contraceptives,

**Population-based surveys are usually conducted every 5 years, but CPR updates are often needed more frequently.**

**Accurate contraceptive logistics data may provide a low-cost alternative to surveys for regularly estimating CPR.**

**Dispensed-to-user data are considered the “gold standard” for logistics data, but forecast and issues data are acceptable proxies.**

and male condoms) for all women of reproductive age (WRA), i.e., 15 to 49 years of age, from DHS datasets. Based on a combination of DHS, population data, and logistics data, for each of the short-acting methods we developed 3 models that could be used to generate country-level, public-sector prevalence estimates. Models included: direct estimation using CYP conversion factors, bivariate linear regression, and multivariate linear regression.

To model prevalence estimates using CYP conversion factors, we converted logistics data on the number of injectable contraceptives, oral contraceptives, and male condoms distributed to CYP, using the conversion factors recognized by the United States Agency for International Development (USAID), and then divided by the number of WRA for each country.<sup>20</sup> For the regression models, we likewise examined each method separately, first using a bivariate model and then adjusting for a previous national prevalence observation. We evaluated each model for each method by examining how accurately the model-generated prevalence values matched the referent DHS values.

This research was deemed to be exempt from institutional review board (IRB) approval by the John Snow IRB.

### Data, Indicators, and Country Inclusion

We obtained public-sector logistics data from the Procurement Planning and Monitoring Report (PPMR) and the Pipeline Monitoring and Procurement Planning System (PipeLine). PPMR data track information on contraceptive stock levels and on product distribution. Such data enable the Coordinated Assistance for Reproductive Health Supplies group, convened by the Reproductive Health Supplies Coalition, to better address supply issues.<sup>21</sup> PipeLine is used by program managers to plan procurement based on estimated future needs and to subsequently track shipments and product distribution.<sup>22</sup> More than 50 countries currently report or have reported since 1997 public-sector contraceptive logistics data via PPMR or PipeLine. The USAID | DELIVER PROJECT, which receives the data and manages both systems on behalf of countries and donors, provided the data for this analysis.

Country programs report their logistics distribution data by different metrics, including forecast data (amount expected to be dispensed to users during the period); issues data (amount

distributed to health facility dispensaries, health facility stores, or lower-level warehouses, from health facility stores, district stores, or other higher-level warehouses); and dispensed-to-user data (actual amount provided to clients). While dispensed-to-user data are considered to be the “gold standard” for logistics data, forecast and issues data are recognized as acceptable proxies for tracking distribution and planning purposes in the absence of dispensed-to-user data.

Public-sector, country-level prevalence values for short-acting methods were obtained from the DHS program for 30 countries for which there were DHS data for time periods overlapping the logistics data (Table 1). These DHS data were used as dependent variables in the regression models and as the reference national contraceptive use values for evaluation of all 3 models.

For each country, the number of WRA was obtained from the United States Census Bureau International Database based on the year of the DHS and logistics data.<sup>23</sup> When the DHS data spanned 2 calendar years, we used an average of the midyear totals of the numbers of WRA.

### Contraceptive Method and Sector Inclusion

We sought to evaluate how well logistics data could be used to estimate prevalence rates for individual methods. We focused on the 3 most commonly used types of short-acting contraceptive methods—oral contraceptives, injectable contraceptives, and male condoms—assuming the relationship between commodities distributed and national prevalence for these commodities in a specific year is likely stronger than for long-acting methods, for which efficacy lasts over multiple years. Long-acting methods were also excluded due to the lack of countries with overlapping logistics and DHS data ( $n < 20$ ).

DHS collects data on both private and public-sector CPR, but PPMR and PipeLine primarily collect public-sector distribution data. Therefore, we limited our analysis to public-sector prevalence of the short-acting methods.

### Calculating Average Distribution From Logistics Data

For each country, we sought to determine the amount of each commodity distributed per 100 WRA in a given time period. For male condoms and oral contraceptives, which are often distributed to clients at least once per month, we calculated average monthly distribution (AMD). For injectable

**TABLE 1.** Countries Included in the Analysis, Data Sources, and Periods of Analysis

Country	Country Code	DHS Collection Dates	Previous DHS	Contraceptive Logistics Data Source	Logistics Data Dates
Bangladesh	BD	7/2011–12/2011	2007	PPMR	6/2011–12/2011
Bolivia	BO	8/2003–1/2004	1998	Pipeline	7/2003–2/2004
Burkina Faso	BF	5/2010–12/2010	2003	Pipeline	4/2010–1/2011
Cameroon	CM	2/2004–9/2004	1998	Pipeline	1/2004–10/2004
Côte d'Ivoire	CI	12/2011–5/2012	1998–99	PPMR	11/2011–6/2012
Ethiopia	ET	4/2011–9/2011	2005	PPMR	1/2011–1/2012
Ghana	GH	9/2008–11/2008	2003	Pipeline	8/2008–12/2008
Guinea	GN	2/2005–6/2005	1999	Pipeline	1/2005–7/2005
Haiti	HT	1/2012–6/2012	2007	PPMR	3/2011–9/2012
Honduras	HN	10/2005–5/2006	--	Pipeline	9/2005–6/2006
Jordan	JO	7/2002–10/2002	1997	Pipeline	6/2002–11/2002
Kenya	KE	11/2008–3/2009	2003	PPMR	10/2008–5/2009
Liberia	LR	12/2006–4/2007	--	Pipeline	11/2006–5/2007
Madagascar	MD	11/2008–7/2009	2005	Pipeline	10/2008–8/2009
Malawi	MW	6/2010–10/2010	2006	PPMR	5/2010–11/2010
Mali	ML	4/2006–12/2006	2001	Pipeline	3/2006–12/2006
Mozambique	MZ	5/2011–12/2011	2005	PPMR	4/2011–6/2011
Nepal	NP	1/2011–6/2011	2006	PPMR	1/2011–7/2011
Nicaragua	NC	9/2001–12/2001	1998–99	Pipeline	8/2001–1/2002
Niger	NI	2/2012–7/2012	2006	PPMR	6/2013
Nigeria	NG	6/2008–11/2008	2003	Pipeline	7/2008–12/2008
Pakistan	PK	10/2012–4/2013	2006–07	PPMR	12/2012–3/2012
Philippines	PH	6/2003–9/2003	1998	Pipeline	2/2003–11/2003
Rwanda	RW	9/2010–4/2011	2009	PPMR	6/2010–5/2011
Senegal	SN	10/2010–5/2011	2005	PPMR	7/2010–7/2011
Tanzania	TZ	12/2009–5/2010	2006	PPMR	9/2009–6/2010
Togo	TG	2/1998–5/1998	1988	Pipeline	1/1998–6/1998
Uganda	UG	6/2011–12/2011	2006	PPMR	1/2011–12/2011
Zambia	ZM	4/2007–10/2007	2003	Pipeline	3/2007–11/2007
Zimbabwe	ZW	9/2010–3/2011	2007	PPMR	6/2010–6/2011

Abbreviations: DHS, Demographic and Health Surveys; Pipeline, Pipeline Monitoring and Procurement Planning System; PPMR, Procurement Planning and Monitoring Report.

contraceptives, we calculated average quarterly distribution (AQD) because the primary form of injectable contraceptive used in the countries included in our analysis, depot medroxyprogesterone acetate (DMPA), is administered to clients once every 3 months. We converted any distribution data for monthly injectable contraceptives into the equivalent for quarterly injectables to aggregate the data and calculate injectable AQD. Oral contraceptive AMD was calculated from aggregated progestin-only and combined oral contraceptive logistics data because the DHS does not differentiate between these 2 oral contraceptives when reporting results.

AMD and AQD were combined with population data to calculate the average amount of each commodity distributed per 100 WRA in order to provide a population-standardized estimate of distribution of each method in each country based on the logistics data available. As our outcome indicator—public-sector contraceptive prevalence for short-acting methods—is population-based, it was important that we had population-based dependent variables.

## Analysis

For each country, we examined the CPR for modern methods (mCPR) as well as the prevalence rate for each short-acting method and the public-sector market share from the DHS in order to assess both the contributions of the short-acting methods and the public-sector market for these methods to overall modern contraceptive use. As public-sector, short-acting methods account for the vast majority of mCPR in most countries examined, quantifying their relative contributions provides insight into how reflective our models might be of overall mCPR. We then created 3 models, using the logistics data, to estimate country-level, public-sector prevalence rates for each short-acting method and evaluated the performance of each model.

For the first model, we estimated the public-sector prevalence rate for each method using CYP conversion factors: we converted logistics data on injectable contraceptives, oral contraceptives, and male condoms into CYP and then divided the method-specific CYP by the number of WRA for each country to estimate the prevalence rates for each short-acting method.

For the second and third models, we applied bivariate and multivariate linear regressions, respectively. For each contraceptive method, the bivariate model examined the association between public-sector AMD or AQD per 100 WRA (independent

variable) and the public-sector prevalence rate for that method from the most recent DHS (dependent variable). The multivariate model examined the same association, adjusting for previous public-sector prevalence rate for each method (from the prior DHS), a potential confounder given that current contraceptive requirements and current use are both influenced by historic rates of contraceptive use. To meet the assumptions for linear regressions, due to a skewed dataset, we applied a natural log transformation to both the prevalence rate for each short-acting method (dependent variable) and AMD or AQD per 100 WRA (independent variable) in the bivariate and multivariate models.<sup>24</sup>

Thus, the equation for the bivariate model was:

$$\ln(\text{CPR}) = \beta_0 + \beta_1 \ln \left( \frac{\text{AMD}_{m,t}}{100 \text{ WRA}} \right)$$

where  $\beta_1$  is the coefficient for the public-sector commodity distribution data as measured by the logistics data for the corresponding time period,  $\beta_0$  is the slope intercept, and  $(\text{AQD or AMD})_{m,t}$  per 100 WRA is the LMIS-based distribution data of oral contraceptives, injectable contraceptives, or condoms for method  $m$  in year  $t$  divided by 100 WRA to simulate the prevalence rate for each method.

The multivariate model was built upon the bivariate model by adding 1 covariate—the term  $\text{CPR}_{m,t-i}$ , which is the DHS-based estimate of prevalence of use for method  $m$  in year  $t-i$ , where  $i$  is the interval since the last survey. Thus, the equation was:

$$\ln(\text{CPR}) = \beta_0 + \beta_1 \ln \left( \frac{\text{AMD}_{m,t}}{100 \text{ WRA}} \right) + \beta_2 \text{CPR}_{m,t-i}$$

Using these models, we calculated model-generated, public-sector prevalence estimates by method for each of the 30 countries based on country logistics data (AMD or AQD/100 WRA) for the CYP, bivariate, and multivariate models. We summed the model-generated values for condoms, injectable contraception, and oral contraceptives to create multivariate, bivariate, and CYP “combined public-sector, short-acting methods” models. The results these models provide for each country can be interpreted as a “best estimate” for that country’s prevalence rates for each short-acting method.

Oral contraceptive data from 2 countries (Bangladesh and Zimbabwe) were dropped from analysis due to data analysis concerns. These 2 countries had substantially higher AMD/100 WRA values for oral contraception ( $>20/100$  WRA) than the other 28 countries, and therefore were

influential outliers with undue weight in the regression models. Additionally, 2 other countries (Madagascar and Niger) did not have logistics data on condoms and 1 country (Uganda) did not have data on oral contraceptives, so these countries were excluded from the analyses for the respective methods.

All analyses were performed using Stata version 12 (College Station, TX).

## Evaluation of Models

We evaluated the bivariate, multivariate, and CYP-based models by comparing the referent DHS prevalence rates for each short-acting method with the model-generated prevalence rates for each method using multiple metrics, including mean absolute error (MAE) and proportion of countries where the modeled prevalence rate by method was within 1, 2, or 5 percentage points of the referent prevalence rate. MAE is a standard calculation for model comparisons. To generate the MAE, we first subtracted model-generated prevalence rate from the referent prevalence rate. The absolute value of this difference, per country, is the model absolute error value. The MAE is the average of these values. For our models, high MAE values correspond to high error values (less accurate models). We chose 1, 2, and 5 percentage-point cutoffs as levels of precision that would have programmatic value.

## RESULTS

### Method Mix and Market Share

While most of the CPR in countries was attributable to oral contraceptives, condoms, and injectables, method mix varied substantially in the countries examined (Table 2). In Bangladesh and Zimbabwe, oral contraceptive use at the time of the DHS was high (about 27% of WRA). In Malawi, injectable contraceptives were used by 19.2% of WRA, while in Cameroon and Pakistan, male condoms were the most prevalent method (9.7% and 8.8% of WRA, respectively).

In the countries in this study, most women using any type of contraception received their method from a public-sector facility, e.g., a government clinic or hospital (Table 2). However, the source of the method varied when analyzing market share by individual product—the majority of women using injectable contraceptives reported receiving the method from public sources, while those using condoms were more likely to get them from nonpublic sources such as NGOs, private pharmacies, or other

private stores. With oral contraceptives, there was more variation between countries in public versus nonpublic sources of supply.

The role of the public sector varied between survey years (data not shown). For instance, in Bolivia, although the oral contraceptive prevalence rate remained constant at approximately 3% over the 5-year period between surveys, its public-sector market share increased from 20% in 1998 to 32% in 2003–2004. On the other hand, in Nepal, where the prevalence rate for injectable contraceptives declined slightly from 8% to 7%, the public market share for injectable contraception decreased more substantially from 82% in 2006 to 69% in 2011.

### CYP Model and Regression Models

For each of the 3 models (bivariate, multivariate, and CYP), we used logistics data to create model-generated prevalence estimates for each contraceptive method and country (see Supplemental Table 1 for injectable values, Supplemental Table 2 for oral contraceptive values, Supplemental Table 3 for male condom values, and Supplemental Table 4 for values for all short-acting methods combined).

The significant  $P$  values ( $P \leq .001$ ) in the bivariate regression models indicate a strong linear relationship on the natural log scale between the public-sector prevalence rates and logistics data for all short-acting methods (Table 3). The proportion of variance explained varied by method—the model  $R^2$  term was highest for injectable contraceptives (0.90), followed by oral contraceptives (0.48) and condoms (0.28). The bivariate model  $\beta_1$  coefficients were 0.72, 0.45, and 0.44 for injectable contraceptives, oral contraceptives, and condoms, respectively. As the regressions were conducted on a log-log scale, these coefficients can be interpreted as the **marginal percent increase** in the prevalence rate of a method given a 1% rise in AMD or AQD/100 WRA. Thus, based on the  $\beta_1$  coefficient for injectable contraceptives, a marginal increase of 10% in the AQD of injectable contraceptives per 100 WRA would be associated with a corresponding marginal increase of 7.2% in the prevalence rate for injectables.

After controlling for the prevalence rates of each short-acting method from previous surveys in the multivariate model, the association between the model-generated, public-sector prevalence rates and the referent DHS prevalence rates remained significant for both injectables ( $\beta_1 = 0.62$ ,  $P \leq .001$ ,  $R^2 = 0.91$ ) and oral contraceptives ( $\beta_1 = 0.23$ ,  $P \leq .05$ ,

**Public-sector prevalence rates for injectables, oral contraceptives, and condoms were significantly associated with logistics data in the bivariate model.**

**TABLE 2.** Modern Contraceptive Prevalence Rate (mCPR), Prevalence Rates of Short-Acting Methods, and Public-Sector Market Share, by Country, From DHS

Country	mCPR (%)	Prevalence (%)			Public-Sector Prevalence (%)			Public-Sector Market Share (%)		
		OC	IC	MC	OC	IC	MC	OC	IC	MC
Bangladesh	52.1	27.2	11.2	5.5	12.2	7.4	0.9	45.0	66.5	16.8
Bolivia	23.7	2.5	5.3	3.1	0.8	4.0	0.2	31.5	74.5	7.5
Burkina Faso	14.3	2.8	5.1	3.1	2.3	5.0	0.3	83.4	97.3	8.9
Cameroon	13.5	1.3	1.1	9.7	0.6	0.8	0.6	49.3	75.0	6.4
Côte d'Ivoire	13.9	6.1	1.9	5.0	1.4	1.7	0.2	23.4	89.2	4.2
Ethiopia	18.7	1.5	14.0	0.3	1.0	12.1	0.0	67.3	86.3	11.7
Ghana	13.5	3.6	4.2	3.6	0.5	3.7	0.1	12.8	87.0	2.7
Guinea	6.8	1.6	1.1	2.5	0.7	0.9	0.2	42.0	86.2	7.5
Haiti	21.6	1.7	11.7	5.8	0.4	5.5	0.7	22.4	46.6	11.2
Honduras	37.7	7.1	8.6	2.3	2.0	6.2	0.6	28.4	72.2	24.2
Jordan	41.2	7.5	0.9	3.4	2.7	0.4	1.3	36.5	46.7	37.3
Kenya	28.0	4.7	14.8	2.6	2.0	9.7	0.5	42.6	65.3	20.5
Liberia	11.7	3.8	3.7	3.5	2.2	2.6	1.4	56.8	69.1	40.9
Madagascar	23.0	4.8	14.1	1.0	2.8	11.7	0.0	57.3	82.9	4.9
Malawi	32.6	1.9	19.2	2.7	1.6	16.2	1.2	81.8	84.4	46.1
Mali	6.2	2.6	2.2	0.5	1.0	1.7	0.0	36.8	76.7	3.7
Mozambique	12.1	4.3	4.3	2.9	3.7	4.1	1.0	86.2	95.4	34.8
Nepal	33.2	3.2	7.0	3.3	1.6	4.8	1.1	50.9	69	32.3
Nicaragua	43.9	9.0	9.1	2.2	5.3	6.8	0.8	59.4	74.3	35.8
Niger	11.0	5.0	1.9	0.1	4.1	1.8	0.1	82.9	94.4	69.2
Nigeria	11.1	1.6	2.0	4.7	0.3	1.1	0.2	19.0	54.7	4.0
Pakistan	26.1	1.6	2.8	8.8	0.8	1.6	1.6	47.7	56.5	17.8
Philippines	23.5	8.4	2.0	1.2	4.8	1.9	0.3	56.6	92.5	27.4
Rwanda	25.2	3.9	14.6	1.8	3.7	14.2	0.9	94.2	97.1	51.4
Senegal	8.9	2.9	3.7	0.6	2.4	3.5	0.1	82.4	94.8	20.7
Tanzania	23.6	5.1	8.5	4.2	3.7	6.8	0.7	73.5	80.0	17.0
Togo	7.9	1.1	1.7	3.4	0.4	1.6	0.5	39.5	91.6	15.0
Uganda	20.7	2.1	10.7	3.2	1.0	4.2	0.9	45.7	39.1	28.6
Zambia	24.6	7.4	6.2	5.0	4.5	5.7	2.6	61.3	92.1	51.7
Zimbabwe	40.5	27.3	6.1	3.5	20.2	5.4	1.6	73.8	88.4	45.9

Abbreviations: CPR, contraceptive prevalence rate; DHS, Demographic and Health Surveys; IC, injectable contraceptives; MC, male condoms; mCPR, CPR for modern methods; OC, oral contraceptives.

**TABLE 3.** Association Between Referent Public-Sector Prevalence Rates and Average Monthly or Quarterly Logistics Distribution Data, by Contraceptive Type and Model Type

Model and Contraceptive Type	N	$\beta_0$	$\beta_1$	$\beta_2$	R <sup>2</sup> -adj
Bivariate Model					
Injectable contraceptives	30	-4.11	0.72***	NA	.90
Oral contraceptives <sup>a</sup>	27	-4.46	0.45***	NA	.48
Male condoms	28	-6.49	0.44***	NA	.28
Multivariate Model					
Injectable contraceptives	28	-4.21	0.62***	5.7	.91
Oral contraceptives <sup>a</sup>	25	-4.97	0.23*	34.93***	.72
Male condoms	26	-6.66	0.19	171.93***	.48

<sup>a</sup> The analysis was restricted to countries with <20 average monthly distribution per 100 women of reproductive age.

\* $P < .05$ , \*\* $P < .01$ , \*\*\* $P < .001$ .

$R^2 = 0.72$ ) but lost its significance with male condoms ( $\beta_1 = 0.19$ ,  $P > .1$ ,  $R^2 = 0.48$ ) (Table 3). Similar to the bivariate model, multivariate model  $\beta_1$  coefficients can be interpreted as the **marginal percent increase** in the prevalence rate of a method given a 1% rise in AMD or AQD/100 WRA.

The model equations can also be used to create model-generated estimates of a country's public-sector prevalence rate for each method. For the injectables bivariate model, the slope intercept ( $\beta_0$ ) is -4.11, and  $\beta_1$  is 0.72 (Table 3). Taking Tanzania as an example with its AQD/100 WRA of 10.1 in 2009–10, the bivariate model generated a public-sector injectables prevalence rate estimate of 8.6% (see Supplemental Table 1). The multivariate model yielded an injectables prevalence rate estimate of 8.7%, and the CYP model an estimate of 10.1%. These can be compared with the referent DHS value of 6.8%.

The Figures compare model-generated prevalence rate values with those from the referent DHS (Figure 1 for injectables, Figure 2 for oral contraceptives, Figure 3 for male condoms, and Figure 4 for all short-acting methods combined). In cases where the model-generated prevalence values match the referent DHS values exactly (i.e., data points falling on the gray line with a slope of 1), the model provides a completely accurate estimation. The data points present a comparison of the model-generated and referent prevalence rates: green diamond for the bivariate model; orange square for the multivariate model; and purple triangle for the CYP model. Model-generated public-sector

prevalence values for countries above the line are overestimated while those below are underestimated. Again, using Tanzania injectable contraceptives as an example, the bivariate model overestimates the “true” injectables prevalence rate by 1.8 percentage points; the multivariate model by 1.9 percentage points; and the CYP model by 3.3 percentage points. For context, we note that the 2010 Tanzania DHS's margin of error for the public-sector injectables rate is 0.8 percentage points.

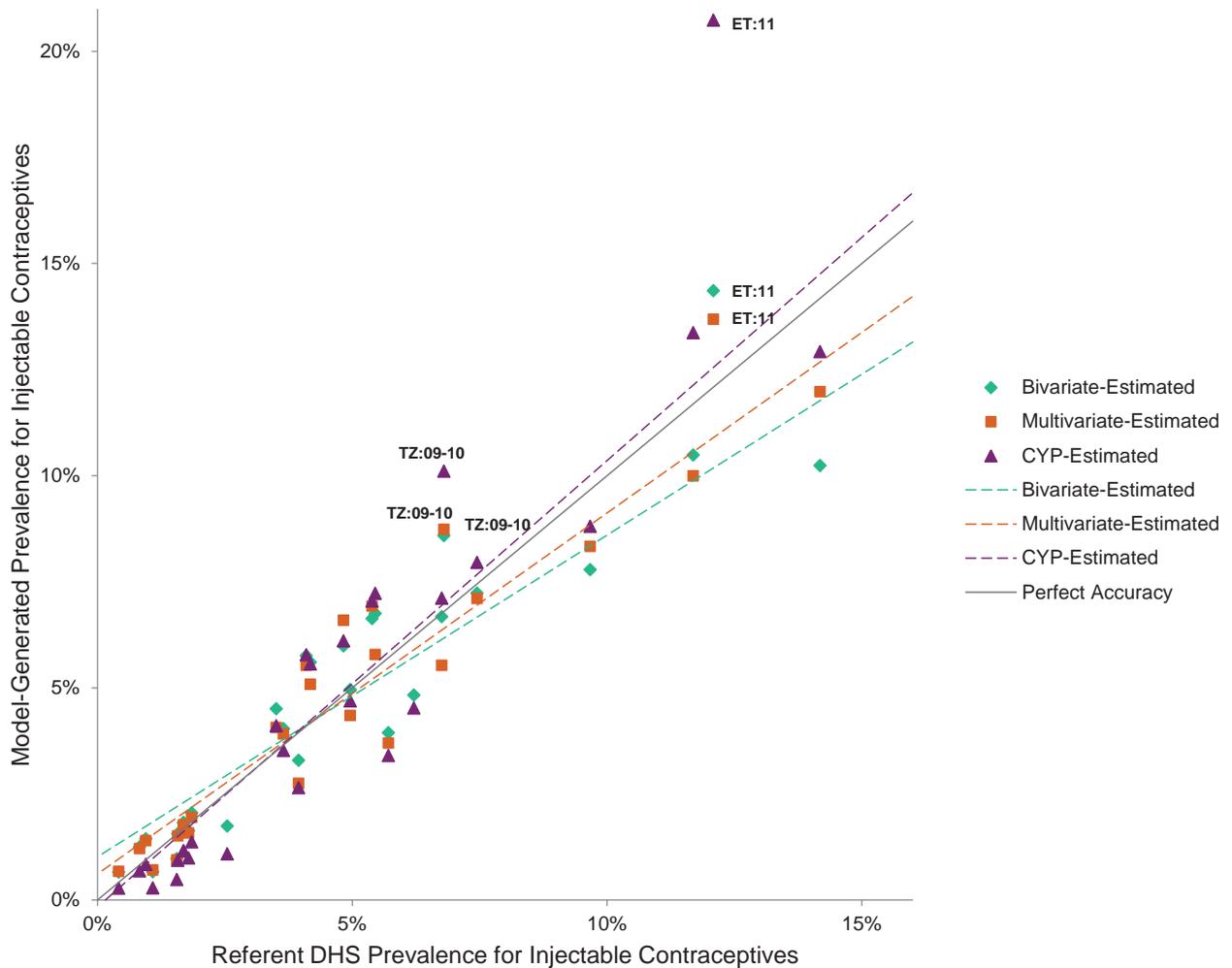
In general, the model-generated estimates for injectable contraception (across all models) were more accurate than for other methods—the majority of data points fell closer to the gray line, and the overall spread of the points were neither overestimates or underestimates (as seen by the slopes of the model lines, which were closer to that of the gray line) (Figure 1). For oral contraceptives, the bivariate model fared least well, differentially underestimating the oral contraceptives prevalence rate for higher ( $\geq 4\%$ ) values (Figure 2). For condoms, there were 6 countries that fell far above the gray line for the CYP model, indicating substantial overestimation (Figure 3). Similarly, the countries that fell below the gray line for the bivariate model reflect its underestimation for higher values.

## Model Evaluation

As mentioned earlier, we evaluated each model by comparing model-generated public-sector prevalence rates for each short-acting method with

**Model-generated prevalence estimates were generally more accurate for injectables than for other methods.**

**FIGURE 1.** Public-Sector Injectables Prevalence Rate Estimates



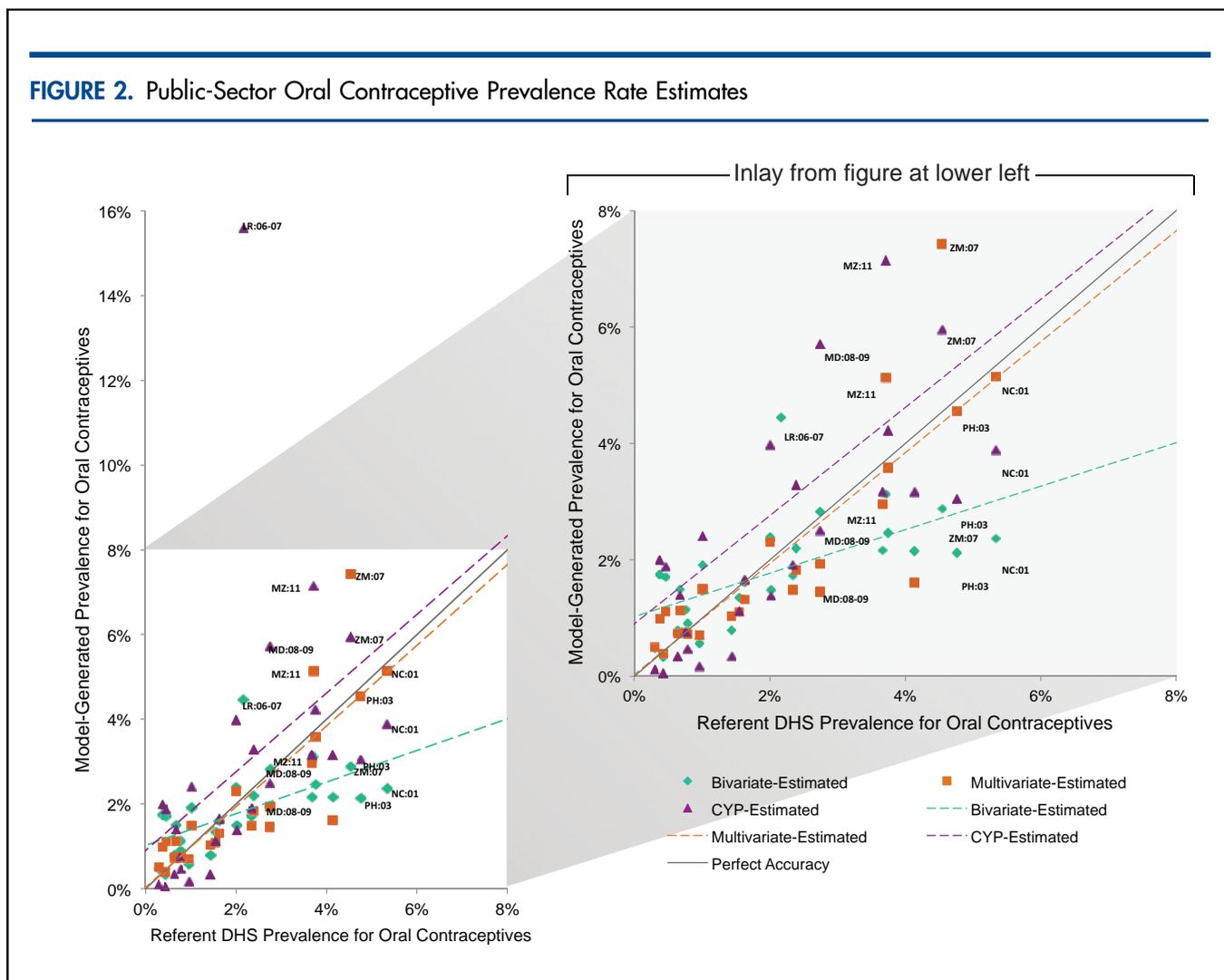
**While all 3 models generally performed well at estimating contraceptive prevalence, the regression models provided more accurate estimates than the CYP model.**

corresponding DHS values using MAE and by examining the proportion of countries where the model-estimated prevalence rate was within 1, 2, or 5 percentage points of the DHS referent value for the method. We also evaluated the maximum absolute error, which shows the highest model error for any country for a specific method, and the median error—a measure which is less sensitive to outliers. Models with lower mean, median, and maximum error perform better than those with higher values.

Models performed well at estimating public-sector prevalence rates from logistics data. The MAE for the individual method models ranged

from 0.3 to 2.4 percentage points (Table 4). However, the regression models performed better than the CYP-based estimation model, as seen by the fact that the regression models’ error values were lower across all contraceptive methods. With the exception of the CYP condoms model, all method-specific models were able to accurately estimate, to within 2 percentage points, a country’s public-sector prevalence rate for each method for at least 85% of the countries in the analysis (Table 4, the “2 Percentage Points” column). Models fared less well in estimating accuracy to within 1 percentage point.

**FIGURE 2.** Public-Sector Oral Contraceptive Prevalence Rate Estimates



For the combined short-acting methods model, on average (based on MAE), we were able to estimate countries' public-sector CPRs attributable to these short-acting methods to within 1.4 percentage points using the multivariate model and to within 1.9 percentage points using the bivariate model (Table 4).

The "error" (i.e., the difference between the model-generated values and the DHS values) for each country and for each model, as well as patterns of error, compared with the referent values can be seen in the appendix figures at the end of this article (Appendix Figure 1, Appendix Figure 2, Appendix Figure 3).

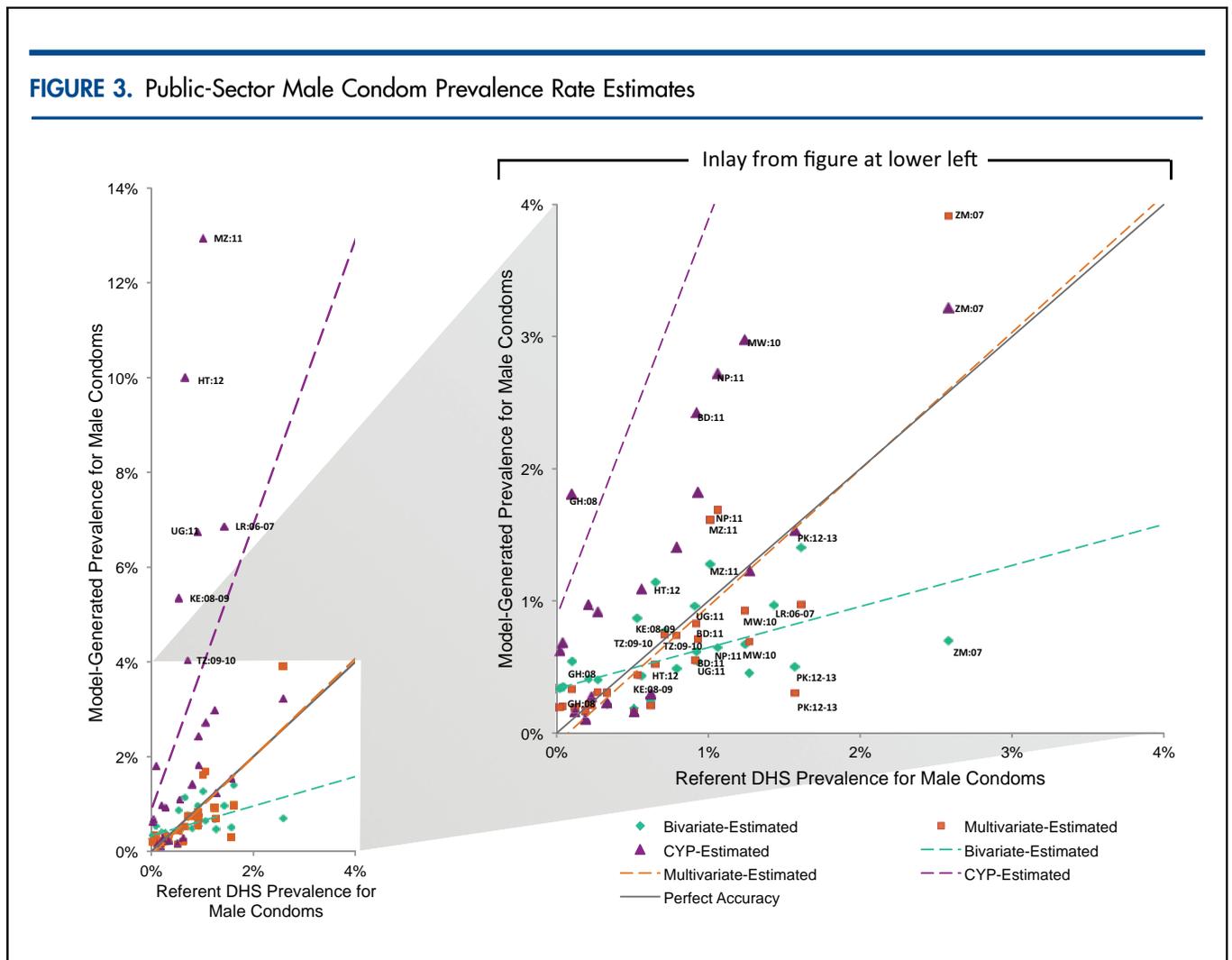
For most models, the error terms are scattered around zero throughout the x-axis, indicating that they are not systematically biased. As previously

noted, however, the bivariate models for oral contraceptives (Appendix Figure 2) and condoms (Appendix Figure 3) tend to underestimate the prevalence rates for countries with higher public-sector prevalence values and overestimate prevalence rates for those with lower public-sector prevalence values, while the condoms CYP model tends to systematically overestimate prevalence rates (Appendix Figure 3).

## DISCUSSION

CPR is a vital indicator needed by country governments, international donors, and other stakeholders for measuring national and subnational progress against global initiatives, such as FP2020, Scaling Up Nutrition, and Every Woman

**FIGURE 3.** Public-Sector Male Condom Prevalence Rate Estimates



**All models, except the CYP condoms model, estimated public-sector prevalence of short-acting methods to within 2 percentage points in at least 85% of countries.**

Every Child, and for gauging health outcomes. These development partners need robust methods for estimating evolving CPRs, which population-based surveys cannot always provide due to their costs and limited frequencies. Timely and disaggregated CPR estimates thus require high-quality data that are routinely collected and reported.

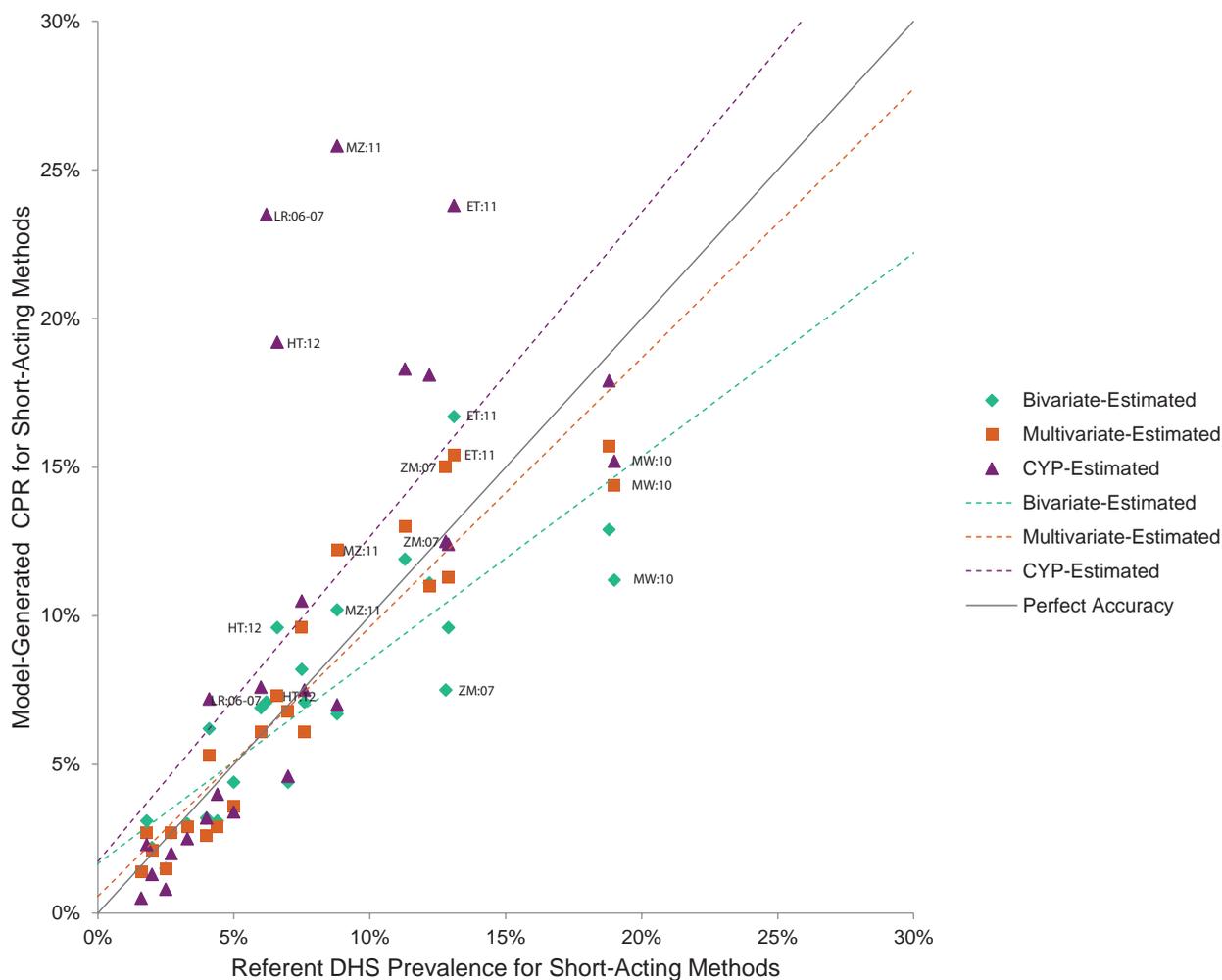
Our results show a close correlation between the logistics distribution data being collected and actual use of family planning methods, demonstrating the quality of the current logistics data provided through the PPMR and through PipeLine. These results point to the effectiveness of health systems strengthening activities that have focused on strengthening national supply chains and improving data visibility for supply chain management. The results also point to the valuable role that accurate logistics data can

play in estimating prevalence of short-acting methods in the interim between nationally representative surveys to help countries monitor their performance and track their progress.

All models, with the exception of the CYP-based model for condoms, were able to estimate public-sector prevalence of short-acting methods to within 2 percentage points in at least 85% of countries. For tracking the general picture of contraceptive prevalence in a country, the potential 2 percentage-point error may provide enough accuracy for planning or for estimating progress in years between surveys. On average, all models except the condoms CYP model performed well, but the regression models were more accurate.

While all 3 models estimate public-sector prevalence of short-acting methods, some differences

**FIGURE 4.** CPR Estimates for Public-Sector Short-Acting Methods



exist in terms of complexity and accuracy of the models. The CYP-based model offers the simplest calculation method. It estimates contraceptive prevalence based on existing CYP conversion factors, so its interpretation is straightforward—increases in commodity dispensed correlate directly with increases in contraceptive use for the method. No statistical tools are needed, and the only data required are logistics (distribution) and population data. The bivariate and multivariate regression models, although more accurate for a greater number of countries, are also more complex; they

were created using regression techniques following a natural log transformation of both the logistics (AMD or AQD) and DHS prevalence data for the method. While being the most consistently accurate, the multivariate regression model also requires a previous prevalence estimate for the method. Further, in the multivariate models, the strength of the relationship between AMD/100 WRA and the referent prevalence rate decreased for oral contraceptives and ceased to be significant for condoms, indicating that one of the best predictors for current use of oral contraceptives or condoms might be previous use of orals or

**The CYP model offers the simplest calculation method while the regression models were more accurate.**

**TABLE 4.** Evaluation of Model Accuracy and Precision

Model	Difference Between Model Estimates and DHS Referent Values			Proportion of Model-Estimated Values Within 1, 2, and 5 Percentage Points of the DHS Value		
	Maximum Absolute Error (%)	Mean Absolute Error (MAE) (%)	Median Absolute Error (%)	1 Percentage Point (%)	2 Percentage Points (%)	5 Percentage Points (%)
<b>Injectables</b>						
Multivariate	3.8	1.0	0.6	57	89	100
Bivariate	7.0	1.1	0.7	57	90	97
CYP	8.6	1.4	0.8	54	86	93
<b>Oral Contraceptives</b>						
Multivariate	2.9	0.6	0.4	84	92	100
Bivariate	3.0	0.9	0.6	67	89	100
CYP	3.4	1.0	0.8	60	92	100
<b>Condoms</b>						
Multivariate	1.3	0.3	0.2	92	100	100
Bivariate	1.9	0.4	0.3	93	100	100
CYP	14.4	2.4	0.6	62	77	85
<b>All Short-Acting Methods</b>						
Multivariate	4.6	1.4	1.3	35	74	100
Bivariate	7.8	1.9	1.2	40	64	88
CYP	17.0	3.4	1.5	43	61	78

condoms, respectively. In contrast, the relationship for injectable contraceptives remained significant ( $P < .001$ ). When we combine this information with the fact that the condom bivariate and condom CYP models over- or underestimate prevalence rates differentially, we note that estimating condom prevalence rates using logistics data is problematic. For detailed program planning purposes, when high accuracy is more important, the bivariate and multivariate regression models provide slightly more accurate estimates on average—in our analysis their average and maximum error values were smaller.

Country-specific factors that would directly affect the relationship between logistics data and contraceptive use data are not captured in our analysis. These include differences in our logistics data sources (forecasted dispensed-to-user; versus issues

data, which tend to be higher than dispensed-to-user data; versus actual dispensed-to-user data) and possible differences in wastage rates in individual countries. Much of our data represented either forecasted dispensed-to-user data or movements of stock from central levels to peripheral levels rather than actual data on contraceptives dispensed to clients. Given the more direct link between commodities dispensed to users and commodities used (as opposed to commodities issued at a higher level and those used by clients), we would expect greater accuracy and precision from each model as donors and country governments continue to strengthen their LMISs and actual dispensed-to-user data become more available.

The strengths of the results of our models vary between contraceptive methods, indicating some

inherent limitations in using logistics data to estimate prevalence rates. Contraceptives such as condoms (especially) and oral contraceptives dispensed by health facilities may not be used immediately (or completely) by clients. In addition, linking logistics data for condoms, which have a dual purpose of preventing sexually transmitted infections (STIs) and unintended pregnancy, with family planning survey data is complicated. Women may not report their use of condoms for contraception during a DHS survey because they associate the condoms more with STI prevention, they associate condoms as a method that their partner uses (not one that the women themselves use), or they might report using another more effective contraceptive method, in which case that method is recorded rather than condoms.<sup>25–27</sup> Additionally, condoms dispensed from STI clinics may be used for family planning but may not be captured in the logistics data. In comparison, oral and injectable contraceptives have a single use, and thus the link between dispensing and intended use is stronger. This may help explain why the results for condoms are not significant for the multivariate model and why the higher error terms in the condoms CYP model for several countries with high HIV prevalence were seen (Appendix Figure 3).

Some outliers may also be explained by situations in which methods are provided by the public sector to NGO or private outlets; in these cases, clients would have reported receiving these products outside the public sector, and this use would not be captured by the DHS public-sector prevalence values. However, in some countries, PipeLine and PPMR capture these products along with the products destined for public-sector consumption. Conversely, in countries with weaker or rebounding public systems, NGOs may provide products to public-sector facilities, and therefore the logistics data are not captured in PipeLine or PPMR.

The accuracy of our models and similar research in Rwanda at the district level strongly suggest that these models could also be used to help countries evaluate district-level contraceptive prevalence for improved in-country targeting of family planning resources.<sup>12</sup> Current tools for estimating CPRs, namely national population-based surveys, are rarely representative at such disaggregate scales due to sampling constraints.

Lacking private-sector logistics data, we focused on public-sector logistics data and CPRs, and thus we were unable to estimate overall country prevalence rates for short-acting methods. In principle, the same strategy for developing the

models should be possible with private-sector logistics data where they are available. In the countries for which we had data, the average public-sector market share was 53% for oral contraceptives and 78% for injectable contraceptives, while for male condoms it was 24%. In countries with high public-sector market share, contraceptive prevalence estimates and trends from public-sector logistics data will be more reflective of the overall contraceptive prevalence than in countries where the public-sector market share is low. While in all cases, we recommend seeking both public- and private-sector data, the latter are even more critical for condoms given the higher private-sector market share.

Additionally, when evaluating the models, we are comparing the results against DHS-based estimates, which (although considered the current gold standard for most demographic and health indicators) have their own limitations.<sup>28</sup> The standard errors for statistics related to contraceptive method use and public-sector source of supply vary by survey (typically calculated in the range of 2–3 percentage points), and results are calculated to fall within a  $\pm 2$  times the standard error of that statistic in 95% of cases. Additionally, results are based on lengthy interviews, and responses might be biased or misinformed. For example, social marketing products can be provided at public-sector facilities directly by health workers or in a kiosk within the public facility. During the survey, clients may not differentiate between the public versus social marketing sources and may report the public sector as the source of these social marketing products.

## Future Research

As with similar models, adding more data is likely to strengthen their predictive power. A greater availability of actual dispensed-to-user data and of country-specific wastage rates would improve the reliability of using logistics data to estimate prevalence rates by method.

The CYP model consistently overestimated public-sector condom use levels, indicating a possible need for further research reexamining the existing conversion factors and the DHS condom use values in more detail. Future research should focus on country-specific factors that might be used to adjust CYP conversion factors or produce country- or region-specific conversion factors in order to improve the accuracy of the model for condoms. Data permitting, future

**Countries could use routine logistics data with these models to evaluate district-level contraceptive prevalence, and thus better target family planning resources.**

research should also include total condom use in the regression models instead of condom use specifically for contraceptive purposes.

Due to the limited number of countries ( $n=30$ ) for which we had overlapping DHS and logistics data, we included only one additional variable in the multivariate model. As the number of countries with both logistics data and population survey-based prevalence data by method expands, future research could include additional variables such as demand generation initiatives, product costs, product flow between sectors, consistency of product availability, gross national income per capita, HIV prevalence, and average education level. These factors would be especially relevant for cases where the logistics data represent issues data, rather than dispensed-to-user data, as most of these covariates would influence whether or not clients accessed services at the facility level.

Additionally, while short-acting methods currently dominate the method mix in most countries, as the international community focuses on expanding long-acting method options, we anticipate that their contributions to the CPR will increase substantially. Due to lack of a sufficient quantity of overlapping logistics and DHS data, we were unable to adequately construct models for long-acting contraceptive methods. As more data become available, it will be important to develop models for these long-acting methods.

Further research should also explore expanding the models to estimate prevalence rates beyond the public sector, through the addition of data from nonpublic sources, when available, or by adding market share data along with the public-sector logistics data. With sufficient data, the models could be expanded to estimate total CPR, allowing countries to track their progress against national and global family planning goals.

**Our models demonstrate strong, significant relationships between public-sector contraceptive logistics data and referent public-sector prevalence rates for short-acting methods.**

### Limitations

We selected countries for this study on the basis of overlapping DHS and logistics data availability. As a result, the number of data points included in each model is quite small ( $n\leq 30$ ). This affected our analysis in 2 ways. First, the selection criteria may have introduced bias into the results if countries that have better data availability have stronger associations between prevalence rates by method and contraceptive distribution. Second, with the limited data points, we were unable to

create separate datasets for model building and model validation. Countries that were not included in the analysis may behave differently than those that were included. While we constructed our models based on the best available data, testing it on countries not included in the model construction would provide us with a better evaluation of the models' external validity.

Additionally, because the models use data from many countries to estimate results for a particular country, potential for variation exists where the relationship between logistics data and the prevalence rate within a country is stronger or weaker than the average of the countries used in creating the model.

For 2 countries, Bangladesh and Jordan, the DHS included only ever-married women as respondents for the women's questionnaire. While the majority of WRA in both of these countries were currently (80.4% in Bangladesh) or previously in union (54.4% in Jordan) at the time of the surveys, patterns of contraceptive use among these women might differ substantially from women who had never been married. Consequently, the model results would have been affected. A final limitation of the models, which estimate future prevalence rate of short-acting methods from the past relationship of the logistics data and the DHS prevalence rate data, is that they rely on an implicit assumption that the relationship between logistics data and client use remains constant over time. As countries improve the quality of their logistics data, and as more countries begin collecting information on contraceptives dispensed to users rather than contraceptives issued from warehouses, the models may need to be recalibrated.

## CONCLUSIONS

With less than 5 years remaining to meet FP2020 goals, national family planning program managers and international donors need frequently updated data on current CPRs in order to most effectively target limited program resources. Demonstrating the strength of the relationship between logistics data and prevalence estimates for short-acting methods is an important first step in showing the potential of using logistics data to provide a low-cost alternative for generating routine CPR estimates. Our results show a strong relationship between public-sector contraceptive logistics data and public-sector prevalence rates for short-acting methods, demonstrating

the quality of current logistics data and their ability to provide relatively accurate prevalence estimates. Using logistics data for estimating condom use levels, however, should be done with caution given the relative weakness and limitations of the condoms models. Future work relating subnational logistics data with CPR, and tracking that relationship over time, is needed; there is also a need for expanding the models to estimate prevalence rates by method beyond the public sector through the addition of data from nonpublic sources, when available, or by adding market share data along with the public-sector logistics data.

As the international community continues to work to improve the health of women and children, investments in health information systems and supply chains will be essential to meet the challenges to improve access to contraceptives and reduce unmet need for family planning. It will be equally important for family planning and supply chain program managers to work together to share and effectively use these data.

Depending on the data available, the level of precision sought, and the importance of being able to describe the model used to a general audience, national and international stakeholders can use any of the 3 models to estimate country-level prevalence rates of short-acting methods at times when timely estimates from nationally representative survey data are not available. These models provide a starting point for generating these interim estimates. Given the additional complexities of the regression-based analysis, we recommend use of the CYP-based model (accurate to within 2 percentage points for most countries) for estimating national prevalence rates by method. The results from these models should be triangulated against other available data to allow stakeholders to best prioritize family planning and supply chain interventions.

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**Competing Interests:** None declared.

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#### Peer Reviewed

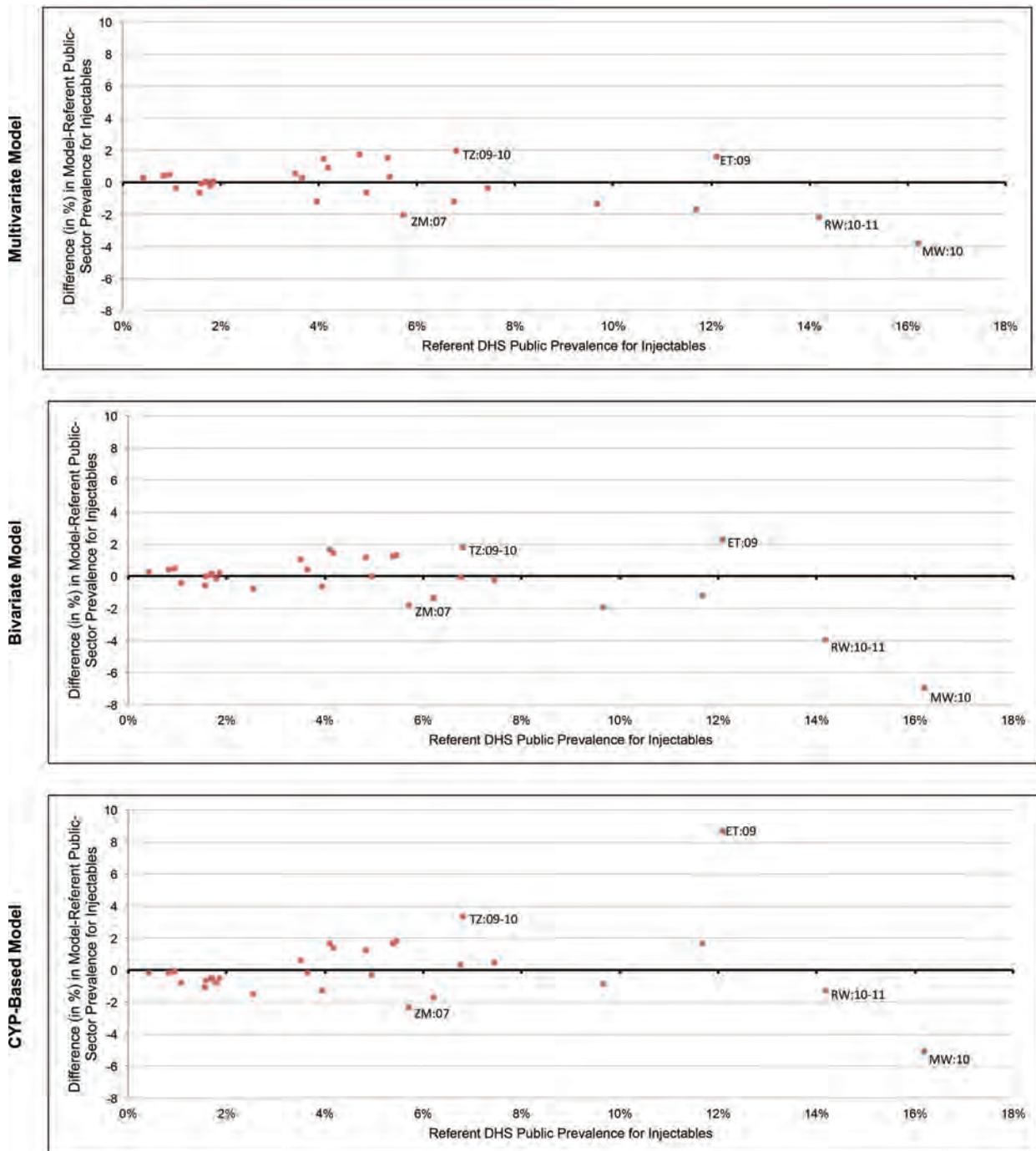
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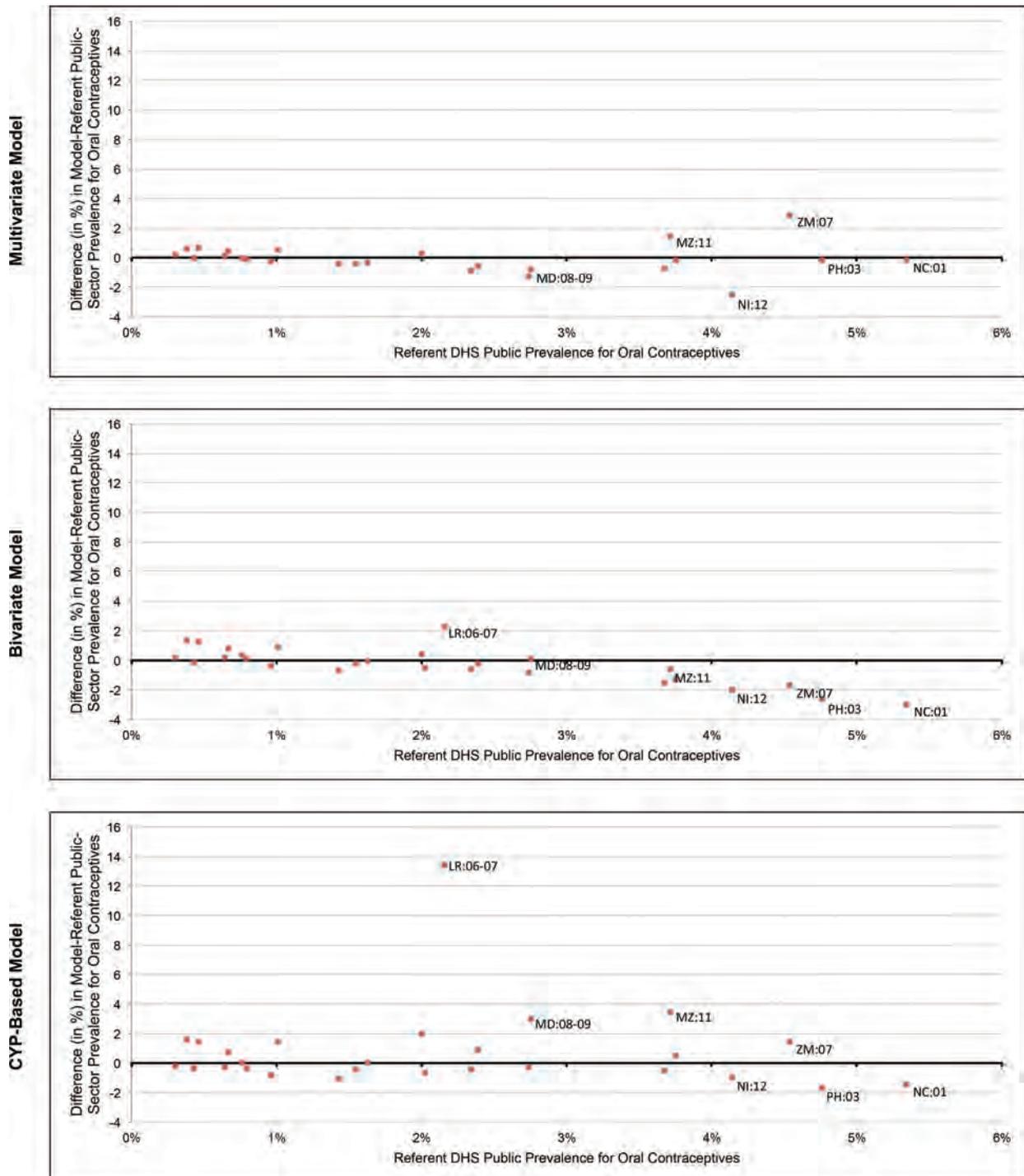
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**APPENDIX FIGURE 1.** Difference Between Model-Generated and Referent DHS Public Injectables Prevalence Rate

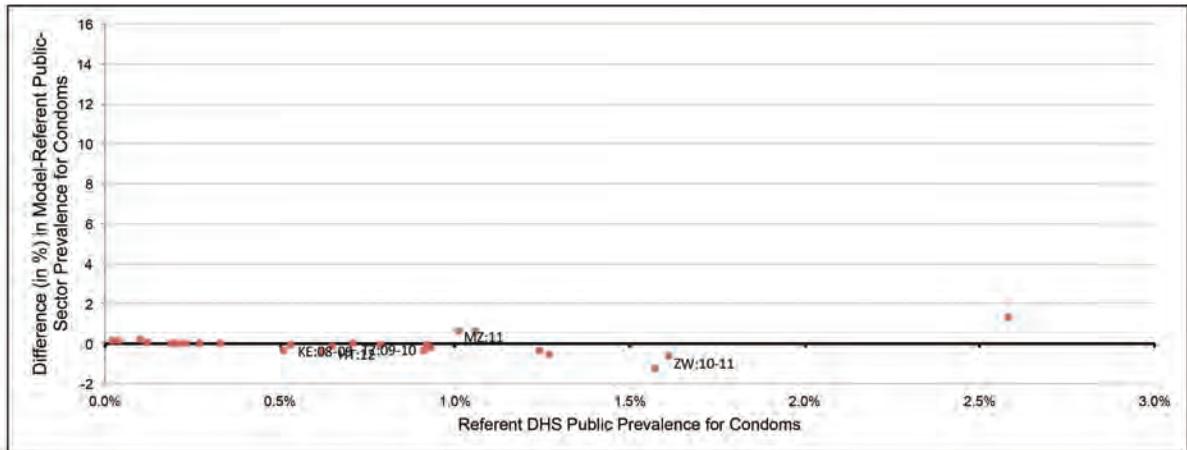


**APPENDIX FIGURE 2.** Difference Between Model-Generated and Referent DHS Public Oral Contraceptives Prevalence Rate

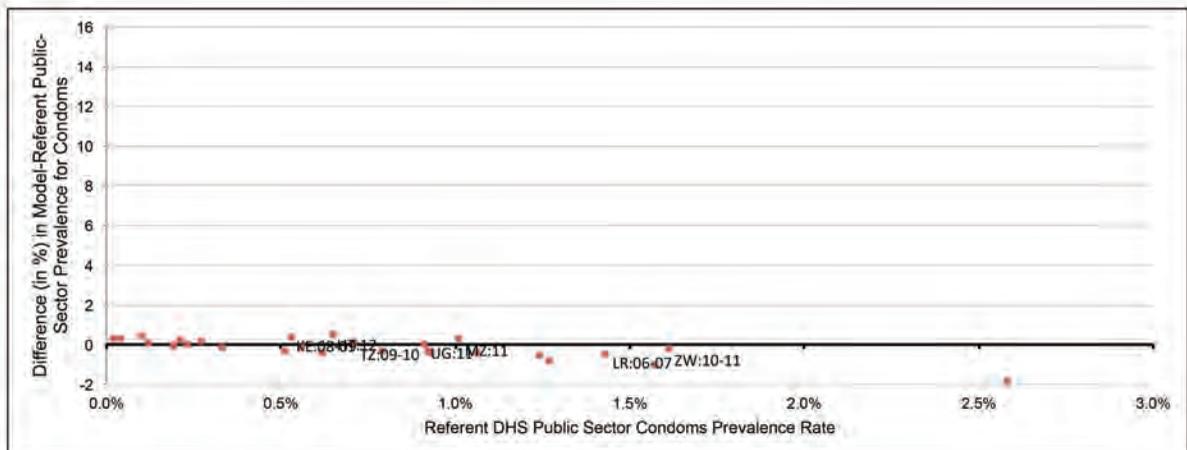


**APPENDIX FIGURE 3.** Difference Between Model-Generated and Referent DHS Public Condoms Prevalence Rate

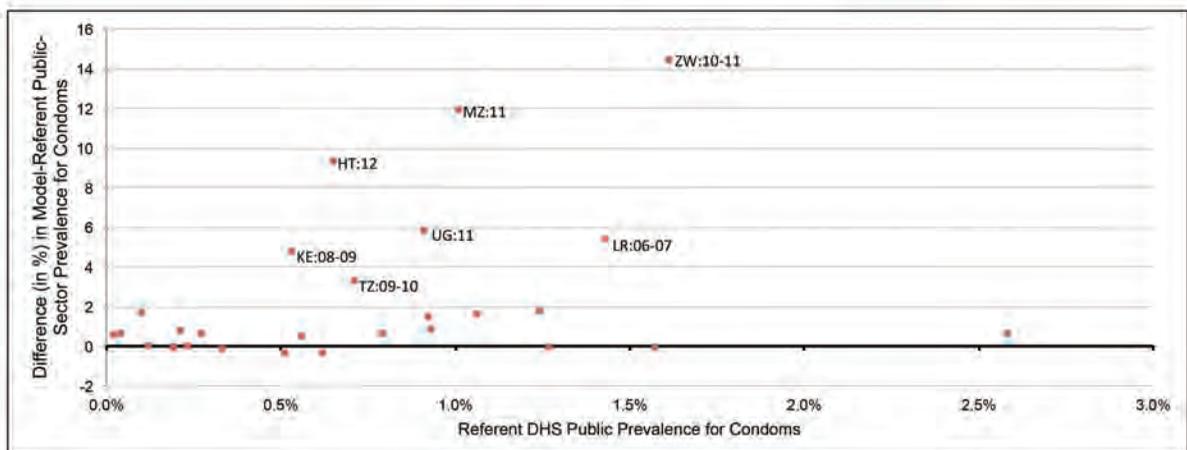
Multivariate Model



Bivariate Model



CYP-Based Model



## ORIGINAL ARTICLE

# The Astronomy of Africa's Health Systems Literature During the MDG Era: Where Are the Systems Clusters?

James F Phillips,<sup>a</sup> Mallory Sheff,<sup>a</sup> Christopher B Boyer<sup>a</sup>

The volume of literature on health systems in sub-Saharan Africa has been expanding since the 2000 MDG era. Focus has remained generally on categorical health themes rather than systems concepts. Topics such as scaling-up, organizational development, data use for decision making, logistics, and financial planning remain underrepresented. And quite surprisingly, implementation science remains something of a "black hole." But bibliometric evidence suggests there is a shift in focus that may soon address these gaps.

## ABSTRACT

Growing international concern about the need for improved health systems in Africa has catalyzed an expansion of the health systems literature. This review applies a bibliometric procedure to analyze the acceleration of scientific writing on this theme. We focus on research published during the Millennium Development Goal (MDG) era between 1990 and 2014, reporting findings from a systematic review of a database comprised of 17,655 articles about health systems themes from sub-Saharan African countries or subregions. Using bibliometric tools for co-word textual analysis, we analyzed the incidence and associations of keywords and phrases to generate and visualize topical foci on health systems as clusters of themes, much in the manner that astronomers represent groupings of stars as galaxies of celestial entities. The association of keywords defines their relative position, with the size of images weighted by the relative frequency of terms. Sets of associated keywords are arrayed as stars that cluster as "galaxies" of concepts in the knowledge universe represented by health systems research from sub-Saharan Africa. Results show that health systems research is dominated by literature on diseases and categorical systems research topics, rather than on systems science that cuts across diseases or specific systemic themes. Systems research is highly developed in South Africa but relatively uncommon elsewhere in the region. "Black holes" are identified by searching for terms in our keyword library related to terms in widely cited reviews of health systems. Results identify several themes that are unexpectedly uncommon in the country-specific health systems literature. This includes research on the processes of achieving systems change, the health impact of systems strengthening, processes that explain the systems determinants of health outcomes, or systematic study of organizational dysfunction and ways to improve system performance. Research quantifying the relationship of governance indicators to health systems strengthening is nearly absent from the literature. Long-term experimental studies and statistically rigorous research on cross-cutting themes of health systems strengthening are rare. Studies of organizational malaise or corruption are virtually absent. Trend analysis shows the emergence of organizational research on specific priority diseases, such as on HIV/AIDS, malaria, and tuberculosis, but portrays a lack of focus on integrated systems research on the general burden of disease. If health systems in Africa are to be strengthened, then organizational change research must be a more concerted focus in the future than has been the case in the past.

## INTRODUCTION

The global literature on health systems policy, implementation, and research has proliferated in recent decades.<sup>1</sup> In sub-Saharan Africa, investment in health systems development has been transformative,

generating a wide array of scientific and policy articles on problems encountered and lessons learned.<sup>2-6</sup>

This commitment to health systems development in Africa can be traced to modality innovations, disease-control initiatives, and vertical programs launched in the 1970s and 1980s.<sup>6</sup> The 1978 Alma Ata Conference catalyzed critically important health systems action and writing.<sup>7-9</sup> The subsequent focus of the international community on health systems integration, reform, and decentralization received impetus from international

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partnerships. For example, the “sector-wide approach,” financed by the World Bank and other international initiatives,<sup>10</sup> influenced policies and program implementation throughout the region.<sup>11,12</sup> With the onset of the United Nations Millennium Development Goals (MDGs)<sup>13,14</sup> and corresponding concerns about capabilities of African countries to achieve them, donor assistance, funding, and priority programs directed attention to the need for health systems strengthening in sub-Saharan Africa.<sup>5,10–18</sup>

Private funding, particularly from the Bill and Melinda Gates Foundation,<sup>19</sup> has also been critical to the climate of support for health systems development. Global engagement with systems issues gained further traction in 2007, when an expert World Health Organization (WHO) panel developed a framework specifying essential components of health systems functioning comprised of 6 essential interdependent “building blocks.”<sup>20</sup>

This paper aims to take stock of this proliferation of financing, programming, and research that occurred in the wake of these historic milestones by conducting a bibliometric review of keywords associated with articles about health systems in sub-Saharan Africa published during the MDG era (1990–2014). Our aim is to clarify health systems themes emerging from the literature and gain insights that could address future research priorities and needs.

## METHODS

We applied a bibliometric procedure to analyze scientific writing on health systems in sub-Saharan Africa published between 1990 and 2014. The term “bibliometrics” is characterized by its originators as “the application of mathematical and statistical methods to books and other media of communications.”<sup>21</sup> (The term “scientometrics” is used interchangeably with the methods of bibliometrics.<sup>22</sup>) The assumption in conducting a thematic bibliometric analysis is that published literature directly reflects a body of scientific research and practice<sup>23</sup> and that words that co-exist within abstracts and keyword lists represent ideational associations that can be used to interpret underlying themes and concepts. Termed “co-word analysis,” scales and associations can be constructed that reduce the volume of terms into indices representing common themes.<sup>24</sup>

## Data Preparation

This analysis reviews publications published between January 1, 1990 and June 6, 2014 and

catalogued in the Elsevier Scopus database, one of the largest peer-reviewed citation libraries for science, technology, medicine, the arts, and humanities. We selected the Scopus database owing to its commitment to expert selection and assignment of indexed keywords to each article entry, including standardized Medical Subject Headings (MeSH) and Emtree medical terms (controlled vocabulary thesauri created by MEDLINE and Embase, respectively).<sup>25</sup> Articles, reviews, notes, editorials, articles in press, and book chapters containing terms of interest that appeared in the title, abstracts, or keyword lists were selected, conditional upon the mention of sub-Saharan Africa as a region or inclusion of at least one sub-Saharan African country or sub-region, allowing for linguistic or political contextual language commonly used.

For the purpose of this study, only index keywords selected by Scopus professional indexers were used, a procedure that avoids author-introduced indexing bias.<sup>25</sup> Terms used to search for literature relevant to the analysis encompassed “health system,” “health care system,” “health program,” and “health service,” mindful of the fact that many activities undertaken by health programs have systems implications, but with the specific goal of reviewing literature that explains, describes, or guides the development of health systems in sub-Saharan African countries. Terms that conveyed no analytical meaning such as “human,” “article,” “male,” or “female,” as well as countries that are not part of the sub-Saharan African region, were eliminated. Only indexed keywords with an occurrence of 10 or more were selected for analysis. This preparatory process improved data quality, minimized ambiguity, and enhanced logical coherence of results.

Further analysis was conducted to compare articles published prior to the MDG era with those published during the MDG era. For this comparison, we used a stricter keyword occurrence cutoff of 25 or more and also applied relevance scoring to obtain higher specificity in the time analysis. Data were then divided by publication date to create 2 libraries of articles published during the pre- and post-2000 periods: 1990–1999 and 2000–2014, respectively. The final libraries were loaded into the bibliometric visualization mapping software VOSviewer,<sup>26</sup> which calculates the optimal 2-dimensional scaling solution for the co-occurrence of the indexed keywords.

**Several historic milestones prompted a climate of support for health systems development in the global health field.**

**Bibliometric analysis applies mathematical and statistical methods to terms used in publications to understand underlying themes and concepts.**

## The VOSviewer Co-Word Optimization Procedure

Co-word analysis assumes that underlying themes in a field of publication are defined by patterns of keywords that appear in lists provided by each publication.<sup>27</sup> Thus, when a library of literature is analyzed, the ideas, concepts, and methods that constitute a field of knowledge are defined by clusters of keywords that reflect commonality within a field of scientific research.<sup>21–27</sup> Although the notion that associations can be used to define underlying indices of relationships is not new,<sup>28</sup> the application of these concepts to textual data is only recently gaining currency.<sup>1,21–24,26,27,29–34</sup>

Several alternative strategies for visualizing textual data are prevalent in the bibliometric literature.<sup>30,31</sup> Some, such as the VOSviewer software, incorporate features that generate bibliometric maps for visualizing keyword associations in ways that are analogous to the astronomer's depiction of objects in space:

- The frequency that terms appear defines the size of their visual representation as a labeled item.
- Their relative position in 2-dimensional space defines their relative association—all possible pairs of keywords that are commonly associated are positioned in close proximity of one another, and terms relatively unassociated with each other are mapped as remote from one another.
- Their clustering as sets of common colored keyword items define related conceptual domains, whereby sets of words that appear together more often in publications than can be attributed by chance share a common cluster of knowledge.

The relative position of keywords in a map is analogous to the concept of gravitation. The relative proximity of each possible pair is an index of the weight of their association, adjusting for all other possible associations in the keywords under study.

In practice, the operationalization of the mapping procedure applies optimization techniques to the positioning of groups of keywords in 2-dimensional space.<sup>33,34</sup> The VOSviewer software, used for the analysis presented in this paper, modifies the standard optimization procedure for multidimensional scaling to maximize the common variance defined by the relational positioning of keywords.<sup>34</sup> The VOS procedure

also uses a relevance score to enhance the identification of ideational galaxies.<sup>34</sup> The result of the computation process is a map in which terms that are relatively common to a general library of articles in an analysis appear at the center of a universe of knowledge, while keywords that are weakly associated are peripheral. By separating analyses by time of publication, clusters of terms defining galaxies can be created over successive time periods, allowing researchers to visualize changes in the thematic focus of research fields over time.

## Identifying Change Points in the Volume of Literature

In addition to the bibliometric analysis of keywords, we applied spline regression to test whether the publication volume trend changed over the MDG period relative to the trend in the 1990s. The term “spline regression” refers to an econometric method for testing hypotheses that a time series trajectory has changed at a discrete point in time. The method estimates the relative slope of trajectories and the point in time that a significant disjuncture occurred.<sup>35</sup> To pursue this analysis, “change points” are statistically defined in the pace of health systems publications in sub-Saharan Africa during the period of 1990 to 2013. We excluded 2014 on the basis of incompleteness. Our motivation for pursuing this line of inquiry was to divide the literature into time groups representing citations published before and after these “change points” so that they may be thematically mapped using the VOSviewer software. These thematic maps, in turn, could clarify how the pace of health systems research changed over time in response to key events. To identify significant “change points,” we used spline regression models of the form:

$$y_i = \hat{\beta}_0 + \hat{\beta}_1 x_i + \hat{\beta}_2 (x_i - T_0) u_i + \epsilon_i$$

where,

- $y_i$  = The number of publications in year  $i$
- $x_i$  = Integer year of publication tally
- $T_0$  = The potential change point year
- $u_i$  = A step function which is equal to 0 if  $x_i < T_0$  and is equal to 1 if  $x_i = T_0$ .
- $\epsilon_i$  = An error term for year  $i$

Spline knot values from 1991 to 2012 were estimated and compared using Akaike's Information Criterion (AIC).<sup>36</sup> The knot from the model with the lowest AIC was selected as the

“changepoint.” We then applied splines of increasing polynomial order to optimize fit. This procedure permitted appraisal of whether the advent of the MDGs in 2000–2001 accelerated the pace of publication through inference on the models with knots at 2001. An estimate for  $\beta_2$  that is positive and significantly different than zero is indicative of an acceleration. This hypothesis was tested using t-tests and an  $\alpha = .05$  level of significance.

## Hypotheses

Hypotheses guiding this analysis are implied by keywords that are associated with global frameworks for cross-cutting issues in health systems research and policy. In particular, the WHO health systems building blocks define essential capabilities for sustaining and strengthening health systems functioning (Table).<sup>20</sup> We posited that the health systems literature emerging from Africa would reflect this consensus, with clusters of keywords corresponding to the 6 WHO building blocks. Moreover, there are essential elements of successful health care functioning that define consensus thinking about the essential elements of successful primary health care in Africa. These include research on the quality of care, effective communication within systems and with the population served, effective organizational functioning, appropriate capabilities to use and scale-up innovation, means of adapting systems to social contexts, and strategies for maximizing access to essential care through scaling-up innovation or organizational reform (Table).<sup>1,23</sup> Bibliometric maps are expected to visualize clustering, centrality, and ideational content that reflect these compelling appeals for “systems thinking.”<sup>2–5,37–53</sup> We therefore posited that the 10 themes outlined in the Table would be reflected in bibliometric estimates of relationships comprising keywords in our database.

## Limitations

No bibliometric map is an exact representation of reality. Restricting the textual complexity of an entire body of scientific knowledge to size, color, and distance displayed across 2 dimensions will always be a simplification of the governing web of relationships portrayed. However, the bibliometric map represents an exploratory tool that can suggest associations, in analogy to the correlations that can be calculated in statistical analyses. Just as correlations are associations that

are not necessarily causally defined, bibliometric associations and clusters are exploratory rather than explanatory.

The VOSviewer assumes that a web of co-occurrence can be adequately captured in 2 dimensions. In fact, multidimensional spatial analysis may be required for a given investigation, particularly if concepts and issues under investigation are too complex to define in the restrictive assumptions that the procedure employs.

A further limitation concerns mapping bias that could arise from our choice of a cutoff for keyword occurrence. Inclusion of all keywords contributes “noise” that arises from the tendency of authors or Scopus reviewers to list synonyms as separate keywords. We have attempted to eliminate obvious redundancy, but the inclusion of all keywords, no matter how rare their occurrence may be, obfuscates rather than clarifies the visualization process. We have determined that limiting the analysis to keywords that appear at least 25 times in the articles under review is consistent with the goal of analyzing nearly all of the articles in the library. Lower cutoff values would not add articles to the analysis.

Health systems development often involves donor-funded projects and consortia that produce manuals, conferences, reports, and web-based products that are unpublished and unindexed by Scopus or other citation databases. Published papers may inadequately represent the health systems contribution of unpublished reports.<sup>54</sup> However, the focus of our review remains the products of scientific and policy teams and their peer-reviewed publications.

A final limitation concerns the challenge of representing the results of data visualization in publication-based maps. The number of keywords and their relationship is an intractable problem of graphics. To address this challenge, we present our results at <http://arches.columbia.edu/health-systems-research/> in a format that permits viewers to explore results, expand displays, and examine relationships within clusters with the same degree of flexibility that the authors have been equipped by VOSviewer to pursue.

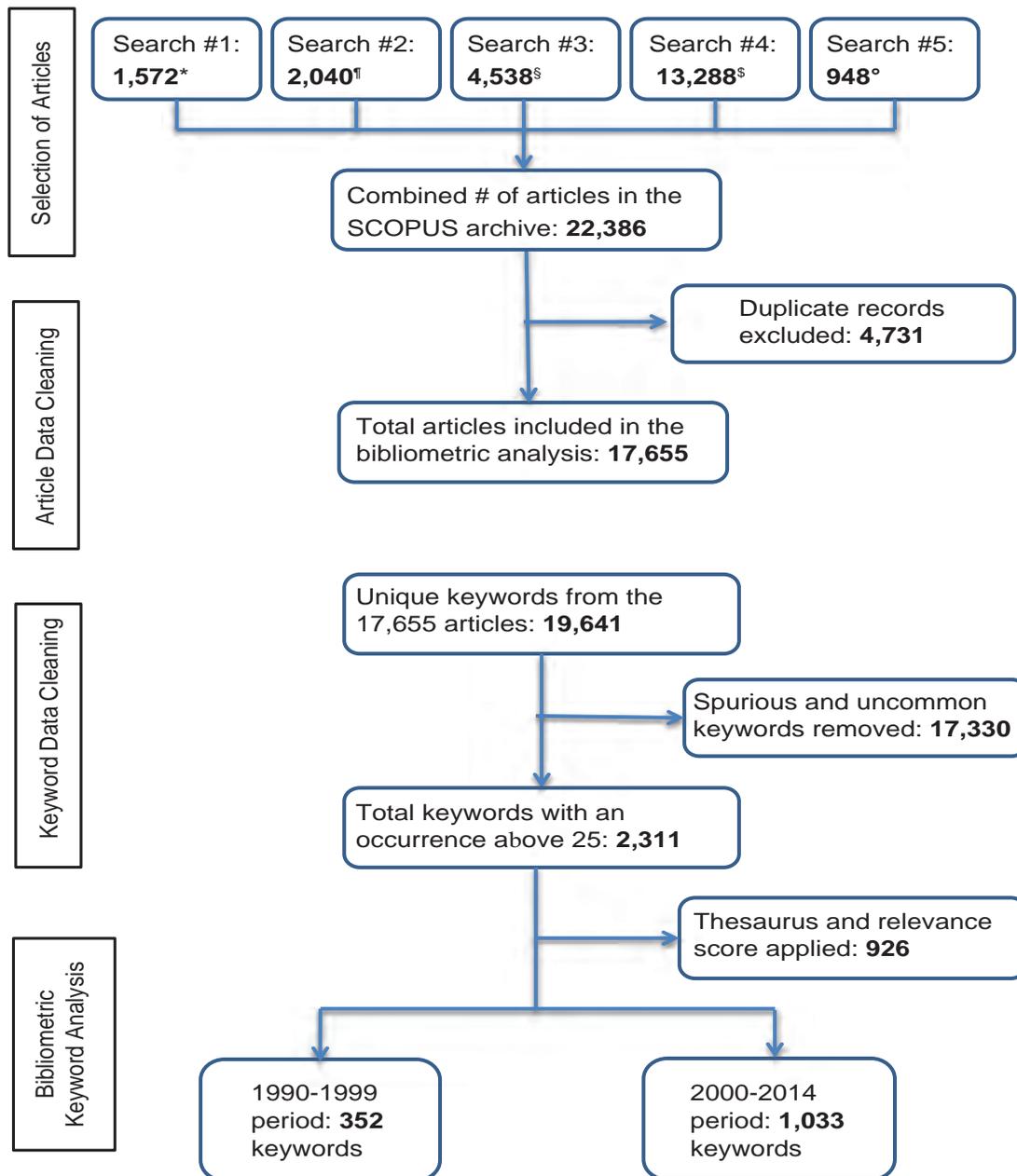
## RESULTS

Our search initially yielded 22,386 articles. After excluding duplicate records, 17,655 articles remained, which comprised the final set of articles included in the bibliometric analysis (Figure 1). From these articles, 2,240 keywords

**TABLE.** Expected Keyword Themes From sub-Saharan African Health Systems Publications Published Between 1990 and 2014, Based on Global Frameworks for Health Systems Development

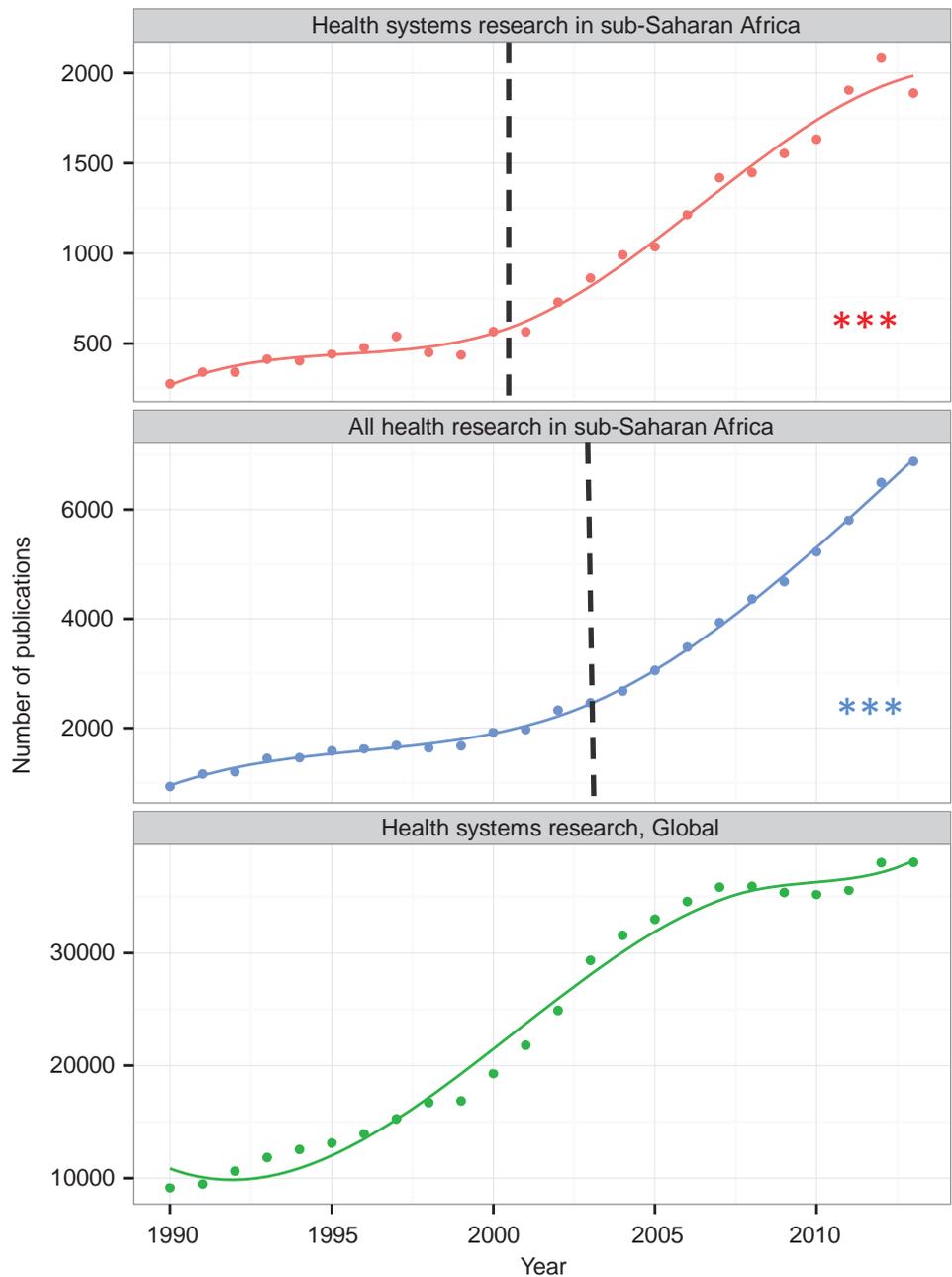
Health Systems Frameworks	Expected Keyword Themes	Related References
<b>WHO Building Blocks (World Health Organization<sup>20</sup>)</b>		
1. Access to essential health technologies	Expanding health coverage	Kruk <sup>37</sup>
	The range of health care options: the development, provision, and evaluation of health technologies and access to technologies	Travis et al., <sup>5</sup> Fonn <sup>38</sup>
	Community health services: community health centers, community health worker, community health planning, community participation, community engagement	Freeman et al. <sup>39</sup>
	Quality assurance, quality management, quality indicators, quality improvement	Kinney et al. <sup>40</sup>
2. Availability of providers of health services	Manpower and personnel operations: the training, deployment, and management of service providers	Cometto, Campbell, & Sheikh <sup>41</sup>
3. Information resources for health service decision making	Health information management systems: the design, implementation, and use of information for decision making at critical levels of the system	Boerma et al. <sup>42</sup>
	Communication and knowledge management: interdisciplinary communication, dissemination, research utilization, organizational communication	Shakarishvili et al. <sup>43</sup>
4. Capabilities to provide equipment, facilities, and supplies for operations	Logistics systems: the implementation, evaluation, or reform of logistics, equipment procurement, facilities development, and commodity supply systems	Bornbusch & Bates <sup>44</sup>
5. Planning, budgeting, and financing operations	Financial planning and management: activities for planning, budgeting, and managing resources for sustaining services	Friberg et al. <sup>45</sup>
6. Provision for leadership and governance of the health care system	Leadership systems: operations for developing, implementing, and sustaining leadership and governance systems	Fiszbein, Ringold, & Rogers <sup>46</sup>
<b>Cross-Cutting Research Themes</b>		
7. Systems research	Inter-building block themes, multilevel analysis, systems research, mixed qualitative and quantitative measurement, systems evaluation, operations research, implementation science	deSavigny & Adam <sup>47</sup>
	Experimental, quasi-experimental, and plausibility designs; evaluation methods	Remme et al., <sup>48</sup> Habicht et al. <sup>49</sup>
8. Organizational diagnosis	Bottlenecks, malaise, corruption, theft, mismanagement	Gilson & Mills <sup>50</sup>
<b>Cross-Cutting Implementation Themes</b>		
9. Scaling-up organizational change	Scaling-up, decentralization, using innovation, restructuring	Simmons et al., <sup>51</sup> Yamey <sup>52</sup>
10. Adaptive systems: "open systems" indicators	Social organizational context: economic status, educational attainment, gender issues, family characteristics, family relationships, social organization	Shalley & Gilson, <sup>53</sup> Gilson et al. <sup>3</sup>

**FIGURE 1.** Scopus Search Strategy and Bibliometric Data Preparation Process



\* TITLE-ABS-KEY (“health system”) + full country list  
 † TITLE-ABS-KEY (“health care system”) + full country list  
 § TITLE-ABS-KEY (“health program”) + full country list  
 § TITLE-ABS-KEY (“health service”) + full country list  
 ° TITLE-ABS-KEY (“health system” or “health care system” or “health program” or “health service”) + (all African Regions)

**FIGURE 2.** Annual Volume of Publications About sub-Saharan African Health Systems Research, sub-Saharan African Health Research in General, and Health Systems Research Globally, 1990–2014



The point at which the volume of literature changed, estimated using spline regression, is shown with a dotted line, which occurred at the advent of the Millennium Development Goals (MDGs) in 2000–2001 for health systems research in Africa and in 2003 for health research in Africa. Statistical significance at  $P < .0001$  is denoted with 3 asterisks. There was no association of the onset of the MDG era with global health systems research.

occurring at least 10 times were included in the overall analysis of the literature published between 1990 and 2014, and 2,311 keywords occurring at least 25 times were included in the 2 time analyses comparing the pre-MDG era with the MDG era. After applying thesaurus and relevance scoring to the 2,311 keywords,<sup>34</sup> 352 keywords from the 1990–1999 period remained and 1,033 keywords from the 2000–2014 period.

As [Figure 2](#) shows, the volume of health systems publications expanded over the 1990 to 2014 period both globally and for the sub-Saharan African region. (The data for literature on health research in sub-Saharan Africa and for literature on health systems research globally are based on trends in much larger datasets than the main dataset of 17,655 articles analyzed in this paper, which focuses specifically on health systems research in sub-Saharan Africa.) The rate of increase in this expansion accelerated significantly in 2003 for all health research in Africa and in 2001 specifically for health systems research from the region. There is no evidence of an MDG-associated upward trend for health systems research globally. However, the overall rate of global expansion of publication was more pronounced than was observed in sub-Saharan Africa. Nonetheless, the expansion of health systems publications over the period was substantial in Africa, with regression results suggesting an acceleration in the immediate post-Millennium era. In 2000, only 460 sub-Saharan African health systems articles were published with keywords connoting a focus on health systems topics; by the end of 2013, this annual figure had increased to 1,401.

### Themes in the sub-Saharan African Health Systems Literature, 1990–2014

[Figure 3](#) presents a visualization of bibliometric results for the 17,655 publications published between 1990 and 2014 that are included in the analysis. In this map (and subsequent maps included in this article), the relative size of each circle corresponds to the keyword occurrence in our health systems library; the circles are, in turn, grouped into thematic clusters represented by a common color.

Clustering results are inconsistent with our posited configuration of keyword galaxies. Rather than reflecting systems themes, bibliometric galaxies define 5 domains of health science research and action:

1. A red cluster that is dominated by indicators of morbidity, mortality, and relevant research themes
2. A blue cluster dominated by indicators of family planning programming and related outcome indicators and social and behavioral determinants
3. A green galaxy for systems indicators that focus on research, training, and policies concerning personnel issues, mainly regarding nursing
4. A cluster shaded yellow at the center of [Figure 3](#) defining a thematic focus on maternal health
5. A small and peripheral purple cluster identifying dental health and related topics

This configuration of themes contrasts with health systems frameworks and relationships anticipated in the [Table](#).<sup>3,37–53</sup> For example, keywords related to the WHO building block of “access to essential health technologies” are dispersed in [Figure 3](#). Topics that define systems planning are equivalently dispersed: “organization,” “health care delivery,” and “health care planning” appear in the blue cluster, while health care personnel indicators are in the green cluster, and keywords for “program” appear in the red cluster.

Despite this counter-systemic clustering, there is evidence of coherent clustering of health research themes in general. Zooming in on specific sections of [Figure 3](#) provides clarification of the labeling of terms in each major cluster. For example, keywords most central to [Figure 3](#) (i.e., the red cluster) and intensely cited in the literature concern services for primary health care patients,<sup>55</sup> organizational issues related to provider-client relationships,<sup>55–57</sup> access to care,<sup>37–40,55–57</sup> the quality of services,<sup>50,56,58,59</sup> and the management of frontline workers<sup>60</sup> ([Figure 4](#)). These “high-density” keywords comprise indicators of the provision of essential care or indicators of demand for care and primary health care service themes that are deemed crucial to accelerating the MDGs.<sup>5,17,18,40,47,60,61</sup> Keywords relevant to quality of care cluster with indicators of epidemiological research on morbidity and mortality (e.g., malaria, fever, tuberculosis, or conditions associated with pregnancy) or covariates defining age categories,<sup>40,55–58,62</sup> such as adolescents, infants, or children under 5, as shown by the red cluster in [Figure 3](#) and the

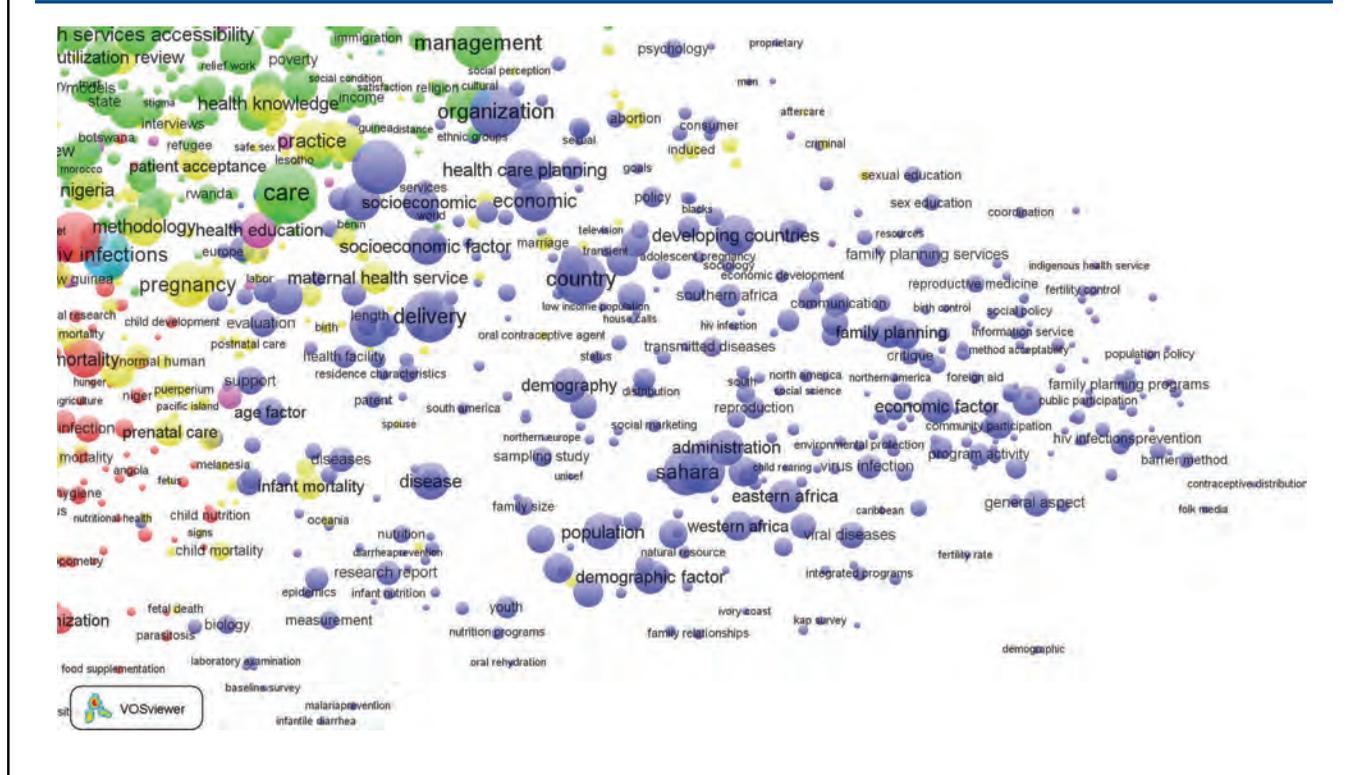
**The volume of publications on health systems in sub-Saharan Africa expanded between 1990 and 2014, from 460 articles in 2000 to 1,401 by the end of 2013.**

**Clustering of keyword themes from the published literature on health systems in sub-Saharan Africa do not coincide with the 6 WHO building blocks.**





**FIGURE 5.** Bibliometric Map of Keywords From Publications on Health Systems in sub-Saharan Africa, 1990 to 2014: Expansion of the Blue Cluster of Keywords Related to Family Planning Programming



more general systems themes of supervision, management, and systems capabilities that enable such workers to function effectively.<sup>18,41,46,63</sup> Keywords connoting WHO building block themes concerning the design, implementation, and use of information for decision making,<sup>18,63–67</sup> health information management, and research utilization are advocated in reviews, but as yet, are not prominent in the African health systems literature,<sup>5,53,68,69</sup> and keywords concerning internal organizational communication and knowledge management<sup>53,68,69</sup> are rare.<sup>67</sup> Keywords from literature focused on the building block of implementation, evaluation, or reform of logistics, equipment procurement, facilities development, and commodity supply systems<sup>44,70</sup> are also rarely pursued. The fifth WHO health systems building block represents planning, finance, budgeting, and managing resources for sustaining services.<sup>45,71</sup> Health economics research is prominent in the health systems literature, but keywords relevant to the measurement of the strength, readiness, and

functioning of health systems<sup>72,73</sup> are not, suggesting that management and systems science is making less of a contribution to sub-Saharan African health systems publications than other health science or general policy topics. Clearly, apart from extensive work on the (first) care and access building block, the informative and widely cited WHO framework has yet to demonstrate bibliometric evidence of an impact on country-specific health systems writing and research.

This conclusion is particularly salient for the sixth “governance” building keywords that connote indicators of the implementation and evaluation of strategies for developing, managing and sustaining leadership.<sup>74–79</sup> Results show that keywords associated with this theme are uncommon. One notably peripheral keyword display is labeled “corruption,” but indicators of organizational diagnosis, bottlenecks, mismanagement, dysfunctions, or malaise<sup>80</sup> are so rare that relevant terms do not appear in the bibliometric maps.







indicators of the provision of health services were central to the general body of literature, with the term “health care” clustering with terms of fixed-facility functioning and delivery (green cluster) as well as family planning indicators and social determinants of reproductive health (blue cluster). But the dominant keyword is “delivery” rather than indicators of how delivery systems are developed, changed, or strengthened.

Themes in red connoting morbidity outcomes, such as malaria and tuberculosis, and infant and child health and survival endpoints, cluster with green health care and maternal health themes on the left side of Figure 8. This cluster is remote from the literature galaxy in blue—the cluster of keywords related to health delivery, family planning, HIV, and financing. The lack of central cross-cutting keywords or clusters connotes a distinct lack of integration between health from an epidemiological perspective (red and green clusters) versus health systems

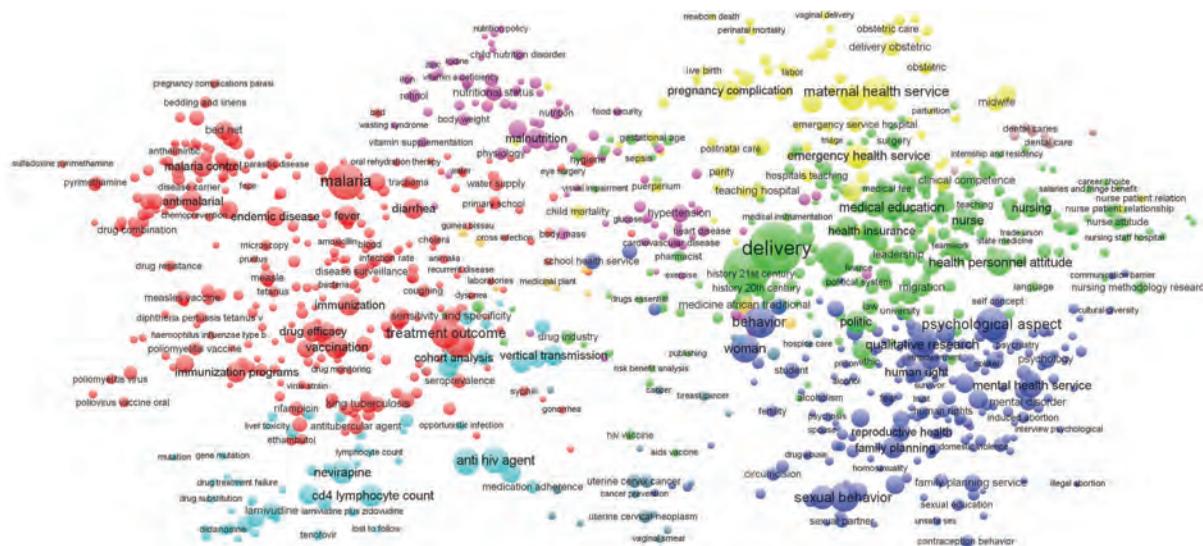
thinking in the 1990s. The yellow cluster representative of government and life expectancy is relatively central but lacks the degree of density that would connote thematic cohesion.

### The Health Systems Literature After the MDGs, 2000–2014

The configuration of Figure 9 for the post-2000 era represents a continuing prominence of service delivery, but a shift in the focus of health systems publications after 2000. Seven key clusters emerge:

1. A red cluster, with a focus on infectious disease morbidity as in Figure 3, except for the separate clustering for nutrition and non-communicable disease indicators and for HIV/AIDS keywords
2. The nutrition and non-communicable disease indicators are shaded purple

**FIGURE 9.** Bibliometric Map of 1,033 Keywords From Publications on Health Systems in sub-Saharan Africa, 2000 to 2014



Thematic clusters are represented by a common color: red, health technological research; green, manpower and training; yellow, maternal and oral health services; blue, health care delivery, economic and social covariates of health, and family planning; purple, non-communicable diseases; turquoise, HIV/AIDS; and a small peripheral cluster at the top right for dental public health.

3. The new turquoise cluster represents HIV/AIDS keywords
4. The yellow cluster for maternal health keywords remains as a separate cluster but is shifted to a peripheral position, indicating diminished centrality
5. A blue cluster is associated with family planning and reproductive health as well as reproductive tract cancers as in [Figure 3](#) and [Figure 8](#), but with more evidence of keywords on gender and social issues
6. A green cluster, as in [Figure 3](#) and [Figure 8](#), but with less emphasis on particular countries such as South Africa, and more general themes concerning manpower, leadership, and other systems issues
7. A peripheral and minor cluster at the top right for keywords associated with dental public health

The red cluster and the emergence of the separate turquoise cluster parallel the funding pattern of prominent international institutions and foundations such as The Global Fund to Fight AIDS, Tuberculosis and Malaria and the Bill and Melinda Gates Foundation, with a preponderance of keywords related to programs and technologies for the treatment and prevention of HIV/AIDS and malaria, tuberculosis, respiratory infections, and other diseases of childhood, as well as prevention programs such as immunization promotion or polio eradication. Although thematic clusters related to medical modalities and morbidity outcomes (left side of [Figure 9](#)) remain separate from clusters denoting health systems (right side of [Figure 9](#)), the overall density and centrality of the map is suggestive of higher integration of the health systems literature in general, a possible consequence of thematic integration and MDG focus.

In comparison to [Figure 8](#) (pre-MDG), cross-cutting themes represented by [Figure 9](#) are more numerous and emerge from different clusters that bridge the gap between epidemiological and systems keyword indicators. The purple cluster with terms such as malnutrition, obesity, and hypertension reveal an emerging focus on non-communicable diseases. Furthermore, the association of this cluster with non-communicable diseases portrays an emerging focus on sources of the burden of disease that were not priority themes of the Alma Ata "Health for All" agenda.<sup>9</sup> The continuing focus on infectious disease, in

conjunction with the emerging focus on the management and prevention of non-communicable disease, is consistent with the development of a health systems literature that has an increasingly balanced focus on the burden of disease, in general, rather than a literature that is focused on childhood illness and infectious disease.

The map in [Figure 9](#) is also indicative of greater thematic diversity after 2000 than what prevailed in the 1990s: reproductive health and maternal health keywords remain prominent in the post-Millennium era but are arrayed as equidistant clusters from the center of the map, suggestive of greater integration. Health systems indicators (shaded green) are more prominent, more often indicators of general policy themes, and coterminous with service delivery indicators. This feature of [Figure 9](#) is representative of the growing consistency of the health systems literature with systems thinking itself. In particular, keywords associated with the green cluster mirror the 6 building blocks of the WHO Health Systems Framework<sup>20</sup> and include keywords describing policy, service delivery, education, personnel and personnel development, and financing. The proximity of these keywords with other cross-cutting themes such as family planning, reproductive health, and emergency care further support the notion of the emergence of a more coherent health systems literature in the 2000 to 2014 period than had prevailed in the 1990s.

While the comparison of [Figure 8](#) and [Figure 9](#) is suggestive of greater integration, the literature throughout both periods portrayed is more focused on epidemiology, socio-demographic, and health research rather than systems analysis per se. Indeed, the dominant new theme in the health systems literature in the post-Millennium era is HIV/AIDS. An entire HIV cluster (turquoise) emerges in the post-2000 period that is separate from other sources of morbidity. Keywords related to HIV/AIDS in the pre-2000 bibliometric map of [Figure 8](#) (blue cluster) represent HIV/AIDS strictly from an infectious disease standpoint. Concomitance with keywords such as family planning and sexual behavior further exemplifies how HIV was perceived as contributing to sexually transmitted infections rather than a standalone pandemic. The post-Millennium map of [Figure 9](#) is indicative of thematic change with HIV/AIDS becoming a prominent theme of health systems research, possibly reflecting the impact of the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund, as well as the establishment of MDG

**Although medical modalities remain separate from health systems in MDG-era publications, there is a general trend of greater integration of the concepts than in the 1990s.**

**A new HIV/AIDS cluster emerges in the post-2000 publication era.**

Number 6 to combat HIV/AIDS, malaria, and other diseases. In [Figure 8](#), HIV/AIDS is represented by 4 keywords and 1,144 occurrences, whereas in [Figure 9](#), HIV/AIDS has a distinct cluster comprised of 59 keywords and 7,375 occurrences.

Thematic shifts from [Figure 8](#) that are evident in [Figure 9](#) attest to the well-known influence of international investment in research, implementation, and policy trends and themes in sub-Saharan Africa. From the onset of post-independence development of health service implementation, capabilities and subsequent investment in the implementation of modality and disease-control focused health initiatives, health systems revenue, capacity, and dissemination capabilities have developed markedly throughout the region. For example, systems policies, plans, and action in Africa were influenced by the “Expanded Programme for Immunizations,”<sup>99</sup> the WHO-sponsored “Integrated Management of Childhood Illness” initiative,<sup>100</sup> and global programs focused on the control of specific diseases or the amelioration of health problems. Initiatives fostering system integration, reform, and decentralization directed particular attention to Africa.<sup>101</sup> World Bank programs in sub-Saharan Africa prior to the MDG era were also influential.<sup>10</sup> Even initiatives that were not directly systems focused, such as the smallpox eradication campaign, the global campaign against malaria, and the polio eradication campaign, contributed to systems development.<sup>6</sup> The 1978 World Health Assembly was transformational,<sup>8</sup> and the challenge of implementing its primary health care agenda was productive.<sup>9</sup>

Family planning programs developed in the early African post-independence era<sup>102</sup> were expanded in the pre-MDG era, first with US support commencing in the 1960s<sup>103</sup> and subsequently by the emergence of support from the United Nations Population Fund (UNFPA) and World Bank.<sup>104</sup> Response to this investment in the health systems literature has been catalyzed, in part, by international conferences<sup>103</sup> and by expanding commitments of European and foundation donors to service system development.<sup>104,105</sup> The emergence of South Africa from apartheid and opportunities for its universities to engage in collaborative partnerships contributed significantly to health systems research in the region. Taken together, these initiatives underpin the health systems literature prior to 2000.

The MDG era was associated with an expansion of systems research and greater thematic diversity, reflecting greater attention to systems

thinking within each domain of health research and policy dissemination.<sup>5,10–18,68,69</sup> Bilateral and multilateral foreign aid initiatives associated with the MDG agenda provided additional impetus for health systems development.<sup>2,12–15,17,104</sup> The expansion of foundation support, targeted on MDG goals, has been critical; support from the Bill and Melinda Gates Foundation for health initiatives has been transformative.<sup>19</sup> In particular, the global response to the HIV/AIDS crisis generated revenue, research, and systems capability throughout Africa.<sup>106</sup> International conventions, donor programs, and international priorities that emerged have accelerated investment in health systems more generally,<sup>73,74,106</sup> enhancing capabilities to understand problems, document responses, and finance the pursuit of effective results.

## CONCLUSION

The volume of the health systems literature from sub-Saharan Africa has been expanding, with considerable potential for contributing to evidence-based systems development throughout the region. Critically important frameworks for action, research, and policy have been published and widely cited.<sup>5,18,20,47,50,72–74,81,82,106</sup> The pace of expansion was associated with the onset of the MDG era, with concomitant acceleration in the publication and proliferation of themes consistent with systems deliberations. This expansion of analytical writing is much needed, as systems constraints to health development are widely acknowledged to be more prominent in sub-Saharan Africa than in any other region. The MDG era has been associated with shifts in the focus of health systems publication from polarized separation of family planning from primary health care into a more holistic body of literature reflecting a greater degree of integration. This conclusion is suggested by the contrasting configuration of pre-2000 literature from post-2000 publications.

Yet, despite this marked expansion of systems publication, the literature reviewed in this bibliometric analysis is expanding at a slower pace than is evident globally. Moreover, the content of country-specific systems writing, as portrayed by keyword galaxies, remains more focused on describing component solutions or disease-specific epidemiological outcomes of discrete technical interventions rather than on methods or results that focus on the process of changing organizational functioning or strengthening health systems.

Bibliometric supernova that have emerged are indicators of specific diseases, such as HIV/AIDS or systems research in specific countries, such as South Africa. Keywords connoting “stars” in the constellation of knowledge are dispersed rather than grouped into prominent displays of health systems galaxies. There is an absence of thematic clustering that our health systems literature review was posited to portray.

Indeed, “systems thinking,” as promoted by several landmark reviews, commentaries, and frameworks and summarized in the Table, has yet to become a feature of Africa’s country-specific health systems literature. Results of our review lend support to recent appeals for greater attention to capacity building in health systems research and health systems trials,<sup>90</sup> as well as greater attention to systems thinking in international donor-supported programs on the ground.<sup>106</sup> Our hypothesis that bibliometric analysis would visualize elements of systems frameworks has not been supported by the results. Gaps are evident. There is a remarkable lack of attention to organizational malaise, dysfunction, corruption, or inefficiency. There is also a lack of attention to developing and deploying analytical and evaluation methods that are characteristic of holistic systems strengthening, a core goal of the initial MDG framework. Instead, the literature cites systems keywords as indicators in health research rather than as outcomes or endpoints in systems scientific investigations. Implementation science is underemphasized. If health systems are to be strengthened through the improved functioning, structure, and design of organizations that implement programs, then the challenge of designing, launching, and sustaining evidence-based organizational change and development must be a more concerted focus of health systems research in Africa in the future than has been the case in the past.

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**Systems thinking has yet to become a feature of Africa's health systems literature.**

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## FIELD ACTION REPORT

# Covering the Last Kilometer: Using GIS to Scale-Up Voluntary Medical Male Circumcision Services in Iringa and Njombe Regions, Tanzania

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Interactive GIS maps created by overlapping facility data including roads and infrastructure with population and service delivery data permitted strategic deployment of mobile voluntary medical male circumcision (VMMC) services to underserved rural communities. The percentage of VMMCs performed in rural areas jumped from 48% in 2011 to 93% in 2014.

## ABSTRACT

**Background:** Based on the established protective effect of voluntary medical male circumcision (VMMC) in reducing female-to-male HIV transmission, Tanzania's Ministry of Health and Social Welfare (MOHSW) embarked on the scale-up of VMMC services in 2009. The Maternal and Child Health Integrated Project (MCHIP) supported the MOHSW to roll out VMMC services in Iringa and Njombe, 2 regions of Tanzania with among the highest HIV and lowest circumcision prevalence. With ambitious targets of reaching 264,990 males aged 10–34 years with VMMC in 5 years, efficient and innovative program approaches were necessary.

**Program Description:** Outreach campaigns, in which mobile teams set up temporary services in facilities or non-facility settings, are used to reach lesser-served areas with VMMC. In 2012, MCHIP began using geographic information systems (GIS) to strategically plan the location of outreach campaigns. MCHIP gathered geocoded data on variables such as roads, road conditions, catchment population, staffing, and infrastructure for every health facility in Iringa and Njombe. These data were uploaded to a central database and overlaid with various demographic and service delivery data in order to identify the VMMC needs of the 2 regions.

**Findings:** MCHIP used the interactive digital maps as decision-making tools to extend mobile VMMC outreach to “the last kilometer.” As of September 2014, the MOHSW with MCHIP support provided VMMC to 267,917 men, 259,144 of whom were men aged 10–34 years, an achievement of 98% of the target of eligible males in Iringa and Njombe. The project reached substantially more men through rural dispensaries and non-health care facilities each successive year after GIS was introduced in 2012, jumping from 48% of VMMCs performed in rural areas in fiscal year 2011 to 88% in fiscal year 2012 and to 93% by the end of the project in 2014.

**Conclusion:** GIS was an effective tool for making strategic decisions about where to prioritize VMMC service delivery, particularly for mobile and outreach services. Donors may want to consider funding mapping initiatives that support numerous interventions across implementing partners to spread initial start-up costs.

## BACKGROUND

Voluntary medical male circumcision (VMMC) has been shown to reduce female-to-male HIV transmission by approximately 60% in randomized controlled trials.<sup>1–3</sup> Cost and impact modeling has suggested that rapid scale-up of VMMC among men ages 15–49 years would drastically reduce HIV transmission.<sup>4</sup>

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**Outreach campaigns and mobile services were introduced to extend VMMC services to underserved areas.**

**Project staff used GIS daily to plan the location of mobile services.**

In 2009, the Ministry of Health and Social Welfare (MOHSW) of Tanzania incorporated VMMC into its national prevention strategy, targeting males aged 10–34 years, particularly in 11 regions where male circumcision was low. Although the national prevalence of male circumcision among 15- to 49-year-olds was 67% in 2009, it was as low as 23% in some regions of the country.<sup>5</sup>

Tanzania’s “National Strategy for Male Circumcision for HIV Prevention (2010–2015)” set a target for 2.8 million boys and men aged 10–34 years to receive VMMC services in 11 of the country’s 34 regions. In Iringa and Njombe (which, at the time of project inception, were a single region called Iringa), the national strategy specified that 264,990 males aged 10–34 years should receive VMMC by 2015 (Figure 1).<sup>6</sup> At the time, Iringa had one of the lowest male circumcision prevalence rates (29.1%) and the highest HIV prevalence (15.7%) of any region in the country.<sup>5,6</sup>

The Maternal and Child Health Integrated Project (MCHIP), led by Jhpiego and funded by the United States President’s Emergency Plan for AIDS Relief (PEPFAR) through the United States Agency for International Development (USAID), supported the MOHSW to roll out VMMC services in Iringa (and after partition in 2014, when the regions became separate, in Iringa and Njombe). MCHIP provided support in a number of areas, including training health care providers, providing commodities and equipment to health facilities, facilitating demand creation activities, guiding logistics, and providing technical and managerial support in quality assurance, supervision, and mentoring to the regional and district medical authorities. In addition, in the first 9 months of the program, MCHIP focused on assisting the regions to establish fixed VMMC sites where routinely scheduled services were offered several days a week.

The purpose of this article is to describe the program’s evolving use of geographic information systems (GIS) technology to strategically plan and implement outreach campaigns in order to extend VMMC services to remote rural areas and achieve rapid scale-up.

## PROGRAM DESCRIPTION

As in many other countries rolling out VMMC with PEPFAR support, the VMMC program in Tanzania set very ambitious targets. In the first year of implementation (October 2009 through September 2010), 22,970 males received VMMC

services in Iringa and Njombe. While improvements in efficiency allowed the program to almost double coverage to 42,667 males in the following year, it was clear that service delivery models needed to be even more efficient if the project were to reach the regional target of 264,990 men by 2015.

Fixed sites (within public health facilities) offered VMMC services on scheduled days to clients willing to seek services at central locations, but the project needed to bring services out of urban areas and into rural areas where demand was high but access to VMMC was low. To respond to this need, VMMC service delivery models in Iringa and Njombe evolved to include campaigns and mobile sites over time (Box).

Beginning in 2010, campaigns became a norm in addition to fixed site services. In campaign service delivery mode, VMMC is offered at specified sites for a specified time frame, accompanied by demand creation activities such as use of peer promoters, billboards, radio announcements, or public announcements. However, most dispensaries in which campaign services are situated are located in urban areas and within close proximity of each other. To further extend the reach of VMMC services, there was a push to scale to lower rural health facilities to reach men in more remote areas. Starting in 2014, full-time mobile outreach VMMC teams were introduced. In this highly flexible approach, mobile teams of VMMC providers, counselors, and demand creation agents with the necessary equipment (such as autoclaves and surgical tools) travel year-round to underserved areas to provide VMMC services wherever they are needed. The length of the period of service delivery in each site depends on demand at that site.

Mobile and campaign services are time- and resource-intensive and require difficult decisions around where to place the services to reach the greatest number of potential clients. Such decisions are especially difficult when the geographic area is large, population density is low, and infrastructure is poor. To prioritize locations and populations for campaigns and mobile VMMC services in remote rural areas, MCHIP developed an approach in which project staff used GIS daily for planning mobile services, in an attempt to achieve maximum coverage.

## GIS and Its Application for Health

A GIS is a “computerized data management system used to capture, store, manage, retrieve,

**FIGURE 1.** Voluntary Medical Male Circumcision Focus Regions in Tanzania

Map image adapted from Sémhur/Wikimedia Commons/CC-BY-SA-3.0.

analyze, and display spatial information.”<sup>8</sup> Data captured and used in a GIS can be exported and represented on digital and paper maps. GIS allows a user to represent data (also called “attributes”) referenced by their geospatial coordinates. Precise placement of administrative boundaries, roads, or terrain features can be linked to or overlaid with other data points that have been collected and enriched with latitude and longitude, or “geocoded.” Such systems provide us with ways to determine relationships between data elements that may not otherwise be obvious.

Used in many disciplines, GIS is increasingly being applied in public health. For instance, GIS

has been used to track malaria risk by overlaying disease prevalence with environmental factors and types of vectors.<sup>9,10</sup> Similarly, GIS has been used for predicting dengue fever<sup>11,12</sup> and schistosomiasis<sup>13</sup> risk. There are several, but fewer, documented uses of GIS for program implementation more generally (e.g., mapping existing service delivery locations, catchment areas, or geographic accessibility).<sup>14</sup>

MCHIP’s use of GIS in Tanzania evolved throughout the life of the VMMC program in 2 distinct phases, from the use of static, imperfect, and infrequently updated maps to the use of more dynamic, interactive, and iteratively updated maps.

**GIS has been used in several areas of public health such as to track malaria risk and predict dengue fever.**

### BOX. Voluntary Medical Male Circumcision (VMMC) Service Delivery Definitions

**Routine services:** Services provided on a regularly scheduled basis (may be at fixed sites or outreach sites).

**Campaign services:** Services provided in high volume with intensive demand creation (may be provided at any type of site).

**Mobile services:** VMMC services provided by a mobile team that may be delivered at an outreach site or at a non-health facility location (e.g., in tents or in a municipal building).

**Fixed site:** An established VMMC site in a health facility that provides services on a routine basis and that may also participate in campaigns.

**Outreach site:** A health facility where a team from the outside provides VMMC services—either on a regularly scheduled basis or as part of a campaign or mobile team activity.

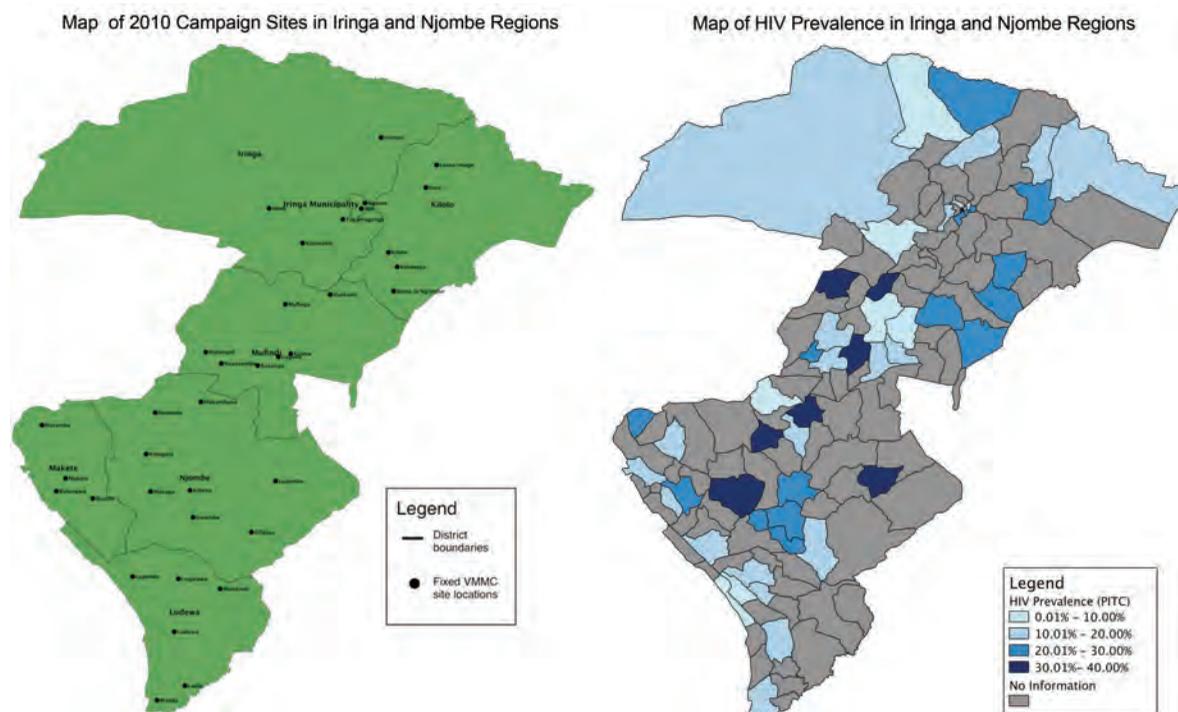
Source: PEPFAR, 2013.<sup>7</sup>

### Phase 1: GIS and Mapping to Plan Outreach Service Locations

Our use of GIS for service delivery planning arose organically in response to implementation needs to better know the context of the areas in which outreach was being conducted and to focus our resources in areas where need or potential demand for VMMC services was highest.

We conducted our first outreach campaigns in 2010 without the use of GIS. Later, we planned a 2012 campaign by performing a simple comparison of potential campaign site locations with HIV prevalence in Iringa and Njombe using maps of subnational administrative boundaries (Figure 2). This initial mapping used geocoded health facility data from Iringa available from previous work by the MEASURE Evaluation project,<sup>15</sup> using open-source GIS software called QGIS.<sup>16</sup> The mapping exercise allowed quick visual identification of areas with high HIV prevalence to target for VMMC outreach.

**FIGURE 2.** Maps Used to Plan 2012 Voluntary Medical Male Circumcision Outreach Campaign, Iringa and Njombe Regions, Tanzania



After we began the 2012 outreach campaigns, we combined coverage data of VMMC performed on the maps to identify locations that we had not yet reached. Maps showing projected census data reflecting total ward population were layered with points of various sizes representing facilities and the number of circumcisions performed up to that point (Figure 3). We then further refined the maps to show the number of circumcisions performed overlaid with population data specific to the target population (i.e., males aged 10–49) down to the ward level (Figure 4). The coverage estimations overlaid with population and subnational administrative boundary data were useful both for planning areas to target with VMMC outreach campaigns and for retrospectively gauging outcome measures of a particular outreach effort.

## Phase 2: Interactive Mapping With Geocoded Facility Data

With our initial success in using GIS to better understand the location of underserved populations within Iringa and Njombe, we began to envision new uses for the maps as well as areas for improvement regarding the variables fed into the maps.

For the initial GIS work, we had used coordinates collected by project staff as well as existing coordinates from publicly available data, but the coordinates from publicly collected data were frequently inaccurate. For example, maps of subnational administrative features included an undefined and incomplete data set of roads. Moreover, static subnational administrative maps overlaid with collected data did not display all of the information relevant to conducting VMMC outreach services. Program planners realized that in more remote areas where outreach was conducted, effective planning required advance knowledge of many more extenuating factors, such as accessibility via roads, availability of electricity and water, space availability at a facility, and the total catchment population of the facility.

This level of data, however, was not generally or widely available for health facilities in Iringa and Njombe regions. We thus actively sought to enrich the health facility points on the map with the necessary data on each particular facility's infrastructure, accessibility by road, mobile network coverage, and specific populations served. To do this, we fanned out, collecting key data for mapping, including catchment population for the

facility (counted from facility registers), landmarks, infrastructure, and digital photos from every health facility in Iringa and Njombe. Latitude and longitude readings were collected at every facility in the regions using inexpensive Global Positioning System (GPS) units, which were also used to track the vehicle's path to the facility over roads that do not appear on road maps.

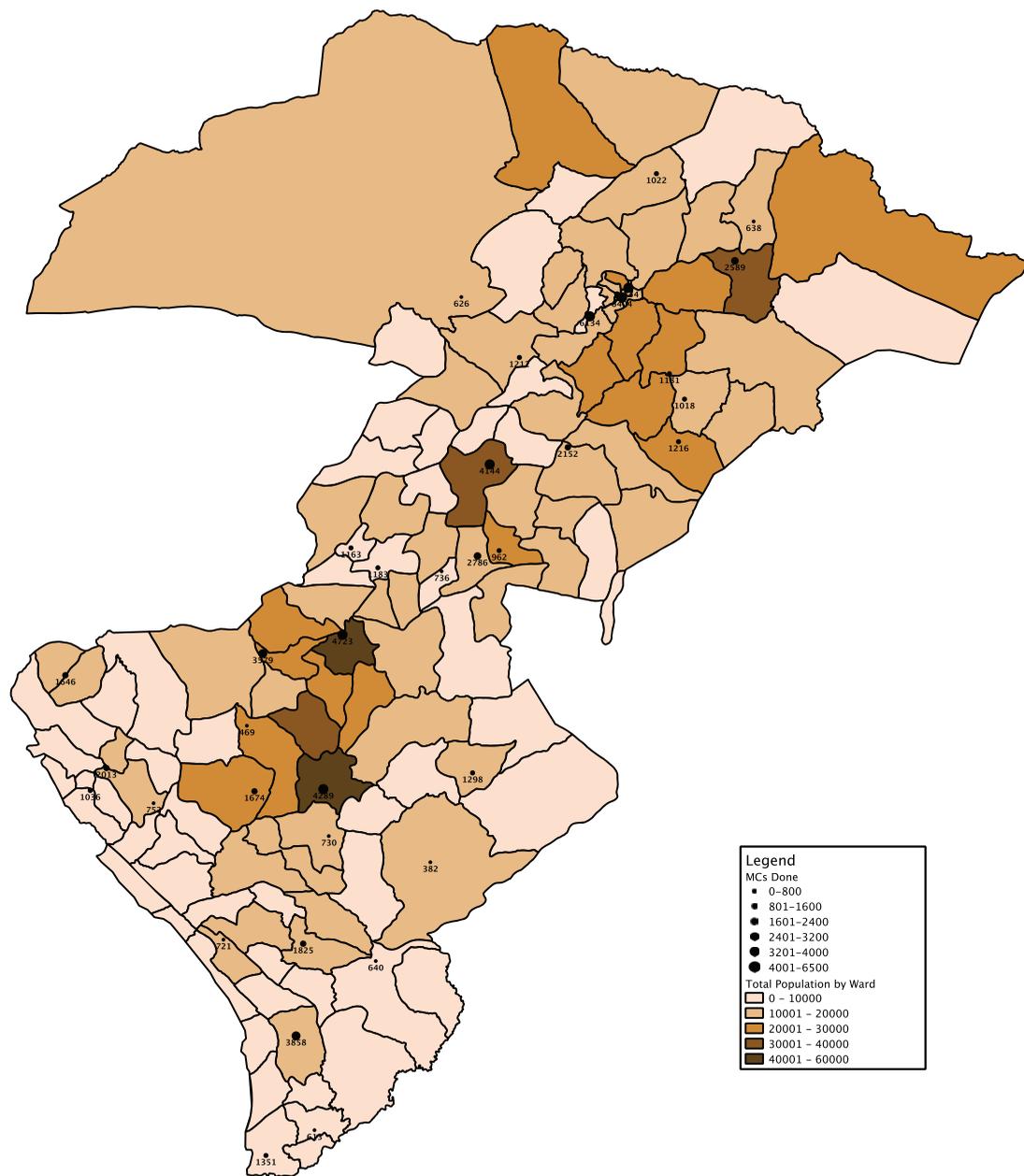
Development of the early maps for the project was somewhat cumbersome, requiring data entry each time a new map was to be generated and specialized skill from a monitoring and evaluation staff member to configure the map to display the desired layers. After being created, these maps were corrected or updated with new information infrequently. To address this issue, the project sought to make maps more interactive and accessible for relevant project staff.

Using the additional geocoded data collected from facilities, the project began entering the data into a database that could be imported into Google's free-for-use Maps Engine<sup>17</sup> and, later, open-source software called OpenLayers.<sup>18</sup> These applications, in contrast with the previous QGIS software, not only gave us the ability to perform the same types of overlay of facility location on population and coverage data but also allowed for interactivity with points on the map. For example, after accessing the map in an Internet browser, a user can zoom in to a particular area, click on a point, and view the specific data collected for that facility (Figure 5). Google Maps and OpenLayers also incorporate satellite imagery "basemaps"—maps depicting background reference information such as landforms, roads, and landmarks—rather than just administrative and physical boundaries (Figure 6). These satellite views further augmented the maps with visual data to inform campaign planning in terms of facility accessibility.

Using OpenLayers allowed us to link the maps directly to the project's monitoring database, resulting in not only interactive maps but also maps that are updated as soon as new data are entered or submitted. These maps are dynamic, providing for quick turnaround between data collection and analysis of maps for program planning.

With a wealth of new information, we became accustomed to using the maps on a daily basis to plan upcoming program activities. For instance, the maps from our database could be rapidly configured to show an outreach team the lower-performing facilities in a given area, for

**FIGURE 3.** Map of Total Population Layered With Number of Voluntary Medical Male Circumcisions Performed, by Ward, Iringa and Njombe Regions, Tanzania, April 2012

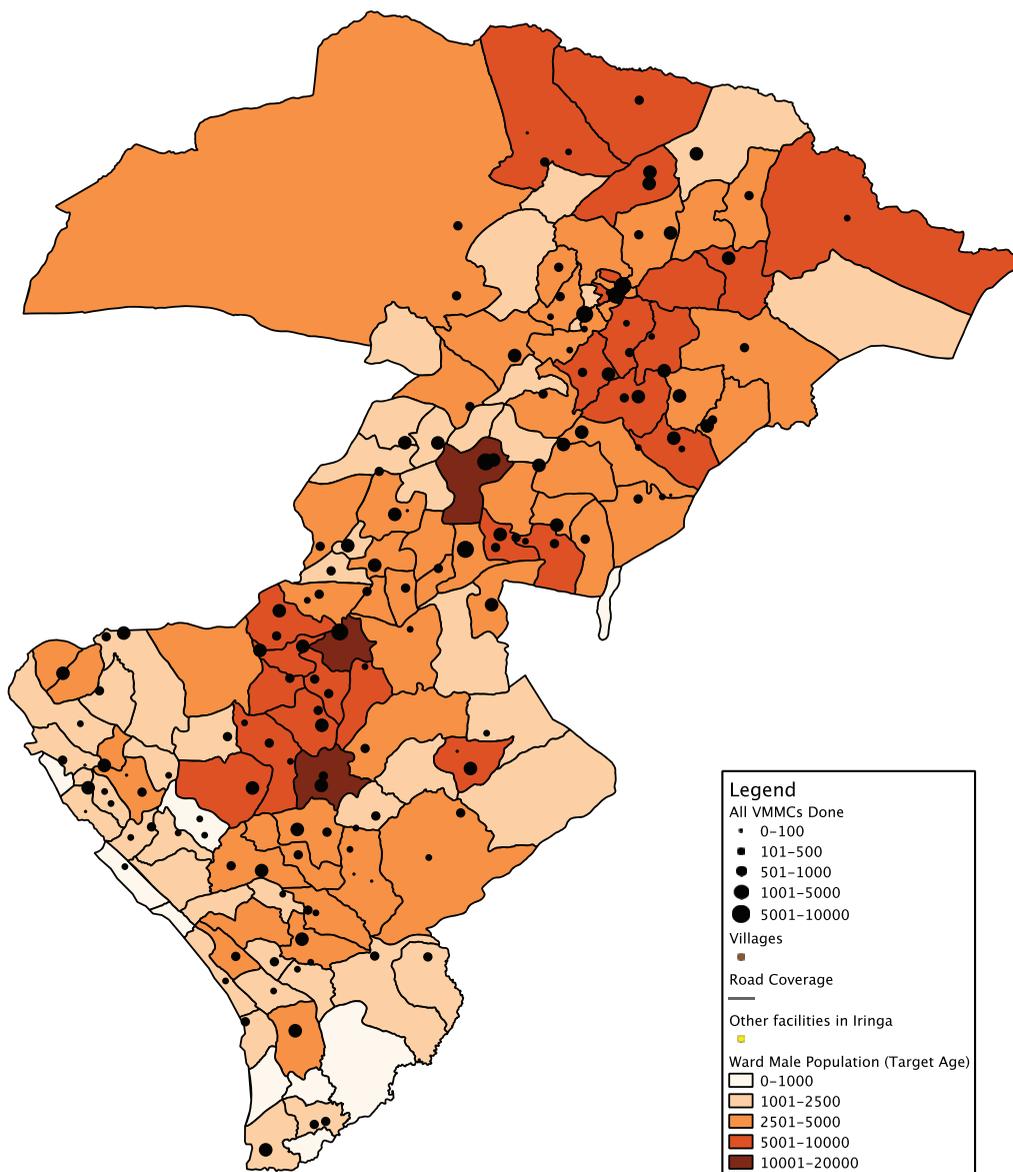


Abbreviation: MC, male circumcision.

example, those that had performed between 0 and 1,000 VMMCs. Based on this information, the team could plan to focus on service provision in a particular area. Then, using the map overlay

that displays road conditions, the team could make an informed decision about the area it could reach in a given time period (if at all). If roads are unpaved and in bad condition, for

**FIGURE 4.** Map of Male Population Ages 10–49 Layered With Number of Voluntary Medical Male Circumcisions (VMMCs) Performed, by Ward, Iringa and Njombe Regions, Tanzania, August 2013



example, a team may decide to wait until a rainy season is over. Figure 7 illustrates one such map that displays both underserved sites and the quality of the roads that lead to them.

Retrospectively, the maps provided ways to track progress, display project monitoring data in new ways, and tell compelling stories to stakeholders about the program’s performance.

## FINDINGS

Between 2010 and 2014, the MCHIP team mapped 714 health facilities in Iringa and Njombe regions, along with relevant geocoded data—the most comprehensive mapping of health facilities in these regions to date. Using maps created from these data, MCHIP performed outreach services at

**By September 2014, the project had achieved 98% of the VMMC target in Iringa and Njombe.**

346 facility and non-facility locations during that time period.

The regional authorities of Iringa and Njombe, with the support of MCHIP, had circumcised 267,917 men by September 2014. Of these, 259,144 were aged 10-34, representing 98% of the target of 264,990. Based on the 2011–12 Tanzania HIV/AIDS and Malaria Indicator Survey (THMIS) male circumcision prevalence data and Jhpiego program data, Njombe and Iringa have gone from being among the regions with the lowest prevalence of male circumcision (29.1% at project inception<sup>5,6</sup>) to approaching 82% of the adult male population being circumcised, surpassing the national strategy's regional targets.

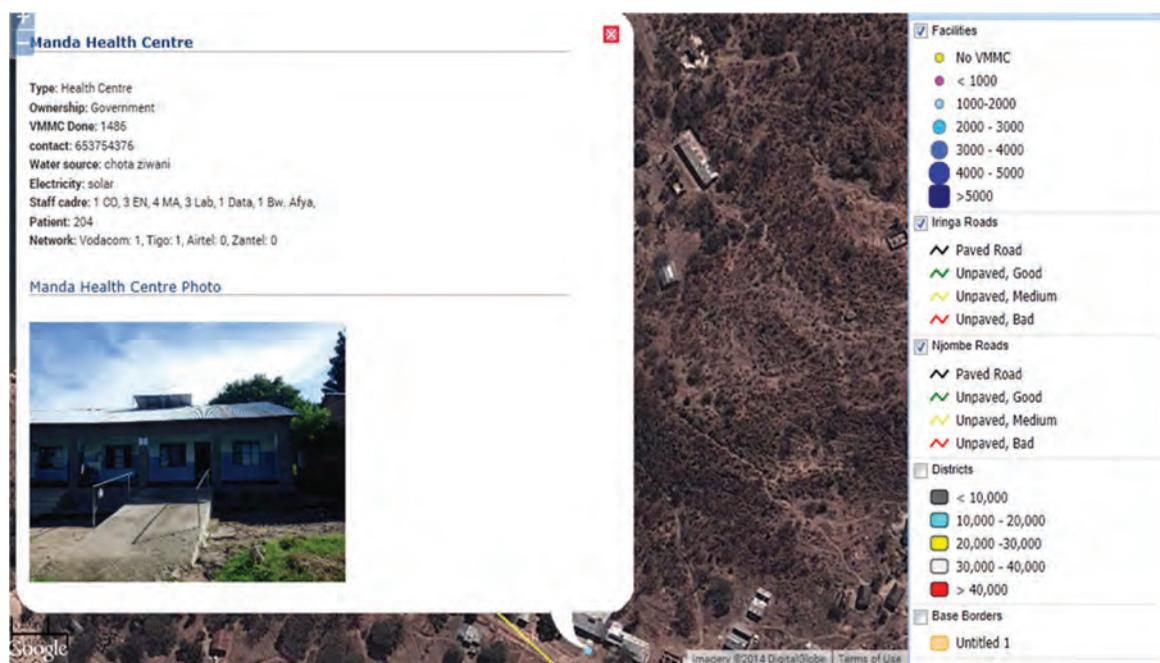
The use of GIS to collect and analyze the geographic distribution of the focus population, along with the availability of VMMC services in previously unreached areas, enabled more effective scale-up to rural lower-level health facilities by providing project staff with data that could be used to identify ideal sites for outreach. By the end of the project, nearly 4 times as many VMMCs were performed in the

fiscal year than at the beginning of the project, rising from about 23,000 VMMCs in fiscal year 2010 to nearly 88,000 VMMCs in fiscal year 2014 (Table). Furthermore, the project reached substantially more men through rural dispensaries and non-health care facilities each successive year after GIS was introduced in 2012 (Figure 8).

## DISCUSSION

In Iringa and Njombe, Tanzania, use of GIS and mapping was one of several strategies to improve coverage and efficiency of VMMC scale-up. Because our use of GIS technology was part of a comprehensive planning and monitoring strategy, attribution of a particular number of circumcisions solely to our use of GIS is not possible. Without the use of GIS and digital maps, however, our provision of VMMC outreach services would have been far less focused on areas with specific need and potentially more costly, for example, if outreach teams were deployed to sites where unmet need was low or infrastructure was unavailable.

**FIGURE 5.** Interactive Map Displaying Information on Manda Health Centre Site, Njombe Region, Tanzania



**FIGURE 6.** Interactive Map Displaying Satellite Imagery of Facility Layout

### Using GIS to Reach Clients in the “Last Kilometer”

The global health community frequently invokes the concept of the “last mile” or, in the case of Tanzania, the “last kilometer” to refer to achieving coverage for those clients who are the most difficult to reach. In terms of our VMMC outreach campaigns, the necessity to reach clients in the “last kilometer” was literal. For VMMC to reach highest public health impact for HIV prevention, rapid scale-up of services is necessary even in the most remote and difficult-to-access areas. Without the use of GIS, programmatic decisions regarding where to locate outreach services would have been broadly conceptualized: the program would have simply held campaigns in areas of Iringa and Njombe where male circumcision rates were low. By using GIS, we were able to fine-tune our outreach effectiveness, making decisions considering age of population versus circumcision rates, catchment areas of facilities where our teams had already provided outreach, accessibility of facilities where outreach was performed, and which model of service would best suit the level of infrastructure (e.g., using mobile units in areas with potential demand but no health facilities).

### Using GIS Data for Decision Making

Mapping has long been recognized as an important public health tool, hearkening back to the classic anecdote about John Snow, the Broad Street pump, and the cholera outbreak.<sup>19</sup> Frequently, however, use of maps for public health stops after the simple plotting of points. Latitude and longitude remain simply coordinates without other geocoded data to which we can link those points.

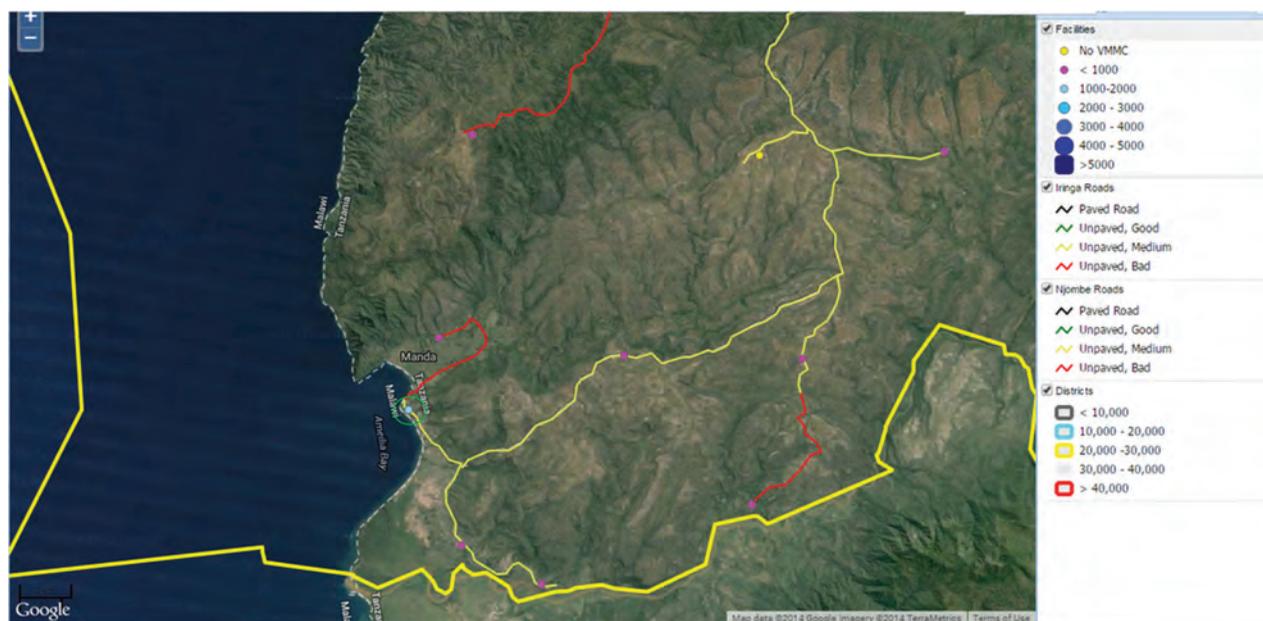
By dispatching teams to collect relevant data about health facilities’ infrastructure, accessibility, and catchment areas, we were able to create dynamic, interactive maps that informed our program planning and served as a monitoring tool for our outreach efforts. Once a facility is geocoded and present in the database, it is possible to attach any number of variables to that record in the database. This approach has applicability to a wide variety of public health services, especially those which require outreach services.

**Using GIS allowed us to fine-tune our outreach campaigns.**

### Replicating and Expanding the Approach

After the success with GIS for VMMC scale-up in Iringa and Njombe, the project is using the same

**FIGURE 7.** Interactive Map of Facilities Performing 0–1,000 Voluntary Medical Male Circumcisions (VMMCs)<sup>o</sup> and Quality of Roads



<sup>o</sup> Shown as yellow (no VMMCs) and pink (< 1,000 VMMCs) circles.

approach to scale-up VMMC in Tabora region of Tanzania. GIS work in Tabora will leverage the same methods for data collection and mapping established for Iringa and Njombe; initial steps will be collecting facility data and synchronizing it with our existing database. Since the mapping features of OpenLayers are interactive and represent the entire world, not just the areas where we have worked, all the data, from Iringa and Njombe as well as Tabora, will be available to program staff and filterable by data elements of any uploaded data point, allowing cross-regional analysis.

Many potential applications for the use of GIS beyond VMMC exist, particularly for programs that require outreach and are attempting coverage of a particular age strata or population type, such as planning and mapping outreach efforts for vaccination campaigns, where the children of eligible age can be quantified using local government records. The type of mapping facilitated by GIS can also be used to track coverage and service delivery of HIV care and treatment services, as well as many other service delivery areas. Our

project's particular maps are available to any organization implementing health activities in Iringa and Njombe regions.

## LESSONS LEARNED

### GIS and Mapping Software Selection

The approach to using GIS detailed in this article arose organically, with no particular approach for selecting software. This is not necessarily a best practice, and the project ultimately switched software several times to better meet project needs. In future implementations of GIS to improve public health program implementation, requirements for software and mapping functionality should be laid out in advance of selecting software.

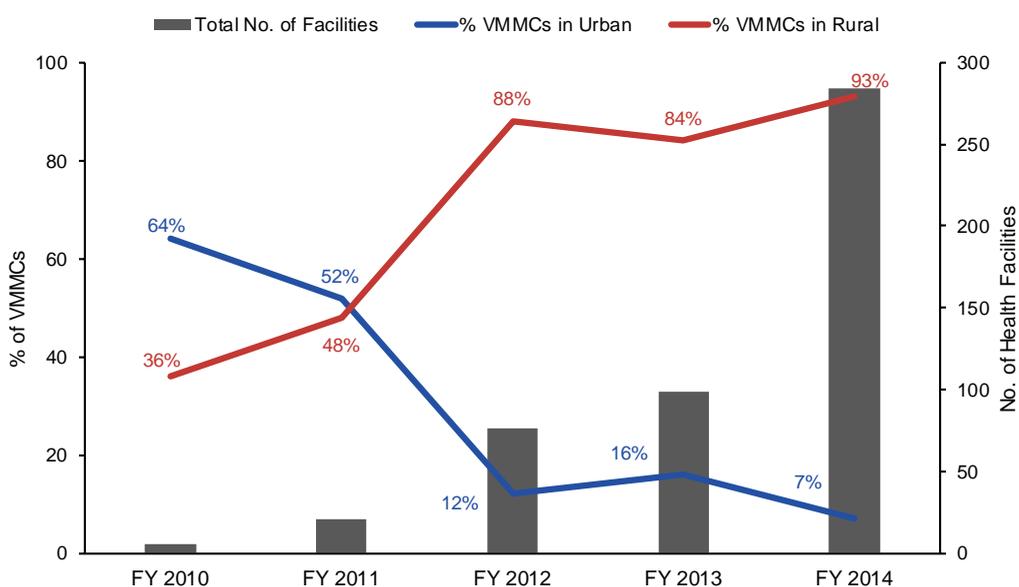
Moreover, while we tout the free-for-use nature of much of the software we used as a benefit, we also note that such software can come with caveats. For instance, the Google software service agreement gives Google the right to access data within limited purposes of “operating, promoting, and improving our services, and to develop new ones”; however, the user retains

**TABLE.** Number of VMMCs Performed in Urban Versus Rural Settings and Description of Facilities, Iringa and Njombe Regions, Tanzania, Fiscal Year 2010–2014

Year	No. of VMMCs	No. (%) of VMMCs Performed in Urban Facilities	No. (%) of VMMCs Performed in Rural Facilities	No. of Facilities	Description of Facilities
FY 2010	22,970	14,634 (64)	8,336 (36)	5	All hospitals
FY 2011	42,667	22,345 (52)	20,322 (48)	21	11 hospitals and 9 health centers
FY 2012	49,949	5,977 (12)	43,972 (88)	76	13 hospitals, 21 health centers, and 42 (lower-level) dispensaries; the 42 dispensaries contributed 46% of the achievement for the year with the hospitals and health centers contributing the remainder
FY 2013	64,407	10,069 (16)	54,338 (84)	99	10 hospitals, 13 health centers, and 76 dispensaries; dispensaries contributed 75% of the achievement for the year
FY 2014	87,924	6,125 (7)	81,799 (93)	284	12 hospitals, 24 health centers, and 248 dispensaries; dispensaries contributed 81% of the achievement for the year

Abbreviations: FY, fiscal year; VMMC, voluntary medical male circumcision.

**FIGURE 8.** Percentage of VMMCs Performed in Urban Versus Rural Health Facilities and Total Number of Health Facilities Reached, by Fiscal Year, Iringa and Njombe Regions, Tanzania, 2010–2014



intellectual property rights over the data.<sup>20</sup> For the purposes of our project, in which only facility-level/aggregate data were collected and uploaded, the project felt that this service agreement was acceptable. However, such privacy and security concerns are an important factor in the decision to use any type of software. Security of data in cloud-based systems particularly is an issue, especially if a project wishes to collect and/or map patient-level data.

### Cost Implications of GIS Implementation

While we described many ways in which we believe GIS allowed the project to be more efficient in allocating resources, planning for start-up costs, or merely the anticipated high cost of GIS, could be perceived as barriers to use by program managers. Any project using GIS requires initial setup of a database, data collection, deployment of GIS software, and initial site mapping (if no geocoded site data already exist)—all of which have costs associated with them and could be perceived as barriers. We minimized many of the costs associated with these activities by incorporating them into our normal project monitoring and evaluation activities and level of effort allocated for project staff. However, the time necessary for start-up data collection and mapping can be substantial; sharing existing map data among projects at the country level would be advantageous to reduce costs in this area.

### CONCLUSION

GIS was a useful tool to prioritize delivery of VMMC services in specific areas and to particular population groups, providing maximum effectiveness for scale-up in 2 regions of Tanzania, and it ensured that supply of services matched demand. After incorporation of GIS into the VMMC program for strategic planning, the MOHSW with MCHIP support was able to double regional targets for VMMC, improving efficiencies that have the potential for both epidemiologic and cost benefits for the program. Use of GIS can be an effective means to make strategic decisions about service delivery and coverage, especially in the context of mobile and outreach services, for other VMMC programs as well as for other areas of health service delivery. In the future, ministries of health and donors may want to consider funding mapping initiatives that support numerous interventions, spreading any initial start-up or data collection costs among implementing partners rather than placing a burden on each intervention

individually. Although this approach will require coordination among stakeholders, the benefits of geospatial coordination may be great for country programs.

Health information system platforms that include GIS and digital mapping capabilities as part of their core functionality, such as the District Health Information System 2 (DHIS2), are becoming increasingly widespread in low- and middle-income countries. Correspondingly, geocoded data and spatial analysis of health service delivery data will be increasingly important. Incorporating GIS into programmatic efforts paves the way for smarter, more responsive, and more cost-efficient public health planning, increasing the likelihood of appropriate and effective use of public health resources.

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**Competing Interests:** None declared.

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**Use of GIS can be an effective means to make strategic decisions about service delivery and coverage.**

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## INNOVATION

# Remote Sensing of Vital Signs: A Wearable, Wireless “Band-Aid” Sensor With Personalized Analytics for Improved Ebola Patient Care and Worker Safety

Steven R Steinhubl,<sup>a</sup> Mark P Marriott,<sup>b</sup> Stephan W Wegerich<sup>c</sup>

**This wireless sensor technology, currently being field-tested in an Ebola Treatment Unit in Sierra Leone, monitors multiple vital signs continuously and remotely. When connected with enhanced analytics software, it can discern changes in patients’ status much more quickly and intelligently than conventional periodic monitoring, thus saving critical health care worker time and reducing exposure to pathogens.**

Continuous, remote monitoring of multiple vital signs in patients with Ebola, coupled with personalized data analytics, can warn health care workers of critical changes in patients’ status much earlier than with conventional intermittent monitoring—which typically occurs just every 8 hours—and without risking the safety of health care workers. This sophisticated technology, in turn, could lead to earlier initiation of lifesaving interventions, better health outcomes, and reduced risk of spreading the virus.

A consortium of academic and industry partners, STAMP<sup>2</sup> (which stands for Sensor Technology & Analytics to Monitor, Predict and Protect Ebola patients), has developed such a novel, wearable patient sensor—resembling a band-aid—that tracks and wirelessly transmits multiple vital signs to remote health care workers in non-red zone observation areas. The technology, which includes the MultiSense sensor coupled with state-of-the-art, real-time data analytical capabilities, called Personalized Physiology Analytics (PPA), sends patient-specific automated alerts of any important changes in the patient’s condition without requiring the health care worker to constantly monitor display screens.

The technology was developed in response to the Grand Ebola Challenge, sponsored by the United States Agency for International Development (USAID), to develop innovative solutions to improve the safety of health care workers and care of patients with, or at high risk for, Ebola virus infection.

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## MULTISENSE: WIRELESS, WEARABLE SENSOR

There has been tremendous growth over the last several years in the field of mobile health (mHealth), and especially in wearable, wireless sensors.<sup>1</sup> One example of a state-of-the-art wearable sensor is the MultiSense patch being developed by Rhythm Diagnostic Systems. MultiSense is a battery-powered, flexible strip, measuring 4 X 1.2 inches and weighing less than 15 grams (Figure 1). It is waterproof with a patented adhesive for reliable adherence to the chest in most situations. The patch has a proprietary low-noise electrocardiogram (ECG) design and is able to simultaneously track and record a number of physiological parameters beyond the single-lead ECG, including (Figure 2):

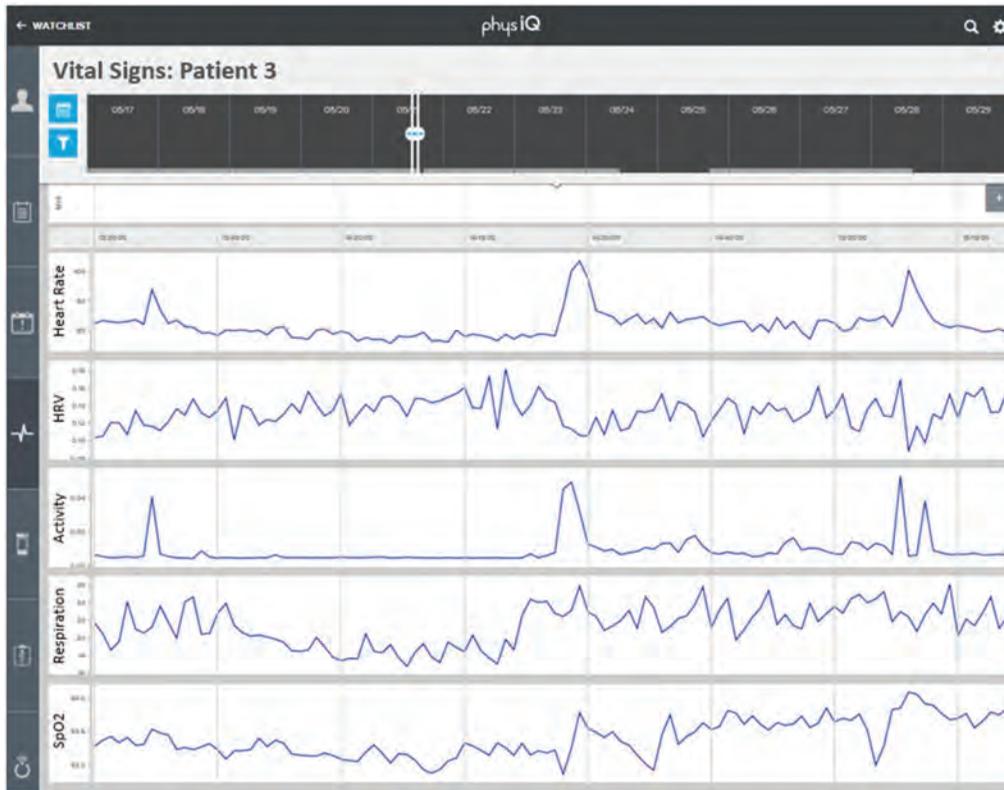
- Heart rate
- Pulse synchronized oxygen saturation
- Temperature
- Respiratory rate
- Depth of respiration
- Motion/position

The ability to reliably identify relative changes in blood pressure is also currently being optimized. The second-generation MultiSense patch is Bluetooth-enabled and can stream the data continuously, in real-time, to a smart phone or other device via Bluetooth LE. It has a low overall cost of manufacturing and is disposable. The patch is designed to be used on a single individual for 60+ days of monitoring, with adhesives changed as appropriate (typically every 4–10 days).

**FIGURE 1.** MultiSense Patient Sensor: Small, Wearable, and Wireless or via USB



**FIGURE 2.** Illustrative Data Output for an Individual Patient From MultiSense Patient Sensor



Top to bottom: heart rate, heart rate variability (HRV), activity level, respiration rate, and SpO2 (oxygen saturation).

## PPA SOFTWARE: PERSONALIZED PHYSIOLOGY ANALYTICS

Coupled with the PPA data analytics technology, MultiSense provides a detailed snapshot of patients' dynamic physiologic status based on their measured parameters and how they interact with each other. The analytics software, developed by physIQ, uses machine-learning algorithms that are purely data driven rather than based on any fixed set of parameters. Thus, the PPA software can be applied to a wide range of vital signs parameters including those measured by the MultiSense.

PPA is used to detect subtle changes in an individual's physiological characteristics from

learned baseline physiological behavior. Importantly, PPA detects changes in the interrelationships between parameters, which can be missed when examining parameters individually against population statistics. These detected deviations are generally within the normal range of variation seen in an individual's vital signs, thus making it possible to detect change well in advance of symptoms or decompensation when an adverse health condition progresses, such as with Ebola infection.

Using a component of PPA called Similarity Based Modeling, each patient's current vital signs are compared with the patient's baseline in real-time, to develop a series of residuals.<sup>2,3</sup> These residuals are then fused into a single Multivariate

**FIGURE 3.** Illustrative Patient Watch List Displaying Multivariate Change Index (MCI)<sup>o</sup> Trends for Multiple Patients



<sup>o</sup> The MCI is a single derived measure of a patient's status based on continuous tracking of a series of differences from the patient's current vital signs compared in real-time with the patient's baseline vital signs, representing the change in a patient's physiology over time.

Change Index (MCI)—a combined, personalized index that is much more sensitive than any one vital sign. The MCI represents the change in the patient's physiology over time, identifying the early signs of a developing or worsening medical condition. Further, health care workers can view the MCIs of all monitored patients simultaneously, as shown in [Figure 3](#), providing exception-based, efficient monitoring of a large population by limited clinical staff, especially important in low- and middle-income countries where health care workers are commonly a scarce resource.

## CURRENT STATUS AND NEXT STEPS

STAMP<sup>2</sup> solution, after receiving approval from the Sierra Leone Ethics Committee, is currently undergoing field testing in Sierra Leone in collaboration with the International Medical Corps. Once validated in a population admitted to an Ebola Treatment Unit for suspected Ebola infection, a number of other uses are possible and can be evaluated. For example, the technology can be used to remotely monitor individuals exposed to Ebola, such as family members of patients, who are considered to be at especially high risk. In addition, similar technologies can be used to monitor health care workers directly, for example, to monitor early signs of heat stress

while deployed in the field, as well as for more personalized, passive but continuous monitoring after returning home to detect important changes prior to the development of symptoms or to detect the earliest signs of temperature elevation not dependent upon population-based averages.<sup>4</sup>

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**Competing Interests:** Mark Marriott is an employee of Rhythm Diagnostic Systems, and Stephan Wegerich is an employee of phyIQ.

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